

## CONSTRUCTION OF A PATIENT SAFETY PROGRAM AT A PUBLIC TEACHING HOSPITAL: DOCUMENTARY RESEARCH\*

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**ABSTRACT:** Documentary research on the trajectory of a public teaching hospital in the construction of a Patient Safety Program. Two hundred documents were consulted from the period between 2004 and 2012, at a federal public hospital in the South of Brazil, using data collected between May 2012 and April 2013. The documentary analysis evidences strategies essential for the implementation of a program. These include: situational diagnosis with use of quality tools; internal audits using customized tools; professional with exclusive dedication and expertise in the field of quality; multiprofessional team training; encouragement of collective construction, support from management and involvement of leaderships. The program was a forerunner among federal public hospitals. Developed before the Brazilian legislation that regulates the matter, the hospital complied with most of the requirements of Board Resolution 36 from July 25<sup>th</sup> 2013.

**DESCRIPTORS:** Patient safety; Quality of health care; Quality management.

### CONSTRUÇÃO DE PROGRAMA DE SEGURANÇA DO PACIENTE EM HOSPITAL PÚBLICO DE ENSINO: PESQUISA DOCUMENTAL

**RESUMO:** Pesquisa documental sobre a trajetória de um hospital público de ensino na construção de Programa de Segurança do Paciente. Foram consultados 200 documentos do período de 2004 a 2012, em um hospital público federal do sul do Brasil, com dados coletados entre maio de 2012 a abril de 2013. A análise documental evidencia estratégias essenciais à implantação de um programa. Entre elas, diagnóstico situacional com utilização de ferramentas da qualidade; auditorias internas com instrumentos customizados; profissionais com dedicação exclusiva e expertise na área da qualidade; capacitações direcionadas à equipe multiprofissional; incentivo à construção coletiva, o apoio da direção e o envolvimento de lideranças. O programa foi vanguardista entre os hospitais públicos federais. Desenvolvido previamente à legislação brasileira que normatiza a matéria, cumpriu em grande parte com as demandas da Resolução de Diretoria Colegiada nº 36 de 25 de julho de 2013 do Ministério da Saúde.

**DESCRITORES:** Segurança do paciente; Qualidade da assistência à saúde; Gestão da qualidade.

### CONSTRUCCIÓN DE PROGRAMA DE SEGURIDAD DEL PACIENTE EN HOSPITAL PÚBLICO DE ENSEÑANZA: INVESTIGACIÓN DOCUMENTAL

**RESUMEN:** Investigación documental acerca de la trayectoria de un hospital público de enseñanza en la elaboración de Programa de Seguridad del Paciente. Doscientos documentos fueron consultados en el periodo de 2004 a 2012, en un hospital público federal del sur de Brasil. Los datos fueron obtenidos entre mayo de 2012 y abril de 2013. El análisis documental muestra estrategias esenciales a la implantación de un programa. Entre ellas, la del diagnóstico situacional con utilización de herramientas de calidad; auditorías internas con instrumentos customizados; profesionales con dedicación exclusiva y expertise en el área da calidad; capacitaciones direcionadas al equipo multiprofesional; incentivo a la construcción colectiva, apoyo de la dirección y participación de liderazgos. El programa fue de vanguardia entre hospitales públicos federales. Desarrollado antes de la legislación brasileña que normatiza la materia, ayudó en las demandas de la Resolución de Directoría Colegiada nº 36 de 25 de julio de 2013 del Ministerio de la Salud.

**DESCRIPTORES:** Seguridad del paciente; Cualidad de la asistencia a la salud; Gestión de la calidad.

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## ● INTRODUCTION

As from the end of the 1990's, the field of patient safety has been a global concern in the health area. The report *To Err is Human: Building a Safer Health System* (1999)<sup>(1)</sup>, the most influential study on the theme, disclosed the dramatic reality of patient safety incidents in the health area.

