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Accreditation for excellence of cancer research institutes: recommendations from the Italian Network of Comprehensive Cancer Centers

...it is doctrine that moves the world.

He who takes no position
will not sway the human intellect.
William Thayer Shedd, 1820-1894 (dogmatic theology)

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ABSTRACT

A panel of experts from Italian Comprehensive Cancer Centers defines the recommendations for external quality control programs aimed to accreditation to excellence of these institutes. After definition of the process as a systematic, periodic evaluation performed by an external agency to verify whether a health organization possesses certain prerequisites regarding structural, organizational and operational conditions that are thought to affect health care quality, the panel reviews models internationally available and makes final recommendations on aspects considered of main interest.

This position paper has been produced within a special project of the Ministry of Health of the Italian Government aimed to accredit, according to OECI model, 11 Italian cancer centers in the period 2012-2014. The Project represents the effort undertaken by this network of Comprehensive Cancer Centers to find a common denominator for the experience of all Institutes in external quality control programs.

Fourteen shared "statements" are put forth, designed to offer some indications on the main aspects of this subject, based on literature evidence or expert opinions. They deal with the need for "accountability" and involvement of the entire organization, the effectiveness of self-evaluation, the temporal continuity and the educational value of the experience, the use of indicators and measurement tools, additionally for intra- and inter-organization comparison, the system of evaluation models used, the provision for specific requisites for oncology, and the opportunity for mutual exchange of evaluation experiences.

#### Introduction

The Italian Clinical Comprehensive Cancer Research Centers are a homogeneous group of research institutes offering a comprehensive approach to the issue of cancer. Such institutes are able to study and treat the disease from prevention through early diagnosis, treatment, and palliative care, by optimizing management processes.

The Institutes, officially recognized by the Ministry of Health of the Italian Government as "Istituto di Ricovero e Cura a Carattere Scientifico (IRCCS)", take part in a National Network, the "Alliance Against Cancer", active since 2002 in the development of common clinical, scientific and organizational issues <sup>1</sup>. Also through this Network, Italian cancer research centers collaborate within larger, international programs, specifically those of the OECI (Organization of European Cancer Institutes), which links the most important European cancer centers<sup>2</sup>.

Recently, the continuous search for excellence of these IRCCS and scientific international initiatives in this area stimulated these comprehensive cancer centers to debate the need for a model of accreditation of excellence specific for cancer centers and for which, at this time, internationally recognized models are lacking. Another specific aspect stimulating a search in this area is represented by the fact that IRCCS should be accredited by law (DL n 288/2003) according to international criteria (http://www.salute.gov.it/imgs/C\_17\_pubblications\_1552\_allegato.pdf).

The interest of Italian oncological IRCCS was consolidated during a preparatory phase over a few years which led in 2011 to the start of a Special Research Project funded by the Ministry of Health and aimed to accredit Italian Institutes according the international model recently set up for accreditation to excellence of comprehensive cancer centers by OECI<sup>3</sup>.

Through the project "Tailored Accreditation Model for Comprehensive Cancer Centers: validation through the applicability of the experimental OECI-based model to the Network of Research Cancer Centers of Alliance Against Cancer", in the period 2012-2014, 11 cancer centers will obtain OECI accreditation (European model of Accreditation for Cancer Centers). The OECI model of accreditation, created to satisfy the need for an "accreditation of excellence" for European Comprehensive Cancer Centers, accounts for aspects such as the highly innovative and multidisciplinary characteristics of such institutes, the improvement of professional and organizational quality, the continuous improvement of care for cancer patients, as well as particular aspects such as activities in the fields of prevention, screening, research, education and popularization of knowledge and innovation <sup>3</sup>.

