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Healthcare quality costs based on an ISO 9000 model

Leonardo Sedevich-Fons
Department of Management Control, Núcleo de Asistencia Profesional, Córdoba, Argentina

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Abstract

Purpose – The purpose of this paper is to put forward a quality cost management model for healthcare organizations, which is based on the quality management systems proposed in ISO 9000 international standards.

Design/methodology/approach – The model suggested here arose from the individual study of quality in healthcare, quality management systems and quality cost theories; and the analysis of problems emerging when these tools are combined in practice.

Findings – The traditional quality cost model, usually implemented in manufacturing companies, can also be applied to healthcare organizations that manage their processes according to ISO 9000 quality management systems.

Research limitations/implications – This document is a general description of the model proposed and, therefore, just presents overall guidelines to managing quality costs in healthcare organizations.

Originality/value – Since most healthcare organizations are still stuck in the quality assurance stage, there has been little research conducted on quality cost specifically focused on this industry.

Keywords Health care, Quality management, Budgetary control, ISO 9000 series, Quality in healthcare, Quality management system, Quality cost, Total quality management

Paper type Research paper

1. Introduction

Originally, quality programs merely included activities involving product inspection at the end of the production line in order to detect noncompliance with specifications. With the passing of time, quality control was complemented with root cause analysis and failure prevention activities through the use of statistical tools, thus giving rise to quality assurance. Both quality control and quality assurance were thoroughly focused on fabrication tasks and therefore mainly applicable to product manufacturing companies.

Over the last few decades the unit of analysis of quality programs has shifted from the product to the process, and their scope has widened to encompass every activity that can affect overall effectiveness and customer satisfaction. One of the most well-known quality models that emerged during this period at international level is the ISO 9000 Quality Management System (QMS), which is based on the process approach. According to these standards, organisations should be managed as a system consisting of four cyclic sequential macro-processes: management responsibility; resource management; production or provision; and measurement, analysis and improvement (International Organization for Standardization, 2008). As these new more flexible systems were implemented, quality programs were no longer limited to manufacturing companies but started to be applicable to other industries, such as those providing services.

At the present time, quality programs are evolving towards a philosophy called Total Quality Management (TQM) whose primary objectives are continual improvement and

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long-term sustainable growth. This concept is based on QMS principles such as effectiveness and customer satisfaction, but also takes into account efficiency and resource optimisation through the use of economic measurement tools such as quality cost.

The purpose of this document is to describe a quality cost model for healthcare services that helps these organisations move towards the TQM concept, taking as a reference the QMS model proposed by ISO 9000 international standards. Nonetheless, there are some factors that make this task difficult. First, "... in most of the world, healthcare organisations and services are operating at or below the stage of quality assurance" (Clinical and Laboratory Standards Institute, 2004) and therefore the use of ISO 9000 QMS is not widespread in this industry. Second, some intrinsic limitations make the existing Quality Cost theory difficult to adapt to the ISO guidelines, not least for organisations providing services. Therefore, before proposing a healthcare quality cost model, it is mandatory to address these two difficulties individually.

Section 2 is intended to solve the first of these problems by offering a QMS model which is specifically formulated for healthcare organisations and which fulfills the requirements set out in ISO 9001 international standard. Afterwards, section 3 suggests some adjustments that should be made to the traditional quality cost theory so that it becomes suitable for QMSs, thereby providing a solution to the second problem. Finally, the main topics related to quality cost management in healthcare organisations are analysed in section 4, including the description of different categories, a measurement methodology and the benefits of its implementation. An outline of the contents of this paper, describing the components of the main model suggested, is shown in Figure 1.

2. Quality management systems in healthcare institutions

2.1 From quality assurance to quality management

The concept of Quality in Healthcare has been defined from various points-of-view by different international agencies over time. A fairly complete, precise definition is that introduced by the Council of Europe, that asserts that "Quality of care is the degree to which the treatment dispensed increases the patient's chances of achieving the desired

