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Keystone, Colorado, USA
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**Abstracts of
the 18th
Cochrane
Colloquium
and the 10th
Campbell
Colloquium**

Supplement 2010

Editorial

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EDITORIAL

Abstracts of the 18th Cochrane Colloquium and the 10th Campbell Colloquium

Howdy Pardners — Welcome to Colorful Colorado!

10th Annual Campbell Colloquium and 18th Annual Cochrane Colloquium, Keystone Colorado, 18–22 October 2010

This conference constitutes the first joint Colloquium of the Cochrane and Campbell Collaborations — leading organizations in the production of systematic reviews of the effectiveness of interventions in the fields of health and social care. With more posters, oral sessions and workshops than ever before — presented at one of the highest altitude scientific conference venues in the world, Keystone Conference Center — the meeting lives up to its theme: “Bringing evidence-based decision making to new heights”.

We thank all who have made this meeting a success, especially the attendees, presenters, members of the Colloquium committees, and the publishers of this book of poster, oral, and workshop abstracts — Wiley-Blackwell.

Robert Dellavalle, MD, PhD, MSPH

Local organizer

Nick Royle

CEO Cochrane Collaboration

Eamonn Noonan

CEO Campbell Collaboration

Abstracts of the 18th Cochrane Colloquium and the 10th Campbell Colloquium

Oral session A

Consumer Issues and Shared Decision Making

Session A1: Information – Presentation and Access

Negative versus positive framing of health information messages

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Background: The success of evidence based practice and participation with healthcare decisions depends inherently on the clear and effective communication of health messages. **Objectives:** To evaluate the effect of negative versus positive framing of the same health information (e.g. 20% chance of dying vs. 80% chance of surviving) on understanding, perception, persuasiveness, and behavior of health professionals and consumers. **Methods:** We followed Cochrane methodology. We electronically searched Medline, Embase, PsycLIT and CENTRAL. We included parallel and cross-over studies with health professionals and consumers evaluating one of two types of framing: attribute framing (positive or negative encoding of a specific attribute of a single item) and goal framing (positive or negative framing of the consequences of performing or not performing an act). We standardized the outcome effects using standardized mean difference (SMD). We conducted pre-planned subgroup analyses based on the type of message (screening, prevention, and treatment). **Results:** We identified 35 eligible studies reporting 51 comparisons. With attribute framing, participants understood the message better when it was framed negatively (SMD -0.58 [95% CI -0.94 to -0.22]; moderate effect size). Although positively framed messages may have been better perceived (SMD 0.36 [95% CI -0.13 to 0.85]; small effect size), there was little or no difference in persuasiveness (SMD 0.07 [95% CI -0.23 to 0.37]) and behavior (SMD 0.09 [95% CI -0.14 to 0.31]). With goal framing, loss messages were perceived as more effective for screening topics (SMD -0.30 [95% CI -0.49 to -0.10]; small effect size) and may have been more persuasive for treatment topics (SMD -0.50 [95% CI -1.04 to 0.04]; moderate effect size).

There was little or no difference in behavior (SMD -0.06 [95% CI -0.15 to 0.03]). **Conclusions:** Contrary to commonly held beliefs, the available evidence suggests that framing may have little if any effect on behavior.

How could press releases about evidence increase the uptake of evidence concepts in media reporting? An exploratory study

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Background: Evidence-based information needs to compete effectively for attention in the media, which may also be able to familiarise the public with more sophisticated concepts of proof. **Objective:** To develop hypotheses on ways to increase the extent of evidence concept coverage within media reports. **Methods:** In 2009, we piloted a structured press release program, with individually pre-determined objectives to facilitate media content analysis. Ten press releases were produced in German, with 5 also released in English. To identify resulting German media reports, the PMG (a national press monitor) and Google News were systematically searched. For this analysis, we included only major lay media reports. We classified media releases as either “low” or “high” in the extent to which evidence concepts dominated the press release’s content. The text of media reports was searched for key words for evidence, and for specific mention that the report was based on more than a single study. **Results:** One press release resulted in no major media reports, and the other 9 resulted in 82 reports (range: 1 to 22). A total of 43 of 82 reports included an “evidence” word or phrase and/or indicated that the data were based on more than a single study (52%). The media report was more likely to mention an evidence concept if discussion of evidence was “high” in the press release (RR 1.91 ; 95% CI 1.12 to 3.26). Only 12 of 82 reports used a word or phrase meaning evidence or proof (15%), compressing methodology into brief lay catchphrases (“summarised study results” rather than “meta-analysis”). All reports mentioned the name of the institutional author (the “authority”). **Conclusions:** Increasing the amount of space devoted to discussing methodology in a press release may increase the transportation of evidence concepts. As journalistic practice strongly favours naming the information source, emphasis on marketing the association of evidence/methodology with authoritative “brands” remains a priority. If we hope to transport more evidence concepts within media reports, we need to extend our vocabulary of very brief phrases or words that convey these concepts effectively to lay people.

How evidence-based are the pharmaceutical industry's printed promotional material presented to physicians: a multinational study

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Background: A major marketing technique used by pharmaceutical companies is direct-to-physician marketing. The physician-industry interaction affects prescribing and professional behavior. Pharmaceutical sales representatives frequently visit 70% to 90% of physicians during their daily practice. Promotional Material is considered useful (58% of residents), influential (22% of physicians) or inappropriate (12–60% of physicians). **Objectives:** To determine if references provided by printed promotional material (PPM) presented to physicians by pharmaceutical representatives support its statements. We will also assess the validity of PPM against the best available evidence. **Methods:** A consecutive sample of all PPM distributed in a family medicine practice (Hospital Italiano de Buenos Aires, Argentina), a general medicine practices (Consultorios de la Clínica Reina Sofía, Bogotá Colombia) and an internal medicine practice (Centro Médico San Joaquín, Santiago de Chile, Chile) was collected between January 1 and March 30, 2010. Reprints and monographs were excluded. We will evaluate the number and accuracy of PPM's statements supported by cited references; and the correctness of references cited in PPM according to the International Committee of Medical Journal Editors as well as the availability of those references in area libraries. Adverse reactions, warnings about drug interactions and contraindications will also be collected. Relevant clinical information of the material will be translated to PICO format question to systematically search in TRIP Database (first step) and/or MEDLINE (PUBMED). We will assess the quality/risk of bias of identified systematic reviews and randomized controlled trials using the AMSTAR instrument and the Cochrane Handbook respectively. PPM will be classified as "adequately", "insufficiently" or "inadequately" supported and cited. Two independent reviewers will grade the quality of PPM's evidence using the GRADE system, and will contrast the strength of its statements against the best available evidence to classify them as correct, incorrect or misleading.

Results will be presented at the Colloquium

Who, why, what, where & when – questions about usage of The Cochrane Library

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Background: Investigating usage and user activity, and identifying trends for The Cochrane Library are essential tools for providing high-quality, timely evidence for The Cochrane Collaboration. It assists in constructing a picture of how people use The Cochrane Library around

the world, and allows us to identify the way in which reviews from The Cochrane Database of Systematic Reviews are accessed. **Objectives:** By looking at the 2009 full year and 2010 first quarter usage data for The Cochrane Library, it is possible to establish trends, usage patterns and user preferences surrounding The Cochrane Library and the databases within it. **Methods:** For the period of 1st January 2009 to 31st December 2009, plus the 1st January 2010 to 30 April 2010, the number of unique visits to www.thecochranelibrary.com, number of visits by country, and most accessed Cochrane reviews on Wiley InterScience were taken from the Wiley InterScience Data Warehouse, an analysis tool that stores and tracks usage data. Another set of usage data was obtained from all other licensed providers of The Cochrane Library, showing the number of abstracts and full text articles that were accessed during 2009 from Wiley InterScience, EBSCO, OVID, La Biblioteca Cochrane, BIREME and www.cochrane.org. **Results:** Data taken from all providers of The Cochrane Library show that during 2009: A search of The Cochrane Library took place every second; A Cochrane abstract was viewed every 2 seconds; A full text article was downloaded every 3 seconds. **Conclusions:** In summary, usage of The Cochrane Library in 2009 has increased considerably in comparison to 2008 and previous years. Over half the world's population now have access to The Cochrane Library via one-click access (no login required), and it is clear that worldwide usage of The Cochrane Library is increasing as a consequence.

Oral session B

Diagnostic Test Accuracy Review Methods

Session B1: Quality

The assessment of quality of meta-analyses in diagnostic research – a systematic review

Brian Harvey Willis¹

¹Health Methodology, University of Manchester, UK

Background: Over the past twenty years the number of meta-analyses in diagnostic research has increased dramatically and this has coincided with methodological and statistical developments in the field. The current state of quality or the effect the recent developments have had on quality has not been evaluated and motivates this review. **Objective:** To assess the quality of published meta-analyses of diagnostic test studies. **Methods:** The following databases were searched: MEDLINE, EMBASE, CINAHL, Cochrane, PsychInfo, HMIC, AMED, and Global Health. Studies were included if all of the following were satisfied: Evaluated a diagnostic test; measured test performance; searched two or more databases; stated the search terms and inclusion criteria; used a statistical method to summarise performance. Quality was evaluated on two levels. The review process was assessed by its compliance with PRISMA and by qualitative appraisal; the component primary studies were assessed by adapting the QUADAS tool. Data were extracted on the study characteristics, items in PRISMA and QUADAS. Fisher's exact test and the Z test were used when making comparisons. **Results:** There were 237 studies included. Overall the

quality of meta-analyses has improved and reviewers are increasingly assessing the quality of the component primary studies. In five PRISMA items there were statistically significant improvements between the periods 2001–2004 and 2005–2008. However, in many items including investigating heterogeneity, analyses were not performed in the majority of studies. Qualitative appraisal revealed insufficient detail to allow reproducibility of results and inadequate consideration towards ensuring completeness. The results of applying QUADAS demonstrated there were not only deficiencies in the reporting in the primary studies, but quality assessments by reviewers were also not fully reported. **Conclusion:** Although there has been an improvement in the quality of meta-analyses there are still many deficiencies in both the review process and reporting that future reviewers need to address.

Quality appraisal of studies on prognostic and diagnostic risk models: a systematic review

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Background and Objective: Prognostic and diagnostic risk or prediction models are frequently encountered in the medical literature. Various recommendations exist of good clinical prediction research. We investigated the methodological quality of studies on the development, validation or implementation of prediction models. **Methods:** We searched PUBMED using a validated search strategy to select prediction studies in six general journals (*Annals of Internal Medicine*, *British Medical Journal*, *Lancet*, *New England Journal of Medicine*, *PLoS Medicine*, and *Journal of the American Medical Association*). Studies were included based on pre-defined inclusion criteria. We used an exhaustive item list to score the quality of the papers, based on recent recommendations for multivariable prediction research. Two reviewers independently scored the studies, and a third in case of doubt. **Results:** The search strategy revealed 347 hits. At the time of this abstract, we finished three journals and retrieved 29 papers for full text review. 26 of these described 59 developed models. Only three (10%) studies involved a validation (of a previous developed model) or the quantification of a model's impact on patient outcome. Of the 26 studies, five had both an etiological and prognostic aim. Even though they may require a different design and analyses, two (40%) gave information of the missing value per predictor, and none reported on the number of patients with missing values; all etiologic-prognostic studies reported on loss-to-follow-up. The predictive accuracy of the prediction models was reported in 13 of the 26 studies. Only 6 of the 26 studies used any form of internal or external validation and in 26 (100%) the number of events per studied predictor was not mentioned or too low for ≥ 1 of the presented model(s); both aspects commonly lead to overfitted models. **Conclusion:** Despite various recent recommendations for conducting studies on diagnostic and prognostic prediction modeling, the vast majority does not follow these guidelines.

Methodological quality assessment of comparative test accuracy studies

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Background: Advice on Cochrane Diagnostic Test Accuracy Reviews (DTARs) highlights the importance of comparative test accuracy studies and encourages their inclusion. These studies measure the results of two index tests and a reference standard in the same population. The theoretical advantage is that, unlike indirect comparisons, the difference between test accuracies is not confounded by differences in study methods, populations and reference standards. There may therefore be implications for the assessment of methodological study quality. **Objective:** To explore problems arising in the methodological quality assessment of direct comparison studies. **Methods:** We will use the existing suggested approach to quality assessment in DTARs, based on QUADAS, in at least two systematic reviews containing comparative test accuracy studies and identify problems, including issues not addressed. We will propose solutions and seek wider consensus on these amongst groups like the UK and the Continental Europe Support Units for Cochrane DTARs. **Results:** We have already conducted methodological quality assessment in one relevant systematic review on PET and PET/CT for the recurrence of breast cancer. Although the sources and extent of bias in within-study comparisons are not fully known, in this case they appear to be less than those associated with absolute estimates of test accuracy. However, there was an additional need to consider the time interval between the two index tests as well as between the index test and the reference standard, and there may be potential issues relating to the order of index tests. The possibility of selection bias emanating from the requirement to receive two sets of index tests has been previously noted. **Conclusions:** The issues of methodological study quality affecting direct comparison studies do appear to differ in several important respects from those affecting single arm test accuracy assessments. They may actually be simpler to assess, but this requires further investigation.

The number, coverage and quality of diagnostic test accuracy studies in Nephrology

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Background: The validity of a systematic review depends on assessing the totality of evidence. It is unknown how many diagnostic test accuracy studies (DTAS) are published in Nephrology and other specialties. **Objectives:** To establish the number, coverage and quality of DTAS in Nephrology compared to other specialties. **Methods:** DTAS in 13 specialties of internal medicine were identified using MEDLINE MeSH terms and the clinical queries filter 'diagnosis optimized' from 1966–2008. Results were 'standardized' by adjusting for total citations within each specialty. Coverage within Nephrology was explored by classifying citations into eleven subspecialty topic areas. A modified

Figure 1. The percentage of diagnostic test accuracy studies compared with total citations in nephrology and twelve other specialties of internal medicine from 1966 to 2008.

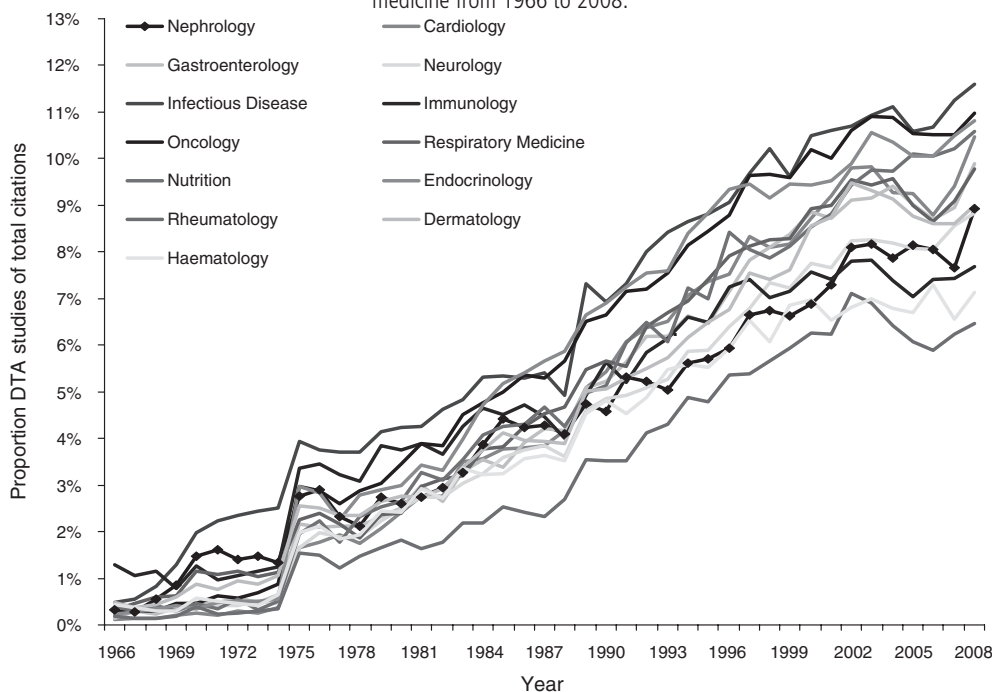
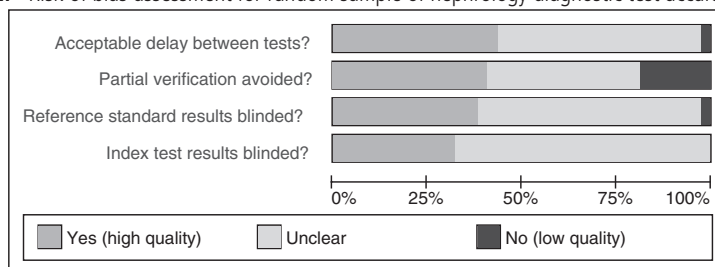


Figure 2. Risk of bias assessment for random sample of nephrology diagnostic test accuracy studies.



QUADAS tool was used to assess risk of bias in a random sample of studies. All stages were conducted by two authors working independently. **Results:** Publication of DTAS increased over time across all specialties, however Nephrology (22,230 total) published fewer relative to other specialties (Mean: 59,764, SD \pm 34,855). When adjusting for total citations 5.1% of citations in Nephrology were DTAS (Mean%: 5.9, SD \pm 1.0, Range: Rheumatology 4%, Infectious diseases 7.6%) (Figure 1). Within Nephrology subspecialty topics, diabetic nephropathy, renal artery obstruction and urinary tract infections published a greater proportion of DTAS than the mean, and kidney transplantation, hemodialysis, nephritis, peritoneal dialysis, urolithiasis, acute kidney injury, renal tubular transport and renal failure were under-represented. Only 47 of 300 sampled (to date) citations examined accuracy of diagnostic tests in a defined population (the remaining studies examined tests in genetic techniques, microbial sensitivities or were review articles). Of these 47, quality was suboptimal (Figure 2). **Conclusions:** The total number and relative proportion of DTAS published in Nephrology is low compared to other medical specialties and quality of nephrology DTAS is poor. However, we did not compare quality across specialties and publications are

only surrogate markers of research. Increased familiarity with DTAS methodologies and the QUADAS tool may improve research quality.

Session B2: Design and Methods

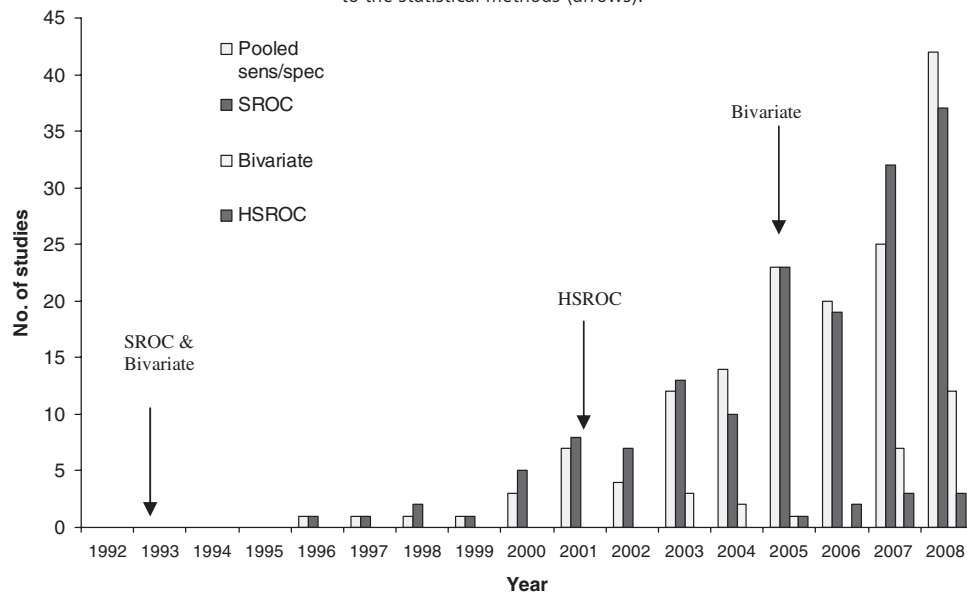
Uptake of newer methodological developments and the deployment of meta-analysis in diagnostic test research – A systematic review

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Background: The last decade has seen a number of developments in the methodology used in systematic reviews and meta-analysis of diagnostic test studies. It is of interest to ascertain whether such developments have permeated the wider research community and on which applications they are being deployed. **Objective:** To assess the uptake and deployment of the main methodological developments in

Figure 1. The distribution of included studies per statistical method per year. Also shown is the year of publication of the seminal papers corresponding to the statistical methods (arrows).



the meta-analysis of diagnostic tests, and identify the tests and target disorders most commonly evaluated by meta-analysis. **Methods:** Eight databases (including MEDLINE and EMBASE) were searched. A six step algorithm was used to select studies on meta-analyses of diagnostic tests. Data were extracted on the study characteristics including statistical and quality assessment methods used. Appraisal was both quantitative and qualitative. **Results:** 237 studies met the inclusion criteria. The number of meta-analyses on diagnostic tests has increased over the last 5 years, but the uptake of new statistical methods lags behind. Pooling the sensitivity and specificity or using the summary ROC remain the preferred methods for analysis in 70% of studies, with the bivariate random effects and HSROC model being used in only 22% and 5% of studies respectively. In contrast between 2006 and 2008 the QUADAS tool was used in 40% of studies with even more citing it. Broadly radiological imaging was the most frequent category of tests analysed (36%), with infection (22%) and cancer (21%) being the most common categories of target disorder. Nearly 80% of the tests analysed were those normally used in a secondary care specialist setting. **Conclusion:** Although quality assessment in meta-analyses has improved with the introduction of QUADAS, uptake of the newer statistical methods is still lagging. Furthermore there is a preponderance of meta-analyses evaluating specialist tests in specialist settings, in contrast to where the majority of diagnostic tests are deployed in practice.

Systematic reviews of clinical decision rules: prognostic, diagnostic, both, either or neither?

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Background: Clinical decision rules (CDR), or clinical prediction rules, are tools for clinicians 'at the bedside' to assist patient

management. Undertaking systematic reviews of CDR in predicting adverse consequences of infection in cancer offered challenges in synthesising such data. **Objective:** To highlight challenges raised by systematic reviews of the discriminatory ability and predictive accuracy of CDR and serum markers of infection in febrile neutropenia (FNP) in children and young people and posit solutions. **Methods:** We use the results of two reviews (HTA Registry of Systematic Reviews, CRD32009100453 and CRD32009100485) to identify challenges in study design and synthesis. Markov chain Monte Carlo (MCMC) models using advanced hierarchical statistical modelling taking into account multiple and different thresholds between studies were used for meta-analysis. **Results:** We found 24 studies describing 17 different CDR in 8388 episodes of FNP. No study compared different approaches and two CDR, producing two and three-level test results, were subject to meta-analysis. 26 studies examined 13 markers in 3585 episodes; four datasets were pooled. A range of methodological problems with the primary studies were identified. These included: small event-per-variable ratios, lack of shrinkage of predictive estimates, failure to examine for non-linear relationships, use of data-driven variable selection and cutpoint determination, premature categorisation of continuous data, lack of examination of missing data, and suboptimal examination of clustered data. Many of the problems could be assisted by the collection of individual participant data (IPD). Depending on the clinical question, a 'diagnostic' or 'prognostic' approach to synthesis becomes more clinically meaningful. **Conclusions:** 1. CDR studies contain similar problems as prognostic and diagnostic studies and may be best assessed using IPD. 2. MCMC models can be used to synthesise the information efficiently these are not available. 3. Advancing a philosophy of prediction, rather than 'diagnostic accuracy' or 'prognostics' may aid clinicians to understand tests better.

Studies predicting adverse outcomes from febrile neutropenic episodes in children and young people with malignant disease suffer similar methodological flaws as prognostic and diagnostic test accuracy studies

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Background: A common cause of admission for children with malignancy is neutropenic fever. When managed aggressively, adverse outcomes are rare, but many children are over treated with this approach. A risk stratification clinical decision rule (CDR), or serum markers of inflammation or infection, which predicted those at very low risk of significant complications could be used to reduce intensity and/or duration of treatment. Those at high risk could receive aggressive management. **Objective:** To identify, appraise and synthesise evidence on the discriminatory ability and predictive accuracy of CDR and serum markers of infection in febrile neutropenia (FNP) in children and young people undergoing treatment for malignant disease. **Methods:** The two reviews followed "Systematic reviews: CRD's guidance for undertaking reviews in health care" and were registered with the HTA Registry of Systematic Reviews, CRD32009100453 and CRD32009100485. Study validity was assessed using a modified QUADAS questionnaire. Univariate random-effects models were used to synthesise test accuracy and narrative techniques to describe methodological aspects. **Results:** We found 20 studies describing 16 different CDR in 8388 episodes of FNP. No study compared different approaches and only one CDR was tested across multiple data sets. We found 26 studies examining 13 different serum markers in 3585 episodes of FNP. Inconsistency and heterogeneity limit the conclusions that can be drawn from these data. A range of methodological problems were identified. These included: small event-per-variable ratios, lack of shrinkage of prognostic estimates, failure to examine for non-linear relationships, use of data-driven variable selection and cutpoint determination techniques, premature categorisation of continuous data, lack of examination of missing data and no techniques

to address this, and suboptimal examination of clustered data. **Conclusions:** 1. Firm clinical conclusions cannot be drawn through heterogeneity of CDR, tests and outcomes. 2. Risk stratification studies contain similar methodological problems as prognostic and diagnostic studies.

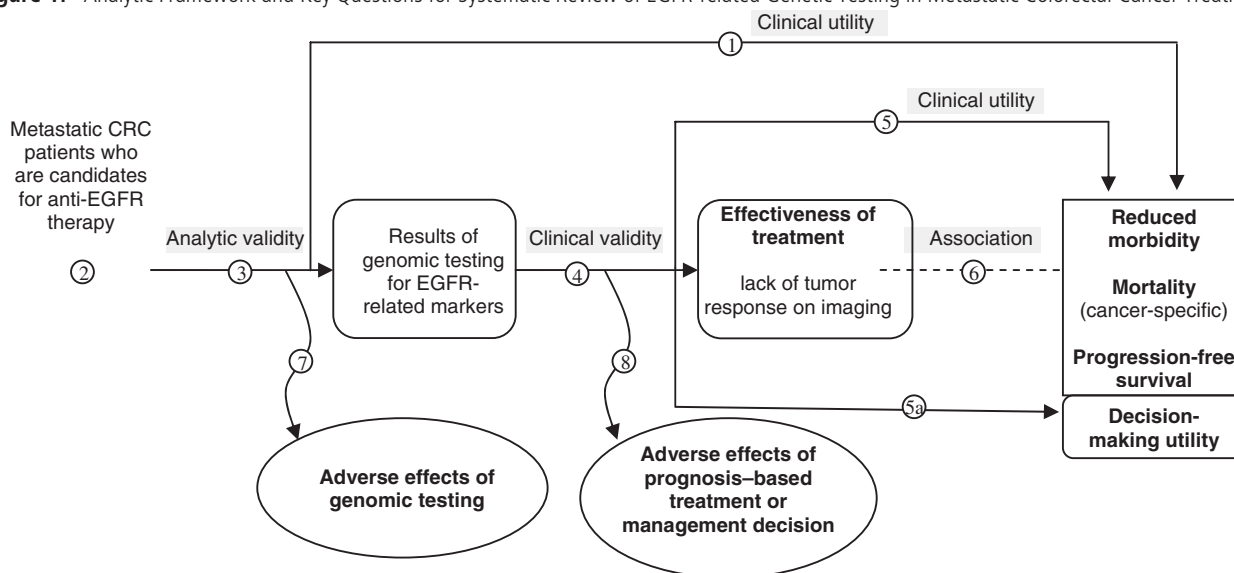
Challenges in conducting systematic reviews for diagnostic and prognostic testing in genomics and personalized medicine (GPM)

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Background: GPM is a rapidly growing field that spans multiple applications, e.g., screening, diagnostic, prognostic, pharmacogenomic. GPM tests, however, generally lack readily-available population-based evidence about clinical utility and net health impacts to support informed decision-making. **Objective:** To describe the important methodological challenges to reviewers in the field of GPM given the differences in the development of evidence in genomic testing. **Methods:** We are working with the CDC Office of Public Health Genomics and the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group to develop systematic review methods in GPM, using a systematic review of epidermal growth factor receptor (EGFR) related tests in guiding monoclonal antibody treatment in colorectal cancer as a case example. **Results:** Building on the work of the USPSTF and EGAPP, we developed an analytic framework to help reviewers and decision makers conceptualize and operationalize important questions when synthesizing and considering the evidence for a genomic test (see Figure). This framework helps reviewers understand the differences in analytic validity, clinical validity and clinical utility, as established by EGAPP. This framework also includes important questions around harms, systematically addressing

Figure 1. Analytic Framework and Key Questions for Systematic Review of EGFR-related Genetic Testing in Metastatic Colorectal Cancer Treatment.



both serious adverse effects requiring clinical attention, as well as ethical, legal, and social issues that concern patients. Evidence generation for genetic testing is complicated by a weak regulatory environment, strong proprietary interests, and direct-to-consumer marketing. Therefore, much of the evidence is either unpublished or proprietary. We are piloting horizon scanning activities that will help us develop consistent search strategies for grey literature and determine when to update searches. We are developing minimum standards for identifying proprietary data, most relevant for reviewing analytic validity. Analytic validity will be important to consider, for example, if there is concern about reproducibility of test across platforms or laboratories, or issues around test performance and optimal diagnostic thresholds. **Conclusions:** Given the methodologic challenges unique to synthesizing the evidence in the clinical benefit from genetic testing, systematic reviewers interested in this growing field need to collaborate with one another to aid the development of the science of reviewing GPM applications. 1. Does the use of genetic prognostic markers (BRAF/PIK3CA/PTEN) in patients with metastatic colorectal cancer (mCRC) for decisions related to anti-EGFR use or dosing decisions reduce morbidity and/or mortality compared to those who are not tested? 2. How are persons with metastatic colorectal cancer (mCRC) who would be eligible for use of genetic testing to determine cancer treatment decisions using anti-EGFR antibodies identified in clinical care? 3. What genetic prognostic markers (BRAF/PIK3CA/PTEN) related to use of anti-EGFR antibodies have been developed in mCRC? What tests (including consideration of manufacturer, mutations/codons, and method or technology) are in use for each marker? In what treatment settings (i.e., first line metastatic treatment, second line metastatic treatment, neoadjuvant treatment, other) are they applied? For each of these genetic tests in each treatment setting, what is their analytic validity (i.e., sensitivity and specificity for detecting the genetic mutations of interest)? 4. For each of these genetic tests in each treatment setting, what is their clinical validity (i.e., how well do they predict non-response to anti-EGFR antibody treatments as measured by disease progression/tumor growth?) Do factors such as race/ethnicity, diet, or other medications, affect these associations? 5. For each of these genetic tests in each treatment settings, what is their clinical utility (i.e., do treatment choices or management decisions related to not using anti-EGFR antibodies based on these test results lead to improvement in all-cause mortality, colorectal cancer-specific mortality, progression-free survival, reduced morbidity (e.g. reducing harms by avoiding exposure to ineffective treatments), and/or quality of life, compared with treatment choices or management decisions made in the absence of this prognostic information)? (a) Are these tests useful in medical, personal, or public health decision making? 6. How strong is the association between tumor response as measured by imaging studies and health outcomes and over what time period has it been established? 7. What are the harms of performing genetic tests (i.e. BRAF/PIK3CA/PTEN) related to anti-EGFR therapy for patients, including incorrect genotype assignment leading to potential use of ineffective treatments, ELSI risks, and other risks associated with this testing? 8. What are the harms of decisions surrounding the use or non-use of anti-EGFR therapy informed by the results of genetic testing compared to treatment management decisions made without this prognostic information, including delayed treatment or other concerns?

Oral session C

Editorial Processes and Supporting Review Authors

Session C1: Guidelines and Reporting

How empty are empty reviews? A report on empty reviews in the CDSR and an invitation to participate in the development of reporting guidelines

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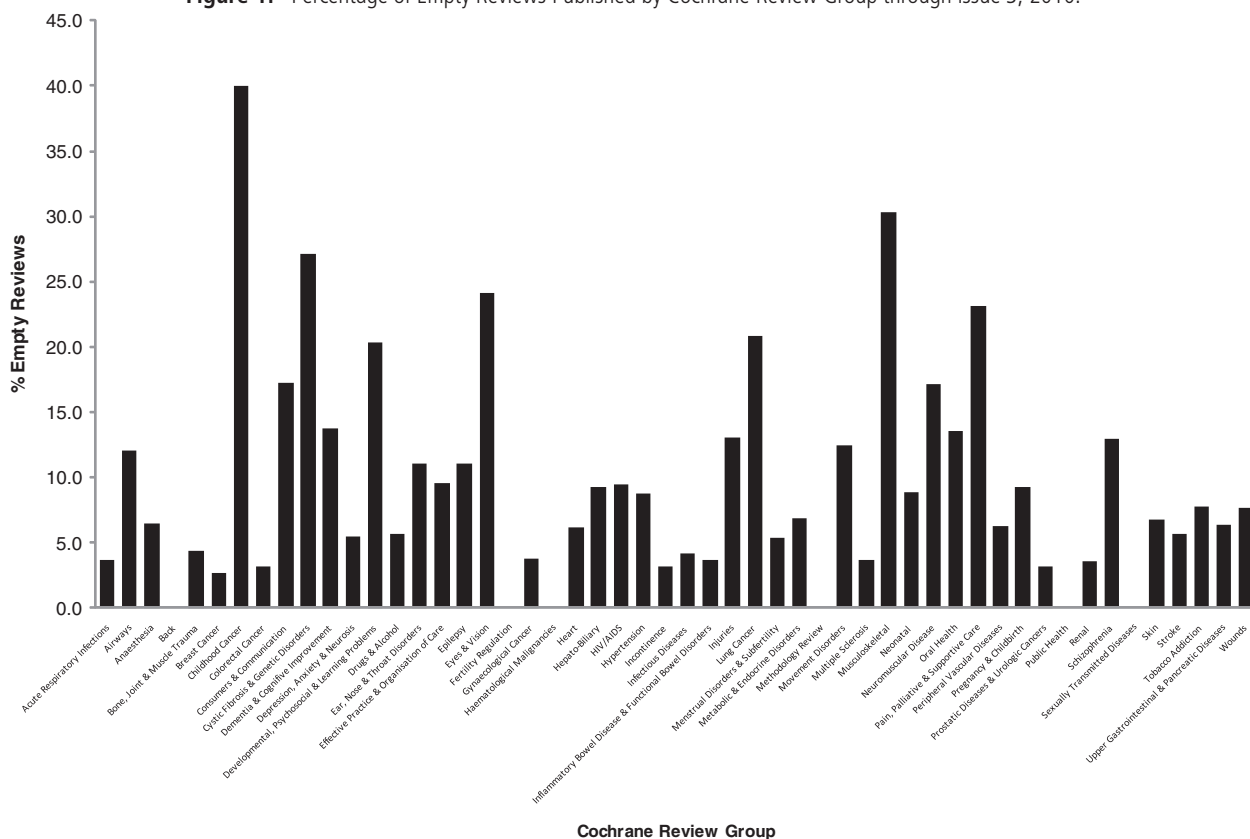
Background: Users rely on *The Cochrane Database of Systematic Reviews* (CDSR)^{1,2,3,4,5} for the best available evidence in making health and social care decisions. However, some evidence suggests that “empty reviews” in the CDSR provide limited implications for practice or make recommendations without consideration of bias in excluded studies. **Objectives:** To report our findings on the reporting of empty reviews, to seek input for the development of recommended guidelines for reporting empty reviews to the Cochrane Methods Group, and to invite participation in the guideline development process. **Methods:** Following the suggestions of Moher et al.⁶ for the development of reporting guidelines, this project has identified the need for reporting guidelines for reviews without included studies by reviewing the literature, identifying all empty reviews within the CDSR, describing these reviews, examining how these reviews report implications for practice and consulting with other systematic review

Table 1. Number of empty reviews by year of publication*.

Year of publication	Number of empty reviews published in CDSR
1995	2
1996	2
1997	3
1998	5
1999	8
2000	9
2001	22
2002	20
2003	25
2004	21
2005	29
2006	40
2007	52
2008	42
2009	69
2010*	25

*2010 accounts for reviews published through Issue 3, 2010.

Figure 1. Percentage of Empty Reviews Published by Cochrane Review Group through issue 3, 2010.



groups to find existing guidelines for reporting empty reviews. This information is presented for discussion in this forum to further prepare for focus groups with Cochrane/Campbell users and a formal guideline consensus meeting with invited Cochrane/Campbell contributors.

Results: At present the reporting of empty reviews in the CDSR is inconsistent and the *Cochrane Handbook for Systematic Reviews of Interventions* does not provide reporting guidelines. Through Issue 3, 2010, there are 374 empty reviews reported in the CDSR, representing 9% of total published reviews and 0% to 40% of reviews by Cochrane Review Group (Figure 1). The publication of empty reviews appears to be increasing over time (Table 1). **Conclusions:** Guidelines for the reporting of empty reviews are needed. We invite the open discussion of Cochrane and Campbell contributors regarding recommendations towards the development of guidelines. We hope to encourage participation by interested colleagues in a future, more formal consensus meeting.

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Developing Quality Guidelines for Observational Empirical Work

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Background: Randomized trials (RCTs) cannot answer numerous important policy questions in the social sciences-experiments may be politically or ethically impossible, RCTs may not identify the effect of interest (such as variation in response), or a decision may be needed before (lengthy) RCTs can be conducted. Yet almost no work has

been done to develop quality guidelines for observational empirical work. Unfortunately, as such work becomes easier to conduct, more and more contradictory claims abound, and separating the wheat from the chaff becomes harder and more critical. **Objectives:** The goal of this presentation is to examine why the social sciences have not developed effective evidence-based (EB) quality guidelines and systematic reviews for observational work and to lay out how they should begin to rectify this problem. **Argument and conclusions:** I argue that the lack of guidelines in the social sciences is partly due to a misguided philosophy of science in the social sciences, but also partly due to the fact that the EB policy movement has (often intentionally) ignored the non-experimental, observational research that social scientists must use. Developing substantive-as opposed to reporting-guidelines, however, is challenging. To demonstrate the difficulties analysts face, I develop prototype quality guidelines for one methodological issue: controlling for simultaneity in criminological research. I show that the number of required criteria grows rapidly, and that there is little evidence about how to select between various methodological options. Given its methodological complexity and sensitivity to small errors, observational research will require guidelines that are more complex than those used in experimental settings, but this argues *for* developing such guidelines. And guidelines will force researchers to carefully evaluate the empirical tradeoffs of various methodological options. Furthermore, systematic reviews of observational research will help policymakers better understand the collective implication of wide-spread, and often seemingly-contradictory, research programs.

AGREE II: Advancing development, reporting, and evaluation of practice guidelines

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Background: Two studies were conducted to improve the development, reporting, and evaluation of practice guidelines. **Objectives:** Study 1 assessed the performance and usefulness of the Modified AGREE (M-AGREE) Instrument and a generic rating scale (GRS). Study 2 assessed the validity of the beta version of the AGREE II Instrument (B-AGREE II). **Methods:** Study 1 involved 156 participants (clinicians, developers/researchers, policy makers) who read a practice guideline, assessed it with either the M-AGREE and GRS (condition 1) or the GRS alone (condition 2), and completed a series of questionnaires which evaluated the usefulness and feasibility of the instrument(s) and required improvements. Study 2 involved 30 participants being randomly assigned to one of two practice guideline packages and evaluated it with the B-AGREE II. Each package included purposefully designed high and low quality excerpts of practice guideline content; one quality version of each item reflected in each package. Participants completed an assessment survey of the B-AGREE II. **Results:** In Study 1, all M-AGREE items and GRS items were rated as useful by participants and no differences emerged as a function of user type. All M-AGREE domains, except editorial independence, predicted users' endorsement of and intentions to use a guideline. The act of applying the M-AGREE did not influence GRS, endorsement or intention to use scores. In study 2, content designed to be of high

quality was rated higher than content designed to be of low quality; in 18 of the 21 items, the differences were statistically significant. The User's Manual was rated by participants as appropriate, easy to use, and able to assist in differentiating good quality practice guidelines from poor quality practice guidelines. **Conclusions:** The results of these studies led to the final version of the AGREE II, a new international standard in guideline development, reporting, and evaluation.

Establishing the database of systematic review glossary

Yaolong Chen

Background: With the development of systematic reviews, more and more new terms or glossaries which related to systematic reviews (systematic review glossary, SRG) are appearing. But same non-normal terms became an obstacle of researching and using systematic reviews (see table). Standardization of glossary is important and necessary for both the Cochrane and Campbell Collaboration. Collecting and unifying these SRGs will promote the development of systematic reviews and knowledge translation. **Objective:** Investigating what and how many are SRGs and establishing the database of collection and analysis and the translating system for non-English speaking countries. **Methods:** Eight databases (to March 2010) including MEDLINE, EMBASE, SCI, CBM, CNKI, VIP, WANGFANG, Cochrane library and relevant websites were searched. The search terms were "evidence-based medicine", "systematic review", "Meta analysis", "glossary", "terminology", and so on. **Results:** There are about 500 terms related to systematic reviews published or as an appendix in 200 articles, 50 books and 100 websites. There are three main questions need to be discussion: Firstly, there is no determinate definition for the SRGs; Secondly, SRGs appeared overlapping in the field of clinical epidemiology, epidemiology, medical statistics, medical literature retrieval, clinical medicine; Thirdly, many people misunderstand, misuse and abuse the SRGs. Fourthly, Non-English speaking countries need a guideline to translate the SRGs correctly. **Conclusion:** It's time to collect and unify the SRGs. Chinese Cochrane center has initiated a project to achieve the goal, and it also wants to seek cooperation with Cochrane and Campbell Collaboration or other related organizations.

Table 1. Same meaning, different terms in systematic reviews..

Systematic Reviews	Meta analysis	Cluster randomized trials
systematic review	meta-analysis	Cluster randomised trials
systematic overview	meta analyses	Group randomized trials
systematic evaluation	meta-analyses	Group randomised trials
umbrella review	metaanalysis	Community trials
evidence-based review	metaanalyses	Field trials
evidence based evaluation		

Session C2: Methodological Considerations

Overviews of reviews – methodological considerations of the Biologics for rheumatoid arthritis Cochrane overview

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Background: Cochrane Overviews of reviews (Cochrane Overviews) are Cochrane reviews designed to compile evidence from multiple systematic reviews of interventions for a single health condition into one accessible and usable document. They are becoming more popular as they summarize evidence for efficacy and safety of the interventions considered. General methods are described in the Cochrane Handbook.

Objectives: To compare the methodology for Cochrane overviews as described in the Cochrane Handbook with the methods used in an overview of the efficacy and safety of abatacept, adalimumab, anakinra, etanercept, infliximab, and rituximab in patients with rheumatoid arthritis (RA). **Methods:** We undertook an overview of Cochrane reviews for biologics in RA. In order to perform indirect comparisons of the six biologics using network meta-analysis methodology we had to expand on the methodology envisioned for Cochrane overviews in the Cochrane Handbook. We compared the methods we used for the biologics for RA overview to those in the Handbook and described the additional data needed for our analysis. **Results:** Data for all the outcomes considered in the overview were not available in the individual systematic reviews and more information was needed from the original studies. **Conclusion:** Our experience showed that data extraction from original studies and re-analysis are necessary for a comprehensive overview of different treatments for a single condition.

Comparison of protocols to published articles for randomised controlled trials

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Background: Publication of complete trial results is important for clinicians, consumers and policy makers in order to make better-informed decisions about health care. The phenomenon whereby

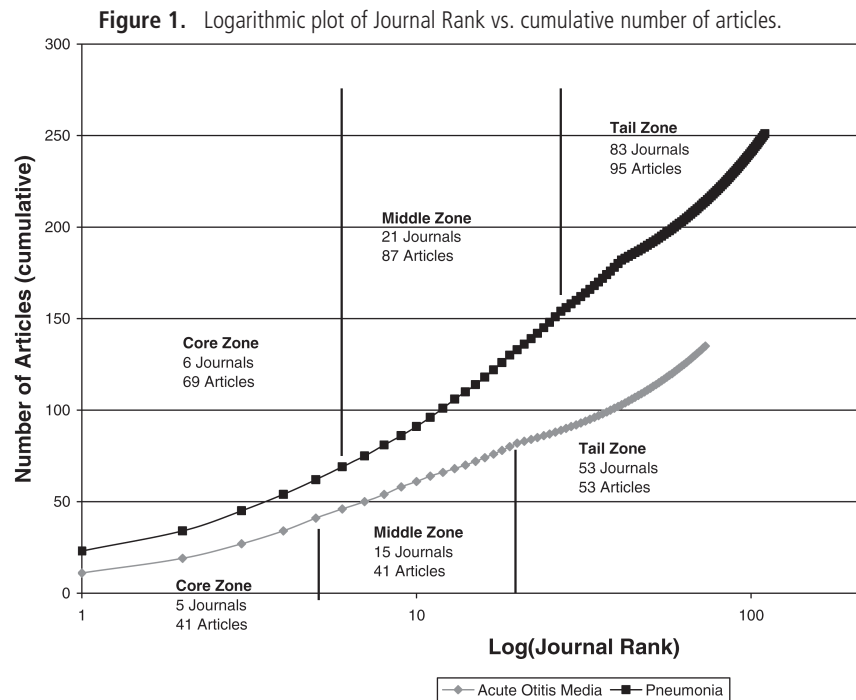
studies that are not submitted or published based on the strength and direction of the trial results has been termed 'publication bias.' An important issue which has received less attention is adherence to the protocol. There is evidence to show discrepancies between what was originally planned in the protocol compared to the publication. **Objectives:** To assess protocol adherence of RCTS, by considering cohorts of clinical trials that have assessed any aspect of the reporting of RCTS compared to information stated in the protocol. **Methods:** Studies will be identified through electronic searches, known item searching and scanning reference lists. Any cohort study comparing protocols to publications of primary studies for any aspect of trial design or analysis will be included. Studies will not be excluded based on language of publication or a quality assessment. **Data regarding:** differences between protocol and publication, quality of the primary RCTs (however measured in the included cohort study) and the quality of the included cohort study, will be included according to pre-specified criteria. Potentially eligible studies may not compare all aspects of the protocol to the trial report. Therefore any study that evaluates any difference between protocol and publication will be included. If the cohorts are sufficiently similar and there is no evidence of substantial heterogeneity, results will be combined in a meta-analysis, otherwise a descriptive summary of the designs and outcomes of the included cohort studies will be provided. **Results:** There is a Department of Health deadline for completion in September. Therefore, results will be presented at the colloquium. **Conclusions:** Protocols should be adhered to and substantial changes to the protocol should be submitted to the ethics committee. Any differences between the protocol and final publication should be discussed in the trial report and justified.

Bradford's law to predict the size of the literature in cochrane reviews

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Background: Bradford's Law is a mathematical formula that shows few journals account for the many articles on a subject. If journals are grouped into zones of roughly equal numbers of articles, Bradford's Law predicts the number of journals in each zone. This enables a prediction of how much relevant information will be missed if a search is incomplete. **Objectives:** Following examination of Bradford's Law upon Cochrane reviews on *acute otitis media* and *pneumonia* it was found the Law, which is based on diminishing return in searching exhaustively, did not conform. A previous analysis of all Randomised Controlled Trials (RCTs) in the MEDLINE database found that the distribution showed variations from the standard Bradford Law. Whilst there are numerous papers reporting the productivity of cited journals in health, the impact of Bradford's Law upon a systematic reviewers need to search beyond core journals has not been studied. **Methods:** Titles, abstracts or keywords were searched in the Cochrane Library for reviews of treatments of *acute otitis media* and *pneumonia*. References to the conditions were sorted to generate a cumulative distribution for the subject. **Results:** For a *cute otitis media*, 71% of the core journal



articles were included in the reviews, versus 35% of non-core journal articles (Figure 1). For *pneumonia* the numbers were 43.5% and 30%, a similar trend but with much reduced magnitude of difference. Less than half of all included articles came from core journals (*otitis media* 47% and *pneumonia* 38%). From the tail zone for *pneumonia*, the number of studies exceeded those from the core. Eighty-six per cent of all studies and 92% of included studies came from MEDLINE indexed journals. **Conclusions:** The study found that less than half of all included articles came from core journals. This confirms that searching non-core journals is necessary to capture the relevant literature and to avoid bias.

GRADE: reasons for downgrading the quality of evidence in recent Cochrane Reviews

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Background: The use of GRADE for evaluating the quality of evidence is recommended in latest version of the Cochrane Handbook (2008). GRADE specifies four quality levels (high, moderate, low and very low). Starting point is a high quality rating for a body of evidence based on randomized clinical trials. This rating can be downgraded, depending on the presence of five factors: within-study risk of bias, directness of evidence, heterogeneity, imprecision of the effect estimates and risk of publication bias. **Objectives:** To assess the use of GRADE in recently published Cochrane Reviews and to analyze reasons for downgrading. **Methods:** Our analysis will be based on all GRADE profiles in Cochrane Reviews published as new or updated reviews from 2008 until issue 6 2010. **Results:** In a pilot study, performed on the 33 new reviews in Issue 3, 2010, we found 4 GRADE profiles. In one review, the evidence for all outcomes was rated as high quality. The

authors explained in several footnotes why they did not downgrade. In the other reviews the quality was downgraded: one review included a trial with results from a post hoc analysis of a sub-set of a larger trial and downgraded the quality of evidence because of reporting bias and indirectness. In the second review, with two trials and one outcome of interest, the quality of evidence was downgraded two levels because of poor study design, without further details. The confidence interval was wide (OR 0.61, 95% CI 0.09–4.27), but downgrading for imprecision was not mentioned. In the last review there was only one trial for each outcome. For each outcome, 4 to 5 reasons for downgrading were given, including 'confidence interval includes the null'. **Conclusions:** GRADE is a methodologically rigorous and user friendly system, but in practice there is some inconsistency in applying the system.

Session C3: Writing and Development

Joining the club—www.cochranejournalclub.com

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Background: Journal Clubs have been used for over 100 years to promote an increased awareness of research, educate students to critique and use research findings, and to aid in the translation of research into practice. **Objectives:** To develop a regular online Cochrane Journal Club (CJC) with a broad focus, covering academic and clinical subjects suitable for researchers, medical students, trainees and registrars. To collect data on visitors to the site and to survey users to ascertain if CJC is meeting their educational requirements. **Methods:** Working with Mike Clarke (Director, UK Cochrane Centre) and David Tovey (Editor-in-Chief of The Cochrane Library) workflows

were developed to facilitate the identification of suitable Cochrane Reviews. Authors of selected reviews are invited to create the additional educational content with guidance from Mike Clarke. Wiley-Blackwell host CJC and increase the visibility of each edition by targeted promotions. Usage is recorded on the visitors to the site, and an online survey was used to collect data from users between 22nd February and 30th April 2010. **Results:** CJC was launched in October 2009. As of March 2010, five editions have been published, attracting a total of 12,063 unique visits from 139 countries. 950 individuals have signed-up to receive alerts each time a new edition of CJC is published. Preliminary results from the user survey indicate that most users work in a hospital or university, in Asia, Europe or North America and are from a broad age range. Most users heard of CJC via an email alert and use the material presented to further their own understanding of the Cochrane Review. **Conclusions:** Usage and email sign-ups have exceeded our expectations and there has been overwhelmingly positive feedback to the project. CJC was selected as resource of the month by the Royal Society of Medicine in November 2009.

Stimulating research development: the effect of a patient-clinician partnership that identified and prioritized research needs in urinary incontinence

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Background: Research often neglects important gaps in existing evidence. As a result clinicians and patients must make decisions about treatments without reliable evidence about their effectiveness. Gaps in the evidence range from specific unanswered questions about treatments to broad areas of uncertainty requiring larger programmes of research to generate the evidence needed to inform clinical decisions. **Objectives:** A UK partnership of 8 patient and 13 clinician organisations, reported at the 2009 Singapore Colloquium, identified and prioritized gaps in the evidence that affect everyday clinical decisions relating to the treatment of urinary incontinence. This presentation will assess the effect of the research prioritization exercise. **Methods:** UK organisations consulted memberships to identify "evidence gaps" affecting treatment decisions. Gaps were also identified in systematic reviews' research recommendations. Initial shortlisting of 226 evidence gaps by organisations was followed by use of established consensus methods at a prioritization workshop. A "top ten" was produced and published in research and clinical journals. Subsequently, reviews of research databases and peer consultation are being used to identify new research or funding applications relating to the prioritized topics. **Results:** Since publication, at least four funding applications relating to prioritized topics have been made and a fifth is in preparation. One large application has been awarded. Two new systematic reviews are under way. All have referenced the prioritization work. These new research activities consider optimal pelvic floor muscle training regimens, effectiveness of urodynamic investigations and aspects of tension-free vaginal tape surgery, intermittent self-catheterization and neurogenic bladder management. **Conclusions:** The partnership successfully developed and employed

a methodology for identification and prioritization of research needs by patient-clinician consensus. Since publication of the partnership's work, new research activity has been identified relating to five of the ten prioritized topics. Prioritization through patient-clinician consensus is effective in informing the development of clinically useful research.

Passport to publication? Do methodologists publish after Cochrane Colloquia?

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Background: A Cochrane methodology review shows that approximately half of conference abstracts reporting biomedical research are subsequently published as full reports. This presents difficulties to systematic reviewers who seek to identify a relevant dataset which is as complete and unbiased as possible. We wished to assess the equivalent publication rate for methodological research. We used data from a project to enhance the Cochrane Methodology Register (CMR), which was funded by The Cochrane Collaboration and involved linking records for the same empirical study. On entry to CMR, records are assigned codes relating to subject area and type of report and we sought to assign additional coding to link together records for the same research. **Objectives:** To assess the extent to which abstracts of methodology research, initially presented at Cochrane Colloquia, have subsequently been published as full reports; overall and within specific areas of methodology (e.g. statistics and information retrieval). **Methods:** CMR was searched for abstracts reporting methodology research, which had been presented at oral and poster sessions at Cochrane Colloquia (1997–2007). CMR, PubMed and EMBASE were searched for full publications for the same research. **Results:** CMR contained 909 abstracts of methodology research from 11 Colloquia. Preliminary data suggest that up to 600 (66%) of these have not been published in full. We found full publications for 310 abstracts (34%). The mean time to first full publication was just under two years. Most research was published in full within four years after the abstract presentation, with a few studies appearing up to a decade later. Analysis of the publications by methodology area is ongoing. **Conclusions:** The rate of full publication of Cochrane Colloquia abstracts related to studies of research methodology seems to be lower than that for biomedical research more generally.

Systematic reviews registers as a Cochrane Field activity

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Background: The Cochrane Child Health Field (CHF) has developed a register of child-relevant Cochrane Systematic Reviews (CSRs). Developing a register that contains and describes SRs within a Field's scope is valuable in order to: 1) make relevant evidence regarding important healthcare decisions readily accessible to decision-makers; 2) identify gaps in the evidence base where SRs are required; 3) assist with prioritization of topics for synthesis; 4) describe the quantity and quality of primary research contributing to SRs; 5) provide a basis for methodological research to identify and understand biases in SRs and primary studies; and, 6) provide a basis for recommendations regarding

the conduct and reporting of relevant primary research. **Objectives:** The objectives of this presentation are to describe the development of the CHF SR register and to highlight the value to Cochrane Fields of developing registers relevant to each Field's scope. **Methods:** We will review the methods the CHF has implemented to develop and maintain its register, with special attention paid to how our Field defined its scope and developed a screening algorithm. **Results:** The CHF SR Register currently contains 1,046 SRs with over 60 data points on each SR, including general characteristics, characteristics of included studies, and methodological approaches. We will discuss the information the CHF now has about the Cochrane SRs in its scope and the analyses that have been based on the information in the SR Register. We will describe plans for methodological work based on the information contained in the Register. Lastly, we will discuss methods for updating the register, and our plans for including non-Cochrane SRs. This information may assist other Fields in carrying out similar work. **Conclusions:** We believe that SR Registers are important work for Fields in order to understand the nature and comprehensiveness of SR evidence in the Field's scope.

Oral session D

Education and Training

Session D1: Web Tools

Motivational analysis of the health professionals in the usage of online evidence retrieval systems

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Background: The online database is an Internet-based resource for evidence-based practice (EBP). It offers an easy access to EBP information and facilitates the integration of evidence into practice by providing summarized recommendations for clinical services.

Objectives: This study aims to understand the motives of health professionals in the use of online database. **Methods:** A constructed questionnaire survey was carried out to examine the correlation of access to online evidence retrieval systems with the motivation among 2975 nationwide representatives in the regional teaching hospitals of Taiwan. Statistical analysis was performed by chi square test using commercial available software. **Results:** The most common motivation to access the online database was class assignment (62.2%), followed by searching information for clinical practice (56.1%), instruction preparation (37.8%), personal interest (28.3%), research need (22.4%), contest for literature search and critical appraisal (18.9%), and medical accreditation (11.1%). In addition, the motives among health professionals who accessed the Cochrane Library were associated with searching information for clinical practice, class assignment, instruction preparation, personal interest, research need, and medical accreditation ($P < 0.01$). Furthermore,

the health professionals who had positive belief, attitudes, knowledge or skills of EBP more often accessed the online databases to search information for clinical practice ($P < 0.01$). **Conclusions:** The current study depicts the motivations of the access to online databases among the health professionals of the regional hospitals in Taiwan. The data lead to the suggestion that continuous education can accelerate the application of online evidence database and further enhance the implementation of EBP.

A web-based tool for adjusting costs for currency and prices year

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Background: International comparisons of the costs of interventions are important for a number of different applications. One specific application relates to systematic reviews that aim to incorporate evidence on the costs of interventions collected from included studies. Since included studies are often conducted in different countries and/or at different times, estimates of costs are often expressed in different currencies and/or price years. In these circumstances adjustment of costs to a common target currency and price year is necessary to facilitate meaningful comparisons and synthesis of the evidence across studies. **Methods:** A web-based tool utilising GDP deflator indices and Purchasing Power Parities conversion rates was programmed using C#. The tool automates adjustment of costs to target currency and price year. **Results:** Version 1.0 is available for use by authors of systematic reviews and other analysts, free of charge, at <http://epi.ioe.ac.uk/costconversion/default.aspx>. **Conclusions:** This tool can be used as a first-line approach to cost adjustment in systematic reviews of social and behavioural interventions and as a optional approach in systematic reviews of health care interventions where more sophisticated methods of adjustment are not feasible. Its benefits include increased speed and accuracy of adjustments and use of an explicit, reproducible methodology consistent with the systematic review process.

Using machine learning to reduce the systematic review workload

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Background: Screening abstracts for eligibility is a vitally important, but tedious step in the systematic review process. Typically, electronic searches for a review yield several thousands of abstracts, which are then perused by the reviewers and either excluded from or included in the review according to some predefined criteria. This is a laborious, expensive process. **Objectives:** To reduce the burden on researchers conducting systematic reviews by applying machine learning (ML) techniques to expedite abstract screening. In particular, to build a classification model from a manually classified subset of the entire

corpus of citations retrieved via the search strategy and then use this model to automatically include or exclude the remaining citations. **Methods:** For our classification model we use the Support Vector Machine (SVM), a state-of-the-art algorithm well suited to textual data. To expedite the training of the model—and thereby reduce the reviewers' workload—we use a technique known as active learning, in which the expert interactively trains the SVM by providing labels for abstracts sequentially (i.e., designating them as 'eligible' or 'ineligible'). The relatively low prevalence of eligible abstracts and the caveat that a semi-automated screening process for systematic reviews must not wrongly exclude any relevant abstracts presents novel challenges for ML algorithms. We have developed new methods that address these challenges. **Results:** We ran experiments on several datasets from previously conducted reviews. Simulating active learning, we show that our method can reduce workload by 40 to 50%, without wrongly excluding any relevant studies. **Conclusions:** Our preliminary work indicates that the burden on researchers conducting systematic reviews can be reduced substantially without sacrificing thoroughness.

Cochrane Canada Live: webinars to benefit the Collaboration and beyond

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Background: Online learning is an important means to facilitate the educational needs of those producing and using systematic reviews. Online learning initiatives, such as the UK Cochrane Centre Online Learning Resources, have already been underway in the Collaboration to address those needs. The Canadian Cochrane Centre, through a partnership with the Pan American Health Organization/World Health Organization, has developed a webinar (web seminar) broadcast stream to help fulfill a role in education for those in the Collaboration and beyond. **Objective:** To describe the *Cochrane Canada Live* webinar broadcast stream as a new educational resource. **Description:** *Cochrane Canada Live* is the broadcast webinar stream coordinated by the Canadian Cochrane Centre using the Elluminate Live!® interface. The interface allows real-time interaction among the moderator, speaker, and participants and includes features such as live polling, application sharing, web touring, file transfer, handling multimedia files, and the ability to record and archive for later viewing. The first and ongoing research webinar series was launched in 2009 and addresses topics related to systematic reviews. The speaker will discuss the grassroots development of this series, the purposes we hope that it serves for the Collaboration, how the interface works, and our vision for the future.

Oral session E

Global Health and Equity

Session E1: Health Equity

Using Cochrane reviews to help reduce fetal and other perinatal deaths in high income countries

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Background: Currently several interlinked international groups are examining the epidemiology of stillbirth, potential interventions to reduce stillbirth rates, and research gaps and priorities in low, middle and high income countries. **Objectives:** To outline the contribution of Cochrane reviews to stillbirth policy and research priority development. **Methods:** As part of the high income project, we assessed all relevant Cochrane reviews (254 reviews from Cochrane Library issue 4, 2009) for their ability to identify interventions with the potential to reduce stillbirths or to reduce factors known to be associated with stillbirths in high income countries (informed by a systematic review of 63 cohort and case control studies from high income settings undertaken by the authors and other colleagues). **Results:** Only 11 (4.3%) of the 254 Cochrane reviews reported a significant reduction in stillbirth. While we judged that a further 139 (54.7%) were unable to confirm or refute stillbirth reductions due to insufficient trials or participants, they helped indicate which interventions might affect modifiable factors (such as smoking cessation interventions for pregnant women). Together with perinatal research gaps identified by the WOMBAT Collaboration, these findings are being integrated in the larger project, to help rank feasibility of interventions and research priorities. There was some evidence of selective outcome reporting bias at both the review and trial level. **Conclusions:** Clearer reporting of perinatal deaths in Cochrane reviews (and trials), particularly separate reporting of fetal and neonatal deaths and more attention to selective reporting of stillbirth outcomes is required. While few Cochrane reviews contain enough trials and participants to show differences in stillbirth rates, they are essential for indicating promising interventions, informing future stillbirth policies and research agendas. The contribution of Cochrane reviews can be maximised by linking with other study designs and as part of larger projects aimed at improving health outcomes.

Meeting the challenges of undertaking and communicating complex reviews with 'messy' messages: the case of the health effects of mixed income communities

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Background: Reviews that address policy questions crossing several public sectors such as health, housing and planning pose challenges for review preparation and engagement including the problem of 'empty reviews', dealing with diverse study designs and communicating uncertainty. There is, however, little guidance on how to proceed in these circumstances. **Objectives:** We describe how we reviewed the literature addressing the health and social effects of mixed income communities (MICs) and reflect on our experiences of dealing with a diverse but thin evidence base. Our review was a pilot rather than a full systematic review and was part of a larger study informing a planned new MIC in the East End of London in the UK. **Methods:** We employed traditional and novel systematic review methods in

anticipation of a diverse literature. We searched comprehensively, appraised and coded studies using a standardised framework but planned flexibility into our synthesis methods. We engaged with users throughout the process, held a multi-professional workshop to discuss findings and planned different formats to present recommendations. **Results:** A total of 56 studies met our inclusion criteria. All but two of the evaluation studies were case studies of one or more MICs and we were not able to draw firm conclusions about the impact of MICs on health or social outcomes. Content and thematic analysis were used to draw out findings on factors related to the planning and implementation of MICs and recommendations were presented in the format of practice principles and hypotheses to test in new primary research. **Conclusions:** This study illustrates several strategies for synthesising and communicating the useful lessons captured within study findings in reviews which reveal a weak evidence base in relation to questions of cause and effect. Further work is needed to evaluate the added value and costs of such strategies.

What's the point of evaluating effectiveness? Perspectives from a low income setting

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Background: Effectiveness research is highly valued within the evidence-based movement. However there has been little research to explore whether this priority is equally valued in low income countries, despite increased efforts to encourage the use of research in decision-making. **Objectives:** This study aimed to explore perceptions of the usefulness of research for public health decision-making in Ghana. It aimed to understand the perceived value of research and to identify the types of research considered useful for decision-making. **Methods:** Semi-structured interviews were conducted with 69 researchers, decision-makers and other stakeholders working in the field of public health in Ghana. **Results:** The concept of research was broad, incorporating routine data, government reports and even informal conversations and observations. Research was dichotomised into 'big', formal, academic research and 'small', applied research such as operations research. So-called 'small research' was highly valued, due to its speedy completion and its focus on topics pertinent to service delivery; big research was not always considered necessary. Effectiveness research, one type of 'big research', was not highly valued with regards to complex public health interventions and policies. Interviewees tended to feel that 'effective' policies and programmes could be designed once there was a thorough understanding of the situation. There was an implicit assumption that as long as these interventions were implemented well, they would be effective and so evaluations were not necessary. **Conclusions:** The lack of emphasis on evaluation and the broad definitions of research in Ghana may impede the applicability of the concept of evidence-informed decision-making. Those hoping to encourage research use in low income countries such as Ghana should be aware of, and open a dialogue about, the possible

differences in perceptions and values and what they mean for efforts to support evidence-informed decision-making.

Supporting policy-relevant reviews and trials in low and middle-income countries

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Background: Achieving the millennium development goals in low and middle-income countries (LMIC) will depend on policymakers accessing the best evidence about services that work, and integrating this evidence into their national health systems. With this in mind, researchers and policymakers from Africa, Europe, and North and South America came together to form SUPPORT (SUPporting Policy-relevant Reviews and Trials); with the aim of promoting evidence-informed policymaking in LMIC. **Objective:** To present SUPPORT's objectives and achievements. **Methods:** SUPPORT set out to summarise systematic reviews on priority interventions for reducing maternal and child mortality as well as health systems arrangements for their cost-effective delivery; and develop tools to support the use of research evidence to inform policy decisions and the conduct of pragmatic trials when reliable evidence is lacking. **Results:** From 2006 to 2010 SUPPORT produced more than 200 summaries of reviews with discussion of the relevance of findings to LMIC, the Policymaker Tools (STP), Trial-Management Tool (TMT) and Trial-Funding Tool (TFT); conducted workshops for over 280 policymakers in Africa and South America; and developed both a trial-management and systematic review course. STP is a series of articles that address four areas: supporting evidence-informed policymaking; identifying needs for research evidence on problem clarification, options framing, and implementation planning; finding evidence to inform these steps; and going from evidence to decisions. TMT and TFT are packages of resources to improve trial management and access to support on trial funding for LMIC researchers respectively. The policymaker workshops empower policymakers to become informed users of research-based evidence. **Conclusion:** SUPPORT provides a model of how researcher-policymaker partnerships and cross-continental linkages can be used to improve the use of reliable research evidence in policymaking and to fill in gaps where there is lack of reliable evidence. SUPPORT materials are available free on the SUPPORT website (www.support-collaboration.org).

Session E2: Health Evidence and National Policy

Cochrane reviews inform UK national policy on disinvestment from ineffective interventions

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Background: Rising healthcare costs and a thirst for innovation, coupled with the economic crisis, mean that healthcare systems

around the world are under increasing pressure. Rather than 'cutting costs', the 21st century focus is on identifying 'efficient' 'value for money' strategies that are sustainable and equitable, and lead to improvements in the quality of care and, ultimately, patient outcomes. The National Institute for Health and Clinical Excellence (NICE) is responsible for providing national guidance on promoting good health and preventing and treating ill health in the UK. **Objectives:** In 2006, NICE commissioned the UK Cochrane Centre (UKCC) to produce quarterly reports of new or updated Cochrane reviews whose authors had concluded that an intervention should not be used or should only be used in research. These are used to identify potential disinvestment topics within the National Health Service. **Methods:** The UKCC checks the Implications for practice section in new and updated Cochrane reviews in each issue of The Cochrane Library, and in all Cochrane reviews once a year. It provides a list of reviews to NICE, where an evaluation is done to ascertain current usage of the intervention in the UK, identify existing NICE guidance or economic evaluations, estimate the financial implications and determine whether additional research is required. The evaluation is summarised and, from July 2010, will be available as a monthly report on the NICE website, through its NHS Evidence 'quality and productivity' portal. If appropriate, topics are also assessed for inclusion in the NICE guidance programme. **Results:** As of March 2010, more than 400 topics have been evaluated. **Conclusions:** Cochrane reviews, particularly those of established technologies, are an important source of potential topics for disinvestment to inform national policy and research.

Bringing policy makers closer to systematic reviews: Brazilian strategies

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Objectives: to describe the method used by the Department of Science and Technology (DECIT) of the Ministry of Health of Brazil to bring policy makers closer to systematic reviews. **Methods:** the criteria used in selecting systematic reviews strategic projects include larger budgets projects and projects with great pressure for response by public managers. Operationally, for each project selected, five players are involved in the process: (1) the research coordinator; (2) the Ministry of Health's disease area; (3) the specialized external consultant; (4) DECIT; and (5) inter-institutional financial partnership (Ministry of Science and Technology). The analysis process begins with the coordinators' presentation of the research proposal, and it is followed by comments and suggestions from the Ministry of Health's disease area and from the external consultants. In addition to mediating the debate, DECIT intercedes in administrative and juridical issues with the financial partnership. **Findings:** between 2007 and 2009, eight systematic reviews were followed up, evaluating: statins and fibrates for dyslipidemias (2 projects); anti-cytokines for rheumatoid arthritis (2 projects); antivirals for hepatitis B (2 projects); and enzyme replacement therapy (2 projects). All the projects were modified (to a greater or lesser degree) according to healthcare decision-makers' interests as the policy makers provided needed information and supplies for conducting the research in the best manner. **Conclusions:** this process made possible the systematic reviews foster actions carried out

by DECIT to be rationalized and better directed. On the other hand, significant project modifications caused difficulties in the administrative procedures. It ought to minimize lapses of time between the research response and decision-making requirements.

The utilization of systematic review and meta-analysis in China

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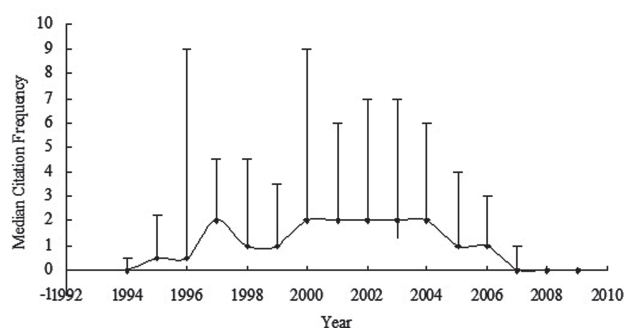
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Background: Distance from research to practice always exists. The dissemination and utilization of systematic reviews/ meta-analyses (S/Ms) as the best evidence is increasingly concerned. China, as the largest developing country with more than 1.3 billion people, in where it is very important to push the local production and utilization of S/Ms for the improving of health decision making, research, and clinical practice.

Objective: To learn and analyze the citation of S/Ms published in Chinese journals for accelerating the translation of them. **Methods:** We searched the Chinese Medical Citation Index (CMCI) database (up to Feb. 2010) using the term "systematic review" and "meta-analysis" to identify S/M. SPSS 15.0 software was used for statistical analysis.

Results: 2810 records were retrieved, and finally 2294 S/Ms were included. They were published in 610 journals from 1994 to 2009. The median publishing number of each journal was 2 (Min-Max: 1–272). The total citation frequency for these papers was 2863, with an average number 1.25 (Min-Max: 0–57) for every one. 1420 S/Ms (61.9%) have never been cited. The average citation frequency of each Systematic review was lower than that of each meta-analysis ($Z = -2.316$, $P = 0.021$). There had no statistical difference of the average citation frequency of each S/M published in "evidence-based medicine" titled journals and other journals ($Z = -1.661$, $P = 0.097$). No relationship was found between the citation frequency of a paper and its reference's number ($r = 0.040$, $P = 0.117$). A descent tendency for the citation frequency was found from 2004 (Figure). **Conclusions:** Most of the S/Ms published in Chinese journals are not cited or low cited. The condition is becoming worse. This reflects that the utilization level of S/Ms is still low in China because of miscellaneous reasons. It is necessary to conduct more translation research and practice to shorten the distance from research to practice.



Linking Evidence to Policy: Supporting the Use of Research Evidence within African Health Systems

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Background: In order to provide good quality, universal and equitable health care, managers need to make well informed decisions. This necessitates access to and use of reliable research evidence. For some health systems questions, evidence is still not accessible in forms that facilitate its use. **Objectives:** To describe how the SURE project aims to facilitate policymakers' access to and use of research evidence that is relevant, reliable, accessible and timely. **Methods:** A consortium was established and priority health system issues identified within each African partner country. Country teams will develop policy briefs that will draw on evidence from the Cochrane Library, among other sources. Policy dialogues will be organised to discuss the policy briefs and engage stakeholders in considerations of the health systems problem, options for addressing the problem and strategies for implementing the options. Rapid response mechanisms and a clearing house for policy-relevant research will be developed and pilot tested to respond to policy makers' urgent needs for research evidence. User friendly formats are also being developed for summarising and presenting policy briefs and rapid responses, and these are being user tested. **Results:** A consortium of teams from 11 African countries supported by teams from 3 European countries, Canada and the World Health Organization has been established. Each African partner will have prepared at least one policy brief and organised at least one policy dialogue by October 2010. Policy questions include expanding the use of health workers to deliver cost-effective interventions; improving the governance of health districts and reducing maternal and infant mortality. Pilot testing of a rapid response service will be completed in June 2010. User testing and development of clearing houses are ongoing. **Conclusions:** Concerted efforts are needed to ensure that relevant evidence is accessible and used appropriately by policy makers to inform decisions about health systems. This is particularly challenging and important in settings with severe constraints on resources and many competing priorities, such as African countries.

Session E3: Applying Evidence Locally

The urgent needs for building the capability of systematic reviews in the Asia Pacific countries

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Background: Systematic reviews (SRs) become more and more important for the healthcare decision- and policy-makers nowadays. The SRs development varies in countries of Asia-Pacific region. Different

promotion strategies are required to develop the SRs for countries in the region. **Objectives:** To identify the current development and influence factors to SRs publication in the Asia Pacific region. **Methods:** We compared the performance of 11 selected countries/regions with regard to their published SRs retrieved from PubMed during 1989–2008. Other social and healthcare determinants, such as, the total number of physicians, and gross domestic product were also taken into account. **Results:** Of the 11 studied countries/regions, Australia produced over half of the SRs (51%), followed by China (10%), Japan (10%), New Zealand (9%), Hong Kong (5%) and India (5%). A comparison of the overall health science publications indicates that Australia, New Zealand, Hong Kong, Singapore, and Thailand had relatively high productivity in SRs. The ranking was similar as we carried out the analysis by taking into account of the total number of physicians in each country. Further analysis showed that fewer than 5% of SRs were published in Cochrane Database of Systematic Review (CDSR) in Japan, South Korea and Taiwan. **Conclusions:** Among the Asia-Pacific countries and regions, Australia has set an outstanding example in the development of SRs. To some extent, New Zealand, Singapore, Hong Kong, China, and India have also contributed significantly to this body of knowledge. Japan, South Korea, and Taiwan can improve more in producing SRs, in particular Cochrane SRs. The findings re-addressed that building the capacity of SRs required supports from both local government as well as regional Cochrane entities. To bring together all research partners in the region, particularly those with Cochrane entities, is crucial to reduce unnecessary barriers and accelerate the progress in SRs research.

Evidence-based recommendations for promoting physical activity among older people: Global evidence, local decisions

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Background: The majority of adults are not consistently physically active globally. Older people are recommended to participate in exercise activities but they may not even understand what exercise is according to results from a qualitative interview study. **Objective:** This review aims to develop a physical activity guideline for both older people and health care professionals who have a role in instructing and promoting physical activity among older people. **Methods:** A systematic search of the literature was conducted using a range of electronic and evidence-based databases to identify evidence. Inclusion criteria were guidelines, systematic reviews or randomized controlled trial design; study samples were age 60 years and over, physical activity or exercise was of a main focus. Data extraction and quality appraisal were carried out independently by two reviewers; a third reviewer was consulted when required to solve discrepancies. **Results:** A total of five guidelines were included, two from American College of Sports Medicine and one each from The National Institute for Clinical Excellence (NICE), Austrian Department of Health and Ageing and Canadian Fitness and Lifestyle Research Institute. Overall recommendations were listed for both older adults and health care professionals. Apart from physical activity recommendations on frequency, duration and intensity, evidence suggests that older people are encouraged to be

physically active by making plans and plans should include a gradual approach to increase physical activity over time using multiple bouts of activity as opposed to previous recommendation of continuous bouts when appropriate. **Conclusions:** The results of this review provide thorough evidence for recommendations of physical activity among older people. Effective ways of providing tailored recommendations on physical activity for older adult population were listed. Future study tested feasibility and effectiveness of this evidence-based guideline is warranted.

When can research conducted elsewhere be useful here? Perceptions of local applicability and transferability

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Background: The use of research that is not appropriate for a setting could be as harmful or wasteful of resources as the non-use of appropriate research. Before using research conducted elsewhere, decision-makers must decide whether it is applicable and transferable to their setting. **Objectives:** To understand what factors are considered important when assessing local applicability and transferability. **Methods:** Interviews were conducted with 69 public health researchers, decision-makers and other stakeholders in Ghana. **Results:** Six dimensions of local applicability and transferability were identified (table 1). The most influential dimensions and factors were the ease with which the intervention could be implemented, the study's congruence with interviewees' previous experiences and the need for

Table 1. Dimensions and factors inherent in local applicability/transferability.	
Dimension	Factors
Setting	Intervention need Country-level similarity Population-level similarity
Ease of Implementation	Intervention characteristics Capacity to implement Sustainability of implementation
Congruence	With beliefs and values With previous experience With other evidence
Effectiveness	Original study findings Potential effectiveness
Adaptation	
Study design/methods	Sampling methods Size/coverage of intervention Validity Analysis/other information about findings

the intervention. Little attention was paid to study findings. Judgements of an intervention's potential effectiveness tended to be based on the ease of implementation or knowledge of similar projects. Adaptation was considered to be crucial, although often conceptualised not as a factor within local applicability/transferability assessments, but rather a distinct, essential step in the research use process. **Conclusion:** Those attempting to encourage research use in policy and practice should be aware of the importance of encouraging *appropriate* research use, rather than merely pushing for *more* use. This study suggests that the factors of local applicability/transferability frequently cited in the literature as being important do not reflect those considered to be most important by stakeholders in Ghana.

Session E4: Clinical Trials

Transparency of Chinese trials: The results are fully published after registered in WHO primary registries?

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Background: Full result publication is one of the main way to improve trial transparency. **Objective:** To investigated the result publication rate of Chinese trials registered in WHO primary registries. **Method:** We searched 11 WHO primary registries to screen the registration record of Chinese trials. The progress of each trial was analyzed. We searched the results full texts by tracing the result publication citations in the registration record. For completed trials without citation, we searched PubMed, EMBase, Chinese Biomedical Literature Database (Chinese), China Knowledge Resource Integrated Database, Chinese Science and Technology Periodicals Database by key words and registration number to find the result publication. We called the authors of completed trials of unavailable results publication by systematic search to ask for the results publication. **Results:** A total of 1294 Chinese trials records were identified. We analyzed the results publication of 1171 (428 in ChiCTR and 743 in clinicaltrials.gov) records. The results publication rates of Chinese trials in clinicaltrials.gov and ChiCTR were 36.6% (53/145) and 36.3% (89/245) respectively. The results publication rate of trials sponsored by industry was lower than sponsored by non-industry (24.1% vs. 42.1%). Publication rate of non-randomized trials was higher than randomized trials (23.7% vs. 19.6%). Publication rate of interventional study was higher than observational study (38.5% vs 32.1). **Conclusion:** Result publication rate of registered Chinese trial was low with no significant difference between ChiCTR and clinicaltrials.gov. Effective mechanism is needed in China to promote the result publication based on trial registration system.

Knowledge gaps and priorities for clinical trials in tropical diseases: gleanings from the Cochrane Library

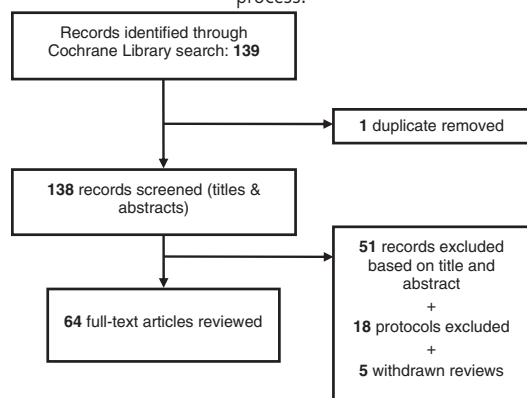
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Background: Tropical diseases research in general has played a vital role in finding solutions for many health threats faced by

Figure 1. Flow chart describing review selection and inclusion/exclusion process.



humankind especially in Sub Saharan Africa and other developing countries. Funding available for tropical disease research is not commensurate with the disease burden. Identifying knowledge gaps and priorities for clinical trials would encourage judicious investment of limited research funds on most important research questions. Cochrane systematic reviews on tropical diseases have addressed important questions that have relevance for health policy and practice, and involved rigorous searches of published and unpublished trials. The Cochrane Database of Systematic Reviews (CDSR) therefore represents a good source of information on gaps and priorities for clinical trials in tropical diseases. **Objectives:** To synthesise available information on knowledge gaps and priorities for clinical trials from Cochrane Systematic Reviews in tropical diseases. **Methods:** Cochrane Library Issue 1, 2010 was searched for systematic reviews of tropical infections. The words Malaria, Tuberculosis, Schistosomiasis, Onchocerciasis, Leishmaniasis, Chagas, Dengue, Meningitis, Lymphatic Filariasis and African Trypanosomiasis were used to search the Cochrane Library for anywhere they appeared in the Title, Abstract and Keywords of reviews. The search results were screened and reviews excluded based on title/or abstract and duplicates removed. Protocols and withdrawn reviews were also excluded. Full papers of remaining reviews were obtained and information on the included trials collected. **Results:** The search of the CDSR yielded 139 records. Figure 1 shows the review selection, inclusion/exclusion process. Sixty-four reviews (688 trials and over 432,791 participants) were found. Majority of the reviews were treatment interventions (73.4%) while the rest were prevention interventions. 70.3% (45/64) of the reviews authors' expressed the need for more trials. 14.1% (9/64) of the reviews reported poorly done trials. **Conclusions:** There is a dire need for improved funding for larger, high quality trials in tropical infections with priority given to prevention interventions.

An international register of ongoing systematic reviews

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Background: Support is growing for the prospective registration of protocols for systematic reviews. As for clinical trials, registration could be an important means of combating publication and selective outcome reporting biases. Registration could also help avoid unnecessary duplication; encourage collaboration; and create opportunities for new methodological and other research. Until now, there has been no international centralised, comprehensive register of ongoing reviews. Existing registration of protocols has been limited to individual organisations, such as the Cochrane and Campbell Collaborations. However, more than 80% of systematic reviews are generated outside these organizations, and an international register, open to all, has the potential to have a major impact. **Objectives:** Our intention is to develop, implement and manage an international web-based register of ongoing systematic reviews with health-related outcomes. **Progress to date:** The Register uses the existing IT platform and infrastructure that supports production of the three publicly accessible databases at the Centre for Reviews and Dissemination (CRD): DARE, NHSEED and HTA. To ensure that the Register is fit for purpose and acceptable to potential contributors and users, a Delphi exercise was undertaken in 2010 to define a minimum dataset. The Register offers free public access, is electronically searchable and open to all prospective registrants. Registration requires provision of the minimum data set. After acceptance, the register entry is loaded as a permanent entry and a unique identification number issued. If a protocol is available for the review, this is loaded as well. Each record will also include an audit trail of amendments and links to resulting publications. **Conclusions:** As the Register develops, it will contribute to improvements in the quality of systematic reviews and the decisions that rely upon them; supporting the efficient use of funding and timely updating, and providing a way of assessing the risk of bias in systematic reviews.

CONSORT in China

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Background: CONSORT and other related reporting guidelines have made impressive progress in the past 14 years. The publication of CONSORT 2010 Statement in several high impact factor medical journals in the world indicated that the content of reporting quality of RCTs is being perfected. However, the dissemination and implementation of CONSORT in China is unknown. **Objective:** To describe the current status and development of reporting guidelines such as CONSORT and PRISMA in China. **Methods:** We searched three main medical databases CNKI (China National Knowledge Infrastructure/Chinese Academic Journals full text Database), VIP (a full text database of China) and CBM (China Biomedicine Database) using the term "CONSORT" from 1996~2010. **Results:** The CONSORT was first introduced into China in 1997. There were 91 papers related to CONSORT and other reporting guidelines. 33 papers were translation (36%), 22 papers were reviews on reporting quality of RCTs (24%) in China, the other papers were about comments, letters and so on. Most papers (29) published in Chinese journal of evidence based medicine; Less than 5% Chinese clinical medical journals which

indexed in MEDLINE or EMBASE had recommended CONSORT in their "Instruction to authors". **Conclusions:** The dissemination and implementation of CONSORT in China need to be improved. In order to make the achievement of the CONSORT series benefit more widely, especially in developing countries and non-native English speaking countries, we would like to suggest three measures on which we should focus that effort. Firstly, medical editors should recognize and pay more attention to the reporting guidelines because their key roles in the publication and spreading medical information; secondly, medical researchers and clinicians should actively carry out the clinical trial registration policy; last but not least, medical schools should introduced reporting guidelines into medical education as early as possible.

Oral session F

Investigating Bias

Session F1: Assessing Risk of Bias

Randomisation to protect against selection bias in healthcare trials

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Background: Randomised trials use the play of chance to assign participants to comparison groups. The unpredictability of the process, if not subverted, should prevent systematic differences between comparison groups (selection bias). Differences due to chance will still occur and these are minimised by randomising a sufficiently large number of people. **Objectives:** To assess the effects of randomisation and concealment of allocation on the results of healthcare trials. **Methods:** We performed a comprehensive systematic search (September 2009). Eligible study designs were cohorts of trials, systematic reviews or meta-analyses of healthcare interventions designed to compare random allocation versus non-random allocation or adequate versus inadequate/unclear concealment of allocation in randomised trials. We assessed the risk of bias. Outcomes of interest were the magnitude and direction of estimates of effect and imbalances in prognostic factors. **Results:** A total of 16 studies met our inclusion criteria. All studies were at high risk of bias. When studies compared the impact of random and non-random allocation, we found larger estimates of effect in non-randomised trials in studies of the same intervention and same condition (1 study, 31 trials), we found conflicting evidence across different interventions for the same condition (2 studies, 200 trials), and in studies

across different interventions and different conditions (8 studies, 486 trials + 74 meta-analyses). When studies compared adequate and inadequate/unclear concealment of allocation across different interventions and conditions, 3 studies (621 trials) found larger estimates of effect in trials with inadequate concealment of allocation, and 2 studies (376 trials) did not find statistically significant differences.

Conclusions: It is generally not possible to predict the magnitude, or even the direction, of possible selection biases and consequent distortions of treatment effects from trials with non-random allocation or randomised trials with inadequate or unclear allocation concealment.

Risk of bias tool evaluation: process and results

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Background: Version 5 of the Cochrane Handbook introduced the Risk of Bias (ROB) assessment tool, which represents a more comprehensive undertaking than previous quality assessments. There is a need to evaluate its implementation, examine barriers and facilitators to its use, and consider availability of training. **Objectives:** To obtain feedback from a range of stakeholders within the Cochrane Collaboration regarding their experiences with and perceptions of the RoB tool and associated guidance materials. **Methods:** We used qualitative and quantitative methods to evaluate the ROB tool. Four focus groups were held with international participants (n = 25). These followed a semi-structured format with a list of pre-specified topics, and were transcribed. Their results informed development of two questionnaires used in online surveys (distributed through established Cochrane mailing lists) of (a) review authors and (b) managing editors and other review group staff. We enquired about experience and perceptions of the ROB tool, incorporation of ROB assessments in meta-analyses, and training requirements. **Results:** We received 190 responses from authors who had used the RoB tool, 132 from authors who had not, and 58 from review group staff. RoB assessments take, on average, 10–60 minutes per study to complete: 83% of respondents deemed this acceptable. Most respondents thought that RoB assessments were better than past approaches to trial quality assessment. Most authors liked the standardized approach (81%) and the ability to provide quotes to support judgments (74%). About a third of participants did not like the increased workload, and found the wording describing judgments of ROB to be unclear. Most authors (75%) thought availability of training materials was sufficient, but many expressed an interest in online training. **Conclusions:** Overall, respondents identified positive experiences and perceptions of the RoB tool. Revisions of the tool and associated guidance, and improved provision of training, may improve implementation.

Assessment of risk of bias in prognostic studies

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Background: Prognostic studies aim to assess the ability of diagnostic tests or clinical observations to predict future events, or to evaluate associations of risk factors and health outcomes in populations of patients [1]. Prognostic research has to date received much less attention than research into therapeutic or diagnostic areas [2]. As more and more of these studies become available, the demand for summarising prognostic studies in systematic reviews, health technology assessments, and guidelines is increasing. Consistent, reproducible assessment of the methodological quality of primary studies is key to the interpretation of secondary research. Where studies of prognostic tests use a test accuracy type design (health outcome being treated as the reference standard) it may be reasonable to assess their methodological quality using a modified version of the QUADAS tool [3]. However, many observational prognostic studies appropriately assess the association of possible prognostic factors, or of having tests done or not done, or of certain test results, with health outcomes using a multivariate regression modelling approach. Tools are needed to standardise the assessment of the risk of bias in observational prognostic studies. **Objectives:** We are currently preparing five reports for the German Institute for Quality and Efficiency in Health Care (IQWiG) on the clinical effects and the diagnostic and prognostic accuracy of positron emission tomography (PET) in various oncological indications. These reports also include primary studies of prognostic tests, which are of a multivariate regression model design, i.e. not test accuracy studies. **Methods:** Based on the methods described by Altman [1] and Hayden [4], we developed a tool for the assessment of risk of bias and variation of effects of this type of prognostic studies consisting of 17 items in 5 domains. **Results/ Conclusions:** We would like to present and discuss results and experiences with this tool.

