

# The patient safety journey in Portugal: challenges and opportunities from a public health perspective

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**Despite improvements in healthcare interventions, the incidence of adverse events and other patient safety problems constitutes a major contributor to the global burden of diseases and a concern for Public Health. In the**

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last years there have been some successful individual and institutional efforts to approach patient safety issues in Portugal, unless such effort has been fragmented or focused on specific small areas. Long-term and global improvement has remained elusive, and most of all the improvement of patient safety in Portugal, must evaluate not only the efficacy of a change but also what was effective for implementing the change.

Clearly, patient safety issues result from various combinations of individual, team, organization, system and patient factors. A systemic and integrated approach to promote patient safety must acknowledge and strive to understand the complexity of work systems and processes in health care, including the interactions between people, technology, and the environment. Safety errors cannot be productively attributed to a single human error.

Our objective with this paper is to provide a brief overview of the *status quo* in patient safety in Portugal, highlighting key aspects that should be taken into account in the design of a strategy for improving patient safety. With these key aspects in mind, policy makers and implementers can move forward and make better decisions about which changes should be made and about the way the needed changes to improve patient safety should be implemented.

The contribution of colleagues that are international leaders on healthcare quality and patient safety may also contribute to more innovative research methods needed to create the knowledge that promotes less costly successful changes.

**Keywords:** public health; patient safety; adverse events; health strategy; health policy.

## 1. Introduction

*“Patient safety is a fundamental principle of health care. Every point in the process of care-giving contains a certain degree of inherent unsafety.”*

World Health Organization, 2008

Health care systems worldwide share common goals in order to improve the quality and safety of care, despite some differences in structure, resources, accountabilities and priorities. Patient safety is widely recognized as an essential component of health care. For that reason improving patient safety, and broadly the quality of health care, has become a core issue for many countries.

It is well established that health care services around the world occasionally and unintentionally harm patients. In recent years different studies have estimated that around 4% to 17% of hospital admissions result in an adverse event and that up to half of these events were preventable (Leape *et al.*, 1991; Wilson *et al.*, 1995; Thomas e Brennan, 2000; Vincent, Neale e Woloshynowych, 2001; Schioler *et al.*, 2001; Baker *et al.*, 2004; Aranaz-Andrés *et al.*, 2008). As a result, addressing patient safety represents an important challenge that is receiving attention in the public health domain. However, no matter what systems and precautions are put into place, it should be recognize that health care will always involve risks and the consequence of accepting these risks will have strong clinical, social and economic impacts.

In this special issue of the Portuguese Journal of Public Health the current paper has two main goals in mind: i) to outline what have been the most important developments of patient safety worldwide and, particularly in Portugal; and ii) to emphasize a number of key aspects that could contribute to the debate of patient safety in Portugal and help to draw a consensual strategy in this field.

To accomplish these purposes we start by describing some of the most relevant progresses in the area of patient safety in the last decade with particular focus on the experiences that we've witnessed in Portugal. With this we seek to emphasize the central role that patient safety issues have had, and will continue to have in the health policy agenda of many countries, including our own. Subsequently, we debate some key aspects and approaches to improving patient safety based on the knowledge we have about our health care system and supported on the best available evidence. These recommendations could help to draw a “roadmap” that could be used to navigate future strategies for improving patient safety in Portugal.

To help us achieve these ambitious aims we have the privilege to include the contributions of four international leaders on quality and patient safety who are in the forefront of international development in the patient safety domain: John Øvretveit (Karolinska Institute, Stockholm, Sweden); Niek Klazinga (Academic Medical Centre, University of Amsterdam, The Netherlands); Rosa Suñol (Avedis Donabedian Institute, Autonomous University of Barcelona, Barcelona, Spain) and Darcey Terris (Mannheim Institute of Public Health, Social and Preventive Medicine, University of Heidelberg, Germany). This combined contribution presents a unique opportunity to identify and discuss some of the challenges, threats and opportunities that Portugal will likely face in the near future within the field of patient safety.

## 2. An introduction to patient safety in Portugal

Improving the safety of patient care is a significant challenge for the Portuguese health care system, as it is for many health services around the world. We must have in mind that total safe health care is an ideal which may never be realized. However the creation of a healthcare system that is aware and systematically reflects, learns and acts to reduce unintended patient harm is a reasonable and achievable aim (Conklin *et al.*, 2008).

In Portugal, there is an overall awareness, and a growing concern about patient safety issues. This “movement” has become more visible in the last decade, mainly due to the hospital accreditation process and by the pressure to increase accountability. In the past years hospitals across Portugal have made unprecedented commitments to quality and safety, with many demonstrating some important progress, particularly in the area of: i) reporting and learning systems for adverse events; ii) electronic prescriptions and automatic drugs delivery systems; iii) patient falls prevention; and iv) reduction of *Methicillin Resistant Staphylococcus Aureus* (MRSA) and other health care-associated infections (Sousa, 2006).

However all of these examples come from local and detached experiences. This is a central issue as our health care system is organized around a national health service (NHS) model, accessible to all citizens (universal), and which is comprehensive and patient centered (Barros e Simões, 2007). Moreover there is a growing body of evidence that emphasizes the role of strong leadership, political commitment and involvement of all stakeholders around patient safety

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actions. For these reasons the development and implementation of a national strategy for patient safety (which, in our opinion, should be thought of in global terms and implemented locally) is crucial.

In the beginning of this year, the Health Ministry created the Department of Quality in Health (Departamento da Qualidade na Saúde) This department is depending on the Directorate General of Health (Direcção-Geral da Saúde), which is the body of the ministry responsible for planning, regulating, coordinating and supervising all health promotion, disease prevention, healthcare activities, institutions and services, whether or not they are integrated into the NHS. This can be seen as a reinforcement of the importance of quality in the health policy agenda from now on. One of the first steps of the Department of Quality in Health was to define a ten-year strategy for quality improvement initiatives. In this strategy, one the main focus is improvement in patient safety.

Nevertheless, it is important to be aware that the complexity of health care organizations and the multifactorial character of “safety problems” require systemic and integrated approaches to patient safety issues. It is essential to know what good ideas in patient safety may be recognized and emphasized while implementing a strategy. Also, and probably even more importantly, what must we have in mind to implement them?

