Leveraging Existing Assessments of Risk Now (LEARN)
Final Report

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A. STRUCTURED ABSTRACT (200 words maximum)

Purpose:
To prospectively identify generic mechanisms of healthcare risks to target patient safety improvement.

Scope:
Frequently safety vulnerabilities and risks that exist at one institution also exist at other institutions. The objective of this study was to identify these generic risks across institutions.

Methods:
The LEARN method consists of a meta-analysis of existing risk assessment. Risk assessments were collected from institutions across the country. Medium- to high-risk failure modes and failure mode causes were cataloged. The LEARN review revealed common risks. An assessment of the quality of risk assessments was also conducted.

Results:
Sixteen risk assessments were collected from across the country. Over 400 fail-points were described. Of these, 296 had a risk priority number designating them medium to high risk.

Meta-analysis of fail-points identified generic issues that lead to harmful errors and patient safety risk with relative frequency. Prominent generic risks included:

- Unreliable hand-off of clinical information regardless of the process or context
- Missing information
- Lack of feedback in medical care systems

Assessment of the quality of risk assessments revealed that these assessments did not represent the possibility of both omission and comission events in most assessments.

Key Words: Risk Assessments, Patient Safety, Pediatric, Ambulatory

B. PURPOSE

Given the limited research on pediatric patient safety in emergency medicine, this project stemmed from the need to develop knowledge to provide effective patient safety activities in order to improve children's emergency medical care services. Pediatrics is a high-priority population, and patient safety in ambulatory care is a high-priority focus. This project allowed us to adapt a successful engineering methodology for identifying risks to the context of children's medical care. The United States Department of Energy (DOE) employs a standardized methodology of prospective risk assessment to analyze a corpus of risk assessments in order to determine significant generic risks and risk contributors. By adapting these DOE methods and criteria to analyze existing risk assessment from National Association of Children's Hospitals and Related Institutions (NACHRI) member institutions, we were able to provide knowledge about significant risks and risk contributors in children's emergency medical care. These adapted methods were able to provide us with prioritized risks and risk contributors in children's medical care. Thirty existing risk assessments from NACHRI member institutions were analyzed for the purpose of this project. The resulting risks and risk contributors in the systems and processes of children's emergency medical care, as well as the adapted methods, were disseminated through a NACHRI-hosted webinar, the NACHRI website, and other relevant mechanisms. Specifically, the aims of this project were:

1. To adapt the US DOE methods and criteria for analysis of multiple existing risk assessments for use in healthcare
2. To apply the adapted methods and criteria to existing risk assessments about emergency medical care systems and processes gathered by NACHRI

3. To identify significant generic risks and risk contributors related to children's emergency medical care
4. To disseminate results through NACHRI and other mechanisms. Specifically, we will disseminate:
    a. The identified significant generic risks, risk contributors and potential safety interventions for children's emergency medical services, and
    b. A toolkit of the adapted methods and criteria for analysis of existing risk assessments

The relevance of this research to public health is that it adapts a method for meta-analysis of existing risk assessments to more comprehensively identify significant generic risks associated with the high-risk ambulatory care context of emergency medicine and other medical contexts and presents a method for customizing general risk assessments to inform safety improvement for the high-priority population of pediatric patients.

C. SCOPE

C.1. Emergency Medical Care for Children

Annually, children make ~29 million visits to Emergency Departments (EDs) in the United States for medical care, and nearly 30% of all ED visits are made by children.[1] The number of pediatric ED visits increased by almost 20% in 1997–2003. Children's hospitals are an important source of pediatric emergency care and tend to be the best prepared. There are two primary organizational forms of children's hospitals: a free-standing hospital or a large pediatric service within a general hospital that is designated as a children's hospital. Of all ED visits by children, 18% are visits to pediatric EDs in hospitals that have pediatric expertise and appropriate pediatric equipment, policies, and procedures.[1] Thus, the vast majority of pediatric ED visits are made to general hospitals that treat adults and children in one department. EDs that treat both children and adults are unlikely to have pediatric-trained emergency physicians, on staff, and many lack basic pediatric equipment and supplies essential for emergency medical care. The outcomes for pediatric trauma patients treated at children's hospitals are significantly more favorable, resulting in lower mortality rates, shorter lengths of stay, and lower charges than those treated at adult hospitals. Furthermore, the IOM found that only 6% of EDs have the supplies deemed essential for managing pediatric emergencies, and only ~23% of EDs have a pediatric emergency physician on staff.[1]

Although most pediatric ED visits are made by children >5 years old, nearly 97 of 100 infants in the United States has an emergency department visit.[1] The most common ED diagnoses for children overall are for fever, upper respiratory infection, asthma, otitis media, and viral syndromes.[1]

For older children, the most common diagnoses are superficial injury and/or contusion, sprains, and strains. Only 4% of all pediatric ED visits result in a hospital admission.[1]

As is true of general emergency medical care, pediatric emergency medical care is challenged by unpredictability. The volume of pediatric patients presenting at any one time in an emergency department is unpredictable which can lead to potentially serious delays. Most emergency medical care for children is for relatively minor illnesses, and relatively rare but serious illnesses can be difficult to recognize. Overall, pediatric emergency medicine is a high-stakes, chaotic work environment that presents clinicians with significant knowledge and skill challenges. This underscores the importance of designing systems of pediatric emergency care that can improve the reliability and the safety of pediatric emergency medical care.

C.2. Pediatric Patient Safety in Emergency Medicine

In 2003, there were 113.9 million visits to emergency departments and the number of visits has been increasing consistently across the past decade.[1]

Emergency departments have high patient volumes, overcrowding, and, by definition, high patient acuity. “Emergency care services are delivered in an environment where the need for haste, the distraction of frequent interruptions and clinical uncertainty abound, thus potentially exposing patients to a number of threats to patient safety.”[1] The potential for risk in the emergency department is also associated with frequent patient hand-offs, incomplete and frequently inadequate patient information, and the potential for medication errors.

Emergency care for children is highly complex and highly risky. Of all emergency department visits, 27% are for children.[2] Children have unique emergency treatment needs. “Once children are critically ill or injured, their bodies will respond differently than adults in similar medical crisis."[3] The IOM’s report *Future of Emergency Care: Emergency Care for Children - Growing Pains*[2] provides a current assessment of children’s emergency care, and it highlights many patient safety issues, including overcrowding, noise, chaos, high and fluctuating volumes, stress experienced by clinicians who care for multiple patients at once over a 24-hour period, multiple patient hand-offs, and limited access to patients’ relevant clinical information.[1] Though these represent emergency medical care conditions for all patients, the IOM highlights additional conditions of special concern for children. These include difficulty recognizing imminent serious physiological decline, medication prescription complexity, children’s limited ability to communicate symptoms, and additional obstacles with the patient identification of children.[4] The IOM report highlights and corroborates similar issues in children’s emergency medical care as those of the child-specific risk factors that have been shown to lead to patient safety risk for children[3] (Table 1).

