



DISCUSSION PAPER

Regulation/Accreditation

If a tree fell in the forest but no one heard, is it because they did not want to hear?

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Summary

The objective of this paper is to raise awareness about the value of quality improvement (QI) methodologies and performance measurement techniques to the safety of care.

Since the times where quality improvement techniques were of exclusive use of industrial sector to nowadays, there has been a great challenge on the application of performance measurement and improvement to the delivery of health care.

Health care organizations that implement QI effectively expect to contribute for the global safety of the delivery of care. Yet, there is a lack of research to systematically demonstrate how organizational experience in QI strategies can contribute to the improvement of safety of care as well. The increase in mobility of patients within the European countries is requesting safe care across borders and the adoption of common techniques and evidence-based guidelines. A few projects have already introduced the

concept of European harmonization within external evaluation models with recommendations. Accreditation and indicators play a senior role on the external auditing methodologies and they constitute the core subject of this paper on patient safety research.

This paper presents for discussion the idea that the next step should belong to the research area within a cooperative agenda between European countries in order to set up evidence based guidelines and tools, that may contribute to the harmonization of health services delivery of care and to the excellence of European medical services.

Keywords:

Patient safety; accreditation; clinical indicators quality improvement; performance measurement

Introduction

Health is a multi factorial reality where the health care plays a significant role (Lalonde, 1974). Pressure on the health services all over the world has created the need to look to quality of services as a measurable attribute of care that needs an economic valorization and social value. Medical care initially viewed as a professional responsibility has been raised as a national policy issue and more recently as a European level policy with the patient safety agenda.

Quality improvement methodologies and techniques were originally developed in the manufacturing sector and its application to service delivery has been a challenge that has motivated experts on the last two decades.

Regarding the health sector the big challenge has been on the application of performance measurement and improvement to the delivery of care. The factors for the increasing interest on health service and systems performance are identified and consensual around main topics: rising costs of health care delivery, technological advance, aging populations, health market failures, poor quality and variations in practice, medical errors and injuries, lack of accountability, inequalities and sheer uncertainty (Kelley E. and J. Hurst, 2006b).

Quality services, in healthcare or other industries, have safety as an integral dimension of their responsibility. It is therefore not possible to think of quality separately from safety, but as an inclusive concept and strategy to assure that not only the right things are done but that they are done without harming the recipient or the provider.

Paradoxically, the healthcare systems around the world are now facing a dilemma when dealing with the “old” concept of quality and the “new” imperative of safety: *are strategies to enhance safety different from those already in place for quality/performance improvement?*

We, across the Portuguese healthcare system, may soon face the same questions as others in Europe and other continents. It is therefore important that a clear framework be designed and adopted for our healthcare system where not only the strategies for improving performance are considered, but also the way we will demonstrate that improvement has taken place and is sustained. The purpose of this paper is to address questions that are applicable to all European healthcare systems.

Also the continuous quality improvement philosophy has been the scope of the interventions to improve quality of care and reduce undesirable events despite the lack of scientific and documented evidence about the effectiveness of these efforts. Much more research has to be developed to get conclusions on these questions and on the attempt to link with performance improvement of health care organizations.

Traditional strategies and tools toward quality assurance (QA) and quality improvement (QI) as regulation, accreditation, indicators, clinical audit and peer review, etc, are accepted as positive ways to improve safety despite the lack of evidence as well.

The search for evidence of the main interventions should be addressed on international basis and as reference for policymakers and governmental strategies, both national and international.

At the same time we have observed a general growing of external inspection by the Governments interested in showing citizens that quality of care is a top priority of the political agenda. Quality and accountability concepts started to show up on most of European plans of health care. Again most of the external assessment initiatives are lacking on validity and evaluation about results of care (Shaw Charles, 2001). In fact accreditation, ISO certification, EFQM projects side by side with statutory inspection is disseminated without evidence about the clinical benefit and the differences between them.

It is a fact that a pool of several initiatives lacking integration and comparison has appeared in most of the European countries.

So two research questions ought to be addressed: (1) *In what way QA and QI techniques are able to contribute to the safety of patients and direct care providers ?* (2) *What specific elements of each technique or methodology are associated with safe care performance and which ones are not related to the improvement of patient/provider safety ?*

What is safety in the delivery of health services? And who is affected?

Safety is on the international agenda and on most of the national agendas as well. The launch of the World Alliance for Patient Safety has helped to raise patient safety to the top priorities of the political agendas. The same idea came out from the Luxembourg Declaration with a clear emphasis on the establishment of structures and processes to demonstrate tangible improvement on the safety of care.

At the same time European citizens appear to be more concerned about the risk of facing a medical error when dealing with health care services (European Commission, 2005).

Therefore there is an urgent need to assess the impact of safety strategies. The immediate question remains strategic, or at least a tactical one:

should safety be part of QI programmes, including accreditation, or should it be developed independently and in parallel ?

There are four “audiences” affected by the level of safety in health services:

1. the recipients (patients and indirectly their families);
2. the providers (medical team);
3. the community; and,
4. the financing organizations (government, private).

