

## Sentinel Events

*(Reprinted from Joint Commission Perspectives, March/April 1997)*

In this issue of Perspectives, we introduce a new section on Sentinel Events. It will serve as a forum for health care organizations that have experienced a sentinel event to share their story, to describe what they have learned, and to offer some advice to other organizations. Health care organizations that have not experienced a sentinel event, but have developed strategies for preventing potential sentinel events also are encouraged to submit articles. In addition to these case studies, articles in this section will cover topics such as the Joint Commission's own Sentinel Event Policy and how to conduct a root-cause analysis.

The Joint Commission implemented its Sentinel Event Policy in 1996 and has made some revisions since that time. The definition of a sentinel event in the Policy was revised in November of 1997.

The Joint Commission defines a sentinel event as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

Such events are called "sentinel" because they signal the need for immediate investigation and response. Accredited organizations are expected to identify and respond appropriately to all sentinel events occurring in the organization or associated with services that the organization provides, or provides for. Appropriate response includes a thorough and credible root cause analysis, implementation of improvements to reduce risk, and monitoring of the effectiveness of those improvements. Organizations' activities in response to sentinel events will be routinely assessed as part of all triennial and random unannounced surveys.

The first case study in this new section is written by Doni Haas, RN, director of risk management at Martin Memorial Health Systems in Stuart, Fla., where a medication error resulted in the death of a 7-year-old boy. Medication errors are among the most common sentinel events that have been brought to the Joint Commission's attention.

Representatives of Martin Memorial also gave a presentation about this sentinel event at a 1996 conference on "Examining Errors in Health Care: Developing a Prevention, Education, and Research Agenda." This multidisciplinary conference, which was held in Rancho Mirage, Calif., was convened by the Joint Commission, the American Association for the Advancement of Science, the American Medical Association, and the Annenberg Center for Health Sciences.

**In memory of Ben--A case study**  
**By Doni Haas, RN, director of risk management**  
**Martin Memorial Health System, Stuart, Fla.**

"Please don't let this happen to another child," pleaded the family of 7-year-old Ben. His active, happy, and healthy life had been prematurely and abruptly ended in December of 1995 when a medication error occurred during routine ear surgery at Martin Memorial Medical Center in Stuart, Fla. The family's grief was intense. The sincerity of this request moved us to examine our response to Ben's tragic accident and to ask ourselves, "Have we done enough?"

This is why we have chosen to share what was truly our darkest hour with others in the health care field. We believe there are many lessons to be learned from this case. It illustrates a

commitment to integrity and sensitivity for our patients= needs that flows from the board and administration on through all of the staff. This environment has created over time a sense of trust in and cooperation with our risk management efforts that enabled us to proceed in our investigation as a team looking for a solution, not as an authority figure seeking to place blame.

We conducted a root-cause analysis and have made procedural changes in our operating room that will reduce the likelihood of this type of error occurring again. Health care providers should examine their own processes carefully and consider the suggestions that are covered in this article.

### **December of 1995**

Ben came to Martin Memorial Medical Center for an elective tympano mastoidectomy procedure on Dec. 13, 1995. Following an uneventful induction of general anesthesia, the procedure called for the infiltration of a local anesthetic Lidocaine 1% with Epinephrine 1:100,000 - that the circulating nurse and scrub tech had prepared prior to the case. Ben reacted immediately to the infiltration with a dramatic rise in his blood pressure and pulse. He was immediately treated and stabilized.

Shortly thereafter, his cardiogram had a profound change, his blood pressure fell, his heart rate slowed, and cardiac arrest ensued. Ben was resuscitated and placed in the intensive care unit. His family waited there for answers as Ben lay comatose. I met with his mother and tried to ease her anxiety. I told her we were working very hard to find the answers and would keep her informed.

On Dec. 14, Ben died in the tertiary care center where he had been transferred. Everyone in the hospital was devastated. I called the family to express my sympathy. His mother was upset about something she had read in the newspaper. I promised two things. First, I would exhaust my resources to find the family answers. Second, I would then tell them what I found and would not release information to the public and the press.

It is very important in handling unusual events to establish a relationship with the family members. They need support, and they need answers. They deserve both. As the risk management director for our health system, I had been summoned to the operating room at the time of the child's cardiac arrest. This was critical to the eventual resolution of this case. It provided the opportunity to preserve key evidence, capture the memories, and develop rapport with the family.

### **Preserving evidence**

The analysis of the event provided the factual cause. This made the resolution possible and perhaps made this case easier than many. Previous risk management training had conditioned physicians and staff to preserve the "evidence" and work quickly and openly with the risk manager.

We had no formal sentinel event plan in place. Rather, it was a combination of the efforts of many individuals, supported by a strong sense of institutional integrity and sincere sensitivity to the grief and pain of this family that guided us. This is not about textbook medicine. This is one-on-one caring about others.

