

Making Health Care Safer for Children: A Proceedings Summary of the American Academy of Pediatrics Conference on Pediatric Patient Safety

An invitational conference held at the Hotel Sofitel, Rosemont, Illinois - May 2002

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TABLE OF CONTENTS

Foreword

Acknowledgments

INTRODUCTION

INTRODUCTORY COMMENTS

E. Stephen Edwards, MD, FAAP, President-Elect, American Academy of Pediatrics

BACKGROUND, HISTORY, AND KEY ISSUES

Carole Lannon, MD, MPH, FAAP

Director, AAP Steering Committee on Quality Improvement and Management

PLENARY SESSION

A BEST PRACTICE IN PATIENT SAFETY: MEDICATION RECONCILIATION

Medication Coordination for Children with Cancer

Glenn Billman, MD, Medical Safety Officer

Children's Hospital, San Diego, California

PLENARY SESSION

THE NEED FOR A PARADIGM SHIFT: DEVELOPING A CULTURE OF LEARNING

Creating a Culture of Patient Safety

Julianne Morath, Chief Operating Officer/Vice President of Care Delivery

Children's Hospitals and Clinics – Minneapolis-St Paul, Minnesota

PANEL DISCUSSION

PATIENT SAFETY – MEASUREMENT AND TECHNOLOGY INNOVATIONS

Innovations in Measurement and Technology for Pediatric Patient Safety

Shawn C. Becker, BSN, RN

Director, Patient Safety Initiatives, US Pharmacopeia

The Patient Safety Research Program – Ecology of Medical Care for Children

Susan Dovey, MPH

Analyst, American Academy of Family Physicians

Medication Errors and Adverse Drug Events in Pediatric Inpatients

Rainu Kaushal, MD, MPH

Instructor in Medicine, Harvard Medical School
Staff Physician, Brigham and Women's Hospital
Staff Physician, Children's Hospital, Boston

Patient Safety in Neonatology – The Vermont Oxford Network Experience

Gautham Suresh, MD

Assistant Professor, Department of Pediatrics
University of Vermont College of Medicine
Vermont Oxford Network Center for Patient Safety in Neonatal Intensive Care

Enhancing Patient Safety in Children’s Hospitals: The Collaborative Approach to Quality and Safety

Cheri Throop, RN

Vice President, Quality and Improvement, Pediatrics Division
Child Health Corporation of America

The UNC Medication Safety Program

Rowell Daniels, PharmD

Assistant Director of Pharmacy
University of Carolinas Hospitals, UNC Health Care System

PATIENT SAFETY SIMULATION

Organizing and Improving Care in the Health Care Microsystem

Julie J. Mohr, PhD, MSPH

Director, Quality Research in Pediatrics
University of Chicago

SMALL GROUP BREAKOUT DISCUSSIONS

ABSTRACT

Background:

The 1999 Institute of Medicine (IOM) report, *To Err is Human*, highlighted the fact that errors in health care are a leading cause of death and injury. Studies of adult patients estimate that between 44 000 and 98 000 Americans die in hospitals each year as a result of errors in the care that is supposed to help them. In response to the IOM report, the American Academy of Pediatrics published a policy statement, *Principles of Patient Safety in Pediatrics*, which emphasized the Academy’s commitment to providing the best and safest healthcare for infants, children, and adolescents.

The medical literature contains little information about patient safety issues in children’s healthcare; currently the evidence base is primarily in adult inpatient settings. Nearly 70% of child health care takes place in ambulatory settings; therefore, we likely know very little about the true extent of safety issues in pediatrics. In addition, children pose unique patient safety challenges including, but not limited to, weight-based dosing, communication/caregiver issues, and perhaps less capacity to “buffer” errors.

Invitational conference: In May 2002, the American Academy of Pediatrics (AAP) hosted an invitational conference to develop an agenda to address pediatric patient safety. The conference brought together pediatricians from various AAP entities, as well as clinicians and researchers from other agencies and organizations, including the National Patient Safety Foundation, the American Academy of Family Physicians, the American Pharmaceutical Association, the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality, the Child Health Corporation of America, the Pediatric Pharmacy Advocacy Group, and the National Association of Children’s Hospitals and Related Institutions.

Meeting objectives: The intent of the interdisciplinary conference was to:

- Review the issues of pediatric patient safety from a multidisciplinary perspective.
- Identify the systemic gaps that cause medical errors and set an agenda to bridge and reduce these gaps in pediatrics.
- Develop a better understanding of the “state-of-the-art” and “best practices” related to patient safety issues in pediatrics.
- Enable the AAP to prioritize key initiatives related to making healthcare safer for children.
- Utilize the conference information and materials in future AAP educational offerings on patient safety and quality of care.

Conclusions: Conference attendees identified the following set of initiatives that the Academy and its partners can pursue to promote patient safety in pediatrics.

The Academy should:

- Develop an action agenda, *Making Healthcare Safer for Children*, to raise awareness about pediatric patient safety issues and highlight best practices in patient safety for:
 - patients and families
 - American Academy of Pediatrics members
 - various settings in which children receive care and therapeutics
- Facilitate the collaboration of individuals, institutions, and organizations to make health care safer for children
- Seek resources and support efforts to improve the quality and safety of healthcare for children

Conference participants as well as additional interested Academy members, AAP committees and sections, and patient safety experts will be asked to assist in strategies that will advance the action agenda proposed by conference participants. Building on the recommendations of conference participants, key efforts will be organized along the themes of policy and advocacy, ambulatory and inpatient care safety and the multiple interfaces involved in coordinating care for children, and tools for improvement (e.g., resources and information technology).

FOREWORD

The 1999 Institute of Medicine report, *To Err is Human*, focused attention on medical errors and the need to improve patient safety. In response, the American Academy of Pediatrics developed a policy statement, *Principles of Patient Safety in Pediatrics*, to highlight the Academy’s

commitment to improving the health care system to provide the best and safest health care for infants, children, adolescents, and young adults.

Although most patient safety research has focused on adult care issues and not as much is known about *pediatric* patient safety issues, the AAP believes that there is much that we can do to focus on improving the quality and safety of care for children. For example, we can learn from the adult field as well as be aware of much that is already being done to make pediatric care safe. The Academy convened this conference in order to learn from those who are already making a difference in improving care for children.

ACKNOWLEDGMENTS

The conference organizers wish to acknowledge Wyeth Consumer Healthcare for its generous support of this conference and the publication of these proceedings. Additional acknowledgments go to the conference speakers and faculty, including E. Stephen Edwards, MD, FAAP, President-elect, American Academy of Pediatrics; Glenn Billman, MD, San Diego Children's Hospital; Julianne Morath, Children's Hospitals and Clinics, Minneapolis; Julie Mohr, MSPH, PhD, Director, Quality Research in Pediatrics, University of Chicago; Rainu Kaushal, MD, MPH, Brigham Women's Hospital; Gautham Suresh, MD, Vermont Oxford Network; Cheri Throop, RN, Child Health Corporation of America; and Rowell Daniels, PharmD, University of Carolina Hospitals. Additional thanks are due to the following American Academy of Pediatrics staff people who served as small group breakout discussion session facilitators and scribes – Modena Wilson, MD, FAAP, Department of Committees and Sections; Edward Zimmerman, MS, Department of Practice and Research; Michael Glasstetter, JD, Department of Chapter and State Affairs; Junelle Speller, Department of Practice and Research, and Elaine Vining, Department of Federal Government Affairs. And deep appreciation to Junelle Speller, Karen Wanatowicz, and Pat Wajda in the AAP Department of Practice and Research, who organized all details related to the conference. Additional thanks to Kira Friediani and Laura Brown from the Children's Primary Care Research Group at the University of North Carolina.

Finally, to all participants who gave so generously of their time, knowledge, and expertise to ensure the success of the conference – thank you!