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Observer bias in randomised clinical trial. An analysis of trials with both blinded and unblinded outcome observers

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Background: Observers responsible for outcome data collection in randomised clinical trials are frequently not blinded. It is often assumed that outcomes are more reliable if observers are blinded, but there is scant reliable empirical evidence on the typical degree of observer bias, and on which factors that are associated with such bias. Previous reviews have compared blinded observers in one group of trial with unblinded observers in another group of 'similar' trials, and risk confounding by known or unknown factors, for example concealment of allocation. **Objectives:** To estimate the degree of observer bias in randomised clinical trials, and to identify factors associated with large observer bias. **Methods:** A systematic review of randomized clinical trials with both blinded and unblinded evaluation of the same binary outcome. We searched PubMed, PsycInfo, Embase, The Cochrane Methodology Register, Google Scholar, and HighWire Press. We will compare the odds ratio for an unwanted event in each trial for the blinded and for the unblinded assessment. We define observer bias as the relative odds ratio (ROR): $OR^{unblinded} / OR^{blinded}$. We plan to summarise the RORs using random effects models. Furthermore, we will study whether the estimated observer bias is larger in outcomes involving a) large inter-observer variations (i.e. a high degree of subjective judgment, e.g. global clinical improvement), b) close observer involvement in the trial (e.g. they are clinicians that also treat patients); and c) close patient-assessor interaction (i.e. the outcome is sensitive to patient behavior). **Results:** At the time of abstract submission we had identified 14 eligible trials. **Conclusions:** Pending.

Session F2: Outcome Reporting Bias

Is multivariate meta-analysis a solution for reducing the impact of outcome reporting bias in systematic reviews?

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Background: The prevalence and impact of outcome reporting bias (ORB) in trials on Cochrane reviews has been examined [1]. ORB was suspected in at least one trial in 34% of 283 Cochrane reviews. However, in this situation trials may report other outcomes that are correlated with the missing outcome of interest; one can then utilise a multivariate meta-analysis to jointly synthesise all the reported outcomes and 'borrow strength' across them [2]. This approach has the potential to reduce the impact of ORB. **Objectives:** (i) To compare the performance of the multivariate meta-analysis approach

compared to the univariate approach; (ii) To determine whether the “borrowing of strength” in a multivariate meta-analysis can reduce the impact of ORB, and by how much. **Methods:** A simulation study was conducted considering the fixed effect bivariate meta-analysis setting. In each simulation, the bias and coverage of the pooled meta-analysis result was assessed. Data were simulated for situations where a) both outcomes were reported in all studies, and b) outcome data were informatively missing. **Results:** Results show that the “borrowing of strength” in a multivariate meta-analysis can reduce the magnitude of the impact of ORB. Bias, mean-square error and coverage are improved using the multivariate meta-analysis approach, with improvements increasing as the correlation between outcomes increased. **Conclusions:** The reliability of meta-analysis can be improved if more attention is paid to missing outcome data. If a high percentage of data is missing, reviewers should be encouraged to contact the trialists to confirm whether an outcome was measured and analysed and, if so, to obtain the results. If this is not possible, a multivariate meta-analysis approach is a potential statistical solution for reducing the impact of ORB.

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Investigating outcome reporting bias in Cochrane Cystic Fibrosis and Genetic Disorder (CFGD) reviews

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Background: Outcome reporting bias (ORB) has been identified as a threat to the validity of evidence-based-medicine. Trial outcomes with statistically significant results are more likely to be published than non-significant outcomes. The ORBIT study investigated ORB in Cochrane reviews (Kirkham et al, 2010a) but only considered primary outcomes and included only two CFGD reviews. The prevalence and impact of ORB in CFGD reviews is unknown. **Objectives:** To assess ORB in primary and secondary outcomes in CFGD reviews and included RCTs; To assess the impact of ORB in a review using a sensitivity analysis; To compare review outcomes between protocol and review as in a recent paper by Kirkham et al, 2010b; To investigate the heterogeneity in the reporting of outcomes. **Methods:** Reviews published by the CFGD Group that identified at least one trial were included. This project followed the methodology developed during the ORBIT study where outcomes not reported or partially reported were classified based on the suspicion of ORB. **Results:** 82 reviews published prior to 2010 were included; 21 identified no RCTs. Sixty-one reviews were considered further containing 405 included trials and 21 trials excluded due to ‘no relevant outcome data’. Between protocol and

review, there were three reviews that upgraded secondary outcomes to primary, 15 downgraded primary outcomes to secondary, two reviews included outcomes that were not in the protocol and two reviews excluded outcomes that were originally in the protocol. Nine reviews removed secondary outcomes between protocol and review and six reviews added secondary outcomes. Sixteen review protocols did not distinguish between primary and secondary outcomes. The assessment of ORB is ongoing at present. **Conclusions:** ORB is a problem in all areas of research. A core set of outcomes for genetic disorders will be an important step in reducing ORB and standardising outcome measures in these clinical areas.

Educational Intervention Outcome Reporting Bias

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Background: There is a well-known tendency for studies to be published in peer-review journals when the results are statistically significant. Bias can also exist within the study when details about study methods are missing or omitted and when outcomes gathered in the original research are not reported in the final publication. When conducting a meta-analysis, these circumstances can obscure the magnitude and or direction of the treatment effect under study. **Objective:** The goal of this research is to estimate the magnitude of publication bias in the educational sciences. **Methods:** Dissertations related to education from 96 “very high” research universities were collected from 2001 through 2005. Those dissertations using an intervention involving preK-12 students and were ultimately published comprised the universe of relevant studies. All intervention outcomes were coded in both the dissertation and published version. The discrepancies in study outcome reporting between dissertation and publication were examined. **Results:** The initial search yielded 12,904 dissertations. Of those, we have screened 4,102 dissertations which resulted in 199 studies containing and intervention on preK-12 students. Only 16 of those 199 were ultimately published. Examination of these 16 studies provides evidence of prominent outcome reporting bias based on statistically significant treatment effects (OR = 2.43, RR = 1.48, p < .0031). **Conclusions:** The results of this study provide evidence of non-trivial outcome reporting bias in education research. Outcome reporting standards may help alleviate the magnitude of this effect in education but to our knowledge no such initiatives have been implemented specifically targeting educational intervention outcomes. The remaining two thirds of the study pool will be analyzed for this presentation.

Is there any evidence of selective reporting of outcomes in abstracts of Cochrane reviews?

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Background: Cochrane abstracts are the most frequently accessed and used part of a Cochrane review. In randomized trials, evidence

shows that authors don't always report the primary outcome in the abstract, and are more likely to report a clinically or statistically significant outcome. This may also be the case in abstracts of systematic reviews. **Aim:** To assess whether reporting of outcomes is consistent between the full text and abstract of Cochrane reviews. **Methods:** We included all new reviews published in Issue 4, 2009 of *The Cochrane Database of Systematic Reviews*, where the primary outcome(s) were clearly stated in the full text and a meta-analysis had been conducted ($n = 64$); we excluded non-intervention reviews. We assessed the nature of any non-concordance between the full text and abstract in reporting of primary and secondary outcomes. **Results:** The median number of primary outcomes per review was two (range 1 to 10). Only 44 (69%) reviews reported all primary outcomes from the text in the abstract. Twelve (19%) reported only some of the primary outcomes in the abstract, compared with the full text, and eight (13%) failed to report any primary outcomes in the abstract. Of the 56 (88%) reviews that reported one or more primary outcomes in the abstract, only four (7%) stated this was a primary outcome, and only eight (14%) reported the relative and absolute effect size and 95% confidence interval or P-value. In 33 reviews (59%) there was no absolute effect size given, in 11 (20%) the result was only stated as "significant" or "not significant", in three (5%), only a NNT was given, and in one (2%) only the relative effect size was stated with no P-value or confidence interval. **Conclusions:** Our preliminary findings suggest evidence of incomplete and selective reporting in abstracts of Cochrane reviews. Detailed analysis will be presented at the Colloquium.

Session F3: Assessing Bias

Recommendations for updates to the Cochrane Collaboration's Risk of Bias assessment tool, based on an evaluation of its initial implementation

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Background: Version 5 of the Cochrane Handbook introduced the Risk of Bias (ROB) assessment tool, which represents a more comprehensive undertaking than previous quality assessments. **Objectives:** To develop recommendations for changes to the ROB tool, based on an evaluation of its initial implementation. **Methods:** The Bias Methods Group, supported by the Cochrane Library Editorial Unit and funded by the Cochrane Opportunities Fund conducted an evaluation of the ROB tool. We used findings from focus groups to develop questionnaires that were used in online surveys of Cochrane stakeholders. A meeting of Cochrane methodologists, review authors, managing and coordinating editors, and Editorial Unit staff developed draft recommendations. **Results:** Overall, there was a positive response to the introduction of ROB assessments. Several areas for potential

improvements were identified. The main recommendations arising from the evaluation include: ● Immediate/short term: – Change wording of bias judgements from "yes/no" to "low/high risk of bias" – Introduce category headings for selection, performance and detection, attrition, reporting, and other bias – Manually split assessment of blinding into participants/personnel and outcome assessment – Clarify guidance, particularly for incomplete outcomes and selective outcome reporting, and assessment of "other sources of bias" – Produce clearer and more explicit guidance on decision making for incorporation of ROB assessments into meta-analyses. ● Medium term (implementation with RevMan6 or later): – Structurally split assessment blinding into participants/personnel (performance bias heading) and blinding of outcome assessment (detection bias heading) – Weight ROB graphs by study size – Provide an algorithm for reaching a summary assessment of ROB per study/outcome – Develop online guidance and training materials including an online FAQ bank and examples of assessments. **Conclusions:** We hope that these changes will make it easier for authors to use the ROB tool, improve the reliability of assessments and improve the quality of Cochrane reviews.

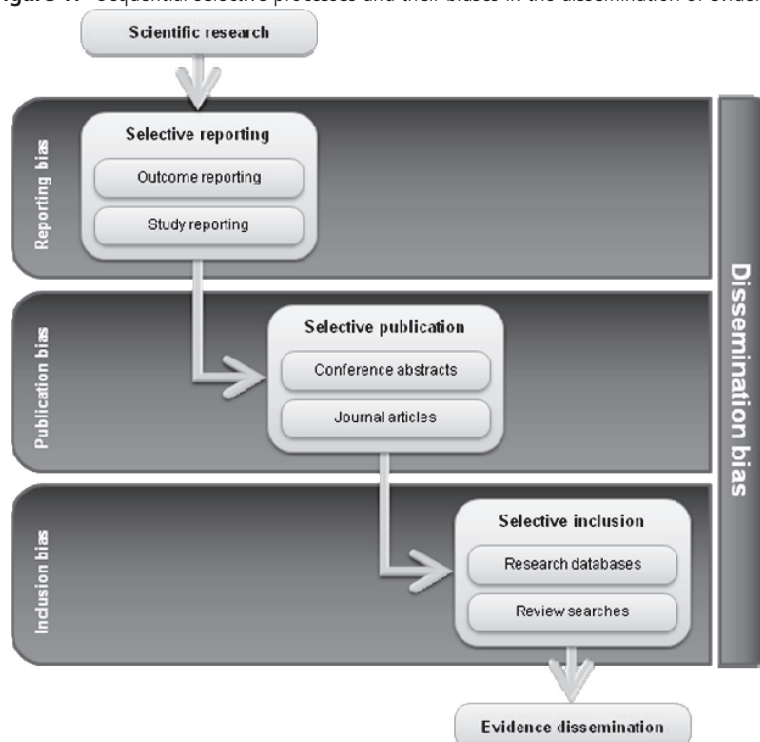
Beyond publication bias

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Background: The systematic error introduced by summarizing data that are not representative of the available evidence is commonly referred to as publication bias. Although it has been acknowledged that this term is inaccurate and alternatives have been proposed, to date no coherent terminological framework has been developed. **Issues:** The term publication bias is unfortunate in two respects: it insufficiently differentiates between biased processes and biased results, and it is inaccurate in that it describes more than just the bias induced by selective publication. **Alternatives:** A distinction can be made between selective processes and their respective biases. Process-selectivity can be present in the reporting of outcomes and studies, the publication of studies in paper-based and electronic media, and the inclusion of studies in databases and reviews. These selective processes can but do not necessarily lead to reporting bias, publication bias, and inclusion bias, respectively. Instead of using publication bias as a pars pro toto—a term that names a part to describe the whole—dissemination bias is more appropriate as a summary term. The distinction between selective processes and biased results described above can also be applied to statistical methods in meta-analysis, differentiating methods that assess data trends associated with a selective dissemination process from methods that attempt to correct for the bias that may have been induced by the selective dissemination. Rank correlation and regression tests belong to the former category, and selection models or imputation techniques that provide bias-corrected estimates belong to the latter. **Conclusions:** The proposed terminological framework (Figure 1) explicitly defines selective processes in the dissemination of evidence and their potentially resulting biases. The ideas are extended to the classification of meta-analytical statistical methods that deal with selectivity and bias. The terminology can be implemented in the planning and reporting of meta-analytical studies.

Figure 1. Sequential selective processes and their biases in the dissemination of evidence.

The use of trial protocols to assess risk of bias due to selective reporting in Cochrane systematic reviews: A cross-sectional survey

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Background: Selective reporting of outcomes of trials in systematic reviews could result in biased estimates of efficacy and safety. Access to trial protocols would facilitate detection of risk of bias due to selective reporting. **Objectives:** To evaluate the extent to which Cochrane systematic reviews seek and use trial protocols in risk of bias assessments of selective outcome reporting. **Methods:** All new intervention reviews in Issue 3, 2010 of the *Cochrane Database of Systematic Reviews* were assessed independently by three investigators for strategies to locate trial protocols. Characteristics of included studies, risk of bias and ongoing studies tables were evaluated for reference to trial protocols in assessing risk of bias. A subset of included trials published from 2005 was sought from the WHO search portal, clinicaltrials.gov, the Australian and New Zealand Clinical Trials Registry and the metaRegister of Controlled Trials (mRCT). **Results:** Twenty eight intervention reviews included 367 included studies, of which 333 were randomized controlled trials (RCTs); six additional reviews had no included studies. Only 14 (41.2%) reviews specifically searched trials registries, of which only three searched the WHO search portal; eight searched clinicaltrials.gov. Thirty nine ongoing trials were identified; 15 were from trials registries, the rest from conference proceedings, published protocols or drug-company registers. Eight reviews did not assess included trials for risk of selective reporting bias; sixteen assessed this from the study report, and five reviews used the protocols of 12 trials to assess selective reporting. Of 117 RCTs

published from 2005, only two were identified in trials registries (both in clinicaltrials.gov and one in mRCT and the WHO search portal). **Conclusions:** The use of trial protocols to detect selective reporting bias is limited by the lack of uniform methods in systematic reviews to locate them and low rates of prospective registration of clinical trials.

The robustness of results on weight loss in trials on sibutramine—a comparison of results from unpublished study reports with the corresponding published reports

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Background: On average, attrition in trials of anti-obesity drugs is one third. There are many ways to analyse data sets with missing data, which leaves room for a variety of effect estimates. Intention-to-treat analysis needs imputation and a common method is to use the last observation carried forward (LOCF), although this can be problematic. Additional analyses are usually available in the unpublished clinical study reports that have been submitted to the regulatory authorities in the registration application. **Objectives:** We aimed to explore the robustness of the results in trials on weight loss by comparing results from unpublished reports submitted to the Danish Medicines Agency (DMA) and their corresponding published reports. **Methods:** We included trials on obese patients randomised to placebo or sibutramine in approved doses. We searched for published reports electronically and by inquiries to the producer. **Results:** We included 21 DMA reports and in 9 (43%) cases we identified a publication. The median trial duration was 12 weeks. At abstract submission, we had only

extracted data on 4 (19%) of the DMA reports and the corresponding published versions. The median number of datasets analysed was 4.5 and 1 in the DMA and published reports, respectively. The DMA reports contained analyses of completers ($n = 4$) and available data ($n = 3$) and used LOCF ($n = 4$) and more advanced methods for imputation ($n = 2$), but the published reports only reported LOCF analyses ($n = 4$) and completers' analysis ($n = 1$). In general, the LOCF analyses were conservative, but in one trial the LOCF analyses found the greatest treatment effect of sibutramine, and only these were reported in the publication. **Conclusion:** LOCF is not always conservative and an analysis with a reliable imputation method should be published. Final results and conclusion will be presented at the colloquium.

Session F4: Effects of Industry Funding

The Financing of Drug Trials by Pharmaceutical Companies and its Consequences. A Qualitative, Systematic Review of the Literature on Possible Influences on the Findings, Protocols, Quality, Authorship, Access to Trial Data, Trial Registration and Publication of Drug Trials

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Background: In recent years, a number of studies have shown that clinical drug trials financed by pharmaceutical companies yield favourable results for company products more often than independent trials do. Moreover, pharmaceutical companies have been found to influence drug trials in various ways. This analysis provides an overview of the findings of current, systematic studies on the topic. **Methods:** Publications retrieved from a systematic Medline search on this topic from 1 November 2002 to 16 December 2009 were independently evaluated and selected by two of the authors. These publications were supplemented by further articles found in the reference sections. **Results:** 57 publications were included for evaluation. Published drug trials financed by pharmaceutical companies were found to yield favourable results for the drug manufacturer more frequently than independently financed trials. The results were also interpreted favourably more often than in independently financed trials. A number of studies revealed that many trials financed by pharmaceutical companies are never published and that favourable results are published multiple times. Further studies showed evidence of other problems including influence on study protocols, incomplete trial registration, constraints of publishing rights, withheld knowledge of adverse drug reactions, and the use of ghost writers supplied by the pharmaceutical companies. The methodological quality of trials financed by pharmaceutical companies was not found to be any worse than that of trials financed in other ways. **Conclusions:** Published drug trials financed by pharmaceutical companies may present a distorted picture. Public access to trial protocols and results must be ensured. Moreover, more effort should be made to carry out drug trials independently, without the financial support of pharmaceutical companies.

Did the authors have full access to the data? Comparison of protocols and reports of industry-initiated trials in The Lancet

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Background: Bias in industry-initiated trials is common and some journals try to reduce it by requiring manuscript authors to declare that they had full access to the data. But the word "data" is open to interpretation and access does not equate usage. **Objectives:** To investigate which type of data academic corresponding authors had access to in industry-initiated trials and how they used this access. **Methods:** We included a sample of industry-initiated randomised trials published in The Lancet in 2008 or 2009 and corresponding trial protocols provided by The Lancet. For each protocol and published paper, we extracted information on data management, analysis, ownership of data and access to data. We will also ask the corresponding authors which type of data they had access to and whether and how the access was used. We will compare the information from protocols, published papers and the author survey. **Results:** We identified 169 papers of randomised trials published in The Lancet in 2008 or 2009 and included 68 industry-initiated trials. An additional 13 industry-sponsored trials that apparently had independent data management and analysis will be analysed separately. We retrieved trial protocols for all 81 trials. *Results will be presented at the Colloquium.* **Conclusions:** Awaits results from data analysis.

Association between industry affiliation and position on rosiglitazone and cardiovascular risk: a cross sectional systematic review

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Background: Evidence of the association between authors' conflicted financial relationships and conclusions in scientific reporting has incited extensive transformation of viewpoints and policies on conflict of interest. **Objectives:** To explore an association between authors' position on rosiglitazone and the risk of myocardial infarction and conflicted financial relationships; and to estimate the prevalence of accurate disclosures in the published literature. **Methods:** On 4/10/2009, we searched Web of Science and SCOPUS for articles citing either of two publications (a meta-analysis of small trials and a subsequent large trial) contributing key data to the controversy. To be included, studies had to comment on rosiglitazone and the risk of myocardial infarction. We sought information about the authors' conflicted financial relationships disclosed in the report itself and searching SCOPUS, PubMed, and Google for relationships disclosed elsewhere. Two reviewers blinded to the financial relationships

Table 1. Position on Rosiglitazone Safety and Conflicted Financial Relationships.

Conflicted financial relationship	Risk of Myocardial Infarction with Rosiglitazone				Use of Rosiglitazone			
	Favorable N = 31	Neutral N = 84	Unfavorable N = 65	Rate Ratio (95% CI)*	Favorable N = 29	Neutral N = 129	Unfavorable N = 44	Rate Ratio (95% CI)*
Any manufacturer	29 (94%)	32 (38%)	18 (28%)	3.38 (2.26 to 5.06)	23 (88%)	46 (40%)	10 (26%)	3.36 (1.94 to 5.83)
Rosiglitazone manufacturer**	27 (87%)	25 (24%)	13 (20%)	4.29 (2.63 to 7.02)	21 (81%)	30 (26%)	9 (24%)	3.60 (2.00 to 6.48)
Pioglitazone manufacturer**	20 (65%)	31 (30%)	14 (22%)	3.96 (2.45 to 6.39)	19 (73%)	30 (26%)	10 (26%)	3.28 (1.88 to 5.73)
None	2 (6%)	52 (62%)	47 (72%)		3 (12%)	70 (60%)	28 (74%)	

*comparing favorable vs. unfavorable views; **these are not mutually exclusive categories.

independently classified each article as presenting a favorable, neutral, or unfavorable view on the risk of myocardial infarction with rosiglitazone and recommendations on use of rosiglitazone. **Results:** Of 202 included reports, 108 (53%) had a conflict of interest statement. Ninety authors (45%) had conflicted financial relationships. Authors of articles presenting a favorable view of the risk of myocardial infarction with rosiglitazone were significantly more likely to have financial relationships with antihyperglycemic agent manufacturers in general, 94%, and with rosiglitazone manufacturers in particular, 87%, compared to authors of articles presenting an unfavorable view, 28% (rate ratio 3.38 (95% CI: 2.26 to 5.06)) and 20% (rate ratio of 4.29 (95% CI: 2.63 to 7.02)), respectively. **Conclusions:** Disclosure rates of conflicted financial relationships were unexpectedly low and showed a clear and strong linkage with authors expressed views. These findings, while not necessarily causal, underscore the need for further progress

in reform for the scientific record to be trusted.

Inconsistent reporting of analyses in selected industry-sponsored clinical trials

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Objective: To compare clinical trial information contained in internal company documents with publications, to examine validity and completeness. **Methods:** We examined clinical trials, sponsored

Table 1. Comparison between protocols and publications on criteria for including participants in intent to treat (ITT) analysis¹ by study number.

Criteria for including participants in ITT analysis	Study Number													
	945-209		945-291		945-210		945-224		945-271		945-276		945-411	
	Protocol	Publication	Research report ¹	Publication	Protocol	Publication	Protocol	Publication	Protocol	Publication	Research report ¹	Publication	Protocol	Publication
Did not mention this type of analysis								X						
Type of analysis mentioned but no details on criteria were reported				X					X					
All patients randomized to treatment	X	X	X		X	X	X			X				X
Completed treatment at minimum dose and/or for a minimum duration		X	X		X	X	X			X	X	X	X	X
Data available for baseline level of outcome variable							X						X	X
Data available after randomization for a specified or unspecified number of visits/days			X			X					X			
Completed minimum duration of follow-up after randomization and/or in baseline period	X													

¹We used internal company research reports for two trials (945-291 and 945-276) where the protocol was not available.

by Parke-Davis/Pfizer, assessing off-label uses of gabapentin. For each trial, we compared internal company documents, including protocols, statistical analysis plans (SAPs), and research reports, with publications. One author extracted data on number of participants for each item on the CONSORT statement's flow diagram as well as details of types of analyses for primary outcomes (e.g., ITT, per protocol). A second author verified abstracted data against original documents. **Results:** We identified 12 published trials for four off-label indications of gabapentin: migraine prophylaxis (two trials), bipolar disorders (three trials), and neuropathic pain (seven trials). The number of randomized participants reported in the publication disagreed with the number in the internal company research report for 3/12 trials. Seven different types of analyses for the primary outcome were described in trial protocols, SAPs and publications: ITT, modified ITT, per protocol, evaluable, efficacy evaluable, evaluable for efficacy, and "population to be analysed." Seven different definitions for ITT analysis were described in the protocols and publications across 7/12 trials and each definition used different criteria to specify which participants were included in the ITT analysis (Table 1). 5/12 trials did not specify an ITT analysis. There was a disagreement in the definition of ITT between the protocol and publication for all four trials that defined ITT analysis in both the protocol and publication. Disagreements were also observed for other analyses. **Conclusions:** Reporting of key analysis information from selected industry-sponsored trials was inconsistent, incomplete, and may be incorrect. Trial protocols should be made publicly available, and both protocols and published reports must specify the primary type of analysis and criteria used to include participants in the analysis.

Oral session G

Knowledge Translation – Policy Makers

Session G1:

Evidence-Based HIV Behavioral Prevention: A Research-to-Practice Model Used by the Division of HIV/AIDS Prevention at the U.S. Centers for Disease Control and Prevention (CDC)

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Background: Behavioral medicine and public health prevention are moving rapidly towards using evidence-based practices. Consistent with this movement, the Centers for Disease Control and Prevention (CDC) emphasizes the use of the current and best scientific evidence in making policy and programmatic decisions for HIV prevention. The CDC's Division of HIV/AIDS Prevention (DHAP) developed a Research-to-Practice (R-to-P) Model in 2002 to translate scientific evidence into program practice. **Objectives:** To describe the DHAP's R-to-P Model. **Methods:** The R-to-P Model consists of three activities: Prevention Research Synthesis (PRS), Replicating Effective Programs (REP) and Diffusion of Effective Behavioral Interventions (DEBI). PRS

conducts on-going systematic reviews to identify evidence-based interventions based on rigorous efficacy criteria that assess quality of study design, implementation, analysis, and strength of evidence. REP works with researchers and community-based partners to translate evidence-based interventions into user-friendly packages for agencies. DEBI coordinates the dissemination of packaged interventions by providing training, technical assistance, and other capacity building through the national network of STD/HIV Prevention Training Centers and capacity building assistance providers. **Results:** PRS has reviewed over 500 U.S.-based behavioral interventions for reducing HIV risk. Sixty-nine evidence-based interventions (EBIs) published through June 2009 were identified. Twenty-one REP packages have been completed. DEBI is currently disseminating 23 interventions (REP and other packages) to community-based organizations, health departments, and medical clinics. **Conclusions:** The DHAP's R-to-P Model covers three important steps to translate scientific evidence from the research literature into practical materials that can be used in affected communities: research synthesis, technical translation, and large-scale dissemination with training and technical support. This model may be adopted by other fields that consider scaling up evidence-based prevention practices.

The Evidence-Based Health Policy Project: Wisconsin's Knowledge-Exchange Model

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Background: A knowledge-exchange process, conducted in safe-harbor venues by a non-aligned honest broker, has the potential to transform health policy decision-making at the highest levels of state government and the private sector. The Evidence-Based Health Policy Project (EBHPP) is a unique, cross-sector collaboration between the University of Wisconsin Population Health Institute, the La Follette School of Public Affairs and the Wisconsin Legislative Council, a non-partisan service agency of the state legislature. The project connects lawmakers, researchers, and public and private sector leaders to consider timely and relevant research, advance the use of evidence in the decision-making process, and increase university faculty involvement in topical issues of state health policy. **Objectives:** 1) Provide policymakers, in both the public and private sectors, with timely, nonpartisan, high-quality information for evidence-based decision-making; and 2) Increase the involvement of UW faculty research and teaching activities in topical issues of state public policy. **Methods:** The knowledge-broker process involves mining data from throughout the peer-reviewed and grey literature and emerging work-in-progress, while helping users differentiate strength of evidence ranging from systematic reviews to case study. Several venues and formats support EBHPP goals: 1) legislative briefings; 2) invitation-only forums for off-the-record dialogue; and 3) "methods exchange" meetings to facilitate relationship-building among legislators and researchers on topics of mutual interest. **Results:** Stakeholder participants include legislators and legislative staff, executive agency officials; scholars/academics; industry executives; providers/purchaser/payers; and advocates. Since January 2007, the program has produced 19 programs with over 900 participants. Over 90 percent of participants surveyed, self-reporting pre- and post-knowledge, show

increase in knowledge following EBHPP programming. The project has demonstrated impact on several specific legislative proposals and in regulatory considerations. The EBHPP has become a trusted and established resource for public-policy makers, researchers, and private sector partners. **Conclusions:** Partnerships such as the EBHPP can bridge research with practice, advance the use of evidence in the health policy arena, and speed the translation of university-generated research to decision-leaders in the public and private sectors.

Improving the health status of ex-prisoners: Hard lessons learned in reviewing complex interventions with multiple outcomes

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Background: As elegant as the underlying principles of systematic reviews may be, concern among researchers increasingly points to the difficulties encountered when studied interventions are complex and the potential outcomes diverse, as is nearly always the case when social components arise. This is especially true at the design stage and, as covered in Singapore, in packaging meta-analytic results so that they are meaningful for day-to-day use in practice. **Objectives:** Using the work presented by panelists in the Complexity in Cochrane reviews plenary from the Singapore Colloquium, this paper reports on attempts at an *a priori* management approach of these issues for a systematic review on interventions aimed at improving the health status of ex-prisoners. **Methods:** The authors use standard Cochrane systematic review methods, as well as those offered by the equity and economic methods groups. The authors anticipate and delineate the inherent complexities of the review in an attempt to preserve detail and package findings for practitioners. **Results:** A wealth of information regarding evidence is archived and described, and is illustrative of the complexities that were unanticipated in the design states. Though few studies meet the necessary rigor for inclusion, results fall prey to those foreshadowed by Paul Glasziou in last year's plenary – takeaway points are more difficult from meta-analyses than from individual Randomized Control Trials (RCTs). **Conclusions:** This study reemphasizes the need to address and capture the profound complexities inherent in multiple component interventions with complex populations and in complex settings. The authors provide multiple examples of pre-review attempts to describe and archive these complexities for narrative review and to preserve some of the original intent of the interventions so they may be repackaged with the review results so they are equally as usable as those from RCTs. And simple as results from meta-analyses seem, research in the medical field increasingly suggests that gleaning specific meaning from systematic reviews for incorporation into day-to-day practice has proven to be a challenge. This is especially true when the studied interventions are complex and the outcomes diverse, which is nearly always the case when interventions contain a social component.

Session G2: Relevance and Accessibility

The conduct of policy relevant systematic reviews including qualitative research: a framework for good practice

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Background: The pressure for policy making in health and social care to be evidence-based continues to grow. From a narrow focus on systematic reviews and meta-analyses of RCTs, it is increasingly recognised that such limited focus provides answers to limited kinds of questions. Policy makers are increasingly aware that other types of study design, including non-randomised quantitative, and qualitative research, are required to provide the answers to questions such as why does this intervention work, how and for whom, as well as to assess the effectiveness of complex interventions. With this recognition is a drive to develop robust methods of synthesising such research, which can develop in the course of a project to respond to both the available literature and the needs of the policy maker.

Objectives: To produce a good practice framework for reviewers and policy makers working together about producing systematic reviews that include qualitative research. **Methods:** Based on a critical review of 10 key suggested methods for systematically reviewing and synthesising qualitative research alone, or in combination with other non-randomised quantitative study designs, a Good Practice Framework for researchers and policy makers has been developed.

Results: For key stages of a review – developing research question, scoping the review, identifying relevant literature, initial assessment of study reports, preliminary analysis and synthesis, full analysis and synthesis and dissemination – the framework offers suggestions for both methodological approaches and joint working between reviewer and policy makers. As the messages are largely process related, most can be used whichever specific mechanisms for synthesis is preferred.

Conclusions: There is clear interest in robust yet flexible methods for reviewing a broad evidence base to inform policy making. This framework suggests that sufficient time, flexibility and responsiveness needs to be built into such reviews in order to maximise appropriateness, adaptability and rigour.

Prioritising investment in public health: Translating cost-benefit analysis evidence for policy makers

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Background: It is often stated that decisions to invest public resources should be informed by effect and economic evidence. This objective faces two challenges. First, many fields suffer from a paucity of evaluation work. Second, even in fields where evidence of cost-effectiveness is available, such as healthcare, it only has limited impact on policy making. **Objective:** This paper presents the results of a project to 'translate' and present effectiveness and economic evidence so that it is more relevant and accessible to decision makers. Specifically, the objective is to develop and apply a methodology to prioritise investments in public health interventions. **Method:** The method employed comprised the following steps: 1. Engagement with

decision makers to identify interventions to include in the analysis, and the criteria against which they should be assessed. 2. Reviews of the evidence. 3. Construction of economic models. 4. A discrete choice experiment. 5. The development of a web tool to allow decision makers to localise the results of the analysis and to benchmark other interventions against those included in the analysis. **Results:** 14 public health interventions were included in the tool. The results suggest that: 1. Increasing tax on cigarettes and alcohol, mass media campaigns, and brief interventions delivered by GPs perform well in meeting decision makers' objectives. 2. Screening retirees for depression and providing support to carers with depression perform relatively badly at meeting decision makers' objectives. **Conclusion:** The project provides information that is useful to public health decision makers. Perhaps more importantly it demonstrates the proof of concept of a tool to facilitate decision makers' access to and use of evidence.

Using text mining to facilitate policy relevant systematic reviews

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Background: Social policy-makers approach the task of evidence informed policy from a perspective of 'what is the most effective intervention to resolve a particular problem in a particular group'. Therefore, to achieve policy relevance, systematic reviews need to start from the same premise. However, the broad scope of such reviews necessitates comprehensive searches that generate high numbers of citation hits that have to be manually screened to identify relevant studies. Reviewers frequently face the problem of how to complete reviews within the available resources. This paper reports on the use of text mining to select studies for a review about engagement in culture and sport. This is the first time, as far as we are aware, that such technology has been deployed in a systematic review. **Objectives:** To: (i) report on a project that used text mining to support the selection of relevant studies; (ii) discuss the appropriateness and utility of this approach. **Methods:** Text mining technology was used to support the process of selecting relevant studies. **Results:** Using text mining reduced the number of potentially relevant citations that reviewers had to manually screen from 68,000 to 12,429. By using this new technology, the number of days spent identifying relevant studies was less than half the number that would have been required if we had manually screened all 68,000. Limited quality assessment suggested that the text mining was accurate at identifying studies on a topic basis, but less accurate at distinguishing research from non-research. **Conclusions:** *Where there are limited resources for identifying relevant studies through the traditional approach of manually screening citations, text mining may be an appropriate alternative. *Text mining does not lead to 'bias free' reviews, but can dramatically reduce the time taken to screen studies and produce reviews that are transparent in about what has been done.

Resources to improve accessibility of systematic review evidence for decision-makers: a systematic scoping review

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Background: Systematic reviews are not always reported in a format that makes the evidence easily accessible to decision-makers. A range of resources are available to assist users of systematic reviews¹ but to our knowledge the field has not been systematically reviewed. We aimed to identify, describe and evaluate existing resources (online and other) aimed at making the results of systematic reviews more accessible to healthcare decision-makers. **Methods:** Resources (for example, web sites, databases or printed/electronic publications) were eligible for inclusion if they were exclusively or primarily derived from systematic reviews, were aimed at healthcare decision-makers and had stated criteria for inclusion. There had to be some repackaging or 'translation' of review content by the service provider. We searched electronic databases (MEDLINE, EMBASE and CINAHL) from 1990 to October 2009 and abstracts of the Cochrane Colloquium and HTA International (2000–2009) for descriptions and evaluations of such resources. We also screened selected web sites and surveyed over 50 international organisations in the field by e-mail. Resources were described in a narrative synthesis. Evaluation studies were assessed for quality using existing methods for surveys, adapted as necessary. **Results and Conclusions:** Six published studies identified via literature searches were included in the review, five of which included some form of evaluation. Internet searches and the survey are currently ongoing and are expected to be completed by April 2010. Full results and conclusions will be presented at the Colloquium.

Reference

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Session G3: Challenges in Applying the Evidence

Evidence to action. Dealing with conflict of interest in moving from systematic reviews to guidelines

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Background: The Cochrane Handbook specifies that Cochrane reviews should not make recommendations. Ultimately, however, the impact of Cochrane reviews depends on their use in guiding clinical practice. Incorporation in clinical practice guidelines enhances the impact of Cochrane reviews. Conflict of interest can corrupt the process of appropriate incorporation of review findings into guidelines. The American College of Chest Physicians guidelines for anti-thrombotic therapy represent a prominent guideline facing the challenges of

developing recommendations on the basis of systematic reviews. **Methods:** We conducted an iterative process to develop an approach to guideline development that included input from a wide variety of individuals involved in the anti-thrombotic guidelines to develop a process designed to achieve two goals: 1) Result in recommendations free of conflict of interest. 2) Allow the full benefit of input from clinical experts. **Results:** Primary responsibility for each chapter rests with a methodologist without important conflicts of interest. A committee of academic physicians reviews a potential panel member's financial conflicts and decides if they are acceptable, unacceptable, or acceptable provided future industry involvement is restricted. Experts who are approved during this review but are judged to have important financial or intellectual conflict of interest can participate in collecting and interpreting evidence. Only panel members without important conflicts can, however, participate in the development of recommendations, a process from which conflicted participants are excluded. **Conclusion:** This process is innovative in that it puts far more emphasis on intellectual conflict of interest than previous approaches, that it places final responsibility for the guidelines with an unconflicted methodologist, and that it represents a strategy for comprehensive input from experts while – hopefully – keeping recommendation uninfluenced by conflicts. These approaches may facilitate optimal use of Cochrane and other systematic reviews in guiding clinical practice.

Generalisability of evidence for healthy public policy: an examination of external validity in a systematic review of the health impacts of housing improvement

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Background: The utility and external validity of research evidence is emerging as an issue in need of more scrutiny in the reporting of studies and systematic reviews purporting to be policy relevant. **Objective:** To assess the external validity of research evidence in a systematic review of the health impacts of housing improvement. **Methods:** We adapted an existing tool (Green & Glasgow, 2009) to assess the external validity of studies reported in a recent systematic review. The tool focussed on the transferability of the intervention and outcomes to other settings and populations, and the costs and implementation of the intervention. **Results:** There was considerable variation in the implementation of the intervention and the potential to benefit among the study sample. Some housing programmes were delivered according to need and others delivered across neighbourhoods regardless of individual need. Few studies reported details of variation in implementation, and sample sizes were often too small to merit sub-group analysis. A small number of studies reported intervention costs; three studies conducted an economic analysis comparing the intervention costs with the relative improvements in health and quality of life among residents. Within the largest group of studies judged to be similar, i.e. warmth improvements, the direction of reported health impacts varied. The characteristics of the intervention, context, and study population emerged as a determinant of the reported health impacts. **Discussion:** Clearer reporting of the intervention, including cost and implementation, could promote the transferability of single studies to specific policy and practice contexts. The systematic review examined had a broad scope and there was extreme heterogeneity among the studies. In addition to variation in study methods, there was wide

variation in the intervention, outcomes, study population and context. Further examination of this heterogeneity contributed to a refinement of the hypotheses around housing improvements and health impacts.

Systematic reviews of different study types addressing public health questions: possibilities and pitfalls

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Background: Public health initiatives are often complex and pose particular challenges for researchers engaged in both their evaluation and the subsequent systematic review of such evaluations. Typically, such reviews will include information from non-randomised quantitative and qualitative research for which a number of methods have been proposed, but no gold standard has emerged. **Objectives:** This presentation will use examples from a number of recent reviews around diverse topics, including preventing cardiovascular disease and skin cancer, to illustrate the potential and pitfalls of some current approaches, including around identifying relevant studies, quality appraisal, methods of analysis and synthesis, and how reviews of quantitative and qualitative research may inform each other. These examples are taken from the author's work for the UK's Centre for Public Health Excellence at the National Institute for Health and Clinical Excellence. **Methods:** Systematic reviews of qualitative and quantitative research to evaluate public health interventions using formal methods of narrative synthesis and meta-ethnography. **Results:** Undertaking systematic reviews to address policy makers' public health questions offers one way of ensuring a rigorous approach to gathering and considering evidence is used. Expanding what is considered valid as evidence to include alternative study designs offers the possibility to help, for example, explain discordant quantitative findings or illuminate potential difficulties in terms of implementation and acceptance. **Conclusions:** While much progress has been made towards developing robust and valid methods for the review and synthesis for non RCT data, many uncertainties remain including: how to frame questions so that the most pertinent qualitative, as well as quantitative, research can be considered, how to weight contradictory findings from different study designs, what a synthesis of mixed evidence might look like and how to assess the quality of qualitative research.

Affiliational bias in arguments regarding the use of systematic reviews in health policy decision making

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Background: Systematic reviews inform public- and private-sector drug coverage and other health policy decisions. Arguments for and against this use of systematic reviews may be related to authors' affiliations, income sources, and ideological backgrounds. For example, when meta-analyses concluded that exposure to second-hand smoke was harmful, the tobacco industry produced the majority of the critiques that attacked the methodology. **Objectives:** In order to inform policymakers about the forms of bias that may fuel the discourse surrounding the policy uses of systematic reviews, we

describe the basic arguments. We identify possible biases of the presenters of the arguments and rebuttals. **Methods:** We perform a critical review of articles that evaluate the scope, methods, or process of systematic reviews of pharmaceuticals and other health interventions. We examine the arguments that are being made, and the distinguishing characteristics of those making the arguments. **Results:** Arguments that aim to instill doubts about findings unfavorable to industry, criticize methods, and question interpretation of results are most often made by industry-affiliated critics. Other arguments focus on inappropriate cost containment and the lack of applicability of systematic reviews to develop drug formularies for programs that serve diverse or “non-standard” populations. Arguments supporting policy uses of systematic reviews are most often made by proponents of evidence-based medicine, academic researchers, and payers. Arguments focus on systematic reviews’ standardized study designs and wide acceptance, their usefulness in developing policy that ensures access to effective medicines while limiting wasteful spending on ineffective and expensive treatments, and reviewers’ lack of financial ties to industry. **Conclusion:** Values play a role in health policy decisions and the evidence that informs its development. Biases and financial conflicts of interest need to be transparent and taken into account when policy makers evaluate arguments regarding the use of systematic reviews in health policy and drug coverage decisions.

Session G4: Realist Review

A realist review of community-based participatory research in health: insights for synthesizing large, heterogeneous, and complex bodies of literature

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Background: This study is a systematic realist review to assess the benefits of Community-Based Participatory Research (CBPR) in health. Realist review is a relatively new methodology for reviewing complex interventions and programs. It holds the promise of generating knowledge about the context and mechanism features of interventions, which are not routinely assessed in reviews of experimental studies. We chose the approach because CBPR is complex, often difficult-to-measure, yet may play a significant role in determining research and health outcomes. The only previous systematic review of CBPR, commissioned by the Agency for Healthcare Research and Quality, failed to demonstrate a link between research outcomes and the participatory process. We hypothesize that this failure was due to a lack of fit between review methodology and the characteristics of community participation in research. In collaboration with leaders in the field of realist review and CBPR, our review design has been developed and tailored for assessing the evidence of participation, to ensure credibility and reliability of results, and to build theory for

understanding the benefits of community-academic partnerships that underlie program outcomes. **Objectives:** To systematically review the benefits of CBPR using a realist review approach. **Methods:** Key concepts in realist review methodology will be described and exemplified. These include: middle-range theory, demi-regularities, and context-mechanism-outcome (CMO) configuring. **Results and Conclusion:** Twenty-six sets of CBPR health interventions are currently being synthesized. The methodology, methods and preliminary results will be reported as well as insights gained from conducting a realist review for this large, heterogeneous, and complex body of literature.

The invisible mechanism of engagement: a realist review of social and emotional wellbeing programs for Australian Aboriginal children and youth

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Background: Although Aboriginal peoples account for 2.5 percent of the overall population, they are disproportionately represented in statistics related to the utilisation of mental health services, hospital separation for injury and self-harm, and incarceration. To date, no systematic reviews of Aboriginal social and emotional wellbeing (SEWB) provide decision-makers in the Aboriginal community-controlled and government sectors with culturally applicable and transferable advice on what works, for whom and in what circumstances. **Objective:** To distil from programs on the prevention of mental health difficulties and promotion of SEWB among Aboriginal children and youth the relationships between context, mechanisms and outcomes. **Method and Results:** This realist review was based on the following priority areas identified in Australian policy documents and by policy-makers: crime and violence, substance misuse, adverse mental health, cultural pride, strengthening families, strengthening communities and education. A systematic search of academic databases and the grey literature retrieved 46 Australian programs implemented from 1998–2008 for which program processes or impact information was reported in relation to Aboriginal children and youth SEWB. Social identity theory and the cultural respect framework were ‘candidate theories’ that informed propositions in the initial theoretical framework. From testing these propositions and assessing evidence for “fitness of purpose”, engaging participants emerged as a universal pathway that cut across all program types. Contextual factors associated with participant recruitment, engagement and attrition will be discussed in relation to program impacts and outcomes and specific mechanisms operating within the engagement pathway. “Best bets” identified by policy makers in South Australia will be presented. **Conclusions:** History, time in addition to factors related to the implementing community, sponsoring organisation, inter-agency collaboration and the workforce emerged as powerful influencers of engagement. This review finds that “upstream” investments need to be made to establish and maintain participant engagement in order for programs to impact SEWB.

Banning smoking in vehicles with children: Lessons from a realist review

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Background: Smoking is significant global public health problem and legislation is often used to control it. Many countries have laws banning smoking in public places and some have banned smoking in vehicles carrying children. Not all such legislation has been effective. To assist policy makers guidance is needed on whether such legislation would be acceptable to the public or even work. **Objectives:** Review the effects of legislation as a tool in tobacco control using the example of bans on smoking in vehicles carrying children. **Methods:** Realist review method was used as no RCTs and few evaluations exist in this area. Initial programme theory and important potential threats to legislation and candidate middle range theories that might explain these threats were developed. Searching and pearling, initially identified 65 studies relevant studies. As new avenues for enquiry emerged, additional studies were sought. **Results:** Our results will focus on the additional insights a realist review can bring. For example, despite the absence of RCTs and the limited number of evaluations on the effects of such legislation, the realist review method enabled us to identify a structurally coherent framework (or programme theory) that explained and increased understanding of the 'threats' that a piece of legislation faces from conception to enforcement. The method allowed us to identify the underlying mechanisms that appear to operate to threaten public health legislation and also the contextual influences that caused these mechanisms to operate. Our initial findings indicate that these threats may well be transferable across other legislative domains. **Discussion and Conclusion:** This review is in progress and will be completed in September 2010. Our review indicates that despite the 'paucity' of evidence in this field, sense can be made of when it is that public health legislation may be appropriate and likely to succeed.

Oral session H

Knowledge Translation – Consumers

Session H1: Informing Healthcare Decision Making

Improvement in adopting evidence-based medicine – a cross-sectional study

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Background: Since the beginning of 2007, the National Health Research Institutes has provided evidence-base medicine (EBM) information resource support, including free access to the Cochrane

Library, and promotional activities in the regional teaching hospitals of Taiwan. **Objectives:** This study aims to identify the relationship between physicians' self-efficacy in EBM improvement with their perception, barriers and behavior toward EBM. **Methods:** A cross-sectional postal questionnaire was sent to the physicians of 14 regional teaching hospitals that were randomly selected by cluster sampling during October 2008 to February 2009. All physicians in the selected hospitals participated in this survey. The physicians who had a significant improvement in their attitude, belief and behavior of EBM within one year were enrolled into the favorable group (n = 251). In contrast, subjects who did not perceive significant improvement regarding EBM were categorized as the unfavorable group (n = 293). **Results:** The physicians in the favorable group were more likely to use the electronic resources ($p < 0.001$) and online database ($p < 0.05$) to retrieve EBM information, especially on English online database ($p < 0.05$). The multivariate liner regression analysis also indicated that they had more favorable perceptions ($\beta = 0.387$, $p < 0.001$) including current attitude, perceived knowledge or skill and understanding of technical term. The barriers of applying EBM they encountered were lower ($\beta = -0.132$, $p < 0.01$) than the unfavorable group. They were more often accessing the online evidence retrieval systems to search medical information ($\beta = 0.031$, $p < 0.05$). **Conclusions:** The perceived improvement in adopting EBM could play an important role for physicians to apply EBM. Our study suggests that raising the physicians' self-efficacy in EBM improvement will accelerate and enhance the implementation of EBM.

Bringing the culture of Cochrane to a professional medical association

Richard Rosenfeld

Objective: To describe strategies used by a professional medical association, the American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS), to work with Cochrane in educating membership about the importance of high-quality systematic reviews as a basis for evidence-based healthcare. **Methods:** A proactive strategy was implemented, supported by AAO-HNS leadership, to involve the Cochrane Collaboration in the association's peer-reviewed journal, annual meeting, and guideline development initiative. **Results:** A quarterly feature, the Cochrane Corner, was added to the association's journal, *Otolaryngology–Head and Neck Surgery*, highlighting a Cochrane review of relevance to the readership with expert commentary by the journal editor, editor of the Cochrane ENT section, and an invited content expert. To increase the number of systematic reviews published by the journal a travel grant program was begun, supported by the publisher, allowing four AAO-HNS members to attend the annual Cochrane Colloquium in return for agreeing to submit a systematic review for publication consideration to the journal within 12 months of the meeting. Travel grant recipients are highlighted at the annual AAO-HNS scientific meeting, which also features miniseminars and invited lectures from Cochrane editors on review methodology and interpretation. Last, the AAO-HNS has outsourced the literature reviews for clinical practice guideline development to trial search strategists at the Cochrane ENT section, keeping the strategist involved in all correspondence related to guideline development. **Conclusions:** By involving Cochrane in the association's journal, annual meetings, and guideline development process, the AAO-HNS has substantially raised member awareness of Cochrane as the preeminent producer

of high-quality systematic reviews of healthcare interventions. The result has been a win-win situation benefiting both the AAO-HNS and the Cochrane ENT Group, stimulating new collaboration, quality improvement, and continuing education.

The 20 × 20 International Panel for Consumers in Arthritis Research: an initiative of the Cochrane Musculoskeletal Group

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Background: The Cochrane Musculoskeletal Group (CMSG) has an active group of consumers who comment on Cochrane reviews and protocols in an effort to make the work of the Cochrane Collaboration more relevant and meaningful for all people with musculoskeletal conditions. To build on this success, and to expand the role of consumers in research, we wish to make our consumer group more representative of the international membership of the CMSG. We are in the process of assembling an international panel of people with arthritis who would be consulted regularly about research priorities, goals, choice of outcomes, patient values, and knowledge translation. **Objectives:** (1) To assemble 20 consumer leaders from 20 countries who will recruit 20 consumers in their country that can provide input into arthritis research activities such as systematic reviews and priority-setting. (2) to assess other models and methods for assembling international Consumer groups and audit our current activities. **Methods:** Following a scoping review of the literature (Spring 2010) on methods for engaging patients in research, and performing an audit of our current recruitment and retention strategies for patient volunteers, we will explore the extent to which our current methods are based on evidence. Further, we will perform an environmental scan of other international consumer organizations and explore gaps in our knowledge about effective recruitment and retention strategies. **Results:** The results of the scoping review and the mapping exercise to determine the extent to which CMSG activities are based on evidence will be presented. **Conclusions:** This review of the evidence behind consumer engagement initiatives and an audit of our current practice will allow us to assess the feasibility of adapting other international models for our purpose provides clear direction in planning new initiatives.

Answering clinical questions at the point of care using Cochrane evidence

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Background: Many summaries and commentaries of Cochrane Reviews are available, but what doctors and other healthcare professionals need at the point of care (before/during/after a patient encounter) is answers to clinical questions. **Objectives:** To develop new Cochrane content—the “Cochrane Clinical Answer” (CCA), based largely upon the PICO (patient, intervention, comparison, outcome) format. To generate a number of CCAs to assess how easy it is to create this content, to develop the template for this content, and to validate the CCA format via user testing to inform further content generation and product development. **Methods:** The Cochrane Editorial Unit developed a CCA template and co-ordinated a pilot project inviting a small number of Cochrane entities to write CCAs. All participating entities were asked to provide feedback on the time taken to create a CCA and provide feedback for template development. Members of the Nordic Cochrane Centre designed the user testing plan, and Wiley–Blackwell co-ordinated the first phase of iterative qualitative user testing, conducting one-to-one interviews with physicians during March 2010. **Results:** 13 CCAs were submitted by 7 different entities, answering clinical questions in the areas of asthma, malaria, tuberculosis rheumatoid arthritis, transplantation and neonatal medicine. The median time taken to produce a CCA was 2.5 (range 1–10) hours. Results from user testing will be included when complete. **Conclusions:** CCAs have been received positively within The Cochrane Collaboration, but there are still challenges in the creation of this content for use by physicians at the point of care. In the future the template will be revised in response to user testing and author feedback, with the aim of creating a new Cochrane product optimised to translate Cochrane evidence into practice at the point of care.

Clinical toss-ups: in defense of resource-preserving shared decision-making

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Background: Shared decision-making introduces evidence-based medicine into the doctor-patient interaction to effectively consider best treatment options and interject patient values. This strategy preserves patient autonomy in clinical problems where mortality and morbidity are similar across options. While shared decision-making is heralded as an optimal doctor-patient engagement strategy, there are human factors to confuse this interaction. **Objectives:** Apply dual insights from behavioral economics and bioethics to determine fair and just principles to structure choices among clinically viable alternatives, while preserving patient autonomy within the limitations of health care resource constraints. **Methods:** Case analysis of two paradigmatic situations: non-medically indicated surgical birth and pharmacological management vs. percutaneous coronary intervention in stable angina. **Results:** A simple rule: offer the frugal choice as the default, with the option to over-ride showing documented evidence-informed choice offers a fair and just shared decision-making strategy. We argue that autonomy should be viewed as a negative right (refusal of unwanted intervention) wherein a patient does not have the unfettered positive right to simply choose a desired treatment. Unfettered shared decision-making trusts the patient to be the agent of rationality, an expectation unsupported by data and insights from

behavioral economics. Patients often value expensive interventions even when the best evidence does not support such interventions. They also are loss averse and value doing something over doing nothing, even when intervention is accompanied by iatrogenic risk. **Conclusions:** On the basis of prudent resource use, the equipoise model of shared decision-making is not viable, and is not a defensible extension of the autonomy principle. We instead suggest an evidence-fettered, resource-sensitive approach to the presentation of information in shared decision-making. We argue for general application in circumstances where the 'best' decision is unclear, or where the evidence supports more than one clinical option to reach a similar outcome.

Session H2: Evidence and the End User

Courriels Cochrane: a knowledge translation project

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Background: Courriels Cochrane are French translations of P.E.A.R.L.S., excerpts taken from abstracts of Cochrane reviews disseminated by email to primary care physicians. We linked the Information Assessment Method (IAM) to Courriels Cochrane to stimulate physicians' reflection and document ratings of relevance, cognitive impact, information use, and patient health benefits. **Objectives:** To disseminate IAM in French and to assess the impact of Courriels Cochrane on physicians. **Methods:** Out of 125 P.E.A.R.L.S., 40 were selected based on two criteria: relevance and newsworthiness to primary care, and translated into French. After an editorial process, which included contextualization, only 30 were retained. Participants were recruited among physicians who subscribe to cma.ca in French. By email, participants received one Courriel Cochrane per week. We assessed outcomes using IAM. For each completed questionnaire, physicians earned continuing medical education credit. **Results:** From October 2009 to January 2010, 14 Courriels Cochrane were emailed to 899 physicians. Of those, 98 physicians submitted 474 ratings. The most frequently reported items were: Cognitive Impact: 'I learned something new' N = 178 (38%) and 'information confirmed I did (am doing) the right thing' N = 169 (36%); Relevance for at least one patient N = 374 (79%), Application: 'to justify or maintain patient management' N = 181 (48%); Expected Health Outcomes: 'avoiding unnecessary or inappropriate interventions' N = 118 (32%). Dissatisfaction was reported in 12 cases (3%), due to a problem with the information in 10 cases (2%). **Conclusions:** Courriels Cochrane can have a positive impact on practice. Further research could confirm this finding.

The characteristics of the Cochrane Library users: a nationwide survey of the regional hospitals in Taiwan

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Background: In order to promote the implementation of evidence-based practice (EBP), the National Health Research Institutes (NHRI) has offered free access to Cochrane Library (CL) for the health professionals of the regional hospitals in Taiwan since the beginning of 2007. **Objectives:** The current study is designed to verify the characteristics of the CL users. **Methods:** A constructed questionnaire was designed for survey analysis. A total of 2806 valid questionnaires from the regional teaching hospitals in Taiwan were collected by 2009. **Results:** Approximately 32.3% participants used CL at least once per month during the past year. The physicians more often accessed CL than the nurses ($P < 0.001$). Respondents with either higher academic degree or faculty position or administrative position were more likely to use CL ($P < 0.001$). In addition, the users of CL tended to have more positive belief, attitudes, knowledge and skills of EBP. They suffered lesser barriers to EBP than non-users. In addition to CL, the users also more often accessed the other online evidence retrieval databases, including the Index to Chinese Periodical Literature, the Chinese Electronic Periodical Services, the Cumulative Index to Nursing & Allied Health Literature, MD consult, MEDLINE, ProQuest, and UpToDate. **Conclusions:** CL has not been widely used in the regional hospitals of Taiwan. The current study has identified the personal characteristics of the CL users. These data provide evidence for future strategy design to encourage health professionals to access CL.

Knowledge translation by consumers: Development of a promotion kit for use by consumers to promote the work of the Cochrane Collaboration and dissemination of Cochrane reviews

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Background: At the 2009 Canadian Cochrane Symposium, consumers identified "Promotion" as one of four priority activities for 2009-2010. It was felt that Canadian members of CCNet (Cochrane Consumer Network) could promote the Cochrane Library and the work of the Cochrane Collaboration to their local consumer health groups, charities, churches, schools and other social networks. **Methods:** Training will be provided and promotion packages will be developed during a consumer workshop at the Canadian Cochrane Symposium in May 2010. Following the symposium, participants will be equipped to plan a promotion activity in their local area. **Evaluation:** Evaluation forms will be given immediately after the promotional activities. An online survey will be given 1 month after the promotional activity. In depth

interviews with the Cochrane consumers who perform promotional activities will take place after the event to identify challenges and opportunities. **Outcomes:** Based on the results, and experiences of the participants, we plan to develop a Promotion Kit that any Cochrane consumer could use to guide the dissemination of reviews or to promote the Cochrane Collaboration. This process would at minimum include: How to identify and prioritize stakeholders / end users, Strategies to make initial contact with end users, Communication ideas e.g. newsletters, websites. The Promotion Kit would also include existing material used by other Cochrane entities.

Comparing user preferences and understanding for two formats of evidence profiles. A randomized trial

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Background: The 9th iteration of the American College of Chest Physicians antithrombotic therapy guidelines (AT9) is applying the Cochrane/GRADE system to assess the quality of evidence and move from evidence to recommendations. Guideline panellists use the evidence profiles—standardized tables that provide identical information to the Cochrane Summary of Findings tables with additional information regarding the rationale for quality of evidence judgments—to summarize the quality of evidence and estimated effects for important outcomes. **Objective:** To determine user preferences, understanding and time spent finding key information presented in two different formats of the GRADE evidence profiles. **Study design and setting:** Using email invitations and an online questionnaire (SurveyMonkey), we will invite 116 eligible AT9 panellists and randomize them to receive two formats of the evidence profile, one that approximates a currently recommended version (standard), and one with a number of important modifications (experimental). The modifications are: 1) placing explanatory information in the table instead of the footnotes; 2) eliminating observed event rates derived from included studies; 3) presenting calculated risk differences instead of raw absolute event rates; and 4) placing the relative effects in the table before the absolute effects rather than after them. We will create standard and experimental profiles for each of two clinical questions. We will measure user responses in terms of preferences, accessibility of information (easy to find, easy to use and helpful in making recommendation), correct comprehension and time needed to comprehend information in the evidence profile. Following completion of the initial part of the survey, respondents will review the alternative version and express their preferences between the two. **Results and conclusion:** We will conduct the study spring 2010 and present results at the Cochrane Colloquium. Results will inform formatting of evidence profiles and Summary of Findings tables for systematic reviews and practice guidelines.

Oral session I

Methods For Preparing Reviews (Non-Statistical)

Session I1: Addressing Heterogeneity

Recommendations for investigating clinical heterogeneity in systematic reviews: A methodological review

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Background: While there is some consensus on methods for investigating statistical and methodological heterogeneity, little attention has been paid to clinical aspects of heterogeneity. **Objective:** To present a critical overview of suggested methods for investigating clinical heterogeneity in systematic reviews (Part 1) and to compare this to methods in a sample of Cochrane reviews (Part 2). **Methods:** Part 1: We included resources providing suggestions for investigating clinical heterogeneity between controlled clinical trials included in systematic reviews. We searched databases (Medline, EMBASE, CINAHL, Cochrane Library, CONSORT database), reference lists, and contacted experts. We extracted recommendations, assessed resources for risk of bias (ROB), and collated the recommendations. Part 2: We included the 100 most recent Cochrane Reviews, extracted their methods of investigating clinical heterogeneity and compared this to findings from part 1. **Results:** We included 84 resources including narrative reviews, methodological reviews, statistical methods papers, and text books. These resources generally had a low ROB and there was minimal consensus among them. Resources suggested that planned investigations of clinical heterogeneity should be made explicit in the protocol of the review, clinical experts be included on the review team, that a set of clinical covariates should be chosen (Consider variables from the participant level, intervention level, outcome level, research setting, or others unique to the research question), that have a clear scientific rationale. Cochrane reviews under report methods for investigating clinical heterogeneity and do not follow current recommendations. **Discussion:** Formal recommendations are required for investigating clinical heterogeneity in systematic reviews of controlled trials.

Heterogeneity and complexity within reviews of social research: the perspective of 'divergent' reviews

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Background: Policymakers often begin with a particular problem (e.g. an imperative to reduce obesity) and look to research to tell them which

interventions are effective in impacting on that problem. Systematic reviews conducted to inform this process thus often start from a given, 'known', outcome but do not pre-specify their populations or type of intervention. Such reviews are further complicated in social research because interventions are often multi-faceted, and it is difficult to identify the 'active ingredients' that make them effective in any specific case. Reviewers must therefore mediate between the diverse and uneven nature of the research evidence they identify and the need to produce useful and useable findings for their users.

Methods: A long-standing programme of systematic reviews for a Government department will be used as a case study. **Results:** The key challenge has been to identify ways of explaining differences between the results of primary studies. To this end, 'qualitative' evidence from those closest to the issues being explored and data from process evaluations has been synthesised alongside evidence of effectiveness from trials. Generalisability across studies has been aided by the production of tools to describe key population attributes in standardised ways. Alongside traditional statistical methods, such as sub-group analyses and meta-regression, the use of standardised tools and the inclusion of qualitative research enable reviewers to synthesise a messy evidence base in ways that are useful and meaningful.

Conclusions: Many reviews might be characterised as coming from a 'convergent' viewpoint; different (but similar) studies are brought together in order to identify a common measure of effect. Systematic reviews of social research are often 'divergent' in nature: heterogeneity is a given, and the requirement is for review methods to support reviews that make sense of this diversity while maintaining the core principles that underpin robust research synthesis.

The assessment of clinical heterogeneity: an empirical investigation

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Background: Several measures for assessing statistical heterogeneity are available. Similar to high degree statistical heterogeneity the presence of considerable clinical heterogeneity (also called clinical diversity) precludes combining of study results by means of meta-analysis. **Objective:** To assess the inter-rater agreement regarding clinical heterogeneity. **Methods:** Five published meta-analyses that investigated cardiovascular endpoint in type 2 diabetes provided data on several RCTs. From these, seven case scenarios (each consisting of five to seven studies) were presented containing various patient characteristics (e.g. age, diabetes duration, cardiovascular diseases, blood pressure) and eligibility criteria in tabulated form. Based on these data, eight raters (from four institutions) with experience in clinical diabetes treatment, conducting systematic reviews in diabetes or both (most common) decided whether the extent of clinical heterogeneity precluded meta-analysis. Free marginal multi-rater kappa was calculated overall and for each of four distinct outcomes: mortality, cardiovascular events, health-related quality of life and glycosylated haemoglobin A1c (HbA1c). **Results:** The overall kappa was 0.29 (95%-confidence interval [95%-CI] 0.13 to 0.45). For the three patient-relevant outcomes mortality, cardiovascular events and health related quality of life, the results were -0.01 (95%-CI -0.07 to 0.05), -0.08 (95%-CI -0.13 to 0) and 0.44 (95%-CI 0.20 to 0.66), respectively. Regarding HbA1c a kappa of 0.81 (95%-CI 0.56 to 1)

was found. **Conclusions:** With the exemption of HbA1c, the observed inter-rater agreement was low, much lower than we expected. For the endpoints mortality and cardiovascular events, kappa was about zero indicating agreement in the range of chance only. There is a definite need to further explore what constitutes clinical heterogeneity, ways to operationalise it and to determine possible implications for pooling effect estimates.

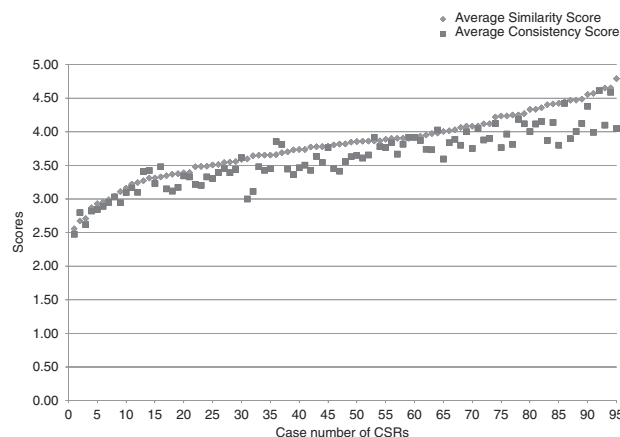
Assessment of trial similarity and evidence consistency for indirect comparisons: preliminary results

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Background: Adjusted indirect comparisons (AIC) are increasingly used for evaluating healthcare interventions in situations where there is limited head-to-head trial evidence. However methods for assessing validity of AIC have not been systematically developed and tested.

Objectives: To investigate clinical similarity of trials in AIC, and clinical consistency between direct comparisons (DC) and AIC. **Methods:** The Cochrane Database of Systematic Reviews was searched for Cochrane reviews (CSRs) that contained sufficient data to enable both DC and AIC analysis. Two reviewers independently extracted data using a standardized proforma. Clinical diversity and similarity were assessed by comparing characteristics of participants, interventions, and outcome measures. The results of the assessment of trial similarity and clinical consistency were expressed through 'similarity' and 'consistency' scores, ranging from 0 (very low) to 5 (very high) for average of the three components. Similarity of trial quality was also scored from 0 (very low) to 5 (very high). **Results:** 95 CSRs were included in analyses, involving a total of 1109 trials (332 trials for direct and 777 trials for indirect comparisons). 75 CSRs investigated pharmaceutical interventions and 11 CSRs included surgical interventions, the remaining 9 CSRs involved different interventions including rehabilitation, psychoeducational, etc. For trial similarity assessment, 31 cases scored from 4 to 5, 57 cases from 3 to 4, 7 cases lower than 3. For clinical consistency assessment, 16 cases scored from 4 to 5, 70 cases from 3 to 4, 9 cases lower than 3. In terms of quality similarity scores, 6 cases scored 5, 54 cases



were in the range of 4 to 5, 25 cases from 3 to 4, and 10 cases lower than 3. **Conclusions:** Evaluation of the validity and appropriateness of the AIC by assessing the trial characteristics and qualities is feasible. Validation of the similarity and consistency score is in progress.

Session 12: Quality

Scales to assess the quality of acupuncture clinical trials: a systematic review

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Background: The quality of controlled trials is of obvious relevance to systematic reviews. If the “raw material” is flawed then the conclusions of systematic reviews (SR) cannot be trusted. Since in 1980’s the concern about study quality was first formally raised, many quality assessment instruments have been developed and employed in systematic reviews. Unfortunately, there is no gold standard instrument yet available. **Objective:** To identify the consistency among the three most popular quality assessment instruments and the suitability for rating acupuncture studies for migraine patients. **Methods:** Extensive electronic database searches were performed. The quality of included studies was assessed and extracted by two independent reviewers using 3 different instruments, namely Jadad scale, Internal Validity Scale (IVS) and Oxford Pain Validity Scale (OPVS). The Spearman rank correlation coefficient was used to assess correlations between the scores obtained with the different scales. Sensitivity analyses were performed to evaluate the relationship between scores of quality assessments and pooled odds ratios for frequency and intensity of migraine. **Results:** A data set of 32 randomized clinical trials (RCTs, including 15 studies published in English and 17 Chinese literatures) from a systematic review concerning the efficacy of acupuncture therapy in patients with migraine was used. None of all 17 involved Chinese studies presented good quality (more than 60% of maximum score) in any instruments. The English literatures showed moderate correlation between Jadad and IVS, but not with OPVS. Furthermore, the results of the systematic review (evaluating the effectiveness of acupuncture for migraine) were influenced by the scales used. **Conclusion:** Validity of Jadad and IVS for accessing acupuncture studies is questionable. A valid and reliable scale for the assessing the methodology quality of acupuncture trials needs to be developed.

Should we exclude poorly reported qualitative studies from systematic reviews? An evaluation of three reviews of qualitative data

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Background: Ongoing debate persists regarding whether assessing the quality of qualitative studies included in systematic reviews is valid or meaningful. **Objectives:** This research aimed to determine whether the exclusion of qualitative studies based on key elements of reporting had any effect on the results of a synthesis. **Methods:** Three systematic reviews of qualitative data were performed on topics relating to public health and education. All included studies were

appraised by two reviewers using criteria from Dixon-Woods’ key prompts for assessing qualitative studies (QSHC 2004), i.e. whether the sampling and methods of data collection and analysis were clearly described. Better reported studies provided clear details on all or most of these criteria. By contrast relatively less well-reported studies gave few or no such details. Thematic analysis was used as the method of synthesis in two reviews, and a version of framework synthesis in the third. In each case, a sensitivity analysis was performed in which relatively poorly reported studies were excluded, and an assessment was made about whether and how the synthesis was affected by the exclusion of these studies. **Results:** On the basis of quality of reporting described above, 1/20, 9/20 and 10/19 studies were excluded from the three reviews. By excluding these studies, only one review was affected, with only a single major theme and its two related sub-themes excluded from the synthesis. Otherwise, these exclusions did not affect the synthesis findings in a meaningful way. **Conclusions:** An evaluation of the findings of three systematic reviews indicates that the exclusion of poorly-described qualitative studies does not appear to affect either the overall results of such systematic reviews, or the richness of their findings. Excluding such studies from the data extraction and synthesis processes would save time and, potentially, also enhance the internal validity of the findings of systematic reviews of qualitative data.

Applying the GRADE tool in systematic reviews: inter-rater reliability and sources of discrepancy

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Background: GRADE was developed to address shortcomings of tools to assess quality of a body of evidence. This is a key step in making recommendations to inform decision-making. While much has been published around GRADE, there are few empirical and systematic evaluations. Our objective was to assess GRADE for systematic reviews (SRs) in terms of reliability and identify areas of uncertainty. **Methods:** We applied GRADE to 2 SRs (n = 48 and 125 studies). Two reviewers graded evidence independently for outcomes deemed clinically important *a priori*. Inter-rater reliability (IRR) was assessed using kappas for 4 main domains (risk of bias [RoB], consistency, directness, and precision) and overall strength of evidence (SoE). **Results:** For the first SR, 51 outcomes were graded across 6 comparisons. IRR was: $\kappa = 0.41$ for RoB; 0.84 consistency; 0.18 precision; 0.44 overall SoE. Kappa could not be calculated for directness as one rater assessed all items as direct; assessors agreed in 41% of cases. For the second SR, 24 outcomes were graded across 11 comparisons. IRR was: 0.37 consistency and 0.19 precision. Kappa could not be assessed for other items; assessors agreed in 33% of cases for RoB; 100% directness; 58% SoE. Precision created the most uncertainty due to difficulties in identifying “optimal” information size and minimal clinically important differences and making assessments when there was no meta-analysis. Other sources of discrepancy were recorded and resolutions proposed. GRADE evaluations in other SRs are ongoing. **Conclusions:** As researchers with varied levels of training and experience use GRADE, there is increased risk for variability in interpretation and application. This study shows variable

agreement across the GRADE domains, reflecting areas where judgment is required. Further evaluation is required to enhance consistency and ensure the same methodological rigour that is applied to other steps of a SR is applied to grading the evidence.

Characteristics and quality of reporting of cluster-randomized trials in children: an assessment using the CONSORT statement for CRTs (CONSORT-CRT)

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Background: The extension of the CONSORT statement to cluster-randomized trials (CRTs/CONSORT-CRT) provides reporting guidelines for CRTs but the quality of reporting of CRTs has generally been poor. The use and quality of reporting of CRTs in children has not been evaluated. **Objectives:** To summarize the characteristics and to evaluate the reporting of all published reports of CRTs in children since 2004. **Methods:** Four databases (Medline/Embase, CINAHL, Cochrane Central Register for Controlled Trials) were systematically searched for reports of CRTs evaluating interventions and reporting health outcomes in children (age: 0–18 years). Characteristics of included studies were summarized and quality of reporting was assessed using CONSORT-CRT. **Results:** Of 1,949 identified references, 200 were assessed as full text and 106 were included in the review. The number of published CRTs in children increased since 2004. The greatest proportion of CRTs was undertaken in Europe (29%), with Africa, Asia and South-America together accounting for 42% of CRTs. CRTs were most frequently in obesity prevention (diet/physical activity interventions; 19%), infectious disease (14%) and undernutrition (13%). The majority used schools as units of randomization (72%) and enrolled 1,000-10,000 children per study (52%). Reporting was generally poor, with 36% of CRTs inadequately reporting on more than half of the CONSORT-CRT criteria. 16% and 22% of studies, respectively, clearly reported on random allocation sequence generation and implementation, and allocation concealment. It was not clearly reported how clustering was accounted for in sample size calculations or analyses in 40% and 35% of CRTs, respectively. **Conclusions:** An increasing number of CRTs are undertaken in children, but their reporting warrants improvement. The requirements for children-specific elements of reporting should be explored with the aim to improve the quality of reporting of CRTs in this population group, and consequently their planning and implementation.

Session I3: Assorted Topics

Mapping the evidence in neurotrauma: The results of the Global Evidence Mapping (GEM) Initiative

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Background: Evidence maps build on systematic review methods to find, review and organise research evidence in a broad clinical area. The Global Evidence Mapping (GEM) Initiative has developed evidence maps for traumatic brain injury (TBI) and spinal cord injury (SCI) in prehospital, acute and rehabilitation and long-term care settings. **Methods:** Development of the evidence maps involved four steps: question development, prioritisation, searches and data extraction. Question development involved four data collection exercises: consultation with experts, a preliminary literature search, mapping workshops and a survey. The data from these exercises was coded and answerable clinical questions generated for each of the identified codes. The questions were prioritised using an online survey. Searches were run in seven English, four non-English and two clinical trials databases. Citations were reviewed against a priori inclusion criteria first by title and abstract and then in full-text. Data were extracted on the number of relevant studies and the design of each included study. **Results:** One hundred and twenty-nine questions were generated. Sixty of these questions were prioritised and evidence maps have been completed for 53 of these questions. Several evidence gaps were identified. For ten of the 53 mapped questions (19%) the evidence maps did not identify any relevant primary comparative research studies. For twelve of the 53 priority questions (23%) we found more than one comparative primary study, but no systematic review. For the remaining 31 of the 53 prioritised questions (58%) there is either a systematic review, or only one comparative study has been conducted. **Conclusions:** The GEM Initiative evidence maps can help researchers and research funding bodies to target areas where primary research and systematic reviews are needed to answer questions of clinical importance, and help clinicians, policymakers, patients and carers determine where evidence is available to guide healthcare decisions.

Epidemiology and study characteristics associated with reporting of subgroup analyses

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Background: Several studies have examined reporting of subgroup analyses in randomized trials. None have, however, addressed study characteristics associated with reporting versus not reporting of subgroup analyses. **Objectives:** To investigate, in randomized trials, the extent to which investigators reported subgroup analyses and claimed subgroup effects, and the study characteristics associated with reporting of subgroup analyses. **Methods:** We searched MEDLINE for randomized trials published in 2007 in 108 Core Clinical

Table 1. Characteristics of reported subgroup analyses and claimed subgroup effects.

Number of trials reporting of subgroup analyses	130
Total number of subgroup analyses per trial, median, mean (range)	5, 8 (1–45)
Total number of subgroup analyses that are most likely conducted, median, mean (range)	6; 11 (1–112)
Number of trials that specified at least one subgroup analysis a priori	56 (43.1%)
Number of trials that used test of interaction for at least one analysis	56 (43.1%)
Number of trials reporting subgroup analyses for a primary outcome	100 (76.9%)
Number of trials that claim a subgroup effect	55
Number of subgroup claims per trial, median (range)	1 (1–12)
The highest strength of subgroup claim in trials	
Claim of a strong subgroup effect	24 (42.9%)
Claim of a likely subgroup effect	19 (33.9%)
Suggestion of a possible subgroup effect	12 (23.2%)
Number of trials claiming subgroup effects for a primary outcome	41 (73.21%)

Journals defined by the National Library of Medicine covering all clinical and public health fields. Using standardized, piloted forms with detailed instructions, two reviewers independently screened and abstracted data. We used univariable and multivariable regression to examine the association of five pre-specified study characteristics with reporting versus not reporting of subgroup analyses. **Results:** Of 3662 citations identified, we randomly selected 700 reports. Our interim analysis (complete analysis will be available for the Colloquium) included 283 trials, of which 130 (45.9%) reported subgroup analyses, and 55 (42.3% of those reporting subgroup analyses) claimed subgroup effects (Table 1). Analyses showed that high impact journals and medical trials were independently associated with reporting of subgroup analyses (Table 2). A test of the interaction between funding source and significance of the primary

outcome suggested that, among trials funded by private-for-profit organizations, study investigators reported subgroup analyses more frequently when the main effect was not statistically significant (OR 2.93, 95%CI 1.22–7.20), whereas no difference was present in trials without funding from private-for-profit organizations (OR 0.79, 95%CI 0.38–1.64, interaction $p = 0.025$). **Conclusions:** Subgroup analyses are frequently reported in randomized trials, and subgroup effects frequently claimed. Medical trials and those published in high impact journals were more likely to report subgroup analyses. Trials funded by private-for-profit organizations were more likely to report subgroup analyses if the result was not statistically significant for the primary outcome than if it was significant.

Correspondence between Cochrane classification of trials and MEDLINE publication type indexing

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Background: The US satellite of the Cochrane Eyes and Vision Group (CEVG@US) received funding from the National Eye Institute, NIH, to handsearch the US-based vision science literature for randomized controlled trials (RCTs) and controlled clinical trials (CCTs). **Objectives:** To compare RCTs and CCTs identified by handsearching with articles assigned MEDLINE publication type [randomized controlled trials (PT-RCT)] and [controlled clinical trials (PT-CCT)]. **Methods:** We identified RCTs and CCTs by handsearch and subsequently searched MEDLINE for those published 1966 and later. We determined the proportion of articles identified by handsearching that were classified in MEDLINE as PT-RCT or PT-CCT, and the proportion that were indexed as PT-RCT or PT-CCT, but not classified by us as RCT or CCT. **Results:** We identified 2,215 RCTs and 469 CCTs by handsearching 223 journal-years, excluding trials published before 1966 and in publications not indexed in MEDLINE. Most reports classified by us as RCTs had been indexed in MEDLINE as PT-RCT (73.9%; 1,637/2,215), but most CCTs were not indexed as PT-CCT (21.3%; 100/469).

Table 2. Factors associated with reporting versus not reporting of subgroup analyses.

Study characteristics	OR (95% CI) (univariable)	P value (univariable)	OR (95% CI) (multivariable)	p-value (multivariable)
High impact vs. other journals	4.87 (2.94–8.07)	<0.001	3.02 (1.60–5.70)	0.001
Medical vs. surgical trials	2.67 (1.49–4.88)	0.001	2.13 (1.11–4.12)	0.023
Sample size per arm (quartile)		<0.001		0.11
<30	Referent group			
30–99	1.72 (0.82–3.62)	0.15	1.31 (0.59–2.91)	0.50
100–316	5.50 (2.63–11.47)	<0.001	3.03 (1.32–6.93)	0.009
317 or larger	6.21 (2.96–13.02)	<0.001	2.33 (0.94–5.78)	0.068
Not-significant vs. significant primary outcome		0.13*		0.025*
Trials funded by private-for-profit organizations	2.08 (0.94–4.59)		2.93 (1.22–7.20)	
Trials funded by other sources	0.95 (0.50–1.80)		0.79 (0.38–1.64)	

*p-value for the test of interaction between significance of main effect with source of funding.

Conversely, many articles were indexed as PT-RCT ($n = 161$) or PT-CCT ($n = 115$) although we did not classify them as trials. Sometimes the reports we classified as describing RCTs were indexed as PT-CCT ($n = 22$) and sometimes CCTs were classified as PT-RCT ($n = 24$). In a subset of articles from one journal, more articles were incorrectly indexed with PT-RCT or PT-CCT when published in 2000 or after compared with those dated before 2000 (40 versus 10).

Conclusions: A meaningful proportion of articles we identified and classified as RCT and CCT are not indexed by these publication types in MEDLINE. Handsearching is a necessary adjunct to electronic database searching for trials for systematic reviews.

Session I4: Synthesis and Qualitative Data

When it rains: synthesizing umbrella reviews of educational interventions

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Background: Cochrane reviews originated to examine medical treatments, i.e., drugs and devices. Now the systematic approach is also applied to interventions intended to help people use the medical treatments. However, methodological heterogeneity in 'umbrella reviews' limits the ability to conduct meta-analysis. Search strategies are also challenging. We address implications of reviewing such interventions, make comparisons with reviewing a clinical treatment, and offer alternatives for synthesizing results. **Objective:** To provide alternative methods for synthesizing results of educational intervention reviews. **Methods:** We used concept mapping to illustrate the factors influencing the ability to conduct meta-analysis. Educational interventions can vary by content, dose (contacts), format (didactic; discussion), or context (clinic; community). Literature searches are complex; key words (education, counseling, evaluation) are not unique to the review topic. We compared the design heterogeneity in our reviews of theory-based interventions for contraceptive use and of steroidal contraceptive effect on carbohydrate metabolism. **Results:** Of 26 trials in the theory-based review, 8 randomly assigned clusters and 18 assigned individuals. We identified five groupings for the theoretical basis, e.g., Social Cognitive Theory with or without another model. Outcomes included pregnancy and contraceptive use. Design differences in this review precluded any meta-analysis. To synthesize results, we grouped studies by theoretical basis and comparison intervention. The metabolic review had 28 contraceptive comparisons with varying outcomes across studies (e.g., glucose area under the curve; fasting blood glucose). Three comparisons involved meta-analysis. One progestin group had 11 different comparisons across 10 trials. Education-related literature searches produced twice the number of citations found for metabolic issues. **Conclusions:** Reviews of clinical interventions may have design heterogeneity similar to reviews of educational interventions. Alternative ways to present results from heterogeneous studies, such as grouping them conceptually, aid interpretation. Such systematic reviews can then provide useful information about effective methods and research needs.

Synthesis methods in systematic reviews of effectiveness, cost-effectiveness and qualitative evidence: an example from public health

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Background: There is growing interest in the use of qualitative evidence to contribute to systematic reviews of the effectiveness and cost-effectiveness of interventions, particularly social interventions in preventive health. A number of approaches to qualitative synthesis, and to mixed-methods synthesis of qualitative and quantitative data, have been put forward. It is unclear to what extent different methods of synthesis may impact on the conclusions to be drawn from mixed-methods reviews. **Objective:** This review of interventions to promote HIV testing among men who have sex with men (MSM) included three types of evidence: effectiveness, cost-effectiveness and qualitative evidence. We aim to explore the issues encountered in utilising these three types of evidence, and the impact of using different methods of qualitative synthesis. **Methods:** Effectiveness and cost-effectiveness studies were synthesized narratively. The first phase of qualitative synthesis was thematic and aggregative, with the findings presented in a matrix cross-tabulated with the effectiveness and cost-effectiveness synthesis. In a second phase of synthesis, we developed interpretive constructs from the qualitative data which were used to provide a further level of insight into the findings regarding interventions. **Results:** The thematic synthesis identified a number of potential barriers and facilitators of uptake of HIV testing interventions among MSM. The second phase of synthesis enabled us to develop a more complete understanding of some of these factors, such as fear of status disclosure, and to illuminate effectiveness findings in more detail. **Conclusions:** The conclusions drawn from mixed-methods reviews may depend on the nature and extent of the synthesis of qualitative data undertaken. Different synthesis methodologies have unique contributions to make to mixed-methods systematic reviews. However, questions remain about the validity and transparency of such approaches.

Systematic reviews, comparative effectiveness reviews, and overviews of reviews: their strengths, limitations, and value for end-users

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Background: Several methodologies have emerged within the arena of evidence synthesis, including systematic reviews (SRs), comparative effectiveness reviews (CERs), and overviews of reviews (overviews). A SR collates relevant evidence from individual studies using systematic methods to avoid bias. CERs use SR methodology and seek to describe the relative benefits (or harms) of a range of interventions compiling evidence from all relevant studies. Overviews compile information from multiple SRs relevant to a single health problem. **Objectives:** Our objective was to compare the methods of these different types of reviews, and discuss their advantages and disadvantages, using interventions for bronchiolitis as an example. **Methods:** We conducted two Cochrane SRs examining glucocorticoids

and epinephrine (respectively) for bronchiolitis. We completed a CER and network analysis to simultaneously examine glucocorticoids and bronchodilators for bronchiolitis. We completed an overview of interventions for bronchiolitis, based on the currently available Cochrane SRs. **Results:** Each SR provided evidence for a single intervention through pair-wise, direct comparisons. Each review focused on a different intervention; therefore, end users must read each SR to inform decision-making. The overview synthesized data from 7 Cochrane SRs, each of which examined a different intervention. This allows the reader a quick overview of the available Cochrane evidence, but overviews are dependent on the methods and decisions employed at the SR level. The CER allowed us to examine the relative effectiveness of different treatments. Through a network analysis we were able to simultaneously compare multiple treatments by combining direct and indirect evidence. While potentially more expensive and time-consuming to produce, the CER provides a comprehensive synthesis of all available (or promising) interventions for a given condition. **Conclusions:** We will provide the results and

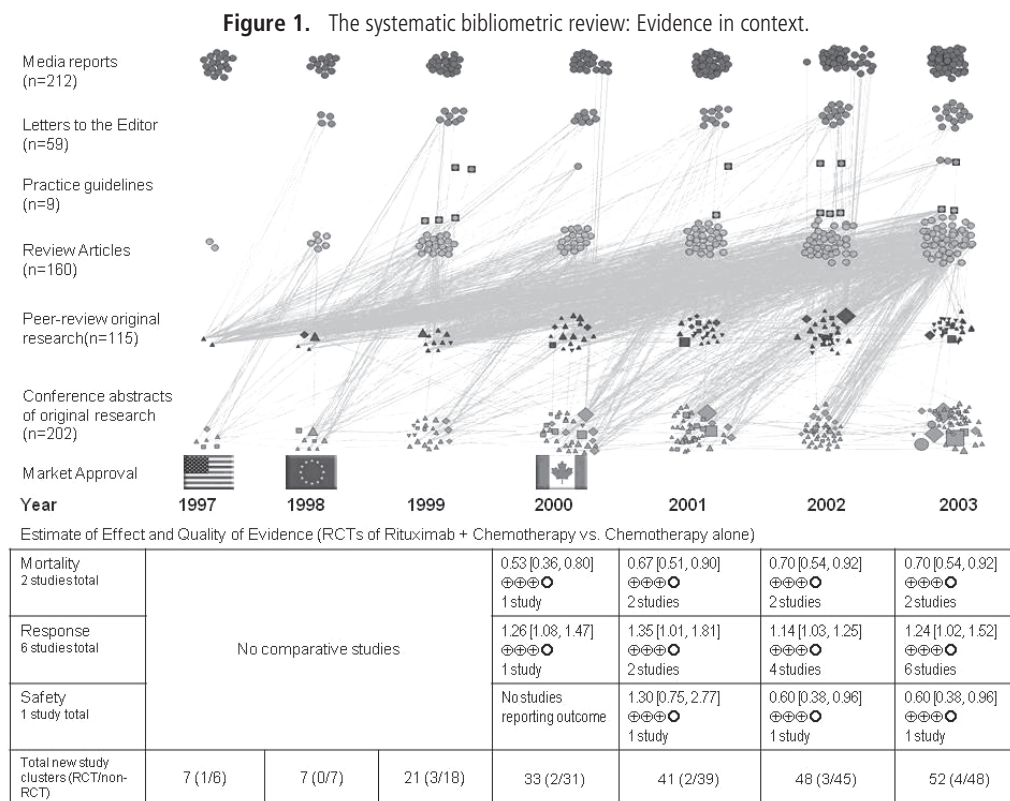
conclusions from each of these syntheses and discuss their relative value and possible shortcomings for the end user.

