AHRQ Grant Final Progress Report

Title:

Crossing An Invisible Quality Chasm: From NICU to Ambulatory Care

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Abstract:

Purpose:
We performed a Healthcare Failure Modes and Effects Analysis™ (HFMEA) to proactively assess the risks of the transition of fragile infants from neonatal intensive care to ambulatory follow-up and qualitatively evaluated the HFMEA process.

Scope:
Over 20,000 neonates annually make the potentially risky transition from the neonatal intensive care unit (NICU) to home in the United States, often into the care of primary care physicians whom they have never met. The result is fragmented care, missed appointments, inappropriate use of the emergency room, and frequent readmissions to the hospital.

Methods:
The HFMEA team was led by a patient safety specialist and included neonatologists, general pediatricians, nurses, discharge planners, a social worker, and a parent of a premature infant. The process was evaluated using a facilitated debriefing session with the team, interviews of key informants, and a content analysis of documentation generated throughout the project.

Results:
The HFMEA process identified 40 high-risk failure modes and 75 associated high-risk causes. Clear thematic categories included poor communication among care providers in the hospital, between care providers and parents/caregivers, or between the hospital-based care providers and providers after discharge. Additionally, community-based care providers lacked knowledge and skills to care for fragile infants. A mitigation plan was developed to address the failure modes and causes that were within the control of the institution. Evaluation of the HFMEA process revealed a high level of involvement, with over 250 hours of professional time devoted to this risk-assessment process. Though the HFMEA method holds promise for improving the safety of care transitions, the full effort required to realize the potential benefit of an HFMEA requires additional evaluation to confirm its value over less-intensive means of achieving safer care transitions.

Key Words: adverse events, NICU, patient safety, quality improvement, risk assessment

Purpose:

Proactive evaluation of error-prone healthcare processes may inform interventions to prevent adverse patient outcomes. Healthcare Failure Mode and Effect Analysis™ (HFMEA) is one such approach to improving patient safety. HFMEA is a systematic, team-based method of identifying potential errors and risks in healthcare processes and prioritizing targets for intervention or redesign. The method is well described by DeRosier et al. and has been successfully implemented in the Veterans Affairs health system. To our knowledge, HFMEA has been used in only two published pediatric studies, neither of which involved neonates. Furthermore, HFMEA has not been used in any setting to study care transitions during the discharge process. We applied HFMEA to identify risks in care transitions involving the discharge of newborns with complex conditions. We also assessed the team's perceptions of advantages and challenges of using HFMEA in the high-risk neonatal setting.

Scope:

Infants born prematurely or with complex congenital abnormalities are surviving to discharge in growing numbers. Over 20,000 neonates make the risky transition from the neonatal intensive care unit (NICU) to home each year in the United States, often to the care of primary care physicians (PCPs) they have never met. Efforts to minimize lengths of stay in the NICU contribute to increased complexity of healthcare needs at the time of discharge. To ensure safe and effective monitoring and coordination of care for fragile neonates, an efficient “handoff” from the intensive care specialist to the ambulatory care provider is critical. Despite their potential significance, little is known about the specific vulnerabilities that involve care transitions from the NICU to home.

Studies from the adult literature reveal significant vulnerabilities around the point of discharge from the hospital. About half (49%) of hospitalized adults experience at least one medical error following hospital discharge, and approximately one fifth (19-23%) of discharged patients experience an adverse event. Most errors and adverse events in this transition involve communication breakdowns in handoffs between inpatient care teams, patients (or their caregivers), and/or PCPs. However, few published studies describe the risks of care transitions in the pediatric population.

Previous studies have measured attendance at follow-up appointments using a conceptual approach that implies that the root of the problem is lack of compliance on the part of caregivers rather than systematic difficulties that lead to delayed or inadequate follow-up. One study found that 28% of children discharged from pediatric (not neonatal) intensive care did not receive timely medical follow-up. Most published research on this transition in pediatric patients focuses on the effect of insurance on follow-up or describes early discharge programs.

