

fifgu Risk Prioritisation as a Tool to Guide Veterinary Public Health Activities at the Regional Level in Italy

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Summary

In this study we ~~describe how we~~ developed a model for risk prioritisation and characterisation focused on zoonoses and food safety for diseases of interest in veterinary public health at a regional level in Italy. A previous model (Discontools) based on scorecards was used as a basis to develop the new model. A Formalised Consensus Process approach involving academics and veterinary officers was used to develop scorecards and relative form and guidelines. Scorecards include several areas of interest, with different categories and coefficient of importance. The following areas were identified: relevance of the disease, socio-economic impact, impact on public health, impact on trade, impact on animal welfare, control tools. A guide and a form were finalised in order to fill scorecards. Scorecards were filled by consulting available data, literature, and expert opinions. Among bovine diseases, mastitis (*Salmonella aureus*) showed the highest score; ~~Query~~ fever was the highest among small ruminants; among swine diseases the highest was salmonellosis; while among other animal diseases, toxoplasmosis had the highest score. The approach described in this study is designed to aid professionals in risk prioritisation, decision-making, and to improve disease control systems at a regional level in Italy. It also facilitates risk characterisation in different backgrounds and the identification of data holes in specific areas of interest for the diseases considered.

Keywords

Public health; Animal diseases; Infectious diseases; Zoonosis; Risk prioritisation; Food safety

La Graduazione-Prioritizzazione del Rischio come Strumento per la Sanità Pubblica Veterinaria a Livello Regionale.

Riassunto

I sistemi per la graduazione-prioritizzazione del rischio possono fornire un utile strumento alle attività di sanità pubblica veterinaria; a tale scopo è stato sviluppato un modello (scorecard), focalizzato su zoonosi e sicurezza alimentare, da applicare a livello regionale. Prendendo come base il modello Discontools, la fase di sviluppo ha seguito i criteri del Formalized Consensus Process e ha visto coinvolti sia accademici sia veterinari pubblici.

Le scorecard sono state compilate in base ai dati disponibili, alle informazioni presenti in letteratura e alle opinioni degli esperti. Il modello definitivo prevede un punteggio teorico massimo pari a 1000 ed è suddiviso in aree d'interesse di diversa importanza, a loro volta scomposte in varie categorie. Nello specifico, le aree d'interesse sono rappresentate da rilevanza della patologia; impatto socio-economico; impatto sulla salute pubblica; impatto sugli scambi commerciali; impatto sul benessere animale e strumenti di controllo. Al fine di redigere razionalmente le schede sono stati sviluppati anche una guida interpretativa e un modulo informativo, da compilare per ciascuna malattia. Sono state identificate 38 patologie d'interesse e, attualmente, sono stati assegnati i punteggi a 23 di queste. Le malattie con punteggio più elevato sono risultate: mastite da *Salmonella aureus* nei bovini; febbre Q nei piccoli ruminanti; salmonellosi nei suini e toxoplasmosi negli altri. Questo modello è stato concepito per facilitare l'identificazione delle priorità e migliorare i sistemi di controllo a livello regionale, inoltre, si prefigge di graduare il rischio in differenti contesti e individuare eventuali carenze di dati relativi a una malattia, in una data area d'interesse.

Parole chiave

Sanità pubblica, Malattie animali, Malattie infettive, Zoonosi, Graduazione-Prioritizzazione del rischio, Sicurezza alimentare

1. Introduction

The European Union (EU) requests standards for veterinary public health and food safety in both operative procedures and official controls. These are clearly articulated in 'White Paper on Food Safety' (COM, 1999, 719) and in regulation EC No 882/2004. These standards define the mandatory requirement and objectives for Nations within the EU. Further, Standard Operating Procedures (SOPs) for Competent Authorities should be adopted to fulfil EU requisites. To satisfy these requirements, Lombardy regional government and the Department of Veterinary Science and Public Health (DIVET) of University of Milan, Italy, set up a shared initiative focused on developing a three-year programme aiming to improve the efficiency, efficacy, and quality of regional veterinary services. Developing a model for risk-prioritisation on relevant diseases for human and animal health in Lombardy was one of the tasks of this project.

