

The coherence of control and audit activities in quality management in clinical hospitals

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Abstract

The objective of this article is to evaluate the coherence of control and audit activities related to quality management in clinical hospitals (in Poland). Research conducted in a selected hospital in Poland has shown the use of a few similar solutions, which may be regarded as a good reason to consider whether the initiation of corrective actions is necessary. The basic conclusion resulting from the conducted analysis concerns the necessity of reviewing the control and audit function with a view to eliminating the needless performance of such control activities, including a possibility of reducing their scope by way of combining similar tasks. The collected data give rise to a statement about the necessity of conducting a more thorough check of collected information together with its recording carriers, which will allow the integration of control and audit activities.

Paper type: case study

Keywords: control, audit, quality management, hospital

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Introduction³

The objective of the analysis is to evaluate the coherence of control and audit activities related to quality management in clinical hospitals in Poland. The reason for taking up this subject has been the authors' observation of the co-occurrence of various management solutions aiming at the improvement of the quality of medical services provided by health care institutions. Such an observation has led to the formulation of a research question concerning the coherence of control and audit activities conducted in relation to quality management.

Coherence is understood as the consistency of a research area, time, manner, conclusions, etc. resulting in a high degree of mutual concordance.

The applied research method has been based on a critical analysis of the literature on the subject of quality management systems in hospitals and a study of a particular case comprising an evaluation of the content of reports and documents as well as the co-author's own observations conducted in the selected research object, i.e. the John Paul II Specialist Hospital in Kraków.

1. A review of the main systemic solutions in the field of quality management used in hospitals

Systemic solutions (models, programmes) related to quality management systems (QMS) and applied in hospitals can be divided into two groups. One of them comprises universally applicable solutions which are not sector-specific, i.e. solutions developed for organisations of various types and sizes as well as functioning in any sector. The other group consists of sector-specific programmes dedicated to hospitals. The most popular and important of such programmes from the point of view of the research objective are presented synthetically in the further part of this article. Table 1 includes a summary of these approaches.

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Table 1 A summary of systemic solutions and programmes related to quality management in hospitals

Systemic solutions and programmes related to quality management	
general (non-sector-specific)	dedicated (sector-specific)
<ul style="list-style-type: none"> • Quality Management Systems consistent with the ISO 9001 standard • EFQM • TQM • management control 	<ul style="list-style-type: none"> • Hospitals Accreditation Programme • The Hospital without Pain • EN 15224:2012 • Health care sector services – Quality management systems – Requirements based on the EN ISO 9001:2008 standard

General (non-sector-specific) systemic solutions

The most popular quality management systems (QMS), also in hospitals, are the ones consistent with the ISO 9001 standard. Such a quality management system comprises of a set of guidelines based on quality principles oriented towards the fulfilment of a customer’s requirements. According to estimations, 152 medical institutions in Poland have acquired certifications for the implementation of their QMSs based on the ISO 9001 standard (Stępniewski, Karniej, & Kęsy, 2011, p. 443). It should be added that some hospitals in Poland have implemented integrated quality management and environmental management systems (the ISO 14 001 standard, e.g. the system implemented in the Dr Józef Rostek District Hospital in Racibórz [*The Quality Book of the Integrated Quality Management and Environmental Management System*, 2013]) or occupational health and safety management systems (the BS OHSAS 18 001 standard, e.g. the system implemented in the Health Care Institution in Wadowice [*Certificates*, 2014]).

The Excellence Model of the European Foundation for Quality Management, which can constitute a basis for the development of a QMS, should also be regarded as one of the general solutions. This model consists of nine elements concerning potential (leadership, employees, strategy, partnership, resources, processes, products and services) and results (comprising employees’ results, customers’ results, society’s results as well as business results). One of its parts is an evaluation and correction of the used methods on the basis of the monitoring and analysis of achieved results as well as learning (*An Overview of the EFQM Excellence Model*, 2012, p. 6).

Management control is a unique type of the systemic approach to management. It can be defined as “all activities undertaken with a view to ensuring the achievement of objectives and execution of tasks, such activities being conducted in a manner that is compliant with the law, effective, economical and timely” (Article 68 of the Public Finances Act of 27 August 2009, *Journal of Laws* of 2013, item 885). Management control means “adopted in an organisation, a system supporting management (procedures, instructions, rules, mechanisms) which is used by the

management to acquire certainty that the organisation's objectives will be achieved" (a managerial meaning), but also "a broadly understood process of checking and evaluating" (a functional meaning) (Płoskonka, 2006, p. 204). Managerial control is described by means of standards divided into five groups. The last of them is monitoring and assessment, which in turn consist of monitoring self-assessment and internal audit (Małecka-Łyszczek, 2015).

