Risk Assessment of Pediatric Emergency Transfers
Final Report

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A. STRUCTURED ABSTRACT

Purpose: The goal of this project was to identify and address risks in the emergency transfer of pediatric patients between hospitals.
Scope: Six hospitals with comprehensive pediatric services comprising the *Pediatric Patient Safety Consortium* ("Consortium") each selected a specific emergency transfer process to evaluate.
Methods: Risks were assessed using a prospective risk analysis method, Failure Mode Effects and Criticality Analysis (FMECA). FMECA teams included clinicians from each receiving hospital and clinicians from two hospitals that refer pediatric patients (referring hospitals) to the receiving hospital. Initial FMECA sessions focused on the creation of a process map of the selected emergency transfer process. Next, each FMECA team evaluated the identified steps in the process for potential failure modes and causes. Then, the teams determined the frequency, consequence, and safeguards of each failure mode. Results were "binned" or aggregated across participating hospitals into generalizable risk categories. Finally, the results were used to develop a *standardized pediatric emergency transfer form*.
Results: Six FMECAs were conducted and examined the process of transfer from a referring hospital ED to receiving hospitals PICU (3), floor (2), and trauma team (1). Results strongly supported the development and use of a universal, standardized "transfer" form to resolve identified risks. The *Chicago Metropolitan Area Pediatric Transfer Form* was developed and tested at participating hospitals. In addition, the form is currently being integrated into the AHRQ project (R18 HS017912-01).
Key Words: Pediatrics, Emergency Medicine, Patient Safety

B. PURPOSE

The objective of the **Risk Assessment of Pediatric Emergency Transfers** project was to proactively assess the risks during transfers of pediatric patients from referring emergency departments (EDs) to the six Chicago area hospitals with inpatient pediatric services that comprise the *Pediatric Patient Safety Consortium* (receiving hospitals), to condense the results into a single set of risks, and, based on the identified risks, to design a standardized process and toll to be used by all of the EDs and hospitals involved in these transfers. Specifically, the goals of this project were:

Aim 1. To conduct a set of proactive risk assessments, using a Failure Modes Effects and Criticality Analysis (FMECA), of the communication, documentation, and transfer processes of pediatric patients between referring EDs among six hospitals with pediatric in-patient services that comprise the Pediatric Patient Safety Consortium in the Chicago area;

Aim 1.1 To model potential failures related to known child-specific risks in each FMEA;

Aim 2. To condense the results of these FMECAS into a single set of specific communication, documentation, coordination, and systemic risk factors in emergency transfer of pediatric patients between referring EDs and hospitals with inpatient pediatric services;

Aim 2.1 To examine the potential impacts of the fact that different organizations performed the analyses with different data, participants, and scope by the application of a *risk binning* approach to the six FMECAs;

Aim 3. To create a standardized process and tools to address communication, documentation, and coordination during transfers of pediatric patients between referring EDs and hospitals with pediatric in-patient services; and

Aim 4. To field test and refine using a PDSA methodology the standardized process and tools at the Consortium hospitals and referring EDs.

Aim 5. To develop and disseminate a *Toolkit* to a sample of EDs and the hospitals receiving in-patient pediatric referrals and to elicit feedback about generalizability and potential for implementation.

C. SCOPE

C.1. Background

C.1.1. Research on ED transfers

In a 2004 report by Beckman, a review of 191 reported inter-hospital transport incidents revealed that communication problems, inadequate protocols, and inadequate training and equipment were prominent. Errors of problem recognition and judgment, failure to follow protocols, inadequate patient preparation, and haste and inattention were common. Serious adverse outcomes occurred in 55 reports (31%), including major physiological derangement (15%), patient/relative dissatisfaction (7%), prolonged hospital stay (4%), physical/ psychological injury (3%), and death (2%). Of the contributing factors identified, 46% were system based and 54% human based. Seventy-five reports (39%) identified equipment problems relating to battery/power supply, transport ventilator and monitor function, access to patient elevators and intubation equipment.[1]

In a subsequent audit of 100 adult inter-hospital transfers over 14 months, Ligtenberg et al. found that adverse effects occurred in 34% of transports.[2] The study suggests that “70% of these events could have been prevented by better preparation and communication before transfer.” Based on these results, these researchers’ major concern was the lack of preparation before the transfer of a patient, which they believe can be improved by achieving better communication between referring and receiving hospitals prior to transport, as well as mandating transport personnel to strictly adhere to an established checklist and protocol. The mortality rate of patients who were transferred to the medical intensive care unit from outside hospitals was assessed. Of the 3,347 patients studied, it was found that the overall mortality rate for transfer patients to the medical intensive care unit was 25% (95% confidence interval, 23-26), significantly higher than the 21% (95% confidence interval, 19-22) mortality rate among those admitted directly.

In a study of 1,942 children who were admitted to the same facility via inter-hospital transport, increases in mortality reportedly occurred simultaneously with the implementation of computerized physician order entries (CPOEs), indicating that conflicts introduced by system integration and errors in "human-machine interface" can negatively influence patient safety in the context of pediatric inter-hospital transport.[3]

Although there is no literature that specifically relates to the communication, documentation, and assessments of pediatric transfers between Emergency Departments (EDs) and hospitals with pediatric in-patient services, there is good reason to believe that such transfers are equally, if not more, problematic.

C.1.2. Patient Safety and ED Transfers

Issues such as overcrowding, rushed and chaotic environments, frequent provider interruptions,[4] provider fatigue, and limited information about patient's medical histories impact patient safety in the ED[5,6] and are likely to influence the documentation and communication of clinical information during an ED transfer.

