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Review Article

Patient involvement in the safety of care: an integrative review

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ABSTRACT

The aim of this integrative review was to survey the strategies adopted by health institutions that involve patients in care as a barrier to prevent incidents. A search was conducted in MEDLINE, LILACS, CINAHL and PubMed databases using the descriptors ‘patient safety’, ‘iatrogenic’, ‘medical error’ and ‘involvement’. The review included studies in full text published between 2003 and March 2016 in English, Spanish or Portuguese. It was found that the effective communication and the development of patients’ autonomy are the most advocated strategies. The level of evidence of studies was limited to four and six. The assessment or description of institutional practices involving patients in their safety emerged as a gap in scientific knowledge. The impact of this review is to demonstrate the need for randomized studies to identify effective interventions, directing health institutions towards change in the organizational culture, focusing on safety and patient-centered care.

Descriptors: Patient Safety; Iatrogenic Disease; /prevention & control; Nursing.

INTRODUCTION

The patient safety issue has gained worldwide focus nowadays. Some initiatives have been developed to improve work processes from the reduction of errors in health and safety improvement. The World Alliance for Patient Safety[(1)] stands out among such initiatives. It was created by the World Health Organization (WHO) in 2004, and aims to mobilize global efforts for health care safety, directing public health policies to the context of prevention of incidents[(1-2)].

An incident is understood as an event or circumstance arising from care without a relationship with the underlying disease. Incidents can be classified as follows: incidents without damage are those who affect the patient and do not result in apparent damage but constitute a hazard; adverse events necessarily result in some harm to the patient, whether temporary or permanent, plus worsening of the health situation, increased hospital stay, need for additional procedures and/or substitution of treatment, and even death; near miss are incidents that for some reason were intercepted and did not reach the patient; and notifiable condition is a situation with potential for damage, but in which the incident does not happen[(3)].

The worldwide concern with the issue of safety is due to evidence supporting prevalence of 10% of adverse events among patients in need of health care[(4)]. In Brazil, studies show prevalence of adverse events ranging from six to 18.7%[(5-8)], and incidence of 38.4%[(8)]. However, about 66.7% of these events are considered preventable[(6)].

A retrospective study performed in a surgical clinic of a university hospital showed 82% prevalence of incidents without injury[(7)]. Among the various types of identified incidents, those related to the clinical process such as care omission, inadequate checks, and failures during technical procedures stand out. Other incidents involved medication errors, accidents with patients, and incidents related to organizational structure such as equipment maintenance, management of blood products and material resources[(7)].

Thus, health care may expose patients to various situations of risk, and hospitalization is an intervening factor for the occurrence of an unexpected event[(9)].

The involvement of patients in the care actions is a strategy that has been stimulated to prevent these incidents. In this perspective, the WHO created the program Patients for Patient Safety. It brings together patients, professionals, managers and damage victims as partners and contributors to improve safety, and encourages placing patients in the center of care and their inclusion as full partners in the assistance[(10)].

Another program with the aim of involving patients in care for error prevention in health care is the 'Speak Up' created by the Joint Commission in 2005. It offers counseling to patients and stimulates their questioning during care for the clarification of their doubts and their involvement in the decisions[(11)].

A study conducted in Denmark with cancer patients found that safety was neither an item receiving special attention from patients nor the subject of communication/discussion between health professionals[(12)]. On the other hand, both professionals and patients mentioned the importance of patients' involvement in care to increase safety of care. Among the obstacles to the non-involvement of patients, were highlighted the limited knowledge about conceptual aspects of patient safety, the unfamiliarity with specific techniques of patient involvement in their safety, and concern with the potential negative impact in the doctor-patient relationship[(12)].

From this perspective, and considering that patients are the last barrier to the occurrence of errors, the aim of this study was to survey the strategies used by health institutions that involve patients in the care process with a view to prevent incidents, through a literature review.

The relevance of the study is to identify evidence of clinical practice in recent studies about how to

ensure patient involvement in care with a view to improve quality and safety of patients during health care.

METHODOLOGY

This is an integrative literature review, which is a rigorous method for the synthesis and analysis of knowledge on a specific subject with the aim to facilitate the implementation of results of significant studies in clinical practice(13).

This type of study involves six stages, namely: the first is the preparation of the guiding question of the study; the second is the search or sampling of the literature; the third is the data collection; the fourth is the critical analysis of the included studies; in the fifth are discussed the results; and in the sixth is presented the synthesis of knowledge(14). One of the integrative review features is peer research, in which two researchers perform an independent search for subsequent discussion and, when they find discrepancies, a third investigator is assigned.

