Chapter Four

Safety Crusade

Mrs. Mary McClinton, age sixty-nine, arrived at Virginia Mason Medical Center on November 4, 2004, having been diagnosed with a brain aneurysm, she was scheduled for a complex, but not particularly dangerous invasive radiology procedure. The plan was for doctors to insert a miniscule stent to keep blood flowing freely through an artery and then inject dye enabling doctors to see her bloodstream flow on an imaging test.

The procedure seemed to go beautifully. Mrs. McClinton, a beloved member of her church and community, was wheeled to recovery. But she awakened from anesthesia in horrific pain, her legs swelling visibly. The interventional radiologist immediately called a Patient Safety Alert and a clinical team worked feverishly to try and save her life. Doctors and nurses struggled mightily throughout the night and in the ensuing days, but Mrs. McClinton steadily worsened. As the hours ticked past her vital organs began an inexorable process of shutting down.

This chapter tells the story of what happened to Mary McClinton and why. More broadly, it tells the story of Virginia Mason's safety journey—a journey where the loss of Mrs. McClinton would mark its low point, at the same time inspiring the entire medical center to new and much safer heights. It is the story of a safety journey that was transformed into a safety crusade.

Patient Safety Alerts™

Five years before Mrs. McClinton arrived at Virginia Mason, the historic 1999 IOM report *To Err Is Human,* was published. It detailed the epidemic of medical errors in the United States and made clear that the American medical culture—Virginia Mason included—reflexively resisted disclosing and discussing medical errors. Dr. Gary Kaplan and his Virginia Mason colleagues wanted to change that. To do so, they sought to probe the level of comfort providers within the medical center had for reporting and discussing safety issues. Thus, in 2002, they started measuring the "culture of safety" using a proven measurement tool developed by a provider insurance conglomerate (Physician Insurers Association of America (PIAA); Virginia Mason switched to an Agency for Health Care Research and Quality (AHRQ) tool in 2005 and has used it ever since).

"We wanted a baseline measure and, not surprisingly, it showed there was low trust in terms of being able to report," says Cathie Furman, RN, senior vice president for Quality and Compliance. The research found that most Virginia Mason employees believed that if they self-reported medical mistakes they would be punished or would lose their jobs. There was very little trust that the administration would adopt a blame-free approach and use information about errors to improve the safety of care. At the time, like every other hospital, Virginia Mason used what were known as quality incident reports (QIRs) each time an error was discovered. Typically, however, the QIRs would sit on a shelf collecting dust for months, only to be filed away and forgotten.

The Virginia Mason Production System (VMPS) presented an entirely different way to deal with error prevention. Cathie Furman joined Kaplan and the team for the first Japan trip and was amazed that every worker in the Toyota plant was empowered to stop the line to prevent a defect. When she saw a worker stop the line she thought, "That's interesting. In the health care environment that would mean that someone's going to yell and scream at you. I mean, how could an assembly line worker stop a multimillion-dollar line? And all these people came, but they weren't coming to yell and scream, which is exactly what would have happened if it was a nurse. They felt that it was more important for that worker to get the resources that he or she needed to fix the problem before it went to the next worker. They weren't going to pass that defect on. That was *huge* in our eyes."

As they embarked on a process to establish a stop-the-line system at Virginia Mason, one concern raised was that mistakes in health care were so numerous that a stop-the-line approach might potentially stall or even paralyze the system. "The fear," says Furman, "was that we would never get the line started again."

Kaplan insisted, however, that such a process be developed and put into place at Virginia Mason. To demonstrate a seriousness of purpose, the responder to a stop-the-line call would not be a supervisor or manager but an executive—someone senior enough to send a message that Virginia Mason Medical Center was serious about protecting patients. During an executive committee meeting, Kaplan asked for a commitment from everyone present to drop what they were doing and respond to stop-the-line calls—or, as they were to be called at Virginia Mason—Patient Safety Alerts (PSAs).

Implementing the program was not a simple matter. Defining a defect in a medical setting presented a challenge. During the committee meeting there was agreement that a PSA would be called when an event constituted a near miss or inflicted actual harm. During preliminary conversations, though, doctors pushed back. They argued that many instances of harm—ventilator-acquired pneumonia, for example—should not be considered an error because these things happen in medicine. Complications, they argued, were inevitable. "If I have to do surgery on a dirty wound, there's going to be an infection," one doctor said. "Am I supposed to call a PSA on that?" The definitions were not so neat and tidy—not at the start anyway. During the next year or so there was a good deal of discussion seeking to define more precisely terms such as "error" and "near miss."

There were other complex questions. What would happen, for example, in the event that a clinician and administrator disagreed on whether an event met the standard of a PSA? What if a clinician called a PSA and the executive in charge did not agree it met the standard? These were difficult discussions where the correct path was often not at all obvious. The Virginia Mason leadership was passionately committed to improving safety, however. An indication of this commitment came early on with a clear rule: If there was a disagreement over whether a problem rose to the level of a PSA, it would go directly to Cathie Furman for her judgment. Then, if she was uncertain for any reason, she would go to Gary Kaplan. Thus, if a PSA was to be overruled it would have to be done with the agreement of the executive in charge, along with Furman and, in certain cases, Kaplan as well. This sent a signal throughout the medical center: With the CEO directly in the PSA loop, the message was clear—*this matters.*

Nonetheless, the team struggled from the start working through definitions and designing policies. Only significant events could be categorized as PSAs; all other mistakes fell into the old category of QIR. "It was not smooth from the get-go," says Furman. Yet they persevered, learning with each step along the way, fixing, amending, and revising as they went.

