Medical Errors in the NICU

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Case Topics – Medical errors and adverse events in healthcare:
1. Terminology and definitions
2. Identification, measurement and epidemiology of safety events
3. Causal and contributory factors – systems (WHO) approach
4. Prevention of errors – generic solutions (culture, teamwork, communication, leadership)
   and specific solutions (computerized order entry systems, checklists, hand-hygiene,
   equipment redesign, cognitive forcing strategies)
5. Responding to safety events – including second victim and disclosure to family

Overview

In recent years it has become recognized that several thousand patients each year in the
United States suffer from preventable harm as a result of medical errors1. This module will
introduce and orient Neonatal-Perinatal medicine fellows to an important topic – patient safety.

Participants will learn the definitions of various terms related to patient safety in neonatal
care, such as medical error, near-miss, adverse event, preventable adverse event and diagnostic
error. They will review the epidemiology of patient safety events. They will understand the
causes of and contributors to medical errors, and learn about the effects of safety events on
patients, families and health professionals. They will learn how to take a proactive approach to
error prevention and the importance of a safety culture in organizations. Participants will learn
about analysis of safety events and about the ethics and best practices for disclosure of
unanticipated events to patient families. There will also be a brief discussion about medical-legal
aspects of safety events.

Use of cases and practice simulation will equip learners with skills to minimize
preventable harm to their patients, and to deal with difficult patient safety situations (including
disclosure) in their clinical neonatology practice. Knowledge from this module may also help
fellows who assume administrative leadership roles in the future, such as Medical Director of a NICU.

**Suggested Reading:**


**Learning Objectives**

After participating in this module, the learner will be able to:

1. Define common terms used in the patient-safety field, such as medical error and adverse event.
2. Identify various types of patient safety events and accurately measure the incidence of such events.
3. Recognize that errors most often originate in poorly designed systems of care and that solely blaming individuals for them does not prevent these events.
4. Recognize that, in addition to potentially causing harm to patients, errors also can cause grave psychological harm to health professionals.
5. Describe ethical principles underlying the need to disclose errors and adverse events to patient families, how best to perform such disclosure, and the role of apology as part of the disclosure process.

**Case Summary:**

As the neonatology fellow on call, you are called emergently to the bedside for infant with acute hypotension, bradycardia and frequent apnea. The infant, Max, is a 5-day old male born at 30
weeks’ estimated gestational age who has been stable on nasal continuous positive airway pressure (nCPAP) 6 cm of water with a FiO2 of 0.21 and advancing on enteral feeds with parenteral nutrition (PN) via an umbilical venous catheter. Soon after arrival to the bedside, Max’s oxygen saturation drops to 40% and the heart rate drops to 50 beats/min. You immediately provide positive pressure ventilation without improvement, then intubate the infant and start chest compressions for 3 minutes and give a dose of epinephrine. You obtain a blood gas with metabolites that shows severe respiratory and metabolic acidosis and a serum potassium of 9 mmol/L. You adjust ventilator settings and notice EKG changes consistent with hyperkalemia. You immediately stop the PN that contains potassium and start a 10% dextrose infusion. You administer a calcium gluconate bolus and a sodium bicarbonate dose while preparing an insulin and glucose infusion. The serum potassium level slowly improves and you briefly update the family at the bedside. You then review Max’s medical chart and the PN bag and discover that PN bag contains 3 times the amount of maintenance potassium chloride that infant should be receiving. You review the PN order and verify it was correct but not sure what happened during preparation of the bag in the pharmacy. Max’s mother is at the bedside in emotional distress, realizing that her infant was very close to dying.

Alternate Cases

1. As the neonatologist on service, you are caring for a 6-day old infant born at 28 weeks’ gestation who has been on nCPAP 6 cm of water since birth and is on gradually advancing enteral feeds. A chest radiograph was obtained for increased apnea/bradycardia and showed low lung volumes with the tip of the umbilical venous catheter (UVC) in the liver parenchyma. You increase nCPAP support to 8 cm of water and decide to leave the UVC in place as most likely this infant will attain full enteral feeds in the next 48 hours. The next day, the infant decompensates requiring cardiopulmonary resuscitation. Abdominal ultrasonography reveals a large cystic lesion in the liver around the tip of the umbilical venous catheter.

2. As the neonatologist on service, you are caring for a 2 week old infant born at 27 weeks’ gestation who has been on nCPAP 8 cm with worsening respiratory and metabolic acidosis requiring intubation and escalation of support in addition to inotropic medication. You review the radiographs obtained over the past couple of days and notice that the infant had radiological findings of necrotizing enterocolitis (NEC) 2 days ago which was not previously noticed. The infant’s mother is at the bedside crying as she realizes her baby is very sick.