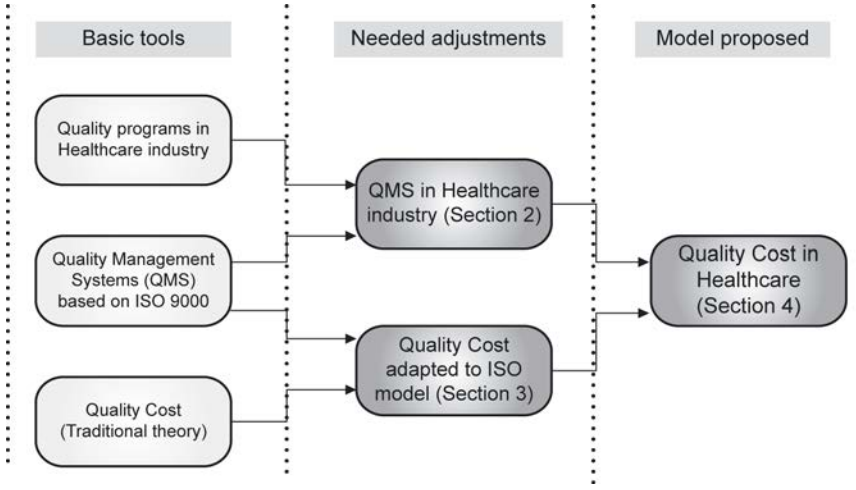

Figure 1.
Component parts of a healthcare quality cost model based on ISO 9000

results and diminishes the chances of undesirable results, having regard to the current state of knowledge" (1998, cited in Legido-Quigley *et al.*, 2008).

Quality in healthcare comprises a group of aspects or dimensions associated with this service, such as effectiveness, efficiency, access, safety, equity, appropriateness, timeliness, acceptability, patient centredness, continuity of care, and evidence based treatment. Hospital Accreditation, a model initially suggested by the Joint Commission on Accreditation of Healthcare Organisation (JCAHO), is probably the main ongoing international initiative aiming to foster Quality in Healthcare. It consists of a procedure by which an external party assesses the degree of compliance of the organisation services with those dimensions previously mentioned. From this, it may be inferred that both quality concept and quality programs being used at present in healthcare belong to the quality assurance stage and, therefore, most institutions within this industry have not as yet implemented a QMS.

The reasons for which healthcare quality programs are less developed than those of other industries are related to particular characteristics of this service. First, it is believed that the significance of customer satisfaction in healthcare is limited because patient perception is not always representative of the quality level and because strong government regulations do not allow raising prices due to higher quality. Furthermore, process standardisation is considered to be a more complex task in healthcare, given that the effects of medical treatments on human beings are much less predictable than those of fabrication activities on products. Finally, it is asserted that international recognition, such as ISO certification, is seldom a necessity for these kinds of organisations because, with some exceptions, healthcare services are not typically for export.

Despite these complicating factors, it is proven that QMSs have been formulated to enhance the performance of organisations of any type (public or private) belonging to any industry sector (product or service), thereby including healthcare institutions. Some of the advantages of implementing a QMS, if as compared to typical quality assurance programs, are as follows:

- It fosters organizational continual improvement rather than trying to achieve a temporary state of wellbeing to pass an audit.
- It allows aligning the specific objectives of each medical department with the overall policies of the institution.
- It involves process standardization through the use of documented procedures, thereby helping clinicians detect and correct errors.
- It takes into account every process of the organization, including ancillary activities such as food provision to patients, invoicing tasks and IT management.
- It considers patient and family members' satisfaction, which has a strong impact on the reputation and image of any care organization.
- It permits demonstrating the implementation of quality programs through certification to international standards, which might be a distinguishing feature of any institution.
- It serves as a solid base for implementing other specific quality actions to comply with mandatory models such as Hospital Accreditation programs.

As a consequence of the diffusion of the benefits that health services may obtain from QMSs, some formal guidelines promoting the use of these programs have emerged in the last few years. Two of the most acknowledged standards in this field are the "IWA

1: Quality management systems – Guidelines for process improvements in Health Service Organizations" (International Organization for Standardization, 2005) and the "HS1-A2: A Quality Management System Model for Health Care" (Clinical and Laboratory Standards Institute, 2004). Another important initiative in this field is the National Integrated Accreditation for Healthcare Organizations program, which was introduced in the US in 2008 so as to integrate the traditional Hospital Accreditation requirements and those included in ISO standards (Det Norske Veritas, 2010).

