Chapter 2 System Safety in the NICU

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A neonatal intensive care unit is similar in important ways to so called “first-time safe” systems in high-risk enterprises like nuclear power and aviation. All such first-time safe systems are complex, and they include hazards that require identification and control in order to minimize harm. The adaptation and application of safety methods and tools used in other industries is regarded as a worthy approach to improving safety in healthcare systems. Since 2005, NICQ collaborative teams have been working with the application of system safety methods as a means to identify and control hazards and thereby improve patient safety.

Studies of NICU incident reporting systems identify a wide range of errors, adverse events, and risks. Comparing the findings from these systems is problematic since different reporting and analysis methods were used to collect and classify incident information. The NEOSAFE report presents a more in-depth analysis of incidents and may be more inclusive of the kinds of hazards in NICUs, but is limited to experience in eight NICUs in the Netherlands. What is clear is this: there is considerable opportunity for improvement.

What Is System Safety?

System safety is a management approach to maintaining and improving safety that is comprehensive and thorough. It involves a philosophy that strives to reduce the risk of harm to a level that is “as low as reasonably achievable,” recognizing that resources to prevent harm are limited. A variety of management and engineering tools are used to identify, define, and control hazards in a systematic manner, focusing on system components and how they work together.

One of these tools is the system safety precedence sequence, shown in Figure 2.1. The system safety precedence sequence is based on reliability analysis and sets out a hierarchy of general hazard control strategies. Obviously the most reliable hazard control involves the elimination of the hazard, but it is not uncommon to neglect such an opportunity. The conscious use of the precedence sequence enables improvement teams to work with higher levels of reliability and to move away from the reliance on more training and education. This does not mean that provider knowledge is unimportant or that it should it be neglected, but rather points out the fallibility of hazard control that relies exclusively on this approach.
System safety also includes careful consideration of risk that attempts to quantify it subjectively, or empirically when possible, to inform decisions about resource application in control of hazards. The approach also strives to include safety consideration at all phases of a system’s life cycle; it is not a discrete activity that occurs only when a problem is identified or experienced, although it includes sophisticated incident investigation methods. ³⁵

A key principle of system safety is that safety is a line management responsibility. For the NICU, this means that the responsibility for safety should not be referred to a safety officer, specialist, or team. It is the responsibility of all—from the front line of care to unit leadership. Safety is a key result area like other performance goals (for example, fiscal responsibility).

Proactive methods of system safety direct attention to the identification and control of hazards before an event occurs.⁷ With limited resources and safety expertise in a busy NICU, this is challenging. However, every change provides an opportunity to consider hazards and improve safety. Participants in the NICQ collaboratives have been committed to making system safety a consideration in all change. The goal has been to identify, analyze, and improve hazard control as a parallel activity to all improvement activity.
Hazard Identification and Definition in Neonatal Care

Patient safety in the NICU presents a formidable challenge because of the complexity of care provided, the reliance on technology, and the vulnerability of the patients, mainly preterm infants, who have very limited tolerance for error. Given this challenge, an approach to safety improvement that engages some of the specific methods and tools of system safety is appropriate. The NICQ projects have provided an opportunity to apply system safety tools across multiple units. As a result, the collaboratives have been able to learn and share findings, engaging in a wide scope of improvement efforts across many different hazards (see the Hazard Index at the end of this chapter).

An effective hazard management process guides improvement activity from hazard identification through to control monitoring, as shown in Figure 2.2.

Figure 2.2 Hazard Management Process

Hazards are identified through a variety of methods, and it is important to have the means for taking preventive action when a hazard becomes known. Hazards can be identified by sources external to the NICU—for example, through The Joint Commission, through networks and associations such as the Vermont Oxford Network’s NICQ projects, and through literature, especially the growing body of literature concerned with patient safety. While a typical response to learning about hazards in other units is often “that would never happen here,” a much more useful response is to examine the system at play in one’s own unit. This can be as simple as clearly defining the hazard, examining the control measures in place, and assessing effectiveness by reviewing near misses or through observation and conversation with providers and/or parents.
Vigilance and review of local experience, including incidents and near misses (or “free lessons,” as they are sometimes called) are other sources of hazard identification. When an incident occurs, the associated hazard or hazards should be defined in a way that helps an improvement team consider various mechanisms, not just the exact mechanism associated with a particular event. This affords more thorough and proactive review and more effective ameliorative action.