This first report increased the levels of knowledge on safety in care in different countries, raised the professionals' awareness, accelerated governmental initiatives to improve the safety of health care and originated many other studies. Since then, private and governmental institutions in different countries have made efforts to elaborate and implement indicators, national improvement targets and patient safety programs through educational campaigns<sup>(2-3)</sup>.

In that report, a proactive, educational and non-punitive approach of errors is approached, which stimulates the multifactorial analysis of the incidents. The suggested model transcends the superficial treatment of errors, in which the most visible and weakest is eliminated from the context to investigate the deepest and most difficult, that is, the systemic approach.

In the Brazilian reality, in 2002, the Sentinel Network of the National Health Surveillance Agency (ANVISA) is highlighted<sup>(4)</sup>, intended to create a group of hospitals that act as a network that notifies and act upon suspected product-related problems in the post-commercial phase. In 2011, Board Resolution 63 was published on November 25<sup>th</sup> 2011<sup>(5)</sup>, which sets the Requirements of Good Functioning Practices for Health Services and establishes strategies and actions focused on patient safety.

The National Patient Safety Program (PNSP) was launched in April 2013, sustained by the publication of Ministry of Health Decree 529 on April 1<sup>st</sup> 2013. On July 25<sup>th</sup> of the same year, ANVISA published RDC 36, which established patient safety actions in health services. These laws focus on the development of strategies, products and actions targeting health managers, professionals and users targeting patient safety, with a view to mitigating the occurrence of adverse events in health care<sup>(6-7)</sup>.

In the Brazilian reality, a gap is perceived between the questioning period on the theme and the launch of the National Patient Safety Program. Nevertheless, the knowledge in this area, produced dynamically, put pressure on the institutions to develop their own work methods for the purpose of safety.

At the institution where the research was developed, the quality improvement actions are developed against the background of its mission, declared in 2002, in which it assumed the commitment to deliver accredited care to the community. Consequently, in 2003, the Hospital Accreditation Committee was created to implement a Quality Program in the organization, for which the method had to be defined to improve the quality of care.

In this study, the construction trajectory of a patient safety program at a public teaching hospital is described.

## ● METHOD

A documentary research was undertaken. This type of study uses different and varying sources. The documents represent a rich and stable data source and, as they survive over time, they are important data sources in historical research. The studies elaborated based on documents offer a better view of the problem or hypotheses that guide its verification by other means<sup>(8)</sup>.

The documentary research involved the following steps:

1) Determination of objectives: collection of information related to patient safety;

2) Elaboration of work plan:

2.1. Information sources: five types of institutional documents were defined, which were: 50 proceedings of meetings by the Hospital Accreditation Committee – HAC (from February 2006 till May 2010); 22 meetings of Quality Committee – QC (from June 2010 till August 2012) and 37 proceedings of

internal meetings by the Quality Management Advisory Office – QMAO (from June 2010 till May 2012); 09 annual planning documents by Hospital Accreditation Committee and Quality Committee (2004 till 2012); Internal Regimen of QMAO; 81 scripts of verification items for internal quality audits; and five training projects between April 2010 and August 2012, totaling 200 documents. These documents were filed at the Quality Management Advisory Office of a large federal public teaching hospital that delivers tertiary care, located in a capital in the South of Brazil.

**2.2. Collection of material:** the data were collected between May 2012 and April 2013 through detailed reading of the documents, in which fragments were identified that disclosed a relation with the theme patient safety.

**2.3. Data treatment:** documents were selected for the period from 2004 till 2012, which were submitted to thematic analysis, and six categories were constituted, related to the construction phases of the Patient Safety Program at the hospital: preliminary diagnosis of patient safety; planning (first phase); sensitization/training of hospital community; planning (second phase); reporting, investigation and monitoring of indicators; and development of improvement cycle.

**2.4. Presentation of results:** the documentary sources were coded using letters followed by the document number, when applicable, the abbreviation of the place of origin of the document and the year it was registered. The results were discussed based on Brazilian law RDC 36, from July 25<sup>th</sup> 2013<sup>(7)</sup>, concerning patient safety.