"The other thing we learned in the first couple of years was deciding that PSAs had to be *significant* created all sorts of complexity because what was significant to the eye of the reporter versus the executive who owned it could be

quite different. We would spend so much time trying to figure out whether it was a PSA or not that we really increased the lead time, and we weren't actually focused on the necessary corrective action."

An important step forward came in February 2005, when the QIR category was eliminated at Virginia Mason, and it was decided that all events involving the safety or well-being of a patient would be deemed a PSA. Three color-coded categories were established based on potential severity. Red PSAs involve anything life-threatening, any never-event, and anything that poses or could pose serious harm to a patient. Also included within the red category are actual or near misses, wrong-site surgery, accusations of sexual misconduct, security issues, and disruptive behavior by staff or patients. In addition, the red category included all issues considered to be reportable events by the National Quality Forum, including falls with injury and Grade 3 or 4 pressure ulcers. Orange PSAs are somewhat less severe in intensity, but they often involve interactions between or among different specialties or departments. Thus, getting to the bottom of the matter will likely involve more resources and a more intense, cross-departmental effort. In all, about 1 percent of PSAs are red, 8 percent orange, and the rest yellow. A yellow PSAs is a slip or a latent error, something that employees recognize as carrying the potential for error but not immediately life threatening. Furman says yellow can be "anything from an outdated tuna fish sandwich"—which could sicken a patient—"to nurses being frustrated that the elevators aren't functioning properly," thus delaying patient treatment.

Because the PSA program was somewhat complex, at least at the outset, and because it was new, it required extensive staff education. Furman and her team developed case studies—real stories from Virginia Mason—to make the PSA concept clear. At monthly meetings throughout the medical center, including gatherings of managers, department heads, professional staff, and so on, she and her team would tell a new story. This was important because she was finding a reluctance on the part of many staff members to call a PSA. Staff members were deeply committed to protecting patients, but they worried about repercussions. "Staff have told me that they don't report because they have reported before and nothing ever happened," says Sarah Patterson. "They say that if they reported they would be shunned by their co-workers for telling and that it takes too much time to report. These reasons sync up with what we have learned from other high-risk industries about why people don't report errors." Nurses feared the wrath of doctors who, in turn, feared committing a breach of camaraderie, perhaps professional deference. No one, it seemed, wanted to be seen as stepping on anyone else's toes. And with the program still in its infancy, there was no proof yet that it could have a real impact on protecting patients.

A Nurse's Courage

Then came a dramatic episode that served as a powerful catalyst supporting the PSA program. A nurse was ready to provide chemotherapy to a cancer patient when she noticed that the patient had not yet received an echocardiogram (to ensure a strong heart) and given a urine sample (to determine alkaline level). This was a simple oversight, she thought. She pointed this out to the doctor, who she assumed would order the testing. He did not. Instead, the physician grew annoyed with her and ordered the chemo to commence. Trying to be positive, the nurse noted that the protocol required both tests before treatment. The doctor brushed her aside and told her to begin treatment.

The nurse had a decision to make: do as instructed by the doctor or make a stand that she believed to be in the best interest of the patient. She chose the latter and placed a call to Dr. Jacobs, Chief of Cancer Services. After she explained the situation, Jacobs thanked her and contacted the doctor, making a point to say the nurse was correct—that the echocardiogram and urine test were necessary prerequisites to the chemo infusion. After the call from Jacobs, the physician, now livid, called the nurse and let loose, verbally abusing her on the telephone, dressing her down for challenging him and then for reporting him.

Her response? She phoned Dr. Jacobs again and explained what had just happened. Jacobs did not hesitate. He promptly called a PSA saying the doctor had been abusive and unprofessional. The doctor was called, told he had acted unprofessionally by ignoring protocols and verbally abusing a nurse, and taken offline while the matter was investigated.

Word of this story raced through the medical center. Senior executives in the hospital personally thanked the nurse and encouraged all staff members to report anything they deemed a threat to any patient. The message from executives was emphatic: You call in a PSA, we've got your back.

A Doctor's Courage

For generations the cultural norm in medicine has been that mistakes were discussed in private circles within the hospital or physician practice—if at all. It is this very culture, says Sarah Patterson, that must be challenged and broken down to create a genuine culture of safety within the medical center. "It's really changing the mindset in health care about defects and errors," she says, "that we shouldn't talk about them, we've got to hide them. The system puts it all on the backs of individual doctors and nurses, saying, 'You've got to do the best you can to protect your patients. There's no system out there. It's just all you.' We've got to change that mindset, and we've got to change the culture."

Given the nonstop, high-risk nature of the work, Patterson says doctors and nurses, just to make it through the day, "have to minimize in their minds the risk their patients are exposed to. It creates an environment where people tolerate things that shouldn't be tolerated: Lapses, not following standard work, not building in enough checks. The PSA system is really our signal to the organization that we need to change this culture. We're making good progress, but it's a big change. People come to us trained at other institutions, then we have to start from scratch again every time we get a new nurse, a new doctor and say, 'It needs to be different here, and you need to be a part of this.'"