The first aim of the project was to draw up a position paper on specific issues regarding accreditation of excellence, which resulted in this present paper. In particular, based on participants' experience and most recent international guidelines/recommendations (Joint Commission International, ISO Certification, Accreditation Canada International, OECI), the document defines the most relevant elements of the models most commonly used in Italy and how to best use such Accreditation/Certification to avoid

self-referentiality in the quality of cancer services and to achieve the best results from the economic and organizational efforts made to improve services to cancer patients

(http://www.jointcommissioninternational.org/jci-accredited-organizations/;

www.internationalaccreditation.ca/en/home.asp; http://www.iso.org/iso/iso\_9000\_selection\_and\_use.htm;

www.oeci.eu/Documents/OECI\_ACCREDITATION.pdf).

The present position paper is based on current knowledge and takes into consideration current laws and guidelines

#### Background

An "external evaluation of quality is identified as a systematic and periodic evaluation process performed by an external agency or other body, aimed at verifying whether health services possess certain prerequisites regarding structural, organizational and operational conditions that are thought to affect health care quality."

Over the last 10 years, an ever-increasing number of agencies and societies have been created that support or (by their proxy) sometimes replace local government agencies. They evaluate the quality of services through their compliance to laws, standards and prerequisites that should be reference models for Health Services. This necessitated a huge economic effort for administrations that has often been considered out of proportion in terms of the resulting, yet "required", improvements and also saw a marked confusion in involved personnel who had to put in more time and effort, which is often considered unnecessary, if not an outright hindrance to clinical activities.

#### Method

After a preliminary discussion among representatives of different institutions taking part in the project, a panel of experts was identified, representing not only experts in quality but also the clinical and scientific world of cancer research centers. They collected documents and discussed pros and cons concerning the following certification/accreditation systems when applied to comprehensive cancer centers, specifically:

- · Joint Commission International JCI Accreditation;
- · Accreditation Canada International (ACI);
- · OECI Accreditation;
- · ISO 9001:2008 Certification:
- · Peer Accreditation.

Besides these "voluntary" accreditation systems, the compulsory institutional Italian accreditation was discussed.

Each "statement" is introduced by a "rationale", which, while not validated by scientific studies, represents the conclusions drawn after the extensive debate between experts concerning the specific statement. In conclusion, the statements herein reported focus on specific aspects of the accreditation models, which are considered particularly relevant by Italian comprehensive cancer centers.

Statements

# Statement 1. As it is accountable to citizens for quality and reliability of services, each cancer center must undergo external verifications by one or more authorized agencies.

Rationale. In order to avoid self-referentiality in all efforts to improve services to the citizen, the OECI Network proposes that all organizations treating cancer should undergo a process of external quality control. Systematic external controls and the expertise of those who perform them allow not only the reproducibility of a method but also constant comparison of results and the ensuing monitoring and improvement of quality.

### Statement 2. The premises for an external quality control are a heavy involvement and motivation from all levels of leadership throughout the organization.

Rationale. Panelists agreed that medium/long-term staunch support and personal involvement by all levels of leadership throughout the organization (managerial and widespread leadership) were key elements for any program of external quality evaluation to become significant and not just a formal application and to implement quality improvement and cultural growth within the organization. Many experiences of programs which started but were never completed because the leadership support ended resulted not only in a waste of resources but also in staff demotivation.

## Statement 3. Any cancer center implementing programs of external quality control must involve the entire organization, not just some parts of it, and must include all care and research personnel.

Rationale. The position paper writers believe that all participants should be involved in the improvement process both in the clinic and research areas. This belief stems from the fact that cancer institutes have a high degree of complexity. Many multidisciplinary and multiprofessional services are needed for the diagnosis and study of the disease, which constitute the different acts (clinical, administrative, research) the patient faces and whose interdependence is very high.

In order to avoid differences in the language and tools used, it is necessary that all parts of the institute participate in the improvement process, even if to different degrees. Many SQ (JCI, ACI) do not even allow for the accreditation of single parts of an institute, whereas the ISO Certification Board, which theoretically allows it, requires that all main institutional as well as transversal processes are controlled by specific, system-managed procedures.

