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The need to establish a national patient safety program in Brazil

ABSTRACT

The aim of the study was to promote reflection on the need to create a national incident notification system based on a brazilian patient safety program. Incidents in health care harm patients and encumber the health care system. Although a quality assessment program has been recently launched in health care institutions, the Brazilian Ministry of Health does not yet have a program which systematically assesses negative outcomes of health care. This article discusses the need to establish a national patient safety program in Brazil, aiming to promote a culture of patient safety and quality health care in the Brazilian Unified Health System.

DESCRIPTORS: Patient Safety. Program Evaluation. Unified Health System. Quality Assurance, Health Care.

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INTRODUCTION

For a long time the results of health care have been used to assess the quality of health care services. The Babylonians paid for medical services according to results and, in the Middle Ages, doctors whose services had negative outcomes had parts of their bodies mutilated.[17]

Negative health care results are mainly known as any type of adverse event with the potential to harm patients[20] and can furnish significant data for creating a safer health care system.[14] The incident may harm (adverse event), or not, the patient or be a near miss, which is also classed as a potential adverse event.[4,23]

Negative health care results were reported by the Institute of Medicine (IOM) in 1999,[11] when an estimated 44,000 to 98,000 deaths in the United States were caused by errors in patient care. Since then, health care results or outcomes have been subject to scrutiny as they are directly related to patients' health care quality and safety. Patient safety is defined as the act of avoiding, preventing or improving adverse results or injuries resulting from the medical-hospital care process.[21]

Faced with increased worldwide awareness after the publication of this shocking report, the World Health Organization (WHO) launched the World Alliance for Patient Safety in 2004.[a] This awakened member countries, including Brazil, to their commitment to developing public policies and practices aimed as patient safety.

In Europe, it is estimated that 10.8% of patients in hospitals were subject to adverse events, 46% of which were avoidable.[22] In Southeastern Brazil, a study of hospitals in Rio de Janeiro, RJ, estimated the incidence of these events at 7.6%.[13]

Although the Ministry of Health and the *Agência Nacional de Vigilância Sanitária* (ANVISA – National Health Monitoring Agency) promoted World Alliance for Patient Safety initiatives, such as the campaign to introduce safe surgery protocols in hospitals, adherence on the part of the health care services is low, for the very reason that there is no institutional culture of patient safety. This is reflected in the high incidence of avoidable adverse events in Brazilian hospitals, which account for around 67% of all adverse events.[13,20]

Although there are some positive aspects to the Brazilian health care system, such as universal vaccination coverage and the national transplant system, the high frequency of adverse events related to medications and hospital infections is a cause for concern.[13,20] These events are attributed to a lack of government policies[b,c,d] incentivizing health care institutions to participate in quality and accreditation programs.[15,16] There are currently Brazilian hospitals providing health care services without evaluating their processes or using such results to improve quality.[d]

It is, therefore, necessary to be aware of the reality of such incidents in Brazil, which can be obtained by health care institutions becoming involved in monitoring them and in dealing appropriately with the data, in addition to reporting to government bodies. However, the fact that an organized flow of information exists does not in itself generate knowledge. This can only come about through the interdisciplinary interaction of those involved.[14]

The aim of this study was to provoke reflection on using a national incident notification system as the basis for a Brazilian Patient Safety Program.

BRAZILIAN UNIFIED HEALTH SYSTEM QUALITY AND PATIENT SAFETY

In 2011, the Ministry of Health launched the Health Care Network Training and Quality Improvement Program, the QualiSUS Rede.[e] Although this was an important step forward in the Brazilian Unified Health System (SUS) quality development, the project did not include incentives to adopt a hospital accreditation program, nor a strategic objective directly linked to patient safety, something the IOM and WHO considered essential to quality.