Specifically in the fourth phase of the integrative review, the selected literature should be classified by level of evidence according to the method used in order to help with assessment of the accuracy and characteristics of the studies. Level 1 includes evidence from meta-analysis of multiple controlled and randomized clinical trials; Level 2 are evidence from individual studies with experimental design; Level 3 consists of evidence of quasi-experimental studies; Level 4 indicates evidence of descriptive (non-experimental) or qualitative approach studies; Level 5 describes evidence from case or experience reports; and Level 6 are evidence based on expert opinions(14).

The guiding question adopted for this study was: what are the strategies used by health institutions that involve the participation of patients in their safety during health care? For the selection of articles were performed various combinations using the keywords ‘patient safety’, ‘iatrogenic’, ‘medical error’ and ‘involvement’ in Portuguese and English. The consulted databases were MEDLINE, LILACS, CINAHL and PubMed.

The criteria for including the articles were: abstracts available in the aforementioned databases; publication period between January 2003 and March 2016, studies available in full text; publications in English, Spanish or Portuguese.

Data collection was performed by three researchers independently and completed in April, 2016. The selections were compared to verify the compatibility of the findings and discuss the differences. The data were summarized in a table to allow the comparative analysis of the studies, and discussed descriptively.

RESULTS AND DISCUSSION

From a survey in the databases, were located 21 studies. After reading titles and abstracts and collating data among researchers, were excluded five studies that did not meet the established inclusion criteria. Sixteen studies were selected, of which six were located in MEDLINE, four in LILACS, one in CINAHL and five in PubMed. Two studies were indexed in more than one database, and in total, fourteen studies were analyzed. They are summarized in Table 1.

Table 1: Summary of studies on patient involvement in care as a preventive strategy of incidents organized by year of publication.

Authors. Title / Journal (Year)	Objective / Type of study /Level of evidence	Evidence found in the conclusion of studies
Harvard Health Letter. Patient, protect thyself? / Harvard Health Publications (2006)	To report the importance of patients for error prevention. / Expert opinion based on the literature. / Evidence 6.	Patient involvement in the care reduces the chance of adverse events. Open communication between doctor and patient increases safety.
Entwistle VA. Differing perspectives on patient involvement in patient safety. / Qual Saf Health Care (2007)	To discuss the advantages of patient involvement in their health care. / Expert opinion based on the literature. / Evidence 6.	Points patient involvement as an ethical issue. The perspectives of this practice include respect for the patient, improved communication, and it favors the development of the autonomy of patients and their families.
Bartlett G, Blais R, Tamblyn R, Clermont RJ, MacGibbon B. Impact of patient communication problems on the risk of preventable adverse events in acute care settings. /CMAJ (2008)	To assess the association between communication problems and preventable adverse events. / Randomized study of 2,355 medical records of patients admitted to 20 general hospitals in Quebec. / Evidence 1.	Prevalence of 2.7% of adverse events, of which 29% were preventable. The emergency admissions increased by 64% the risk of adverse events. Patients with changes in communication were more prone to adverse events (46% vs. 20%, $p = 0.05$).
Cernadas JMC. Patients and parents participation to prevent medical errors. / Arch Argent Pediatr. (2009).	To defend patients' participation in self-care to reduce medical errors. / Expert opinion based on the literature. / Evidence 6.	Informing patients, parents and/or caregivers about the care plan and providing guidance on how to help health professionals to reduce medical errors is an important tool to ensure patient safety.
Bagnulo H, Barbato M, Godino M, Basso J. Risk assessment under effect circumstances. / Rev Med Urug (2010)	To address current subject areas on the safety of care. / Expert opinion based on the literature. / Evidence 6.	Highlights the need for patients and families recognizing the adverse event, developing the patient for self-care, and guiding caregivers with behavior that is inappropriate or reflects a negative culture for safety.
Hall J, Peat M, Birks Y, Golder S, PIPS Group, Entwistle V et al. Effectiveness of interventions designed to promote patient involvement to enhance safety: a systematic review. / Qual Saf Health Care (2010)	To assess the effectiveness of interventions of patient involvement with health care. / Systematic review. / Evidence 1.	Fourteen experimental and quasi-experimental studies and a systematic review were identified. The best results of incidents of patient safety are found in environments with patient involvement in care. There is limited evidence on the effectiveness of these interventions.
Gallotti RMD, Morinaga CV, Rodrigues MA, Velasco IT, Martins MA, Tiberio IC. A new method for the assessment of patient safety competencies during a medical school clerkship using an objective structured clinical examination. / Clinics (2011)	To assess the development of skills for patient safety through the Objective Structured Clinical Examination (OSCE). / Descriptive study with 95 medical students. / Evidence 4.	Less than 60% of students offered the patient an apology after a medical error. Points the OSCE as a useful tool for the development of skills in the doctor-patient relationship, patient-centered care and recognition of errors, aspects that must be addressed in the training of health professionals.
Ward K, McEachan RR, Lawton R, Armitage G, Watt I, Wright J. Patient involvement in patient safety: Protocol for developing an intervention using patient reports of organizational safety and patient incident reporting. / BMC Health Services Research (2011)	Development of a tool for incident report by patients. / Descriptive study. / Evidence 4.	The incident report by patients is a reliable means about their safety and brings a different perspective when compared to that of health professionals, which promotes subsidies for clinical practice and organizational learning.
Wegner W, Pedro ENR. Patient safety in care circumstances: prevention of adverse events in the hospitalization of children / Rev Latino-Am Enfermagem (2012)	To analyze the perception of adverse events with 15 companions or caregivers and 23 healthcare professionals. / Case study of qualitative approach in an inpatient pediatric unit. / Evidence 5.	The monitoring and surveillance by the companion and an effective communication between professional-caregiver-child reduce adverse events. The caregiver's presence was a requirement for the safety culture in children's hospitalization.

