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When Errors Occur, 'I'm Sorry' Is a Big Step, But Just the First

When Sandra Coletta took the helm as president and CEO of Kent Hospital in Warwick, R.I., in October 2008, she received a trial-by-fire course in the management of medical error. Two years earlier, in July 2006, a high-profile medical error had occurred in Kent's emergency department when heart monitoring that a doctor ordered for a patient never happened, and the patient died hours after seeking help in the ED. When Coletta began her post at Kent, the legal case was still pending.

"No one from the hospital had talked to the family," Coletta says. "They had only been contacted by lawyers." The hospital had taken a causality defense, its initial position being

BY TRACY GRANZYK WETZEL

that the patient's death could not be proven to be a result of its failure to monitor.

For Coletta, it was black and white. The hospital had made an error and was not owning up to it. The family was not getting answers they deserved, and no one was healing, including the caregivers involved in the error.

"There are many pressures from all fronts not to get involved, especially from a legal or public relations perspective," says Coletta. Instead, knowing it would be the only way for everyone involved to begin the healing process, Coletta chose to sit down with the family and do the unthinkable in a medical lawsuit—apologize.

"A lot of focus went into the fact that I apologized, but what would anyone do if they made a mistake and someone suffered a loss? Say 'I'm sorry,'" says Coletta. "Many CEOs would want to do the same, but they are constrained by so many telling them not to do this."

An accountant by training, Coletta quickly embraced a culture of full disclosure early in her tenure at Kent, much to the surprise of her peers.

While greater emphasis is now being put on saying "I'm sorry" to patients and families affected by medical error, those at the forefront of the full-disclosure movement know it is only a start. "It meant a lot to the family to hear 'I'm sorry' because they had not heard it before, and they were thankful," emphasizes Coletta. "But just saying 'I'm sorry'? What is the value in that alone?"

It is the work Kent Hospital and the patient's family have agreed to pursue together that will ensure a similar event does not occur to another family. Out of the loss has emerged the Michael J. Woods Institute, which will focus on the redesign of health care delivery from a human-factors perspective, embracing a systems approach to the prevention of medical error, now the cornerstone of a new culture emerging at the hospital.

"A year or two from now, I think we will see a totally different hospital when it comes to staff and patient satisfaction," says Lisa Greenlund, director of risk management and safety at Kent. "We need CEOs like Sandy who clearly are representatives for patient safety and full-disclosure programs. She is not afraid to advocate for these programs and speak the truth. Her example will lead the rest of the staff to follow."

Coletta says she will never really know if

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the error made in Kent's ED contributed directly to the patient's death, but to her it doesn't matter. What matters is that the physician ordered the patient's monitoring, and no one followed through. An error was made, and she strongly believed the patient's family deserved to know.

The Right Thing To Do

Ralph Gabarro, CEO of Mayo Regional Hospital in Dover, Maine, took a similar approach when faced with a medication dosing error in the emergency department that directly contributed to a patient's death. On June 4, a 52-year-old man arrived at the emergency department in anaphylactic shock. He received 0.3 mg of epinephrine, and when his symptoms did not resolve, he was given another dose; but this time he mistakenly received 3 mg, 10 times the normal dose, and died.

"When the error occurred, Cheryl Roberts, our director of quality and risk management, immediately identified the need and the value of disclosing this fact to the family," Gabarro says. "She pledged to get back to the family when we knew more."

"Disclosure to the family started that night at the hospital," Roberts says. "I sat down with the intern on call, the ER physician and the family, and we talked to them. We met with them again after the medical examiner's report, and then again after the root-cause analysis to talk about what we were going to change, and I have been in touch to make sure she [the patient's wife] is OK."

"This was just the right thing to do," continues Gabarro. "We have a trusting relationship with those we serve. People come to us in a vulnerable position, and we can either build that trust or destroy it by our actions. It didn't take us long to know what we had to do."

The error prompted Mayo Regional to transform many of its processes related to the outcome of its root-cause analysis and to further emphasize a culture of safety at the hospital.

"We now use EpiPens in the ER," Roberts says. "In the past, no one would think to use an over-the-counter medication in the hospital, but we have gone to these because a nurse [using an EpiPen in the same situation] would have had to give 10 individual doses, making the same error obvious."

The EpiPens cost approximately 50 times more than the generic epinephrine, but Gabarro says, "this points out if you focus only on cost

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president and CEO
Institute for Healthcare Improvement



and exclude quality, you can expose yourself to greater risk and potentially negative outcomes."

