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3:00 P.M. January 5, 2001

“Dr. Ellington wrote an order for 0.8 milligrams (mg) per hour of morphine,” Nurse Ginny Swenson explained to Patrick O’Reilly, a newly hired nursing school graduate. Swenson had just wheeled Matthew, the ten-year old patient, from the intensive care unit into his new room on the medical/surgical floor.¹ She described Matthew’s condition and instructed O’Reilly to program the electronic infusion pump so that the child would receive his prescribed dosage of morphine. Swenson then returned to her unit, leaving O’Reilly alone with Matthew. O’Reilly was not familiar with this type of electronic infusion pump, having only operated one during a training exercise. Recognizing his lack of experience, O’Reilly sought and obtained help from Nurse Molly Chen, who agreed to help him program the pump. Unfortunately, none of the nurses on the floor were accustomed to using these pumps because patients in this unit typically did not need continuously infused painkillers. To program the pump, Chen needed to enter both the morphine concentration and the appropriate rate of infusion. The nurses did not see a concentration listed on the medication label; however, Chen utilized information on the label to calculate the concentration. See **Exhibit 1** for a copy of this label. She also entered the rate of infusion at 0.8 mg per hour, as Nurse Swenson had instructed. Following hospital procedures that required a second person to double check intravenous medications, O’Reilly verified Chen’s calculations and the settings that she had programmed into the machine. Then, Chen returned to her other patients, and O’Reilly helped Matthew settle into his new room.

After several minutes, O’Reilly glanced at Matthew’s face and realized instantly that something had gone terribly wrong. Matthew’s face had turned blue, and he was experiencing respiratory arrest. O’Reilly’s stomach dropped. Had he given Matthew an overdose of morphine? He immediately turned off the narcotic, began ventilating the patient with a breathing bag, and asked someone to call Dr. Ellington. Within minutes, Dr. Ellington arrived on the floor and confirmed that Matthew had received several times the ordered dose of morphine. Recognizing that this dosage could be lethal, Dr. Ellington administered a drug that reversed the effect of the morphine. Thankfully, within seconds of receiving this drug, Matthew’s breathing returned to normal, and he

¹ A similar version of the following incident took place at Children’s Hospitals and Clinics in Minneapolis, Minnesota. However, to protect patient and staff confidentiality all names, dates, and some details in describing this incident have been changed. Names and descriptions in the rest of the case are factual.

Doctoral Candidate Anita Tucker prepared this case under the supervision of Professors Amy Edmondson and Michael A. Roberto. HBS cases are developed solely as the basis for class discussion. Cases are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

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made a full recovery. However, the incident left O'Reilly shaken and concerned. How could this have happened? Was he responsible for this near-fatal accident?

4:00 P.M. January 6, 2001

Dr. Chris Robison, Associate Director of Medical Affairs, shut the door and looked at the nine people who had been directed to attend a "sequence of events interview" following Matthew's overdose. Attendees included those directly involved in providing care for Matthew, the pharmacist who prepared the morphine bag, several supervisors, and two scribes. The group spent several hours participating in a focused event analysis – a structured problem-solving procedure employed to identify the causes of medical accidents – and to determine how the hospital could avoid such accidents in the future. See **Exhibit 2** for a glossary of medical safety terms.

Robison began the meeting by distributing a handout that summarized the procedure they would employ to conduct the focused event analysis. He explained:

We have four objectives today: to understand what happened, to identify opportunities for improvement, and to support the caregivers, patient, and family that were involved. Today, we will focus primarily on documenting the process flow of yesterday's events. We have three ground rules for this discussion. First, it is a blameless environment; we are not here to find a scapegoat but to identify failures in our operating system. We want to reveal all of the issues and problems in an open discussion. Second, this process is confidential. Please do not reveal the name of the patient or the identity of the caregivers. Third, we ask you to think creatively about how to improve our systems and processes. Try to envision the patient as your own child and to identify systems that you would like to have in place to ensure your child's safety.

During the session Robison asked questions in order to identify, understand, and diagram the sequence of events that led to the morphine overdose. Robison started by asking O'Reilly to describe what happened, and then expanded the discussion to incorporate other perspectives. As they talked, Robison recorded the details carefully on an overhead projector. As he facilitated the discussion, Robison made sure that the physicians did not dominate. He frequently asked, "Have we documented the process accurately? Are we missing something?" Ultimately, the group created a single process flow diagram documenting the sequence of events.

2:00 P.M. January 7, 2001

Julie Morath, Chief Operating Officer at Children's, sat in her office reviewing the findings from the focused event analysis. As she finished reading the report, Dr. Robison and his boss, Dr. Terry Hart, entered her office. Robison and Hart facilitated all focused event studies at Children's. The subsequent discussion covered three difficult issues. First, they discussed the causes of the accident and the changes that should be implemented to prevent similar accidents in the future. Second, they wondered how much they should tell Matthew's family. Finally, they grappled with the issue of responsibility and accountability for the incident. In this discussion, they were keenly aware that the stakes were high and that they had little time to make a decision. Matthew's family would want to know who was responsible for this accident, and would want the individual(s) held accountable.

Children's Hospital and Clinics

Children's Hospital and Clinics (Children's) was formed in 1994 when Minneapolis Children's Medical Center merged with Children's Hospital-St. Paul. Brock Nelson, who had been the chief executive of the St. Paul hospital since 1983, became the CEO of the new organization. By 2001, Children's provided medical services for infants, children, and adolescents in six facilities located throughout the Minneapolis-St. Paul metropolitan area. Medical services ranged from primary care to complex procedures such as open-heart surgery and cancer treatment. The hospital had 270 staffed beds, 3,455 employees, and approximately 1,500 physicians who practiced at its facilities. See **Exhibit 3** for other operating statistics and measures of financial performance.

Julie Morath

Julie Morath became the Chief Operating Officer of Children's Hospital in May, 1999. She brought 25 years of experience in patient care administration to the job, as well as her training and expertise as a registered nurse. Prior to joining Children's, she worked for five years as system vice president for improvement at Allina Health Systems – a firm that operated 19 hospitals and 48 clinics throughout Minnesota.