Authors. Title / Journal (Year)	Objective / Type of study /Level of evidence	Evidence found in the conclusion of studies
McDonald KM, Bryce CL, Graber ML. The patient is in: patient involvement strategies for diagnostic error mitigation. / BMJ Qual Saf (2013)	To describe strategies for patient involvement in the reduction of misdiagnosis. /Expert opinion based on the literature. / Evidence 6.	Advocates the involvement of patients to improve the accuracy of medical diagnoses. Guides patients about questions that should be asked to the professional who provides diagnosis, and encourages the patients' proactive attitude.
Hrisos S, Thompson R. Seeing it from both sides: do approaches to involving patients in improving their safety risk damaging the trust between patients and healthcare professionals? An Interview Study. / Plos one (2013)	To analyze the implications of patient involvement in care. / Qualitative study performed with 16 patients, four family members and 39 health professionals. / Evidence 4.	Safety initiatives involving the patient should encourage joint work between professional-patient, with the aim of increasing safety. A collaborative approach should be emphasized to avoid negative tension in the professional-patient relationship.
Mohsin SS, Sara G, Bryony DFP. Involvement in medication safety in hospital: an exploratory study. / Int J Clin Pharm (2014)	To analyze patients' reports on safe care with medication and the support offered by health professionals for this involvement. / Descriptive study with 100 patients and 104 healthcare professionals. / Evidence 4.	Female patients and those younger than 65 years had significantly higher level of involvement. Pharmacists and nurses were more likely to offer support to patients who ask questions about their medicines.
Berger Z, Flickinger TE, Pfoh E, Martinez KA, Dy SM. Promoting engagement by patients and families to reduce adverse events in acute care settings: a systematic review. / BMJ Qual Saf (2014)	To analyze how the interventions that encourage the participation of patients and family members in care were implemented. / Systematic review. / Evidence 1.	Eighteen 18 studies showing the importance of guiding patients to their involvement in care were identified. Despite the incentive for such involvement in the prevention of nosocomial infections, falls and pneumonia associated with mechanical ventilation during care transitions and surgical checklist, effective measures are insufficient.
Ridelberg M, Roback K, Nilsen P. Facilitators and barriers influencing patient safety in Swedish hospitals: a qualitative study of nurses' perceptions. / BMC Nursing (2014)	To list the factors that facilitate and inhibit patient safety. / Descriptive, qualitative study developed with 12 nurses linked to general hospitals in Sweden. / Evidence 4.	Factors intrinsic to patients can influence their safety. Thus, the positive interaction between patients and health professionals, and the patient involvement in care are favorable factors to safety.