Approval for this documentary research was obtained from the Ethics Committee for Research involving Human Beings on May 16<sup>th</sup> 2012, registered under Ethical Evaluation Certificate – CAAE02144512.0.0000.0096 and approval number 22316.

## ● RESULTS

The implementation trajectory of the Patient Safety Program, included the summarized description of the activities evidenced in the documents, is displayed in Figure 1.

The hospital under analysis was the first federal teaching hospital to obtain an accreditation certificate by the National Accreditation Organization(ONA).

Figure 1 – Descriptive synthesis of main strategies applied at the hospital in the context of the Patient Safety Program, 2007 – 2012. Curitiba, PR, Brazil, 2013 (continues)

<b>Preliminary Diagnosis: 2007-2009</b>
Inclusion of item on patient safety in verification items of internal audits; Project for creation of exclusive advisory office for quality management.
<b>First phase of planning: 01/2010-03/2010</b>
Approval of Quality Management Advisory Office (QMAO); Approval of leadership training project; Definition of risk assessment tool to be used (adapted Healthcare Failure Mode Effects and Analysis - HFMEA); Identification and analysis of more than 140 risks during workshops targeting the leaderships; Establishment of subprojects to treat the different risks; Search for accreditation certificate through Brazilian Accreditation System – National Accreditation Organization (ONA).
<b>Sensitization/training: 04/2010-08/2010; 02/2011-03/2011</b>
Organization of courses and workshops focused on leaderships, nurses and specific groups, such as support teams (nutrition, maintenance, reception and others); Forum open to entire hospital community, focusing on international patient safety targets and 10 steps for safety by COREN-SP (2010); Training for incident reporting.
<b>Second planning phase: 08/2010-09/2010</b>
Development of incident reporting tool; Definition of analysis method for incidents with severe patient damage – root cause analysis (RCA).

<b>Reporting/investigation/monitoring of indicators: 03/2011</b>
Definition of incident treatment flows; Start of reporting by hospital community; Start of investigations of severe incidents by QMAO; Definition of indicators aligned with target contracts of functional units; Definition of tasks of Internal Quality Groups (IQG) for the implementation of patient safety improvement strategies.
<b>Development of improvement cycle: 01/2012 – 08/2012</b>
Review of incident reporting and investigation forms; Characterization of incidents according to International Classification for Patient Safety (ICPS), class 1 – incident type; Updating and creation of standard operating procedures - SOP; Updating of incident treatment flows; Characterization and dissemination of institutional safety profile focused on the number of reports per unit, incident type, degree of damage and recommendations for qualification actions; Forum of best practices and challenges faced by IQG; Organization accredited at Level I by ONA, works to maintain the certification.

## ● DISCUSSION

The teaching hospital studied planned the implementation of a method to improve the safety of patient care, a fact that tends to demand a cultural change. This action represented a great challenge in view of the institutional profile: a public teaching hospital. Authors acknowledge that, in this kind of institutions, the public good may be neglected, as employment stability discourages the professionals from improvement and encourages accommodation<sup>(9)</sup>.

It was observed, however, that the construction of the Safety Program led to an intense valuation of the collective construction, entailing results that revealed formal leaderships and professional committed to transform the reality.

It is highlighted that internal audit are important mechanisms to diagnose the reality, which permit knowledge on the organization's weak and strong points, objectively guiding the development of actions towards improvement<sup>(9-10)</sup>.

One factor that influenced the evolution of the program was the creation of a specific department called Quality Management Advisory Office (QMAO), directly subordinated to the hospital board, with professionals who exclusively worked to develop quality and patient safety strategies. An institution that aims to implement quality management should have professionals serving on its staff with full-time dedication to this function<sup>(10)</sup>.

The multidisciplinary teams' construction of the Healthcare Failure Mode Effects and Analysis (HFMEA) worksheets evidences a proposal for the hospital community to change its culture, abandoning passiveness towards a pro-active attitude, cooperation among the different areas involving leaderships and systemic approach of risks in the different phases of the work process<sup>(1,11-12)</sup>.

