# Quality and Control in the Healthcare: A Win-Win Mix?

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## *1. Introduction*

The healthcare sector features several peculiarities and specificities, expression of its uniqueness and diversity from the other economic activities. In particular, it distinguishes in the financing typologies, whether they are public or private, which depends from the constitutional rights granted to the citizens or people in general, and the regulatory law framework in each State worldwide. Regardless of the financial aspects, a quality and effective service must be supplied, under appropriateness of the health care provided and efficiency in the resources allocation.

The healthcare organizations are generally managed by various kinds of professionals, and their processes undergo to law enforcements and professional best practices, and must grant some minimum healthcare level, so as to safeguard the patients, their caregivers, their families and their right to health and prevention. The healthcare organizations so are set up as "professional bureaucracies", where often the audit activity, whether it is internal or external, plays an outstanding role in the fulfillment of the requirements imposed by the law or by the professional best practices

In this contribution, that is a preliminary theoretical analysis based on the existing literature in the field, we argue that it is possible for any healthcare organization to perform a quality service, under a proper management and respectful of the laws, whenever the audit services are structured in a continuous process, relevance-based, focused on those variables that feature quality in the healthcare.

In particular, we conducted a scoping scientific literature review, based on the results of the research on the main scientific databases (Scopus, Science Direct, EBSCO Host, Inder Science, Thomson Reuter's Web of Science, and Google Scholar). The retrieved studies are summed up in this contribution, in the mean to connect the healthcare audit structure and the healthcare quality requirements. The second paragraph explores the principal audit activity features and the healthcare organizations peculiarity; the third paragraph individuates the main audit activities performed in the healthcare. The fourth paragraph defines the theoretical framework of connection between audit activities and quality of the service. The fifth paragraph concludes.

## 2. Audit activity insights

Any organization needs to improve quality in an organization, whether it is process quality, management quality, product quality, financial efficiency, effectiveness, or reporting quality, etc. This quality can be assured through the audit activity, in particular when the auditee is in doubt of its quality, condition or state of the matter and is not capable of to getting rid of these doubts or uncertainties (Lee and Alan, 1984) or when the public interest needs to eliminate information asymmetries. Management control and audit may refer to different activities within a corporate body, performed by diverse actors in different moments of the corporate life. Different meanings of the term audit and management control have been provided. The regulatory oversight is under all kinds of activities aimed at finding or verification of the degree of adherence of the work the company a provision written possessing normative (laws, regulations, statutes, procedures, etc.) (Franzoni and Salvioni, 2014).

The operation of control is the inspection, be it episodic or continuous, of the actions undertaken within the corporate body. The reference point for those who exercise this kind of control could still be compliance with written rules, but the difference compared to regulatory oversight, the audit focuses mainly on the nature of executive actions rather than on those conducted by the company's leaders (Patel and Rushefsky, 1999)Social control is the one in which companies are represented as the community of individuals (Catturi, 2003); it is natural to point out that the behavior of business operations is conditioned not only by formal mechanisms, but also by shared cultural values within the body of an economic or organizational unit (Brusa and Dezzani, 1983).
When it is right and works on social controls, it focuses points at the attitude of the individual to respect the principles of behavior and the collective operation. This form of control is relevant in the contexts in which the company staff has a highly skilled vocational training. The peculiarities of the groups of control operating in a business context, allow to explain the employee management strategies, the presence or absence of forms of cooperation among individuals and among structures in which they take part, the degree of adherence to the guidelines spelled by senior management and the staff's attitude towards users. The management control or results control constitutes a mechanism by means of which the management of a business entity is guided toward goals. What is subjected to monitoring is not the company but the result it produces. This type of control assumes that business objectives are defined and quantified and that these are reported to the responsible organizational units.
Objectives are usually expressed in quantitative or monetary terms, qualitative therefore not be translated or closely linked to the term money. The four types of corporate control are the main forms implemented in healthcare enterprises. There are no pure forms of audit and control. Very often there is a mix of more or less developed controls according to different business functions (Helms and Stern, 2001).