Another Ministry of Health initiative was to monitor the SUS performance rate (IDSUS), which aims to measure the health care system's performance with regards access – potential and actual – and the effectiveness of primary health care, outpatient and hospital care and emergency care on a national level.[f] This measurement is achieved through quality indicators.

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[a] World Health Organization. APPS web-based registration mechanism open. Geneva; 2012 [cited 2012 jun 2]. Available from: http://www.who.int/patientsafety/en/

[b] Capucho HC. Sistemas manuscrito e informatizado de notificação voluntária de incidentes em saúde como base para a cultura de segurança do paciente [tese de doutorado]. São Paulo: Escola de Enfermagem de Ribeirão Preto da USP; 2012.

[c] Ministério da Saúde. Portaria GM/MS nº 529, de 1 de abril de 2013. Institui o Programa Nacional de Segurança do Paciente (PNSP). *Diario Oficial Uniao*. 2 abr 2013;Seção1:43-4.

[d] Petramale CA. O projeto dos hospitais sentinela e a gerência de risco sanitário hospitalar. In: Capucho HC, Carvalho FD, Cassiani SHB. Farmacovigilância - Gerenciamento de Riscos da Terapia Medicamentosa para a Segurança do Paciente. São Caetano do Sul: Editora Yendis. 2001. p. 191-224.

[e] Ministério da Saúde. Portaria nº 396, de 4 de março de 2011 Institui o projeto de formação e melhoria da qualidade de rede de saúde (Quali-SUS-Rede) e suas diretrizes operacionais gerais. *Diario Oficial Uniao*. 9 mar 2011.

[f] Ministério da Saúde. Índice de Desempenho do SUS – IDSUS. Brasília (DF); 2011 [cited 2012 jun 2]. Available from: http://portal.saude.gov.br/portal/saude/area.cfm?id_area=1080

None of the indicators established in the IDSUS are directly linked to patient safety, such as the rate of incidents in emergency care. On the other hand, in the IDSUS, the indicators are dealt with as the percentage of in-hospital deaths from acute myocardial infarction, which calculates the risk of dying from this condition after admission for this reason, and thus indirectly estimate delays in pre-hospital care and in diagnosis.[d] The use of this indicator in the Brazilian government's program can be viewed as a step forward, albeit a small one.

The project envisages a differentiated allocation of funds for those regions which reach higher levels of quality. This type of program has been successfully carried out in other countries. In England and the United States, e.g., in addition to sharing safety indicators between institutions in the country, with the aim of recognizing and establishing quality and safety levels in hospitals, those which achieve the highest levels are compensated with differentiated remuneration.[3,9]

This model of payment by quality is known as pay for performance (P4P)[7] and is an alternative to the fee-for-service system widely used in Brazil, which promotes the overuse of resources, especially health care technologies, and gives no guarantee that the additional cost and ease of access result in effective improvements in the level of health care provided to the population cared for.[7]

O P4P is being developed in many countries, including Brazil. In England, the model for using this system, the payments make up 30% of the income of some clinics.[7,12] It is expected that P4P leads to the service users themselves choosing the service they want to treat them, based on publicly reported performance indicators. Constance et al[6] showed that publishing those reports is an effective mechanism for improving health care quality.

Brazil still faces the challenges of high turnover of health care professionals in public services, as well as qualitative limitations of human resources, inappropriate use of technology and poor continuity of care provided to patients.[1,20] Even so, a small number of hospitals in Brazil are dedicated to teaching and researching and do not influence improvements in health care practices due to the disconnection between teaching, research and health care, the poor use of evidence based health care in patient care and the fact that research into patient safety is limited to centers of excellence.[1,16,20]

Faced with the situation exposed in the report, in which policies implanted by the Ministry of Health proved to be insufficient to stimulate critical examination of patient safety, establishing specific goals to prevent avoidable harm and minimize the risk of incidents, it was proposed that a national patient safety program, linked to federal government quality programs, be set up. Such a program should involve the Ministry of Health, ANVISA, *Agência Nacional de Saúde Suplementar* (ANS – National Supplementary Health Agency) and the Ministry of Education, the latter being an important ally in training health care professionals, especially in teaching hospitals.