Concerning the training, the focus on the leaderships is highlighted, an institutional action that supports one of the premises in the current patient safety model, which emphasizes the importance of the leaders' role in the improvement of the processes and the latent conditions that lead to errors and patient safety incidents<sup>(1,11,13)</sup>.

It is underlined that the nursing team professionals are important patient safety agents, who stay with the patients and their relatives and can assess their changes when these happen<sup>(13)</sup>. In addition, they remain alert to the patient, surpass the physicians by a rate of at least 5:1 in incident reports and feel much more comfortable to discuss errors with their supervisors<sup>(14-15)</sup>.

The institution under analysis adopted an incident reporting system, which contributes to identify patient safety problems. Self-reporting is the most common method to measure the safety level<sup>(11)</sup>.

It comes with limitations though, the most important of which is considered the professionals' low compliance. In an American study, it was proven that only 14% of the adverse events are identified by means of this method, appointing difficulties for the team to perceive what an incident is and what should actually be reported as the main motive for underreporting<sup>(15)</sup>.

Consequently, it is recommended to measure the safety level by combining methods that can identify active errors, adverse events and latent conditions for error<sup>(11,16)</sup>.

Defining a strategy to analyze severe incidents is an important action in quality and safety management. It is highlighted that root cause analysis is considered a method that involves the interdisciplinary review of the incident, mainly focused on the processes and system, which prevents the emphasis on the human factor as a causal factor. The final objective is the identification of the contributing factors, which permit knowledge on the reality and support the proposal of changes to improve the systems' performance and reduce the risks of reoccurrence<sup>(17)</sup>.

Characterizing the hospital profile related to the number of incidents reported, the degree of patient damage and the incident type offers a systemized and in-depth situational diagnosis, which permits comparisons internally and external to the organization and impels the institution to make decisions<sup>(17)</sup>.

Quality certification represents an important management tool, as it is based on requisites and standards that make the institution understand the factors to improve its performance, to systematically understand the strengths and opportunities for improvement and helps it to promote internal cooperation among the different areas, processes and team professionals<sup>(18)</sup>.

Assessing the accreditation stimulates the organizations to constitute barriers to prevent, avoid and mitigate the risks for the patient<sup>s(19)</sup>.

## ● CONCLUSION

Setting up a patient safety program aligned with the strategies defined in Brazilian legislation requires knowledge, focus, dedication and persistence.

Organizations with the dimensions of the hospital under analysis are live organisms, where the care processes cannot be postponed, considering that they take place in accordance with the needs that emerge. Therefore, it is highlighted that action planning is decisive, and that each institution has its own culture and reality, which should be taken into account. The model with the greatest chance of success is scientifically grounded and adapted, in a participative manner, to the institutional reality.

It is highlighted that the analysis of the documents evidenced that some strategies were essential for the construction of the Patient Safety Program at the institution. These include the situational diagnosis involving the use of quality tools; audits using customized tools; professionals with exclusive dedication and expertise in the field of quality; training for the multiprofessional team; encouragement of collective construction and involvement of formal and informal leaderships, especially the hospital board. The quality certification process is considered the factor with the strongest positive impact in the implementation of the program.

The program was a forerunner among federal teaching hospitals and was developed before the Brazilian legislation that regulated the matter. The hospital complied with most of the requirements of Board Resolution 36 from July 25th 2013 when the program was constructed.

Nevertheless, the strategies that put the patient in a central position in care should be intensified; other methods besides reporting should be adopted to identify incidents; and information should be shared, especially when concerning learning from errors.

At public institutions, the challenge to construct a Patient Safety Program may seem bigger, in view of the premise that the progress is slower. Appropriate strategies can make it possible to obtain information from the professionals and the environment they work in though, with a view to working on the changes required in the hospital organization.

Despite the many publication on the theme patient safety, deeper knowledge is needed on the reality of safety in health organizations in Brazil. In that sense, the recent Brazilian legislation provides support for reliable strategies to be implemented in the field of patient safety.

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