Case Questions

- Did this infant experience a medical error or an adverse event or both? How are these terms defined?
- What are some examples of medical error?
- How common are medical errors and what impact do they have on patient outcomes?
- What are the risk factors for medical errors and adverse events?
- What is the preferred analytic approach to medical error?
- What conditions and factors led or contributed to the error or adverse event in this case?
- How does organizational culture contribute to the occurrence of such events?
• What are the different approaches to measuring safety (or lack of safety) in the NICU?
• How should you report a medical error or adverse event?
• Describe different measures that can be taken to avoid medical errors and promote patient safety.
• If you are involved either directly or indirectly in a serious medical error, what thoughts and emotions are you likely to experience?
• What type of safety events should be disclosed to the patient’s family?
• When, how, and by whom should disclosure to the patient’s family occur?
• What is the role of an apology during the disclosure process?

Case Discussion

Did this infant experience a medical error or an adverse event or both? How are these terms defined?

In this case, the infant suffered a potentially fatal medical error (error of execution) and adverse event. In alternate case #1, the infant suffered a potentially fatal medical error (error of omission) and adverse event. In alternate case #2, the infant suffered a medical error (diagnostic error).

The following list provides definitions of some commonly used terms related to patient safety:1,2,3,4,5

Medical Error
An error is defined as a discrepancy in planning or execution (error of planning, or error of execution) that leads to an adverse outcome or the failure to achieve a goal. Errors can include issues in systems, procedures, and products. However, an error does not always result in an adverse outcome and therefore must not be defined by one. Similarly, an adverse outcome may happen without a preceding error.

Medication Errors
Occurs at any stage in the medication use process from placing the order through administration to the patient and the monitoring process, whether or not it results in an adverse drug event.

Adverse Event
An adverse outcome caused by the medical management rather than a patient's main ailment. It may be caused by a medical error (named as preventable adverse event) or may occur without a preceding medical error.

Adverse Drug Event
An injury related to the use of a drug
Near Miss
An error is defined as near miss if it does not result in an adverse outcome either because it was discovered or stopped before it reaches the patient, because of the patient's resilience, or due to proper procedures that manages the error after it reaches the patient.

Patient Safety
A term used to describe freedom from accidental injury and error and applies to initiatives aimed at preventing adverse outcomes due to medical error. Patient safety is ensured and the likelihood of errors is minimized through three activities: shedding light on potential errors, lessening the severity of the error, and preventing them altogether.

Latent Errors
Errors that usually lie dormant in the system for long periods of time. It includes errors in the design, organization, training or maintenance that lead to operator errors.

Sentinel Events
An unanticipated error that involves severe physical or psychological trauma or in extreme cases death, or that increases the risk of said outcomes. These events are called "sentinel" because they require immediate investigation and response.

Error of Omission
Occurs when a crucial intervention or procedure is not carried out, leading to severe morbidity or mortality.

Negligence
when the care provided fails to meet the standard of care reasonably expected of an average physician qualified to take care of the patients with similar medical conditions.

The Institute of Medicine (IOM) in their report ‘Crossing the Quality Chasm’ described the following six domains of quality and aims for the health care system:

1. Safe: Avoiding harm to patients from the care that is intended to help them.
2. Effective: Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and misuse, respectively).
3. Patient-centered: Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
4. Timely: Reducing waits and sometimes harmful delays for both those who receive and those who give care.
5. Efficient: Avoiding waste, including waste of equipment, supplies, ideas, and energy.
6. Equitable: Providing care that is uniform and proper with disregard to personal characteristics (e.g. ethnicity, nationality, gender, socioeconomic status, or sexuality).

What are the risk factors for medical errors and adverse events?
Errors are caused by multiple factors related to humans, the systems of care, and the organizational culture.
The WHO Framework, based on the work of Charles Vincent\(^1\)\(^,\)\(^7\) details the conditions that contribute to medical errors and/or adverse events:

**Work Conditions: W**
- Inadequate staffing, excessive patient-nurse ratio, excessive workloads
- Undesirable shift patterns and work schedules that promote exhaustion
- Equipment poorly fabricated, absent, or in disrepair
- Poor layout of work environment
- Lack of administrative and managerial support
- Protocols and standard procedures not available or hard to access
- Use of unclear written communication and verbal communication methods that are prone to misinterpretation; unclear task design or lack of clarity of the organizational structure and about when and how to seek help
- Inadequate supervision or reassurance
- Poor team structure, functioning, and leadership