This paper reports the methodological approach that was employed to develop this model and its application into the Veterinary Prevention Programme (VPP) by the Lombardy government from 2011 - 2014..

Lombardy is the largest contributor to Italian Gross Domestic Product (GDP) for agro-food production. Indeed, as reported by Regional Government Statistics, the agronomic industry has a value of over 6.35 billion euros, with 70916 farms present in the region. Numerically, the most represented livestock are poultry (over 27 million), swine (5.16 million) and bovine (1.5 million). When the share of regional contribution to the national output is considered, swine meat represents 40% of the total, milk production 37%, bovine meat 26%, poultry meat 19%, and egg production 17.7% (Pieri and Pretolani 2011). The food industry is also well-developed, with an output value of €5.2 billion and over 40000 employees. These data highlight the strategic value of the agronomic and food industries in the region and, consequently, the importance of zoonoses control and food safety.

In the context of food safety, risk characterisation is defined as an integration of hazard identification, hazard characterisation, and exposure assessment whose purpose is to estimate the adverse effects likely to occur in a given population, including uncertainties (FAO and WHO 1995). This definition can also be adopted in veterinary public health for the risk characterisation of infectious diseases. In the last decade, different organisations have developed models for risk characterisation and risk-prioritisation of infectious disease. The focus of these organisations was, obviously, dependent on their objectives. For example, WHO suggested a model for ranking priorities in communicable diseases that considered eight criteria: burden of disease, severity, epidemic potential, potential threat/changing pattern, health gain opportunity, social and economic impact, international regulations or programmes, and public perception (WHO 2006). A working group of EU Chief Veterinary Officers proposed a complex model (34 criteria in 6 areas of interest) for public health, farming economy, society, and trade (Council of the European Union 2008). The Dutch Emerging Zoonosis Information and Priority systems (EZIPs) assigned a score to 86 zoonoses through 7 criteria that considers the likelihood of the disease being introduced, the sensitivity of the population, and the impact on public health and economy (EZIPs 2010. Priority system ver. 1.0.).

Assessing and balancing a large number of variables represents the most relevant obstacle to developing a single model that is applicable in different geographical areas (DISCONTTOOLS 2012).

In order to identify the priorities and risks of a given disease, a reliable model should consider the level of risk of a particular disease in all sectors of interest. It should moreover simplify the decision-making process into a rational, scientific, and clear procedure that allows quick and efficient responses when considering known or emerging diseases. The main purpose of this study was to develop a trustworthy tool (scorecard) to characterise the risk of animal

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diseases in specific areas (health, economic, international trading, control programmes, *etc.*) within the region.

2. Materials and Methods

In order to define the risks and priorities relating to the diseases of interest in the Lombardy region, we developed a scorecard (Figure 42) based on the model finalised by the Discontools project (DSP) (DISCONTTOOLS 2011a, b). Discontools is a European project that analyses several animal diseases. These diseases belong to 3 different groups: epizootic, zoonotic, and disease affecting food-producing animals (DISCONTTOOLS 2013). The DSP scoring model evaluates a disease in the entire EU and provides a scoring system relating disease knowledge, impact on animal health and welfare, public health, wider society, trade, and disease control tools. Compared to the DSP model, the scorecard we developed was focused mainly on human health, food safety, and the economic impact of diseases. Moreover, our target was a relatively restricted area, Lombardy Region, when compared to EU.

2.1 Scoring criteria

Using the DSP model as a basis, we organised an expert panel (EP) for each animal species, tasking veterinarians (academics and public health officers) with the establishment of a proper scoring system. A guide and a form were also developed by EP in order to assign proper scores for each category. The form encompasses all of the information required to assign a proper scoring, and the guide explains how to assign the information in a score a numerical value from 1 to 5. The Formalised Consensus Process (FCP) (Haute Autorité de Santé 2010) was applied to develop the final version of the scorecard model, guide, and form. Formalised Consensus Process is a procedure that includes a systematic review of literature, an assessment of issues, initial proposals, a discussion and improvement of proposals and,

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finally, a validation of operational recommendations. In this specific case, the process included the following steps:

