Crossing the Quality Chasm in Neonatal-Perinatal Medicine

Dan L. Ellsbury, MD

WHAT IS THE QUALITY CHASM?

In its landmark report, Crossing the Quality Chasm, the Institute of Medicine summarized the current state of quality in The American health care system1: “Between the health care we have and the care we could have lies not just a gap, but a chasm.”

What is the genesis of the quality chasm? At no time in history has the growth in medical science and technology been so rapid. Since the publication of the first randomized clinical trials more than 50 years ago,2 there has been an explosion of research activity in medicine. Over the past 30 years, these trials have increased from 100 per year to more than 10,000 annually.3,4 New medications, medical devices, and other technologies have demonstrated a similar escalation in number and complexity, resulting in an increasingly vast array of therapies that clinicians must assimilate and translate into state-of-the-art care.

Faced with such rapid changes, the health care delivery system has fallen far short in its ability to translate this knowledge into daily clinical practice. On average, 17 years is required for new knowledge generated by randomized controlled trials to be incorporated into general practice.5 A quality chasm is evident in all health care populations, including adult, pediatric, and newborn patients. Underuse, overuse, and misuse of therapies is commonplace and some patients are harmed as a result.6–11

THE QUALITY CHASM IN NEONATOLOGY

There is ample evidence of a quality chasm in neonatal intensive care. Large variations in use of established therapies exist and medical errors are frequent. Unexplained center-to-center variability in outcomes is present in multiple neonatal networks throughout the world.6,9,10,12–14 This article discusses a few examples of treatments that are underused, overused, or misused in current neonatal intensive care.
**Breast Milk**

A large volume of data supports breast milk as the optimal nutritional source for premature infants. Its use is associated with improved neurodevelopmental outcome and reduced rates of necrotizing enterocolitis and nosocomial infections. Despite this knowledge, fewer than half of very low-birth-weight infants receive breast milk at the time of discharge from neonatal ICUs (NICUs). Significant intercenter variability in breast milk use has been demonstrated.\textsuperscript{15,16}

**Antenatal Corticosteroids**

Treatment with antenatal corticosteroids is associated with an overall reduction in neonatal death, respiratory distress syndrome, intraventricular hemorrhage, necrotizing enterocolitis, respiratory support, intensive care admissions, and systemic infections in the first 48 hours of life. Antenatal corticosteroid use has improved since the National Institutes of Health consensus statement,\textsuperscript{17} but suboptimal administration rates persist.\textsuperscript{18–23}

**Surfactant**

Infants with established respiratory distress syndrome who receive animal-derived surfactant treatment have a decreased risk of pneumothorax, pulmonary interstitial emphysema, mortality, and bronchopulmonary dysplasia. Despite this evidence, its use remains suboptimal and variable.\textsuperscript{24–27}

**Central Line Bundles**

Central line bundles are a small group of key procedures and processes that, when done together, decrease the rate of catheter-associated blood stream infections. The bundle is simply a concept that has been successfully used to maximize compliance with sterile technique during central catheter insertion and care. The bundles have been successfully used in adult and pediatric ICUs and similar success is now seen in the neonatal ICU setting.\textsuperscript{28–33}

**Oxygen**

Supplemental oxygen is a heavily used medication in NICUs. High blood oxygen levels contribute to oxidative injuries in premature infants, including the development of retinopathy of prematurity and bronchopulmonary dysplasia. Despite this knowledge, it is common practice to functionally remove the ability of oxygen saturation monitoring systems to detect hyperoxia by setting the alarm limits to greater than 95% or even by functionally disabling the alarms. Oxygen management strategies to avoid hyperoxia have been successfully implemented but variation in oxygen use persists.\textsuperscript{34–43}

**Thermal Support**

Silverman and colleagues\textsuperscript{44} linked cold stress with mortality more than 50 years ago. Cold stress can lead to harmful side effects, including hypoglycemia, respiratory distress, hypoxia, metabolic acidosis, coagulation defects, and delayed transition from fetal to newborn circulation. Simple interventions to improve the thermal environment at birth are available. Despite the known association between cold stress and poor outcomes, and the ready availability of simple thermal support interventions hypothermia on admission to NICUs remains common in premature infants.\textsuperscript{44–49}

**Antibiotic Duration**

Antibiotics are heavily used in NICU care for the treatment of sepsis, pneumonia, and other infections. Prolonged exposure to antibiotics is associated with the development
of resistant organisms, fungal infections, and necrotizing enterocolitis. Despite these concerns, many infants continue to receive antibiotics after initial cultures are found to be negative and the infants appear clinically well.\textsuperscript{50–53}