The panelists agree that the OECI accreditation model evaluates all quantitative and qualitative clinical and research characteristic of participating institutes<sup>3</sup>.

# Statement 4. The most effective moment for improvement is group self-evaluation, which leads to the most profitable changes for the organization, and its participants must involve and motivate all operational levels.

Rationale. From reported experiences, it was concluded that the initial phase of using external evaluation systems, when rules/prerequisites/standards are first faced, defines the moment when change is decided and the start of a "virtuous", extremely educational process that leads to the achievement of improvement objectives as well as to the achievement of required standards. The process includes knowing that some missing essential elements need to be fulfilled and deciding how to obtain them (with or without the help of consultants). Such an effort makes one reconsider in a different and novel way any process that seemed coherent and sufficient for its aim. This allows the group to grow and to build new mental patterns based on innovation and research.

# Statement 5. In order to be beneficial to the organization applying it, each system of external quality evaluation must be interpreted, transferred and used for a long time, planning a mechanism of continuing self-evaluation.

Rationale. We analyzed the different phases that characterize the use of systems of external evaluation and described the possible phases for their implementation:

- 1. exact application of prerequisites supervised by external (consultants) or internal (Head of Quality) experts;
- 2. questioning and reflecting on application modalities;
- 3. search for novel ways to implement prerequisites;
- 4. "maturity" of the system (that can vary from Unit to Unit) where prerequisites are only an occasion for improvement. People tend

to go beyond set standards when looking for other new evaluation systems, thus creating a virtual circle.

It is clear that, besides motivation, this process calls for continuing education, substantial changes in mentality, and a medium-to long-term period. A period shorter than 3-5 years would probably result in a waste of resources, since there would not be the aforementioned virtual effect, but it would frustrate the most motivated among the personnel and would lend justification to any skeptics and to those who most resist change.

Statement 6. Within programs for institutional accreditation, local government agencies (Regions) should provide for prerequisites regarding professional quality, clinical expertise, clinical pathways and evaluation of results.

Rationale. All Regions are finalizing institutional accreditation programs as required by national laws (DL 502/517 dated 1992 and DPR on minimal prerequisites dated 01/14/1997). Regions should develop institutional accreditation programs taking into account not only structural and organizational aspects, but also the verification of prerequisites of processes, clinical results and innovations

The panelists hope that institutional accreditation programs will follow the route, already taken by some Regions, of evaluating and somehow rewarding the most virtuous institutes on the road to excellence. A prerequisite to achieve this is constant research of the motivated and aware collaboration of professionals, especially if they have had experience with clinical audits.

Statement 7. Agencies and institutions that carry out the external quality evaluation must provide for the verification group to comprise qualified evaluators with basic and specialized health knowledge as well as knowledge of verification of health systems developed through adequate education programs.

Rationale. The evaluation of an organizational system is divided into two large areas: system prerequisites and specific prerequisites. The verification team must be able to evaluate both areas. It is for this reason that most evaluation agencies try to guarantee the presence of system evaluators and technical experts. Thanks to the experience acquired, the participants of the position paper suggest that evaluators should be chosen with basic education in the health field and work experience in health facilities (physicians, nurses and technicians). The knowledge of system verification (mental openness, maturity, capacity of judgment) that needs to be acquired is thus based on the analysis of basic competences of different professionals.

Statement 8. Undergoing an external quality verification has a strong educational value and facilitates the improvement of safety and quality procedures.

Rationale. The culture of quality — as a working method, as an improvement tool and as a moment of growth for the organization — is built through the observation of external quality verification, the involvement of as many professionals as possible, and the sharing of the criteria upon which the evaluated system is based. Participating in external quality verification mainly means to learn quality, to understand the meaning of prerequisites, and to participate in the process of systematic revision that leads to highlighting areas for improvement, thereby increasing the safety of both patients and personnel.

Statement 9. Each model of external quality evaluation must allow and plan for the monitoring and verification of processes and results.