- A systematic review of literature relating to models for risk characterisation, prioritisation, and the management of veterinary public health.
- Comments and suggestions were collected in joint meetings between EP and ~~veterinary~~ Veterinary officers ~~Officers~~ of Lombardy region (VOL) in order to refine the questions to be included in the assessment of any single criteria. This led to a first draft of the scorecard, relative guide, and form.
- The draft was discussed with VOL, and the ‘weight’ of the different areas of interest (Table 1), and categories within each area were established (Figure ~~1~~2).
- Finally, pilot scorecards were tested addressing 3 well-known diseases (bovine tuberculosis, bovine brucellosis, and enzootic bovine leucosis). Results were examined in a joint meeting between EP and VOL. This discussion generated the final structure of scorecard, relative guide, and form.

2.2 Expert panel

The expert panel that developed the model consisted of veterinarians with either an academic or a public health management background. The Department of Veterinary Science and Public Health provided 7 academics with at least 10 years of experience in research and the control of infectious and/or parasitic diseases. Veterinary officers of Lombardy region provided 5 veterinarians with at least 10 years of experience in veterinary public health within Lombardy.

2.3 Systematic review

The systematic review started with the following question: Are scoring models for risk characterisation in veterinary public health available?

In February 2011 we performed an electronic search of the Web of Science (WOS) database., General settings were ‘All years’ and ‘All databases’, while the keywords included:

'veterinary' AND 'public health' AND 'risk characterisation' OR 'scoring' OR 'prioritisation'. As a control, the same search was carried within the PubMed database.

A total of 101 documents were found in WOS (19 in PubMed). Papers were considered admissible if they were written in English and peer-reviewed. We therefore excluded 16 out of 101 papers.

The expert panel conducted a quality assessment on the 85 articles that remained. A ranking system signified the pertinence of each papers:

- Score = 0 (no pertinence): Scientific documents completely outside the topic, such as risk management in clinical veterinary medicine, epidemiology of antimicrobial resistances, new diagnostic techniques, risk factors for single aspects of a disease or for species health/welfare-specific problems.
- Score = 1 (low pertinence): Scoring systems regarding a specific aspect of a given disease, general methodology, and scientific opinion about risk characterisation or disease prioritisation.
- Score = 2 (medium pertinence): Scoring systems applied in distinct sectors or in more than one disease; specific scientific opinion on ~~prioritisation~~-zoonoses or food safety.
- Score = 3 (high pertinence): Scoring models for different animal diseases of interest in public health and applicable in distinct sectors.

A total of 67 documents scored 0, 15 scored 1, 3 scored 2, but no papers registered a score of 3. Since none of the scientific works were classified as highly pertinent, the DSP model acted as a starting point for compiling scorecards and reviewing methods (6)₂ and ~~therefore then~~ acted as a source of additional information.

2.4 Disease selection

Thirty-eight diseases of major interest in the Lombardy region, classified by the animal species they affect, were selected for assessment. This is summarised in Table 42. These diseases were chosen by veterinary officers because they are either widespread in the region, or because they would have a serious potential impact if introduced, or they are reportable diseases. Specifically, 11 bovine diseases were selected. Six of them are reportable diseases included in the regional eradication plan (bovine tuberculosis, bovine brucellosis, enzootic bovine leucosis), or considered to be a major risk for human health (BSE, listeriosis, salmonellosis). The remaining diseases were selected due to their economic impact and/or because they are a possible threat to public health (BVD, IBR, Paratuberculosis, *contagious S. aureus* mastitis, *Str. agalactiae* mastitis).

Five small ruminant diseases were included because they are zoonoses (brucellosis, query fever), or for their economic relevance and for their negative impact on animal health.

Seven swine diseases were included; 3 of them represent a risk for human health (salmonellosis, swine erysipelas, trichinosis) while the other 4 are a relevant threat for swine health and/or economics (Aujeszky's disease, classic swine fever, swine vesicular disease, PRRS).

We assessed 4 major poultry diseases due to their economic relevance (fowl typhoid, Newcastle disease) and their impact on public health (avian influenza, avian campylobacter).

