# 2. Never Events

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## *"Never Events"*

The term "Never Events" was first introduced in 2001 by Dr. Ken Kizer, M.D. in response to a series of medical errors which he felt were completely avoidable, such as "wrong side surgery." This was against a background of the 1999 Institute of Medicine report which proclaimed that between 44,000 and 98,000 patients died each year as a result of medical errors in US hospitals. That the report probably considerably exaggerated the number of patients injured is immaterial. No patient should die from medical errors. The fiscal impact amounted to an estimated $9.3 billion dollars annually and 2.4 million extra hospital days. The report has been widely criticized because of extrapolation which is inappropriate, but it does not matter – it is part of our national culture.

Dr. Kizer and the National Quality Forum (NQF) proposed a series of serious reportable events to increase public accountability and consumer access to critical information and healthcare performance. The NQF approved 28 events in 6 categories: surgical, products or device, patient protection, care management, environmental, and criminal.

Dr. Kizer and the NQF claimed that these categories shown in Table 2.1 are the result of "widespread discussion among representatives of all parts of the health care system." While I am not certain this is entirely the case, and I will take issue with several of the "Never Events," compared with what followed from CMS, these seem highly reasonable with some caveats. My concern, however, is that, however well intentioned these efforts are, they do not seem to bear in mind that there is a downside to all of these "improvements" in medical practice. This is the issue of whether physicians are professionals or employees. I would argue that any "improvement" which increases the feeling that physicians are employees, rather than professionals, ultimately damages patient care to a much greater extent than anyone realizes. I will return to this theme later.

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Table 2.1. The National Quality Forum's Health Care "Never Events" (2006).

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| *Surgical events* |
| Surgery performed on the wrong body part |
| Surgery performed on the wrong patient |
| Wrong surgical procedure performed on a patient |
| Unintended retention of a foreign object in a patient after surgery or other procedure |
| Intraoperative or immediately postoperative death in an American Society of Anesthesiologists Class I patient |
| Artificial insemination with the wrong sperm or donor egg |
| *Product or device events* |
| Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care facility |
| Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used for functions other than as intended |
| Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facility |
| *Patient protection events* |
| Infant discharged to the wrong person |
| Patient death or serious disability associated with patient elopement (disappearance) |
| Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a health care facility |
| *Care management events* |
| Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration) |
| Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products |
| Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility |
| Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a health care facility |
| Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates |
| Stage 3 or 4 pressure ulcers acquired after admission to a health care facility |
| Patient death or serious disability due to spinal manipulative therapy |
| *Environmental events* |
| Patient death or serious disability associated with an electric shock or electrical cardioversion while being cared for in a health care facility |
| Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances |
| Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility |
| Patient death or serious disability associated with a fall while being cared for in a health care facility |

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Table 2.1. (continued)

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| Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility |
| *Criminal events* |
| Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider |
| Abduction of a patient of any age |
| Sexual assault on a patient within or on the grounds of the health care facility |
| Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the health care facility |

## *Comments on "Never Events"*

One cannot argue that surgery performed on the wrong side, on the wrong patient, or the wrong surgical procedure performed on a patient are not egregious. However, some comments on the NQF "Never Events" are warranted:

1. "Unintended retention of a foreign object in a patient after surgery or other procedure."
   While I agree that this should never happen, the surgeon does not control the situation in which this does happen. Complicated operative procedures that go on for 7 or 8 hours are not unusual in academic medical centers. Operations of such long duration rarely have just one scrub tech or nurse or one circulating nurse. Instead, the surgeon usually has three different technical or nursing teams, not including breaks for lunch and other mandated breaks. The setting in which sponges are retained or, more likely, laparotomy pads (since surgeons such as myself do not use sponges anymore because they are too likely to get lost) is that there are counts when the team is switching over and these are put in plastic bags. These counts are done quickly so as not to delay the operative procedure. At the end of the procedure, there is a count in which there is confusion as to how many lap pads were actually used and sometimes the count is wrong. By this time, the surgeon has started closing the abdomen and then asked whether there is anything in the abdomen. With the abdomen partially closed, one does not have a clear look at the abdomen because the incision is partially closed and, rather than open the incision again, one does the best they can. Some institutions such as the Mayo Clinic have dispensed with counts.

They completely close the patient and do an X-ray on the way to the recovery room. Most operating rooms do not have the setup or the space to do this. Of course any "witch hunt," as to the responsible person, usually ends up on the back of the surgeon, rather than the system, thanks mostly to our "friends" from the plaintiff's bar.