Because of the child's reaction immediately following the infiltration of the local anesthetic, the two syringes and their vials were identified as the key evidence and were taken directly from the sterile field and handed to the director of surgical services by the scrub tech. The director then handed this "evidence" directly to me.

In the pharmacy, we identified all lot numbers and immediately activated our medication recall process throughout our system. Our pharmacist prepared a voluntary report for the U.S.

Pharmacopeia. One of the two syringes had a minute amount of clear liquid in it, the other had 3 cc. The pharmacist transferred a portion from that syringe into a third syringe for testing. All syringes and vials were then sealed in wax. We then located a laboratory and researcher at the University of Georgia to test the sample.

### **Root-cause analysis**

The root-cause analysis required a reconstruction of what the participants actually experienced. This eliminated what I have heard referred to as "hindsight bias," which happens when investigators look backwards and tend to only see the forks in the road that the person decided to take, not the route itself.

Every person who had anything to do with the case was identified and interviewed privately by me. Together we reviewed each and every step of his or her role in the case. We drew diagrams and flowcharts. I lined the walls of a sealed office with the "evidence."

After each interview, I compared the information with the previous reports. Often a "witness" had to return to clarify the information as new information was gleaned from others. This was a very time consuming process, but critical to understanding practice. Staff and physicians cooperated fully and honestly.

In frustration, I expanded the interviews to staff not involved in the actual case. This provided valuable insight. It was only then that I began to identify subtle variations in practice that, when combined with other variations, made error possible.

During this time, the administrator, a registered nurse, had activated a task force of operating room staff to examine the process for the transfer of medications to the sterile field. I shared variations in practice with this task force.

### **Laboratory results**

Approximately one week after Ben's death, the medical examiner ruled the death an idiosyncratic reaction to the local anesthetic. I notified him that we were testing the samples of the Lidocaine 1% with Epinephrine 1:100,000.

The CEO approved the assignment of a pharmacist to the risk management department to devote full-time efforts to the investigation. We looked at all of Ben's previous admissions for clues to his reaction. There were none. We pored over the literature, journals, and authoritative textbooks. There were no answers.

Many contacts were made with other facilities to identify their processes. Repeatedly, we confirmed that our practice was exactly like everyone else's. Each and every step of the process had been identified down to the most minute detail, and the staff members involved knew the process perfectly. They were long-term employees with unblemished records who were highly respected by their colleagues, staff members, and management.

We did not expect the laboratory results. Six days after Ben's death on December 20, 1995, the University of Georgia reported that the solution in the syringe we had sent did not match the solution in the vial of Lidocaine 1% with Epinephrine 1:100,000. The University was unable to tell us exactly what it was and requested another sample.

We sent another sample and consulted with our risk consultant at MMI Companies, Inc., in Deerfield, Ill, and laboratories across the country to identify a laboratory that could confirm the University of Georgia's analysis. On January 4, 1996, we located National Medical Services in Willow Grove, Penn. The laboratory was capable of content identification and was willing to allow our pharmacist to accompany the sample throughout the process.

Our pharmacist hand delivered the actual syringe from the case on January 5 and remained with it throughout the testing process. Two days later, we received written confirmation from both laboratories that the syringe of Lidocaine 1% with Epinephrine 1:100,000 actually contained Topical Adrenalin 1:1000. There had, indeed, been a tragic error.

Arrangements were made to meet with the family the next day, which was Jan. 8. Accompanied by the anesthesiologist, I shared the test results with the parents and their attorneys and told them how very, very sorry we were. Later that day, the involved members of the surgical team, the executive team, and the board of directors were given notice.

Our insurance carrier and our defense attorney had guided our investigation and had been kept apprised of the findings over the past few weeks. They were on standby to assist with closure. Later on the evening of Jan. 8, the hospital, accepting full responsibility for the error and the results of the error, reached a voluntary settlement with the family and prepared a mutually acceptable press release.

### **Conclusion**

In this and in all of our investigations, there were two motives that drove our risk management team. First, we searched to find exactly what it was about our systems that placed patients at risk of injury and placed competent, caring professionals in an environment where error occurs. Second, we firmly believed that our patients and their families deserved a complete and honest explanation.

The revised procedure was put into place within 28 days of the event and is offered to all surgical teams. We have found this revision eliminates several steps in the process for the transfer of medications from a non-sterile to a sterile field. Intermediary containers are eliminated.

We feel compelled to share this experience so that this never happens again to anyone. Every step in any process needs to be viewed as an opportunity for error. Opportunities for error are opportunities for improvement that must not be ignored. It does not matter how long a process has been "the standard." Challenge it.