This message was delivered with tremendous force in an incident during 2003, when Dr. Daniel Hanson, a talented young hospitalist who had served for five years as Chair of the Quality Assessment Committee, made a mistake. Dr. Hanson was filling out a paper prescription one day (this was about nine months before Virginia Mason had computerized physician order entry). He wrote an order for atenolol, a beta-blocker, for a fragile, elderly patient. In doing so, Dr. Hanson wrote: "25 mgms QD"—calling for 25 milligrams daily. There were two immediate problems: First, the Joint Commission had made it quite clear that QD was a potentially dangerous abbreviation and had recommended that clinicians discontinue its use. Their fear was that in the world of physician scribble the abbreviation could be too easily confused with QOD (every other day), and QID (four times a day). The second problem was that the 25 was scribbled so that it was not entirely clear.

"It was late in the evening, and we were all busy trying to wrap things up for the day," recalls Dr. Hanson. "The patient was very sick and fragile with heart disease. The atenolol would help slow his heart rate and lower his blood pressure." Dr. Hanson wanted to start the patient on a low dose of the medication and then increase it if needed. When the order reached the pharmacy, however, the pharmacist read the 25 as 75. Some patients tolerate such a dose well, but this patient was much too sick for that. When the medicine was administered, the patient's heart rate slowed dangerously and his blood pressure dropped to an unsafe level. That night, he was transferred to the intensive care unit (ICU), where the staff sought to reverse the effects of the drug, but it was too late. It was clear the patient was in very bad shape and, in fact, he died soon thereafter.

The reality was that the patient was so sick that his life expectancy would have been months, at best. Nonetheless, an error had contributed to his death. Dr. Kaplan asked Dr. Hanson to address his colleagues at a physician meeting about the incident. Doctors had talked about errors in the past, of course, but almost always in small groups. Hanson brought a couple of slides, including one showing his handwritten order. About half those present thought it read 25 mgms and the rest thought it read 75. It was an order, in fact, that any one of the doctors

present could have written. Hanson's handwriting was hardly perfect, but neither was it as illegible as that of many of his colleagues in the room. Doctors sat in silence, watching as Hanson became openly emotional about the incident.

Dr. Hanson took the blame, yet a PSA investigation found that there had been a series of breakdowns along the way. The ward clerk who received the prescription from him should have stopped the line on seeing that QD was written on the script. The same was true of the pharmacist and the patient care nurse. The problem was not Dr. Hanson—the problem was that the system had failed. There was not a culture of safety yet at Virginia Mason. "We can't just write orders and walk away—we have to be good team members," Hanson told his colleagues. The message to all physicians was, as Hanson put it, "we can't just step in, fire off an order and not be accountable for how it's interpreted." Hanson's colleagues listened carefully to his remarks. They knew how difficult it must have been for him and many expressed admiration for the courage it required for him to stand up in such a large forum and talk about the mistake.

Seven years after the mistake, in 2010, Dr. Hanson viewed the safety culture at Virginia Mason as dramatically transformed. He says when he goes to conferences around the country it is quite clear that Virginia Mason is far ahead of most other medical centers in its safety journey. "I go to these national meetings and see people struggling with things we are way beyond," he says.

Cathie Furman sees this a defining moment on the Virginia Mason safety journey. "For a well-respected hospitalist who is chair of the quality committee to stand up in a room full of his peers and describe what he had done—it was a profound moment. Everyone talked about it for months afterward. It was such a powerful example, and I have no doubt that countless times after that doctors stopped and thought about that before writing a prescription. I suspect some real mistakes were avoided because Dan Hanson had the courage to stand up there and tell his story."

Why Shouldn't *Everybody* Get a Flu Shot?

Every year in the United States an average of 35,000 people die from influenza, and it was clear to Virginia Mason clinicians and administrators that they needed to provide immunization for as many patients and staff as possible. It was especially important to protect the large number of geriatric patients cared for within the medical center, for these patients were especially vulnerable to the flu. To streamline the immunization process, an RPIW was convened with a diverse team of staff members, including doctors, nurses, administrators, and a medical assistant. The goal of the RPIW was to design the most efficient way possible

to deliver flu shots to patients and employees. In the process, a drive-thru flu shot plan was established that would enable patients to get their shots far more quickly and conveniently—no parking, walking to the clinic, sitting in a waiting room, and so on. Under the plan, patients would drive through a circular drive, where teams of clinicians would deliver the shots in seconds. The major effort by patients would be to roll down their windows and roll up their sleeves.

During the course of their work designing a plan for patients, the team came across some alarming statistics about the failure of most health care workers to get immunized. They discovered that on average, only about 40 percent of health care workers in the United States received the flu vaccine each year. Nurses tended to run below that level—somewhere around 36 percent. At Virginia Mason overall it was slightly better, with about half the employees receiving immunizations annually. In the past, few had paid attention to this fact, but now that the patient was at the top of the Virginia Mason strategic plan, it seemed somewhat embarrassing that so many doctors, nurses, and other staff members—people in daily physical contact with sick patients—were not immunized.