The National Patient Safety Program is necessary as it is in line with modern perceptions of quaternary prevention health care, which aims to detect individuals at risk of excessive health care interventionism, which implies unnecessary actions and suggests ethically acceptable alternatives, attenuating or avoiding adverse effects.[2,19]

This approach is especially important in Brazil, which has experienced exponential growth in the new technologies available in the health care market over the last ten years, especially after the establishment of ANVISA, and has a very recent evidence-based legal framework on the incorporation of technology[g] and is investing in a humanized health care model.[1]

The Patient Safety Program should be disseminated in the various institutions which make up the health care system, in all of the states, with the aim of obtaining and sharing knowledge of health care results, including negative results. Therefore, establishing a national incident notification system should be a priority of a national patient safety program which includes, at the very least, goals for managing the risks involved in health care, such as correctly identifying patients, reducing hospital infections, reducing errors in surgical procedures and medication, which are included in the WHO nine solutions for patient safety.[h]

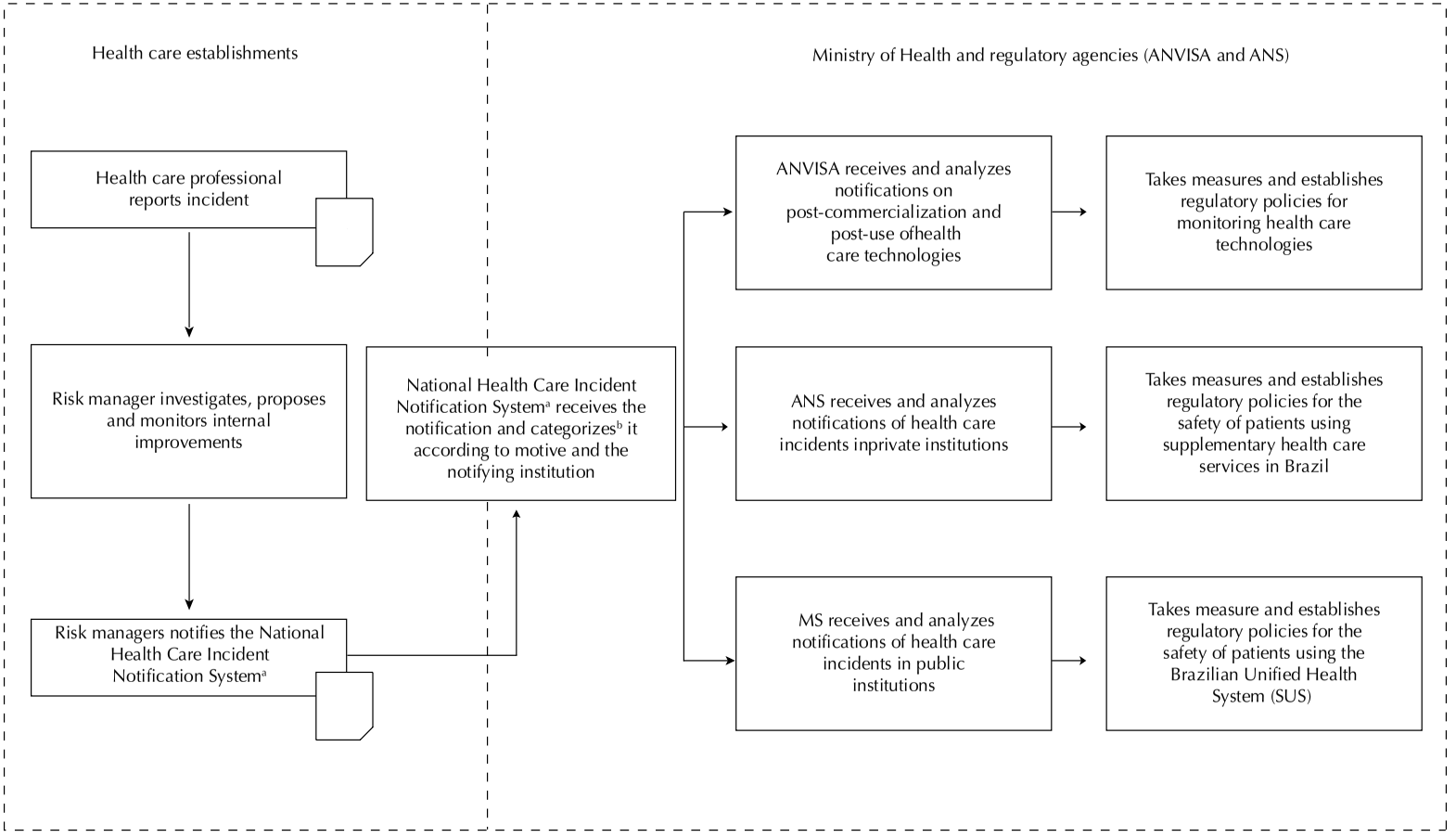
Incident notification system

Notifications by health care professionals, patients and their carers are important in identifying incidents in health care, it is a low cost method, and it involves professionals providing health care in a policy of patient-centered continuous improvement.

In order to guarantee that health care institutions produce data for decision making and taking responsibility for improvements in quality, investment in developing local capabilities and already existing information systems is essential.[10]

The experience of ANVISA with the Sentry Network is a good example of how cooperation between the

[g] Brasil. Lei nº 12.401, de 28 de abril de 2011. Altera a Lei nº 8.080, de 19 de setembro de 1990, para dispor sobre a assistência terapêutica e a incorporação de tecnologia em saúde no âmbito do Sistema Único de Saúde - SUS. *Diario Oficial Uniao*. 29 abr 2011:1.
