

Accreditation and Quality in the Italian National Health Care System: a 10 years-long review

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ABSTRACT

Background: Italian accreditation and OECl accreditation are recognized as tools to ensure an adequate level of quality in healthcare setting. The aim of our study was to review the scientific literature about these topics looking for original experiences of accreditation.

Methods: In March-April 2019 we conducted a search on original peer-reviewed papers in the electronic database PubMed (MEDLINE). The key search terms were "accreditation AND Italy", "hospital accreditation AND Italy". We looked for studies published between 2009 and 2019, reporting information about Accreditation experiences.

Results: The literature search yielded 562 publications. Finally, we identified 16 manuscripts eligible for the review. The studies were published between 2010 and 2016; they were conducted from 2007 to 2015; they involved a minimum of 1 to a maximum of 183 centres located in different Italian regions and cities. They concerned different fields such as oncology, haematology, health physics, health direction, paediatrics, and surgery. Accreditation led to a general enhancement of quality, and offered suggestions for further improvement.

Conclusion: Each healthcare system should achieve the best possible levels of quality and safety. Accreditation, combined with further strategies could ensure the highest level of quality.

Key words: accreditation system, Italy, quality, review

INTRODUCTION

Today, more and more people are aware of the

offered alternatives and the rising standards of services, thus, their expectations, in several settings, have increased in an important way [1].

The concept of “quality”, if referred to a service, could be linked to perceived expectations in comparison with perceived performance of a specific service, and may therefore be defined as “the difference between perceived expectations and performance” [2].

The assessment of quality is a very discussed topic, for this reason, is not always easy to find a proper definition of “quality of medical care” and what it really means. Many problems can be identified at this fundamental level, and are the reasons why it is remarkably difficult to define the concept [3]. We found the definition of the Joint Commission as “the degree to which patient care services increase the probability of desired outcomes and reduce the probability of undesired outcomes given the current state of knowledge” [4], and the definition given by the Institute of Medicine (IOM - Washington) as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” [4].

In several countries, including Italy, the concept of quality applied to healthcare facilities is strictly connected to the so called “accreditation” process.

The concept of accreditation of healthcare facilities, as a tool to ensure and guarantee the quality, was born at the beginning of the last century in North America. Historically, the concept dates back to 1910 when Ernest Codman, the Boston surgeon, proposed it to colleagues to evaluate the outcomes of hospital care and to make them public.

In 1913, a specific program was set up to evaluate the quality of hospital care through the development and the adoption of the so called *Minimum Standards for hospitals in 1919* [5].

According to the definition furnished by Jovanovic in 2005, the term accreditation means the systematic assessment of hospitals against accepted standards. Generally, accreditation has developed for hospitals, but during the years, it has been applied also to primary care, laboratories services, and other healthcare sectors [6].

In Italy, the term “accreditation” was introduced in the Italian health legislation in the early ‘90s, with the adoption of decrees 502/92 e 517/93 [7]. The aim of this process, was and is to ensure, to reach, and to guarantee a high level of quality service and to select public or private service providers that work as part of, or on behalf of, the Italian National Healthcare System (INHS) [8]. Accreditation is therefore a progressive movement toward a greater standardisation, uniformity and quality of the health services delivered to citizens [9].

In the Italian context, the requisites for accreditation are additional and different from the minimum requirements for authorization, which are *ex ante* requisites: the satisfaction of these further (general or specific) requisites usually guarantees good performance [10].

In application of the above-described general provisions, the Decree of the President of the Republic (DPR) of January 14th, 1997, approved “the policy and coordination act of the Regions and the Autonomous Provinces of Trento and Bolzano, concerning the minimum structural, technological and organizational requisites for public and private structures to carry out health care activities” [11]. Conversely, the additional requisites for accreditation, are defined by the Regions/Autonomous Provinces in a totally independent way and are one of their prerogatives [11].

The accreditation of the Organization of European Cancer Institutes (OECI) accreditation, instead, is specific to oncology and therefore its standards are tailored to a cancer center, both in terms of language used in the standards manual and in terms of patient needs [12].