Dr. Joyce Lammert was a member of the workshop team, and she says after the team had conducted its basic review of the literature, Suzanne Tyler, a Virginia Mason supervisor, cut to the heart of the matter. "What's with the 30 or 40 percent" immunization rate among health care workers, she asked. "I don't understand why we don't require *everyone* who works here to get the vaccine. Do you know that 50 percent of the people with flu have no symptoms? So half the people in this room could have the flu during flu season and not even know it and not even feel bad and when we cough or breathe or touch we could be spreading the flu. If we're putting the patient first, we're not protecting them when they come in here."

It was an amazing moment—not unlike the breakthrough moment on the cancer center design when a nurse had said "Let's design it so we bring everything to the patient rather than having the patient chase around the medical center for services." Suzanne Tyler was not a physician or a nurse and did not hold a particularly senior position at the medical center. Nonetheless, it was the quality of her idea that mattered. It was a moment that revealed the power of welcoming all voices on an RPIW. When Tyler made her point, the workshop team members looked at one another and knew immediately that she was right—that immunization against the flu should be required of every employee in the medical center. Dr. Bob Mecklenburg, Chief of Medicine, was sitting across the table from Tyler when she asked why they didn't require everyone to get the vaccine, and he was struck by it. "You know," he said, "that's a very good question. That's a *very good question*." Says Dr. Lammert, "It was so obvious that this was putting the patient first."

The workshop recommendation requiring all employees to receive a vaccine every year was readily approved by medical center leadership including the board. Gary Kaplan was excited by the new policy, seeing it as the embodiment of patient-focused care. "We're going to be the first in the world to say if you want to be a Virginia Mason employee, you must have a flu shot as a fitness for duty requirement, just like the TB test, just like a background check," he says.

Lammert then led an extensive effort, beginning in the winter of 2005 in preparation for the 2006 flu season, to educate the Virginia Mason workforce about the new policy. Predictably, there was pushback. "I remember a professional staff meeting where we had more than a hundred physicians in the room," says Kaplan, "and I was explaining why this was important, and one of our physicians who is from another country raised his hand and said, 'I came to America for freedom. You can't tell me what to put in my body.' And I was about to say, 'You're right, you have choices, and you can choose not to work here.' But I didn't have to, because one of our pulmonary and critical care doctors stood up, turned to him and said, 'Let me tell you something. I take care of those people in the ICU who get respiratory failure from the flu and never again are we going to give our patients the flu in my hospital.' So that's when I knew—and I got chills just standing there and thinking about it—when I knew that we were getting serious traction on putting the patient first."

The most intense pushback came from the nurses' union, which filed a grievance against the medical center, arguing that the policy should be part of the collective bargaining process. An arbitrator and federal court agreed with the union, resulting in union nurses having the option to be immunized or not. The union also opposed Virginia Mason's policy requiring nonimmunized staff to wear a mask during the flu season, but an administrative law judge rejected the nurses' assertion and ruled that Virginia Mason had the right to require masking as part of its infection control policy. The result: 98 percent of Virginia Mason employees received flu vaccine and 2 percent wore masks.

Mecklenburg considered this a key moment in the Virginia Mason journey: "This story is important because what might well become national policy some day comes from an administrator who steps back and takes a look and says, 'What's wrong with this picture? Why doesn't *everybody* at VM have a flu shot to protect our patients?' The breakthrough concept did not come from any of us executives who were hoping for an incremental change. She changed the rules for 5,000 employees—and possibly many more health care workers in our community and in our nation."

An interesting footnote to the issue was that the following year, as flu season approached, whether to be vaccinated was, for the great majority of Virginia Mason employees, a nonissue.

Mrs. Mary McClinton

In November 2004, Mary McClinton was dying and nobody at Virginia Mason knew why. Throughout that night and into the following days the team worked feverishly to try and solve the mystery.

After intensive study of every step during the procedure, there came a breakthrough: The radiologist said the only explanation he could think of was that the medical team had inadvertently injected something caustic into her system. It was the only explanation that made any sense. Everyone involved had gathered together to try and figure it out—interventional radiologist, anesthesiologist, endocrinologist, radiologist, nurses, and prep table technician. This thinking led the team to the prep table in the room where the procedure had taken place. On the table were a variety of instruments and supplies used in the procedure, including three stainless steel bowls containing contrast dye, saline solution, and chlorhexidine, an antiseptic used to cleanse bacteria from the skin before an incision is made to reduce the chances of infection. All three liquids were clear—identical in appearance.

During the course of such a procedure the interventional radiologist stands over the patient and is handed whatever he needs from the prep table. The experienced technician in charge of the prep table might have wanted to make sure he not only kept up with the demands of the procedure, but that he was a step ahead—anticipating the radiologist's need. Thus, in advance, he placed a label on an empty syringe marking it as "contrast dye." But then, a calamitous mistake: Instead of filling the syringe with contrast dye, he mistakenly filled it with chlorhexidine. During the procedure, the interventional radiologist was handed this syringe and unknowingly injected chlorhexidine into Mrs. McClinton. Nineteen days later she died.