A safe system is therefore one that minimizes the physical and psychological harm to recipients of services; does not put the providers at risk for harm; protects the community from preventable consequences of harmful or potentially harmful care delivery; and, does not unnecessarily burden the financing of the system by providing redundant, inappropriate or inconsiderate services.

This definition aims at stressing *that safety in care is more than patient safety*. The comprehensiveness of this definition should be reflected in modern healthcare system’s vision to propose, implement, and evaluate strategies where quality and safety of care are used as a continuum, and their evaluation within the context of social expectations.

Should safety be measured differently from quality?

A look at the “safety” measures shows that the traditional and existing measures of quality/performance improvement are proposed to also be measures of safety. For example:

1. Complications of surgery (due to misuse of prophylaxis or the surgical act itself);
2. Falls (due to inappropriate medication/dose, risky environment, patient-to-nurse ratio);
3. Readmissions (due to complications or inappropriate patient/family education);
4. Returns to operating room (due to improper surgical care);
5. Mortality;
6. Patient restraints and their unnecessary harmfulness; and,
7. Etc....

These measures are at the core of many initiatives to improve safety in healthcare. Two international projects have already proposed such measures and are in the process of testing them. The WHO’s Europe Office has embarked upon an indicator project to assist European countries in introducing the concepts and tools for quantifying key aspects of clinical and organizational performance. The PATH Project was initiated in 2003 and is now in its second phase of testing (Veillard J et al, 2005).

The OECD Health Care Quality Indicator Project was launched in 2001 with the long term objective of developing a set of indicators that reflect a robust picture of care quality that can be reliably reported across countries with the help of a set of comparable data

(Kelley E and J. Hurst, 2006a). A set of indicators to be included in the OECD Health Data is the expected result from the second phase of this project. According the most initial findings of the OECD HCQP nowadays there are a limited number of indicators available for cross-national comparison of care delivered. Patient Safety has been identified has one among five top areas of research and consequently of improving of data systems (Mattke, Epstein and Leatherman, 2006). At the present phase it involves twenty three countries.

Yet, within the framework of the more global definition of safety, we propose that additional measures should eventually be part of the safety/performance improvement strategies and tools. For example:

- Injuries to physicians/nurses (needle sticks, assaults, infectious diseases).
- Additional cost to the healthcare system due to redundant and unnecessary services.
- Level of patient and family compliance post discharge due to inappropriate education about the regimen, and potential side-effects.

Quality improvement initiatives within the Portuguese healthcare system

The Portuguese Ministry of Health, back in 1999 (França M., Boavista and Ribeiro, 2000) following the steps of other European countries as England with the National Institute of Clinical Excellence (NICE) and France with the creation of the Agence Nationale d'Accreditation et d'Evaluation en Santé (ANAES) have initiated a strategy on quality for the NHS health care units and adopted a dual strategy of healthcare performance improvement as a partner to Portuguese hospitals and long-term care organizations:

1. helping hospitals achieve accreditation; and,
2. providing hospitals, primary care centers and long-term care organizations tools to improve performance.

A. Accreditation

Accreditation of an organization is similar to the licensure of an individual to provide services. It is an accountability framework whereby through the accreditation process organizations discover the areas in need for improvement; and, when accredited they demonstrate to society that they are qualified to provide high levels of services.

Accreditation has got its genesis on a set of minimum standards created in 1917 by the American College of Surgeons. From a professional and corporative initiative the accreditation has turned in to the most common and longest established program for external assessment of healthcare organizations (www.isqua.org.au, Accessed June 2007).

In the last decade accreditation programs have grown in number of initiatives and countries adherence, especially European. By 2004 year 26 programs were active or in development in 18 countries (Shaw D. Charles, 2006). Most of these programs were launched in western European countries. The initial focus has been on the improvement of hospitals to extend on a second phase to secondary and tertiary care services.(Shaw D.Charles, 2006). Accreditation has shown a capacity to adapt easily to different objectives and national needs and characteristics as well. However some of the programs seem not to achieve the sustainability to succeed after the initial enthusiasm and do not show significant growth.

Most of European countries have accreditation programs follow the worldwide trend of using accreditation for the dual purpose of helping hospitals to improve their care and provide a platform for external accountability about their qualifications to provide high quality care. The philosophy that is under the political decision is the attempt to create organizational based approaches to improve care through systematic peer review.

Accreditation has often been contrasted to licensure, while licensing requires compliance with minimum standards in order to protect public safety; accreditation requires compliance with “good practice” standards (Rooney LA and P. van Ostenberg, 1999).

The direct relationship that accreditation has to safety of care results from the activities on risk reduction in the care processes. Most accreditation programs have around 60% of standards related to risk management and patient safety with a clear tendency of reinforcement and autonomy. Consequently, the ongoing assessment and evaluation of compliance with accreditation standards produce valuable data which can be used as a resource for safety of care research and performance improvement..