Lack of adequate pediatric medical knowledge and skills is another contributing factor to patient safety risks for pediatric ED patients and, consequently, for documentation and communication during a subsequent ED transfer. Physicians with limited pediatric training or experience are responsible for the majority of patient care in many EDs.[7] In many parts of the country; doctors who staff emergency departments are not residency trained in neither emergency medicine nor pediatric emergency medicine.[8] Such clinicians may assess, evaluate, and treat pediatric patients similar to adult patients because of lack of training and experience, which can lead to unsafe pediatric transfers.[9,10]

C.1.3. Emergency Department Use by Children

Between 1994 and 2004, ED visits increased by 18%, equivalent to an increase of 1.5 million visits. During this period, the number of hospital EDs decreased by about 12.4%.[11] ED use is particularly prevalent in urban areas: though two thirds of all EDs are located in metropolitan statistical areas (MSAs), 86% of annual ED visits occur in these hospitals.

Approximately 22.9 million ED visits were for children less than 15 years old, of which 3.9 million were for children less than a year of age. The IOM Report, *Emergency Care for Children* estimates that 30% of all ED visits are made by children Estimates for the IOM report show that, in 2002, approximately 1% children seen in the ED were transferred from an ED to another hospital. Assuming that 1% of pediatric ED patients are transferred, an estimated 290,000 children less than 15 years old were transferred from an ED in 2004.

About 7% of pediatric ED visits are made to a children's hospital, the most specialized centers of care for children in the United States.[12] Some general hospitals have a separate pediatric ED. Estimates generated for the IOM report suggests that only 18% of pediatric ED visits are to Children's Hospitals or to pediatric EDs in general hospitals.[7] The majority of pediatric ED visits are made to hospitals that treat children and adults in the same department, are unlikely to have a pediatric emergency medicine physician on staff, and may lack basic pediatric equipment and skills.[8,13] An estimated 19% to 26% of pediatric ED visits are to hospitals in non-urban areas,[7] yet most lack around-the-clock physician coverage, have few pediatric patients, and lack a pediatric in-patient service.[8] However, only half of hospitals with EDs but no impatient pediatric services have written transfer agreements with other hospitals.[9]

The creation of the federal Emergency Medical Services for Children (EMS-C) Program in 1984 has contributed significantly to improvements in emergency medicine care for children through a multitude of EMS-C protocols, training courses, guidelines, and procedures. More recently, the Pediatric Emergency Applied Research Network (PECARN) has been developed to promote research into the prevention and management of acute illnesses and injuries in children and youth. Research about the processes and systems involved in the transfer of pediatric patients has not yet been comprehensively addressed.

C.1.4. Clinician to Clinician Communication

There has been an increasing recognition of the importance of effective communication in healthcare[14] and one paper stated that "Most common patient/staff management issues identified were communication and liaison issues…"[15] In addition, communication was identified as a contributing factor in nearly 70% of sentinel events reported to The Joint Commission, of which many involved breakdowns in communication between clinicians.[16]

Hand-offs and transitions (e.g., change of shift, transfers, and discharges) require effective transfer of information.[17]

In the US, the cost of medical errors has been estimated at $29 billion.[18] Many of these costs are associated with communication problems leading to additional hospital admissions and re-admissions, increased length of stay, treatment of morbidities from delays in treatments, inappropriate use of drugs, and duplication of treatment.

Clinical communications between clinicians (e.g., treatment order, critical result report, transfer instruction, etc.) are a major part of providing healthcare. Given that many of these communications are critical, the reliability of such communications is essential to safe, high-quality healthcare. There has been little attention paid to the reliability of clinical communications between clinicians in medicine. Most communication work in healthcare has focused on communications between the clinician and the patient. The effectiveness of communications between clinicians in medicine has, perhaps, been taken for granted because clinicians are assumed, as highly trained, skilled individuals, to communicate effectively. The evaluation of communication systems (e.g., ways of communicating, processes for communicating) to ensure the effectiveness and reliability of clinician to clinician communication are only just beginning to be studied, developed, and implemented.

C.2. Context

C.2.1. Transition of Care or Patient Transfer Communications

Following the publication of the Institute of Medicine's report "To Err Is Human" and the recognition of the magnitude of patient safety risk, it has become increasingly obvious that communications between clinicians during transitions of care (e.g., nurse shift changes, attending MD change of service, transfer of a patient from one unit to another), assessments of a patient's status (e.g., communication among the members of a care team), and delivery of medical care (e.g., ordering a test or medication,) involve substantial patient safety risk.

One categorization of communication looks to the underlying source of the error, with an eye toward prevention[19]:

System failures, in which communication channels are used infrequently, are non-functional or non-existent.

- **Corrected by improving use of existing systems or creating new systems.**
- These are both common and preventable failures.
- Represent opportunities to use information technologies to improve communication channels using electronic communications and the electronic medical record.

Message failure in which there is poor or non-existent transfer of information.

- **Corrected by improving and standardizing methods of transfer**
- Requires a framework for shared understanding
- Requires deliberate practice

Reception failure in which there is misinterpretation or late arrival of proper information.

- Corrected by improving the receiving skills of practitioners
- **Creation of shared understanding leads to common goals and expectations for the prompt and precise delivery of information**

The transfer of patient care responsibilities (handoff or transition) is a particularly important point in care and has been characterized as both an opportunity for rescue and a threat to safety.[20,21] Omissions to the content of the communication or poorly standardized communication practices may lead to uncertainty in patient care after transition.[22] A recent report showed that 100% of postoperative patient handoffs in a pediatric ICU contained at least one miscommunication, with a median of five errors per patients.[23,9]

Patient transfers, such as those between an ED and an inpatient service at another hospital involve two or more individuals working within several different systems. The Joint Commission has responded to the risk of error at patient handoff by endorsing a requirement for healthcare organizations to "implement a standardized approach to "handoff" communications, including an opportunity to ask and respond to questions" in their 2006 guidelines.[10,24] However, there is little research conducted in healthcare setting that provides what a handoff is, how to perform it, and how to teach it.[25,11,12]

C.2.2. Proactive Risk Assessment:

C.2.2.1. Failure Modes Effects Analysis (FMEA)

There are a wide variety of approaches to risk assessment in high-risk industries. These approaches vary in complexity and level of analytical effort in relation to the complexity of the systems being analyzed, the perceived level of risk, and the current reliability of the systems. In situations when failure events are likely to occur, 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.[26]

The FMEA is a widely used engineering quality method that helps to identify and counter weak points in the early conception phase of products and processes. Significantly, FMEA can be implemented as a combination of both prospective and retrospective analysis. Effective FMEA applications in high-risk industries are based on the discipline and comprehensiveness of the FMEA method with inclusion of what has happened along with what might happen.

