www.jpnim.com Open Access eISSN: 2281-0692
Journal of Pediatric and Neonatal Individualized Medicine 2013;2(2):e020230
doi: 10.7363/020230

Review

Errors in Neonatology

Antonio Boldrini[1,2], Rosa T. Scaramuzzo[3], Armando Cuttano[1]

[1]Centro di Formazione e Simulazione Neonatale "*Nina*", U.O. Neonatologia, Azienda Ospedaliero-Universitaria Pisana, Pisa, Italy

[2]University of Pisa, Italy

[3]Institute of Life Science, Scuola Superiore Sant'Anna, Pisa, Italy

Proceedings

Proceedings of the 9th International Workshop on Neonatology · Cagliari (Italy) · October 23rd-26th, 2013 ·
Learned lessons, changing practice and cutting-edge research

Abstract

Introduction: Danger and errors are inherent in human activities. In medical practice errors can lean to adverse events for patients. Mass media echo the whole scenario.

Methods: We reviewed recent published papers in PubMed database to focus on the evidence and management of errors in medical practice in general and in Neonatology in particular. We compared the results of the literature with our specific experience in *Nina* Simulation Centre (Pisa, Italy).

Results: In Neonatology the main error domains are: medication and total parenteral nutrition, resuscitation and respiratory care, invasive procedures, nosocomial infections, patient identification, diagnostics. Risk factors include patients' size, prematurity, vulnerability and underlying disease conditions but also multidisciplinary teams, working conditions providing fatigue, a large variety of treatment and investigative modalities needed.

Discussion and Conclusions: In our opinion, it is hardly possible to change the human beings but it is likely possible to change the conditions under they work. Voluntary errors report systems can help in preventing adverse events. Education and re-training by means of simulation can be an effective strategy too. In Pisa (Italy) *Nina* (*ceNtro di FormazIone e SimulazioNe NeonAtale*) is a simulation center that offers the possibility of a continuous retraining for technical and non-technical skills to optimize neonatological care strategies. Furthermore, we have been working on a novel skill trainer for mechanical ventilation (MEchatronic REspiratory System SImulator for Neonatal Applications, MERESSINA). Finally, in our opinion national health policy indirectly influences risk for errors.

Keywords

Errors, neonatology, malpractice, simulation, adverse events, near miss.

Corresponding author

Prof. Antonio Boldrini, U.O. Neonatologia, Azienda Ospedaliera Universitaria Pisana, Via Roma, 67 – 56126 Pisa, Italy; tel./fax: +39 050 992029; e-mail: antonio.boldrini@med.unipi.it.

How to cite

Boldrini A, Scaramuzzo RT, Cuttano A. Errors in Neonatology. J Pediatr Neonat Individual Med. 2013;2(2):e020230. doi: 10.7363/020230.

Introduction

Danger and errors are inherent in human activities. Even the best performers sometimes may fail.

In medical practice, errors occur about at an estimated rate of 44,000-98,000/year. It is a significant number, if compared to road accidents (i.e. 43,458/year), deaths lung cancer (i.e. 42,297/year) or from AIDS (i.e. 16,516/year) [1].

Fortunately, not all errors lead to adverse events for patients, so that many Authors define this complex scenario as an hidden epidemic. However, more and more frequently it is no longer hidden, since non specialistic newspaper focus on medical practice, often pretend to investigate for guilty people.

In our opinion, it is hardly possible to change the human beings but it is likely possible to change the conditions under they work. In this review paper we will consider the whole scenario and argue our opinion.

Methods

In order to deeply analyze the topic, we reviewed recent published papers in PubMed database (peer-reviewed publications published since 2000 up to April 2013), and reported and discussed the most relevant ones in our opinion.

We focused on the evidence and management of errors in medical practice in general and in Neonatology in particular, therefore we searched in the database the following keywords: errors AND medical practice / errors AND neonatology / medication errors / errors AND technology / errors AND adverse events.

In the second part of our work we compared the results of the literature with our specific experience, expanding discussion with the results and considerations derived from the original experience of the Training and Neonatal Simulation Centre *Nina* in Pisa (Italy) [2].