### **3. Safety and quality: two sides of the same coin**

Many countries have, like Portugal, taken initiatives over the past decade to address safety problems in health care. In the aftermath of the US report “To Err is Human” patient safety has gained momentum in the world of health care policy makers as well as amongst health care professionals and managers. Although the safety problems should surely not be underestimated, it should also be recognized that health care systems have been addressing issues like post-operative infections and bedsores already for a far longer period, but previously under the heading of quality assurance. The safety paradigm has introduced new thinking and methods to deal with iatrogenic risks but at the same time we should not neglect or dispose of effective quality improvement methods. Quality and Safety are two sides of the same coin. Quality tries to optimize the (evidence based) effectiveness of health care. Safety addresses the minimization of risks that come with the delivery of health care. As such they are complementary and methods to address them have all in common that

they consist of a combination of measurement and change. Therefore it seems wise not to separate quality and safety in the organizational arrangements that are set up to address them. Especially when new institutes are set up to address safety issues, policy makers should make sure that they capitalize on previous quality investments rather than allowing a situation were quality and safety initiatives, methods and institutions end up competing each other (Arah e Klazinga, 2004; Groene *et al.*, 2009)

For example, in The Netherlands, there has been a long history of quality initiatives. In the seventies of the 20<sup>th</sup> century peer-review became mandatory amongst medical specialists and general practitioners, in the eighties national programmes for (evidence based) guidelines were set up that are still functioning in 2009 and in the nineties systems of voluntary hospital accreditation and visitation of specialty groups were set up. Together with the legal obligation of periodically recertification of medical professionals this has created an infrastructure for quality assurance and quality improvement that is able to address many of the effectiveness issues in health care. The safety agenda of the past ten years tries to build of this, although also new initiatives have been taken. Like many other countries The Netherlands had a national study in 2007 to assess the magnitude of the safety problems in our hospital system (Wagner, Zegers e De Bruijne, 2009) and both adverse event reporting and reporting of a specific set of safety indicators have been institutionalized via the inspectorate of health. At the moment additional initiatives are taken to develop local safety management systems and like Portugal a national programme exists that addresses specific themes closely aligned to the initiatives of the world safety alliance.

Quality and safety have gotten even more attention since the introduction of new health care reforms in 2006. These reforms have transformed the previous system of financing of health care through sick funds for two third of the population into an obligatory national insurance plan, executed by various private insurance companies. Transparency is one of the corner stones of this “regulated market” approach and likewise quality and safety indicators have become increasingly important. Apart from the quality and safety indicators reported publicly by the inspectorate of health, a national institute for the systematic measurement of patient experiences has been put in place and national instruments have been validated to report on patient experiences. These initiatives, however, have also demonstrated the complexity of valid measurement and effective change.

As in Portugal, the quality of record keeping is the cornerstone of valid and reliable measurement. In the quality and safety work of the OECD this has also become apparent. Although data on mortality and cancer can be retrieved in a reliable and comparable way from most countries, administrative data-bases and let alone Electronic Health Records still have many limitations for generating good information on quality and safety. For example the calculation of safety indicators from administrative databases, after the example of the Agency for Research and Quality in Health Care in the US, has been done at present in a growing number of countries but comparability is limited through the lack of coding of secondary diagnosis in the data-bases, the lack of coding whether certain conditions were present at admission, the lack of standardized procedure codes and limitations in the use of unique patient identifiers (UPI) (Droesler *et al.*, 2009).

Addressing these general issues is essential if we want to make progress in the systematic measurement of safety and quality indicators. Especially the possibility to follow up on patients outside the hospital setting through UPI's, linking data bases or using a uniform Electronic Health Record is paramount for progress.

Effective change, on the other hand, is linked to the capacities, motivation and incentives structures of professionals. There is not one golden bullet approach and like the approach in Portugal, various initiatives are necessary to induce change. Safety culture is for sure an important component, but safety culture can only arise when sufficient levels of professionalization exist and health care services are designed, resourced and managed in such a way that safe care can be delivered. This asks for a delicate balance between professional push and societal pull. As stated at the beginning of this paragraph, this pushing and pulling is in essence nothing new.

#### **4. Aiming at a systemic and integrated approach to patient safety**

Health care organizations have become more complex dealing with a lot of factors that interact and are really beyond patient safety. The increasing complexity creates uncertainty as to how to proceed, not only at an organizational and technological level, but also at an individual and social level. Errors are always related with a series of causes that state and determine human behavior, and not exclusively related to individual factors (Altman, Clancy e Blendon, 2004; Uva *et al.*, 2008).

Research demonstrates that adverse events are not just a series of random, unconnected one-time-only incidents but result from a chain of events that can be attributed to related root causes (Altman, Clancy e Blendon, 2004). As a result, the Public Health approach to patient safety should use a systemic and integrated approach (*Figure 1*) aiming to implement and sustain a comprehensive risk control system, instead of focusing on only errors arise from human mistake or other singular error origins.

As show in *Figure 1* a systemic and integrated approach to patient safety should be patient-centred; promoting a culture of learning and openness; taking into consideration good hospital design and ergonomics; developing capacity and knowledge; supporting strong leadership; encouraging good reporting systems and epidemiologic knowledge of adverse events and; be based on research and innovation.

Although we would prefer errors not to occur every problem, slip, mistake or error that does occur should be embraced as an opportunity to better understand work complexity and process variability (Battles e Stevens, 2009). Understanding the environment means been aware of the work itself recognizing the ways that work is actually done in each situation. For example, if a physician prescribes a wrong medication the typical response is to identify who wrote the prescription and even after a single error penalize the prescriber. Instead it would likely be more beneficial to analyze organizational constraint (e.g. work schedules; time pressure; workload and communications between professionals) that may lead to errors and work to establish objective attribution of responsibility for errors. This would lead to developing and implementing solutions to avoid the same mistake in the future. For example, there are rules governing hand washing, but little attention is given to identify the reasons why health professionals do not always adhere to hand washing protocols. Does someone check if there are convenient located washing facilities? Is there a time pressure or high workload that creates and added burden to taking an extra step?