While working for Allina, she attended the Executive Sessions on Medical Errors and Patient Safety at Harvard University. These sessions introduced her to the notion that medical errors typically result from a series of small breakdowns in complex systems, not simply from the mistakes or incompetence of one nurse or doctor. Morath embraced the concepts that she learned at these sessions, and was eager to apply the concepts “on the front lines” in order to improve patient safety. She explained her personal transformation on this issue:

The health system produces health, but it also produces harm. I had spent my entire career worrying about patient safety and cautioning people to be more careful. I came to recognize that these small-scale attempts to fix problems were not enough. While my job at Allina was intellectually stimulating, it was too distant from front-line action where care is administered to effectively create change and make a difference with regard to patient safety. The sessions at Harvard made me realize that I could truly have a significant impact if I could lead a corporate-wide initiative that focused an entire organization on safety as a top priority.

Concurrent with Morath's desire to have more responsibility for patient safety, CEO Nelson found himself in need of a Chief Operating Officer. Nelson explained how he came to hire Morath for the position:

I knew that I wanted an experienced person for the position. I did not know Julie well, but she had a reputation for being an excellent manager and an expert on patient safety. I told the recruiter, 'I want someone like Julie Morath.' After I said that, we decided to try to hire Julie.

Morath relished the opportunity to launch a major initiative on patient safety at Children's:

The traditional COO role did not excite me, but I was excited about having the ability to highlight patient safety and to create a culture where the concept of 'do no harm' was explicit rather than implicit. The opportunity to focus and align teamwork and operations around the science and principles of safety was the exciting challenge.

During the interview process, Morath began to talk with Children's employees about her vision and her ideas concerning patient safety.

As part of my entry into the organization, I had carefully crafted conversations around the topic of safety with people who would have to be on board with the initiative. I did spade work, talking about how we could align the whole organization so that safety was not just a problem for people out on the front lines but was owned by administrators who designed and operated many of the hospital's systems. It is difficult to broach the topic of safety because most people get defensive. Talking about safety implies that we are doing things "wrong." However, I found that most people had been at the center of a health care situation where something did not go well. They were quick to recognize that the hospital could be doing things better than it was.

Taking Charge

When Morath joined Children's, patient safety became her top priority. She began by assembling a core team of people to help design and launch the Patient Safety Initiative. By August of 1999, she had enlisted the help of several 'key influencers'—people who others in the organization respected for their medical expertise, experience, track record at Children's, and dedication to providing exceptional patient care. Morath and Nelson partnered with Dr. Terry Hart, the hospital's Medical Director, to garner his input and suggestions and to insure that he understood their strategy for enhancing patient safety. They believed that Dr. Hart's leadership would be instrumental in building support for the effort among doctors and nurses at Children's.

With the help of this core team, Morath set out to accomplish three critical tasks during her first few months at Children's. First, she spent time making presentations to hospital staff about national research on medical errors. Second, she conducted focus groups to learn more about patient safety issues at Children's. Third, she developed a detailed strategic plan for the Patient Safety Initiative. See **Exhibit 4** for a timeline of events related to this initiative.

Presenting Medical Accident Data

Morath began by providing the hospital staff with evidence regarding the size and scope of the problem of medical errors in the United States. She presented data from the Harvard Medical Practice Study on the frequency and causes of medical errors. For example, she explained to staff members as many as 98,000 people died annually from medical errors, higher than the number of individuals who die annually from motor vehicle accidents, breast cancer, or AIDS. For additional information about medical error rates, see **Exhibit 5**, which presents data from a subsequent report that summarized findings from recent research, including the Harvard study.

Morath found that many people initially were reluctant to believe that errors might be a significant problem at Children's. She explained how the staff reacted to her early presentations:

People were at first skeptical of the applicability of the national data. I asked them, "Okay, this data may not be applicable. So, tell me, what was your own experience this week regarding patient safety and was that satisfactory?" As people began to discuss incidents that they originally thought were unique or idiosyncratic, they realized that most of their colleagues had experienced similar events.

During her numerous presentations to hospital personnel, Morath highlighted the need for a change in the way that medical professionals thought about accidents. She repeatedly described her philosophy on patient safety:

Health care is a very complex system, and complex systems are, by their very nature, risk-prone. The culture of health care must be one of everyone working together to understand safety, identify risks, and report them without fear of blame. We must look at ways to change the whole system when we manage to zero defects.

Through these efforts, Morath tried to convince the staff that errors were indeed a problem for all health care organizations including Children's and that a new approach to safety could reduce accidents. She also attempted to persuade the staff that talking more openly about errors would improve patient care without damaging people's careers or exposing the hospital to new legal risks.

Conducting Focus Groups

In these early months, Morath also started to gather data on the current state of patient safety, and to dismantle the barriers that prevented people from discussing medical accidents. She enlisted Susan Wiecker, a market researcher, and Ginger Malone, a registered nurse, to conduct confidential focus groups throughout the organization. Planning began in August 1999, and Malone conducted the interviews in October. Morath wanted to involve many people from different areas of the organization and hoped to use the sessions to get people energized about the initiative and thinking creatively about ways to enhance patient safety. Malone conducted 18 focus groups with doctors, nurses, pharmacists, and many others throughout the hospital. These sessions created much enthusiasm for the safety effort. Employees and clinical staff felt relieved to have a safe place to discuss their experiences with medical errors. Morath commented on the impact of the focus groups:

As we conducted the focus groups, my office became a confessional. People who had been involved in medical accidents, even at a time and place distant from here, carried that experience with them in a vivid way. The need to talk about the experience was so important to them. It is devastating to fail a patient and especially devastating to fail a child. Each and every person involved with an accident holds onto that incident.

Neonatal intensive care nurse and union leader Linda Hamilton described how the focus groups motivated her to become a key participant in the Patient Safety Initiative:

After our focus group, I signed on to be involved with the quality initiative. In fact, I relished the idea because no one wants to be involved in an unfortunate accident where a patient is harmed or dies. We have all seen, heard, or been part of an accident. There is nothing worse. It is devastating for the person and family involved. The nurse is also left hurting for the rest of her or his life. I was willing to do anything that I could to prevent future accidents.

The most controversial aspect of this effort involved getting approval to hold a focus group with a set of parents. Hospital employees feared that starting a discussion about medical accidents would alarm families, and perhaps might imply that the hospital was not safe. Ultimately, Morath did obtain the Board's approval to conduct a focus group with parents. During the discussions, families indicated that they were well aware of many medical errors and "near misses." Rather than increasing anxiety, the focus group provided a welcome opportunity for parents to speak openly about their own experiences, and to offer suggestions for improving patient care. Together, the employee and parent focus groups provided a wealth of information about the current state of patient safety, identified some of the underlying causes of medical errors at the hospital, and surfaced many suggestions for how to enhance existing processes and systems.