The year of publication of the studies ranged from 2006 to 2014. There were no publications dealing specifically with patient involvement in safety issues during the period between January 2015 and March 2016. The studies addressing the importance of patient involvement in the care for reduction of incidents were limited to methods with evidence levels 4 and 6, corresponding to 71.4% of the findings (ten publications). An only study presented evidence level 5 and dealt specifically on how companions/caregivers and health professionals recognize the adverse events in care circumstances. Three studies were classified with the best level of evidence (level 1), and they showed the importance of communication among those involved in the care and quality of guidance offered to patients/companions to maintain safety.

With this integrative review, was identified a gap in scientific knowledge; the studies evaluating or describing the practice of institutional programs with patient involvement in care in health institutions, and focused on reduction of incidents and safety improvement.

The analysis of results allowed their distribution into two categories: 'Strategies of patient involvement in safe care' and 'Education of healthcare professionals for patient involvement in care'. The presented discussion addresses various aspects converging in communication, which emerged as an essential tool for the management of safe care.

The impact of these results is evidence that there must be much progress in actions involving patients as the central axis of care, and considering them as the last barrier to prevent the occurrence of incidents, which is a still incipient practice in the routine of health services. The hospital setting was the study scenario of articles, and it is necessary to expand the discussions on patient involvement in the safety of health care to other practice settings, including primary health care and institutions with specialized services.

Strategies of patient involvement in safe care

The strategies found for patient involvement in safe care were the following: open/effective communication between patients, caregivers and health professionals; the development of patient autonomy for self-care; patient involvement in care; the availability of manuals and/or explanatory booklets on the pathological process of patients; and empowerment of patients for the perception of risks.

The interaction between health professionals and patients can facilitate or hinder the maintenance of safety[15]. Environments in which patients do not receive information about the care, and with low professional-patient interaction are considered unsafe environments[15]. On the other hand, a positive interaction can encourage safety.

In this perspective, communication is an extremely important tool for the effective relationship between professionals and patients, contributes directly to the prevention of incidents[16-17], and is pointed as an ethical issue in the context of health care[18].

For an effective communication, it is necessary to use clear and objective language, avoid technical terminologies, provide complete and accurate information to patients and allow/create opportunities to clarify doubts[17]. In addition, there should be an increasingly open communication[16] in a way to establish a

symmetrical relationship and minimize possible power relations.

Especially in the context of pediatric hospitalizations, the establishment of an open and effective communication between health professionals and caregivers has been encouraged[17,19-21], which is influenced by the complexity of care and frailty of patients.

Some strategies for patient involvement to reduce incidents stand out, namely the orientation of patients, parents and/or caregivers about the care plan, offering information about how they can help health professionals to reduce medical errors, and the encouragement of their participation in the supervision and monitoring of care[17]. However, strategies must be well worked by the health institution to avoid possible tensions and feelings of distrust in the patient-professional relationship[22]. By ensuring an open dialogue with patients so they know who to contact when something goes wrong, safety is positively favored because they may help with predicting imminent risk situations[15].

Patients with communication problems are more prone to adverse events compared to patients without these problems, in a ratio of 46% against 20%. This information proves the importance of effective communication to improve patient safety[20].

In an attempt to solve possible problems in the doctor-patient relationship often occurring in normal physiological conditions, the early recognition of patients' communication problems through professional evaluation in the first contact can help the adoption of necessary measures to minimize inter-relational interferences[20].

Patient empowerment in care is also an incident reduction strategy and directly related to communication between professionals and patients[17]. Empowered patients interact effectively and contribute to obtain better results[23]. To this end, patients should be made aware about their health situation and safety issues, taking into consideration that many patients can be experiencing hospitalization for the first time[15]. Thus, basic information about the health work process can promote patient safety.

It is important that patients know and inquire about the procedures they will undergo. By contrast, professionals must inform patients about issues related to their health status, establish a relationship of trust, and stimulate information exchange[21,24]. Therefore, in the context of safety, professionals must encourage patients to develop knowledge and skills that help them in decisions about their health.

The availability of booklets on different pathologies and treatments is a strategy that favors patients' understanding about their health problem and enables them to discuss and clarify certain doubts with professionals[24]. The assessment of patients' understanding about the guidance/information provided increases their safety[15], hence it should be a systematic practice.

The involvement of patients in self-care is closely linked to the relationship established with health professionals. The bases for this relationship must be trust, respect for the patients' doubts, and listening to their questions, thus establishing the bond and developing their autonomy[23].

Despite the encouragement to patients' involvement in care to increase their safety, its applicability in health institutions is scarce[25]. A study performed through extensive literature search showed the limited

evidence of effective interventions of this practice[26], which may be related to low adherence of health professionals. Thus, interventions should be analyzed to broaden the perspectives of real patient involvement in care, so that it is as close as possible to the involvement considered desirable[27].