For instance, if an event occurred in which a test delay caused a clinically significant treatment delay and it involved the mechanism of missing patient information on a specimen, it would be prudent to generalize the hazard to also include a mechanism in which the patient identifier on a specimen was incorrect. Although this is a different hazard, a review of specimen labeling processes presents an opportunity to address more than one specific hazard in a proactive manner.

Participating NICQ teams were guided to undertake preliminary hazard analysis and share findings and improvement activity. The Hazard Management Worksheet, shown in Figure 2.3, was used in this analysis to guide hazard definition, risk scoring, control review, and control improvement.

**Figure 2.3 Hazard Management Worksheet**

<table>
<thead>
<tr>
<th>Care Process: Respiratory - NCPAP</th>
<th>Patient group:</th>
<th>Topic area: Daily Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Description:</td>
<td>Safety Controls:</td>
<td>Probability</td>
</tr>
<tr>
<td>Skin Breakdown / Nasal Septum Erosion due to Pressure from CPAP Prongs</td>
<td>Prongs and application technique</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>Education for nursing and respiratory staff</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Poster and fact sheet on application and maintenance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standard team of respiratory therapists</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Protocol on application and maintenance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NCPAP equipment bin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Simplified application and use of steri-strips on prongs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ongoing monitoring of nasal septum erosion</td>
<td></td>
</tr>
</tbody>
</table>

Step 1: Define the hazard, identify source, mechanism and harm.
Step 2: Review/evaluate controls that reduce risk of mishaps or resulting harm.
Step 3: Assess and score risk (Risk Scoring Matrix).
Step 4: Make changes to reduce risk.
Step 5: Implement and standardize changes and establish monitoring.

<table>
<thead>
<tr>
<th>Revised Controls:</th>
<th>Date:</th>
<th>Probability</th>
<th>Severity</th>
<th>Risk score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>E</td>
<td>III</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Eliminated all choices for equipment and application technique</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Validated competency for application technique</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application process review on morning rounds</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>On-the-job remediation on application techniques</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Continue tracking of nasal septum erosion associated with NCPAP</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Analysis by: [poster by] Hackensack  
Contact: See NICQ.org for poster

A hazard definition includes three parts: source, mechanism, and harm. This is not a rigid structure, however. What’s more, hazards are often referred to in a truncated form for ease of communication or because information can be inferred.
Writing a hazard definition is a powerful exercise; each component offers different clues on how to make improvement as well as on the associated risk. To see the value of highlighting the component parts of a hazard definition, consider a hazard defined simply as mislabeled specimens. But if you rewrite this definition as Blood specimen (source) not labeled or labeled incorrectly (two mechanisms) resulting in delays or errors in care (potential harm), you get more information and enable a more thorough and comprehensive preventive response. Similarly, a hazard defined as weight dosing might be better defined as: Inaccurate or out-of-date patient weight (mechanism) leading to medication dose (source) calculation error (potential harm). For more examples of hazard definitions, see the Hazard Index at the end of this chapter.

**Risk and Safety Resource Application**

The concept of risk is not new to clinical decision making. For example, it’s involved in consideration of treatments with either uncertain or potentially adverse effects. A more formal consideration of risk as part of safety improvement is an extension of this kind of thinking.

A simplified risk scoring matrix was developed based on system safety tools as part of the NICQ 2005 collaborative (Figure 2.4).² This tool enables teams to consider risk, which is a product of severity and probability, in a subjective manner in order to create a score on which to base further action and consider the potential effect of improvement action. A variation of the tool was used by Snjiders and applied in a similar manner.²

**Figure 2.4 Risk Scoring Matrix**

<table>
<thead>
<tr>
<th>Severity of Harm</th>
<th>Probability of Occurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>F. Impossible</td>
</tr>
<tr>
<td>I. Death</td>
<td></td>
</tr>
<tr>
<td>II. Serious</td>
<td></td>
</tr>
<tr>
<td>III. Minor</td>
<td></td>
</tr>
<tr>
<td>IV. No Harm</td>
<td></td>
</tr>
</tbody>
</table>

1. Take immediate action to reduce risk
2. Monitor closely, seek additional controls
3. Control adequate, monitor change
**Probability of Occurrence**

The probability that a hazard will occur is a system characteristic based on several factors—generally, mechanism and exposure. The mechanism informs teams about how to make changes in their systems, while exposure brings into play considerations such as how frequently a process is performed. For instance, if breast milk is stored in a central location, the selection of the correct breast milk will be a step that is repeated for each feeding. Exposure to the possibility of this mechanism resulting in a breast milk error can be reduced or eliminated by storing the patient’s milk in their room or at their bedside. While this is not possible for many units, those moving to single-patient rooms have the opportunity to implement such a countermeasure to reduce exposure.