With respect to healthcare, by considering the unique environment, patient population, and capabilities and limitations of the individual healthcare organization, FMEAs can generate new, useful, and important information to support improving patient safety that cannot be obtained solely by implementing standard industry recommendations in an organization.[27] Recognizing that any change in a process or system, including an evidence-based safety intervention, may introduce unintended and unanticipated consequences, using the FMEA method in an iterative manner is a valuable tool for proactively identifying and managing these risks to ensure optimal benefit from the intervention.

The Joint Commission requires that all hospitals seeking accreditation conduct at least one FMEA each year, to prospectively identify and address risks that may exist in their institutions.[28] However, the process of conducting a thorough FMEA is both time and resource intensive.

C.2.2.2. Failure Modes Effects and Criticality Analysis (FMECA)

The Failure Mode Effects and Criticality Analysis (FMECA) is one of several hazards analysis techniques used in high-risk industries and can be implemented as both a retrospective and a prospective analytic method that (1) predicts how and where processes may fail and result in significant detrimental consequences and (2) constructs strategies to prevent those failures or to protect against or to mitigate their effects if they occur. A key advantage of the FMECA method is that it helps to counter the common temptation of most organizations to focus on solutions for the most evident and visible weaknesses of a process or system. On the other hand, it will also identify those breakdowns in a process that management commonly assumes are problematic but actually are low risk contributors (e.g., failure to present confirmation slip to the blood laboratory). The FMECA method can be used in an iterative manner to support re-design of processes to insure the effectiveness of the intervention(s) and to assess the impact of their implementation.

In general, the FMECAs were found to be an excellent way to identify potential medical process weaknesses leading to high patient risk. Based on this identification, along with cost and other administrative considerations, medical process improvements were devised. The following selection priorities were found to be useful: (1) improvements that help prevent the failure mode are better than those that mitigate the consequences; (2) improvements which most directly address the failure mode are favored; (3) simple improvements are better than complex ones if they do the job; (4) passive features that prevent failures are better than administrative controls; and (5) improvements with the highest reliability are favored.

C.3. Setting

The Chicago *Pediatric Patient Safety Consortium* ("*Consortium*") consists of six diverse hospitals with pediatric inpatient services in the Chicago metropolitan area: Advocate Lutheran General Children's Hospital, Advocate Christ Hope Children's Hospital, Children's Memorial Hospital, John H. Stroger Jr. Hospital of Cook County, Mount Sinai Hospital, and Loyola Ronald McDonald Children's Hospital. In order to reduce institutional bias and identify generalizable process risks, we worked with all six *Consortium* sites. Across the *Consortium* institutions, 50,000 pediatric patients are admitted each year.

The benefits of working with the *Consortium* are multifold. These institutions represent a wide variety of healthcare settings, including teaching hospitals, community hospitals, freestanding children's hospitals, urban hospitals, and suburban hospitals. This range of facility characteristics allows for generalizablity of group findings. Additionally, by aggregating results, each institution's confidentiality is protected.

All participants involved in the FMECAs were knowledgeable about the issues related to transfer/transport of pediatric patients. In total, 18 institutions participated. The receiving and referring hospitals who participated in this project represent a large percentage of the emergency services available to children in the local community of metropolitan Chicago. Participating hospitals are shown in Table 1.

Table 1. Participating Hospitals

FMECA	Consortium (Receiving) Hospitals:	Referring Hospitals:
A	Advocate Christ Hope Children's Hospital	Advocate Trinity Hospital St. James Olympia Fields
B	Advocate Lutheran General Hospital	Northern Illinois Medical Center (NIMC) Northwest Community Hospital
C	Children's Memorial Hospital	Our Lady of Resurrection West Suburban Hospital
D	John H. Stroger Jr. Hospital of Cook County	Provident Hospital St. Anthony's Hospital
E	Loyola University Ronald McDonald Children's Hospital	Elmhurst Memorial Gottlieb Memorial Hospital
F	Mt. Sinai Children's Hospital	South Shore Hospital St. Bernard Hospital

C.4. Participants

Each *Consortium* receiving hospital selected an internal team of clinicians involved in the pediatric emergency transfer process. Each Consortium receiving hospital then identified two hospitals that refer pediatric patients to their hospital (referring hospitals). The Northwestern University research team then contacted each referring hospital with a request to participate in the FMECA project. Referring hospitals were asked to select two to four participants involved the emergency transfer process who would be available participate in the project. Receiving and referring institutions were encouraged to select representatives from various units/departments and disciplines (e.g., ED charge nurse, PICU attending, transport team director).

D. METHODS

D.1. Study Design

D.1.1. Target Patient Population Involved in Pediatric Emergency Transfers

As of 2004, there were 215,290 children under the age of 5 years and 236,481 children between the ages of 5 and 18 years in Chicago. In 2005, over 3,500 children were transported to the six hospitals participating in the *Pediatric Patient Safety Consortium* as shown in Table 2. These hospitals represent only a portion of healthcare facilities involved in transports of pediatric patients in the greater Chicago area.