Table 1. Child-specific risk factors and IOM categories of differences between children and adults

Child-Specific Risk Factors[9]	**IOM Categories of Difference between Children and Adults[12]**
▪ Physical characteristics (small and variable size and morphology)	▪ Anatomical differences (small size, greater body to surface area to body mass ratio, head proportionally larger, tongue is large relative to the oropharynx, etc.)
▪ Physiological development (immature physiological systems, variable signs and symptoms, medication prescribing challenges)	▪ Physiological differences (respiratory and heart rates vary, higher metabolic rates, immature immunologic systems)
▪ Cognitive social emotional development (limited ability to communicate, regulate behavior and emotions)	▪ Developmental differences (communication barriers) ▪ Emotional differences (greater, varying emotional needs, sensitivity to environmental factors during treatment)
▪ Minor Legal Status (decision making and consent parental responsibility for medical management, supervision requirements	

An important issue in emergency care of children is the pediatric training and knowledge of clinicians. The additional medical requirements of children with special healthcare needs (feeding tubes, oxygen, shunts, etc.) that increase complexity[24] and need for expertise further intensify these challenges in institutions with non-pediatric-trained clinicians, including non-pediatric-trained residents.

Resuscitation is a core practice of emergency medicine. The medical care provided during a resuscitation is determined not only by the clinical situation but also by a series of age and size factors particular to each child. In children, the complexity of the tasks involved in resuscitation is increased by the unique component of variability of pediatric age and size, introducing logistical factors, many of which involve complex computation. One tool that has been found to be helpful to reduce this complexity is the “Broselow cart” and the “Broselow tape” that groups children by size, according to a corresponding color. The appropriate equipment and medication dosages are color coded to correspond to each size group, thus assisting with safe emergency management of the patient.[5]

However, there are many other high-risk contexts in the emergency care of children that have not been fully explored or addressed. One substantial challenge in emergency medicine is the overwhelming volume of patients, which commonly can lead to delays of up to 24 hours for treatment.[2] These delays can be of significant consequence for very ill children.[6]

The IOM has laid out an expectation for "provider organizations to have safeguards in place to protect pediatric patients from the EMS and ED environments"[12] while acknowledging the significant challenge regarding the need for improved information with respect to error, error risk, and approaches to reduce errors in emergency and trauma care for children. The report establishes an agenda that recommends increased research and evidence-based solutions.[1]

C.5. Risk Assessment

C.5.a Error Science and Medicine

The study of error and safety in the 20th century came late to medicine. The aviation industry dramatically reduced crashes and deaths by studying risks and developing systemic methods for improving safety and reliability. In 1979, the Three Mile Island nuclear accident prompted concerns about the safety of nuclear power and led to a system-level focus of error prevention. Reason developed the Swiss cheese model, through which he depicted alignment of "holes" in the layers of defense that result in an incident.[6] Studying errors that have occurred retrospectively can provide insight, but preventing errors with prospective assessment of systems and processes can provide insight and safe and reliable redesign without harm from an error. By applying these methods, the medical field of anesthesia reduced death rates associated with anesthesia from 1 in 20,000 persons to 1 in 200,000 persons in two decades. Although the exact incidence of error and harm is unknown for pediatric emergency care, it is understood that pediatric emergency care is a high-risk field and a high-priority context for study and improvement. Addressing the systems that either facilitate or fail to prevent errors has become central to good management of many industries, but in medicine such efforts are relatively new. To understand the principles of system-level thinking for safety, Schenkel summarizes and slightly modifies, to apply to medical care safety, four points made by the design theorist Don Norman[7]: "1) Understand the causes of error and design to minimize those causes; 2) Make it possible to undo actions or make it harder to do what cannot be undone; 3) Make it easier to discover and to correct the errors that do occur; and 4) Change the attitude toward errors. The admission and study of mistakes are what permits improvement."[8] These are the principles on which prospective risk assessment methods and safe design are built. We propose to apply these principles to the understanding of significant risks and risk contributors in pediatric emergency medical care and in the design of safety improvement strategies.

C. 5.b. Risk Assessment Methods

To improve patient safety, medicine has reached out to other high-risk industries that have developed methods to understand existing risks and to reduce the likelihood of their occurrence. To further the diffusion of risk assessment methods from high-risk industries into healthcare organizational practice, The Joint Commission has required accredited institutions to conduct annual prospective risk assessments regarding a topic of interest. There is strong evidence that this method, performed effectively, will identify significant failure point in healthcare processes and support the prioritization of safety improvement activities. Comprehensive assessment of the risks inherent in medical care processes is a worthy yet time-consuming and resource-intensive activity. Assessment of risk, as a standard practice in medicine, represents an advancement in safety practice. In medicine, however, an FMEA provides risk information for an individual institution, yet such information is infrequently shared with other institutions with similar processes that might benefit from its results. The high-risk, high-reliability industries from which these FMEA methods have been derived have evolved and have developed methods for the analysis and synthesis of risk assessment results to identify generic risks that can be and are disseminated broadly for use in risk-reduction activities.

There is a wide variety of approaches to risk assessment in high-risk industries. These approaches vary in complexity and level of analytical effort. This variation is driven by the complexity of the systems being analyzed, the perceived level of risk, and the current reliability of those systems. In situations when failure events are likely to occur, risk assessments or hazard evaluation techniques can be effectively employed. A hazard evaluation study is an organized effort to identify and analyze the significance of hazardous situations associated with a process or activity.[9] Included among these hazard evaluation techniques is the FMEA. According to the AIChE Guidelines, the FMEA is a systematic tabular method for evaluating and documenting the causes and effects of known types of component failures. This method has been adapted for use in the healthcare industry and is used extensively to analyze healthcare processes in response to The Joint Commission requirement.[10] In application to the healthcare environment, component failures are replaced by process step fail-points, and an assessment of the likelihood of failures is added. The method is then used to produce a risk-ranking of process faults (on the basis of likelihood and outcome/consequence). his risk information is used to identify the most significant (e.g., highest risk) failures to support the development of interventions and controls to reduce risk and thereby improve patient safety. FMEAs that define how "critical" a failure might be are sometimes referred to as Failure Modes and Effects and Criticality Analysis (FMECA).[11]

Root-cause analysis (RCA) is a process designed for use in investigating and categorizing root causes of events with safety, health, environmental, quality, reliability, and production impacts.[12] The RCA is a four-step process involving 1) data collection; 2) causal-factor charting; 3) root cause identification; and 4) recommendation generation and implementation. To be thorough, an RCA must include the following: determination of human and other factors; determination of related processes and systems; analysis of underlying cause-and-effect systems through a series of "why" questions; identification of risks and their potential contributions; and determination of potential improvement in processes or systems.[13] Often, an RCA will employ a hazard evaluation technique (e.g., FMEA) for analysis of underlying cause-and-effect systems with a series of "why" questions and identification of risks and their potential contributions.