Three equine diseases were included, 2 of which are reportable diseases without zoonotic potential (equine infectious anaemia, equine viral arteritis) while the third (trichinosis) is also a threat for food safety.

Finally, 8 animal diseases were included within the category 'other'. These are disease of interest for public health that either do not fit within only 1 of the previous categories (campylobacteriosis in pets, leishmaniasis, rabies, toxoplasmosis, West Nile fever, opisthorchiasis) or they represent a major problem for beekeeping (nosemosis, varroosis).

Table 1: Diseases of interest in Lombardy, subdivided by species.

2.5 Scorecard final model

The scorecard model that we developed represents the first result of this study. Figure 1 reports the model development flowchart, while Figure 2 shows the scorecard and its application on bovine tuberculosis, as an example. The final model of the scorecard includes 6 areas of interest: disease relevance, socio-economic impact, impact on public health (human), impact on trade, animal welfare, and control tools. Each area was characterised into different categories, as is briefly described in the following sections.

Figure 1: Model development operational flowchart.

Figure 2: Scorecard model applied to bovine tuberculosis.

2.5.1 Relevance of the disease

'Relevance of the disease' has a coefficient of 1 and 11 categories based on epidemiological and scientific criteria. The most relevant categories are 'presence of the disease' and 'frequency of the disease'. 'Presence of the disease' analyses where the infection is reported (in the region, in Italy or in EU), while 'frequency of the disease' assesses disease epidemiological patterns (from sporadic to endemic). The scores for these 2 categories are multiplied between themselves and provide over one-third of the final score of this area. The other 9 categories examine the scientific data related to the disease; e.g. the number of species involved, speed of spread, reservoirs, variability of the agent, immunology.

2.5.2 Socio-economic impact

'Socio-economic impact' has a coefficient of 2 and 4 categories. Two categories consider actual impact, represented by current losses on production and quality in the region and by the cost of the control plan (if present). The other 2 consider the potential socio-economic impact of a disease (direct and indirect). The direct impact analyses the cost of control (therapies, vaccination, culling, etc.) and the risks on production losses. The indirect impact analyses potential market loss, damages to tourism, and threats to biodiversity. Both categories consider the worst-case scenario.

2.5.3 Impact on public health

'Impact on public health' has a coefficient of 3, 7 categories, and it represents the most important area of the scorecard. This area considers relevance to regional/national/international laws. It includes the category 'Zoonotic potential', which analyses the human-animal interface and the routes of spread between animals and humans. It includes also a category detailing the 'Likelihood of occurrence', which considers the incidence of the disease in the region. 'Spread in humans' and 'Impact on human health' represent respectively categories examining the likelihood of transmission between humans and the severity of the disease. 'Impact on food safety' reflects both the likelihood of contamination in food and the infectious dose. 'Bioterrorism potential' evaluates the availability of the agent and its potential to cause substantial harm if used as a biological weapon.

2.5.4 Impact on trade

'Impact on trade' has a coefficient of 2 and 4 categories. Three categories consider the impact of a disease in regional/EU/international trade according to the current legislation. Their

scores are based on a potential restriction on trades if an outbreak occurs or if the disease is endemic; the risk of losing an 'area-free' status (when present), and the degree of difficulty in regaining this status.

The fourth category analyses the potential for zoning in order to control an outbreak (from the single positive farm to the entire country).

2.5.5 Impact on animal welfare

'Impact on animal welfare' has a coefficient of 1 and 4 categories. Three categories measure the potential impact of disease in animal health and welfare (duration, frequency, and severity). The fourth category considers the potential restriction on 4 out of the 'Five Freedoms'. 'Freedom from Fear and Distress' was not included because it was not considered relevant to the scope of the scorecard. 'Impact on animal welfare (duration)' and 'Potential frequency of severe distress' are multiplied between themselves and provide over two-thirds of the final score of this area.

2.5.6 Control tools

'Control tools' has a coefficient of 1 and 4 categories. The category 'Proper tools for diagnosis' encompasses the availability of certified kits within ~~the nation~~Italy; laws ruling surveillance; control techniques described by international organisations (OIE, WHO, UE), and the availability of the DIVA test. 'Proper tools for prevention' and 'Proper tools for control' categories examine obstacles, incentives, strategies, and available vaccination in order to assess the status of surveillance, prevention, and control in the region. Finally, 'Proper tools for therapy' considers the presence of protocols for therapy (if allowed) and related legislation.