An integrated and systemic approach to patient safety must explicitly acknowledge essential aspects of the work system as described by Carayon and colleagues (2007):

- i) we cannot look at one element of work in isolation;
- ii) whenever there is a change in work (e.g. introduction of a new technology) one needs to consider the effects on the entire work system;
- iii) the work (re) design needs knowledge and expertise in a variety of elements, e.g.

environmental design (such as lighting and noise), cognitive ergonomics (such as information processing and human error), physical ergonomics (such as anthropometrics), job design (such as autonomy and work demands) and organizational design (such as team work, schedules and human resources management).

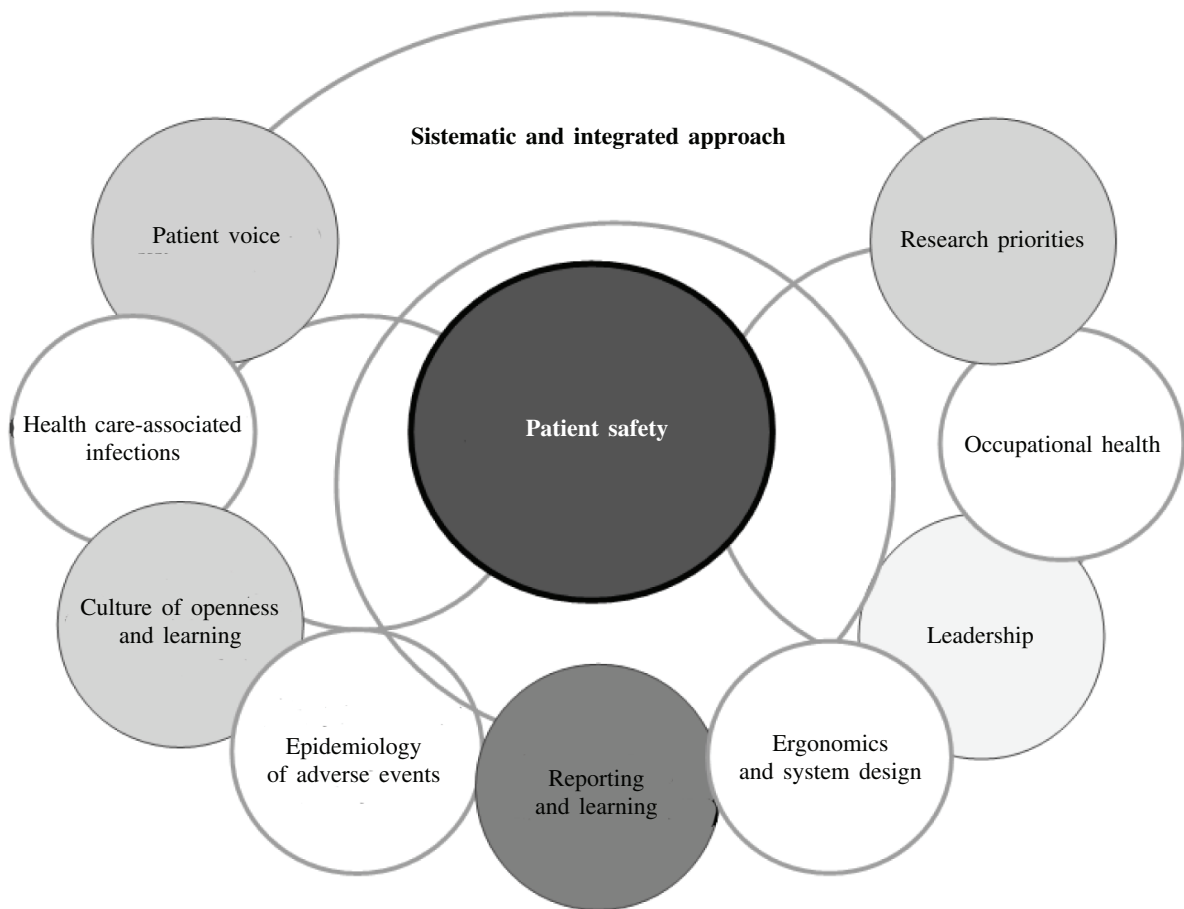
require systemic approaches, but not necessarily complex ones.

### 5. Implementing safety solutions proven elsewhere

One of the more popular recent approaches to quality improvement has been to focus on implementing changes which have been found to be effective for improving patient care in controlled trials. Examples are ensuring that beta-blockers are prescribed for chronic heart failure or appropriate prescribing and monitoring of anticoagulants for patients at risk of blood clots. Quality improvement is made using methods such as guidelines and feedback to ensure such evidence based practices are used in daily practice.

In addition, the work system can influence employee and organizational outcomes, such as job satisfaction, burnout and worker safety (Carayon *et al.*, 2006). This model assumes that patient safety and worker safety are interrelated — that improving work design can have a beneficial impact on both patient safety and worker health and safety (Kovner, 2001; Sainfort *et al.*, 2001; Carayon *et al.*, 2006). These aspects could be integrated in any patient safety strategy based on an understanding of complex systems that

**Figure 1**  
Systemic and integrated approach to patient safety





One approach to patient safety is similar: to apply to local settings the practices or equipment which have been found to reduce adverse events to patients in study settings. Reviews of research have found evidence of the effectiveness of a number of “patient safety practices” (PSPs) (USA. AHRQ, 2001). If these “PSP-solutions” are fully implemented, then we can expect very similar results in terms of reduced adverse events in many settings.

It is important to note that these more certain PSPs solutions are patient treatments, or like patient treatments. They are simple standardisable changes which have been evaluated and proven using controlled trials. For most of these we can expect fewer adverse events if we ensure the change is made. Some of the research challenges which this paper raises and considers are:

- What is the evidence of effectiveness of strategies or actions to ensure that these proven changes are carried out consistently (implementation approaches)?
- Would an implementation strategy which is successful in one setting work in another?
- What is the evidence of effectiveness of other more complex patient safety interventions such as new models of teamwork or hospital rapid response systems, and how might these be evaluated?
- How can we discover which context factors are important for helping implementation and supporting patient safety interventions?

Answering these questions is important for providing policymakers and leaders who are implementing changes with the information they need in different settings in Portugal. Knowing a patient safety intervention reduces adverse events in a USA teaching hospital study, where efforts were made to ensure the change was implemented only provides some of the knowledge which implementers in Portugal need. This is knowledge to answer their questions about, would it work here, what do we need to do to make sure it works and how do we implement it?