There is, in literature, a great amount of studies about these topics, however, the aims of the present study are: i) to explore what has been published on these topics applied to the Italian context; ii) to analyze and discuss original experiences of accreditation and OECI accreditation and the results derived from them. We considered original experiences: studies conducted by authors who reported strengths or weaknesses of their structures emerged from the accreditation process; studies conducted involving multiple structures that participated to experimental programs (usually through surveys) with the aim to describe, monitor and improve clinical or organizational performances and therefore to improve the accreditation system.

METHODS

In March, April and May we performed a search for original peer-reviewed papers in the electronic database PubMed (MEDLINE). The key search terms were “accreditation AND Italy”, “hospital accreditation AND Italy”. We searched for studies published between 2009 and 2019, reporting information about accreditation experiences.

We considered eligible for the review articles (original articles, but also letters to the editor and short communications if containing original data) that reported clear data on: i) Italian region or city in which the study was conducted; ii) number of centres involved in the study; iii) original and interesting results derived from the experiences of accreditation. We considered eligible for the review studies written in English or Italian.

Studies were selected in a 3-stage process. First we analysed the titles; then the abstracts from electronic searches. Finally we collected and read the full manuscripts and their citations lists to retrieve missing articles and to select the eligible manuscripts according to the inclusion criteria.

RESULTS

The literature search yielded 562 publications. The titles of these manuscripts were screened, resulting in 68 studies considered potentially eligible for abstract analysis (193 studies were duplicate, 53 were review, 316 were excluded because focused on topics not in line with the aim of the study).

After the abstract analysis 12 studies were further excluded, so the full texts analysis was conducted on 56 manuscripts. Finally, we identified 16 manuscripts eligible for the review (20 excluded because not in line with the aim of the study, 20 because published before 2009) (10-25) (Fig. 1).

The articles were published between 2010 and

2016, the studies have been conducted from 2007 to 2015; they involved a minimum of 1 to a maximum of 183 centres located in different Italian regions and cities. They were focused on the field of: oncology, haematology, health physics, health direction, paediatrics, surgery.

The principal results of our review are shown in Table 1.

As reported in Table 1, the accreditation process led to a general improvement of quality in the examined services and to several efforts to resolve critical points.