**Human Conditions: H**
- Mismatch between skills of health care worker and requirements of the job
- Health care worker is ignorant, lacks good health, is very emotional, is stressed, or does not conform to safety standards.
- Patient’s condition is very serious
- Patient has speech or hearing impairments that limit communication
- Patient personality and social factors make care more difficult

**Organizational Conditions: O**
- Financial constraints and economic pressures encourage production and efficiency over safety
- Equipment, personnel, or other resources are either lacking or are not allocated to patient safety
- Lack of policies, standards, goals, and regulations make it difficult to work safely
- Excessively stringent regulations encourage violations
- Medical-legal environment

The “Swiss cheese” model of error causation by James Reason\(^1\)\(^,\)\(^8\) demonstrates how most healthcare systems are built with several layers of defenses intended to prevent medical error from reaching the patient. However, each layer of defense is imperfect and may not always prevent the error from propagating to the next level of defense. Therefore each layer of defense is like a layer of Swiss cheese, with the holes in each slice of cheese representing the flaws that allow the error to propagate. An error reaches a patient when ‘all the holes in the layers of Swiss cheese line up’ (i.e., all the defenses break down one after the other) so that the error propagates through all the defenses without any constraints.

**What are some examples of medical error?\(^1\)\(^,\)\(^9\)\(^,\)\(^10\)**

Errors related to medication and parenteral nutrition administration:
Administration of the wrong drug (e.g. look-alike sound-alike drugs, such as Humulin vs Humalog), administration to the wrong patient, or administration by the wrong route (e.g. IV instead of SQ), by the wrong method (e.g., rapid administration of calcium or potassium), giving multiple drugs that interact negatively, dosing error (e.g. administration of ten-fold the regular dose of a drug, use of wrong infusion rate, or sub-therapeutic dosing of medications), or a mistake in compounding of parenteral nutrition leading to severe hyperglycemia.

Surgical errors:
Surgery on the wrong patient, or on incorrect site (e.g. incision for inguinal hernia repair is performed on the incorrect side), leaving a surgical instrument inside the abdomen, etc.

Errors related to invasive procedures:
Placement of an endotracheal tube in the esophagus instead of trachea during anesthesia with subsequent brain asphyxia and death, insertion of a chest tube into the incorrect side of the chest to drain a pneumothorax, malposition of an umbilical venous catheter inside the liver resulting in necrosis of the liver, insertion of a feeding tube into the trachea.

Diagnostic errors:
Failure to identify a patient’s disease or condition (e.g. sepsis or pneumoperitoneum), or mistaking one disease for another.

Other errors:
Mismatched blood transfusion, intravenous infusion of milk, mistakes in patient identification (e.g. administration of the breast milk of one mother to another mother’s infant; or discharging an infant to the wrong family).

*What is the preferred analytic approach to medical error? What conditions and factors led to the error or adverse event in this case?*

Traditionally, the healthcare provider involved in a medical error or adverse event was likely to be blamed for the adverse outcome and was subject to punishment or possibly job termination.

After the influential Institute of Medicine report ‘To Err is Human’ it became better understood with increasing awareness among most health care institutions that:

1. Errors are typically a result of many different cohesive factors.
2. Errors are not typically one individual’s mistake.
3. Applying the strategy of blame to an individual or a group hinders the process of recognizing and repairing the error.
4. Looking beyond obvious causes with a realistic understanding that humans are capable of making errors, and such errors should be expected. Imperfections in the cognitive processes (i.e. memory, attention, concentration, and the degradation of human performance due to fatigue and stress) are what lead to these errors, and are intrinsic to all humans.
The system approach focuses on determination of how the error occurred and the risk factors associated with it, and not to place blame on anyone.

An example, in medication errors, monitoring medication orders is essential to analyzing an adverse event. Tracking all involved providers and processes can help the root cause analysis process, better inform the disclosure, and reflect respect for the team members.

**What is the role of organizational culture in the occurrence of such events?**

The safety culture of an organization has been defined as the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to and the style and proficiency of an organization’s health and safety management. In organizations with a strong safety culture, healthcare workers feel more comfortable in reporting near misses and errors, don’t feel as though they will be punished, avidly point out potential hazard, and consider protecting patients crucial.\(^{10, 12, 13, 14}\)

In order to create a safety culture, leaders should make safety a precondition by inciting conversation about safety, promise-making and forgiveness, who demonstrate their commitment to safety, and those who allocate resources and time to patient safety. This especially holds true for industries in which high-risk, complicated activities are routinely undertaken notwithstanding time constraints such as nuclear power plants, naval aircraft carriers, and air traffic control centers.