Another example is one of the 11 AHRQ-recommended practices: appropriate prophylactic antibiotics administered to the patient 1 hour before surgery. We know that if this is done consistently and appropriately, then we will reduce post-surgical infection rates. But we know less about how to get the change (implementation), than we know about what will happen if we do make this change. The implementation challenge is how to ensure this practice is carried out consistently, for every patient,

every time as appropriate. One patient safety research challenge is to find whether one way of implementing this change — such as training, reminders and feedback — is effective in different settings, or whether different implementation strategies are equally effective in different settings, and depend on different context factors such as number of nursing personnel and their motivation.

A different type of example is a rapid response system (RRS) for identifying and responding to rapidly deteriorating patients in hospital. This is a more complex change which includes training on vital signs criteria, and establishing a medical emergency team of critical care specialists which can be called by any nurse or doctor to advice about care to prevent deterioration and admission to an ICU (Øvretveit e Suffoletto, 2007; DeVita *et al.*, 2006). The implementation challenge for this patient safety change is greater, as more resources, personnel and negotiations are needed. Also, the certainty that this change will result in fewer adverse events is less than for the antibiotics working on the patient physiology. In addition, there is little research about how to implement different types of RRS.

The questions and issues raised above are being addressed by the newly emerging science of implementation and groups of researchers studying implementation. Concepts which are useful to both researchers and practical implementers distinguish between a before/after change and the actions taken to achieve this change.

### **Change content: The before/after change**

*Example 1:* before patients did not receive antibiotics one hour before surgery; after the change all patients receive the antibiotics as appropriate.

*Research questions:* does this reduce post-surgical infection rates? If yes, then we would expect this in most settings, if we ensure the change is implemented?

*Change implementation actions or strategy:* what was done to get the before/after change.

*Example 2:* training, reminders and feedback.

*Research question:* was this effective for achieving the change?

*Context:* factors which help and hinder implementation and which may affect outcomes of a safety intervention.

*Example 3:* financial incentives or regulatory requirements for a safety change, or the organizations safety culture.

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*Research questions:* which factors and how much do they influence implementation? Which context factors are necessary for implementation?

Implementation research uses a number of different research designs and data gathering methods. Important to all are theory models of the paths of influence through which the intervention has its immediate and ultimate effects, and interacts with its context.

Theories used in public health to model health promotion and other public health programmes have been drawn on to theorize implementation and intermediate results in evaluating complex safety interventions. This field of research is already providing some of the missing information which implementers need to decide about adopting and adapting a safety change to a local setting. The journal "Implementation Science" publishes many of these studies.

To improve patient safety in Portugal, we need to know not only the efficacy of a change but also what was effective for implementing the change. What works elsewhere might not work in Portugal because the change cannot be implemented fully, or the cost of doing so is too high compared to other changes. Other changes might be less costly, but the evidence of efficacy might be less strong.

## **6. Patients' safety: suggestions for making it work**

During last years patients' safety has become one of most growing topics in scientific literature. Health care policymakers, quality and public health professionals have been attending multiple meetings and debating in all possible forums the need to increase patients' safety and to disseminate its' principles and practices. At the same time a lot of initiatives have been taken worldwide to enhance the visibility of this topic and to engage all possible stakeholders in the effort. These include at European level, public declarations from politicians (e.g. Council of Europe, EU Parliament), initiatives from key international organizations (e.g. WHO, OCDE) and coordination and common efforts from governments (e.g. EUNetPas project, etc.). At this stage, the question emerges about what the practices that seem to better support are implementing patients' safety efforts and which can be seen as a guiding experiences when developing a national strategy in a country.

### **i) Make patients' safety a national strategy**

Building a National strategy means clear leadership and commitment from national authorities. Basic indicators for measuring this commitment can be the visibility of the topic in public interventions from key leaders and budget dedicated to it. Perhaps initiatives like the organization of the first EU meeting on patients' safety by Sir Liam Donaldson during the UK presidency in UK, or his public comparsence explaining to citizens that errors occur, systems need to be improve and a national effort is needed to address the issue, can be considered by other national leaders. Budgetary issues are also very important. Some countries have made an important effort to introduce and spread patients' safety in their countries. Among them, the Ministry of Heath in Spain has increase their budget from 1,2 million Euros in 2004 to 17,4 Million Euros in 2007 (for training, raising awareness, implementing safety practices and research).

When designing a national strategy, it can be useful to include all possible interested groups in the effort and leave them take their own part of the work. These can be clinicians, managers, scientific societies, existing quality groups etc. Too frequently a new initiative is also the chance to exclude old groups and make others emerge, and implementing patients' safety, at this stage, is so complex that needs to prevent all avoidable resistances. To address it the concept of "alliance" promoted by World Health Organization in its World Alliance for Patients' safety program seems to be useful. The concept "alliance" includes all and appeals to responsibility of all involved parties. In our experience in Catalunya in which more than 100 centers are involved in implementing safety practices, the alliance concept has been one of the success factors for involving clinicians and managers from the beginning.

### **ii) Develop an open and safety culture**

The need of an open and safety culture is one of the common topics of all policies in patients' safety. Patients' safety culture require a lot of effort, but the effort need to be mainly focus in leaders and managers more than in professionals who very easily understand that errors are usually system problems. We use to ask to Chiefs of Departments: How many of you have been told of an error from one of your professionals in the last month? And when no hands rise next question is: Have you think why they don't tell you?

An open and safety culture need time, but not only time. Context is also very important for developing it and countries like Denmark with a non blaming law for protecting and making mandatory reporting errors has been an important lesson for all European countries. In some countries, achieve a similar law will need some years but in the mean time efforts can be made with journalists and politicians to convince them not to use patients' safety as a way to blame others. Some countries have also successfully used "patients' champions" (patients or families that have directly suffered an important error and make a public effort to explain that a non blaming safety culture is needed to be able to talk about risks and face them).

Professionals' responsibility is to speak up and tell others when a risk is perceived. And this is also difficult. This means that nurses and junior doctors will speak up on practices that senior doctors' do and this is not easy for anyone of them. Here also some examples could be of interest. A senior surgeon use to say when entering the operating theater: "...my pride is not to believe that I'm perfect. I will appreciate that anyone that sees something that can be dangerous for the patient, please speak up". Here also, Germany and other countries experience, having make public the request of a very senior doctor (like a president of a medical college) asking everyone to speak up can be of interest.

