

Criteria for the Evaluation of Italian Scientific Institutes for Research, Hospitalization and Healthcare (IRCCS): Comparison with European Standards and Certification Models

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Abstract. The definition of the title “Istituto di Ricovero e Cura a Carattere Scientifico” (IRCCS) and how this title is given by the Italian Ministry of Health is presented. Specifically, the first assessment of a commission concerning the essential information for the accreditation process is introduced. Moreover, the two years review process that aims to collect last updated information of the IRCCS, to identify level of excellence and critical aspects, is also explained. The present Italian forms and international manuals like Joint Commission, OEI and HCERES were schematized using UML diagrams. The current IRCCS accreditation forms are presented with the suggested updates organized in some levels of structuring. We compared the Italian forms with the manuals required to obtain international certifications (Joint Commission and OEI) and we analyzed the criteria for the evaluation of research units in France (the HCERES standards). Although it is a preliminary study, the use of UML diagrams allows to schematize a new accreditation model, in line with European guidelines and the most important international certifications.

Keywords. IRCCS, UML Diagrams, accreditation, certification, OEI, Joint Commission, HCERES.

1. Introduction

The name of IRCCS or technically “Istituto di Ricovero e Cura a Carattere Scientifico” indicates Scientific Institutes for Research, Hospitalization and Healthcare in Italy [1]. The IRCCS title is granted by Italian Ministry of Health, and it only concerns a very limited number of institutes throughout the nation (they are now 51). With this title, they receive funding and they are part of a Network that allows greater interaction and collaboration with other institutes with the same research, clinical and professional development purposes. They become a benchmark for the whole public health system

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for both the quality of patient care and the innovation skills in the field of scientific organization.

Hospitals that do research obtain accreditation from the Ministry of Health after the assessment of a commission concerning the essential information for the accreditation process, which is based on a form, specifically filled by the personnel of the hospital. This form collects all the information for the correct assessment of the necessary requisites to become IRCCS. Then, every two years, there is a review process that aims to collect updated information on the research activities, the certifications, and the financial report of the IRCCS in the previous two years to identify level of excellence and critical aspects of previous and ongoing programs. Until now this form is filled out by the IRCCS in an unstructured way with a manual copying process without any interaction with structured databases.

The purpose of this paper is to try to compare the manuals required to obtain international certifications, such as Joint Commission and OECI (Organization of European Cancer Institute), to analyze the criteria for the evaluation of research units in France and to analyze the IRCCS accreditation form to update it in content and to suggest levels of structuring.

2. Materials and methods

As for the materials, we considered several manuals and forms:

- a) The current IRCCS accreditation form that is used to identify the level of excellence of the Italian hospitals and to confirm their title of IRCCS [1].
- b) The criteria for the evaluation of research units in France: they are the High Council for the Evaluation of Research and Higher Education (HCERES) standards [2]. With this information we can compare the methodology used by HCERES to evaluate research entities in France and the one used by the Italian Government with IRCCS.
- c) The manuals of international certification, like Joint Commission [3] and OECI [4], where we can find the instructions that the hospital must follow to be certified.

As for the methods, we analyzed the materials with UML Diagrams [5] using Microsoft Visio. In fact, UML, short for Unified Modeling Language, is a standardized modeling language consisting of an integrated set of diagrams. It was born to help system and software developers in visualizing and documenting the software systems [6] and to model large and complex systems like the manuals and the forms, that we have just considered. The UML Class Diagram [7] is the one that was mainly used and it clearly maps out the structure of a particular system by modeling its classes, attributes, operations, and relationships between objects.

3. Results

This preliminary study of analysis and schematization of existing certifications is functional to a comparison between these and the current IRCCS accreditation module, which will have to be updated and improved. For this reason, in *Figure 1* we report the UML Class Diagram of the current form that is used for the confirmation of the accreditation to IRCCS. In this diagram we can clearly see the different classes, each

representing a different section of the form. Each class is described by attributes and entities, and sometimes even by specific subclasses.

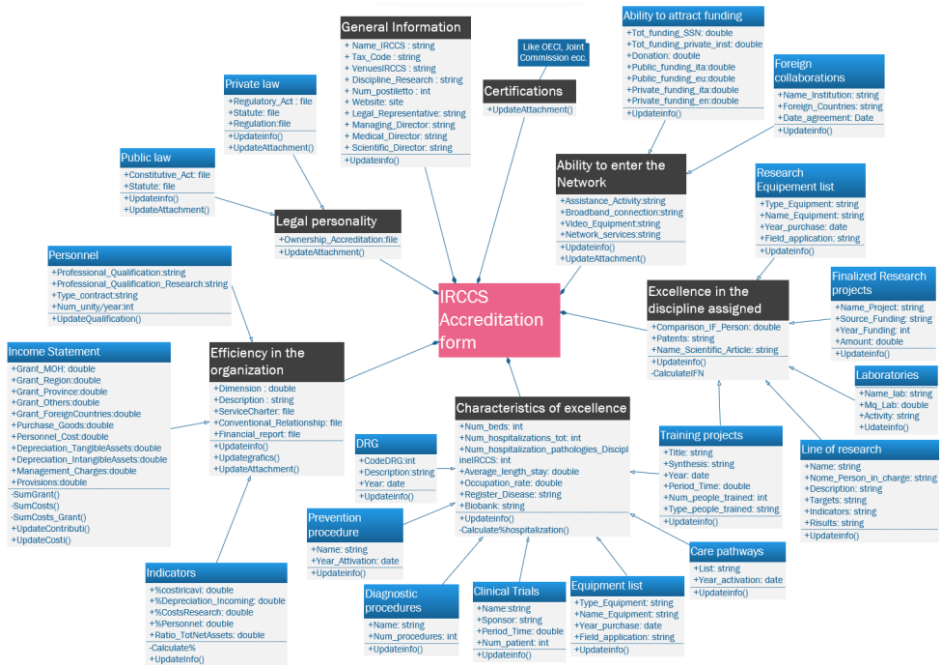


Figure 1. UML Class Diagram of the current IRCCS accreditation form.