Healthcare enterprises feature as "professional bureaucracies" of defined organizations (Mintzberg and others, 1979). A professional bureaucracy is characterized by a number of features. First of all, several of the operations conducted within healthcare organizations are controlled by professionals; these organizational figures have a broad autonomy in performing their tasks and, often, the activities are not standardized. Therefore, it appears difficult to forecast results. The behavior professionals are strongly inspired to inspired to, is rooted in the formal and informal rules of conduct which define associations of professional category the formal and informal rules of conduct definite associations of professional category (Brescia et al., 2016). Moreover, the continuous education of professionals requires a period of training and socialization, which often takes place in a different context from what will be the organizational field (Bert et al., 2016). The power in these structures is based more on possessed skills than on the organizational position held or on specialization. Furthermore, professionals proxy the fiduciary relationship between the organization and the patients, becoming genuine mediators among them. All these features hamper the dissemination of the audit and management control activities in healthcare organizations.
Some of the aspects of the professional bureaucracy can give rise to the results of the final assessment and audit outcomes (Abernethy and Stoelwinder, 1995), in particular because of the strong professional autonomy, poor standardization and programming of healthcare service (Jones and Dewing, 1997).

Therefore the importance of the informal control and of the presence of a trust relationship between doctors and patients gathers momentum (Borgonovi, 1990). While in traditional industrial systems the features of the product or service provided can affect the relationship between the customer and the enterprise, in healthcare organization the trust relationships weighs largely on the physicians and their personal qualities. The relationship existing between doctor and patient qualifies the highlighted way due to the phenomenon in health economics known as an agency relationship established between the two roles. The patient experiences certain symptoms that suggest a decrease of ~~its~~ his level of health, but he is not able to translate it in terms of service demand. The patient should then turn to another agent, the doctor, who describes the symptoms. The doctor acts as a patient's agent making available his/her professional expertise to translate his state of need in the diagnosis, and then asks the question of performance. At this point the doctor acts as a patient's agent making available his/her professional expertise to translate his state of need in the diagnosis, and then asks the question of performance. The relationship of trust between doctors and patients can possess the obvious repercussions on the fate of the corporate management, in particular when the control had frowned upon by medical and health personnel that could exploit the relationship with the user to disable the control formalized in question. Audit and feedback generally lead to small but potentially important improvements in professional practices. The effectiveness of audit and feedback Seems to depend on baseline performance and on how the feedback is provided (Jamtvedt et al., 2006).

Audit in terms of quality management is defined as a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively in order to determine the extent to which audit criteria are fulfilled. The quality of an audit is a tool that helps to help not only improve quality, but also reduce costs. It may be defined as a systematic and independent examination to determine whether quality activities and related results are consistent with the intended purpose and whether those plans were implemented effectively and are suitable to achieve specific objectives. The term "quality management system" means an organizational structure, procedures, processes and resources necessary for the implementation of quality (Biancone et al., 2016). According to the Rational Management Theory, any organization (either private or public, whatever the dimension is) can be managed through three specific "rational" macro-phases. A first phase is called "Planning". In this phase, all the initiatives and actions are forecasted, planned and defined coherently with the vision, the mission, the target and the budget of the organization. In the second phase, named "Executing", those actions are implemented and performed. In the third phase, titled "Controlling", a gap analysis is conducted between the deliverable and the achieved performance; therefore corrective actions can be proposed and implemented. The three phases are cyclic and backed by several documents, in particular budgeting statements and reports, accountancy and final balance statement (Puddu, 2011), under the financial, economic and, preferably, social aspects (Migliavacca et al., 2016).

A poor quality product in the industry definitely does not have such a great impact on the quality of the client's life as a poor customer service provided in healthcare, for this reason the monitoring of the quality of service will acquire a connotation of ethics and good practice (Kinn, 1997) Some disadvantages of audit were perceived as diminished clinical ownership, fear of litigation, hierarchical and territorial suspicions, and professional isolation. The main barriers to clinical audit can be classified under five main headings. These are lack of resources, lack of expertise or advice in project design and analysis, problems between groups and group members, lack of an overall plan for audit, and organizational impediments. Key facilitating factors to audit were also identified: they included modern medical records systems, effective training, dedicated staff, protected time, structured programs, and a shared dialogue between purchasers and providers (Johnston et al., 2000). Clinical audit can be a valuable assistance to any program which aims to improve the quality of health care and its delivery. Yet without a coherent strategy aimed at nurturing effective audits, valuable opportunities will be lost. Paying careful attention to the professional attitudes highlighted in this review may help audit ~~to~~ deliver on some of its promise.