Formulating the Strategic Plan

During the second half of 1999, Morath launched a strategic planning process to define the organization's goals and objectives for the next five years. Patient safety was one of the four main "planks" of this strategic plan. To further emphasize the importance of her patient safety agenda, Morath coined the acronym SAFE to summarize the four components of the hospital's strategic plan - SAFE stood for Safety, Access, Financial, and Experience. Each plank represented a promise that the hospital made to its patients and their families. For example, the safety plank promised to "do no harm." Similarly, the experience plank promised "nothing for me without me", emphasizing the hospital's commitment to involving patients and their families in the decisions that the clinical staff made about their health care.

Each plank identified clear goals and critical tasks required to accomplish them. The *safety* component of the plan established the objective of achieving zero defects in the delivery of clinical care and medication to patients. Key tasks for the coming year included developing a new safety reporting system and auditing two high-risk medical procedures, followed by implementation of appropriate process improvements. Another goal set was improving *access*, which involved eliminating deferrals, improving cycle time, and increasing the number of patients served each year. The *financial* component of the plan established goals related to cash flow, return on capital, and productivity. Finally, the *experience* "plank" focused on enhancing patient/family satisfaction as well as improving relationships with physicians and other employees. For more information on the content of the strategic plan, see **Exhibit 6**.

Nelson believed that the strategic planning process was a useful tool for aligning the organization behind a clear set of objectives, particularly with respect to patient safety.

What is hard in many organizations is to align upper management and front-line workers. If these people sit down at a table to have a discussion, often you have a disconnect between the administrators and the people working hard providing patient care. The patient safety agenda is the first initiative that I have seen that brings everyone together because everyone has the same goals. I can translate these goals to all levels in the organization and relate what we are doing to address patient safety to their work. The person pouring mashed potatoes feels as important as a doctor does. Physicians, pharmacists, nurses, technicians, physical therapists all have the same interests. I don't have to spend my time telling people why this is important. I have to show them that I mean it and that I have a plan in place, but I don't have to convince people that this is a good idea.

Implementing the Patient Safety Initiative

In September 1999, the Board of Directors approved Morath and Nelson's aggressive plan to implement a patient safety agenda. The plan had three main components. First, Morath wanted to transform the organizational culture to provide an environment conducive to discussing medical accidents in a constructive manner. Second, she aimed to develop the infrastructure required to implement safety improvements. Third, she launched a project to overhaul the medication administration system at the hospital.

Culture

Morath set out to create a culture that welcomed open and frank communication about safety issues. She wanted to establish an environment in which everyone focused on learning from past

mistakes, rather than “pointing fingers” when something went wrong. To that end, Morath took several important steps. She created forums where staff members could come together to discuss safety issues and to learn more about current research in the field. Second, she instituted a “blameless reporting” system for recording medical errors. Third, she created a common language that everyone could utilize to discuss accidents. Finally, Morath established a new disclosure policy regarding how to communicate with parents about medical accidents.

Patient Safety Dialogues Morath created a series of sessions for Children’s employees and clinical staff to come together to learn about the current state of research on medical safety, as well as to discuss other safety-related topics. She invited national speakers to Children’s to give mini-courses on safety. Speakers included Dr. Henri Manasse, Jr., Chairman of the Board of the National Patient Safety Foundation, and Dr. Richard Cook, a professor at the University of Chicago Medical School. Attendance at such events grew from approximately fifty people to over two hundred. To supplement these seminars, Morath gathered literature on the science of safety into a self-study packet that employees could complete for continuing education credits. Many employees took advantage of this opportunity to learn about the science of improving safety in complex systems.

Blameless Reporting Morath orchestrated a new system for reporting medical accidents, which she called “blameless reporting.” The idea was to allow people to communicate confidentially and anonymously about medical accidents without being punished, so as to surface as many of the problems as possible, and to determine the underlying causes of these accidents. To implement this, the hospital staff created a new Patient Safety Report. To complete the old form, employees simply checked off the appropriate boxes in order to help administrators categorize the incident and thereby provide aggregate data to national agencies that monitored the type and frequency of medical accidents. By contrast, the new form also asked employees to describe the incident in their own words, and to comment on the events that occurred as well as the potential causes of the situation. See **Exhibit 7** for a copy of the new safety report.

Hamilton commented on how this policy differed substantially from the traditional way that accidents had been handled at Children’s:

When accidents happened in the past we nurses were disciplined, “You have to be more careful.” It was not always formal discipline, because the union contract stipulated that disciplinary action could not be imposed on nurses unless there was a pattern of bad behavior. However, the informal reprimand was something like, “You bad nurse.” It was a blame and shame culture. It used to be, “Who did it?” Now it is, “What happened?”

Blameless reporting encouraged front line workers to use patient safety reports to discover and eliminate breakdowns in hospital systems and processes. Dr. Thomas Hellmich offered an example of how blameless reporting had changed people’s behavior:

I was involved in a case where there was a child in cardio-respiratory arrest. I responded to the code. There were significant—I’ll say errors—during the code, though these errors did not affect the outcome for the patient. Immediately after it was over, the first thing we did was to say, ‘What can we learn from this?’ This would not have happened a year earlier. It wasn’t the old ABC model of medicine: Accuse, Blame, Criticize. What kicked in was a different model: blameless reporting. We sat down and filled out a safety report and acknowledged all the different components that went wrong and did root cause analyses. Through a series of follow-up meetings, we made different kinds of improvements including providing more training for that unit on how to run a code.

However, not everyone was enthusiastic about this new approach. Several employees expressed concern about the inability to reprimand individuals involved in such events. Some unit managers wondered how they could hold people accountable if they were not able to discipline people for making mistakes. Moreover, some members of the professional staff still believed that many errors occurred due to incompetence rather than failed systems. They worried that blameless reporting might make it more difficult to identify poor performers in their units.

Language To foster candid dialogue about medical accidents, Morath tried to change the way that people discussed safety issues. Ginger Malone explained:

We have spent a lot of time in the last two years really understanding what words to say and what words not to say. Even as fundamental as the word 'study' - we try to use it instead of 'investigation.' They have very different meanings. We try to talk about medical 'accidents'. We really don't use the term 'errors' because, to nurses and others, it feels very punitive. We talk more openly about 'systems' failures and not 'people' problems.