Session 15: Incorporating Patient Outcomes

Systematic Bibliometric Review: A new methodology presenting patient-centred outcomes in the context of reviews, guidelines, and media reports. Part 2: A case study of Rituximab for non-Hodgkin's lymphoma (NHL) 1997–2003

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Background: Practice pattern analysis identified variable and widespread use of Rituximab for NHL in academic cancer centers before



Legend for Figure: Systematic bibliometric review outputs. In these figures, we juxtapose the relationships between document types and original research, and the estimates of effect for original research data of patient-centered comparisons and outcomes. Each point represents one document. Grey = conference abstracts of original research; Red = peer-review original research; Green = review articles (green with black boxes = systematic reviews; all other represent narrative reviews); Orange = practice guidelines (orange with black boxes = practice guidelines citing a systematic review); Lavender = Letters to the editor or editorials; Blue = media reports. For original research documents (grey or red), symbols represent study design: ◆ = randomized controlled trial; ▲ = case series; ▼ = case study; ■ = database study; ● = other. Symbol size represents number of enrolled patients. We demonstrate the body of original research documents (grey and red) and study clusters, juxtaposed against the cumulative meta-analysis estimate of effect and quality of evidence. We display how original research documents (grey or red) are cited by review articles (green), practice guidelines (orange), editorials (lavender), and media reports (blue). Flags represent marketing approval dates for the United States (1997), European Union (1998), and Canada (2000). *This study appeared as a conference abstract and reported grade 3 or 4 adverse events in aggregate. †This study was the peer-review publication of the 2001 conference abstract. The estimate of effect represents the proportion of grade 3 or 4 infections. Authors did not report grade 3 or 4 adverse events in aggregate.

guideline recommendations and randomized trial results. **Objectives:** We conducted a systematic bibliometric review of rituximab for NHL to understand the quality of patient-centered outcomes and context of this evidence represented by related documents. **Methods:** We searched 3 primary data sources (1997–2003) for 5 document types: original research (abstracts, peer review publications), reviews (systematic, narrative), guidelines, editorials, and media reports. We developed the term “study cluster” to describe how one original research study may present different results and outcomes in separate publications over time. We conducted cumulative meta-analysis on 4 patient-centered outcomes (mortality, tumour response, safety and quality of life (QOL)) and used GRADE to classify the quality of evidence. Direct citation relationships between original research documents and other documents were analyzed and visually represented. **Results:** Of 6,798 documents, 757 met inclusion criteria (317 original research, 160 reviews (9 systematic), 9 guidelines, 59 editorials, 212 media reports). The 317 original research documents represented 209 study clusters and 8,483 evaluated patients (median per study 20, interquartile range, 5–41). Of 209 study clusters, 2.9% ($n = 6$) were randomized controlled trials (RCTs) and reported data on outcomes of interest; none reported QOL. The quality of evidence was moderate. We identified 1,571 direct citations to the 317 original research documents (90.1% reviews, 1.6% guidelines, 6.9% editorials, 1.1% media reports). The first RCT with patient-centered outcomes appeared in 2000, whereas the first guidelines appeared in 1999. Of 212 media reports, 92% ($n = 195$) cited no original research (Figure). **Conclusions:** Of 757 rituximab documents, RCTs of relevant comparisons and outcomes represented <3% of original research. In contrast, review articles, guidelines, editorials and media reports outnumbered the relevant original research. The systematic bibliometric review facilitated the visualization, contextualization and interpretation of these complex relationships.

Determining the importance of outcomes used for evaluating therapies for children with asthma

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Background: In order for systematic reviews to inform clinical decisions, it is vital that the included studies measure important, appropriate outcomes. Most clinical trials in childhood asthma measure outcomes reflecting short-term disease activity, but not functional status, quality of life (QoL), or long-term effects of treatments (1). **Objectives:** To identify which outcomes are most important to parents of young people with asthma, young people themselves, and clinicians. **Methods:** Clinicians completed a two-round Delphi survey. Parents, recruited in asthma clinics, participated in both rounds. Young people, aged at least 13 years, participated in the first round. In Round 1, clinicians were asked to suggest outcomes they felt were important in clinical practice. Parents and young people were asked, using open questions, how they judged whether they were satisfied with anti-asthma medication. Responses were classified into appropriate corresponding outcomes by two researchers independently. In Round 2, participants were shown outcomes suggested by at least 10% of responders in Round 1. They scored the importance of each

from 0–4, and selected the three most important. **Results:** Forty-six clinicians completed Round 1, and 43 of these completed Round 2. Thirty-eight parents and 11 young people completed Round 1, and 50 parents completed Round 2. Of 18 outcomes listed in Round 2, those ranked as most important related not just to short-term disease activity, but also QoL, functional status and long-term treatment effects. **Conclusions:** In childhood asthma, certain outcomes are infrequently measured in clinical trials but are highly important to clinicians and parents. This limits the usefulness of such trials. When identifying outcomes of most importance for a Summary of Findings table, systematic reviewers should be aware of such discrepancies.

Reference

1. Sinha et al (2009) Outcomes in Clinical Trials of Inhaled Corticosteroids for Children with Asthma Are Narrowly Focussed on Short Term Disease Activity *PLoS ONE* 4(7):e6276.

Challenges using patient reported outcomes for functional abilities and quality of life in older adults

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Background: Research in older adults increasingly focuses on important patient reported outcomes (PRO). While these outcomes often better capture net health impact than traditional disease-specific outcomes, they pose methodological challenges for systematic reviewers. **Objective:** To describe methodological challenges for reviewers of primary evidence using health-related quality of life (HRQOL) or functional status measures in older adults. **Methods:** We conducted a systematic review of multi-factorial assessment and management strategies in older adults to prevent functional decline. We describe the challenges in measurement properties, comparability, and standardization in conducting meta-analyses for PRO. **Results:** Among 62 RCTs, 41 self-reported measures of functional status (20 ADL, 13 IADL, 8 combined ADL/IADL) were reported. Instruments were occasionally misclassified or not reported; measurement properties for instruments (e.g., development population, validity, independent validation, responsiveness to change) were never reported. Population considerations further complicated outcome interpretation, as measures of functional status and HRQOL have different measurement properties in different risk populations and approaches to defining and reporting patient risk across trials were inconsistent. Inability to determine when measures are appropriate hampers separating true null effects from measurement error. Pooling functional status or HRQOL measured by multiple instruments required use of unitless measures and assumptions that measurement tools cover the same domains. Hand-checks of domains addressed by instruments illustrates that these assumptions may be questionable. Inconsistent reporting of data and issues of directionality required substantial data manipulations to allow pooling. Finally, there were challenges in the interpretation of clinically meaningful differences. Although methods on how to define clinically important differences in PRO exist, application of these methods was complicated by the pooling of multiple different measures, differences in participants' baseline risk, and the variability

in the natural history of functional decline. **Conclusions:** We caution systematic reviewers in pooling PRO measures in meta-analyses across studies of older adults without paying attention to the risk status of populations, validity of measurements, measurements properties in different risk populations, and the ability to interpret the clinical significance of pooled estimates.

Can we trust patient reported outcomes in the absence of blinding? Preliminary results from an analysis of trials included in systematic reviews of interventions for chronic conditions

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Background: The importance of patient perspective in disease and healthcare is now widely recognized. It is common when studying therapeutic interventions to employ patient assessments of health. Patient-reported outcome is an umbrella term applicable to any health data reported by the patient, such as symptoms, functional status, satisfaction with therapy, or treatment adherence (Acquadro et al 2003). PRO measures extend the range of patient outcomes that can be assessed beyond traditional measure of survival or objective clinical efficacy to capture the patient perspective on symptoms overall health status and the impact of disease and treatment on quality of life (Acquadro et al 2003; Walters 2009). Given their increasing use in appraising intervention effectiveness, understanding the potential bias and the magnitude of the bias they may be vulnerable to is important in careful synthesis and interpretation of evidence. **Objective:** To explore the potential bias in patient reported outcomes in the treatment of chronic conditions where patients are not blind to treatment. **Methods:** Analysis of data from trials included in 17 meta-analyses examining interventions to treat chronic conditions. For each study in the included meta-analyses outcomes were subdivided into objectively assessed, or a PRO. Meta-analyses were included where objective measures showed no statistically significant effect of the intervention but also included a PRO. Studies were also defined as having been blinded or not blinded. Logistic regression models were used to compare intervention effects on PROs in trials with and without blinding. **Results:** Lack of blinding was associated with considerably greater estimates of effect in PROs for patients suffering from chronic conditions. **Conclusions:** Particular caution needs to be exercised in the interpretation of patient reported outcomes where there is a lack of blinding this is particularly so in reviews where there is also a lack of studies reporting outcomes for objective measures for treatment effectiveness.

Oral session J

Searching And Information Retrieval

Session J1: Databases

More needle, less haystack – identifying ongoing trials with the Pan African Clinical Trials Registry

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Background: Cochrane review authors face difficulties identifying ongoing trials in regions where trials registries do not exist. In 2007, the South African Cochrane Centre established the Pan African Clinical Trials Registry (www.pactr.org) to provide a platform to prospectively register all clinical trials conducted in Africa. In 2009, www.pactr.org became a World Health Organization (WHO)-endorsed primary register displaying the required 20-item minimum dataset. **Objectives:** 1) To categorise interventions in trials registered on www.pactr.org and map these to published Cochrane reviews or protocols 2) To demonstrate the use of searching www.pactr.org for review authors. **Methods:** We downloaded details of trials registered on www.pactr.org on 23 March 2010. Two independent investigators extracted trial data, including disease and intervention details. We searched the *Cochrane Database of Systematic Reviews (CDSR) 2010, Issue 2* for published reviews or protocols evaluating the interventions reported in these trials. **Results:** Twenty-five trials are registered on www.pactr.org. Thirteen are randomized controlled trials of efficacy, meeting Cochrane review criteria. We categorized nine trials evaluating treatments, three evaluating prevention interventions and one assessing diagnostic algorithms. The nine treatment trials evaluate drugs for malaria (2), tuberculosis (2), and hyperkalaemia (1), drugs for anaesthesia (1), fluids for surgical irrigation (1), provision of economic incentives (1) and effects of patient advocates (1) on adherence. The three prevention trials evaluate drugs for preventing malaria (2) and behavioural interventions for reducing risky sexual behaviour in HIV-positive adults (1). Our search of *CDSR* identified nine reviews and one protocol where data from eight of the above ongoing trials would be eligible for inclusion. No review reported these. **Conclusion:** Searching www.pactr.org identified ongoing African trials which should ideally be included in updates of reviews. Access to www.pactr.org is free and authors are encouraged to search it using the disease field. Sensitivity may be greatest for topics prevalent in resource-poor settings.

Do Cochrane reviews search databases of ongoing trials, and how well do they report these searches?

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Background: Records for more than 100,000 clinical trials are publicly available on registries that meet international requirements for data quality and transparency. The extent to which systematic reviewers are using these registries to identify potentially eligible studies is unknown. **Objectives:** To assess if and how Cochrane reviewers are searching databases of ongoing studies. **Methods:** All new protocols and reviews published in Issue 2, 2010 of The Cochrane Database of Systematic Reviews were eligible except overviews, diagnostic accuracy reviews and methodology reviews. Two authors independently evaluated the search strategy of each protocol and review and extracted data on the search of databases of ongoing studies. Disagreements were resolved by consensus. **Results:** 41 protocols and 26 reviews were included. A search of a database of ongoing trials was mentioned in 25 (61%) protocols and 10 (38%) reviews (Table 1). Of these 35 documents, only 1 review and 1 protocol specified the terms for this search. Searches for ongoing studies are likely to be inefficient (eg searching the same data through different web sites) and inadequate (eg limited to a single

Database	Protocols	Reviews
WHO ICTRP	3	0
ClinicalTrials.gov	14	9
ANZCTR	3	0
Other WHO Registry	3	0
ISRCTN	5	2
mRCT	3	1
Current Controlled Trials	16	4

database). Review authors often conduct high effort/low yield tasks such as handsearching conference proceedings or contacting experts, but do not search structured databases of trials (low effort/potentially high yield). There are also problems with accuracy (eg listing databases to be searched that are not yet publicly available) and clarity (eg imprecise names such as “the NIH database”). **Conclusions:** Search strategies for ongoing or prospectively registered trials in Cochrane protocols and reviews are poorly documented. There is confusion about the various databases and registers that exist and the overlap between them. The WHO ICTRP database, which includes records from most of the databases mentioned by review authors, is being underused. Suggestions for clearer guidance will be proposed.

Improving search efficiency for economic evaluations in major databases using semantic technology

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Background: Increasingly systematic reviews seek evidence from study designs which are hard to identify efficiently: economic evaluations, adverse effects reports, observational studies, quality of life studies and diagnostic test accuracy studies. Semantic technology software understands automatically the meaning of text written in natural language and may offer approaches to improve the retrieval of difficult to identify study designs. One such issue for systematic reviewers is identifying economic evaluations. Searching for economic evaluations is problematic because they are difficult to distinguish efficiently from other economic studies. **Objectives:** This research explores whether semantic technology post-processing software can help to improve search efficiency for difficult to identify study designs such as economic evaluations. **Methods:** We identified a gold-standard set of economic evaluation records from the NHS EED database: cost-benefit studies, cost-effectiveness studies and cost-utility studies. We identified a comparison set of records of other forms of economic study from MEDLINE. Using these two sets of records we trained semantic technology software to discriminate economic evaluations from other economic studies. We tested the performance of the semantic technology software in identifying economic evaluations accurately and then adapted the software to obtain further improvements. **Results:** Initial testing produced 90% sensitivity (recall) and 85% precision. The final results will be presented at the conference. **Conclusions:** Initial testing shows promise for improving the precision of searching for economic evaluations among records identified in a major bibliographic database. The potential for improved efficiency may be even greater in databases such as EMBASE where extensive indexing seems to impede

efficient retrieval. Semantic technology, for post-processing of search results achieved from sensitive searches, may offer a solution to the current challenges of identifying ‘hard to focus’ study designs such as economic evaluations, adverse effects reports, observational studies, quality of life studies and diagnostic test accuracy studies.

CRD databases: new interface, new content

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Background: The CRD databases are a key resource for health professionals, policy makers and researchers, providing free access to quality assessed evidence to inform health and social care policy and practice. The literature evaluating the effectiveness and cost-effectiveness of health care interventions is growing year on year, and these studies can be difficult and time consuming to identify and appraise. **Objectives:** DARE and NHS EED assist decision-makers by systematically identifying and describing systematic reviews and economic evaluations, appraising their quality and highlighting their relative strengths and weaknesses. The HTA database provides a comprehensive listing of in progress and published health technology assessments, many of which are not accessible from any other readily searchable source. The CRD databases contain over 45,000 records, including over 6,000 quality assessed reviews and over 7,000 abstracts of quality assessed economic evaluations. Each year at least 1,200 quality assessed abstracts are added to DARE, and 480 to NHS EED. **Developments:** The databases are continually evolving to best meet user needs, keep pace with developments in research and exploit new technologies. This presentation will describe the major improvements to be implemented in 2010. Details of the process for production of content include; the added value of the databases as a whole; the rationale behind the content of DARE, NHS EED and the HTA database and the different types of records contained in each. In particular the structure of abstracts, and the value of the quality assessment processes will be highlighted. The introduction of a new content management system and public interface offers a range of improvements and innovations, including real time publication of abstracts; easier identification of abstracts of interest through improved filtering, browse facilities, and MeSH search; enhanced facility to save and export searches; as well as the introduction of a range of alert options.

Session J2: Qualitative / Heterogeneous Information

Breadth and depth of review questions: mixed methods, mapping, reviews of reviews and other methods for enabling analysis of broad questions and heterogeneous data

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Background: Systematic reviews often have narrowly focused review questions such as reviewing the efficacy of a very specific intervention. Such a narrow focus can make it easier to achieve homogeneity of research studies in the review but may limit the applicability of the review findings. A narrow focus may prevent the consideration

of very similar interventions and may create empty or nearly empty reviews whereas a differently constructed review question may have included more studies and provided meaningful results for application to policy and practice. Similarly, rapid evidence assessment reviews are frequently proposed as a means to provide prompt responses to policy questions yet these can be very narrowly focused reviews with limited applicability. **Objectives:** The purpose of this symposium is to examine a range of methods for considering broad questions and heterogeneous data whilst maintaining the necessary rigour of systematic reviews. **Methods:** Examination of the advantages and disadvantages of approaches to enable breadth in reviews in relation to: (1) reviews of effectiveness; (2) reviews of other research questions. **Results:** The presentation will consider these issues in relation to Cochrane and Campbell methods and (i) mapping; (ii) reviews of reviews; (iii) quality and relevance appraisal; (iv) mixed methods and mixed knowledge reviews. **Conclusions:** The importance of selecting appropriate methods for enabling breadth and depth of question and working with heterogeneity of data when undertaking individual reviews and programmes of reviews.

Transparent two stage approach to identification and selection of qualitative literature for meta ethnographic synthesis

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Background: Systematic reviews of qualitative research offer an opportunity to better understand patients' experience of living with disease and treatment. Noblitt and Hare's meta ethnographic synthesis method has become a popular way of synthesizing qualitative literature to generate new insights. However, where there is an extensive amount of qualitative literature this method is impractical, whilst using only selected literature in a synthesis is likely to influence conclusions. A good rationale for choosing particular studies to synthesize is required. **Objectives:** To combine standard systematic review methodology with "mapping" of literature to identify papers to include in a meta ethnographic synthesis of qualitative studies describing the lived experience of patients with chronic obstructive pulmonary disease (COPD). **Methods:** We searched electronic databases and identified studies for potential inclusion. Study setting, aims, theoretical underpinning, sampling approach, participant characteristics, methods, key findings and study quality were abstracted by two independent reviewers. Reviewers made a subjective assessment of the "richness" and novelty of the data. We generated a diagram representing the typical trajectory and disease related life events of a patient with COPD and added the studies we identified. We attempted to express the amount of data in the individual papers visually on the diagram. We used this process to identify studies to include in the meta ethnographic synthesis. **Results:** We identified 48 studies including PhD theses, published up to February 2007. Mapping revealed that most studies involved patients with very advanced disease and there were few studies around the time of diagnosis or when symptoms were mild. This two stage review process allowed us to identify studies to include in our more detailed meta-ethnographic synthesis and made the rationale for study selection more transparent. **Conclusions:** This

two stage approach may prove useful to other researchers interested in the synthesis of voluminous qualitative literature.

A systematic review of Knowledge Transfer and Exchange Practices: Challenges in the search and relevance steps

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Background: Knowledge transfer and exchange (KTE) is a burgeoning practice at research organizations worldwide. However the effectiveness of KTE practices has not been routinely/consistently evaluated. The need for such evaluation has been voiced (Lavis et al, 2003, Eccles et al, 2005). One potential reason for the lack of evaluation is the paucity of tools and methods for evaluation across various disciplines. **Objectives:** This presentation will consider the approach used to critically review the broad scope of literature on evaluation of KTE practices and tools. **Methods:** A team of researchers and decision makers followed a systematic review process developed by the Institute for Work & Health using a Cochrane-like approach and a "best evidence synthesis" framework. The basic review steps include: formulation of research question and search terms; decision-maker/stakeholder meetings; literature search; relevance review; quality appraisal; data extraction; evidence synthesis; decision-maker/stakeholder key messages; and report preparation. Many of the steps required an iterative approach. **Results:** The search was conducted in MEDLINE, EMBASE, CINAHL, PsycINFO, ERIC, CAB Abstracts, LISA, Social Science Abstracts, and Business Source Premier. The search resulted in 13066 titles and abstracts, 744 titles and abstracts were initially found to be relevant and 309 full articles moved on to quality appraisal (QA). QA was an iterative process with classification of articles on study methods and measurement approaches as a necessary component. Data extraction and synthesis steps are pending and will be presented. **Conclusions:** The review approach focused on transparency, reproducibility, and minimizing bias and was easily adapted to this review topic. However a significant number of challenges were encountered due to the large volume and diversity of the KTE literature and the mixed methods approach to this review. The review team met and came to consensus on the approach required at each step of the review.

Search wide and dig deep: identifying 'views' research for systematic reviews

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Background: Searching for views studies, (i.e. mostly qualitative research reporting people's experiences, opinions and understandings

about health issues), is acknowledged to be a challenging process. The EPPI-Centre conducted four systematic reviews of people's views in the areas of obesity, walking and cycling and transition to motherhood. All reviews were used as evidence for UK evidence-informed decision making. Analysing where studies have been found is useful to inform future reviews, and to assess the utility of using a range of research sources (e.g. databases, websites, library catalogues, reference checking). **Objectives:** To assess the value of research sources used to identify research for four systematic reviews of research reporting people's views about health related issues. **Methods:** A retrospective analysis was carried out. This included identifying from which search sources the included studies in each review were located, calculating the number of studies unique to each source and the precision of the results from searches of bibliographic database sources. Publication type was considered in the analyses. Additional comparisons were made of studies from two of the reviews, as these were within the same topic area. **Results:** Interim analysis of three reviews reveals that of a total of 118 included studies, N = 65 (55%) were identified through searches of ASSIA, Psycinfo, CINAHL and Pubmed. For one review, database precision ranged from 0.22–1.64%. A total of N = 95 (81%) studies were uniquely identified on one research source, of which N = 65 (55%) were not identified through searches of major bibliographic databases. Data will be presented for each type of search source and for individual reviews. **Conclusions:** Comprehensive searching for views involves screening many irrelevant studies. While literature is often found amongst a few sources, there is value in searching widely. Reasons why some sources provide more unique studies include publication type and relevancy of databases to review topics.

Session J3: Expanded Search Strategies

Handsearching for reports of diagnostic test accuracy studies: adding to the evidence base

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Background: Guidance for conducting Cochrane systematic reviews of effects and diagnostic test accuracy (DTA) studies recommends handsearching be considered to enhance the retrieval of relevant studies. However, there is little published evidence of the benefits of handsearching for reports of DTA studies. **Objectives:** This study investigated the contribution of handsearching to identifying studies for a review of DTA of 18F-FluoroDeoxyGlucose – Positron Emission Tomography – Computerised Tomography (18F FDG-PET-CT) for colorectal cancer. **Methods:** Candidate journals to handsearch were identified by selecting reviews of FDG-PET for colorectal cancer and collecting the references of the studies included in those reviews. The ten highest yielding journals to which we had electronic access were handsearched from 2005 to June 2009. The results of the handsearch were compared with the results of database searches conducted for the systematic review for the same years. **Results:** 573 journal issues were handsearched in 185 hours yielding 25 candidate DTA records. 1 candidate record per 7.4 hours of handsearching. The handsearch

yielded previously unexamined reports, but none were relevant. Of the 29 studies included in the review (retrieved by database searching) only three were published in the handsearched journals. **Conclusions:** Handsearching is time consuming and expensive. In this review, handsearching did not yield unique studies relevant to FDG-PET-CT in addition to database searching and reference checking. This may be because the databases searched were highly sensitive and FDG-PET-CT studies tend to be consistently described and hence easier to retrieve. Handsearching may be more helpful for less clearly defined diagnostic tests. Identifying the highest yield journals to handsearch for imaging studies is problematic because studies are published in journals from many disciplines.

A search strategy for prognostic reviews and for reviews on diagnostic and prognostic prediction models

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Background: Prognostic reviews are gradually increasing, including reviews on prognostic and diagnostic risk or prediction models. To properly review existing evidence, an accurate search strategy is needed. **Objective:** We validated and updated a previously introduced search strategy for multivariable prediction models, for its ability to identify studies on the development, validation, impact or any other evaluation of a diagnostic or prognostic prediction model, regardless the context. We also studied how to update the search strategy to include non-multivariable prognostic factor studies. **Methods:** We used PUBMED to identify all prediction studies from six general journals in 2008 (Annals of Internal Medicine, BMJ, Lancet, NEJM, PLoS Medicine, JAMA), by applying the search strategy. The so-identified studies were compared by a complete hand-search of these journals by two reviewers, which was considered as the reference standard. We included all studies which developed, validated or otherwise evaluated a prognostic or diagnostic risk score/model with at least 2 predictors. We calculated the accuracy (sensitivity and specificity) of the search strategy. When writing this abstract, three journals were yet fully hand searched. **Results:** The hand search revealed 1542 hits (i.e. all publications in the three journals, excluding publication types like comments or editorials). The search strategy revealed 172 hits. After abstract and full text screening, 29 were identified as prediction studies. The hand search revealed 31, i.e. 2 false negatives by the search strategy (both impact studies); sensitivity = 94%. 1368 hits were true negative by the search-strategy and 143 false positive; specificity = 91% (1368/1511). The search strategy missed 8 studies searching for new (independently associated) predictors; sensitivity = 74%, which we considered too low. The strategy will be updated for use for prognostic study reviews in general. **Conclusion:** Application of the search strategy results in a very low number missed diagnostic and prognostic prediction model studies, with a relatively low number of false positives.

Extending the search to find ongoing and unpublished trials – A survey of methods and results of Cochrane reviews

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Background: Cochrane reviews aim to minimize bias by using explicit, systematic methods of high quality. Publication and selective outcome reporting bias are the Achilles heel of any systematic review. Registration at inception of trials in online clinical trial registries can reduce these biases by enabling reviewers to identify unpublished studies or outcomes. **Objective:** To explore the extent to which Cochrane reviewers search online clinical trial registries for ongoing and unpublished studies, how those search results are reported, and the possible impact thereof on the results of the review. **Methods:** We included all reviews of which the protocol was first published in the Cochrane Database of Systematic Reviews 2008. One reviewer (AvE) extracted data on whether trial registers and other sources of ongoing trials were searched, how this was reported, and how the identified ongoing or unpublished trials contributed to the authors conclusions. **Results:** To date we assessed only Issue 4, 2008 of the Cochrane Library and we included 40 reviews. (NB: at the Colloquium results regarding all 179 identified reviews will be presented). Searching for ongoing trials was performed in 31 of the 40 reviews (77.5%). Used methods were contacting experts (42.5%), handsearching of conference abstracts (50%), and online clinical trial registries (25%). Four reviews identified extra studies through this additional search. Only one reviewer mentioned that not finding any unpublished studies could have led to bias. ClinicalTrials.gov was searched substantially more often (70%) than WHO ICTRP Search Portal (30%), by which 10 registries can be searched simultaneously. **Conclusions:** In this sample a majority of Cochrane reviews did not search online clinical trial registries for identifying ongoing and unpublished studies. In only a few reviews the possible impact of publication bias was explicitly mentioned. There's a need for more guidance for identifying and addressing ongoing and unpublished trials.

McMaster Premium Literature Service (PLUS) performs well for identifying new studies to be included in updates of Cochrane Collaboration systematic reviews

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Background: Nearly 25% of systematic reviews are out of date within two years of publication and "updating burden" is an important problem. The McMaster Premium Literature Service (PLUS) contains a database of pre-appraised, original studies from high impact clinical journals with a small fraction of the entries in major databases. Limiting screening burden by searching PLUS may reduce the time required to update a review. **Objectives:** We compared the performance of PLUS to that of the Cochrane Trial Registry (CCTR), Medline and EMBASE for locating studies added during an update of a review. We investigated the effect of studies not found in PLUS on review result. **Methods:** A sample of new studies in updated Cochrane Systematic Reviews was used to establish a reference standard. Searches were performed for each study in PLUS, CCTR, Medline and EMBASE. Where a primary study was not indexed in PLUS, we examined the effect on the review of excluding the study. We compared the result of each review including only new studies in PLUS to the result using only those not found in PLUS (non-PLUS) via ratio of odds ratios (ROR). **Results:** Ninety-eight updated reviews with meta-analyses were identified and 71 had a meta-analysis that included a study retrieved by PLUS. The relative recall rates for PLUS, CCTR, Medline and EMBASE were 23%, 95%,

90% and 86%, respectively. PLUS contained all new studies for 13 of 71 reviews. No statistically significant difference between PLUS and non-PLUS new studies was found when RORs were pooled across 39 reviews (ROR 0.929; 95% CI, 0.79–1.093). Nineteen updated reviews had no new studies indexed in PLUS. **Conclusions:** PLUS included less than a quarter of the new studies in Cochrane Review updates but the majority of reviews in our sample were unaffected by the use of PLUS as a sole source of literature. This may be because PLUS captures the most important studies.

Oral session K

Statistical Methods

Session K1: Evaluating Treatment Effects

Estimating treatment effects on patient-important outcomes from surrogate markers: the case of venous thrombosis

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Background: Although Cochrane reviews should not include recommendations, their impact depends on usefulness in guiding clinical practice. A focus on surrogate outcomes is therefore problematic because it does not permit a tradeoff between patient-important desirable and undesirable consequences of alternative management strategies. This problem has become particularly evident in guidelines for anti-thrombotic therapy that have previously used reductions in asymptomatic venous thrombosis, measured by venography, to guide recommendations. **Methods:** A group of thrombosis experts and methodologists explored options for estimating the impact of prophylactic anti-thrombotic therapies on symptomatic venous thrombosis and pulmonary embolism. **Results:** We found that most randomized trials of anti-thrombotic prophylaxis were powered only for asymptomatic thrombosis. Trading off reduced thrombosis with increased bleeding requires estimates of patient-important events. We identified three possible strategies: i) Pooling estimates of symptomatic thrombosis from randomized trials. Limitations of this approach include few events for many questions. ii) Using estimates of the ratio of asymptomatic to symptomatic events to estimate the occurrence of the latter. Imprecision of estimates and variability in threshold for asymptomatic events across venography interpreters limits this approach. Both these first two approaches are also limited by underestimation of symptomatic events as a result of treatment of venographically discovered events. iii) Applying relative risk reductions from a composite of asymptomatic and symptomatic events to baseline risks from observational studies. Methodological limitations of observational studies, and uncertainty about whether relative risk reductions in asymptomatic events apply to symptomatic events limit this approach. When observational studies have enrolled representative patients and conducted surveillance allowing accurate estimation of symptomatic events, this last approach is probably superior. **Conclusion:** Venous thrombosis prevention illustrates challenges in using impact of therapy on surrogates to estimate impact on patient-important outcomes. Although every approach has limitations,

this estimation is necessary to make trade-offs required to guide clinical practice.

Modeling treatment effects on patient-important outcomes from surrogate markers in systematic reviews: the case of antiviral therapy for chronic hepatitis B

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Background: The impact of systematic reviews depends on their usefulness in guiding practice. A focus on surrogate outcomes substantially weakens the applicability of evidence because it does not permit a tradeoff between patient-important desirable and undesirable consequences of alternative interventions. **Objectives:** To estimate the treatment effect on development of cirrhosis in a systematic review of combination therapy of lamivudine plus interferon- α (ie, experimental) versus lamivudine (ie, control) for chronic hepatitis B (CHB), in which only surrogates were measured. **Methods:** We pooled trials reporting HBeAg seroconversion, and generated pooled HBeAg seroconversion rates in experimental and control groups. Cohort studies provided estimates of the risk of developing cirrhosis in CHB patients with and without HBeAg seroconversion. Assuming similarity of patient characteristics in cohort studies and trials, we applied estimates of cirrhosis rate from cohort studies to estimates of proportion of patients with and without HBeAg seroconversion from the meta-analysis to estimate the risks of developing cirrhosis in experimental and control groups. We calculated the absolute risk reduction (ARR) based on the estimated risks. We incorporated variances from the trial and cohort study data to generate 95% confidence intervals of ARR. **Results:** Pooling estimates from 5 trials involving 1095 patients suggested that combination therapy had a higher HBeAg seroconversion rate than lamivudine (31.8% versus 18.2%; RR 1.76, 95% CI 1.29 to 2.41; ARR 13.6%, 95% CI 5.9% to 21.2%). Modeling suggested a small and uncertain absolute difference in the development of cirrhosis between combination therapy and lamivudine alone (ARR 0.90%, 95% CI -0.15% to 3.37%). **Conclusions:** Our results suggest that combination therapy, relative to lamivudine, improves HBeAg seroconversion. However, its effect on the development of cirrhosis, if it exists at all, is small. The modeling provides a novel approach that may provide important insights that could influence the advisability of administering toxic and expensive therapy.

LOST to follow-up Information in Trials (LOST-IT): the potential impact on the estimates of treatment effect

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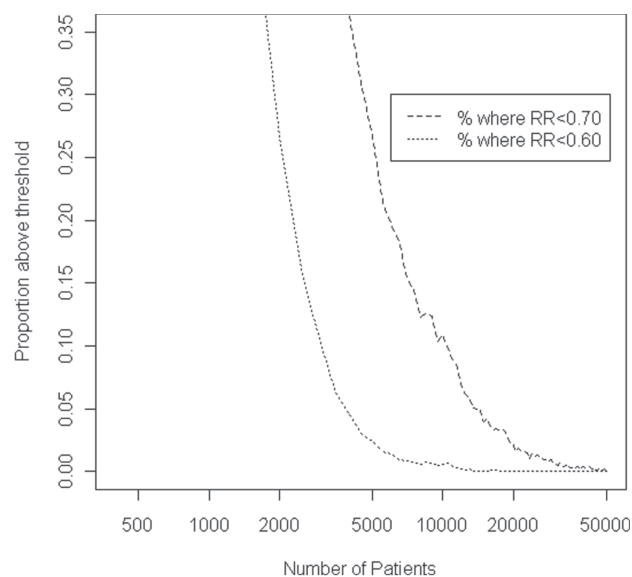
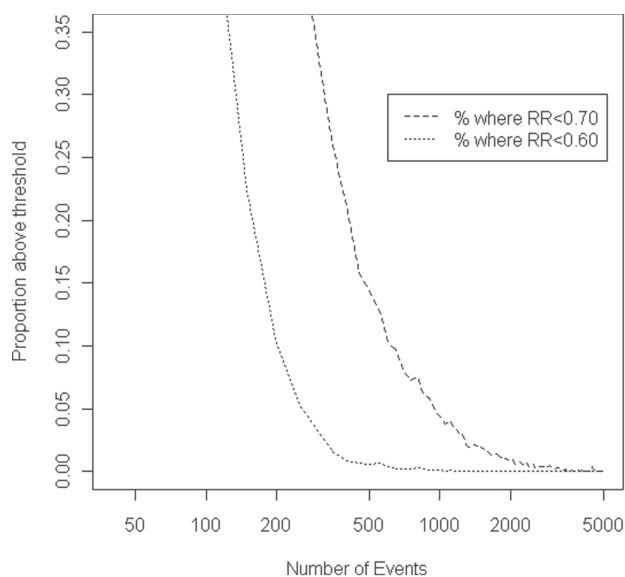
Background: Incomplete ascertainment of outcomes in randomized controlled trials (RCTs) is likely to introduce bias if reasons for unavailability of patient data are associated with the outcome of interest. The primary objective of our study was to assess the potential impact of loss to follow-up on the estimates of treatment effect. The secondary objectives were to describe (1) the reporting of loss to follow-up information, (2) the analytic methods used for handling loss to follow-up information, and (3) the extent of reported loss to follow-up. **Methods:** We conducted a systematic review of reports of 236 RCTs recently published in five top general medical journals. We included RCTs with statistically significant effect estimates with respect to primary outcomes that are patient-important and expressed as binary data. To assess the potential impact of loss to follow-up on the estimates of treatment effect we will, for varying assumptions about the outcomes of participants lost to follow-up (LTFU), calculate (1) the percentage of RCTs that lose statistical significance and (2) the mean change in effect estimate across RCTs. The different assumptions we will test are the following: (1) none of the LTFU participants had the event; (2) all LTFU participants had the event; (3) all LTFU participants in the treatment group had the event; none of those in the control group had it (worst case scenario); (4) the event incidence among LTFU participants (relative to observed participants) increased, with a higher relative increase in the intervention group; and (5) the event incidence among LTFU participants (relative to observed participants) increased in the intervention group and decreased in the control group. **Results:** We will present our results at the Cochrane Colloquium. **Discussion:** The results of this study may have important implications for clinical trialists, systematic reviewers and users of the medical literature.

When can we trust 'early' statistically significant treatment effect estimates in cumulative cardiology meta-analyses? – a simulation study

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Introduction: Meta-analyses that only include a cumulative small number of patients and events ('early' meta-analyses) are often underpowered to detect realistic treatment effects. Nevertheless, many examples of statistically significant 'early' meta-analyses exist in the medical literature. Statistically significant results in early meta-analyses can only occur if 1) the treatment effect is overestimated; 2) the standard error is underestimated. Most meta-analysts typically assume time-lag or publication bias is the cause of 'early' statistical significance, but theoretical considerations suggest that random error (the play of chance) can also substantially impact the results of 'early' meta-analyses. We performed a simulation to explore the extent to which random error causes overestimation of treatment effects in 'early' statistically significant cardiology meta-analyses. **Methods:** To facilitate a 'realistic' cardiology random-effects model metaanalysis simulation, we surveyed all meta-analyses on mortality from the Cochrane Heart Group and utilized the observed distribution of trial



sizes, trial control group event rates, and trial treatment effects to set the simulation parameters. We simulated 10,000 meta-analyses with an overall true treatment effect of 0.80 relative risk, individual trial effects varying around 0.80 with possible extremes of 0.60 and 1.05 (i.e., moderate heterogeneity). We performed cumulative meta-analysis on each of the 10,000 simulated meta-analyses. Among statistically significant (one-sided $\alpha = 0.025$) cumulative point estimates, we calculated the proportion that were smaller than 0.70 and 0.60. **Results:** Among the surveyed meta-analyses, trial sizes varied between 40–400 (25%), 401–1000 (65%) and 1001–10,000 (10%) and control group event rates ranged from 1% to 15%. Figures 1 and 2 present the proportion of statistically significant meta-analyses that yielded RR estimates smaller than 0.70 and 0.60 in relation to the cumulative number of events and patients. **Conclusion:** In 'early' statistically significant meta-analyses, random error alone may cause overestimation. Depending on what is considered a 'clinically important' overestimate, about 8,000–20,000 patients or 400–2,000 events are needed to avoid spurious results.

Session K2: Assorted Topics

Multiple-treatments meta-analysis for categorical outcomes

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Background: Meta-analyses of outcomes with three or more mutually exclusive categorical responses (e.g., cause-specific death, other death and no death) typically employ binomial models by collapsing or ignoring categories (e.g., death vs. no death or cause-specific death vs. no death). Besides requiring multiple analyses, such methods may introduce bias and inefficiency by only analyzing part of the data and

ignoring correlation among the dependent responses. **Objectives:** Develop a model to compare multiple treatments that form a network with a categorical outcome. The model is applied to analyze the effect of statins on cardiovascular outcomes. The trials form a network with four types of treatments (high and low dose statins, fibrates and controls) and report on an outcome with six categories (fatal and non-fatal stroke, fatal and non-fatal myocardial infarction, other causes of mortality and no event). **Methods:** We apply a multinomial Bayesian model estimated using Markov chain Monte Carlo that can incorporate missing outcomes or treatments. Such missing data may arise when some studies report only some outcome categories or treatments and not others. **Results:** We analyze data from 23 randomized trials in which each trial compares two of the four treatments. Nine of the trials report all six outcome categories; the others report some subset, usually because they do not split the stroke or myocardial infarction outcomes into fatal and non-fatal groups. Using a non-informative prior distribution for the treatment effects, high dose statins reduce fatal and non-fatal myocardial infarctions compared with control treatments. Posterior probabilities of events in each study indicate that statins reduce the chance of poor outcomes and increase the probability of no event. **Conclusions:** We demonstrate how to estimate the relative effect of multiple treatments on multiple categorical outcomes and produce valid simultaneous uncertainty estimates. This model should have many applications in the clinical literature.

Assessing the effect of adjusting for funnel plot asymmetry in networks of interventions

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Background: Several methods for testing and adjusting for funnel plot asymmetry can provide useful results when applied to a large set of fairly homogeneous trials [1]. As Cochrane reviews typically include few or heterogeneous studies, methods to adjust for small study effects are not

often used. Networks of trials comparing several interventions for the same condition are increasingly considered in evidence synthesis and they can offer, under certain assumptions, an interesting opportunity to explore small study effects particularly for those comparisons with few studies. **Objectives:** To explore extensions of established regression approaches for testing and adjusting for small study effects in the context of multiple-treatments meta-analysis. **Methods:** We present how different methods for testing and evaluating small study effects adapt to multiple-treatments meta-analysis context. We use multiple-treatments meta-regression extending the variations of Egger's meta-regression as described in a recent review paper [1]. The fit of the models and changes in inconsistency are monitored and several assumptions regarding the exchangeability of coefficients across comparisons of interventions in the same network or between networks in the same field are evaluated. We apply the methods to various networks of interventions and we observe the impact of adjustment in the relative ranking of the competing treatments. **Results:** Funnel plot asymmetry was present in some pairwise comparisons and adjustment had some effect in the relative effectiveness of pairs of treatments. However, when the entire network was considered, adjustment for small study effects was not associated with material changes in the fit, heterogeneity or consistency.

Reference

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Combining Hierarchical Linear Modeling and non-regression-based effect size metrics in a meta-analysis of single-subject experimental research

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Background: The evidence-based practice movement and the need to summarize data from single-subject experimental designs (SSEDs) within meta-analyses have prompted the development of techniques for calculating SSED effect sizes (ES). The two most promising approaches seem to be the "family of non-overlap metrics" and the application of hierarchical linear modeling (HLM) (Parker, Hagan-Burke, & Vannest, 2007; Shadish & Rindskopf, 2007). Non-overlap metrics such as Non-overlap of All Pairs (NAP; Parker & Vannest, in press) or Percentage of Non-overlapping data (PND; Scruggs, Mastropieri, & Casto, 1987) use the amount of non-overlapping data in SSEDs as an indicator of performance differences, i.e., the extent to which data in baseline versus intervention phases do not overlap is an accepted indicator of the magnitude of treatment effect. These non-parametric approaches are not impacted by data assumptions of normal distribution, equal variance, and serial independence (which are commonly not met by SSED data). Their disadvantage on the other hand is the inability to describe trend and variability in the data as well as being insensitive to the magnitude of mean level shift. HLM procedures allow a more fine-grained analysis of effects on level and slope as well as a more accurate analysis of overall treatment effect that takes into account inter- and intra-subject variability. **Objectives:** This presentation will

demonstrate how to combine HLM and non-regression ES procedures within a meta-analysis of SSED data. **Methods:** A sample data set of 15 published SSED studies including 42 participants was taken from a recent meta-analysis of intervention research in autism spectrum disorders (Wendt, 2009). Interventions applied graphic symbols to increase communicative development. HLM procedures described by Van den Noortgate and Onghena (2003, 2007) were applied to combine data from individual cases. The level-1 model measures within-subject effect of treatment change from baseline to treatment phases. The level-2 model explains why some subjects show more change than others and assesses higher order mean effects. The intervention effect on each participant was estimated by using empirical Bayes (EB) techniques (Morris, 1983). To assess data overlap between phases as a supplemental measure of treatment effect, the non-regression NAP and PND were calculated additionally. **Results:** Although HLM procedures yielded a fine-grained analysis of overall effect of the intervention phases within the SSEDs, they were inapplicable for analyzing generalization and maintenance phases due to few cases reporting these data. Also, cases that presented with slightly different outcome measures could not be included in the HLM analysis. These instances were more accurately described by the NAP and PND metrics. **Conclusions:** For more heterogeneous data sets it is recommended to supplement an HLM synthesis of SSEDs with non-regression metrics. With only a small number of cases available, it seems difficult to get reliable estimates of population characteristics such as mean effect and variation over cases of this effect. EB estimates of individual participant effect are only informative if there are enough cases to combine; they tend to be biased towards the overall estimate and are not directly comparable to NAP and PND.

Bivariate meta-analysis of predictive values

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Background: Because predictive values tend to vary more with changes in prevalence than other measures of diagnostic accuracy, direct meta-analysis of positive predictive values is discouraged. However, it is unclear whether meta-analyzing predictive values directly will indeed produce different results than first obtaining summary estimates of sensitivity and specificity and calculating predictive values by Bayes theorem. **Objective:** To compare the conventional bivariate logitnormal model for meta-analysis of test accuracy studies, which results in summary estimates of sensitivity and specificity, with an alternative bivariate logitnormal model of the positive and negative predictive value. **Methods:** From a set of meta-analyses that included a consecutive series of eligible patients, we estimated a summary sensitivity and specificity for each review, using the bivariate method for meta-analysis. Then we used the mean prevalence to calculate predictive values. The bivariate model was also used to directly obtain summary estimates for predictive values. The final estimates for predictive values were compared, as well as heterogeneity measures and the $-2 \log$ likelihood to compare how the models fitted the data. **Results:** Sixteen reviews fulfilled our criteria and were analyzed

with both models. Of these 16 reviews, 10 showed a lower $-2LL$ for the predictive values model, and 6 showed a lower $-2LL$ for the conventional model. The estimated predictive values did not differ significantly. **Discussion:** Our results do not show a significant preference for either the conventional model or the direct model for predictive values. Although predictive values may be preferred by clinicians, the question remains whether, for example, the effect of covariates on predictive values can be interpreted the same way as their effect on sensitivity and specificity. Recently, a trivariate model of sensitivity, specificity and prevalence was published. We will compare the above models with this model as well and present those results during the Colloquium.

Session K3: Challenges and Reliability in Meta-Analysis

Improving the Interpretation of Health-related Quality of Life Evidence in Meta-analyses

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Introduction: Systematic reviews of randomized trials that include measurements of health-related quality of life (HRQL) potentially provide critical information for patients and clinicians facing challenging health care decisions. When, as is most often the case, individual randomized trials use different measurement instruments for the same construct (such as physical or emotional function), authors typically report differences between intervention and control in standard deviation units (so-called "standardized mean difference"). This approach has statistical limitations (it is influenced by the heterogeneity of the population) and is non-intuitive for decision makers. **Objective:** To present an alternative approach: reporting results in minimal important difference (MID) units (the smallest difference patients

Table 1. Pooled mean differences from trials included in cochrane review.

	Point estimate (95% Confidence Interval)
CRQ	
Dyspnea	1.06 (0.85, 1.26)
Emotional Function	0.76 (0.52, 1.00)
Fatigue	0.92 (0.71, 1.13)
Mastery	0.97 (0.74, 1.20)
Overall	0.94 (0.57, 1.32)
SGRQ	
Activities	4.78 (1.72, 7.83)
Impacts	6.27 (2.47, 10.08)
Symptoms	4.68 (0.25, 9.61)
Overall	6.11 (3.24, 8.98)

Notes: Scores on the SGRQ have be multiplied by minus 1 (to change the sign of summary scores); MID for each of the HRQL instruments: CRQ MID = 0.5 points difference on the 7-point scale; SGRQ MID = 4 points difference on the 100-point scale.

experience as important). **Methods:** Using a Cochrane review of respiratory rehabilitation for COPD, we compared the existing method with our method using 16 trials that employed two widely used disease-specific HRQL instruments: the Chronic Respiratory Disease Questionnaire (CRQ), and the St. Georges Respiratory Questionnaire (SGRQ). **Results:** For the CRQ and SGRQ, the pooled MD for each of the domains as well as the total score exceeded the MID (see Table 1). Combining all studies yields an overall pooled estimate in SD units of 0.77 (95% CI 0.62, 0.91), $I^2 = 58\%$ (Figure 1). Applying the new method the pooled estimates in MID units are, for the CRQ, 1.86 (95% CI, 1.45 to 2.27) and for the SGRQ, 1.53 (95% CI, 0.81 to 2.24). Combining all studies in MID units yields an overall pooled estimate of 1.75 (95% CI, 1.37 to 2.13), $I^2 = 32\%$ (Figure 2). This suggests a large effect: the pooled estimate is almost twice as great as the smallest difference patients perceive as important. **Conclusions:** The MID approach provides a potential solution to both the statistical and interpretational problems of existing methods.

Figure 1. Pooled estimate in SMD units.

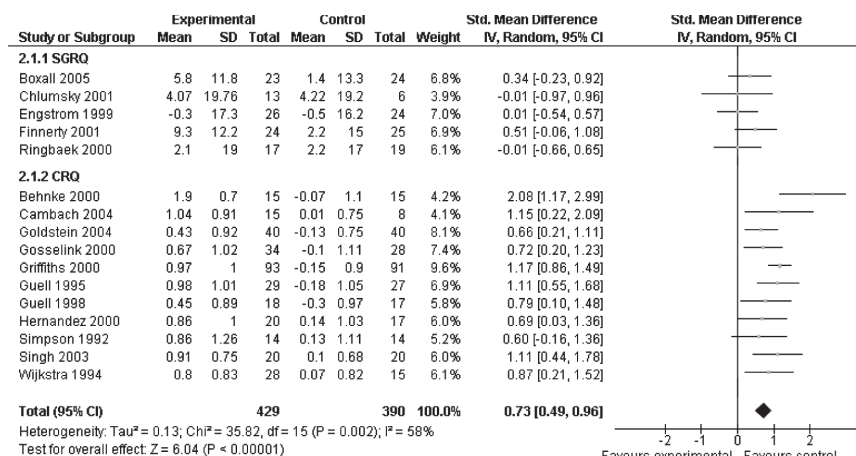
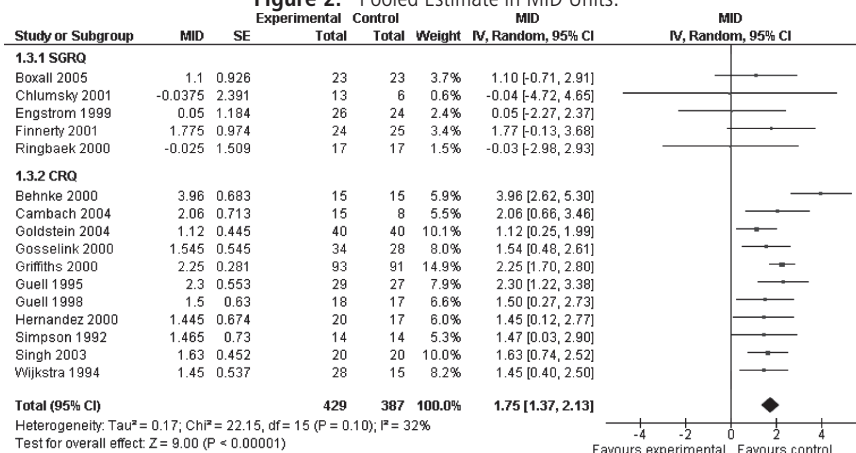


Figure 2. Pooled Estimate in MID Units.



Challenges in the assessment of heterogeneity in systematic reviews of diagnostic test accuracy studies

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Background: The results of diagnostic accuracy studies (sensitivity and specificity) often show wide variation. Estimates of I^2 or the Q test, commonly used in meta-analysis of randomized trials, can be inaccurate when the number of studies is small, and may not be helpful for diagnostic meta-analysis, as heterogeneity of both sensitivity and specificity should be assessed simultaneously, taking into account the correlation that might exist between sensitivity and specificity.

Objectives: To discuss the difficulties surrounding the assessment of heterogeneity in diagnostic meta-analysis. **Methods:** We recently carried out a series of systematic reviews on the diagnostic performance of symptoms, signs, and laboratory tests in the identification of colorectal disease. Quality assessment using the QUADAS tool, and data extraction was performed by two reviewers independently. We presented pooled estimates of sensitivity and specificity using the bivariate random effects approach, but refrained from pooling when there was considerable clinical or statistical heterogeneity. **Results:** Heterogeneity was partly explained by differences in study design (e.g. cohort or nested case control design), sources of bias (e.g. verification bias), and prevalence of disease, but there was wide unexplained heterogeneity in results. Different approaches for assessing statistical heterogeneity were applied, exploring their influence on the decision to present pooled estimates. These approaches include: observation of forest plots; use of statistical tests or I^2 ; use of a priori defined cuts-off for maximal variation in point estimates or for optimal values of diagnostic performance; selection of other measures of performance; analysis of between-study variation (τ^2), and observation of the prediction ellipse. **Discussion:** Results of the analyses will be presented during the conference using illustrative examples. Recommendations will be given regarding approaches that may facilitate the assessment of (statistical) heterogeneity in diagnostic systematic reviews, and may help decisions regarding the presentation of pooled estimates of results.

Perpetuation of inappropriate meta-analysis methods? Analysis of systematic reviews cited by systematic reviews

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Objective: To describe citation patterns of multiple systematic reviews on a related topic. **Methods:** We included systematic reviews of prostaglandin analog eye drops for glaucoma identified by searching PubMed, EMBASE, and The Cochrane Library up to September 2009 without date or language restrictions. We extracted from each systematic review the number of studies and participants included, publication date, journal, funding sources, and whether a meta-analysis was conducted. We examined whether the statistical methods for meta-analysis were appropriate. One author extracted the data and another verified the data against the original publication. For each systematic review, we examined the reference list to identify all citations to previously published systematic reviews on the related topic. We also searched the Web of Science database on March 25, 2010 to verify citations and obtain the total number of citations for each review. **Results:** We identified 16 systematic reviews with meta-analysis (Figure). One or more inappropriate statistical methods were used in 8/16 reviews. Six described pooling data from similar treatment arms across studies resulting in a non-random comparison (e.g., six bimatoprost, and 11 travoprost arms were pooled and compared in a review including 27 trials); three described an incorrect formula to calculate the variance of the effect estimate. Systematic reviews using inappropriate meta-analysis methods were cited more often by subsequent reviews compared with systematic reviews using appropriate methods, many of which were not cited at all. The most frequently cited review (71 times) incorrectly pooled individual treatment arms. No review using inappropriate methods cited a review with appropriate methods. Reviews using appropriate methods did not cite reviews with inappropriate methods as often. **Discussion:** A critical assessment of previous systematic reviews on a given topic is imperative before initiating another. Additional systematic review topics should be examined for possible perpetuation of inappropriate statistical methods and findings.

Table 1. Items identified for the assessment of credibility of subgroup analyses.**1. Is the study or studies associated with a low risk of bias?**

- Definitely high risk of bias
- Probably high risk of bias
- Probably low risk of bias
- Definitely low risk of bias

2. Is the study power adequate to detect a subgroup effect?

- Definitely not
- Probably not
- Probably yes
- Definitely yes

3. Is the subgroup variable a baseline characteristic?

- Definitely not
- Probably not
- Probably yes
- Definitely yes

4. Was the subgroup variable used as a stratification factor at randomization?

- Definitely not
- Probably not
- Probably yes
- Definitely yes

5. Is the evidence supporting a subgroup effect based on a within-study rather than a between-study comparison?

- Completely between-study comparison
- Mostly between-study comparison
- Mostly within-study comparison
- Completely within-study comparison

6. Was the subgroup hypothesis specified a priori?

- Definitely not
- Probably not
- Probably yes
- Definitely yes

7. Were the categories for the subgroup variable specified a priori?

- Definitely not
- Probably not
- Probably yes
- Definitely yes

8. Was the direction of the subgroup effect pre-specified?

- Definitely not
- Probably not
- Probably yes
- Definitely yes

9. **Was a small number of subgroup analyses conducted?**
- Definitely not
 - Probably not
 - Probably yes
 - Definitely yes
10. **Does the interaction test suggest a low probability that chance explains the apparent subgroup effect?**
- Definitely not
 - Probably not
 - Probably yes
 - Definitely yes
11. **Is the subgroup effect independent from other subgroup effects?**
- Definitely not
 - Probably not
 - Probably yes
 - Definitely yes
12. **Is the size of the subgroup effect large?**
- Definitely not
 - Probably not
 - Probably yes
 - Definitely yes
13. **Is the subgroup effect consistent across studies addressing the same research question?**
- Definitely not
 - Probably not
 - Probably yes
 - Definitely yes
14. **Is the subgroup effect consistent across related outcomes within study?**
- Definitely not
 - Probably not
 - Probably yes
 - Definitely yes
15. **Is a dose-response relationship present for subgroups with ordinal categories?**
- Definitely not
 - Probably not
 - Probably yes
 - Definitely yes
 - Not applicable
16. **Is there a compelling biological rationale that supports the hypothesised subgroup effect?**
- Definitely not
 - Probably not
 - Probably yes
 - Definitely yes
17. **Is the subgroup effect a quantitative rather than a qualitative difference of treatment effects?**
- Definitely not
 - Probably not
 - Probably yes
 - Definitely yes

methods articles addressing the issue of sub-group analysis credibility and consulted with a group of 18 methodologically trained individuals participating in a review of sub-group analysis in RCTs. The steering group of the study decided on item wording and response options. We plan to ask 5 external senior methodologists to evaluate the draft instrument for clarity, completeness, and redundancy. We will apply the instrument to a sample of primary studies and meta-analyses that make claims regarding sub-group effects. Two raters will independently evaluate each article; results will allow estimation of reliability and conduct of a factor analysis that will guide possible item reduction. Exploration of construct validity will include 1) examining the relation between application of the instrument to particular sub-group analyses versus authors' claims in those same analyses 2) in situations in which conclusions regarding sub-group effects are definitive, examining the extent to which application of the instrument at an earlier time – when fewer studies were available – predicts the ultimate outcome. **Results:** Item generation yielded 17 items including issues of power and statistical significance, a priori hypothesis generation, within or between study comparison, and the methodological quality of the original studies (Table). We have decided on a four-point scale for response options (e.g., definitely not to definitely yes). We anticipate data from subsequent stages of the project will be available at the time of the Colloquium. **Conclusion:** Our instrument should prove helpful to Cochrane reviewers evaluating possible sub-group effects.

OpenMeta-Analyst: open-source, cross-platform software for advanced meta-analysis

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Background: Meta-analysis is increasingly used as a key source of evidence synthesis to inform clinical practice. The theory and statistical foundations of meta-analysis continually evolve, providing solutions to many new and challenging problems. **Objectives:** To combine the strengths of general statistical packages (flexibility) and dedicated meta-analysis programs (ease-of-use) for performing meta-analyses in a stand-alone, cross-platform, open-source meta-analysis program. To this end, we are developing a new R package that contains both basic and advanced meta-analytic methods, including an interface to OpenBugs to fit Bayesian models, with a consistent Application Programming Interface (API), and a Graphical User Interface (GUI) that allows novice analysts (who may not speak R) to easily use this package. **Methods:** All analytic methods in OpenMeta are written and executed in the R programming language; this allows us to leverage previously written meta-analysis code, including Bayesian applications such as network meta-analysis written in BUGS. Moreover, researchers can implement their own methods in R and plug them into the software. However, the underlying use of R is transparent to end-users; OpenMeta is a stand-alone program, with a spreadsheet-based graphical user interface (GUI) written in the Python programming language. Both R and Python are themselves open-source and cross-platform. **Results & Conclusions:** We introduce OpenMeta; a new, cross-platform, entirely open-source version of our Meta-Analyst software. OpenMeta has been designed to handle complex data structures, including multiple treatment groups, multiple follow-ups (network meta-analysis) and

multiple outcomes. It provides many advanced meta-analytic routines and features an intuitive GUI. Moreover, OpenMeta features flexible plotting functionality through R.

Constancy of relative indices of treatment effect across different definitions of response derived from continuous scales: secondary analyses of individual-patient trial database of second-generation antipsychotics

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Objective: In randomized controlled trials and their meta-analyses, continuous outcomes are often dichotomized to define response, using various cutoffs. We set out to find a summary index of treatment effectiveness which remains constant across different definitions of such scale-derived response. **Design:** Secondary analyses of individual patient data from 10 randomized controlled trials examining second generation antipsychotics for schizophrenia (n = 4278). **Methods:** We ran meta-analyses to produce odds ratios (OR), risk ratios (RR) and risk differences (RD) and their 95% confidence intervals (CI) for different definitions of response, using cutoffs of 10% through 90% reduction on the symptom severity rating scales. Constancy of these indices was first examined through visual inspection, by way of I-squared statistics to quantify heterogeneity, and by way of coefficients of variation. If any of these indices were found to remain reasonably constant, we next examined the concordance between the number needed to treat (NNT) predicted from them and the observed NNT. **Results:** The visual inspection, I-squared statistics and coefficients of variation all suggested that OR and RR remained reasonably constant across various definitions of response, especially for those using thresholds of 10% through 70% reduction in the symptom severity. The NNTs predicted from OR and RR agreed well with the observed NNTs, with ANOVA intraclass correlation coefficients of 0.96 (95% CI: 0.92 to 0.98) and 0.86 (0.72 to 0.93), respectively. **Conclusion:** The relative measures of treatment effectiveness may remain reasonably constant across different scale-derived response definitions and, in conjunction with varying control event rates, can give accurate estimates of NNTs. This will allow individually matched estimates of NNT, depending on the level of response that he/she wishes to achieve.

How much should studies at high risk of bias be downweighted in meta-analyses?

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Background: The Cochrane Handbook for Systematic Reviews of Interventions suggests that studies assessed to be at high risk of bias should be excluded from the primary meta-analysis. An alternative strategy is to include but downweight results from such studies. The BRANDO (Bias in Randomised AND Observational studies) database of meta-epidemiological studies provides new empirical evidence on

appropriate downweighting, based on increases in heterogeneity due to bias, and between-meta-analysis variability in mean bias. **Objectives:** To quantify the average downweighting of studies at high risk of bias, based on application of the bias model formulated by Welton et al (*JRSS A* 2009;**172**:119–136) and new evidence from the BRANDO study. **Methods:** We calculated the median increase in (i) the variance associated with a study at high risk of bias, and (ii) the variance of the meta-analytic summary. Analyses was stratified by outcome type (mortality / other objectively measured / subjectively measured) and also by bias domain (inadequate blinding / sequence generation / allocation concealment). **Results:** For blinding, bias-adjustment led to a median 10% increase in the variance of study results and 12% increase in

variance of the summary effect. Discarding results from studies at high risk of bias led to a median 66% increase in variance of the summary effect, representing a substantially greater loss of information. Studies with subjectively measured outcomes were downweighted the most (51% median increase in study variance after bias adjustment). Results for other bias domains, and after adjusting for multiple domains, will also be presented. **Conclusions:** Empirically-based downweighting of results from studies at high risk of bias may be more appropriate than discarding information from such studies. There is evidence that studies with subjectively measured outcomes may be particularly affected by flaws in trial conduct, and therefore that results from such studies should be downweighted the most.

Poster sessions

P1: Using the Vote Cards to Encourage Active Participation and to Improve Critical Appraisal Skills in Evidence-Based Medicine Journal Clubs

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Background: Evidence-based medicine (EBM) journal clubs are used by health care practitioners to critique and to keep up-to-date with relevant health literature. Vote cards—using three different colored cards (green/yellow/red), allowing participants to express their opinions (agree/doubt/reject) toward the quality, design and possibility of clinical practice regarding to article that was being reviewed. However, the effectiveness of using vote cards in EBM journal clubs has not been well evaluated. **Objectives:** To assess the overall efficacy of using vote cards in EBM journal clubs. **Methods:** EBM journal club is held on a weekly basis in Department of Surgery in Taipei Medical University Hospital in Taiwan. The participants include medical students, resident doctors and primary care faculty members. The article is selected based on a clinical based question and it's relevant to participants' field. Prior to the session, the moderator helps the presenter to search and decide the best evidence. After the presentation, participants will use the vote cards to critical appraise the article and to decide how the results can be applied in their own practice. After using vote cards for a twelve-week period, the effectiveness of the vote cards is being evaluated based on the survey among participants. **Results:** Among 66 respondents, 97.0% agreed that vote cards can improve overall quality, 97.0% agreed it has encouraged active participation, 93.9% agreed it helped to stimulate critical appraisal skills, and 93.9% rated the vote cards more favorably than traditional hand voting. For future implementation, 93.9% of them agreed that vote cards should be used in future EBM journal clubs. **Conclusion:** Using vote cards in EBM journal clubs was appreciated by most of the participants and may encourage active participation and improve critical appraisal skills. Thus, we suggest the use of vote cards regularly in EBM journal clubs.

P2: Magnitude of MDR-TB and its risk factors in Sichuan, a southwest province with high TB burden in China

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Background: It was estimated that China carried the highest number of multidrug-resistant tuberculosis (MDR-TB) cases in the world. Sichuan is a populous province located in the southwest of China, where the disastrous 'May 12th Wenchuan Earthquake' (2008) broke out. Surveillance data showed that TB was most serious infectious diseases in Sichuan. No evidence of high quality about local magnitude of MDR-TB and the risk factors are available at present. **Objectives:** To

investigate magnitude of MDR-TB in Sichuan against other provinces in China, and find out the risk factors to inform policy-making. **Methods:** • Secondary study: systematic review procedure was applied to investigate the magnitude of MDR-TB. • Primary study: logistic regression model was applied to analyze the risk factors. **Results:** The primary, acquired and combined MDR-TB prevalence of 2005 was 2.64, 6.20 and 3.84 times of 1985 respectively, all showing an upward trend ($P < 0.05$). They were higher than the national average level in Sichuan ($P < 0.05$), ranking 11th, 3rd and 6th respectively. Anti-TB treatment history was significantly correlated with MDR-TB (Odds Ratio, OR 11.93, 95%CI 6.80-20.94), and the factors which hindered the whole course (at least 6 months), full dose and standard treatment process might contribute to the development of drug resistance, such as resources limitation, variations of DOTS implementation and children vaccination among different areas, floating population, incomplete supervision of medicine taking, unreasonable regimen, poor compliance, unavailable of anti-TB drug, and the National Essential Medicine List for Local Use not providing enough guidance because of the lack of drug combination and dosage. **Conclusions:** MDR-TB especially acquired MDR-TB in Sichuan should be paid special attention. It is necessary to increase financial support for local research and activities, and to provide high quality evidence to understand the crucial point of MDR-TB control, so as to enhance the relevance and sustainability of policy-making.

Key words: Multidrug-resistant tuberculosis (MDR-TB); Epidemiology; Risk factors; Sichuan Province.

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P5: Management of Small Abdominal Aortic Aneurysms

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Background: Management of small AAAs (4.0–5.5cm) is a grey area in clinical practice. Two randomized controlled trials (RCTs)—the United Kingdom Small Aneurysm Trial (UKSAT) and the Aneurysm Detection and Management Trial (ADAM) in the United States—attempted to address the question, comparing immediate open surgical repair to surveillance and selective surgery. Neither trial showed improved survival with either treatment but revealed possible survival differences for patients within some AAA size and age subgroups. Likewise neither trial had adequate statistical power to evaluate differences within subgroups. **Methods:** We will investigate the treatment-survival association within AAA size and age subgroups using the pooled UKSAT and ADAM patient-level data. A propensity-adjusted Cox model will be developed to assess the associations of interest. **Results:** Analysis of the table-based currently available showed that subgroup-specific survival treatment differences may be statistically significant after pooling data from the two trials—we recently received the final datasets from the ADAM and UKSAT trials and results from the patient-level meta-analysis will be available to be presented at the Colloquium. **Conclusions/Significance:** This study will provide immediate information to discern patients with small AAAs for whom selective surveillance is the best treatment option from those who will benefit more from immediate surgery, facilitating development of improved treatment guidelines based on AAA size and patient

age. Although endovascular repair for AAA has shown no long-term benefits over open surgery for AAAs >5.5cm, potential benefits for small AAA are still being investigated. Two RCTs (PIVOTAL/CAESER) are comparing endovascular repair and selective surveillance for small AAA—neither trial individually has the statistical power to mirror this study subgroup analyses. Results from our research are critical for improving small AAA management and will be instrumental in designing future research and treatment guidelines.

P6: The reliability and validity of estimating unclearly reported blinding status in randomized clinical trials

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Background: The Cochrane handbook classifies the risk of bias associated with blinding as: yes, no, or unclear. The usefulness of the rating could be enhanced if the currently “unclear” ratings could be accurately classified as “probably yes” or “probably no”.

Objectives: To test the reliability and validity of classifying blinding, when unclearly reported in randomized trials, as likely or unlikely done.

Methods: Following calibration exercises, two reviewers assessed the blinding of patients, providers, data collectors, outcome adjudicators, and data analysts in a duplicate and independent manner using a detailed instructions manual. The response options were: definitely yes, probably yes, probably no, and definitely no. After disagreement resolution, we attempted to contact authors for data verification. For each of the 5 questions, we assessed reliability by calculating kappa and weighted kappa using quadratic weights between the two reviewers for the 4 response categories and for 2 collapsed categories (probably yes merged with definitely yes, and probably no merged with definitely no). We assessed validity by calculating agreement between reviewers’ consensus and verified data. **Results:** Of 233 included reports, the percentage with unclear blinding status varied between 48.5% (patients) and 84.1% (data analysts). We obtained author verification for 46% of reports. Reliability was moderate for blinding of outcome adjudicators ($\kappa=0.52$) and data analysts ($\kappa=0.42$), and substantial for blinding of patients ($\kappa=0.71$), providers ($\kappa=0.68$) and data collectors ($\kappa=0.65$). Reliability improved when analyzing

weighted agreement and collapsed categories (Table). Validity was moderate for blinding of data analysts ($\kappa=0.42$), almost perfect for blinding of patients ($\kappa=0.96$), data collectors ($\kappa=0.93$), and outcome adjudicators ($\kappa=0.85$), and perfect for blinding of providers ($\kappa=1$).

Conclusions: With the possible exception of blinding of data analysts, use of “probably yes” and “probably no” can enhance the assessment of blinding in randomized trials.

P7: Giving a prominent role to methodologists with GRADE expertise in a clinical practice guideline: a qualitative exploration

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Background: Unlike other clinical practice guidelines, the American College of Chest Physicians 9th edition of the Antithrombotic Guidelines is giving methodologists a prominent role. A clinical epidemiologist with GRADE expertise is leading each of the guideline’s fifteen chapters as its editor. The lead content expert serves as the chapter deputy editor. A new conflict of interest policy is placing equal emphasis on intellectual and financial conflicts and allowing panel members with important conflicts to contribute to the evidence review but not to the recommendations. The goal is to utilize the experience and insight of experts while ensuring that financial and intellectual conflicts do not influence recommendations. **Objectives:** To explore participating editors’ and deputy editors’ views regarding the structural and process changes. **Methods:** We completed the first phase of the study in the summer of 2009 before the guidelines chapter panels initiated their work. We conducted semi-structured personal interviews with 23 chapter editors and deputy editors and analyzed data qualitatively.

Results: Editors and deputy editors agreed that the changes will help in the handling of conflicts of interest and the public perception of the guidelines. While editors believed the changes will ensure more rigorous evidence-based guidelines, some deputy editors were worried that methodologists’ lack of content expertise could hurt the quality of the guidelines. Editors were worried about their lack of content expertise and the possibility of conflicts with content experts. Deputy editors perceived their title as an unfair demotion. They also expressed frustration with the conflict of interest policy as they perceived it as judging experts as ethically suspect and intellectually compromised.

Conclusions: Editors and deputy editors agreed the changes would help in handling conflicts of interest but disagreed on the impact on

Table 1 (P6): Results of reliability and validity testing for the blinding questions.

Question	Reliability (n = 233)			Validity (n = 107)
	Kappa (4 categories)	Weighted kappa (4 categories)	Kappa (2 categories)	Kappa (2 categories)
Blinding of patients	0.71	0.88	0.90	0.96
Blinding of providers	0.68	0.83	0.90	1.0
Blinding of data collectors	0.65	0.76	0.82	0.93
Blinding of outcome adjudicators	0.52	0.60	0.66	0.85
Blinding of data analysts	0.42	0.50	0.43	0.42

For the collapsed 2 categories’ analyses, we merged “probably yes” with “definitely yes”, and “probably no” with “definitely no”. Weighted kappa is based on partial agreement using quadratic weights.

guideline quality. While editors were worried about their involvement, deputy editors expressed frustration with their “demotions”.

P8: Analysis of conflicting results of 2 non-randomized controlled trials

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Background: In the framework of a systematic review on patients with rhabdomyosarcoma with vs. without autologous stem cell transplantation, we identified a total of 4 non-randomized controlled studies. Two studies reported statistically significant, yet contradictory, estimates of the overall survival at 3 years. Klingebiel 2008 reported 22% vs. 55% and Hosoi 2007 reported 53% vs. 18%. The difference of treatment effect in 2 further non-randomized studies did not reach statistical significance. Carli 1999 reported 40% vs. 28% and Suita 2005 reported 73% vs. 52%. **Objective:** The aim of this analysis was to explore potential influence factors potentially explaining the contradictory results. **Methods:** We investigated risk of bias and compared study and patient characteristics. The distribution of prognostic factors, such as age of patients, histological subtype, bone metastasis, and tumor size were also analyzed, to search for a possible explanation of the differences between the studies. **Results:** Criteria for assignment of patients to the treatment groups were not reported and a considerable number of enrolled patients were not analyzed in both studies. Patients with embryonal rhabdomyosarcoma younger than 10 years of age were excluded from Hosoi 2007 but included in Klingebiel 2008. Controls were treated differently in Hosoi 2007 (standard chemotherapy) and Klingebiel 2008 (oral maintenance). Other heterogeneous disease and treatment conditions, such as bone marrow involvement and type of chemotherapy were observed. Differences regarding proportions of prognostic factors between the treatment groups, such as age and histologic subtype were noticeable but were based on small numbers of patients. **Conclusion:** High risk of bias, heterogeneity of disease and treatment conditions, and unbalanced distribution of prognostic factors might have contributed to a possible distortion of results.

P9: Use of systematic review evidence to inform local decision-making in the National Health Service: a case study of eating disorders

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Background: In the English National Health Service (NHS), Primary Care Trusts are responsible for commissioning a range of health services. As part of a major five-year research project, we are providing a knowledge translation service to local decision makers, translating existing evidence into actionable messages that they can use to inform local commissioning questions. We recently evaluated the evidence base for inpatient admission for adolescents with eating disorders compared with other models of service provision to support a possible reorganisation of services. **Methods:** In response to a commissioning request, a researcher attended a meeting with commissioners and clinicians to clarify the research question. A concise evidence briefing

was prepared using existing sources of synthesised and quality-assessed evidence. The main sources were the Cochrane Database of Systematic Reviews, the DARE, NHS EED and HTA databases and systematic reviews performed to inform the NICE guidance on eating disorders. Evidence was contextualised to the local setting and comments from commissioners were incorporated before the briefing was circulated and then discussed at a second meeting. **Results:** A Cochrane review of alternatives to admission for young people with mental health problems found limited evidence to guide decision-making.¹ One randomised trial compared inpatient admission with specialist outpatient treatment and treatment as usual in the community for adolescents with anorexia nervosa.² The trial found no differences in outcomes between groups. Specialist outpatient provision was the most cost-effective option. The group agreed to move towards providing more services on an outpatient basis and limiting the use of inpatient placements. The briefing document has been used to inform strategic commissioning at a regional level. Evaluation of the format and content of the briefing is in progress. **Conclusions:** Evidence briefings based on systematic reviews can be useful for healthcare decision-makers and warrant further methodological development and evaluation.

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P10: Comprehensive systematic review of complex interventions facilitated by means of new software program.

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Background: Broad review questions and patient driven outcome on both effectiveness and harm of complex interventions often require an extensive and integrated evidence approach. Modern software systems facilitating the heavy workload of such reviews are not many. The DistillerSR online program developed by Evidence Partners (www.evidencepartners.com) is one. It allows for complex reviewing strategy, filter applications, diverse form building, immediate data export and extraction of results, constant monitoring of workload, thereby facilitating project managing and enabling reviewers to be located at different sites. **Objectives:** To demonstrate the utility of software system in an ongoing comprehensive systematic review on ECT for depression and to present preliminary results. **Methods:** A comprehensive literature search was undertaken, including databases MEDLINE, ISI, PsycINFO, EMBASE, Cinahl, British Nursing Index, Ovid Nursing, SveMed+, Cochrane Central Register of Controlled Trials. All identified references were initially title screened by hand and thereafter uploaded into DistillerSR for further streamlining, abstract screening and full text data extraction. The workload was undertaken by two reviewers at all levels. **Results:** Of 4973 identified references, 910 were uploaded into DistillerSR and filtered along 2 main streams A) Qualitative or B) Quantitative. Only 4 of 62 studies along the A) Qualitative (about the lived experience of ECT) stream were found explicitly qualitative in methodology and suited for final data extraction

and integration. Along the B) Quantitative stream, 720 references were further filtered into 3 arms 1) RCT 2) non RCT about cognitive function (long-term memory impairment) and 3) non RCT about maintenance/continuation ECT for further full text reviewing and data extraction. Inter-rater reliability was high, overall weighted kappa 0.72. **Conclusions:** Managing broad systematic reviews of complex interventions is assisted by specially adapted modern online software systems where online review team collaboration, streamlining and filtering of a large number of references is made possible.

P11: Development of a generic working definition of 'supportive care'

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Background: The term 'supportive care', despite its everyday and widespread use, remains an ambiguous concept that lacks clarity. This research was carried out on behalf of The Cochrane Pain, Palliative and Supportive Care Review Group (PaPaS) to provide a clearer focus for the group that would inform title selection and facilitate more appropriate assistance for review authors. **Objective:** The primary objective was to develop a generic working definition of supportive care that could be applied to a range of diseases and chronic illness.

Methods: Initially an in-depth review of the literature was carried out to identify existing generic and disease specific definitions of supportive care as well as descriptions of supportive care. Following the literature review a modified two-phase Delphi study was performed. Participants included experts in the area of supportive care identified during the literature review in addition to charities or their representatives. A draft definition of supportive care was developed based upon the outcome of the Delphi study and the findings were presented to members of the PaPaS editorial board for further comment. **Results:** The literature review identified one brief generic definition of supportive care with no explanation of its origin. A further 17 disease specific definitions were identified all relating to cancer. The literature review led to the development of 100 statements for inclusion in phase I of the modified Delphi study. Twenty-six responses were received to phase I of the Delphi study and 17 responses to phase II. General agreement was received during the second stage of the Delphi process and a final draft definition of supportive care subsequently developed. **Conclusions:** This research has provided clarity regarding the meaning and general understanding of supportive care. The draft definition has been endorsed and adopted by PaPaS. The final definition would benefit from broader consultation to determine its acceptability amongst a wider range of health professionals and service users.

P12: Evidence-Based Practice in the Human Services in China

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Background: In China, human services are provided actively in the field of developmental disorders, school education, clinical psychology, caring and nursing, and social welfare in general. Human services are in an initial stage, and with more government control as compared with Western countries. Contemporary China is facing many social problems as a result of dramatic social dynamics, e.g. extremely unbalanced income distribution per capita, unreasonable use limited health resources, deficits in the young generation's education and safety, and an emerging aging society. **Objective:** Present an account of the current situation and future developmental strategies of EBP in public health and other human service areas in China. **Methods:** Systematic review of randomized controlled trials and meta-analyses published by Chinese researchers. **Results:** Chinese Cochrane Center has a strong track record in developing various aspects of EBM in China. EBP is a new but promising trend of development in the country. In 2009 China ranked seven, fifth and second in terms of the number of Cochrane reviews, protocols, and titles, respectively, among contributing countries. In China, EBM has also been applied in the Essential Medicine List and the Chinese health care reform. Recently, Campbell Collaboration's criminology group has established a Chinese language website. Chinese Clearinghouse for Evidence-based Practice and Policy (CCE) is under development and targeting child welfare, mental health and aging services. **Discussion:** Although social and cultural contexts in Western countries and China are different, some evidence-based interventions developed and tested elsewhere may be used in China. Initially such interventions must be assessed by culturally competent professionals to determine their suitability for implementation in China. Ultimately, transported interventions must be tested for effectiveness in the Chinese context. A culture shift from authoritarian to evidence-based decision making ought to be a key factor in developing EBM, EBP, and the supporting research in China. So, the methodology of conducting high quality efficacy and effectiveness research as well as developing high quality reviews in all fields of the human services should be promoted urgently in China. Both the strategy for promoting the EBM and the CCE are anticipated to narrow the gap between research and services delivery.

P13: A Survey of the Effects of Sending Influenza A (H1N1) Evidence Through the Short Messages System to Doctors of Township Health Centers in China

Yaolong Chen

Background: In late March and early April 2009, an outbreak of H1N1 influenza A virus infection was detected in Mexico, with subsequent cases observed in many other countries, including the China. The most timely translation and dissemination evidence from Cochrane library and other evidence based resources were vital for doctors in rural areas. **Objective:** Assessing the effectiveness of sending Influenza A (H1N1) evidence through the Short Message Service (SMS) to the doctors in rural areas in China. **Methods:** From 10th November to 29th December, we sent 30 short messages (1,600 words) about

etiology, diagnosis, treatment, prevention and vaccines on Influenza A (H1N1) evidence at seven P. M. every Tuesday and Friday to 114 doctors of seven Township Health Centers in Gansu province. And then we conducted a telephone survey of these doctors at 30th December. **Results:** A total of 89 doctors answered (response rate 67.8%). 86 doctors (96.6%) received our short messages, 47 doctors (54.7%) said the short messages helped them a great deal (reliable, useful and readable), and 83 doctors (96.6%) said they expected to keep on receiving our short messages. **Conclusions:** Short Message Service seemed to be a good way to disseminate best evidence especially for pandemic. And it can be used in rural area in developing countries for the fast spread, low cost and convenient reading.

P14: Evidence-Based Decision-Making in China

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Background: In November 1997, the Chinese Evidence-Based Medicine Center (CEBMC) was established and in 1999, the Chinese Cochrane Center was successfully registered with the Cochrane Collaboration. Since then the concept of "evidence-based decision-making" became more and more popular for not only clinicians but also policy makers. **Objective:** To describe the current status and development of evidence-based decision-making in China. **Methods:** We searched three main medical databases CNKI (China National Knowledge Infrastructure/Chinese Academic Journals full text Database), VIP (a full text database of China) and CBM disc (China Biomedicine Database Disc) using the term from 1991~2010. The search terms were "evidence based", "evidence-based medicine", "evidence-based decision-making", and so on. **Results:** There were more than 30 000 papers discussed with evidence-based theory and practice in Chinese academic journals, five Evidence-Based Medical Journals and more than 50 evidence based books published from 1996 to 2010. More than 10 Virtual Research Center of EBM (Ministry of Education) were established and five Asian-Pacific conferences on Evidence-Based Medicine were held. **Conclusions:** The concept of "evidence-based decision-making" has been widely accepted in China. More and more government officials, researchers and consumers become interested in evidence-based principles. Evidence-based Decision-Making is under rapid development in China.

P15: A study of knowledge and attitudes towards Evidence based medicine (EBM) among medical students and Interns at Manipal University, India

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Background: Recent scientific meetings such as the joint Cochrane Collaboration & Evidence based Health Care (EBHC) conference in Vellore have highlighted the importance of raising awareness of medical students in the concept of EBM. Early adoption by students could possibly be further enhanced by their involvement with some of the activities undertaken by the Cochrane Collaboration.

To date very limited research has been carried out on the knowledge and attitudes towards EBM among medical students and Interns.

Objective: Our study intends to survey the knowledge and attitudes towards EBM among medical students and Interns at Manipal University, India. **Methods:** Final year medical students and interns completed a previously piloted 14-question survey. MCQ's included: awareness of the components of EBM, the hierarchy of evidence, barriers to the practice of EBM and familiarity with healthcare databases and the Cochrane Library. **Results:** Eighty percent of respondents were final year medical students and the remainder were Interns. A number of the participants had attended a course/workshop on EBM and all were keen to learn more about the concept and the work of the Cochrane Collaboration. Generally respondents were familiar with the hierarchy of evidence and most were aware of *The Cochrane Library*. The majority of the respondents felt that the lack of time was the main barrier to the practise of EBM but agreed that if resources were readily available they would be willing to acquaint themselves with the concept. **Conclusion:** Overall there was a positive attitude and fair knowledge level amongst participants towards EBM, the Cochrane symposium for students was positively contributory towards this. The final study will further examine the correlation between different grades of education and the awareness about Cochrane Collaboration.

P16: Systematic Bibliometric Review: A new methodology presenting patient-centred outcomes in the context of reviews, guidelines, and media reports. Part 1: Methodology description

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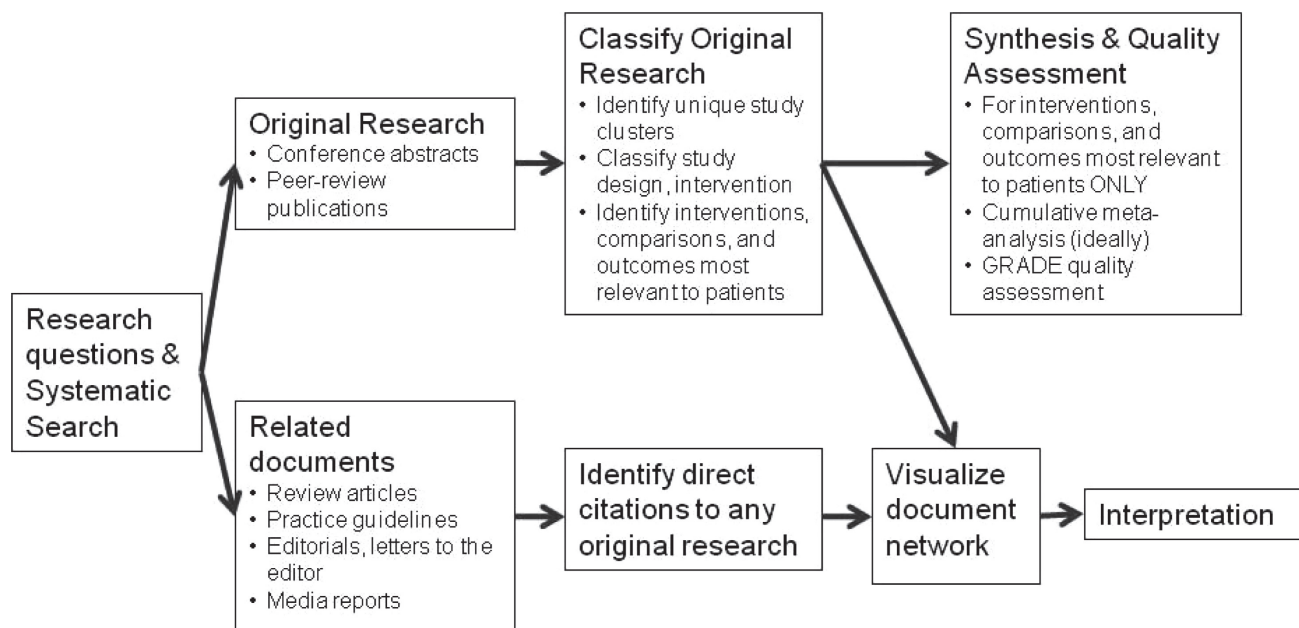
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Background: We have a gap in current methodologies to present evidence in meaningful context. While use of systematic reviews by different stakeholders to inform healthcare decisions is improving, other documents such as practice guidelines and media reports may influence demands for access to, or funding of new healthcare technologies.

Objectives: We describe a new methodology to contextualize the quality of patient-centered outcomes evidence represented by related documents including reviews, practice guidelines, editorials, and media reports. **Methods:** The systematic bibliometric review focuses on 2 key concepts: (1) Informed by systematic review methodology – quality of evidence for patient-centred outcomes using cumulative meta-analysis and the GRADE approach and (2) Informed by bibliometric methodology – Quantity of original research, related documents, and citation relationships between original research and related documents (e.g., reviews, practice guidelines, editorials, media reports). It includes 4 steps: (1) research questions and document selection; (2) data extraction and analysis; (3) document network relationships; (4) document network visualization (Figure).

Results: The primary output from the systematic bibliometric review is a 1-page figure juxtaposing (1) the evidence – the annual cumulative meta-analysis estimate of effect and quality of evidence by patient-centered outcomes (GRADE) against (2) the context – the network of relationships between related documents and original research. **Conclusions:** The systematic bibliometric review aims to help decision-makers conceptualize, interpret, and visualize the quantity, quality, and relevance of original research data within a network of related documents. Applications of this methodology

Figure 1 (P16): Overview of key systematic bibliometric review steps.



include support for clinical and policy decisions, and identification of research gaps. Further research is needed to understand the utility and acceptability of this methodology by evidence consumers. Please see related abstract, "Systematic Bibliometric Review: A new methodology presenting patient-centred outcomes in the context of reviews, guidelines, and media reports. Part 2: A case study of Rituximab for non-Hodgkin's lymphoma 1997–2003".

P18: A survey on literature searching of systematic review in traditional Chinese medicine filed

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Background: The application of the method of systematic review (SR) in traditional Chinese medicine (TCM) filed provide high quality evidence resources for TCM clinical practice, the problems of TCM trials identified from the production of SRs provide valuable information for improving their quality. However, the quality of SRs have high effect on their conclusions, the literature searching is one of the most important links. **Objective:** To analysis and compare the literature searching status of TCM SRs published in the Cochrane Library (CL) and Chinese Journals, to provide reference for improving literature searching of TCM SRs. **Methods:** We searched the CL (Issue 4, 2009) and the Chinese Biomedical Database (CBM, from 1978 to July 31, 2009) to identify SRs in TCM field. A self-designed data extraction table was used for data extraction. The SPSS 15.0 software was used for data description and analysis. **Results:** 341 (CBM: 245; CL: 96) SRs were included. Compared with the CBM reviews, Cochrane reviews searched more databases (media: 4 vs. 6; $Z = -7.862$, $P = 0.000$). The top three databases searched by the authors of Cochrane and CBM reviews were MEDLINE (100%), EMBASE (88.4%), CENTRAL (74.7%),

and CBM (75.9%), CNKI (70.2%), CENTRAL (60.4%), respectively. 42 CBM reviews didn't report what databases were searched. Of the CBM reviews, 47.7% reported the exact time range covered by the search, 14.4% reported either the beginning or the end date of the time range, and the remaining 37.8% did not report the time range at all. Only 20 CBM reviews reported at least one detailed searching strategy. Fifty CBM reviews reported the gray literature was searched, 134 reported the hand-searching was conducted. **Conclusions:** There are big problems in literature searching of TCM SRs. These problems include inadequate selection of object databases, poor repeatability of searching process, inadequate searching for gray literature, uncertainty function of hand-searching, etc. Practice guideline need to be developed to standardize the literature searching of TCM SRs.

P19: Ethical review reporting of Chinese trials records in World Health Organization primary registries

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Background: Ethic review reporting in trial registration record is one of way to improve the transparency of trials to protect the participants. **Objective:** To investigate the report rate of ethical review in the registered Chinese trials records. **Methods:** We identified Chinese trials record in WHO primary registries and clinicaltrials.gov to July 14, 2009. We calculated the report rates of ethical review and each of the 20 items in WHO's Trial Registration Data Set. We assessed correlation of the item's report rate with the ethical review report rate. We also searched PubMed, EMBASE, CNKI, and CBM (from the establishment of each database to July 14, 2009) to collect the full texts

of completed trials to calculate the report rate of ethical review in the result publications. **Results:** A total of 1247 records were identified, and 687 (55.1%) reported ethical review. The records reporting secondary sponsor(s), contact for public queries, and key secondary outcomes were more likely to report ethical review information (66.3% vs. 44.3%, 38.1 vs. 28.5%, 53.9 vs. 51.8%). The ethical review report rate of trials sponsored by industry was lower than those sponsored by non-industry (40.9% vs. 51.9%). The report rates of ethical review for self-supported trials (83.5%) and trials with unidentified sources of monetary or material support (66.7%) were lower than the average ethical review report rate for records in the Chinese Clinical Trial Registration Center (ChiCTR). The ethical review report rate was not high in the result publications (84.3% in clinicaltrials.gov, 50.0% in ChiCTR). **Conclusion:** Registered Chinese trials record report ethic review inadequately. Incomplete registration is correlated with not reporting ethical reviews. Medical Journal should inspect ethic review more critically.