## *3. Audit and the healthcare organizations*

Managerial and financial control and audit are crucial whatever the kind of organization or the service provided(Spano and Tradori, 2015). In the healthcare, both the health and prevention right for all the human beings address the control activity to foster the conformity of the service provision to the evidence-based medicine best practices, to the law enforcements and to the customer satisfaction and perceived quality. Moreover, audit and control in the healthcare ensures the public and private interests satisfaction, though in the last years the world economic environment had caused a continuous expenditure reduction for the healthcare, in particular in those countries where the healthcare is a public-provided and constitutionally granted service. The lack of (public) financial resources obligate healthcare organizations to seek for the most efficient ways to supply their services, without affecting the quality and not excluding people from the service, though ensuring pertinence to the (public) funder.

All these requirements broach to the importance of a thorough audit and control activity in the healthcare organizations. Traditionally, those control activities focus on the mere financial accounts, law requirements fulfillment and economic efficiency of the structure. In particular, we can pinpoint two families of audit and control activities(Shaw, 1980):

- internal audits, which are controls carried out by the organization personnel, devoted to the efficiency, effectiveness, pertinence and safety of supplied services, whose outcome is represented by internal reports for managerial advisory;
- external audits, performed by independent third parties on the entire organization, based on explicit criteria (e.g. Joint Commission International, Accreditation Canada, ISO certifications, other institutional systems, etc.);

  which can be furtherly classified (Shaw, 2000)in:
- first party audit, when the auditor is internal to the organization;

- second party audit, when the auditor is external but directly mandated by the management, e.g. outsourced audit;
- Third party audit, performed by external and independent entities (JCI, etc.).

In the healthcare organizations, due to their peculiar services and customers, different audits are performed for different reasons. Financial and economic audits evaluate financial efficiency, resources management, expenditure policies(Bovaird, 2009), while Managerial audits assess the organizational processes of the healthcare services, e.g. informative systems, pharmaceutical stocks management, etc.(Nabelsi and Gagnon, 2016; Scott and Westbrook, 1991).

At a broader level, system audits focus on a single hospital structure, or parts of, or on an entire healthcare district and National and regional audits generally focus on specific issues, with multi-centered studies to address problems investigation(Baldassarre et al., 2016; Gervasio et al., 2017).

Moreover, often the healthcare organizations undergo to a Quality or Certificatory audit, provided by third entities to achieve the certification under precise regulations, such as ISOs and similar quality standards(Tricker, 2016). Furthermore, the healthcare prevalent audits are the Clinicalaudit (Cunningham et al., 2016), either peer-reviewed or external, which analyzes the practices of the physicians and the related clinical risk management, and the Medical audit (Herrscher and Goepfert, 2016), which analyzes the health care process for the patients, and distinguishes itself from other audits for its utterly specific professional requirements.

Medical and clinical audits are voluntary managerial and quality improvement policies, which have systematic and formalized approaches. The difference underlying the two types of audit concerns the aspects included in the analyses, exclusively medical and care-related for the medical audit, and inclusive of the structural, procedural and outcome aspects in the clinical one.

The structure evaluation in clinical audit is cyclical and step-conceived: definition of health care quality criteria; data collection; performance evaluation and comparison with the standards; gap analyses; quality improvement through clinical and management change implementation(Engle et al., 2017; Weaver et al., 2016).

On the contrary, the medical audit does not include the structure evaluation, and focuses on healthcare aspects different from time to time. Those aspects are individuated at both a local general level and a hospital level. The medical audit has nine areas of interest for the medical audit, and various dimensions are taken under consideration by medical audits(Huges and Humphrey, 1996):

1. practice activity analysis;
2. case studies;
3. disease and process audit;
4. seeking patients' view;
5. service indicators and the use of routinely available information;
6. working in peer groups;
7. practice visiting;
8. practice annual reports;
9. prevention and facilitation activities.

Each of the areas individuated tries to solve one of the problems of the medical audit, such as care activity description and measurement, data collection and assessment, reporting of the data and evaluators' role.

## *4. Healthcare and quality*

The concept of quality in the healthcare has been thoroughly investigated by researchers across the world, independently on whether the healthcare service is granted publicly or supplied by private companies. Quality is a subjective point of view, depending on the grade and type of involvement of the single person in the organization(Mosadeghrad, 2014).

In particular, it is directly linked to the patient's and relatives' satisfaction (Laroche et al., 2005), together with their loyalty (Boshoff and Gray, 2004; Kasiri et al., 2017) and the economic health of the organization (Alexander et al., 2006; Ittner and Larcker, 1997; Lega et al., 2013). As Lohr (1991) pointed out, a quality provision of healthcare services increases the likelihood of meeting the desired care outcomes and is consistent with the current medical knowledge.