**Metoclopramide**

Metoclopramide is heavily used in premature infants for the treatment of gastroesophageal reflux, apnea-associated reflux, and bowel dysmotility despite a significant lack of evidence of efficacy or safety. The known central nervous system adverse effects in the adult and pediatric populations are particularly concerning with the use of this medication. Despite this information, the drug remains heavily used in NICUs.\textsuperscript{54–65}

**H2-Blockers**

H2-blocking drugs are commonly used in premature infants for the treatment of gastroesophageal reflux associated apnea. However, evidence does not support a major role for gastroesophageal reflux in the etiology of apnea of prematurity. Treatment of reflux with H2-blockers will not prevent apnea, and may expose the infant to adverse medication effects. Of great concern, H2-blocker use has been associated with development of necrotizing enterocolitis, possibly due to alteration of gut microbiota from the modification of gastric pH.\textsuperscript{60,61,63,65,66}

**Cefotaxime**

Cefotaxime is one of the most commonly used antibiotics in NICUs. Cefotaxime use with ampicillin, as compared with ampicillin and gentamicin, however, was associated with higher mortality when used as empiric treatment for sepsis in the first 3 days of life.\textsuperscript{67} Cefotaxime and other third-generation cephalosporin use is a significant risk factor for the development of invasive candidiasis in extremely low-birth-weight infants. Cefotaxime use is associated with the development and spread of extended-spectrum β-lactamases, which confer resistance to all penicillins and cephalosporins.\textsuperscript{65,68–72}

**The Quality Chasm Exists in Neonatology**

As demonstrated by these examples, a quality chasm exists in neonatology, and, unfortunately, this list is by no means complete. All of the therapies on this list are important targets for NICU quality improvement efforts and several have already been the subjects of successful quality initiatives.

**SYSTEMS THINKING**

*Health care has safety and quality problems because it relies on outmoded systems of work. Poor designs set the workforce up to fail, regardless of how hard they try. If we want safer, higher-quality care, we will need to have redesigned systems of care.*

*Institute of Medicine\textsuperscript{1}*

*Central Law of Improvement: “Every system is perfectly designed to achieve the results it achieves.”*

*Donald Berwick\textsuperscript{73}*

Systems thinking is a key element of quality improvement. Without a clear grasp of basic systems theory, attempts at improvement are impeded. It is critically important to understand that the system drives the outcome (central law of improvement). If outcomes are poor in a NICU, it is because that NICU’s system is perfectly designed...
to generate that poor outcome. Changing the outcome first requires changing the system.

Deming defined a system as a network of interdependent components that work together to try to accomplish a specific aim.\textsuperscript{74,75} Systems may be simple or complex and may be further described as mechanical or naturally adaptable systems.\textsuperscript{76–82}

**Simple Systems**

Simple systems possess minimal components with simple relationships. For example, a home apnea monitor detects apnea in an infant and triggers an audible alarm. The electrodes are designed to detect the apnea event; the alarm is designed to alert the caregiver. These two components function together as a simple system to detect and report an event.

**Complex Systems**

Complex systems possess multiple, interrelated components that work together for a specific purpose. A central monitoring station in a NICU is a complex system that displays multiple measurements on several patients, displays audio and visual alarm events, and records, stores, and displays data trends. The components function together to enable NICU staff to detect a variety of physiologic abnormalities in several patients simultaneously, enabling them to intervene before harm occurs.

**Mechanical Systems**

Mechanical systems are highly predictable systems. The stimulus and response are well understood, and the outcome can be anticipated, even in a variety of circumstances and environments. The previous monitor examples are also examples of mechanical systems—simple mechanical systems and complex mechanical systems.

**Adaptive Systems**

The components of adaptive systems are capable of responding in multiple unpredictable ways, and these responses may then interact in multiple unpredictable ways. The introduction of living beings (from humans to microorganisms) introduces an element of chaos into any system. In the monitoring scenario, if the purpose of central monitoring is to minimize the duration of time with oxygen saturation levels above 95%, then the human elements—the baby’s physiologic responses and the nurses’ responses to the alarm data—create an adaptive system.

**COMPLEX ADAPTIVE SYSTEMS**

All of these system types exist in health care but generally function together as components of a complex adaptive system. Why bother to categorize systems? If a system model is not understood, system redesign may be ineffective or even counterproductive. If the human parts of a system are expected to behave like components of a mechanical system, system redesign is flawed and the outcome poor.

