Ann Ig. 2022 Nov-Dec; 34(6): 627-634 doi: 10.7416/ai.2022.2501. Epub 2022 Feb 3.

SHORT REPORT

Implementation of a quality management system according to ISO 9001:2015 standards in an Angiology Unit: an Italian experience

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Key words: Certification, improvement, ISO, narrative analysis, quality management system, organization, performance

Parole chiave: Certificazione, miglioramento, ISO, analisi narrativa, sistema di gestione della qualità, organizzazione, performance

Abstract

Background. *The International Standardization Organization operates the world's most widely recognized quality management system standard, the ISO 9001:2015. In the healthcare sector, the adoption of this standard within an organization helps to improve the overall performance and provides a foundation for development and continuous progress. Our study aims to describe the implementation process of a quality management system according to the ISO 9001:2015 standards in an Angiology Unit of an Italian University hospital.*

Methods. *The project was structured in 5 operational phases, which were carried out during a time frame of 14 months (March 2018-May 2019) and entailed several improvement actions associated with quality and safety outputs such as clinical management, clinical practice, safety, and patient-centeredness.*

Results. *Implementation of the quality management system led to the improvement of many aspects of the processes performed in the Angiology Unit, both in the outpatient and day hospital setting. Overall, the project positively impacted on systems for patient safety, particularly in communication and data transmission, and clinical leadership.*

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Annali di Igiene : Medicina Preventiva e di Comunità (Ann Ig)
ISSN 1120-9135 https://www.annali-igiene.it

Conclusions. *The implementation of the ISO 9001 certification is a process that apparently may seem expensive in terms of resources used, commitment, work, comparison, but it leads to substantial and always progressive improvements in the offer of Services to the user, safety both for the users and for the healthcare personnel involved, in addition to the care processes that translate into significant benefits in terms of quality of care for patients, as well as management savings for the organization.*

Introduction

Italian hospitals are strictly evaluated by national and regional authorities in terms of key performance indicators. However, it seems that the efficiency and effectiveness of quality management systems (QMS) may vary considerably from one hospital to another. QMS is the set of all activities that serve to structure, implement, control, and improve a product or service delivery. The International Organization for Standardization (ISO) 9001 defines the requirements of a QMS for an organization; the latest revision is from September 2015 (ISO 9001:2015) (1, 2). Based on this standard, an organization can obtain certification of its QMS from an accredited body, which is an essential tool in healthcare for managing the services provided to patients and for improving organizational processes and managerial efficiency (3, 4).

The Angiology Unit of the University Hospital of Padua (Italy) had already obtained excellence certification from the Italian Society of Angiology and Vascular Diseases (Società Italiana di Angiologia e Patologia Vascolare, SIAPAV), but decided to improve its QMS according to the new ISO 9001:2015 standards. Following the introduction of the 2015 version, the Quality and Accreditation Unit launched initiatives aimed at encouraging and supporting the adoption of the new standards by the hospital's services. The new 2015 version required a 'risk and opportunities' analysis approach that was carried out focusing the attention on the planned/expected results of the project and establishing risk containment plans.

The aim of this short article is to report, with a narrative approach, the experience of the QMS implementation project, from planning, to improvement actions, to outputs on management and safety of care. This was the first time for an Angiology Unit from the Italian public health system to undergo this process.

Methods

Setting

The University Hospital of Padua (Azienda Ospedale Università, AOU) is a large tertiary hospital and one of the largest hospitals in Italy (over 1,600 beds). The staff comprises over 4,000 personnel, including over 1,000 residents of the University of Padua. The Angiology Unit provides clinical and instrumental services for the prevention, diagnosis, and treatment of vascular pathologies. The Unit serves as a vascular hub for the province of Padua and a reference center in the Veneto region. Healthcare services are provided both on an outpatient* and day

*Patients coming with a regular prescription from the reservation service, pediatric reservation service, specialists, departments within the hospital, emergency rooms, and affiliated healthcare facilities.