Mrs. McClinton had been a patient of Dr. Robert Mecklenburg for many years. As it happened, Mecklenburg was not only Chief of Medicine, he was also Mrs. McClinton's primary care physician, and the night of the mistake he happened to be on call when he received a request for a consultation to see a very sick patient in the ICU. Mecklenburg was stunned to see that the patient was Mary McClinton. Mecklenburg not only knew Mrs. McClinton, but he knew members of her family as well, and he sat with them at the hospital during their vigil even as her condition steadily worsened. In the days after the procedure, Mecklenburg, along with so many other Virginia Mason clinicians, tried to understand what had gone wrong and then tried everything they could possibly think of to save Mrs. McClinton's life. As chief of the Department of Medicine, Mecklenburg felt strongly that the entire Virginia Mason community needed to know what had happened to one of their patients, reflect on it, and learn from it.

Mecklenburg and Dr. Mindy Cooper, chair of the medical center's Quality Assurance Committee, authored a memorandum to Virginia Mason staff explaining what had gone wrong. Mecklenburg and Cooper knew that sending the memo throughout the medical center would result in the press getting a hold of the story, but this deterred neither them nor Gary Kaplan nor the board of directors. The Virginia Mason community—and the greater Seattle community they served—deserved the truth. One week after the incident, the memo was sent electronically to all Virginia Mason employees. It explained that "the solution used to clean skin before and after procedures was recently changed from a brown iodine-based solution to a colorless antiseptic," and thus was identical in appearance to the dye. "At some time during the procedure, the clear antiseptic solution was placed in an unlabeled cup identical to that used to hold the marker dye … that is injected into blood vessels to make them visible on x-rays … The antiseptic solution is highly toxic when injected into a blood vessel. Acute and severe chemical injury to the blood vessels of the leg blocked blood flow to muscles, causing profound injury and swelling of the leg. Kidney failure, a sudden drop in blood pressure, and a stroke followed." The essential truth of the matter, the doctors wrote, was that no individual should be blamed—no individual *would* be blamed—because it was a system failure. Responsibility for the error, they wrote, rests with "all of us."

Mrs. McClinton's death was a grievous loss, not only for her family, including two brothers, a sister, and four adult sons, but it was also a loss for many others in her community of Everett, Washington, where she worked at the Greater Trinity Missionary Baptist Church helping needy people find work. She had done so much fine work for disadvantaged people—including during the years she worked as a vocational coordinator in Alaska prior to moving to Washington in 1996—that she was made an honorary member of the Tinglit tribe, a great honor for anyone not born into the tribe.

After thirty years of practicing medicine, Mecklenburg had seen many medical mistakes, and he had witnessed patients dying, but, as he put it, "I had never seen the full effect of a death like that on the larger community and the family." Perhaps this was owed to having been Mrs. McClinton's physician, or perhaps his familiarity with the family. Perhaps it was even in part due to his heightened focus on the patient as a result of the new approach at Virginia Mason.

"What I really hadn't seen before through thirty years of being a doc was the collateral damage of a medical mistake," he says. "This family was torn apart by this, as was the community, and the ICU nurses and the providers at Virginia Mason and the sense of self of the entire medical center. So this was two orders of magnitude more devastating than I had ever seen before. What you may not fully realize is that you may have affected hundreds of other people in a profound way that will never be redeemable."

In a newspaper article about the matter, reporters cited Virginia Mason's forthright admission. In a front-page story, the *Seattle Times* noted that Virginia Mason "took the unusual step of publicly explaining, and apologizing for, the error." In the article, Mrs. McClinton's son Gerald said he was pleased the hospital did not try to conceal the mistake. He said physicians at Virginia Mason had treated his family well and that the hospital had approached his family about a settlement. Given the preventable nature of the mistake he was deeply upset. Then he added a crucial point—a point that speaks as painfully as it does eloquently to the nature of this as a system failure. Gerald McClinton said that although he was "getting angrier by the minute," he added, "I don't know really who I should be getting angry at."

Publicly, Virginia Mason officials expressed deep sorrow and regret along with a determination to learn from this event. Dr. Bob Caplan was quoted in the newspaper saying that "we just can't say how appalled we are at ourselves and the suffering of this patient and her family and friends. … In many ways, this open and honest communication is our way of trying to honor her." Learning from such mistakes, he said, was essential, adding that "you can't understand something you hide."

Privately, however, the men and women of Virginia Mason wept. They pounded the table in anger. They felt a sense of despair. How could they have done this? After all their hard work to protect patients, how could they not have seen the massive flaw inherent in the three clear liquid bowls on that prep table? It was a shattering moment for Kaplan, his leadership team, and the board of directors—for every staff member at Virginia Mason. They were two years into an arduous yet intoxicating journey on the VMPS path—far enough into it, they believed, that this sort of catastrophic event was not supposed to happen. Very quickly, however, they realized that their journey had barely begun; they had a great deal of work to do to make Virginia Mason a safe environment every day for every patient. No sooner had that realization settled on the medical center than the clinical and administrative leaders vowed that they would do whatever was necessary to make Virginia Mason the safest hospital anywhere.

As would be expected, the death of Mary McClinton prompted the Seattle press to compare Virginia Mason with other medical centers in terms of safety. The *Seattle Times,* citing data from the state's Department of Public Health, wrote that "Virginia Mason had reported more 'adverse events' over the past three years" than the three other major Seattle hospitals. Within the article there was a critically important caveat added by the Department of Public Health official, however. She told the newspaper that, in fact, Virginia Mason was generally more conscientious about reporting such incidents.