For example, consider this medical error: breast milk is given intravenously to an infant. A mechanical systems viewpoint of this error is to consider the nurse the “defective” part of the system and the correction to “remove the faulty part.” From a complex adaptive systems perspective, the analysis and correction of the problem is different: the syringes used for breast milk and for intravenous lipids are identical, the milk and lipids are similar in appearance, and the double-check system was not used due to unavailability of a second nurse. System redesign includes modification of the syringe types, such that the enteral syringe is visibly different from the...
intravenous syringe in design and unable to physically connect to intravenous tubing. Nurse staffing design during high activity periods are assessed and modifications designed to enable double checks to occur as planned during high activity time periods.

TYPES OF CHANGE: TINKERING AND SYSTEM CHANGE

Two general categories of change are tinkering and system change. Tinkering (also known as first-order change) generally refers to simple changes imposed on individuals, such as trying harder or being more careful. These effort-based changes, although sometimes useful, are unlikely to yield sustained improvement.73

System change (also known as second-order change) refers to redesign of a system to always produce the desired outcome. Additional individual effort is not the primary design of the change. Over time, system changes are more likely to yield sustained improvement than tinkering. For examples of system change and tinkering in NICUs, see Table 1. Any change introduced into a complex adaptive system can have unintended and unpredictable results. It is imperative that changes be tested and refined via plan-do-study-act cycles (see the article by Ellsbury and Ursprung elsewhere in this issue) to avoid unintended consequences.

USING SIMPLICITY TO CROSS THE CHASM OF COMPLEXITY

Despite the labyrinthine processes and pathways of complex adaptive systems, it is heartening to realize that simplicity is a key factor in modification of these systems. Plsek76 describes three simple rules for human complex adaptive system modification: (1) general direction pointing, (2) prohibitions, and (3) resource or permission providing. This approach is counterintuitive from a mechanistic perspective—more

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<thead>
<tr>
<th>Problem</th>
<th>Tinkering</th>
<th>System Change</th>
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<tbody>
<tr>
<td>Physicians orders are illegible, causing medication errors</td>
<td>Chastise physicians, tell them to try harder</td>
<td>Computerize order entry or use typed standardized order sets to minimize the need for handwriting</td>
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<tr>
<td>Breast milk use is low in premature infants</td>
<td>Suggest that the hospital hire more lactation consultants</td>
<td>Evaluate NICU staff opinions, correct opinions that formula and breast milk are equivalent; create process to provide breast pumps shortly after delivery</td>
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<tr>
<td>Oximeter alarms are not set as ordered</td>
<td>Sanction nurses who are noncomplaint</td>
<td>Establish a root cause for noncompliance (education, alarm defaults), provide education, modify preset alarm defaults</td>
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<tr>
<td>Surfactant is not always available when needed in the delivery room</td>
<td>Ask nursing staff to remember to order the drug from pharmacy when a delivery may occur</td>
<td>Establish a ward stock of surfactant that is immediately available for any delivery</td>
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complexity should require more rules. But for complex adaptive systems, it is the case that “less is more.” Systematic breakdown and control of all component parts is not possible; the adaptive components and interrelationships are not predictable. Simple rules must be established for a system, rules that create the conditions for purposeful self-organizing behavior under which widespread and diverse natural experimentation occurs focused on generating the desired outcome. An example of this approach is the Pediatrix Comprehensive Oxygen Management for the Prevention of Retinopathy of Prematurity initiative. A few simple rules were used to govern this project: educate the NICU staff, redesign the system to avoid hyperoxia, and monitor compliance with the changes. Each NICU was encouraged to adapt the program to the specific environment of that NICU. The details of implementation varied between the NICUs, which often found different paths to the same outcome. The result was that in a large national network of NICUs, severe retinopathy of prematurity showed a marked and sustained decrease (see the article by Ellsbury and Ursprung elsewhere in this issue).

SUMMARY

A quality chasm exists in neonatal intensive care. Despite years of clinical research in neonatology, many therapies continue to be underused, overused, or misused. A key concept in crossing the quality chasm is the central law of improvement (every system is perfectly designed to achieve the results it achieves). An appreciation of the NICU as a complex adaptive system is integral to successful system redesign. The unpredictability of human factors and the dynamic complexity of the NICU system are not amenable to rigid reductionist control and redesign. Change is best accomplished in this complex adaptive system by use of simple rules, such as (1) general direction pointing, (2) prohibitions, and (3) resource or permission providing. These rules create the conditions for purposeful self-organizing behavior under which widespread natural experimentation occurs focused on generating the desired outcome.

A great opportunity exists in neonatology. Years of knowledge, obtained from the hard and insightful work of many researchers, sit uselessly on the shelf, ready and waiting to be applied in daily neonatal intensive care.

Knowing is not enough; we must apply. Willing is not enough; we must do.

–Goethe

REFERENCES

35. Ellsbur y DL. Quality improvement program for the reduction of retinopathy of prematurity [abstract]. E-PAS 2006;59:3602.469.