Rationale. The panelists stress that all models for external quality evaluation must provide for the methodical and constant use of indicators to monitor the most critical processes. Not only must external quality verifications be able to register the implementation of a system that "theoretically" leads the organization to a certain expected level, but they must also prove the real degree of reliability and efficacy of implemented processes by monitoring "sensible" indicators. We also suggest that shared indicators (for type and modality of data collections) be used, so as to allow a useful comparison among facilities/organizations. Finally, at least in the beginning, we suggest choosing significant but not too many indicators whose data should be easy to extract by the institutional IT system so as to optimize resources. In a subsequent period, indicators may be further integrated, modified or even eliminated and substituted with more significant indicators.

Statement 10. Institutions are recognized as research institutes based on quality certification according to internationally recognized procedures (DL 288/2003). Lacking further laws, Italian research institutes have applied different models (general: Joint Commission, ISO 9000:2008, Accreditation Canada; specialized: JACIE, JCI Lab, EFI). Such models are not incompatible among themselves and might usefully be integrated with a specific model for oncology such as OECI.

Rationale. Having evaluated the models of external quality evaluation in various situations, the representatives of institute members of OECI consider that the main problem is interpretation of the organizational reality on which the model was defined. By definition, the interpretation is valid until proven otherwise, that is until the results of the model application prove its inconsistency and allow for a better interpretation. We concluded that the interpretation of organizational reality is essentially the basis on which different models are integrated. It was also stressed how important it is that a specific model exists, created by oncology professionals, that provides a basis of shared prerequisites for the development of quality in centers which apply for OECI accreditation

Statement 11. The evaluation model must take into account the distinctive features of a cancer center:

- ability to interact within a network in accordance with the National Oncology Plan;
- integrated and multidisciplinary approach to the patient;
- treatment innovation through the quick transfer of research results in clinical practice;
- specific needs of the cancer patient and his/her family;
- distinctive nature of communication with the cancer patient<sup>5</sup>.

Rationale. When the agency for external quality evaluation applies the model in cancer institutes, certain features must be taken into account, which are specific to the treatment of cancer patients<sup>5</sup>, as illustrated in the Italian National Oncology Plan (http://www.salute.gov.it/imgs/C\_17\_pubblicazioni\_1440\_allegato.pdf).

Statement 12. The system used by cancer institutes should provide for specific evaluation criteria on the use of antiblastic and high-risk drugs, of radiotherapy, of nuclear medicine and imaging, and of traditional and molecular pathology used for classification and for therapeutic appropriateness.

Rationale. When evaluating the quality of services rendered, there are some processes cited in this statement that are specific to oncology. The evaluating agency should possess the necessary knowledge and use the most up-to-date guidelines to compare whether what has been done is consistent with the best scientific evidence.

Statement 13. Shareholders should recognize the efforts made by cancer institutes to obtain quality certifications from qualified agencies, including through the assignment of subsidies to support their improvement activities and the clinical excellence they represent.

Rationale. Systems for quality management and evaluation can be used with different aims. For example, they can guide the institute's strategic choices, monitor the progress of services and results achieved, orient the behavior of personnel towards uniform procedures and clinical pathways, increase teamwork skills, allow the comparison of one's results with those of other similar organizations, inform citizens and orient their choices, and encourage the development of improvement ventures. However bringing them to fruition requires a lot of energy, time, dedicated resources and especially the availability of reliable and valid systems for the collection, processing and presentation of data. Regions should therefore provide for specific awards for institutes which can prove

that they have implemented and supported structured systems for external quality evaluation and that they have developed specific, useful and effective improvement projects in critical areas. However, it should be pointed out that the introduction of subsidies might provoke opportunistic behaviors among professionals, thus neutralizing all improvement efforts.