Mistake Proofing

The PSA system failed to save Mary McClinton's life, but the team wanted to make sure that never again would a patient receive an injection of chlorhexidine. The PSA deep dive made it terribly obvious that there should never have been three unlabeled stainless steel bowls of clear liquid on the prep table. That was a fundamentally flawed system where human error was not only possible, but seemed inevitable. Was mistake-proofing achievable in this case? In fact, the team found, it certainly was. Why did chlorhexidine have to be in a bowl at all? Why not place it on a stick that could be used to swab the skin? That would make it impossible to place the solution in a syringe. It would ensure that what happened to Mary McClinton never again happened to another Virginia Mason patient.

That particular fix—chlorhexidine on a swab stick—was a wonderful example of process improvement and mistake-proofing. Another example involved altering the arrangement of instruments on an anesthesia cart. Traditionally, a couple of dozen items were placed on a cart in no particular order. Often the carts appeared messy and unprofessional. However, no one ever thought of the cart in quality or safety terms. No one had ever thought about the cart and its design as a way to increase safety for patients. But knowing the tools and concepts of VMPS, Dr. Bob Caplan had exactly that thought. Working with his team, Dr. Caplan redesigned the cart in a much more orderly fashion. He did so by creating a shadow board showing the exact location for each tool or piece of equipment. A photograph of the proper arrangement was placed atop each anesthesia cart under a clear piece of Plexiglas (wiped down between cases). Each piece of equipment would be placed on a picture of itself, leaving no doubt where anything should go. The cart also instantly showed gaps—which pieces were missing. As Dr. Caplan puts it, "At 3:00 a.m. you don't need to worry about your memory. All the essential information is there. At 7:00 a.m. a faculty instructor can tell at a glance if the resident—new or experienced—has set up the anesthesia workspace according to specification. At any time of day, an assistant can enter the room and determine at a glance if there is something missing that needs to be replaced or provided. The very first time that I had a novice resident use the shadow board, she looked up at me and said, 'Dr. Caplan, I've been training for three months, and this is the very first time that I've been confident that I've set up correctly!' What a marvelous experience for her … and what a telling lesson for those of us who are educators."

A Culture of Safety

The question now for Virginia Mason was this: What's next? How do we go about changing—in the most fundamental way possible—the culture of safety

within the medical center? In the answer to these questions, the death of Mrs. McClinton became the essential catalyst for change, for it coincided with the Virginia Mason goal-setting process for the following year. When Mary McClinton died, each major department had set goals and the list of major goals for 2005 was up to thirteen. After her death, Gary Kaplan and his senior leadership team made a decision to set all that aside and establish a single goal for the entire medical center: Safety. "It was the catalyst that bumped us into really being passionate about safety," says Dr. Bob Caplan. "I think after that we really began to appreciate the meaning of stop-the-line. We knew that some people had come into the radiology suite before that event and had looked at the setup and had wondered in their head, 'I wonder if that's safe?' But the wondering hadn't gone any further. This is the event that taught us that stop-the-line is a real concept. You really have to call out the safety hazard when you see it. After that our Patient Safety Alert system really took on meaning in our organization. It became evident to people that you need to inspect to be safe, and you not only need to inspect your own work, you need to—no matter how difficult it might be—inspect the work of others, and you have to be ready to call out the defects and take action."

There were many changes in the aftermath of Mrs. McClinton's death, including the alignment of executive compensation with measurable safety improvements. More than anything else, though, it was the commitment by the organization—the leadership in particular—to continue along the VMPS path that spurred work toward greater safety. Elizabeth Dunphy, RN, believes that the death of Mrs. McClinton helped to solidify the notion that "I have a duty and responsibility to report a problem, and I trust nothing bad will happen to me in doing that." Mrs. McClinton's death, she says, "developed a level of trust and accountability that 'I need to stand up, and I need to do the right thing no matter what.' … It also gave this organization clarity around what the PSA process is and that the intent behind it is true discovery and prevention and the rigor it will take for us to mistake-proof it, to make it perfect. And we can't make health care perfect until we make every single process perfect. So it's to the level of detail of every syringe, every bowl, every basin, anything you touch needs to be done correctly. It really pulled us back into the reality of what we were trying to do. We were a few years into our journey, and we thought we were pretty good, and we learned humility, and I don't think we have forgotten it, nor will we ever forget it."

After Mrs. McClinton's death, Virginia Mason leaders heard that other hospitals had precisely the same conditions—unlabeled clear solutions in stainless steel bowls on procedure tables. The public disclosure of Mrs. McClinton's death served as a catalyst for these hospitals to change their process and adopt a new medication/solution labeling policy several months prior to the Joint Commission

issuing a sentinel event alert based on the type of error in the McClinton case. The reality is that transparency on the part of Virginia Mason led to many other organizations significantly improving their safety procedures—and perhaps saving lives.

Evolution of the PSA System

The PSA system had not saved Mrs. McClinton, but it had done a great deal of good, and it was evolving into a powerful method for protecting patients. The system had been inaugurated in the fall of 2002 and by the start of 2004 informal surveys revealed that 100 percent of the medical center staff knew what a PSA was and an estimated one third of employees had reported a PSA. Why so much progress so quickly? The key was that when a PSA was called revealing a system flaw, the administration responded immediately by fixing that problem. Thus, when employees saw that they were getting rapid action in response to PSAs, it generated confidence and trust in the system. People believed in it because they had seen it work on problems they cared about—problems in *their* department, on *their* floor, affecting *their* patients. It was no longer an abstraction—a shiny new program from Japan. Thus, the more PSAs were met with prompt corrective action, the deeper and broader the belief throughout the medical center in the system.