**Severity of Harm**

The severity associated with hazards involves other considerations such as the patient’s underlying condition but also factors that may be amenable to change. For instance, actions to reduce the magnitude of a source of potential harm—for example, limiting the availability of concentrated drugs—has the potential to reduce severity, as do actions that recognize and respond quickly and effectively when an event occurs.

NICQ teams included a consideration of the risk score as part of their work with the Hazard Management Worksheet. The example provided in Figure 2.3 illustrates how one team scored the risk of skin breakdown or nasal septum erosion due to pressure from CPAP prongs, scoring the risk both before and after changing their practices and instituting new hazard controls. This is a subjective, team-based assessment that has the shortcomings that come with this kind of assessment; however, by paying attention to the components of risk, teams are provided with more options for improvement. Furthermore, in the absence of any formal consideration of risk, a team’s actions are based on tacit assumptions. Formal consideration of risk creates change by contributing to the shared understanding and agreement on how to apply limited safety resources. Risk scoring is an iterative process that ought to occur following a review of current hazard control as well as during and after changes to improve control.

**Hazard Control**

“How do you know what you’re doing to control hazards is good enough?” This is a great question and one that led to the development of a worksheet to aid review of hazards and controls (see Figure 2.5). The items on the worksheet provide a reminder of key prevention principles and methods to support a team’s review of a hazard and to help them answer that question. Of course, there is no magic answer and it is best to consider this an open question, but the worksheet enables an enumeration of how many controls are in place (to provide redundancy) and whether specific and more reliable methods have been deployed.
### Figure 2.5 Hazard Control and Barrier Evaluation Worksheet

<table>
<thead>
<tr>
<th>Hazard:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ELIMINATE IF PRACTICAL</strong></td>
<td></td>
</tr>
<tr>
<td>1 check</td>
<td></td>
</tr>
<tr>
<td>☐ Hazard eliminated (harm impossible)</td>
<td>☐ Hazard controlled or minimized</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SAFETY PRECAUTIONS</th>
<th>拴</th>
<th>GENERATE PRECAUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 count</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Design for Minimum Hazard</td>
<td></td>
<td>Number of barriers “in-the-world”</td>
</tr>
<tr>
<td>2. Install Safety Devices</td>
<td></td>
<td>[you can take a picture of it]</td>
</tr>
<tr>
<td>3. Use Safety Warnings</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Procedures and Administrative Controls</td>
<td></td>
<td>Number of barriers “in-the-head”</td>
</tr>
<tr>
<td>5. Personnel Training, Awareness, Knowledge</td>
<td></td>
<td>[training, procedure, policy]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SHOW-THE-MODEL: Consider using both types of barriers. Multiple barriers are better.</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 count</td>
</tr>
<tr>
<td>Prevention Barriers (prevent causes)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have you considered any proofing?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Eliminate</td>
<td>☐ Feedback</td>
</tr>
<tr>
<td>☐ Replace</td>
<td>☐ Confirmation</td>
</tr>
<tr>
<td>☐ Facilitate</td>
<td>☐ Redundancy</td>
</tr>
<tr>
<td>☐ Detect</td>
<td>☐ Physical Constraint</td>
</tr>
<tr>
<td>☐ Mitigate</td>
<td>☐ Affordances - position, color</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have you considered and designed using human factors science?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Omission affordances identified</td>
</tr>
<tr>
<td>☐ Effective reminders deployed</td>
</tr>
<tr>
<td>☐ Checklist deployed to guide task</td>
</tr>
<tr>
<td>☐ Forms constrain unsafe actions</td>
</tr>
<tr>
<td>☐ Labels are legible and readable</td>
</tr>
<tr>
<td>☐ Illumination adequate for task</td>
</tr>
<tr>
<td>☐ Warnings salient and meaningful</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have you considered all system components?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Managed Environment</td>
</tr>
<tr>
<td>☐ People</td>
</tr>
<tr>
<td>☐ Procedures</td>
</tr>
<tr>
<td>☐ Hardware</td>
</tr>
<tr>
<td>☐ Task</td>
</tr>
</tbody>
</table>

*This worksheet provides summary concepts. Additional resources available at NICQpedia.*

While the worksheet directs users to more detailed references on the NICQpedia website, the following sections briefly describe what each part of the worksheet addresses.