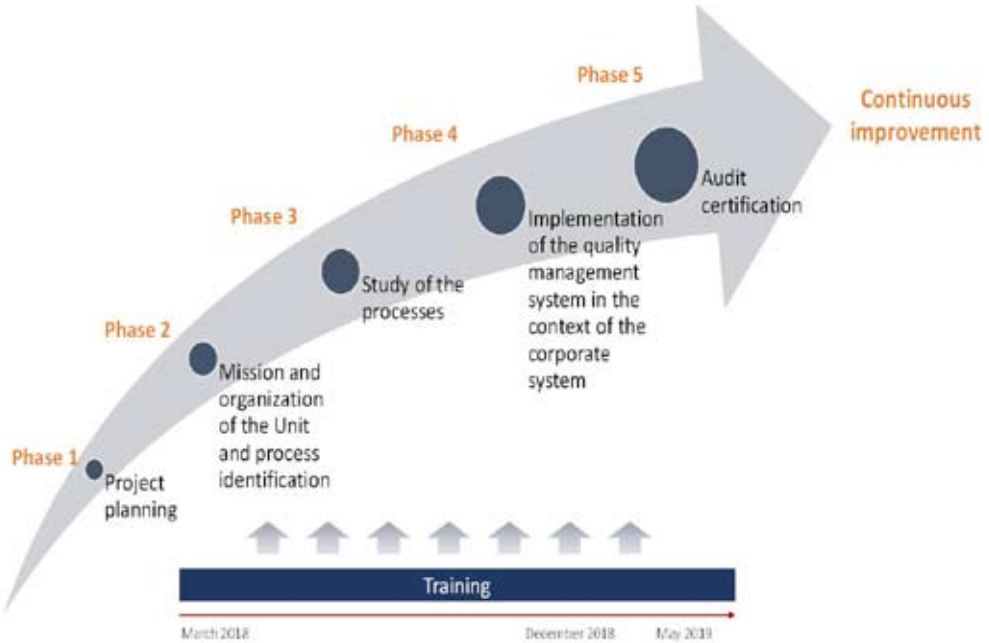

Figure 1 - Phases of the QMS implementation process.

hospital** basis. Outpatient activities are provided on a scheduled or urgent manner, both for adult and pediatric patients, and focus mainly on the treatment of vascular ulcers. Patients requiring close-monitoring medical treatment and highly-specialized wound care are treated at the day hospital service. Furthermore, the staff provides consultations for other services, both within and outside AOU.

Project and steps for ISO 9001 ertification

The project was structured in 5 operational phases, which were carried out during a time frame of 14 months (from March 2018 to May 2019). Figure 1 depicts the main features of the various project phases and the timeline of development. Phase 1 involved the University Training Unit, the Quality and Accreditation Unit and the Angiology Unit management, and laid the foundations for the development of the project, in a process called 'scope and quote'. From phase 2 to 4, specific training was provided to staff through an external trainer. A Failure Mode and Effect Analysis (FMEA) approach was adopted for the analysis and focused on process outputs (4-7). Table 1 summarizes the peculiar elements in terms of input and output.

Since phase 4, a management review has been conducted periodically, in order to assess the efficiency and effectiveness of the QMS, and to approve improvements on an ongoing basis. The review of the correct application of quality standards in the Unit was based on the analysis of the quality policy, the quality objectives, and the services provided, and on the subsequent implementation of corrective actions or identification

**Complex structure coordinated by medical and nursing staff with the task of daily admission for a patient with a complex illness. During the stay, the patient undergoes instrumental investigations, laboratory tests and specific therapy with multi-disciplinary care.

Table 1 - Inputs and outputs of the outpatient and day hospital processes.

ISO 9001 process analysis		SWOT analysis
Process input Patient identification with proposed adult/paediatric medical assessment by: general practitioner hospital specialist physician specialist physician from another Institution Operational instructions: physicians nurses administrative staff patient	Process output Patient care, with discharge reports delivered to the patient and saved on the IT platform. Therapeutic prescription and cost accounting. Data management control: data relating to services provided saved on the IT platform. Health Services Office: sending hospital discharge forms for accounting purposes.	Strengths: identification of the operational processes; monitoring of the examination/taking charge time of the patient; early identification of possible non-conformities. Weaknesses: need for computerised support integrating the reporting system, image storage and drug prescription. Opportunities: relationship with territorial and extra-territorial healthcare services. Threats: competition with private facilities.

of opportunities for improvement (8, 9). Phase 5 entailed certification of the QMS and adherence to the requirements of UNI EN ISO 9001:2015 by a third party.