2.2 ISO 9000 quality management systems in healthcare

As mentioned in the introduction, QMSs based on ISO 9001 international standard suggest the use of the process approach, which comprises four main activities: Management responsibility; resource management; production or provision; and measurement, analysis and improvement. Figure 2 displays an ISO QMS model in a form specifically applicable to healthcare organisations.

This system comprises four macro-processes each of which consisting of several activities:

(1) *Planning*: This macro-process includes three processes that are carried out by top management. The first one involves setting out general objectives and formulating the strategy to achieve them, taking into consideration the organization's mission, vision and policies. Subsequently, managers must design the institution process map (such as the one shown in Figure 2 but with a higher degree of detail), implement document and record control guidelines (considering integrity and confidentiality issues), and launch the procedures and forms necessary to operate the system (such as clinical protocols and medical history forms). The third activity of this macro-process requires top managers to periodically review the data generated by the system's measurements and then to determine overall improvement actions.

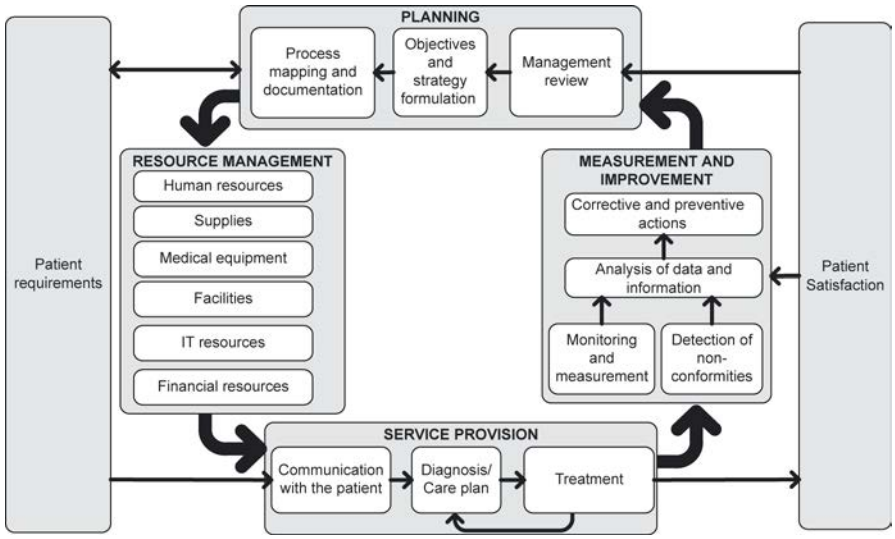

Figure 2.
QMS in healthcare organizations

(2) *Resource management*: The main purpose of this macro-process is to identify and supply the means needed to achieve the organizational objectives. It usually comprises several activities for each kind of resource. Human resources management encompasses both workforce development activities (job profile formulation, recruitment, performance appraisal and training) and personnel administrative tasks (new staff paperwork, payroll chores and employee database maintenance). Supplies management involves the purchase, storage and distribution of drugs (analgesics, antibiotics, vaccines) and other medical supplies (syringes, bandages, lancets); as well as supplier relationship activities. Medical equipment management comprises several processes, such as analyzing the needs for new machinery, making purchase decisions, selecting suppliers, monitoring equipment performance, and carrying out maintenance and calibration work. Facilities management includes different issues concerning the overall infrastructure (such as space allocation, ventilation, lighting, temperature, emergency exits, signage, parking and waiting rooms) and others related to clinical support services (such as maintenance, cleaning, food provision, electric power, security, and medical waste disposal). IT resource management entails planning, providing and maintaining the hardware devices and software systems which are necessary to manage all the organization's processes. Finally, financial resources management involves the assessment of needs and availability of funds and the performance of other money-related tasks; including collection of accounts receivable (from patients and health insurance institutions), bank deposits and withdrawals, supplier and employee payments, and loan requests.