Indeed, Morath emphasized the avoidance of several words that were indicative of a culture where people "pointed fingers" at others, rather than trying to learn from mistakes and failures. For example, she stressed the use of the word "examination" as opposed to "investigation" for reviewing a medical accident. She believed that the former suggested a process of careful and systematic inquiry, while the latter conjured up images of the police interrogating a suspect. For a complete list of "Words to Work By" at Children's, see **Exhibit 8**.

Disclosure Policy Morath also wanted to change how the hospital communicated with families when accidents occurred. In the past, hospital staff remained tight-lipped after an incident. Typically, the hospital's attorneys recommended that staff members provide families with very few details and never admit any wrongdoing. Under the new disclosure policy, the hospital contacted the family soon after an incident occurred, explained the procedure for examining an accident, and described what they had learned from their initial inquiry. They also promised to keep the family informed as they learned more about the causes of the accident.

Nelson's views regarding the disclosure issue had changed dramatically after a meeting with a distraught family in September 1999. The family's teenage son had died in the previous year from an aggressive form of cancer after initially receiving a benign diagnosis at Children's. The family sued, but was unsuccessful because the Minnesota courts only allow malpractice cases in which the patient has at least a 40% chance of survival from the time of the initial diagnosis. After losing the suit, the family requested a meeting with the CEO. They brought pictures of their son, tearfully spoke of his pain, and demanded an apology and explanation. They received neither from Nelson, who offered these thoughts on the meeting:

The family had requested a meeting with me because they had a lot of ongoing issues with staff, and clearly, we had made a mistake. Before the meeting our risk manager and lawyer advised me to follow two rules: don't volunteer information and don't admit the hospital made a mistake. We met with the family, and I adhered to the advice. When the meeting was over, my staff members congratulated me for conducting myself so well, because I hadn't given any information or admitted wrongdoing. I told them it was the worst meeting in my life and said I would never do that again. We stonewalled the family. It was terrible.

By February 2000, the Board had approved the new "complete disclosure" policy endorsed by Morath and Nelson. Shortly thereafter, Nelson asked to meet with the family for a second time. He apologized for the misdiagnosis, explained what had happened, and offered assistance to the family. Nelson recalled the meeting:

I met with family a second time, and this time, I told them what had happened with their son's misdiagnosis. It was very emotional. I had tears in my eyes. We were able to resolve the situation. After the meeting we hugged each other. It was my own personal epiphany because there could hardly be anything worse than losing a child. Even if your child had only a 1% chance to live, to take that away from a child because of a misdiagnosis is tragic.

Infrastructure

Morath established several structures and processes to oversee and implement the patient safety initiative. In particular, she assembled a core team responsible for leading the initiative and approving major policy changes. As discussed earlier, she developed a new patient safety reporting system. In addition, she established a new process for examining serious accidents.

Patient Safety Steering Committee With Nelson's support and assistance, Morath appointed a Patient Safety Steering Committee (PSSC) to oversee the safety initiative. She served as the Chair of this committee, which included many physicians as well as nursing union leaders, a Board member, and a parent. The team convened for the first time in November 1999. Over time, the team grew from ten original members to nineteen participants. Each of these individuals spent approximately five hours per month on the PSSC. See **Exhibit 9** for a list of the team members.

Dr. Thomas Hellmich, emergency room physician and Vice Chief of Staff-elect, served as an original member of the PSSC. He explained how Morath selected him for the team:

I think that Julie picked me to be on the PSSC because I expressed an interest in her safety agenda. I attended meetings with her, in which she would discuss information on patient safety. I would email her to say it was interesting information, and the next thing I know, she sent me a contract describing what was going to be required if I got involved. It wasn't a binding contract, but she wanted to make sure that each person knew it was going to be a commitment--not just another meeting. She wanted to make sure that she got our attention, and she succeeded. I am on many committees, and this one has been different from the beginning.

Morath took no major actions without approval of the PSSC, which took collective responsibility for setting goals for the safety initiative, and for revising hospital policies and procedures. For example, the committee developed the new Patient Safety Report, and created the Focused Event Analysis process for examining the causes of serious medical accidents. The PSSC also reviewed the findings from accident inquiries and monitored the progress of the safety initiative.

Focused Event Studies The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) required hospitals to conduct investigations following serious medical accidents, known in the trade as sentinel events. Under the leadership of Dr. Hart, the PSSC revised the hospital's policy regarding when and how to conduct inquiries. First, the committee decided to not only conduct "focused event studies" following sentinel events but also after less serious incidents or "near misses." Morath, Hart, and the rest of the team believed that they could learn a great deal about improving patient safety by applying this structured problem-solving procedure more frequently.

Second, the PSSC shifted the focus of the required investigation process from identifying and reprimanding the individuals responsible for the accident to conducting a confidential, "blameless" analysis of the incident. This process was aimed primarily at documenting the sequence of events as accurately as possible and identifying all contributing systemic failures. Finally, the new policy

required the leaders of a focused event analysis to disclose information about the accident, the inquiry process, and the analysis's findings to the family as soon as possible.

Dr. Robison commented on the focused event analysis that occurred after Matthew's morphine overdose:

I don't think we could have gotten as thorough an understanding of what happened to Matthew if I had talked with people individually. There was so much point and counterpoint during the meeting. We saw the event from the nurse's perspective and then from the respiratory therapist's and then the doctor's. It is not that people only perceive things consistent with their viewpoint, but that they have actually only touched one part of the elephant. I have found that most people think that they know where the failure was and what failed. However, when they come into one of these meetings, they realize that there were ten possible defenses in the system. They come to understand its complexity. They recognize that there were aspects of the situation they didn't even know existed. These focused event analyses develop disciples that then go out into the organization understanding the complexity of medical accidents.

Dr. Hart explained that the facilitator needs to be highly sensitive to cues suggesting that one or more points of view have not been explored thoroughly during the meeting:

Sometimes after the meeting there is post-session chatter, or people will stroll up to Chris or me and add new information that is pretty important. We don't purposely structure the discussions this way, but we do schedule our time so that we don't have to rush off after a meeting. Another thing we are going to start experimenting with is having two facilitators: one to facilitate and another to observe nonverbal behavior to make sure we are not missing something.

While most employees lauded the new focused event analysis approach, several expressed concerns. Hart and Robison felt that they did not have the time, staff, or resources to follow up on each issue that emerged during a focused event analysis. Major responsibilities associated with their "normal jobs" made it difficult to find time for follow-up efforts. Also, the PSSC did not have a systematic way to ensure that recommended procedural changes were implemented, or to measure the effectiveness of changes. Finally, it was unclear whether the new approach had changed the hospital's legal risk profile. Given that Children's had been conducting focused event studies and disclosing more information to families for a short period of time, the PSSC could not determine the ultimate effect on the hospital's legal exposure.