Results

The implementation of the QMS led to the improvement of many aspects of the various processes performed in the Angiology Unit. Currently, about two years after the project was completed, it is possible:

- to obtain objective information from the context analysis, on the basis of which it is possible to carry out: assessments of the needs of medical and nursing staff in order to respond adequately to the workload; have a clear distribution of responsibilities within the staff; assess the need for new equipment (e.g. ultrasound imaging machine, capillaroscopy machine etc.);

- to obtain objective data on the performance of processes through sets of indicators that allow monitoring of key parameters of outpatient and day hospital processes.

For outpatient processes, the following indicators were monitored: the average response time to urgent requests for inpatients; the average waiting time for outpatients to be assessed; the percentage of inpatients needing urgent care (this indicator was adopted to contextualize the first indicator); and the average response time to requests for urgent consultations for inpatients (Table 2). For the processes of the day hospital activity, the monitored indicators were: compliance with the waiting lists for each priority class; and efficacy of the analgesic therapy (through the use of pain monitoring scales) (Table 3) (10, 11).

Overall, the main implementations achieved in the activities were as follows:

- a clear picture of the procedures being performed and the responsibilities of the professionals involved, with the possibility of identifying ways to improve the procedures for operational controls (e.g. e.g. drug storing and drug expiration date, emergency trolley equipment, refrigerator temperature, oxygen tank and equipment, and management of drugs and free samples);

Table 2 - Performance of the outpatient activity processes.

	Indicator	Reference value	Second semester 2018	2019	First semester 2020	2020 vs 2018 (5) Indicator 4: 2020 vs 2019	2020 vs Reference value
Ambulatory process	1. Average response time to urgent requests for in-patients (from Emergency or other wards) (1)	Up to 24hrs	2h 33'	2h 14'	2h 8'	↓ -76% (-25')	↓ -91% (-21h 52')
	2. Average waiting time for out-patients to be seen (2)	Up to 30'	38'	43'	37'	↓ -3% (-1')	↑ +23% (7')
	3. The percentage of in-patients (from Emergency or other wards) needing urgent care, compared to urgent and not urgent admitted patients (3)	Total number of urgent and not urgent admitted patients afferent to the Angiology Unit	83%	80%	75%	↓ -10%	/
	4. Average response time to requests for urgent consultations for in-patients (4)	Up to 24hrs	Indicator used since 2019	2h 43'	2h 33'	↓ -23% (-10')	↓ -89% (-21h 27')

(1) The response times are intended from when the Angiology Unit receives an urgent call to when the medical report is completed.
(2) The waiting times are intended as the maximum period of time that elapses from being admitted to when the medical report is completed. For the requests of out-patient consultations, the priority regimes according to the Regional Law n. 30, art. 38 enforced since 30.12.2006 are: Class U (Urgent) to be performed within 24 hrs; Class B (Short term) to be performed within 10 days; Class D (Deferrable) to be performed within 30 days; Class P (Programmable) to be performed within 60-90 days.
(3) This indicator was adopted to contextualize the indicators 1 and 4.
(4) The response times are intended from when the Angiology Unit receives an urgent call to when the medical report is completed.
(5) 2nd semester 2018 is the starting date for the application of the indicator

Table 3 - Performances of the day hospital (DH) activity processes.