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INTRODUCTION

In May 2002, the American Academy of Pediatrics (AAP) hosted an invitational conference on pediatric patient safety as a means to develop and implement an effective and far-reaching agenda to address issues of children's healthcare safety. The conference brought together

pediatricians from various AAP entities, as well as clinicians and researchers from other agencies and organizations, including the National Patient Safety Foundation, the American Academy of Family Physicians, the American Pharmaceutical Association, the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality, the Child Health Corporation of America, the Pediatric Pharmacy Advocacy Group, and the National Association of Children's Hospitals and Related Institutions. Professionals with expertise in children's health care, patient safety, policy development and implementation, and quality improvement science were in attendance.

The purpose of the interdisciplinary conference was to:

- Review the issues of pediatric patient safety from a multidisciplinary perspective.
- Develop a better understanding of the “state-of-the-art” and “best practices” related to patient safety issues in pediatrics.
- Identify the systemic gaps that cause medical errors and set an agenda to bridge and reduce these gaps in children's healthcare.

As a result of this conference, the Academy will:

- Determine key initiatives the Academy and its partners can pursue to promote patient safety in pediatrics.
- Utilize the conference information and materials in future AAP educational offerings on patient safety and quality of care.

INTRODUCTORY COMMENTS

E. Stephen Edwards, MD, FAAP

President-Elect, American Academy of Pediatrics

I'd like to thank everyone who made this patient safety conference possible, starting with Wyeth Consumer Healthcare, who funded the conference.

The idea for the conference originated with the former AAP Committee on Quality Improvement and is being carried through by the new Steering Committee on Quality Improvement and Management. My special thanks to Carole Lannon, Laura Brown, and Kira Friediani, as well as Ed Zimmerman, Modena Wilson, Junelle Speller, and all the other terrific AAP staff who have put this conference together.

The whole country is talking about patient safety and medical errors. A computer search of newspaper and broadcast outlets over the last year revealed more than 1000 references to each of these issues. A separate search for stories about “medical errors and children” turned up 348 hits. Another search for stories about “patient safety and children” revealed more than 500 hits.

The media has largely reported on the problems, but not on the solutions, because solutions have not been readily available. That's why we're here, to offer some solutions. Our work at this conference is fulfilling a great need. As you know, there are three key elements in the current dialogue on pediatric patient safety:

1) The Institute of Medicine report failed to identify problems in pediatric patient safety and failed to offer solutions.

- 2) There is no recognition of the fact that infants and children are at an increased risk for harm because of their limited reserves (small body size) and the increased opportunities for errors due to weight-based dosing for virtually all pediatric medications.
- 3) Very little information is available on the type and extent of problems in ambulatory care, although a vast majority of children's health care is provided in this setting.

The purpose of the conference is threefold. First, the conference will begin to establish a dialogue to develop a better understanding of patient safety issues in pediatrics. Second, the conference will enable the Academy to identify the gaps in the system that cause medical errors. And third, the conference will identify a set of initiatives the AAP and its partners can pursue to bridge and reduce those gaps. A report on the conference and related outcomes will be published in *Pediatrics*.

To me, the issues of patient safety and quality are one and the same, and quality continues to be the Academy's top priority. If you don't have quality, what have you got? In any industry, in any profession, quality has to be the number one goal.

Apollo 15 astronaut David Scott was asked what thoughts ran through his mind as he waited to blast off. He said, "You just sat there thinking that this piece of hardware had 400 000 components... all of them built by the lowest bidder." Bureaucracies and bottom lines can, and have, taken a toll on quality, and have shaken people's confidence as a result. We can restore that confidence through our work here today.

As I mentioned, our number one objective continues to be high-quality health care for all children. I see quality as part of a triad, along with access to health care and appropriate pediatrician reimbursement. Only when all three of these are in place can quality be achieved.

Last week's decision by a federal appeals court should go a long way toward empowering that triad. As you may know, the court reversed a lower court's dismissal of a suit brought to force Michigan to provide more health care services for poor children. The AAP Michigan Chapter and other advocacy groups brought this case forward. It now goes back to US District Court in Detroit for another hearing.

The case argues that the state is not living up to its obligation to provide the early and periodic screening and diagnostic and treatment services required by federal law for Medicaid recipients under age 21. In its ruling, the Court of Appeals said the state is required to live up to the welfare requirements because they are federal law, not merely a contract between the federal government and the states. It also ruled that the US District judge wrongly dismissed the suit on the grounds that state officials couldn't be sued for not fulfilling the requirements. With the case now sent back to district court, the two sides should get a chance to argue whether Michigan is providing enough health care for children. The AAP at the national level supported the Michigan Chapter in this lawsuit, and will continue to do so.

The Academy scored another major victory with the FDA decision to suspend the 1998 regulation called the "Pediatric Rule," which guarantees pediatric drug studies. In April, the FDA reversed its decision to suspend the Pediatric Rule and will also continue to defend the legal authority of the rule in court. However, the FDA also stated it will open up the Pediatric

Rule for public comment in order to update the rule and maximize the benefit from the recently passed law, the Best Pharmaceuticals for Children Act. The Academy will play an active role to see that the updated rule remains beneficial to children. At the same time, with the Pediatric Academic Societies and the Pediatric AIDS Foundation, we are urging Congress to pass legislation that would codify the Pediatric Rule.

A somewhat unlikely ally in the quest for quality is the AAP Task Force on Terrorism. In their high-level meetings with government officials, Task Force members stress the fact that children are not simply little adults, and should not be treated as such. As the AAP plays a prominent role in preparing for acts of terrorism, perhaps we can see some good result, as we educate decision-makers about the true needs of children.

The work of this conference is supported by many other initiatives within the AAP, and the recommendations that result from this conference will receive the same such support. I am proud to be a part of this groundbreaking conference, and I trust that each of you shares my pride.

I leave you this morning with the words of Thomas Edison. He said, “If we all did the things we are capable of doing, we would literally astound ourselves.” I have no doubt that your work here will be astounding, and I thank each of you for your dedication to patient safety and quality pediatric care.

BACKGROUND, HISTORY, AND KEY ISSUES

Carole Lannon, MD, MPH, FAAP

Director, AAP Steering Committee on Quality Improvement and Management

In 2001, the American Academy of Pediatrics (AAP) published a policy statement, *Principles of Patient Safety in Pediatrics*,¹ which described the Academy’s commitment to improving the health care system to provide the best and safest health care for infants, children, adolescents, and young adults. In response to the 1999 Institute of Medicine (IOM) report, *To Err is Human: Building a Safer Health Care System*,² a set of principles was established to guide the profession in designing a health care system that maximizes quality of care and minimizes medical errors through identification and resolution. This set of principles provides direction on setting up processes to identify and learn from errors, developing performance standards and expectations for safety, and promoting leadership and knowledge in this arena.

The 1999 IOM report noted that errors in health care are a leading cause of death and injury.² Between 3% and 4% of hospitalized patients are harmed by the care that is supposed to help them. On average, of 100 hospitalized patients, 7 are exposed to a serious medication error that harms or potentially harms them. It is estimated that between 44 000 and 98 000 Americans die in hospitals each year as a result of errors in their care. The IOM defines patient safety as “freedom from accidental injury while receiving healthcare services.” The safest health care environment is one where clinical care is measured and managed and desired clinical outcomes are achieved.

Currently the patient safety evidence base is primarily in *adult inpatient* settings. Because the majority of children’s health care takes place in ambulatory settings, we know very little about

pediatric issues in patient safety. Researchers have postulated that children pose unique patient safety challenges because of the need for weight-based dosing, communication/caregiver issues, and perhaps less capacity to “buffer” errors because of their small size.

Few epidemiologic data are available regarding medication errors in the pediatric setting. In 2001, a groundbreaking study entitled *Medication Errors and Adverse Drug Events in Pediatric Inpatients*³ was published. The objectives of the study were to assess the rates of medication errors, adverse drug events (ADEs), and potential ADEs; to compare pediatric error rates with previously reported adult rates; to analyze the major types of errors; and to evaluate the potential impact of prevention strategies.