We conducted the HFMEA at Texas Children's Hospital (TCH), a freestanding pediatric hospital currently licensed for 639 beds, including a 76-bed Level III NICU and a 62-bed Level II nursery. The 10-member HFMEA team was led by a hospital-based patient safety specialist and included neonatologists, general pediatricians, nurses, discharge planners, a social worker, and a parent of a premature infant. The team met from October 2007 through April 2008. The institutional review board of Baylor College of Medicine approved the study.

Methods:

Using the HFMEA methodology outlined by DeRosier et al., the team initially developed a flow diagram that identified the main processes and subprocesses involved in the discharge of a high-risk infant. Once members agreed that all pertinent steps were listed, the team brainstormed for all potential errors that might occur (failure modes) at each step of the process. Each failure mode was then scored on two parameters: the probability that it could occur (frequency score) and the severity of the potential outcome if it did occur (severity score). Frequency and severity were rated on a numerical scale and decided by group consensus. For each identified failure mode, the product of the frequency and severity scores was computed to generate a hazard score. Potentially "high-risk" failure modes were defined as those with hazard scores of at least 50% of the maximum possible score.

The HFMEA Decision Tree tool (U.S. Department of Veterans Affairs) was used to identify opportunities for intervention. Each low-scoring failure mode was evaluated to determine whether it was a single-point weakness, a step in the process that was so critical that its failure would result in system failure, or an immediate adverse event. Single-point weaknesses were reclassified as "high risk." Next, we eliminated vulnerabilities with effective control mechanisms already in place and failure modes that were so obvious that no mitigation plan would be needed. The team then listed potential contributory factors ("causes") for each of the remaining high-risk failure modes and scored these factors using an approach similar to that of the hazard score. The resulting final list of high-risk failure modes and causes was used to guide the development of a comprehensive mitigation plan.

Because the HFMEA methodology had not been used previously to study the neonatal discharge process, qualitative data were collected from participants at the end of the project to learn about their experiences. A list of challenges that were encountered by the team and their possible solutions was generated by synthesizing data from the following three sources:

1) A facilitated debriefing session was held with the entire team to assess team members' perceptions of the components of the HFMEA method and the application of HFMEA to care transitions within the NICU population. Team members' opinions were solicited about what went well during the HFMEA project and what did not, their perceptions of the value of HFMEA after its evolution over time, and suggestions for improving the process. The transcribed notes were then analyzed to identify and organize content themes that emerged from the debriefing session.

2) Key informants (principal investigator, patient safety specialist, social worker, general pediatricians, neonatologists, and a parent) were then interviewed to expand upon issues identified in the team debriefing. Additional issues were explored related to the time commitment required from team members, the comfort level of team members with their skills in this area, the resources needed, and technical aspects of the HFMEA method.

3) A content analysis of all documentation maintained by the patient safety specialist, including meeting agendas and detailed minutes, was conducted to enrich findings from the debriefing and the interviews.

Results:

The team held 20 1.5-hour meetings from October 1, 2007, to April 30, 2008. The team began by developing a high-level flow diagram of the discharge process, starting with identifying the patient for discharge and ending when a follow-up appointment took place. The team broke down each of the high-level steps into multiple individual sub-steps. Figure 1 shows the resulting diagram of the discharge process from the NICU to a primary care pediatrician.

Figure 1
High Level Process Map with Sub-steps

High-Level Process	Sub-steps
1. Patient identified for discharge ⇩	A) Attending physician decides time for discharge B) Attending discusses decision with rest of care staff C) Caregiver identified and notified
2. Discharge needs identified ⇩	A) Caregiver teaching initiated B) Consulting services contacted for follow-up recommendations C) Consulting services document recommendations for follow-up in medical record D) Baylor Clinical RN attempts to schedule appointments E) PCP is identified and contacted by licensed care provider (NNP, resident, fellow) F) Baylor Clinical RN ensures appropriate home care orders are written G) Care coordinators arrange for home care and equipment needs H) Discharge prescriptions are written and given to caregiver I) Caregiver acquires medications J) Discharge formula orders given to caregiver
3. Patient discharged from NICU 3 or 2 ⇩	A) Conduct weekly discharge planning rounds (NICU 2 only) B) Discharge orders are written by licensed care provider C) Baylor Clinical RN prepares discharge packet D) Discharge packet given to caregiver by Baylor Clinical RN E) TCH discharge instructions completed and given to caregiver by bedside RN F) Newborn state screening performed per state requirements or at discharge G) For all Baylor patients, discharge data form is faxed to primary care pediatrician on next business day after discharge H) Hard copy of discharge data form is mailed to PCP I) Copy of discharge summary is faxed to PCP
4. Interim support ⇩	A) Home healthcare B) Primary care pediatrician C) TCH Emergency Department D) NICU staff E) Neo attending F) Specialists G) Vendors H) Community emergency departments I) CPS J) Community pharmacist K) Caregivers