In the case of independent health care institutions maintained by local governments, management control is not obligatory, unlike in the case of public sector entities. Nevertheless, some public hospitals have properly prepared documentation regulating the manner of conducting a management audit (e.g. the Prof. Ludwik Bierkowski Independent Public Health Care Institution of the Ministry of the Interior in Poznań, the Rev. Jerzy Popiełuszko Independent Public Health Care Institution – the Bielański Hospital) (Regulation no. 21/2013 of the Director of the Prof. Ludwik Bierkowski Independent Public Health Care Institution of the Ministry of the Interior in Poznań of 17 April 2013 concerning the implementation of the Management Control Regulations in the Prof. Ludwik Bierkowski Independent Public Health Care Institution of the Ministry of the Interior in Poznań; Kamiński, 2014).

Besides the aforementioned proposals, we should mention the general guidelines for the development of QMSs ensuing from the standards of total quality management (TQM) or based on the Deming Cycle (Nogalski & Rybicki, 2002, p. 128). This type of partial solutions should be identified with more broadly understood TQM, which in practice – contrary to its name – does not necessarily have to adopt the form of a systemic solution comprising a whole organisation. Despite a large number of meanings assigned to this concept, TQM can be understood as "a set of systematic activities conducted throughout the organisation in order to achieve its objectives effectively and efficiently by providing customers with products and services of a satisfactory quality, at satisfactory prices, and in a timely manner" (Ćwiklicki & Obora, 2011, p. 13).

Dedicated (sector-specific) solutions

The group of solutions dedicated to hospitals and aiming at the improvement of the quality of health care services in Poland includes the *Hospitals Accreditation Programme*. In the years 2008–2014 the programme was modernised within the scope of the project called *Supporting the process of accrediting health care institutions* and financed by EU funds.⁴ The result of the programme was the successful

⁴ The details about the Hospitals Accreditation Programme can be found on the website of the *Supporting the Accreditation Process* project at <http://www.wsparcieakredytacji.cmj.org.pl/> (*Wsparcie procesu akredytacji*, n.d.) and the website of the Centre for the Accreditation and Monitoring of Quality in Health Care Institutions at <http://www.cmj.org.pl/akredytacja/> (*Ośrodek Akredytacji Centrum Monitorowania Jakości w Ochronie Zdrowia*, n.d.).

accreditation of more than 190 hospitals. As in the case of other accreditation processes, the version of accreditation dedicated to hospitals means “a voluntary and systematised process of evaluation oriented towards the stimulation of improved quality and safety of health care as conducted by independent auditors” (*Accreditation of Hospitals*, 2013, p. 2). The total number of 123 standards is divided into eight groups such as: comprehensive character of care, patients’ rights, quality improvement, safety of care, a team of co-workers, medical documentation, organisation of an entity, and others (*The Accreditation Programme for Basic Health Care Institutions. The 2011 Standards*, 2011, p. 4).

Another dedicated programme related to the quality of the provision of medical services is *The Hospital without Pain* initiated by the Polish Pain Research Association (*Szpital bez bólu*, n.d.). The institutions which have received certificates participate actively in the improvement of the quality of post-operative pain management.

The standard dedicated to the quality of health care services is EN 15224:2012, which has not been translated into Polish. Published in 2012, the standard includes references to the ISO 9001 standard of 2008 (Trela, 2014, p. 122).

The list of the aforementioned programmes can be supplemented by solutions which contribute indirectly to the improvement of the quality of medical services but which, however, do not have a systemic character. An example of such a solution is *evidence based medicine* referred to within the context of medical service quality assurance by Opolski, Dykowska and Możdzonek (2003, p. 121). This term is used to refer to the process of making clinical decisions based on the best available evidence included in clinical research, taking into consideration patients’ preferences (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996, pp. 71–72).

2. A typology of control and audit activities in quality management

The subject matter of this article comprises control and audit activities occurring in quality management; therefore, it is necessary to present and explain their major types.