From the patient's point of view, on the other hand, the supply of medical services meets the quality requirements when their performance "maximizes benefit to health without correspondingly increasing the risk" (Donabedian, 1980) and when the "provision of care exceeds patient expectations and achieves the highest possible clinical outcomes with the resources available" (Øvretveit, 1993). A rather recent study individuated some of the most important attributes a quality healthcare service should have (Mosadeghrad, 2012). In the study, a questionnaire was provided to different people, either patients, physicians, nurses, managers and with different degrees of instruction. The study identified one hundred and eighty one attributes, as reported in table 1.

| | | | | |
|---|---|---|---|---|
| Acceptability | Collaboration | Empowerment | Kindness | Responsibility |
| Accessibility | Colour | Enthusiasm | Legitimacy | Responsiveness |
| Accountability | Comfort | Environment | Listening | Result-oriented |
| Accreditability | Commitment | Friendliness | Love | Re-usability |
| Accuracy | Communication | Equality | Loyalty | Robustness |
| Ability | Comparability | Equity | Maintainability | Safety |
| Adaptability | Compassion | Ethics | Measurability | Satisfaction |
| Adaptively | Competence | Evidence-based | Motivation | Security |
| Adequacy | Competitiveness | Excellence | Necessity | Sensitivity |
| Advisability | Completeness | Exclusivity | Objectivity | Shape |
| Aesthetics | Comprehensibility | Existence | Openness | Size |
| Affordability | Concern | Expertise | Orderliness | Skill |
| Amenities | Confidence | Extensibility | Passion | Soundness |
| Appearance | Confidentially | Facilities | Patience | Speed |
| Applicability | Conformity | Familiarity | Patient-centeredness | Stability |
| Appreciability | Conscientiousness | Fault-free | Performance | Structure |
| Approachability | Consideration | Feasability | Pleasantness | Suitability |
| Appropriateness | Consistency | Flexibility | Politeness | Support |
| Assurance | Continuity | Formality | Precision | Sustainability |
| Attentiveness | Convenience | Friendliness | Predictability | Sympathy |
| Attitude | Cooperation | Funciotnality | Presence | Timeliness |
| Attractiveness | Coordination | Growth | Price | Tranquillity |
| Authenticity | Correctness | Guidance | Privacy | Transparency |
| Authority | Courtesy | Health | Professionalism | Trustworthiness |
| Autonomy | Coverage | Helpfulness | Profitability | Understanding |
| Availability | Creativity | Honesty | Prudence | Uniformity |
| Awareness | Credibility | Hospitality | Punctuality | Uniqueness |
| Balance | Creditworthiness | Humanity | Purity | Usability |
| Beauty | Dependability | Individuality | Quiet | Usefulness |
| Benevolence | Durability | Informative | Readability | Utilisazion |
| Brightness | Ease | Innovativeness | Reasonableness | Validity |
| Capacity | Education | Integrity | Relevance | Value |
| Care | Effectiveness | Intelligence | Reliability | Visibility |
| Cheerfulness | Efficacy | Intensity | Repeatability | |
| Choice | Efficiency | Involvement | Reputation | |
| Clarity | Eligibility | Joy | Respect | |
| Cleanliness | Empathy | Justice | Response | |

**Table 1 - Quality healthcare service attributes (Mosadeghrad, 2012) - our formatting**

All the attributes identified have been furtherly classified in two main categories: tangible and intangible. The tangible attributes of healthcare services, entitled "Environment", concerns the physical facilities and the professionals, technicians and other personnel involved in the provision of the service. Intangible attributes of quality healthcare services are furtherly divided in four sub-categories: "Empathy", "Efficiency", "Effectiveness" and "Efficacy".

In particular, "Empathy" refers to the ability of understanding and caring provided to the customers, including interpersonal relations attributes such as effective listening, trust, respect, confidentiality, courtesy, sympathy, understanding, responsiveness, helpfulness, compassion and effective communication between providers and clients.

The "Efficiency" attributes are those which refer to the quantity and quality of resources involved in the provision of the service, and shows the ratio between the costs and the benefits of it. "Effectiveness" and "Efficacy" of care refer to the degree to which the organization achieve the expected results and outcomes (both clinical and financial).This framework, called of "Five E's", is capable of define all the attributes (and the relevance to each category of people involved in the healthcare service) that have to be taken under consideration for a high-quality care service.