P20: Assessing the quality of the evidence for preterm labor tocolysis trials

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Background: Tocolytic therapy to stop preterm labor is an important intervention in obstetrics. Despite the many randomized controlled trials (RCTs) of different interventions, no comprehensive updated summary evaluation of the evidence has been undertaken. **Objective:** To assess the quality of tocolysis RCTs and to determine trial factors contributing to better quality evidence. **Methods:** The Cochrane Central Register of Controlled Trials, MEDLINE, MEDLINE In-Process, EMBASE, and CINAHL were searched for terms "preterm labor", "tocolytic", or "obstetric labor, premature" up to August 1, 2009. Data regarding study design, characteristics, number of participants, and outcomes reported were extracted by at least 2 review authors. Study quality was assigned utilizing the Cochrane Handbook methodology and categories. Trends for quality over time, the impact of study size, and the individual drugs compared were analyzed for impact on overall quality of trials. **Results:** Of the 3,197 titles initially identified, 89 RCTs of tocolytic therapy were reviewed. Of the 6 quality areas, 10 (11.2%) trials satisfied all areas, while only 1 trial (1.1%) met 1 area. The mean number of adequate areas was 4.1 ± 1.2 . Overall, 52 (58.4%) of the trials achieved high quality categorization. The total number of subjects was weakly correlated with the number of adequate quality areas ($p=0.007$). The mean number of quality areas was higher for placebo-containing trials (4.7 vs. 3.9, $p=0.009$) and lower for calcium channel inhibitor-containing trials (3.6 vs. 4.3, $p=0.03$). More recent trials demonstrated higher quality ($p=0.036$). Compared to studies performed in Asia (37.5%), those in North America (71.8%) and Europe (57.1%) were rated as high quality studies more frequently ($p=0.03$). Controlling for multiple trial factors, the location and decade were significant predictors of overall trial quality. **Conclusions:** The majority of tocolysis RCTs are of high quality. Larger trials, more recent trials, and placebo-controlled trials were associated with higher quality scores.

P21: The development of systematic review and Meta-analysis

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Background and objectives: Systematic reviews and meta-analyses (SRMAs) are the important sources of useful evidences for decision making. In order to present the profile of their development, we conducted a study by searching major electronic literature databases.

Methods: Three databases including Ovid-Medline (1950–2009), Ovid-Embase (1980–2009) and Science Citation Index Expanded (SCI-E, 1956–2009) were searched in March 2010. The search terms were "systematic reviews OR meta analysis" in title, and "Cochrane database of systematic reviews" in publication name. The number of articles cited in each database was counted. The citations found in SCI-E were analyzed by the analysis function of ISI Web of Knowledge.

Results: More than 20,000 articles were identified in each database (Table 1). Considering the overlap and complement in different databases, there were nearly 30,000 SRMAs. The first systematic review was published in 1954 (Eichler W); and the first meta-analysis article was published in 1977 (Smith ML & Glass GV). The proportion of Cochrane systematic reviews (CSRs) was 22.4% in Medline.

By analyzing articles in SCI-E, we acquired some other information:

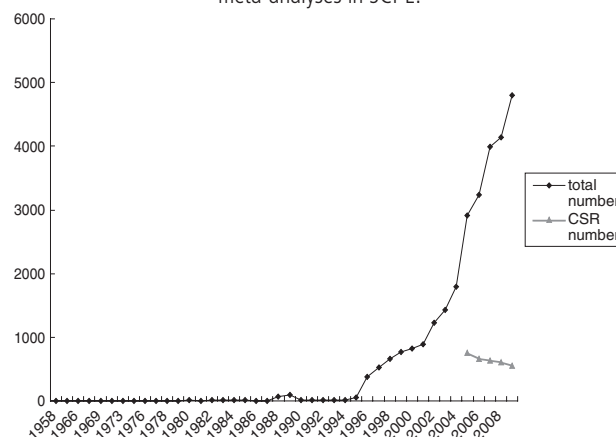
- 1) The publication of SRMAs skyrocketed since 1996 (Figure 1);
- 2) Besides the subject of general & internal medicine, the published

Table 1 (P21): The quantity of systematic reviews and meta-analyses published in three database.

Years	Ovid-Medline (CSRs%)	Ovid-Embase (CSRs%)	SCI-E (CSRs%)
2005–2009	16274 (19.1%)	16391 (19.4%)	19069 (16.9%)
2000–2004	8303 (37.4%)	4843 (0)	6171 (0)
1995–1999	2248 (1.7%)	2039	2381
1990–1994	821 (0)	838	60
1980–1989	261	199	233
1954–1979	13	0	21
Total	27920 (22.4%)	24310 (13.1%)	27935 (11.5%)

Cochrane systematic reviews: CSRs

Figure 1 (P21): The development of systematic reviews and meta-analyses in SCI-E.



SRMAs mainly focused on clinical neurology, gastroenterology & hepatology, oncology, and other subjects; 3) About 60% of the article authors came from Europe. USA, UK, Canada, Netherland, Australia, Germany, Italy, France, China and Spain were the top ten high-yield counties. The proportion of CSRs in SRMAs was higher than 15% in Thailand, South Africa, New Zealand, Ireland, Australia, India, UK and Brazil. **Conclusion:** Along with the fast development of EBM, the number of SRMAs have boosted in the last 15 years. The SRMAs have played important roles in different countries and different subject areas.

P22: Difficult decision-making on weight-bearing exercise recommendation for women – evaluation of the effect of a without-weight bearing walking intervention on bone mineral density among menopausal women

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Background: Previous studies have found that walking could have positive effects on maintaining Bone Mineral Density (BMD) among postmenopausal women. However the majority of this group tends to be sedentary. Barriers to maintaining regular physical activity among postmenopausal women are found to be the lack of accessibility of physical activity facilities and the convenience and safety of the mode of physical activity. Walking is viewed as an easy, less costly physical activity and could be adopted with limited time and location. Six-month or longer walking interventions, with extra weight bearing, were found to have an effect on maintaining (BMD). It has been less widely investigated whether the same effect can result from a shorter periods of walking intervention and without weight bearing. **Objective:** Aims to examine the effect of a 12-week walking intervention, without weight bearing, on maintaining BMD among postmenopausal women. **Methods:** A randomized controlled trail design was used to test the effect of the walking intervention. Participants were recruited from an east township of Taiwan. A total of 57 participants was randomized to either a control (n=28) or intervention group (n=29). Control group participants received a usual care when needed. Participants in intervention group received a 12-week, without-weight-bearing walking intervention. **Results:** At 12th week follow up, mean change of BMD was similar in two groups ($p=.5$). Aerobic steps were increased in intervention group. Scores of exercise self-efficacy and exercise outcome expectation were also improved significantly. **Conclusions:** A 12-week, without-weight-bearing walking intervention may increase postmenopausal women's physical activity, exercise self-efficacy and exercise outcome expectation but the effect on maintaining BMD was not found. Future study testing the effect of longer period, without-weight-bearing walking intervention or vice-versa on maintaining BMD is warranted. Only then maintaining or improving BMD through walking activity among postmenopausal women could be feasible.

P23: A latest survey on national training workshop on Cochrane systematic review in China

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Background: With more promotion activities on Cochrane systematic review (CSR) in China and CSR was indexed by SCI, more and more Chinese show their interests on CSR. It give us a challenge to keep the quality of training workshop on CSR. **Objective:** To identify review authors' training needs and better support them to conduct CSR. **Methods:** We designed a quantitative survey to collect all participants' feedbacks on the training contents and quality, arrangements, and their difficulties at the end of the training workshop on CSR in July 2009. There were a little modification about survey items than before. **Results:** 1) The response rate was 73.6% (81/110). 2) 110 participants from 23 provinces in China and the number of trainers was almost twice than previous years. 72.1% (57/79) said they got training information from web. 3) Only 12.5% (10/80) cleared their review topics and 3.9% (3/76) registered a title in Cochrane review group before training. 4) 65.3% (47/72) participants were satisfied with the arrangement of the workshop and 75.9% (60/79) achieved their purpose after training. The top contents and quality were: Meta-analysis and statistics (83.9%, 68/81), results analysis and explanation (82.7%, 67/81), trials selection, inclusion and extraction (82.1%, 64/78). 5) The rate of relevance to the workshop were: contents 70.4% (57/81), PPT 68.4% (54/79) and textbook 51.9% (42/81). 6) 90.1% (73/81) recognized difficulties existed and the difficulties were: trials identified (57.5%, 42/73), methodology (45.2%, 33/73), language (35.6%, 26/73), data analysis (31.5%, 23/73), and time (23.2%, 17/73), labours (20.5%, 15/73) and RevMan (13.7%, 10/73), etc. **Conclusions:** Participants were rapidly increased in last year and most of them were benefited from the CSR workshop. However, updated training materials and trials identification were their top needs. Web-based resources are good platform to learn more on CSR.

P24: Missing Data in Systematic Reviews: A table might help

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Background: Missing data in Cochrane reviews is a common problem. The problem is often difficult to detect and the impact hard to estimate. There are few methods for assessing missing data from included studies in reviews. Selective outcome reporting may have different effects on different outcomes and time points (e.g. secondary outcomes and follow-up data may be more vulnerable than the primary outcome). The potential impact of missing data should be assessed for each analysis in a review. **Objectives:** To describe the amount of data potentially missing from studies included in a systematic review, and to assess its potential impact on the results. **Methods:** We conducted a systematic review and made a table including the number and percentage of (i) included trials and (ii) included participants in each analysis. We then (i) described the relationship between outcomes and the amount of data reported and (i) compared information in the table to tests for bias. **Results:** Results of analyses with few included studies were sometimes inconsistent with the primary analysis. Effects in analyses with large amounts of missing data were larger than anticipated. Funnel plot asymmetry was large for analyses that included a low percentage of included studies and participants. In large analyses, our table complemented tests for bias and aided assessments of internal and external validity. In analyses of secondary outcomes and time points, these descriptive statistics offered more information

Table 1 (P24): Studies and participants in each analysis.			
		Included Studies	Included Participants
<i>Comparison 1</i>		N=	N=
Primary Outcome	Post-Treatment	N (%)	N (%)
	Follow-up	N (%)	N (%)
Secondary Outcome	Post-Treatment	N (%)	N (%)
	Follow-up	N (%)	N (%)
Secondary Outcome	Post-Treatment	N (%)	N (%)
	Follow-up	N (%)	N (%)
<i>Comparison 2</i>		N=	N=
Primary Outcome	Post-Treatment	N (%)	N (%)
	Follow-up	N (%)	N (%)
Secondary Outcome	Post-Treatment	N (%)	N (%)
	Follow-up	N (%)	N (%)
Secondary Outcome	Post-Treatment	N (%)	N (%)
	Follow-up	N (%)	N (%)

than available tests for bias. The table also drew our attention to the different sizes of analyses in the review and differences in their external validity. The table was easy to make. It facilitated our discussion of bias and generalisability. Similar tables might be useful in other reviews.

P25: Presenting clinically relevant information on diagnostic performance in systematic reviews: the use of predictive values (PPV and 1-NPV)

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Background and Objective: We conducted a systematic review on diagnostic tests in primary care for identification of patients with an increased risk for colorectal cancer (CRC). We aimed to present the results in an informative way for primary care physicians.

Data Sources: PubMed, EMBASE and reference screening. **Study eligibility criteria:** Studies were selected if the patients were adults consulting because of non-acute lower abdominal symptoms; tests included signs, symptoms, blood tests, or faecal tests. **Study appraisal and synthesis methods:** Two reviewers independently assessed study quality using the QUADAS tool and extracted data. We presented pooled estimates of sensitivity and specificity using bivariate analysis. We also calculated pooled estimates for the positive predictive value (PPV) and 1 minus the negative predictive value (1-NPV), representing the risk of CRC after a positive test result and after a negative test result, respectively. We refrained from pooling when there was considerable clinical or statistical heterogeneity.

Results: Evidence for test performance in primary care was scarce and varied widely. In contrast to our expectations, however, PPV and 1-NPV more often showed statistical homogeneity than sensitivity and specificity. This enabled statistical pooling of predictive values for age, gender, rectal bleeding and constipation, where this was not possible

for sensitivity and specificity. For example, sensitivity of constipation was very poor and specificity ranged between 0.53 and 0.90. Pooled estimates of predictive values clearly showed that constipation was not associated with an increased risk of CRC, with a pooled estimate for PPV of 0.06 (0.0–0.18) and 0.10 (0.07–0.14) for 1-NPV. When pooled estimates could not be presented ranges of predictive values were still of interest. **Conclusions:** Estimates of PPV and 1-NPV seem to provide clinically useful information. However, caution in their use is needed, and sources of heterogeneity and other prerequisites for meta-analysis of predictive values should be explored.

P26: Do variations in specific aspects of study design produce discrepancies in the benefits of effects in Cochrane intervention review?

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Background: Cochrane reviews address questions about the effects of health care. Certain specific aspects of the study design and its conduct are therefore to be considered when defining the eligibility criteria for the subjects of a Cochrane review. Both restrictive study design criteria and more liberal design criteria are found in the published Cochrane reviews. The question therefore arises: Do trials with inadequate randomization exaggerate the intervention effects. **Objectives:** To explore any discrepancies of intervention effects between Cochrane reviews that include studies with liberal criteria only, and the set of reviews that include studies with restrictive criteria only (after the studies with liberal criteria have been removed from the review). **Methods:** As an illustration, three reviews from the published Cochrane reviews of intervention studies were selected. The included studies in Cochrane review incorporating (i) non-randomized studies, and (ii) randomization without allocation concealment were assessed. Risk of bias and the benefits of intervention effects were comparing with the original results and the results after removal of the included studies with liberal criteria. **Results:** At the time of writing, this work is still ongoing. However, the differences were brought into focus. Full data will be presented at the colloquium. **Conclusion:** Excessively broad criteria can raise a concern about discrepancies in the resulting intervention effects. Ways to eliminate such discrepancies are suggested.

P27: Ratio of geometric means to analyze continuous outcomes in meta-analysis: comparison to mean differences and ratio of (arithmetic) means using empiric data and simulation

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Background: Effect measures for meta-analyses of continuous outcomes include mean differences (MD), standardized MD (MD in pooled standard deviation units, SMD), and ratio of (arithmetic) means (RoM). Recently, ratio of geometric means using either ad hoc (RoGM_{adhoc}) or Taylor series (RoGM_{Taylor}) methods for estimating variances have been proposed to pool skewed data. **Objectives:** To compare treatment effects and heterogeneity of RoGM_{adhoc} and RoGM_{Taylor} to MD, SMD, and RoM using empiric data and simulation.

Methods: We searched the Cochrane Database of Systematic Reviews (2008, Issue 1) for reviews reporting continuous outcomes; from each review we selected the meta-analysis with the most (and at least 5) trials. Meta-analyses were conducted using each effect measure. Pairwise differences between methods in treatment effect and heterogeneity (Cochrane's Q) p-values, compared separately, were assessed using non-parametric sign tests, and asymmetry of discordant pairs (statistically significant result for only one of two effect measures) using Exact tests. Simulation parameters employing both normal and log-normal distributions were chosen to be representative of those commonly encountered in meta-analyses of continuous outcomes. **Results:** 232/5053 systematic reviews met inclusion criteria. $RoGM_{Taylor}$ exhibited similar treatment effects, with more heterogeneity ($p < 0.0001-0.008$) for distributions with median coefficient of variation ($CV \leq 0.6$), and less heterogeneity ($p = 0.0002-0.0004$) for distributions with median $CV > 0.6$ when compared to MD, SMD and RoM. $RoGM_{ad hoc}$ exhibited more extreme treatment effects ($p < 0.0001-0.17$) and greater heterogeneity ($p < 0.0001$) compared to all other effect measures. Most heterogeneity comparisons also demonstrated statistically significant asymmetry of discordant pairs. Simulation confirmed these results. **Conclusions:** RoGM using Taylor series to estimate the variance may be considered for pooling continuous outcomes of skewed data in which CV is high. However, given clinicians' lack of familiarity with geometric means and acceptable performance characteristics of RoM in most situations, RoM is a reasonable alternative ratio method for pooling continuous outcomes even in such cases.

P28: Problem-based learning versus lecture-based learning in a course of evidence based medicine

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Background: Problem-based learning is recognized as promoting integration of knowledge and fostering a deeper approach to life-long learning, but is associated with significant resource implications. This paper utilizes preliminary data from both the facilitator and student viewpoint to determine whether the use of this novel methodology is feasible with large groups of students in evidence based medicine.

Objectives: To investigate the effectiveness of problem-based learning in comparison with lecture-based learning in evidence based medicine in undergraduate medical education. **Methods:** Participating students were assigned to the lecture based learning (LBL) group and PBL group. The examination scores, questionnaire, and seminars were used to evaluate the teaching effectiveness. SPSS 11.5 software was used for statistical analysis. **Results:** 107 students were included in the study, the baseline characteristics were balanced between the two groups. The examination mark was higher in the PBL group than in the LBL group, there were significant differences between the two groups in the attitude of the LBL. The students of PBL group revealed a high overall satisfaction with the course. **Conclusions:** The problem-based program appeared to be more effective than the lecture-based program in EBM teaching.

P29: Is Cochrane review effective for the selection of essential medicine list of China: a case of antihypertensive medicines?

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Objective: Cochrane reviews were considered as evidence of highest quality for evidence-based decision-making. WHO has applied Cochrane reviews in selection of essential medicines. Here, we assessed whether Cochrane reviews are effective for selection of essential medicines in China. **Methods:** We searched the most recent Chinese essential medicines list, and used antihypertensive medicines as examples in our study. We searched the Cochrane Library for reviews that specifically address effects of these medicines. **Results:** Nine antihypertensive medicines were identified, including captopril, enalapril, sodium nitroprusside, magnesium sulfate, nitrendipine, indapamide, phentolamine, and two compound reserpine tablets. The search identified 25 Cochrane reviews; only 3 reviews, however, specifically addressed the effects of these individual medicines. The other reviews typically assessed the effects of a class of medicines (e.g. ARB, diuretics). One study showed that captopril and enalapril were effective in lowering systolic and diastolic pressure compared to placebo; no evidence of direct comparison of these two medicines was reported. Another study suggested that magnesium sulphate was ineffective in reducing blood pressure and had significant adverse effects. The third review concluded that reserpine was more effective, relative to placebo, in reducing systolic blood pressure. **Conclusion:** Limited evidence can be available to assist in selection of essential medicines. Some Cochrane reviews that typically assess drug class effect compared with placebo may not address comparative effectiveness of individual medicines.

P30: Identifying barriers and facilitators to home safety interventions for the families of pre-school children

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Background: Injuries are the leading cause of childhood death in most countries; steep social gradients exist in mortality and morbidity. The majority of pre-school injuries occur in the home but the science of implementing research into practice in the field of injury prevention has received little attention. **Objectives:** To describe key barriers and facilitators when implementing health promotion and injury prevention interventions. **Methods:** We used the papers included in the Cochrane systematic review of home safety education and provision of safety equipment for injury prevention (Kendrick 2007) that was updated in 2010 using the same search and review strategy. Each paper was screened to ensure that children under 5 years were included. Subsequently, they were included if they specified two of the following criteria: detail of the intervention, process measures and/or information about barriers and facilitators. Two authors independently reviewed each paper and extracted data. Framework analysis was used: an iterative process whereby the initial themes were identified after the

first 10 papers had been reviewed jointly, four further themes were identified after 25 papers. Previous summaries were then coded for the new themes. **Results:** 42 papers were included. Seven key barriers and seven facilitators were identified in the implementation of health promotion and injury prevention interventions. The barriers include the complexity of the interventions, length of follow-up, cultural barriers, contamination of controls, physical barriers, behavioural barriers and deliverer constraints. Facilitators relate to: the approach used, whether the message was focused, minimal changes were involved, characteristics of the deliverer, accessibility to equipment, behaviour change and whether incentives were built-in. **Conclusions:** Barriers and facilitators will be used to develop an Injury Prevention Briefing which will be evaluated in a randomised-controlled trial to be undertaken in the community in the UK.

P31: Development of a software tool to facilitate the literature selection process for systematic reviews

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Background: Within the framework of a systematic review, a critical task is the reliable selection of potentially relevant literature from a comprehensive pool of references stored in a database. **Objectives:** To facilitate the literature selection process, we developed and tested a new software tool. **Methods:** We developed and tested this tool within the framework of several systematic reviews conducted by the German Institute for Quality and Efficiency in Health Care. The technology is based on a Visual Basic for Applications (VBA) EXCEL® macro. The interface for Reference Manager or Endnote is provided by tag-format import / export facilities. The tool covers the entire process, starting with the title / abstract screening, to obtaining and evaluating potentially relevant full-text publications, to the documentation of the selection process as a whole by one or more independent raters. One key feature of the tool is the support of the screening process by highlighting individually defined keywords within specific data items. This should help to ensure the selection of relevant and the preclusion of irrelevant references. The applied set of key words, which can be organized by colour and font type, will be refined in an ongoing learning curve. The tool further supports the merging of separate databases (e.g. processed in parallel by several raters) and the compensation of inter-rater differences. **Results:** A literature search for systematic reviews on positron emission tomography (PET) found 6533 datasets, corresponding to 3660 pages (2500 letters per page) that had to be screened. The tool's reduction in effort, compared to manual screening, was estimated as being 44% (translating into 1600 pages less), depending on the length of the datasets (15% reduction for every multiple of 500 letters). This model is likely to estimate the real reduction in effort, as experienced in the PET project. **Conclusions:** Using this software tool in the literature selection process may save resources and improve precision.

P32: Testing and revising an algorithm for the classification of study designs in systematic reviews of interventions and exposures

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Background: Systematic reviewers may include nonrandomized studies to provide a more detailed picture of the current knowledge of an intervention. We previously described the development and testing of an algorithm to assist in the classification of study designs in systematic reviews (SR) of interventions and exposures. Such a tool may be used to inform key steps of the review process. **Objectives:** This study builds on our previous findings by testing the algorithm within the context of a single SR and refining the algorithm to further enhance reliability. **Methods:** The algorithm was applied to 51 studies included in an SR of the effectiveness of diabetes education. The reference standard classification was developed by 2 researchers who independently classified the studies; disagreements were resolved through discussion with a third reviewer. Four testers, varying in training and experience, independently applied the tool to the same 51 studies. Inter-rater reliability and accuracy against the reference standard were measured and areas of disagreement identified. **Results:** The 4 testers agreed on the classification for 12 studies; 3 agreed on 19; 2 agreed on 17. For 3 studies, there was no agreement. The overall level of agreement was fair ($\kappa=0.36$). Agreement for testers with graduate level training was moderate ($\kappa=0.47$). All 4 testers agreed with the reference standard for 11 studies. Agreement between the reference standard developers was moderate ($\kappa=0.57$). Two decision nodes were modified. Testing of the revised algorithm is ongoing and results within the context of a second SR will also be presented. **Conclusion:** The algorithm helped classify studies and identify difficulties due to lack of reporting. The results concur with previous findings showing better reliability among individuals with more training and experience. Additional testing and refinement using different samples will enhance the utility of the tool.

P34: In a systematic review, is consequence of exposure the same as effect of intervention? Reflections on the challenges in conducting a systematic review on the sexual consequences of Female Genital Mutilation/Cutting

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Background: A plethora of guidance for systematic reviews on the effectiveness of interventions exists. Organizations such as the Cochrane Collaboration have contributed to an emerging consensus of 'best practices' and the development of tools to answer questions of effectiveness and harm of controlled interventions. Much less research synthesis work has been developed for questions of consequences of natural harm/exposure. **Objective:** To present some methodological challenges in conducting a systematic review of the consequences of a socially prescribed practice through a recently completed systematic review about the sexual consequences of female genital mutilation/cutting (FGM/C). **Methods:** The search retrieved 3700 records, which were screened for inclusion. Included studies were subject to quality assessment, data extraction, and synthesis including meta-analysis. **Results:** Across the 17 samples a total of 12,755 women between the

ages 15–77 from nine different countries were included. All studies compared women with FGM/C to women without FGM/C. Among several challenges in our systematic review, three were particularly complex: 1) Identifying appropriate quality assessment check-lists for observational studies investigating not effectiveness but the relation between exposure (FGM/C) and consequences (sexual outcomes). Most check-lists are design specific (e.g. cross-sectional, cohort), not research question specific. 2) Some health issues do not lend themselves to manipulation—thus, to what extent, if at all, is it reasonable to apply GRADE for studies not assessing effect but rather relationship? 3) Communicating the increased likelihood of an adverse sexual outcome from FGM/C rather than causal effect of the practice was linguistically demanding. **Conclusions:** Questions of consequences of practices do not always lend themselves to RCTs, but for observational study designs guides and tools available to systematic reviewers are scarce. There is a need to organize the relevant methodological challenges and develop resources to advance such research.

P35: Direct and indirect comparison of complex health-care interventions in overview of reviews: non-pharmacological interventions for non-specific low back pain

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Background: A wide variety of pharmacological and non-pharmacological interventions are available for non-specific low back pain (NSLBP). However, there are few head-to-head trials available of non-pharmacological interventions for NSLBP, and it is not clear which intervention should be the first choice. **Objective:** We aimed to conduct an overview of Cochrane systematic reviews (CSRs) on NSLBP by summarizing both direct and indirect evidence to identify the most effective non-pharmacological treatment for low back pain. **Methods:** We searched the Cochrane Library for reviews examining interventions for NSLBP. We extracted data on type of intervention, patients' characteristics and outcome measures, and calculated standardized mean differences of treatment effect. Active interventions were compared using direct comparison (DC) and adjusted indirect comparison (AIC). **Results:** We included 3 reviews involving 109 trials examining non-pharmacological interventions (massage, exercise therapy and acupuncture) for NSLBP. The common

	Point Estimate	95% CI (Low)	95% CI (High)
Indirect Comparison			
Massage vs Control	−0.92	−1.35	−0.48
Exercise vs Control	−0.41	−0.66	−0.16
Acupuncture vs Control	−0.73	−1.19	−0.28
Direct Comparison			
Massage vs Acupuncture	−1.11	−1.43	−0.79
Massage vs Exercise	−0.79	−1.38	−0.19

outcomes in these reviews were pain, functional status and work absenteeism, and we chose to evaluate pain as our primary outcome. The direct comparison trials showed that massage was statistically significantly better than exercise therapy or acupuncture. The indirect comparisons also indicate massage may be better than acupuncture or exercise, although the difference between massage and acupuncture was statistically non-significant by the indirect comparison (Figure & Table 1). The discrepancy between DC and AIC estimates was statistically significant when massage was compared with acupuncture ($p = 0.01$) and not significant for the comparison of massage and exercise. **Conclusions:** We illustrate the feasibility of conducting an overview of reviews in a complex area, and succinctly summarize the relative effects of competing interests in an accessible format. Massage appears to be the first-line option for patients with NSLBP as compared to exercise or acupuncture.

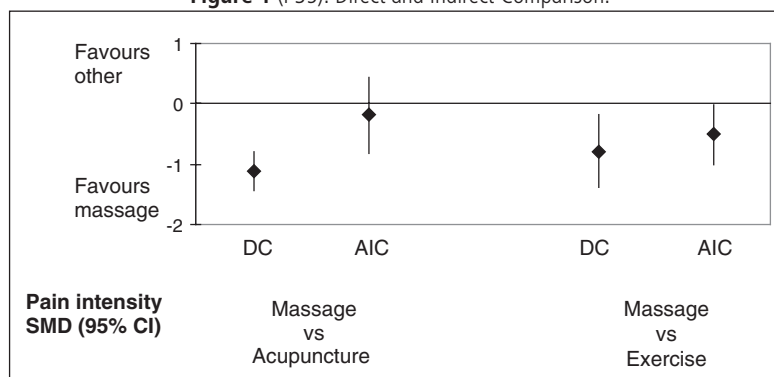
P36: Structured summaries in French to facilitate access to findings of Cochrane Systematic reviews to primary care physicians: a Swiss initiative

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Background: One challenge of the Réseau francophone Cochrane (RFC) is to disseminate Cochrane Systematic reviews (CR) to French-speaking people. We developed a one page summary to facilitate the dissemination of CR results to primary care physicians (PCPs). **Objectives:** The aims of this study were to describe the structure and

Figure 1 (P35): Direct and Indirect Comparison.



development process of the summary and to evaluate the perceived usefulness of the summaries by PCPs. **Methods:** We developed a structured summary that was approved by the main medical journal in the French speaking part of Switzerland. CRs were selected using the following criteria: potential interest for PCPs, conclusive results, recent and new. The summaries were written by a person with methodology skills and by a senior clinician specialist of the corresponding question, under the supervision of an expert. The editorial team reviewed all abstracts before sending them for publication. We aimed at publishing 6–8 abstracts/year. One year after the first publication, a short 5-question form was e-mailed to the 172 PCPs participating to teaching and research activities at the University of Lausanne. **Results:** The CR summary includes the following items: clinical scenario, clinical question, context, results, limitations, CR authors' conclusion, and answer to the clinical question. Between January 2009 and February 2010, 9 summaries were published. The survey response rate was 24% (n = 41). Fifty-nine percent of the responders (n = 24) mentioned having seen the abstracts. Among them, 67% mentioned they read all summaries and 33% mentioned they read only those who interested them; the format of the summary was reported to be adequate by 63% of PCPs; 70% responded that the summaries were helpful in their clinical practice. **Conclusion:** The survey response rate was not high enough to draw strong conclusions, but they indicate an interest among the PCPs in the French-speaking part of Switzerland toward such an initiative.

P37: Searching for success in a public health intervention review

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Background: The interdisciplinary nature of public health makes identifying studies for systematic reviews a much more complex process than that for reviews in clinical medicine. Having just completed a particularly complicated review of public health interventions, we will consider whether it was necessary or valid to search as many sources as we did. **Objectives:** To identify and compare information sources and to assess their contribution to papers reviewed in full text and to those which were included in the review. To establish whether the included papers were all retrieved in the exhaustive literature search. **Methods:** A literature search was conducted in 25 databases using a comprehensive list of search terms. In addition, a range of 'snowballing' methods was used. We will examine the full text papers identified from each source, including those that were unique to that source. **Results:** The comparison will identify the sources that contributed potential and actual papers for the review. **Conclusions:** The findings will have implications for those developing search protocols and will contribute to the guidance available to authors embarking on systematic reviews of public health interventions.

P38: Culturally-oriented Strategies for Communicating Cochrane Evidence on Malaria and HIV/AIDS prevention and Control in a Developing Country Setting: A Community-focused Approach

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Background: The Nigerian Branch of the South African Cochrane Centre (SACC) is engaged in an initiative to involve local consumers and has already organized a successful consumer workshop at the Nigeria Contributors' meeting in February 2008 (funded through the Cochrane Discretionary Funding). In 2009, the Branch received support through the Cochrane Opportunities Fund to enhance consumer participation and involvement in dissemination of relevant Cochrane information.

Objective: To describe the processes adopted to engage workshop participants to develop innovative culturally-based strategies (drama, storytelling and community campaign/advocacy) for communicating Cochrane evidence on malaria and HIV/AIDS prevention and control in Nigeria. **Methods:** We conducted two workshops in each of the four regions in Nigeria (south west, north central, east central, and south-south); the first being a two day workshop (phase 1) and the second a follow-up one day workshop (phase 2). The first two-day workshop was organized to: (1) introduce consumers to Cochrane's high-quality healthcare information on malaria and HIV/AIDS, and (2) to support them to develop tools for dissemination. A second one-day workshop was held three months later to further develop dissemination materials and support consolidation. **Results:** Overall, representatives of 67 community-based, nongovernmental, and civil society organizations in each of the four workshop locations used the information shared from Cochrane Reviews to develop culturally-based strategies for communicating Cochrane evidence on malaria and HIV/AIDS prevention and control. Details of each of the group's strategies will be presented at the Colloquium. **Conclusions:** Activity-oriented workshops for consumers/community organizations can be a useful way of developing culturally appropriate tools for communicating Cochrane evidence on malaria and HIV/AIDS prevention and control in developing countries.

P39: The Child Strategy: The Pan African Clinical Trial Registry's effort, in collaboration with the World Health Organization to increase clinical trial research in children

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Background: Very little is known about the landscape of clinical trials recruiting children in Africa. To combat this dearth of information, The World Health Organization (WHO) is co-ordinating a multi-regional initiative to increase clinical trial activity and registration involving children worldwide. The Pan African Clinical Trials Registry (www.pactr.org), based at the South African Cochrane Centre, provides a platform

to prospectively register all clinical trials conducted in Africa. In 2009, in partnership with the WHO, www.pactr.org developed a Child Strategy to encourage prospective registration of African child-focused trials. **Objectives:** To increase the rate of registration of clinical trials that recruit children in Africa. **Methods:** The Child Strategy aims to: 1. To develop an awareness of the global and continental need to register clinical trials and the dearth of information on pediatric trial research; 2. To encourage trial work utilising children as participants in the region; 3. To increase the number of registered trials conducted on the African continent; The Child Strategy aims to increase awareness of pediatric clinical trial issues to encourage debate and policy development through hosting collaborative meetings that will bring together clinicians, researchers, policy makers and funders. The Strategy will call together regional journal editors with the hope that they can develop a statement supporting clinical trial registration and ethical oversight. Additionally active dissemination of the importance of trial registration and oversight will be undertaken to develop a network of informed stakeholders in the region with the ultimate goal of developing regional policy for clinical trial research. **Conclusions:** Through www.pactr.org registration initiatives the Child Strategy aims to build a prospective database of child focused trials on the continent to fill gaps in knowledge. The Strategy aims to increase awareness,

assist in the development of policy and create a supportive environment for clinical research using child participants.

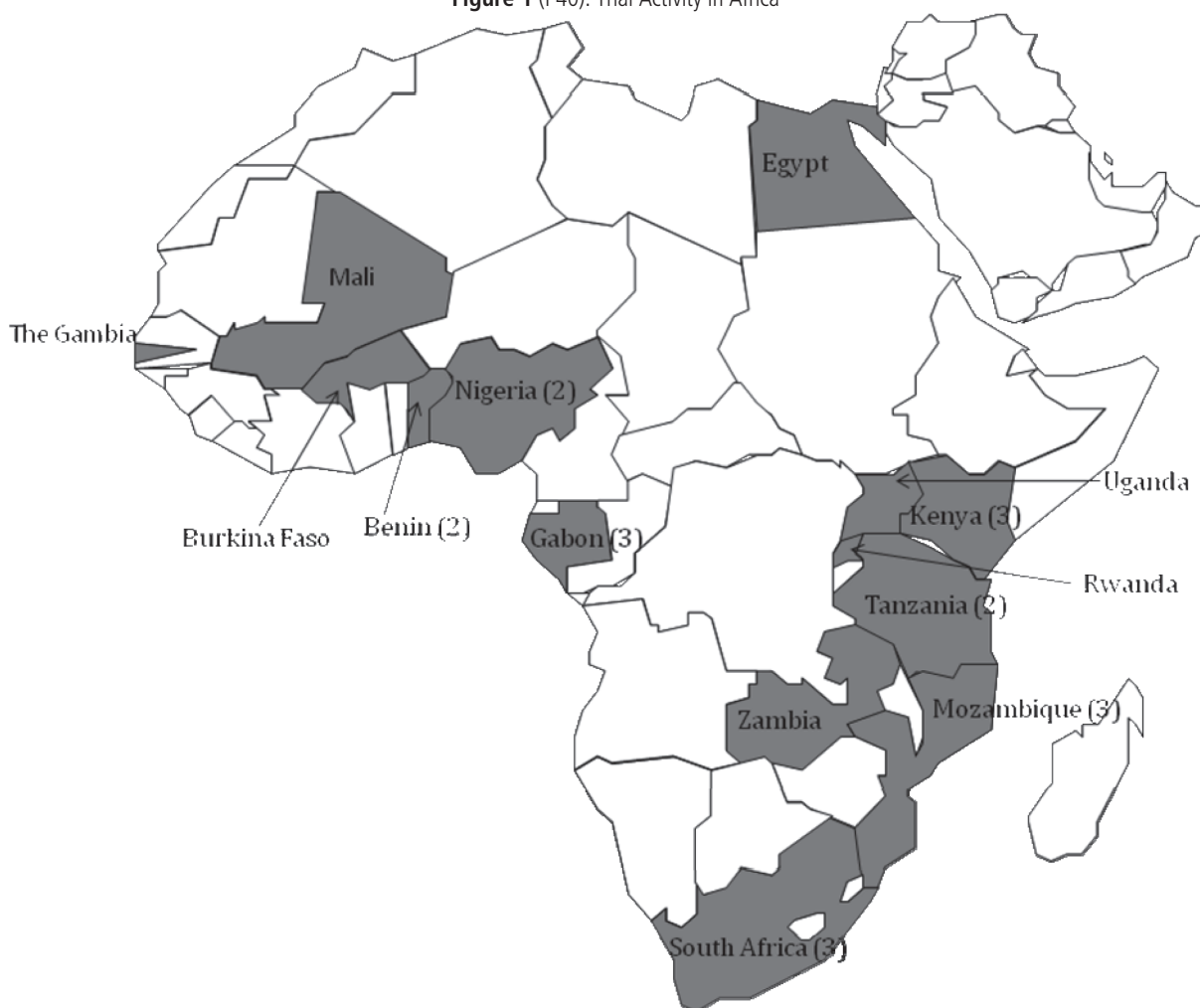
P40: Filling the Gaps: The World Health Organization and the Pan African Clinical Trials Registry efforts to combat an unclear child-focused clinical trial landscape

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Background: Cochrane reviews of child-focused interventions regularly conclude that there is insufficient trial data in children. The World Health Organization (WHO) is co-ordinating a multi-regional initiative to increase clinical trial activity and registration involving children worldwide. The Pan African Clinical Trials Registry (www.pactr.org), based at the South African Cochrane Centre, provides a platform to prospectively register all clinical trials conducted in Africa. In

Figure 1 (P40): Trial Activity in Africa



2009, in partnership with the WHO, www.pactr.org developed a Child Strategy to encourage prospective registration of African child-focused trials. **Objectives:** 1. To describe trials in children registered on www.pactr.org 2. To establish a baseline of registered trials recruiting children on PACTR to expedite future assessments of the Child Strategy **Methods:** We downloaded details of trials registered on www.pactr.org on 11 March 2010. Two independent investigators extracted trial data, including details of disease and participant ages. **Results:** Eleven of 23 (48%) registered trials research children's health. Of five trials in pregnant women, two evaluate drug prevention for malaria and one drug treatment, one evaluates anaesthesia for Caesarian Section, and one assesses patient advocacy for preventing mother-to-child HIV transmission. In infants, two trials evaluate HIV vaccines; in older children, one assesses antiretrovirals in HIV-infected children and one evaluates drug treatment for malaria. A trial promoting adherence via economic incentives includes children and adults with tuberculosis. A meningitis vaccine trial includes participants aged 1 to 29 years. Trial activity is present in 14 African countries (see map). **Conclusions:** The low number of registered trials on PACTR reflects the nascent stage of www.pactr.org, which has been a Primary Registry in the WHO Registry Network since September 2009. Encouragingly the proportion of child-focused trials is almost half of all registered trials. As www.pactr.org grows, free access to identify ongoing trials in Africa will develop the registry into a key continental information resource.

P41: A graphical meta-analysis module for facilitating transparent healthcare decision-making

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Background: We have developed an Excel based graphical user interface for evidence syntheses developed in R or WinBUGS. This interactive tool aims to facilitate transparent healthcare decision-making by allowing in-depth access to meta-analysis to a wider community of stakeholders. **Objectives:** This graphical interface allows evidence synthesis to make use of the advanced statistical and graphical analysis provided by R and WinBUGS and at the same time it enables users not only to run the meta-analysis but also to have control over its structure. It aims to facilitate interactive adjustment of meta-analysis for relevance and potential biases. Originally it has been developed as one of the modules of the Transparent Interactive Decision Interrogator (TIDI) that aims to facilitate transparent and efficient decision making in HTA. This module can be used as part of TIDI where meta-analysis is used to inform health economic decision models or as stand-alone interface to help in any healthcare decisions that are made based on evidence synthesis. We suggest this concept, could be taken further to be accessible online, and ultimately integrated into the systematic reviews within the Cochrane library. This would allow the reader to incorporate their beliefs, carry out sensitivity analysis or tailor the analysis for a particular patient population. **Design:** The interface is programmed in Visual Basic. It allows interactive selection of studies (to be included in the meta-analysis) from among those whose data is stored in the Excel spreadsheet of the interface. An extension

to Excel, called RExcel, passes the data to the meta-analysis running in R or WinBUGS (via R2WinBUGS). The results are then returned to the Excel spreadsheet in a tabular format as well as using interactive forest plots. The interface gives also the possibility to explore the impact of adjusting the primary studies in the meta-analysis for potential biases.

P42: Stepping outside our comfort zone – knowledge translation in practice

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Background: There are a number of approaches for encouraging knowledge translation. The UK's Economic and Social Research Council facilitates one such approach by funding academics to work in government on placements for up to a year. This scheme enabled one systematic reviewer to spend a year within England's National Audit Office. The Office audits all national government spending combining auditing financial accounts with programme evaluation. Projects range from evaluating major defence projects to reviewing initiatives for tackling problem drug use. This ESRC placement provided a range of opportunities for knowledge sharing and translation.

Objectives: This study set out to reflect on such placements as a means of facilitating knowledge translation and draw out lessons for systematic reviewers. **Methods:** An action research model was employed with data collected through a reflective diary and analysed qualitatively. **Results:** This analysis highlighted a mismatch between the researcher's understanding of 'policy and practice' and the reality. Differing priorities and pressures meant that requirements for, understanding of and commitment to research quality differed significantly across the audit and research worlds. The value of bridging these two worlds was apparent, with knowledge translation occurring in both directions: technical research knowledge into audit, and experiential knowledge into research. Furthermore, whilst the initial intention was to deliver research knowledge in the form of results, the fellowship centred on developing research methods skills, enabling more sustainable change. **Conclusion:** Stepping outside of our comfort zones to work with users of systematic reviews enhances the process of knowledge translation, with scope for more relevant and translated research. By translating not only research results, but also research skills more sustainable transformation can occur.

P43: The role of patients reporting evidence. Pacientesonline: the site for patients, done by patients

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Background: Pacientesonline was born in 2005 with the clear objective to be place for patients made by patients understanding the enormous difficulty of obtaining reliable information in Spanish language. The starting point was the difficulty of finding reliable information for non-English speaking. **Objective:** To provide quality and evidence based information to patients to help them on health decision making. **Methods:** Pacientesonline is a site aiming to improve the dissemination and communication on the available information obtained from reliable sources and based on

scientific evidence. The content is divided in notes, that are created from the queries received in our mail contact and by our own research criteria of noteworthiness. It includes the issues more prevalent worldwide: hypertension, obesity, thyroid, sexually transmitted diseases. Many notes also emerge from the interviews with different doctors identifying patient needs (climacteric, lymphomas, rheumatology). When enough material is assembled, we create Special Reports linking different notes on a particular theme (ie: breast cancer, lymphedema, mammography, sentinel node). **Results:** Pacientesonline include 14 sections with more than 4,000 internal pages. Interaction with users has facilitated to overcome the Internet barrier: four of this sections have linked face-to-face events: evidence-based medicine, patient safety, Doctor-Patient meetings and RAMPA. From May 2005 to March 2010 pacientesonline has received 1,073,876 visits, been one of the most popular independent health information webpages in Latin America' **Conclusions:** Patients Online is an example of knowledge translation to patients. The volume of visits illustrates the need of independent and reliable patients health information sites that are based on reliable scientific evidence. This initiative, initially designed as a dissemination tool, has also emerged as a capacity building provider due to the user requests and needs.

P44: Strategies to improve recruitment to randomised controlled trials

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Background: Recruiting participants to trials can be extremely difficult. Identifying strategies that improve trial recruitment would benefit both trialists and health research. **Objectives:** To quantify the effects of strategies to improve recruitment of participants to randomised controlled trials. **Methods:** We searched the Cochrane Methodology Review Group Specialised Register (CMR), MEDLINE, EMBASE, ERIC, Science Citation Index Expanded, Social Sciences Citation Index, National Research Register, C2-SPECTR and PubMed. Randomised and quasi-randomised controlled trials of methods to increase recruitment to randomised controlled trials were included. **Results:** We identified 27 eligible trials with more than 26,604 participants. There were 24 studies involving interventions aimed directly at trial participants, while three evaluated interventions aimed at those recruiting participants. Some interventions were effective in increasing recruitment: telephone reminders to non-respondents (RR 2.66 95% CI 1.37 to 5.18), use of opt-out, rather than opt-in, procedures for contacting potential trial participants (RR 1.39 95% CI 1.06 to 1.84) and open designs where participants know which treatment they are receiving in the trial (1.25 95% CI 1.18 to 1.34). However, some of these strategies have disadvantages, which may

limit their widespread use. For example, opt-out procedures are controversial and open designs are by definition unblinded. The effect of many other recruitment strategies is unclear; for example the use of video to provide trial information to potential participants. Many studies looked at recruitment to hypothetical trials; the applicability of such to real trials is unclear. **Conclusions:** Trialists can increase recruitment to their trials by using the strategies shown to be effective in this review: telephone reminders, use of opt-out, rather than opt-in, procedures for contacting potential trial participants and open designs. Some strategies (e.g. open trial designs) need to be considered carefully before use since they also have disadvantages.

P45: Comparison of the diagnostic criteria and efficacy evaluation criteria in randomized controlled trials of traditional Chinese herbal medicine

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Background: Consistency of diagnostic criteria and efficacy evaluation criteria, if undetected, could lead to inaccurate estimates of effect and hence undermine the validity of clinical practice. It has been greatly ignored. One of the main reasons is that most Chinese authors lack relative knowledge. **Objective:** To identify randomized controlled trials (RCTs) of traditional Chinese herbal medicine (TCM) to find out the gap of the diagnostic criteria and efficacy evaluation criteria; to study how to reduce the consistency of diagnostic criteria and efficacy of the evaluation criteria. **Methods:** Published RCTs of TCM were sought from Chinese Science Citation Database (1989 to September 2009). Chinese Scientific Journal Full-text Database and Chinese Journal Full-text Database were used to acquire full-text for included RCTs. Two reviewers independently extracted data and assessed relative data with disagreements resolved by consensus. Analysis of diagnostic criteria and efficacy evaluation criteria were carried out for each study, and results compared where there was consistency of outcome reporting. We classified the diagnostic criteria and efficacy evaluation criteria three groups, standard of TCM, Western Medicine (WM) and integrated TCM-WM. **Results:** The searches returned 1809 potentially relevant articles. After application of inclusion

Table 1 (P45): The consistency of diagnostic criteria and efficacy of the evaluation criteria

Diagnostic criteria VS efficacy of the evaluation criteria	Studies (%)
WM VS WM	335 (43.7)
WM VS TCM	48 (6.27)
WM VS integrated TCM-WM	20 (2.61)
TCM VS WM	41 (5.36)
TCM VS TCM	49 (6.41)
TCM VS integrated TCM-WM	7 (0.92)
integrated TCM-WM VS WM	171 (22.35)
integrated TCM-WM VS TCM	58 (7.58)
integrated TCM-WM VS integrated TCM-WM	36 (4.71)
Total	765 (100)

Table 2 (P45): The organization for developing standard

Organization for developing standard	Diagnostic criteria		Efficacy of the evaluation criteria	
	TCM	WM	TCM	WM
WHO	—	33 (8.19)	—	14 (2.56)
Ministry of Public Health in China	17 (17.53)	25 (6.20)	25 (16.13)	114 (20.84)
State Administration of Traditional Chinese Medicine	41 (42.27)	—	63 (40.65)	—
Chinese Medical Association	11 (11.34)	90 (22.33)	16 (10.32)	35 (6.40)
Books/references	7 (7.22)	52 (12.90)	11 (7.10)	40 (7.31)
Conference	5 (5.15)	28 (6.95%)	5 (3.23)	42 (7.68)
Unclear	16 (16.49)	131 (32.51)	35 (22.58)	302 (55.21)
Association	—	44 (10.92)	—	—
Total	97	403	155	547

criteria, 765 studies were included. Table 1 showed that 403 studies' diagnostic criteria and 547 studies' efficacy of the evaluation criteria were WM, 97 studies' diagnostic criteria and 155 studies' efficacy of the evaluation criteria were TCM, 265 studies' diagnostic criteria 63 studies' efficacy of the evaluation criteria were integrated TCM-WM; Table 2 showed the organization for developing standard, standard of TCM were developed by Ministry of Public Health in China and State Administration of Traditional Chinese Medicine, standard of WM were developed by Chinese Medical Association, Books and Ministry of Public Health in China, but the diagnostic criteria and efficacy evaluation criteria were unclear in most studies.

Conclusion: There were discrepancy between diagnostic criteria and efficacy evaluation criteria in RCTs. The researchers should adopt the consistency diagnostic criteria and efficacy evaluation criteria in RCTs of TCM in the future.

P46: Scaling the Tower of Babel; the impact of including foreign language articles in a large-scale systematic review

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Background: It has been argued that the inclusion of research in languages other than English (LOE) in systematic reviews is costly, time-consuming and unnecessary as it is often of poor quality and is unlikely to change the results of meta-analyses. Current advice from Cochrane suggests that reviewers make decisions about the inclusion of articles in LOE on a case-by-case basis. **Objective:** To explore the impact of a recent decision to include studies in LOE in a large-scale systematic review and scoping review of photodynamic therapy in cancer. **Methods:** We devised a comprehensive search strategy which included searching databases in LOE and writing to those conducting trials in photodynamic therapy worldwide. We engaged native speakers or experienced translators to help identify and data extract papers in LOE. **Results:** In addition to indirect costs involved in database searching and recruitment of native speakers / translators, the direct cost of LOE papers was £117. Thirty-three studies in LOE were identified as possibly relevant. Of these, one trial, published in Chinese, was included in the systematic review, fifteen in the scoping review and the remainder excluded. The included Chinese trial on palliative photodynamic therapy for oesophageal cancer reported

longer follow-up than the other seven trials in the group and considered adverse effects. **Conclusion:** Although the inclusion of papers in LOE in this review incurred extra time and cost, there was a gain in the completeness of results. Furthermore, in a controversial topic area, we demonstrated a commitment to thoroughly identifying and assessing all the relevant literature, enabling us to state with increased confidence the need for better quality research. We believe these factors helped to increase the credibility of our review and suggest that studies in LOE should be considered for inclusion in systematic reviews unless there is a clear justification for their exclusion.

P47: Editorial policies of open access journals in pediatrics: survey of author instructions

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Background: Transparent reporting of research evidence is a prerequisite for systematic reviews. Several studies analyzed whether established journals in general medicine and specialties such as pediatrics endorse recommendations aiming to improve reporting quality[1],[2]. Despite evidence showing benefits of these recommendations, the proportion of endorsing journals has been moderate to low and varied considerably. For instance, 55% of pediatric journals indexed in the Journal Citation Report referred to the Uniform Requirements for Manuscripts (URM) of the ICMJE but only 23% recommended trial registration[2]. **Objectives:** We investigated whether the proportion of journals endorsing these recommendations is different in open-access (OA) journals in pediatrics. We hypothesized that these journals may be more flexible in adopting innovations in their publication practice. **Methods:** We identified 41 journals publishing original research articles in the subject category "Pediatrics" of the Directory of Open Access Journals (www.doaj.org). From the online author instructions we extracted information regarding endorsement of the URM and of five major reporting guidelines such as the CONSORT statement, disclosure of conflicts of interest and requirement of trial registration. Two investigators collected data independently. **Results:** The URM were mentioned by 27 (66%) of pediatric OA journals (Table 1). Conflict of interest policies were stated by 25 (61%). Thirteen (32%) required or recommended trial registration prior to publication

Table 1 (P47): Author instructions about recommendations aiming to improve publication practice.

Recommendation	Geographical location of editorial office No. (% of column total)						
	All journals N=41	Africa N=1	Austral-Asia N=11	Europe (without UK) N=11	North America N=6	South America N=9	UK N=3
Uniform Requirements for Manuscripts (ICMJE)	27 (65.9)	1 (100)	7 (63.6)	7 (63.6)	2 (33.3)	7 (77.8)	3 (100)
Trial registration	13 (31.7)	1 (100)	3 (27.3)	2 (18.2)	1 (16.7)	3 (33.3)	3 (100)
Conflict of interest	25 (61.0)	1 (100)	7 (63.6)	6 (54.5)	2 (33.3)	6 (66.7)	3 (100)
CONSORT	12 (29.3)	1 (100)	5 (45.5)	1 (9.1)	1 (16.7)	1 (11.1)	3 (100)
STROBE	3 (7.3)	1 (100)	2 (18.2%)	0 (0)	0 (0)	0 (0)	0 (0)
STARD	8 (19.5)	1 (100)	3 (27.3%)	1 (9.1)	0 (0)	0 (0)	3 (100)
MOOSE	8 (19.5)	1 (100)	3 (27.3%)	1 (9.1)	0 (0)	0 (0)	3 (100)
QUOROM/PRISMA	8 (19.5)	1 (100)	3 (27.3%)	1 (9.1)	0 (0)	0 (0)	3 (100)
EQUATOR	4 (9.8)	0 (0)	1 (9.1)	0 (0)	0 (0)	0 (0)	3 (100)

of a trial report. Advice about reporting guidelines was less often provided. CONSORT was referred to most often (12 journals; 29%) followed by other reporting guidelines (MOOSE, PRISMA or STARD) (8 journals, 20%) and STROBE (3 journals, 7%). The EQUATOR network, a platform of several guideline initiatives, was acknowledged by 4 journals (10%). **Conclusions:** In pediatrics, the proportion of journals referring to certain recommendations such as URM or trial registration is larger in OA journals than in established journals. Further research should clarify what the motivations and barriers are in implementing such policies and if they differ between established journals and OA journals.

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P48: Estimating risk differences and NNTs with adjustment for balanced covariates

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Background: It is known that the consequence of adjusting for balanced covariates in logistic regression is on one hand a loss of precision but on the other hand an increased efficiency in testing for a treatment effect. The reason for the latter is that the downward bias induced by omitting the covariate is avoided. However, these results are based upon investigations of the regression coefficients and the corresponding odds ratios (ORs). **Objectives:** This study investigates the effect of adjusting for balanced covariates in logistic regression when the risk difference (RD) and its inverse, the number needed to treat (NNT), are used as effect measures. **Methods:** RDs and NNTs with adjustment for covariates are estimated by using an

adaptation of the average risk difference (ARD) approach (*Stat. Med.* 2007, 26: 5586-5595). Precision and relative bias of the estimates and coverage probabilities of the corresponding confidence intervals are investigated by means of a simulation study. **Results:** In contrast to the results for ORs, estimation of RDs and NNTs with adjustment for balanced covariates does not lead to a loss of precision. The standard errors of the adjusted estimates are reduced by about 20% if the covariate has a strong effect and large variance. Thus, the adjustment leads to a gain in precision. No relevant bias and coverage probabilities close to the nominal level were found for both the crude and the adjusted estimation of RDs. **Conclusions:** In addition to increased power for testing treatment effects, an adjustment for balanced covariates leads to reduced standard errors and shorter confidence intervals if the treatment effect is presented in terms of RDs and NNTs. In meta-analyses of clinical trials, in which the application of an absolute effect measure is appropriate, it is preferable to use adjusted risk differences to estimate the pooled treatment effect.

P49: Reviewing for cost effectiveness model parameters

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Background: Health technology assessments (HTA) include a systematic review of the clinical effectiveness evidence and a cost-effectiveness model. The development of the cost-effectiveness model usually requires additional information beyond clinical efficacy. Depending on the timing, size and number of information requirements the reviewer can be faced with considerable difficulties ensuring that the reviewing is done in a timely and systematic fashion. There is tension in terms of the need to ensure that this process is transparent and reproducible. Different model parameters may require different levels of resource depending on their importance. While there has been research on searching for model parameters, there is little guidance regarding to best practice in the selection and use of evidence within models. **Methods:** A focus group was held with 15 experienced systematic reviewers, information specialists and health economic modellers. Framework analysis was used to draw out emergent themes from the transcribed data. **Results:** Six key themes were identified including: current practice

for reviewing for model parameters, level of information required for parameters, timing of the reviewing, ideal practice, areas for further research and problem structuring. Reviewing, searching and modelling need to be seen as integrated tasks and the whole team should be involved in the structuring of the decision problem. Good communication was deemed to be essential and more time should be spent on the most important parameters. The ability to make assessments on the quality of information was also considered important. Future research needs include training for focussed searching, problem structuring, quality assessment and the validation of parameter estimates. **Conclusions:** This preliminary investigation highlights several key concerns and indeed potential deficiencies in the process of identifying, selecting and using evidence to inform model parameters. Guidance should focus on how this process may be best operationalised.

P50: Training for patients and citizens representatives: evaluating the PartecipaSalute courses

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Background: PartecipaSalute "Participate in Health Care" is a project on citizens and patients' involvement in healthcare developed by the Mario Negri Institute, Italian Cochrane Centre, Zadig editorial company since 2003 – supported by a bank foundation. Within its activities, the PartecipaSalute project annually holds a course aimed at training patients' associations and lay members of ethics committees on clinical research and healthcare decision-making. **Objectives:** To describe a training programme for consumers and to evaluate the impact on participants' knowledge and satisfaction. **Methods:** Knowledge is evaluated through a 13-item questionnaire on clinical research issues submitted before and after the course and a self assessed

form on the topic covered by each module. Satisfaction is evaluated using a form on quality, performance, relevance of each speaker (4 items) and an overall survey both self administered. A discussion with participants about the organization, methods and contents is organized during the course. Report of participants' future activities tied to the topics of the course are solicited. **Results:** One hundred fifteen patients representatives attended to the courses (2007–2010). The educational modules cover basic concepts of clinical research, conflict of interests, uncertainty in medicine, strategies of health information, ethic committees, credibility of patients' associations. Each module begins with workshops that discuss a relevant practical example. The number of correct answers to the 13-item questionnaire increased after the course (2007: 56–69%, 2008: 70–83%; 2010: 53–66%). The mean value of the self assessed knowledge increased after the course. Data on the satisfaction of participants are available. **Conclusions:** We observed a knowledge gain, an increased satisfaction, and a more enthusiastic involvement in the courses participants. After the course, most participants accepted to join PartecipaSalute working groups. A controlled evaluation of the course's impact on attitudes, behaviors and activities developed by participants is needed.

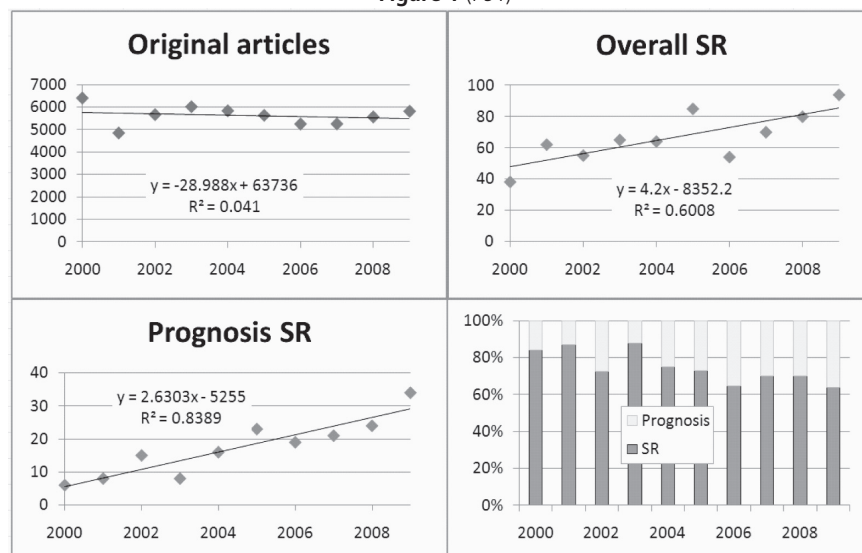
P51: Systematic reviews in the prognosis field: a critical appraisal of six core clinical journals

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Background: The methodology to conduct systematic reviews (SR) of prognostic issues is not yet fully developed and unanimously agreed. In particular, risk of bias assessment and quality scoring of research (both primary studies and SR) are meant to be largely inconsistent. **Objectives:** To measure the role for SR dealing with prognostic issues, using the following bibliometric indicators: proportion of all SR over all published articles, proportion prognostic SR over all

Figure 1 (P51)



systematic reviews, temporal trends in those proportion, adherence of prognostic SR to PRISMA and MOOSE guidelines. **Methods:** JAMA, BMJ, Annals of Internal Medicine, Circulation, Stroke and Blood were searched for: a) total number of articles b) number of SR c) number of prognostic SR. The figures were extracted for any year from 2000 to 2009. The search for items a) and b) were performed on PubMed, while item c) was hand-searched. The SR about prognosis were analyzed with the MOOSE and PRISMA checklist. All searched and assessments were performed by two of the authors. **Results:** Main results are shown in Figure 1. While the overall number of original article remained the same, SR and particularly prognostic SR showed a significant increase over the last 10 years. JAMA and Stroke showed the steeper increase in the proportion of prognostic SR, Blood the flattest profile with a mean of 1 SR per year. The fulfillment of PRISMA and MOOSE requirements was generally low. **Conclusions:** Notwithstanding the methodological flaws inherent in prognostic research, the space allocated in core clinical journal to prognostic systematic reviews increased over the last 10 years.

P52: Conducting A Systematic Overview: Quality Improvement of Diabetes Treatment

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Background: There is a large volume of systematic reviews addressing quality of care initiatives in diabetes. To date, modest attempts have been made to synthesise the evidence to make it accessible for policy or decision makers. **Objectives:** To complete a comprehensive overview of systematic reviews assessing the effects of quality of care initiatives in diabetes management. **Methods:** The Cochrane Effective Practice and Organisation of Care Group undertook the overview in two phases. The first involved indentifying all relevant systematic reviews; "evidence mapping" reviews into primary intervention areas; performing quality appraisal of the reviews; and summarising preliminary findings from key reviews of select intervention categories. The second phase involved refining the outcomes of interest and selecting an appropriate and comprehensive taxonomy to classify the range of interventions and their targets (health care providers, patients and their care-givers, and health care systems). Dual data extraction was completed for relevant moderate-to-high quality reviews. Decision rules were created to help synthesize the evidence within and across reviews. Summary findings of the effects of the interventions on improving the management and quality of care of persons with diabetes were compiled. **Conclusions:** Conducting overviews enables a higher level analysis with a broader scope to allow for multiple questions and interventions. Consequently, the overview methodology can be used as a critical appraisal tool of the best evidence. The overview process is a relatively new approach to synthesizing systematic review evidence and, while methods are not well established, it is a growing area of interest.

P53: College Nursing Students' Knowledge of and Self-efficacy in Evidence-based Practice in Taiwan

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Background: Delivering evidence based patient care has been emphasized in nursing education and clinical settings. There is a call to educating current and future nurses on the use of evidence-based practice (EBP). Many studies had explored EBP among hospital nurses, but there is limited information and research regarding knowledge of and self-efficacy in EBP among nursing students. **Objectives:** This study aimed to explore the knowledge of and self-efficacy in evidence-based practice in college nursing students in Taiwan. **Methods:** A cross-sectional design was used. The Taiwanese version of the Self-Efficacy Evidence-based Practice (SE-EBP) scale were distributed to a convenience sample of 90 nursing students studying in the two-year bachelor nursing program in a college in Taiwan, and 66 nursing students completed the survey, giving a response rate of 73.3%. **Results:** None of the participants had ever received any EBP course in their nursing education before. This sample had a moderate level of EBP knowledge with a mean total score of 5.21 (range 4–8), a moderate level of EBP self-efficacy with a mean total score of 142.89 (range 37–229), and a moderate level of EBP outcome expectancy with a mean total score of 42.38 (range 4–76). This study results show that there is a lack of knowledge and skills of EBP as well as self-efficacy in EBP among nursing students. EBP self-efficacy was significantly correlated with EBP outcome expectancy ($r = .88$, $p < 0.001$), indicating that nursing students with higher levels of confidence in EBP also had higher levels of expectation that EBP would lead to good patient outcomes. However, EBP knowledge was not significantly correlated with EBP self-efficacy ($r = .13$, $p = .31$) and EBP outcome expectancy ($r = .20$, $p = .10$). **Conclusions:** This result indicates that there is a need to integrate EBP concepts and skills into nursing education curriculum. The understanding of nursing students' knowledge of and self-efficacy in evidence-based practice can provide baseline data to further develop educational program related to EBP. The findings will help nursing educators develop nursing education curriculum to improve the knowledge of and self-efficacy in EBP among nursing students and further promote their evidence-based clinical practice in their future clinical work.

P54: Evaluating external validity, applicability and transferability of evidence to primary care setting

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Background: Practitioners and decision makers need sufficient information on the external validity of trials in a systematic review

to evaluate the applicability and transferability of the results to another population and setting. **Objectives:** To review the clinical trials of an ongoing Cochrane review in order to determine the extent to which external validity dimensions were reported, develop a conceptual framework to evaluate the applicability and transferability of the evidence to a primary care setting and apply it to the review. **Methods:** We applied the external validity tool (Green 2006) to evaluate 'reach and representativeness'; 'implementation and consistency of effect'; 'maintenance and institutionalization' for the included studies of an ongoing Cochrane review on patient record systems in dental practice and developed a conceptual framework to demonstrate the factors that needs to be considered in evaluating the applicability and transferability of the results to a primary care setting. **Results:** One trial had a low (53%) participation rate (reach and representativeness) and the actual delivery of the intervention was 62% ('implementation and consistency of effect'). The only demographic factor reported was socioeconomic status. A majority (78%) of participants remained in the study after one year ('maintenance and institutionalization'). The second trial failed to report sufficient information on the recruitment strategy; the actual delivery and follow up was limited with (3% drop out). The conceptual framework helped to identify several factors that need to be considered to evaluate the applicability and transferability of the results of the review to a primary care setting. **Conclusion:** An external validity tool can help in judging the applicability and transferability of the evidence. The conceptual framework can help systematic reviewers and knowledge users to identify factors that needs to be considered in judging the applicability of evidence to a primary care setting.

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P55: Validation of the EBP process assessment scale (EBPPAS): a scale to measure practitioners' views about evidence-based practice

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Background: The success of the evidence-based practice¹ (EBP) movement depends on the effective dissemination of the EBP process model through training and its adoption by practitioners. This study reports on the validation of a scale that can be used in evaluations of the impact of such trainings and in surveys of practitioners regarding their views of EBP. **Objectives:** This study assesses the reliability, sensitivity, and criterion and factor validity of the EBPPAS, a 51-item scale that measures orientation toward EBP and five subscale constructs: self-efficacy, attitudes, perceived feasibility, and intentions to engage and self-reported engagement in EBP. **Methods:** Social work practitioners and MSW students were surveyed in four areas: Texas, Missouri, New York and Toronto. Systematic random sampling was used to recruit practitioners in all areas except New York, where all social work field instructors from a large university were

surveyed. All MSW students were invited to participate in the study at four large schools of social work known for emphasizing EBP. Additional data was gathered in pretests and posttests of 97 practitioners participating in EBP continuing education workshops. Confirmatory factor analysis (CFA) procedures were used to assess the scale's factorial validity. **Results:** The overall scale had excellent internal consistency ($\alpha = .94$), and four of the five subscales had alphas ranging from .83 to .91. Criterion validity was established in two ways: 1) Significant pre to post workshop change (with large effect sizes) and by significant correlations of the scale and subscales with prior exposure to EBP. The pre-post workshop change also supported the sensitivity of the scale. The CFA suggested the hypothesized five-factor structure of the scale had acceptable to good fit ($X^2/df=2.45$, CFI=.90, RMSEA=.05, SRMR=.06). A second-order CFA supported an overall scale factor. **Conclusions:** This study provides preliminary support for the reliability, validity and sensitivity of the EBPPAS.

¹Evidence-based practice is defined as "the integration of best research evidence with clinical expertise and [client] values" (Sackett and colleagues, 2000, p.1).

P56: Citation rates of systematic reviews of interventions for hypertension and blood pressure

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Background: The Cochrane Hypertension Group is interested in examining characteristics contributing to some Hypertension systematic reviews being cited more often than others. Determining how often Hypertension reviews are cited in other research papers may help inform the process of selecting and updating reviews. **Objectives:** To ascertain how often a sample of Hypertension Group reviews are cited in other research publications; to determine whether or not there is a relationship between the number of included studies in a review and the number of times that review has been cited; to compare the number of times cited (TC) for reviews which only include pharmacological interventions with those which only include non-pharmacological interventions; to determine whether or not there is a difference between the TC for reviews in which the study population is limited to hypertensives and for those in which the study population also includes non-hypertensives. **Methods:** A sample of 20 Hypertension reviews will be chosen for the study. Google Scholar, which retrieves publications not yet indexed by Web of Science or Scopus, will be searched to ascertain the TC per year for each review. Attributes of frequently- and infrequently-cited Hypertension Group reviews will be examined. **Results:** Complete results of the study will be available in October 2010, including the total TC for all sampled reviews, average TC for each review, TC per number of included studies for each review, and the number of citations per year for each review. **Conclusions:** The results of the study will be used to assist the Cochrane Hypertension Group in selecting new topics for reviews and in prioritising the updating of existing reviews. Citation analysis provides insight into the characteristics of highly-cited Hypertension reviews.

P57: Modelling to assist knowledge translation of diagnostic test accuracy reviews (DTARs): a necessary evil?

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Background: Translating the results of test accuracy evaluations, and reviews thereof, into recommendations for practice is acknowledged to be challenging. Part of this challenge is that policy decisions are ideally based on clinical effectiveness (impact on patient outcome) and cost-effectiveness, whereas DTARs deliver estimates of the error rates associated with making diagnoses using particular tests. This information although necessary, is unlikely to be considered sufficient by policy-makers. One suggested solution is to encourage reviewers to introduce information about the consequences of true positive, true negative, false positive and false negative results in order to anticipate what patient outcome might be. The GRADE system does this too, but also encourages quantification and suggests consideration of costs.

Economic modelling is a more formal approach to the structuring of a decision and provides a framework for collating separate sources of information on different aspects of the wider impact of a new initiative. It does not have to incorporate costs. There is a long history of using it as an evaluative tool for tests because it is uncommon for the effect of tests on patient outcome to be assessed directly. Most commonly we have evidence on accuracy, and independently evidence on the effectiveness of treatments which might be applied when the test result is positive.

Objective: To consider the potential role of modelling in assisting knowledge translation of DTARs. **Methods:** Case-study. **Results:** A simple model will be prepared, or adapted should an existing model be available, to complement one of the existing Cochrane DTARs **Conclusions:** Provisionally modelling is likely to be of assistance in knowledge translation and may indeed challenge the appropriateness of current approaches. The difficulty for the Cochrane Collaboration

would be how to incorporate the results of modelling exercises into an already complicated and daunting review format.

P58: Systematic review when there is no evidence . . . (2) Developing a methodology for a qualitative analysis of expert reviews on IMEs

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Background: We have undertaken a systematic review of Independent Medical Evaluations (IMEs); however, 74 of the 88 published studies that we retrieved on this topic are low quality: narrative reviews, editorials, case reports, or letters to the Editor. **Objective:** To develop a coding system for reviewing narrative reports on IMEs. **Methods:** In an iterative process on a heterogeneous test set of reviews, 2 reviewers independently identified major themes. We developed coding rules through discussion and disagreement was solved with a third reviewer. After several rounds of coding eligible articles, clusters around themes emerged. We built a coding tree with domains, sub-domains and items. When the tree structure became stable, as evidenced by new articles generating no new codes and disagreement among reviewers became minimal, we applied our coding strategy to all eligible studies.

Results: In 7 rounds of code-development we identified 8 domains, 49 sub-domains, and 67 items within sub-domains. Table 1 demonstrates examples of the final the coding tree. Two reviewers applied the coding tree to each eligible study, independently and in duplicate. Following agreement on coding for an article, we stored codes and the associated text in a database and produced a transcript, sorted according to sub-domains and items. **Conclusions:** Our empirically developed

Table 1 (P58): Illustration of the coding tree for generating the transcript of the meta-review on IMEs. This will serve as the starting point for a qualitative analysis.

Level 1 8 Domains	Level 2 Sub-domains (n)	Level 3 Items (n)
	n	Examples
0. Definition	—	—
I. Objectives	9	Adjudicate claims [I.1.]; establish restrictions [I.7.]; establish maximal medical improvement [I.8.];
II. Contextual Issues	5	Limitations of treating physicians [II.1.]; medical vs. non-medical factors [II.4.]
III. Problems	10	Partiality of IMEs assessors [III.1.], lack of standards [III.2.]; lack of transparency [III.5.]
IV. Ways to improve	9	Ensure impartiality of assessors [VI.1.]; standards for IME performance [IV.3]
V. Patients' rights & Ethics	5	Disclosure policies [V.1.]; consent forms [V.2.]; duty of care by IME assessors [V.4.]
VI. Legal issues	7	Legal challenges to IME in court [VI.1.]; doctor-patient relationship [VI.4.]; legal guidelines [VI.6.]
VII. Business	4	How to set up an IME business [VII.1.]; IMEs are financially lucrative [VII.4.]
	49	
		67
	Total of 117 codes	

coding system captures and reorganizes all relevant themes on IMEs addressed in narrative reviews, case reports and letter to the Editor. The resulting transcript will form the basis for a comprehensive qualitative analysis¹ which we anticipate will be completed for the colloquium.

¹See abstracts Kunz, Guyatt, Busse (1)

P59: Efficacy of Steroids in esophagic burns caused by caustics in children

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Background: Caustics produce injuries such as burns. It may cause inflammatory fibrosis injuries and esophagus stenosis permanently. Steroids use is controversial in these cases. Immediate cortisone use after the event in laboratory species may relief granulomas. This is the reason why it is highly recommended to use it. Other authors describe that steroids do not get any relief in esophagus morbidity. This is the main dilemma in these patients. **Objectives:** Assess the therapeutic efficacy of steroids in children whit caustic injury of the esophagus and its stenosis. **Types of Studies:** Randomized Controlled Clinical Trials and Quasi randomized with steroids(prednisone, hidrocortisone, metilprednisolone and dexametasone) in children who swallowed

caustics. **Patients:** Children (1mo thru 18yr) who swallowed caustics **Quality of Methodology:** At least two reviewers independently assessed clinical trial quality with CASP (Critical Apraisal Skills Programme) for clinical trials, and with Jadad's scale. **Results:** 18 papers were identified, only 2 were included: Anderson 1990 and Bautista 1996. These papers had 96 patients. There was not disagreement in inclusion. **Author's Conclusions:** Steroids show a relevant effect in children who swallowed caustics. Bautista has many variables included in analysis while Anderson does not. In all cases antibiotic therapy is mandatory in high doses. 3rd degree esophagic injuries cause stenosis and stricture more frequently than others.

P60: The analysis of influencing factors of Cochrane Library usage from 2006 to 2008 in a medical center

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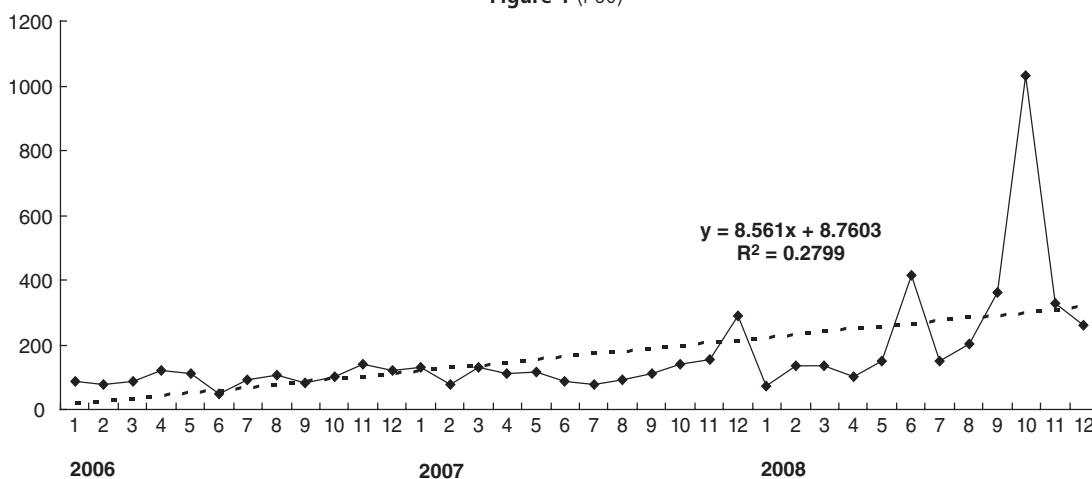
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Aim: Cochrane Library was the most important database for evidence based practice. The aim of this study is to investigate the utilization of Cochrane Library in a medical center in Kaohsiung Taiwan. **Methods:** The data collected Cochrane Library usage and UpToDate usage in a

Table 1 (P60)

CASP de Ensayos Clínicos: Anderson y Bautista			
Preguntas CASP		Anderson	Bautista
1.- ¿Se orienta el ensayo a una pregunta claramente definida?		SI	SI
2.- ¿Fue aleatoria la asignación a los tratamientos?		SI	NO SE
3.- ¿Fueron adecuadamente considerados hasta el final del estudio todos los pacientes?		SI	SI
4.- ¿Se mantuvieron ciegos al tratamiento los pacientes, los clínicos y el personal del estudio?		SI	SI
5.- ¿Fueron similares los grupos al comienzo del estudio?		SI	SI
6.- ¿Al margen de la intervención en estudio los grupos fueron tratados de manera similar?		SI	SI
7.- ¿Cómo de grande fue el efecto del tratamiento?		NO SE	NO SE
8.- ¿Cómo es la precisión de la estimación del efecto del tratamiento?		NO SE	NO SE
9.- ¿Pueden aplicarse estos resultados en tu medio o población local?		SI	SI
10.- ¿Se tuvieron en cuenta todos los resultados de importancia clínica?		NO	NO
11.- ¿Los beneficios a obtener justifican los riesgos y los costes?		NO	SI
Escala de Jadad para valoración de la calidad de un ensayo clínico			
		Anderson	Bautista
Aleatorización	No= 0; Si= 1;	1	1
Doble Ciego	No= 0; Si= 1;	1	1
Descripción de Retiradas y pérdidas	No= 0; Si= 1;	0	0
Aleatorización Apropiada	No= 0; Si= 1;	0	0
Enmascaramiento Apropiado	No= 0; Si= 1;	1	1
	Total	3	3

Figure 1 (P60)



medical center censored by the electric automatic censor system in a hospital library from 2006 Jan to 2008 Dec. **Results:** The Cochrane Library usage increased significantly ($r^2 = 0.280$, $P = 0.001$) in this hospital, and the total usage was 6,211 in the 3 years period. The peak usage in 2006 was in Nov ($n = 139$) that we have an evidence based practice contest on Dec 30th 2006. The peak usage in 2007 was in Dec ($n = 289$) that a contest on Jan 26th 2008. The 2 highest hit in 2008 were in Jun 2008 ($n = 415$) and Oct 2008 ($n = 1,030$) that there were 2 potential teacher training courses on the same months. MD consult database also had the same trend hit as the Cochrane Library hit and increased usage in the 3 years period ($r^2 = 0.604$, $P < 0.001$). The total usage was 23,138 in the 3 years period. We did not find the same usage variation of UpToDate database ($r^2 = 0.001$, $P = 0.873$) in the same period in the hospital. The total usage of UpToDate was 63,943 in the 3 years period. The usage occupation is doctors (55.0%), nurses (32.7), technician (9.9%), and administrators (2.4%) in Cochrane Library. The usage of UpToDate is different from Cochrane Library usage as in doctor (89.3%), nurses (5.3), technician (5.0%), and administrators (0.4%). **Conclusions:** The usage of Cochrane Library is increasing year by year but is still not as popular as UpToDate in our hospital except in teaching courses or contests motivation. The usage of Cochrane Library is about 1/10 of the usage of UpToDate in a medical center.

P61: From education to action: the Cuban centre of clinical trials promoting the evidence for taking decisions in health.

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Background: To generalize and to systematize the evidence-based decision-making depends not only on knowledge about the best available evidences. This is related to organizational structures and models, physical and political conditions and national legislations that contribute or not to foment that culture, to generate a change of mind and to implement the model. But knowledge is essential for getting this change and it's needed in Cuba. Publication of Cuban clinical trials is dispersed and inconsistent, the editorial

policy doesn't adhere to international standards; the production of systematic reviews is missing the same as the formation about it; the contribution to the Cochrane Collaboration is poor, the knowledge of this organization, their information resources and other potentialities are undervalued. Some initiatives in this way have been carried out in Cuba such as the creation of the Cochrane Group, the accessibility to evidence information resources and some hand-searching projects but are not enough. Education and instruction continue being essential premises to guarantee the necessary cognitive component, to convince and to stimulate the transition toward this new dimension in decision-making. **Objectives:** To encourage evidence based approaches in Cuban health system by providing knowledge and promoting the Cochrane Collaboration. **Methods:** A research-development project was proposed by the Coordinating Centre of clinical trials and approved by Ministry of Health. It's related to the creation of a national network for promoting the evidence and the Cochrane Collaboration, designing information services and educational resources and developing continuing education programmes. **Results:** Till now are facts: the creation of the first Cuban website devoted to information about theory, methodology and practice in the use and generation of evidence. The website includes a column for the promotion of the Cochrane Collaboration as well as educational lessons and Supercourse, and information resources. A national group of leaders in the field has been created and has engaged the former Cuban Cochrane Group in order to stimulate the work of that organization in the country. Four foreign experts have already been integrated as partners for fomenting the exchange of experiences. A new project for hand-searching has been recalled with the Iberoamerican Cochrane Centre and a policy for it has been proposed and approved by the CClb. A central web-database of previous and current hand-searched trials is designed to improve the access and contribute to develop systematic reviews in prioritized health topics in Cuba and others developing countries. A continuing education e-learning programme which includes topics such as evidence-based medicine methodology, systematic reviews, meta-analysis was designed. Some motivational seminars and oral communications in national events have been developed for introducing related topics and promoting information sources. A combined work has settled down with medical sciences journals to modify their editorial policy toward the endorsement to international standards. Strategies for promoting and extending the Cuban Registry of Clinical Trials

are planned. **Conclusions:** These Cuban initiatives increase the use of available evidences; they enlarge the knowledge about it; they stimulate the clinical trials publication, improve their quality, minimise the biases and promotes the development of systematic reviews when they are relevant for Cuba and other developing countries. The network seeks to be a reference point on the CC through giving conferences, chats, trainings and other promotional materials. It's now a priority: motivational activities and diagnosis of knowledge and attitudes on the evidence to know how to direct motivation. A diagnostic questionnaire has been designed and validated by experts and it has been applied in a sample of institutions. Another priority is to promote the production of evidence and influence the editorial policy of the Cuban medical journals. This last issue is related to my dissertation topic. Now we are preparing a workshop on international requirements and standards in the publication of clinical trials for publishers and editors of medical journals.

P62: Meta-analysis of proportions: a review and comparison of statistical methods for combining results from several binomial trials

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Background: Although Cochrane intervention reviews focus on randomized trials, the interest may lie in non-comparative binary outcomes. In treatment evaluation, pooling absolute risks from several single-arm studies may be required. In diagnostic accuracy assessment, separate meta-analyses of sensitivity/specificity estimates may be necessary when bivariate models do not converge. Appropriate statistical methods must be applied to combine binomial data from several trials. **Objectives:** We aimed to review available methods and to compare their statistical performance. **Methods:** Methods must handle overdispersion, where the observed variation exceeds that predicted from the binomial distribution, which might result from unmodelled heterogeneity. First, we considered the use of variance-stabilizing transformations followed by standard fixed-effect or random-effects meta-analysis of transformed proportions and back-transformation of the combined estimate. Second, we considered two hierarchical models, the beta-binomial and logistic-normal models, using both the frequentist and Bayesian approaches. We programmed all methods using R software. To compare methods, we carried out an empirical study. Monte Carlo simulation studies are underway. Scenario parameters included the number of individual studies, the study sample size, the true proportion and an overdispersion/heterogeneity parameter. The comparison criteria were bias, mean squared error, and coverage probability. **Results:** The empirical study was based on a meta-analysis of the perioperative risk of stroke or death after carotid angioplasty and stenting of carotid stenosis. In 42 studies totalling 4910 symptomatic patients, 366 patients experienced stroke or death within 30 days. There was evidence of large heterogeneity and overdispersion. The estimates of absolute risks of 30-day stroke or death ranged from 6.94%, 95%CI 5.68–8.44 to 7.65, 95%CI 6.31–9.10. **Conclusion:** A range of methods is available for the meta-analysis of proportions. Our results should provide general guidance to choose a relevant method, in particular when there are few studies or when the underlying true proportion is near 0 or 1.

P63: Maintenance of Exercise and related factors among Older People

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Background: Despite well documented health benefits of exercising, only one third of older adults participated in regular exercise globally. Studies investigated factors related to maintenance of exercise among older people found that social support, exercise experience, self-efficacy, outcome expectation and awareness of exercise may have played important roles in older people's exercise behaviours. Understanding impact of factors related to maintenance of exercise may contribute to decision making about tailored physical activity intervention that could enhance maintenance of physical activity among older people. **Objective:** To investigate the impact of exercise maintenance factors among older people living in rural area. **Methods:** A retrospective study design was used to survey a group of older people who have participated in a walking trial between 2003 and 2004. Data were collected through fact-to-face interviewing with the use of a structured questionnaire. Hypothesis was tested through statistical analysis of logistic regression with the use of SPSS 12.0 software. **Results:** A total of 108 participants was recruited. There were 76% of participants self-reporting to involve in regular physical activity and 69% of participants meet our requirement of being in a maintenance stage. Three factors were included in a logistic model to explain maintenance of mild physical activity and explained 53% variance of the dependent variable. Exercise self-efficacy was an only predictor of older people's moderate physical activity and explains a total variance of 24%. **Conclusions:** Design of physical activity intervention aiming at enhancing maintenance of physical activity among older people needs to take factors of exercise self-efficacy, exercise outcome expectation and number of chronic disease into consideration. Improving exercise self-efficacy may be particularly crucial in increasing maintenance of moderate physical activity in older people. Future study investigating factors related to maintenance of physical activity among older people living in urban area is warranted.

P64: A new definition of evidence in Evidence-based healthcare

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Background: With the rapid development of evidence-based healthcare during the past two decades, evidence and evidence-based methods were not only used in the field of health care, but also applied to other non-medical fields. Since we are talking about "evidence based decision-making" we first need to see what we really mean by the word "evidence" and what connotations and extensions it contains. **Objective:** To find out whether the evidence has been defined and compare with the advantages and disadvantages of these definitions. **Methods:** Eight databases (to March 2010) including MEDLINE, EMBASE, SCI, CBM, CNKI, VIP, WANGFANG, Cochrane library and relevant websites were searched. The search terms were "evidence-based medicine", "evidence-based healthcare", "concept", "definition", and so on. **Results:** Seven definitions were included (see table). **Conclusions:** Only two definitions were based on systematic reviews. The other definitions can not fully reflect the concept of

Table 1 (P64): The different definitions of evidence.

Time	Country	Institution & person	Definition	Source
1999	UK	UK Government Cabinet Office	<ul style="list-style-type: none"> ●professional advice. ●research articles. ●statistical data. ●advisory opinions. ●policy evaluation. ●network resources. ●consultation results. ●cost estimation. ●results based on statistical model 	Expert's Opinion
2000	Canada	David Sackett	By best research evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens.	Expert's Opinion
2000	UK	Higgs	A kind of knowledge from absorbing several streams of information	Expert's Opinion
2002	Canada	Zarkovich	Evidence could therefore be seen to possess two facets: the scientific, factual facet and the more personal, contextual facet.	Expert's Opinion
2004	UK	Jo	<ul style="list-style-type: none"> ●medical research. ●clinical experience. ●The experience of patients and their families. ●local circumstances 	Expert's Opinion
2005	Canada	Canadian Health Services Research Foundation	Evidence is information that comes closest to the facts of a matter.	systematic review
2008	Canada	Gordon Guyatt	Any empirical observation constitutes potential evidence, whether systematically collected or not.	Expert's Opinion
2009	China	Yaolong Chen	Evidence is the information from systematic reviews	systematic review

evidence because some are too wide or complicated and some are too narrow or simple, we recommend using the definition that *evidence is the information from systematic reviews*. The definition derives from the methods of systematic reviews and it is easy to understand and dissemination.

P65: Changing Professional Behaviour: An Updated Overview of Systematic Reviews

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Background: The Cochrane Effective Practice and Organisation of Care Group (EPOC) supports systematic reviews of professional, organizational, financial, and regulatory interventions to improve health care delivery and care systems. Since 2007, EPOC has worked with the Canadian Agency for Drugs and Technologies in Health (CADTH) to publish and update a website summarizing reviews of interventions to improve evidence-based prescribing practice and drug use. **Objectives:** To collect and summarize in an overview, interventions targeting prescribing and other professional behaviours. **Methods:** Systematic reviews published between 1966 and 2009 were identified from Medline, Embase, and The Cochrane Library. Two reviewers abstracted data from the reviews. Vote counting was used as the common metric for data synthesis. Interventions were classified as effective if more than two-thirds of included studies showed benefit. Reviews that were of moderate to high quality were included in the analysis. All relevant reviews are available at: www.rxforchange.ca.