DISCUSSION

Already in 1990, it was proposed a first definition

FIGURE 1. Flow diagram for identifying studies included in our review

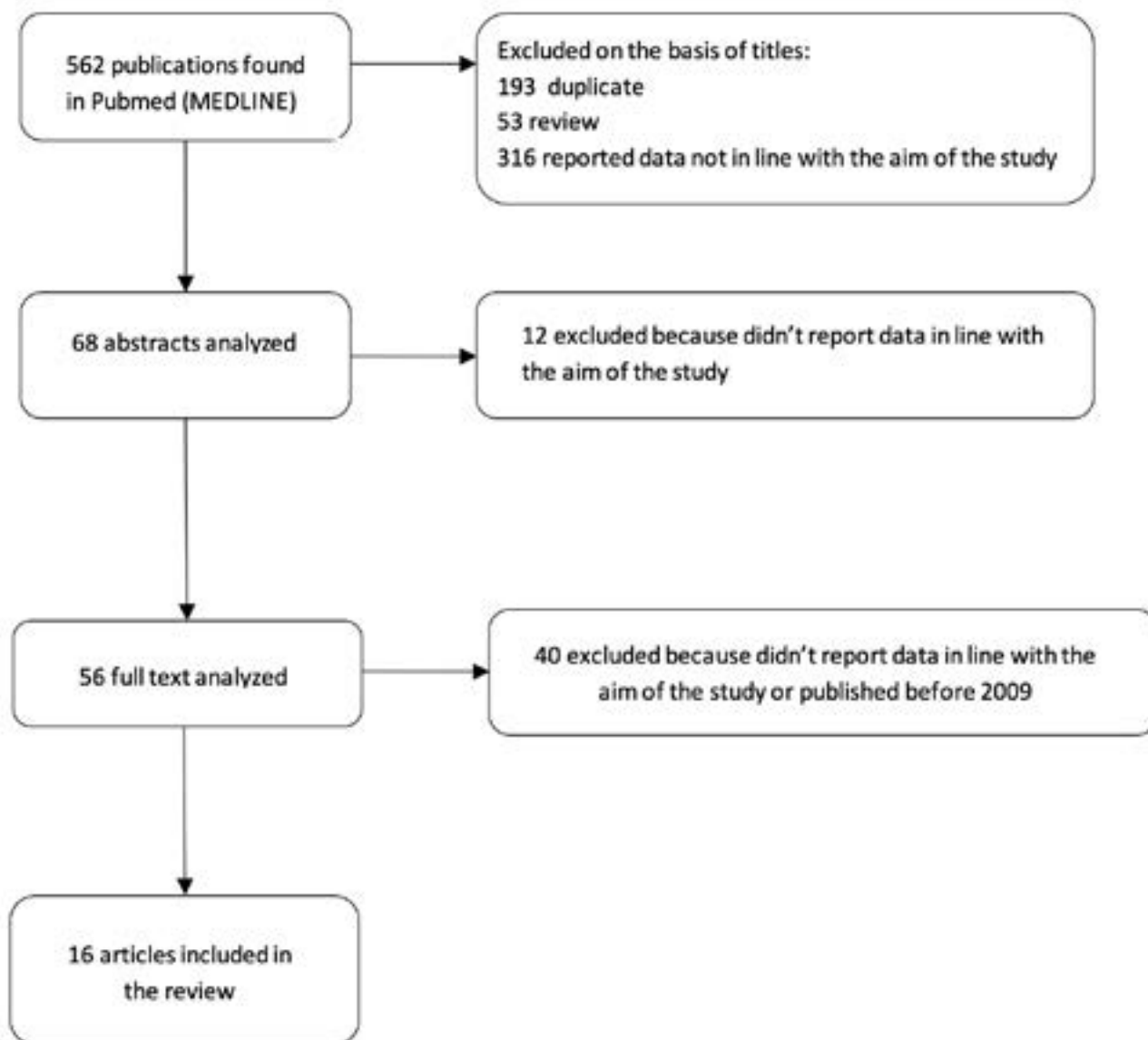


TABLE 1. Selected characteristics of the studies included in our review ordered by year of publication (*= OECl accreditation; **=year of publication; n/s=not specified or not clearly reported in the text)

| Author, year** | Region | Type of Centers | Involved Centers (N) | Study Period | Main Findings |
|-----------------|---|---|----------------------|--|---|
| Tomasini, 2010 | Emilia Romagna (Ravenna) | Transfusion structures and Blood Donation Centers | 10 | 2007-2009 | <ul style="list-style-type: none"> - Increasingly homogeneous distribution of donations throughout all the days of the week - Better training of the staff - Reduction of non conformities |
| Liumbruno, 2011 | Multiple | Transfusion Services and Blood Donation Sites | 183 | 2009 | <ul style="list-style-type: none"> - 38.8% Transfusion Services declared that they had gained ISO 9001 certification (negative gradient from North to South and Islands) - Availability of a trolley for emergencies and of a defibrillator in areas dedicated to blood collection, as well as the presence of staff trained in BLS in the same areas - 53.6% Transfusion Services had blood donation sites run by donor associations |
| Ergasti, 2011 | Lazio | Hospital Directions | 30 | 2008 (first phase) 2009 (second phase. End of this phase not specified) | <ul style="list-style-type: none"> - Use of a checklist to monitor the performances in 10 fields: <ul style="list-style-type: none"> Management of documents Organization, Politics, Objectives and Quality Management of human resources Infrastructures and management of technological resources Management of healthcare services Informatics system Management, evaluation and improvement of quality Purchases management Medical Records Services Charter - All the examined hospitals reported scores >70%, with a maximum of 86.7% |
| Mannucci, 2014 | Multiple | Haemophilia Centers | 21 | n/s | <ul style="list-style-type: none"> - Good possession of disease-related requirements - Lower possession of organizational requirements by most Haemophilia Centres |
| Albanese, 2014 | Multiple | Pediatric cardiology and cardiac surgery | 8 | n/s | <ul style="list-style-type: none"> - Definition of minimum standards for health personnel (pediatric cardiac surgeon at least 120 cardiac operations per year; interventional cardiologist at least 60 interventional procedures per year; pediatric cardioanesthesiologist/intensivist at least 160 anesthesia procedures per year) - Definition of minimum standard number of beds - Definition of the product requirements, which represented the technical/professional needs for any given lesion |
| Piras, 2015 | Sardinia (Cagliari) | Bone marrow transplant center | 1 | 2010-2012 | <ul style="list-style-type: none"> - Creation of a quality team - Creation of an organization chart, and of a processes map - Quality examination at the end of each year - Structural changes (environment, health personnel, informatics) - Regular trainings about the management of quality |
| Canitano, 2015 | Lazio (Rome) | Cancer Institute* | 1 | 2015 | <ul style="list-style-type: none"> - Improvement action plan with 26 actions - Computerized ambulatory medical record project - Training courses |
| Chiusole, 2015 | Veneto (Padua) | Cancer Institute* | 1 | n/s | <ul style="list-style-type: none"> - A specific procedure was written: it introduced the required elements of uniformity and traceability, with a precise registration of the activities in order to ensure that information flows are always documented - Ongoing digitization of clinical documentation - Creation of a team to discuss cases of sarcoma whose decisions taken collectively were recorded both in a specific form and in the patient's medical record. - Multidisciplinary care in genitourinary oncology |
| Da Pieve, 2015 | Friuli Venezia Giulia (Aviano, Pordenone) | Cancer Institute* | 1 | 2012 | <ul style="list-style-type: none"> - Commitment of leadership at all levels - Flexibility in process management - Change in monitoring and outcome measurement |