Medication Administration Project

The third major component of the safety initiative consisted of an effort to overhaul the hospital's medication administration system with the goal of achieving zero defects. Morath wanted to use this effort to demonstrate how the organization could improve patient safety by redesigning the hospital's systems and processes. She believed that this project would motivate everyone to change the way they thought and acted about patient safety. As she said, "Who could argue with having a medication system for kids that was 100% reliable? Moreover, everybody here knows the complexity and the difficulty of the existing medication administration system." Mark Thomas, Pharmacy Director, explained how Morath recruited him for this project:

I started working at Children's in September 1999, and had been here less than a month when Julie called me to her office. She said, 'Mark, I am so excited that you are here. In many

respects, I have been waiting for you to arrive.' She explained her patient safety agenda, and asked me to take charge of this project to improve the medication administration system. She told me that the goal was to achieve zero defects. At this point, I was reeling because I knew that this was a challenging goal. From my standpoint, it was almost impossible, but I was excited because she was very supportive of me and confident that we could achieve the goal.

Morath did not want Thomas to focus only on processes internal to the hospital's pharmacy. She asked him to consider the entire process flow associated with medications, from the time a physician prescribed a drug to the time it was administered to the patient. She asked him to pay particular attention to each "handoff" in the system, i.e. when individuals transferred information and/or physical items to one another. She expected to find many opportunities to simplify existing processes.

Safety Action Teams In November 1999, Casey Hooke, a clinical nurse specialist, decided to create a "safety action team" in the Hematology/Oncology unit in Minneapolis. This cross-functional team of eight employees began to meet monthly to discuss medication safety issues. After the meetings, the team members briefed their co-workers about the problems they discussed and the improvements they hoped to implement. Each person also gathered ideas and suggestions to share with the rest of the team at the next meeting.

Two other units observed Casey's efforts and launched Safety Action Teams in their areas. Witnessing these successful efforts at the local level, the PSSC directed the manager of each clinical unit at Children's to establish a Safety Action Team in 2001. Ginger Malone explained why these local teams generated many of the key ideas for enhancing patient safety: "Innovation principles are the same as safety. People closest to the work know the work best."

Malone believed that Safety Action Teams provided a powerful vehicle for workers at the front lines to root out unnecessary complexity and to remove barriers that prevented them from providing effective care to patients. In many cases, Malone felt that these barriers emerged because the administrative and support staff did not fully comprehend how seemingly simple policy changes complicated the way doctors and nurses performed their daily work. Malone provided an example of how the Safety Action Teams gave "voice" to the concerns of those on the front lines:

In the summer of 2000, a nurse infused a large and potentially harmful amount of fluid into a patient when using a kangaroo-feeding bag. At the meeting of the Safety Action Team, she talked about the near miss and asked what could be done about it. They researched the question, and discovered a safer feeding bag that could prevent this type of accident in the future. They took the research to Materials who suggested that the theoretical advantage was not worth the cost. The nurses began to use the safety reporting system to direct attention to the problems with the kangaroo-feeding bags, and they launched a direct e-mail campaign to senior management. Ultimately, the hospital agreed to purchase the safer equipment. This shows how the safety reports are being used as a method of communication and as a vehicle for change.

Good Catch Logs Casey Hooke's team also initiated the "Good Catch Log" as a way of capturing information that could be used to prevent medication errors. Good Catch Logs are located in locked medication rooms on each floor of the hospital. If a nurse "catches" a problem that could have resulted in a medication error, she can describe the situation in the log. Nurses felt comfortable with this process because they could record events in the log anonymously, and no one other than nurses or pharmacy staff had access to the rooms in which the logs were located. Mark Thomas commented on the development of the Good Catch Logs:

One of the early challenges of the safety action teams was simple: What were we going to talk about? Where do we get this information to start chewing on? The concept came fairly quickly at the first meeting where the nurses developed the concept of a “good catch log”. This is completely outside of our current reporting system, which focuses on documenting accidents. Here, nurses can report accidents waiting to happen.

Dr. Bruce Bostrom felt that the Good Catch Logs provided more useful information than the typical safety-related report. He explained:

Most forms are not suited for anything other than satisfying JCAHO requirements. They enable administrators to count the number and type of accidents, but they do not help us make changes to our systems. Our standard reports might indicate that there were thirty cases of a particular problem, but you don't know why those problems occurred.

The leader of each Safety Action Team periodically gathered the Good Catch Logs, reviewed the entries, and summarized the information in preparation for the next team meeting. Each Team revised policies and procedures based on information provided in the logs. As nurses realized their entries often led to concrete changes, they became even more comfortable writing in the logs. As one nurse commented, “Now we feel like someone is listening and doing things about our concerns.”

Moving Forward

By January 2001, Morath was quite pleased with the level of commitment and dedication to the patient safety effort. However, as the initiative matured, Morath recognized the need to tackle some controversial questions about the safety program. She and the PSSC struggled with four key issues.

Disclosure and Legal Risk

First, members of the PSSC worried about whether the benefits of enhanced disclosure to patients and families exceeded the risk of additional lawsuits. One surgeon expressed a view held by many at Children's, namely that talking openly about accidents was inviting trouble. He worried that the hospital “had crossed the stars by talking openly about accidents.” Dr. Terry Hart acknowledged the risks, “Absent tort reform and regulatory reform, I think we are walking out on the diving board, absolutely.”²

Others believed that the hospital had not moved boldly enough with respect to parental involvement in the safety improvement effort. Dr. Bruce Bostrom thought that parents had experience and knowledge that was underutilized by the hospital staff:

It might be beneficial to have “Parental Good Catch Logs” in every patient's room. However, we still have a culture that is fearful of having parents involved in good catches and near misses.

More generally, Morath and Brock met with the hospital's legal advisors to go over plans for the patient safety initiative. Recognizing that predicting future behavior of patient families was not possible, the Board of Directors and its key advisors approved the initiative.

² Shapiro, J. P. (July 17, 2000). America's Best Hospitals. U.S. News and World Report.