Results: Over 300 reviews were identified; 150 met the quality criteria and addressed professional, organisational, financial or regulatory interventions. Generally effective interventions included printed educational materials, interactive educational meetings, educational outreach, local opinion leaders, and audit and feedback. There were eight high-quality reviews addressing multi-faceted interventions. Five of the identified intervention categories (all within organizational categories) contain no reviews. **Conclusions:** A number of interventions are generally effective for changing professional behaviour. For those interventions where data are not available, efforts should be made to conduct reviews to assess the effectiveness.

P66: Training practitioners in the EBP process: an effective continuing education training model

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Background: While much has been written on the potential benefits of the evidence-based practice (EBP) process¹ for improving the integration of research into practice, very little has been done to train behavioral health practitioners in this model. It is critical to identify effective training methods to maximize the successful adoption and implementation of this model. **Objectives:** This study developed and evaluated the effectiveness of a full-day EBP process continuing education training workshop, which is based on diffusion of innovations theory, adult learning theory, and the extant EBP literature. **Methods:** A replicated pretest, posttest, 3-month follow-up design was used to assess the impact of the training on behavioral health practitioners' self-efficacy and knowledge pertaining to EBP, attitudes

toward EBP, perceived feasibility of EBP, intentions to engage in EBP, and self-reported engagement in EBP. The design was replicated with four disparate continuing education training groups in two large urban cities. The EBP Assessment Scale ($\alpha = .94$, Rubin & Parrish, 2009) and 10 knowledge questions were used to measure the dependent variables. All data were collected using anonymous data collection procedures, and doubly-multivariate repeated measures analyses were used to analyze the impact of the training over time. **Results:** The repeated measures MANOVA and the univariate post-hoc analyses found significant ($p < .001$) change and moderate to strong effect sizes for each of the dependent variables in the desired direction for all trainings combined and for each independent training. There was also significant ($p < .001$) change from pretest to 3-month follow up with regard to self-reported engagement in EBP. **Conclusions:** This EBP training model appears promising for training practitioners in the EBP process, but future research should test its effectiveness with other practitioners and settings.

¹The EBP process is defined as “the integration of best research evidence with clinical expertise and [client] values” (Sackett and colleagues, 2000, p.1)

P67: Establishing Chinese Clearinghouse for Evidence-Based Practice and Policy

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Background: The scope of the Cochrane Collaboration recently has been extended from prevention and treatment of diseases to public health, health decision-making, and areas beyond the medical health field. The population served by the collaboration has thus been extended from health professionals to policy makers, even all health consumers. The Cochrane Collaboration has established partnerships with governmental health departments, the World Health Organization, the Campbell Collaboration, and other organizations. The Chinese Cochrane Centre has also established wide-ranging strategic cooperation with related institutes and organizations. **Objective:** To establish the Chinese Clearinghouse for Evidence-Based Practice and Policy (CCEBPP) for improving the quality and using efficiency of research evidence on social work practice and related human services. **Methods:** A project was introduced from abroad for dissemination and training of the knowledge related to evidence-based practice and policy. Then, evidence addressing specific problems identified from China was produced and practiced in these fields. **Results:** Chinese Cochrane Centre had joined hands with USC School of Social Work, Hamovitch Center, for establishing CCEBPP. The plan included two steps. For the first step, a working group and a website would be established; the related contents of the California Evidence-Based Clearinghouse for Child Welfare would be translated and introduced into China; as well as a series of workshops would be held. For the second step, an advisory committee and a scientific panel would be established; a series of programmes addressing the Chinese problems would be identified for local evidence production, practice and dissemination. **Conclusions:** The CCEBPP will become an important supplement of the Chinese Cochrane Centre. It will be helpful for improving the quality and using efficiency of research evidence on social work practice and related human services.

P68: Generalizability of results from randomized trials; A systematic overview of possible approaches

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Background: Randomized controlled trials (RCTs) constitute the preferred evidence source for recommendations regarding the effect of treatment. Unfortunately, patients participating in RCTs frequently differ importantly from most patients seen in practice. Therefore, guideline developers must decide whether results are generalizable to the target population not represented in RCTs. **Objective:** To identify methods to help decide the circumstances under which the results from RCTs can be generalized to patients who were not represented in these trials. **Methods:** A systematic search in Medline, Embase and other sources was done to identify possible methods that help to decide whether results are generalizable. **Results:** A frequently recommended approach is that the trial population should be representative of the broad patient group. This approach implies that numerous exclusion criteria applied in trials would diminish the generalizability. To evaluate the extent of the generalizability, one examines the in- and exclusion criteria of trials and infers from these whether the trial population was sufficiently representative. Other authors suggest that, because they include a broader range of patients, observational studies constitute the optimal source of evidence if no RCTs have directly addressed the target population. Another approach suggests applying the results of RCTs to patients in practice unless there is a compelling reason to believe the results would differ substantially as a function of particular characteristics. This approach is supported by empirical evidence that, in general, treatment effects seldom differ to an important extent across subgroups of patients. **Conclusion:** We propose this last approach, focusing on RCTs unless there is compelling reason not to do so. Compelling reasons will most often be found with respect to issues of rare adverse effects, for which observational studies are likely to provide the best estimates.

P69: Investigating and improving the understanding of Cochrane Diagnostic Test Accuracy Reviews (DTARs)

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Background: Over the past 5 years, The Cochrane Collaboration has been developing its approach to the synthesis of test evaluations culminating in the publication of the first Cochrane DTAR in 2008. During the process of providing support it has become clear that the complexity of many parts of the DTARs will be challenging even for those who are familiar with the general Cochrane review format. There is a need to further explore understanding of completed Cochrane

DTARs in order to refine their presentation and improve impact. **Objective:** To explore understanding of the three currently available Cochrane DTARs. **Method:** We have been funded to examine the perceptions of two groups: policy-makers and their advisers and clinical groups to whom the three reviews should be relevant. The initial step will be to get opinions on what are the key features of each of the completed reviews from authors. The second will involve sending a brief questionnaire to about 150 individuals to identify potential candidates for in-depth interviews. They will be asked about their overall understanding of one of the three completed DTARs. The third step will comprise approximately 40 individual, face to face interviews drawing on cognitive interview techniques with purposive sampling of respondents. For those in whom the initial questionnaire indicates little experience in interpreting test accuracy reviews the main focus will be on whether they can locate, understand and interpret the key elements of the DTAR. For those in whom the initial questionnaire indicates an advanced level of understanding of test accuracy reviews, the focus will be on eliciting suggestions for improvement and exploring the reason for any disagreements about the DTAR's interpretation. **Results:** The one year project will start in mid-2010. We will expand on the approach we intend to adopt at the Colloquium and present any early findings.

P71: Measuring update ability of evidence-based practice online point-of-care information services

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Background: Point-of-care information services (PoCISs) provide to physicians comprehensive and condense evidence into easily digestible formats. Publishers encourage physicians to use them in their clinical decision-making and tag these services as regularly updated. **Objective:** This study measures the updating ability of relevant evidence for medical practice by international PoCISs. **Methods:** Out of 18 PoCISs available in 2008, we selected the top-five ranking for coverage, editorial quality and evidence-based methodology: Clinical Evidence, Dynamed, EBM Guidelines, EMedicine, UpToDate. Updating ability was defined as the incidence proportion of newsworthy systematic reviews (SRs) inserted in PoCIS content out of newsworthy SRs potentially eligible. These were all the SRs signalled by two literature surveillance journals (ACP Journal Club and Evidence-Based Medicine Primary Care and Internal Medicine) and

the Cochrane SRs labelled as "Conclusion changed" in the Cochrane Library from April to December 2009. For each SR we defined: "birth" as the publication date in the two literature surveillance journals or in the Cochrane Library; "death" as the occurrence of its citation in PoCIS. SRs were censored when two independent investigators agreed on the inclusion of that evidence. The monitoring of PoCIS started in June 2009 and will last one year. We report the planned interim analysis at December 2009. We assessed the updating cumulative rate using Kaplan-Meier survival analyses. Cox model was used to estimate hazard ratio (HR) between the first PoCIS and the top second ($p = 0.025$ two-sided for statistical significance). We intentionally avoid reference to the service name. Anonymity will be discharged with the final analyses. **Results:** The interim analysis included 125 SRs. One service has an updating process which strongly dominates the others (HR First vs two top seconds: 5.43, IC 95% 3.63–8.12 and 5.14, IC 95% 3.38–7.83, both $p < 0.0001$). The fourth and fifth-ranked PoCIS delineated survival curves close to the bottom. **Conclusion:** These differences in updating ability are possibly justified by different approaches to content development. Nevertheless our results identify a clear update lead.

P72: Patient involvement in shared decision making: what ways promote patient participation and engagement?

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Background: Patient participation in shared decision making has been increasingly important and much research has been done in the last decade. Quite a number of different ways aiming to promote patient participation in shared decision making have been developed. **Objective:** To investigate different ways of promoting the participation of the patient in shared decision making. **Methods:** We searched MEDLINE, EMBASE and CBM using the search term 'shared decision making', 'shared determinant', 'patient value preference in decision making' and 'patient and doctors' communication'. We selectively reviewed the evidence which likely to promote patient participation in shared decision making. Synthesis and conceptual framework was developed, illustrating the known and putative ways that could promote the engagement of patient in shared decision making. **Results:** 179 articles were selected describing different ways and five categories of ways were identified that

Category	Articles No. (%)	Priority ways
All articles	179 (100)	—
Communication-related	77 (43)	Graphic forms, decision boards, telemedicine, shared record files, electronic health records
Education-related	44 (24)	Interactive videos, medical websites, medical literatures, information leaflets, guidelines
Teamwork-related	25 (14)	Transdisciplinary models, nurse-led interventions
Assessment-related	19 (11)	Shared decision-making questionnaires, decision support analysis tools, audio-taped investigations
Family-related	14 (8)	Engagement of family members in shared decision making

promote patient involvement in shared decision making such as: 1) communication-related (e.g. graphic forms); 2) education-related (e.g. interactive videos); 3) teamwork-related (e.g. transdisciplinary models); 4) assessment-related (e.g. shared decision-making questionnaires), 5) family-related (e.g. surrogate decision-makers). Details in Table 1. **Conclusions:** There is a great number of ways to promote patient involvement in shared decision making. However, further researches are needed to examine their limits, advantages and disadvantages of the possible ways.

P73: 'Parto do Princípio': Brazilian women network for active maternity

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Background: 'Parto do Princípio' is a network of social activists created in December of 2005. 250 volunteers, spread over 16 Brazilian states, work together over the Internet through online forums. These women bring their expertise from areas such as Communication, Law, IT, Medicine, Graphic Arts, Administration and Nursing. The network presents itself through an official website www.partodoprincipio.com.br, a blog and the social network Orkut, providing information, creating awareness and supporting women who want to give birth actively and consciously, based on scientific evidence and the World Health Organization's recommendations.

Actions: Through these channels, 'Parto do Princípio' helps women find answers to their questions and doubts and allows them to discuss with other likeminded women. The network also endorses and spreads the 'Ten Steps of the Mother-Friendly Care' issued by the Coalition for Improving Maternity Services - CIMS, as well as the 'Companion Law', in effect in Brazil since April 2005, which warrants laboring women the right to have an accompanying person of her choice during labor, childbirth and postpartum in any Brazilian public hospital. 'Parto do Princípio' organizes annual photo exhibits in several Brazilian cities, following the yearly theme launched by the 'Alliance Francophone pour l'Accouchement Respecté' – www.afar.info. Throughout Brazil, 'Parto do Princípio' promotes GAPPs, an acronym for "Parto do Princípio Childbirth Support Groups". This is the way the network spreads the word to a wider audience, reaching out to women who not necessarily have access to the internet and to those who would like to talk to a "live" person about everything concerning pregnancy and childbirth. The groups advertise their meetings, which are always free of charge, over PP's website and by word of mouth. What women attending these meetings usually look for, apart from basic information, is support, exchange of experiences and tips on how to prepare themselves for a positive birth experience. One of the main accomplishments of the network so far has been the denunciation of the scandalous C-section rates in private hospitals in Brazil to the Office of the Attorney General through a 35 page long detailed report, in September of 2007.

Perspectives: In 2010, 'Parto do Princípio' intends to start several actions creating awareness about the 'Companion Law', as it is still unknown to a majority of pregnant women and widely disrespected by doctors and hospitals. 'Parto do Princípio' will also make sure the case about the abusive number of C-sections in the private sector – about 85% —shows some result.

P74: Correcting for bias in per protocol data: Instrumental variable meta-analysis

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Background: Intention-to-treat (ITT) is the standard data analysis method which includes all patients regardless of receiving treatment. Therefore, it is also a counter-intuitive type of analysis as it counts patients who did not receive treatment. Per protocol (PP) analysis includes only patients receiving treatment, but is considered to provide biased estimates. Instrumental variable (IV) analysis has been proposed as a technique to control for bias when using PP data. **Objectives:** To correct for bias by applying IV analysis methods using PP data from previously published individual patient data meta-analysis (IPDMA) (JCO2005;23:5074). **Methods:** We used center prescribing preference as an IV to assess the effects of methotrexate (MTX) in preventing chronic graft-versus-host-disease (cGVHD) in patients receiving stem cell (PBSCT) or bone marrow (BMT) transplant in 9 randomized controlled trials (1107 patients). IV methods are applied using 2-stage logistic, Probit and GMM models. **Results:** ITT analysis showed a statistically significant harmful effect with the use of day 11 MTX resulting in odds ratio (OR) of 1.34 (95% CI 1.02–1.76). The results using the PP data showed no difference in the rates of cGVHD with MTX use [OR 1.31 (95%CI 0.99–1.73)]. The IV estimates also showed no difference in the rates of cGVHD with use of MTX. IV IPDMA further corrected the results toward no difference in the odds of cGVHD between PBSCT vs. BMT, pointing to the possible beneficial effect of MTX in preventing cGVHD in PBSCT arm (OR 1.14; 95%CI 0.83–1.56; see table 1). **Conclusion:** IV estimates correct for bias and may be closer to "the truth" than both PP and ITT. The IV results indicate that MTX may be beneficial, contradicting the ITT analysis. To our knowledge, this is the first IV meta-analysis, which we report in the context of IPD MA.

P75: Reviews in the area of occupational health and safety literature: results of a four-year pilot

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Background: In 2004, the Institute for Work & Health (IWH) launched a prevention systematic review initiative. Funded by the Workplace Safety and Insurance Board (WSIB) of Ontario, this pilot built on the existing experience at IWH which has been conducting clinical reviews

Table 1 (P74)

Model	Odds Ratio	95% CI
Adjusted Logistic (ITT)	1.34	(1.02, 1.76)
Adjusted Logistic (PP)	1.31	(0.99, 1.73)
IV Probit ($\times 1.6$)	1.14	(0.83, 1.56)
IV Probit ($\times 1.8$)	1.16	(0.81, 1.65)
IV Two-stage Logistic	1.22	(0.64, 2.17)
IV Logistic GMM	1.20	(0.62, 2.34)

since 1994, and houses the Cochrane Back Review Group (CBRG). The prevention review initiative was undertaken in response to a concern raised by non-research partners in the prevention system that there was limited accessible evidence about the effectiveness of interventions for protecting workers' health. **Objectives:** This presentation will describe a systematic review program in the area of occupational health and safety. **Methods:** Aspects of the four year pilot will be explored. We will focus on the description of the IWH Stages of the systematic review and challenges and benefits of our approach. We will elaborate upon the adaptations required from the clinical reviews process from CBRG and the reasons for each adaptation. Overall challenges of program initiation and sustainability will also be assessed. **Results:** To date the program has delivered 17 reports to the WSIB and the broader Occupational Health and Safety audiences, held 32 stakeholder consultations and meetings, produced nine peer-reviewed publications and given 32 conference presentations. We have published three methods papers from our experiences from this pilot project that describe adaptations. **Conclusions:** This four-year pilot produced systematic reviews of the effectiveness of interventions to prevent workplace injury, illness and disability. Conducting reviews in the area of occupational health and safety literature requires significant adaptation of the methods used to conduct clinical reviews.

P76: The utility for identification of best available evidence of a register of controlled studies that evaluate interventions to prevent alcohol-impaired driving

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Background: To facilitate identification of effective interventions to prevent alcohol-impaired driving, we created a register of relevant research studies and systematic reviews by searching 11 bibliographic databases, contacting 97 government agencies, and handsearching conference proceedings. **Objective:** To test the register's utility in relation to existing systematic reviews. **Methods:** We selected three published reviews evaluating school-based programs, designated driver programs, and mass media campaigns, respectively. Together they cited 22 studies with designs eligible for the register (i.e., randomized, quasi-randomized, controlled before-after and interrupted time series studies). To evaluate the register's comprehensiveness (proportion of review citations found in the register), we searched it for exact citations or related/follow-up studies. To assess the register's added value (studies eligible for but not cited in the published reviews), we screened the remaining 764 citations and the reference lists of systematic reviews included in the register, examining full-text reports to confirm eligibility based on the reviews' inclusion criteria. Finally, we screened the register for studies completed since the reviews were conducted, to assess its utility for updates. **Results:** The register included 16/22 (73%) review citations: 100% for designated-driver programs, 73% for school-based programs, and 60% for mass media campaigns. It included 15/18 (83%) journal articles but only 1/4 (25%) government/technical reports. The register yielded three additional eligible studies of school-based programs, increasing the total relevant studies identified by 14%. We also identified four new studies usable

for updates of two of the reviews. **Conclusion:** A register created through database and hand searches can enhance systematic reviews of interventions to prevent alcohol-impaired driving by increasing identification of available evidence and assisting updates. However, additional effort is needed to identify government reports and other gray literature. The register is regularly updated and incorporated into the Cochrane Injury Group's specialized register, making it accessible to researchers and policy-makers.

P77: The Cochrane HIV/AIDS Group and rapid advice for the World Health Organization: lessons learned

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Background: The World Health Organization (WHO)'s internal guidance for guideline development recommends using Cochrane methods to the extent possible, as well as using the GRADE approach to allow a structured and transparent judgment of the quality of evidence for each outcome of interest. The Cochrane Review Group on HIV/AIDS (CRG) has worked with WHO for nearly 10 years. In 2009, WHO asked the CRG for help in rapidly updating its guidelines for adult and adolescent antiretroviral therapy (ART) and for prevention of mother-to-child HIV transmission (PMTCT). **Objectives:** To inform the development of two WHO guideline updates by rapidly preparing more than a dozen systematic reviews as well as more than 50 GRADE evidence profiles. **Methods:** After long-distance discussions with WHO in early 2009 to formulate PICO questions, the CRG assembled 8 review teams and began its work. Expert GRADE consultants provided instruction and ongoing support. The project was finished in time for WHO's consultative meetings in October. Based on the CRG's work and consensus reached at the meetings, WHO released its "rapid advice" preliminary guidance for both new guidelines in November. **Results:** Developing PICO questions during in-person meetings may be more efficient than over telephone and e-mail; authors should receive methods training before projects begin; it may be hard to gather enough of the right people to do the work; strategies should be made in advance for obtaining important but not-yet-published data; GRADE evidence profiles for observational data can be complex and tricky to prepare; when devising contractual documents, CRG finance personnel should anticipate bureaucratic delay. WHO requested that in future review projects, a separate abstract be written for each GRADE profile to articulate its data. **Conclusions:** With sufficient preparation, CRGs can respond effectively to requests for rapid advice from WHO and other policy makers.

P78: The strategies and measures of promoting improvement of the quality of clinical trials in China

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Background: Numbers of authors so called "randomized controlled trials (RCT)" were published and grown quickly in past years in China.

We have found that only about 7% of them were authentic RCTs; we also found that only about 1% clinical studies were reviewed by ethics committee. There is potential risk of misleading health care providers, patients, health policy decision makers and systematic review authors by the false information. For the purpose of improving the quality of clinical studies of China, we have developed and are practicing series strategies and measures. **Methods:** 1. Promoting transparency in three stages of clinical trials: register the trial before beginning of a trial, transparent the processing of trial, promoting good reporting practice of the trial. 2. Promoting improvement and practicing of the ethics review system in China. **Results:** A clinical trials quality control system has been constructed and working in China: 1. We established Chinese Clinical Trial Registry (ChiCTR) in October, 2004, register free clinical trials. ChiCTR joined WHO ICTRP to be a Primary Registry from July, 2007. Up to now, 810 trials have been registered. 2. We initiated "Chinese Clinical Trial Registration and Publication Collaboration (ChiCTRPC)" in June 2006 by ChiCTR and 48 key Chinese medical journals aim to promote using of mandatory policy of trial registration in China. 3. We established a voluntary use ChiCTR eCRF System for providing a free service of management of clinical trial raw data. In which system, the case records and the real-time results of the trials to be sent to the central depositor, the raw data and calculated data except the private information of the participants can be public accessed. 4. We established Chinese Ethics Committee of Registering Clinical Trials (ChiECRCT) in 2008 to review the registering trials those do not be reviewed by other ethics committees.

P79: A framework for determining the applicability and practical feasibility of a systematic review: experience from the area of risk assessment for food and feed safety

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Background: Systematic reviews (SRs) are suitable for summarising evidence for clearly specified clinical questions. Food and feed safety

risk assessments (FFSRA), however, address broader topics. No methodological framework exists for refining such broad problems into specific, reviewable questions, and for assessing the practical feasibility of SRs. **Objectives:** To develop a framework for refining broad problems, determining questions suitable for SRs, and prioritising questions for formal SRs in the area of FFSRA. **Methods:** The European Food Safety Authority (EFSA) formed a working group of SR methodologists from The Cochrane Collaboration, other research groups, and experts in FFSRA, and developed, through multiple group discussions, an initial generic framework for the application of SRs to broad food and feed safety problems. **Results:** The first step in assessing suitability for SRs involves determining the question type, which may include interventions or exposures with the well-known "PICO" structure; test accuracy questions ("PIT" structure – Population(s), Index test(s), Target condition(s)); and descriptive questions ("PO" structure – Population(s), Outcome or condition(s) of interest). The "key elements" (e.g. P, I, C and O) form either "closed-framed" questions (where all key elements are specified) or "open-framed" questions (one or more key elements are unspecified). Open-framed questions are less suitable than closed-framed questions for SR, but may be refined into closed-framed questions by specifying the missing key elements (e.g. through further research) or by revising the question. We also propose a procedure for prioritising which questions to answer by SR, through considering the relative importance of different parameters and issues of practical feasibility. **Conclusions:** A framework for planning and prioritising SRs in FFSRA is being developed, and will continue to evolve as experience is gained through initial implementation. It may have useful implications for improving transparency in FFSRA and for early stages of planning Cochrane reviews.

P80: Quality assessment of clinical practice guidelines for mammography screening in women aged 40–49 years

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Background: With the recent controversy surrounding mammography screening, the quality of clinical practice guidelines (CPGL) is critical.

Objectives: To assess the quality of CPGL for mammography screening in women aged 40–49 years. **Methods:** We searched the National Guideline Clearinghouse and Medline for CPGL published from 2005 to 2010, including guidelines that provided recommendations on the frequency of mammography screening in asymptomatic women aged 40–49 years at average risk. Five independent reviewers rated the quality of the guidelines and underlying evidence reviews using AGREE and AMSTAR instruments, respectively. **Results:** Eleven guidelines fulfilled inclusion criteria. Ten were appraised; one provided insufficient data for assessment. All guidelines referenced an underlying review; two referenced the same review. Three reviews were rated good, one was moderate, five were poor quality. Most reviews did not provide a list of included or excluded studies, describe the methods used to combine the findings, or assess publication bias. Many failed to state conflicts

of interest or inclusion of grey literature. On overall assessment of the guidelines, two were strongly recommended, one was recommended, and seven were not recommended or the reviewers were unsure. Most guidelines clearly presented their scope and recommendations, but the rigor of development, applicability, and stakeholder involvement varied considerably across CPGL. Eight guidelines recommended routine screening in the target population and two recommended against such screening. The latter two guidelines had good quality reviews and were strongly recommended. **Conclusions:** CPGL on mammography screening in the target population were of variable quality and the majority were not recommended by reviewers. The underlying evidence reviews were of variable quality and half were rated of poor quality. The two guidelines recommending against routine screening, were of good quality and strongly recommended by the reviewers.

P81: Economic support for Cochrane review authors: which is the magnitude of its effect?

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Background: One of the main problems encountered by people living in Low and Middle-Income Countries (LMIC) who want to conduct a Cochrane systematic review (SR) is the lack of protected time. At a rough estimate, less than 10% of the Cochrane reviews are authored by people from a developing country. **Objectives:** To: 1.-conduct a survey to gather general information about the economic assistance offered by Cochrane entities to review authors. 2.-assess the impact of economic assistance on the number of published SRs. 3.-establish the scope and relevance of the healthcare topics addressed by these reviews. **Method:** Contact details of all Cochrane entities listed in the Web page of the Cochrane Collaboration (<http://www.cochrane.org/contact/entities.htm>), were extracted into a worksheet in February 2010. Based on this information, an e-mail to invite the contact person of each Cochrane entity to participate in a survey about the economic support provided to review authors was sent in March 2010 (maximum three attempts). A short survey was developed to collect the following relevant data: provision of funds to support review authors (Yes/No), type of economic support (bursary, scholarship, grant, other), total number of applicants, list of countries of the applicants, total number of recipients, list of countries of the recipients, number and titles of SRs published in the Cochrane Library. These data will be entered into a database and double checked. All responses will remain confidential and only aggregated data will be presented. **Results:** Up to now, more than 70% of all Cochrane entities answered the invitation e-mail (76/106). Among these, 92% agreed to participate (70/76). Only 6 entities sent their apologies for not being able to collaborate. The survey was launched May. **Conclusions:** The results of this survey will provide practical information about the financial contribution for review authors within the Cochrane Collaboration and the applicability of reviews which do get funded to LMIC.

P82: Creating a national research agenda for improvement science

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Background: Quality improvement and patient safety are high priorities, yet insufficient progress has been made in improvement science. Improvement projects are often focused at microsystem levels, precluding sufficient data for rigorous and generalizable conclusions. Furthermore, advancements in the field are hampered by the lack of a national research agenda with clearly defined priorities to systematically build knowledge. **Objectives:** The NIH-funded Improvement Science research Network (ISRN) is a national network for improvement and translational science. This has established a national research agenda in improvement science. **Methods:** Multiple data sources contributed to selection of priorities for the national research agenda. A national web-based survey was conducted with stakeholders in quality and patient safety research (n=560). Environmental scans of existing research priorities in the field were conducted. Using these data, a consensus-building meeting was held with academic and practice scholars and leaders to determine priorities for a national improvement research agenda. **Results:** Survey respondents were deemed to be representative of the targeted interprofessional group thought to be leaders in improvement science. The expert panel deliberations led to development of a national improvement science research agenda. Priorities are classified in the following topics: coordination and transitions of care, high-performing clinical systems and microsystems, integration of best practices into care, and learning organizations and culture of quality and safety. **Conclusions:** This represents the first national agenda for the development of improvement science. The ISRN creates collaborative research teams of academicians and clinicians in acute-care settings to conduct improvement studies and uses a unique technology infrastructure (see <http://www.improvementscienceresearch.net>). The ISRN research agenda will inform the selection of a demonstration project to test the infrastructure for implementing multi-site studies. The results of this multi-site research will advance knowledge translation and ultimately inform policy decisions related to quality improvement.

P83: Critical analysis of the factors associated with enteral feeding in preventing VAP: a systematic review

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Background: Early enteral feeding is considered the best nutritional support among critically ill patients, and is mostly achieved via nasogastric (NG) tube. However, nasogastric tube feeding per se may be related to a number of complications, especially increasing the possibilities of aspiration among endotracheal intubated patients. **Objectives:** The objective of this systematic review was to synthesize the factors associated with enteral feeding in order to prevent VAP and to describe the characteristics of these factors. **Methods:** A comprehensive search was undertaken involving all major databases

from their inception to September 2008 using medical subject heading terms associated with enteral feeding in relation to VAP. Eligible studies included randomized controlled trials, controlled before-and-after (pre-post) studies and meta-analyses. To generate the characteristics of the factors associated with VAP, the reported components of these trials were pinpointed and categorized. **Results:** A total of 14 papers were found that had investigated the factors linking enteral feeding and VAP. For these, 11 were randomized controlled trials, one was a meta-analysis and 2 were case-controlled analyses. The sample sizes varied from 10 to 2,528 subjects. Three major issues were identified based on the purpose of study interventions, and these were the effects of feeding method (continuous vs. intermittent), feeding site on aspiration (gastric vs. small bowel) and the timing of enteral feeding (early vs. late). **Conclusions:** Intermittent enteral feeding and with a small residual volume feed can reduce gastroesophageal reflux and increase total intake volume and early feeding can reduce ICU mortality. Nonetheless, the effects of these choices on preventing VAP still need further evaluation. A set of clinical guidelines based on these evidence-based findings with respect to enteral feeding is required, particularly one that covers all aspects of the enteral feeding process.

P84: Evidence-based practice and continuous education program in Taiwan

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In order to promote the evidence-based nursing and make a connection with international network of evidence-based nursing, the evidence-based practice and continuous education program was established on September 2008 in Taiwan. Based on Joanna Briggs Institute evidence-based model, the main strategies of the program are to cultivate the evidence-based nursing core members and empower the motivations and operational power to promote evidence-based nursing around the four hospital-university units around Taiwan. The main goal of the Evidence-based practice and Continuous education program is to promote the *Globalization of clinical guidelines model* of development and applications of clinical guideline. The program is lead by the partnership between Department of Health and Taiwan Joanna Briggs Institute Collaborating Center. Four Operation University-Hospital centers are established around Taiwan. Based on the perspective of evidence-based nursing of Sigma Theta Tau International Position, a clinical guidelines development model has been established for development the clinical guidelines by using triangulation research approaches, including quantitative and qualitative systematic review for receiving the research evidence, focus group for inviting the experts opinions, survey method for examining the appropriateness of evidence based utilization. Furthermore, the comprehensive systematic review courses and the train-the-trainer courses are used to enhance the evidence-based nursing core members in Taiwan. Until 2009, sixty-six teachers and clinical nurses completed the systematic review training courses and ten completed the train-the-trainer course. 27 clinical guidelines have been completed. Furthermore, Nursing Care Chinese Language Field of Cochrane Nursing Care Network (CNCN) was established in 2009. The mission and the values of the program, strategies of the program operation, the content of the program, the

outcomes of the program, and an example of the clinical guideline of ventilator-dependent care development will be illustrated.

P85: Facilitating evidence-informed health policymaking: the SUPPORT tools

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Background: Knowing how to find and use research evidence can help policymakers and those who support them to do their jobs better and more efficiently. More systematic processes and tools are needed to support such evidence-informed policymaking.

Objective: To describe a series of tools developed by the SUPPORT Policy relevant Reviews and Trials (SUPPORT) project to help ensure that health policies are informed by the best available research evidence. **Methods:** The tools are based on experience from workshops for policymakers on evidence-informed health policy. The materials were adapted from these workshops as well as from other evidence-based healthcare resources and resources identified through searches of relevant databases (primarily PubMed), websites and through personal contacts. The tools were revised based on feedback from policymakers and researchers. **Results:** The SUPPORT tools address four areas: (1) Supporting evidence-informed policymaking; (2) Identifying needs for research evidence; (3) Finding and assessing research evidence, and; (4) Going from research evidence to decisions. Each tool is structured using a set of questions that guide readers through the tools and indicate how to undertake activities to support evidence-informed policymaking effectively and efficiently. These activities include, for example, using research evidence to clarify problems; assessing the applicability of the findings of a systematic review about the effects of options to address problems; and organising and using policy dialogues to support evidence-informed policymaking. The SUPPORT tools include examples and resources from disparate settings and are relevant to low-, middle- and high-income countries. **Conclusions:** The SUPPORT tools can aid the use of the best research evidence available to inform health policy decisions. They are available as a series of articles (www.health-policy-systems.com/supplements/7/S1) and a book (www.kunnskapssenteret.no/Publikasjoner/8879.cms), and have been translated into Chinese, French, Portuguese and Spanish.

P86: Differences in addressing heterogeneity in Cochrane reviews

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Introduction: In the past two years we have been conducting several overviews of physical therapy reviews. The majority of the included reviews investigated the effectiveness of exercise therapy. Although the Cochrane Handbook specifically outlines how clinical, methodological and statistical heterogeneity can be identified and addressed, we found that in these reviews it was not always clear how this was done. We also

noticed inconsistencies in addressing heterogeneity between Review Groups. The goal of this methodological study is to put our findings in a broader perspective and to systematically investigate the methods used regarding clinical, methodological and statistical heterogeneity in reviews within the field of exercise therapy. **Objectives:** To assess differences in methods used to address heterogeneity when considering a meta-analysis between in Cochrane reviews and between review groups and assess to what extent the used methods conform to the methods described in the handbook. **Method:** The Cochrane Library will be searched from 2008 to August 2010 for reviews using the following search terms: exercise OR exercise therapy. Published reviews restricted to exercise interventions will be included. The protocols of the included reviews will be recovered in Archie. Two reviewers will independently select reviews and extract data. A data extraction form will be used that includes the items described in the handbook regarding different types of heterogeneity, such as: identify inconsistency of results (visual or statistical tests), unit of analysis, pre-specified sensitivity analysis, using fixed or random effects meta-analysis, effect measures (mean difference or standardized mean difference), exclude studies from analysis. The extracted data will be categorised per review group. Differences between review groups and handbook methods will be described and discussed. **Results:** The results will support development of more consistency between review groups and further development of methods in meta-analyses to maintain the high quality of Cochrane reviews.

P87: Evaluating three informal capacity building networks for systematic reviews

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Background: Formal and sustainable structures based on a centre with branches model are important in ensuring the sustainability and continuity of the Cochrane Collaborations activities and output. However, political, economic, time and cultural factors may complicate and even limit the establishment of formal research groups. Informal groups can provide an alternative way of involving clinicians and researchers in the Collaboration and thereby increasing the output and dissemination of Cochrane reviews. **Objectives:** To evaluate the processes for building research capacity within three informal networks linked to the Cochrane Collaboration: The Iranian Cochrane informal network (ICInet), the Virtual training and mentoring international network (ViTaMIN project) and the Brazilian Oral Health Group. **Methods:** We used the framework proposed by Cooke 2005 to evaluate the three networks. We evaluated the research capacity build-up at structural level and also determined which principles had been used in building capacity. **Results:** All three networks

had individual and organization support levels; however, whilst the individual support was more robust, the organizational support level was informal. The three networks and the collaborative spirit within the Cochrane Collaboration ensured that the networks were able to develop linkages and produce partnerships to help support building of research capacity. This was by way of helping individuals develop the necessary skills which are essential to the systematic review process especially for clinicians, by improving levels of confidence and by ensuring that the research was relevant to current practice which was enabled through the involvement of clinicians and consumers. The networks also supported the dissemination of Cochrane reviews. However, the strategies to ensure sustainability and continuity were limited. **Conclusion:** Informal networks have the ability to support capacity building for systematic reviews; however, additional strategies need to be developed to ensure the sustainability and continuity of informal networks.

Cooke J. A framework to evaluate research capacity building in health care. *BMC Fam Pract.* 2005 Oct 27;6:44.

P88: Sensitivity and specificity rarely vary with prevalence

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Background: Anecdotal evidence shows that sensitivity and specificity tend to vary with prevalence, but empirical studies systematically examining this relationship are not available. **Objective:** To investigate the impact of prevalence on sensitivity and specificity in a large set of meta-analyses of diagnostic accuracy studies. **Methods:** From a set of 30 meta-analyses, containing 487 diagnostic accuracy studies, we selected meta-analyses with at least 10 studies that had included a consecutive series of eligible patients and in which the prevalence between studies varied at least 20 percentage points. We obtained summary estimates of sensitivity and specificity for each review, using the bivariate logitnormal method for meta-analysis, including prevalence as a covariate to investigate its effect on sensitivity and specificity. **Results:** Twenty-one reviews fulfilled our criteria. They contained between 10 and 39 studies, with a range in prevalence between 20 and 78 percentage points. Overall, prevalence had a significant effect on both sensitivity and specificity. However, when analyzing the reviews separately, prevalence had a significant effect on both sensitivity and specificity in only two reviews. In four reviews, prevalence had a significant effect on specificity only. In none of the reviews prevalence had a significant effect on sensitivity only. **Conclusions:** Diagnostic accuracy may change with varying prevalence, but it is not common to find significant effects on accuracy statistics in individual systematic reviews. This may in part be due to the limited power of meta-regression to explain heterogeneity with study level covariates, aggravated by the generally low prevalence (median 35%; 25th percentile 15%). Because the main underlying mechanism how prevalence may alter diagnostic accuracy are differences in disease spectrum and case-mix, we will further investigate these relationships as well and present those data during the Colloquium.

P89: Affiliational bias in arguments regarding the use of systematic reviews in health policy decision making

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Background: Systematic reviews inform public- and private-sector drug coverage and other health policy decisions. Arguments for and against this use of systematic reviews may be related to authors' affiliations, income sources, and ideological backgrounds. For example, when meta-analyses concluded that exposure to second-hand smoke was harmful, the tobacco industry produced the majority of the critiques that attacked the methodology. **Objectives:** In order to inform policymakers about the forms of bias that may fuel the discourse surrounding the policy uses of systematic reviews, we describe the basic arguments. We identify possible biases of the presenters of the arguments and rebuttals. **Methods:** We perform a critical review of articles that evaluate the scope, methods, or process of systematic reviews of pharmaceuticals and other health interventions. We examine the arguments that are being made, and the distinguishing characteristics of those making the arguments. **Results:** Arguments that aim to instill doubts about findings unfavorable to industry, criticize methods, and question interpretation of results are most often made by industry-affiliated critics. Other arguments focus on inappropriate cost containment and the lack of applicability of systematic reviews to develop drug formularies for programs that serve diverse or "non-standard" populations. Arguments supporting policy uses of systematic reviews are most often made by proponents of evidence-based medicine, academic researchers, and payers. Arguments focus on systematic reviews' standardized study designs and wide acceptance, their usefulness in developing policy that ensures access to effective medicines while limiting wasteful spending on ineffective and expensive treatments, and reviewers' lack of financial ties to industry. **Conclusion:** Values play a role in health policy decisions and the evidence that informs its development. Biases and financial conflicts of interest need to be transparent and taken into account when policy makers evaluate arguments regarding the use of systematic reviews in health policy and drug coverage decisions.

P90: New software for early stage of systematic reviews

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Background: Sometimes, the workload involved in performing a sound systematic review (SR) is underestimated. When performing a SR, one of the most important steps is a first very sensitive screening of the studies, usually done by pairs of independent reviewers. This process is not only time-consuming, but it also is complicated, tiresome, and prone to mistakes. A computer-software designed to cope

with the overwork of the initial phases of a SR would be of great help. There is a generalized lack of development in this regard, and the available options are not very accessible. Even RevMan 5.0.23 does not include such functionality yet. **Objectives:** The objective of this study is to show the advances in the development of a web-based software to serve in the initial phases of a SR process. **Methods:** We developed a new online software that helps in performing the first following consecutive stages of a SR: importation of citation from a reference manager software (Endnote), screening by title/abstract, first consensus, uploading of full-text, screening by full-text (tracking exclusion reasons), second consensus based on full-text, and distribution of full-text for quality assessment and data collection. Its main characteristics are: a) ability to manage different projects; b) differentiation of roles assigned to reviewers, administrators and librarians; c) possibility to work simultaneously in a multi-language environment; d) adequate, equitable and timely delivery of full-texts for evaluation and data abstraction (thus reducing email overload and delays); e) real-time tracking of the whole process for each role; f) building the study flowchart; g) possibility to work simultaneously in different SR's stages; h) configurable inclusion/exclusion criteria and other relevant features. **Results:** Results will be shown during the Colloquium. **Conclusions:** A computerized tool that organizes the initial phases in SR saves time, reduces workload for each involved role, and probably enhances SR's methodological quality.

P91: An innovative box plot for assessing data trends associated with selective dissemination of evidence

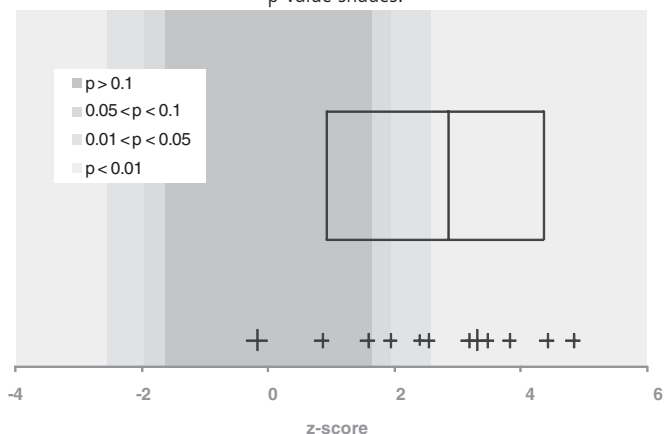
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Background: Box plots are widely used in exploratory data analyses of data from primary research. However, they are commonly not used in meta-analyses because of their inherent inability to integrate the relative weights of studies. **Methods:** We developed a horizontal box plot that uses the central 80% of the data points of the per-study

Figure 1 (P91): A box plot of the z-score with individual values and p-value shades.



standardized estimates (z-scores). The z-score is the effect estimate of an individual study, weighted by the inverse of the standard error. Similar to the Galbraith plot, this makes the units interpretable as standard normal deviations. Furthermore, the 0 value on the box plot's axis corresponds to the null-hypothesis, which makes it possible to integrate p-value limits in vertical shades. The individual study z-scores are shown at the bottom of the plot. **Results:** The plot can be used to identify data trends that are associated with the selective dissemination of evidence, e.g. missingness of studies with insignificant results. Asymmetry of the box around its central line indicates that the studies are distributed with different density around the median of the standardized effect. The plotted residuals at the bottom and the p-value shades can be used to assess whether the part of low study density coincides with high p-value (insignificant) ranges, indicating that the data trend may have been caused by selective dissemination processes.

Conclusions: The proposed box plot (Figure 1) is consistent with common meta-analytical techniques and allows for straightforward assessment of data trends associated with selective dissemination of evidence.

P92: Quality of reporting of trials abstracts needs to be improved: a survey of four leading Chinese medical journals of traditional Chinese medicine

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Background: The abstract of journal article may be the only way for people of non-Chinese speaking countries to know about trials in traditional Chinese medicine (TCM). However, little is known about the reporting quality of these trial abstracts. **Objective:** To assess the reporting quality of abstracts of randomized controlled trials (RCT) published in four Chinese TCM journals; to identify any differences in reporting between the Chinese and English version of the same abstract. **Method:** Two reviewers hand-searched the Chinese Journal of Integrated Traditional and Western Medicine, the Chinese Journal of Integrative Medicine, the China Journal of Chinese Materia Medica and the Chinese Acupuncture & Moxibustion for all abstracts of RCTs published between 2006 and 2007. Two reviewers independently assessed the reporting quality of all eligible abstracts based on the CONSORT extension for reporting abstracts of RCT. **Results:** We identified 345 RCTs with both a Chinese and English abstract. More than half of Chinese abstracts reported details of the trial participants (68%; 234/345), control group intervention (52%; 179/345), the number of participants randomized (73%; 253/345) and benefits when interpreting the trial results (55%; 190/345). Reporting of methodological quality and trial results were poor; only 2% (7/345) included details of the trial design, 3% (11/345) defined the primary outcome, 5% (17/345) described the methods of random sequence generation, and only 4% (13/345) reported the number of participants analyzed. No abstracts provided details on allocation concealment and trial registration. The percentage agreement in reporting the Chinese and English version of the same abstract ranged from 84% to 100% across individual checklist item. **Conclusion:** The reporting quality of

abstracts of RCTs published in these four TCM journals needs to be improved.

P93: Estimating the sample size of a clinical trial to make a meta-analysis conclusive. An example on meta-analysis of inhaled isoniazid chemoprophylaxis for tuberculosis in purified protein derivative negative HIV-infected individuals

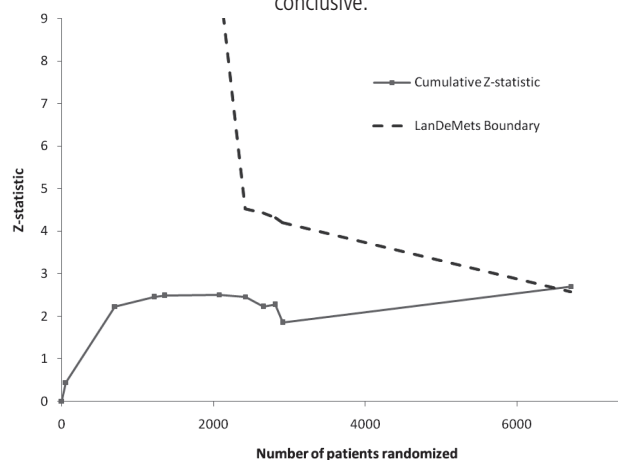
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Introduction: Many meta-analyses may provide misleading or inadequate inferences about the reliability of the evidence when an insufficient number of events and patients exist from trials that have been pooled. Nowadays most meta-analyses are frequently updated and subjected to significance testing as new trials emerge. This scenario is akin to interim analyses in randomized clinical trials (RCTs) where statistical monitoring boundaries and sample size requirements are used to efficiently and reliably establish whether the experimental treatment is superior. A growing body of evidence suggests that statistical monitoring boundaries yield similar utility when applied to meta-analysis. In addition, they can be useful for determining how many patients need to be randomized in future trials before the meta-analysis can be deemed conclusive and reliable.

Methods: We performed prospective meta-analysis of RCTs that evaluated the effectiveness of isoniazid chemoprophylaxis versus placebo for preventing tuberculosis among HIV-positive individuals testing purified protein derivative negative. We calculated the required meta-analysis sample size, generated adjusted thresholds for statistical significance using trial LanDeMets monitoring boundaries

Figure 1 (P93): LanDeMets monitoring boundaries applied to the meta-analysis of isoniazid chemoprophylaxis versus placebo for preventing tuberculosis among HIV-positive individuals testing purified protein derivative negative. A future trial with projected sample size of 3800 patients is added to make the meta-analysis cross the LanDeMets monitoring boundaries, thus making the meta-analysis statistically conclusive.



and approximated the total number of patients required in future trials to make the meta-analysis statistically significant according to the adjusted thresholds. **Results:** The meta-analysis included nine trials comprising 2911 participants and yielded a relative risk of 0.74 (95% CI, 0.53-1.04, $P = 0.08$). To deem the meta-analysis statistically significant according to the adjusted thresholds set by the monitoring boundaries, a future RCT would need to randomize 3,800 participants (figure 1). **Limitations:** The projected future trial sample size of 3800 is only reliable to the extent that the underlying assumptions made for the required meta-analysis sample size are reasonable approximations of the 'truth'. **Conclusion:** Statistical monitoring boundaries provide a framework for interpreting meta-analysis according to the adequacy of sample size and project the required sample size for a future RCT to make a meta-analysis conclusive.

P94: The GFC: Generally Failing to Comply with trial registration?

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Background: Trial registration is an ethical, moral and scientific obligation. Mandatory trial registration was introduced by the International Committee of Medical Journal Editors (ICMJE) in September-2005, in an effort to promote transparency of trial design and reporting, and reduce potential biases. **Objective:** To evaluate the number of randomised controlled trials (RCTs) that have been

Table 1 (P94): A- Factors associated with trial registration B- Factors associated with declaration of trial registration in related study publications.						
A: Study registered?		No (%)	Yes (%)	Unstandardised Odds ratio	95% CI	P value
		202 (77)	60 (23)			
Sample size						
<100		122 (49)	20 (8)	1	Referent	<0.0001
100-400		56 (22)	26 (10)	2.8	1.5, 5.5	
>400		12 (5)	14 (6)	7.1	2.9, 17.6	
Date of publication						
2006		64 (27)	16 (7)	1	Referent	0.06
2007		58 (25)	16 (7)	1.1	0.5, 2.4	
2008		52 (22)	28 (12)	2.2	1.1, 4.4	
Funding						
Government		17 (13)	17 (13)	1	Referent	0.34
Pharmaceutical		44 (33)	25 (19)	0.6	0.2, 1.3	
Other		19 (14)	10 (8)	0.5	0.2, 1.5	
Blinding						
Not blinded		158 (63)	41 (17)	1	Referent	0.017
Blinded		32 (13)	19 (8)	2.3	1.2, 4.4	
Randomised						
No		2 (1)	0 (0)	N/A		
Yes		186 (75)	60 (24)			
B: Study registration declared?		No (%)	Yes (%)	Unstandardised Odds ratio	95% CI	P value
		30 (50)	30 (50)			
Sample size						
<100		11 (18)	9 (15)	1	Referent	0.84
100-400		12 (20)	14 (23)	1.4	0.4, 4.6	
>400		7 (12)	7 (12)	1.2	0.3, 4.8	
Date of publication						
2006		9 (15)	7 (12)	1	Referent	0.21
2007		5 (8)	11 (18)	2.8	0.7, 12.0	
2008		16 (27)	12 (20)	1.0	0.3, 3.3	
Funding						
Government		4 (8)	13 (25)	1	Referent	0.01
Pharmaceutical		14 (27)	11 (21)	0.2	0.06, 1.0	
Other		5 (10)	5 (10)	0.3	0.06, 1.6	
Blinding						
Not blinded		24 (40)	17 (28)	1	Referent	0.05
Blinded		6 (10)	13 (22)	3.1	1.0, 9.7	
Randomised						
No		0 (0)	0 (0)	N/A		
Yes		30 (50)	30 (50)			
Statistically significant results? (P<0.05)						
No		10 (21)	8 (17)	1	Referent	0.76
Yes		18 (38)	12 (25)	0.8	0.3, 2.7	

registered and the proportion that declare this registration in related publications. **Methods:** We investigated a cohort of trial reports from the Cochrane Renal Group's specialised register. We included any kidney transplantation RCTs reported in peer-reviewed journals between October 2005 and December 2008. Registration status was established by searching the WHO international clinical trials registry platform, which links international clinical trial, registers. Registration declaration was established by examining study publications for trial registry identifiers. We assessed potential predictors of trial registration and of registration reporting using logistic regression. **Results:** 432 reports of 262 studies were included. 60 (24%) studies were registered. 30 (50%) registered studies declared their trial registration number within the study publication. Studies with larger sample sizes and those that were blinded were significantly more likely to be registered (Table 1a). Studies that were registered were significantly more likely to declare this on publication if blinded but significantly less so if funded by a Pharmaceutical company (Table 1b). Potential predictors of trial registration and registration declaration are reported in Tables 1. **Conclusions:** The majority of RCTs in kidney transplantation reported from 2005 onwards have not been prospectively registered, and even when registered often do not cite registration status when publishing study results. While these results may not be generalisable to other specialties, it does seem that there is a general failure of compliance with trial registration.

P95: Why The 20th Cochrane Colloquium will be held in Nanning, Guangxi, China

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Nanning is the capital city of Guangxi Zhuang Autonomous Region located in southern part of China. With an urban population of about 2.45 million composed of 36 ethnic groups (including Zhuang, Yao, Molao ethnics etc), Nanning has not only been listed among China's most livable cities, but also one of seven cities worldwide to win the 2007 Habitat Scroll of Honor Award offered by United Nations (UN). As one of China's opening-up frontier city, Nanning has been successfully competed as the permanent venue of China-ASEAN Expo in 2004 with its ever-green environment and international competitive abilities. A large trade fair among south eastern Asian countries has been held annually in Nanning every November. As Cochrane Colloquium firstly being held in China, Guangxi Medical University is very much honored to host the colloquium in Nanning. Since the EBM Center of GMU was funded by Ministry of Education of China in 2008, Guangxi Medical University(GMU) has been promoted as key member of development of Evidence Based Medicine(EBM) in China. To approach this goal, teaching reform has been conducted to meet the social needs and international standard. The EBM center of GMU has gathered many excellent EBM education groups and undergraduate students to take part in 15 subjects. So far, total thirty-nine papers written by students has been published on international journals cited by Science Citation Index(SCI) recently. As the new member of Cochrane Colloquia Family, we are keen on sharing the research achievements with you for improvement of our clinical research and practice, to enhance clinical trials transparency and cultivate high-quality experts of EBM in China. We believe that Nanning as a renowned city for its cultural fusion fills

with opportunities and Challenges will gives a better stage for EBM development in China. The government of Guangxi is very supportive to the 20th Cochrane Colloquium and ready to offer any necessary supports of manpower and material resources. Welcome to Nanning, Guangxi, China and looking forwards to sharing all achievement in EBM with you in the ever green city, Nanning !

P96: Do systematic reviews really accurately use the risk of bias assessment to draw conclusions?

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Background: The Cochrane Handbook claims that the evaluation of the validity of included studies is essential for the analysis, interpretation and conclusions of systematic reviews. Therefore, reviews should include not only a risk of bias assessment but also should discuss how the limitations in the design and execution could affect the validity of their conclusions. **Objectives:** To evaluate to what extent the risk of bias assessment is properly considered to formulate the conclusions in set of published systematic reviews. **Methods:** Two reviewers will independently assess a set of systematic reviews used to develop a practice guideline on the surgical management of femoral fractures. We will use AMSTAR (Shea 2007), paying special attention to the relevant items that address whether the reviews documented any formal quality assessment (item 7), and if this assessment was used accurately to formulate the reviews' conclusions (item 8). We will estimate an agreement coefficient between these two items, but will also qualitatively check the extent to which the quality of information was used to draw conclusions in the reviews. **Results:** So far, we have assessed 15 systematic reviews (5 Cochrane vs. 10 non Cochrane). Although 9 of these reviews properly considered the limits in design and execution of the included trials to formulate their conclusions, the rest (6 reviews, 40%) did not assess the quality of the included studies or did not use the quality assessment to discuss its impact on the review results. At this moment we are increasing the sample of assessed reviews to accurately estimate if these preliminary results could be considered significant. **Conclusions:** There still exists clear room for improvement in the way that the quality assessment of included studies is used to draw conclusions in systematic reviews. This issue is of special relevance for the usefulness of reviews in the process of knowledge translation, given the importance of bias assessment for allowing an appropriate evaluation of the confidence in the estimates derived from reviews.

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P97: An Evaluative system and Effects Research of Problem Based Learning

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Background: More and more medical schools in China start to use problem-based learning(PBL) throughout their education, therefore, the

evaluation on the effectiveness of PBL becomes extremely important.

Objective: To establish an assessment system of PBL curriculum which is suitable for Chinese student characteristics and education system, and to assess the effectiveness of PBL curriculum. **Methods:** 93 students in grade 4 and 89 in grade 3 were involved in this group control study and before-after study. Self-assessment scales were used to assess the effectiveness of PBL curriculum. The reliability and validity of Capacity Assessment Scale were tested by Cronbach's α coefficient and correlation coefficient method respectively. From the first timepoint to the second timepoint, an independent samples *t* test was used to analyse the difference of ability between grade 4 and grade 3 students, and the difference of student self-assessment, peer assessment and instructor ratings in grade 4 and grade 3 students. **Results:** Cronbach's α coefficient of Capacity Assessment Scale was 0.810, Pearson correlation coefficients between 0.4–0.7. The professional quality, the role of awareness, analytical reasoning ability, information management capacity, communicative capability of the grade 3 and 4 students involved in PBL curriculum had statistically significant difference between the first and second timepoint ($P < 0.05$). From the first timepoint to the second timepoint, there was no significant difference ($P = 0.310$ and 0.506 , respectively) in self-assessment and student peer assessment of 93 students in grade 4, and a statistically significant difference ($P < 0.001$) in instructor ratings; there was a statistically significant difference ($P < 0.001$, respectively) in self-assessment and instructor ratings of 89 students in grade 3, and no statistically significant difference ($P = 0.116$) in student peer assessment. **Conclusion:** Competency Assessment Scale is designed rationally, and its reliability and validity is in a high level. This scientific assessment system can improve the accuracy of the evaluative results. PBL curriculum can improve the professionalism, role awareness, analytical reasoning ability, information management capacity, the communicative capacity of student. At the same time, early propaganda of PBL ideological can improve the effectiveness of PBL curriculum.

P98: Smoking cessation in pregnancy: re-analysing equity in a Cochrane Review

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Background: A Cochrane review about smoking cessation in pregnancy concluded that interventions can reduce the proportion of smokers, and the incidence of low birthweight and preterm births (Lumley *et al.* 2009). The review did not investigate to what extent interventions benefit disadvantaged women. Arblaster and colleagues (1996) proposed that promising interventions for reducing health inequalities include: systematic intensive approaches to health care; multiple components built on a multi-disciplinary approach; improvement in access; involvement of peers; attempts to address the needs of the population; and health education when combined with social support or structural strategies. **Objectives:** To conduct a secondary-analysis of a review of smoking cessation in pregnancy, in order to assess the impact of interventions on health inequalities. Further the current study examines whether interventions matching those Arblaster and colleagues propose as promising for reducing

health inequalities are more effective. **Methods:** Subgroup analyses were conducted to assess the relative impact of interventions on women differing in their socioeconomic status (SES), ethnicity and age. Assessment of effectiveness of different elements of interventions was conducted. These elements include structural measures, social networks or incentives; addressing the expressed concerns of pregnant smokers; and involving pregnant smokers, their partners or their community in the intervention design. **Results:** In relation to becoming smoke-free in late pregnancy, interventions were equally successful whether women had low SES or not. Too few data were available to allow further analysis of ethnic minority, or younger women. Interventions with incentives were more effective than those without. Interventions were as effective with or without peer support, or if they were designed in collaboration with pregnant smokers. **Conclusions:** As smoking cessation programmes are effective for low SES women, it is important that programmes are widely implemented. Analysis is ongoing to identify promising elements for smoking cessation interventions.

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Arblaster L. (1996) A systematic review of the effectiveness of health service interventions aimed at reducing inequalities in health. *Journal of Health Services Research and Policy* 1: 93-103.

P99: Treatment adequacy of Chinese medicine in Cochrane systematic reviews: an investigation

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Background: One of the main objectives of Cochrane systematic reviews is to inform practice by presenting evidence strength and information on health care interventions. For traditional medicine, it is very important that the reviews evaluate the treatment adequacy by looking at all information in relation to the interventions reviewed.

Objectives: To evaluate completeness of reporting of interventions for the treatment adequacy in Cochrane reviews on Chinese herbal medicine and acupuncture. **Methods:** All Cochrane systematic reviews with at least one trial included on Chinese herbs or acupuncture published in The Cochrane Library (Issue 1, 2010) were identified and data on treatment were extracted and evaluated based on STRICTA for acupuncture and CONSORT for herbal medicine. **Results:** Ninety Cochrane reviews have been identified on Chinese medicine, including 63 reviews on herbal medicine and 27 reviews on acupuncture. The reviews of acupuncture described rationale in the background (27/27), defined the intervention in the inclusion criteria (14/27), elaborated needling details (27/27), treatment regimen (26/27), co-intervention (8/27), practitioner's qualification (11/27), controls (27/27), as well as treatment adequacy in the discussion (15/27). For herbal reviews, the rationale of the treatment was described in the background (55/63), the intervention was defined in the inclusion criteria (31/63),

treatment adequacy was discussed in the discussion (38/63), while the characteristics of the interventions (3/63), quality of herbal products (0/63), and practitioners' qualification (0/63) were seldom described in the results, while treatment regimens (57/63) and control interventions (57/63) were elaborated in most of the reviews. **Conclusions:** There is great space for improvement of reporting on treatment adequacy in Cochrane reviews on herbal medicines and acupuncture so to inform the practice from review finding. International standards such as STRICTA and CONSORT for herbal medicine can be references for collecting and reporting information on treatment of acupuncture or herbal medicine. This study was funded by the grant No. 2006CB504602 by the National Basic Research Program in China (973 Program) and the "111" project (no. B08006). This work was funded in part by Grant Number R24 AT001293 from the National Center for Complementary and Alternative Medicine (NCCAM). The contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of the NCCAM, or the National Institutes of Health.

P100: Consumer involvement in The Cochrane Collaboration

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Background: The Cochrane Collaboration has a long history of consumer involvement with consumers involved in its democratic processes since the beginning of the organisation. However over the past seventeen years considerable variability in the practices and support for consumer involvement has emerged across the Collaboration. There has been relatively little study of consumer involvement in the organisation. Most information about consumer involvement comes from selected case studies and surveys with low response rates. **Objectives:** This study sought to find out how consumers are involved in The Cochrane Collaboration. **Methods:** The study used an action research approach with the entity modules on the Cochrane Library as a primary source of data to determine how consumer involvement is described and understood across the whole of the Collaboration. The availability of an entire cohort of entity modules compensated for data limitations. Entity modules were examined to determine what different entities believe important to communicate to others. These data were supplemented by interviews, reports and data sources. Theoretical conceptualisations of consumer descriptions and roles were verified by presentation to key stakeholders for feedback. **Results:** Three overlapping groups of consumers operating in the Collaboration were identified: consumer volunteers; consumer facilitators; and consumer organisations. Consumer tasks can be categorised into three main areas: involvement in decision-making; involvement in the preparation of reviews; and involvement in promotion and dissemination. The majority of consumers in the Collaboration are involved directly with review groups and are not associated with the Consumer Network. **Conclusions:** The findings suggest that new strategies are needed to support consumers who want to be involved in the Collaboration but further progress on supporting consumer involvement will be determined by how future consumer involvement will be funded as this will determine the types of strategies that can be employed and how they will be implemented.

P101: A unique web service to facilitate the study selection process in systematic reviews

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Background: Searching for and selecting studies according to Cochrane quality criteria can be cumbersome. A range of bibliographic databases should be used, with highly sensitive search strategies but relatively low precision. This results in large numbers of references which then must be examined by several reviewers independently. These tasks currently require the use of several softwares and keeping track of the whole process is uneasy. **Objectives:** We aimed at developing a unique interface to facilitate the management of references and the study selection process by several reviewers. **Methods:** We developed a web service which allows importing the references identified from the major databases (including CENTRAL, Medline, Embase, Lilacs, Science Citation Index). Users can input the search strategies and dates of search for each database. We implemented an algorithm to automatically identify duplicate records of the same report. The system also allows linking together multiple reports of the same study. Multiple user accounts allow reviewers examining references independently. Step-by-step assessment of titles and abstracts with a consensus procedure for disagreements is handled. Measurements of agreement are produced at each step. Finally, the numbers of hits retrieved by the electronic searches and the numbers of selected records are automatically documented in a flow chart of the whole study selection process. The web service was developed using the Python Programming Language. **Results:** So far, the web service is operational. An evaluation study is underway, involving physicians and librarians. We expect that the use of this tool will result in saving time and increasing the accuracy of study selection. Results will be presented at the conference. **Conclusions:** We expect this free web service – a unique interface to perform the whole selection process- to be a helpful tool for Cochrane reviewers.

P102: Are all Cochrane reviews born equal? Methodological quality across different Review Groups

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Background: High quality systematic reviews are increasingly recognized as providing the best evidence to inform healthcare decisions at different levels. The quality of a review – and then the confidence that a decision maker puts on its findings – depends on the extension to which its design will generate unbiased results. Published reviews vary considerably on their quality, with Cochrane reviews rating consistently better than non-Cochrane ones. However, little is known about the quality of reviews across different Review Groups in the Collaboration. Considering that the review production process in the Collaboration is highly decentralized some variation is expected, but its magnitude is not known. **Objective:** To compare the methodological quality of systematic reviews produced by different Cochrane Review Groups. **Methods:** We selected a random sample of reviews published in the February 2010 issue of the Cochrane Library. Each selected review was independently assessed by two evaluators using the AMSTAR tool. The percentage of reviews from each Review Group meeting each of

the eleven AMSTAR items was calculated. Likewise the proportion of reviews from each Review Group meeting a 'high-quality' score was calculated. Data were analyzed using non-parametric approaches.

Results: In our initial assessment of a sub-sample of reviews there were some differences in the 'quality' of them. However, we have not completed the assessment of the full sample in order to attribute that difference to the Review Groups where they were produced.

Conclusions: It might be differences in the 'methodological quality' of reviews produced by different Review Groups. If this is verified in the analysis of the whole sample of reviews more work should be done within the Collaboration to assure appropriate quality standards of its main product.

P103: Implementing evidence through a systematic search

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Background: It is an increasing priority for clinicians and lawyers to define the evidence base in relation to child abuse. Due to the paucity of evidence, we have conducted a series of systematic reviews to define the evidence base underpinning the identification and investigation of cases of suspected physical child abuse. Although Evidence Based Medicine is traditionally dominated by the randomized controlled trial as the gold standard, this research field can only be addressed through observational studies. **Objective:** To outline the methodology used to address the questions: how do you distinguish inflicted from non-inflicted brain injury? What is the optimal imaging strategy to explain these injuries? **Methods:** An all language literature search was performed across 20 databases, information sources and relevant websites of published or unpublished studies for the years 1970–2008. In addition, a range of 'snowballing' techniques were used to increase the sensitivity of the search. The search retrieved in total 7802 references which were imported into bibliographic software. The titles were scanned for duplicates and relevancy, 5861 references were sent to principle investigator for the second scan based on inclusion criteria, of which 305 studies were reviewed. **Results:** We have identified, by multilevel logistic regression analysis, key clinical features that predict inflicted brain injury and clarified the optimal investigation strategy. The findings informed The NICE guidance "When to suspect child maltreatment" <http://guidance.nice.org.uk/CG89> and the recent joint Royal College of Paediatrics and Child health and Royal College of Radiology Standard for diagnostic imaging of suspected non-accidental injury in children. Findings are disseminated by peer review publications, a dedicated website www.core-info.cf.ac.uk and leaflets for other childcare professionals. **Conclusion:** This review challenges long held views of paediatricians and provides an evidence base for child protection professionals. It has identified research priorities where evidence is lacking.

P104: Hidden conflicts of interests in meta-analyses of pharmacological treatments

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Background: Industry supported randomized controlled trials (RCTs) and meta-analyses are more likely to yield conclusions that favor sponsors' interests, even controlling for study quality. Reporting guidelines require authors of RCTs and meta-analyses to report study funding and potential conflicts of interest (COI), but there is no formal requirement to report funding and potential COI of included RCTs in meta-analyses. **Objective:** To investigate the extent to which meta-analyses transparently report industry funding and author financial ties of included RCTs. **Methods:** A sample of meta-analyses of pharmacological treatments published January-September 2009 that investigated at least one drug patented in the US was selected. Up to 3 meta-analyses, beginning with the most recently published, were selected from general medicine journals with impact factor ≥ 10 . In addition 3 meta-analyses were sampled from each of 5 specialty medicine areas with the highest 2008 global therapeutic sales (oncology, cardiology, respiratory medicine, endocrinology, gastroenterology) and from the most recent Cochrane Library issue. For specialty areas, the top impact-factor journal was searched, followed by the second highest-rated journal until 3 eligible meta-analyses were identified. **Results:** Only 2 of 29 selected meta-analyses reported funding sources of included trials and none reported author financial ties or author affiliations. Based on preliminary data from 90% of included RCTs (460/510) in the 29 meta-analyses, 53% (245/460) had industry funding, author employment, or other author financial ties: 43% (199/460) of included RCTs reported study funding from pharmaceutical sponsors, 25% (113/460) reported at least one author employed by industry, and 17% (76/460) reported other author financial ties. In 6 meta-analyses, 100% of included trials had at least one link to industry, but none reported included RCT funding or potential COI. **Conclusion:** Information on funding and potential author COI often disappears when data from RCTs are incorporated into meta-analyses.

P105: Conflict of interest in clinical practice guidelines: a systematic review

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Background: There is an emerging literature on the existence and effect of industry relationships on physician behavior. Little is known, however, about the effects of these relationships and conflict of interest (COI) on clinical practice guideline (CPGL) development and recommendations. **Objectives:** To perform a systematic review of the financial relationships and COI between CPGL authors and industry and to evaluate the effects of these relationships on CPGL recommendations. **Methods:** We searched Medline (1980 to March, 2010) for studies that examined the effect of COI on the development and/or conclusions of CPGL. Two reviewers independently identified potential studies from the literature search and data abstraction was reviewed by a second author. We performed a narrative synthesis as there was substantial heterogeneity among studies. **Results:**

Ten studies fulfilled inclusion criteria; 8 were conducted in the US. All studies reported on financial relationships of CPGL authors and the pharmaceutical industry; 1 study also examined COI with diagnostic testing and insurance companies. The majority of guidelines have authors with industry affiliations. Nine studies categorized financial relationships: consultancies (8 studies, % of authors with relationship, range 1–80%); research support (8 studies, range 4–78%); equity/stock ownership (5 studies, range 2–17%); any COI (3 studies, range 56–87%). Four studies reported multiple types of financial interactions for individual authors (number of categories per author: range 2 to 10 or more). Five studies described a potential effect of COI on the CPGL; in 4 studies the evidence did not support the CPGL conclusions and the guideline authors had financial ties that benefited from the conclusions. Most authors believed that their relationships did not influence their recommendations. **Conclusions:** Few studies describe or quantify the effects of financial relationships on the development and/or recommendations of CPGLs and further research is needed to explore and quantify this important source of bias.

P106: Statistical heterogeneity and the choice between fixed- and random-effect models: an exploratory analysis of Cochrane reviews

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Background: Two methods of combining intervention effect estimates are used in Cochrane meta-analyses (MA): fixed-effect (assuming a single common effect underlies every study) and random-effect (assuming intervention effects follow a distribution across studies) models. There is debate about which model should be used in presence of statistical heterogeneity and to what extent Cochrane review authors ought to describe reasons for their choice of model. **Objectives:** 1) To describe the frequency of the use of fixed versus random effects models in Cochrane reviews, 2) to explore consistency between decisions to use fixed or random effects models and the assessment of statistical heterogeneity. **Methods:** A random sample of 500 reviews was taken from a database of 2,500 Cochrane reviews. Reviews that included at least one MA were selected and the following data extracted from the first MA reported: number of trials, outcome measure, effects estimation model, criteria for selection of effects estimation model, heterogeneity measures, criteria for interpretation of heterogeneity. **Results:** Of 100 reviews (median year of first publication: 2001, interquartile range [IQR] = 1998.5, 2007; median year of last update: 2005, IQR = 2003, 2009) 63% conducted at least one MA: 44 (69.8%) used fixed-effect and 19 (30.2%) used random-effect models. Twenty-one (33%) described criteria for statistical heterogeneity. Twenty-four reviews reported the intent to pool results using a fixed-effect model in absence of heterogeneity, but to use a random-effect model otherwise. Eleven MA used fixed-effect models in presence of considerable heterogeneity ($p > 0.01$, $I^2 > 50\%$). Additional results are presented. **Conclusions:** Careless use of fixed-effect or random-effect approaches to MA can lead to misleading inferences about treatment effects. Careful consideration of methods for statistically pooling comparable but heterogeneous studies remains critical to making legitimate inferences. Explicit guidance in the Cochrane Handbook regarding the choice of statistical model is required.

P107: Learning assessment of healthcare professionals enrolled in the improvement course on Evidence-based healthcare via teleconference

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Background: Brazil has today one of the major mass teaching initiatives in Evidence-Based Healthcare for healthcare professionals. In December 2009, the third edition of the distance improvement course was initiated with about 2,900 enrollments. The 150-hour course, developed along a whole year, was given by members of Brazil Cochrane Center in the Syrian-Lebanese Hospital's Education & Research Institute, supported by Brazil Health Ministry. Students actively participated in the course through an Internet platform, which presented ancillary materials and tutored discussion forums for doubts solving and aids to develop research projects. **Objective:** Assessing the course effects on concept learnings and competency developments in Evidence-Based Practice; featuring the enrolled students' social-economical profile, as well as their satisfaction level with the course. **Methods:** Learning was measured by two evaluations taken at the beginning and ending of the Internet-platform course. Students first filled in a questionnaire about their profession, age, computer skills, etc. Afterwards, they answered to a 20-multiple-choice question evaluation about the contents exposed during the course. Question structure was based on existing concepts of knowledge and skills assessment in Evidence-Based Medicine, such as question formulation, available evidence search, evidence critical evaluation, among others. The research projects carried out and an interview on the students' satisfaction with the course were also assessed. **Results:** For the partial results, we concluded that 800 students answered both evaluations. Satisfaction level with the course was around 97%, and 99% of students would recommend the course to a colleague. In March 2010, a new edition of this course was initiated with 2,600 enrollments, reflecting the course impact on the professionals' lives. Complete results will be presented at the proper time. This experience is clearly reproducible in different scenarios.

P108: How many randomized trials on the therapeutic interventions for a specific clinical condition are covered by Cochrane reviews?

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Background: For evidence users it has become impractical to answer specific questions by reading primary studies. The increasing amount of information is difficult to manage and what is obtained is prone to publication bias. Systematic reviews can provide an unbiased synthesis of existing evidence, so they have become key to assist clinical decisions. At present there are many reviews answering similar questions. We know Cochrane's are more rigorous than other reviews, but we have little information about what is the proportion of evidence actually covered by Cochrane reviews. **Objectives:** To compare the coverage of Cochrane vs non-Cochrane reviews of the therapeutic evidence in a specific clinical condition. **Methods** EPITEMONIKOS is a database in development that will provide access to the included studies of systematic reviews for a similar question. This study is part of the first scoping review created for this project. We selected the topic "prevention and treatment of thromboembolic disease" because of its

relevance for several specialties and the variety of interventions in this area. So, many existing studies and reviews were anticipated. Our study considers the following steps: 1) MEDLINE search using a hedge for reviews with emphasis in specificity; 2) Selection of articles intending to systematically synthesize evidence; 3) Extraction of all randomized trials included in those reviews; 4) Description of each study and classification into a clinical question framework; 5) Calculation of the coverage of Cochrane reviews (percentage of studies included in Cochrane reviews); 5) Studies not covered will be classified as: question not covered by any Cochrane review, study published after search date of corresponding review, excluded study, study missed by the Cochrane review). **Results and conclusions:** 217 reviews have already been identified. The search (updated monthly) will be last updated on September 30. Results and conclusions will be presented at the Colloquium.

P109: Efficacy of proseal laryngeal mask vs classic laryngeal mask in children. Systematic Review

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Background: Classic laryngeal mask was introduced in anesthesia in 1988. Initially it was used as a facial mask substitute, but later on it was used in procedures where endotracheal tube was utilized, including those with positive pressure. It is useful when an endotracheal tube can not be used. Safety and efficacy in pediatric patients was probed. Original design of this laryngeal mask was modified and a new coupling with a hole for a drainage probe was added. **Objective:** Efficacy and safety of classic laryngeal mask vs proseal laryngeal mask in children. Search methods for identification of studies.- Literature was searched in data bases of: Cochrane, Embase, Pubmed, Lilacs, Scielo with next Mesh terms: laryngeal mask proseal, laryngeal mask, airway, with next limits: children OR pediatrics, OR infant. We made gray literature search in anesthesiology meetings memories. None limitation in language or time was applied. **Type of Studies:** Randomized Clinical Trials and Quasirandomized in children Data Extraction and analysis. Two reviewers independently (LACPM and ERM) assessed eligibility of each and every single paper. Disagree was solved by a third reviewer. Methodology quality was assessed by Jovell and Grade Working Group Scales. **Results:** There were 565 patients in 8 papers. None of them was blinded by the characteristics of the dispositives. Clinical efficacy is almost the same in both laryngeal masks, but O₂ saturation is better in proseal laryngeal mask. Laryngeal mask malposition appears in 5–15%, but is solved when it happens. Air blowing into gastric chamber occurs more frequently in classic laryngeal mask (not a single paper reports the confidence interval). **Conclusion:** Proseal laryngeal mask is better than classic laryngeal mask in airway management in children.

P110: Contribution of pharmaceutical manufacturer data submissions in identifying relevant studies for systematic reviews

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Background: For systematic reviews it is critical to identify as complete a set of relevant studies as possible. Given the limitations of electronic

searching, use of additional means for identifying relevant studies is desirable. To address this need, the Drug Effectiveness Review Project (DERP) routinely solicits published and unpublished data from pharmaceutical manufacturers. Incorporation of stakeholder input also provides DERP the opportunity to improve the transparency of the systematic review process. **Objective:** To compare volume and types of relevant studies identified via pharmaceutical manufacturer solicitation versus those from electronic searches. **Method:** By October 2010, data from pharmaceutical manufacturer submissions and electronic searches will be collected for approximately 30 DERP reports conducted since 2007. Data regarding characteristics and volume of literature will be extracted by one reviewer and checked by another. The proportion of final included studies obtained through the pharmaceutical manufacturer submission process will be identified. Characteristics of studies identified by each method will be explored (e.g. direct comparisons, subgroup analyses, publication status). **Results:** Preliminary analysis found that pharmaceutical manufacturer submissions identified at least one additional publication for 75% of DERP reviews completed in 2009. Mean total number of citations submitted by manufacturers was 263 [standard deviation (SD), 193]. Among those, the mean number of citations not already identified by electronic searches was 5 (SD, 7), or approximately 2%. Mean number of included studies from all sources is 67 (SD, 43). Hence, the overall contribution of manufacturer submissions towards the relevant studies is about 7%; with only 5% of those being direct comparison trials. **Conclusions:** Initial findings indicate that pharmaceutical manufacturer submissions contribute <10% of the final set of included studies. Although this proportion is small, these additional studies include highly relevant direct comparison studies. The number of studies screened to identify these few important studies was large.

P111: Answering questions put forward by local musculoskeletal pain clinicians in the UK

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Background: A multidisciplinary group of clinicians with academic partners in North-west England was established to develop critically appraised topics (CATs) addressing questions on musculoskeletal care generated in practice. CATs are disseminated locally to healthcare practitioners, managers and commissioners to inform decision-making. **Objective:** To examine the evidence used in these CATs and assess the contribution of Cochrane Reviews. **Methods:** Local clinicians and managers suggest questions, usually relating to the effectiveness and implementation of interventions. Questions are refined and a health librarian conducts a systematic search, which is then critically appraised by the team. Highest quality evidence that directly addresses the question is selected and the CAT is written with a clear clinical bottom line before being disseminated locally. **Results:** Of 23 CATs that have now been developed, nine (39%) original questions were addressed in at least one systematic review, six of which were Cochrane Reviews. A further four questions were partially answered by systematic reviews, for example one CAT focused on the effectiveness of stabilisation exercises for shoulder impingement, however the review selected as best evidence addressed exercise

in general. For two other CATs at least one RCT related to the question asked. However, eight (35%) CAT questions could not be answered with certainty either because only low quality, or no research was found. **Conclusions:** Around a third of musculoskeletal pain clinicians' questions had no high quality evidence with which to answer them. Researchers may not address many decisions that clinicians have to make and clinicians may find it difficult to interpret published evidence and apply it to their own practice, illustrating that there is still a research/practice divide. However, providing the evidence, e.g. from Cochrane reviews, is available and given the right support, local groups can help translate research for other clinicians in a way that is timely and accessible.

P112: Methods to synthesize evidence across trials reporting multiple behavioral outcomes

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Background: Trials evaluating behavioral interventions often report numerous outcomes. Synthesizing evidence across multiple outcomes can be problematic. **Objectives:** To describe methods of prioritizing outcomes and pooling across heterogeneous behavioral and related outcomes; to address concerns about selective reporting of outcomes.

	Martinson 2008	Pinto 2005	King 2002	Total # trials	Outcome group
Behavioral Outcomes, Self-Reported					
Any/Total PA or PA unspec (min/wk)			X	8	1
Leisure PA (min/wk)				1	1
Mod- to vigorous-intensity PA (min/wk)		X		5	1
Mod intensity PA (can get min/wk)				1	1
Endurance PA (min/wk)				1	1
Walking (can get min/wk)				2	1
Leisure walking (min/wk)				1	1
Mod- to vigorous-intensity PA (MET-min/wk)				2	2
Walking (MET-min/wk)				1	2
Energy expenditure (kcal/kg/day)				2	2
Mod+ Energy expenditure (kcal/kg/day)				1	2
Leisure PA (kcal/kg/wk)				1	2
PA (kcal/wk)	X	X		3	2
Walking (steps/day)				1	2
Walking (sessions/wk)				0	2
PA (sessions/wk)				1	2
Mod+ PA (sessions/wk)				0	2
PA (min/session)			X	2	2
Energy expenditure ratio				1	2
PASE score				2	3
PACE score				2	3
YPAS total activity score				2	3
% meeting ACSM criteria or 150+ min mod+				8	4
% active per PACE				1	4
% mod PA 5+ days/wk	X			1	4
% vigorous PA 3+ days/wk	X			1	
% Maintaining PA at follow-up	X			1	
Behavioral Outcomes, Objective					
VO2max				5	5
Treadmill duration (min)				2	6
2-min walk, meters				1	6
Accelerometer counts		X		1	6
Intermediate Outcomes					
BMI	X		X	7	7
Waist circumference				3	7
Weight				1	7
SPB			X	6	8
DPB			X	6	9
Total Cholesterol				5	10
HDL				3	11
LDL				2	12
Adverse events					
Falls				2	
Injuries				1	
Hospitalization				0	

Methods: We conducted a systematic review of behavioral counseling interventions to improve diet and/or physical activity for the United States Preventive Services Task Force. **Results:** We included 64 counseling trials with a large range of outcomes. The number of relevant outcomes ranged from 4 outcomes in the physical activity counseling literature to 50 outcomes in the dietary counseling literature. We worked with the USPSTF, to define a hierarchy of acceptable outcomes, prioritizing intermediate outcomes (e.g., blood pressure, lipids, and weight) over self-reported behavioral outcomes. Thirty-six of the 64 trials reported intermediate outcomes, 32% of physical activity trials, 64% of the dietary trials, and 82% of the combined physical activity and dietary trials reported intermediate outcomes. All trials included some type of behavioral outcome. In the absence of robust reporting of intermediate outcomes, we focused on behavioral outcomes. An extensive audit of outcomes reported in each trial revealed a large variation in behavioral outcomes in both bodies of literature. Using physical activity trials as an example, there were 4 commonly reported categories of self-reported physical activity measures, objective measures were not commonly reported (see Table 1). However, within these 4 categories of outcomes, there was a large variation in the types of measure used (see Table 1). We used a measure of this heterogeneity in our meta-regression to determine if the measurement type influenced on effect size. To address concerns about selective reporting of outcomes, we evaluated the consistency of direction and magnitude of effect across behavioral and intermediate outcomes, as well as across counseling trials. **Conclusions:** An *a priori* hierarchy of outcomes is needed when conducting quantitative and qualitative synthesis across trials reporting numerous behavioral outcomes. An audit of trial outcomes is an important step to determine ability and acceptability of pooling outcomes.

P113: The Role of feeding programs in achieving Millennium Development Goals (MDGs) One and Two: The School and Preschool feeding exemplar

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Background: In 2004, in developing countries, more than 126 million children under five years of age were underweight and 147 million were stunted. Throughout the life cycle, under-nutrition contributes to mortality, increased risks of infection, lowered cognitive performance and chronic disease in adulthood. The consequences of under-nutrition in early childhood are particularly severe. Estimates suggest that more than 50% of deaths in children under 5yrs are attributable to under-nutrition. Systematic reviews (SRs) provides well need evidence to support policy development. **Objective:** This paper will explore the role SRs on the use of school and preschool feeding programs in achieving MDGs One and Two (Eradicating Extreme Poverty and Hunger and Achieving Universal Primary Education). **Methods:** Findings were extracted from two Cochrane/Campbell SRs on the effectiveness of school and preschool feeding programmes for improving health of disadvantaged children and reducing health inequities. The

first review included children 5–13yrs and the second included children 2–5yrs. Outcomes included psychosocial development, nutritional status, and school achievement and attendance. Data from reviews were stratified on two levels; within country by SES (where available) and by High and Upper Middle Income Countries (HUMIC) and Low and Lower Middle Income Countries (LLMICs). **Results:** Findings from the first SR revealed, in LLMIC's, significant positive changes in mean: weight (0.48kg; 95%CI 0.16–0.80), school attendance (2.5%; 95%CI 1.06–3.94), math score (0.13 SMD; 95%CI 0.02–0.24), and IQ (4.01 WMD; 95%CI 1.07–6.95). All outcomes except for attendance (0.8–2.8%; SD not-reported) within HUMIC's did not show any significant changes. Results from SR II are in progress. Analysis will explore the influence of supplementary feeding programmes on socioeconomically disadvantaged children in LLMICs. **Conclusion:** Increasing the capacity of these supplementary feeding programmes may improve attainability of the MDGs 1 and 2, particularly in at risk LLMICs. SRs are useful tools for informing development of policies in LLMICs.

P114: Systematic reviews when there is no evidence . . . (1) A qualitative analysis of expert reviews on independent medical evaluations (Preliminary results)

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Background: Independent medical evaluations (IMEs) are used by insurers, employers, and the courts to acquire an unbiased opinion on patient's medical condition; however, these commonly used assessments are often criticized for a lack of impartiality and limited standardization. **Objective:** A systematic review of all literature on IMEs. **Methods:** A comprehensive search of 5 electronic databases, without time or language restrictions, revealed 88 eligible unique citations; 74 were narrative reviews, editorials, case reports or letters to the Editor. Two reviewers developed a coding system to categorize themes in eligible articles, coded all articles independently and in duplicate, and compiled a transcript with all passages per theme across reviews for qualitative analysis (details in Kunz, Guyatt, Busse (2)). **Results:** Narrative review characteristics. Most reviews were authored in North America (67/74=90%) and few articles were published prior to 1990 (7%) or between 1990–1995 (8%). A steep increase occurred thereafter: 1995–1999: 30%; 2000–2004: 28%; 2004 to October 2008: 24%. Authors' declared affiliations with universities (46%); hospitals (15%); a company that arranged IMEs (8%); insurance companies (9%); and legal firms (7%), 19% reported no affiliation. Eight percent of authors were in private practice. Most articles (40%) addressed general IME issues, assessment of musculoskeletal disease (26%) or mental health assessment (23%). Reviews focussed on workers' compensation (28%); legal/forensic issues (26%); the insurance perspective (13%); return-to-work-issues (12%) or were professional self-reflections (18%). Reviews were targeted towards 5 groups: clinicians/family physicians (26%); mental health professionals (22%); medico-legal professionals (18%); professionals engaged in musculoskeletal assessments (16%) and; IME professionals in general (12%). **Project status:** We have coded 75% of articles and will report the results of our qualitative analysis at the colloquium. **Conclusions:**

P115: Are systematic reviews original research? – survey of editors of core clinical journals

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Background: Research synthesis has growing impact in evidence-based medicine and knowledge translation. Systematic reviews (SR) represent a cornerstone of research synthesis and require scientific rigour. Nevertheless, SR are often criticised as “secondary research” and not granted the status of original research. Journal editors are gatekeepers in the publication process. Their appraisal of a study design may reflect but also influence which value it receives in the scientific community. **Objectives:** To investigate the attitudes of editors of core clinical journals towards SR and their value for publication. **Methods:** We identified all 118 journals labelled as “core clinical journals” in Pubmed’s Journal Database in April 2009. The journals’ editors were surveyed by email in April–August 2009 and asked whether they 1.) consider SR original research projects; 2.) publish SR; and 3.) for which article section they would consider a SR manuscript. **Results:** Editors of 65 journals (55%) responded to the first email or the reminder (Table 1): Editors from general medical journals responded more frequently than editors from speciality journals. Most respondents consider SR original research (71%) and almost all journals (93%) publish SR. Some editors regarded use of Cochrane methodology or a meta-analysis as quality criteria; for some respondents these criteria were premises for consideration of SR as original research. Journals place SR in various sections ranging from “Review” to “Feature article”. **Conclusions:** Currently, editors of most core clinical journals regard SR as original research. However, individual commentaries suggest that this is a grey area and attitudes differ widely. Based on these results

a debate about the definition of “original research” in the context of SR is warranted. Appropriate academic recognition of high-quality SR would provide incentives for researchers to conduct them and for funders to support them.

P116: A Meta-analysis (MA) of the Effect of World-Wide Psychosocial HIV Interventions on the Sex Behaviors of Persons Who Use Drugs

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Background: Users of opiates and stimulants are at sexual risk for HIV that can be reduced by psychosocial interventions. **Objectives:** We examined efficacy of 44 worldwide sexual risk reduction intervention studies with drug users (outcomes: unprotected sex, condom use, number of sex partners). We compared the results to our previous MA results (published in 2002) of 33 interventions conducted in the United States (US). The 44 interventions included the 33 interventions (published 1988–1999). **Methods:** We conducted comprehensive searches for sexual risk reduction intervention studies (experimental or quasi-experimental designs, 1988–August 2009). Effect sizes

Table 1 (P115): Characteristics of core clinical journals by responder status and answers to question 1 and 2.

Number (%)	RESPONDERS N=65	NON-RESPONDERS N=53	TOTAL N=118
General clinical journal*	13 (20)	4 (8)	17(14)
(Sub)Speciality Journal	52 (80)	49 (93)	101 (86)
Country of publication			
USA	51 (79)	50 (94)	101 (85)
England (UK)	12 (18)	3 (6)	15 (13)
Other	2 (3)	0 (0)	2 (2)
Impact Factor (JCR 2007) median (range)	2,99 (0,3–52,6)	3,60 (0,4–69)	3,23 (0.3–69)
Answer to Q1 – “Do you consider a SR an original research project?”	Yes: 37 (57) Under premises: 9 (14) No: 19 (29)	(Not applicable)	
Answers to Q2 – “Do you publish SR in your journal?” **	Yes: 54 (84) Rarely: 6 (9) No: 4 (7)	(Not applicable)	
* e.g. JAMA, BMJ, NEJM, Annals of Surgery ** only 64 valid answers			

were converted to odds ratios (OR); an OR < 1.0 indicated less unsafe sexual behavior in experimental groups at follow-up. **Results:** Psychosocial interventions had modest additional benefit compared to shorter, control educational interventions ($k = 44$; OR, 0.87; 95% confidence interval [CI], 0.77–0.97), and larger positive effect compared to minimal interventions ($k = 7$; OR, 0.62; 95% CI, 0.47–0.83). Cumulative MA showed significant effect (OR = 0.88; 95% CI, 0.78–0.99) by 1996, similar to previous MA results. US ($k = 38$; OR, 0.87; 95% CI = 0.77–0.99) and non-US studies ($k = 6$; OR = 0.82; 95% CI = 0.63–1.06) had small effect, similar to previous MA results ($k = 33$; OR, 0.86; 95% CI = 0.76–0.98). Individual ($k = 43$; OR, 0.83; 95% CI, 0.73–0.94), network ($k = 4$, OR, 0.75; 95% CI, 0.47–1.18), and structural ($k = 2$; OR, 0.75; 95% CI, 0.60–0.94) interventions had similar effects; network and structural interventions seem promising. Meta-regression showed that HIV status (self-report or study test results; 0–20% vs. > 20%) was associated ($B = 0.27$, $p = 0.04$) with sexual risk reduction. **Conclusion:** Current and previous MA had similar results. Psychosocial interventions provide modest sexual risk reduction justifying offering them to drug users. Moderate-duration interventions may have diminishing returns. Stronger-effect interventions are needed.