2.6 Data Sources

General and scientific information on all the diseases analysed came from scientific papers and reviews. Only documents published in academic journal with an impact factor (IF) reported on Journal Citation Reports (JCR) were considered. Additional sources of information were scientific books, OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Diseases Technical Factsheet provided by the Center for Food Security and Public Health (CFSPH) of Iowa State University and by Center for Disease Control and Prevention (CDC).

Epidemiological data came from World Animal Health Information Database (WAHID), European Food Safety Authority (EFSA) reports, European Centre for Disease Prevention and Control (ECDC) reports, CDC reports, Italian national epidemiological bulletin, and official reports by VOL.

2.7 Scoring

For each of the previous categories a score was calculated (from 1 to 5). Moreover, a correction factor ("coeff." in Figure 42) to ensure an identical score for each category within the same area and a weight based on relevance (Table 2) were applied in each area of interest. The final score is the sum of the scores of all areas and the maximum theoretical score is 1000. Microsoft Excel™ was used to perform all the calculation. Every area presents a critical level (Table 2) based on its score (maximum theoretical level 100%).

Table II: Summary of areas of interest, weight, and criticality levels. This latter ones Criticality levels represent the percentage of maximum theoretical score that the disease reaches in the related area of interest, based on its score in that area.

3. Results

Once scorecards and the relative values were defined, they were approved by Regional health authorities and included in the VPP. They were made available on the Regional Veterinary Office website with access restricted to the Regional Veterinary Service officers.

Since then, users have been employing scorecards in assessing disease risk priorities. The diseases considered affect different food-producing species and, in a few cases, pet animals. Overall, 23 diseases out of the 38 selected were evaluated before the deadline defined by the Regional government. Table 3 reports the results of total and partial scores for these diseases. Diseases present in Table 1 but not included in Table 3 are still under scrutiny, and part of an on-going process.

[Near Here] Table III: Diseases final scores and criticality levels, subdivided by species and sorted by final score (high to low).

The final scores among bovine diseases vary from 327 to 547. *S. aureus* mastitis and salmonellosis represent the top ~~of the rankposition~~ with a score, respectively, of 547 and 537, whereas IBR and enzootic bovine leucosis occupy the bottom ~~of the rankposition~~ with a score, respectively, of 441 and 327. Moreover, Bovine Viral Diarrhoea (BVD) has the highest critical level within the area ‘relevance of the disease’ (80%); bovine tuberculosis within ‘socio-economic impact’ (65%); salmonellosis and bovine brucellosis within ‘impact on public health’ (74%); paratuberculosis and BVD within ‘impact on trade’ (55%); contagious mastitis (*S. aureus* and *S. agalactiae*) within ‘impact on animal welfare’ (54%); paratuberculosis within ‘control tools’ (85%).

Query fever obtained the highest score among small ruminant diseases (551) while contagious agalactia registered the lowest (401). Furthermore, Query fever represents the most critical disease within 'relevance of the disease' (73%) and 'control tools' (75%) areas.

In swine diseases, salmonellosis reached, with 615, the highest score by far, while PRRS had the lowest, at 359. In addition, salmonellosis presents 3 areas of interest with a critical level above 70% ('relevance of the disease', 'socio-economic impact', and 'impact on public health').

All poultry and equine diseases are still under assessment, while 3 out of 8 diseases within the category 'other' have a final score. Among the latter, toxoplasmosis obtains the highest score (575).

4. Discussion

Several models have been developed to prioritise disease on a broad scale (6), but none of them addressed scenarios involving specific areas and economic impact on a regional level. Different approaches and models for risk characterisation and prioritisation in veterinary science, zoonosis, and food safety have been proposed (WHO 2006 - EZIPs 2010, Welfare Quality 2012 - Schmidt *et al.* 2013). However none of these models were appropriate for this project, with the exception of the recent publication of the DSP model (DISCONTTOOLS 2011b). The DSP model facilitates identification and balance of both areas and categories within the scorecard. We applied this approach in order to develop a specific scorecard that prioritises animal diseases with a zoonotic potential, and that could impact the agro-food industry at a regional level. It should be noted that though some of the same diseases were considered in DSP and in our project, the scorecards that were developed were in fact different because of the different aims of these two projects.