**How common are medical errors and what impact do they have on patient outcomes?**

Medical errors are a leading cause of death in North America; between 44,000 and 98,000 patients are estimated to die each year in the USA as a result of medical errors. A systematic review by de Vries et al in 2008\(^{15}\) using eight studies with a total of 74,485 patient records were selected. The median overall incidence of in-hospital adverse events was 9.2%, with a median percentage of preventability of 43.5%. More than half (56.3%) of patients experienced no or minor disability, whereas 7.4% of events were lethal. Operation (39.6%) and medication-related (15.1%) events constituted the majority.

Using conservative estimates, deaths due to medical errors exceed the number attributable to the 8th leading cause of death in North America. Patients injured as a result of a medical error spend longer time in the hospital and have higher hospital costs in addition to increased risk of death. Medical errors are estimated to cost between US$17-billion and US$29-billion per year in lost income, lost household production, disability and additional health care costs.\(^{16, 17}\)

**What are the different approaches to measuring safety (or lack of safety) in the NICU? How should you report a medical error or adverse event?**

Eric Thomas and Laura Peterson\(^{18}\) presented a conceptual model for measuring latent errors, active errors, and adverse events as follows:

1. **Error Reporting Systems** for witnessed errors via a structured data collection system is a powerful tool. Reporting systems (e.g. surveys of providers, interviews, etc.) help to
involve healthcare providers in safety activities and locate errors. However, reporting and hindsight bias may be present as providers may not report errors due to fear of a loss of reputation or fear of a lawsuit.

2. **Malpractice claims analysis**: can provide multiple perspectives from patients, providers, and lawyers that can uncover latent errors. Still, hindsight and reporting bias are disadvantageous.

3. **Morbidity and mortality conferences and autopsy**: The goal of these is to learn from previous medical errors and their subsequent events. They can also identify latent errors and are required by the Accreditation Council for Graduate Medical Education. Hindsight bias and reporting bias remain potential disadvantages.

4. **Administrative Data Analysis**: Administrative/billing data may provide a source of data for measuring errors and their adverse events. Problems may include incomplete data that could be subject to bias from reimbursement policies and regulations.

5. **Chart review**: is a commonly used method that utilizes readily available data, however, judgments about the presence of adverse events by chart reviewers are known to have only low to moderate reliability (precision) secondary to incomplete medical records and hindsight bias.

6. **Electronic medical record**: is an inexpensive method after the initial investment, allows monitoring in real time and can integrate multiple data sources, but is susceptible to programming and/or data entry errors and not a good method for detecting latent errors.

7. **Observation of patient care**: Potentially accurate and precise and can detect more active errors than other methods, however, it is difficult to train reliable observers, and there is potential for the Hawthorne effect. There are concerns about confidentiality and this method is not good for detecting latent errors.

8. **Clinical surveillance**: Considered the most precise and accurate method of measuring adverse events and is ideal for assessing the effectiveness of specific interventions to decrease explicitly defined adverse events. However, it provides relatively less contextual information on the latent errors that cause adverse events, and furthermore, may be costly.

**Describe different measures to avoid medical error and promote patient safety.**

The WHO (Work, Human and Organizational conditions) framework to promote patient safety:

**Work conditions** can be improved by ensuring adequate staffing models and work schedules, minimizing distractions, using principles of human factors engineering to improve equipment design, design of technology interfaces (such as in the electronic medical record), labeling of medications, tubing and equipment, name alert, and barcoding devices. Interventions designed to increase concentration and diligence among healthcare workers are not effective: human errors are unavoidable. Instead, work conditions should be designed in a way that minimizes errors: as stated by Reason\(^8\): “We cannot change the human condition, but we can change the conditions under which humans work.”

**Human conditions** can be improved by reducing fatigue (by restricting the duration of work shifts, overall worked hours and by encouraging naps), ensuring better training and support during work, screening for and correcting vision, hearing and cognitive impairments, reducing reliance on memory (through use of checklists and point-of-care cognitive aids), promoting
teamwork, and training health professionals to communicate clearly and succinctly, with confirmation of important messages by the receiver and sender (‘three-way communication’). Simulation is another important intervention to promote safety, particularly around rarely performed procedures and infrequent events.

**Organizational conditions** can be improved by providing adequate staffing and resources, such as proper information technology, changing the culture to encourage staff to speak up, using a non-punitive approach to errors and adverse events (and using a punitive approach only when absolutely necessary), role-modeling by leaders, executive walk rounds, allocation of adequate resources to safety projects, education and training, and supporting proper disclosure programs and programs to help second victims.