P118: Analysis and assessment of systematic reviews of Chinese herbal medicine published in Cochrane Library

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Objective: To analyze and assess the systematic reviews of Chinese herbal medicine published in Cochrane Library. **Methods:** We searched all reviews of Chinese herbal medicine in Issue 1, 2010 of the *Cochrane Database of Systematic Reviews*. For each review, we collected information of the title of review, publication year, number of authors, country of first author, institution of authors, databases of electronic searches, number of trials included, treatment of disease, interventions used in the treatment groups and types of outcome measures. **Results:** We identified 57 systematic reviews of Chinese herbal medicine published in Cochrane Library. The number of authors in these reviews ranged from 1 to 10. The first author of 45 (78.9%) reviews came from China, next was UK ($n = 8$), first author of the remaining 4 reviews came from Netherlands, Canada, USA and Australia. Authors of 43 (75.4%) reviews were without Traditional Chinese Medicine (TCM) experience. Number of electronic searching databases in these reviews ranged from 4 to 15, 10 (17.5%) reviews did not examine any Chinese database. In all 57 reviews, 43 types of diseases were involved, 9 reviews focused on treatment of stroke. The number of trials included in the reviews ranged from 0 to 75, 7 (12.3%) reviews were empty. Twenty four reviews were focused on single herbs, including injection, pill, capsule or Tang, while other 33 (57.9%) reviews concerned comprehensive Chinese herbs, interventions in these reviews were "Chinese herbal medicines, Chinese herbs, Chinese medicinal herbs, Herbal medicines, Traditional Chinese medicinal herbs, and so on", the types of included Chinese herbs in these 33 reviews ranged from 0 to 69. Only 5 reviews concerned TCM outcome. **Conclusions:** Widely varied interventions

for systematic reviews of Chinese herbal medicine would lead to the clinical heterogeneity of included studies and not appropriate for Meta-analysis, then limit the generalizability and clinical application of reviews. It would also cause the difficulties of collecting trials and updating reviews. So we suggest systematic reviews of Chinese herbal medicine focus on a specific topic, avoid the selection of comprehensive Chinese herbs. Because the clinical trials of Chinese herbal medicine were mainly published on Chinese journals, so the systematic reviews of Chinese herbal medicine should search Chinese databases, however, in our study, 17 percent reviews did not search any Chinese database, it would lead to selection bias. In addition, because of the unique characteristics of TCM, if there were no TCM practitioners when doing systematic reviews of Chinese herbal medicine, the included studies with clinical heterogeneity may be combined, then affect the reliability of the evidence.

P119: The ALOIS Community

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Background: In July 2009 the Cochrane Dementia and Cognitive Improvement Group (CDCIG) launched ALOIS –an online, study-based register of controlled trials in dementia management and prevention and cognitive enhancement in healthy (www.medicine.ox.ac.uk/alois). The site was initially designed, created and maintained by a small core team based predominantly in the UK. The processes that were set up to maintain ALOIS and the tasks involved in keeping the tool both up-to-date and comprehensive meant that any voluntary assistance offered was readily accepted. This was just the beginning.

Aims: In early 2010 a project began with the aims of creating a specific and defined role and infrastructure for those wishing to volunteer with ALOIS. The project had two main strands. The first was aimed at recruiting those interested in becoming involved with evidenced-based dementia care. The second strand concerned the creation and development of the software infrastructure and workflows to support this volunteer community. **Methods:** The core ALOIS team and web developers set about creating a defined and user-intuitive community area on the existing ALOIS site. This process involved working with existing volunteers to find out what they required and wanted from such a space. This included not only easy access to their task list but also access to one another, a forum where ideas and learning could be shared, better ways of logging problems or questions with the core team, a volunteer profile area where volunteers could list their specialisms and talk a little about their background and interest in dementia. **Results:** We are still at the early stages of this project but already a volunteer community area is in existence. The space enables users to view their task list which usually comprises a list of references to potential RCTs and CCTs that need to be 'studied' by the volunteer. This studyfication takes place on the site. Once done the volunteer submits his/her work for checking by the TSC before being published. Volunteers are also able to communicate with each other through the development of a forum and can access all the required documents needed to help them with their task (such as the full papers to references and the CDCIG coding manual). **Conclusions:** This ALOIS community work with CDCIG to help to maintain an up-to-date and comprehensive study register. They also learn more about evidenced-based work in this area. At present around one third of the ALOIS community are carers of those with dementia. ALOIS

aims to make information about evidenced-based dementia practice accessible to all as well as providing people with the opportunity to make a difference in this area.

P120: What factors predict original research citation rates? Analysis of media reports, editorials, guidelines and reviews of Rituximab for non-Hodgkin's lymphoma (NHL; 1997–2003)

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Background: As new healthcare technologies emerge, information sources such as media reports, editorials, guidelines, or reviews may influence decision-makers' perceptions of the efficacy of a new treatment. **Objectives:** To understand citation relationships between original research of Rituximab for NHL and these information sources.

Methods: We searched American Society of Hematology conference abstracts, MEDLINE, and EMBASE (1997–2003) for original research reports of Rituximab for NHL, regardless of study design. We also sought review articles, guidelines, editorials and media reports of Rituximab for NHL, and identified direct citations to the research cohort. Using multivariable regression analysis, we hypothesized the following predicted higher citation frequency: earlier publications, randomized controlled trial (RCT) study design (vs. non-RCT), peer-review publication (vs. conference abstract), documents listing any author affiliated with industry, and studies with larger sample sizes. **Results:** We identified 317 original research reports and 440 related documents. The research reports included 12.9% (n = 41) RCTs, 36.3% (n = 115) peer-review publications, and 21.1% (n = 67) listing any author affiliated with industry. The median (interquartile range) number of evaluated patients was 27 [9 to 53]. The 440 related documents included 36.3% (n = 160) reviews, 2.0% (n = 9) guidelines, 13.4% (n = 59) editorials, and 48.2% (n = 212) media reports; 51.3% (n = 226) cited no original research in the cohort, the majority, media reports (86.3% (n = 195)). The 214 documents represented 1,571 direct citations (90.1% reviews, 1.6% guidelines, 6.9% editorials, 1.1% media reports). The multivariable analysis was statistically significant (p < 0.001), with all hypothesized predictors except RCT study design independently associated with higher citation frequency.

Conclusions: Rituximab RCT study design did not predict higher citation frequency, and few media reports cited original research evidence. Evidence consumers need to be vigilant about the types of original research evidence cited to support clinical or policy decisions. We need more research to understand the content and quality of cited studies.

P121: Validation of a PubMed search filter for identifying studies including children

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Introduction: For physicians and other medical professionals, it is important to find relevant information on their field of interest. Various search filters, especially for identifying clinical trials and systematic reviews, have been developed. The aim of this study was to develop a PubMed search filter for identifying studies including children for the Cochrane Childhood Cancer Group (CCG), and to validate this search filter. **Materials and Methods:** The CCG search filter has been developed by identifying keywords and MeSH headings from relevant publications and by discussions with experts in the field. We validated the search filter by calculating the sensitivity and precision, and compared these results with six other known search filters for children (PubMed Limit All Child, three by Kastner *et al*, Child Health Field, and BestBets). Sensitivity was calculated by dividing the number of retrieved relevant randomized controlled trials (RCTs) and controlled clinically trials (CCTs) by a Gold Standard set of relevant studies. This new Gold Standard was developed by collecting all RCTs and CCTs reported in Cochrane intervention reviews that included children (1951–2008). The precision of the 7 filters was calculated as Number Needed to Read (NNR) in a set of records focussed on children obtained from PubMed in September 2008. All records were assessed by two authors individually to determine whether a study included children or not. In case of disagreement a third author was consulted. **Results:** The five child search filters from CCG, Child Health Field, BestBets, Kastner (filter for 'best sensitivity') and PubMed showed a high sensitivity to detect studies including children (98.2, 98.1, 98.2, 97.6 and 97.3 respectively). Two of the three child search filters from Kastner *et al* performed less well in PubMed; their sensitivity was 46.4 and 54.2 respectively. These filters were regarded as the filter for 'best specificity' and the filter for 'best optimization of sensitivity and specificity' by the authors. The results of the differences in precision will be discussed at the Colloquium. **Conclusion:** All search filters for identifying studies including children performed rather similar, except for two search filters developed by Kastner *et al*, which performed less well. Based on the results of this study recommendations can be made for the improvement of the CCG child filter.

P122: Comparing the Impact of the Cochrane library in Web of Science and Scopus

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Background: Citation analysis can provide an insight into the publishing habits of the research community. Information is available not only on publishing authors and research groups, but also on those who are citing particular pieces of work. **Objectives:** This study will examine the citation Impact of the Cochrane Library, as observed through the lens of Thomson Reuter's Web of Science and Elsevier's Scopus. **Methods:** Publication and citation data will be downloaded from Web of Science and Scopus and analyzed to examine the differences and similarities between the groups of citing and cited authors, and between the journal metrics derived from these two data sources. **Conclusions:** New scales and ranking systems may provide a different picture of citation activity. Is this picture more or less indicative of the Impact of the Cochrane Library?

P123: Shared decision making in health care: a literature review

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Background: The topic of shared decision making has been studied for over years, and its importance has been increasingly recognized. **Objective:** To investigate the publication of shared decision making in health care setting in literature including their coverage of classification, year of publication, country of origin and disease distribution. **Methods:** Three databases including MEDLINE, EMBASE, and CBM were searched from 1996 to 2009. The search terms were 'shared decision making', 'shared determinant', 'patient value preference in decision making' and 'patient and doctors' communication'. Two reviewers initially worked independently including selecting, identification and evaluation the available data.

Results: There were 903 articles published from 1996 to 2009. Data were collected and represented for the following aspects. 1) Most articles mainly discussed or providing the general descriptions of shared decision making and ways of how to promote this new model. 2) The number of articles for shared decision making increased over the past years, especially after 2000. The number of articles published from 2006 to 2009 increased by 677% (433/64) compared with the number from 1996 to 1999. 3) Among the total of 903 articles, only 13 (1%) were from developing countries. 4) Diseases coverage mostly were cancer (34%), psychological and neuropathy disease (17%) and cardiovascular disease (10%) respectively. **Conclusions:** More researches are needed to examine the influences, limits, and possible dangers of shared decision making if there is any. Developing countries should carry out more researches on shared decision making. More research should be conducted on other specialist areas especially chronic diseases.

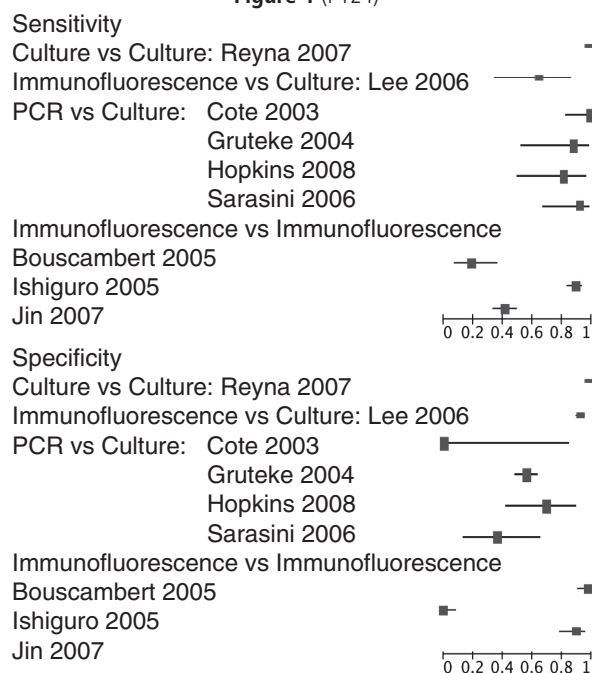
Table 1 (P123): Representation of year, country and disease in articles for shared decision making. (Zhang et al.)	
Characteristic	Trials No. (%)
All articles	903 (100)
Publication by year	903 (100)
~1999	64 (7)
2000~2004	323 (36)
2005~2009	516 (57)
Coverage by country	903 (100)
USA	399 (44)
UK	126 (14)
Germany	98 (11)
Netherland	42 (5)
Australia	33 (4)
Coverage by disease	410 (100)
Cancer	138 (34)
Psychological and neuropathy disease	71 (17)
Cardiovascular disease	39 (10)
Gynecological disease	24 (6)
Chronic pain	22 (5)
Respiratory disease	22 (5)
Orthopedic disease	20 (5)
Renal disease	17 (4)

P124: Diagnostic accuracy of human metapneumovirus. Systematic review

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Background: Respiratory viruses are common. Specific etiology remains without identification at least at 50% of the cases. Human Metapneumoviruses were identified en 2001; it is an important etiologic agent in low respiratory airway diseases in children. There are 4 diagnostic tools for human metapneumoviruses: serologic diagnosis, culture (gold standard), RNA detection by RT-PCR and antigens. There is no treatment for this infection. **Research Question:** In pediatric patients with respiratory airway infections caused by human metapneumovirus, what is the diagnostic accuracy (sensitivity, specificity, positive and negative predictive value) of PCR, culture, immunofluorescence and serologic diagnosis? **Objective:** Identify diagnosis accuracy (sensitivity, specificity, positive and negative predictive value) of PCR, culture, immunofluorescence and serologic diagnosis for human metapneumovirus in pediatric patients with lower airway infection or data to build 2x2 table. **Methods:** **Types of studies:** Diagnostic accuracy papers. **Search Strategy:** **Keywords:** Human Metapneumovirus, PCR, culture; immunofluorescence, serologic studies, antibodies, diagnostic test, diagnostic, diagnostic accuracy. We did search in these data bases: Lilacs, Artemisa, Scielo, Pubmed, Embase. **Methodology Quality:** All papers included in this review were measured with Stard and Quadas scales. **Results:** We got 169 papers. 147 were dismissed because they were not diagnostic accuracy papers or because they had incomplete data. At the end we had culture against culture (one paper), immunofluorescence against culture (one paper), PCR against culture (four papers), immunofluorescence against PCR (fourteen papers) and PCR against PCR (2 papers). **Conclusion:** The diagnostic test with the

Figure 1 (P124)



best diagnostic accuracy was culture. PCR is a useful diagnostic test with a good diagnostic accuracy but more studies are needed in order to get best evidence.

P125: Children with asthma and steroid treatment. A meta-ethnography synthesis on how Cochrane reviews findings have been considered in international guidelines

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Background: Asthma is a high-prevalent capricious disease with multiple triggering factors and frequent medical admissions. Steroids are the first line treatment, but cause important adverse effects. The American National Heart Lung Blood Institute, together with WHO, promoted a global plan of International Guidelines (IG) supporting steroids use to control asthma. Selective disclosure of the results of Cochrane Reviews (CR) appeared in IG. **Objectives:** Balancing risks and benefits of different steroids routes to control asthma using a meta-ethnography synthesis to state third order interpretations for future independent research. **Methods:** Meta-ethnography is an interpretive method clarifying concepts, expressing synthesis and lighting new hypotheses to policy-makers. We searched, matched and categorized concepts and outcomes from CR and IG, focusing on different steroid routes for treating asthma, and synthesizing third order interpretations in the attempt to state hypotheses, not elicited in original papers. **Results:** 32 CR and 7 IG were retrieved and categorized. The concept of risk showed conflicting understanding. In IG meant exacerbation requiring corticosteroids while in CR it referred to adverse event with steroid use. In IG the evidence was limited to small, single-centre studies yielding recommendations based on extrapolation from trials of add-on therapy and hiding adverse effects. In CR evidence showed similar net benefit with different steroid routes or doses. These findings, in IG, guided to mismatches of benefits, including earlier discharge and fewer relapses, far from being balanced with the evidence of adverse events. Third order interpretations showed reducing height in children with inhaled steroids, incompletely reported in IG. Cooperative management with families and steroid-sparing drugs, assessed in dated IG, reappeared in third order interpretations. **Conclusions:** Bewildering conflict of interests and low quality exists in authoritative IG showing selective disclosure of recommendations derived from CR. Third order interpretations elicited innovative approaches stifled in IG and stimulate testable hypotheses for future CR.

P126: Application of the Knowledge to Action cycle in a Public Health Setting

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Background: The Knowledge to Action loop is a conceptual framework used to describe the movement of knowledge into action. It integrates the functions of knowledge creation, with that of knowledge

application. This model was used as the basis for a 3-day advanced evidence-based practice course for practitioners in public health. **Objectives:** To increase the practitioners' skills and knowledge in applying the cycle to public health practice, and to describe the challenges encountered. **Methods:** Three directly relevant case studies were developed before the workshop: an infectious disease response (communicable disease), addressing physical inactivity in a regional community (health promotion), and a community level intervention for food supply (public health nutrition). The knowledge to action cycle was taught in steps as lecturers, and applied by each disciplinary group. The groups undertook searches of the literature and applied critical appraisal tool whilst supported by their regional epidemiologists. **Results:** Participants struggled in defining the problem and identifying the applicable knowledge. The lack of systematic reviews specific to the topic increased the challenge of the task. For example, the public health nutritionists literature search only found a Cochrane registered title on food security. Each group was observed in accessing and assessing published literature throughout the workshop. Upon conclusion, each working group was able to present their response to the case-example using the framework. **Conclusions:** The challenges experienced were partly due to the complex nature of public health work, and also the lack of comprehensive synthesis research relevant to public health. The KT cycle appears to be a useful framework to public health although these is some scope for adaptation to the particular context. Knowledge translation is enhanced through the support of epidemiologists.

P127: 'Clustering' documents automatically to support scoping reviews of research

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Background: Scoping reviews differ from systematic reviews in that they are limited to a preliminary assessment of the potential scope and size of the relevant research literature, and indicate potential research gaps. They are often conducted on the title and abstract level, and describe different aspects of the research literature, for example, study design, population, intervention elements and outcomes. The EPPI-Centre conducted two such scoping reviews for the Department of Health in England. **Objectives:** To assess the value of automated clustering using text mining to provide rapid descriptive codes across a range of study characteristics in order to generate themes across research records. **Methods:** Studies included in two public health-related systematic scoping reviews that have previously been coded by researchers across a range of characteristics at the title and abstract level were uploaded to the text mining software. The clustering function was employed to generate descriptive codes for all research records. Comparisons were made between the automated and researcher-assigned codes. **Results:** Preliminary results indicate clustering can be useful in describing literature for scoping reviews thematically in terms of topic focus, population groups and well-described study designs. Researcher input and knowledge of the literature enhances the usefulness in application. Optimal use of the function is a combination of researcher checking and reassigning ambiguous codes, variation of the minimum word length

for clustering (longer descriptive labels result in smaller, more focused clusters) and undertaking manual free-text searches in conjunction with cluster-assigned codes. **Conclusions:** Clustering is a promising tool in contributing to rapid scoping reviews, although there are limitations owing to the diverse terminology used in describing public health literature.

P128: Two examples of synergy between an Academic institution and policymakers in Argentina

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Background: Interaction between researchers and policymakers related to knowledge transfer has been motive of review and mythological analysis. **Objectives:** To describe two examples of synthesis of evidence in response to government requirement **Methods:** A systematic approach was used to search, retrieve and synthesize relevant evidence in response to questions formulated by policymakers of the national Ministry of Health. Electronic searches in specific databases (MEDLINE, LILACS and DARE/Cochrane, etc), meta-searchers (Clinical Excellence) and hand-searching were performed. Study selection was done in two phases: 1. Population, intervention and outcome criteria were applied by two reviewers to select eligible studies; 2. Cochrane Effective Practice and Organization of Care Review Group evaluation criteria were applied by one reviewer in order to select included studies. Evidence was synthesized and presented in a friendly format **Results:** Case 1 community participation in dengue control; Question; What is the effectiveness and/or cost-effectiveness in the short, medium and long term of community based strategies either isolated or combined with other strategies to prevent and/or control of dengue vector? 1563 references were recovered. Of these, 135 studies met the eligibility criteria and 77 were potentially relevant to the report: 3 studies were systematic reviews (synthesize 62 of 77 retrieved articles), 3 economic evaluations and 10 were not included in systematic reviews Case 2 2009 H1N1 influenza in pregnancy Questions a) Are antiviral drugs safe and effective for the prevention/treatment of influenza in pregnant women? b) What is the effectiveness and safety of influenza type A (H1N1) in pregnant women? 200 references were retrieved, of which 115 met the eligibility criteria. Of these, 98 articles were included for analysis. Two brief reports containing key messages were presented to policymakers. **Conclusions:** Rapid response can be developed in a clear, transparent and systematic way at the request of policymakers to help informed decisions.

P129: How well do the malaria rapid diagnostic tests for detecting the asymptomatic carriers in the endemic countries?

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Background: Good-quality microscopy remains the standard laboratory method for the diagnosis of malaria. However, access to

good-quality microscopic examination in endemic countries is limited, as resources are often lacking. The polymerase chain reaction (PCR) has also been established in the diagnosis of malaria. But, the expertise and the infrastructure required preclude its routine use in many health care settings. Rapid diagnostic tests for malaria (RDTs) detect parasite antigens in lysed blood from a finger-prick blood sample. This test is fast and easy to perform without special equipment or special skills. To date, systematic reviews of the accuracy of various RDTs in well controlled research settings using symptomatic patients in the endemic areas with either microscopy or PCR are available. People living in endemic areas often harbor *Plasmodium* parasites, but are asymptomatic. This asymptomatic state poses an important source of continuous malaria transmission within in the region. The accuracy of RDTs where people are primarily asymptomatic has not been assessed systematically. Hence, a research question arises: Whether RDTs are useful for detection of malaria in primarily asymptomatic people in the endemic countries? **Objectives:** To evaluate the accuracy of RDTs for detection of malaria in primarily asymptomatic people. **Method:** The method recommended in the Cochrane systematic review of diagnostic test accuracy is applied. The included studies identified for this meta-analysis compared the accuracy of RDTs with reference microscopy and/or PCR. The relevant study population is primarily asymptomatic people residing in endemic areas. **Results:** The diagnostic accuracy, and the risk of bias of studies identified for this analysis will be presented. **Conclusions:** The use of RDTs for rapid mass surveillance in malaria control so as to reduce the transmission and consequently the magnitude of malaria will be justified.

P130: Systematic Review Methods for Observational Studies: Challenges and Solutions

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³ *Centre For Research on Children and Families, McGill University, Montreal, Quebec, Canada*

Background: Systematic review methods have been well established for interventions studies. However, less is known about how to manage reviews of observational studies. Grant submissions for observational studies require researchers to articulate state of art knowledge to substantiate the rationale for the study. Although 'cherry picking' studies that adequately generate this rationale are appreciated, reviewers have no way of knowing if these studies are representative of what is known. Therefore, a more systematic way of collating knowledge is required. **Objectives:** The purpose of this presentation is to identify a protocol for systematically reviewing observational studies, how this compares to protocols for reviewing intervention studies, and the challenges that researchers faced and solutions generated in developing this protocol. We were interested in parenting of children with neurodevelopmental disorders, how parenting differed from that of parenting children without neurodevelopmental disorders, as well as the correlates of parenting. **Methods:** Campbell Collaboration protocol for intervention studies was adapted to conduct a systematic review of observational studies related to parenting of children with chronic health conditions and disabilities. Over 10,000 abstracts were generated using a keyword search in 6 different databases. Abstracts were submitted

to first and second level initial screening, strict screening, and data extraction. **Results:** Challenges associated with the systematic review of observational studies include management of an inordinate quantity of data, multiple outcome measures, measures that purport to evaluate the same phenomenon but are conceptually disparate, measures of varying quality, studies that report correlational data but have no comparison or control group, studies that report only within group analysis, management of multiple findings (correlations and regression analysis). **Conclusions:** Although conducting a systematic review of observational studies is challenging, the issues are shared across substantive areas and require consensus building that can only be achieved through collaboration.

P131: Musculoskeletal and pain research design and quality

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Background: Musculoskeletal and chronic pain complaints account for large numbers of health care services and a disproportionate amount of expense. However, there is substantial doubt about the effectiveness of many tests and treatments in those clinical areas. **Objectives:** To critically appraise the literature on testing and treatment of musculoskeletal and chronic pain problems. To provide evidence-based guidance for testing and treatment. To suggest improvements in research design and execution in these areas.

Methods: Researchers posed answerable clinical questions, searched MEDLINE, Cochrane databases, EMBASE, PEDro, CINAHL and other sources, screened thousands of studies and reviews, and critically appraised selected studies using methodologies adapted from the Cochrane back group, other Cochrane approaches and USPSTF.

Results: This structured appraisal of individual studies revealed considerable risk of bias. Reviewers found widespread design and execution problems such as use of subjective outcomes; small group size; lack of case/diagnostic definitions; non-standard or "black box" interventions; no true control groups; crossover among groups; unacceptable drop out rates; short-term follow-up only; and failure to assess harms. Known variables affecting these complaints, such as SES, education, job control and latitude, job and task satisfaction, satisfaction with care, locus of control and litigation, were seldom included as variables. Function was seldom used as an outcome. Most "systematic" reviews suffered from incomplete searches, non-standard study grading, selective use of studies, and inadequate or incorrect interpretation of results. Results were often heterogeneous.

Conclusions: These errors reduce the likelihood that the resulting conclusions or guideline recommendations would be consistent or reproducible. This presentation will suggest an agenda for research to produce more robust evidence to support clinical practice and patient information. Functional outcomes and relative efficiency are primary concerns.

P132: Patients' perspectives on maintaining their personal medication information to improve patient-provider communication and facilitate shared decision making: a survey

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Background: Empowering patients to be more proactive in managing their medication information and engaging them in shared decision making is an important step towards optimizing drug therapy and preventing medication errors. **Objectives:** To investigate patients' attitudes and beliefs about creating and managing their personal medication list and its impact on communication and shared decision making with health care providers. **Methods:** Survey and structured interviews among a consecutive sample of patients attending the pre-operative clinic for elective surgery at UCSF September 2009–March 2010. Survey data were analyzed using descriptive statistics and qualitative data were analyzed to identify common themes for maintaining or not maintaining a medication list. **Results:** Of 192 eligible patients, 140 patients completed the survey (73% response rate). Patients averaged 61 years of age (range 22–89 years), 51% male, predominantly Caucasian (77%) and completed some level of college education (78%). Most patients brought a medication list to their clinic visit (79%) after receiving telephone reminders and written instructions from clinic staff, however few reported that a health care provider recommend they maintain a medication list and discuss it at every health care visit (36%). Among the 111 patients with a list, 87% reported improved communication with their doctor and common reasons for maintaining a list included improved self-management of their medications and convenience. Common themes among patients without a list included lack of importance or need (e.g., can remember their medications) and expectations that providers and hospitals will maintain accurate medication information within their health records. **Conclusions:** Personal medication lists maintained by patients provide an opportunity to improve communication and facilitate shared decision making between patients and health care providers. Interventions that encourage and empower patients to maintain a medication list and make it accessible for review with providers are needed.

P133: What do test-treat trials measure?

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Background: Will introducing a new diagnostic test benefit patient health? This question underpins the evaluation of diagnostic tests. Randomised controlled trials (RCTs), that randomise patients to diagnostic strategies and evaluate patient outcomes after the implementation of subsequent treatment, are the methodological gold-standard. However RCTs are only as informative as the outcomes they measure. This choice is particularly tricky in test-treat trials, since outcomes must evaluate the effects of a whole care pathway: diagnosis, consequent decision-making and treatment. Outcomes that fail to capture the effects of these complex interventions are likely to produce misrepresentative evaluations of performance. **Objectives:** To

evaluate the methodological validity of outcome selection in test-treat RCTs. **Methods:** Published test-treat RCTs were identified through the Cochrane Central Register of Controlled Trials (Issue 2 2009, years 2004–7). Included RCTs evaluated test-treat strategies of any diagnostic modality and assessed patient outcomes after treatment. A new framework that explains the mechanisms by which tests might benefit patient health is used to analyse each test-treat comparison, hypothesise which outcomes should be measured to fully capture all putative benefits of a strategy, and extract and examine the outcomes that have actually been measured. **Results:** Of 12,619 titles, 106 (0.8%) articles reported RCTs of test-treat interventions evaluating at least one patient outcome. A wide range of clinical settings and testing modalities are represented, the most common being cardiovascular medicine (33%) and imaging (39%) respectively. A summary of outcomes measured is presented alongside an appraisal of whether they capture the theoretical processes of change as identified by the framework. **Conclusion:** Comment is given on the degree to which outcomes measured in test-treat RCTs capture the likely processes of change to patient health offered by the new strategy. The presentation will conclude with thoughts on how frequently published evaluations may be misrepresenting the performance of test-treat interventions.

P134: Generation of quality indicators based on systematic reviews

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Background: Evidence-based quality indicators are a reliable tool to objectively measure the degree in which the correct care is provided, given the current state of knowledge. Researchers and policy-makers may use them to compare performance of care over time in a single centre or between similar centres. **Objectives:** To develop an evidence-based quality indicator set that measures the appropriateness of acute obstetric and delivery care in a hospital setting. **Methods:** We did a comprehensive search on the most important bibliographic sources (i.e. The Cochrane Library, Clinical Evidence and databases of clinical practice guidelines) to identify those therapeutic procedures for which a major recommendation (in favour or against) could be formulated based on high quality systematic reviews (SR). We used the GRADE instrument to assess the strength of recommendations. We followed a structured process that combined scientific evidence and expert advice to develop a quality indicator set based on the selected major recommendations for obstetric and delivery care. **Results:** We identified 303 SR, 48 of which were of high quality and assessed acute therapeutic procedures. Only 20 SR lead to a strong recommendation in clinical practice. Input from a group of experts led to the exclusion of two recommendations due to difficulties in applicability. We thus developed a total of 18 quality indicators: eight of them referred to prepartum care, eight referred to delivery, one referred to postpartum and one referred to incomplete miscarriage. These quality indicators were further tested for their validity in a pilot study of a random sample of 100 pregnant women seeking care in three hospitals. **Conclusion:** It is possible and feasible to develop evidence-based quality indicators to measure the appropriateness of care in Obstetrics. SR can provide an important source of evidence when developing indicators based on the current state of knowledge.

P135: Incorporating quality of efficacy documentation in health economic evaluations

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Background: Grading of Recommendations Assessment, Development and Evaluation (GRADE) is now commonly used to grade the quality of outcomes based on systematic reviews such as Cochrane reviews and health technology assessments (HTAs). Model based health economic evaluations are an important part of HTA reports in several countries. Policy recommendations are frequently based on this type of analysis. A Bayesian framework is often applied to these economic evaluations. In a Bayesian framework, models for economic evaluation should be based on parameters with uncertainty described by a probability distribution. For efficacy parameters based on meta-analyses, it is common to use probability distributions based on the mean and standard error from a meta-analysis. This does however not reflect the uncertainty related to study quality. **Objectives:** To explore the usefulness of GRADE in health economic evaluations. **Methods:** We incorporated results from GRADE into all efficacy parameters indifferent models developed by the Norwegian Knowledge Centre for the Health Services (NorCaD, MOON, COSMO and MOCCA). Models were the run both with GRADE incorporated and without to show whether there was any difference in cost-effectiveness. **Results:** We performed regular cost-effectiveness analyses which showed substantial differences in results when GRADE was incorporated, compared to when GRADE was not incorporated. We also performed some expected value of perfect information analyses which showed that incorporating quality of trials in analyses would imply that it is more cost-effective to conduct new research. **Conclusions:** The use of GRADE in health economic evaluations gives results that are different and changes the uncertainty around the conclusions. If GRADE is an appropriate tool to assess the quality of outcomes, then we believe that the inclusion of GRADE in health economic evaluations is more appropriate than not including it.

P136: International activity within Cochrane Review Groups

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Background: Since 2000, a periodic count has been done of members of Cochrane Review Groups (CRGs), subdivided by country of residence. Initially, this used data from The Cochrane Library but for the audits in 2009 and 2010, it used 'Archie' (The Cochrane Collaboration's Contact Database). **Objective:** To assess international activity within CRGs. **Methods:** Data were retrieved on 9 February 2010 for all contributors to CRGs whose contact details were in Archie. One author (CA) analyzed the data by role within the CRG and country of residence. People listed more than once were counted each time. **Results:** Among 51 CRGs, there were 27,724 contributors from 110 countries. There were 17,637 people (103 countries) in 2008; 13,047 (97) in 2005; and 5436 (64) in 2000. The substantial increase in the recorded number of contributors over the past two years is due in part to the change of data source from The Cochrane Library to Archie. In 2010, 21,122 (76%) contributors were listed as authors, compared

with 18,057 (75%) in 2009; 10,698 (61%) in 2008 and similar proportions in earlier years (e.g. 7543 (58%) in 2005 and 2840 (52%) in 2000). Some of the increase since 2008 is due to Archie's inclusion of authors of registered titles that have not reached the protocol stage (these were not included in The Cochrane Library). There are now 5315 contributors in countries with low- and lower-middle, and upper-middle income economies (19% of the total), compared to 18% (4364 contributors) in 2009 and 6% (307) in 2000.

Conclusions: The number of people involved in the work of The Cochrane Collaboration continues to grow, as does its international diversity. There is a continuing increase in contributors from low- and middle-income countries. Other data analysis will be shown in the poster. The data are available at www.cochrane.org.

P137: Epidemiology, quality and reporting characteristics of systematic reviews on TCM published in China journals

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Background: Systematic review (SRs) on Traditional Chinese Medicine (TCM) have become increasingly popular in China and have been produced in large numbers. But the broad range of epidemiological characteristics, reporting detail and scientific validity of these systematic review is unknown. **Objective:** Through examine these SRs in term of the broad range of epidemiological and reporting characteristics and scientific validity to identify the research status of these review on TCM current published in China Journals, and further improved and guide the development of SRs on TCM in China. **Method:** Four Chinese databases including Chinese Biomedicine Literature Database (CBM), Chinese Scientific Journal Full-text Database (CSJD), Chinese Journal Full-text Database (CJFD), and Wangfa Database were searched for SRs on TCM in the end of the Dec.2009. The search terms included "systematic review", "Meta-analysis", "Traditional Chinese Medicine" and "Chinese herbs" (Mesh or Emtree). Data were collected using a Excel form designed to examine the epidemiological and reporting detail. AMSTAR checklist were used to appraise the scientific validity of these SRs. **Results:** In total 369 systematic reviews were identified, involving 146 disease, 20 herbs, 11 decoctions and 10 pills. All reviews were categorized as therapeutic. 49.8% (184) review were written by Clinicians, and nearly half (176 [47.7%]) reviews were reported in specialty journals. Fund sources were not reported in all reviews. Only one-third (120 [32.5%]) reviews were published in Chinese Science Citation Database (CSCD) cited by journals and the impact factor of nearly half (169 [45.80%]) reviews were zero. Information retrieval were not comprehensive in nearly half (166 [45.0%]) reviews. Most (224 [68.8%]) reviews reported information about quality assessment, while less half (161 [43.6%]) reviews reported assessing for publication bias. Statistic mistakes appeared in nearly one-third (108 [29.3%]) reviews. Most (339 [91.9%]) were not reported conflict interests. Though 97.6% reviews used the term "systematic review" or "Meta analysis" in the title, no any reviews were updated after they were published two or more years. **Conclusion:** Systematic reviews on TCM

were published in large number in China Journals in recently years. Though the range of disease and chinese herbs were wide, the quality of these review were worrying. The information reported from these reviews were not comprehensive and even some were mistake. It did not only provide evidence for clinicians but also misled them. Hence, the most urgent and important thing is to improve the quality of SRs on TCM, not accelerate the quantity of SRs in China.

P138: The effectiveness of teaching in Evidence-Based Medicine in Eastern Taiwan

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Background & Objectives: "Evidence-Based Medicine" is core element of medical education in the 21st century. The purpose of this study was to understand the application of the "problem-based learning" in the promotion of the effectiveness of Evidence-Based Medicine. The study were conducted evidence-based medicine educational and promotional activities at a teaching hospital in eastern Taiwan from April 2008 to March 2009. Subject from various medical teams including five doctors, fifteen nurses, three pharmacists and two medical laboratory scientist. **Methods:** Teaching methods are divided into three stages: the core members to review the information of EBM, Clinical questions raised, as well as the actual operation, group competitions about literature search. All members learning contents are included: 1. Listed in the possible formation of problems; 2. Search for the information strategy; 3. For information on the critical principles and selection criteria; 4. How to apply the clinical care of patients. Applications discussed in peer group learning for professional growth and enhance the effectiveness of cooperative learning groups, and thus to achieve organizational learning and knowledge renewal goals. We used the Liker scale development of the questionnaire is divided into very dissatisfied not satisfied, general, satisfied and very satisfied. Data were analyzed using descriptive analysis results in active time, the learners in a satisfactory accounting for 82.6%, and 82.3% the participants have selected the topic satisfied with the arrangements, about 86% reported that panel discussions is a good way of learning. **Results:** Participants in the group competitions benefited the most are the PICO 83% followed by the search strategy 61%, references are cited 60% and conclusion sum up accounts 52%. Participants are expressed through participation in group discussions can enhance each other's feelings. The greatest difficulties encountered in the event are: the process of accounting practices are not familiar with: 43.48%, the time is too short: accounting for 39.1%, the subject too difficult to account for 4.35%. **Conclusions:** In the "literature search strategy approach", "literature appraisal skills," and "systematic literature review", participants felt that the content of this learning was more difficult, the future consider providing a way EBM advanced classes, expanding the content of the three domain to achieve training purposes. In conclusion, in order to contest the promotion of EBM teaching activities, in addition to learning through group cooperation to enhance the members learning motivation and interest, the participants also significantly increased the effectiveness of learning.

P139: Awareness and use of evidence-based medicine databases and The Cochrane Library among physicians in Croatia

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Objective: To assess awareness and use of evidence-based medicine (EBM) databases and The Cochrane Library among physicians in Croatia. **Methods:** A cross-sectional study with a telephone survey was performed among 573 physicians (88.6% response rate from contacted 647 physicians) from family practice and 4 major university hospital centers in Croatia. The main outcome measures were physicians' awareness of The Cochrane Collaboration, awareness and use of The Cochrane Library, access to EBM databases and access to Internet at work. **Results:** Overall, 54% of respondents said they had access to EBM databases, but when asked which databases they used, they mostly named non-EBM databases. The question on the highest level of evidence in EBM was correctly answered by 53% respondents, 30% heard of The Cochrane Collaboration, and 34% heard about The Cochrane Library. They obtained information about The Cochrane Library mostly from colleagues and research articles, whereas the information about EBM was gained mainly during continuous medical education. There were more respondents who thought The Cochrane Library could help them in practice (58%) than those who heard about The Cochrane Library (30%). Only 20% of the respondents heard about the initiative for the establishment of the Croatian branch of The Cochrane Collaboration. Family physicians had significantly lower level of awareness, knowledge and use of EBM and The Cochrane Library than physicians from university hospitals. **Conclusion:** There is insufficient awareness among physicians in Croatia about EBM and Cochrane organization. There is a need for educational interventions about EBM for the benefit of health care in Croatia.

P140: The Cochrane Library publicity – media coverage around the world

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Background: Reviews from The Cochrane Library, published in the Cochrane Database of Systematic Reviews are often reported by newspaper and broadcast journalists, and bloggers. Press releases highlighting selected new and updated Reviews are an important part of the publication process and marketing strategy for The Cochrane Library. **Objectives:** The objective of Wiley-Blackwell's publicity strategy is to raise the international profile of The Cochrane Library through professional and consumer media, and to increase usage. **Methods:** A number of new and updated reviews are selected

for publicity activity from each issue of The Cochrane Database of Systematic Reviews. During 2009 the selection took place each quarter, and since January 2010 this has become a more frequent process to coincide with the change monthly publication. By analysing the resulting coverage, including a regional breakdown of where different reviews are reported, we can provide an interesting snapshot of the issues of interest to the international community. We also look for a corresponding increase in usage for the articles that are most widely reported. **Results:** Usage of The Cochrane Library on Wiley InterScience continues to increase month on month. A portion of this successful usage development is a result of Wiley-Blackwell publicity strategy. Increasingly our press releases are highlighted and reported via social media, including blogs and Twitter. An up-to-date analysis of international coverage, including the most publicised Reviews of 2009 will be presented when complete. **Conclusions:** Media coverage of new and updated Cochrane reviews raises the international profile of The Cochrane Library in both professional and consumer media, and increases usage of Cochrane Reviews. In the future we need to be aware of the differences in reporting in different media and regions, including the continuing increase in the use of social media tools to promote Cochrane Reviews.

P141: Are you listening? Podcasts from The Cochrane Library; a review

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Background: Podcasts from The Cochrane Library were first launched in January 2008. Since then, there has been an increase in acceptance from authors to record podcasts, but also a huge increase in usage for Cochrane podcasts. Now, with monthly publication, and fewer podcasts published, but more frequently, how will this affect the usage? **Objectives:** The poster will highlight the dissemination of podcasts around the world, and analyse who is listening to the podcasts from The Cochrane Library from 2008 to April 2010. It will also cover the developments of the podcasts from the pilot project in 2008 through to the first quarter of 2010, with monthly publication and additional features. **Methods:** Cochrane podcast statistics are collected on a regular basis and disseminated to authors. These statistics will be used to form the basis of the poster, with comparisons of usage from quarterly publication during 2008 and 2009, alongside the monthly publication of January – April 2010. **Results:** We know from the previous years, what a huge success the podcasts have been for The Cochrane Library. With the move to monthly publication, and the addition of Cochrane Journal Club podcasts, the results from the usage data will raise future development questions that will keep the Cochrane Podcasts evolving. There are some interesting questions also raised about the 'missing' data that we don't have access to. **Conclusions:** Cochrane podcasts have been a huge success since 2008. By analysing the results from 2008 through to April 2010, it will be clear how the pilot project has evolved and will raise further development questions that need to be addressed, moving into 2011. We are hopeful that by sharing the statistical information about the podcast usage, it will engage more authors and review groups to participate in Cochrane podcasts.

P142: The quantity and quality of evidence of pandemic

Yaolong Chen

Background: It is estimated that 10% to 15% of people worldwide contract influenza annually, with attack rates as high as 50% during major epidemics. Global pandemic viral infections have been devastating because of their wide spread. But the quantity and quality of evidence of pandemic are still unknown. **Objective:** To investigate the quantity and quality of evidence of severe acute respiratory syndrome (SARS), Avian H5N1 and Influenza A(H1N1) so as to provide best evidence for policy makers, researchers, clinicians and patients. **Methods:** Four databases including MEDLINE, EMBASE, CBM, Cochrane library were searched from 2003 to 2010. The search terms included SARS, severe acute respiratory syndrome, avian H5N1, influenza virus A H5N1, swine influenza, Influenza A(H1N1). **Results:** More than 20 000 papers focused on SARS, Avian H5N1 and Influenza A(H1N1). But there were only 43 systematic reviews and 115 randomized controlled trials, less than 1% of all papers. Among these higher quality evidence 34 papers (21%) came from China and 20 papers (13%) about Traditional Chinese Medicine. **Conclusions:** Although there were a lot of papers published about pandemic, few of them were higher quality evidence. A fifth of evidence come from China research institution and most of them were related to Traditional Chinese Medicine. Complementary and Alternative Medicine may give us a new treatment method in the case of pandemic.

Table 1 (P142)

		2003 SARS	2006 Avian H5N1	2009 Influenza A(H1N1)
All	CBM	8832	736	290
	MEDLINE	3669	2297	1631
	EMBASE	3941	2754	1401
	Total	16442	5787	3322
SR	CBM	9	0	0
	MEDLINE	6	2	2
	EMBASE	16	7	2
	Cochrane Library	10	1	1
Total*	31	9	3	
RCT	CBM	25	0	0
	MEDLINE	13	31	23
	EMBASE	13	23	10
	Total*	46	41	28

*Remove Duplicate

P143: Evaluation of COREL (Collaborative online Revman learning) an alternative training method of Cochrane systematic review process

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Background: Collaborative online learning is a training approach that incorporates the principles of didactic online learning from web based

tutorials and traditional interactive workshops. A prototype online course *COREL (Collaborative Online Revman learning)*, was developed to implement *Cochrane Systematic review* training, over a period of 3 years. It involved: A team of 3 or more peers with a shared registered 'Title' -one of whom is the facilitator, *Cochrane Information Management System (IMS)* which includes *Revman* and *Archie* forms the workspace in which collaboration is accomplished, *Cochrane Systematic Review* or the protocol which is the interactive, facilitated process for the learning experience and *Video/Audio conferencing* which supports synchronous collaboration activities. **Objective:** To evaluate the effectiveness of *COREL* training program. **Methods:** Data from records of synchronous collaborations, IMS and Revman database history of the *Cochrane systematic reviews* included in the *COREL* program and an author- post workshop evaluation survey adopted from the regular training workshops were analyzed. **Results:** 28 titles included in *COREL-11* full reviews, 10 published protocols, 6 ongoing protocols, and 1 registered title. There were 3 to 7 authors in each program, including 1 to 2 facilitators; total number of authors and facilitators in the program 30 and 6 with author proficiency level 1,2 and more than 2 reviews- 11,10 and 9 after training in the program. Number of synchronous encounters in the individual program ranged 2 to 5 and number of asynchronous encounters (authors- IMS access frequency) ranged 31 to 98, average time to publication for protocol is 6 months, for review 15 months. Author rating of usefulness and satisfaction with content, presentation, online learning, discussions, time and organization convenience, and perceived advantage over the conventional training method were overall positive. **Conclusion:** The training for systematic review authoring provided via the *COREL* program is effective in terms of author proficiency, satisfaction, and review productivity.

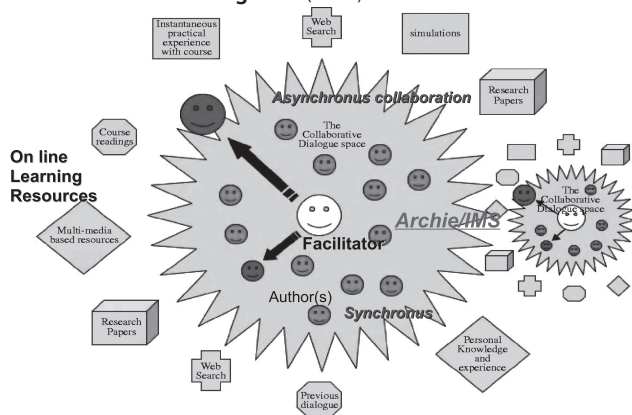
P144: Multiple statistical comparisons in systematic reviews: A quantification of the issue in reviews of anaesthesiological interventions

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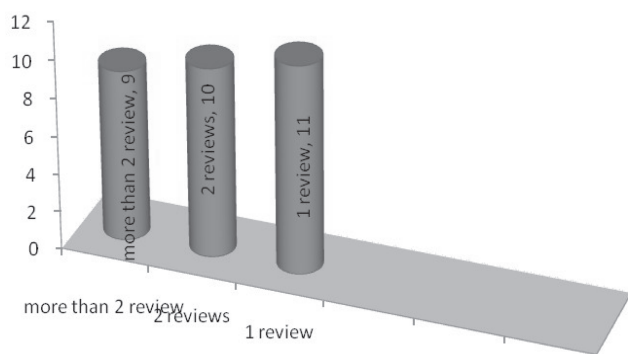
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Background: Systematic reviews with meta-analyses often contain high numbers of statistical comparisons. Multiplicity increases the risk of type I error beyond the nominal chosen 5% and may result in spurious conclusions. Few attempts have been made to address this problem. This omission is concerning because systematic reviews are considered to be the highest quality of evidence. Because of the emphasis on bias evaluation and structure and because of the editorial processes involved, Cochrane reviews may contain more multiplicity than their non-Cochrane counterparts. **Methods:** We examined all the systematic reviews published by the Cochrane Anaesthesia Review Group (CARG) containing a meta-analysis. These reviews were matched according to type of intervention and years of publication with equivalent non-Cochrane reviews. Three investigators independently counted the number of pooled comparisons in each review. **Results:** The over-all median number of pooled comparisons was 10 (IQR 6 to 19) with 12 (range: 1 to 1872) in the Cochrane reviews and 8 (range: 1 to 62) in the non-Cochrane reviews ($P=0.01$). Sensitivity analyses based on bias-control of included trials were in 42% of Cochrane and 28%

Figure 1 (P143): COREL



Source: Sorensen and O Murchú (2005)

Figure 3 (P143): COREL – RESULTS
AUTHOR PROFICIENCY

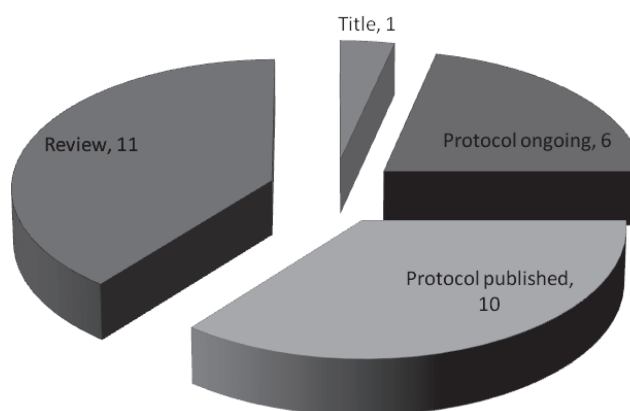
of non-Cochrane reviews and there was a difference in the number of comparisons added due to these analyses ($P=0.02$). A primary outcome was quoted in 63% of Cochrane and 51% of non-Cochrane reviews. The issue of multiple comparisons was addressed in 2% of Cochrane and 7% of non-Cochrane reviews. **Conclusion:** The quantity of multiplicity varies substantially but is high in systematic reviews of anaesthesiological interventions. CARG Cochrane reviews contain a statistically significant higher number of pooled comparisons compared with their non-Cochrane counterparts, possibly due to more analyses of the impact of bias control on the pooled estimates. It is concerning that few efforts are made to address sources of increased type-I error risk in systematic reviews.

P145: The influence in clinical care by Evidence-based Medicine after the 1-year course training

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Aim: Evaluate the effect of influence on the clinical care after Evidence-based Medicine (EBM) course 1-year training in Pediatrics.

Figure 2 (P143): COREL – RESULTS
COREL OUTPUT

Methods: The evaluation is tested after the 1-year EBM teaching course. The student has the PICO from the question that he found from his pediatric patient care in the same month. The question is "Are probiotics needed in the care of diarrhea children." The EBM report include 5 steps, i.e., ask a question, database access, critical appraise, clinical apply, audit. The evaluate lists contained 7 questions, includes "1. student have better understanding of EBM, 2. student has learning benefit from the class, 3. the EBM class necessity, 4. searching and presenting by student, 5. improvement of the ability of database search, 6. suggest the teaching class continue, and 7. the report is not evidenced enough and needs further evidence". The evaluate list score in each question will be graded in 5 levels: very good as 5 point, good as 4 point, no comment as 3 point, poor as 2 point, worse as 1 point. **Results:** We have 35 test taker and only 27 have the fully answered scores. The other 8 imperfectly answered evaluate lists were excluded. The resident test takers approved the significantly improving learning benefit while it is against in the visiting staff ($n=12$). There is no difference in the male or female test taker. 18 test takers approve the student has better understanding of EBM while 8 against it. 20 test takers approve the student has learning benefit from the class while 7 against it. 25 test takers approve the EBM class necessity while 2 against it. 27 test takers approve the searching and presenting by student while 4 against it. 22 approve the students' improvement of the ability of database search while 5 against it. 24 suggest the teaching class continue while 3 against it. We have 5 test takers tested again 1 month later and the correlation coefficient is 0.92. **Conclusions:** Most students and visiting staff approve the 1-year EBM teaching course though some persons against it. This inspires us that the more EBM teaching course and the more applying on the clinical patient care is needed in the future.

P146: Editorial policy in Cuban medical journals and the evidences production process: reality and perspectives

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Background: It's considered that Cuban Clinical Trials reporting doesn't reflect the powerful clinical research of the country. The almost

null generation of systematic reviews is a fact and it requires being stimulated. To find a clinical trial not published is difficult, sometimes they are hidden if they report no expected results. Searching and locating published trials is equally difficult overall because of the lack of indexing and classifying consistency of documents, and the poor description of the research methods. Multiple international initiatives look for standardising the process and improving the quality and honesty of the report. The influence of the International Committee of Medical Journal Editors (ICMJE) uniform requirements, the public registration of clinical trials and the CONSORT statement in the Cuban medical journals is ignored. **Objective:** To evaluate the adherence of Cuban medical journals to these requirements. To evaluate the endorsement of reports to the CONSORT statement. **Methods:** The instructions to authors of the journals were revised for identifying parameters related with those requirements. The journals editors/managers were interviewed for evaluating their knowledge in this respect. A clinical trial from the last year of each journal was evaluated, according to selected items of the CONSORT. **Results:** This work is part of a national project for promoting the evidence, the collecting stage it is at 90% and it should conclude in May 2010. Till now no journal refers the CONSORT and the public registration explicitly, although the Cuban register exists from 2006. In few cases they are recommended "partially" the ICMJE requirements. Some ignorance exists in general and the requirements have not had incidence in the editorial policy, what affects the quality of the report process. The evaluated reports don't fulfil at least the most elementary Consort items. **Final considerations:** An educational and formative work is required for professionals in general and for editors/managers for modifying the editorial policy and to make it complete. The project has conceived the promotion of the requirements through information and communication services and other educational resources through the web and formative workshops. Some examples of those solutions are shown.

P147: Identifying Priority Health System Questions for Low- and Middle-Income Countries: Experiences from the Norwegian satellite of the Effective Practice and Organisation of Care (EPOC) group

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Background:

Health systems in low- and middle-income country (LMIC) settings face major challenges from the high burden of infectious diseases and the growing burden of chronic illnesses, combined with severely constrained resources. There is therefore a need to identify priorities for, and conduct, systematic reviews of interventions relevant to health system questions in these settings, and to build capacity to prepare and support the use of relevant systematic reviews. The Norwegian Satellite of the Effective Practice and Organisation of Care Group (EPOC) was established to support the production of Cochrane reviews that address questions related to health systems in low- and middle-income countries. **Objectives:** To describe the experiences of the Norwegian EPOC satellite to identify priorities and build capacity to develop reviews on health systems questions relevant to LMIC. **Methods:** We review our experiences in: Establishing linkages with organisations working on

health system questions; recruiting and supporting review authors from LMIC; facilitating the production of reviews on questions relevant in these settings; and identifying priority topics by mapping the gaps where good quality up-to-date reviews are not available. **Results:** Currently, review authors from 12 countries have developed or are developing Cochrane reviews. These countries are Kenya, Uganda, Nigeria, South Africa, Tanzania, Cameroon, Bangladesh, China, India, Chile, Argentina and Iran. These reviews address questions about health insurance, health financing and human resources for health, among others. Collaborations with organisations like the Norwegian Agency for Development Cooperation (Norad), the Alliance for Health Policy and Systems Research (AHPSR), the World Health Organization, the Evidence-Informed Policy Network (EVIPNet), the South Asian Cochrane Network and the South African Cochrane Centre have been established. A preliminary list of priority topics for reviews has been generated and will continue to be updated. **Conclusions:** A focussed effort by The Norwegian satellite of the EPOC group has facilitated preparing, updating and making accessible reviews to inform decisions on how to provide effective, efficient and equitable health services in LMIC.

P148: A newly established network for Japanese healthcare professionals for translating the Cochrane Database of Systematic Review abstracts

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Background: A language barrier still exists in Japan to fully disseminate the Cochrane Database of Systematic Reviews (CDSR). The Medical Information Network Distribution Service (Minds) Center subsidized by a research fund from the Ministry of Health, Labor and Welfare in Japan started a service of distributing Japanese translations of the abstracts of CDSR in June 2006, although Oral Health and Tobacco Addiction Group reviews were not included in that service mainly due to lack of both sufficient funding and qualified individuals to carry out the translation work. **Objectives:** To organize the network of healthcare professionals for translating CDSR abstracts and to establish a quality assurance mechanism of the translation process. **Methods:** The Japanese Collaboration for Oral Healthcare Reviews (JCOHR, Head: Nobuhiro Hanada), a non-profit organization of healthcare professional volunteers, was founded in November 2007 to launch the Japanese translation of the CDSR abstracts. Both translators and reviewers were recruited through an internet discussion group. The translation process included draft translation, reviews by a relevant expert, and then public inspection within the discussion group. All procedures were performed through internet and no external funding was required. **Results:** As of March 2010, ninety-four healthcare professionals had registered with the JCOHR as either translators or reviewers in order to contribute to this project. The translation of Oral Health Group reviews was started in December 2007 and finished in February

2008. All Japanese translations were made available to the public through Minds website (<http://minds.jcqh.or.jp/>). In March 2010, the JCOHR also started to translate the Tobacco Addiction Group reviews. **Conclusions:** The JCOHR has successfully implemented the translation and updating of the Cochrane Oral Health Group reviews, as well as the Tobacco Addiction Group reviews. By conducting this translation project, the network of healthcare professionals is therefore considered to have played an important role in introducing the Cochrane Project throughout Japan and thereby disseminate the latest EBM knowledge at a low cost and with a high longevity.

P149: A survey of knowledge experience and acceptance toward percutaneous endoscopic gastrostomy among medical staff

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Relative to the Western countries, percutaneous endoscopic Gastrostomy (PEG) in Taiwan are rarely what doctors and patients accepted for use in patients with clinical indications. This study aims to explore the properties of health care workers, cultural background, cognition, whether health care professionals recommend that patients affected a catheter. The object to the experience of Taiwan medical care of patients with long-term tube feeding and health care personnel 146, self-made of structured questionnaire data collection, recovery of purposive sampling methods, research since December 2008 to January 2009 on 28 February. According to the findings of the study, using knowledge of nasogastric tube for more than a month or more recommended percutaneous endoscopic gastrostomy, rate of 12%; early wound infection rate of 10–30%, 26% accuracy rate; early wound infection, antibiotics, accuracy should be injection 23%; replace the PEG is not necessary for the correct rate 56%; the uprooting of PEG is not necessary for the correct rate 84%. Experience, to take care of 1–10 patient accounting for up to 72%; does not recommend the "PEG" had it is 53%. In acceptance, to recommend the "PEG" had it is 52%. The worry is 59% worry about postoperative care difficulties, 50% are worried that the abdominal insert a tube, 25–45% do not know the PEG advantages and disadvantages. Nursing staff a significant tendency not recommended doctors catheter ($p = 0.000$); a significant tendency for women than men are not recommended for catheterization ($p = 0.000$); whether the contraindications and physician cases recommended catheterization or not significantly related ($p = 0.035$). Proposed future national staff survey, emphasis on the setting up of medical teams and promoting in-service education.

P150: Consumer impact on arthritis research

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Objective: To demonstrate the relevance and value of consumer involvement in arthritis research with examples specific to the Canadian Arthritis Network (CAN). **Methods:** CAN supports integrated, multi-disciplinary and multi-institutional research and training. The consum-

ers (people living with arthritis) on CAN's Consumer Advisory Council have extensive and varied advocacy and self-management experience, representing a range of professional experiences, ages, cultures, and languages. Consumers work with researchers, students, and stakeholders to shape research and training initiatives. CAC impacts research through: membership on committees and integration into CAN's governance structure, collaborating and advising on research projects, participating in training activities, and engaging in knowledge translation and exchange. **Results:** ●Consumers are voting members on the Research Management Committee, act as peer reviewers on the Scientific and Medical Advisory Committee and the Training and Education Committee and have observation status on the Board of Directors. ●Consumers collaborate with researchers on research projects. ●Consumers participate and present at training activities of consumers, researchers and CAN trainees. ●Consumer act as co-presenters in each session at the CAN Annual Scientific Conference. ●Consumers are involved in knowledge translation and exchange activities on many levels. ●Consumers are regularly involved with writing articles and papers in various publications and deliver presentations to national and international audiences. **Conclusion:** Consumer participation in CAN's research-related activities provides people living with arthritis the opportunity to work with researchers on CAN's mission of a world free of arthritis. This poster showcases the relevance and value of consumer involvement in arthritis research by using examples specific to the Canadian Arthritis Network.

P151: Electronic searching versus handsearching of conference abstracts

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Introduction: Handsearching of conference abstracts is time consuming, but necessary for both identifying randomized controlled trials (RCTs) and controlled clinical trials (CCTs) not available in medical databases like PubMed/Medline and Embase, and for establishing and updating the Trials Registers of Cochrane Review Groups. Nowadays conference abstracts are often not only available in print, but also as a pdf file, which makes it possible to perform an electronic search of these abstracts. The aim of this study was to compare the results of an electronic search of conference abstracts with the results of handsearching. **Materials and Methods:** The 2008 conference abstracts of the International Society of Paediatric Oncology (SIOP) meeting were searched electronically using the following keywords: evidence, intervention, protocol, clinical trial, random, trial, controlled, RCT, CCT, phase, treatment arm, assign and stratif. Searches were performed for each keywords separately. The results of the electronic search were compared with the results obtained by handsearching the printed version of the abstract book (i.e. reading all included titles and abstracts). **Results:** Forty relevant abstracts were identified by electronic searching. No abstract was detected using the keyword CCT. Handsearching of the printed version of the 2008 SIOP conference abstracts identified no additional abstracts. **Conclusion:** Electronically searching SIOP conference abstracts can be used to identify abstracts of trials in pediatric oncology. Many keywords have to be used

to identify all RCTs and CCTs, but less abstracts have to be evaluated by searching the electronic version. However, these results need to be confirmed in a larger study including more conference abstracts.

P152: A sign of the times: helping more with less

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Background: For the Cochrane Back Review Group (CBRG) to move towards its vision that *decision-makers concerned with neck and back pain and other spinal disorders will make evidence-informed healthcare decisions by using high quality Cochrane reviews of the best available evidence*, we should facilitate the successful and timely production and utilization of our reviews. In an effort to determine how we could best support our stakeholders, given our limited resources, the CBRG decided to seek input from their lead authors, editorial and advisory board members, and healthcare decision-makers to see what they felt would be helpful. **Objectives:** To determine: (i) what services the editorial office can offer to help authors complete and maintain high quality reviews in a timely fashion and (ii) how to make our website more useful to review authors and healthcare decision-makers. **Methods:** Questionnaires were developed and posted on survey monkey. Emails were sent to lead authors of all CBRG registered titles (N = 6), published protocols (N = 9) and reviews (N = 40), editors, advisory board members, consumers, and members of clinical networks associated with the Institute for Work & Health with links to the questionnaires. Two reminders were sent, a week apart, in an attempt to increase the response rate. Descriptive analyses were completed and compared with past surveys (CBRG 2005; The Cochrane Collaboration Author survey 2009) to identify trends. **Results:** Twenty-six of 55 authors responded (47%) to queries of which editorial office services they found helpful; 160/650 authors, editors, peer referees and other clinical decision makers responded to our queries about our website. Findings will be reported in the final presentation. **Conclusions:** The CBRG editorial office will use survey results to inform their editorial process and the assistance and information they offer their authors.

P153: Raising awareness about the Cochrane Collaboration and South African Cochrane Centre in Ethiopia

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Background: The South African Cochrane Centre (SACC) serves as the reference centre for individuals in 25 African countries, including Ethiopia. However, there is only one Cochrane review author in Ethiopia and awareness about the Cochrane Collaboration (CC) and SACC is poor in the country. **Objectives:** To describe the initiative to raise awareness about the CC and SACC in Ethiopia. **Methods:** An awareness raising presentation was conducted on the CC and SACC at the Ethiopian Public Health Association (EPHA) Conference on October 27, 2009. Participants asked questions, discussed and

evaluated the session. **Results:** Eighty participants attended the EPHA presentation. None of the participants had knowledge of the CC or SACC before the presentation. After the presentation, 67% indicated having excellent knowledge, 44% claimed learning a great deal and 89% rated the session valuable. The feedback from participants was positive and is being used to conduct a baseline survey of health professionals and develop a one-day seminar on the CC for senior management. The baseline survey is collecting background information for seminar participants to consider in their discussion to generate recommendations to promote Cochrane activities. To date, 26 questionnaires were completed and returned (response rate 49%). The majority (89%) of respondents were males, 46% ≤30 years of age, 31% academics, 62% worked in public sector, 44% heard the CC from a colleague, 77% didn't know the SACC was the reference centre for Ethiopia and 86% had no idea how the CL was accessed in the country. **Conclusions:** There is a lack of awareness about the CC, SACC and CL in Ethiopia. The experience gained was valuable and lessons were learned. The awareness campaign will continue to target health professionals and policy-makers.

P154: Using citation-management software for more efficient screening of search results in systematic reviews

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Background: There is little published methodology to inform the process of screening search results for systematic reviews. The *Cochrane Handbook* recommends the use of bibliographic or reference management software as tools for managing references and removing duplicate citations. The Handbook doesn't mention, and perhaps it is not generally realized, that this kind of software can accelerate and simplify the screening process in other ways. **Objectives:** To use the EndNote software to improve the efficiency of the screening process. **Methods:** In 2009, the Cochrane HIV/AIDS Group worked with the World Health Organization to develop "rapid advice" on several topics relevant to the prevention of mother-to-child HIV transmission (PMTCT). We performed one comprehensive set of searches for 4 separate reviews, incorporating a broad range of PMTCT terms, each relevant to at least one of the reviews. We merged the combined results into EndNote, and, using EndNote's tool, removed duplicates. We then used EndNote's "Search references" feature, which permits searches for up to nine terms at once, to eliminate those containing terms indicative of animal studies. We put these into a separate EndNote file of "less-likely" references. We repeated this procedure with numerous other irrelevant terms, in sets of nine, searching specifically in titles. We later reviewed the "less-likely" references to identify any that might yet be relevant. **Results:** The searches produced 13,945 references, of which 4,018 (29%) were duplicates. From the 9,927 remaining, we sequentially removed 6,592 (66%) additional references from the results, leaving 3,335 (24% of studies originally identified) studies to review. No studies that were excluded were found to be eligible on subsequent review. **Conclusions:** Citation management software can serve as a tool for screening search results. Careful and appropriate use of such software can greatly increase the efficiency of this stage of the systematic review process.

P155: Searching for and including non-randomised trials in Cochrane reviews: is it worth the effort?

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Background: In a recent Cochrane review we evaluated the effectiveness of lay health workers for maternal and child health. For some areas, including vaccination, we identified few randomised trials (RCTs) from low- and middle-income countries (LMICs), limiting the applicability of this evidence for these settings. Furthermore, it is often suggested that substantial evidence from non-randomised studies is available and should be included in effect reviews. We therefore carried out a second review where non-randomised studies were included. **Objective:** To assess whether including non-randomised studies impacted on the evidence obtained and its usefulness for decision making. **Method:** We compared the number of studies found in each review and the risk of bias of the RCTs and non-randomised studies. We assessed whether the inclusion of non-randomised studies would have changed our conclusions regarding the intervention effects. **Results:** In addition to the seven RCTs included in the Cochrane review, we included an additional two controlled before-after studies (CBAs), both from LMICs, and one interrupted time series study from the USA. One of the CBAs did not include sufficient data to easily assess outcomes. For the other two studies, the results were similar overall to those found in the Cochrane review, generally indicating that lay health workers improved the extent to which immunisation was up to date, compared to usual services. The non-randomised studies had a higher risk of bias than the RCTs. **Conclusions:** Despite including non-randomised studies, only three such studies were found. These studies contributed to our understanding of the range of interventions that might be implemented. However, their findings did not provide significant additional evidence regarding the effectiveness of lay health workers for vaccination and did not change the Cochrane review conclusions. For this question at least, substantial additional evidence on effectiveness was not found from non-randomised studies.

P156: The Effects of Evidence-Based Nursing Training Program on Nurses' Knowledge, Attitude, and Behavior

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Background: Evidence-based nursing (EBN) is the essential of quality care. To ensure evidence-based practice relies on the nurse's competence. However, little study reports the content and effectiveness of the EBN training program. **Purpose:** The purpose of this study was to evaluate the effectiveness of an EBN training program on

nurses' knowledge, attitude, and behavior. **Methods:** The study was a pretest-posttest research design. Seventy-two nurses received an EBN training program. The program includes: (a) 18 hours lectures, including concepts and steps of EBN, sources and search of evidences, critical appraisal, evidence-based practice and guideline development, teaching in EBN, (b) 10 weeks' small group practicum and mentoring, and (c) 9 hours presentation and sharing. The EBN knowledge, attitude, and behavior were measured using a questionnaire before and after implementing the training program. The Paired-t statistics was used for analyzing the effectiveness of the training program.

Results: There was no significant difference of EBN knowledge and attitude scores between pretest and posttest. However, the posttest score of EBN behavior was significantly higher than the pretest ($p < .001$). **Conclusions:** The EBN training program improves the evidence-based nursing behavior. The content of this program can be a reference for designing a systemic training program of other institutes.

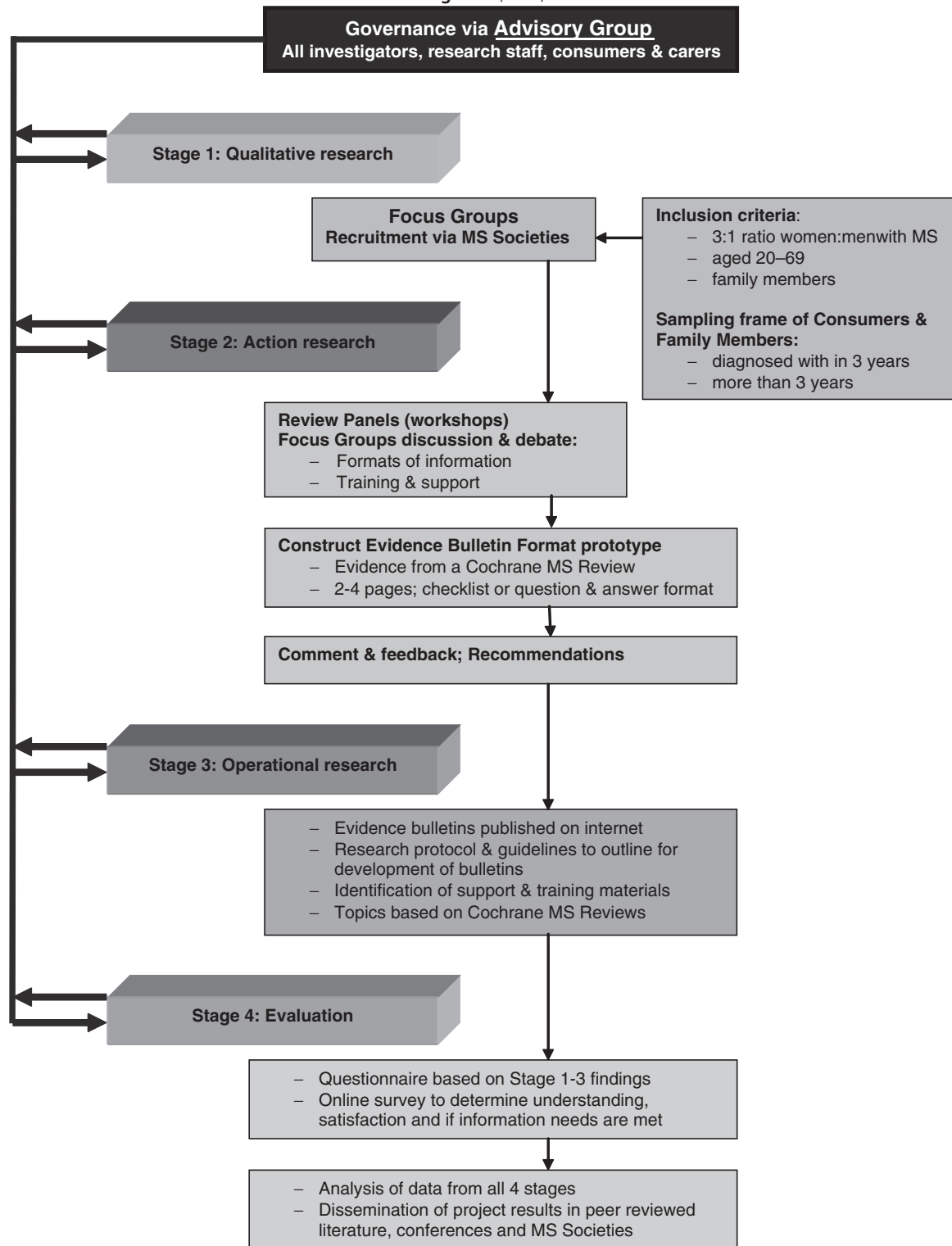
P157: Integrating and deriving evidence, experiences and preferences (IN-DEEP): developing research-based health information applicable to decision making and self-management by people with multiple sclerosis

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Background: Access to accurate, relevant and easily understood information facilitates informed decision making, all of which improves disease management for consumers and their physicians. **Objectives:** To make high quality evidence more accessible and meaningful to consumers and their families for use in their self-management decisions via the internet, using multiple sclerosis (MS) as the initial focus. **Methods:** The project realises collaboration between international researchers, with Italian and Australian consumers, and Italian and Australian MS Associations taking the lead. The research has four stages (Figure 1), each step building on the last. In the first stage, we will explore with people with MS and their families how they find, assess and use health information from research about the effectiveness of treatments. Drawing from people's experiences, in the second stage we will develop a template for writing summaries of the latest research in a format that enables people using the information to make it applicable and meaningful for their personal circumstances. In the third stage, we will develop a model for presenting the information on the Internet aimed at people with MS and their families. The fourth stage is to evaluate the model to ensure that it meets people's needs and helps them find and

Figure 1 (P157)



assess information for managing their health. **Intended outcomes:** The project will lead to the provision of high quality research-based information for people with MS and their families that is responsive to their expressed need; be used to guide future strategies by MS societies. **Conclusions:** The potential significance of this research is

learning how people integrate research information into their decision making and how they assess and make sense of new information. It will provide an international model for sharing and exchanging information and expertise where the primary focus is information and education for people with MS.

P158: Specialized Quality Assessment for Special Trials: A Quality Reassessment of Cross-over Trials Involved in Cochrane Systematic Reviews

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Background: Quality assessment is crucial in systematic review, because it affects the credibility of the conclusion. Presently there are many quality assessment standards for randomized control trial (RCT) and they are widely applied to cross-over trials. This way of assessment is inexpedient because cross-over trial is different from RCT. Though there is no definite quality assessment standard for cross-over trial so far, Cochrane handbook recommended that four points should be considered: appropriate cross-over design, randomized treatments order, carry-over effects and unbiased data. Besides, some universal issues between cross-over trial and RCT, such as blinding and lost of follow up, also affect the quality of cross-over trial. **Objective:** To evaluate the limitation of the current quality assessment for cross-over trial. **Method:** We performed a computer search for Cochrane Systematic Reviews (CSR) which included cross-over trials in Cochrane Library (2009, issue 4). Part of CSRs were randomly sampled and the cross-over trials included were reassessed with a nine-items standard, which was composed by the four recommended points and five universal items. The former quality assessment results in CSRs were extracted. **Result:** A total of 637 CSRs which involved cross-over trials were found. Only one of them considered the particularity of cross-over design. 155 cross-over trials were included in the 50 samples and 128 of them were reassessed. Risk of bias in carry-over effects, appropriate cross-over design and unbiased data existed to different degrees (see table1), but hardly considered in the former assessment. **Conclusion:** The current quality assessment standards for RCT is not comprehensive enough to assess cross-over trials and serious defects existed. We recommend that the quality assessment standard should be improved when cross-over trials are involved.

P159: Randomised and controlled clinical trials in The Cochrane Hepato-Biliary Group Controlled Trials Register and their inclusion in Cochrane Hepato-Biliary Group systematic reviews

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Background: The Cochrane Hepato-Biliary Group (CHBG) Controlled Trials Register contained approximately 11,500 references on hepato-biliary randomised and controlled clinical trials in August 2009. Issue 3, 2009 of the Cochrane Library, contained 107 reviews and 92 protocols published by the CHBG. We did not know how many of the references in the Register were already included in the CHBG reviews and how many remained to be included. **Objectives:** To find out the approximate number of hepato-biliary trials included in the CHBG reviews and the number of those that remain to be included. **Methods:** We found the total number of trials and the overall total of the number of references to each of the trials included in the 107 CHBG reviews. From these two figures, we could obtain the average number of trials per review and the average number of references per trial. We also calculated the percentage of overall total number of included references in the published reviews out of the total number of references in the Register. **Results:** In total, 1106 trials with 2408 references were included in the 107 reviews, i.e., 21% of the references in the CHBG Register. The average number of trials in a CHBG review was 10, and the average number of references per trial was 2. Hence, when the 92 published protocols are developed into reviews, another 16% of the references in the Register could be included. **Conclusions:** Our rough estimation that about 37% of the references in the CHBG register is utilised by published and ongoing reviews points that the CHBG needs to more than double its production until all collected references are studied in CHBG systematic reviews. The forthcoming study-based register may give more precise estimates of possible reviews remained to be developed and the possible number of references to be included in review updates.

P160: Ideal conditions or usual practice? The position of trials from two Cochrane reviews within the pragmatic-explanatory continuum

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Background: 'Pragmatic trials' intend to guide users in choosing between options for care in a common environment and 'explanatory trials' intend to test the causal relations in a research hypothesis. There

Table 1 (P158): The result of quality reassessment

Description	Bias	Appropriate cross-over design*	Randomized treatment order*	Carry-over effects*	Unbiased data*	Allocation concealment	Blinding	Incomplete outcome data	Selective outcome reportinge	Other bias
Good %(n)		78.9 (101)	15.6 (20)	33.6 (43)	82.0 (105)	24.2 (31)	58.6 (75)	52.3 (67)	1.6 (2)	8.6 (11)
Unclear %(n)		4.7 (6)	78.9 (101)	59.3 (76)	9.4 (12)	74.2 (95)	13.3 (17)	17.2 (22)	95.3 (122)	73.4 (94)
Poor %(n)		16.4 (21)	5.5 (7)	7.0 (9)	8.6 (11)	1.6 (2)	28.1 (36)	30.5 (39)	3.1 (4)	18.0 (23)

Note: * Special items for cross-over trials (Nearly all of them were neglected in the CSRs)

are few trials that are purely pragmatic or explanatory. **Objectives:** To determine the position of trials from two Cochrane reviews within the pragmatic-explanatory continuum **Methods:** We selected the trials of two Cochrane reviews. One on mouthrinses for halitosis and the other one on interventions for oral submucous fibrosis (Fedorowicz 2008a, Fedorowicz 2008b) and assessed them using the pragmatic-explanatory continuum indicator summary (PRECIS) tool (Thorpe 2009). **Results:** None of the studies were purely pragmatic or explanatory. They tended to be more 'explanatory' than 'pragmatic' especially in areas of flexibility of the experimental and comparison intervention, follow up intensity and more pragmatic in the selection of primary outcomes. There was insufficient information available to judge about the practitioner expertise in comparison and control group. **Conclusion:** The PRECIS tool is a useful tool in differentiating the pragmatic and explanatory aspects in a clinical trial. It can help clinicians in understanding the potential relevance of the results of the study for their future practice and systematic reviewers in providing practice and research recommendations.

Thorpe KE, Zwarenstein M, Oxman AD et al. A pragmatic-explanatory continuum indicator summary (PRECIS): a tool to help trial designers. *CMAJ*. 2009;180(10):E47–57.

Fedorowicz Z, Aljufairi H, Nasser M, Outhouse TL, Pedrazzi V. Mouthrinses for the treatment of halitosis. *Cochrane Database of Systematic Reviews* 2008a, Issue 4.

Fedorowicz Z, Chan Shih-Yen E, Dorri M, Nasser M, Newton T, Shi L. Interventions for the management of oral submucous fibrosis. *Cochrane Database of Systematic Reviews* 2008b, Issue 4.

P161: The assessment of fatigue in multiple sclerosis, Parkinson's disease and stroke: a systematic review of measurement properties

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Background: A large number of questionnaires are used to evaluate fatigue in neurological rehabilitation. The clinician or researcher measuring fatigue has to consider that each questionnaire is characterized by its own underlying concept, measurement properties, and feasibility for use in practice. A systematic review of measurement properties, which critically appraise and compares the content and measurement properties of all questionnaires measuring fatigue, is lacking. However, such a review may support clinicians in selecting a questionnaire to evaluate fatigue in patients with neurological disorders. **Objective:** To systematically search and critically appraise studies on measurement properties of self-report questionnaires that evaluates fatigue in patients with multiple sclerosis (MS), Parkinson's disease (PD) and stroke. **Methods:** A search was performed in MEDLINE, EMBASE, CINAHL, PsycINFO and SPORTDiscus. We combined a search filter to identify studies on measurement properties with both mesh and text words for fatigue, multiple sclerosis,

Parkinson's disease and stroke. References of relevant articles were tracked. Studies on the development or evaluation of measurement properties of fatigue questionnaires used in patients with MS, PD or stroke, were included. The COSMIN checklist was used to assess the methodological quality of the studies. We used a standardized data collection form to extract data. Two independent reviewers performed study selection, assessment of methodological quality and data collection. **Preliminary results:** We included 26 studies (19 MS, 4 PD, 3 stroke) that evaluated 24 different fatigue questionnaires. The methodological quality and reporting on measurement properties between studies varied widely. Studies assessed measurement properties such as reliability and validity, however, details about the aspects of fatigue assessed and the feasibility of the questionnaire were often not reported. **Preliminary conclusions:** Questionnaires show adequate measurement properties, however, results are mainly based on fair quality studies. The concept of fatigue seems to be an important consideration in selecting a questionnaire.

P162: Knowledge of Evidence Based Medicine (EBM) terminologies and use of EBM resources at the University of Ilorin Teaching Hospital, Nigeria

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Background: Evidence-based medicine (EBM) incorporates results of health care research when making decisions about the clinical care of individuals. To practise evidence based medicine, clinicians need to understand and use terms such as "relative risk reduction," "confidence interval," and "number needed to treat. Whether physicians in Nigeria have knowledge of EBM and apply them in their clinical practice is largely unknown. **Objectives:** To determine self reported awareness of EBM terminologies and the use of EBM resources by doctors at the University of Ilorin Teaching Hospital, Nigeria. **Methods:** A questionnaire-based survey of 150 randomly selected doctors at different levels of training at the University of Ilorin Teaching Hospital, Nigeria was conducted to find out their knowledge of EBM terminologies and use of EBM resources. The respondents rated their understanding of various terminologies used in EBM as "Would not be helpful for me to understand," "I don't understand but would like to," "I already have some understanding," and "I understand this and could explain to others." **Results:** A total of 135 of 150 (90%) randomly selected doctors at various levels of training (medical officers, consultants, senior and junior registrars) from all the departments (Medicine, Surgery, Obstetrics and Gynaecology and Paediatrics) in the hospital completed the questionnaires. About 70% of the respondents do not understand and would like to know EBM terminologies (such as relative risk, confidence interval, number needed to treat). Most of the respondents (93%) have never had any formal training in critical appraisal, search strategy or courses related EBM. More than 90% do not use any evidence based resources to help in clinical decision making. Only about 10% reported using the Cochrane Library to help in decision making. About 80% of the respondents do not have access to internet or relevant bibliographic databases online at the convenience of their home or local medical library but resort to limited hours at internet cybercafés which are commercial and local business shops. **Conclusion:** The findings from this study show that

use and awareness of EBM is very low at the University of Ilorin Teaching Hospital, Nigeria. However, the respondents were willing to learn and apply the principles of EBM if given proper training. The implementation of evidence-based interventions will help to improve patient outcomes. Therefore there is a need to create awareness of evidence based medicine at various levels of care in Nigeria. EBM should be incorporated into undergraduate and postgraduate medical curricula in Nigeria. This will help to increase awareness and use of EBM and ultimately improve patient outcomes.

P163: Making identifying Oral Health Group (OHG) reviews in the Cochrane Library easier and faster

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Introduction: At present the reviews in the OHG section of the Cochrane Library are organised according to key words in the title. This means that reviews pertaining to endodontic treatment for example could be found under a heading which does not reflect this. Therefore it was felt that reorganising the reviews could make it faster and easier for users to identify relevant reviews. **Methods:** A group of authors and clinicians accessing the OHG on a regular basis were asked about their views on the ease of use of the current mapping system for the reviews and their opinion on alternative methods for mapping the reviews. Alternative methods included organising reviews in alphabetical order, according to the dental specialities they related to or according to the background of the corresponding author (i.e. field of study). **Results:** The majority of respondents indicated that identifying reviews could be made easier and mapping them according to the dental specialities they relate to would help achieve this. **Conclusion:** Over the next few months I will reorganise the reviews in the OHG independently from current topic list according to the dental specialties they relate to, I will then re-evaluate the ease of use of the new system. This information will be presented at the Cochrane Colloquium. The hope is that this restructuring will help make the OHG section more user friendly, increase dissemination of information from reviews and also to identify specialties in which reviews are lacking in order to inform future reviews.

P164: The Evidence of Mealtime Music Listening for Older Adults with Dementia: A Systematic Review

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Background: Many studies have been carried out to establish the effects of music therapy on behaviors of older adults with dementia with positive findings. However, the current evidence of the effects of music listening during mealtime on older adults with dementia is unclear, and information of implementation of music listening during mealtime for older adults is also limited. **Objectives:** This paper

describes the evidence of the effects of mealtime music listening for those with dementia and to provide implications for implementation and practice. **Methods:** A review was undertaken by searching English and Chinese electronic databases with specified search terms for the period of 1994–2010. The Cochrane library, CINAHL, PubMed, and PsychInfo databases were searched. The search was limited to articles in the English and Chinese language and peer-reviewed journals. Randomised controlled trials and quasi-experimental studies that evaluated the effects of music listening or compared music listening with other interventions during mealtime for older adults with dementia were eligible for inclusion. Two reviewers independently carried out study selection, data extraction and quality assessment. **Results:** Seven research-based articles were included and all of these studies used quasi-experimental design. The majority of the studies used relaxing classical music and did not indicate whether or not the music was familiar or preferred by the participants. Only one study specifically used pleasant familiar music for those with dementia. All studies reported that music listening during mealtime influenced the behaviors of older adults with dementia in a positive way by reducing the occurrence of agitated behaviors. One study specifically evaluated mealtime music listening on feeding problems and reported significant improvement on feeding problems, food intake, and nutrition status of those with dementia. However, the small sample sizes and lack of randomisation in these studies mean that caution is needed in drawing conclusions. **Conclusions:** This review concludes that music listening during mealtime has the potential in reducing agitated behaviors and improving feeding problems of those with dementia. However, the evidence of the effect of mealtime music listening for older adults with dementia is not strong due to some methodological limitations in the reviewed studies. There is a need for further research using more rigorous research designs with comparison groups. Music listening with relaxing or pleasant familiar music is an inexpensive, accessible, and non-invasive non-pharmacological intervention which is suitable to be used for older adults during their mealtimes at home or in long-term care facilities. Social, cultural, and environmental factors need to be considered while implementing music therapy for older adults during mealtime. The presence of familiar music during mealtime can be used to introduce the sense of familiarity into a new environment and may stimulate their remote memories associated with positive feelings. Music that elicits positive memories from the past will have a soothing effect on those with dementia, which would further reduce agitation. Incorporation of familiar music listening during mealtime has the potential to provide a therapeutic approach to manage behavioural problems and feeding problems of older adults with dementia and improve their quality of life.

P165: Grey literature in systematic reviews: a practical approach to searching and including in systematic reviews

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Background: There is growing recognition that grey literature can be useful in systematic reviews. Searching for grey literature can be difficult, as it is not produced for commercial purposes, lacks bibliographic controls and may not be indexed in major databases. While there are publications that provide useful information about numerous sources for finding grey literature, detailed information

about how to systematically search them is often not provided. Similarly, practical advice is lacking on how to incorporate potentially large yields into a review. **Objective:** This poster will describe a systematic and practical approach to searching and including grey literature in a systematic review based on a review about participatory ergonomics. **Methods:** Our approach included sources that could be searched systematically, such as databases that include grey with peer-reviewed literature, databases focused on specific grey literature types (eg. conference proceedings, dissertations), Internet search engines, Internet repositories and a library catalogue. Documents were also identified through hand-searching of conference proceedings or were recommended by subject experts, stakeholders, or review team members. Our full search strategy was modified to accommodate those databases with less sophisticated search capabilities. **Results:** Test searches in Google, Google Scholar and six Internet repositories produced unmanageably large yields or non-relevant results and were not included in the review. Seventeen electronic databases were searched. The yield from all sources was 2151 unique references (51% grey, 44% peer, 3% both, 2% unsure). Grey and peer-reviewed literature was tracked throughout the review. Fifty-two documents progressed to data extraction (37% grey, 63% peer). **Conclusions:** This poster describes an approach to searching for grey literature that is both systematic and practical. It focuses on those sources that can accommodate search strategies and allow download of references into bibliographic software programs. Issues of time and resources will also be discussed.