Table 2. Number of Transported Pediatric Patients by Consortium Hospital

Consortium Hospital	Number of transported pediatric patients	
	To	From
John H. Stroger-Cook County	330	-
Sinai Children's	354	50
Loyola Medical Center		
Lutheran General Children's	396	59
Hope Children's	1271	87
Children's Memorial	1263	126

D.1.2. Organization of the Research Project

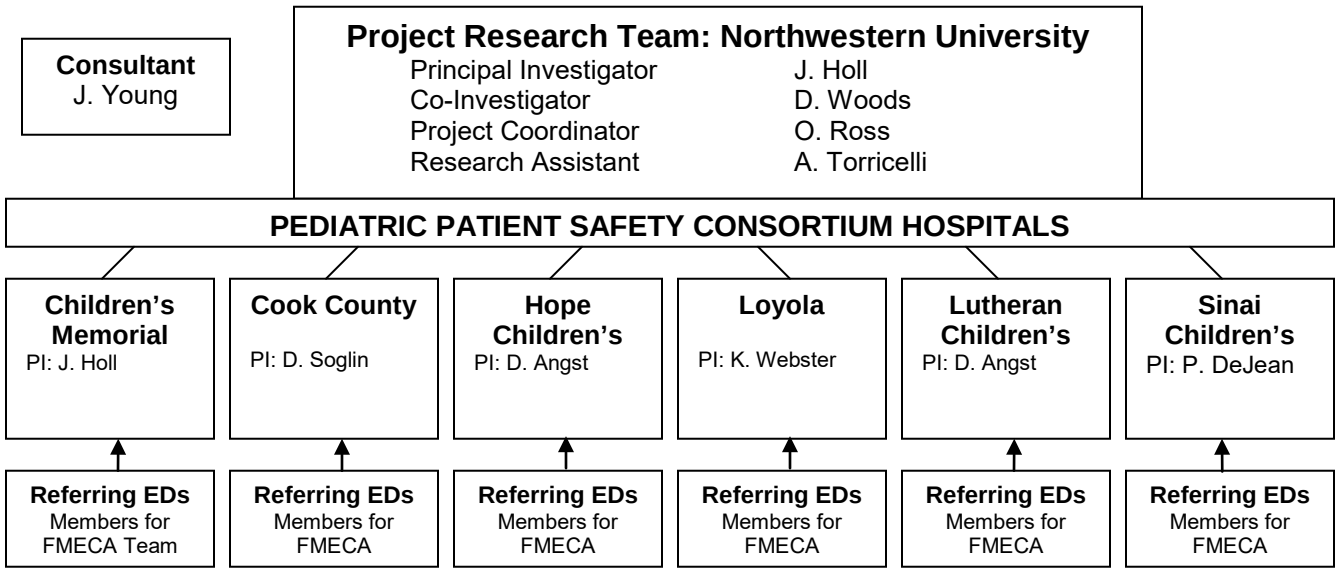
As shown in the Organizational Chart in Figure 1, the research project was lead by the Principal Investigator (PI) in collaboration with the Co-Investigators (Co-Inv), Project Coordinator (P. Co.), and Research Assistant (RA) at the Northwestern Center for Patient Safety at the Institute for Healthcare Studies, Northwestern University, Chicago, IL. Each of the six *Consortium* Hospitals has a *Consortium* Principal Investigator (Site PI) and, at some hospitals, a Co-Investigator (Site Co-Inv) and Research Assistant (Site RA).

As in past projects, the entire Project Research Team continued to have multiple half-day, in-person meetings. Additional in-person meetings were held as needed. A 60-minute conference call was held every other week to discuss project progress.

Each *Consortium* site identified two or three EDs that regularly refer patients to their *Consortium* hospital. Two clinicians from each of these EDs who are involved in and most knowledgeable about the transfer process were invited to participate in the FMECA sessions.

Mr. Jonathan Young served as a Consultant on the risk binning and aggregation of results through a series of conference calls and by electronic transmission of documents for his review.

Figure 1. Organizational Chart



D.2. Aim 1: Conduct the FMECAs

D.2.1. Creation of the Six FMECA Teams

The Principal Investigator from each of the six *Consortium* institutions identified clinicians and staff who are involved in and knowledgeable about the issues related to the transfer/transport of pediatric patients (e.g., ED charge nurse, PICU attending, transport team director) to participate as representatives for their institutions in the FMECA sessions.

Each Site PI reviewed their institution's data about pediatric transfers from referring EDs and identified the two to three referring Emergency Departments that routinely transfer pediatric patients to their institution. The Site PIs identified key clinicians and staff involved in and knowledgeable about the transfer of pediatric patients from these referring EDs. These clinicians and staff were invited to participate in the FMECA.

The NU team coordinated the FMEA sessions, including obtaining IRB approval at each of the participating sites and then bringing together the representatives from the referring and receiving institutions. Meetings were held at the receiving institutions and referring hospital participants were provided with a small stipend for their time. Facilitating interaction between the key players in the selected process from across disciplines and/or institutions was an integral part of the FMECA.

D.2.1.1. Application of the FMECA Process

Each *Consortium* site FMECA team followed the steps below which shows the *Phases* of the FMECA method, specifies the phase in which each FMECA step(s) occurs, and identifies the key outcome measures.

FMECA Step 1: Differentiate and define the boundaries of the transfer process

This step was accomplished by the Project and Site PIs. They delineated and defined the operating environments within the *Consortium* institutions to be evaluated. The selection was guided by the following key questions: 1) where to bind the process, 2) whether to assess every type of patient associated with the process, and 3) whether to assess the process separately or collectively for each department/service/unit/ward.