And last but not least the concept of a "second victim" shall be of use. The "second victim" is the professionals at the end of the chain who make the final act that conduct to the error. Considering this people also victims, support can be provided to them and ways to apologize to patients' are easiest to find.

### iii) Support safety practices

Most of the time safety practices require an important change in daily behaviors (hand washing) or substantial organizational changes (safe surgery, preventing medication errors etc.). It is not enough to say to professionals and managers "hand washing is important", operational efforts have to be taken in place. Quality literature include important bibliography of effectiveness of using different approaches to achieve change including feed-back of practice, reminders or the use of collaborative projects including a group of hospitals interested in same topic working together (Bosch *et al.*, 2007). For that reason substantial methodological, practical and operational support is needed when patients' safety practices have to be concretely applied in a given setting. These mean to design and develop in

advance the needed instruments, strategies and accompaniment to make it possible and to apply them following the quality knowledge.

The situation on implementing safety practices in Europe is still very challenging. In a purpose sample of hospitals from 9 countries audited in 2007 a considerable proportion do not yet comply with basic patient safety strategies — for example, using bracelets for adult patient identification and correct labeling of medication (Suñol *et al.*, 2009). This means that when trying to improve patients' safety we are faced to a very important effort. Probably the most important single advice to be provided when developing a national strategy would be to persist, persist and persist. But at the same time a great number of patients, professionals, managers and policymakers are committed to the task and hopefully we will be able to accomplish it.

## 7. Opportunities for a lean health system

Total health expenditure (THE) as a percentage of gross domestic product (GDP) is higher in Portugal than the average found among European Union (EU) member states. Specifically, in 2004, only Germany and France spent a higher percentage of their GDP on THE. Conversely, when THE is expressed in US\$ purchasing power parity (PPP) per capita, Portugal's expenditure is significantly below the EU average. This contrast reflects Portugal's relatively low GDP, as compared to other countries within the EU (Barros e Simões, 2007). It is not surprising, then, that many of the Portuguese health reforms implemented to date have focused on improving health system efficiency, defined as the cost of care associated with a given level of health care quality (Guichard, 2004; USA. AQA, 2006).

Positive gains in efficiency have been observed in response to the Portuguese reforms, but the improvements have been relatively small, at least as evaluated in the short-term (Barros e Simões 2007; Afonso e Fernandes, 2008).

Accordingly, Portugal may be fertile ground for an integrated, systems-level approach to implementing a Lean health care system — i.e. a health care system that focuses on eliminating waste and creating value based on patient-identified needs (e.g., goals for health care quality and safety). The concepts and tools used in creating a Lean system originally came from industry, specifically the Toyota Production System (Varkey, Reller e Resar, 2007). Increasingly, however, Lean approaches have been implemented to improve the quality and safety of health care delivery (Bahensky, Roe e Bolton, 2005; Laing e



Baumgartner, 2005; Kim *et al.*, 2006; Ben-Tovim *et al.*, 2007; Upenieks, Akhavan e Kotlerman, 2008; Dickson *et al.*, 2009).

A Lean production system utilizes three main tools for improvement. The first is “value stream mapping”, where value-added and non-value-added activities in production processes are identified. Waste is reduced through elimination of non-value added activities and process steps are organized so “services ... are delivered when the customer needs them and how the customer requests them.” (Varkey, Reller e Resar, 2007). Value, here, is clearly assessed from the customers’ perspective.

The second tool is “kaizen workshops” (e.g. improvement workshops), where ideas for improvement are identified, rapidly tested and implemented. Kaizens typically focus on improvement ideas generated by front-line staff. Quick turn-around is emphasized to generate immediate success in improvement efforts (Varkey, Reller e Resar, 2007).

The third tool includes “5S strategies”, or housekeeping tasks, where routine assessment of work standards and processes are conducted and standardization and maintenance of improvement achievements are emphasized and expanded. The 5S strategies include: 1) sort, 2) straighten, 3) shine, 4) systemize, and 5) sustain (Varkey, Reller e Resar, 2007). Using health information systems as an example, “sort” might include developing physician interfaces that focus on the data routinely required in patient-centered care and avoid noise created from data that are less frequently needed. “Straighten” would then concentrate on organizing the interface structures so that the routine data are easily inputted or accessed.

Cleaning data systems, e.g., ensuring archive data locations are known, data are secure, and data are accessible when needed, would be included under “shine”. Reinforcing processes and creating work standards (e.g., data entry protocols) falls under the 5S strategy of “systemize”. Finally, “sustain” would refer to the institutionalization of periodic reviews of the information systems, repeating the sort, straighten, shine and systemize strategies to ensure prior improvements are maintained and new improvement opportunities are identified and addressed (e.g., through Kaizens).

Arguably, reducing waste, while improving quality, is a desirable goal regardless of the context. In a Lean approach, the first step is to eliminate waste (e.g. non-value-added activities), reducing costs and freeing resources that can be applied in improvement or other value-added activities. For example, when a Lean approach was taken to the radiology

departments of three hospitals looking to eliminate waste in computer tomography (CT) scanning, an annual increase in revenues of \$750,000 was achieved (Bahensky *et al.*, 2005). In settings like Portugal, where controlling rising health care costs, increasing infrastructure, and improving the safety and quality of service delivery are concurrent priorities, Lean approaches to system improvement may be particularly fitting.

Lean approaches to health care improvement are typically focused on a given health care service, within a department, facility or small group of facilities.

Implementing a Lean approach to health care improvement, at any level, is not without challenges. For example, multiple stakeholders and divergent perspectives on value (e.g., arising from disconnects between a physician’s and a patient’s goals) need to be balanced in health care delivery, in part due to the information asymmetries present (e.g., physicians have greater information about health care options, processes and likely outcomes, as compared to patients) (Young e McClean, 2008). Further, the alignment of Lean thinking with the culture and values of Portugal must be assessed, and if deemed appropriate to proceed, the tools utilized in a Lean approach should be explicitly adapted to the Portuguese context.