Errors in medical practice

A medication error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient. Considering general, theoretical aspects as regards consequences, we can distinguish active failure, causing immediate consequences versus latent failures, which remain dormant in the system until a triggering event will make them manifest [3].

This second group is a paradigm for the Swiss Cheese Theory [4]: every accident does not generally depend on a single error, being on the contrary the last result of a chain of co-factors.

When considering causes, we can distinguish errors of commission versus errors of omission. The first type is due to the execution of medical assistance not needed or applied incorrectly. The second type happens in case of missing application of health care, that should have been necessary for the patient, based on medical knowledge and professional experience.

Both errors of commission and omission can be related to individual (15%) or system (85%) causes [5]. This last group includes all the organization errors (daily work planning, emergency planning, equipment availability or accessibility, lacking in communication systems, inadequate supervision, stressful environment or poor welfare for workers).

A specific field of error is drugs use. Errors can occur at each step from prescription to transcription, preparation, distribution and administration. As forwards drugs, not always adverse events due to errors, but errors may lead to adverse events for patients (**Fig. 1**). In defining errors referred to drugs, generally: i) a wrong dose is intended as unexplained deviation of more than 10% (over or under the correct dose); ii) a wrong time is intended as administration later than 30 minutes for emergency drugs; iii) a wrong rate is intended as 24-hour-volume of fluid deviation more than 10% or hourly rate deviation more than 50% (over or under the correct rate); iv) a wrong preparation technique is an incorrect dilution even though the correct drug dosage or mixing of incompatible drugs; v) a wrong administration technique is the incorrect method of administration, i.e. incorrect route as like as i.v. instead of intramuscular or orally. Finally, omission errors can occurs, in case of failure to prescribe or administer drug [3].

Since the publication of the IOM report [1], patient safety issues have received more attention from the scientific community and national agencies.

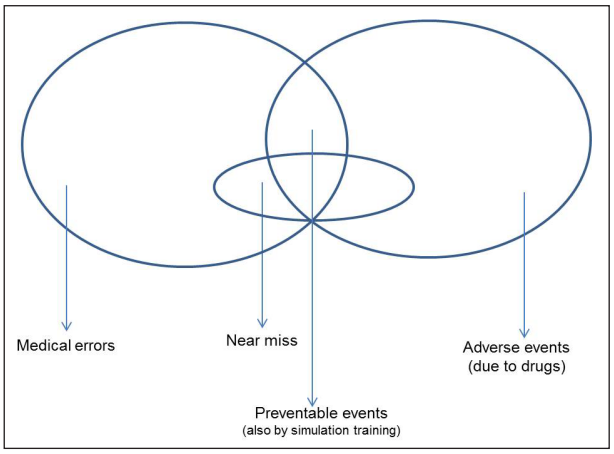

Figure 1. Theoretical scheme of errors' potential outcome.

The US Food and Drug Administration has systems for reporting medication and device-related errors, as well as EMEA and AIFA in Italy for drugs. The World Health Organization (WHO) has estabilished surgical safety checklists and surveillance systems for healthcare-associated infections and childbirth injuries [6]. Indeed, it is actually stated that the prospective, continuous incident reporting followed by the implementation of prevention strategies are effective procedures to improve the quality of care and patient safety [7]. In this way, every error, when recognized and stated, becomes an incentive for improvement of professional activity. Indeed, it can be possible to map risk factors, that may be related to the institutional framework (i.e. management and organizational factors, including economics), to working conditions, to the specific healthcare tasks, to the team (e.g. unbalanced professional composition, failed written or oral communication, etc.), to individual factors (e.g. education, skills, voluntee) or even to patients' characteristics themselves.

In Italy, the Clinical Risk Unit in the Governance disseminated a list of alert events, that includes: a procedure carried out in the wrong patient or in the wrong part of the body, the suicide of an hospitalized patient, instruments or other materials left into the surgical site, reaction to transfusions because of AB0 incompatibility, death or severe lesions due to drugs, female patients' death during or related to labor or delivery, violence to hospitalized patients, death of an apparently healthy newborn with birthweight > 2,500 grams within 48 hours after birth [8].