In addition, the Project team conducted a review of all patient safety websites, technical reports, and publications (e.g., Joint Commission, National Patient Safety Foundation, AHRQ, National Quality Forum) and listservs (e.g., IHI, NACHRI, CHCA) for data and reports related to patient transfer in general and, more specifically, pediatric patient transfer from Emergency Departments to a high level of care.

FMECA Step 2: "Walk down" of the process

The FMECA team "walked down" the entire process of transfer of an ED pediatric patient to another institution. This included gathering all information about the steps that a healthcare team go through when arranging a transfer, such as documents that need to be completed, faxed, or transferred; procedures and policies that are followed; and communications held between clinicians and staff both within the ED and with the hospital to which the patient is being transferred. Through this process, each FMECA team created a process map of their selected transfer process.

FMECA Step 3

The FMECA teams met for two to three sessions lasting approximately 3 hours each. About five to eight participants attended each session. The Site PI at each institution attended most sessions. The Project PI (Dr. Holl), Co-Investigator (Dr. Woods), or Project Coordinator (Olivia Ross) attended the sessions at each FMECA. Additionally, the FMECA sessions were audiotaped. The Research Assistant utilized the recording, when necessary, to assist in the completion of the FMECA worksheets.

Conducting the FMECA in each *Consortium* institution had two important benefits for the institutions: (1) accomplishment of The Joint Commission's PI.3.20, which requires healthcare institutions to perform one prospective risk assessment every year on one high-risk healthcare process, and (2) improved organizational attitudes toward patient safety. A key goal is to model the FMECA as an organizational process rather than just apply FMECA as a research tool.

FMECA Steps 5 and 6

The final steps of identifying patient risks, frequency, and consequence measures were accomplished by the each FMECA teams.

D.2.2. Aim 1.1. Adaptation of the FMECA Process to Address Child Specific Factors

Drs. Woods and Holl adapted the FMECA process to address the identified child specific factors that contribute to patient safety risk for children. Mr. Young provided consultation about the practical integration of these factors when assessing each step of the FMECA, such as the creation and inclusion of a score for these factors in Table 4.

Though pediatric medical and surgical care has adapted many practices and processes in order to address these differences, understanding the nature and the extent to which such child-specific factors affect the safety of pediatric medical and surgical care processes remains unaddressed. Child-specific factors have been shown to contribute risks to patient safety in children's medical care. These child-specific factors include:

- Physical characteristics: small size and weight, morphology, variation in size, weight, and form of children
- Developmental: physiological development and growth, and cognitive social emotional development
- Minor/legal status: decision-making, consent, parental responsibility for medical management, variable confidentiality laws, and supervision requirements.

D.2.3. Data Sources and Collection

Standardized worksheets were developed for use by each FMECA team. Table 3 is an example of the worksheet. For each medical process step, different failure modes were postulated and recorded. For each failure mode identified, the cause (e.g., human factor, equipment failure) was assessed. The frequency of each failure mode was estimated as well as the consequence of each failure mode. The effectiveness of existing safeguard(s) (if any) to prevent the failure mode(s) were recorded. Frequency, consequence, and safeguard effectiveness estimations will be made by selecting the appropriate corresponding categories. The categories will define a range of frequency, consequence and effectiveness of the safeguards, as shown in Tables 4, 5, and 6.

Table 3. Example of a FMECA Worksheet

Step ID	Process Steps	Failure Mode	Failure Mode Causes	Frequency Score	Conse-quence	Consq. Score	Safe-guard	Safe-guard Score	Risk/ Bin
SOURDOUGH									
Example: Making Toast									
EX 1	*Slice bread*								
1a	*Find bread knife*	*Can't find knife*	*Knife not in cutting block*	*F2*	*Delay in making toast*	*C2*	*Use butter knife to cut bread*	*S3*	
1b	*Use cutting board*	*Cutting board is dirty*	*Used previously*	*F3*	*Bread gets dirty*	*C3*	*Wash cutting board after use*	*S2*	

Table 4. Frequency of the Failure Mode 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)

Table 5. Consequence of the Failure Mode Categories

Category	Consequence	Description
C0	None	No impact on the chance of failure mode
C1	Little	Little impact on the chance of failure mode
C2	Some	Some impact on the chance of failure mode
C3	Significant	Significant impact on the chance of failure mode
C4	Certain	Almost certain chance of failure mode

Table 6. Safeguard Effectiveness Categories

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

The combination of frequency, consequence, and safeguard effectiveness categories was used to calculate a level of patient risk that was defined as High, Medium, or Low. The patient risk level for a failure mode was evaluated based on the Safeguard Effectiveness Category.

For example, Table 7 illustrates the risk categories for Safeguard Effectiveness Category S3. Category S3 is for cases in which the safeguard was standard professional practice but was not a formal procedure or check (e.g., noncompulsory but routine checks of patient charts).

Table 7. Risk Matrix for Safeguard Category S3

Safeguard Effectiveness Category S3					
FREQUENCY	**CONSEQUENCES**				
	C0	C1	C2	C3	C4
F1	Low	Low	Low	Medium	Medium
F2	Low	Low	Medium	Medium	High
F3	Low	Medium	Medium	High	High
F4	Low	Medium	High	High	High

Example 1: If the frequency category is Frequent (F4), the consequence is Significant (C4), and the safeguard effectiveness is Standard Practice (S3), and the resulting risk to the patient is considered to be high.

The chart for Safeguard Effectiveness Category S1 has more frequency/consequence combinations that lead directly to high risk, because the failure mode is undetectable, and no safeguard exists. For Safeguard Effectiveness Category S5 the opposite is true. More frequency/consequence combinations lead to low and medium risks, because there are formal safeguards and applicable procedures in place. Failure modes classified as high risk will be identified for additional review.