TABLE 1 (CONTINUED). Selected characteristics of the studies included in our review ordered by year of publication (*= OECI accreditation; **=year of publication; n/s=not specified or not clearly reported in the text)

| Author, year** | Region | Type of Centers | Involved Centers (N) | Study Period | Main Findings |
|------------------|--|-------------------|----------------------|--------------|---|
| Deriu, 2015 | Lombardy (Milan) | Cancer Institute* | 1 | 2012 | <ul style="list-style-type: none"> - Collaboration among several parts to improve quality - Involvement of support personnel - Development of research to improve diagnosis and treatment of cancer |
| Lacalamita, 2015 | Apulia (Bari) | Cancer Institute* | 1 | 2013-2014 | <ul style="list-style-type: none"> - Strong research environment - Well organization of patients flow - High level of information and technology - Stop smoking program for the employees - Integrated palliative and supportive care - Need to increase the Internal Audit System - Need to involve patients in the development of institute's services |
| Mazzini, 2015 | Emilia Romagna (Reggio Emilia) | Cancer Institute* | 1 | 2013 | <ul style="list-style-type: none"> - Improvement of multidisciplinary work - Extensive involvement of professionals at both operational and managerial level - Investments in other areas: multidisciplinary work and clinical pathways; supportive, psychological and palliative care; the role of patients and of information and communication |
| Orengo, 2015 | Liguria (Genoa) | Cancer Institute* | 1 | n/s | <ul style="list-style-type: none"> - Reorganization of oncology/haematology operations - Creation of a terminal care team |
| Roli, 2015 | Lombardy (Milan) | Cancer Institute* | 1 | 2015 | <ul style="list-style-type: none"> - Multidisciplinary teamwork - Improvement plan for supportive care - Evaluation of patients' psychological distress |
| Ancarani, 2015 | Emilia Romagna (Meldola, Forlì-Cesena) | Cancer Institute* | 1 | 2013 | <ul style="list-style-type: none"> - Improvements in several areas: research, quality system, patients' pathway |
| Loizzo, 2016 | Calabria (Cosenza) | Health Physics | 1 | n/s | <ul style="list-style-type: none"> - Identification of the HPU (Health Physics Unit) Responsible for the Quality (RSQ) - Clear definition of delegated responsibilities - Identification of internal and external interfaces - Government of the internal and external communication - Government of the equipment supplied with documentation of their scheduled maintenance (documentation and inventory) - Evidence of a monitoring scheme / mentoring for new staff - An Information System sufficiently developed - Management of documentation under control - Presence of procedures for the assets realization and adequate publication inside the HPU - Annual Report Drafting of the activity results, discussed with the Corporate Strategic Direction |

of quality of care as *"the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge"* [26].