[h] World Health Organization. WHO launches 'Nine patient safety solutions. Geneva; 2007 [cited 2012 jun 2]. Available from: http://www.who.int/mediacentre/news/releases/2007/pr22/en/index.html



ANVISA: *Agência Nacional de Vigilância Sanitária* - National Health Monitoring Agency; ANS: *Agência Nacional de Saúde Suplementar* – National Agency of Supplementary Health Care

[a] Fictitious name

[b] The computerized system identifies the motive and the individual notifying is able to see the body responsible

Figure. Simplified flowchart of the National Health Care Incident Notification System.

government and health care institutions is possible and can promote the development of safety and quality services, either by a culture of voluntary reporting or by adhering to quality programs.

The number of notifications from hospitals belonging to the Sentry Network to the *Sistema de Notificações em Vigilância Sanitária* (NOTIVISA – Health Monitoring Notification System) increased by 48.8% in the first year after the system was established, compared to the previous year. ANVISA stimulated the hospitals in the network to participate in quality and accreditation programs and 30% of these hospitals were participating in programs of this type in 2008.[c]

Although the ANVISA initiative was important in encouraging quality in hospitals, it affected only a small percentage of the more than 8,000 Brazilian hospital institutions, corresponding to around 13% of hospital beds in the country.[c]

For this reason, the role played by the government bodies that receive the data on health care results is essential, as it is their responsability to encourage improvements at short-term with the aim of avoiding harm coming to the patients. Using an online computerized systems, i.e., data can be sent and received instantly, is an essential step for a country the size of Brazil to develop a national patient safety program. Moreover, a Brazilian pay per performance model must be established to benefit those institutions that are committed to the continuous quality improvement model.

The model for the national incident notification system could be useful in developing a culture of patient safety within the SUS, as shown in the Figure.