## **8. Key aspects in drawing a roadmap for patient safety in Portugal**

There are some key aspects that must be taken into account in the design of a strategy or a roadmap for patient safety in Portugal, namely:

### **i) Creating, sharing and disseminating knowledge to improve safety**

One of the greater challenges of implementing safety programmes worldwide is the lack of available data on what has worked and what has not. Many international organizations (e.g. World Alliance for Patient Safety; the Joint Commission International and, the European Commission for Health and Consumer Protection) have been collaborating to build the knowledge and evidence-based on patient safety through research programmes and by sharing best practices and solutions that have show good results (Conklin *et al.*, 2008; Sousa, Furtado e Reis, 2008; WHO, 2008). For example in partnership with the WAPS, the JCI designed a process for developing new solutions, as well as adapting existing ones with

a specific focus on global dissemination of what works in improving patient safety. The first set of nine patient safety solutions was launched in May 2007. The solutions identified and developed each year, since the beginning of the collaboration, provide a unique opportunity to examine systems of care and make changes to enhance the safety of patients (Pronovost *et al.*, 2005; WHO, 2008).

Very recently, the European Commission for Health and Consumer Protection has proposed three policy areas for future action in order to improve patient safety. One of these areas was to “develop and use knowledge and evidence” (Conklin *et al.*, 2008). This area comprises of actions such as: i) “mapping and reviewing national patient safety policies and initiatives to provide a basis for mutual sharing of information and knowledge”; ii) “developing and promoting a research agenda on patient safety, in particular at the European level ...” iii) “promoting the use of research and other evidence-gathering to develop efficient interventions and communicate solutions across the EU”; iv) “pooling data, information and expertise on patient safety and wider quality strategies to share good practices ...”.

In Portugal we should be aware of and keep informed about these international activities by participating as an active “teammate” and, most importantly by using recommended policy actions as national patient safety goals. At the same time it will be important to create and foster national networks that include all stakeholders (health care professionals, decision-makers, researchers, patients and their families), with the final aim of identifying, developing, adapting and disseminating effective solutions for patient safety.

## **ii) Complex systems requires innovative and comprehensive approaches to patient safety**

The most prevalent thought when something goes wrong during health care delivery is to find out “who did it?” instead of “why is this happening?”. Accordingly to Frankel, Frederico and Leonard (2008) this approach is understandable in health care because it makes organizations feel as if they have responded to a problem and therefore taken action. However, the majority of errors that cause harm involve conscientious, competent individuals who, through a series of system failures, make a mistake that leads to an unintended and sometimes dramatic result. Consequently, placing blame on an individual does not address the underlying issues that cause the error and does not prevent it from happening again. There are no doubts that patient safety issues result

from a various combinations of individual, team, organizational, and patient factors (Reason, 2002; Berwick, 2003; Sousa, Furtado e Reis, 2008; Uva *et al.*, 2008). The focus on improving care by redesigning systems, tasks and the workforce necessarily emphasizes the multiple causal factors of errors. This approach, supported by evidence from other industries (e.g. aviation, mining and nuclear), examines system factors as causes of errors rather than blaming individuals (Singh, Petersen e Thomas, 2006; Kosnik, Brown e Maund, 2007; Shaw e Calder, 2008).

## **iii) Patient safety and health care workers health and safety**

Hospitals and other healthcare units are extremely complex systems where many interdependent elements interact to achieve the goal of the better healthcare. This is provided in workplace environments very specific. Designing hospital and clinic work layouts systems and workflows (macro systems); workplaces and instruments or other medical accessories (micro systems) requires not only engineering knowledge or organizational/managing awareness based on healthcare processes. The health provider, interacting with these organizational and technical systems must be the core of these complex systems. Some authors refer to these elements as sociotechnical or anthropotechnical systems.

Those approaches look at: (1) the role of individual characteristics of providers (e.g. skills, knowledge, experience); (2) the nature of the work performed (e.g., competing tasks, procedures/practices, patient load, complexity of treatment); (3) the physical environment (e.g., lighting, noise, temperature, workplace layout, distractions); (4) the human-system interfaces (e.g., equipment location, controls and displays, software, patient charts); (5) the organizational/social environment (e.g., organizational climate, group norms, morale, communication); and (6) management (e.g., staffing, organization structure, production schedule, resource availability, and commitment to quality), to understand the systems (Henriksen *et al.*, 2008).

This work system model also has influence on employee health and safety such as job satisfaction, burnout or occupational accidents (Carayon *et al.*, 2006). This model assumes that patient safety and healthcare safety are also both sides of the same coin that determines improving the work design can have a beneficial impact on both patient safety and worker safety (Kovner, 2001; Sainfort *et al.*, 2001; Carayon *et al.*, 2006) which are interdependent.

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Accordingly Leplat (2000), microsystems interactions can be identified at three levels:

1. First level — the work determinants (internal — individual, and external — technical, organizational and social);
2. Second level — the activity (the way and how worker perform in fact his work);
3. Third level — results or consequences of work (health worker outcomes and organizational/economical results).

Specifically, health care professionals do something (their work) in predetermined work conditions (those presents in the healthcare unit) to produce, in this case, better health care outcomes. Understanding work means understanding the activity (second level — activity analysis) and the prescribed task (first level — task analysis), with consideration of all of the demands and work constraints. Once the work is understood, the next step can be taken to match worker needs and capabilities with the work, the workplace and the work-layout demands.

For example, ergonomic data can be an important input to the work redesign process. Hospital design and healthcare buildings must be conceived assuming real dimensions for those that work or stay there (e.g. bed spaces, circulation spaces, working spaces, related spaces, common spaces or main area spaces). Looking at general design specifications used long-term in manufacturing environments (Sanders e McCormick, 1993) and transferred to health units:

1. Importance — main components need to be placed in well-located places (e.g. for nursing care that should include patient care supplies, surgical supplies, patient gowns, isolation gowns, gloves, hand hygiene materials, CPR supplies and medical sharps disposal container);
2. Frequency-of-use — repeatedly used equipments need to be placed in suitable locations (e.g. thermometer, blood pressure cuffs, disposable examination gloves);
3. Functional — things should be grouped according to their function (e.g. intravenous supplies should be grouped together because they correspond to the function of IV insertion and line care);
4. Sequence-of-use — performing some tasks must be done through a definite sequence of patterns of activities (e.g. urinary catheter insertion kits should be arranged in order to fit the sequence of pattern of activities that mean the first element on top should be the sterile gloves and other steps as required in the procedure).