These techniques have been effectively employed to reduce risk in many high-risk industries, including healthcare. The AIChE Guidelines for Hazard Evaluation Procedures includes the following list of benefits of a hazard evaluation program: fewer accidents over the life of a process, reduced consequences of accidents that do occur, improved emergency response, improved training and understanding of the process, more efficient and productive operations, and improved regulatory and community relations.

As an example, use of a FMEA to evaluate the slips and falls prevention process in one hospital resulted in a 50% reduction in slips and falls over a 2-year period.[14]

C.6. Joint Commission Requirement for Prospective Risk Assessment

In 2001, in response to the IOM report *To Err is Human*, The Joint Commission put forward a new set of standards focused on patient safety.[15] Subsequent to these new requirements, numerous FMEAs and other risk assessments have been conducted. The learning from these risk assessments can be leveraged through a group analysis method to identify and share significant generic risks and risk contributors to improve the safety of emergency medical care services for children.

Risk assessment methodologies, such as Failure Mode Effects Analysis (FMEA), have been shown to be effective for identifying, assessing, and addressing risks in many life critical industries that must function with high reliability, including medicine.[9, 10] Although prospective risk assessments are being conducted at healthcare institutions across the country in response to the requirement of The Joint Commission, an important opportunity is being missed – using these risk assessments to identify generic risks and risk contributors to improve the understanding of similar processes across institutions. By adapting methods from other high-risk industries, risk assessments from multiple institutions can be analyzed for use toward improving our understanding of the significant risks and risk contributors of healthcare processes more generically. Using such tools could contribute to the goal of medicine achieving comparable success in reducing errors and risk as the DOE has markedly achieved in improving safety.

D. METHODS

D.1. DOE Safety Analysis Methods

The "Safety Analysis" process utilized by the DOE is used to develop controls (safety interventions) for non-reactor nuclear facilities. Briefly, the "Safety Analysis" method includes four basic steps that involve several sub-steps. These steps include:

1. Identify Hazards: Completed by the participating institutions prior to this grouping of risk assessments
2. Perform Hazard Evaluations: Use the failure events from existing risk assessments
3. Select Candidate Accidents:
   A. Bin failure events into accident categories and other relevant criteria
   B. Select representative cases (emblematic case scenarios representing a particular contour of risk) to further evaluate and identify risks and risk contributors
4. Identify Safety Controls/Interventions: Identify potential measures to reduce risk

Several differences were found between the types of risk results that exist in the nuclear industry and healthcare.

1. Risks are substantially more common and frequent
2. Risk chains can be more complicated and intricate leading to an under representation of failure modes and failure mode causes
3. A theoretical basis for causation of risks is less well defined to nonexistent for many existing risks in healthcare risks (i.e., physics is the primary theoretical basis for causation in the nuclear industry)
4. The application of risk assessment technologies in healthcare is new and quality of risks results needs improvement, particularly across the dimensions of comprehensiveness, application of data to assessments and more complete representations

The DOE Safety Analysis method was therefore modified, and the following steps represent this modification and the resulting LEARN Meta-analysis of Risk Assessments enables a Meta-Analytic review of risk results across institutions and domains of healthcare.

D.2. Adaptation of Methods to Healthcare

The terminology, context, and processes differ in medicine that of other high-risk industries, and these differences in medicine must be accommodated for effective application. The following sections describe the initial modifications of the process and criteria necessary for this method to be effectively applied to pediatric emergency medical care. The process and criteria described here will be further modified iteratively through use.

The US DOE method has been adapted for the healthcare industry, for example, applying different accident category event types that are appropriate to medicine, evidence-based criteria found in the available patient safety literature of performance shaping factors, and patient characteristics (child-specific risk factors) will be considered for their contribution to the nature of the existing risks.

Step 1: Identify Hazards

This step will have already been completed in the form of the topic to be studied. Table 2 provides an example the type of information received in the risk assessments for analysis.[16]

Table 2. Example FMECA worksheet for correct of blood transfusion

Step ID	Step	Success Criteria	Failure Mode	Cause	Freq Cat	Cons Cat	SG Cat	Comment	Risk
5.10	Document results in computer or down-time log	Correct cross match	Enter incorrect information into computer or into log	Human error interrupted	F1	CP4	S5	Computer or log entry triggers blood issuance	High
5.11	Print or handwrite cross match results on blood unit tag in lab	Document correct patient and blood type	Incorrect or illegible hand-written label	Human error	F2	CP1	S2	Only make hand-written labels during computer down-time (<1% of time). If info is wrong, the Fenwal armband on patient will catch the error.	Low
5.12	Attach printed (or handwritten) blood unit tag to donor blood and Fenwal # sticker	Correct tag on correct unit	Put wrong tag on unit	Process multiple specimens at a time	F2	CP3	S2	Later, the Red Cross label will be checked against the unit tag	Med