Accountability

Unit managers and administrators also expressed concern that the blameless reporting system undermined their ability to hold individuals accountable for poor performance. Similarly, families often wanted to find a specific individual to blame for an accident, rather than focusing strictly on systemic failures that contributed to a serious incident. The father of the teenager who died in 1998 after the misdiagnosis at Children's explained his frustration with the apparent lack of accountability: "In my business, if I screw up and lose some money, I could lose my job. There are consequences. A life is lost here. Where are the consequences?"³

Measuring Results

The PSSC grappled with the difficulty of trying to measure the effectiveness of the safety initiative. Its members wanted to know whether the benefits outweighed the costs. Morath could not yet provide any hard numbers to justify the initiative financially, but intuitively, she felt that the initiative was worth the expense. She commented, "Can we afford to have the Patient Safety Initiative? I think that I can build a business case showing that improved quality provides a cost benefit." Still, the PSSC struggled to find measures that could be used to evaluate the success of the initiative. See **Exhibit 10** for some measures of performance at Children's.

Some members of the PSSC expressed concern that the organization had not dedicated enough resources to implement improvements to the hospital's processes. Dr. Bostrom explained that it was very challenging to provide exceptional care for his patients, while trying to oversee implementation of broad changes in hospital systems and processes. He described the problem:

Mark Thomas asked me to take on a particular project, and I agreed to do it. But, I haven't accomplished anything because I am still trying to get a meeting organized. I could really use a person who can take responsibility for organizing the meeting, rather than having to do the calling and coordinating myself. I am responsible for patient care. I can't say to my patients, 'I am sorry. I can't meet with you now because I have to attend a meeting or arrange a meeting.' Corporations have project managers. We don't have enough slack resources to execute these improvement projects.

Thomas also wondered if the hospital had utilized its valuable resources in the most effective manner during the safety effort:

We have been struggling with the identity of the medication safety team. We do things, but I don't feel as though we are achieving as much as we could. I think we are trying to get too much done at one time. We have fifteen members of the medication safety team. How do we work with these huge teams? We can spend a whole meeting discussing an issue, but we are getting very little done.

Morath was aware of these concerns:

People are starting to question how we are going to move from theory and concepts to actually changing the hardwiring of the hospital. They ask, 'Do we have the infrastructure to deliver on the safety agenda?' The willingness is there, but we need to make sure we have enough resources to handle issues that arise. The good news is that we now have the appetite for action.

³ Ibid.

Leadership

Children's also faced an important challenge related to leadership of the Safety Initiative. As Chief Operating Officer at Children's, Morath came to recognize that she could not devote all of her time to the safety effort. She had many other duties and responsibilities that required her attention. She concluded that the hospital needed to hire someone else to lead the effort on a full-time basis, and to become the new Chair of the PSSC. In January 2001, Nelson and Morath hired Dr. Eric Knox to fill this role. Dr. Knox was a retired perinatologist (a specialist in high-risk births) and a nationally recognized expert on medical safety. Naturally, some worried that a change in leadership might inhibit progress on the initiative, particularly at this crucial stage in its development. However, Morath believed that the organization could make a smooth transition:

I wanted Eric, or someone with similar knowledge and clinical experience, for this job. It was just a matter of when. I wanted to make sure there was enough DNA in the organization around the issue of patient safety so that the initiative would survive without my direct management.

Others believed that this DNA did exist in the organization, but worried that Morath's leadership would be hard to replace. Moreover, they wondered what Morath's role in the safety effort should be now that Dr. Knox had been hired. They certainly did not want the safety initiative to become another easily dismissed management fad. Dr. Hellmich explained:

Julie Morath has brought impassioned leadership to the hospital on the topic of patient safety. In my ten years here I have seen many management whims float through that didn't amount to much. I could tell that this had a very different mission. I don't anticipate it going away, but one of our challenges now is to convince people on the front-lines that this isn't just another fad of the month.

Matthew's Morphine Overdose

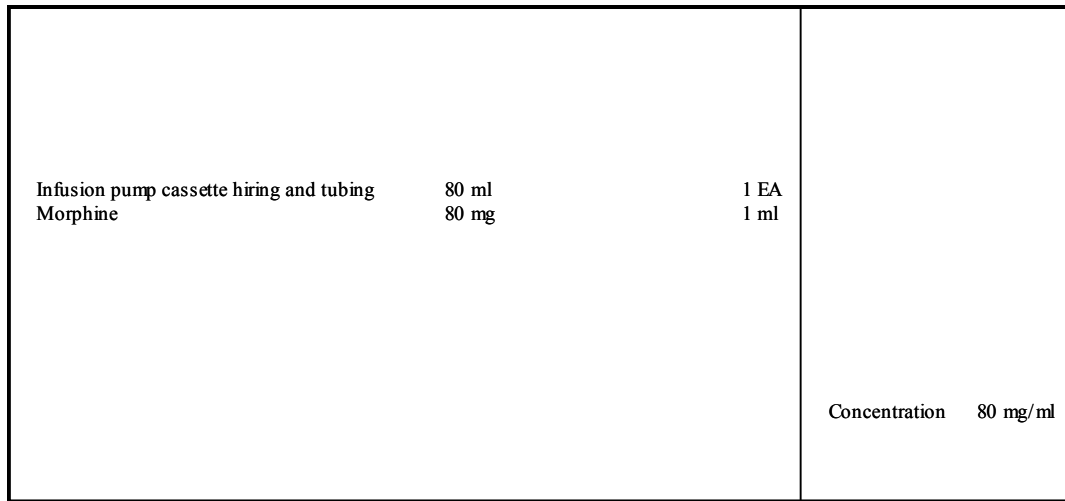
1:00 P.M. January 10, 2001

Once again, Morath turned her attention to the case of Matthew's morphine overdose. She expected the child's parents to arrive at her office at any moment. As Morath waited, she began to anticipate the tough questions that his parents might ask: What are the names of the individuals responsible for Matthew's overdose? How could they make such a serious mistake? How are you going to hold them accountable for this potentially fatal error? Is it true that these same doctors and nurses could still be treating Matthew today, and if so, what are you going to do about this?

Morath had wrestled with these questions for days, but still had not settled on an answer with which she felt completely comfortable. How should she respond to these questions? What was the right approach in this situation?

Exhibit 1 The Morphine Cassette Label

This is a representation of the label on the morphine cassette. The pharmacy had delivered the electronic infusion pump to Matthew's room with the cassette already inserted. This label was too large to fit completely on the front of the cassette. Therefore, a portion of the label appeared on the front and was visible to the nurses as they looked at the pump. The remainder of the label extended onto the side of the cassette, and thus was not visible to the nurses as they looked at the pump.