Of the 10 778 orders reviewed, the authors found 616 medical errors, 115 potential ADEs, and 26 ADEs. Of the 26 ADEs, 5 were preventable. While the preventable ADE rate was similar to that of a previous adult hospital study, the potential ADE rate was *3 times higher* in children. Most potential ADEs occurred at the stage of drug ordering and involved incorrect dosing, anti-infective drugs, and intravenous medications. Physician reviewers judged that computerized physician order entry could have prevented 93% of ADEs and ward-based pharmacists 94% of ADEs. Medication errors and ADEs that are *preventable* are important errors from the perspective of patient safety as we can learn what systems changes might be implemented to improve safety.

The study found that common errors related to life-threatening potential ADEs included: ordering high or low doses of medication; ordering medications despite known allergies; ordering medications without indicating the route of administration; and incorrect dispensing of pharmacy medications.

There is much that needs to be learned about the unique pediatric patient safety issues related to the different settings where children’s health care is provided: children’s hospitals compared with community hospitals and academic medical centers; the various ambulatory care settings; home care; and schools and child care settings. Very little is known about patient safety in the outpatient setting. In a recent study, the types of errors involving in outpatient settings were primarily related to issues involving medication, charting, diagnostics, and clinical judgment.⁴

When patient safety in inpatient and outpatient settings is compared, various differences have been noted: the inpatient setting is usually technologically and clinically complex and the outpatient setting tends to be logistically complex. A well-developed infrastructure exists in inpatient settings, whereas the infrastructure in outpatient settings is often not well developed. In inpatient settings, handoffs generally occur within the confines of the health system; in outpatient settings, numerous transitions are required with a variety of individuals in different settings (e.g., schools, community organizations). In inpatient settings, Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and other institution-based regulations exist; in outpatient settings, less regulation exists. The policies and procedures in inpatient settings are generally well developed whereas in outpatient settings protocols are usually less well developed and fewer checks and standards exist.

The causes of error include complexity, human factors, and system design. The more difficult or intricate a process, the more that opportunities for error increase. For example, there are many steps in assuring appropriate medication order and delivery and the probability of error increases with the number of steps. Human factors research focuses on interrelationships between humans, the tools they use, and the environment in which they live and work.⁵ Error can also result from system itself. Complex systems fail because of the combination of multiple small failures, each of which on its own may be insufficient to cause an accident. Reason calls these ‘latent failures’ and notes that their pattern constantly changes.⁶ Improving systems involves leadership, reporting/tracking, training, and advances in technology.

The program for this meeting will provide information about gaps in children’s healthcare, innovative safety programs in pediatrics, and opportunities to discuss and prioritize key next steps to make healthcare safer for children.

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PLENARY SESSION

A Best Practice in Patient Safety: Medication Coordination

Medication Coordination for Children with Cancer

Glenn Billman, MD, Medical Safety Officer

Children’s Hospital, San Diego, California

I will present a program that we developed and implemented, *Medication Coordination for Children with Cancer at Children’s Hospital in San Diego*.

Background

The Children’s Hospital in San Diego is a 297-bed tertiary hospital with 54 pediatric intensive care unit beds and 43 neonatal intensive care unit beds. The hospital represents 35 pediatric subspecialties and provides care at 50 locations throughout the region. There are 12 000 annual inpatient visits, 220 000 outpatient visits, and 16 000 surgeries at the hospital. With approximately 100 children diagnosed with cancer annually, more than 2 000 children receive care by the physicians and nurses in the hematology-oncology department. A large percentage

of the patients served are uninsured and live in poverty. The patient population represents extraordinary ethnic diversity in the region; more than 50 different languages are spoken in San Diego's schools.

Focus on hematology-oncology patients

To make healthcare safer for children at our institution, Children's Hospital in San Diego chose to focus on improving medication safety. Staff chose hematology/oncology patients as the initial concentration of the medication safety project because:

- *Patients with cancer are particularly vulnerable to gaps in medication coordination.* Patients with cancer make frequent hospital and/or clinics visits and have complex and frequently changing medication protocols, often with highly toxic medications. These patients see multiple care providers at multiple sites.
- *National and local data show gaps in the coordination of care across sites.* Studies in children have revealed that medication use occurs as intended only 50% of the time¹ (National Council on Patient Information and Education, 1989). Twenty weeks after diagnosis, children with cancer self-report a medication compliance of only 60%. A pilot study conducted at Children's Hospital in San Diego confirmed a gap in medication coordination with drug or dose variances detected in 30% of cancer patients admitted to the oncology service.
- *Breakdowns in medication coordination have serious consequences.*
- *Breakdowns in medication coordination cause significant disruptions to the delivery of care.*

The project, *Medication Coordination for Children with Cancer at Children's Hospital in San Diego*, developed the following mission statement: "We believe that every child with cancer deserves an optimal healing experience that assures perfect coordination of care across the continuum whether they are treated by us for one hour, one day or one year. Therefore, every aspect of the patient and family experience must be built on the principles of providing the right care, in the right place, and at the right time."

The aim of the project is that "by July 1, 2002, 100% of children with cancer will experience care that is free of medication variances among patients, families and caregivers." Prevention of medication variances is used as a process measure for the goal of eliminating patient harm because 1) literature supports this relationship², 2) on a practical level, medication variances may be measured and monitored in real time, whereas harm may not become evident for months to years, and 3) only a small fraction of medication variances will actually result in patient harm.

To achieve the aim of the project, it was determined that optimal care for children with cancer requires totally effective communication regarding medication use among numerous people of varying disciplines in multiple locations over time, including the families themselves. Project staff segmented all aspects of the patient's care by identifying the entities involved, including family, physicians, pharmacy, nursing, and information systems, and noted the initial lack of coordination in treatment. It was determined that medication variances were often identified at admission during questioning by nursing staff — the most important area to address so that optimal medication coordination would be achieved.

One nurse prospectively identified the following types of medication variances while admitting patients to the hematology-oncology service during a one-month period:

- the patient/family unaware aware that child was to take the medication (15%),
- patient/family unaware of the dose to take (15%),
- the patient/family was noncompliant with the medication,
- medication omitted from admission orders (37%),
- incorrect dosage ordered on admission orders (22%),
- incorrect dosing schedule ordered on admission order (7%).

These results identified the need for a process that would ensure that patients and their caregivers possess the most accurate and up-to-date medication list possible. Project staff devised a grid to prioritize activities and selected two interventions based on a literature review and multidisciplinary brainstorming:

- First, patients/families were instructed to bring in *all* of their child's medications *every time* they came to the hospital or clinic.
- Second, a standardized form, the Medication Coordination Form, was developed to compare intended and actual home medication use with medication orders written upon admission. The process for implementing these interventions includes assessing what medication the child is currently taking at home, determining whether or not all home medications should be continued through the admission ordered, and determining whether any home medications ordered during the admission are ordered with the correct dose/schedule/route.

Three types of improvement were observed. First, care team-related medication variances dropped from 21% to 1% of medications ordered by the end of Cycle 2. Second, patient/family-related medication variances dropped from 9% to 4% of medications prescribed by the end of Cycle 2 (this class of variances now represents the dominant type of residual variances). Finally, an increase was observed in the percentage of patients that completed medication coordination upon admission. Opportunities to incorporate this medication coordination process into the information technology system that the San Diego Children's Hospital uses is now being studied.

Children's Hospital, San Diego, utilizes the MEDITECH system as its hospital-wide information system. An analysis of the current overall information technology environment at the hospital was undertaken and all areas utilizing the system were identified. Three strategies to enhance the clinical information technology at the hospital were defined. These include: 1) replacing the paper-based Medication Coordination Assessment with MEDITECH electronic database (implementation date: August 1, 2001); 2) making the MEDITECH electronic database available across the care continuum; and 3) establishing physician order entry with alerts. The electronic database will be utilized for variance tracking and variance resolution, ie, the electronic database may be automatically queried to capture identified medication errors. The electronic database also will be utilized to validate home medication at discharge and home medication in the clinic.

Preliminary findings regarding the number of days between emergency department visits by hematology/oncology patients related to adverse drug events show that between the end of

November 2001 and mid-April 2002, the number of days between visits has consistently increased.