When high-risk medications such as heparin or insulin are given to a patient, guidelines require that two nurses be present to check one another's dose. As a result of the error, a process change was instituted that adds epinephrine to the high-risk medication list at Mayo Regional.

Additional process improvement at the hospital resulted from the event:

- Time-outs, which allow any caregiver to stop a procedure in progress and receive answers or clarification to their questions, was extended from the operating room to the entire hospital;

- A decision was made not to use the EpiPen Jr. for pediatrics because it looks too much like the adult version. The decision then led to discussions with the manufacturer about improving its medication labeling processes;

- A universal way of referring to the subcutaneous and IV dosages of epinephrine with greater clarity was instituted.

"We could not have imagined all we have gained from this," Gabarro says. "It's sad that what triggered it was such a monumental loss."

Executive Ownership

Gabarro, now a graduate of Voluntary Hospitals of America's 15-month patient safety fellowship, emphasizes the need for ownership at the CEO level, as well as patience, while transitioning to a full-disclosure program. "It is a journey," he says. "Leaders need to realize this does not occur overnight."

Maureen Bisognano, newly appointed president and CEO of the Institute for Healthcare Improvement, believes full-disclosure programs are more than just the right thing to do; they're also a critical step in the process of healing for both the patient and caregiver and a prudent business decision for hospitals.

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Bisognano says some hospitals that have gone to full-disclosure programs have seen malpractice costs reduced. "They have found they pay out smaller, more frequent amounts but that the overall amount paid out has been decreased," she says.

Putting Policies in Place

Denise Dudzinski, associate professor, department of bioethics and humanities at the University of Washington School of Medicine, says it is important that hospitals have a clear set of policies in place for how they will handle disclosure of adverse events, whether near misses or worse.

"Without policies, hospitals will always grapple with the ethical question first," says Dudzinski, who co-authored an article on the subject in the Sept. 2 issue of the *New England Journal of Medicine*. Beyond disclosure, policies should call for an immediate review of the event and fix any root causes, the article notes.

Bisognano suggests hospitals contemplating full disclosure consider three key components to help pave the road to success. To begin, the leadership team should be involved in talking with families who have experienced a medical error.

"When you see, hear and feel things from the patient's point of view, it can change leadership's view of the situation," Bisognano says. "If a CEO would talk to families, they would get a much different view than looking at the paperwork from their office."

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Second, a subset of the leadership team should be sent on learning missions and talk executive-to-executive at institutions like the University of Michigan Health System, which launched its own full-disclosure program in 2001. The UMHS, which includes 913 beds, three hospitals, 38 health center/clinics and a medical school, recently released data covering a 12-year period that compared legal claims and costs before and after its program was initiated. The study showed a decrease in new legal claims, time-to-claim resolution and total liability costs after the new program was implemented.

The third component Bisognano suggests is to put into place a strong process for supporting caregivers involved in medical error.

'It's About Conversations'

Awareness of the positive results related to the adoption of full-disclosure programs is growing, and the University of Illinois Medical Center at Chicago has been reaping those benefits since initiating its own program in 2006. Once a student of the University of Michigan's full-disclo-

sure ideology, UIMC has now become a leader in the effort.

"Many believed if you told the patient you made a mistake, you would write a check right there," says John DeNardo, CEO at UIMC. "What we have found is that there is not an increased tendency to sue, but rather a reduction."

Timothy McDonald, M.D., anesthesiologist and UIMC's chief safety and risk officer, in June was awarded a \$3 million grant from the Agency for Healthcare Research and Quality to see how greater transparency impacts patient safety and litigation.

"It's not just about disclosure at the end," McDonald says. "It is about having the conversations at the beginning—reporting events, investigating, communicating through the consent process, communicating with one another. The belief is that this is what changes a culture and thus reduces the occurrence of medical error—fewer lawsuits and claims are a result."

To that end, the father and sister of a patient who was harmed by medical error at UIMC now sit on its medical staff review committee. The

committee reviews reports of error and near-misses throughout the hospital, evaluating how best to resolve the situations.

"We talked long and hard about including the patient representatives on the committee and selected them very carefully," says William Chamberlain, chief medical officer at UIMC. "It has been good because even when you say you want to be patient-centered, it's hard to remember sometimes what that means. Patients and families remind you of how something looks to an outsider."

From a business perspective, McDonald says full disclosure is simply the smart thing to do. Defending cases where a known medical mistake is made is a bad business model.

"More dollars often end up going toward defending cases that could have been saved by being principled up front," he says.—Tracy Granzky Wetzel is a freelance writer in Chicago. ●



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