**Eliminating Hazards**

The first consideration for all hazards should be: Can the hazard be eliminated and done so safely, without introducing more risk? A good example of this is review and consideration of the use of heparin for line flushes and line maintenance care following
tragic outcomes. If normal saline can safely be substituted, the hazard of heparin overdose may be effectively eliminated. The point to having this on a worksheet is to challenge thinking and ensure this dramatic improvement potential is not overlooked but carefully considered.

**IMPLEMENTING THE SAFETY PRECEDENCE SEQUENCE**

The worksheet includes a shortened version of the safety precedence sequence shown in Figure 2.1. A review team must challenge the prevailing reaction, which is to simply introduce more education or a new policy or enforcement. These responses may appear inexpensive and easy to implement, but they are often founded on the false premise that people can achieve perfection. The resulting hazard control is often difficult to sustain and can add administrative burden or waste time, often leading to workarounds. While it is not inappropriate to attend to education and awareness, an improvement team needs to understand the fallibility of relying primarily on this kind of control. In his classic human factors book, *The Design of Everyday Things*, Donald Norman differentiates between “knowledge in the head” versus “knowledge in the world.” Education requires a provider to remember and act on knowledge. When hazard control is more salient — “you can take a picture of it” — there is less reliance on the fallibility of human performance. As John Grout says in *Mistake-Proofing the Design of Health Care Processes*: “Putting knowledge in the world is an attractive alternative to trying to force more knowledge into the head. Knowledge can be put in the world by providing cues about what to do. This is accomplished by embedding the details of correct actions into the physical attributes of the process. In health care, for example, mental energies that were used to generate precise action and monitor compliance with procedures stored in memory are now freed to focus on those critical, non-routine deliberations required for the best possible patient care.”

**SETTING UP BARRIERS TO MINIMIZE HARM**

When making improvements in safety, it is important to address not just the prevention of events and occurrences, but also the response should the hazard controls fail. The concept of barriers and safety was popularized by James Reason in his so-called “swiss-cheese” model. Energy-barrier analysis is a system safety technique that uses the same principle: that blocking the progression of an untoward event with physical or procedural barriers is key to prevention. If the most important objective of safety is to prevent or minimize harm to the patient, we fall short if we do not consider countermeasures that mitigate the severity of harm when an error occurs.

Another system safety metaphor that uses the barrier concept is the bow-tie model shown in Figure 2.6. This model directs us to deploy countermeasures that acknowledge that adverse events will happen. These countermeasures need to both detect such an event and limit the level of harm experienced as a result. An example of this is naloxone hydrochloride (narcan) for narcotic overdose. Control of the narcotic overdose hazard is not just about prevention - it includes a response countermeasure.
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that will limit harm. It’s a simple concept that is sometimes overlooked; the worksheet directs a reviewer’s attention to consider this as part of safety improvement.

**Figure 2.6 The Bow-Tie Model**

![Bow-Tie Model](image)

**ERROR PROOFING**

Error-proofing or mistake-proofing is an approach that has been adapted from a manufacturing quality improvement methodology. It aims either to make errors impossible or to make them visible so a process is interrupted for correction before any adverse outcome occurs. This method is called Poka Yoke and originally developed by Toyota, whose improvement philosophy and methods have recently been employed successfully in several healthcare systems. 11, 15, 16

**USING HUMAN FACTORS SCIENCE**

Human factors principles in the worksheet refer to the NICU Human Factors Checklist series. 17 This was developed to guide changes based on human factors science and to educate NICQ participants, fostering a culture that focuses on system reliability. The approach taken with the series was to engage front-line teams in review and evaluation of their systems. The term “checklist” was applied in this instance to mean a self-assessment tool for the proactive evaluation of system characteristics, and not, as is frequently used in safety procedures, to mean a list to guide you in following procedures or real-time inspections of work factors.

**The Future: Collaborative System Safety Developments**

The application of system safety methods provides an opportunity for continued collaboration to improve safety in the NICU. In particular, an index of hazards and
controls, along with safety experience, can form a common reference point for improvement. The context of each NICU varies, but shared experience affords a larger realm in which to learn about often rare events. The pool of knowledge that stems from such experience is larger and this can accelerate improvement and avert tragic outcomes for infants and families. NICQpedia is a development that affords such opportunities on a global scale.