In particular, we can argue that a healthcare service that has a good Environment, highly Empathetic and Effective (under the clinical and medical point of view) can also achieve a good Efficiency and Efficacy under the economic and financial dimensions (Dahlgaard et al., 2011; Kaplan, 2012; Liu et al., 2006; McDermott et al., 2011; Navarro-Espigares and Torres, 2011).

### *5. Seeking quality in the healthcare through audit activities: a theoretical framework.*

As stated previously, the quality in any organization, in the service provided and in the processes undergoing in its structure, can be assured through the audit activity. This happens in particular when the auditee is in doubt of its quality, condition or state of the matter and is not capable of to getting rid of these doubts or uncertainties (Lee and Alan, 1984).

In the healthcare organizations, the audit is various and structured in different typologies (see par. 3), so that the activities might be under control by several different professionals or organization's personnel. In the healthcare, in particular, the presence of audit not strictly related to the financial and economic aspects of management, to foster the maximization of the outcome in the defined quality attributes, the audit activity should be focused on an holistic approach, where the whole activity is audited and taken under control, suiting the needs of the organization's management.

The theoretical framework proposed in order to ensure the meeting of quality healthcare requirements, can be individuated as the "P.R.A.C.T.T.I.C.S." approach, whose name is derived from the acronym of the assumptions of the framework.

**Periodicity**: audit is planned, must be recurrent and continuous, performed step by step, and this leads to the necessity of conducting periodic audits, whatever the typology of audit is under consideration, in order to achieve the best result with limited (time) resources;

**Relevance**: auditors cannot consider all the aspects of the organizations' activities, and must perform risk management practice to cover the uncertainties and potential events that have the most important (negative) effects if occur or have the greater probability of happening.

**Accountability**: the individuation of the accountable subject in each step of every audit activity, both for the auditor and the auditee, must be conducted thoroughly, in order to keep all the components of the organizations aware of their risks and responsibilities and consenting a better overall performance, even if the accountability for the auditors is questioned by professionals over academics (Gendron and Bédard, 2001).

**Cyclicality**: the audit process is divided in three separate phases of activity, called Programming, Executing, Controlling (Migliavacca et al., 2016; Puddu, 2011) that are recurrent and continuous.

**Thoroughness**: audit must cover all the aspects of the management of an organizations, being them related to law, financial aspects, clinical or medical occurrences, process necessities, and so on, under the relevance assumption.

**Task separation**: in order to improve the quality of the audit activity, and reduce risks related to errors, manipulation or frauds, each control task and the related responsibilities must be cross check and separation amongst relevant areas of accountability.

**Independence**: both in the literature and the practice, an effective independent audit Committee is seen as one of the determinants of audit service effectiveness (Al-Ajmi, 2009; Dhaliwal et al., 2006).
**Competence**: the expertise of the auditors in the area of analysis and the observance of high quality standards are a main driver of a service quality driven audit (Eichenseher and Shields, 1983; Shockley and Holt, 1983).
**Structure**: due to the complexity of the healthcare organization, and its diffused professional ties, the different typologies of audit must be well structured, and must communicate between each other, in order to achieve a better understanding of all the areas audited (for instance, between the clinical audit and the financial audit, where the effect of a treatment must not be constrained by cost-cuts when the effectiveness and the impact on the patient is preferable to a financial saving for the organization, and so on), avoiding litigations between auditors (Palmrose, 1988).

## *6. Conclusions and open questions*

The evaluation of healthcare quality is certainly a complex subject, also due to the fact that it is a multidimensional concept, but is an important determinant of the systematic improvement. The criteria of timeliness, accessibility, acceptability, appropriateness and safety contribute to expressing aspects of efficacy, can be considered also not as autonomous evaluation criteria, but as its members, even as its preconditions. On the other hand, the audit produces a list of corrective actions (or improvement actions) of the profiled process, which, once approved, are put in place to overcome the weaknesses found and thus achieve higher levels of quality.The audit allows a more efficient reallocation of resources, the identification of process innovations, the boost to collaboration and will share solutions for improvement. In this contribution, that is a preliminary theoretical analysis, we analyzed the importance it has a "good audit" on the quality of the healthcare service. In the future, we aim to analyze whether the link between audit and quality is really present, and through questionnaires and interviews and data analysis, we analyze quantitatively the phenomenon.

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