All such alert events are called sentinel events. A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response. In any case, they are sign of a disfunction in health system and cause decreased confidence from people to healthcare.

Errors in Neonatology

Even in Neonatology there is an increasing interest on topics related to medical errors, both by scientific community and mass media.

Nevertheless, few data are available on neonatal malpractice claims yet. The first data reported about Italian situation regard a wide population studied by means of a 6-year-long survey. Among over 190 claims, the majority regards events in delivery room and nursery (almost 40% each) while a lower percentage in NICU (about 20%) and a minimun number of cases the transport system (almost 1%) [9].

However, Authors previously reported that errors in NICU are up to 8 times greater than in other departments and there is a correlation between outcome and organizational structure so that even inside the NICU high levels of coordination and teamwork lead to a lower lengths of stay and mortality [10].

The NICHD workshop on patient safety in 2011 pointed out some specific issues of patient safety in neonatology. In particular, the main domains of errors are: i) medication and total parenteral nutrition; ii) resuscitation and respiratory care; iii) invasive procedures; iv) nosocomial infections; v) patient identification; vi) diagnostics. A number of factors may enhance injury risk, that is directly related first of all to size, prematurity, vulnerability, and underlying disease conditions of newborn patients, but also to multidisciplinary teams involved in the care of sick newborn infants (and consequent problems in coordination), working conditions providing fatigue, a large variety of treatment and investigative modalities needed in the care of high-risk newborn infants (e.g. ventilator, central catheter, medications, bed-side tests) despite of scarcity of well-tested, safe and effective devices and instruments for use specifically in the NICU [6]. Unfortunately, adverse events may cause life-long morbidity [11].

As regards iatrogenic adverse events, some considerations are mandatory. In any rapidly changing medical field, treatments and procedures may be instituted without controlled outcome measurement that might reveal untoward effects. This lack of controlled measurements has certainly been true in neonatology. A recent research composed by three papers considers Neonatology since it was born, in the 1920s and defines three historical periods. The first period, from 1920 to 1950, is the "Hands-Off" years: infant care was only a nursing task comprised primarily of warming, feeding, and isolation. This attitude began changing in the 1940s with the obvious success of exchange transfusions for erythroblastosis fetalis, and the advent of antibiotics in the 1950s. The realization that retinopathy of prematurity was an iatrogenic disease spawned research in oxygen monitoring and aided in the development of infant ventilators in the 1960s. A "therapeutic exuberance" leaded to the "Heroic" years, from 1950 to 1970. Pediatricians became used to enter in the nursery and there was a "great spirit of innovation, somewhat lacking in discipline": this was just the period of the most striking care changes and errors. Finally, from 1970 the "Experienced" years have been started, during which neonatal practice has become a bit more uniform with refinement of many of the new methods introduced in the "Heroic" years. Fewer errors are apparent, perhaps because of lessons learned, the introduction of randomized controlled studies, or, simply, failure to recognize adverse results in our complex system of care [12-14].

In sum, the research presents cautionary tales in a historical setting and underlines that most of errors relate to historical developments in neonatology and might not have happened in another era. An example of this is using high oxygen concentrations in caring for premature infants, resulting in retinopathy of prematurity or chronic lung disease (i.e. "old bronchopulmonary dysplasia") [12-14].

Of course, defining an error as an act that unintentionally deviates from what is correct does not mean that the errors are unavoidable [12-14].

The reported historical prospective demonstrates that every change in hospital procedures should involve a consideration of the effect on neonatal patients.

Although all these historical features, some problems still remain unsolved in Neonatology and account for big clinical risks. First of all, despite the many years of hard use in premature infants and in critical condition, surprisingly few drugs have been rigorously tested in randomized clinical multicenter studies. Little is known about the pharmacology of these drugs in infants with different birth weight, gestational age and chronological age [15].

Technological devices necessary to support patients (e.g. mechanical ventilators) may not work because of a manufacturing defect or because the users are not able enough. Moreover, they are often used longer than previewed and sometimes are not correctly cleaned or stored.