Developing and establishing a single computerized system receiving notifications from all health care institutions should aim to facilitate the process of sending these notifications and making decisions based on them, to minimize risks and avoid adverse events, to improve the quality of care and increase patient safety at all levels, from the smallest health care clinic to the Brazilian public health system; to increase knowledge of the risks and incidents which occur in Brazilian institutions, to guide health care managers' planning and actions; to improve the quality of data sent; to ensure the clarity of the information sent; to preserve confidentiality of those who report and of the data reported; and, finally, to reduce the cost of the notification process.

As the system becomes more frequently and efficiently used for the voluntary notification of incidents, especially those that are potentially adverse, making decisions as to interventions necessary for avoiding harm will be quicker, which could reduce the unnecessary costs of treating adverse events which could have been avoided.

Therefore, autonomy and being pro-active should be encouraged in health care institutions. While waiting for the government to take action, institutions themselves should also work on internal improvements, aiming to encourage patient safety and quality health care. Thus, health care establishments should not only have access to a computerized system for sending notifications of risk management to the national system but also for management to receive notifications from their institutions health care team. Moreover, the system should allow the institution to follow the progress of analysis of the data sent to the national system.

The computerized system is an important strategy in encouraging quality together with sustainability as it obviates the need for paper, reduces spending on materials and reduces waste such as paper, ink cartridges and pens. In addition, other aspects justify the establishing of such a system, these being:[5]

- it eliminates the institutions' need for systems for sending internal documents and data to the national notification system, which reduces the time needed for information to arrive and the cost of sending them;
- it may prevent information being misplaced or lost, especially if it is backed up in a database with a security copies, avoiding the need for physical storage space, as well as making the data easier to handle and to analyze for management indicators;
- it is possible to request further information on incidents without making data collection more difficult, improving the quality of information and increasing participation on the part of health care professionals, which is not possible when using a paper system.

As for social aspects of sustainability, it reduces the time spent on sending reports, which increases health care professionals' participation in the notifications as well as increasing the time available for them to spend with patients, thus becoming more involved with patients and their carers in the process of monitoring risks and incidents in health care. These individuals are important sources of voluntary notification in a national policy. An online computerized system of notifications would make it possible for anyone with internet access to report an incident.

Countries that already have a national patient safety policy, such as England, The United States, Australia and Canada allow service users and their carers to report risks and incidents they have experienced or observed in the health care system, and these are essential to encouraging quality health care.

The national notification system should be hosted on an interactive site that provides free notifications, safety

tips, information on adverse events, protocols on how to implement safety programs in the health care system, online courses and seminars, such as the Institute for Health Improvement for hospitals in the US. This portal would have the dual function of maintaining and encouraging adherence in institutions and disseminating and encouraging the adoption of best practice in patient safety through exchanges between themselves.

Establishing a computerized notification system for health care incidents in the Brazilian Health Care System, based on a culture of patient safety, appears to be a viable and necessary strategy to characterize health care, through which managers will be systematically made aware of incidents occurring in the health care provided to service users in public and private institutions, without having to depend on research carried out exclusively to this purpose. Thus, guidance will be provided in outlining risk management strategies for patient safety, increasing the quality of services supplied to the Brazilian population.

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HIGHLIGHTS

The Ministry of Health recently launched the *Programa Nacional de Segurança do Paciente* (National Patient Safety Program) so that patient safety activities would be promoted within the Brazilian Unified Health System (SUS). This is a praiseworthy initiative and was the main focus of the article, which dealt with important issues that were not included in the abovementioned program. These issues refer to the way in which the Government aims to remunerate those institutions which obtain the best results for providing services and also to how data derived from notifications are treated, so as to promote the knowledge generated and to improve the services provided by the SUS.

The article sheds light on improvements in health care policies for patient safety, in which it is possible to see that activities involved in the culture of safety also proliferate and generate good results in public hospitals. Thus, attention is drawn to important discussions for all institutions and especially for managers of the system so as to improve the national program and trigger continuous improvements in patient-centered services.

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