Portion of label on the side of cassette that was visible to Nurses Chen & O'Reilly

Portion of label on the side of the cassette that was not visible to Nurses Chen & O'Reilly

Exhibit 2 Glossary of Medical Safety Terms used at Children's Hospital and Clinics

| Term | Definition |
|---|--|
| Patient Safety Event | Any identified defect, error, medical accident, near miss medical accident, sentinel event, medication error, significant procedural variance, or other threat to safety that could result in patient injury. |
| Defect | A feature of the healthcare delivery system and its participants that creates the possibility of an error or medical accident. |
| Error | An event or act of commission or omission with unintended, potentially negative consequences for the patient, independent of whether there were any negative consequences. This includes: system error (latent error or failure), unintended individual error, events or acts with either actual or potential negative consequences, completed errors and intercepted errors, errors of judgment and errors of action. This excludes malfeasance (intentional acts or events with potentially negative consequences) and an event of judgment that is now known to be an error only because of previously unavailable information, changed clinical condition, new technology, etc.) |
| Medical Accident | An unintended event in the system of care with actual or potential negative consequences to the patient. Medical accidents can result from defect, failure and error within the system of care. |
| Near Miss accident | An event that would have constituted an accident but which was intercepted at the point of patient care service before it actually reached the patient. |
| Near Miss Medical accident requiring disclosure | A near miss accident that is apparent to the family either in specific detail or because of the general level of activity, or a near miss accident which has caused a change in the treatment plan and so affected patient care even though the accident never reached the patient directly. |
| Sentinel event | A sentinel event is a category of medical accident defined by Joint Commission on Accreditation of Healthcare Organizations to include the following: <ul style="list-style-type: none"> a) The event has resulted in an unanticipated death or major permanent loss of function not related to the natural course of a patient's illness or underlying condition, or b) The event is one of the following (even if the outcome was not death or major permanent loss of function): suicide of a patient in a setting where the patient receives around-the-clock care, infant abduction or discharge to the wrong family, rape, hemolytic transfusion reaction involving administration of blood products having major blood group incompatibilities, surgery on the wrong patient or wrong body part |
| Near miss sentinel event | A near miss medical accident, which if it had occurred would carry a significant chance of a serious adverse outcome. |
| Medication error | Any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health-care professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems. These systems include: prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution, administration; education; monitoring; and use. Events are included whether it reaches the patient or not (near miss) or causes patient injury or not. |
| Hazardous Condition | Any set of circumstances (exclusive of the disease or condition for which the patient is being treated) which significantly increases the likelihood of a serious adverse outcome. |

Source: Children's Hospital and Clinics, Minneapolis, Minnesota, Policy Number 703. "Medical Accidents and Disclosure, Including Sentinel Events." Vice President of Medical Affairs. November 15, 2000.

Exhibit 3 Financial Performance Data and Operating Statistics**2000 Financial Performance Data for Children's Hospital and Clinics**

| | |
|-------------------|----------------------|
| Revenue | \$271,799,000 |
| Expenses | <u>\$267,245,000</u> |
| Operating Income | \$4,554,000 |
| Investment Income | <u>\$7,700,000</u> |
| Net Income | \$12,254,000 |

2000 Operating Statistics for Minneapolis and Saint Paul hospitals

| | |
|--|---------|
| Number of staffed beds | 270 |
| Admits | 12,261 |
| Emergency room visits | 64,030 |
| Outpatient visits | 129,829 |
| Number of physicians who practice at the hospitals and clinics | 1,506 |
| Employees (2,087(<35hrs), 1,368(>35hrs)) | 3,455 |

Specialized services include:

Asthma, cardiology, cancer, diabetes, premature birth, pulmonary diagnosis, child abuse, urology, epilepsy, developmental problems, rehabilitation therapies, adolescent development, emergency transport and care, newborn and pediatric intensive care, outpatient and inpatient surgery, diagnostic services, primary care.

Exhibit 4 Timeline of Events

| Date | Activity |
|----------------|--|
| 1997 – 1999 | <ul style="list-style-type: none"> While employed at Allina Health Systems, Morath attends Executive Sessions on Medical Errors and Patient Safety at Harvard University |
| May 1999 | <ul style="list-style-type: none"> Julie Morath becomes COO of Children's Hospitals and Clinics |
| July 1999 | <ul style="list-style-type: none"> Safety agenda developed with key stakeholders |
| August 1999 | <ul style="list-style-type: none"> Morath presents information about medical errors from the Harvard Practice Study to employees and physicians Morath hires Ginger Malone as Innovation Manager. Malone begins planning how to collect data on current safety standing |
| September 1999 | <ul style="list-style-type: none"> Board of Directors approves patient safety plan and goals. Goals are: 1) Develop culture of high reliability for patient safety, 2) Build infrastructure to support learning from errors and failures at both work process and management system levels, 3) Implement medication zero-defect workplan Brock Nelson, CEO meets with family of teenager who died after misdiagnosis, but "stonewalls" them and does not reveal any information about the misdiagnosis |
| October 1999 | <ul style="list-style-type: none"> Ginger Malone and Susan Wiecker conduct focus group sessions on accidents and health care workers' ability to talk about accidents Morath gives Mark Thomas the goal of creating a Medication Administration system with zero medication defects. Thomas leads the Medication Safety Team. |
| November 1999 | <ul style="list-style-type: none"> Morath assembled Patient Safety Steering Committee, which she chaired, comprised of 'key influentials' within the organization Blameless reporting starts. Patient Safety Steering Committee develops revised Safety Report Casey Hooke, RN, CNS and a Hematology/ Oncology pharmacist pilot a Safety Action Team in Hematology/ Oncology unit at the Minneapolis campus. |
| February 2000 | <ul style="list-style-type: none"> Board of Directors approves plan to disclose information about medical accidents to families Nelson meets with misdiagnosed teenager's family again and this time explained the incidents that led up to the misdiagnosis |
| July 2000 | <ul style="list-style-type: none"> Board of Directors approves new policy on Focused Event Analyses developed by the Patient Safety Steering Committee. |
| January 2001 | <ul style="list-style-type: none"> Eric Knox, MD, hired as Director of Patient Safety Organizational initiative for all managers of clinical units to start a Safety Action Team |

Exhibit 5 Selected Information from the 1999 Institute of Medicine report on medical safety⁴

- Medical errors kill 44,000 to 98,000 patients annually.
- Errors cause more deaths each year than breast cancer, motor vehicle accidents, and AIDS.
- It is estimated that each year in our nation's hospitals, 6.7 percent of all admitted patients will experience a medical accident.
- Of those accidents, 3.1 percent will be Adverse Events and 13 percent of those Adverse Events will be fatal.
- Of these accidents, in total, 72 percent of them are recurring and, therefore, are predictable and preventable.
- Two out of every 100 admissions experienced a preventable adverse drug event, resulting in average increased hospital costs of \$4,700 per admission.