Among the several strategies to improve the quality of care, accreditation procedures are believed to be suitable measures to improve it and to enhance patient satisfaction [27]. Accreditation is defined as a systematic, periodical, reserved and sometimes voluntary strategy: through its methods, based on preset quality standards, it permits to assess the health services that may result or not in some certification level [28,29]. As reported in the introduction,

hospital accreditation was started by The American College of Surgeons 100 years ago, and since then the number of hospital accreditation programs has expanded rapidly. The World Health Organization identified 36 nationwide healthcare accreditation programs in 2000 [30]. Accreditation is an essential part of healthcare system in more than 70 countries and it is often provided by an external and independent review, assessment or audit [31].

In the Italian setting, 21 models for regional accreditation could be identified and, although they are similar for several characteristics, significant differences.

These models were summarized in a study by the National Agency for Regional Health Care Services (Agenzia Nazionale per i Servizi Sanitari Regionali - Age. Na.S.) published in 2009 [32]. The quality criteria most frequently found in the regional provisions are: patient satisfaction, service access, communication, continuous quality improvement, presence of guidelines and protocols, information and data management, technology assessment, appropriateness and continuity of service provision. This topic was updated and revisited by Age.Na.S. in 2013, with the consequent summary of the regional planning for authorization and accreditation with a focus on the measures adopted for temporary accreditation [33].

In our review, we examined 16 studies which reported original experiences of accreditation and certification in order to improve quality in several settings. The number of studies published on this topic is very high, but articles reporting Italian original experiences are very few: several areas have not been investigated and a complete overview is not available today.

Some studies surveyed staff, stakeholders or other hospital representatives before, during and after a certification and/or accreditation process. Some studies showed higher quality in accredited hospitals but it could not be excluded the possible presence and influence of extraneous factors [34].

The most commonly used approach to evaluate accreditation systems was a perception of benefits approach, which allows individuals to record their interpretations of improvements in the quality of service, changes in practices and their satisfaction with the process [35]. However, the results that we have presented not always indicated that hospital accreditation process is correlated with patient satisfaction and with service quality as perceived by patients. These evidences have been previously highlighted in 2010 by Sack et al. in Germany who affirmed that an accreditation is not linked to improved patient satisfaction [27].

Based on our findings, accreditation is a positive process to improve quality. However, not always all the components representing the "quality" are improved in the same way by accreditation process. Achieving and maintaining an accreditation status requires a significant investment of resources, in order to have a quantifiable improvement in healthcare delivery and outcomes [35]. As reported also by Algahtani et al. in the arabic environment, accreditation must be considered an essential and primary requirement to improve the quality in the healthcare system and should be encouraged the participation in accreditation by health professionals, particularly physicians [36]. But alone is not sufficient to ensure a total improvement in quality.

Concluding, the main objective of each healthcare system should be able to achieve the best possible levels of quality and safety, reducing variations and improving activities using standardised processes. Several authors

support this consideration and it is mandatory that all efforts should be made to provide safe, effective, efficient and patient-centred healthcare assistance [37].

Italian accreditation system aims to achieve harmonised quality standards across Regions and to implement continuous certified improvement efforts [38].

As De Pieve et al. has already reported, however, each accreditation system has strengths and weaknesses which are more or less evident on the basis of the institution in which they are implemented [17]. This variability and the possible influence of external factors, are the reason why it is very important a periodical critical analysis in order to systematically redefine the quality standards. However, as it can be observed, the implementation of accreditation in Italy led to the constant improvement in several areas, such as research, quality system, patient pathways, and could facilitate the benchmark and it exchange of good practices: this is absolutely the major strength of the implementation of the accreditation in Italy. Further studies and efforts should be made to ensure the minimum standards for healthcare quality and to find new strategies that, combined with accreditation, could ensure the highest level of quality.

Conflicts of interest

No one to declare

Funding

No one received for this study

Ethics

No ethical approval is required as it is a review of the literature

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