Cathie Furman heard increasing levels of positive feedback from the staff about the PSA system. "They'd say, 'Oh, wow, that's been bugging me forever. You guys finally fixed it. Maybe you're really serious about this,' she says. "That's when the floodgates really opened."

Still, there were questions, discussions, and disagreements about what warranted a PSA call and what constituted a red PSA versus an orange. With the most serious PSAs revealing a process or structural problem, there were sometimes disagreements about when the underlying system problem was truly solved—solved enough to make sure that whatever had gone wrong would never go wrong again. "We were still learning how to mistake-proof," says Furman. "When is it closed? When have we fixed it? Sometimes the executive, quite frankly, would just want to get rid of it and would be wanting to close it and the Patient Safety Specialist wasn't sure, or maybe the Patient Safety Specialist thinks it's ready to close and I don't think it is ready."

A significant change to the PSA process came in January 2007 when Virginia Mason established a requirement that all red PSAs would have to be presented to the Quality Oversight Committee of the medical center board of directors by the executive responsible for that PSA. Furman considers this a breakthrough. These executives are quite senior within the medical center, accomplished men

and women accustomed to giving many presentations, but Furman notices that when they have to go before the board committee on a red PSA they tend to get anxious. "They make sure they've got their ducks in a row, but the board doesn't always accept their corrective action plan," she says. "Sometimes they say, 'You know, I am not convinced this isn't going to happen to another patient. You've got to go back, and we want you to do A, B, and C.' That's been really good. I think it's really increased the robustness of the process, and the public board members are very much engaged in this work."

The deep involvement of board members in PSAs is another powerful signal to the medical center staff that the process is taken seriously. Whenever a red PSA occurs board members are immediately notified and receive a monthly update on the case until it is resolved. No red PSA can be closed until the board says it is closed. "We're saying the board members are the ones that are going to decide if we've adequately mistake-proofed our processes," says Kaplan. "They're smart people, and they want to make sure it is mistake-proofed and sometimes they send it back: 'You need to look even closer at this. We're not sure this is yet fully mistake-proof.'"

In addition to overseeing red PSAs, board members also come face-to-face with patients at board meetings. Patients—or patient family members—are invited to tell their stories and engage in discussion with board members. Some stories are positive, but many—even most—are not. The board pushes to hear cases where the hospital has not performed as well as it should. "It's extremely powerful," says Lynne Chafetz, Virginia Mason general counsel. "It really connects the dots to 'what are we here for.' It is one thing to have a manager talk about a patient, but it's much more powerful to have a patient in the room."

Initially, there was a fear within the medical center that PSAs might increase the exposure of clinicians at Virginia Mason—as well as the hospital itself—to medical malpractice claims. Had this been the case, of course, the program would have been doomed. But not only do PSAs not increase the likelihood of malpractice, Kaplan argues the program actually decreases such risks. Importantly, the state of Washington has in place a regulation allowing health care organizations to file a Coordinated Quality Improvement Plan with the state Department of Health. If a plan is filed, information and documents specifically created for, collected, and maintained by an approved plan are provided a higher level of protection from discovery in legal proceedings. This encourages organizations to improve quality through careful and thorough review of its processes without an increased fear of medical malpractice claims.

The folks at Virginia Mason had found that for every eight patients who encountered an adverse event, only one sued. "And that's generally because of two things," says Furman. "They want an apology, and they want to make sure that nobody else is affected in the same way. With the Patient Safety Alert

system, because we know sooner rather than later that something has gone wrong, the first thing we do is apologize. We disclose, we apologize, and we take care of whatever their additional costs are for the harm." One particular case, for example, involved surgery gone awry. The surgeon operating in a difficult area made an error, immediately announced that there had been a mistake, and summoned help. When the patient woke up the doctors informed the patient and spouse precisely what had happened. Although there was a financial settlement, there was a belief on the part of Virginia Mason executives that the amount of that settlement might have been dramatically different if they had not been apologetic, honest, and transparent.

The dollars-and-cents result of this openness policy has been significant. Malpractice actions against the medical center have decreased significantly since implementation of the PSA system and transparency. From 2007 to 2008 Virginia Mason professional liability insurance expenses declined 26 percent. They declined an additional 12 percent the following year. (Symbolic of the sweeping change has been changing the name of the risk management department to the Patient Safety Department.) Says Cathie Furman, "We have risk insurance carriers who are clamoring to get us on their program," carriers who want Virginia Mason to teach other medical centers a similar approach to risk mitigation. Insurers, she says, see the Virginia Mason approach "as huge risk mitigation." Thus, while other providers in their area are experiencing increases in the costs of their malpractice premiums, Virginia Mason is achieving double-digit decreases.

As the PSA system develops and matures, clinicians are able to tackle more complex issues. There are many errors throughout the country, for example, with antithrombotic medications. Too much of the medication and patients bleed; too little and they clot. At Virginia Mason clinicians found that these medicines were among the top drugs that triggered PSAs. Thus, they instituted a program in 2009 specifically targeting the safe use of these drugs. Data over time also showed that oversedation was another PSA trigger, and the medical center convened a medication collaborative to tackle that issue.