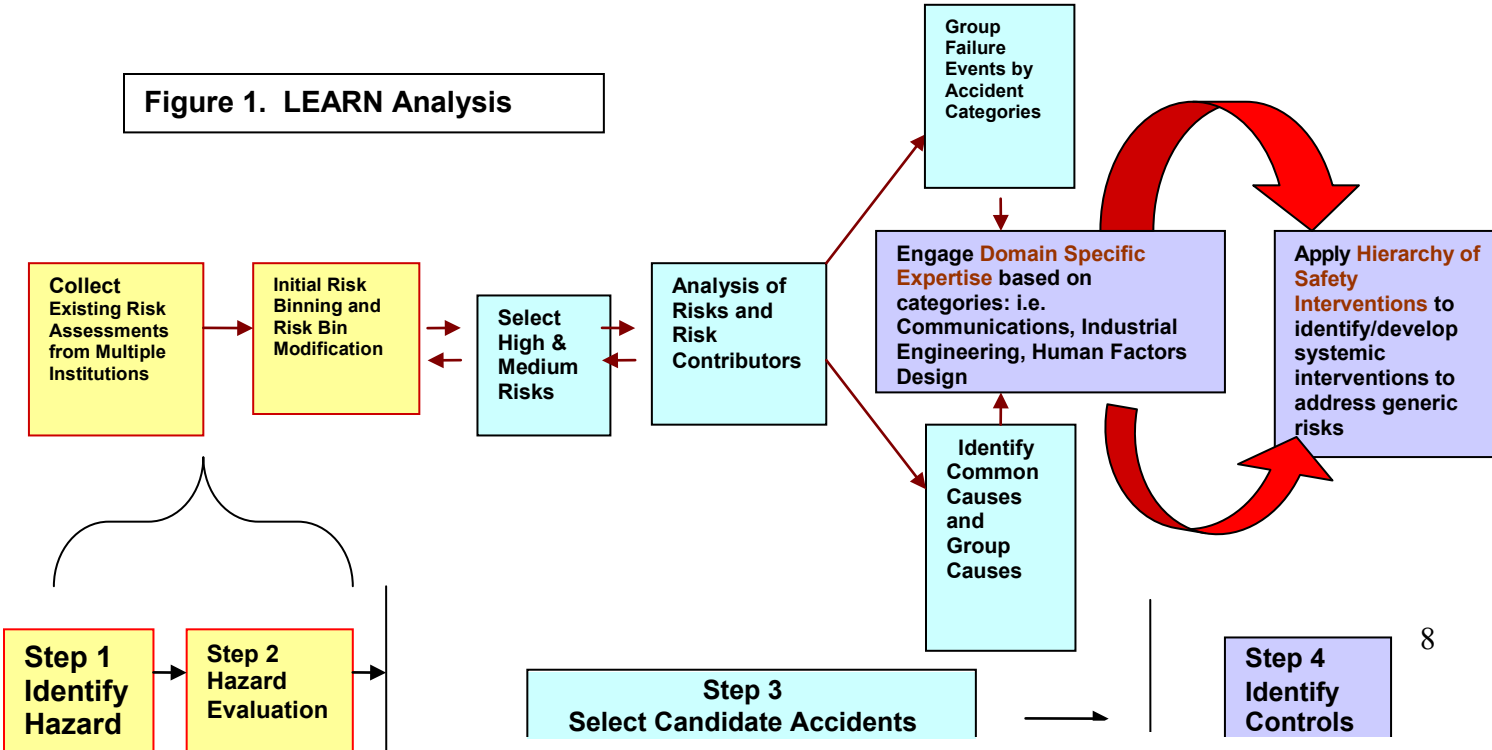
Step 2: Hazard evaluations (FMEA, RCA, etc.)

Risks for this analysis are described as the answers to the following questions:

- What can go wrong? (failure events)
- How likely is it? (frequency)
- What are the consequences? (harm)

Existing risk assessments will be the results of the completion of this step and should include an assessment of the fail-points, their frequency, consequence, and existing safeguards.

Figure 1. LEARN Analysis



Step 3: Build a database of Medium- and High-Risk Failure Modes across risk assessments

Review failure modes across risk assessment and build a database for analysis of the risk results.

Category	Failure Mode Summary	Failure Mode	FMEA 1	FMEA 2	FMEA 3	FMEA 4	FMEA 5	Total
	Faulty equipment	Decreased quality of transfer call				1		1
	Lack of communication	Less effective communication/ Poor hand off			1			1
Communication- Message Miscommunicated					1	1		2
	Lack of communication	Less effective communication/ Poor hand off			1			1
	Lack of data	Delay waiting for chart to be ready				1		1
		Fax not received in lab	1					1
		Labs not received				1		1
		Results delayed or do not arrive			1			1
	Patient error	Patient eats breakfast before fasting lab draw					4	4
	Staff/Human error	Not separated from "heads up" call when patient arrives, call is not made		1				1
	Unknown	Call has to be re-routed			1			1
Communication- Message Not Received			1	1	3	2	4	11
	Faulty equipment	Access line goes down			1			1
		Fax machine not checked	1					1
		Fax not working, out of paper	1					1
		Fax not working, out of paper, not checked	1					1
		Low quality phone connection			1			1
	Lack of communication	Physician not notified of critical level					2	2
		Referring hospital unaware that they can speak with any nurse				1		1
	Lack of data	Another institution is waiting to hear about a bed			1			1
		No feedback for referring hospital			2			2
	Staff/Human error	Wrong room					1	1
	Unknown	Sheet is not faxed		2				2
Communication- Message Not Transmitted			3	2	5	1	3	14

3.A: Risk Binning Analysis Protocol to Identify Significant Risks

The categories of *frequency* and *consequence* are to be used in combination to identify the significant (relatively higher) risks through a process called “risk binning.” The following tables Tables 3 and 4) illustrates a matrices for the application of these sets of criteria. In this schema, risks assessed in risk bin IV are low to moderate in consequence and extremely unlikely to beyond extremely unlikely. The highest risks with the highest consequence are in Risk Bin I, the next highest in Risk Bin II, and so forth. Failure events in Risk Bins I and II (High and Medium Risks) become the focus for targeted attention.

Table 3. Risk bin categories

Consequence Level	Beyond extremely unlikely(<10^{-6} /yr)	Extremely unlikely (10^{-4} to 10^{-6} /yr)	Unlikely (10^{-2} to 10^{-4} /yr)	Anticipated above 10^{-2} /yr
High	III	II	I	I
Moderate	IV	III	II	I
Low	IV	IV	III	III

Table 4. Frequency and Consequence of Failure Mode Categories and Safeguard Effectiveness Categories

Category	Frequency	Description
F1	Remote	Possible, no known data (happens once in 10 years)
F2	Uncommon	Documented but infrequent (happens once a year)
F3	Occasional	Documented and frequent (happens once a month)
F4	Very Frequent	Documented, occurs routinely (happens more than once a month)
Category	**Consequence**	**Description**
CP0	None	No impact on the chance of failure mode
CP1	Little	Little impact on the chance of failure mode
CP2	Some	Some impact on the chance of failure mode
CP3	Significant	Significant impact on the chance of failure mode
CP4	Certain	Almost certain chance of failure mode
Category	**Safeguard Type**	**Description**
S1	Multiple checks	Hospital procedure has a formal built-in check and other safeguards
S2	Formal check	Hospital procedure includes a formal built-in check
S3	Standard practice	Standard practice includes a check
S4	Noticeable	Worker notices and responds
S5	Non-detectable	The failure is not detectable

Step 3.B. – *Categorize the Hazard Results by Type*
In the nuclear industry, the next step is based primarily on grouping failure events by causes, physical characteristics, and the potential for severity of consequences for particular relevant phenomena, such as fire. These groups are called “failure categories” in this study. Typically, in the nuclear industry, for important topics such as facility handling or processing of nuclear material, the types of classifications would include such cases as fires, leaks, and load drops.