Developing this scorecard addresses two main obstacles that have been reported in similar studies (Parker et al. 2012): The sources of information and the consensus within the working group. Tools for prioritisation should be constructed on scientific evidence; nonetheless, this evidence is not always available due to lack of data and absence of literature. In conditions where scientific evidence is scarce, consensus methods should be used to achieve agreement among experts (WHO 2006). These approaches are time-consuming, but they provide a solid method to overcome obstacles.

Lack of data was occasionally problematic when scorecard forms had to be filled. This was particularly noticeable when the frequency of the disease and any categories encompassing costs of control plans were considered. Data deficiencies slowed down the process of filling out forms and explain why scorecard ~~produces-developed~~ were not covering all the diseases in Table 1. Nonetheless, the discovery of these deficiencies also represents an important opportunity to identify and address gaps within surveillance or control plans.

Final and partial scores of the 23 diseases analysed to date are the result of 10 to 30 pages of forms detailing collected information. Hence, descriptions and discussions of scorecards for every single disease are not possible in this paper alone. However, some of the final scores (Table 3) were unexpected, which merits a brief discussion. Classical zoonosis, i.e. bovine tuberculosis, received lower scores when compared to other diseases such as *S. aureus* mastitis. The relatively low score of bovine tuberculosis is due to the disease free-status of Lombardy. Otherwise, *S. aureus* mastitis is highly prevalent and, even if they are not considered to be zoonotic, represent a possible source of exposure to MRSA strains (Graveland et al. 2011, Grundmann et al. 2006). Specifically, *S. aureus* infections are currently a matter of concern for public health due to the ability of the bacteria to evade immune defences (Fedtke et al. 2004 - Zecconi and Scali 2013) and the increasing diffusion of MRSA in both human and domestic animal (Graveland et al. 2011, Grundmann et al. 2006, Baptiste et al. 2005

- David and Daum 2010). Furthermore, *S. aureus* can produce enterotoxins that may lead to food poisoning even after thermal processes (Asao *et al.* 2003, Le Loir *et al.* 2003).

Therefore the risk of human exposure is potentially high and the specific scorecard emphasises the importance of the problem for public health in the Region, in contrast to the common belief that the problem is confined only to dairy herds. These results therefore confirm the usefulness of the model when applied in a specific area.

Prioritisation tools are becoming increasingly important in developing health policies and strategies in preventive human and animal medicine and food safety. These tools are available to assess and control important food safety aspects such as contamination during food processing, but there are very few of them focused on animal diseases and their impact on human health and food safety. Among available models, none are applicable in a definite geographical area because of the requirement that they also fit with the specific socio-economic characteristics of that area, and not only with disease epidemiological patterns. The tool we developed tries to fill these gaps, encompassing diseases with zoonotic and food poisoning potentials.

The scorecard model proposed represents the results of both research and veterinary expertise in veterinary public health. It was conceived to fit the Lombardy Region characteristics, but it can be applied in similar geographical or political areas.

Areas of interest and related categories were built to be as objective as possible and the scoring criterion was developed to be clear and easy to understand. However, it is important to stress the objective of our scorecard model is not to provide a sterile scoring system, but a dynamic tool to help professionals in the prioritisation and decision-making process.

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7. Conflict of interest/competing interests

The authors declare no conflicts of interest.

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Codice campo modificato

9. Captions

9.1 Tables

Table I

Diseases of interest in Lombardy, subdivided by species.

Table II

Summary of areas of interest, weight and critical levels. Critical levels represent the percentage of maximum theoretical score that the disease reaches in the related area of interest, based on its score in that area.

Table III

Diseases final scores and critical levels subdivided by species and sorted by final score (high to low).

9.2 Images

Figure 1

Model development operational flowchart

Figure 1

Scorecard model applied to bovine tuberculosis.