Falls were another significant trigger for PSAs. "Hospitals around the world are actually quiet factories for falling," says Furman. "About three patients fall for every 1,000 patient days around the world. We didn't really pay much attention—it was just business as usual—until we began to look at our Patient Safety Alerts, and we realized this is something we really need to focus our attention and focus our abilities on." They have done so in a variety of ways, including probing the link between medications and falls. Pharmacists now investigate every fall resulting in injury to determine whether there might have been a pharmacological explanation. They've made significant headway in reducing the number of falls with injuries by establishing Falls University, a multidisciplinary team that reviews all falls, completes root cause analyses, spreads the lessons,

and implements best practices throughout the medical center. This process has revealed that a majority of falls occur while toileting. The solution: standard work including hourly nurse rounds where nurses help guide the patient to the bathroom, reducing the need for patients to venture out on their own. Nurses also make sure the bed is in the safest position to prevent falls and that the bed alarm—for patients who are not supposed to get up on their own—is switched on. "But here's the conundrum," Furman says. "Next year we're going to be focused on reduction of urinary tract infections, which are caused by indwelling urinary catheters. We've got some improvement work going on there, which is great, but when we take out the catheters on patients, guess what? They're going to get up and go to the bathroom. The number one reason for people falling is going to the bathroom. So how do you measure when we're doing better?"

Such vexing issues notwithstanding, PSAs have made an enormous difference in the quality and safety of care at Virginia Mason. The more than 15,000 individual cases where a PSA has been called since 2002 are obvious places where quality and safety were improved—and in some cases lives saved. But much more broadly the PSA data help identify systemic problems that need to be solved with new policies and processes; by implementing standard care or by going back and conducting an RPIW to try and find a solution. In the moment, PSAs help clinicians provide higher quality, safer care to an individual patient and if they accomplished no more than that, they would be enormously valuable. More fundamentally, though, PSAs are learning opportunities where benefits go far beyond an individual patient. They result in changes to processes that lead to standard work and mistake-free procedures. This benefits many patients now and in years to come.

Bob Caplan uses the example of a patient with a deep venous thrombosis, a clot in his leg, which was treated in a very conventional way with a devastating outcome. "By going back and studying that event in our Patient Safety Alert process," says Caplan, "we realized that we weren't content with conventional approaches to the management of deep venous thrombosis. We could discern by looking at the current medical literature that there's about to be a shift and there's about to be a better way to do it. That Patient Safety Alert drove us to those realizations, allowing us to take care of our patients with leg clots in a much better way than if we had just continued on with the conventional and standard approaches.

"This is a great example of how Patient Safety Alerts make a difference. If you're a practitioner and you get back a report that says your patient has a clot in the lower leg, it's not really clear in the current literature what is the best way to treat that. And this case that I'm talking about, this Patient Safety Alert, involved a clot in the lower leg that was treated in a conventional manner. We didn't like the way it evolved. As we investigated this PSA our radiologist said,

'You know, every time we give a reading that a patient has got a clot in the lower leg the practitioner asks us almost invariably what to do about that.' It's because the state of knowledge was so indistinct about that. Now what we're doing is at the bottom of the radiology report we're providing the practitioner with what we consider to be better guidance and guidance that's going to give us better outcomes. That's an example of how a Patient Safety Alert makes a big difference and pushes us forward in care."

The PSA system was significant enough that five years after its inauguration, Cathie Furman and Bob Caplan published an article about it in *The Joint Commission Journal on Quality and Patient Safety* (July 2007, Vol. 33, No. 7), in which they concluded:

> The PSA system has proven to be the single most important tool to make our care safer. It provides a quick, timely process for improvement and feedback to our staff that their concerns will be listened to. Lessons learned are …
>
> 1. Executive leadership is a prerequisite.
> 2. Reporting should be easy, with multiple methods available.
> 3. "Significant" is in the eye of the beholder: Open the floodgates for all concerns.
> 4. Claims management staffing will go down as Patient Safety Alerts go up. Right before the start of the PSA system, we had six claims managers and three RN reviewers; we now have three claims managers and five patient safety specialists.
> 5. Be prepared to change the processes of care as the organization learns from the PSAs.

In the culture of safety consciousness at Virginia Mason one of the most important events each year is the awarding of the Mary McClinton Patient Safety Award. There is an air of reverence around this award that is perhaps unlike anything else within the medical center (a staff focus group rated this award as the number one form of recognition given to staff). It is awarded annually to one of the teams within Virginia Mason that has made outstanding progress toward a safer patient environment. At the second annual presentation of the award, in 2007, Gary Kaplan stood up to speak.

"The auditorium was packed," he says. "Mary's sister was there, all four of her sons and her pastor was there, our staff, managers, physicians—standing room only. I was making a presentation of our progress on our safety journey; it was really a chronicle of our progress. I had not planned on doing this but on the spur of the moment I said, 'How many people here have actually called

in a PSA?' Well over two thirds of the audience of 300 or more people raised their hands. And I got chills. I said, 'Wow, could you raise your hands again, please and just look around. Think about what this says about our community and how we are now behaving in terms of patient safety, and how we are thinking.' … To me, that was awesome."