Within the ISO standard certification process, there is an obligation to conduct an internal audit. A reference to such an audit is included in item 8.2.2. An internal audit. It has to be planned in advance; its conduct is the responsibility of internal auditors. Audit reports are usually submitted for analysis to the representative for the quality management system.

An internal audit outside the QMS context is frequently identified with management control. It means “an independent and objective activity whose objective is to support the entity’s manager in the achievement of its objectives and the exe-

cution of its tasks by way of systematic management control assessments and consulting activities.”⁵ The following parties participate in the assurance tasks of internal audits: the process owner (who is directly related to the object of the audit), the internal auditor (who conducts the assessment procedure), and the user (who receives and uses the assessment). On the other hand, the participants of the consulting activities include the internal auditor (who offers advice) and the client (the entity’s manager seeking advice) (Stawny, 2011, pp. 81–82).

In the case of management control, it is important to indicate potential sources of information about its status, including functional (internal, managerial), self control, self-assessment, institutional internal control, internal audit, and external control (Mituś, 2015, p. 138). Their synthetic definitions are presented in Table 2.

Table 2 *The types of control occurring in the assessment of the status of management control*

Term	Description
Self-control	the employee’s checking whether his activities are performed correctly
Functional control (internal control in a narrow sense, managerial control)	carried out by the entity’s management [...], managers of various levels (departments, divisions, organisational units, etc.) who, by virtue of their positions, exercise supervision of subordinate employees or work teams. [...] it is possible to distinguish vertical functional control exercised by the entity’s management and organisational unit managers as well as horizontal functional control exercised by particular organisational units (e.g. a legal office) or positions (a specialist for legal affairs)
Self-assessment	The conduct of self-assessment should be documented and self-assessment itself should constitute a separate process of management control assessment to be carried out at least once a year. Self-assessment is conducted using first of all various survey forms and questionnaires including questions or theses related to the particular processes occurring in the entity under evaluation or to its operating areas
Institutional internal control	control conducted by the controller located within the organisational structure of the controlled entity
External control	control conducted by the controller from outside the organisational structure of the controlled entity

Source: based on Mituś, 2015, pp. 136–163.

⁵ Article 272 clause 1 of the Public Finances Act of 27 August 2009 (*Journal of Laws*, no. 157, item 1240, as amended).

3. An assessment of the interdependence of control and audit activities as exemplified by the John Paul II Specialist Hospital in Kraków

Within the scope of their research, the authors have conducted an assessment of the interdependence of control and audit activities in only one hospital, i.e. the John Paul II Specialist Hospital in Kraków (hereinafter KSS). The selection of this particular health care institution has been deliberate. It is justified by the fact that this hospital has implemented a number of the most popular quality management solutions presented in the previous sections of this article.

The KSS maintains the following quality management systems:

- The quality management system based on the ISO 9001:2008 standard (The Quality Office, n.d.) – certified for the first time in 2004, recertified in 2013 and valid until 2016. It comprises treatment, care, diagnostics and rationalisation in the following specialities: angiosurgery, chemotherapy, cardiology, cardiosurgery, intensive care, pulmonology, thoracosurgery, neurology, infectious diseases, and hepatology of children and adults, in both inpatient and outpatient health care systems.
- The environmental management system based on the ISO 14001 standard – certified in 2015.
- Accreditation – recertification in March 2013 within the scope of the Hospitals Accreditation Programme conducted by the Centre for the Accreditation and Monitoring of Quality in Health Care Institutions. This accreditation expired in March 2016.

The above list should be supplemented with *The Hospital without Pain* certificate awarded in April 2010 to the Clinic of Cardiosurgery, Angiosurgery and Transplantation, the Anaesthesiology and Intensive Care Ward, as well as the Anaesthesiology and Pulmonological Intensive Care Ward.

The control and audit activities conducted in the KSS have been identified on the basis of the review of the KSS's documentation and the co-author's own observations. These activities include self-control, functional control, institutional internal control exercised by the following organisational units: the Hospital Infections Department, the Occupational Health and Safety Department, the Pharmacy Control Team, the Transfusiology Department, internal audits conducted by certification bodies with respect to the ISO 9001, ISO 14001 standards, by the Quality Monitoring Centre and the Pain Treatment Team. The descriptions of particular activities include information on their subject matters, a department or area subject to control/audit, collected data, an objective of and reason for an activity, a legal basis, connections with quality management systems, frequency and duration, applied methods and participants. The synthetic result of the performed research is

presented in Table 3. The characterisations included in the table can be compared on the basis of the criteria selected for their description.