Finally, system to match newborns to their mother is always under study, in order to optimize time and modalities to avoid changelling: this is a common nightmare in parents' imagination worldwide.

Discussion and conclusions

In our opinion identifying errors should be the first, main instrument to prevent them.

A voluntary, anonymous, Internet-based reporting system for medical errors in neonatal intensive care has been used among health professionals from over 50 hospitals in the Vermont Oxford Network: people were asked to report errors, near-miss errors, and adverse events by a freetext entry in phase 1 (17 months) and a structured form in phase 2 (10 months). Such a system allowed to focus on type of errors and on potential causes so that a broad range of medical errors in neonatal intensive care could be identified and a multidisciplinary collaborative learning could be promoted [16]. Actually, we believe that similar specialty-based systems have the potential to enhance patient safety in a variety of clinical settings.

Not surprisingly, voluntary reporting has been resulted more effective than mandatory reporting. Multi-institutional, voluntary, non-punitive, system based incident reporting is likely to generate valuable information on type, aetiology, outcome and preventability of incidents in the NICU. However, the beneficial effects of incident reporting systems and consecutive system changes on patient safety are difficult to assess from the available evidence and still remain to be investigated in a deeper way [17].

We think that technological features can represent another useful strategies. In fact, introduction of computerized physician order entry systems clearly reduces medication prescription errors: however, clinical benefit of computerized physician order entry systems in pediatric or ICU settings has not yet been completely demonstrated. The quality of the implementation process could

be a decisive factor determining overall success or failure [18].

As regards technology, however, staff must be well trained. Training in simulation is actually useful in order to manage devices over than to face unexpected dramatic event, to minimize clinical risk preventing errors and to optimize team work. Simulation training is an effective tool to modify safety attitudes and teamwork behaviors in emergency situations, since sustaining cultural and behavioral changes requires repeated practice opportunities. Embedding in situ simulation as a routine expectation positively affected operations and the safety climate in a high risk clinical setting [19].

In Pisa (Italy) *Nina* (*ceNtro di FormazIone e SimulazioNe NeonAtale*) is a neonatal simulation center dedicated but integrated within a Hospital Unit, so deeply linked to the real daily healthcare activities but functionally separated from it [2]. It offers the possibility of a continuous retraining for technical and non-technical skills to optimize neonatological care strategies.

Furthermore, we have been working on a novel skill trainer for mechanical ventilation. MEchatronic REspiratory System SImulator for Neonatal Applications (MERESSINA) is a software-controlled mechanical system able to replicate the respiratory act of a newborn. The high-fidelity in anatomy and function of human airways and lungs makes it a reliable device to train neonatologists, anesthetists, nurses in the intensive care units (NICUs): it will represent an innovative tool for medical training of mechanical ventilation. It could be also proposed as an effective instrument to test mechanical ventilators for improving respiratory assistance in NICU [20, 21].

Finally, we would consider that institutional decisions become necessary sometimes to prevent medical errors. As an example, in Portugal hospital birth points with less than 1,500 deliveries per year were closed: as a direct consequence, neonatal mortality rate fold down from 8.1 to 2.7 per 1,000 live births [22]. This focus on the opportunity of empower specialized health center, in order to prevent errors due to human poor experience. Of course such a policy is not painless, but may be mandatory in a long term perspective.

We trust that brave choices sometimes address a new course.

Declaration of interest

The Authors declare that there is no conflict of interest.