Group failure modes by type: In medicine, we recommend initial categories in the following ranges: event types, (i.e., medication, diagnostic, etc.); activity (communication, decision making, physical execution of a task, etc.); contextual factors (i.e., work environment, team factors, etc.); and factors related to particular patient populations (e.g., child-specific risk factors) followed by the process of: 3.A. “Risk Binning” and “Selection of High/Medium Risks”

Criteria: Medicine Event Types
This set of categories is appropriate to healthcare and was developed by reviewing patient safety events. These categories are effective for designating medical care processes in both hospital-based and ambulatory medical care.[16]

1. Preventive medicine (immunization and preventive screening)
2. Diagnostics (medical history and physical examination, diagnostic testing, reading, recording, and interpreting results)
3. Treatment
   A. Medications, blood products, fluid, diet (ordering, transcribing, dispensing, and administration)
   B. Surgical and non-surgical procedures (preparation, performance of the procedure, and post-procedural care)

   C. Appointment scheduling, referral, and follow-up communications
   D. Other medical treatments (psychiatric, social services, and discharge planning)
4. Patient monitoring (monitoring of patient status)
5. Patient communication (communication, education, consent, and confidentiality for preventive care diagnostics, medications, non-surgical procedures and surgical care, post-surgical care, and other medical treatments)
6. Patient identification
7. Equipment related (equipment malfunction, equipment availability, and use of equipment)
8. Administrative (medical record related and other clinically significant administrative processes)

Criteria: Active/Passive

1. Omission
2. Commission

Criteria: Risk Factors - Contextual Factors in Medicine

The contextual factors used in this analysis follow the framework presented by Charles Vincent as "factors that influence clinical practice."[18] These include the following:

1. Institutional context (economic and regulatory context).
2. Organizational and management factors (financial resources, policy standards and goals, and safety culture priorities).
3. Work environment (staffing levels and skills mix, workload and shift patterns, design, availability, and maintenance of equipment, and administrative and managerial support).
4. Team factors (verbal communication, written communication, supervision and help seeking, and team structure).
5. Individual staff factors (knowledge and skill, motivation, physical and mental health).
6. Task factors (task design and clarity of structure and availability and use of protocols).

Criteria: Focus

1. Communication
2. Decision making
3. Execution of a task (not including communication tasks)

Step 3 C: Identify Generic Risks and Risk Contributors:
Common Process Steps, Common Failure Modes, Common Failure Mode Causes and Classified types

Following categorization of risk results and grouping of results across Risk Assessments/Hazard Analyses, we found that common process steps, failure modes, and failure mode causes were represented in the risk results. In addition, these risk results demonstrated common characteristics into which we had categorized these. From this analysis, generic medium and high risks and risk contributors were identified to target for intervention and development of controls.

Step 4: Design of Safety Interventions and Controls

Many of the types of safety risks found in healthcare have a theoretical basis that exists outside of the primary knowledge domain of medicine. Fields include Communication, Cognitive Psychology, Industrial Engineering, Operations Management, Organizational Behavior, Human Factors Engineering, etc. Rather than "reinventing the wheel" in each case, this analysis recommends consultation from individuals who can meaningfully apply domain specific knowledge from fields in the appropriate discipline relevant to the specific categories of generic risk and risk contributors.

The design of potential safety interventions can be informed by the error preventing or mitigating strength of the intervention. The following hierarchy of safety improvement strategies can be applied toward development of potential safety interventions aimed at mitigating the generic risks and risks contributors resulting from analysis of the representative cases. We present here a modified hierarchy of interventions based initially on that which was developed by Vaida and The Institute for Safe Medication Practices. The modified hierarchy of interventions includes:

1. Forcing Functions
2. Automation, Computerization, and Technology
3. Standardization and Protocols
4. Staffing Organization
5. Policies, Rules, and Expectations
6. Checklists & Double Checks
7. Risk Assessment & Communication Errors
8. Education and Information
9. Personal Initiative – Vigilance

It is important to remember that the resulting safety interventions will require further testing for their potential to contribute new or additional fail-points. This LEARN Meta-analysis of Risk Assessments method including the review of institutional artifacts can then become another method for assessment of safety interventions, if through this analysis it is shown that the risks are less frequent or of less consequence based on a particular organizational feature or safety implementation.

D.3. Using General Risks Results to Inform Pediatric Safety Improvement

D.3.a. The Need

"Children are not just little adults"; rather, a number of research findings suggests that children may have a safety risk profile that is distinct from that of adults.[1, 3, 12, 17] In addition, it has been shown that important differences exist between adults and children that contribute to the occurrence of errors and patient safety risk. For children, not only might priorities differ regarding the frequency and harm or consequence but the methods for intervention and safe design may also differ. In a study of the impact of the application of an "out-of-the-box" Computer Physician Order Entry (CPOE) system, Han et. al. demonstrated that an intervention shown to be effective, even in the same institution for adult patients, when applied without being customized for the needs of pediatric patients, can increase morbidity and mortality among pediatric patients.[19] The policy statement of American Academy of Pediatrics states: "The first step in designing these systems is to identify [potential] errors and study their pattern of occurrence within delivery systems to reduce the likelihood of adverse events. A specific concern in pediatrics is the lack of information on errors in the pediatric population and the strategies needed to minimize errors and maximize care … Efforts to improve patient safety and prevent errors should focus on a systems approach … and healthcare organizations should take into account unique pediatric safety issues …."[30]

D.3.b. Child-Specific Risk Factors

Woods and Holl et. al. identified a set of "child-specific risk factors" from an extensive review of the literature and then demonstrated that these factors contribute actively to patient safety events affecting children and that the related harm may be greater in these instances.[23, 17] These child-specific risk factors contributed to 49% of the identified patient safety events and were shown to contribute to patient safety risk in both hospital-based and ambulatory care settings. Though these factors represent a significant reservoir of risk in the medical care of pediatric patients, the general organization of medical systems contribute substantial risk to pediatric patient safety as well.