	Indicator	Reference value	Second semester 2018	2019	First semester 2020	2020 vs 2018 (3)	2020 vs Reference value
DH process	1. Compliance with the waiting lists for each priority class (1)	A = 30 days C = 90 days	A = 14 days C = 55 days	A = 7 gg C = // *(no hospitalizations in class C)*	A = 4 gg C = // *(no hospitalizations in class C)*	↓ A= - 71% (-10 gg) C= //	↓ A= - 87% (-26 gg) C = //
	2. Average variation in pain (NRS scale) from the start to the end of each access (2)	No reference value because it was the first time that the indicator was adopted in the Angiology Unit	-1	-0.7	-0.4	↓ -60% (-0.6)	//

(1) For the consultations of hospitalized patients, the priority classes are defined by the Padua University Hospital rules for the hospitalization waiting list management (DDG AOUPadova n. 1534/2018): Class A: hospitalization within 30 days for the clinical cases that potentially can worsen rapidly and become an emergency or, anyhow, seriously harm the prognosis; Class B: hospitalization within 60 days for the clinical cases that present intense pain, or serious dysfunctions, or serious disabilities, but that neither have the tendency to worsen rapidly to the point they become emergencies nor can the wait cause serious harm to the prognosis; Class C: hospitalization within 90 days for the clinical cases that present pain, dysfunction or disability and neither have the tendency to worsen nor can the wait cause serious harm to the prognosis; Class D: hospitalization within 180 days for the clinical cases that present minimal pain, dysfunction or disability and neither have the tendency to worsen nor can the wait cause serious harm to the prognosis; Class E: hospitalisation without a maximum wait defined by the clinical cases that do not cause any pain, dysfunction or disability. These cases, however, have to be carried out within 12 months. At the Anatology Unit two priority classes are applicable: Class A and Class C
(2) Numerical Rating Scale - NRS (10, 11)
(3) 2nd semester 2018 is the starting date for the application of the indicator

- adoption of tools for continuous improvement, including the reporting of non-conformities to be discussed during joint staff meetings and periodically analysed. During the period of implementation of the QMS, two corrective actions were successfully completed, one of which led to the strengthening of operational controls, and the other to the implementation of urgent consultations requested by the second city hospital, recently administratively attached to AOU;

- availability of tools to conduct regular risk analyses of outpatient and day hospital processes. From the first analysis, some risks emerged which were managed through individual containment actions. Three containment plans were activated which operated on different fronts: the risk of issuing incomplete discharge letters due to the format in use, the risk of incorrect data concerning the activities to which patients are submitted due to missing or incorrect attribution, and finally the risk of incorrect attribution of data concerning medicines ("F" file***). In the first case, a change of the IT has been activated which enables the automatic compilation of the most relevant information in the discharge letter. Internal audits were subsequently carried out to ensure compliance of the management system with the requirements of ISO 9001:2015. After this implementation, no more incomplete letters were issued. In the second case, a manual check of the data was activated, which revealed a significant difference in the total count of services reported by the management control: in 2019, the management control reported 5,030 procedures while in the manual check they were 7,462. In the third case, it was possible to activate the automatic compilation of the "F" file through the patient management software in use in the Unit, although at the end of phase 5 appropriate computerization was still in progress.

Discussion

Although many hospitals implement quality processes such as internal audit and risk management activities, real benefits come from the standardization of processes within the ISO 9001 certification. The adoption of the QMS in accordance with internationally recognized standards has allowed our Unit to consistently provide services in compliance with the requirements indicated by international guidelines and in accordance with results from other organizations (8, 9). The use of appropriate indicators to monitor the performance of processes has allowed us to identify critical issues, to formulate proposals for improvement based on objective data and to intervene when necessary.

The QMS implementation project inevitably required the introduction of changes in daily practice that were sometimes difficult to implement; however, the staff proved to be ready to adopt new working methods when necessary and useful, thus allowing the start of a virtuous path based on awareness and aimed at the continuous improvement of processes. After training and initial period of use of the above-described tools, a more technical approach could be recognized, resulting from the awareness of know-how. The identification of processes, in our case

*** "F" file regulates the compensation of drugs in direct distribution, which includes drugs that are given in an out-patient and home-based manner. To this category belong, among others, antitumor drugs for out-patient and home use (Law 448/98 art. 68 comma 6), drugs in direct delivery (Law 405/01), drugs used in Day Hospital regime, drugs in group H for home use and innovative drugs and innovative and oncological drugs. In order to reimburse direct distribution drugs, they must be written up in the so-called "F" File for all the drugs regulated by Law 405/2001 "Conversion in law, with modifications, of the decree-law 18 September 2001, n 347, on urgent measures in the field of health care expenditures".