It was determined that the biggest challenges for the project were people- and process-related. Staffing issues, frequent admissions, transfers, and discharges, data collection, compliance monitoring, specific roles and responsibilities, and feeling responsible for the process all presented challenges throughout the initiation of this project. The benefits from the project application support patient safety and workflow efficiencies. Time was saved by having physicians write out prescriptions for medication, nurses document visit information, and care managers handle prescription refill requests. Patient safety outcomes include patient compliance with medication regimens at greater than 90%, all variances are identified and can be corrected, legible medication instructions for nurses, pharmacists, and patients, and decrease in readmissions, adverse drug events, and emergency department visits.

On the basis of this experience, the following lessons were learned. The manual problems need to be fixed first. For example, the process flow, data flow, roles and responsibilities, and procedures all need to be analyzed. The project and related goals and objectives need to be built incrementally. Leadership support and “buy in” is crucial; for example, project champions need to be identified and assist in delivering the message of value and benefits. Staff education in the form of initial and ongoing training for nurses and physicians regarding medication coordination enhances the consistency and accuracy of their work. Patients and the reconciliation process benefit greatly when the patients are informed and engaged. Program messages and objectives must be consistent.

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PLENARY SESSION

THE NEED FOR A PARADIGM SHIFT: DEVELOPING A CULTURE OF LEARNING

Creating a Culture of Patient Safety

Julianne Morath, Chief Operating Officer/Vice President of Care Delivery

Children’s Hospitals and Clinics – Minneapolis-St. Paul, Minnesota

Children’s Hospitals and Clinics provide primary and specialty health care to the children of the Twin Cities, greater Minnesota, and the Upper Midwest region. Its major programs and services include adolescent medicine, cardiology, development/rehabilitation, emergency medicine, epilepsy services, child abuse services, hematology/oncology, home care programs, neonatology, pediatric intensive care, pediatric subspecialty clinics, pulmonary diagnostics, surgery (inpatient and outpatient), and urology. Children’s Hospitals and Clinics professional and medical staff members number more than 1400, and include a wide range of physicians and pediatric specialists.

In 1999 the Children’s Hospitals and Clinics, Minneapolis-St. Paul, Minnesota, began its shift toward patient safety and related cultural and institutional changes. This shift was based on the concept of “do no harm” to patients who use these hospitals and clinics for care. The most significant lesson learned in the initial patient safety work is that there needed to be systems in place to anticipate gaps in patient safety and to close these gaps. Staff at the Children’s Hospitals and Clinics embarked on learning and understanding the complexity of patient safety issues and determined that what matters the most is each individual’s personal experience with patient safety. They also learned that stories and conversations create safety and that cases should be kept alive and related issues should be revisited so that ongoing changes can be made. This patient safety focus emphasizes that errors in the hospital and clinic settings are for learning and resiliency; patient safety is not just prevention, it is also recovery. Patient safety situations are prioritized based on themes, and safety requires a team approach.

Patient safety is about believing that patient care can be improved. The following motto serves as the foundation of the Children’s Hospitals and Clinics patient safety efforts: “We will become the safest children’s hospital in the world and then become even safer.” We determined that our efforts have to be at the right level of intervention and have to be sustainable. Our approach represents a *call to action*, rather than a caution to employees, staff, and clinicians to be more careful.

The patient safety manifesto, or the public declaration of an intent for action, adopted by the Children’s Hospitals and Clinics includes the following:

- 1) Declare patient safety an urgent need;
- 2) Accept executive responsibility;
- 3) Gain the necessary knowledge and tools (eg, human factors research);
- 4) Ensure accountability (there needs to be a plan in place and everyone needs to be accountable for his/her part of the plan);
- 5) Confront myths (physicians and other health care providers are infallible);
- 6) Align external controls (how are the public, regulator, professional associations, and boards thinking about patient safety); and
- 7) Accelerate change (having principal investigator effector arm).

Key patient safety concepts, including the Swiss cheese model, the blunt and sharp end model, hindsight bias, and High Reliability Organization (HRO) models, are prioritized as part of the patient safety efforts at Children’s Hospitals and Clinics. The utility of the Swiss cheese model is in looking retrospectively from a systems perspective to identify where holes/gaps are in processes. Children’s Hospitals and Clinics staff utilized aspects of this model to identify possible systems issues that may have had an impact on events and the causes of accidents. There are successive layers of defenses, barriers, and safeguards. Messages for the organization as a whole must focus on the “production versus protection” tension. A mindset of reciprocal accountability has been put in place and mutual trust is emphasized. With regard to mutual trust, we emphasize that the system must trust that you will call out or report *and* hospital/clinic staff and clinicians must trust that the system will listen without blame or retribution for reporting. A final component in this process is that *action* will result from reporting.

Safety action teams are under way in a number of settings at Children's Hospitals and Clinics. These groups have been mobilized to address accountability and action at the front end and to foster rapid cycle, focused improvements. The teams focus on furthering the messages of "fix what you can, tell what you fixed, and find someone who can fix what you cannot."

Different organizational cultures handle patient safety information differently. For example, in a bureaucratic culture errors may be reported or discovered and messengers, those who report errors, are listened to if they report problems. Failure in these situations leads to local repairs and new ideas often present problems. In a generative culture, medical errors are actively sought, and messengers are trained and rewarded. Furthermore, failures lead to far-reaching reforms and new ideas are welcomed. A safety culture is constantly "uneasy," seeking, learning, and changing.

Patient safety promises made to parents and patients at the Children's Hospitals and Clinics include the following:

- 1) You will be safe.
- 2) We will be here when you need us.
- 3) We will be affordable and never turn a child away.
- 4) We will give you our best as a partner in care.

Families are encouraged to participate in the patient safety process and to "stop the line" if they experience and/or see something that does not seem correct. The staff and clinicians at Children's Hospitals and Clinics are committed to tell the truth to families regarding situations that had potential to harm their child or actually did harm the child.

Intense learning about patient safety and the use of a new patient safety-oriented vocabulary have been implemented at Children's Hospitals and Clinics. Physicians and staff have been engaged in this process. *The term "error" is not used to describe causation of an event.* Tactics employed to implement changes related to patient safety include:

- The identification of champions (physicians and others) to serve as thought leaders on patient safety issues.
- A Patient Safety Steering Committee was established to oversee the strategic and tactical directions of the program.
- Focus groups of families, medical students, residents, and others have been convened
- Patient Safety Grand Rounds have been prioritized.
- Dialogues in which members of the Patient Safety Steering Committee participate are ongoing venues to discuss what is new in patient safety at the hospitals and clinics and to share stories and ideas.
- Patient safety orientation and learning packets have been compiled and are disseminated along with patient safety tool kits.

Three identified barriers to patient safety are staffing issues, communication (against a gradient of authority, i.e., staff to physician), and leadership (does leadership have the backbone to address all patient safety-related issues?). To address these barriers, a system for blameless reporting of hazards or near-hazards and accidents has been established. In addition, the Children's Safety Learning Report has the goal of providing feedback via a flexible reporting system in an effort to facilitate action with a focus on learning. Media alerts on patient safety

issues have been disseminated and case studies are shared so that lessons learned can be broadly disseminated. Policy focused on medical accidents disclosures has been implemented and the hospital public relations staff generate ongoing messages about patient safety.

Specific patient safety strategies that have been initiated include an ongoing dialogue and learning, team training, and dissemination of information about medication best practices. Furthermore, audits of high-risk situations and human factors consultations and videotaping are in place; clinical pharmacists have been added to care teams, a patient-family medication safety brochure has been developed, and local Safety Action Teams have been engaged. Reporting at Children's Hospitals and Clinics continues to be tracked. The program is in its third year.

PANEL DISCUSSION

Patient Safety--Measurement and Technology Innovations

Innovations in Measurement and Technology for Pediatric Patient Safety

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The US Pharmacopeia (USP) was established in 1820 with the mission of promoting the public health by disseminating authoritative standards and information used to promote optimal health care delivery. The USP is recognized by federal law and develops standards that are enforceable by the United States Food and Drug Administration (FDA). The USP is nongovernmental and not-for-profit, 501(C)(3). Its work is driven by more than 1000 volunteer members.