5. Follow-up appointment occurs	A) Patient is seen by primary care pediatrician B) Primary care pediatrician follows through on no-show patients

The team identified 114 potential failure modes within the discharge process mapped in the flow diagram. To score failure modes and causes, we initially used the definitions published by DeRosier et al. However, the team found the original HFMEA scoring system unsuitable to grade events in the NICU care transition. Therefore, through consensus, the team created revised NICU-specific definitions that improved the clarity of severity ratings and specificity of probability ratings (see Tables 1 and 2).

Table 1
Revised Severity Categories

Category (Score)	Outcome type	Description of outcome(s) within category
Catastrophic (4)	Patient outcomes	Original HFMEA: Death or major permanent loss of function, suicide, rape, hemolytic transfusion reaction, surgery/procedure on wrong patient or body part, or infant abduction **Revised: It is realistic to think that this failure mode could result in death or serious disability**
	Equipment or facility outcomes	Damage equal to or more than $250,000
Major (3)	Patient outcomes	Original HFMEA: Permanent lessening of body functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, or increased length of stay or increased level of care for 3 or more patients **Revised: This failure mode could (but isn't likely to) really hurt someone or result in a much longer length of stay**
	Equipment or facility outcomes	Damage equal to or more than $100,000
Moderate (2)	Patient outcomes	Original HFMEA: Increased length of stay or increased level of care for 1 or 2 patients **Revised: This failure mode could extend length of stay but is not likely to be fatal, OR could adversely affect health, but not severely**
	Equipment or facility outcomes	Damage more than $10,000 but less than $100,000

Minor (1)	Patient outcomes	Original HFMEA: No injury, not increased length of stay, nor increased level of care **Revised: Slight increase in length of stay, no effect on health outcomes**
	Equipment or facility outcomes	Damage less than $10,000 or loss of any utility without adverse patient outcomes (e.g., power, natural gas, electricity, water, communications, transport, heat/air conditioning)

Table 2
Revised Probability Categories

Score	Description in original HFMEA	Revised description
7	N/A	Daily
6	N/A	Greater than 1x/week
5	N/A	Greater than 1x/month but less than 1x/week
4	Frequent: Likely to occur immediately or within a short period (may happen several times in 1 year)	Greater than 1x/year but less than 1x/month
3	Occasional: Probably will occur (may happen several times in 1 to 2 years)	Less than 2x/year
2	Uncommon: Possible to occur (may happen sometime in 2 to 5 years)	Once every 2 - 5 years
1	Remote: Unlikely to occur (may happen sometime in 5 to 30 years)	Once every 5 - 30 years

Because the hazard scores are simply the arithmetic product of the severity and probability scores, the team recognized that simultaneously scoring the severity and the probability of an event might result in team members adjusting some of the scores to make sure that a certain failure mode or cause would be included in the final model. To explore that possibility, the team re-scored one step of the process independently. Figure 2 shows a comparison of the scores obtained when one sub-step was scored for severity and probability simultaneously versus those obtained when the same sub-step was scored independently at a later meeting. For consistency, the team decided to use the original scoring to develop the final model.

