www.jpnim.com Open Access eISSN: 2281-0692
Journal of Pediatric and Neonatal Individualized Medicine 2017;6(1):e060132
doi: 10.7363/060132
Received: 2016 Nov 01; revised: 2016 Dec 17; accepted: 2016 Dec 21; published online: 2017 Feb 21

Review

Focusing on patient safety in the Neonatal Intensive Care Unit environment

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Abstract

Patient safety in the Neonatal Intensive Care Unit (NICU) environment is an under-researched area, but recently seems to get high priority on the healthcare quality agenda worldwide. NICU, as a highly sensitive and technological driven environment, signals the importance for awareness in causation of mistakes and accidents. Adverse events and near misses that comprise the majority of human errors, cause morbidity often with devastating results, even death. Likewise in other organizations, errors causes are multiple and complex. Other high reliability organizations, such as air force and nuclear industry, offer examples of how standardized/homogenized work and removal of systems weaknesses can minimize errors. It is widely accepted that medical errors can be explained based on personal and/or system approach. The impact/effect of medical errors can be reduced when thorough/causative identification approach is followed by detailed analysis of consequences and prevention measures. NICU's medical and nursing staff should be familiar with patient safety language, implement best practices, and support safety culture, maximizing efforts for reducing errors. Furthermore, top management commitment and support in developing patient safety culture is essential in order to assure the achievement of the desirable organizational safety outcomes. The aim of the paper is to review patient safety issues in the NICU environment, focusing on development and implementation of strategies, enhancing high quality standards for health care.

Keywords

Patient safety, quality, medical errors, Neonatal Intensive Care Unit, neonate.

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How to cite

Chatziioannidis I, Mitsiakos G, Vouzas F. Focusing on patient safety in the Neonatal Intensive Care Unit environment. J Pediatr Neonat Individual Med. 2017;6(1):e060132. doi: 10.7363/060132.

Introduction

Patient safety (PS) exploration for human errors has raised high priority in the health care quality agenda worldwide [1-3]. Medical errors (MEs) seem to be ever present and inevitable in highly complex and technological driven environments as Neonatal Intensive Care Units (NICUs). MEs, referred as incidents, accidents and adverse events (AEs), can cause severe harm (even leading to death) [4]. Gaining widespread public attention, in the USA MEs are estimated as the 3rd leading cause of deaths (~44,000-98,000/year) more than accidents or diseases like AIDS [5-7]. AEs in the NICU occur at 74 events/100 neonates, while medication errors have been identified at 13-91 per 100 NICU admissions and 5.5% of NICU medication orders [5]. NICUs' multidisciplinary care characteristics are: firstly continuous growth and complexity of clinical workload, secondly reliance on technology and thirdly centralization of specialized services. Neonates receive an excess number of medications and invasive procedures for diagnosis and treatment over a prolonged period of time. The Institute of Medicine (IOM) recognizes PS as "the freedom from accidental injury due to medical care or from medical errors". Since IOM's first report *To err is human* in 2000, the American Academy of Pediatrics has taken steps towards PS science understanding and education, with publications such as *Principles of patient safety in pediatrics* in 2001, *Prevention of medication errors in the pediatric inpatient setting* in 2003, *Patient safety in the pediatric emergency care setting* in 2007 and *Principles of pediatric patient safety: reducing harm to medical care* in 2011 [2, 8-11].

Although safety issues are at the frontline of quality improvement in health industry, PS hasn't received wider attention in the NICU healthcare sector [12]. Most publications related to PS in NICUs are dealing with medication use only, with prospective studies lacking [12-16]. Focus on safety issues is pivotal for quality changes in the NICU and ensures better patient care and outcomes. The purpose of this paper is to investigate safety issues in the NICU environment, and examine the development and implementation of prevention measures for a future research agenda.

Medical errors in NICU: definitions, typology and contributory factors

PS minimizes errors by assessing contributory factors, examining possible mechanisms (on a personal or an organizational level) and implementing prevention measures [1]. PS is often based on PDCA (Plan-Do-Control-Act) models and provides risk assessment, causes definition, analysis of incidents and interventions for non-recurrence of errors [17].

MEs are failures (of planned actions) or mistakes (wrong plans) that lead to AEs; otherwise any event that causes patient harm. When harm from errors is avoided, the appropriate term for errors is "near misses" ("close calls") [13]. AEs are caused by harm from or lack of medical interventions, by medical management rather by patient's clinical condition. AEs can largely be prevented, identified earlier or mitigated more effectively and are preventable (errors result) or non-preventable (complications). MEs do not necessarily lead to harm, while AEs cause harm; additionally AEs may not be associated to MEs. Errors severity from permanent harm until fatality, is categorized as E-I (**Tab. 1**) [5].