The USP has been involved in "reporting" programs for practitioners since 1971 and has had 14 consecutive contracts with FDA reporting programs for drugs and medical devices during the past 24 years. The USP established its Medication Errors Reporting Program in 1991. The National Coordinating Council for Medication Error Reporting and Prevention, established in 1995, is comprised of representation from 23 organizations including the American Medical Association, the American Hospital Association, the American Association of Retired Persons, licensing boards, and pharmacy. The Council develops recommendations for promoting reporting and understanding of medication errors. The USP ad hoc Advisory Panel on Medication Errors was developed in 1996 and has become the USP Committee on Safe Medication Use in 2000; this group has become a formal part of the standards-setting process.

The need for a national system for error reporting evolved as hospitals were looking for a nationally standardized format to collect data as well as definitions to help start tracking in facilities. Hospitals were also seeking information regarding what is an acceptable error rate and how they could compare their rates with those of other institutions. Furthermore, hospitals were looking for an anonymous way to share information. As a result, a national database to reduce hospital medication errors entitled MedMARxSM was developed. The database is designed to be Internet-accessible and supports interdisciplinary, nonpunitive, anonymous reporting from hospitals. The system encourages hospitals to practice risk prevention and allows for facility-based reporting via a gatekeeper; it utilizes standard definitions and format and enables hospitals to view reports from others nationwide. Designated staff from each participating hospital enter a

record and the error is categorized; the record detail is extensive and information about the “products” utilized is collected. Several data fields are “required” fields, including age (in the Patient Profile) – this allows for review of the database for pediatric-specific information. The Patient Profile portion of the record exists only for errors that reach the patient.

Between the years of 1995 and 1999, the Medication Errors Reporting Program collected information that included specifics for pediatrics on where errors occurred in the medication use process. It was determined that the vast majority of errors occurred in the “dispensing” category. Furthermore, the program found that the highest percentage of “types” of error in pediatric patients were in the areas of improper dose/quantity and unauthorized drugs. The top products involved in pediatric errors, according to this program study, included intravenous fluids (ie, dextrose 5% solution/sodium chloride 0.9%). This category included the highest number of products involved in pediatric errors that resulted in harm.

In 1999-2000, the MedMARxSM database records were reviewed in greater detail and it was found that errors occurred primarily in the “administering” phase of the medication use process. In this phase of the study, types of error were highest in the areas of “omission” error and improper dose/quantity. The main cause of error was in the area of performance (human) deficit. Factors contributing to the performance deficit errors include, but are not limited to, distractions, workload increase, and inexperienced staff, with intravenous fluids having the highest number of products involved in pediatric errors.

The Patient Safety Research Program – Ecology of Medical Care for Children

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The Robert Graham Center, Policy Studies in Family Practice and Primary Care was established in Washington, DC, in 1999 to conduct research that could be used to bring a primary care perspective to policy deliberations, both in Washington, DC, and at the state level. When the patient safety agenda entered the policy agenda in 1999, the Center incorporated a patient safety component into its “scope of practice” research theme. The studies ongoing within this center are some of the only qualitative patient safety studies focused on the ambulatory or outpatient settings.

To date, data from two studies – one in the United States and one in six countries (including the United States) – have been collected, a secondary data analysis of a malpractice database has been completed, and a synthesis of the literature classifying medical errors in the primary care setting has been prepared.

Defining medical errors is a real problem for primary care physicians and other clinicians. There are discrepancies in definitions of “underuse,” “overuse,” and “misuse”. While definitions are clear about prescribing the wrong medication or performing surgery on the wrong limb/body part, the first was such a minor component of primary care practice and the second almost nonexistent, that program staff were reluctant to use existing medical error definitions when they began work on this project. A focus group of family physicians helped determine the following key goals/objectives of what to study related to patient safety so that it would be appropriate for

their physician colleagues: “Something in your own practice that should not have happened, that was not anticipated and that makes you say ‘that should not happen in my practice, and I don’t want it to happen again.’ It can be small or large, administrative or clerical – anything that you identify as something to be avoided in the future.”

In 2000, 42 US family physicians made 330 error reports in a study designed to compare paper and computer error reporting systems. In 2001, 79 general practitioners and family physicians in Australia, Canada, England, The Netherlands, New Zealand, and the United States made 429 error reports in a study designed to see if different countries had different types of errors. A total of 759 error reports had been received at the time of this conference. Of the 759 reports, 79 involved children ages 0-18 years. Fifty-seven percent of the children were male, 29.1% were of minority race or ethnicity, and for 57%, the physician knew them or their usual source of care well. The main error types in children were medication errors (38%), charting errors (30%), diagnostic errors (18%), and errors in clinical judgment (14%). Patients were harmed in 35 of reports. Most often, this harm was delayed treatment or heightened exposure to greater physical harm, but sometimes children suffered pain or became ill as a consequence of the error. One child was admitted to the hospital.

Reporting physicians identified nine separate health care settings where the errors they reported occurred. These included their own practices, emergency departments, pharmacies, the child’s home, during telephone contact, and in hospitals, laboratories, and radiology clinics. Reporting physicians were asked what might have prevented the errors affecting children. Their responses were categorized as follows: don’t make mistakes (44.7%), provide care differently (32%), more education or training (3.7%), better communication (4.9%), or more resources (2.9%).

The ecology of medical care for children, which is the foundation for these studies, focuses on *where* people receive their medical care. In a one-year period for a sample of 1 000 U.S. children, data suggest that: 721 visit a physician’s office, 425 visit a dentist, 129 receive care in an emergency department, 69 visit a hospital or outpatient department, 28 spend time in a hospital, and 9 receive home health care.¹

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Medication Errors and Adverse Drug Events in Pediatric Inpatients

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Dr. Kaushal and co-investigators at Brigham and Women’s Hospital and Children’s Hospital Boston published a study in the April 2001 edition of *JAMA* entitled *Medication Errors and Adverse Drug Events in Pediatric Inpatients*.¹ This study found that medication errors with the potential to harm a patient occurred three times more often in pediatric inpatient settings compared with hospitalized adults. Children pose unique challenges to the medication use

system including the need for weight based dosing and dilution of stock medications, decreased ability to communicate side effects, and decreased ability to self-administer medications. As a result of this study, the researchers will further patient safety efforts by focusing on projects in the inpatient, outpatient, and policy arenas.

The first project will evaluate the effect of full-time, ward-based pharmacists on decreasing serious medication errors. The second initiative will evaluate on computerized physician order entry (CPOE) on reducing serious medication errors. CPOE refers to electronic prescribing which at the most basic level ensures that orders are complete, standardized and legible. When combined with appropriate software, CPOE systems can provide advice about dose, route and frequency as well as check for drug-drug and drug-allergy interactions. A related study, the Pediatric Outpatient Prescribing Study (POP), will evaluate medication errors in pediatric ambulatory settings. The data collection methodology includes patient surveys, duplicate prescription review and chart review. Six pediatric clinics in socioeconomically diverse communities will be involved in the study. Finally, a policy-related study is underway. In this study, the researchers have examined perceived barriers by senior management to the implementation of CPOE. They are also examining state and federal level policy interventions to overcome these barriers.

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Patient Safety in Neonatology – The Vermont Oxford Network Experience

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The Vermont Oxford Network is a voluntary group of health professionals committed to improving the quality and safety of medical care for newborns and their families through a coordinated program of research, education, and quality improvement. To support its mission, the Network maintains a database for infants weighing between 401 and 1500 g at birth, who were born at or transferred to one of the nearly 400 participating Neonatal Intensive Care Units (NICUs) within 28 days of birth. The Network database has been in operation for more than 10 years and now enrolls more than half of the very-low birth weight infants born annually in the United States. Information from the database is analyzed and sent to Network members on a quarterly basis. The information in the quarterly reports can be used for internal auditing and quality improvement, as well as to provide core data for Network research.