Developing the autonomy of patients, parents and/or caregivers for care reflects in organizational culture changes, especially in the approach of errors in health[17,19-21]. The encouragement of a more proactive role of patients in their own care and safety should be an institutional action, making it more acceptable and practicable both for patients and professionals[22].

Education of healthcare professionals for patient involvement in care

The practice of involving patients in the care within the context of health institutions does not seem to have the same proportion that incentives of the scientific community. This reveals the need to invest in health professional training to promote attitudinal changes and consequently, achieve better healthcare outcomes.

The error notification by professionals is an important tool for health institutions because they direct the management and care actions for each indicator and/or identified failure[17]. The conversation wheel is a technique that can stimulate health professionals to discuss the incidents, and provides opportunities to assume errors. Furthermore, it allows the collective study to recognize failures, influences the development of professional autonomy to act responsibly and prudently, and favors a more assertive decision making[17]. Therefore, recognizing errors is the initial step to promote changes in the work process.

In this same sense, the involvement of patients in error approach in health has been highlighted because they have a different view, which enables the perception of other causes and/or factors that perhaps were not identified by health professionals. The training of these professionals is important so they know how to report the incident occurrence to patients. The approach to incidents affects the patient's decision about taking the incident to court proceedings or not[24]. The main focus of this practice is the mitigation of errors in health to extend the institution capacity of acting preventively.

The use of the OSCE technique (Objective Structured Clinical Examination) as an assessment tool of medicine undergraduate students performance found that the assessment of their skills in the domain 'medical error' got significantly lower scores than the skills in the domains 'doctor-patient relationship' and 'humanization issues'. In addition, among students who approached the medical error with patients, less than 60% offered an apology to the patient[19].

This reality highlights the challenge of educational institutions for the formation of proactive professionals with skills of interpersonal relationship and the adoption of practices and attitudes that converge in the safety culture. Moreover, it reflects the challenge of incorporating to the professional conduct the importance of patient-centered care, transferring to them an autonomy to act for the quality and safety of their own care, without looking like a confrontation[18]. This 'new' approach to care requires the ability to establish a dialogue to investigate accurately the socioeconomic and cultural context of

patients, respecting differences and directing them to comprehensive care instead of curative care[23].

Most studies emphasize the occurrence of adverse events, i.e., when the damage has already occurred. Disseminating the concepts of 'near miss' and notifiable circumstances becomes necessary for believing that the reflection of actions without harm to patient reduces the fear of punishment and expands the possibilities of involving patients in preventive decision making in order to overcome barriers in the process of care, and improve the doctor-patient relationship, consequently preserving all the characteristics of effective communication.

Faced with this, the effective way of managing patient safety certainly continues to be collaborative interventions involving patients, health professionals and researchers[28].

Expert opinion encourages the involvement of patients, also to increase the accuracy of medical diagnoses, which requires the patient's autonomy to raise questions/considerations on the information received from the health professional [29]. However, only with careful management - focused on the development of skills for safety - the practice of patient involvement in the care will exercise its full role in the work of improving the quality of health services.

CONCLUSION

The following strategies of patient involvement in care have been advocated: adoption of open and effective communication between professionals-caregivers-patients; supervision and monitoring of care by the caregiver; permanent conference and review of professional interventions by the patient; recognition of adverse events by patients and family members; provision of information to patients, parents and/or caregivers about the care plan; provision of guidance to patients on how to assist the health team in the reduction of medical errors; informing patients and family members on the occurrence of adverse events; and promotion of patients' commitment with self-care.

No studies evaluating the effectiveness of these strategies to reduce incidents were found, hence these constitute knowledge gaps. Neither there were studies describing the practice of patient involvement in care as an institutional program. Faced with this evidence, further research should be developed with focus on the importance of involving patients in their own care, in the use, contribution and effectiveness of this practice to reduce incidents, and with the aim of improving the work process in health services.

Evidence points to the little dissemination of culture of patient involvement in the care safety perspective. It also points to the emerging theme in the context of assessment of strategies to reduce incidents. The results of this integrative review have limitations because most studies constitute evidence level 6, which raises an alert to the scientific community on the need to stimulate research with more robust methods, focusing on the instrumentalization of health professionals for care centered on patients and their families, a highly recommended practice nowadays.

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