Human error problem in hospitals can be analyzed through the person approach and the system approach, presenting a completely different error management [18]. The person approach focuses on the human factor perspective, on medical and nurse staff's unsafe acts – errors and procedural violations – credited in cognitive process and lack of knowledge. Followers of this approach, by applying litigation measures and procedures, provoke fear for disciplinary measures or blaming. Medical malpractice litigation and subsequently legal liability is an increased phenomenon in healthcare in recent years. Litigation can be viewed even as a strategy to hold governments and health organizations

Table 1. Errors severity.

E: Temporary harm; required intervention
F: Temporary harm; prolonged hospitalization
G: Permanent harm
H: Intervention to sustain life
I: Death

accountable for implementing the right to health [19]. According to Malherbe, litigation contributes to higher medical cost, causes aspirant healthcare professionals, and especially junior doctors, to shy away from certain specialties; furthermore an increased risk of litigation may indirectly prompt practitioners to perform additional (often unnecessary) diagnostic and screening tests, which lead to the rendering of medical services to patients of limited or questionable value for the purpose of avoiding adverse outcomes [20].

The systems approach focuses on safety culture and accepts errors as consequences rather than causes of human acts. It supports that human's tendency to errors depends on the organizational workplace and environment. Deming argues that all errors are mainly systemic in nature meaning that are well rooted into the organization's culture and procedures and cannot be attributed to employees. For healthcare professionals, doctors and nurses, fatigue, sleep deprivation, distraction, anxiety and stress are causal factors but also consequences of poor designed systems that ultimately lead to errors [21]. The Swiss cheese analogy model describes that when "holes" line up, hazards (risk factors or conditions predisposing) lead to dangerous acts (human errors) [18]. Active failures (unsafe acts, procedural violations) as personal factors or latent conditions (lack of training, poor equipment, absence of procedures, bad working conditions, understaffing, inadequate equipment, fatigue, inexperience, etc.) arise as "holes" in the NICU's defense system against errors. If these "holes" are aligned for hazards, they can form a path for errors; when errors reach the patient, the end result could be devastating. In NICU's extremely work-loaded stressful environment, combination of active failures, latent failures and local triggers lead to human errors.

Understanding factors and conditions provoking errors ultimately leads to better error management and finally PS improvement [22]. Contributing factors can be seen on a multilevel approach: working and organizational factors, human factors (at team and individual level) and clinical factors at point of care near the neonate. Working and organizational factors (i.e. staffing, environmental design, inadequate education), as described in the systems approach, directly influence human factors on the individual level as described in the person approach (i.e. lack of experience, unfamiliarity with technology). Human factors on the team level could be lack of leadership or lack of communication, influencing point-of-care performance (**Tab. 2**). Specifically for NICUs, proper organizational/working conditions and elimination of medical practice variation are important key factors for PS agenda.

Safety issues in NICU

NICU, as a highly complex, stressful, technology driven environment, provides multidisciplinary care in critically ill newborns [23]. NICU stay should serve the goal of longer survival with a later sufficient and satisfactory quality of life.

In NICUs, compared to adults in a hospital, errors occur 8 times more often, raising the chance to cause severe harm [24]. Specifically, medication errors lead to harm at a range of 4-27% [24, 25]. Most common MEs are due to medications use (~50%), patient misidentification, wrong or delayed diagnosis and administration or method used for treatment (**Tab. 3**) [13, 24, 25]. Prolonged hospital stay, weight-based dosing, hepatic/kidney immaturity, multistep dilution procedure

Table 2. Causes of human errors.

- Non-adaptation to PS culture
- Unfavorable behavior/attitude/communication among staff; incompetence and/or poor practitioner performance
- Missing critical points from patients history or course of disease; missed or delayed diagnosis
- Non existence and/or proper application of Evidence-Based Care protocols (to achieve standardization of care); non implementation of medical decisions
- Lack of training in PS science
- Weak operational practices
- Weakness in the packaging, design and use of drugs and equipment

PS: patient safety.

Table 3. Domains of errors in NICU.

- Medications/drugs (i.e. IV infiltrations, narcotic medication over sedation, dosing errors, etc.)
- Medical diagnosis (delay, error); diagnostic procedure or testing performance
- Patient misidentification
- Hospital/Nosocomial infections
- Feeding procedure and total parenteral nutrition
- Invasive procedures/catheter infiltrates
- Respiratory care, ventilator use
- Resuscitation
- Treatment (error in administration or method used, operation performance)
- Equipment/delivery device failure

are common causes for medication errors. Most common types of medication errors are those of dosing, prescribing, frequency and route of administration [22, 24]. Gray and Goldmann's comment on medication errors was that it must be assured that "the Right drug is given to the Right dose at the Right interval via the Right route to the Right patient", checked by both doctors and nurses [26]. Antibiotics, analgesic/sedative and electrolytic/fluid agents, as the commonest used drugs in the NICU, are responsible for most medication errors [24].