(3) *Service provision*: This macro-process comprises all the specific clinical activities grouped into three main processes:

- Communication with the patient includes some administrative activities as well as several clinical processes. The first group is composed of patient reception, personal data collection, signing of forms, delivery of information, appointment arrangements, and billing for initial practices; while the second group encompasses the preliminary examinations and tests, performed either in the emergency room or at scheduled appointments.
- The second process must be performed by the general practitioner once the necessary clinical exams have been carried out and its main purposes are to determine the diagnosis and to formulate the care plan for the patient. This care plan may comprise different sub-processes such as inpatient care, outpatient treatments, different kinds of medical tests, or a combination thereof. Moreover, this process also requires monitoring the treatment as it is administered and, if necessary, its reformulation.
- The last process involves the medical treatment itself. It encompasses a set of sub-units such as operating theatres, inpatient units, outpatient offices of different specialties, laboratories and imaging rooms. Furthermore, each of these sub-units entails various clinical activities (patient assistance, surgeries, nursing work, admissions and referrals) as well as several administrative tasks (filling out of forms, billing of services, etc.). The way in which these activities are linked may vary in different organizations.

(4) *Measurement and improvement*: This macro-process includes some processes which are detailed in chapter 8 of ISO 9001 international standard (International

Organization for Standardization, 2008). First, the organization must implement activities to monitor and measure patient satisfaction (through surveys), the effectiveness of medical treatments (through a non-conformity procedure), the achievement of goals of every process (through performance indicators) and the design and functioning of the QMS (through internal audits). Once this data has been collected it must be summarized and completed in order to obtain information that allows managers to learn about the degree of attainment of the general objectives set out during the "Planning" macro-process. Lastly, after having analyzed this information, improvement decisions have to be made which may involve corrective and preventive actions.

3. Quality cost applied to QMSs

3.1 From the original theory to quality management principles

The original Quality Cost theory was first put forward in the middle of the last century as a complement to quality assurance programs. According to it, quality cost is "the cost of carrying out the company's quality mission (meeting the quality needs of consumers)" (Juran, 1962), and may be divided into two broad categories: conformance cost and non-conformance cost.

On the one hand, conformance cost includes all expenditure relating to measures undertaken to minimize product failures. This category is usually split into prevention costs, which are those incurred to avoid failures; and appraisal costs, whose main objective is to detect failures. On the other hand non-conformance cost is composed of the amount of money spent due to failure occurrence. This second category may be disaggregated into internal failure costs (if the failure is detected by internal inspection) and external failure costs (if the defect is discovered by the customer).

The aim of this theory is to predict and display the behaviour of quality costs in a given situation, as it is exhibited in Figure 3.

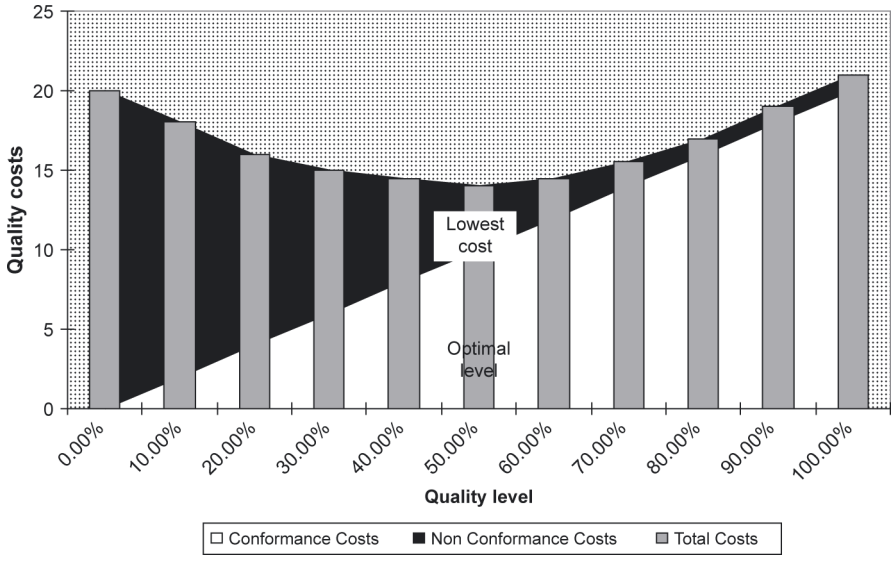

Figure 3.
Quality cost – classical view

Figure 3 shows that as organisations become more concerned about quality, conformance costs increase and non-conformance costs decrease. Total quality costs may be calculated adding both categories for each different quality level. The optimal situation is that level for which total quality cost reaches its lowest possible point.