Table 3 *The types of control and audit activities performed in the KSS*

Specification	Quality audit	Self-control	Functional control	Institutional internal control	Internal audits/control
Subject	knowledge of procedures, up-to-date character of information	performance of medical, administrative, and technical procedures	employees' work and absences	performance of medical activities with respect to epidemiological, OHS, and pharmaceutical aspects	functioning of quality systems, control of customer satisfaction with medical services
Area	particular wards	wards, outpatient clinics, laboratories	hospital's particular organisational units	all employees	wards, outpatient clinics, laboratories, hospital administration
Scope of collected data	knowledge of medical procedures	control of performed medical procedures	supervision of compliance with work regulations and entrusted medical tasks	compliance with OHS, data protection, epidemiological safety procedures, correct maintenance of medical documentation, and correct drug management	consistence of activities with established procedures, information, as well as employees' medical and non-medical duties
Objective and reason	higher quality of medical services	improvement in performance of activities	observation of ward personnel's work and collection of patients' opinions	control of dutifulness and presence at place of work	reception of quality certificates
Legal basis/documentation	Quality book	Quality book	hospital's regulations	Quality book	application filed with certification or accreditation entity
Connections with quality management system	ISO 9001, Accreditation, ISO 14001	ISO 9001	ISO 9001, Accreditation	ISO 9001, ISO 14001, Accreditation	ISO 9001, Accreditation, ISO 14001
Frequency and duration	twice a year	daily	once or twice a year; planned or unplanned	depends on subject matter: from daily to once a year	twice a year

Specification	Quality audit	Self-control	Functional control	Institutional internal control	Internal audits/control
Participants	employee, managers	medical and non-medical personnel	executive board, management, personnel, patients	Infections Department, Transfusiology Department, OHS Department, Pharmacy Control Team, medical and auxiliary personnel	certifier, quality representative, ward employees, patients
Initiator	Quality Department, ward management	Employee, Quality Department	Executive Board	Hospital Infections Department, Pharmacy Control Team, OHS Inspector, Transfusiology Department	Entities conducting ISO 9001, ISO 14001 certification procedures, Quality Monitoring Centre

An analysis of every control or audit activity allows one to draw a few conclusions.

The identified activities result primarily from the principles of the QMS based on the ISO 9001 standard and Accreditation. They concern the knowledge and performance of various (medical, epidemiological, etc.) procedures and therefore, it is possible to ascertain their concurrence with respect to the subject matter of the research. The area of control constitutes another common element; in principle, it comprises all organisational units of the Hospital. It concerns mainly compliance with the provisions of the work regulations or the QMS documentation. The activities can be divided into two groups: quality improvement activities with a prospective or ex ante character, and quality checking activities with a controlling or ex post character. The control and audit activities are conducted on average every second month (with the exception of self-control). The coherence of these activities is also confirmed by the legal basis for their performance, which is the internal documentation, and primarily the QMS documentation.

In consequence of the conducted comparison, it is possible to ascertain that the control and audit activities performed in the KSS are coincident with respect to their subject matter, areas, scopes of collected data, legal basis, and relations to the QMS. Their characterisation allows one to put forward a demand concerning their proper scheduling with respect to the availability of particular employees and the managerial staff.

The collected data constitute a strong basis for a statement about the necessity of conducting a more thorough check of collected information together with its recording carriers, which will allow the integration of the control and audit activities. It is also necessary to take into consideration the degree to which the manage-

ment's expectations related to the particular activities are being met from the perspective of the QMS, which could constitute a basis for modifications in the scope of collected information with a view to preventing potential redundancies and also for the adjustments in the frequency of their performance.

Conclusions

The conducted exploratory research has shown the existence of a number of coincident control and audit activities performed by the various organisational units of the John Paul II Specialist Hospital in Kraków. Taking into consideration the popularity of quality management systems based on the ISO 9001 and 14001 standards and the Accreditation programme in hospitals in Poland, one can ascertain that other hospitals carry out control and audit activities of a very similar character.

The main conclusion resulting from the conducted analysis concerns the necessity of reviewing such activities with a view to eliminating redundant ones, taking into consideration the possibility of reducing their number by way of aggregating similar tasks in Polish hospitals. A successful implementation of such a project would allow the rationalisation of the performance of the control and audit function in hospitals, thus increasing the synergy effect.

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