D.3. Aim 2: Condense Risks from the Six FMECAs

The use of a similarly defined and bounded process for the FMECA at each *Consortium* site; the use of similar steps in the FMECA process; and similar definitions of frequency, consequence, and safeguard type reduced some of the artifacts related to differences in the risk assessment process between sites.

The research team reviewed the risks identified at each institution and compared them across the institutions. The review was accomplished through a qualitative comparison of the results of the six FMECAs including the studied steps and the frequency and consequence assessments in relation to the institution's particular characteristics.

D.4. Interventions

D.4.1. Aim 3: Creation of Standardized Process for Patient Transfer

The aggregate results of FMECAs strongly suggested the need for a single standardized pediatric emergency transfer form to be used by both referring and receiving hospitals. Identified "medium" and "high" risk process fail points were related to lack of knowledge of necessary clinical information by the referring hospital, lack of clear communication of necessary clinical information by the receiving hospital, problems with receiving laboratory or imaging results from the referring hospital, and multiple calls to multiple receiving hospitals.

D.4.1.1. Review of Existing Transfer Forms

Prior to the creation of a new form, a review of all of the transfer forms currently in use in all 18 (referring and receiving) hospitals was undertaken. The review revealed some consistency in content but little consistency in the layout, format, or order of the elements. The standardized form was initially based on the content in the existing forms, particularly with regard to "legal" language regarding consent to transfer and HIPPA compliance. An initial draft of the standardized transfer form was developed based on the content in these forms and risks identified from the FMECAs.

After the basic template was set, each of the FMECA participants was invited to attend an in-person meeting to review and revise the form with regard to (1) content and (2) order of each element, and (3) lay out the elements. For example, an FMECA identified risk such as issues with delayed receipt of laboratory results was addressed in the standardized tool through the inclusion of a new data element that included the telephone number/pager number of a person/place in the referring hospital ED that would have access to the patient's laboratory data. Through an iterative process involving over 15 representatives from across the participating institutions, a consensus was reached on both the content and order of the standardized template. In addition, Ms. Evelyn Lyons, Manager of the Illinois Emergency Medical Services for Children (EMSC) program, Illinois Department of Public Health, attended the meeting. Those clinicians who could not attend the in-person meetings were invited to send their feedback via email. The tool has been further refined through feedback from clinicians at the various institutions via email and telephone.

The first version of the form was developed to be used as a paper form. The form could be printed, and the blank template could be filled in by hand. This type of form is ideal for hospitals with limited technical capacity. A number of the participating referring hospitals do not have computer access in their Emergency Departments. However, many clinicians expressed an interest in having the form as a "fillable" electronic PDF that could be completed on a computer and then, either stored electronically or printed. This form had the added advantage of being able to create "drop down" boxes of categories of responses.

The tool was reviewed by risk management and was field tested by clinicians from participating institutions.

D.4.2. Aim 4: Field Testing of Newly Designed Process and Tools

For the field test, clinicians at three hospitals used the *Chicago Metropolitan Area Pediatric Transport Form* in addition to any emergency transfer documentation required by their current institutional protocol. Clinicians evaluated the clinical accuracy and effectiveness of the form to capture the necessary transfer information and assessed the efficiency of the process that involved use of the form. Debriefing telephone calls were held with the clinicians from each institution who participated in the pilot test to receive feedback about the form. Final adjustments and revisions were made. Minor issues were detected and corrected during the field testing phase.

D.5. Limitations

IRB approval and difficulties with scheduling delayed the progress of the project at some sites and thus postponed overall analyses.

The risk management team from three participating receiving hospitals reviewed the standardized transfer tool and provided specific feedback. Incorporating their recommendations into the current version of the standardized transfer tool delayed the pilot testing and implementation timeline.

E. RESULTS

E.1. Principal Findings

The "medium" and "high" risks identified in the aggregate FMECA bin analysis were:

- Lack of standardization of information deemed necessary to be communicated for a pediatric emergency transfer across the participating hospitals.
  - Each receiving hospital had its own "Transport Form" that serves primarily as the documentation by the transport team during the transfer of the patient.
  - None of the referring hospitals had ever received a copy of the "Transport Forms."
  - The receiving hospitals' physician and bedside nurse do not, typically, use a standardized tool for documenting the "hand-off" received from the referring hospitals' ED physician or bedside nurse.
  - Some of the receiving hospitals have a form used by the receiving physician to document demographic information about the patient and minimal medical information.
  - Significant delays in transfer occur and inadequate or inaccurate information is transmitted because each receiving hospital currently requests different information about a transfer patient or similar information about a transfer patient but in a different format.
  - Patients may be transferred to the incorrect level of care or the appropriate clinicians may not be available at the receiving hospital.

- Lack of a standard process for the emergency transfer of a pediatric patient across the participating hospitals.
  - Referring hospitals are often obliged to contact more than one receiving hospital at a time to request the transfer.
  - Referring hospitals required more than one call to confirm acceptance by some receiving hospitals of a transfer.
  - Receiving hospitals lack any standardize process for transmitting laboratory or medical imaging results for the transferred patient to the appropriate unit/service of the receiving hospital.
  - Lack of standard process leads to delays in transfer or transfer to the wrong level of care.

- General lack of "feedback" or inadequate "feedback" by the receiving hospitals about the outcome of the transferred patient and about the management of the patient at the referring hospital.
  - At present, several of the receiving hospitals send a letter to the referring hospital, but there is significant delay in receipt of the letter, the feedback is not specific, and the letter is often not delivered to the clinicians who provided care for the patient but rather to a manager who was never involved in the patient's care.
  - No process for feedback that is generalizable to the management of a specific condition or about practices or processes nor is there any process for dissemination of any feedback.
  - Receiving hospitals acknowledged purposefully limiting the content of any feedback about the management of a transferred patient to the referring hospitals due to legal concerns.