⁴ Kohn, L, Corrigan, J., & Donaldson, M., (1999), "To Err is Human: Building a Safer Health System," IOM.

Exhibit 6 Children's Hospital Strategic Plan 2000-2005

Mission: Children’s Hospitals and Clinics champions the special health needs of children and their families. We are committed to improving children’s health by providing high-quality, family-centered pediatric services. We advance these efforts through research and education.

Vision: We will be one of the nation’s best pediatric providers, accessible to all children.

| | Strategic Alignment: 2000-2005 Objectives | Strategic Alignment: 2000-2005 Measures | Operational Plan: 2001 Activities/Measures |
|---------------|--|---|---|
| Safety | Achieve zero defects in delivering clinical care and medication use Achieve best of practice in key clinical areas Demonstrate attributes of a high-reliability organization | Implement safety agenda Increase reporting and analysis of risk Eliminate medical accidents Achieve top 10% in key clinical areas | Establish safety reporting system Implement KIDS/pharmacy order technology, Phase I Complete medication safety improvement plant Audit 2 high risk processes/procedures and act on results Establish at least one care team pilot Participation by each director/manager in one safety improvement activity For clinical sites: implement a safety action team |
| Access | Ensure availability to all children, families, and providers who need and seek our services | Eliminate deferrals Improve cycle time between demand and delivering service Increase patients served by 5% per year Develop new programs /sites/services based on family need & preference Increase market share by 5% | Reduce wait time between demand and service Implement KIDS/registration technology Implement “zero-deferral” plan Investigate new satellite facilities/partnerships in metro region Increase accessibility to ESL populations Implement eHealth prototype |

Exhibit 6 Children's Hospital Strategic Plan 2000-2005 (continued)

| | Strategic Alignment: 2000-2005 Objectives | Strategic Alignment: 2000-2005 Measures | Operational Plan: 2001 Activities/Measures |
|-------------------|--|---|---|
| Financial | Ensure affordability Eliminate waste Invest in future Maintain profitability | “A” bond rating Positive cash flow ROIC>cost of capital Contracts with all major payers Annual cost increase <= medical CPI Capital investment is >= depreciation Increase productivity by 10% | Complete revenue stream initiative Increase philanthropy to (\$10.7M) Improve position control Implement Quadramed for program profitability and payer contract modeling Increase business skills of management |
| Experience | Exceed expectations of children and their families Become the employer of choice Build effective physician relationships | >90% of parents/ families “very satisfied” with quality of care > 90% of parents/ families willing to recommended Children’s to others >90% of parents/families “strongly agree” they would return to Children’s Reduce voluntary staff turnover to <10% Design a physician relationship plan | Implement new billing process Strengthen employee retention and recruitment strategies Strengthen cultural competence among staff Advance future state groups Reduce hiring cycle time Implement anti-violence training in all departments Complete at least two service improvement pilots Implement culture survey leadership directives |

Exhibit 8 Words to Work By

| Use | Do Not Use | Why? |
|----------------------|----------------|--|
| Accident or failure | Error | Accident describes a breakdown in a system. They are complex and need analysis. Error suggests that only one factor, usually notes as a human error, was the cause (which is rarely the case). Error is a social attribution and a result of the need to attribute blame or a simple and single cause. |
| Multicausal | Root Cause | Studies show that at least four failures must occur and line up (multicausal) for an accident to happen. Therefore, there is no such thing as a root cause or single source of accident. |
| Learning | Judgment | When we are open to learning from mistakes or failure, we understand how multiple factors work together and we can be proactive in preventing them from happening again. If we are judgmental about situations, we instead are blaming a particular person or event. Learning stops and we are not helping prevent the failure from occurring again. |
| Accountable | Blame | Professionals are accountable for their work, meaning that they have a responsibility to be actively involved in assuring their knowledge and competence to perform their work and to understand how systems work. It also means understanding how they are the human components of systems that sometimes contribute to failure as well as create safety. Blame is used to find an excuse or "bad apple" rather than a greater understanding. |
| Examination or study | Investigation | An examination is what we do to learn how systems work and how the pieces fit together to create the whole. We learn from the results and use them to predict and shape our actions to prevent failure. An investigation assigns blame to someone or something. It is typically a very linear search to determine a single cause. |
| System | Isolated event | An accident results from latent errors or weaknesses in a system. These errors or weaknesses are cumulative and interactive. Therefore, an accident is not an isolated event. |

Source: Children's Hospital & Clinics internal publications

Exhibit 9 Patient Safety Steering Committee Roster - January 2001

| Member | Title |
|---------------------------------|--|
| Audrey Anderson | Communications Manager |
| Don Brunnuell, PhD | Resident Ethicist |
| Bruce Bostrom*, MD | Physician, hematology/ oncology |
| Kathy Clinch*, MD | Vice chief of the professional staff, anesthesiology |
| Louise Cunningham*, MS | Director, quality resources |
| Carolyn Greunke | Parent |
| Linda Hamilton*, RN | NICU nurse, Minnesota Nurses Association (union) Tri-Chair |
| Terril H. Hart*, MD | Vice president, medical affairs |
| Thomas Hellmich*, MD | Physician, emergency medicine |
| Casey Hooke*, RN, MSN, CPON | Clinical nurse specialist, hematology/ oncology |
| Eric Knox, MD | Director Patient Safety, Chair of PSSC |
| James E. Levin*, MD, PhD | Medical director, informatics, and pediatric infectious disease consultant |
| Ginger Malone, RN, MSN | Leader Care Innovation |
| Julie Morath*, MS, RN | Chief Operating officer |
| Cheryl Olson*, RN, MS, CNAA | Vice President, patient care and nursing practice |
| Kevin Roberg* | Parent and member of Children's Board of Directors |
| M. Chris Robison*, MD, MBA | Associate director, medical affairs, and pediatrician in Children's clinic |
| Patsy Stinchfield*, RN, MS, PNP | Nurse practitioner, infectious disease |
| Anne Tegen*, MHA, RHIA, HRM | Director, data and record services and risk management |
| Mark Thomas*, MS, RPh | Director, pharmacy services |

* indicates original member

Exhibit 10 Measures & Statistics Related to Patient Safety Initiative