Despite the fact that this theory has been highly relevant for quality assurance programs, it presents some inconsistencies with current QMSs. One of its limitations is related to the composition and classification of quality costs. First, conformance costs only consider short-term activities associated with manufacturing processes, such as training for production employees, equipment preventive maintenance and product inspection. Furthermore, non-conformance categories solely take into account costs generated in production areas such as those of waste raw materials, manufacturing reprocesses and compensations to customers. Moreover, although this theory explains the behaviour of incurred expenses it disregards opportunity costs, such as earnings forgone because of quality defects.

Some other constraints of the classical Quality Cost model displayed in Figure 3 are those concerning its methodology and purpose. First, this method assumes that the relationships between conformance activities and failures are accurately known, which may be feasible in processes using industrial machinery and raw materials but it becomes more complex in service, management, and support activities. Besides, the principal objective of this theory is to find the short-term optimal situation to reduce costs, whereas the QMS main concern is to improve customer satisfaction.

3.2 Quality Cost theory adapted to the ISO model

From the previous it may be concluded that using Quality Cost principles as a complementary tool for QMSs requires introducing some changes to the original theory.

As for composition and classification, conformance cost should incorporate long-term overall measures into its scope, such as documentation of procedures, training for suppliers and internal audits. Likewise, non-conformance cost, besides focusing on manufacturing activities should also include failures occurring in support processes such as commercialisation, purchasing, human resources and finance. Moreover, apart from considering the direct effect of failures, quality cost should take into account their indirect impacts, such as the decrease in production volumes or the loss of potential sales.

Furthermore, the methodology and purposes of this traditional theory should be reviewed. That is to say, Quality Cost must not be regarded as a predictive tool but rather as an instrument complementary to past performance indicators that the QMS provides. In other words, the main objective of the model has to be to convert physical measures supplied by the QMS (such as hours of training, product units rejected or customer satisfaction degree) into monetary units. As a result, the ultimate function of quality cost measurement would shift from the determination of the short-term optimal situation to the contribution to achieving long-term continuous improvement.

Bearing in mind the adaptations previously described, the quality cost theory may be reformulated to make it compatible with the ISO QMS model. For this purpose, it may be asserted that quality costs "... represent the amount of money that a company has relinquished (either expended or not obtained) due to ineffectiveness or inefficiency when developing its activities" (Sedevich Fons, 2011). Moreover, these expenditures should be classified into three broad categories: Conformance cost, including money spent on both short and long-term prevention and appraisal actions; direct non-conformance cost, encompassing amounts paid because of internal and external

failures occurred in every process; and indirect non-conformance cost, consisting of potential earnings lost due to those internal and external failures.

4. Quality cost model in healthcare organizations

4.1 Composition and classification of quality costs in healthcare

The management model presented in this section is the result of applying the reformulated Quality Cost theory described in section 3 to the healthcare ISO-based QMS disclosed in section 2 (see Figure 1). According to this proposal healthcare quality costs might be divided into conformance costs, direct non-conformance costs and indirect non-conformance costs.

Conformance cost represents the monetary value of the different resources (labor, supplies, equipment, facilities and IT) consumed in all the activities the QMS involves, be it in general or in a specific process. As previously mentioned, conformance cost comprises prevention and appraisal costs:

- Prevention costs are those incurred to carry out activities necessary to avoid failures or errors, such as training for personnel or documentation of procedures. At the level of the organization as a whole, the best examples of preventive actions are those belonging to the "Planning" macro-process, such as the strategy formulation, the process mapping and the management review (see Figure 2). On the other hand, at the level of particular processes, measures such as training programs for nurses, preventive maintenance of imaging equipment and the implementation of billing procedures are good instances of preventive activities.
- Appraisal costs are those attributable to monitoring and inspection activities carried out to detect failures as soon as possible. Data collection, information analysis and internal audits may be cited as examples of appraisal work at the top management level, whereas patient surveys and inspection of stored medications are typical actions for specific processes.

Direct non-conformance cost consists in the monetary value of all the resources (labor, supplies, equipment, facilities and IT) wasted due to past failures or errors. This broad category is usually split into internal and external failure costs:

- Direct internal failure costs are generated by failures or errors occurring in different processes of the organization, but whose effects are not perceived by patients. This category is composed of the cost of the resources consumed in measures carried out to solve those internal failures, such as the repetition of analysis of blood samples, the disposal of expired medication or the rebilling of services.
- Direct external failure costs are those incurred due to failures or errors that, in contrast to the internal ones, have an impact on the patient's perception. Besides the costs of resources used to rectify the failures, this item includes the compensation payments to patients. A good example of external failure is a botched surgery, whose consequential costs could encompass the monetary value of the resources employed in a reconstructive procedure plus the payments made in response to a malpractice claim.