both in the out and inpatient setting, led to the development of operative instructions for the medical, nursing, administrative personnel as well as for patients. This resulted in the assumption of a systematic approach to processes, both in the way they are conducted and in their analysis. In fact, the discussion of possible criticalities allows for a continuous re-examination of the activities and an improvement of the services provided to patients. Overall, the project led to an improvement in patient management and reduced the risk of errors in communication and data transmission, allowing better control of clinical risk and putting the patient at the center of all our activities, as guaranteed by the ISO 9001:2015 Quality System.

In our experience, we deal with some limitations: firstly in outpatient processes sometimes there was a problem of accessibility between different IT systems. This resulted in a loss of time, an increased risk of errors in the transmission of information, an impaired business, and a failure to meet targets. A further issue was the need to manually complete files for the hospital's pharmacy for reporting high-cost drugs administered in the hospital on an outpatient basis or distributed for home treatments, with the risk of medication/patient allocation errors. Finally, we could not compare the results and any improvements achieved with the application of the ISO-9001 standard as no data were systematically collected before 2018 to allow comparison.

Conclusions

Implementing an effective and robust ISO 9001 will help to focus on the important areas for the patients and improve efficiency. The main benefits of ISO 9001 include a better internal management and the possibility to achieve consistent outcome, measured and monitored. Assuming this is a globally recognized standard, in the future we could compare our results with other experiences, in order to promote a standardization of the process. The size of such a project and the costs can be high in terms of time, resources and additional work; however, the relapse in taking charge of the patient turns out to be the best that can be offered.

Acknowledgements: The authors would like to thank the staff of the Angiology Unit: F. Ceccato MD, G. Camporese MD, R.C. Martini MD, E. Baracco RN, M. Bettella RN, N. Griggio RN, S. Morandin RN, F. Nalin RN, A. Noventa RN, C. De Palo RN, O. Scarpazza RN and C. Tonello RN for their contribution to the project.

Riassunto

Implementazione di un sistema di management della qualità in base agli standard ISO 9001:2015 in un'Unità di Angiologia: un'esperienza italiana

Premessa. L'ISO 9001 dell'International Organization for Standardization è lo standard del sistema di gestione della qualità (Quality Management System) più riconosciuto al mondo. Nel settore sanitario, l'adozione di questo standard all'interno di un'organizzazione aiuta a migliorare le prestazioni generali e fornisce una base per lo sviluppo e il progresso continuo. Lo studio mira a descrivere il processo di implementazione di un quality management system secondo gli standard ISO 9001:2015 in un'Unità di Angiologia di un ospedale universitario italiano.

Metodi. Il progetto è stato strutturato in 5 fasi operative, che si sono svolte durante un arco di tempo di 14 mesi (marzo 2018-maggio 2019) e ha comportato diverse azioni di miglioramento associate agli output di qualità e sicurezza come la gestione clinica, la pratica clinica, la sicurezza e la centralità del paziente.

Risultati. L'implementazione del Quality Management System ha portato al miglioramento di molti aspetti dei processi eseguiti nell'unità di Angiologia, sia in ambito ambulatoriale che di day hospital. Nel complesso, il progetto ha avuto un impatto positivo sui sistemi per la sicurezza del paziente (ad esempio la comunicazione e la trasmissione dei dati) e sulla leadership clinica.

Conclusioni. L'implementazione della certificazione ISO 9001 è un processo che apparentemente può sembrare costoso in termini di risorse impiegate, di impegno, di lavoro, di confronto, ma porta a sostanziali e sempre progressivi miglioramenti nell'offerta di Servizi all'utente, di sicurezza sia per l'utenza che per il personale

sanitario coinvolto, oltre ai processi assistenziali che si traducono in benefici significativi in termini di qualità delle cure per i pazienti, oltre che in risparmi di gestione per l'organizzazione.

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