References

1. Kohn LT, Corrigan JM, Donaldson MS. To Err is Human: Building a Safer Health System. Washington, DC: Institute of Medicine, National Academy Press, 2000.
2. Cuttano A, Scaramuzzo RT, Gentile M, Moscuzza F, Ciantelli M, Sigali E, Boldrini A. High-fidelity simulation in Neonatology and the Italian experience of *Nina*. J Pediatr Neonat Individual Med. 2012;1(1):67-72.
3. Aronson JK. Medication errors: what they are, how they happen, and how to avoid them. QJM. 2009;102(8):513-21.
4. Reason J. Human error: models and management. BMJ. 2000;320(7237):768-70.
5. Øvretveit J. Quality evaluation and indicator comparison in health care. Int J Health Plann Manage. 2001;16(3):229-41.
6. Raju TNK, Suresh G, Higgins RD. Patient Safety in the Context of Neonatal Intensive Care: Research and Educational Opportunities. Ped Res. 2011;70(1):109-15.
7. Ligi I, Millet V, Sartor C, Jouve E, Tardieu S, Sambuc R, Simeoni U. Iatrogenic Events in Neonates: Beneficial Effects of Prevention Strategies and Continuous Monitoring. Pediatrics. 2010;126: e1461-8.
8. http://www.salute.gov.it/qualita/paginaInternaQualita.jsp?id=238&menu=sicurezza, last access: September 2013.
9. Fanos V, Tagliabue P, Greco L, Agostiniani R, Carbone MT, D'Agostino P, Correra A. Neonatal malpractice claims in Italy: how big is the problem and which are the causes? J Matern Fetal Neonatal Med. 2012;25(5):493-7.
10. Sexton JB, Berenholtz SM, Goeschel CA, Watson SR, Holzmueller CG, Thompson DA, Hyzy RC, Marsteller JA, Schumacher K, Pronovost PJ. Assessing and improving safety climate in a large cohort of intensive care units. Crit Care Med. 2011;39(5):934-9.
11. Broussard L. Small size, big risk: preventing neonatal and pediatric medication errors. Nurs Womens Health. 2010;14(5):405-8.
12. Robertson AF. Reflections on errors in neonatology: I. The "Hands-Off" years, 1920 to 1950. J Perinatol. 2003;23(1):48-55.
13. Robertson AF. Reflections on errors in neonatology: II. The "Heroic" years, 1950 to 1970. J Perinatol. 2003;23(2):154-61.
14. Robertson AF. Reflections on errors in neonatology III. The "experienced" years, 1970 to 2000. J Perinatol. 2003;23(3):240-9.
15. Ellsbury DL, Ursprung R. A quality improvement approach to optimizing medication use in the neonatal intensive care unit. Clin Perinatol. 2012;39(1):1-10.
16. Suresh G, Horbar JD, Plsek P, Gray J, Edwards WH, Shiono PH, Ursprung R, Nickerson J, Lucey JF, Goldmann D. Voluntary anonymous reporting of medical errors for neonatal intensive care. Pediatrics. 2004;113(6):1609-18.
17. Snijders C, van Lingen RA, Molendijk A, Fetter WPF. Incidents and errors in neonatal intensive care: a review of the literature. Arch Dis Child Fetal Neonatal Ed. 2007;92(5):F391-8.
18. van Rosse F, Maat B, Rademaker CMA, van Vught AJ, Egberts ACG, Bollen CW. The Effect of Computerized Physician Order Entry on Medication Prescription Errors and Clinical Outcome in

Pediatric and Intensive Care: A Systematic Review. Pediatrics. 2009;123:1184-90.

19. Patterson MD, Geis GL, LeMaster T, Wears RL. Impact of multidisciplinary simulation-based training on patient safety in a paediatric emergency department. BMJ Qual Saf. 2013;22(5): 383-93.
20. Scaramuzzo RT, Ciantelli M, Baldoli I, Bellanti L, Gentile M, Cecchi F, Sigali E, Tognarelli S, Ghirri P, Mazzoleni S, Menciassi A, Cuttano A, Boldrini A, Laschi C, Dario P. MEchatronic REspiratory System SImulator for Neonatal Applications (MERESSINA) project: a novel bioengineering goal. Med Devices (Auckl). 2013;6:115-21.
21. Baldoli I, Tognarelli S, Cecchi F, Scaramuzzo RT, Ciantelli M, Gentile M, Cuttano A, Laschi C, Menciassi A, Boldrini A, Dario P. An active one-lobe pulmonary simulator with compliance control for medical training in neonatal mechanical ventilation. J Clin Monit Comput. [In press].
22. Neto MT. Perinatal care in Portugal: effects of 15 years of a regionalized system. Acta Paediatr. 2006;95(11):1349-52.