2. "Intraoperative or immediately postoperative death in a Class I patient."
   I agree that this should never happen, but I can think of one situation in which it may. Malignant hyperthermia usually affects a young, very highly muscled male who is a "very good candidate for general anesthesia." Whether one thinks of this possibility and the response of the anesthesiologist or nurse anesthetist determines whether the patient dies.
3. "Product or device events."
   I have no quarrel with product or device events. In addition, some of the patient protection events are clerical errors, such as the infant discharged to the wrong person, and undoubtedly reflect on the quality of the staff performing the duty. This may appear to be simple, but it can result in disastrous consequence. Patients' elopement and/or suicide relate to the ability to keep track of every single patient, 60 min an hour and 24 h a day. The current economics of hospitals are such that they have too much "administration," some of which is occasioned by the joint commission and some of which is simple inefficiency. Whatever the reason, there are too few people on the line and too many people who are staff. This has nothing to do with physicians and surgeons and more to do with the administrative structure, of which physicians have lost control.

I have difficulty with several other areas, as follows.

4. Maternal death or serious disability in a relatively normal delivery should be very rare. However, amniotic fluid embolism, even if promptly recognized, may be fatal. It may be a reportable event, but is not culpable.
5. I do not believe that it is possible to absolutely prevent elderly patients from falling in a healthcare facility, nor do I believe that it is possible to prevent elderly patients, including those who are disoriented and infirm, from falling while trying to get out of bed when the bed rails are up. Similarly, with respect to criminal events, I doubt that it is possible, to prevent all of these

without an army of security people, which will detract from the nursing ratio. Determined criminals can evade any security net with enough skill.

## The CMS List of "Never Events" and the "No Pay" Initiative

### *The CMS Initiative*

The reason for the CMS initiative is not entirely clear. For the most part, the CMS initiatives follow the NQF list. The CMS initiative was put forth in the recent Federal Register [1]. In this publication, the CMS lists a series of HAC (hospital-acquired conditions) for which payment to hospitals will be withheld. The amount of money is trivial, $20 million, but the purpose, according to Kerry Weems, Acting Administrator, was to make the hospital safer for patients. Unfortunately, the CMS lists of events, and especially those for which payment will be withheld, are not totally preventable. I will now go through some of the events and HAC for which Medicare will withhold, or least proposes to withhold, hospital funds, discussing several of the hospital-acquired conditions (HAC) which I will show are not only not "Never Events" but also cannot be defended as "No Pay" events. The reader is referred to an interesting editorial by Lembitz and Clarke entitled: "Clarifying 'never events' and introducing 'always events'" in which they provided evidence that the "No Pay" category is not only inappropriate but also dead wrong [2].

### *Specific Events*

1. *Prevention of falls*. In a recent editorial, Inouye et al. in the *New England Journal of Medicine* pointed out that "falls are often the result not of medical errors but of disease impairments and appropriate use of medications and other treatments. Falls and injuries can occur even when hospitals provide the best possible care" [3]. As I have pointed out previously in this article, even with bed rails, dementia may lead patients to try and get out of bed, thus falling and injuring themselves.

2. *Catheter-associated urinary tract infection*. Even with the best care, patients with indwelling urinary catheters will develop infections. There is no possible way that the infection rate will be zero. Patients also pick at the catheter and the meatus, thus leading to urinary tract infections.
3. *Vascular catheter-associated infections*. I know a little about this, having organized several programs in hospitals for the administration of TPN. Even at the University of Cincinnati Hospital, in which we had three excellent TPN nurses in a hospital of 600 beds and in which we reduced the infection rate from 27%, when the residents were mixing TPN on the floor, to 0.77%, the rate was not zero. In addition, in the ICU, when patients have a tracheostomy, a subclavian catheter site will inevitably become contaminated, making the catheter prone to infection. Including vascular catheter-associated infection may be well-intentioned, but it is just plain wrong. It bespeaks a group of individuals who clearly do not have any clinical experience in this and no idea of what actually transpires (Dr. Peter Provonost through the Michigan Colloborative has been able to accomplish a zero rate).
4. *Surgical site infection following coronary artery bypass graft-mediastinitis*. It is certainly possible to decrease the incidence of mediastinitis by careful attention to detail, control of blood sugar, preoperative showering with chlorhexidine, and the appropriate use of antibiotics. However, the rate will never be zero, though it may approach 1% as de La Torre and his colleagues have shown [4]. In that paper, a maximum blood sugar of 120 mg/dl was the target. At this time, the consensus is that 120 is too low because of the frequency of hypoglycemia, but a target of below 150 mg/dl accomplishes the same result without the hypoglycemia.
5. *Surgical site infection following bariatric surgery*. This category shows how out of touch the individuals who put together the list really are. While the incidence of surgical site infection is less in laparoscopic bariatric surgery, it probably is about 4–6%. This does not belong on the "No Pay" list.
6. *Surgical site infection following orthopedic procedures*. The orthopedic surgical community has made great strides in decreasing the surgical site infection, but it will never be zero.
7. *Deep vein thrombosis and pulmonary embolism in total knee and hip replacement*. The orthopedic literature in the prevention of deep vein thrombosis led by Harris, among others, was a