A key question is: What are the mechanisms through which these child-specific factors contribute to pediatric patient safety problems and increased safety risk? To begin, each of the primary child-specific factors contributes to increased variability, a principle known to increase the risk of error.[19,28] Variability occurs, for example, because of the wide range in "normal" results in analyses of blood, urine, or cerebrospinal fluid or because of the need to maintain and select from a wide range of sizes of endotracheal tubes or IV catheters in pediatric healthcare. Similarly, the relatively common problem of medication-related risks among pediatric patients is often associated with the variable size, weight, and physiological immaturity of children, which requires the customization of each dose based on weight and age. CPOE systems have received considerable attention as a systemic method to improve medical care safety and provide a striking example of why strategies that work for adults may not be effective for children.[29] Many of the currently available CPOE systems are only beginning to have the capability to account for weight as a variable in the medication calculation process and age in intervals of <1 year.

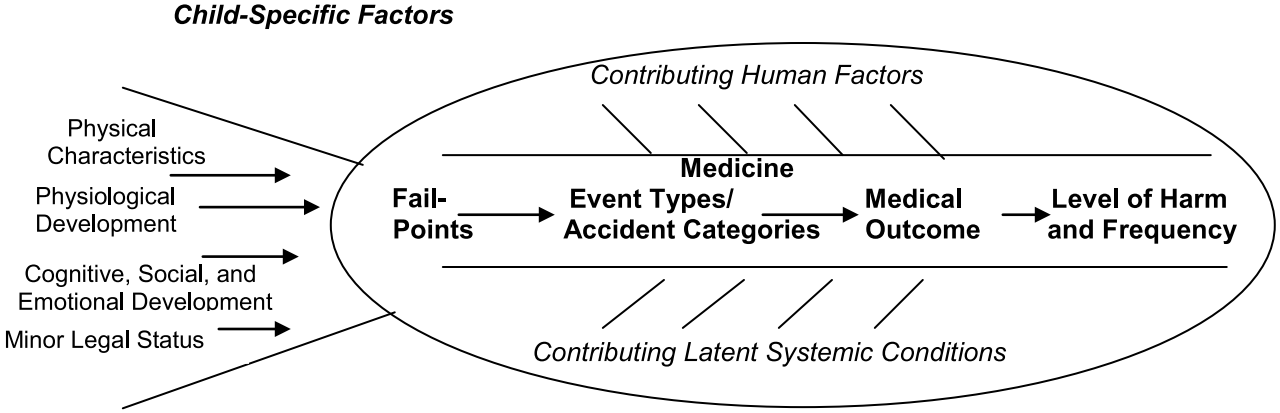
The need to customize medication dosages for children also leads to more steps in the treatment process and increased complexity and offers more opportunity for error.[6,22] Decreased available information is another factor related to error.[8,23] In the care of children, the quality of information is often compromised because of a child's cognitive-social-emotional immaturity, limited communication skills, and constrained ability to understand the impact or consequences of their medical care. Information may also be inadequate because of the changing physiological characteristics of very young children that make test findings more subtle and therefore more difficult to interpret.[8] Immature physiological systems also can be associated with increased volatility of physiologic response and reduced reaction time, which have been shown to increase error risk.[24] The small size of very young children, also, contributes to the increased technical difficulty of performing selected procedures, such as venipuncture or the insertion of intravenous lines or catheters. Treatments such as conscious sedation can cause increased risk because of a child's limited ability to regulate behavior and movement.[25]

D.3.c Conceptual Model

Figure 2 provides a model of the contribution of risk factors and their impact on pediatric patient safety risk and outcomes. ***This model can be used to understand the interaction and contribution of factors to the frequency and consequence of risk in the context of emergency medical services of children.***

Figure 2. Conceptual model for risk assessment for pediatric patient safety[26]

Context of medical care (i.e., emergency medicine)



Child-specific risk factors contribute directly to the nature and occurrence of a fail-point and an event and also to functions, processes, and organizational systems that facilitate or provide barriers that mitigate error. Child-specific risk factors affect the relative frequency and configuration of the "contributing human factors" and "contributing latent conditions." For example, the lack of pediatric knowledge in the assessment of acuity of a pediatric patient is a cognitive factor for clinicians affected by specific needs for information about pediatric patients and the variation generated by the variable signs and symptoms of pediatric patients. The variable size and morphology of pediatric patients requires different-sized and -designed medical supplies and equipment which, in turn can lead to incorrect size selection. This is an error-fraught step that is infrequent in adult medicine, and therefore, may increase the risk of error in the care of a pediatric patient. The outcome may also be affected by the type of equipment (i.e., the selection of a Trilogy pump versus a syringe pump).[18]

An example of the contribution of child-specific factors to latent conditions of pediatric emergency care includes the physiological variability and physiological difference from adults, leading to the limited inclusion of children in medication studies. The significant and potentially risky practice of "off-label" use of medications results from this problem.[12] Although this issue is not exclusive to children's medical care, it is prominent and can affect both the frequency of a failure event and, potentially, the consequence of an event.

The center row of Figure 2 depicts the progression of the event itself with contributing factors having impact at each stage: fail-points lead to the occurrence of an event, which results in an outcome (a level of harm or consequences) and the frequency. The medicine event types can be applied as accident categories (e.g., diagnosis, surgical procedures, medication treatment).

The extent of an increase or decrease in the *frequency* of risk and an increase or decrease in the resulting consequence would be considered based on the criteria. For example, in medication ordering for a child in the emergency department, the application of two child-specific factors must be considered: 1) physical characteristics (variable size) and 2) physiological development factors (limited or variable physiological development). The dosage must be customized on the basis of weight and physiological status (i.e., kidney function). Additional steps in the medication ordering process are required, thus increasing the risk of error. The relatively minor misplacement of a decimal point can easily lead to a 10-fold error. Depending on the medication involved, the frequency and consequence of the error could increase. From this failure category, a selected representative case would be further assessed to identify the potential impact of the performance-shaping factors of emergency medicine, which functions as a high-pressured environment with frequent interruptions, and a need for haste, increasing further the frequency of risk.

D.4 Dissemination

The primary result of this study, the LEARN Meta-analysis of Risk Results, will be disseminated by posting results in established and frequently accessed source.

D.4.a Institute for Healthcare Studies, Feinberg School of Medicine, Northwestern University website

The primary result of this study – the methods to conduct the LEARN Meta-analysis of Risk Results – were posted on the website of the Institute for Healthcare Studies, Feinberg School of Medicine, Northwestern University and were made accessible to anyone who wished to use the methods and employ the developed tools from the LEARN Toolkit.

D.4.b National Association of Children's Hospitals and Related Institutions (NACHRI)

The primary results of this study, the LEARN Meta-analysis of Risk Results, were disseminated by posting results on the NACHRI website. This website included a section on quality and patient safety. Results were made available on the public portion of the website to enable use by both NACHRI members and non-members.