P166: External validity of randomized controlled trials: a sample survey of hypertension trials in China

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Objective: To explore the reporting of information useful in quality judgment and assess the external validity based on a sample of hypertension randomized controlled trials (RCTs) conducted in China. **Methods:** Four databases including the Cochrane Library, MEDLINE, CBMdisc (China Biomedicine Database Disc) and CNKI (Chinese National Knowledge Infrastructure) were searched between January 1996 and December 2006 for all hypertension RCTs conducted in China. Language was limited to Chinese and English. The internal validity of all RCTs was evaluated firstly by a modified scale, trials that fulfilled the minimum quality threshold were included. Information useful in assessing the internal validity and external validity was collected by using a data extraction form. **Results:** 164 RCTs were finally included for more informed assessment of external validity. (1) Representation of samples: 122 (74.4%) RCTs selected secondary or tertiary cares as their trial settings. 81 (49.4%) RCTs described the source of samples, in which 86.3% patients came from hospitals, only 13.7% came from communities. 24.6% patients were ineligible for inclusion criteria in 8 (4.9%) RCTs, 14.5% eligible patients were non-enrolled in 2 RCTs, 16.7% patients in 12 (7.3%) RCTs were excluded in run-in periods. The elderly and women patients were markedly under-enrolled in study population ($P < 0.001$), participants in study population were

younger, more often male, and the under-enrollment of women in study population was significantly associated with the mean age of participants in trials ($P < 0.001$). We also found that those RCTs funded by pharmacy and treated with α -Blocker more excluded patients aged 65 years or older ($P < 0.05$). (2) Intervention: Those RCTs with ARB were the most number (25%), next was the CCB(21%), the least was the diuretic, only 3%. (3) Outcome: Many RCTs had the inadequate duration of treatment follow-up, only 4–8 weeks. 6 RCTs choose the incidence or fatality of cardiocerebrovascular as the outcome, 12 RCTs choose the patient-centered outcomes. Only one RCT made the cost analysis. 96 RCTs (58.5%) described the adverse clinical events. **Conclusion:** The reporting of information useful for assessing the external validity in hypertension RCTs conducted in China was poorly addressed; there is marked room for improvement in quality of reporting. The elderly and women patients were consistently underrepresented in those RCTs, which might seriously affect the external validity of trials. The regulatory agencies of clinical trials in China should play an important role in both improving representation of study population and raising awareness of external validity in clinical trials.

P167: To filter or not to filter? A study examining the use of diagnostic test accuracy search filters on a Cochrane DTA review

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Background: For years now the work of Trials Search Coordinators has been improved by the development of RCT filters for sensitive searches for healthcare interventions (at least for the major the healthcare databases such as MEDLINE). Now, however, with the Collaboration's expansion into the area of diagnostic test accuracy reviews, the question of whether a filter can be or should be applied to searches for studies once again raises its ugly head. **Aims:** The Cochrane Dementia and Cognitive Improvement Group (CDCIG) are now well underway with their first DTA review. The searches for this review will be run without a filter (in accordance with current Cochrane guidance). However, using this review, a small additional study has been designed which will look at the sensitivity and specificity of the search strategies when filters are applied. **Methods:** Searches will be run for this review without a filter. Those results will be assessed for studies for inclusion and exclusion within the review as usual. The searches will then be run again five times; each time with a different, already existing DTA filter. The sensitivity and specificity of each filter will then be assessed using the results from the searches without a filter as the reference standard. **Results:** The results of this study will be of interest to the Cochrane Dementia and Cognitive Improvement Group. They will form the first set of data which may then be used at a later date with data from other CDCIG DTA reviews. The results will be displayed on a ROC curve, and will be sub-divided into included and excluded studies retrieved with and without a filter. **Conclusion:** This is a small study, looking at one review only. While it will not be possible to base further practice on the results of this one study, it is hoped that it will add to the already existing discussion on the subject and provide further evidence on the efficacy (or not) of certain DTA filters.

P168: Nurse related systematic reviews in Cochrane library

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Background: Nurses are the largest component of the health care workforce. The laborious implementation of evidence based results in their practice is partially explainable by their limited access to high quality information resources. The Cochrane Library offers all care providers (including registered nurses) the best evidence currently available for clinical decision making in order to provide the most consistent and best possible care for patients. But the nursing content of the Cochrane Library is not clearly identified. **Objectives:** The study aim is to identify all systematic reviews published in the Cochrane Library that are of direct use for nurses. **Method:** A search strategy using MeSH terms to identify all systematic reviews relevant to nurses and published in the Cochrane database of systematic reviews. Based on the abstract, several data were systematically identified: ● Population: newborn, children, adults, elderly. ● Intervention: prevention, education, care or cure. ● Comparison ● Outcomes: quality of live, self care, . . . ● Setting: hospital, nursing home, home care ● Nurse specialty: intensive care, oncology, pediatric, geriatric, . . . ● Conclusion: no or limited evidence versus applicable evidence ● Need of further research: not needed versus needed ● Latest update. In addition, the presence of a meta analysis, the number of included studies, and relevant data about the authors are presented. **Results:** In December 2009, 1264 results out of 6076 records were identified for "nurs* AND care OR prevention OR clinical OR education in Cochrane Database of Systematic Reviews" in all search field. Analyses are in progress. **Conclusion:** About 21% of the publications in the Cochrane database of Systematic reviews are currently of direct interest for nurses. Improving the knowledge and visibility of the Cochrane Library among nurses could stimulate a better use of this source of evidence.

P169: Peritoneal lavage for severe acute pancreatitis: a systematic review of randomized trials

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Objective: To evaluate the efficacy and safety of peritoneal lavage in the management of severe acute pancreatitis(SAP). **Data sources:** We searched the Cochrane Central Register of Controlled Trials (CCTR) on The Cochrane Library issue 1, 2009 Medline(Pubmed) EMbase CBM,CNKI,VIP and wangfang. Randomized clinical trials, in which peritoneal lavage were compared to other intervention in patients with severe acute pancreatitis. **Review methods:** Full-text articles of the studies that met all the inclusion criteria were retrieved.The data were abstracted independently by two reviewers. We used I^2 and χ^2 measures to assess heterogeneity.Random effects models were applied. Methodological quality of included studies was assessed according to the criteria of Cochrane Collaboration.We used the Cochrane RevMan 5.0.17 for Meta-analysis. **Main results:** Ten studies, encompassed a total of 469 patients including 219 patients were included and analysed. There was no statistically significant difference on mortality

and complications between Peritoneal lavage versus conservative treatment;Peritoneal lavage versus pancreatic resection;Long peritoneal lavage versus short peritoneal lavage;Long peritoneal lavage versus short peritoneal lavage;Peritoneal lavage with antiproteases versus peritoneal lavage only. **Conclusion:** This systematic review shows that the use peritoneal lavage in patients with severe acute pancreatitis does not result in a reduced morbidity and mortality.

P170: Independently conducted focus groups to user test patient information based on 52 Cochrane reviews.

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Background: Consumer feedback may be able to improve the quality and relevance of patient information, but the best ways to do this are unclear. Feedback from members of consumer or self-help groups can provide valuable expert input from an expert patient point of view on many topics, but does not represent most of the likely users of the information. **Objectives:** To assess the feasibility and value of a pilot programme of routine independently conducted focus groups for professionally-written evidence-based patient information, including extended summaries based on Cochrane reviews. **Methods:** Focus groups, usually of 5 people ("testers"), were recruited by an external group of academic experts. The testers were drawn from enrollees of a "patient university", although some were recruited through a university clinic or other means when a specific profile (such as adolescents) was requested by the editorial team. The testers received a small honorarium, were not informed of the identity of the publisher, and were as a rule only able to be a tester once. Each group reviewed 4 items of information, many of which were extended summaries of Cochrane reviews. Testers independently rated the information on a range of criteria such as readability and potential adverse effects (such as anxiety), including criteria related both to patients and their family/friends. The 5 people then participated in a lengthy focus group led by the external experts, systematically discussing each piece of information using guidelines. The rating questions and guidelines were developed with input from the editorial team. Focus groups were taped. Individual ratings, a summary of the focus group discussions and demographic data were provided to the editorial team. **Results:** Between 2008 and early 2010 summaries of 52 Cochrane reviews were tested in 30 focus groups including 136 different testers. The testers were probably representative of the general public in terms of self-help group membership (7%). However, women and people of higher educational levels were over-represented (65% were women; 36% had university-level education). Nearly 70% were 45 years or over. A period of 4 weeks was almost always sufficient for the external group to complete the process. **Conclusions:** The focus groups and external experts provided valuable insight into the way people unfamiliar with evidence summaries reacted to the information, and strongly influenced the development of our methods of communicating about evidence. Groups which were recruited with very specific profiles (be they patients or their family and friends) were particularly useful. However, even groups for whom the information was of no personal interest identified areas for improvement. Focus group methodology provided insight into differing opinions among potential users and could helpfully elaborate on these. The primary convenience sample (patient

university enrollees) reduced costs and time, but it had drawbacks in terms of representativeness. For selected information, this was overcome by profiled recruitment. This methodology will be continued as part of our editorial routine, including using experts with a variety of recruitment options.

P171: Search strategies to retrieve studies related to low- and middle-income countries (LMICs)

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Background: The Norwegian Satellite of the Cochrane Effective Practice and Organisation of Care (EPOC) Group supports the production of Cochrane reviews that address questions regarding health systems relevant to LMICs. To our knowledge there is currently no LMIC filter to help identify relevant studies for these reviews. **Objectives:** To develop LMIC filters for MEDLINE, EMBASE, PubMed and CENTRAL **Methods:** Filters are based on the World Bank list of countries, classified as low-income, lower-middle-income or upper-middle-income economies. Countries either currently or formerly classified as an LMIC are included. Countries are listed alphabetically. However, for a country that formerly had another name, the alphabetic listing is violated in order to group names together. Countries are not grouped according to economies since classification can vary from one year to another. Each filter is a combination of index terms and text words. The following fields are searched: Subject Heading, Key Words, Subject Heading Word, Keyword Heading Word, Title, Abstract, Other Terms, Country of Publication, Place of Publication. **Results:** Filters have been developed for 4 databases. They have not been tested for sensitivity and precision. Number of records retrieved by mid March 2010 is about: MEDLINE (Ovid from 1950): 2 million of 17 million records; EMBASE (Ovid from 1980): 100 thousand of 8 million records; PubMed: 2.5 million of 19 million records; CENTRAL: 18 000 of 600 000 records. Of these 18 000, 295 are submitted from the EPOC Register. Filters can be found by following the link to LMIC Databases on the Norwegian EPOC satellite web site: <http://epocoslo.cochrane.org/>. **Conclusions:** Reviews that address questions relevant to LMICs might benefit from adding an LMIC filter to the search strategies used to identify studies for inclusion. Further evaluation of these filters is necessary.

P172: A systematic review of the effectiveness of concept map on nursing students' critical thinking

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Objectives: This review aims to determine the best available evidence regarding the effectiveness of concept map on nursing students' critical thinking. **Background:** Concept map has shown positive impact on enhancing critical thinking skills in studies. Health care providers are required to have problem-solving and decision making ability in order to offer safe and high quality of care. However, traditional nursing education without diverse teaching and learning strategies is no longer to cultivate students' abilities that are necessitated to

deal with complex clinical situation and decision-making. **Design:** Systematic review. **Methods:** Search of PubMed, CINAHL, Medline and Cochrane database were conducted for data collection. This search was limited to articles published in English between 1999 to 2009 focusing on terms as concept map, concept mapping, mind map, critical thinking, problem-solving, decision-making, nursing, nursing education, and nursing student. 6 articles fit with the inclusive criteria were critically appraised independently by two reviewers. The articles include: 4 quasi-experimental studies and 2 RCT studies. **Results:** Three studies indicated the intervention of using concept map significantly improved critical thinking core in nursing students, and two studies revealed that using concept map increased students' knowledge retention and critical thinking scores on the areas of analysis and evaluation. One study indicated concept map improved their problem-solving ability. **Conclusions:** Concept map helps health care providers to identify main ideas, realize relationships of cause and effect, relationships of parts and whole in a logical way, and connect theory and practice, which are essential contributors to build critical thinking. However, there is a lack of randomized controlled trials (RCT) in this review, and variations of the interventions using concept map might affect the result of the review. Further RCT studies are needed to confirm the effectiveness of concept map on critical thinking in nursing students.

P173: The experience of a Cochrane Review Group Satellite: The Cochrane Eyes and Vision Group US Project

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Background: The US Satellite of the Cochrane Eyes and Vision Group (CEVG), the CEVG US Project (CEVG@US), has been funded since 2002 by the National Eye Institute, National Institutes of Health (NIH) and was recently awarded funding for an additional five years. **Objectives:** To highlight the progress of CEVG@US from 2002 to 2009. **Methods:** CEVG@US supports US-based review authors through consultations with methodologists and educational workshops. US handsearchers identify reports of controlled clinical trials in eye and vision journals and conference proceedings. The CEVG@US also conducts methodological research on identification of evidence gaps and systematic reviews. **Results:** In addition to contributing to over 26% of published CEVG reviews and providing educational opportunities for more than 1,000 individuals, CEVG@US has established key partnerships with professional associations including the American Academy of Ophthalmology and American Optometric Association which enhance the quality of reviews and contribute to the translation of evidence to the appropriate audience. US handsearching efforts have contributed over 8,500 CCTs (350 journal-conference years) to the CEVG specialized register. CEVG@US has begun to convert the register from being citation-based to study-based, and will include international standard diagnostic and intervention coding to facilitate retrieval by healthcare providers. CEVG@US was awarded a grant through the 2007 Cochrane Prioritisation Fund, on using practice guidelines to determine systematic review priorities. This project provided the foundation for a recent award from the NIH to assess the effectiveness of medical

interventions for primary open-angle glaucoma using Bayesian mixed treatment comparison meta-analysis. **Conclusions:** The CEVG@US has supported the aims of CEVG and strengthened the contribution of US vision researchers and authors through multiple avenues. The regional satellite model is an approach other Cochrane entities may wish to implement.

P174: Reporting of missing data and protocol deviation in the description of intention to treat is inconsistent in randomized controlled trials.

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Background: Modified intention-to-treat (mITT) reporting in randomized controlled trials (RCTs) is characterized by varying and, sometimes, multiple types of deviation from intention-to-treat (ITT)[1]. However, it is unknown by how much the missing data affects the post-randomisation exclusions. Moreover, it is unknown whether all the missing data cases are considered in the post-randomization exclusions. **Methods:** 475 RCTs from a previous systematic search. From each trial mITT descriptions were retrieved and identified possible cases of missing data (e.g. descriptions covering lost to follow up, absence of post-baseline assessment, missing outcome) and possible protocol deviation (e.g. patients that did not take the intended treatment). Classification according to the type and number of mITT deviation was performed. Also, data on lost-to-follow up, missing data and withdrawals were recorded when not considered in the post-randomization exclusions. Multinomial regression model was used and odds ratios (OR) with confidence intervals (CI) were calculated. **Results:** The higher the number of types of mITT deviation, the higher the odds of the presence of a potential missing data in the mITT description (OR of trials with 1 type of mITT deviation 4.04 (CI, 2.64–6.22); OR of trials with more than 1 type of mITT deviation 9.47 (CI, 4.95–18.12)). Of 18 trials with mITT descriptions reporting lost-to-follow up, 4 trials reported further lost-to-follow up not considered in the post-randomization exclusions. Of 144 trials that had mITT covering missing data descriptions, 57 had further missing data not considered in the post-randomization exclusions. No trials that reported patients withdrawals in the mITT description, had further withdrawals reported. **Conclusion:** Missing data appears to be an essential component in the mITT reporting. The mITT description is not a consistent and reliable method of reporting.

Reference

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P175: Evidence-based Informed Recommendation for Emergency Management after Earthquake

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Background: On May 12, 2008, a Richter 8.0 earthquake hit southwestern China. 69,227 people died and about 15 million were resettled, infrastructure was damaged. Under the leadership of Chinese government, the Ministry of Health (MOH) and the Health Department of Sichuan province took emergency response. **Objective:** Non-classical systematic review methods were used to summarize the evidence of emergency management in Wenchuan earthquake, aiming to recommend evidence-based emergency management strategy and measures. **Method:** Database of Medline, CBM was searched using keyword of "earthquake". Included literatures were analyzed by descriptive method. **Results:** 4792 articles after initial searching and 488 were included finally. The emergency management performance of the medical institutions as following: 1) 1st -3rd day after earthquake, the main task was searching and rescuing under commanding of the MOH and provincial health department. 2) Medical rescue for the injured was implemented from 3rd day to 1st week. Epidemic prevention also started in this period. About 35,880 medical personnel were recruited, 68,788 patients received treatment. After 10 days, disaster areas were all covered by medical assistance. 3) From 2nd to 4th weeks, transfer the injured and epidemic prevention was the major assignment. 4) From 1st to 3rd month, physical and psychological rehabilitation and population resettled were mainly implemented. Total of 1.064 million people received psychological health education. 5) From 1st month, reconstruction post-disaster was major task. The first quarter GDP of disastrous areas increased 8.9% in 2009. **Conclusion:** Under the leadership of MOH and cooperation of other departments, Health departments at different levels took comprehensive emergency management strategy and measures to meet the requirements of different period after earthquake, and finished the reconstruction both the damage houses and health system. These strategy and measures are helpful to cure the injured timely, prevent epidemic disease and promote rehabilitation.

P176: Are test–treat trials as rare as suspected? A capture-recapture estimate of numbers published

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Background: The ultimate aim of diagnostic test evaluation is to determine which tests have the most favourable impact on patient health. Randomised controlled trials are the methodological gold-standard for evaluating these questions, however it is a common anecdote that such publications are 'rare'. But how rare are they? To date none has attempted to enumerate the true extent of this important evidence-base. **Objectives:** To estimate the number of test-treat randomised trials published within a defined time-period, as indexed in the Cochrane Central Register of Controlled Trials (CENTRAL). **Methods:** A capture-mark-recapture technique was used to estimate the total number of test-treat trials published between 2004 and 2007. CENTRAL (Issue 2, 2010) was searched using two separate ascertainment strategies. The first (S1) used terms related to diagnostic research, and was not restricted by test modality. The

second (S2) was a test-specific search that targeted the names of five mainstream imaging modalities. Studies were included if they randomised patients with suspicious signs/symptoms to receive a diagnostic test followed by the administration of treatment. Trials that did not assess patient outcomes were excluded, as were those that evaluated serial testing or population-based screening. Each search was screened independently by two researchers. **Results:** Search strategies yielded 13,576 (S1) and 12,041 (S2) titles and are currently under review by the second screener. Upon completion, findings will include a 2x2 contingency cross-tabulation of the number of relevant studies retrieved by both or only one of the searches from which an analysis of ascertainment overlap will produce the estimate of total number published. Agreement between screeners will be presented as kappa values. **Conclusions:** The estimate as a proportion of all trials indexed on CENTRAL will be discussed, and challenges encountered in constructing effective strategies for identifying test-treat trials commented on.

P177: Consumers United for Evidence-based Healthcare (CUE): Development of a consumer advocacy coalition in the United States

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Background: CUE was formed in 2003 to contribute to attaining a consumer perspective in evidence-based healthcare (EBHC). The mission of CUE is to promote the health of populations and the quality of individual health care by empowering consumers, public health policy makers, and health care providers to make informed decisions based on the best current evidence through research, education, and advocacy. **Objectives:** To describe a model for consumer contributions to and leadership in EBHC. **Methods:** In 2003, the US Cochrane Center convened an organizational meeting in Washington, DC of consumer advocacy organizations demonstrating interest and leadership in EBHC. CUE staffing includes a half time Coordinator. **Results:** CUE has grown to include 26 organizations covering a variety of health issues (eg, childbirth, autism, breast cancer, complementary medicine) and populations. CUE elected to pursue an internal agenda of education of its constituencies before making specific requests of policymakers. As a result, in 2007 the USCC and CUE launched an online course *Understanding Evidence-based Healthcare: A Foundation for Action*, accessed by thousands worldwide. CUE also provides education for consumers through its annual meetings and workshops, many in partnership with CCNet. Wiley has provided CUE members with a free subscription to *The Cochrane Library*, and many members contribute to Cochrane and other review groups through peer review and development of plain language summaries. The USCC and CUE provide a clearinghouse of consumers well-versed in EBHC, for decision makers who seek consumer input. In 2010, CUE will host its second Summit of consumer advocacy organizations. **Conclusions:** CUE is a vibrant coalition of consumer health and advocacy organizations in the US. It serves as a model for organizing and educating consumer

groups in other regions to contribute to EBHC. **Funding:** Agency for Healthcare Research and Quality.

P178: Applicability of the Newcastle-Ottawa Scale (NOS) for rating quality of cohort studies: using studies regarding the predictors of returning to work after traumatic limb injuries for example

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Background: Systematic review and meta-analysis of observational studies is getting more and more common as systematic review and meta-analysis of controlled clinical trials in order to answer the etiologic or effectiveness questions from the explosion information of scientific literatures. Cohort studies provide the second strongest evidence next to randomized controlled trials in evidence-based health care. In 1997, the workshop in Atlanta had proposed the concerns regarding the reporting of Meta-analysis Of Observational Studies in Epidemiology (MOOSE). However, no uniform checklist tool to assess the quality of cohort studies was recommended. **Objective:** The aim of this study is to evaluate the applicability of the Newcastle-Ottawa Scale (NOS) which is available in the supplementary material part of Cochrane Handbook for Systematic Review of Interventions. We analyze the items of NOS for rating quality of retrieved cohort studies evolving the predictors returning to work after traumatic limb injuries. **Methods:** A librarian conducted a database search of the PubMed/Medline electronic databases from inception to Feb 2010, using medical subheading term (MeSH) and free keyword text of the following search strategy: ((wounds and injuries) OR ("Wounds and Injuries"[Mesh]) OR ("Cumulative Trauma Disorders"[Mesh]) OR (cumulative trauma disorders) OR (injur* OR trauma OR fractur* OR limb injur* OR musculoskeletal injur*)) AND (return to work OR return-to-work OR work re-entry OR sickness leave). No language restriction was imposed. A hand search of the bibliographies of relevant papers was also carried out. Two reviewers independently performed initial screen and assessed of quality indicators after a consensus to the details of coding manual of NOS. Reliability of ratings of NOS items was calculated using kappas and reliability of the total (summed) score between two raters was calculated using intraclass correlation coefficients (ICC). **Results:** Our literature search uncovered 747 articles, irrelevant 479 and 139 of which were discarded after reviewing the titles and abstracts respectively, while 108 of which were abandoned after obtaining the full texts. One additional article was also identified for inclusion by hand searching the reference lists of obtained articles. Therefore, a total of 22 studies were candidates for the NOS appraisal by two independent raters. The kappa value for each of the 9 items (4 of selection, 2 of comparability, and 3 of outcome assessments) were ranged from 0.38 to 1.00. The ICC for the total score was 0.51 (95% confidence interval = 0.36 – 0.66) by Spearman's rho correlation. **Conclusions:** The reliability of ratings of NOS items varied from "fair" to "almost perfect," and the correlation of the total NOS score between two rates was "fair" to "good." However, there are still items (i.e., Demonstration that the outcome of interest was not present at start of study) might not be applicable for the appraisal of this research question since the outcome of returning to work will be always occurred after injuries. **Acknowledgement:** This study was supported by

research grants from the Evidence-Based Medicine Committee of E-Da hospital.

P179: Creating an inventory of health policy trials

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Background: An accessible inventory of fair tests of health policies would be of value when: developing evidence-informed health policies; preparing systematic reviews of effects of health policies; and examining the methods used in randomized trials of health policies. **Objectives:** 1) To prepare a searchable database of randomized trials of health policies defined as delivery, financial and governance arrangements of health systems; implementation strategies; and public health interventions targeted at populations. 2) To collect examples of other research designs which have yielded convincingly unbiased estimates of the effectiveness of such interventions, in order to assess the value of extending the inventory. 3) To identify early cluster randomised trials (CRTs) to add to the James Lind Library. **Methods:** Selection criteria were refined following test searches of Medline and the Cochrane Central Register of Controlled Trials (CENTRAL) and pilot screening. We then searched electronically records submitted by the Cochrane Effective Practice and Organisation of Care (EPOC), Consumers and Communication (COMMUN), and Public Health (PUBHEALTH) Groups to CENTRAL. References in key papers and unpublished databases found through personal contacts were hand searched. Search results are screened by one person with a second opinion being sought where there is uncertainty. **Results:** Electronic searches of CENTRAL resulted in 1085 titles for screening. 300 titles were identified from reviews and personal contacts, 106 of which meet the inclusion criteria. We describe the main categories of interventions in the included trials. **Conclusions:** The results of hand searching, and searching CENTRAL, suggest that between 500 and 700 health policy CRTs have been published. A wide range of health policies have been evaluated using CRTs, but the number of such trials is uncertain and these trials are difficult to identify. Further searching is necessary to make the inventory as complete as possible.

P180: Methodological quality of diagnostic accuracy studies: What's missing in QUADAS

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Background: Systematic reviews on the diagnostic accuracy of a test require a thorough methodological assessment of the included studies. The QUADAS instrument, developed for this purpose, detects risk of bias inherent in patient selection, the execution of the index test, and the reference standard. **Objectives:** We explored whether QUADAS captured all relevant sources of bias when the

index test was compared to a concurrent routine test and when the reference standard is follow-up. **Methods:** We applied the QUADAS tool in a systematic review on positron-emission-tomography (PET) compared to conventional tests for assessing the diagnostic / prognostic value of interim-PET in patients with lymphoma. A comprehensive literature search with 1144 references yielded 7 included studies. Some but not all compared PET to conventional tests. All used follow-up as reference standard. **Results:** We found several limitations: • QUADAS requests a short interval between index test and reference standard. With follow-up as reference standard, studies need to demonstrate sufficiently long follow-up to distinguish recurrence and healing. • Reviewers need to assess the possibility of confounding during follow-up. Limitations when reviewing studies with 2 or more comparison tests: • QUADAS examines the performance of the index, but not the comparator test. • QUADAS does not inquire about mutual blinding of readers reviewing 2 tests with subjective reading (e.g. PET vs. CT). • QUADAS does not explore whether the statistical method takes into account the lack of independence of the results of index and routine test when derived from the same patients. **Conclusions:** Currently, QUADAS lacks certain aspects in assessing risk of bias when comparing a new index test to a concurrent routine test and when the reference standard is follow-up. A QUADAS update should consider these additional criteria.

P182: The Evidence-Based Medicine as a scientific paradigm for the Law: Challenges and alternatives for the construction of the Law Evidence-Based

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The paper seeks to establish the potential relationship between Evidence-Based Medicine (EBM) and Law. To do so, it suggests the methodological deployment of EBM and its adaptation to the legal intervention (legislative and judicial), through the development of systematic reviews that incorporate realistic prediction and monitoring of variables inherent in the complex social environment investigated, in order to ensure and establish the relationship between intervention and outcome, in quantitative and qualitative ways.

P183: NCDHR's Web-based instruction on conducting systematic reviews of evidence-based disability and rehabilitation research

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Background: The National Center for the Dissemination of Disability Research (NCDHR) has twice offered a Web-based distance education course on Conducting Systematic Reviews of Evidence-Based Disability and Rehabilitation Research. The course teaches teams of researchers the steps in the systematic review process as implemented by the Campbell and Cochrane Collaborations. A first cohort participated from

September 2007-April 2008; the second runs from September 2009 to November 2010. Instructors include colleagues from the Campbell Collaboration (C2) Education Coordinating Group (ECG). Participants are taught the rationale and processes of intervention research and systematic reviews as the foundation for informed clinical practice and evidence-based decision-making in disability and rehabilitation and related fields. Other skills taught include techniques to manage data collected through the systematic review process, and analytical skills to assess the quality of evidence in published and unpublished research.

Description: The session will describe the recruitment, organization and instruction provided to the second cohort. The course was designed for teams of upper-level graduate students, post-docs, early career and experience researchers. It is offered at no cost to participants, and the NCDDR asked that all team members commit to participating in all activities and to developing a systematic review. The format combines lecture, group projects, and individual assignments. The NCDDR implemented a competitive process to identify 4 teams that receive tailored consultation throughout the course. The instructors work with the teams to develop and submit their title registration, protocol, and final reviews to the Disability Subgroup of the C2-ECG. Six other teams also applied and continue to audit the course. Lectures are delivered in interactive 90-minute Web-based sessions utilizing interactive software (each session is also recorded). Each course module examines a step in the systematic review process. Teleconferences and email exchange are incorporated between sessions. **Outcomes:** The session will describe results from both cohorts. In the current course, the teams selected for the intensive support will receive a modest stipend from NCDDR upon approval of the title, protocol, and final review. As of March 2010, two titles have been approved, two are in stages of final approval, and two protocols are under review. One team from the first cohort completed a systematic review that is awaiting approval from the Editorial team of the ECG.

P184: "The Cochrane Corner" A research translation strategy with a subtle twist

Charlotte Young

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According to the Agency for Healthcare Research and Quality, the translation of research into usable practice and patient outcomes is a substantial barrier to the quality of care. It is essential to distill and translate evidence so it is usable and relevant audiences are made aware of the findings. This study was designed to engage researchers, practitioners and consumers in an exchange of knowledge to support evidence-informed decision-making and improve health practice and policy. Two members of the Cochrane Nursing Care Network (CNCN) will work with focus groups of practitioners and consumers to identify new, practice-changing Cochrane research reviews that are vital, yet misunderstood or lost in the gap between research and practice. The researchers will highlight important Cochrane reviews; indicate benefits and implications for changes in practice. The translation will be done in the plain words identified by the practitioners and consumers themselves. By tapping into this group of stakeholders through writing a column in their International specialty journal, researchers will present new evidence through a mode long used and trusted by the professional and consumer audience.

P185: Clinical use evidence summaries (CUES) for knowledge translation: preliminary survey of primary care clinicians on the development of focused clinical question and answer summaries based on Cochrane reviews

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Background: Cochrane reviews are increasingly being translated into products aimed at specific audiences, including primary care clinicians. Additional tools are needed to assist time-challenged practitioners in improving their access to evidence-based answers to clinical questions and to facilitate author-practitioner knowledge exchange. Creation of these tools necessitates the active involvement of clinicians in the development phase. **Objectives:** To develop a template for clinical question and answer summaries (CUES); to describe the results of a survey used to develop the template; and to outline a proposed study evaluating the effectiveness of evidence summaries of Cochrane reviews. **Methods:** Clinicians participating in a Cochrane review group workshop, as well as those receiving a quarterly evidence-based therapy newsletter, will be asked to complete a user needs survey designed to inform the creation of a template for presenting focused clinical question and answer evidence summaries drawn from the results of Cochrane reviews. Survey questions will address preferred evidence summary formats, headings, content, subject priorities and length. Interested clinicians will be invited to participate in a study evaluating the effectiveness of the evidence summary template in translating the results of a sample of Cochrane to practitioners. Study participants will be pre- and post-tested on knowledge of information presented in a selection of CUES. **Results:** The results of the preliminary survey will be reported in October 2010. Design and development of the pre-post study to be carried out in early 2011 will be described in further detail. **Conclusions:** Effective development of evidence summaries for primary care clinicians requires the active participation of the target audience in the process. The results of the survey and evaluation of the pre-post study will inform the development of CUES for a Cochrane review group.

P186: Systematic review and cross cultural adaptation of clinical guidelines for the prevention of intravascular catheter-related infections

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Background: Intravascular catheters are the most frequently used medical devices in hospital settings. Although such catheters provide necessary vascular access, their use puts patients at risk for local and systemic infectious complications, and cause significant morbidity, mortality, and excess hospital costs. Implementing evidence-based practice guidelines is vital to prevent catheter-related bloodstream infection (CR-BSI) in the clinical settings; however, there are many evidence-based guidelines developed by different academic societies based on the Western countries. How to search an evidence-based guideline and cross cultural adaptation in different healthcare setting is crucial for the Taiwanese healthcare administrators. **Objectives:** The

objectives of this review were to determine the best available evidence and cross cultural adaptation in clinical settings on the intravascular catheters care in preventing of CR-BSI for adult patients in Taiwan.

Search strategy: The search strategy aimed to find published systematic reviews and clinical guidelines and was limited to reports published in the English or Chinese language from 2000 to 2008. Reference lists of studies that met the inclusion criteria were searched for additional studies. Types of studies: This review included any systematic reviews and guidelines that included the interventions for preventing CR-BSI in adults. Types of participants: The types of participants to be included in this systematic review were aged over 18 years old, using intravascular catheters and staying in the acute care settings. Types of interventions: The review considered systematic reviews and guidelines that aimed any stages of catheter in used in preventing CR-BSI, including catheter insertions, texture of the catheters, daily care and removal of catheters. Types of outcome measures: The outcome measures including: (1) CR-BSI rates, (2) Length of stay and (3) Mortality rates. Types of languages: The review focusing on the language on English and Chinese. **Data collection and analysis:** Critical Appraisal Tool from Joanna Briggs Institute and Appraisal of Guidelines for Research & Evaluation (AGREE) were used for data extracted to determine the current best interventions for preventing CR-BSI. Two sessions of expert focus group were hold to evaluate feasibility and the meaningfulness of each intervention. After revised the interventions based on the focus groups suggestions, a questionnaire survey was conducted to investigate the usefulness of interventions nationwide. **Results:** The search process identified 18,088 systematic reviews and clinical guidelines that addressed the objectives of the review protocol. Fifty-eight articles were selected for further evaluation. After the rigorous appraisal by two independent reviewers, 24 articles were considered to be eligible for the present review and 35 articles were excluded. The data from eligible articles were formed the guideline proposal which including 18 preventing interventions and 36 daily care interventions. According to the evidence level (AHCPR 1992) and recommendation grade (AHCPR 1994), in those 54 interventions, 12 interventions were in IA level of evidence, 9 were IB, 2 were II, and 1 were IIA level, 11 interventions were graded as recommendation A, 7 graded as B and 8 graded as C. 3 interventions were not graded. Two Doctors, 1 infection control specialist and 14 experienced nurses from nationwide formed two focus groups and reviewed the proposed guidelines. Only one intervention was not accepted by the experts due to different race, which is when a patient using CVP needs heparin 2500U subcutaneous injection daily for preventing thrombus. The evidence level of heparization is level I and still included in proposed guideline. A questionnaire (possible answer: yes/no) survey was conduct to investigate the difference between current practice and proposed guidelines, 400 questionnaires were disseminated and 240 participants responded. Five of 54 interventions, the average agreement rate were below 70%; 1 intervention was preventive intervention and 4 were daily care interventions (including the daily heparization). **Conclusions:** The current guideline was confirmed by national experts and evaluated by the first line clinicians. However, the heparization intervention needs to be further investigated, and the other four interventions indicated that the first line clinicians needs further education of catheters daily care for preventing CR-BSI.

P188: Statins for women with polycystic ovary syndrome not actively trying to conceive

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Background: Statins have shown strong evidence of decrease in cardiovascular morbidity and mortality. Given the pleiotropic actions of statins, they are likely not only to improve the dyslipidaemia associated with PCOS but may also exert other beneficial metabolic and endocrine effects. **Objectives:** To assess the efficacy and safety of statins therapy for women polycystic ovary syndrome not actively trying to conceive. **Methods:** We searched randomised controlled trials which compared statin versus placebo or statin in combined with another drug versus another drug alone in patients with confirmed diagnosis of PCOS in the Cochrane Menstrual Disorders and Subfertility Group Trials Register (Issue 3, 2009), Cochrane Central Register of Controlled Trials (CENTRAL (Ovid), third quarter 2009), MEDLINE (1966 to September 2009), References of the identified articles were handsearched were for additional relevant studies. Data were collected and analysed using Rev Man 5. **Results:** Out of twelve studies indentified, two trials were fulfilling the criteria for inclusion in meta analysis. One of them was using atorvastatin (37 participants) other using simvastatin in combination with Oral Contraceptive Pill (OCP) (48 participants). Meta analysis showed that statin shown significant reduction in total testosterone level (WMD -0.93, 95% CI -1.24 to -0.88), total cholesterol level (WMD -0.89, 95% CI -1.19 to -0.58), LDL (WMD -0.82, 95% CI -1.19 - 0.49) and triglyceride (WMD -0.34, 95% CI -0.59 to -0.10). However, statins were not shown beneficial effect in improving fasting insulin, fasting glucose, corticotropic hormones level. There was no evidence of effects of statins on body mass index, body weight waist line. There was no evidence of improvement in menstrual cycle and/or hirsutism, but evidence was very limited. No serious adverse events were reported. **Conclusions:** Statin is effective improving lipid profile in patients with PCOS which ultimately have beneficial effect in treating parameters of metabolic syndrome associated with PCOS. However, no data is available of long term risk of cardiovascular risk profile in women with PCOS. Statins also reduce the biochemical parameter of hyperandrogenaemia (reducing level of total testosterone). However limited data available to show improvement in hirsutism, acne and menstrual cycle. There is no data regarding long term safety of statin in young women.

P189: Organising knowledge translation and dissemination events for health practitioners

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The Cochrane Hypertension Group together with other local academic and health organisations has organized educational events hospitalists, general practitioners, consumers, and pharmacists. **Learning objectives:** Possibilities for Funding for KT and dissemination. Planning an event including logistics and advertising. Creating partnerships and collaboration with local agencies. Best practices for KT - how

to structure the information? Searching for methods of accreditation.
Description: This presentation will highlight the importance of partnerships with local organizations involved in training practitioners, the preparation of materials and the importance of accreditation to attract health practitioners. It will also include information on a successful format for presenting evidence to practitioners and our experiences. **Participant engagement:** Providing them with resources for KT. Assist with finding local organisations with similar goals to create partnerships. Provide a checklist for planing. **Level of knowledge required:** Introductory and/or Intermediate.

P190: A worked example of a systematic review applying an integrative evidence synthesis approach: Factors promoting and hindering Female Genital Mutilation/Cutting

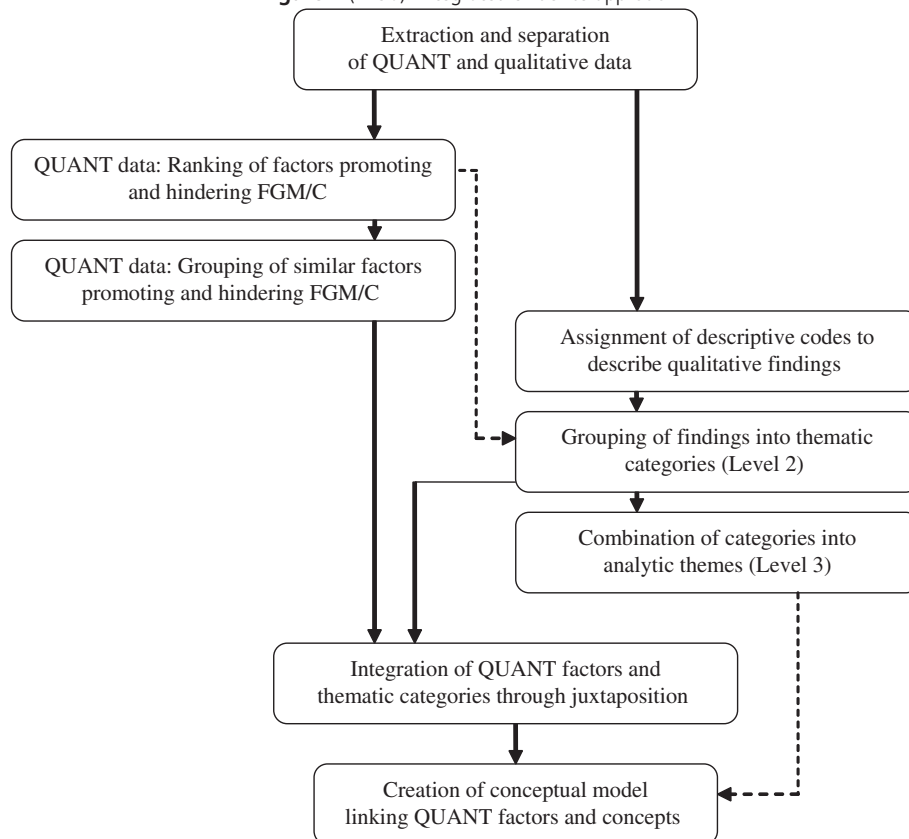
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Background: The issue of and methods for integrating data from different traditions within systematic reviews are receiving increased attention, but clear methods to enable the synthesis of quantitative and qualitative evidence remain in their infancy. Integrative synthesis approaches in systematic reviews of the factors that perpetuate a certain practice present a constructive view into the most appropriate response to populations' needs, and the relevance of and subsequent effectiveness of interventions. **Objective:** We present

a systematic review of factors promoting and hindering female genital mutilation/cutting (FGM/C), which comprised both quantitative and qualitative primary data. Here, we describe the process of integrating qualitative evidence with quantitative evidence in our systematic review. **Methods:** We conducted a systematic review of the factors promoting and hindering the practice of FGM/C as expressed by stakeholders residing in Western countries. We applied recommendations by the EPPI-Centre and the Cochrane Handbook concerning integration. **Results:** We grouped all included studies (n=24) according to their methodological focus, and subsequent study appraisal, data extraction and analyses of quantitative and qualitative evidence were largely completed in separate streams. In our integrative evidence approach (Figure 1), we used quantitative data as our point of departure. We ranked and grouped similar quantitative factors promoting and hindering FGM/C. Qualitative findings were grouped into thematic categories, using apriori codes from the quantitative studies to seek out evidence from the qualitative findings. We integrated factors identified from the quantitative data with the thematic categories from the qualitative data by contrasting and comparing, using a matrix. Finally, we created a conceptual model linking quantitative factors and qualitative concepts together, which delineated the likely determinants of the underlying forces perpetuating the practice of FGM/C. **Conclusions:** While reviews that embed diverse evidence can be systematic, the process is time consuming and challenging. Increased initiatives, including efforts by the Cochrane and Campbell Collaborations, and further worked examples are needed to establish a shared and trusted methodology.

Figure 1 (P190): Integrated evidence approach



P191: Survey of current status and its satisfaction of volunteers in Chinese Cochrane Center

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Background: Since 1999, the Chinese Cochrane Center has been training a large number of volunteers. In order to improve the quality of this training program, we designed this survey. **Objective:** To study the current status and satisfactory degree of **volunteers in Chinese Cochrane Center**, so as to provide suggestion for improving the scientific research capability of medical students. **Methods:** We carried out a survey on 407 student volunteers from EBM Center in West China Medical School, etc with self-designed questionnaires. The data was input and analyzed with Epidata3.0 and SPSS13.0 software. **Results:** 351(86.24%) valid questionnaires were retrieved among all the 407 questionnaires assigned. 80.6% of the respondents are contented in general with the current situation of scientific volunteers' program. 34.7% of respondents thought that lack of basic knowledge and skills was the main factor that

limited the progress of their research work, while for another 31.6% respondents, the main limited factor is that they don't have enough extracurricular time. The most urging training items of the participants are: background knowledge (74.4%) clinical skills (69.8%) documentary management (such as statistics literature retrieval, 64.1%) 21.1% of research activities are not operated in a standardized organizational mode. 96.2% of the respondents emphasized on the necessity of exhibiting their works and achievements in public. "Tutor's instructions"(P=0.027), "training on basic knowledge and skills"(P=0.011) "organizational mode" (P=0.000) are the main factors which affect the satisfactory degree on scientific volunteer programs. **Conclusion:** The satisfactory degree of students who participated in scientific volunteer programs is generally satisfying. Increase of participation rate in scientific research program can be attributed to factors such as establishment of a scientific volunteer recruitment system, improvement of students' research capability, standard organizational modes, standard managing and operating mechanism, embed training lessons into courses and exhibition of research achievements, which plays a positive role in improving the scientific research capability of medical students.

Workshops

WS1: The first rule of journal club is . . .

Collaboration: Cochrane

Methods Group: Wiley

Facilitator(s): Bryony Urquhart, Wiley

Contributor(s): Mike Clarke, Cochrane; Bryony Urquhart, Wiley

Abstract: Medical journal clubs have been used for over 100 years to promote an increased awareness of research, educate students to critique and use research findings, and to aid in the translation of research into practice. Cochrane Journal Club (www.cochranejournalclub.com) was developed to provide the tools that any journal club leader or participant might need to further their understanding of a Cochrane Review and apply the results to clinical practice. Participants will be shown how it is possible to conduct and participate effectively in an evidence-based Journal Club, and will leave the workshop with a clear structure for not only appraising the literature but also finding its applicability to clinical practice. The workshop will be interactive and structured as a journal club session; participation is a requirement of attendance. Cochrane Journal Club resources will be demonstrated, and each participant will receive a Cochrane Journal Club gift. Participants will leave the workshop knowing that the first rule of journal club is DO talk about journal club. . . [with apologies to Brad Pitt]

WS2: Managing the editorial process using workflows in Archie

Collaboration: Cochrane

Methods Group: Cochrane IMS

Facilitator(s): Becky Gray, Cochrane; Liz Dooley, Cochrane; Sonja Henderson, Cochrane; Karen Hovhannisyanyan, Cochrane; Jacob Riis, Cochrane; Monica Kjeldstrøm, Cochrane

Contributor(s): Becky Gray, Cochrane; Liz Dooley, Cochrane; Sonja Henderson, Cochrane; Karen Hovhannisyanyan, Cochrane; Jacob Riis, Cochrane; Monica Kjeldstrøm, Cochrane

Abstract: Objectives: Provide core Review Group staff with skills to enable their Group to make the most of Archie's workflow capabilities to help manage their editorial processes. Description: The workflow system in Archie enables editorial staff to monitor and manage the progress of reviews through the editorial process. The system was introduced in three pilot stages, with an increasing number of Review Groups participating in each stage. Stage 3 started in February 2010 and is open to all CRGs on an ongoing basis. The contents of the workshop will be relevant for core staff from Review Groups who are already involved in the pilot, as well as staff from Groups that are considering joining the Stage 3 pilot. Participants must be familiar with Archie for managing contacts and documents.

WS3: Assessing the risk of outcome reporting bias in systematic reviews

Collaboration: Cochrane

Methods Group: Bias Methods Group

Facilitator(s): Kerry Dwan, Cochrane; Jamie Kirkham, Cochrane; Paula Williamson, Cochrane; Doug Altman, Cochrane

Contributor(s): Kerry Dwan, Cochrane; Paula Williamson, Cochrane; Doug Altman, Cochrane; Jamie Kirkham, Cochrane

Abstract: Objective: To provide the reviewer with a background to the problem of outcome reporting bias and how it might lead to misleading conclusions, to demonstrate how a reviewer might identify such bias in their review, and to present techniques for assessing the robustness of the meta-analysis to such bias. Summary: Within-study selective reporting has been defined as the selection, on the basis of the results, of a subset of the analyses undertaken to be included in a study publication. Sources of bias will be described. The workshop will focus on outcome reporting bias (ORB). Empirical evidence for the existence of ORB is accumulating. In a meta-analysis, often a total number of k eligible studies are identified but only n report the data of interest. The reviewer needs to examine the remaining $(k-n)$ studies to establish whether the outcome of interest was collected but not reported. Methods for the identification of ORB in a meta-analysis and an individual study will be described and illustrated using examples. Participants will be encouraged to undertake such assessments for examples provided and to discuss issues for their reviews.

WS4: Random-effects and mixed-effects models in meta-analysis

Collaboration: Campbell

Methods Group: Campbell Methods Group

Facilitator(s): Terri Pigott, Campbell

Contributor(s): Terri Pigott, Campbell

Abstract: This presentation will discuss random-effects and mixed-effects models in meta-analysis. Both analysis of variance-type models and linear regression (meta-regression) models will be covered.

WS5: QUADAS-2: An opportunity to pilot test an update to QUADAS

Collaboration: Cochrane

Methods Group: Screening and Diagnostic Tests Methods Group

Facilitator(s): Penny Whiting, Cochrane; Anne Rutjes, Cochrane

Contributor(s): Hans Reitsma, Cochrane; Mariska Leeflang, Cochrane; Patrick Bossuyt, Cochrane; Jon Deeks, Cochrane; Jonathan Sterne, Cochrane

Abstract: BACKGROUND: QUADAS, a quality assessment tool for use in DTA reviews, was developed in 2003. A modified version is

recommended for use in Cochrane DTA reviews. Personal experience, anecdotal reports, and feedback via Cochrane suggested that some elements required adaptation. We therefore decided to develop QUADAS-2. **METHODS:** The workshop will be split into two sessions: Session 1. Introduction to QUADAS-2: The first session will be an overview of the development and structure of QUADAS-2: 1. Rationale and scope of QUADAS-2—Initial decisions regarding the scope and structure of QUADAS-2 2. Development of the evidence base—Review of how recent DTA reviews have incorporated quality and used QUADAS—Updated review on sources of bias and variation in primary DTA studies—Web-based questionnaire feedback from reviewers, both Cochrane and non-Cochrane reviewers, who have used QUADAS 3. Generation of items for consideration—Possible list of items informed by results of stage 2 and original content of QUADAS 4. Face-to-Face meeting, Birmingham September 2010—One-day meeting of team of international experts in DTA reviews used to select items for inclusion in QUADAS-2 and make final decisions regarding scope and structure 5. QUADAS-2—The final tool and background document will be presented 6. Evaluation—Evaluation of QUADAS-2 is ongoing; steps will be outlined and available results discussed Session 2. Piloting QUADAS-2: The second half of the workshop will provide a unique opportunity for participants to discuss QUADAS-2 and pilot test QUADAS-2. Feedback gathered during the workshop will contribute to the evaluation, and possible revision, of QUADAS-2.

WS6: Complex Interventions: Mapping It Out with Logic Models

Collaboration: Cochrane

Methods Group: Campbell and Cochrane Equity Methods Group

Facilitator(s): Laurie Anderson, Cochrane; Philip Baker, Cochrane; Daniel Francis, Both; Mark Petticrew, Both; Peter Tugwell, Both; Erin Jeffing, Both

Contributor(s): N/A

Abstract: The methods for evaluating complex interventions are still being debated and argued. Moreover, the role and value of theory in systematic reviews are sometimes contested. Logic models describing mechanisms of action, with consideration of context and policy/social/cultural environments, are one method of including theory. Analytic frameworks, with their map of relationships and outcomes, are also useful for critiquing linkages in evidence in systematic reviews. We propose a hybrid for systematic reviews of complex interventions: a map in which detailed pathways for effectiveness are embedded in a broader picture. Participants will learn how these visual tools can help shape their reviews. Examples from Cochrane reviews and clinical and public health guidelines will be shared. Participants are invited to bring their review topics for discussion in small working groups; audience interaction will be encouraged.

WS7: Introduction to meta-analysis 5: Including non-standard studies and non-standard data

Collaboration: Cochrane

Methods Group: Statistical Methods Group

Facilitator(s): Joseph Beyene, Cochrane; Doug Altman, Cochrane

Contributor(s): Joseph Beyene, Cochrane; Doug Altman, Cochrane

Abstract: Objective: To provide review authors with the knowledge to recognise and address situations in which a simple meta-analysis may not be appropriate. Summary: Cochrane review authors frequently face data that do not apparently fit into the usual dichotomous or continuous data meta-analyses that can be performed by RevMan. Typical examples are: (i) study designs, such as cross-over trials or cluster-randomised trials; (ii) types of outcome data, such as time-to-event data, ordered categorical data or rates. In this workshop we will review such 'non-standard' studies and data, and consider the possibilities for analysing individual studies and combining results in meta-analysis. RevMan offers a 'generic inverse variance' outcome type that can, in principle, be used to perform meta-analyses in all of these 'non-standard' situations. [The workshop is part of a series of five workshops on meta-analysis, but does not require attendance at any of the others in the series.]

WS8: School Dropout Prevention: The Potential for Rapid but Complete Reviews

Collaboration: Both

Methods Group: Campbell Methods Group

Facilitator(s): Sandra J. Wilson, Campbell; Mark W. Lipsey, Campbell

Contributor(s): Sandra J. Wilson; Mark W. Lipsey

Abstract: Policymakers who wish to commission systematic reviews typically desire to have the final product much more quickly than reviewers typically produce them. How to respond to this situation has been a topic of recent vigorous discussion in the Campbell Collaboration. One approach to this situation is to conduct an abbreviated review that is constrained in various ways that allow it to be completed more rapidly than usual. Adopting that approach, however, assumes that a full-review that complies completely with the Campbell procedures and standards cannot be completed fast enough to accommodate policymakers timelines. This discussion workshop is organized around a systematic review effort that was designed, in part, to explore how quickly an experienced team could conduct a full Campbell review given adequate, but not lavish funding support. The topic of this review is the effectiveness of school dropout prevention interventions. A wide scope of interventions was eligible for inclusion so long as school dropout, truancy, or attendance was assessed as an outcome. The aspects of the review that will be presented for discussion include (a) the organization of the team and the sequencing of work to facilitate a brisk pace; (b) the inherent limitations on how quickly the work could be completed; (c) the tasks and procedures that produced the biggest bottlenecks; and, (d) a summary of the scope and results of the final review with the timing and cost required to produce it.

WS9: What do qualitative studies have to add to systematic reviews: A simple explanation of qualitative research and its use in systematic reviews

Collaboration: Campbell

Methods Group: Campbell Methods Group

Facilitator(s): Michael Saini, Campbell

Contributor(s): Michael Saini, Campbell

Abstract: This workshop is an introduction to various qualitative methods, providing those who attend a viable strategy to synthesize evidence without compromising methodological integrity. In the last twenty years, there has been a parallel growth pattern of qualitative research and systematic reviews. A growing number of scholars have argued in favor of broadening systematic reviews to include qualitative inquiry, which has emerged in response to the underutilization of accumulated qualitative studies. There is an acknowledgement that the broad term 'qualitative research' includes vastly different philosophical, theoretical, social, and political commitments [simplify – This workshop will explore the different qualitative approaches. . . . In qualitative inquiry, there is no adherence to a single unified tradition, philosophy or method. Therefore, similar to separate analysis of study designs in quantitative systematic reviews, consideration must be given to the various epistemological stances underpinning each qualitative method when combining studies. This workshop will explore various qualitative methods to be included in systematic reviews, including phenomenology, grounded theory, ethnography, case studies, and participant action research. Epistemological frameworks and the underlying assumptions underpinning these methods will be highlighted, as well as the nuances of qualitative methods across disciplines. Each method will be presented in terms of its purpose, epistemological assumptions, sampling, data collection procedures, data analysis, issues of transferability and ways to assess quality and rigor.

WS10: Reporting Guidelines for Implementation Data in Systematic Reviews: First Consensus Meeting

Collaboration: Both

Methods Group: Campbell Methods Group

Facilitator(s): Paul Montgomery, Campbell

Contributor(s): Paul Montgomery, Campbell

Abstract: Many commentators have noted that systematic reviews frequently lack sufficient information for clinicians and researchers to reproduce interventions, which limits the transportability of research. Without a systematic description of intervention components and delivery, reviewers may also overlook important sources of heterogeneity. For example, effective interventions may appear ineffective if the intervention is delivered poorly or at an insufficient dose. Understanding the actual delivery and uptake of interventions may be particularly important for analyzing and transporting behavioural or complex interventions. A team of systematic reviewers at Oxford University developed a framework for reporting implementation data in systematic reviews. Initial development involved a Delphi panel

of experts, and an Index was piloted. The Oxford Implementation Index was presented at the 2005 Cochrane and the 2006 Campbell meetings. This workshop is the first consensus meeting to develop minimum reporting guidelines for implementation data in systematic reviews. It will seek to identify data that are critical for understanding and undertaking interventions, and it will aim to identify a practical method for including such information in Cochrane and Campbell reviews. Space will be reserved for invited methodologists, guideline developers and reviewers. In advance of the workshop, participants will receive a copy of the index, an explanatory paper and related articles. The workshop will consider further developments (e.g. refining the Index, modifying existing guidelines, expanding the Cochrane Handbook) and participants will be invited to continue to participate in the consensus process.

WS11: Grading the quality of evidence and preparing summary of findings tables for diagnostic tests (Applicability and Recommendations Methods Group)

Collaboration: Cochrane

Methods Group:

Facilitator(s): Holger Schünemann, Cochrane; Jan Brozek, Cochrane; Patrick Bossuyt, Cochrane; Gordon Guyatt, Cochrane; Andy Oxman, Cochrane

Contributor(s): Holger Schünemann, Cochrane; Jan Brozek, Cochrane; Patrick Bossuyt, Cochrane; Gordon Guyatt, Cochrane; Andy Oxman, Cochrane

Abstract: Many organizations apply the GRADE approach to grading the quality of evidence and strength of recommendations for interventions. Cochrane review authors use the GRADE approach to grade the quality of evidence for interventions studies in Cochrane summary of findings (SoF) tables – a presentation of the most important information and findings of a review in a table format. The GRADE working group has suggested a separate approach to grading the quality of evidence for questions of diagnostic accuracy. Using this approach, cross sectional or cohort studies can provide high quality evidence of test accuracy if they are linked to direct information about patient-important outcomes. However, test accuracy is a surrogate for patient-important outcomes, so that these studies often provide low quality evidence for recommendations about diagnostic tests, even when the studies do not have serious limitations. This is due to the recognition that inference from data on accuracy of a diagnostic test or strategy requires information whether applying the test improves patient-important outcomes (i.e. because of availability of effective treatment, reduction of test related adverse effects or anxiety, or improvement of patients' wellbeing from prognostic information). Therefore, studies that provide high quality information about accuracy may provide only low quality evidence of impact on patient-important outcomes, and thus low quality evidence for recommendations about diagnostic test use. Judgments are thus needed to assess the directness of test results in relation to consequences on patient-important outcomes. This workshop will introduce this approach based on examples and hands-on exercises.

WS12: Using GRADEpro to create Summary of Findings Tables

Collaboration: Both

Methods Group: Applicability and Recommendations Methods Group

Facilitator(s): Holger Schunemann, Cochrane; Nancy Santesso, Cochrane; Jan Brozek, Cochrane

Contributor(s): Holger Schunemann, Cochrane; Nancy Santesso, Cochrane; Jan Brozek, Cochrane

Abstract: Objectives: Participants will learn using the GRADEprofiler (GRADEpro) software to prepare Summary of Findings Tables for Cochrane Reviews. This is a guided hands-on workshop using GRADEpro. Description: Summary of Findings (SoF) tables are a relatively new important addition to Cochrane reviews. Although not mandatory, Cochrane review authors are strongly encouraged to include SoF in their reviews. GRADEpro is a simple computer application that can import data and analyses from RevMan 5, facilitate the creation of SoF tables, and export SoF Tables to RevMan. The main feature of GRADEpro is to facilitate the assessment of the quality of evidence (study design/risks of bias, limitations, directness of evidence and sparseness of data) and the conversion and summary of results into relative and absolute effects for individual outcomes. This workshop takes participants through the entire process of creating a SoF using GRADEpro. Participants will work on an example of a Cochrane review or use their own review during the workshop. Each step or decision point of the process is explained and participants immediately practice it before moving to the next step. In addition to the presenter, other trainers are available throughout the workshop to help and support participants or provide more advanced information.

WS13: Who wants to be a meta-analyst – Fourth Edition

Collaboration: Cochrane

Methods Group: Statistical Methods Group; Bias Methods Group

Facilitator(s): Ian Shrier: Cochrane; Joseph Beyene: Cochrane; Robin Christensen: Cochrane; George Wells: Cochrane

Contributor(s): Ian Shrier: Cochrane; Joseph Beyene: Cochrane; Robin Christensen: Cochrane; George Wells: Cochrane

Abstract: Objectives: This workshop will review / teach the audience about important fundamental principles and advanced nuances of meta-analysis methodology using a fun, interactive game show format. Description: Following up on previously well accepted editions of the game show presented in Sao Paulo Brazil, Freiberg Germany and Singapore, this workshop will follow the "Who Wants To Be A Millionaire" game show format. Contestants will be chosen from the audience at random. The contestant is given a question with four possible answers. If the contestant chooses the correct answer, the contestant moves on to the next stage. Each contestant will be given three 'lifelines' (ask the audience, ask a friend, 50–50 choice) to use at their option if they are not sure what the correct answer is. If they make a mistake, they are replaced with another contestant from the audience. To enhance the pedagogical experience, we will occasionally ask the audience how many agree with the stated answer. Members of The Cochrane Collaboration's Statistical Methods Group, including George

Wells, Joseph Beyene and Robin Christensen, will be on hand to explain the answers where needed. To make the game more entertaining, we will include several controversial questions where more than one answer may be correct, but our 'official' answer is that there is only one correct answer. For these questions, the contestant can challenge the answer for bonus points / prizes. If a contestant 'challenges' a question where there is only one answer (i.e. an inappropriate challenge), the contestant is automatically replaced with a member from the audience. Even though audience members are not officially competing themselves, any audience member is allowed to challenge the answer of a contestant before the official correct answer is given. If the audience member is correct, the audience member replaces the contestant and continues to play from the stage the contestant had reached. Other surprises and prizes await.

WS14: Train the trainers: Cochrane editorial skills workshop

Collaboration: Cochrane

Methods Group: Education and Training Methods Group

Facilitator(s): Taryn Young, Cochrane; Jimmy Volmink, Cochrane; Paul Garner, Cochrane; Nandi Siegfried, Cochrane; Harriet Macle hose, Cochrane; Charles Okwundu, Cochrane

Contributor(s): Taryn Young, Cochrane; Jimmy Volmink, Cochrane; Paul Garner, Cochrane; Nandi Siegfried, Cochrane; Harriet Macle hose, Cochrane; Charles Okwundu, Cochrane

Abstract: Objectives: To develop a pool of editorial skills workshop facilitators; Share the experiences of the Cochrane Africa editorial skills workshop Description: The contribution of Cochrane Review authors from middle-and low-income countries (LMIC) has improved over the past few years with The Cochrane Collaboration making dedicated efforts to improve involvement from these countries. However, the number of editors from LMICs remains low. For example, of the 568 editors working with Cochrane Review Groups, only forty-one (7%) are located in LMICs. To meet The Cochrane Collaboration's principles of enabling wide participation and striving for relevance, efforts need to be made to increase the number of editors from resource-constrained regions. The South African Cochrane Centre, in partnership with the Cochrane Editorial Unit and the Effective Health Care Research Programme Consortium are conducting the first Cochrane Africa Editorial Skills workshop to build capacity in editorial skills within the African region. Similar workshops could be held in other LMICs to strengthen editorial capacity. This train-the-trainer workshop will be used to share the experience of developing and running the Cochrane Africa Editorial Skills workshop. Participants will be equipped with resources and skills to lead and facilitate editorial skills workshops in their home countries. We will use brief presentations and discussions through small-group exercises to help participants coordinate and facilitate similar workshops. Participants will learn how to identify participants for the workshop, how to decide on an appropriate agenda and select useful resources, how to best present key concepts and how to evaluate the learning outcomes.

WS15: Get your figures right: preparing images for Cochrane reviews

Collaboration: Cochrane

Methods Group: Cochrane IMS

Facilitator(s): Jacob Riis, Cochrane

Contributor(s): Jacob Riis, Cochrane; IMS team, Cochrane

Abstract: Objectives: Enable participants to spot and fix common errors in images included in Cochrane reviews. Description: In addition to the standard figures generated by Review Manager, authors can include image files from other sources. Images included in reviews are published without central editing and standardization, and must therefore be of high quality before being submitted to the publishers. This workshop will train review group staff and authors in identifying quality problems in figures, and in how they can be avoided or corrected. The focus areas of the workshop will be developed based on an analyses of figures currently published in the Cochrane Library, and on cases handled by the Review Figures Clinic (see www.ims.cochrane.org/support/authors/review-figures-clinic).

WS16: The stats café (today's special: statistics for the terrified)

Collaboration: Both

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Amy Drahota, Cochrane; Mike Clarke, Cochrane; Ann Dewey, Cochrane

Contributor(s): Amy Drahota, Cochrane; Mike Clarke, Cochrane; Ann Dewey, Cochrane

Abstract: Objectives: To gain an understanding of common statistical concepts such as: risks; odds; p-values; confidence intervals; and sample size. Description: This workshop involves working in small groups and rotating around the room to undertake a range of activities. On each table we will place tasters of statistical concepts in easy-to-swallow, bite-sized pieces. Activities on the menu include: –“Chef’s Speciality Sparks Media Mayhem”. Explore the use of risks and odds, and how to express the meaning of the numbers in words. –“Pea-value Platter”. Interpret the results of studies by exploring the meaning of p-values. –“Peppé’s losing the L’Abbé Plot”. Conduct a mini experiment and see the influence of sample size on study results. –“Sampling Sweets with Confidence”. Explore the concept of confidence intervals and how this influences decision-making. It’s all fun and games as Peppé (that’s the café owner) is losing the plot, his chef is playing up again, and the Chef’s Special has sparked a media mayhem. But all Peppé really wants to know is – what sweets should he buy?

WS17: Methods for involving consumers in systematic reviews

Collaboration: Both

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Kristin Liabo, Both; Sandy Oliver, Both; Ruth Stewart, Both; Rebecca Rees, Both

Contributor(s): Kristin Liabo, Both; Sandy Oliver, Both; Ruth Stewart, Both; Rebecca Rees, Both

Abstract: Consumer involvement has long been a priority of the Cochrane and Campbell Collaborations. Even so, many systematic reviewers are unsure how to involve consumers. At this workshop researchers will gain hands-on experience of consumer involvement. The aims of the activities are: – To introduce participants to key aspects of consumer involvement – To give participants specific ideas for how they can involve consumers in their reviews The workshop will start with a brief introduction to consumer involvement, before splitting into groups for two different activities. In the first activity groups will consider how key concepts can be conveyed to a group rarely engaged with Cochrane reviews. They will identify concepts that need clarification and draft appropriate definitions. At the end of the activity each group will feed back their definitions, and the choices of concepts and definitions will be compared across groups and discussed. In the second exercise each group will develop the outline of a protocol for a systematic review. The review title will be provided, and each group will specify the population, intervention and outcomes for the review protocol. Each group will have a facilitator, and each group will use a different method for making decisions on the protocol. In this way, participants will be introduced to how views on systematic review protocols may be elicited through different methods. Subsequent discussion will focus on these methods and how effective they are for facilitating consumer involvement, how participants experienced being part in a group and how it worked to take part in an exercise where they were asked to contribute based on personal rather than professional experience.

WS18: Assessing Risk of Bias in Randomized and Non-Randomized Designs – The Cochrane EPOC approach

Collaboration: Cochrane

Methods Group: Bias Methods Group

Facilitator(s): Alain Mayhew, Cochrane; Rachel Bennett, Cochrane

Contributor(s): Julia Worswick, Cochrane; Craig Ramsay, Cochrane; Jeremy Grimshaw, Cochrane

Abstract: Quality assessment remains a critical component in the conduct of systematic reviews. The Cochrane Effective Practice and Organisation of Care Group (EPOC), a review group within the Cochrane Collaboration, supports systematic reviews of professional, organizational, financial, and regulatory interventions to improve health care delivery and care systems. EPOC includes certain non-randomized designs within the reviews. This inclusion has led to new challenges in using the new risk-of-bias (ROB) quality assessment tool. Objectives: To familiarize participants with the ROB tool. To apply the ROB tool to a variety of study designs, including cluster trials, interrupted time series, and controlled before-after designs. A review of the study design eligibility for EPOC reviews and the ROB tool will be presented. Elements that will be explained in detail include adequate sequence generation, allocation concealment, and blinding. In addition, some of the criteria specific to interrupted time series designs will be described,

such as independence of intervention. Participants will be asked to assess the quality of studies of different designs. Ample time will be provided to discuss both the process of the quality assessment and the findings.

WS19: Improving the implementation of collaboration of findings: The development of an online tool to generate evidence on the costs and benefits of interventions

Collaboration: Both

Methods Group: Campbell and Cochrane Economics Methods Group

Facilitator(s): Alison Martin, Both

Contributor(s): Kevin Marsh, Both; Alison Martin, Both; Tony Munton, Both

Abstract: Background: Evidence-informed policy making requires not only information on the effectiveness of interventions, but also the costs and benefits of interventions. Reviews undertaken by the Cochrane and Campbell Collaborations provide evidence on the relative effectiveness of interventions. The international perspective of the Collaborations, however, means that providing evidence on the cost-effectiveness of interventions is very resource intensive and thus beyond the scope of most reviews undertaken by the Collaborations. That is, the context specific nature of costs and benefits mean that cost-effectiveness analysis would have to be undertaken at a jurisdiction-level. Objectives: The workshop will consider the possibility of developing an online tool to support the translation of review evidence on the effect of interventions into estimates of the costs and benefits of interventions. The objective of the tool is to facilitate policy makers' access to and use of the evidence generated by the Collaborations. The workshop will consider the content of the tool, the methodological challenges posed by producing the tool, and the process for developing and maintaining the tool. For instance, the workshop will address the following questions: ● What evidence would policy makers need the tool to provide? ● What challenges are posed by the dynamic, multi-jurisdiction policy context of the Collaborations? ● What sources of data are available to populate the tool? ● How can the construction and maintenance of the tool benefit from the possibilities of the web, such as "crowd-sourcing"? Description: The workshop will be divided into the following three sections: ● Proposal (30 mins): An outline of a proposed tool and a process for its construction and maintenance (Kevin Marsh). ● Response 1 (15 mins): The challenges posed by the tool (Tony Munton) ● Group discussion (45 mins).

WS20: Specialized Registers: Why & wherefores?

Collaboration: Cochrane

Methods Group: Other

Facilitator(s): Gail Higgins, Cochrane; Karen Blackhall, Cochrane; Lynn Hampson, Cochrane

Contributor(s): Gail Higgins, Cochrane; Karen Blackhall, Cochrane; Lynn Hampson, Cochrane

Abstract: Developing & managing a Specialized Register (SR), populated with controlled trials relevant to the scope of an entity, is core to the work of Trials Search Coordinators (TSCs). The Specialized Register makes a valuable contribution to the Cochrane CENTRAL Register of Controlled Trials (CENTRAL) as part of the Cochrane Library, but it is also a valuable resource for an editorial base for the review production process particularly in relation to supporting authors. This workshop will cover a range of issues in relation to developing & managing SRs: – what is the purpose of a Specialized Register? – Why do we have them & how can we manage them? – how can the development of Specialized Registers be optimized so that they are an integral part of the editorial base review process? Case-studies of different types of registers, e.g. study-based, reference-based, large or small, will be used to see how the use of Specialized Registers can be optimized in terms of integration with editorial processes by examining strategies used to populate these registers & ways of adding value to records by use of entity's topic lists, authors, reviews or keywords around interventions & health care conditions. (The Cochrane Register of Studies may inform aspects of this workshop, but that will depend on the progress of its development).

WS21: Methods for synthesizing correlation matrices

Collaboration: Both

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Betsy Jane Becker, Campbell; Meng-Jia Wu, Campbell; Soyeon Ahn, Campbell

Contributor(s): Soyeon Ahn, Campbell; Ying Zhang, Campbell; Haiyan Wu, Campbell; Betsy Jane Becker, Campbell; Meng-Jia Wu, Campbell

Abstract: Objectives: This workshop will discuss problems associated with synthesizing correlation coefficients. One set of problems this workshop intends to address relates to estimating and synthesizing the correlation and covariance matrices for use in multivariate meta-analysis. A second line of inquiry involves synthesizing correlations across primary studies which do not use parallel measures and synthesizing studies that do not report all subscale-outcome correlations. Description: Multivariate meta-analysis has grown in popularity in recent years. One line of interest relates specifically to meta-analytic structural equation modeling. Two methods have been proposed for synthesizing correlation matrices for use in this type of analysis: Becker (1992) and Cheung & Chan (2005). This workshop will compare these two methods using meta-analytic path modeling techniques. When using multivariate meta-analytic methods, attention must be paid to the accuracy of estimating both the correlation and covariance matrices. This workshop reports on simulation results which indicate inaccurate estimation is likely to occur under certain conditions, most notably when study sample sizes are small to moderate in size. Problems arise when primary study correlations are not comparable or are missing. Synthesizing primary studies that use multiple measures of the target construct present unique problems to the meta-analyst. Most notably among these concerns are non-parallel measurement and subsequently sparse data structures due to heterogeneity in

measurement methods. This workshop will demonstrate a method proposed by Ahn (2008) for handling these circumstances and illustrate its practicality and generalizability. This method will be compared with existing methods for handling such circumstances. A final issue is that of missing subscale-outcome correlations. A missing data framework is adopted to estimate these correlations using maximum likelihood methods (Anderson, 1957). This method is compared to an alternate method using generalized least-squares (Craft, Magyar, Becker, and Feltz, 2003).

WS22: Supporting systematic reviews and hypothesis generation through open access libraries and automated knowledge analyses: Training in tool usage and examples from the Justice Health Field (under registration review)

Collaboration: Both

Methods Group: Cochrane Justice Health Field, undergoing registration review, methods development group

Facilitator(s): Cochrane, Campbell Crime and Justice

Contributor(s): All authors are affiliated with the Cochrane Justice Health Field (under registration review). Gallagher is also associated with the Campbell Collaboration as a member of the Crime and Justice Steering Group

Abstract: Objectives: Specialized registries and Cochrane Central are essential in supporting the systematic review process, particularly in the searching phases of the work. This paper provides descriptions of additional tools under development in the Justice Health Field that are free and designed to further support the systematic review process, the development of new hypotheses, and depictions of knowledge and quality by patient, intervention, setting, and outcome. These tools include open source reference management, coding protocols for quality and study type, and graphing and mapping functions to understand and depict knowledge quality and gaps. All of these are designed to complement and coordinate with the existing structure of Cochrane Central, and to aid potential reviewers in Justice Health and other areas in expediting the review process. Methods: This workshop trains participants in the use of a new open source reference manager (zotero), coding protocols for reference and study level characteristics relevant to the Review Group, Field or Methods Groups' needs, and the utility of using free, automated mapping and graphing tools that allow for visual depiction of knowledge and evidence by condition type and PICO characteristics. A few substantive examples are provided using data collected for the Justice Health Field which allow participants to visually observe differences across conditions of interest and PICO characteristics in the amount, quality and bias in existing evidence. These tools are available to non-Justice Health parties through uploading of conforming databases, so all parties, regardless of substantive interest, are encouraged to attend.

WS23: Practical aspects of developing and using Fields topics lists in Archie

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Denise Thomson, Cochrane; Susan Wieland, Cochrane; Cindy Stern, Cochrane; Iva Seto, Cochrane; Alan Pearson, Cochrane; Eric Manheimer, Cochrane

Contributor(s): n/a

Abstract: Objectives Creating a topics list—a list of Cochrane reviews relevant to its scope—is required of each Cochrane Field. The list is created by putting a “tag” on each relevant reviews in Archie (Cochrane’s Information Management System). To support Field staff in this work, our workshop will do the following:—outline uses for the Fields topic lists feature in Archie—suggest how various Fields have approached the work of developing a review taxonomy—review how best to create topics lists in Archie, and points to consider—discuss how topics lists can support collaboration between Fields and Cochrane Review Groups Description In this workshop, we will discuss and review the following points, with reference to the experience of the Complementary and Alternative Medicine, Nursing Care, and Child Health Fields. 1. Development of a Field classification system for Cochrane reviews Each Field will have particular needs when it comes to identifying reviews that fall within its scope, and developing a classification system that is useful and practical to implement. We will also discuss how review tagging can fit within larger evidence mapping initiatives. 2. Using Archie to create topic lists We will demonstrate how to apply Field tags in Archie to create the topics lists, and how this data can be extracted for other evidence mapping uses. 3. Reviewing where Field topics lists show up on The Cochrane Library and Cochrane.org websites 4. Managing the process Each Field will need to address: the best time to apply a tag (at title, protocol or review stage); how to manage communication with CRGs about individual reviews; whether to tag prospectively or retrospectively; etc. For each Field, these decisions are influenced by available resources, the desired end product, and the number of reviews in its scope.

WS24: Maintaining policy relevance: diverse approaches and mixed methods syntheses for evidence-informed decision making

Collaboration: Both

Methods Group: Facilitators are members of both Cochrane and Campbell Organisations and this workshop does not fall within the remit of one methods group.

Facilitator(s): Josephine Kavanagh, Cochrane; Ginny Brunton, Cochrane; Jan Tripney, Both

Contributor(s): David Gough, Campbell; James Thomas, Both; Mark Newman, Campbell

Abstract: Objectives: To introduce participants to diverse types of research syntheses for evidence-informed decision making in public health and health promotion (HPPH); education; crime and, social care. The EPPI-Centre has conducted evidence syntheses since 1993. Initially building on early methods developed for systematically reviewing the effectiveness of 'clinical' interventions, the EPPI-Centre began translating these methods for questions relating to HPPH. The EPPI-Centre also conduct evidence syntheses for government and associated departments and organizations in the fields of education, social care and justice. UK policy makers were, and remain, interested in complex questions about 'what works for who and under what circumstances?'. However, the range of questions relevant to policy has broadened beyond the scope of effectiveness towards understanding peoples 'views' of health, education and social care. The complexities of people's lives and the circumstances in which they live have become more important to policy makers, especially those interested in reducing health and social inequalities. This broader range of questions has required the EPPI-Centre to extend the range of research drawn on for synthesis. Innovative 'fit for purpose' methods, and approaches to reviewing have been developed. These include: centralizing user involvement, two-stage systematic reviews, systematic mapping, methods for synthesis of diverse study types, and mixed methods syntheses. Description: Facilitators of this discussion workshop will describe how the range of methods and reviewing approaches have developed. Case-studies based on published reviews will be used to illustrate how user involvement, two-stage systematic reviews, systematic mapping, methods for synthesis of diverse study types, and mixed methods syntheses have resulted in policy relevant evidence for decision making across a range of reviews in the areas HPPH, education, social care and justice. Opportunities for interaction and exploration of how these approaches might be improved and translated for different policy and research contexts will be provided.

WS25: Cochrane PICO: Delivering clinical answers at the point of care

Collaboration: Cochrane

Methods Group: Wiley

Facilitator(s): Harriet MacLehose, Cochrane; Bryony Urquhart, Wiley

Contributor(s): Harriet MacLehose, Cochrane; Bryony Urquhart, Wiley

Abstract: Objectives: To inform participants of the objectives and status of the Cochrane PICO project, to demonstrate the Cochrane PICO template and provide participants with the tools they need to create Cochrane PICOs. Description: Doctors and other health care professionals need to find answers to their clinical answers quickly at the point of care (before/during/after a patient encounter). Cochrane Reviews, and abstracts and summaries of Cochrane Reviews, are not optimised for use at the point of care. Cochrane PICOs provide answers to clinical questions using the evidence presented in one or more Cochrane Reviews, in a structured format that is quick to read. Cochrane PICOs act as an entry point to the Cochrane Database of Systematic Reviews, and each Cochrane PICO contains many hyperlinks to specific locations in a full Cochrane Review. In the future, Cochrane PICOs could even be integrated into clinical decision support tools that

interact with electronic health records. The Cochrane Editorial Unit ran a pilot project in early 2010 to generate Cochrane PICOs to test the concept. Seven Cochrane entities were involved in the generation of thirteen PICOs, answering clinical questions in the topics of asthma, malaria, neonatal medicine, rheumatoid arthritis, transplantation and tuberculosis. The Cochrane PICOs were then user tested with practicing family doctors and general practitioners in New Zealand, the USA and UK, using an interview script developed by the Nordic Cochrane Centre. This user testing informed the development of the Cochrane PICO template, and refined the guidance for completing a Cochrane PICO. During the workshop, participants will find out more about the Cochrane PICO pilot project, learn the skills required to write a Cochrane PICO, and find out how they can contribute to the Cochrane PICO project in the future.

WS26: Searching for studies

Collaboration: Cochrane

Methods Group: Information Retrieval Methods Group

Facilitator(s): Bernadette Coles, Cochrane; Carol Lefebvre, Cochrane; Jessie McGowan, Cochrane; Alison Weightman, Cochrane

Contributor(s): Bernadette Coles, Cochrane; Carol Lefebvre, Cochrane; Jessie McGowan, Cochrane; Alison Weightman, Cochrane

Abstract: Objectives: The aim of this workshop is to provide an opportunity for Cochrane review authors to gain a basic understanding of Cochrane Collaboration policy on, and to explore best practice in, searching for studies for inclusion in a Cochrane review. Questions to be considered will include; 1. Where to search for studies? – recommended resources essential to the search process. 2. How to search efficiently? – developing a structured search strategy. 3. What to do with the results? – managing and documenting the search process. Description: This session is primarily aimed at Cochrane review authors who wish to develop a basic knowledge of the searching process and is structured around the Cochrane Collaboration policy for searching for studies as described in Chapter 6 of the Cochrane Handbook for Systematic Reviews of Interventions – 'Searching for Studies'. Studies are the key components of Cochrane reviews rather than published papers but searching for published reports of studies remains the most efficient method of identifying studies. The workshop will highlight each area addressed in the 'Searching for Studies' chapter and explore each stage of the searching process. Topics will include: Developing a search strategy – sensitivity versus precision, Boolean operators and controlled vocabulary. Going beyond MEDLINE – identification and comparison of essential resources, including bibliographic databases and trials registers. Organizing and managing the search results Documenting and reporting the search process. The facilitators for this workshop are all members of the Cochrane Information Retrieval Methods Group and will share their experience and expertise with the participants. The session will include presentations, hands-on practical strategy design and discussion.

WS27: Trials Search Co-ordinators, Archie & RevMan 5**Collaboration:** Cochrane**Methods Group:** Cochrane IMS**Facilitator(s):** Karen Hovhannisyanyan, Cochrane; Gail Higgins, Cochrane; Lynn Hampson, Cochrane; Sheila Wallace, Cochrane**Contributor(s):** Karen Hovhannisyanyan, Cochrane; Gail Higgins, Cochrane; Lynn Hampson, Cochrane; Sheila Wallace, Cochrane

Abstract: Objectives: To enhance Trials Search Co-ordinators (TSCs) skills to use Archie and RevMan 5 optimally in their work. To offer a forum for discussing future improvements to the IMS that could aid the work of TSCs. Description: This workshop will cover a range of ways TSCs can use Archie and RevMan 5 in the Cochrane review writing process and the submission process. Through demonstrations, hands-on exercises, and discussions, the topics will include: ● The life cycle of a Cochrane review in RevMan5 and Archie from the TSCs' perspective ● Archie for TSCs – levels of access/permissions – the contacts database – the Topics lists – running reports – TSC input into reviews – understanding and using workflows ● Importing references into RevMan5 from specialised registers (using MeerKat, ProCite, EndNote or Reference Manager or directly from CDSR, CENTRAL and PubMed) ● reporting search strategies in Cochrane reviews ● editing a CRG module There will also be an opportunity to discuss what TSCs would like future developments of the IMS to cover.

WS28: How to interpret patient-reported outcomes in Cochrane reviews**Collaboration:** Cochrane**Methods Group:** Patient Reported Outcomes Methods Group**Facilitator(s):** Donald Patrick, Cochrane; Gordon Guyatt, Cochrane**Contributor(s):** Caroline Terwee, Cochrane; HCW deVet, Cochrane

Abstract: Objectives: PROs are important for measuring the impact of disease, treatment, health and social policies, and the progress of economic and social development. Reviewers conducting systematic reviews and meta-analyses should specify and label the content and type of measure for every application of a PRO. Just like other outcomes, a major challenge faces reviewers in evaluating the clinical significance of PRO outcomes in studies. The Facilitators will help interpret the clinical significance of the PRO results in the proposed articles. Description: This workshop will be focused on patient-reported outcomes, and will be structured in three parts: –A brief discussion of methods for interpreting PRO outcomes in clinical trials presented in lecture and case-materials provided for discussion –Participants will then use the information provided during the first part to review and comment on 2 published articles focussing on how to interpret outcomes participants –Participants will then use information provided to complete summary of findings tables.

WS29: Systematic reviews of diagnostic accuracy studies. 1: What is a Cochrane diagnostic test accuracy review?**Collaboration:** Cochrane**Methods Group:** Screening and Diagnostic Tests Methods Group**Facilitator(s):** Chris Hyde, Cochrane; Jon Deeks, Cochrane**Contributor(s):** Chris Hyde, Cochrane; Jon Deeks, Cochrane

Abstract: OBJECTIVES: To provide an introduction to the purpose and format of Cochrane diagnostic test accuracy (DTA) reviews, and to highlight their novel features. DESCRIPTION: This workshop will provide an opportunity for those who are not actively contemplating a Cochrane DTA review to learn more generally about this type of systematic review, and for those who do know something about them to update their knowledge in line with a number of changes which have occurred in recent years. Members of The Cochrane Collaboration have been at the forefront of many of these developments. We will discuss the following points: ● The different types of medical tests that can be studied in a DTA review ● Different ways of using tests, and whether each use fits within the structure of a DTA review ● The nature of review questions on test accuracy with particular emphasis on the need for comparison We will guide the audience through a Cochrane DTA review with particular emphasis on up-to-date features. The format will involve a lecture with up to two small group exercises to reinforce the nature of test accuracy questions and the key features of a Cochrane DTA review as time permits.

WS30: Addressing Multiple Treatments I: Cochrane Overviews**Collaboration:** Cochrane**Methods Group:** Not submitted on behalf of a Methods Group; Overviews Methods Group**Facilitator(s):** Lorne Becker, Cochrane**Contributor(s):** Lorne Becker, Cochrane

Abstract: Objectives –To encourage the preparation of Cochrane Overviews by informing participants of some key methodological issues and discussing approaches to their resolution. Description –This is workshop #1 of 3 workshops on Overview methods. While the basic idea behind Cochrane Overviews is simple, there are a number of challenges in actually doing one. Who is the potential audience, what will be the scope of the review, which interventions and outcomes should be included, what to do about key interventions with no Cochrane review, how should protocols or reviews in need of an update be addressed, how should data be analyzed and presented? These and other key issues in the preparation of Cochrane reviews will be discussed. For each issue, presenters will give a brief outline of each issue and participants will be invited to provide insights from overviews they are planning or have been involved with.

WS31: Classifying non-randomised studies (NRS) and the assessing the risk of bias for a systematic review

Collaboration: Cochrane

Methods Group: Non-Randomised Studies Methods Group

Facilitator(s): Barney Reeves, Cochrane; George Wells, Cochrane & Campbell; Bev Shea, Cochrane

Contributor(s): Barney Reeves, Cochrane; George Wells, Cochrane & Campbell; Bev Shea, Cochrane

Abstract: Objective: The workshop aims to improve awareness among editors and reviewers of the key issues when including NRS in systematic reviews of effectiveness. Description: This workshop is aimed at reviewers and editors who are considering whether or not to include non-randomised studies (NRS) to estimate the benefits of an intervention in Cochrane systematic reviews. This situation may arise when there are no RCTs, only poor RCTs or very few small RCTs but where an answer to the question addressed by the review is a priority. Evaluations of public health, practitioner-dependent or device-based interventions may have these limitations. Decision makers typically view some evidence as better than none although Cochrane reviews usually exclude NRS because of concern that the data are at risk of bias. Participants will mainly work in small groups to apply two tools to a single NRS. First, participants will classify the NRS with respect to information about study design (likely to be relevant to setting review eligibility criteria) which the NRSMG recommends extracting from primary studies. Second, participants will assess the risk of bias in the NRS using the risk-of-bias tool supplemented with additional items. The implications of varying amounts and quality of information from primary NRS for systematic reviews of NRS will be discussed. Varying amounts and quality of information is also the norm for systematic reviews of RCTs, so the discussion will contrast the implications for systematic reviews of NRS and RCTs.

WS32: Introduction to meta-analysis 2: Effect measures for dichotomous outcomes

Collaboration: Cochrane

Methods Group: Statistical Methods Group

Facilitator(s): Joseph Beyene, Cochrane; Steff Lewis, Cochrane

Contributor(s): Joseph Beyene, Cochrane; Steff Lewis, Cochrane

Abstract: Objective: To provide review authors with the knowledge to perform meta-analysis with dichotomous outcome data, and to understand the implications of choosing different effect measures. Summary: Dichotomous data are perhaps the most common type of outcome in studies included in Cochrane reviews. However, there are several ways in which a simple 2×2 table from an individual clinical trial can be analysed, and even more ways in which results may be combined across studies in a meta-analysis. This workshop will review the notions of risk and odds, and of risk ratio, odds ratio, risk difference and number needed to treat. It will then discuss the relative merits of the different effect measures, including the implications of swapping interest from 'events' to 'non-events'. A simple overview of the different methods for combining results in meta-analysis will

be provided (including the Peto method, Mantel-Haenszel methods and inverse-variance method). Note that the last of these is newly implemented in RevMan 5, and the rationale for including it will be discussed. Issues will be illustrated by examples. Time will be allowed for discussion of the issues raised. [The workshop is part of a series of five workshops on meta-analysis, but does not require attendance at any of the others in the series.]

WS33: Promoting evidence based policy and practice in different national contexts

Collaboration: Campbell

Methods Group: Campbell Head Office

Facilitator(s): Sundell Knut; Campbell; Mette Deding; Campbell; Campbell

Contributor(s): Eamonn Noonan, Campbell; Arild Bjørndal, Campbell; Sundell Knut, Campbell; Mette Deding, Campbell; Gill Clark, Campbell

Abstract: This workshop will analyse and compare different national experiences with evidence-based approaches in the health and social sectors, with a view to identifying effective strategies for advancing evidence-based policy and practice. It will include a summary of facilitators to an evidence based approach, based on the experience in Sweden; an analysis of the different dynamics in the formulation of policy and practice between the health sector and the social sector, with particular reference to the Norwegian case. The focus here is to clarify what lessons from the growth of evidence based medicine can assist the promotion of evidence based social policy. A further presentation will outline how local authorities in Denmark have embraced evidence-based approaches to social services, and will also identify the obstacles to further progress. The session will include discussions of developments in Canada and Scotland and, and participants will be encouraged to contribute insights from other national contexts. Among the institutions taking part are the Norwegian Knowledge Centre for the Health Services, the National Board of Health and Welfare of Sweden, the Scottish Government and SFI Campbell, Denmark.

WS34: Introduction to search methods for economic studies

Collaboration: Both

Methods Group: Campbell and Cochrane Economics Methods Group; Wiley

Facilitator(s): Ian Shemilt, Both; Laura Simmonds, Wiley; Julie Glanville, Both

Contributor(s): Dawn Craig, Both; Pauline Howarth, Cochrane

Abstract: Objectives: Incorporating summaries of evidence on resource use, costs and/or cost-effectiveness drawn from previously published economic studies can enhance the usefulness and applicability of Cochrane and Campbell reviews as a component of the basis for

decision-making. It can also provide the international context within which economic evidence can be interpreted and assessed to inform development of a de novo economic evaluation. In order to review economic evidence as an integral component of the Cochrane or Campbell review process, it is necessary to locate studies containing such evidence. This economics methods training workshop will provide an introduction to search methods for economics studies, for use in the preparation and maintenance of Cochrane and Campbell reviews. Description: At the end of this workshop, participants will be able to:

- Formulate and execute search strategies to locate economics studies;
- Use search filters for economics studies; and
- Use key electronic literature databases containing economics studies.