- Revealed significant lack of internal knowledge about existing resources, protocols, roles, and responsibilities within each hospital regarding the emergency transfer process.
  - Communication was problematic not only between hospitals but also between units/services within hospitals.
  - Internal processes required in the emergency transfer of a patient were not standardized and were subject to significant variation.

As shown in Table 8, the top 10 failure mode causes of medium and high risk bins (refer to Table 7) include issues regarding training, equipment, resources, communication, access to data, and human factors.

Table 8. Medium and High Risks*: Top 10 Aggregate Failure Mode Causes

Top Ten Failure Mode Causes Summaries: Consortium	**Total**	
Lack of Staff/Training	28	19%
Faulty/Unavailable Equipment or Resources	18	12%
Inadequate Procedure	16	11%
Lack of Communication/Shift Change	15	10%
Lack of data	21	14%
Distracted/busy/human error	18	12%
Cultural Issues	7	5%
Patient Privacy/Insurance Issues	4	3%
Delay in treatment or patient transfer	1	1%
Institution Name Recognition	2	1%
Other	*20*	*15%*
Total number of Failure Mode Causes	*150*	*100%*

**"Medium" and "High" Risk Categories only.*

For example, we believe that the identified lack of training is, however, related to the lack of any standardized process/procedure or tool for staff to use during emergency transfers. Such a tool could be used be part of an orientation or training. With regard to faulty/unavailable equipment or resources, these failures were related to communication devices such as pagers used by the transport team, difficulty getting copies of the transfer patient's record or results. Issues such as inadequate procedure, lack of communication, lack of data are all self-explanatory. Issues related to distraction and task saturation could be mitigated by a more efficient and complete process.

E.2. Key Outcomes

E.2.1. Standardized Transfer Form: Chicago Metropolitan Area Pediatric Transport Form

The key findings identified "medium" and "high" risks were the focus of the design process of a standardized tool. Using the transport forms of all 18 participating institutions as the basis for initial draft, information gained from the iterative FMECA method and the subsequent binned risks was then used to augment the data elements of the initial draft form. Participants requested that the form meet all of the requirements of each of their institutions, specifically with regard to "consent" to transfer and HIPPA regulations. Participants wanted the form to integrate all information that receiving hospital transport teams typically request about a transfer patient.

The initial draft form was reviewed during two in-person meetings with FMECA participants from all of the participating hospitals (both referring and receiving hospitals). The FMECA team designated the form as the *Chicago Metropolitan Area Pediatric Transport Form.* It was agreed by all study participants that the purpose of the form was to be a tool to *achieve standardized communication, assessment, and documentation of clinical information that is critical during the emergency transfer of pediatric patients.*

For the pilot test, three hospital sites used the *Chicago Metropolitan Area Pediatric Transport Form* in addition to the emergency transfer documentation required by their current institutional protocol. Clinicians evaluated the clinical accuracy and effectiveness of the form to accurately capture the necessary transfer information and qualitatively assessed the efficiency of the transfer process using the standardized form. Debriefing calls were held with the clinicians from each institution who participated in the pilot test to receive feedback about the form. Final adjustments and revisions will be made based the minor issues discovered in this pilot phase.

- Creation of a *standardized pediatric emergency transfer form* was overwhelmingly supported by all study participants.
- Creation of the form will lead to a more standardized process because all of the key steps in the transfer process are represented on the form.

E.2.2. Standardized Process

Though a standardized process is not possible, the use of a standardized tool that includes documentation of a series of standardized steps in the transfer process should reduce variation in the transfer process. It should be noted that receiving hospitals benefited from participation in this project because of the opportunity for exchange of information between hospitals. For example, all referring hospitals clearly indicated the desire for a "one-call" process. This process involves the referring hospital having to make a single call to gain acceptance for a transfer of a patient. Only one receiving hospital was able to consistently offer this service. However, the other institutions recognized the need to expedite the "acceptance" process and had begun work on streamlining the process.

E.2.3. Process for Feedback

Study participants have begun to develop a process for the exchange of feedback information about the outcome of the transferred patient as well as about the management of transferred patients. It was agreed upon that the process will require that an ED clinician, responsible for quality and safety at the referring hospital ED, to be designated at the point of contact. All feedback information would be directed to this designated clinician. This clinician would also be responsible for dissemination of feedback to the referring hospitals' ED clinicians. Receiving hospitals were more comfortable with comments being aggregated, de-identified, and disseminated to clinicians involved in pediatric emergency transfers at a referring hospital by a member of the hospital's staff.

The FMECA participants suggested that a forum for the review of pediatric ED transfer cases regarding the quality and safety of care would be an excellent next step. The FMECA participants would like for the forum to include all hospitals in the entire Chicago region and for it to be a virtual forum with meetings taking place via web-conferencing. Initial impressions by the FMECA participants suggested that the forum should be held four to six times a year.

E.2.4. Benefit of Participation in FMECA

Each participating hospital directly benefited from participation in the FMECA through the revelation of emergency transfer risks within their own institution, identification of other processes or systems that could be remedied, and the general need for clarification of clinicians' roles and responsibilities. A key goal of the project was for the study participants to gain knowledge and skills in the actual conduct of an FMECA.

Several of the participants have already identified topics for which they intend to conduct an FMECA at their hospital, as a result of the knowledge and skills gained and through recognition of the value of the prospective risk assessment process to effectively improve safety.

E.3. Discussion

Using the FMECA methodology to assess similar processes across multiple, diverse healthcare settings proved to be a highly effective approach to reaching consensus among a wide range of clinicians, both adult and pediatric, on the risks and then solutions to improving the safety of pediatric emergency transfers. Data from the FMECAs were used to gain support for the development of a standardized tool for use in the process of emergency transfers. Data from the FMECAs were also critical to reaching consensus on the elements to be included in the standardized form. The process maps produced during the FMECA sessions were used to reach consensus on the format and rank order of the elements. The standardization of the elements, in turn, will drive standardization of the steps in the emergency transfer process.