Figure 2

Caregiver identified and notified about potential discharge							
FMEA Step 4 Hazard Analysis							
Failure Mode: First Evaluate failure mode before determining potential causes		Open Scoring			Blind Scoring		
		Severity	Probability	Hazard Score	Severity	Probability	Hazard Score
1C(1)	There is no caregiver identified	3	5	15	3	1	3
1C(2)	Caregiver is not notified	2	2	4	2	2	4

The final model included 40 high-risk failure modes and 75 high-risk causes. Although some, such as insurance-related causes, were eliminated as events not under clinician or hospital control, the following issues were present across most of the identified failure modes and causes:

1. Healthcare providers (attending physicians, consulting physicians, and other healthcare providers) in the NICU tend to act in isolation, which results in a lack of a standardized, coordinated, and comprehensive plan of care;
2. Parents/caregivers may be inadequately prepared for home care and management of fragile neonates due to a lack of consistent and early communication between parents and NICU staff and a lack of a coordinated educational and social services support programs prior to discharge; and
3. Community providers (including PCPs, home health nurses, pharmacists, and community emergency rooms) may lack the required knowledge and skills to manage complex infants, leading to suboptimal office-based care and perceived overutilization of the emergency system.

Once these care transitions issues were identified, the team developed a comprehensive plan for corrective action. The plan, which is still in the design and implementation stages, addresses coordination of information sharing between and among care providers within the NICU to improve parent/ caregiver preparation to assume responsibility for the child's care upon discharge and to enhance PCPs' skills and knowledge to receive these infants into their practices after discharge from the NICU.

Process Evaluation:

Analysis of qualitative data revealed several consistent themes. Overall, the team members felt that the group functioned extremely well, with a high level of involvement from most members and many new insights gained in the process. All team members agreed that the transition from the NICU to ambulatory care was an important process that warranted proactive risk assessment. Furthermore, there was broad agreement that defining all of the various steps in the discharge process led to discussions in which knowledge about discharges and care transitions emerged and was shared for the first time among the various participants in the discharge process.

Concerns about the HFMEA process included the substantial time commitment required to adequately apply the HFMEA method and the relevance of the original HFMEA scoring system to the NICU setting. Moreover, team members uniformly felt that the HFMEA method was limited in capturing the high degree of clinical complexity inherent in the transition from the NICU to a primary care pediatrician.

The total time commitment from all team members for the HFMEA was substantial. The median number of meetings attended by each member was 16, and all members attended at least half of those meetings. A total of approximately 230 hours of professional time was spent in the HFMEA meetings, and the patient safety specialist and the principal investigator together spent an additional 40-50 professional hours outside the group sessions to prepare for meetings. We estimated the value of the professional hours involved in the HFMEA meetings at approximately $20,000.

Conclusions and Implications:

The HFMEA process enabled us to improve our understanding of the critical error points that introduce risk during the transition from NICU to ambulatory environments. We identified risks related to lack of communication between care providers in the hospital, between care providers and parents/caregivers, and between hospital-based and ambulatory care providers. Additional identified risks included potential lack of knowledge and skills among community-based care providers who are responsible for caring for vulnerable infants after discharge. Although the HFMEA holds promise for improving patient safety during care transitions, the value of applying this tool to the complex transition from NICU to community settings requires additional study.

List of Publications and Products:

Moyer VA, Finkel, K, Singh H. Giardino AP. **HFMEA of a Complex Care Transition: How Did We Learn What We Learned?** AHRQ 2008 Annual Conference, Rockville, MD.

Giardino AP, Moyer VA. **From the NICU to Primary Care: The Potential of HFMEA.** Platform Presentation. Quality Colloquium, August 2009. Boston, MA.

Moyer VA, Singh H, Finkel KL, Giardino AP. **Transitions from Neonatal Intensive Care Unit to Ambulatory Care: An Evaluation of Proactive Risk Assessment**. Quality and Safety in Health Care. Invited submission to supplement on ergonomics and human factors. In review, 2010.

Profit J, Kelly PA, Thomas E, Eichenwald E, Moyer VA. **Measuring the Quality of Care Transitions from the Neonatal Intensive Care Unit to the Ambulatory Setting.** Abstract under review, submitted to AcademyHealth meeting 2010