We suggest here some changes:

- To introduce a section among the general information, in which IRCCS can indicate the research scope (MDC).
- To insert some facilities in the part relating to efficiency, concerning risk management and precautions reserved for patients at risk.
- To introduce also specific questions on biobanks in the characteristics of excellence regarding the samples preserved, the recognitions and the certifications obtained and the collections of biological material.
- To introduce a specific section related to the ability to enter the Network, in which the level of the hospital computerization is specifically requested: in particular, it must be ask the hospital to have the electronic health record and an integrated computer system and to make use of telemedicine, teleconsultation and televisions, which are increasingly important in recent years [8].
- To evaluate the level FAIRness of the research system of the hospital [9].
- To ask if the Health Technology Assessment process [10] is supported in the hospital, especially for the purchase of innovative technologies.
- To insert a new final section containing the future prospects of the hospital and the future developments of the research activity.

Finally, a further change, not in contents, but in the structure of the form, could be represented by the connection between the database used with the IRCCS structured data for economic recognition and the pre-compilation of the form, which will have to follow, consequently, an online modelling.

4. Discussion

The literature identifies two models for research evaluation, used by different countries that can also switch with one other. In Italy there is a quantitative model that is focused on the measurement of performance. To this end, it produces reliable and general indicators that allow comparisons between different entities. In contrast with qualitative evaluation used by the French Government, for example, this form of evaluation has the disadvantage of giving less weight to local contexts and interdisciplinary characteristics.

In fact, the French Government created HCERES [2] to evaluate the activities conducted by universities and research institutions. The output is a written report that includes summarized qualitative assessments. This model is a "peer review", that uses qualitative evaluation and involves researchers of the same field who work either individually, by reviewing documents provided by the evaluated entity, or collectively, by sitting in evaluation committees. In the latter case, these committees have a collegial approach based on the confrontation of possibly contradictory points of view and their evaluation strives to find a consensus.

They use some criteria that are similar to the Italian ones: in particular, as for the evaluation of the organization and the material conditions of the scientific staff, the management of financial resources, the decision-making process, the existence of a scientific strategy, the use of tools for monitoring progresses and everything that contributes to the smooth operation of the entity and to its scientific production. Though, there are some important differences between the Italian and the French approach, in particular in the research evaluation method and in the distinction between:

- **Multidisciplinarity:** refers to the juxtaposition of disciplines that broadens the field of knowledge by increasing the amount of available data, tools and methods.
- **Interdisciplinarity:** refers to the cooperation between several disciplines in common projects.
- **Transdisciplinarity:** refers to a scientific approach that goes beyond disciplinary points of view by offering a single approach to a scientific question.

We analyze, also, two important international certifications: Joint Commission and OECI.

As for Joint Commission [3], the manual is divided into chapters and each chapter contains standards (objective to be achieved). Each standard is sub-specified in measurable elements, which are the answers that the organization must give to reach the standard and these are the elements that the inspectors verify at the time of the inspection visit. One of the most important chapters is the patient-centered one: in this section we can find a part that concerns the infection prevention and control, the operating room pathway, safe surgery, falls, medication management and hand hygiene. These standards must all be exceeded because they are considered so critical that the non-compliance of one of them affects the patient safety. There are also standards for Academic Medical Center: these are additional standards and concern medical-university training, for example for doctors in training. There is also a chapter dedicated to ethics. These important sections may be added in the new IRCCS accreditation form because they are not present in the current one and they can help to know better the health organization of the hospital.

As for OECI [4], its mission is to serve as a linking organization, coordinating interdisciplinary cancer treatment and improving the quality of cancer care: this can be achieved by integrating cancer prevention and care, research, development and cancer education. For this reason, OECI has specialized its manual in multidisciplinary

integrated cancer care and research, with a major focus on comprehensiveness. According to studies with UML Diagrams, the domains of the OECI manual include governance, organizational quality, patient involvement and empowerment, multidisciplinary, prevention and early detection, all modalities of diagnosis, treatment and care, translational and clinical research. Some of these standards are common to the IRCCS accreditation form, but there are some differences: in OECI manual there is a main part about the care of the patient and the treatments, instead, as for research, there is a great attention to publications, education and training of doctors and researchers, that are themes under-discussed or pushed into the background.

5. Conclusion

It was interesting to make this comparison between the different models, especially since we want to move towards an automation of the current form for IRCCS accreditation. This is a preliminary study, but from these bases there will be future developments: thanks to the use of UML Diagrams, it will be possible to schematize a new accreditation model that will be updated in content and to suggest levels of structuring. In fact, it will be possible to insert the different characteristics of the manuals studied and to propose a new more usable structure to have an online modelling, precompiling the form with the information taken from the database used with the IRCCS structured data for economic recognition. In this way, hospitals will be able to ask for the confirmation of the IRCCS title by filling out an online form without transcribing all the information on an unstructured module, but with an interaction with structured databases. The Ministry of Health and the commission will be able to evaluate the hospital structure following an updated form, in line with European guidelines and the most important international certifications.

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