Workshop materials are consistent with guidance on the use of economics methods published in the Cochrane Handbook for Systematic Reviews of Interventions and The Campbell Collaboration Economics Methods Policy Brief. The session will comprise a didactic presentation, hands-on exercises using specialist electronic literature databases and opportunities for questions and discussion.

WS35: Meta-Regression with Dependent Effect Size Estimates

Collaboration: Both

Methods Group: Campbell Methods Group

Facilitator(s): Larry V. Hedges, Campbell; Mark W. Lipsey, Campbell; Elizabeth Tipton, Campbell; Emily E. Tanner-Smith, Campbell

Contributor(s): Larry V. Hedges, Campbell; Mark W. Lipsey, Campbell; Elizabeth Tipton, Campbell; Emily E. Tanner-Smith, Campbell; Matthew C. Johnson, Campbell

Abstract: The studies included in a meta-analysis often provide more than one effect size estimate appropriate for analysis because of multiple outcome variables, follow-up measures after posttest, treatment variants compared with a common control condition, and the like. Including all these effect sizes in an analysis, however, is quite problematic because of the statistical dependencies among them. Those dependencies can be modeled as part of the analysis but, to do so, requires estimates of the covariance between the effect sizes within each study, information that is rarely available to the meta-analyst. Failure to account for those dependencies results in erroneous standard errors and compromises all the inferential statistics generated by the analysis. This workshop will present a newly developed technique for estimating robust standard errors under such circumstances that does not require knowledge of the covariance structure of the multiple effect size estimates. An overview of the statistical theory will be presented with an emphasis on meta-regression with dependent effect size estimates. Practical procedures for application will be demonstrated, examples with real and simulated data will be discussed, and software resources will be provided.

WS36: Challenges in systematic reviews of complex social interventions

Collaboration: Campbell

Methods Group: Campbell Methods Group

Facilitator(s): William Turner, Campbell; Paul Montgomery, Campbell; Aron Shlonsky, Campbell

Contributor(s): William Turner, Campbell; Paul Montgomery, Campbell; Aron Shlonsky, Campbell

Abstract: The Campbell Social Welfare coordinating group (SWCG) has, over the years, considered within its scope a wide range of social welfare interventions. Some of the proposed topics have presented particular challenges for reviewers and editorial staff due to the multi-level nature of the social intervention considered, issues pertaining to population and diversity of contexts, as well as issues relating to the appropriateness of methodological criteria of included and excluded studies. Based on their extensive experience as advisors, coordinators and contributors on a number of reviews, the presenters of the workshop will aim to address the needs of reviewers working on systematic reviews of complex social interventions as well as people who contemplate undertaking one. Through discussion and practical exercises consideration will be given to issues involved during the title registration, protocol and research synthesis stages. A number of completed and 'in progress' reviews will be used as case studies to illustrate some of the difficulties and challenges faced by reviewers. Our approach would aim to share with participants insights that could facilitate and expedite the review process. Guidance where other useful resources could be accessed would also be provided.

WS37: Four of a kind: When and how to synthesize study results, first similarity, then heterogeneity

Collaboration: Both

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Jos Verbeek, Cochrane; Jani Ruotsalainen, Cochrane

Contributor(s): Jos Verbeek, Cochrane; Jani Ruotsalainen, Cochrane; Jan Hoving, Cochrane

Abstract: Objectives: The objective of the workshop is to improve the methods for study synthesis in systematic reviews. With the search terms 'intervention*' NOT 'pharmacological', 683 review titles can be found in the Cochrane Library. These are all reviews that include a range of interventions, usually complex ones, and in which the authors have encountered the problem of how to make the most meaningful synthesis of study results. Because the interventions are not all defined at the start of the protocol they are obviously heterogeneous. The result of this is that authors often write that studies were too heterogeneous and could not be combined. Ioannides (2008) has argued that this leads to an underuse of information and meta-analysis should be performed more often. Others have argued that a narrative synthesis might be more appropriate (Rodgers 2009). Description: In the workshop, we will discuss what would be the most appropriate arguments for synthesizing study results. To guide the discussion, we will present a flow chart depicting how to proceed with the synthesizing of study

results that starts with 'similarity of interventions'. We argue that to be similar the interventions should have the same type of operation. This implies that the interventions (and control conditions) on which the review focuses should be conceptually well defined before or during the review process. For similarity of participants, study design, outcome and follow-up time, choices should also be based on how the intervention operates. The workshop will use a participative approach and will use reviews from the Cochrane Library as working material. After the workshop participants will have a clearer understanding of the rationale to decide 'when' and 'how' to synthesize study results in a systematic review. Some understanding of the systematic review process is needed to be able to successfully participate.

WS38: Making sense of scientific evidence: A workshop for consumers and people working with them

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Gill Gyte, Cochrane; Dell Horey, Cochrane

Contributor(s): Gill Gyte, Cochrane; Dell Horey, Cochrane; Amanda Burls, Cochrane

Abstract: Objectives: The aim of the workshop is to help lay people make sense of scientific evidence. There will be discussion of: • different ways to test whether health treatments work • why randomised controlled trials are considered the best way to assess the effectiveness of treatments • the importance of systematic reviews Description: This friendly and interactive workshop aims to help lay people and others without a clinical background develop the skills needed to make sense of scientific evidence. It will help participants appreciate the importance of evidence-based care and understand randomised controlled trials and systematic reviews. It will also assist people to explain issues around evidence-based care in ways that lay people/consumers can understand. Participants will work in small groups. They will review a research paper and discuss how trustworthy they find it and how useful the information in the paper might be in their local situation (critical appraisal). All are welcome and participants should enjoy the workshop and learn from it, whatever their current level of knowledge.

WS39: Equity 101: What Equity Can Do for You!

Collaboration: Both

Methods Group: Campbell and Cochrane Equity Methods Group

Facilitator(s): Erin Ueffing, Both; Elizabeth Kristjansson, Both; Jordi Pardo Pardo, Both; Mark Petticrew, Both; Peter Tugwell, Both; Vivian Welch, Both

Contributor(s): None.

Abstract: Learning Objectives: Participants will gain an understanding of the role that equity can play in systematic reviews. They will learn strategies for addressing equity in their reviews, for considering differential effects in disadvantaged populations, and for communi-

cating equity evidence to stakeholders. Description: International and Canadian stakeholders alike are issuing calls for greater consideration of equity and the social determinants of health; the need for a stronger evidence base on these issues is clear. Including equity in systematic reviews is one way to meet these needs. The workshop will begin with a brief presentation about equity and the Campbell and Cochrane Equity Methods Group. Examples of equity-oriented reviews will be given, along with strategies and methods for considering the effects of interventions in vulnerable and disadvantaged populations. The benefits of addressing equity and the disadvantaged in reviews will be discussed, along with implications for policy-making and decision-making. Following the presentation, breakout groups will be formed and participants will apply equity methods to review topics they select; groups will report back in plenary to finish off the workshop. How You Will Engage Participants: We invite participants to bring their own review topics for discussion in the breakout groups. Throughout the session, participants will be encouraged to ask questions and provide examples from their own experience. Level of Knowledge Required: Intermediate.

WS40: Drupal for entity webmasters

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Chris Mavergames, Cochrane

Contributor(s): Evgenia Slavianova, Cochrane

Abstract: This workshop is for webmasters of Cochrane entity sites using the new Content Management System, Drupal. Participants will have an opportunity for a live Q&A on how to use the system plus some detailed training on various aspects of managing their site. So, please bring your questions and get ready to make your entity's site even better!

WS41: Making an impact: how to get the good evidence into practice

Collaboration: Both

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Tom Lamphigh, Both; Helen Roberts, Both; Aileen McIntosh, Both; Gill Clark, Both

Contributor(s): Tom Lamphigh, Both; Helen Roberts, Both; Aileen McIntosh, Both; Gill Clark, Both

Abstract: Objectives • To highlight and share examples of good practice in getting research into practice • To consider the use of systematic reviews directly and indirectly through mechanisms such as evidence based practice guidelines • To offer ideas about getting evidence into practice drawing upon evidence and experience from workshop participants Description The workshop will focus on the role that evidence has in service delivery and professional practice. This will involve consideration of whether systematic reviews are used directly or whether intermediaries such as professional bodies or other organisations are necessary to ensure evidence based practice.

This workshop will offer an opportunity to showcase examples of where systematic reviews have made a difference. • Cochrane and Campbell reviewers will be invited to give examples of where their work has made a positive difference in informing policy and practice or influencing public attitudes and behaviour • Funders/Commissioners will have an opportunity to discuss their expectations of systematic reviews and how they will be used to facilitate change • Users of reviews, including end point users will be invited to reflect on how Campbell and Cochrane (and/or other) systematic reviews made an impact on their practice It is anticipated that the workshop will lead to a better understanding of the expectations of reviewers, funders and users in relation to the potential impact and use of systematic reviews. The workshop will offer participants the opportunity to share examples of best practice in relation to the dissemination of research whilst building on the recognition that different approaches are needed for different interventions at different times in different places. The workshop builds upon the Spring 2010 UK Economic and Social Research Council, Scottish Government and Campbell Collaboration public policy seminar publication 'Will it work in Scotland: systematic reviews and policy transfer for Scotland'.

WS42: "Why did it only work for that group of people or in that context?" The contribution of theory, context, process and implementation in systematic reviews of effectiveness

Collaboration: Campbell

Methods Group: C2 Process and Implementation Methods sub-group

Facilitator(s): Margaret Cargo, Campbell; James Thomas, Campbell; Michael Saini, Campbell; Karin Hannes, Campbell; Patricia Rogers, Campbell

Contributor(s): Margaret Cargo, Campbell; James Thomas, Campbell; Michael Saini, Campbell; Karin Hannes, Campbell; Patricia Rogers, Campbell

Abstract: Programs work differently for different groups of people and in different contexts. Accounting for this heterogeneity by considering program theory and the factors that shape program implementation can strengthen the interpretation of outcomes in effectiveness reviews and inform policy and practice decision-making. This workshop will update participants on the advances of the Campbell Collaboration's (C2) Process and Implementation Methods sub-group to develop methodological guidance that accounts for program theory, contextual factors, process and implementation in systematic reviews of effectiveness. The scope of the group's work will be outlined and the results of a descriptive study reviewing thirty-two C2 systematic reviews focusing on children and youth will be presented. The study will highlight how reviewers have addressed the conceptual and methodological issues related to theory, context, process and implementation and the challenges encountered in addressing these issues. Each co-presenter will then discuss one implication arising from the results as it relates to the development of methodological guidance, including: 1) critical appraisal instruments developed to evaluate the relevance and quality of process of implementation in trials; 2) issues concerning methods and approaches for the synthesis of different types of studies; and 3) the generalisability of process and implementation

studies to inform systematic reviews of effectiveness. Time will be allotted for participant feedback and group discussion.

WS43: Core outcome measures for randomised controlled trials and Cochrane reviews

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Ian Sinha, Cochrane; Bradley Johnston, Cochrane; Mike Clarke, Cochrane

Contributor(s): Ian Sinha, Cochrane; Bradley Johnston, Cochrane; Mike Clarke, Cochrane; Rosalind Smyth, Cochrane; Paula Williamson, Cochrane

Abstract: Why is this workshop important? Ill health and treatments can affect people in different ways, making it difficult to select the most appropriate outcomes for research. If important outcomes are not measured or reported in RCTs, this has implications for systematic reviewers trying to compare, contrast and combine results from separate studies. Furthermore, outcomes might not be measured or reported in a uniform manner, which makes it difficult to interpret or synthesise results across studies. The development of standardised core outcome sets for all trials of effectiveness in a particular condition would make this easier. It would increase the likelihood that important outcomes are measured and reported, reduce the risk of outcome reporting bias, and increase the power of meta-analyses. Objectives: 1) To discuss the current, generally non-standardised, way in which outcomes are selected and reported in randomised controlled trials (RCTs), and the implications for authors of Cochrane reviews 2) To discuss how outcomes can be standardised and summarise work to date 3) To discuss core outcome sets in relation to summarizing the findings of Cochrane reviews Description of workshop: This workshop will comprise a mixture of presentations and participant discussion. A presentation will set the scene for several key issues and the participants will then be given specific Cochrane reviews to look at. They will work in groups to identify examples of non-standardised selection, measurement and reporting of outcomes, and discuss problems this may cause for systematic reviewers. Subsequent presentations and group discussion will focus on existing work to design core outcome sets for clinical trials, and to identify outcomes of most importance to patients, families and carers. Participants will discuss how similar research could identify appropriate outcomes for Cochrane reviews, and how core outcome sets can be used to help authors preparing summaries of their findings, such as within the Summary of findings table.

WS44: Agenda setting for systematic reviews: Evidence & Equity

Collaboration: Both

Methods Group: The abstract is a joint work between Campbell and Cochrane Equity Methods Group and proposed Cochrane Methods Group on prioritisation and agenda setting

Facilitator(s): Peter Tugwell, Both; Erin Ueffing, Both; Vivian Welch, Both; Sandy Oliver, Both; Mona Nasser, Cochrane; Jordi Pardo, Cochrane; Tamara Rader, Cochrane; Anny Lyddiatt, Cochrane; Brian Buckley, Cochrane; Sally Crowe, Cochrane

Contributor(s): Peter Tugwell, Both; Erin Ueffing, Both; Vivian Welch, Both; Sandy Oliver, Both; Mona Nasser, Cochrane; Jordi Pardo, Cochrane; Tamara Rader, Cochrane; Anny Lyddiatt, Cochrane; Brian Buckley, Cochrane; Sally Crowe, Cochrane

Abstract: Objectives: The workshop aims to inform participants about different tools, methods and processes to develop an agenda setting project with an equity lens for systematic reviews. Description: Systematic reviews of existing research evidence can help service users, practitioners and policy makers to make informed treatment decisions. Yet many reviews are conducted because of individual authors' personal or professional interests rather than in response to a need for a review identified and prioritized in a more inclusive, equitable and systematic manner. Methods for identifying and prioritizing topics requiring systematic reviews are ill-developed. This workshop intends to address these issues with presentations on priority-setting and equity and a discussion. The presentation includes: 1) existing priority setting procedures; 2) their relevance and applicability for prioritizing systematic reviews; 3) how to ensure the involvement and partnership of service users and other stakeholders in the process; and 4) tools that could help investigators to incorporate equity and contextual factors in their priority setting projects. The presentations will be used to stimulate a discussion on the most appropriate strategies and processes for prioritizing Campbell and Cochrane reviews. Participants will discuss a series of questions in break-out groups, then report back in plenary.

WS45: Methods for synthesizing regression results

Collaboration: Both

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Betsy Jane Becker, Campbell; Terri Pigott, Campbell; Ariel Aloe, Campbell

Contributor(s): Betsy Jane Becker, Campbell; Terri Pigott, Campbell; Ariel Aloe, Campbell; Rae-Seon Kim, Campbell; Esra Kocyigit, Campbell; Joshua Polanin, Campbell; Ryan Williams, Campbell

Abstract: Objectives: This workshop will provide an overview of methods for synthesizing results of studies that use regression models as the primary method of analysis. The workshop will present a number of possible indices of effect size for regression results in both intervention and observational studies. The examples presented in the workshop draw from a synthesis of studies examining the differences in teacher quality among teachers with varying qualifications, and from a review of education production function models. Description: The workshop will examine the properties of indices of effect size for regression results. For intervention studies, where the index of interest compares an outcome between two groups, possible indices of effect size include the standardized regression coefficient, and effect sizes based on correlations or semi-partial correlations. The workshop will include a discussion of the properties of the standardized regression coefficient as a measure of group differences, and a method for

creating standardized regression results from correlation matrices. For observational studies, where the synthesis aims to estimate either the unconditional or the conditional relationship between a predictor and an outcome, the standardized regression coefficient and correlations or semi-partial correlations have also been suggested as indices for the effect size. The workshop will present methods for computing these effects from a series of observational studies when the full correlation matrix is not provided. Finally, the workshop will discuss the issues involved in choosing among methods for synthesizing regression results. The examples used in the workshop are from two comprehensive reviews, one on teacher qualifications and teacher quality, and the second on examining the relationship among school inputs such as per pupil expenditure and student achievement.

WS46: Using Internet-based Systematic Review Software in Cochrane Reviews: Overview and Tutorial

Collaboration: Both

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Karla Soares-Weiser, Cochrane; David Albright, Campbell; Peter O'Blenis, none

Contributor(s): Karla Soares-Weiser, Cochrane; David Albright, Campbell; Peter O'Blenis, none

Abstract: Objectives: Provide a practical discussion and demonstration of how a Cochrane systematic review can be conducted using Internet-based systematic review software. Advantages, potentials pitfalls and best practices will be discussed. The participant will gain a solid understanding of how Internet-based systematic review software fits into the overall review process. They will also learn the operational and methodological differences between software and paper-based reviews. Finally, the session will provide participants with a practical understanding of how to configure and run an internet-based systematic review. Description: An increasing number Cochrane and Campbell groups are using or are experimenting with Internet-based software for managing the conduct of systematic reviews. More and more such software systems are becoming available each year. At the Singapore Colloquium, Karla Soares-Weiser, Peter O'Blenis and Harriet McLehose presented a workshop entitled "Tools for Data Extraction in Systematic Reviews" that covered issues relating to data extraction in Internet-based systematic reviews. Attendee feedback indicated that a practical, more hands-on tutorial style would be beneficial. This workshop will provide an overview of how Internet-based review software is being used today. Examples based on past and current Cochrane reviews will be used. The centrepiece of the workshop will be a functional tutorial covering the key tasks of on-line reference management, protocol and form design, reference screening, data extraction and reporting. The tutorial will be provided using the DistillerSR software platform. A list of other available platforms and groups providing this type of software will be provided along with pointers to online resources. The session will conclude with a review of best practices for software-enabled reviews and the important methodological differences between paper and Internet-based studies.

WS47: Developing a good presentation about your consumer organization and its contributions to evidence-based healthcare (EBHC)

Collaboration: Both

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Kay Dickersin, Cochrane; Maureen Corry, Cochrane; John Santa, Cochrane; Janet Wale, Cochrane

Contributor(s): Kay Dickersin, Cochrane; Maureen Corry, Cochrane; John Santa, Cochrane; Janet Wale, Cochrane

Abstract: Objective: To develop a slide presentation that consumers can use to communicate to health professionals the importance of their collaboration in developing systematic reviews Description: To communicate the strength of consumer participation in helping to develop systematic reviews, it is optimal to make presentations in the format health professionals expect. This may not always coincide with an optimal presentation for consumers, who, for example, may not use or even like using "slides". We will begin with a brief summary of guidelines for making good slides and good presentations. We will continue to work "hands-on" as a group to build the foundations of a standard presentation about consumer contributions to systematic reviews and evidence-based healthcare. The completed presentation will be made available to consumer groups for use in their work after the workshop.

WS48: When is a review or protocol ready for publication?

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Harriet MacLehose, Cochrane Editorial Unit; Nancy Owens, Cochrane/Wiley Copy Edit Support

Contributor(s): Harriet MacLehose, Cochrane Editorial Unit; Nancy Owens, Cochrane/Wiley Copy Edit Support

Abstract: Objectives: This workshop will provide Cochrane editorial staff and copy editors with an overview of the copy editing quality standards recently developed by Copy Edit Support (CES) and the Cochrane Editorial Unit (CEU), and practical information on how to incorporate this information into the editorial process for reviews and protocols. At the conclusion of the workshop, participants will: 1. be familiar with the new guidelines that have been developed to ensure copy editing quality standards across all Cochrane reviews and protocols; 2. understand how CES and the CEU have developed the guidelines and supporting publication assessment checklists; and 3. have hands-on experience in using new checklists as part of the editorial process. Description: CES and the CEU have developed guidelines to help standardize quality of copy editing across all published Cochrane reviews and protocols. To help Cochrane editorial staff and copy editors implement these guidelines, CES and the CEU have also developed pre-publication checklists to help determine when reviews and protocols are ready for the final pre-publication copy edit. This workshop will focus on familiarizing participants with the new pre-publication guidelines and checklists: how they were developed, what they include, and how to use them. Facilitators will describe

new developments and answer questions. The session will include a participatory exercise in putting the guidelines into practice.

WS49: Podcasting for The Cochrane Library

Collaboration: Cochrane

Methods Group: Wiley

Facilitator(s): Laura Simmonds, Wiley; Chris Mavergames, Cochrane; Mike Clarke, Cochrane

Contributor(s): Laura Simmonds, Wiley; Chris Mavergames, Cochrane; Mike Clarke, Cochrane

Abstract: This workshop is aimed at Cochrane authors wishing to make podcasts about their systematic review, for inclusion in The Cochrane Library. It would also be of benefit to anyone supporting authors, such as Review Group Co-ordinators. The workshop will take you through step-by-step the process involved in making a recording, from advice on equipment and technical requirements to editorial ideas and tips on achieving the best sound quality. The participants by the end of the workshop, in groups will have a go at preparing the script, and recording the podcast, from a pre-assigned review.

WS50: Navigating The Cochrane Library

Collaboration: Cochrane

Methods Group: Wiley

Facilitator(s): Colleen Finley, Wiley

Contributor(s): Laura Simmonds, Wiley; Colleen Finley, Wiley

Abstract: The workshop will provide basic and intermediate level users with an understanding of the most useful techniques for navigating The Cochrane Library online via www.thecochranelibrary.com. It will demonstrate the most useful tools on the new website launched in early 2010 as well as the most effective ways of finding information. This workshop will also present improved search results from Wiley InterScience, enhanced search setting and alert options and provide an overview of enhancements displayed within Cochrane Reviews. At the end of the workshop, users will have a better understanding of the techniques available for navigating The Cochrane Library. The session will include an online demonstration and participants will be able to complete a series of exercises and practice during the workshop.

WS51: Clinical trials registers: the challenge of searching new resources

Collaboration: Cochrane

Methods Group: Information Retrieval Methods Group

Facilitator(s): Julie Glanville, Cochrane; Carol Lefebvre, Cochrane

Contributor(s): Julie Glanville, Cochrane; Carol Lefebvre, Cochrane

Abstract: Target audience: Trials Search Co-ordinators, other information specialists and review authors interested in searching for

studies. Participants should be experienced in searching databases such as MEDLINE/PubMed. Objectives: Increasing interest in identifying, registering and promoting access to healthcare trials and their results has seen the development of large numbers of trials registers, and more recently, trials results registers. Trials registers provide information on current and recently completed studies and trials results registers provide information on completed studies. Trials registers are important for systematic reviews because they provide opportunities to reduce publication bias. Trials can be identified at an early stage and followed through to completion. Trial protocols can be assessed for relevance and increasingly trial results are recorded within the registers. Trials registers are developing quickly and provide challenges in terms of identification, efficient searching, record de-duplication and record management. This workshop will increase awareness of trial registers as an important resource for systematic reviewers and offer practical advice on searching registers, documenting the search process and managing records obtained from registers. Description: The workshop will begin with a brief overview of the development of trials registers. The introduction will be followed by online demonstrations of key registers highlighting their search features and downloading opportunities. There will then be hands-on exercises if facilities permit or a discussion of search approaches to use with less well-developed interfaces, if online access for the participants is not possible. This is a training workshop – it teaches participants new information and skills, promotes interaction and provides time for hands-on application of the skills being taught (or discussion of search features, depending on facilities available). It builds on information provided in Chapter 6 of the Cochrane Handbook for Systematic Reviews of Interventions, and is being presented by two of the authors of that Chapter.

WS52: The basics of effect size extraction and calculation of a fixed-effect model

Collaboration: Campbell

Methods Group: Campbell Methods Group

Facilitator(s): Robert M. Bernard, Campbell; Eugene Borokhovski, Campbell; Philip C. Abrami, Campbell

Contributor(s): Robert M. Bernard, Campbell; Eugene Borokhovski, Campbell; Philip C. Abrami, Campbell

Abstract: This workshop will deal with the basics of the statistical procedures involved in: 1) effect size extraction and calculation; 2) calculation of individual effect size statistics (e.g., standard error, variance, confidence intervals, Q-statistic); and 3) calculation of the weighted mean effect size and associated statistics using the fixed-effect model (Borenstein, Hedges, Higgins & Rothstein, 2009). Emphasis will be placed on the participants comprehending the principles of calculation and the logic that underlies each equation. One section at the end of the workshop will involve the audience participating in extracting effect sizes from several documents selected from a published meta-analysis of critical thinking interventions. Attendees' results will be entered into a "demonstration calculator," based in Excel and developed by Bernard, around five real examples from: Abrami, P.C., Bernard, R.M., Borokhovski, E., Wade, A., Surkes, M.A., Tamim, R., & Zhang, D.A. (2008). Instructional interventions affecting critical thinking skills and dispositions: A stage one meta-analysis. *Review of Educational Research*, 78(4), 1102–1134. Attendees will extract data

from abstracts of the five articles as a simulation of how extraction is actually practiced. The exercise reveals how each of the equations, from individual effects to summary statistics, are generated for different research designs. The audience will participate in the interpretation of the results that the calculator achieves. The presentation materials and exercises that will be used in this workshop were adapted from PowerPoint slides originally developed by the C2 Methods Group. The materials have been tested and revised over the last five years.

WS53: Prospective meta-analysis: a practical guide

Collaboration: Both

Methods Group: Prospective Meta-Analysis Methods Group

Facilitator(s): Lisa Askie, Cochrane; Davina Gherzi, Cochrane; Jesse Berlin, Cochrane

Contributor(s): Lisa Askie, Cochrane; Davina Gherzi, Cochrane; Jesse Berlin, Cochrane; Kylie Hunter, Cochrane

Abstract: Objectives: This workshop aims to give guidance to those who are thinking about undertaking, or would like to know more about Prospective Meta-Analysis (PMA). Participants will gain an understanding of both the theoretical and practical aspects of conducting a PMA. This will help them to determine whether this methodology is appropriate for the types of research question they wish to address. Description: A Prospective Meta-Analysis (PMA) is a meta-analysis of randomised controlled trials (or other prospective studies) identified, evaluated and determined to be eligible for the meta-analysis before the results of any of those studies become known. They have features in common with large, multi-centre clinical trials and individual patient data meta-analysis. PMA can potentially overcome some of the biases inherent in standard retrospective meta-analyses including selective outcome reporting and publication bias. By the end of the workshop participants will know more about what a PMA is and the possible strengths and limitations of the methodology. The workshop will enable participants to understand: * the key features of a PMA * the strengths of the methodology as well as the limitations * in what circumstances this methodology may (or may not) be appropriate to use * analysis issues including statistical power * study design considerations * how to search for ongoing or yet-to-commence studies that might be eligible for inclusion * practical issues including the processes involved in forming and maintaining a PMA Collaboration and resource needs. Practical examples will be used to demonstrate and discuss these concepts.

WS54: Systematic reviews of diagnostic accuracy studies. 2: Developing search strategies for systematic reviews of diagnostic test accuracy

Collaboration: Cochrane

Methods Group: Screening and Diagnostic Tests Methods Group

Facilitator(s): Ruth Mitchell, Cochrane; Anne Eisinga, Cochrane

Contributor(s): Ruth Mitchell, Cochrane; Anne Eisinga, Cochrane

Abstract: Objective: To enhance further the competencies of TSCs in developing search strategies for systematic reviews of DTA studies

using a practical exercise-based approach. Description: The workshop will be based entirely around two small-group exercises: – Critiquing a search strategy from a published review – Developing a search strategy for a systematic review Participants will work in pairs, and there will be opportunity for discussion and feedback to the wider group at the end of each exercise. Participants will gain skills in areas such as: – Alternative ways of structuring search strategies for DTA reviews – Overcoming problematic terminology for tests and target conditions e.g. where there are no MeSH terms, where there are alternative terms, MeSH terms vs Subheadings etc. – Advanced techniques for optimising sensitivity and precision Intended Audience: Trials Search Co-ordinators (TSCs) and other information specialists. Level of Knowledge: Intermediate to advanced MEDLINE search skills. It is assumed that participants will already have a basic knowledge of diagnostic test accuracy (DTA) studies, and the principles and practice of searching for DTA studies, gained through attendance at one of the ‘Searching for DTA Studies’ workshops run at previous Colloquia or UK and Ireland Cochrane Contributors’ meetings.

WS55: Addressing multiple treatments III: Multiple-treatments meta-analysis advanced methods

Collaboration: Cochrane

Methods Group: Overviews Methods Group

Facilitator(s): Georgia Salanti, Cochrane

Contributor(s): Georgia Salanti, Cochrane

Abstract: Objectives: To understand advanced statistical models and the methodology of multiple treatment meta-analyses, which allow determination of the ‘best’ among a selection of interventions. Description: This is the last workshop in a series of three workshops. The workshop will provide insight to beyond-the-basic multiple-treatments meta-analysis (MTM) models. We will explore the different implementation alternatives (Bayesian versus frequentist) through worked examples. We will discuss some specific methodological issues, such as the underlying assumptions of the MTM models and evidence consistency. We will present established models to check for and incorporate inconsistency and we will discuss applications of multiple-treatments meta-regression models. Finally, we will address concerns regarding the role of bias in MTM models.

WS56: Systematic reviews of diagnostic accuracy studies. 4: Introduction to meta-analysis.

Collaboration: Cochrane

Methods Group: Screening and Diagnostic Tests Methods Group

Facilitator(s): Jon Deeks, Cochrane; Yemisi Takwoingi, Cochrane

Contributor(s): Jon Deeks, Cochrane; Yemisi Takwoingi, Cochrane

Abstract: In this workshop the principles of meta-analysis of diagnostic test accuracy studies will be addressed. We will present a framework for meta-analysis of diagnostic accuracy studies as is implemented within the Cochrane Diagnostic test accuracy reviews. We will start with an overview of the various statistics to express the diagnostic

performance of an index test, such as sensitivity, specificity, likelihood ratios and diagnostic odds ratios. Then methods for graphically summarising results from original studies will be presented: forest plots of sensitivity and specificity, and the ROC plot for presenting paired sensitivity-specificity results. Basic methods for estimating a summary ROC-curve will be presented as they are implemented in RevMan 5, and the rationale for using these methods explained. The workshop will conclude with an overview of possible sources of heterogeneity and methods for assessing heterogeneity.

WS57: When and how to use individual participant data (IPD) in systematic reviews

Collaboration: Cochrane

Methods Group: Individual Patient Data Meta-Analysis Methods Group

Facilitator(s): Jayne Tierney, Cochrane; Lesley Stewart, Cochrane

Contributor(s): Mike Clarke, Cochrane; Maroeska Rovers, Cochrane; Claire Vale, Cochrane; Sarah Burdett, Cochrane

Abstract: Systematic reviews and meta-analyses based on the collection, validation and analysis of individual participant data (IPD) have been described as the gold standard of review, and are being used increasingly across a range of healthcare areas. While many aspects of the IPD approach are similar to the more usual systematic reviews of aggregate data, there are additional aspects of IPD reviews that require differing skills and resource. This workshop will consider the potential advantages and disadvantages of collecting IPD, including benefits arising from improved data quality, benefits afforded by the type of analyses that can be done, and advantages arising from an international multi-disciplinary team approach. Based on our experience, we will provide guidance and practical tips on designing and planning; initiating and maintaining collaboration; collecting and checking IPD and on reporting results. Analysis of IPD will be described but not be dealt with in detail. Reviewers should then be able to decide if the IPD approach is an appropriate approach for their own reviews and if so, be able to start to plan them.

WS58: Systematic reviews of diagnostic accuracy studies. 6: Presenting and interpreting results

Collaboration: Cochrane

Methods Group: Screening and Diagnostic Tests Methods Group

Facilitator(s): Chris Hyde, Cochrane; Rob Scholten, Cochrane

Contributor(s): Chris Hyde, Cochrane; Rob Scholten, Cochrane

Abstract: Objectives: The purpose of this workshop is to provide participants with an understanding of how results of Cochrane Diagnostic test accuracy (DTA) reviews can be presented and interpreted. At the end of the workshop, participants will have been introduced into various ways of presenting DTA results to help end-users to understand better the results of a DTA review. Description: The meta-analysis of diagnostic test accuracy studies is complex and the results of such a meta-analysis are not readily

understandable. Interpretation of test results should be done in view of the purpose of the test(s), the position of the test in diagnostic process and the amount of heterogeneity that is present. The workshop will start with a brief introduction about interpretation of diagnostic tests and strategies for their use in quantitative decision making. Then we will address various ways of how results of a DTA meta-analysis can be presented. Topics included are SROC-curves, confidence ellipses around summary estimates of sensitivity and specificity, Summary of Results Tables and pretest-posttest graphs. Target audience: Authors interested in conducting diagnostic systematic reviews and users of reviews interested in learning about the use of evidence in diagnostic decision making.

WS59: Introduction to meta-analysis 3: Meta-analysis of continuous outcomes

Collaboration: Cochrane

Methods Group: Statistical Methods Group

Facilitator(s): Joseph Beyene, Cochrane; Joanne McKenzie, Cochrane

Contributor(s): Joseph Beyene, Cochrane; Joanne McKenzie, Cochrane

Abstract: Objective: To provide review authors with the knowledge of issues surrounding meta-analysis of continuous outcomes. Summary: Continuous data are commonly encountered in health care. Pooling intervention effects from continuous data presents many issues. Some of these issues will be discussed in this workshop. A brief introduction to meta-analysis of continuous outcomes will be included, consisting of: data extraction (extraction of standard deviations from standard errors, confidence intervals, test statistics, P values); and dealing with outcomes measured on different scales. More complex issues will be discussed including: options for pooling estimates of intervention effect when a mix of results from analyses using change from baseline and final values have been reported; incorporation of results from analysis of covariance and regression models; and use of the generic inverse variance. Issues will be illustrated by examples. Time will be allowed for discussion of the issues raised. [The workshop is part of a series of five workshops on meta-analysis, but does not require attendance at any of the others in the series.]

WS60: Evidence for Low- and Middle-Income Countries: Guidance for Campbell and Cochrane Reviews

Collaboration: Cochrane

Methods Group: Campbell and Cochrane Equity Methods Group

Facilitator(s): Rebecca Armstrong, Cochrane; Arild Bjørndal, Both; Jodie Doyle, Cochrane; Jeremy Grimshaw, Cochrane; Eamonn Noonan, Both; Jordi Pardo Pardo, Both; Mark Petticrew, Both; Terri Pigott, Campbell; David Tovey, Cochrane; Peter Tugwell, Both; Erin Ueffing, Both; Elizabeth Waters, Both; Hugh Waddington, N/A; Howard White, N/A

Contributor(s): Paul Montgomery, Campbell; Aron Shlonsky, Both

Abstract: The need for accurate, synthesized evidence of the effects of interventions to improve health and public health conditions is

clearly important in all contexts, but is even more crucial in low- and middle-income countries (LMICs) where the burden of disease is higher and the consequences of wrong action (or inaction) more grave. Hence, the Cochrane and Campbell Collaborations have a clear obligation to work with international organizations, such as the International Initiative for Impact Evaluation (3IE), to ensure that systematic reviews of health and behavioral health interventions are conducted and reported in a way that are congruent with, and sensitive to, the needs and contexts of decision makers within LMICs. This workshop will consist of a series of themes and will involve both lecture-style presentations and practical activities. Key areas for discussion will include: priority setting to ensure that the right questions are being asked, planning for the review (including recruitment of the 'right' authorship team and funding support), types of study designs, searching for the evidence, and incorporating theory and process evaluations to make sense of findings for varying socio-political contexts. The workshop will also provide advice to participants on how to write recommendations that meet the needs of end users in LMICs.

WS61: Investigating and dealing with bias in systematic reviews

Collaboration: Cochrane

Methods Group: Bias Methods Group

Facilitator(s): Jonathan Sterne, Cochrane; Doug Altman, Cochrane (TBC); David Moher, Cochrane (TBC)

Contributor(s): Jonathan Sterne, Cochrane; Doug Altman, Cochrane; David Moher, Cochrane

Abstract: Objective: The objective of this workshop is to provide an introduction to the different forms of biases and the methods that might be used to detect these biases. Description: The results of a systematic review can be distorted if bias has been introduced into the review process at any stage (e.g. biased location and selection of included studies, high risk of bias in the results of included studies). Accordingly, investigation of the presence, degree, and nature of bias is recommended as a routine part of the systematic review process. The Bias Methods Group draws together researchers interested in this field, and the new Cochrane Handbook contains chapters on "Addressing reporting biases" and "Assessing risk of bias in included studies". The workshop will largely draw upon the work of members of this Group, of which the facilitators are the co-Convenors. We will discuss potential biases that might be introduced into reviews, with an emphasis on reporting biases and the effects of flaws in the methodology of component studies. Particular attention will be paid to publication bias (the publication or non-publication of research findings, depending on the nature and direction of the results), other reporting biases including outcome selection biases, and the empirical evidence on sources of bias in the results of randomised controlled trials. We will demonstrate and discuss graphical and statistical methods that can be used to detect or investigate bias. These include the funnel plot, "trim and fill", tests for funnel plot asymmetry, and meta-regression. The workshop will consist of Powerpoint presentations, and discussions with and among participants.

WS62: Barriers and methodological challenges to evidence-based policy and systematic review in crime and justice

Collaboration: Campbell

Methods Group: Campbell Methods Group; Campbell Crime and Justice Group

Facilitator(s): David Wilson, Campbell; David Weisburd, Campbell

Contributor(s): David Wilson, Campbell; David Weisburd, Campbell

Abstract: This discussion workshop will address barriers and methodological challenges to evidence-based policy and systematic review in crime and justice. We will draw from the experiences our group has accumulated in conducting 25 complete reviews in crime and justice. Several challenges that will be discussed. First, many of interventions and programs examined by our reviews have a limited number of high quality true experimental or randomized studies. As such, roughly 75% of our reviews include quasi-experimental designs. Second, in many areas the existing literature is based primarily on weaker quasi-experimental studies such as simple before/after designs. Third, the studies included are highly variable on factors related to "treatment" and "outcome measures". Finally, several important interventions within our area have geographic units as the focus and not individual offenders, juveniles, or others, such street-lighting, the use of CC-TV, and hot-spots policing. This complicates the computation of effect sizes. Also, the generalizability of the evidence from one country to another is uncertain, which is complicated by the fact that most reviews search only English language studies. These topics and others will be discussed by a co-chair, the editor, and other members of the Crime and Justice Coordinating group.

WS63: To Include or Not to Include NRS in Intervention Reviews: That is the Question

Collaboration: Both

Methods Group: Campbell Methods Group

Facilitator(s): Terri Pigott, Campbell; Barney Reeves, Cochrane Non-Randomised Methods Group; Peter Tugwell, Campbell & Cochrane Equity Methods Group; Erin Ueffing, Campbell & Cochrane Equity Methods Group; Jeffrey C. Valentine, Campbell; George Wells, Cochrane Non-Randomised Methods Group; Larry V. Hedges, Campbell; Maria Benkhalti, WHO Collaborating Center for Knowledge Translation and Health Technology Assessment in Health Equity; Aron Shlonsky, Campbell Social Welfare Group

Contributor(s): Terri Pigott, Campbell; Barney Reeves, Cochrane Non-Randomised Methods Group; Peter Tugwell, Campbell & Cochrane Equity Methods Group; Erin Ueffing, Campbell & Cochrane Equity Methods Group; Jeffrey C. Valentine, Campbell; George Wells, Cochrane Non-Randomised Methods Group; Larry V. Hedges, Campbell; Maria Benkhalti, WHO Collaborating Center for Knowledge Translation and Health Technology Assessment in Health Equity; Aron Shlonsky, Campbell Social Welfare Group

Abstract: The science of, and methods for, systematic reviews of randomised trials have advanced steadily over the last 10 years.

Methods for systematic reviews of other studies (non-randomised studies, NRS) of healthcare effectiveness have not advanced at the same pace. Some systematic reviewers have argued that the principles of systematic reviewing can be applied regardless of the study designs used by the primary studies that provide the available evidence about a particular intervention. Other methodologists, while acknowledging the inherent value of reviewing evidence systematically, are concerned that the principles may not always be applicable. More importantly, during the policy decision-making process, quantitative estimates of effectiveness provided by reviewers may be assumed to be more certain than they truly are. The lack of methodological evidence to inform systematic reviews of effectiveness is important for two reasons: 1. Practitioners argue that many interventions, particularly ones in certain health care fields (e.g. public health or surgery) or which are complex social interventions, are very difficult or impossible to randomise. Both policy-makers and the public need to make decisions about whether or not to participate in such interventions, or to fund them for a community. 2. Systematic reviews of randomised trials have tended to focus on the intended, beneficial effects of interventions, often neglecting to include evidence about serious adverse effects. Because serious adverse effects and harms tend to be rare and may occur a long time after an intervention is administered, they are very difficult to study in randomised trials. This workshop will address the following two questions: a) When can non-randomized studies be incorporated in a systematic review? and b) How are non-randomized studies synthesized in a meta-analysis?

WS64: Creating Summary of Findings Tables

Collaboration: Both

Methods Group: Applicability and Recommendations Methods Group

Facilitator(s): Holger Schunemann, Cochrane; Jan Brozek, Cochrane; Nancy Santesso, Cochrane; Gordon Guyatt, Cochrane; Andy Oxman, Cochrane

Contributor(s): Holger Schunemann, Cochrane; Jan Brozek, Cochrane; Nancy Santesso, Cochrane; Gordon Guyatt, Cochrane; Andy Oxman, Cochrane

Abstract: Objectives: To learn how to create a Summary of Findings Table. This workshop involves small group work, with groups lead by workshop trainers. Description: Summary of Findings (SoF) tables are a relatively new important addition to Cochrane reviews. Although not mandatory, Cochrane review authors are strongly encouraged to include SoF in their reviews. As well as a summary of the results of the review, the Summary of Findings is a tool to ensure that the quality of the evidence is considered along with the magnitude of the effects found in the review. There are three main processes to create a SoF: choosing comparison and outcomes; summarising the evidence in easy to understand numbers; and assessing the quality of the evidence using GRADE. This workshop provides a brief overview of the process and then an opportunity for small group work. Each group will take a Cochrane review and start to create a Summary of Findings Table. During the small group work, participants will discuss the issues around choosing a comparison and outcomes. The GRADE approach is then described and participants can use and discuss the issues for GRADEing the quality of a body of evidence, including the

risk of bias, directness, heterogeneity, precision and publication bias. Hands-on practice will include converting dichotomous and continuous outcomes into absolute effects.

WS65: Development of the Cochrane Register of Studies

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Ruth Foxlee, Cochrane; Gordon Dooley, Cochrane

Contributor(s): Lucie Jones, Cochrane

Abstract: This workshop will update participants on progress of developing the new Cochrane Register of Studies (CRS). This new database will comprise all the Specialized Registers from Cochrane Review Groups and Fields, together with handsearched records from all Cochrane entities and records sourced from MEDLINE and EMBASE and other databases. Participants will be introduced to the main interface of the CRS and guided through a series of scenarios to illustrate how the new system can be used to manage studies and references in Specialised Registers and reviews. There will be an opportunity to discuss how the CRS will impact everyday working practices.

WS66: Getting Cochrane reviews out to the public

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Janey Antoniou, Cochrane; Gill Gyte, Cochrane

Contributor(s): Janey Antoniou, Cochrane; Gill Gyte, Cochrane

Abstract: Objective: To discuss ways of disseminating Cochrane reviews to a wider audience using old and more modern technologies and ways of communicating, and also to discuss how to measure whether they are effective and in what way they are being used. Description: The vision statement of the Cochrane Collaboration says 'Healthcare decision-making throughout the world will be informed by high quality, timely research evidence. The Cochrane Collaboration will play a pivotal role in the production and dissemination of this evidence across all areas of health care'. Raising the profile of this body of evidence among people who use health service around the world could inform their decision-making and give them more informed choices. However, knowledge of this body of literature among ordinary health service users is not high. This workshop will discuss the various ways of dissemination that might reach the public at large and will also consider ways to measure whether people are accessing and using the information provided. We will use the example of the Cochrane Schizophrenia Group which works in collaboration with the mental health charity Rethink and who have attempted to close this gap in knowledge by up-loading plain language summaries from the schizophrenia group onto the charity's website and using Facebook and blogging to attempt to raise awareness of the Collaboration.

WS67: The role of Cochrane reviewers in exposing research misconduct

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Trish Groves, BMJ; Vasilii Vlassov, Cochrane

Contributor(s): Trish Groves, BMJ; Vasilii Vlassov, Cochrane

Abstract: Objective: In this workshop participants will discuss the types and prevalence of research and publication misconduct; consider the current practices of Cochrane systematic reviewers when they find evidence of duplicate publication, plagiarism, and unacceptable data manipulation in primary studies; and discuss whether systematic reviewers could and should expose such misconduct. Description: Scrutinizing primary studies to produce a systematic review can identify a wide range of misconduct in research and publication practices, including duplicate publication, data manipulation, data fabrication, and plagiarism. Despite Chalmers' call three years ago to use systematic reviews as a tool to identify plagiarism (doi:10.1136/bmj.38968.611296.F7), and Jefferson's response (<http://www.bmj.com/cgi/content/full/333/7570/706>) not a single Cochrane review has tackled such misconduct. Authors of systematic reviews regularly identify duplicate publication (eg Gøtzsche PC. Multiple publication of reports of drug trials. *Eur. J. Clin. Pharmacology* 1989; 36: 429–32; Poglia G, von Elm E, Walder B, Tramèr MR. Duplicate publication in systematic reviews on perioperative medicine. 9th International Cochrane Colloquium, Cochrane 2001, 1:op034; von Elm E, Poglia G, Walder B, Tramèr MR. Different patterns of duplicate publication: an analysis of articles used in systematic reviews. *JAMA*. 2004 291(8):974–80 – which reported and incidence of about 40%). Guidance to Cochrane reviewers explains how to handle publication bias from a mathematical viewpoint, but not an ethical one (eg Egger M, Smith GD, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997; 315: 629–34). Neither authors of systematic reviews nor Cochrane editors have the resources to instigate investigations into research and publication misconduct. Could they, however, use objective standardized ways to report apparent misconduct within their reviews? In this way the powerful tool of systematic reviewing could help "to expose very publicly those found guilty . . . of scientific misconduct" (Chalmers I, 2007) and cleanse the scientific record.

WS68: Database selection bias and its affect on systematic reviews: A United Kingdom perspective

Collaboration: Campbell

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Alan Gomersall, Campbell; Chris Cooper, Campbell

Contributor(s): Alan Gomersall, Campbell; Chris Cooper, Campbell

Abstract: The last 10 years has seen the growth in the production of systematic reviews of social policy research and practice issues in response to the United Kingdom government's drive for more evidence informed policy. The UK academic community and social science consultancies have produced several hundred of these supposedly 'invaluable digests' often for government departments preparing new

policy initiatives. There is an expectation on the part of the client that a 'systematic review' is the complete answer to the social policy issue. Whilst the resulting synthesis aims to minimise the effects of bias, it largely ignores the effectiveness or otherwise of the searching process or the strategies which lie behind it. There is now considerable evidence that the searching process is often inadequate, creating additional bias which can seriously damage the findings of the review. Many researchers producing reviews on social issues specific to the United Kingdom have only searched United States produced databases which only selectively cover the UK peer reviewed journals and rarely include UK reports and other grey literature. Some researchers are even failing to search any social science databases at all. Not only are many researchers ignorant of the relevant UK and European databases but so are the peer reviewers! Reliance on Campbell Collaboration recommended databases is not sufficient in many cases and services such as ChildData, Social Policy & Practice, AgeInfo, Social Care Online, rarely used in reviews generated in either the United States or United Kingdom should be added to any list of databases to be searched. The Centre for Evidence & Policy at King's College London is investigating this phenomenon based on records of over 500 systematic reviews published in American and British journals and this workshop will present preliminary findings including examples of recent reviews where if the correct sources had been used a different set of results or recommendations would have been presented. Potential solutions to this bias problem will also be discussed including the justification for including a wider range of sources in the production of systematic reviews.

WS69: Cochrane Reviews: How should we measure quality?

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): David Tovey, Cochrane; Harriet MacLehose, Cochrane; Toby Lasserson, Cochrane

Contributor(s): David Tovey, Cochrane; Harriet MacLehose, Cochrane; Toby Lasserson, Cochrane

Abstract: The Cochrane Editorial Unit is working with other entities within the Collaboration to seek consensus on minimum standards for Cochrane Reviews. In this workshop we will present the work done to date, and invite participants to consider whether the standards identified are appropriate. We hope that at the end of the workshop we will be able to refine the draft standards based on the feedback from participants. The intention is to identify both minimum standards and also features that distinguish an excellent review. The standards should aim to cover the planning, conduct and reporting of the review, and can be used post publication and also by CRGs and review authors in evaluating submissions. The work will build both on work undertaken within the Collaboration and published work from other agencies and researchers.

WS70: Effectively managing preparation of a systematic review

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Philip Baker, Cochrane; Daniel Francis, Cochrane

Contributor(s): Philip Baker, Cochrane; Daniel Francis, Cochrane

Abstract: Objectives: Provide some practical tools and tips to plan, organise and undertake the production of a systematic review. Description: The completion of a systematic review can be a major challenge for authors and editorial groups alike with over 1,600 Cochrane protocols active for >2 years. Authors must not only contend with challenges relating to the methodological aspects of a review, but also those relating to the complex logistical and management issues of an international team, with authors who often have not worked together or even known each other previously, may be spread across various world time zones and not share a primary language. While much emphasis is rightly placed on proper methodology, as shown in the detail placed on this aspect in the Cochrane Handbook, the management of the author team is not well covered. The process and the likelihood of completing a Cochrane review (and within an acceptable time frame) could be vastly improved by applying project management techniques. This workshop will explore techniques and present tools that can be used by authors to assist the team in completing a review. Strategies relating to the following areas will be discussed: • Planning for success • Effective communication strategies • Document management • Building a good team • Estimating the project • Organising and allocating responsibilities • Setting targets and keeping on track • Templates The workshop will emphasise the use of tools that are widely accessible and those developed by the facilitators. Time will be available for participants to discuss and to share experiences as they relate to managing a systematic review. Collaboration: Both Cochrane and Campbell.

WS71: Overcoming geographic, linguistic and resource barriers: How can Review Groups, Fields and Centres work together to support authors?

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Steve McDonald, Cochrane; Joy Oliver, Cochrane; Charles Okwundu, Cochrane; Nandi Siegfried, Cochrane

Contributor(s): Steve McDonald, Cochrane; Joy Oliver, Cochrane; Charles Okwundu, Cochrane; Nandi Siegfried, Cochrane; Adrienne Stevens, Cochrane; Denise Thomson, Cochrane; Yanina Sguassero, Cochrane; Jessica Thomas, Cochrane

Abstract: Objectives: To provide an opportunity for Cochrane Review Groups, Fields and Centres to discuss how they can work together to provide support for authors, especially those that face geographic, linguistic and resource barriers. Description: The Cochrane Collaboration is committed to encouraging participation along regional, linguistic, economic and cultural lines. In recent years, various

programmes targeting mentoring, fellowships and other forms of training and support have resulted in more people becoming involved from more countries and regions. In spite of this, authors continue to struggle to complete their reviews and Review Groups often have limited capacity to provide more intensive support. Many of the barriers to and facilitators of participation in the Cochrane Collaboration are already well known as a result of project evaluations, surveys and regular discussions at Colloquia. This workshop will build on these discussions and explore how the unique geographic, linguistic and content strengths of Centres, Branches and Fields could be better harnessed to help Review Groups to support authors. Following a summary of the barriers and progress made towards supporting review capacity, the focus of the workshop will be on practical solutions (e.g. mentoring, bursaries, web-based support, etc.) and the steps required to implement them.

WS72: Using text mining technologies to support systematic reviews

Collaboration: Both

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Sophia Ananiadou, Both; James Thomas, Both

Contributor(s): As facilitators

Abstract: Objectives: To present and describe text mining services to participants. To discuss methods for their use in systematic reviews. Description: A significant proportion of systematic reviewing time is spent searching for research, deciding whether or not it is relevant and describing similarities and differences within included studies. This workshop will describe, and then be a forum for discussing, emerging technologies to facilitate these activities. We will begin by describing and demonstrating new tools—using ‘text mining’—to help researchers to collect, maintain, interpret, curate, and discover hidden knowledge in text. We will present:—Automatic term recognition: the identification of technical terms or concepts in documents.—Document clustering: which groups collections of documents based on the topics they discuss.—Automatic classification: the identification of underlying patterns and distinguishing features within documents that make them part of a predefined grouping or class and using this information to assign new documents to these classes.—Summarisation: selecting significant information from selected documents to ‘map’ research activity quickly and efficiently. The workshop will then move to a structured discussion covering both potential uses of text mining tools and also issues of bias and transparency that their use might raise in particular parts of the review process:—Searching: identifying possible search terms (term recognition); identifying documents automatically (automatic classification); iterative query expansion (document clustering).—Screening: highlighting key terms (term recognition); prioritising order of screening (term recognition); checking screening results (automatic classification).—Mapping research activity: creating and applying new keywords (document clustering); applying existing keywords automatically (automatic classification); document summarisation (summarisation). Demonstrations of existing services will be presented to the users for hands on experience. Outcomes: Participants will learn about new technologies that might assist them in their work, and their

views will feed through into the future development of these tools and methods.

WS73: How to ask an answerable question for health care and health research – for consumers

Collaboration: Both

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Kay Dickersin, Cochrane; Janie Gordon, Cochrane; Barbara Warren, Cochrane; Liz Whamond, Cochrane; Ming Ming Zhang, Cochrane

Contributor(s): Kay Dickersin, Cochrane; Janie Gordon, Cochrane; Barbara Warren, Cochrane; Liz Whamond, Cochrane; Ming Ming Zhang, Cochrane

Abstract: Objective: To gain hands on experience developing answerable research questions Description: In many countries, those performing systematic reviews ask consumers to contribute to priority setting or to review and comment on topics as they are refined. Because consumers and clinical researchers often do not ‘speak the same language’, consumer questions may be ignored or given a lower priority rank. In 2009, we offered a workshop for consumers focusing on how to ask an answerable question and it was well-attended. Our lecture covered Module 2 in the online course Understanding Evidence-based Healthcare (EBHC), including PICO and examples. In the evaluations, we received encouragement to offer the workshop again, but this time with more opportunities for practicing what we reviewed in a lecture format. For the 2010 workshop, we will circulate the 2009 slides before the meeting to registrants and we will ask for submission of research questions registrants would like to see answered by research. In the workshop, we will (1) break into workgroups to develop answerable questions from those submitted; (2) report back to the larger group the questions each group developed; and (3) comment on the developed questions to refine the topics as would occur in a ‘‘topic refinement’’ or peer review setting.

WS74: AMSTAR: A measurement tool for assessing the quality of systematic reviews inaugural training workshop

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Beverley Shea, Cochrane

Contributor(s): Jeremy Grimshaw, Cochrane; David Henry, Cochrane; Peter Tugwell, Both; George Wells, Cochrane

Abstract: Systematic reviews are now the standard method for synthesizing evidence in formulating recommendation regarding practice, and in making recommendations about policy. The systematic review is a powerful tool, but it is open to misinterpretation, and the methodological quality of published reviews is variable. For instance, there is evidence from several sources that Cochrane reviews, typically, are of superior quality to other published reviews. Because reviews are read, and acted upon, by people who are not necessarily schooled

in the assessment of methodological quality it is important that they have access to suitable measurement instruments. Ideally, such an instrument will be reliable and valid and easy to use. AMSTAR consists of eleven items and has good face and content validity for measuring the methodological quality of systematic reviews, and is now being used quite widely by researchers, decision-making bodies and in teaching. AMSTAR is still being developed but we believe that the instrument has reached a stage where it is suitable for wide application. To encourage its wider use we will hold the first AMSTAR training workshop. The workshop will be led by two researchers who were extensively involved in its development. The workshop will start with an introduction to AMSTAR and a brief history of its development and validation. This will be followed by small group sessions in which participants will be presented with systematic reviews and will have an opportunity to use AMSTAR to perform a rapid assessment of their methodological quality.

WS75: International Initiative for Impact Evaluation (3ie) synthetic reviews of school enrolment, early childhood development and agricultural extension programs in developing countries

Collaboration: Cochrane

Methods Group: Campbell and Cochrane Equity Methods Group

Facilitator(s): Hugh Waddington, Campbell; Anthony Petrosino, Campbell; Claire Morgan, Campbell; Robert F. Boruch, Campbell; Jef Leroy, Campbell; Paola Gadsden, Campbell; Maite Guijarro, Campbell; Birte Snilstveit, Campbell; Howard white, Campbell; Jock Anderson, Campbell

Contributor(s): Hugh Waddington, Campbell; Anthony Petrosino, Campbell; Claire Morgan, Campbell; Robert F. Boruch, Campbell; Jef Leroy, Campbell; Paola Gadsden, Campbell; Maite Guijarro, Campbell; Birte Snilstveit, Campbell; Howard white, Campbell; Jock Anderson, Campbell

This session presents the results of three reviews of economic and social interventions conducted in developing countries, funded by the International Initiative for Impact Evaluation (3ie). Social and economic development programs implement complex interventions in a range of different contexts. 3ie reviews synthesize evidence on what is, or is not, effective, and provide insights into why and how interventions are successful, to enhance policy relevance. The studies are the first attempts to review systematically the evidence from developing countries in education enrolment, daycare, and agricultural extension. All reviews were conducted to Campbell/Cochrane Collaboration standards of systematic review, were developed from a published protocol, and employ a theory-based approach to assess the reasons underlying effectiveness. 3ie is an independent, New Delhi-based organization which operates a grants program to fund impact evaluations and reviews of existing evidence on development interventions in low- and middle-income countries. 3ie is jointly spearheading the production of reviews with its institutional partners, the Campbell Collaboration and the UK Department for International Development (DFID).

WS76: Introduction to meta-analysis 1: Basic ideas for novices

Collaboration: Cochrane

Methods Group: Statistical Methods Group

Facilitator(s): Steff Lewis, Cochrane

Contributor(s): Joseph Beyene, Cochrane; Steff Lewis, Cochrane

Abstract: This workshop will cover the basic ideas of meta-analysis at an accessible level. Topics to be covered include: ● what is a meta-analysis? ● what is a 'forest plot'? ● what are 'odds ratios', 'risk ratios' and 'risk differences'? ● what is heterogeneity? ● what do 'fixed-effect' and 'random-effects' mean? The emphasis of the workshop will be on obtaining a broad understanding of the differences between the various methods available in RevMan, with advice on which might be used when, and why, and what the results mean. [The workshop is part of a series of five workshops on meta-analysis, but does not require attendance at any of the others in the series.]

WS77: What's so good about Archie and RevMan: A workshop for Cochrane authors and editors

Collaboration: Cochrane

Methods Group: Cochrane IMS

Facilitator(s): Sonja Henderson, Cochrane; Liz Dooley, Cochrane

Contributor(s): Sonja Henderson, Cochrane; Liz Dooley, Cochrane

Abstract: Objectives: To demonstrate how Archie and RevMan 5 helps authors and editors when preparing and editing reviews. Description: Archie is an online system that can communicate with RevMan 5. Since the middle of 2006, all Cochrane Review Group (CRG) editorial bases have been using Archie to manage, store and publish their CRG's reviews. With the release of RevMan 5 in March 2008, all authors and editors now have access to Archie. Advantages of the new system for authors and editors include a check-in/check-out system that helps ensure they are always using the latest version of a RevMan file; easier access to protocols and reviews; a quick and easy way to identify differences between versions of reviews; centralised back-up and archiving of reviews; and access to summary reports and other information about the CRG. Current and future developments will allow authors and editors to track the reviews they are responsible for during their preparation and will provide reminders and summaries of their Cochrane work.

WS78: How to change Cochrane processes to accommodate the inclusion of qualitative evidence in systematic reviews of effectiveness

Collaboration: Cochrane

Methods Group: Qualitative Research Methods Group

Facilitator(s): Andrew Booth, Cochrane; Karin Hannes, Cochrane and Campbell; Angela Harden, Cochrane and Campbell; Janet Harris, Cochrane; Craig Lockwood, Cochrane and Campbell; Jane Noyes, Cochrane

Contributor(s): Andrew Booth, Cochrane; Karin Hannes, Cochrane and Campbell; Angela Harden, Cochrane and Campbell; Janet Harris, Cochrane; Craig Lockwood, Cochrane and Campbell; Jane Noyes, Cochrane

Abstract: In 2009, the Cochrane Qualitative Research Methods Group conveners have published the first chapters of their additional guidance to chapter 20 of the Cochrane Handbook on their website, a process that has been continued in 2010. Currently, the group is exploring the variety of ways in which qualitative findings can be integrated in e.g. Cochrane protocols, the basic chapters of the Cochrane Handbook (such as question formulation, searching and critical appraisal) and the software program RevMan. An input from Cochrane reviewers is expected to add to the list of (potential) obstacles that have already been inventoried and need to be addressed by the Cochrane Collaboration. First thoughts, suggestions and concrete ideas on how to potentially change Cochrane processes to accommodate the inclusion of qualitative evidence in systematic reviews of effectiveness and how to move the group's agenda forward will be shared with the public.

WS79: Systematic reviews of diagnostic accuracy studies. 3: Assessment of methodological quality

Collaboration: Cochrane

Methods Group: Screening and Diagnostic Tests Methods Group

Facilitator(s): Penny Whiting, Cochrane; Mariska Leeflang, Cochrane; Hans Reitsma, Cochrane; Anne Rutjes, Cochrane

Contributor(s): Penny Whiting, Cochrane; Mariska Leeflang, Cochrane; Hans Reitsma, Cochrane; Anne Rutjes, Cochrane

Abstract: Background: The Cochrane Collaboration has decided to include systematic reviews of diagnostic accuracy studies in their databases. The "Cochrane diagnostic reviews methodology working group" (CDR) have developed a handbook and software to guide the process of conducting diagnostic reviews. The CDR group has developed a series of workshops, all addressing CDR group guidelines as formulated in the handbook. This workshop concerns quality assessment of diagnostic accuracy studies. Methods: The workshop will include an introduction to the five dimensions of quality assessment: a) concepts of quality b) empirical evidence of bias c) how to assess quality d) how to incorporate quality into systematic reviews e) limitations of measuring and incorporating quality. Statistical methods to deal with design related sources of bias and variation are discussed in a separate workshop. The workshop will include interactive exercises involving the assessment and discussion of some design characteristics by reviewing published articles.

WS80: Introduction to systematic reviews in the Campbell Collaboration

Collaboration: Campbell

Methods Group: Campbell Methods Group

Facilitator(s): Jeffrey Valentine, Campbell

Contributor(s): Jeffrey Valentine, Campbell

Abstract: This session will introduce participants to the Campbell Collaboration and the process of proposing and completing a Campbell Collaboration systematic review. No prior experience in systematic reviewing is required.

WS81: Systematic reviews and information retrieval in the social sciences: Database searching

Collaboration: Campbell

Methods Group: Information Retrieval Methods Group; Process and Implementation Group

Facilitator(s): Anne Wade, Campbell; Margaret Cargo, Campbell; Michael Saini, Campbell

Contributor(s): David Pickup, Campbell; Karianne Hammerstrom, Campbell

Abstract: Objectives: The Campbell Collaboration's commitment to producing high-quality systematic reviews based on thorough and unbiased searches points to the importance of this phase of a review. Yet information retrieval is the most extensive, challenging, and time-consuming, particularly in the social sciences given the multi-disciplinary nature of many research questions and the weak quality in the indexing of the retrieval tools. Given the majority of primary studies will be retrieved from bibliographic databases, the careful planning and implementation of searches is critical (Hammerstrom, Wade, Hanz, and Jørgensen, under review). An understanding of the fundamental components of this phase of a systematic review is important in order to ensure sound information retrieval strategies are used. Consultation with an information specialist or Trials Search Advisor during the information retrieval stage is highly recommended. Description: This workshop will help those wishing to conduct a systematic review in the social sciences, learn the basic steps and procedures for database searching. Using a mock research question to guide the session, participants will learn how to prepare search strategies for different databases and will gain knowledge on how to search two major bibliographic databases in the social sciences: ERIC, and PsycINFO. Developing search strategies for relevant aspects of process and implementation also will be addressed. If time permits, advanced search strategies on two web-based retrieval tools will also be addressed. Wade, C.A.; Turner, H.M.; Rothstein, H.R.; & Lavenberg, J.G. (2006). Information retrieval and the role of the information specialist in producing high-quality systematic reviews in the social, behavioural and education sciences. *Evidence & Policy: A Journal of Research, Debate and Practice*, 2(1), 89–108(20). See <http://www.ingentaconnect.com/content/tpp/ep/2006/00000002/00000001/art00006>

WS82: Addressing multiple treatments II: Basic methods for multiple treatments meta-analysis

Collaboration: Cochrane

Methods Group: Overviews Methods Group

Facilitator(s): Deborah Caldwell, Cochrane

Contributor(s): Deborah Caldwell, Cochrane

Abstract: Objectives: To introduce the concepts and methodology of multiple treatment meta-analysis, a method which allows determination of the 'best' among a selection of interventions. Description: The objective of a multiple treatment meta-analysis (MTM) is to combine all the available trial evidence into an internally consistent set of estimates while respecting the randomisation in the evidence. An MTM provides estimates of the effect of each intervention relative to every other, whether or not they have been directly compared in trials. One can also calculate the probability that each treatment is the most effective. This workshop provides an introduction to the concepts and methodology of MTM within the context of an Overview. We will firstly describe the need for MTM and will then outline the potential benefits compared to conventional pair-wise meta-analysis, such as greater precision in summary estimates and ranking of treatments according to their effectiveness. We will use worked examples to explore the underlying assumptions necessary for MTM and will introduce the importance of checking for evidence consistency. A simple method for checking consistency in a three-treatment MTM will be outlined. This is the second in a series of three workshops.

WS83: Official Campbell Collaboration Users Group workshop: How to write a user abstract for a Campbell review

Collaboration: Campbell

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Merete Konnerup, Campbell

Contributor(s): Merete Konnerup, Campbell

Abstract: Objective: To give an introduction to some of the key challenges – and how to overcome them – when writing a user abstract for a Campbell review. Description: The workshop will combine short lectures, interactive exercises, and group discussions in building abstract writing skills among the participants. Topics covered will be (a) bridging the gulf between story telling traditions in research and in everyday life, (b) risk and other effect sizes in laymen's terms, (c) contextualization, and (d) the evidence – what does it really say? An introduction will also be given to the process involved in producing an official user abstract for a Campbell review. It is very important to note, that if you – on behalf of the type of audience mentioned below – participate in this workshop your organization can become a voting member of the Campbell Collaboration's Users Group given that your organization signs up to writing at least one abstract per year. Target audience: Representatives from organizations engaged in knowledge translation within social and welfare policy, crime & justice, education or other related public policy areas.

WS84: Conducting systematic reviews of prognosis and prognostic factors

Collaboration: Both

Methods Group: Prognosis Methods Group

Facilitator(s): Henrica CW de Vet, Cochrane; Katrina Williams, Cochrane; Jill Hayden, Cochrane

Contributor(s): As facilitators

Abstract: Objectives: This workshop will present the current state of the art for systematic reviews of prognosis and prognostic factors. Using case studies, we will discuss the benefits, limitations and challenges of prognosis systematic reviews. Description: Systematic reviews of prognosis studies are important to inform evidence-based clinical management about prognosis and prognostic factors. The results of primary studies are rarely conclusive; therefore, systematic review can provide a transparent way to synthesize study findings. Observations across studies from different populations, with different exposure and outcome measurements can inform generalizability or identify important sources of heterogeneity of results. Furthermore, approaching systematic review in an exploratory way can point to areas in need of research and it can highlight methodological limitations and assess the potential impact of these. As the research methodology of systematic reviews of prognosis is still under development, this workshop will provide preliminary views. Basic principles to reduce bias and random error are similar to those used for intervention reviews, but there are several challenges unique to systematic reviews of prognosis. There is limited empirical evidence regarding the most appropriate methods for conducting prognosis systematic reviews leading to great discrepancy in the methods used to conduct these reviews. In this workshop we will present current methods and future directions for five key steps of prognosis systematic reviews: ● Defining the review question ● Identifying and selecting prognostic research evidence ● Assessing study quality ● Extracting data ● Synthesizing and interpreting results. The workshop will include: ● Topic and case study presentations ● Opportunities for participant discussion about the benefits and limitations of different approaches and methods.

WS85: Introduction to meta-analysis 4: Dealing with heterogeneity

Collaboration: Cochrane

Methods Group: Statistical Methods Group

Facilitator(s): Joseph Beyene, Cochrane; Georgia Salanti, Cochrane

Contributor(s): Joseph Beyene, Cochrane; Georgia Salanti, Cochrane

Abstract: Objective: To provide review authors with the knowledge to understand and investigate variability across studies in a meta-analysis, and to recognise the limitations of the methods available. Summary: This training workshop will address approaches to dealing with between-study variability, or heterogeneity, in the results of a series of clinical trials. We first will discuss some potential sources of between-study variability, and overview some methods for identifying whether heterogeneity poses a problem in a particular set of studies. We then will focus on issues related to dealing with study variability

once it has been identified. In particular, we will discuss the decision whether or not to combine results; the choice between fixed and random-effects analyses; and the use of subgroup analyses (with a brief mention of meta-regression). Discussion will be supplemented with practical examples from the Cochrane Database of Systematic Reviews. [The workshop is part of a series of five workshops on meta-analysis, but does not require attendance at any of the others in the series.]

WS86: Systematic reviews of diagnostic accuracy studies. 5: Advanced meta-analysis

Collaboration: Cochrane

Methods Group: Screening and Diagnostic Tests Methods Group

Facilitator(s): Petra Macaskill, Cochrane; Constantine Gatsonis, Cochrane; Roger Harbord, Cochrane

Contributor(s): Petra Macaskill, Cochrane; Constantine Gatsonis, Cochrane; Roger Harbord, Cochrane

Abstract: In this workshop we will cover advanced statistical methods for the meta-analysis of studies of diagnostic test accuracy that report estimates of sensitivity and specificity. We will explain the recommended and commonly used hierarchical models (and the relationship between them): (i) the bivariate model, which focuses on the estimation of a summary estimate of sensitivity and specificity; and (ii) the Hierarchical Summary ROC model of Rutter and Gatsonis, that focuses on the estimation of a summary ROC curve. Both methods will be illustrated by means of examples, and the choice of method will be discussed. The use of these models for investigating sources of heterogeneity through the inclusion of study level covariates will be described and discussed. The application of this approach to comparing the performance of alternative tests will be covered. The use of RevMan 5 to display the results of these models will be illustrated.

WS87: Advanced Searching on The Cochrane Library

Collaboration: Cochrane

Methods Group: Wiley

Facilitator(s): Colleen Finley, Wiley

Contributor(s): Laura Simmonds, Wiley; Colleen Finley, Wiley

Abstract: This workshop is designed for regular searchers of The Cochrane Library. It will provide a general overview of the interface, features and functionality followed by a detailed hands-on session, including exercises, searching The Cochrane Library on Wiley InterScience. The workshop will provide participants with the understanding of The Cochrane Library search engine behaviours including Boolean and proximity operators, Medical Subject Headings (MeSH), search strategies, search history, citation export and alerting services. Users will also gain experience in using reference linking via CrossRef and PubMed—an initiative to enable users to click on a reference in The Cochrane Library and be taken directly to the cited material.

WS88: Beyond Medline: How to search for studies of complex interventions

Collaboration: Both

Methods Group: Both

Facilitator(s): Michael Saini, Campbell; Anne Wade, Campbell

Contributor(s): Michael Saini, Campbell; Anne Wade, Campbell

Abstract: Searches for studies involving complex interventions can themselves be complicated, requiring a more comprehensive approach. If too broad, searches can produce information overload and can slow down the systematic review process. Conversely, overly simplistic strategies can compromise the review by missing critical studies relevant to the study's inclusion criteria. Finding the balance of sensitivity and specificity is further strained by the unique complexity of interventions, especially those in the social sciences. For these reviews, conventional information retrieval strategies should be complemented with additional searching techniques to locate further high quality references. Based on lessons learned and information retrieval guidelines in the social sciences, this workshop will address common pitfalls and challenges in developing unbiased and relevant search strategies for reviews involving complex interventions. Topics covered include: consideration for using controlled vocabulary and methodological filters, techniques for including literature from low and middle income countries, strategies for handsearching to avoid duplication, approaches to locating studies from web sources (governments, charity organizations, NGOs, clearinghouses, etc) relevant to the social sciences, and methods for searching mixed-method designs (including qualitative studies). This workshop is geared for both information retrieval specialists and those involved in the development, production, and interpretation of systematic reviews.

WS89: How many studies do you need? A workshop on statistical power for meta-analysis

Collaboration: Both

Methods Group: Campbell Methods Group

Facilitator(s): Jeffrey Valentine, Campbell; Terri Pigott, Campbell

Contributor(s): Jeffrey Valentine, Campbell; Terri Pigott, Campbell

Abstract: In this workshop, we will present methods for using fixed and random effects power analysis in the planning of a meta-analysis. The workshop will focus on methods for prospective power analysis, including suggestions for how to think about important parameters needed for computing prospective power.

WS90: User testing of the Cochrane Register of Studies

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Ruth Foxlee, Cochrane; Gordon Dooley, Cochrane

Contributor(s): Lucie Jones, Cochrane

Abstract: This will be a closed training workshop for Cochrane Register of Studies (CRS) testers. The CRS will comprise all the Specialized Registers from CRGs and Fields, together with handsearched records from all Cochrane entities and records sourced from MEDLINE and EMBASE and other databases. CRS testers who represent a range of Specialised Register management approaches will be identified prior to the Colloquium and invited to attend this workshop. Participants will be introduced to the testing process and will run through some formal testing schedules.

WS91: Commenting on a Cochrane plain language summary

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Gill Gyte, Cochrane; Shirley Manknell, Cochrane

Contributor(s): Gill Gyte, Cochrane; Shirley Manknell, Cochrane; Liz Wager, Cochrane; Participants at a previous workshop held in Cardiff; Cochrane Consumers keen to contribute

Abstract: Objectives: The aim of the workshop is to help people comment on Cochrane plain language summaries through the use of a checklist. Participants will have the opportunity to: • Discuss what is needed in a Cochrane plain language summary • Use a checklist to comment, in small groups, on three Cochrane plain language summaries • Discuss how they found using the checklist and any modifications they would like to propose Description Plain language summaries are probably the most widely read part of a Cochrane review, and commenting on them as part of the refereeing process is, therefore, important work. This workshop will progress the work begun at a similar workshop held at the 15th Annual Meeting of UK and Ireland Contributors to The Cochrane Collaboration, in Cardiff in March 2010. Participants at the Cardiff workshop began to develop a checklist of questions for commenting on Cochrane plain language summary, addressing both content and style. The checklist was further refined by email discussions. Participants at the present workshop will be able to use this checklist on three Cochrane plain language summaries and be able to contribute to the evaluation of the checklist and to any modifications they feel are appropriate. The checklist will then be discussed in a wider forum and, if considered appropriate, it will be made available more widely.

WS92: RevMan 5 for Cochrane Intervention review authors – learn to use all the features hands-on

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Elizabeth D Pienaar, Cochrane; Tamara Kreda, Cochrane; Kate Cahill, Cochrane

Contributor(s): Elizabeth D Pienaar, Cochrane; Tamara Kreda, Cochrane; Kate Cahill, Cochrane

Abstract: Objectives: The purpose of this workshop is to provide review authors with an understanding of how RevMan 5 can make life easier. At the end of the workshop, participants will have been introduced to the new features in RevMan 5 and received guidance in the use of the software. Description: Review Manager (RevMan) is the Cochrane Collaboration's own software, which is developed to assist review authors in writing systematic reviews in the Cochrane format. RevMan is developed by the Nordic Cochrane Centre under the direction of the RevMan Advisory Group and the Information Management System Group. The latest version, RevMan 5, has been updated with a host of new and improved features. The experience of 'what you see is what you get' is strongly improved. The new text editor will allow more formatting in more sections, including subheadings, tables embedded in the text, and nested lists (lists within lists). The track changes functionality and a new note system will facilitate the task of multiple authors working together on a review. There is a new structure for the main text, support for appendices and it will be possible to select a few key forest plots or funnel plots to be displayed in the results section of a review. For intervention reviews, some of the most noticeable methodological changes across reviews are the introduction of Risk of Bias tables and Summary of Findings tables. During this hands-on session participants will be able to use the software and get hands-on experience with the software. A presentation and discussion session will also be held.

WS93: Engaging nurses with the Cochrane Library: The Cochrane Nursing Care Field Evidence Transfer Program

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Cindy Stern, Cochrane; Suzi Robertson-Malt, Cochrane

Contributor(s): Cindy Stern, Cochrane; Suzi Robertson-Malt, Cochrane; Alan Pearson, Cochrane

Abstract: Objectives: The aim of this workshop is to introduce the Cochrane Nursing Care Field's (CNCF) Evidence Transfer Initiative. The aim of this initiative is to enhance the dissemination and uptake of Cochrane Reviews in the nursing care community to improve health outcomes and increase the profile of the Cochrane Collaboration to the nursing community, a group that has been largely under-represented in the Cochrane Collaboration. This workshop will describe the processes involved in this work and clarify to the Collaboration the role the CNCF will play and the importance of such dissemination approaches. Description: The work involved in this project requires us to draw on our growing CNCF membership base who volunteer to develop: 'Cochrane Corner' columns (which are published in nursing care relevant journals), an audio podcast of each column and the subsequent translation of these materials into languages other than English. The CNCF leadership group coordinates this work and quality control mechanisms are in place to ensure content is accurate and of use to those involved in nursing care. The intention of this work is to identify the application of the review to nursing care and to encourage readers/users to access the full review via the Cochrane Library. The CNCF would like to engage members of the Cochrane Collaboration in this program either in developing content or providing feedback.

WS94: Calculation and interpretation of the number needed to treat (NNT)**Collaboration:** Cochrane**Methods Group:** Statistical Methods Group**Facilitator(s):** Ralf Bender, Cochrane**Contributor(s):** Mandy Hildebrandt, Cochrane

Abstract: Objectives: To provide review authors with the knowledge and skills needed to calculate NNTs from trial reports and Summary of Findings (SoF) tables of Cochrane reviews, to verify whether reported NNTs are adequate and to interpret the results. Description: The number needed to treat (NNT) is widely used to present the results of clinical trials. However, incorrect calculations, misuse in specific study situations and misleading interpretation of NNTs are not uncommon in practice, for example in the case of non-significant results or in the situation of survival time data. This workshop will provide an introduction to the use and interpretation of NNTs as effect measure in clinical trials and systematic reviews. It will be shown how to calculate NNTs with corresponding confidence intervals from Summary of Findings (SoF) tables. We will discuss in particular the limitations of NNTs including problems associated with the inconvenient scale, the sensitivity to changes of the baseline risk and the dependence on the follow-up time. Small group practical work will be an integral part of the workshop focusing on adequate calculation and interpretation of point and interval estimates of NNTs in practical examples. Participants should bring pocket calculators, pens and paper. References: Bender, R. (2005): Number needed to treat (NNT). In: Armitage, P. & Colton, T. (Eds.): *Encyclopedia of Biostatistics*, 2nd Ed., Vol. 6, pp. 3752–3761. Wiley, Chichester. Stang, A., Poole, C. & Bender, R. (2010): Common problems related to the use of number needed to treat. *J. Clin. Epidemiol.* 63 (in press).

WS95: Findings and recommendations from the evaluation of the Cochrane Collaboration's Cochrane risk of bias assessment tool**Collaboration:** Cochrane**Methods Group:** Bias Methods Group**Facilitator(s):** Jonathan Sterne, Cochrane; Jelena Savovic, Cochrane; Lucy Turner, Cochrane**Contributor(s):** Doug Altman, Cochrane; Julian Higgins, Cochrane; David Moher, Cochrane; Jelena Savovic, Cochrane; Jonathan Sterne, Cochrane; David Tovey, Cochrane; Lucy Turner, Cochrane; Laura Weeks, Cochrane

Abstract: Objectives: To describe findings and proposed recommendations from the recently completed evaluation of the Cochrane Collaboration's Risk of Bias Tool, and to receive further feedback from Cochrane stakeholders. Description: Version 5 of the Cochrane Handbook and RevMan5 software introduced the Risk of Bias (ROB) assessment tool, which represents a more comprehensive undertaking for review authors than previous quality assessments. The Bias Methods Group, supported by the Cochrane Opportunities Fund, has conducted an evaluation of the ROB tool, using both quantitative and

qualitative research methods, namely focus groups, an online survey, and a discussion meeting with wide representation from Cochrane stakeholders. Results of the focus groups and online survey will be presented, together with a summary of and proposed recommendations following the stakeholder discussion meeting. Workshop participants will have an opportunity to ask questions to the members of the ROB evaluation team and provide feedback on the evaluation process and proposed recommendations. Format of the workshop: Part 1: Presentation by ROB evaluation team to include: the development of the ROB tool; ROB evaluation methods and results; recommendations from the ROB evaluation meeting. Part 2: Small group discussion to discuss the evaluation and provide feedback on recommendations. Part 3: Large group discussion summarising and discussing themes arising from small group discussions.

WS96: Complex reviews of community level interventions: Challenges, lessons learned, and recommendations. An interactive workshop**Collaboration:** Both**Methods Group:** Equity Methods Group**Facilitator(s):** Elizabeth Kristjansson, Both; Catherine Burns, Cochrane; Mark Petticrew, Both; Damion Francis, Cochrane**Contributor(s):** Erin Ueffing, Both; Peter Tugwell, Both; Vivian Robinson, Both; Eamonn Noonan, Campbell

Abstract: Background Community level interventions address mid- and upstream determinants of health, and thus, have the potential for wider impact on health and health equity than many individual level interventions. Yet, conducting reviews of these interventions presents many challenges. These include: developing realistic and informative logic models, incorporating equity, evaluating process of implementation, statistical issues around combining data and around clustering, and finding and working with the appropriate policy makers and stakeholders to facilitate knowledge exchange. Learning Objectives -To share experiences and lessons learned from complex reviews of community interventions. To engage in mutual learning about challenges in reviewing and in knowledge exchange. -As appropriate, come up with recommendations for other reviewers Description This workshop will allow for open exchange of ideas and experiences. Participants and facilitators will share experiences with the challenges described above and lessons learned from overcoming them. To stimulate discussion, facilitators will present an overview of challenges we encountered in two recent Cochrane/Campbell systematic reviews: "Community level interventions to improve food security in developed countries" and "Preschool feeding programmes for improving the health of disadvantaged young children". Then, each of these challenges and experiences in meeting them, and recommendations will be discussed in turn. Within each topic, facilitators will discuss their experiences first, and then ask participants to share their experiences. We will then work together to come up with appropriate recommendations. An outline of the workshop is below: ● Introductions, experiences, reasons for participating (10 min) ● Short presentation on the two reviews; overview of challenges (10 min) ● Developing logic models (15 minutes) ● Incorporating equity (10 minutes) ● Evaluating process (15 minutes) ● Statistical

issues: clustering, combining outcomes (10 minutes). • Engaging policy makers, stakeholders, and knowledge exchange (15 minutes). • Review of recommendations and wrap-up (10 minutes).

WS97: Extrapolation: Applying the results from systematic reviews to whom, when, and how?

Collaboration: Both

Methods Group: Campbell and Cochrane Equity Methods Group

Facilitator(s): Mark Petticrew, Both; Mike Clarke, Cochrane; Russell Gruen, Cochrane; Gordon Guyatt, Cochrane; Elizabeth Kristjansson, Both; Shawna Mercer, Both; Gemma Phillips, Both; Peter Tugwell, Both; Erin Ueffing, Both; Vivian Welch, Both

Contributor(s): As facilitators

Abstract: Background: There is a need for improved guidance on how policy-makers, clinicians, practitioners, and the public can apply (extrapolate) the results from systematic reviews to disadvantaged groups. The question that these stakeholders really have is "In my setting/population, will this intervention have the same effects that it had in the studies in the systematic review?" We are seeking to help researchers, practitioners, and policy-makers using systematic reviews by giving them guidance on this—such as by applying a simple scale for groups of interest. We have already conducted a pilot exercise using a checklist (Extrapolation Checklist) with various members of The Cochrane Collaboration. We are revising the checklist for addressing when and how results from Cochrane and Campbell reviews can be extrapolated to other populations and settings, and are developing testing scenarios. These scenarios reflect different settings and populations globally. They use selected factors from the "PROGRESS-Plus" framework (Place of Residence; Race/Ethnicity; Occupation; Gender; Religion; Education; Socioeconomic Status; and Social Capital, with "PLUS" representing additional axes including age, sexual orientation, and disability). Objectives: –To allow participants to test the new Extrapolation Checklist, addressing when and how results from systematic reviews can be extrapolated—To consider related methodological concerns around equity and systematic reviews
Description: • Introductions (5 minutes). • Presentation on the development of the checklist (10 minutes). • Exercise: Applying the checklist to testing scenarios (15 minutes). • Breakout groups: discussion on exercise experience, with participants considering specific methodological issues. Topics for discussion will be developed beforehand (30 minutes). These will include questions such as "What information would you need to determine whether results could be extrapolated?" • Report back to all participants (20 minutes). • Wrap-up (10 minutes).

WS98: Developing a strategy to assess the extent of residual confounding in primary studies when including non-randomised studies (NRS) in a systematic review

Collaboration: Cochrane

Methods Group: Non-Randomised Studies Methods Group

Facilitator(s): Barney Reeves, Cochrane; Bev Shea, Cochrane; George Wells, Both

Contributor(s): Barney Reeves, Cochrane; Bev Shea, Cochrane; George Wells, Both

Abstract: This workshop is aimed at methodologists and reviewers, especially reviewers who are considering whether or not to include non-randomised studies (NRS) in Cochrane systematic reviews. The risk of selection bias from confounding is a key difference between randomised and non-randomised studies. The Non-Randomised Studies Methods Group recommends that reviewers assess the risk of bias from confounding in primary studies but does not provide detail guidance about how to do so. Participants will discuss: (a) The importance of pre-specifying important confounders in the protocol for a review and possible methods to identifying confounders for pre-specification; (b) How to assess the relative importance of confounders; (c) The extent to which the relative importance of confounders is likely to vary for different outcomes; (d) Data about confounders and adjustment for confounding that reviewers should extract from primary studies; (e) How the data extracted should be used to assess the risk of selection bias from residual confounding; (f) How reviewers should deal with studies which do not report sufficient information to assess the risk of bias from confounding (g) Dealing with heterogeneity between studies with respect to residual confounding. The discussion will inform guidance being developed by the Non-Randomised Studies Methods Group for inclusion in a revision of its Handbook chapter.

WS99: Decision making in primary care: When the evidence is of no use

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Floris van de Laar, Cochrane; Bruce Arroll, Cochrane

Contributor(s): Floris van de Laar, Cochrane; Bruce Arroll, Cochrane

Abstract: Objectives: To demonstrate a number of representative clinical cases from primary health care in which scientific evidence is available, but seems inappropriate, or unusable in daily practice. In addition, we will discuss opportunities to improve this situation. Description: Primary care physicians encounter all kinds of patients who may present with many different sorts of help-seeking behaviour and with a broad range of (co)morbidities. By integrating knowledge of (patho)physiology and epidemiology with information derived from the social context, history taking, physical examination and (sometimes) diagnostic tests, it is sometimes possible to make a diagnosis. At that stage the decision whether therapy is indicated, and if so, what kind of therapy and how it should be delivered, has yet to be made. Research, on the other hand, usually starts with well described patients with clear clinical conditions undergoing standardized interventions or diagnostic tests. The primary care physician operates in the galaxy between the 'dirty' complex reality of individual patient care and 'clean' focused and sophisticated science. In this workshop we will demonstrate real-life clinical problems in primary care in which guidance from guidelines, systematic reviews or other clinical research seems to be unavailable, inappropriate or unusable. Participants are invited to discuss how

primary care physicians should best bridge the gap between practice and science and how The Cochrane Collaboration might help them.

WS100: Using the Cochrane intranet on www.cochrane.org

Collaboration: Cochrane

Methods Group: Not submitted on behalf of a Methods Group

Facilitator(s): Chris Mavergames, Cochrane; Nancy Owens, Cochrane

Contributor(s): Chris Mavergames, Cochrane; Nancy Owens, Cochrane

Abstract: Objectives: This workshop will provide participants with an overview of the information available in the newly redesigned Cochrane intranet, and practical information on how to use this information to improve the quality of their work and communication. At the conclusion of the workshop, participants will: 1. be familiar with the organization and contents of the new Cochrane intranet, and

how these relate to entity functions; 2. understand how the web team has designed and structured the new intranet, using the Drupal interface; and 3. have hands-on experience in practical use of the Cochrane intranet. Description: The Cochrane web team has, as part of its re-design of www.cochrane.org, established a Cochrane intranet for the use of Cochrane entity staff. The Cochrane intranet provides a useful informational resource that, used properly, can be a great asset for improving the quality of work and communication among Cochrane entity staff, but potential users may be daunted by the volume of information and resources available, and discerning the practical application of such information to the daily routine of managing entity tasks. This workshop will focus on familiarizing participants with the new www.cochrane.org intranet: how it is organized, what it includes, and how to use it. Facilitators will describe changes, new features, and updates, and answer questions on the intranet's structure and content. The session will include a demonstration of how Cochrane entity staff can use the intranet, and a participatory exercise in applying the intranet's features to everyday tasks of entity management.

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Please note that workshop facilitator and contributor names can be found listed under each workshop from pages 137-166



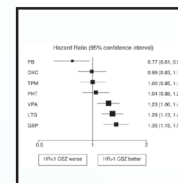
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