Statement 14. The cancer institutes that subscribe to external quality evaluation should perform and document peer visits using shared, proven and effective methodological tools (e.g. safety walk rounds). The peer visit has the following characteristics:

a)?it is advisable for the accreditation of specialized areas or pathways for the treatment of single diseases;

b)?its prerequisites are statements shared by professionals, and professionals define models and criteria for good clinical practice;

c)?methods used are usually self-evaluation and peer review (experts specialized in the specific field);
 d)?it is complementary to systemic models of external quality evaluation.

Rationale. Appropriateness and transparency can be considered values of the system only if the professionals who offer the service are aware of their importance and support them. The professional sets specific objectives for himself/herself and has the responsibility as an expert to use all available scientific evidence as well as to decide whether, when and how to use it. The professionals must specify what type of care they can offer, how closely they can apply the available scientific evidence, and therefore which outcomes can be guaranteed <sup>6</sup>. When making a decision, the professional must propose the best alternatives for the patient's good, in order that the patient can make an informed decision. Applying for accreditation means to make available the documentation of one's activities and the measurements of their outcomes for peer review. The voluntary mutual exchange among professionals through peer review, conducted according to the guidelines of scientific societies, is an outstanding tool for improving the quality of procedures. Self-evaluation (e.g., internal auditing) is of great importance for the smooth running of the accreditation system and for the diagnosis of critical aspects.

#### Conclusions

This document underlines the definitive and global acceptance of the model of "Accreditation for Excellence" by Italian cancer centers. The authors consider it of great relevance that these comprehensive cancer centers become aware of the necessity to adopt common basic principles that can inspire further specific actions. With elaboration of the present position paper, IRCCS have defined the general situation within which to plan actions. The definition of these general principles will help in the adoption and implementation of a model of accreditation based on the European Organization of Cancer Institutes model, which is a program of peer accreditation for comprehensive cancer centers able to consider the clinical and technological standards necessary for a modern cancer facility but also the key role and added value guaranteed by the presence of experimental activities.

Thanks to the funds of the Ministry of Health, the Italian Network of Cancer Research Institutes plans to implement a common model of accreditation for excellence. However, it is clear even from these preliminary phases of the action that it will be necessary to adapt or even improve the process to meet the specific needs of Italian reality and to be more consistent with the qualities/characteristics required by the Ministry of Health, which is particularly interested in increasing the relevance that outcome analysis will have in the future for the verification of facility efficiency.

The process also entails the education of a large group of national auditors who should allow the creation of a stable, qualified Italian "quality" group specifically dedicated to "oncology".

### References

- Lombardo C, Albanese D, Belardelli F, d'Alessandro F, Giacomini M, Rondanina T, Spagnoli LG: Training and mobility: a priority for the
  Organisation of the European Cancer Institutes. How a national mobility initiative could enhance EU cooperation in cancer research contributing
  to the development of a European Research Area: the example of The Italian Comprehensive Cancer Centers' Network "Alleanza Contro il
  Cancro". Tumori, 94: 147-153, 2008.
- Ringborg U, Pierotti M, Storme G, Tursz T; European Economic Interest Grouping. Managing cancer in the EU: the Organisation of European Cancer Institutes (OECI). Eur J Cancer, 44: 772-773, 2008.
- Saghatchian M, Hummel H, Otter R, de Valeriola D, Van Harten W, Paradiso A, Koot B, Ringborg U, Tursz T; Organisation of European Cancer Institutes: Towards quality, comprehensiveness and excellence. The accreditation project of the Organisation of European Cancer Institutes (OECI). Tumori, 94: 164-171, 2008.
- 4. Montaguti U: L'Accreditamento delle strutture sanitarie. Forum Service, Genova, pp 1-190, 2002.
- De Santi A, Morosini P, Noviello S, per il gruppo CARE: Manuale di valutazione della comunicazione in oncologia. Rapporti ISTISAN 07/38, pp 1-103, 2007.
- 6. Morosini P: Indicatori in valutazione e miglioramento della qualità professionale. Rapporti ISTISAN 04/29, pp 1-111, 2004.