Wrong drug infusion rate via pumps, packaging/labelling of drugs, excess oxygen therapy are some examples of medication errors [22]. Stavroudis et al. reported that the most common cited causes of medication errors are human factors, miscommunication and equipment/delivery devices failures [24]. Additionally, patient misidentification and false documentation account for 11-25% of medication errors [27].

Doctors and nurses daily practice has to be characterized by alertness and implementation of appropriate prevention measures to avoid MEs. Regarding AEs, the most common found were due to hospital-acquired infections, catheter infiltrates and accidental extubations [5, 25].

Prevention strategies for safe practices

NICUs safety strategies have to provide a systematic way to report, record and analyze errors, to apply best practices, to learn from causation in order to prevent and control (reduce or even remove) risk for future patients. Error management should be based on two pillars: first incidence limitation of dangerous errors and second creation of systems that tolerate and absorb their damaging effects.

PS strategies for NICU health care service are reported below (**Fig. 1**) [4, 23, 28, 29].

- Building a culture of safety in which staff can report errors, mistakes and AEs without fear of retribution; achieving doctors and nurses shared involvement and responsibility; gaining the commitment of NICU staff via PS information programs; providing PS education.
- Transparency and disclosure: identification mechanism and systematic analysis for errors, i.e. using root cause analysis, cause and effect diagrams.
- Feedback and presenting results: learning lessons to reduce risks and prevent future harm.
- Track progress: setting targets in high risk domains; target drugs safety; reporting and analyzing information formulating trends and patterns, i.e. by using control charts or flowcharts.
- Calling for a systematic program of research; information collection and analysis.
- Committed leadership; spreading best practices.
- Appropriate equipment, organization design and working conditions: technological support; WHO framework (work conditions, human conditions and organizational conditions); policies for reduction of workplace stress.
- Family involvement and patient-centered approach.

Prevention strategies for PS could be leadership walk rounds (with timely detection of errors), repeated peer reviews (i.e. thoroughly discussing differential diagnosis or causes of death for hospitalized neonates), clinical decision support tools, consistent and detailed patient's history data recordings, parental involvement, education (combined with clinical care, using even simulation techniques) and persistency on continuous clinical quality improvement [30]. Information Technology

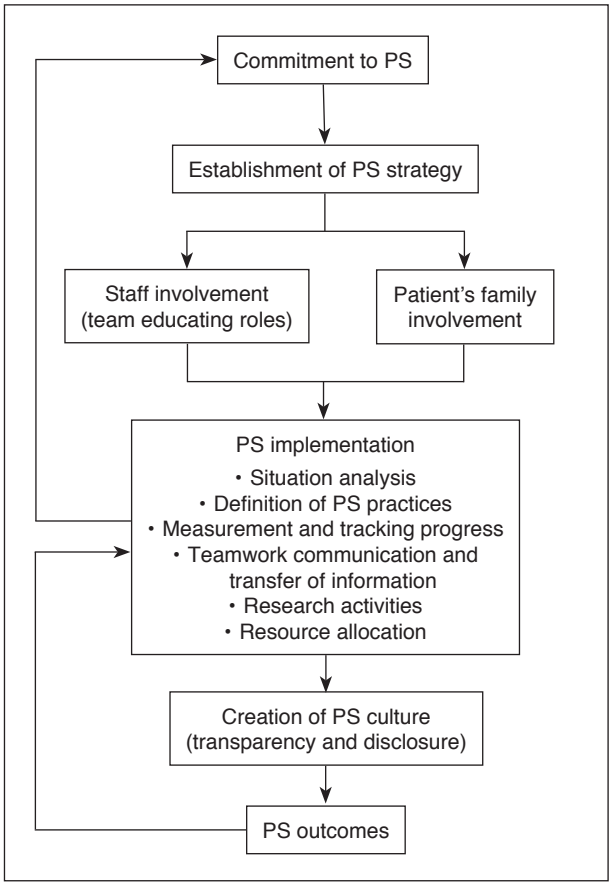

Figure 1. Prevention strategies for patient safety.
PS: patient safety.

applications as electronically provided evidence-based protocols/checklists and diseases-specific care bundles practices, reminders, medication systems bar coding (for medications use or even patient misidentification), updated code sheets and tracking-system for abnormal study results could also strongly support safety [27, 31].

Hospital acquired infections and medication management are good examples for building a safety environment. Prevention policies and best practices – as vigilant hand washing – could make staff view nosocomial infections as unacceptable events, as a failure and not as inevitable consequence of babies vulnerability in the NICU environment. Regarding medication errors, use of protocols and checklists, standard drug concentrations, dose limits, Information Technology applications, doctors-nurses cooperation and clinical pharmacists' participation in NICU walk rounds, are interventions impacting safety [23].