Network staff realized that having the data is not enough and therefore began to work on efforts related to improving outcomes. In order to use the data to achieve measurable improvements in the quality and safety of neonatal intensive care, the Vermont Oxford Network has successfully completed two Evidence-Based Quality Improvement Collaboratives for Neonatology, NICQ 1 and NICQ 2. The first NIC/Q Collaborative, conducted between 1995 and 1998, involved 10 centers and has been reported in the literature.¹⁻³ The second Collaborative, NICQ 2000, included 34 centers and was conducted between 1998 and 2001. The Network is currently

conducting its third learning collaborative, iNICQ, a learning collaborative based on a series of web conferences in which neonatal units will be offered Internet-based training in quality improvement and patient safety. Patient safety has been a prominent focus of the Network Collaboratives since 2000.

With regard to patient safety in NICQ 2000/2002, the focus since 2000 has been on error reporting, definitions and terminology, sharing of case studies in error reduction, human factors checklists, and an organizational culture assessment tool. Reporting is voluntary and anonymous and no information about the reporting person, location, patient ID, time, persons involved in error are requested or provided. Errors are directly reported on www.NICQ.org and there is a free-text reporting format of individual errors with the level of detail left to reporting person. Near-misses and adverse events are included. In a 19-month period, a total of 610 errors were reported. Each reported error is reviewed and classified in discrete categories (additional categories have been added). The classification scheme includes errors of diagnosis, errors of therapy, errors of prevention, and other errors (with subcategories of each). The top three categories of errors were 1) wrong medication OR error in dose, schedule, or infusion rate; 2) error in performance of an operation, procedure, or test; and 3) patient misidentification (from all categories).

The following conclusions were determined based on the analysis of the error reports: voluntary anonymous reporting led to the reporting of a large number of errors; a wide spectrum of errors are being reported; errors of therapy, especially medication errors, are reported more than other categories (although medication errors are reported most frequently, this does not mean that they were most likely to occur); and many more errors are likely not recognized/reported. In addition, the error reporting database is a rich resource for learning about how to prioritize and achieve error reduction. There are many opportunities for easy improvement of patient safety and a more structured reporting system/process is likely to be beneficial. Current efforts are focused on a structured web-based anonymous reporting system.

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Enhancing Patient Safety in Children's Hospitals: The Collaborative Approach to Quality and Safety

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The Child Health Accountability Initiative (CHAI) vision and mission are focused on improving the health care of children in the United States and enhancing the quality of child health services by establishing, via a collaborative multi-site network, evidence-based and consensus-derived outcome measures. The CHAI goals are to design, evaluate, and implement national measures of

quality of care and health outcomes for children utilizing children's hospitals as learning laboratories, and undertaking collaborative projects and research to promote clinical practices that lead to improved health outcomes for children. CHAI has a three-track approach. The first track, Rapid Improvement, focuses on accelerating best practices across CHAI hospitals, standardizing care, rapid use of lessons learned across the hospital, and differentiating care. The second track, Building Bridges, involves securing endorsements, collaboration, sharing measures, and identifying and prioritizing studies. Informing the Field, the third track, involves publications and presentations as well as industry access to CHAI standards.

The following hospitals are 2002 CHAI participants: Children's Hospital of Buffalo, Buffalo, NY; Charleston Area Medical Center, Inc (d.b.a., Women and Children's Hospital, a member of the Camcare Health System), Charleston, WV; Children's Hospital Medical Center, Cincinnati, OH; Cook Children's Hospital, Fort Worth, TX; Arkansas Children's Hospital, Little Rock, AR; Children's Hospital Los Angeles, Los Angeles, CA; Le Bonheur Children's Medical Center, Memphis, TN; Children's Hospital of Wisconsin, Milwaukee, WI; Children's Hospital of Orange County, Orange, CA; Lucile Salter Packard Children's Hospital at Stanford, Palo Alto, CA; Children's Hospital of Pittsburgh, Pittsburgh, PA; All Children's Hospital, St. Petersburg, FL; Children's Hospital and Health Center, San Diego, CA; and Children's National Medical Center, Washington, DC.

The first project, Medication Safety I, was undertaken in 1998 and focused on the following aspect of medication safety: decreasing prescribing errors in the pediatric intensive care unit (PICU). As a result there was a 24.7% decrease in the PICU medical prescribing error rate, a 73.9% increase in intercepted errors, and 49.2% reduction in prescribing errors that were not intercepted.

Medication Safety II focused on improved identification via an organizational review looking at patterns during a 12-month period utilizing the Institute for Safe Medication Practices' self-assessment survey. The goal of this phase of the project was to decrease adverse drug events and potential adverse drug events associated with sedatives and analgesics by 75%.

The third project, Medication Safety III, utilized a "trigger" chart review methodology in a pediatric inpatient setting to identify a greater number of harmful adverse events than traditional voluntary reporting systems. "Triggers" are defined as occurrences, prompts, or flags found on review of the medical record that trigger further investigation to determine the presence or absence of a medication error. This methodology is based on the work of David Classen, MD, with additions by the Institute for Healthcare Improvement's Idealized Design of Medication System. Twelve sites participated in Phase III of the project and more than 900 charts from these sites were reviewed. A trigger list including 24 items was compiled for reference throughout the chart review process. The results of this phase are centered on the following demographics: the average age of the patient is 5.9 years, the principle discharge diagnosis is respiratory, and the most common unit of admission is general medical. Across all sites an average of 13.8 unique medications were used per patient; an average of 69.8 medication doses per patient was found; 1,730 triggers were identified for the study selected patients; and on average, 1.9 triggers per patient were identified.

This initial data supports the following: a modified trigger system identifies more adverse drug events than traditional reporting systems. For example, the rate of adverse drug event identification per 100 hospital days was 40% higher than hospital-wide reporting mechanisms. The most active triggers or those being identified most often, identifying the greatest number of adverse drug events, and having the highest “yield” of adverse drug event identification rate include the following: diphenhydramine; antiemetics; Narcan; sodium polystyrene; PTT>100 seconds (laboratory finding for Prothrombin Time); rising serum creatinine levels; oversedation, lethargy, a fall, hypertension; rash, and abrupt discontinuation of medication.

The next phase of this project, Phase IV, will target the nine most active pediatric triggers, test additional pediatric triggers, use PDA technology for data collection, and embed adverse drug event clinical outcomes into the study design. In terms of safer medication practices, the goal is the adoption of CHAI pediatric triggers and integration into computerized physician order entry as the industry standard.

The CHAI collaborative serves the Child Health Corporation of America (CHCA) alliance-wide patient safety effort by generating and testing appropriate strategies for use by all. This effort focuses on the development of a medication rule sets for computerized physician order entry and pediatric applications of Agency for Healthcare Research and Quality (AHRQ) Patient Safety Best Practices that are currently under development. These AHRQ Best Practices are evidence-based and most have been designed around adult care delivery. The challenge is to define pediatric applications for implementation and monitoring. To date, 95 medication rule sets have been developed through a collaborative of CHAI and CHCA Pharmacy Forum participants. Rule sets provide dose range and standardization parameters, when appropriate, and identify other key administration rules for high-volume medications used in pediatrics. The Child Health Corporation of America Pharmacy Forum, with the support of key hospital clinicians, will spearhead the development of new rule sets for use by all Owner Hospitals (the children’s hospitals comprising CHCA own the corporation).

The UNC Medication Safety Program

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The University of North Carolina Medication Safety program was initiated based on problems with the historical “medication error” process at that institution. These problems included forms that were difficult to complete, extended turnaround time, fear of punitive action, reports that did not reflect the root cause of the medication error, limited peer review, and no single database for reporting. As a result, the Medication Use Safety Committee was established in February 2000 to provide oversight to the Medication Safety Program. This multidisciplinary committee includes physicians, nurses, registered pharmacists, and risk management and continuous quality improvement personnel. A subcommittee specifically focused on patient care also was developed.

In an effort to transition from using “error-oriented” terminology, the phrase “medication variance” was instituted. This includes any preventable event that may cause or lead to

inappropriate medication use and/or patient harm. It includes those events that result in patient harm as well as circumstances or incidents that have the potential to cause patient harm. Severity levels from 0 to 6 were developed, with 0 as the least severe, meaning that no actual incident took place, although the potential for harm exists, and 1, indicating that an incident did not result in patient harm, and 6, the most severe, indicating that the incident resulted in death.