Indirect non-conformance cost is not money spent on resources, but rather profits forgone due to failures or errors occurring during the normal course of operations. These kinds of costs may also be sub-classified into internal and external.

- Indirect internal failure costs are incomes the organization relinquishes because of errors not affecting the patient's impression (internal failures). They typically comprise potential earnings the organization does not realize due to under-utilization of its nominal capacity. For instance, if the appointments for imaging tests are not accurately programmed, the level of activity of this department might be lower than optimal thereby causing revenue losses.
- Indirect external failure costs consist in earnings the organization loses due to a decrease (or a lower-than-expected increase) in the number of patients because of external failures. There are different kinds of these external errors that might cause this undesirable situation. On the one hand, a significant failure, such as a serious malpractice case, could harm the organization's reputation and therefore cause an overall decline in its level of activity. On the other hand, smaller flaws such as errors in laboratory results or mistakes in scheduling appointments might encourage patients to choose a different healthcare provider.

It is important to mention that in the healthcare industry the classification of some items into the quality cost categories previously defined may present certain difficulties. The following are examples of these ambiguous cases:

- Measures that are conceptually "preventive actions" but whose associated expenditures must not be considered quality costs since they are planned steps included in medical procedures. For example, the administration of a drug to a patient in order to prevent further complications.
- Measures that are conceptually "appraisal actions" but whose associated expenditures should not be deemed quality costs given that they are also part of medical procedures. For instance, a preoperative blood test to verify that the patient is in proper condition to undergo a surgery.
- Additional steps that must be performed due to undesirable effects of a procedure, but whose associated expenditures are not quality costs since such results are not caused by failures. For example, a modification introduced in a treatment given that the patient does not respond as expected due to reasons not attributable to errors in the procedure's execution.
- Errors that initially seem to be "internal failures" but are actually "external failures", and so are their costs. For instance, an incorrect dosage of medication administered to a patient that does not cause adverse effects immediately but that could do so later.
- Measures whose costs appear to be "conformance costs" but actually belong to the "non-conformance" category. For example, despite the fact that taking out a malpractice insurance policy contributes to "prevent" the organization from having to pay large sums of money, the premium should be considered an external failure cost instead of a prevention one, given that this expenditure is a consequence of errors.

These particular cases do not represent a major problem for measuring quality costs since perfect accuracy is not essential. Nevertheless, it is imperative to establish criteria to classify the different items in order to make them comparable over time.

4.2 Measurement of quality costs in healthcare

In order to estimate the quality costs for a given period, three main tasks must be performed: Identifying the cost factors or items, describing their effects, and assigning them monetary value. Those healthcare institutions having implemented a QMS model according to Figure 2 are ready to carry out these activities.

First of all, the organisation has to identify the factors causing quality costs, which are the prevention and appraisal actions that have been implemented (conformance costs) and the internal and external failures that have occurred (direct and indirect non-conformance costs). On the one hand, prevention and appraisal measures such as a training program for nurses or the implementation of a patient survey may be identified through the QMS records kept in both the "Management review" and the "Corrective and preventive actions" processes. On the other hand, information on internal and external failures such as the expiration of stored medication or a botched surgery can be found in the QMS records of the "Detection of non-conformities" process.

Once the quality cost factors have been identified their effects must be described. This stage involves calculating the amount of resources consumed by each conformance measure and each failure (direct effects) and estimating the number and kind of services lost for each failure (indirect effects). As far as direct effects are concerned, a breakdown of the resources used to carry out conformance measures and to solve failures may be obtained from the QMS records kept in the different processes forming the "Resource management" macro-process (human resources, supplies, equipment, facilities and IT processes). As for indirect effects, estimates can be made of the additional medical services the institution would have provided had it not committed internal and external errors, by means of analyzing the different reports and indicators issued by the "Analysis of data and information" process.