Several outcomes were not anticipated. The “pent-up” desire by referring hospitals to receive more feedback, not only about the transferred patient’s outcome but also about the management of the patient at the referring hospital, was unanticipated by receiving hospital participants. Though receiving hospitals’ clinicians were enthusiastic about providing feedback, they articulated concerns about restrictions placed by their legal respective hospital legal departments on the level of detail that they could provide in any feedback, particularly if the referring hospital was not affiliated with the receiving hospital. Second, the role of the FMECA in revealing internal or ”within” hospital risks with regard to lack of knowledge about protocols and practices, available resources, and roles and responsibilities of both individual clinicians and of the unit/service was unexpected. The identification of these intra-hospital risks was deemed to be useful to the study participants for their hospital and has lead to the investigation of processes and systems beyond the scope of the FMECA. The conduct of the FMECA with inclusion of clinicians from multiple hospitals that engage in the transfer of patients appears to have enhanced communication, and potentially, coordination of care efforts between referring and receiving hospitals. Additional exchanges of information and meetings resulted from participation in the FMECAs. In addition, by including clinicians from multiple units/services (e.g., adult ED, referring hospital ED, receiving hospital pediatric unit and intensive care) and from multiple disciplines (e.g., nursing, transport team staff, floor and intensive care unit physicians) within each hospital, the FMECA also appears to have enhanced communication and coordination of care within each hospital.

E.4. Conclusion

The six FMECAs, involving clinicians from 18 diverse hospitals that provide care for pediatric patients, identified many generalizable risks during pediatric emergency transfers. The project has resulted in the *Chicago Metropolitan Area Pediatric Transport Form*, a standardized form that includes all of the demographic, administrative, and clinical elements that were identified as critical to the safe transfer of pediatric emergency patients by clinicians from 18 Chicago area hospitals that emergently transfer pediatric patients. Because the form was developed through an iterative and consensus reaching process with both adult and pediatric clinicians from academic medical centers, safety net hospitals, and community hospitals, the form is likely to be highly generalizable to other hospitals that emergently transfer pediatric patients across the United States.

Use of the FMECA process to obtain data for a complex healthcare process about the risks, fail points, root causes of the fail points, and the frequency, consequence, and safeguards of the fail points appears to be an effective method for reaching consensus of the re-design of a healthcare process. It should be noted that participation and enthusiasm for the FMECA sessions was extremely high, which suggests that clinicians are willing and supportive of healthcare process improvements when the process is systematically and fully explored through the FMECA process.

The conduct of multiple FMECAs at multiple, diverse hospitals that all execute the same healthcare process, such as the process of the “emergency transfer of pediatric patients,” was effective in producing generalizable solutions that are well supported by clinicians involved in the process.

Although the focus of this FMECA was to improve the safety of inter-facility emergency transfer of pediatric patients, an additional, though unexpected, attribute of this project was the role of the FMECA to identify “within-”hospital risks, fail points, and root causes in the internal processes of the emergency transfer of pediatric patients.

E.5. Significance

- This project revealed significant risks in the process of the emergency transfer of pediatric patients, risks in the inter-facility process as well as risks within each hospital facility's process.
- The rigorous application of the FMECA method is highly effective in revealing these risks.
- The simultaneous conduct of FMECAs about a complex healthcare process at multiple, diverse healthcare institutions is an effective method to produce solutions to improve the safety of the process that are generalizable.
- The high level of participation and satisfaction in the FMECA method in this project demonstrated that this method is a highly effective approach to engaging clinicians in the re-design of complex healthcare processes.
- Data from the FMECA method were critical in gaining consensus among clinicians for the re-design of the process to improve safety.

E.6. Implications

In 2005, over 3,500 pediatric patients were transferred between the referring and *Consortium* hospitals. All the hospitals have begun the necessary administrative steps, such as review by ED Councils, review by Forms Committees, to adopt use of the *Chicago Metropolitan Area Pediatric Transfer Form*. Though the initial form was a paper, hardcopy form, study participants requested that an electronic, PDF version of the form be developed. Study participants provided guidance about the "drop-down" box response selections for each data element in the form.

In addition, the *Chicago Metropolitan Area Pediatric Transfer Form* is the basis for the AHRQ-funded project, R18 HS 017912-01; Clinical Information Network for Safe Pediatric Emergency Transfers (PI: Woods). This project will develop a web-based version of the form that has the capacity to be transmitted in real time from the referring hospital to the receiving Consortium hospitals.

Further assessment of the generalizability of the *Chicago Metropolitan Area Pediatric Transfer Form* is warranted prior to wide dissemination of the form to healthcare facilities across the United States that engage in pediatric emergency transfers.

Additional technical enhancements of the form, such as interfacing and integration with electronic medical record (EMR) software systems and the creation of algorithms for automatic "population" of data fields with existing relevant EMR data, are highly desirable.

F. BIBLIOGRAPHY OF PUBLISHED WORKS AND ELECTRONIC RESOURCES FROM STUDY

Emergency Transfers Toolkit
http://www.feinberg.northwestern.edu/ihs/program-centers/cps/Pediatric%20Patient%20Safety/ pedmain.html
(Site is currently under construction- soon to be available at www.pediatricpatientsafety.org).

Agency for Healthcare Research and Quality (AHRQ) Presentation
Ross O, Holl J, Woods D, Soglin D, Echiverri S, Angst D, Vickers D, Webster K, Wang J
Risk Assessment of Pediatric Emergency Transfers. Poster presented at: AHRQ 2008 Conference; Bethesda, MD.

National Patient Safety Forum (NPSF) Presentation
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