From February 2000 until the present the pediatric pilot of the Medication Safety Program has been under way. The data collection form was redesigned and a Scantron® form is now used. In addition, the nonpunitive approach with a focus on systems, not people, has been reinforced. The reporting process has been redesigned, and reports are collected daily from units and analyzed by a pharmacist for root causes and opportunities for practice improvement. Reports are also distributed to peer reviewers within 24 hours of collection for additional input. A reporting database has been created.

Historically, 20 pediatric-related medication variance reports were received per month at this institution; with the initiation of the nonpunitive reporting approach, the number of reports increased to 200 to 400 per month, representing a tenfold increase in the number of reports per month. Furthermore, the new reporting system provided more detail as to the types of occurrences. For example, administration variances were determined to be less than 10% of reports (previously thought to be 70%), and prescribing variances now constitute 25% of reports (previously thought to be 6%).

The successes of the pilot program include a significant increase in reporting, quick and in-depth evaluation of reports, the generation of numerous improvement projects, and the move to action beyond blame.

The UNC Center for Medication Safety serves as a clearinghouse for safe medication practices and functions as a leadership group within the institution, state, and nation. Medication Safety Officers from within the UNC Center for Medication Safety review incidents, analyze data, and develop strategies for safe medication use; they include three pharmacists, one nurse, and one pharmacy technician. The program's pediatric pilot project has been expanded to all UNC acute and ambulatory care areas and similar response rates have been reproduced in the adult areas. Staff members are currently devoting a significant amount of time to the analysis and communication of the program results.

Programmatic challenges exist and include lack of physician participation in the completion of reports, the need for more active physician leadership in patient safety, as well as the dissemination of findings to physicians.

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PATIENT SAFETY SIMULATION

Organizing and Improving Care in the Health Care Microsystem

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Research on the delivery of care has focused on the level of the larger organization or at the level of the individual provider. This unit of analysis misses the “microsystem” that is at work at the front lines of patient care. Until the microsystem is recognized as the unit of work and the unit of analysis, there will continue to be a disconnect between the larger organization and the front lines.

A *microsystem* is defined as a small group of clinicians and staff working together with a shared clinical purpose to provide care for a defined set of patients. It is the clinical purpose that defines the essential parts of the microsystem. A microsystem must be large enough to accomplish its clinical purpose, but small enough to allow knowledge of the individual parts and the interrelationships between the parts. Microsystems may be part of a larger organization and are embedded in a legal, financial, social, and regulatory environment. Microsystems can be found everywhere, including pediatric practices, neonatal intensive care units, renal dialysis teams, and cardiac surgery teams. Even though microsystems can be found everywhere, it is important to note that not all microsystems are equal in their ability to achieve excellent clinical outcomes for their patients or excellent performance outcomes for their organizations.

Patients may interact with several microsystems as they navigate the health care system. The handoffs between microsystems can be difficult and confusing to navigate. The essential elements of a microsystem include a core team of health professionals, a defined population of patients, information and information technology, support staff, equipment and environment, and processes and activities specific to accomplishing the aim.

The Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health System*¹, suggests that patient safety is a systems issue, thus potential solutions should be targeted at the system. To translate this recommendation into the daily work of providing care, we must explore the link between patient safety and the microsystem. The overwhelming amount of the daily work of providing care is part of a microsystem – a small, organized patient care unit with a specific clinical purpose, set of patients, technologies, and practitioners who work directly with these patients. The system changes that are required to improve patient safety need to occur where patients and providers meet on the front lines of health care – the microsystem.

In an interactive session designed by Julie Mohr and Paul Barach, participants have the opportunity to explore the interface between safety and the microsystem. The goal of the microsystem patient safety simulation is to practice using tools designed to assess and improve the functioning of the microsystem and to improve patient safety. At this conference, teams of six people per team were assembled, with each team representing a newly formed Patient Safety Task Force. With each member of the Task Force assuming an assigned role (e.g. physician, nurse, parent, pharmacist, hospital administrator), the group discussed a situation involving a sick child. In this scenario, the child and her mother interact with several microsystems; the mother found the handoffs between microsystems to be difficult and confusing and somewhat intimidating. An assigned observer monitored each team. Each Task Force met to discuss the patient safety scenario; they were instructed to review what happened, use an Incident Analysis

Worksheet to identify possible process failures, and to brainstorm possible countermeasures for the failures in process they identified.

The Incident Analysis Worksheet is based on what is known about high performing microsystems.²⁻⁴ Categories contained on the worksheet include leadership, culture, organizational support, patient focus, work environment, interdependence of care team, and information and information technology. Leadership is needed so that the constancy of purpose is maintained and clear goals and expectations are established; leaders also foster a positive culture. There may be several types of leaders, ie, formal leaders, information leaders, and “on the spot” leaders. Culture determines a pattern of values, beliefs, sentiments, and norms that reflect clinical mission, quality of staff work life, and respectful patterns of interpersonal relationships. Organizational support indicates when the larger organization provides recognition, information, and resources to enhance and legitimize work. Patient focus emphasizes meeting all patient needs including caring, listening, educating, and responding to special requests. It also includes smooth service flow and establishing the relationship with community and other resources. Work environment focuses on building design, functionality, and maintenance – for the physician environment and housekeeping; it also includes staffing, education and training, and workload/hours of work. A multidisciplinary care team characterized by trust, collaboration, appreciation of complementary roles, and a recognition that all contribute individually to a shared purpose are the core elements of the interdependence of the care team. Finally, information is key to the entire process. Technology can facilitate and smooth the links between information and patient care by providing access to the rich information environment.

By the end of the simulation, participants learn that the causes of errors belong to the system and, consequently, often lie outside the control of individuals, despite their best efforts. Furthermore, they learn that failures in the system allow an error to occur and go undetected and that solutions for the microsystem include designing the system to prevent errors (or make them less likely), designing procedures to make errors more visible, and designing procedures to mitigate the effects of errors when they do occur.

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SMALL GROUP BREAKOUT DISCUSSIONS

Small breakout group discussions were held during the course of the patient safety conference. Three separate groups focused on patient safety issues: 1) in the various ambulatory

environments; 2) in the inpatient setting; and 3) on policy and regulatory issues specific to the pediatric population. Group participants were charged with identifying the patient safety issues and challenges in their respective settings and developing strategies and action steps. Each group developed recommendations to assist in formulating a clear, comprehensive patient safety agenda for the AAP and its partners. Many of the patient safety strategies were repeated across all three breakout groups including developing a clearinghouse/website of best practices, incorporating patient safety into residency curriculum, and encouraging AAP committees and sections to incorporate patient safety into their strategic plan.

Ambulatory

The majority of children's healthcare takes place in non-hospital settings. Children receive care and therapeutics in numerous non-hospital and non-clinical settings and from a variety of providers: outpatient clinical settings (e.g., public health departments, community health centers, private primary care and subspecialty practices); home from parents as well as home health care professionals; daycare and school settings from health care professionals, administrators, educators, and lay caregivers. In these diverse settings, health care regulations and protocols may be informal, may not be strictly monitored, or may not even exist. Children must rely on adults for health care supervision, which often is shared among custodial and non-custodial parents, relatives, guardians, and others who care for the child on a temporary basis (e.g., babysitters). Because of the diversity of settings in which the child receives healthcare or medications, multiple 'handoffs' often take place within and across informal networks. The more numerous or complex the 'handoffs,' the greater the likelihood that errors will occur. Much of the discussion in the ambulatory breakout group centered on better understanding the types and scope of ambulatory errors, improving communication across the various outpatient settings in which children receive care, and developing practical tools and effective strategies to enhance safety.

Group members recommended that the Academy act on the following:

Understand the type and scope of ambulatory errors

- Work with the AAP Pediatric Research in the Office Setting (PROS) network to test an anonymous medication error reporting system.
- Develop a self-assessment tool for use by ambulatory setting personnel focusing on the outpatient environment, communication with schools, care coordination, information management, and policies and procedures.
- Conduct an AAP Periodic Survey of members on perceived patient safety problems in ambulatory settings.
- Study safety issues in schools and child care centers.
- Advocate for continued funding for epidemiologic studies on pediatric patient safety in the ambulatory setting.