As previously described, patient safety errors cannot be solely attributed to inattention, memory lapse, failure to communicate, exhaustion or ignorance. Errors often can be attributed to poorly designed layouts, workplaces, equipment and drug dispensing systems. “Noisy” working conditions, inappropriate work schedules, insufficient staff and a number of other personal and environmental factors, all should be taken it consideration when creating fault trees or performing root cause analysis aiming at prevention of future events.

Moreover hospital management and health quality must also include aspects, such as ergonomic design that promote other aspects like main areas, inpatient units, circuits, patient rooms, workplaces or used equipments and also organizational processes. That is the “anthropotechnical” perspective.

For all these reasons we defend that a comprehensive strategy for patient safety should take into account the complexity of health care organizations and the multitude of factors leading to both safety problems and patient safety solutions.

#### **iv) Reporting and learning systems for adverse events can lead to significant improvements in patient safety**

Reporting and learning systems are designed to improve the safety of patients. Establishing an effective reporting system and the consequent route cause analysis of the adverse event facilitates: a) monitoring trends over time; b) observing changes following the introduction of new solutions; c) sharing and learning from different interventions, particularly those which are more effective; d) reinforcing a transparent and open culture for patient safety; and e) having an idea of the magnitude, nature and preventability of adverse events and also their clinical, economic and social impact (Clarke, 2006; Williams e Osborn, 2006).

The epidemiology of adverse events has not yet been studied in Portugal. It will be important in the near future to examine the feasibility of applying the methodology previously used in other countries (Leape *et al.*, 1991; Thomas e Brennan, 2000; Vincent, Neale e Woloshynowych, 2001; Baker *et al.*, 2004). By these means we would be able to know more about the incidence, nature and preventability of the adverse events in Portuguese hospitals. Additionally, an epidemiological knowledge of the adverse events would be likely contribute to improvements in quality and help drive new research and innovative approaches toward the reduction of

the adverse events and minimization of their consequences. Furthermore gaining this knowledge would have an important role in identifying and prioritizing which settings and areas should be highlighted and which action should be taken in a strategy to address health care quality and patient safety.

**v) Education, training and research on patient safety are essential**

Human resources are the most valuable assets in health care. The ability to improve health care is considered nowadays as an essential part of the health professional's education and training. Health care safety can be improved through education and training transmitting the appropriate knowledge and skills for improving patient safety (Splaine *et al.*, 2002; Stevens e Splaine, 2008).

More and better knowledge is still necessary for understanding the extent, causes and implications of patient harm, and for developing innovative solutions that can be adapted to different setting and/or contexts. Research is needed to help health care professionals and policy-makers to understand the complex causes of unsafe care, and to come up with practical responses to reduce patient harm (Øvretveit e Klazinga, 2007; Sousa, Furtado e Reis, 2008; WHO 2008). Consequently, one of the greatest challenges is to build the capacity to address research questions that have the most impact on reducing patient risk/harm.

The value of education, training and research on patient safety is widely recognized. Several countries and international organizations (e.g. World Alliance for Patient Safety, European Union; and Institute of Health Improvement) have defined an agenda for research and are working on educational and training programmes for patient safety (WHO, 2008).

Based on the reasons mentioned above, it is essential for Portugal to raise awareness and mobilize resources (e.g. human, technical, and financial) in order to build and reinforce capacity on patient safety education, training and research. It is important that health care professionals, researchers, teachers, patients and their families, and decision-makers (both in health and education) work together toward this goal. The inclusion of patient safety issues on the curricula of different undergraduate and post-graduate courses, such as master and PhD degrees should be priority. Because their multidisciplinary nature, public health researchers, teachers and schools can have a central role in creating capacity through educational

courses and researches programmes and by fostering national and international networks on health care quality and patient safety. Furthermore, it will be important to go beyond research and educational developments to translate knowledge gained to policies and practices.

**vi) Core issues/areas for patient safety include surgery; medication error and health care-associated infections**

Although the need for safe care is apparent in all settings/contexts of health care, there are some areas that present higher risks for error and patient harm because of the nature of the care provided; the acuity of patient illness (severity); the unpredictability of patient volume; or the structure of the system that supports the care (Rhodes *et al.*, 2008; WHO, 2008; Zhang *et al.*, 2009). Moreover, there are some identified contexts where the lack of safety compromises the quality of health care with huge damages to patients, health care organizations and its staff. Among them, are include the surgical care; medication error and health care-associated infections (HAI). Because of their clinical, economic and psychosocial impact, these three areas have been the main focus of national and international research and actions to reduce their frequency by minimizing the causal factors underlying their occurrence. The campaign "Clean Care is a Safer Care" and more recently the "Safe Surgery Save Lives", both promoted by WAPS, are good examples of the importance of these areas, and the consequent impact in health gains when they are addressed (WHO, 2008).

In Portugal, a hand hygienic campaign has been in effect since October 2008. First impressions demonstrate a global acceptance of the campaign. We can easily find containers of alcohol solution and posters with campaign information in all wards, and other services in the hospitals. However, additional research is needed to assess the economic impact (e.g. costs and benefits associated with the implementation) of such changes.

The "Safe Surgery Saves Lives" initiative has the goal to improve the safety of surgical procedures by defining a core set of minimum safety standards. On the basis of these standards a 19-item checklist was developed intended to be globally applicable and to reduce the rate of major surgical complications. The first results have been positive, with the rate of any complication at all sites and the rate of death decreasing from 11% to 7% and from 1.55 to 0.8%, respectively (Haynes *et al.*, 2009). It is fundamental

that Portuguese hospitals uniformly adopt this initiative, in the near future, in order to improve safety and quality of surgical procedures, which we know have a substantial burden of diseases, reflected by clinical, economic and social weights.

In the area of drugs-related errors, initiatives such electronic prescriptions, automated delivery, double-checking before drugs administration, and others solutions have demonstrated benefits that could and should be spread for improvement of health care services. The aim here is to prevent and /or diminish the rate of adverse events related to medication error that are known to be very common and often preventable.