Member outreach, including broadcast e-mails to NACHRI quality program and patient safety directors as well as to patient care executives and medical directors, will be used to draw attention to these results. In addition, new information will be flagged on the website.

To further direct attention to the important findings of the study, a web-based seminar (including a visual presentation and teleconference) was hosted for presentation of methods and findings, discussion of implications, identification of potential interventions to address common risk factors, and answering of questions and collection of input from seminar participants. Audiotapes and presentation slides are accessible through the NACHRI website. There was widespread participation in this seminar. Dissemination of information will expand beyond the NACHRI membership (e.g., the American Academy of Pediatrics "SaferForKids" electronic forum and the AHRQ Child and Adolescent Health ListServ).

D.3.c. Peer-Reviewed Publications and Presentations at National Meetings

The LEARN Team has thus far published two works on the LEARN Meta-Analysis of Risk Assessments method (See below in Publications section). Three additional papers are in the process of preparation for submission to peer-reviewed journals. The findings that these papers will report have already accepted for presentation at the2009 National Patient Safety Foundation Congress, the 2009 Academy Health Annual Research Meeting and the co-located 2009 Child Health Services Research Meeting.

D.3.d. Additional Dissemination Activities

Additional mechanisms for dissemination include presentations and posters at NACHRI meetings, including the NACHRI Annual Meeting and Spring Creating Connections Meeting. Approximately 500 children's hospital executives and medical leaders attend each of these meetings, and >100 participate in the quality improvement and patient safety track of the "Creating Connection Meeting." As appropriate, significant findings and risk factors will be provided to entities, such as The Joint Commission, which has mechanisms in place to alert hospitals of potential risks (e.g., Joint Commission Sentinel Events Alert)

In addition to the identification of risk factors, this study will result in a tested model for analyses of risk assessments effective for identifying significant generic risks and risk contributors for pediatric emergency medicine and may be applicable to other aspects of medical care. It will contribute to the science of patient safety. Reports and peer-reviewed papers will be submitted for publication from the project findings, and a Toolkit of the criteria methods will be developed. If this project is funded, as part of AHRQ's ambulatory care safety program, the reports and findings of project would receive wide dissemination by AHRQ. In addition, the findings and methods and any developed reports will be posted on the Northwestern University, Institute for Healthcare Studies Center for Patient Safety websites.

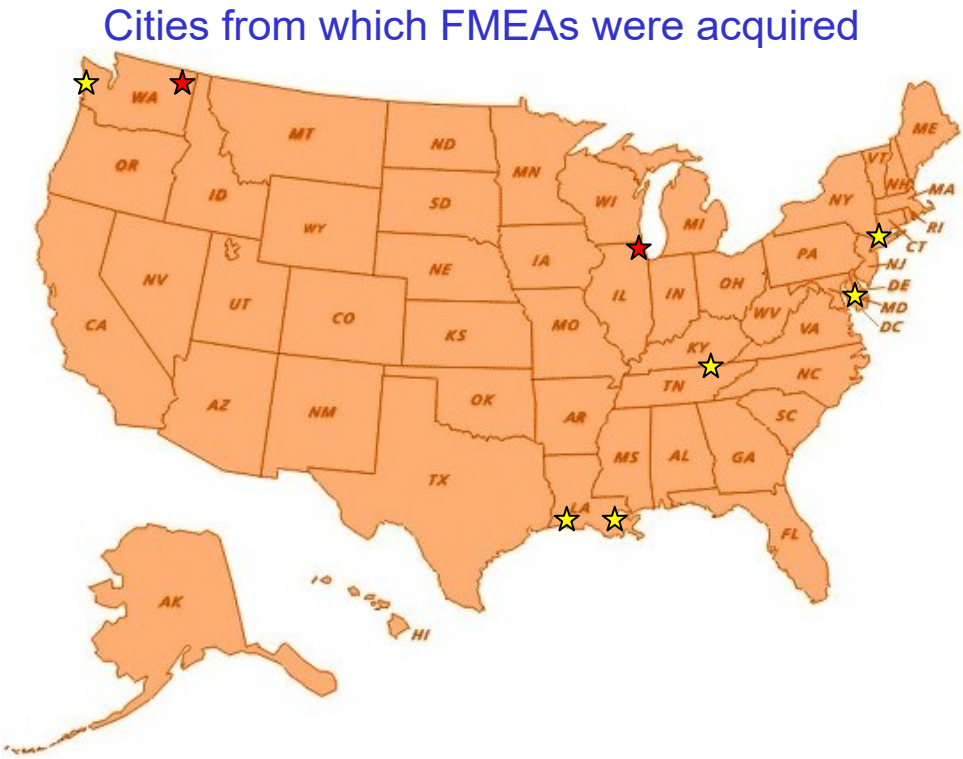
E. RESULTS

E.1. Sample of Risk Assessment Collected and Analyzed

Sixteen risk assessments were collected from different institutions across the United States. The topics of the collected risk assessments included:

- Blood Transfusion
- Standardizing Pediatric Crash Carts
- Specimen Labeling
- Patient Identification
- Emergency Department Patient Flow
- Digital Imaging – Sending

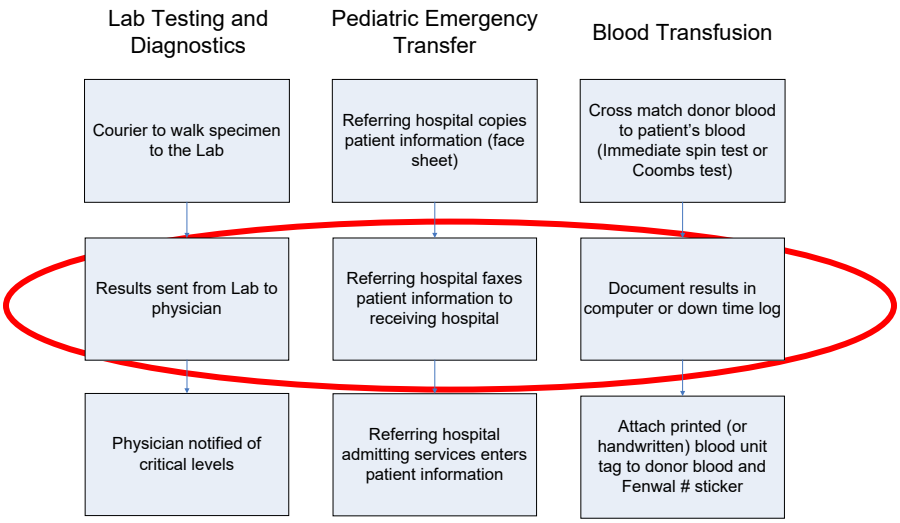
- Digital Imaging - Receiving
- Pediatric Emergency Transport



E.2. Findings

Across these risk assessments, over 400 fail-points are described. Of these, 296 had a risk priority number designating them as medium to high risk. Several of the collected FMEA risks results were conducted on the same process (e.g., pediatric emergency transfers). Many FMEA risk results were from analysis conducted on different processes. Nevertheless, many process steps and failure modes were the same even for FMEA risk results conducted on different topics (e.g., sending information to another department, patient identification, ordering, test labeling, etc.).