Yet, the sustainable and direct link between accreditation and performance improvement (quality and safety as performance dimensions) has not been established. While it is believed that accreditation will help establish a culture of quality and safety (Alexander J.A., Weiner and Griffith, 2006; Kelder J.A, 2007.), the hypothesis that accredited hospitals do offer a better performance remains more a belief (and perhaps a wish) than a demonstrated, replicated, and sustained reality.

What are the confounders in establishing a link between performance improvement activities and accreditation? First, the sequence of the observations should be clarified: is it that hospitals that already have embarked upon performance improvement activities do get more easily accredited? If so, is accreditation an external validation of a strategy already adopted internally by those hospitals?

Or, is the process of getting ready for accreditation a facilitator for embarking upon performance improvement activities? If so, it may be argued that accreditation is among the requisites for improving quality and safety of care, not by the act of accreditation per se, but by its requirements and systematic evaluation of the hospitals activities and outcomes.

B. Performance improvement tools

In 2003, Portugal joined through a Ministry of Health service, the Institute for Quality in Health (IQS) twelve other countries as a participant in the International Quality Indicator

Project (IQIP) (Kazandjian VA et al., 2003; Thomson R et al., 2004). The IQIP is largely documented on European and Asian webpages and peer reviewed literature (<http://www.ospfe.it/index.phtml?id=974>; <http://www.epos-bg.de/cms/index.php?id=95>; http://www.tjcha.org.tw/S_english.asp?catid=4).

While Portuguese hospitals joined the IQIP (called PQIP for Portugal QIP) to improve their overall performance through indicators and learn about better practices from more than 1,000 other hospitals in the QIP, it has been shown that the “quality” indicators of the PQIP are identical to the “safety” indicators now proposed in other European or international initiatives.

Indeed, the PQIP have access to the following indicators that can be used for both quality and safety improvement:

- Antibiotic Prophylaxis,
- Unscheduled Readmissions,
- Unscheduled Admissions,
- Unscheduled Returns to ICU,
- Unscheduled Returns to OR,
- Physical Restraint,
- Documented Falls,
- Unscheduled Returns to ED,
- Patients Leaving ED Before Treatment is Complete.

The Ministry of Health, through central services, will continue to coordinate the PQIP in Portugal, and we believe that the increasing interest of Portuguese healthcare organizations will be well served with the tools and teachings of the PQIP which links safety and quality of care performances through indicators and participants’ training in improvement practices. The worldwide use of the IQIP as a quality improvement and safety enhancement system has been documented (Kazandjian VA et al, 2005)

In November 2002 the International Society for Quality in Health Care (ISQua) organized the 5th International Indicators Summit in Paris. Since that time European countries initiatives have arise on quality indicators.

At the same time most of countries that have implemented accreditation and quality indicators are facing the same challenge of integrating quality indicators within the certification and accreditation processes. As mentioned at the outset, the linkages between performance improvement and accreditation (or vice versa) remain mostly not-established. And, with the purposeful focus on safety, hospitals and health care systems seem to be faced yet with a new challenge beyond that of evaluating the role of accreditation – should there be two distinct philosophies and tools for measuring and improving safety of care as contrasted to quality of care?

So, quality or safety?

We propose that there is no such distinction. Safety is part of quality and the two will be improved simultaneously. Further, the tools for improving safety are identical to those used in performance improvement – what will differ is the set of incentives provided to those organizations showing commitment to and results from improving their performance and accountability. In particular, the use of these tools should be provided training and guidance to realize that existing “quality improvement” tools do measure overall performance, leaving the interpretation about safety to the analyzers of the data. We propose that it should be known if a tree falls in the forest, even if no one was listening at that very moment!

Discussion

Many emphasize that the effectiveness of QI initiatives when combined with accreditation models has not been duly demonstrated despite the common belief that quality of care should be improved. Specially, regarding overall organizational performance, the evidence is still less than systematically reported. However the pressure on health organizations to produce high quality care with decreasing budgets seems to have affected their adoption of QI initiatives, accreditation, or both simultaneously. Some health managers have still difficulties in embarking upon QI projects under financial constraints as recently has happened in Portugal where new initiatives have decreased significantly with the end of the seven year of frame of European funds to QI in health organizations. And this phenomenon can be encountered in other European countries and worldwide (Fabry J., Morales I., Metzger M.H., Russell I., Gastmeier P., 2007). The challenge seems to be one of accountability, where clinical, organizational and financial dimensions need to be reflected in services relevant and appropriate to patients and communities.

Also there’s a need to look for evidence about safety solutions and their availability to be applied worldwide.

In the non existence of clear evidence and or technical orientation most European countries have seen the appearance of multiple initiatives to assess and improve the delivery of care.

There is consensus that the main benefit of accreditation process comes from the effort of preparing for the survey and from the increasing awareness of staff about quality issues (Scrivens Ellie, 1997). In what way the awareness about patient expectations about outcomes of care will shape the national strategies of building QI initiatives along with accreditation is perhaps the next phase of quality improvement in healthcare, in Europe and worldwide.

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