## 9. Conclusions

There is a growing body of knowledge, internationally, of the current challenges faced in patient safety and the possible strategies and solutions to improve the care patients receive. Better care should also be safer care and in this way safety initiatives are intrinsically linked to the health care quality improvement programs that countries have pursued over past decades. The patient safety challenges of the 21<sup>st</sup> century, in Portugal and elsewhere, represent a significant burden of disease and as such, require a systemic, integrated public health approach. However, despite Portugal's past successes in raising awareness and addressing a number of patient safety issues, those efforts have remained fragmented and isolated.

A systemic and integrated approach to patient safety solutions, and the expansion of research to evaluate their implementation and impact, should be central points of a national public health strategy. The effectiveness and efficiency of safety initiatives may be improved by referencing evidence-based approaches in quality and safety and adapting these examples to the Portuguese context and by joining international efforts as a team member and active participant. Also building upon Portugal's existing quality improvement systems and structures is necessary.

Furthermore, although all stakeholders in Portugal need to come together, each assuming their role in identifying appropriate safety solutions and implementation strategies, fundamentally leadership is required at the highest levels. A comprehensive, open safety culture should be nurtured as a societal value, with reporting and learning systems targeting opportunities for improvement, instead of assigning blame. The necessary operational infrastructure also needs to be provided to support safety-related

behaviors in the complex, dynamic health care environments encountered. Education and training of health care professionals and staff members in quality and safety fundamentals and methods could encourage active participation, both in improving the care provided to their patients and their own work situations aiming at a better health and safety promotion also for both.

Moreover, implementation research is needed to identify contextual factors that help and hinder implementation, sustainability and dissemination of safety program successes. Specific methods (e.g. Lean approaches; methods based on the work context and system design) to safety improvements, and focus on critical areas, such as safety improvements in surgery, medication errors and health care-associated infections, may lead to important short-term gains, although a long-term strategy should remain the primary objective. However, policy makers and implementers can build upon these early wins, and the knowledge created, to successfully navigate future strategies for improving patient safety in Portugal.

Lapses or errors in patient safety result from a complex mix of factors and root causes. As a result, improvements in patient safety, and more generally the quality of care delivered will always necessitate a complete and integrated approach that combine all the work components as people, technology and environment, and not only human behavior. Planning and design of all system elements, namely the hospital design, should involve all stakeholders, including patients and their families.

This is an appropriate theme for this jubilee issue of the *Portuguese Journal of Public Health* — as the discussion and proposed solutions presented here represent the first step, in a long, but potentially rewarding patient safety journey for Portugal and its citizens.

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## □ Resumo

### A SEGURANÇA DO DOENTE EM PORTUGAL: DESAFIOS E OPORTUNIDADES NA PERSPECTIVA DA SAÚDE PÚBLICA

As questões relacionadas com a Segurança do Doente, e em particular, com a ocorrência de eventos adversos tem constituído, de há uns tempos a esta parte, uma crescente preocupação para as organizações de saúde, para os decisores políticos, para os profissionais de saúde e para os doentes/utentes e suas famílias, sendo por isso considerado um problema de Saúde Pública a que urge dar resposta.

Em Portugal, nos últimos anos, têm sido desenvolvidos esforços baseados, maioritariamente, em iniciativas isoladas, para abordar os aspectos da Segurança do Doente. O facto de essas iniciativas não serem integradas numa estratégia explícita e de dimensão regional ou nacional, faz com que os resultados sejam parcelares e tenham visibilidade reduzida. Paralelamente, a melhoria da qualidade dos cuidados de saúde (a longo prazo) resultante dessas iniciativas tem sido esparsa e nem sempre a avaliação tem sido feita tendo em conta critérios de efectividade e de eficiência.

A Segurança do Doente resulta da interacção de diversos factores relacionados, por um lado, com o doente e, por outro,

com a prestação de cuidados que envolvem elementos de natureza individual (falhas activas) e organizacional/estrutural (falhas latentes). Devido à multifactorialidade que está na base de «problemas/falhas» na Segurança do Doente, qualquer abordagem a considerar deve ser sistémica e integrada. Simultaneamente, tais abordagens devem contemplar a compreensão da complexidade dos sistemas e dos processos de prestação de cuidados de saúde e as suas interdependências (envolvendo aspectos individuais, tecnológicos e ambientais).

O presente trabalho tem por objectivo reflectir sobre o «estado da arte» da Segurança do Doente em Portugal, destacando os elementos-chave que se consideram decisivos para uma estraté-

gia de acção nesse domínio. Com esses elementos os responsáveis pela governação da saúde poderão valorizar os aspectos que consideram decisivos para uma política de Segurança do Doente mais eficaz. A contribuição de quatro colegas internacionalmente reconhecidos como líderes na área da Qualidade em Saúde e da Segurança do Doente, constitui, por certo, uma oportunidade ímpar para a identificação e discussão de alguns dos principais desafios, ameaças e oportunidades que se colocarão, no curto prazo em Portugal, na área da Segurança do Doente.

Palavras-chave: saúde pública; segurança do doente; eventos adversos; estratégia em saúde; políticas de saúde.

From a public health perspective, there will be a large demand for any effective treatment, for both immediate care and for the purpose of stockpiling medications for future outbreaks. Despite the significant public pressure to access any effective treatment, all countries have limits in their ability to purchase any single treatment. In the United States, Health and Human Services Secretary Alex Azar has indicated there would not be any price controls per se. However, challenges that impede the successful translation of these molecules into drugs are that (i) mRNA is a very large molecule, (ii) it is intrinsically unstable and prone to degradation by nucleases, and (iii) it activates the immune system. Although some of these challenges have been partially solved by means of chemical modification of the mRNA, intracellular delivery of mRNA still represents a major hurdle. The clinical translation of mRNA-based therapeutics requires delivery technologies that can ensure stabilization of mRNA under physiological conditions.

## 2 Challenges and Opportunities in the Post-COVID-19 World.

Challenges and Opportunities in the Post-COVID-19 World. Challenges and Opportunities in the Post-COVID-19 World.

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Although there have been export controls, Germany has flown Italian patients to its hospitals and China has sent ventilators and protective equipment to other countries. In Latin America, efforts are being made to keep borders open while fighting the virus together. The key thing now is to tilt this mixture further in the direction of cooperation. What are the potential risks of regional cooperation from a governance perspective? Lack of trust. The central question is whether the institutions of regional organizations can earn the trust of the citizens of its member countries.