Figure 2. Grouping Process steps across different FMEA Topics



The LEARN team reviewed several FMEAs related to institutional transfers. Based on the initial analysis, common high-risk aspects of institutional transfers included:

1. Lack of standards and inconsistent formats for clinical communication of necessary clinical information
2. Problems with assessment
3. Clarity of what is needed for the patient
4. Frequent information loss communicating across a complex set of procedures due to:
    - Informality of verbal communication
    - Staff workload issues
    - Frequent interruptions
    - Number of hand-offs
    - Information lost or left behind
    - Fax failures

Meta-analysis of medium and high fail points identified several generic underlying systemic issues that lead to harmful errors and patient safety risk with relative frequency. Examples of prominent generic risks included:

- Unreliable hand-off of clinical information regardless of the process or context
- Missing information
- Unreliable information transfer systems
- Lack of mechanisms of systems for verification of task completion or the stage of completion of clinical tasks
- Lack of feedback systems in medical care systems and processes
- Patient, procedure, specimen medication identification and matching.

The quality of collected risk assessments revealed that these assessments did not systematically assess the possibility of both omission and comission events in most assessments.

E.3. Principles for Improving the Quality of FMEA Studies

1. **Scope**: Develop and document scope statement prior to start of analysis
2. **Documentation of FMEA process**: Develop a scope statement, process walk down, criteria for frequency and outcome assessment, constraints, comments, etc.
3. **Event Definition**: Make one failure mode and one failure cause a single entry
4. **Completeness**: Include complete set of failure modes (e.g., error of commission and omission)
5. **Identification of Events**: Develop and use an identification scheme to give each event unique identifier
6. **Negative Accounting**: Make entries for low- and non-risk items in process to help track team decisions and eliminate issues already addressed
7. **Comments/Assumptions**: Freely include comments and assumptions for entries to capture limitations, identify future changes, and pass nuances on to the next team
8. **Safeguards/Recommendations**: Capture potential additional safeguards or recommendations for additional study, analysis, data, etc.

E.4. Conclusions

The LEARN Meta-analysis of Risk Results methods have many potential uses and can be applied in multiple and varied contexts as an informative tool for assessing generic risks and risk contributors in medical care. These methods can be applied directly as suggested here to research the generic risks and risk contributors for a particular population of patients or for a particular type of medical care, such as emergency medical care or cancer treatment.

The results will provide the generic risks, high frequency/high harm, to address and inform whether these issues are cross institutional or are resulting from a particular feature in the organization of care or an institutional artifact at one institution.

> **There is a clear utility for application of this LEARN Meta-analysis of Risk Assessments method for patient safety research and improvement and for organizations that collect safety events and risk assessments, such as State Event Reporting Systems, Patient Safety Organizations (PSOs), safety improvement collaboratives, and healthcare regulatory bodies such as The Joint Commission.**

Also, multi-institutional healthcare organizations may benefit from the availability of such methods. These LEARN Meta-analysis of Risk Assessments methods can be applied to the risk assessment information grouped across the institutions within a network and can be used to inform broader corporate patient safety needs and goals.

Hospital Associations or Patient Safety Organizations could bring together institutions interested in improving the safety of a specific high-risk area of medicine and can drill down on the specific risks and risk contributors and, through the development of cross-association or PSO representative cases, develop safety interventions that could then be tested and supported (if testing proves them effective) through Learning Collaboratives for their members.

Finally, these methods could be used by oversight or regulatory bodies to provide a national overview of generic risks and risk contributors and incrementally move the entire system of medical care to a higher and safer standard, which may in time approximate the level of safety success the DOE has achieved in the nuclear power industry.

E. List of Publications and Products

Woods DM, Holl JL Young J, Wears R, Schwalenstocker E, Reynolds S, Barnathan J, Amsden L. Leveraging Existing Assessments of Risk Now (LEARN) Safety Analysis: A Method for Improving Patient Safety. *AHRQ Advances in Patient Safety: New Directions and Alternative Approaches*, 2008.

Young J, Woods DM, Holl JL, Wears R, Reynolds S, Schwalenstocker E, Ross O, Torricelli A. *PSAM* 2008, May 2008 Hong Kong. Adaptation of US Department of Energy Method of Design Basis Accident Selection to a Study of the Risks to Patients in Pediatric Emergency Medical Care.

A LEARN web toolkit was available at (http://www.feinberg.northwestern.edu/ihs/program-centers/cps/pediatricpatientsafety.html). The toolkit included an overview of the project, information on the LEARN Team, a detailed description of the various analytic methods used to review risk assessments and determine commons elements, background information on risk assessments and the LEARN methodology, as well as important links, tools, and access to papers and publications.

A complete recording of the LEARN Webinar was available on the NACHRI website at http://www.childrenshospitals.net/AM/Template.cfm?Section=Quality2&CONTENTID=40211&TEMPLATE=/CM/ContentDisplay.cfm). Webinar content included an overview of the LEARN project, background on risk assessments and FMEAs in particular, and a description of the LEARN Meta-analysis of Risk Results methodology.

11th Annual National Patient Safety Foundation Patient Safety Congress, May 20-22, 2009, Washington, DC. LEARN (Leveraging Existing Assessment of Risks Now) A Meta-Analysis of Risk Results. Woods DM, Holl JL Young J, Wears R, Reynolds S, Schwalenstocker E, Ross O, Torricelli A.

11th Annual National Patient Safety Foundation Patient Safety Congress, May 20-22, 2009, Washington, DC. Meta-Assessment of Health Care Failure Mode and Effects Analysis Quality. Sullivan R, Woods DM, Holl JL Wears R, Reynolds S, Schwalenstocker E, Ross O, Torricelli A, Young J.

2009 AcademyHealth Annual Research Meeting, June 27–30, 2009, Chicago, IL. Leveraging Existing Assessments of Risk Now (LEARN) for Patient Safety: A Meta-Analysis of Risk Results. Woods DM, Holl JL Young J, Wears R, Reynolds S, Schwalenstocker E, Ross O, Torricelli AA.

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