Finally, both direct and indirect effects must be valued in monetary terms. This task requires having updated information on the unit costs of the different resources and the unit price of the various medical services. Unit cost data are readily available in the QMS records of the "Resource management" macro-process, but especially in those generated in accounting sub-processes such as supplier payments, payroll and depreciation calculation. Similarly, unit price data may be found in some of the QMS records kept in the "Service provision" macro-process, namely in those managed in accounting sub-processes such as service billing.

4.3 Benefits of quality cost management in healthcare

Those healthcare organisations whose activities are managed according to traditional QMS requirements are able to elicit relevant non-financial information on their performance. For example, managers could learn that implementing a new procedure for patient reception has reduced the average waiting time by ten minutes, or that training nurses in key skills has decreased the consumption of medications and disposable supplies by 30 per cent. Undoubtedly, this kind of information is extremely useful as it makes it possible to know whether the actions undertaken have had positive impacts on both process effectiveness and customer satisfaction, which constitute the essence of QMSs. Nonetheless, such indicators fail to consider the monetary effects of those actions. That is to say, a ten-minutes reduction in the patient average waiting time demonstrates a considerable improvement in performance, but it does not inform as to whether the benefits of such a reduction outweigh the costs of having implemented the new patient reception procedure. Likewise, these measures do not provide evidence to confirm that a decrease in the use of medications and

disposable supplies by 30 per cent is enough to compensate for the cost of the training program for nurses.

Quality cost management represents an appropriate complement to QMSs, given that it incorporates monetary units into the traditional analysis thereby solving the problem mentioned in the previous paragraph. In other words, it enables managers to know the economic effect of prevention and appraisal actions through comparing their costs with their benefits. For example, in the first case mentioned previously, quality cost reports would say that the cost of implementing a new procedure for patient reception was $ 100.00 (prevention cost) whereas the benefits brought about by the 10-minutes reduction in the patient waiting amounted to $ 300.00 (avoided indirect failure cost). Similarly, in the second case, these reports would show that although the training program for nurses had a cost of $ 200.00 (prevention cost) it was outweighed by the profits generated by the decrease in the consumption of medication and disposable supplies, which amounted to $ 500.00 (avoided direct internal failure cost). In summary, quality cost information allows managers to know the economic benefits of having implemented the actions suggested by the QMS.

Consequently, it may be asserted that Quality Cost management helps healthcare institutions enhance their "Measurement and Improvement" macro-process given that it informs about the economic effects of each quality action taken. Moreover, adding together the profits from all these actions, managers can estimate the overall net income generated by the QMS as a whole. This group of specific and general financial indicators certainly constitutes a valuable input to the "Management review" and "Objectives and strategy formulation" processes.

5. Conclusions

Healthcare organisations are taking the first steps towards TQM philosophy, which consists in a management approach centred on continual improvement and long-term sustainable growth. In order to reach this goal they need to consider the economic aspects of quality programs through the use of quality cost management systems. However, there are some characteristics specific to healthcare services that have hindered the achievement of this objective. One is that most healthcare quality programs are exclusively focused on clinical assurance issues, without regard for certain key aspects of QMSs. Besides, traditional Quality Cost theory is not easily applicable to these kinds of services, because it was originally developed to suit the needs of manufacturing industries.

Nevertheless, these incompatibilities can be resolved by introducing two modifications to current techniques: The first involves the development of a QMS model which, as well as complying with ISO 9001 requirements, is specifically designed to be implemented in healthcare organisations. The second adjustment consists in adapting the conventional quality cost theory to make it suitable for this healthcare QMS model.

With these modifications it will be possible to identify, classify and quantify quality costs, thereby greatly improving on the information presently available through most healthcare quality programs. As a result, healthcare organisations will be able to integrate financial indicators into their regular data analysis and thereby advance towards TQM principles.

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About the author

Leonardo Sedevich-Fons obtained a degree in Accounting from Universidad Nacional de Córdoba in 2000, and presently is studying for a PhD in Economic Science at the same institution. He held several positions in different Argentine companies before becoming a freelance adviser in 2007. Since then he has led various consultant projects for Argentine companies. As a researcher, he has taken part in several projects, presented works at international conferences and published papers in specialized journals. As a teacher he has worked as a trainer for different private companies. His areas of work and research are: management control, financial measures of quality management, quality costs, balanced scorecard, integration of accounting and quality, and strategic cost analysis. Leonardo Sedevich-Fons can be contacted at: Lsedevich@napcc.com.ar

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