In addition, specific interventions may be used for the prevention of specific types of errors. For example, routine use of a pre-operative checklist can prevent wrong-patient, wrong-site surgery; use of computerized provider order entry systems with decision support can prevent medication errors; hand hygiene prevents health-care associated infections; use of central lines insertion and maintenance bundles prevents central line associated bloodstream infections (CLABSI), designing the nozzles and wall outlets of different anesthesia gases and oxygen with unique shapes so as to avoid misconnections, use of barcoding instead of visual checking to dispense and administer medications or breast milk.

*If you are involved either directly or indirectly in a serious medical error, what thoughts and emotions are you likely to experience?*

Medical errors have a negative impact on healthcare providers involved, leading to physical, cognitive and behavioral symptoms and are referred to as “second victims.” A study by Panella et al in 2014 showed that health care providers remain traumatized and suffer at the psycho-physical level for a significant period of time after being involved in a medical error. Managers of health organizations need to ensure adequate support is given to healthcare providers involved in a medical error. Creation of networks of support at both the individual and organizational levels can be very helpful.  

**What type of safety events should be disclosed to the patient’s family?**

Patients view and define medical errors in very broad terms and may include non-preventable events. Physicians, on the other hand, regard only deviations from accepted standards of care (which may be ill-defined) as error. Likewise, there are differences among physicians and patients with expectations of disclosure. Medical literature demonstrates that 98% of patients wish to be informed of even minor incidents. Patients expect disclosure of all errors that might have caused harm, even remotely. However, physician’s definitions of error are much more narrow; only deviations from well-accepted standards of care are construed as errors. Patients want “information about what happened, why the error happened, how the error's consequences will be mitigated, and how recurrences will be prevented.
All physicians, regardless of their subspecialty area, are ethically obligated to disclose medical errors to patients because, for the apologizer, it is the right thing to do, and especially when he or she deeply believes, this as so. The act and intent of a sincere apology is as healing for the giver as it is for the taker and failure to do so can create a lack of trust.23

Barriers to disclosure of medical errors include embarrassment, guilt, sense of shame, lack of training or confidence in one’s disclosure skills, or a negative institutional culture can make disclosure of medical errors very challenging.

**When, how, and by whom should disclosure occur with the patient’s family?**

In the hospital setting, the attending physician (or a senior administrator) should take primary responsibility for disclosure. The health care professionals performing the disclosure should listen carefully to the family. A well conducted disclosure can reduce the risk of lawsuits, and can hasten the settlement time and reduce legal fees if a law suit is filed.24

The presence of an institutional leader also can signal to the patient and family that the issue is being taken seriously. But this inclusiveness must be balanced against the importance of not overwhelming the family, and the potential time lag for reaching or coordinating providers.

Trainees should always first discuss with an attending prior to approaching a family regarding disclosure of a medical error.

**What is the role of an apology during the disclosure process?**

Apology is an important component of disclosure. Tendering an effective apology is not an easy task. The act and intent of a sincere apology can be as healing for the healthcare professional offering the apology as it is for the recipient.22

A properly performed apology consists of:23

1) Acknowledgement of the error.
2) Explanation of what occurred and why.
3) Acceptance of the responsibility (towards the error or towards further investigation), clear, specific, direct, non-defensive, and sincere.
4) Explanation of how recurrences of the same error will be prevented in the future.
5) Follow-up sessions should be scheduled and communication maintained with the patient after the initial event.
6) Contact information should be provided in case patients and their families have questions.
7) Good documentation of the event and of the communication with the family.

Practice of maintaining a humanistic, care-giving attitude and staying emotionally calm rather than responding in a defensive and adversarial manner is essential for effective disclosures.24
Apologizing to patients for definitive errors is a complex medico-legal issue, and should be done after discussion with the institutional legal counsel. Risk management companies have found that more transparent and proactive apologies evoke a more positive response from the patients. Some malpractice litigation lawyers feel that it is difficult to “go after” a physician who is truly repentant, forthcoming, and apologizing for his or her mistake.

**Conclusion with Suggestions**

Medical errors and adverse events are not uncommon. A substantial proportion of these events is preventable. Identification of errors and safety threats requires a combination of methods including efficient reporting systems. The prevention of medical errors and adverse events requires improving WHO - work conditions (systems of care), human functioning and organizational conditions. Ultimately, healthcare leaders bear the responsibility of creating and sustaining systems of care within which patients receive safe care.

**References:**