The method to achieve PS in the NICU is to use all the available technologies to ensure safety. On the other hand, when system's defenses (high technology), safeguards (medical staff and nurses), barriers (medical rounds, procedures evaluation, administrative controls) are penetrated by hazards, this could lead to harm the neonate as shown by the Swiss cheese model [18].

Human errors are recorded as errors per number of patient days, errors per number of orders written (for medication errors) and in absolute numbers (less preferable). Different error detection systems (EDSs) are used for the identification and measurement of errors, signaling systems failures or defects. EDSs are based on voluntary incident reports (verbally solicited, interviews or questionnaires) [7, 25], medication order sheets, chart reviews, automated methods using trigger tools [13], administrative data bases (PS indicators, ICD codes) [5, 32], electronic health records (EHRs) [33] and coroner's reports and malpractice claims.

Main problems for EDSs is underreporting of errors and retrospective instead of prospective analysis of data. Fear of legal liability, additional work load, lack of time, knowledge and feedback, unfamiliarity with safety culture and terminology raise barriers to reporting systems. Hospital-based occurrence reports identify errors while trigger tools identify AEs.

Trigger tools are "investigation" tools for AEs, identifying errors causing harm. The trigger tool methodology, by shifting measuring from errors to harm, offers a practical and reliable approach for measuring PS. Sharek et al. developed and tested 17 triggers in the NICU environment, identifying > 19 unique AEs with a 5-grade severity ranking for errors [5]. Safety audits can be implemented easily, timely detecting errors, helping staff focus and motivate finally resulting in immediate but also lasting clinical interventions [30].

PS indicators can measure safety at each strategy applied level and domain of errors. Most importantly, indicators allow PS monitoring and timely comparisons, even for international benchmarking. Criteria for selection and implementation of PS indicators should be importance, scientific soundness, utility and feasibility [11]. Infections rate, ventilator-associated pneumonia, medication errors rate, obstetric trauma rate (after vaginal delivery or caesarean section) and nurse-patient ratio can serve as indicators. From all the above it is clear that understanding, estimating and preventing errors as part of a PS culture in a NICU environment is essential and should be embedded in the organization's efforts to enhance resilience, increase efficiency and assure patient satisfaction.

Conclusions

Implementing strategies, detecting errors with a future prospectively designed agenda will offer valuable information for targeting safety in the NICU setting. PS should be seen as a core element of quality healthcare based on best evidence. Identification of errors often reveals their complexity and multiplicity. Focusing on causes and not on fear of legal liability, errors should be regarded as preventable and not as an incurable serious health issue problem. High reliability organizations (HROs), with communication and honesty between all participants (medical/nursing staff and parents), should confront all levels of safety factors. Furthermore, it is often assumed that HROs, especially in healthcare, are capable of reducing the frequency and magnitude of crises due to the collective mindfulness that steers their preoccupation with failure, reluctance to simplify interpretations, sensitivity to operations, commitment to resilience, and deference to expertise [34].

EDSs, quality/safety indicators, engagement of all professionals with commitment to quality improvement provide an excellent base for quality and safety. PS education has to be incorporated

into the Certification Agenda for professional groups in healthcare, doctors and nurses. Future research agenda should include interventions such as development of EDSs specifically designed for use in the NICU; EHRs for clinical decision support tools to make evidence-based decisions; turning strategies to clinical best practices, building networks with other hospitals and spreading best practices. Additionally, engagement of leadership, staff and parents, along with teamwork and communication between health care providers, could ensure maintenance of PS cultural changes. A strong and cohesive PS culture should be embedded in the organization's mission and guide all top management strategic decisions.

In NICU's environment, errors and safety loss may have devastating effects for the rest of a newborn's lifetime and sometimes could lead to loss of human life. For organizations the pursuit of safety in preventing and dealing with failures (human or technical), should create an adjustable system, finally converting errors to knowledge and future non repetition. New ideas, novel approaches and technological driven implementations are needed to ensure PS in the challenging NICU environment.

Take home messages

- PS has raised high priority in the health care quality agenda worldwide, but it hasn't received wide attention in the NICU environment.
- MEs (incidents, accidents and AEs) can cause severe harm.
- PS in health sector can be seen through the person and the system approach, focusing on organizational/working conditions.
- Most common MEs are due to medications use, patient misidentification, wrong or delayed diagnosis and administration or method used for treatment.
- NICU safety agenda should target on strategies implementation, detection of errors and a future research agenda.

Declaration of interest

The Authors declare that there is no conflict of interest.

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