**Hazard Index**

The lists in this section call attention to hazards associated with neonatal care and were compiled as part of the NICQ 2005 and 2007 collaboratives. These lists provide cautionary samples; they do not represent all possible hazards. In each list, sources are denoted as follows:

2. List submitted at NICQ 2007 Cambridge
3. Prework for NICQ 2007 Chicago
4. NICQ 2005 Portland Posters

**Alarms and Monitoring**

- Alarm response (1)
- O₂ saturation range monitoring / maintenance failure: outside ordered profile (2)
- Delay in response to saturation alarms (2)
- Delays in alarm response (2)
- Alarm fatigue (excess and noncritical alarms) with Guardrail™ use for TPN (3)
- Inadvertent contact with touch screen resulting in standby or disabled monitor (3)
- Faulty or disconnected alarms and delayed response hypoxia/bradycardia (4)

**Security**

- Unit access security failure (abduction and other threats) (3)

**Discharge and Transfer**

- Insufficient or inadequate family instruction and teaching; medication error post discharge (3)
- NICU to Special Care Nursery handoff communication failure (3)

**Testing, Assessment, and Diagnosis**

- Mislabeled specimens (1)
- Point of care testing redraws, delays and spills (2)
- Missed or delayed ROP exam (2)
- Failure to report critical lab value such as a critical electrolyte imbalance (4)
- Unrecognized fetal heart rate abnormality (4)
- Inappropriate blood sample labeling; delay, redraw and/or inappropriate treatment (4)

**Infection Prevention**

- UVC lines in place beyond change date (2)
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- Extended use of lines/catheters and potential for BSI (2)
- Inconsistent PICC care and maintenance (2)
- IV line access procedure errors (infection hazards) (2)
- Improper Hep B administration (2)
- Contamination of central line; omission of preventive procedural steps (3)
- Contamination of IV fluids PIV fluids to new PICC line (4)

**IDENTIFICATION**
- Bedside patient ID (1)
- Procedure time out (1)
- Administration of incorrect unit of blood to patient (2)
- Patient identification errors and delays in blood gas testing procedure (3)
- Wrong patient, site, side, or procedure occurrence (4)
- Inappropriate positioning or dislodging of central venous catheters (4)

**HEMORRHAGE AND INJURY**
- Hemorrhage from severed line(s) (4)
- Hemorrhage from umbilical arterial catheter; no dead end on stopcock (4)
- Laceration from exposed scalpel blade (4)

**MEDICATION**
- Heparin overdose (1)
- Weight dosing (1)
- IV rate error (1)
- Erroneous barcodes (1)
- IV infiltration, extravasation resulting from perforation of vessel wall or dislodged needle (2)
- IV lipid over infusion (too fast) (2)
- Untimely, delayed, or missing discharge prescription (2)
- Dosing errors on discharge prescription (2)
- IV pump failure (2)
- Syringe design and labeling deficiency resulting in IV dose given orally (3)
- Medication dispensing and administration errors (for example, dopamine-doxapram mixup) (3)
- Multidose lidocaine vials confused for saline in procedure (3)
- Reversal of HAL and IL rates when bags hung with multichannel pump (3)
- Inappropriate morphine dose calculation (4)
- Delay in communication of antibiotic treatment; sepsis (4)
- Absent or inappropriate syringe labels (4)
- Delay in delivery of medication (pressors); prolonged hypotension (4)
- Wrong rate of infusion programmed into IV pump (4)
- Error in TPN drug doses (4)
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**NUTRITION**
- TPN contaminants (1)
- Feeding guidelines (1)
- TPN order communication delay or error (2)
- TPN volume maximum not controlled when switching from umbilical to PICC line (2)
- Confusing order for feeding readiness score with order for cue-based feeding (2)
- Breast milk administration errors (wrong patient) (2)
- TPN administration process hazards (2)
- Inappropriate addition of supplements to breast milk; inadequate nutrition or bowel injury (4)
- Incorrect placement of NG tube (4)
- Administration of overheated of breast milk (4)

**RESPIRATORY**
- Condensation in breathing circuit with high-flow nasal canula (3)
- CPAP prongs leading to nasal septum erosion or necrosis (3)
- Improper assembly of CPAP; obstruction of air flow to infant (3)
- Accidental extubation (4)
- Lung injury/disease - use of NeoPuff (4)

**ADMISSION**
- Admission hypothermia (1) (3)
- Communication failure re: high-risk OB patient and consequent delay or inappropriate infant care (2)
- Admission process delays (temperature control, respiratory care, IV access, labs) (2)

**MOVEMENT AND TRANSPORT**
- Transport incubator movement injury (facility to helicopter and in/out of ambulance or helicopter (2)
- Patient falling hazards (4)

**RESUSCITATION**
- Error in resuscitation procedure sequence (for example, compression before PPV) (3)

**ENVIRONMENT**
- Inappropriate light exposure to infants (3)

**References**
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