Develop tools and resources

- Develop a clearinghouse of patient safety strategies, policy statements and key articles appropriate for office-based settings.
- Compile a list of 'best practices' for administering medications, particularly in non-hospital settings and disseminate it to pediatric healthcare providers.

- Standardize medical forms, particularly the section on medications, used for communication with schools, child care centers, and home health agencies.
- Create a ‘patient safety’ site with easy access on the Academy’s web page.
- Compile and disseminate information on accrediting bodies’ safety standards, activities, and initiatives.
- Embed patient safety topics into residency curricula and pediatric board examinations.
- Collaborate with other organizations on pediatric patient safety issues (e.g., the American School Health Association and the Centers for Disease Control and Prevention).
- Develop companion self-assessment tools for use by individual practitioners and clinic systems.
- Interact with vendors of patient safety-oriented technological systems to advocate for the use/inclusion of pediatric information.
- Develop a better understanding of computerized physician order entry technologies (e.g., Personal Digital Assistants [PDAs], etc) and make informed statements about them to the membership and others.

Raise awareness and share ‘best practices’

- Create an active campaign to educate AAP members and parents about pediatric patient safety with an emphasis on open discussion of safety issues and the importance of a non-punitive approach to errors.
- Develop a patient safety strategy addressing over-the-counter medications and the use of complementary and alternative medicine.
- Emphasize the importance of standardizing and using medical forms to improve communication with schools, day care centers, and home health agencies.
- Work with the AAP Steering Committee on Clinical Informatics and Technology to evaluate computerized physician order entry and the use of Personal Digital Assistants in ambulatory settings.
- Encourage each Academy committee and section to include a focus on patient safety as part of its goals and objectives.

Inpatient

The participants in this breakout session represented various hospital settings in which children receive care: the community hospital, the academic medical center, the children’s hospital, the emergency department (ED), the neonatal intensive care unit (NICU), and the pediatric intensive care unit. They discussed the need to coordinate care across the multiple inpatient environments, the lack of pediatric-appropriate measures, the paucity of pediatric-specific informatics tools, the task of facilitating the development of ‘culture of safety,’ and the challenges of implementing computer physician order entry. In addition, this group noted that much could be learned from colleagues about innovative efforts already underway. The group also pointed out the conference’s greater emphasis patient safety in the ambulatory setting, perhaps because children receive much of their care in this environment. It was noted that while research needs to be done on patient safety in the ambulatory setting, patient safety research should continue in the inpatient settings, perhaps looking more closely at issues specific to the various areas such as the NICU and ED.

This group recommended that the Academy act on the following:

Raise awareness about patient safety

- Share Patient Safety Conference proceedings with relevant AAP committees and sections in an effort to heighten awareness among groups within the organization and encourage them to consider a patient safety focus in policy statements, manuals, and other resources as relevant.
- Develop an educational piece for parents/families outlining questions they should ask regarding patient safety issues.
- Work with other organizations to implement patient safety training modules with an emphasis on teamwork and non-punitive communication.
- Address patient safety issues in medical school, residency, and CME curriculum.

Develop resources

- Compile all AAP policy statements and key articles on patient safety in one location on the AAP web site so that they are easily accessible with a visible presence.
- Conduct an inventory and establish a database of groups and individuals working on patient safety programs and/or research as well as a clearinghouse of relevant resources.
- Develop a common lexicon for pediatric patient safety to highlight child-specific measures and standards.

Coordinate efforts among groups interested in patient safety

- Take a leadership role in coordinating pediatric patient safety efforts and continue networking efforts and partnership building with organizations and individuals represented at the Pediatric Patient Safety conference and with other key partners.
- Identify key patient safety advocates in inpatient settings and those organizations representing inpatient-oriented institutions. Involve these individuals/organizations in current and future activities.
- Develop a core patient safety coordinating group including representation from anesthesiology, critical care, and the National Patient Safety Foundation to prioritize work and determine the best strategies for the next steps.
- Enhance communication with the Joint Committee on Accreditation of Healthcare Organizations (JCAHO) to increase the visibility and understanding of pediatric-specific issues.

Support the assessment of pediatric patient safety at the local level

- Develop a standard assessment tool and related checklist specifically focused on pediatric patient safety for use by institutions to determine relevant issues related to patient safety.
- Develop a tool kit for use by organizations, residency training programs, AAP Chapters and individual pediatric health care providers/clinicians in their efforts to address pediatric patient safety on the local/institution level. The toolkit should include a module for parents/families, and nonspecialty-focused messages should be emphasized.
- Determine strategies to address conflicting messages in patient safety research and ongoing program activities.

Policy and Regulatory

This breakout group consisted of representatives from the federal Agency for Healthcare Research and Quality (AHRQ), several non-profit organizations dedicated to enhancing patient and pharmaceutical safety and disseminating standards, the AHRQ-sponsored pediatric Center for Education and Research in Therapeutics (CERTs) at the University of North Carolina at Chapel Hill, and academic pediatricians with expertise in information technology as well as those interested in policy issues.

This group proposed that the Academy take action in the following areas:

Legislative

- Support legislation to promote nonpunitive, voluntary reporting and regulations on standards for labeling of drugs used in pediatrics. Also, promote legislation mandating increased communication across various microsystems of care.
- Develop a checklist of priority items that should be included in any legislation and related rules/regulations on pediatric patient safety.
- Disseminate information on the “Best Pharmaceuticals Act” to AAP members.
- Review existing legislation that might need to be amended due to the trend toward patient safety in pediatrics, i.e., Clinical Laboratory Improvement Act (CLIA).

Policy action

- Encourage malpractice insurance carriers to provide discounts as incentives for practices/individual clinicians who participate in educational programs on pediatric patient safety.
- Engage with other organizations and institutions to highlight and advance pediatric patient safety issues (e.g., the Institute for Safe Medication Practices, Agency for Healthcare Research and Quality, United States Pharmacopeia, Association of Health System Pharmacists, Joint Commission on Accreditation of Healthcare Organizations, National Association of Children’s Hospitals and Related Institutions, and the American Pharmaceutical Association).
- Involve the AAP Department of Education in sharing knowledge among members and families using a variety of educational modalities and venues.
- Incorporate patient safety into medical school, residency, and CME curriculum.
- Recommend that the American Board of Pediatrics consider inclusion of patient safety questions on future Board examinations and in programs for maintenance of certification.
- Advocate for pediatric-specific medical and clinical devices, pharmaceuticals, and/or measures.
- Promote the development of sentinel sites in the PROS network that test patient safety interventions.

Summary

Despite good intentions and models of exemplary practices, health care for children is not as safe as it should or could be. Not only does the AAP play a unique advocacy role in children’s healthcare but the Academy also is the primary resource of knowledge-based best practices for clinicians who care for children. The conference attendees acknowledged that, in its leadership

role, the Academy plays a key part in making health care safer for children. Conference participants encouraged the Academy to:

- Raise awareness about pediatric patient safety issues among families, AAP members, committees, sections and chapters, and in the settings in which children receive care and therapeutics.
- Compile safety resources (e.g., standards, measures, tools and best practices) and make available for members and families.
- Facilitate the collaboration of individuals, institutions, and organizations to make health care safer for children.
- Support efforts to improve the quality and safety of healthcare for children.

The Academy will work together with conference attendees as well as additional interested Academy members and patient safety experts to advance the action agenda proposed by conference participants.¹ Building on the recommendations of conference participants, key efforts will be organized along the themes of policy and advocacy, ambulatory issues, inpatient care safety, and tools for improvement (e.g., resources and information technology).

A collaborative effort such as this conference helps develop a common vision, focus efforts, and energize concerned health care leadership. In response, the American Academy of Pediatrics will work to make health care safer for children.

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¹ In one example of post-conference collaboration, the AAP and AHRQ collaborated on a parent education sheet, “Twenty Tips for Pediatric Patient Safety” which is available at www.ahrq.gov. This sheet was distributed in the January 2003 issue of *AAP News*, discussed in newspapers and highlighted on the *Today* show.