great scientific accomplishment. The rate has been greatly reduced and further attempts at reduction will lead to hematomas and infection and loss of the prosthesis. The American Academy of Orthopedic Surgeon has recently recommended different prophylaxis regimens from those proposed by the American College of Chest Physicians.

## *Surgeons: Professionals or Employees*

While I believe the attempts by CMS are well-intentioned, I think they miss the point. A critical issue for me is a gradual transformation of physicians and surgeons from professionals to employees. This has profound implications for the care that patients will receive in this country. Professional obligations are without limit of time and surgeons are always responsible for the patient. Professionals take emergency calls. Employees do not, unless they are paid to do so. Professionals care for the indigent. Employees do not unless they are paid to. Each time another rule is passed by a governmental agency, however well-intentioned, it drives a further nail into the coffin of professionalism. The patient is the loser.

As I have said earlier, "the beatings will continue until morale improves" and it seems the beatings go on. When you finally reduce a once proud profession to employees, you will have shift workers and finally there will be a physicians union. I know that physicians unions are illegal, but there will be strikes. Over a decade ago, when I served as a Governor of the American College of Surgeons, I called attention to the newsreels of Walter Reuther leading the strikes in Detroit for the AFL-CIO and the strikers being beaten by police. I certainly hope that it does not come to that but, at the rate we are going, I believe that a union is inevitable. Not a professional organization but a union. Already the medical students have unions and some of the resident organizations have unions, so as these physicians grow into practice, they will have unions. There will be new work rules.

## *The Quality of Individuals Who Become Physicians and Surgeons*

Many of us who had been involved in surgical education and the education of medical students believe that the quality of the people going into medicine has diminished over the past decade. A congressman from

Table 2.2.

*1. "Never" and "No pay"*
Events which overlap between the NQF and CMS definitions of "never events"
- Surgery on the wrong body part
- Surgery on the wrong patient
- Wrong surgery on a patient
- Foreign object left in patient after surgery
- Death/disability associated with intravascular air embolism
- Death/disability associated with incompatible blood
- Death/disability associated with hypoglycemia (HAC's include diabetic ketoacidosis, nonketotic hyperosmolar coma, hypoglycemic coma, secondary diabetes with ketoacidosis, secondary diabetes with hyperosmolarity)
- Stage 3 or 4 pressure ulcers after admission
- Death/disability associated with electric shock
- Death/disability associated with a burn incurred within facility
- Death/disability associated with a fall within facility

*2. "Never"*
Events which should never happen according to the NQF, but are not listed on the CMS "never events"
- Postoperative death in a healthy patient
- Implantation of wrong egg
- Death/disability associated with the use of contaminated drugs, devices, or biologics
- Death/disability associated with the use of device other than as intended
- Infant discharged to wrong person
- Death/disability due to patient elopement
- Patient suicide or attempted suicide resulting in disability
- Death/disability associated with medication error
- Maternal death/disability with low risk delivery
- Death/disability associated with hyperbilirubinemia in neonates
- Death/disability due to spinal manipulative therapy
- Incident due to wrong oxygen or other gas
- Death/disability associated with the use of restraints within facility
- Impersonating a health care provider (i.e., physician and nurse)
- Abduction of a patient
- Sexual assault of a patient within or on facility grounds
- Death/disability resulting from physical assault within/on facility grounds

3. *"No pay"*
The list of controversy: Adverse events which are classified by the CMS as non-reimbursable "never events", but lack the according definition by the NQF
- Catheter-associated urinary tract infection
- Vascular catheter-associated infection
- Surgical site infection following coronary artery bypass graft (CABG) – mediastinitis
- Surgical site infection following bariatric surgery (laparoscopic gastric bypass, gastroenterostomy, laproscopic gastric restrictive surgery)

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Table 2.2. (continued)

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| • Surgical site infection following orthopedic procedures (spine, neck, shoulder, and elbow) |
| • Deep vein thrombosis (DVT)/pulmonary embolism (PE) in total knee replacement and hip replacement |

Comparison of "never events", as defined by the NQF ("serious reportable events") versus CMS ("non-reimbursable serious hospital-acquired conditions").
Lembitz and Clarke *Patient Safety in Surgery* 2009 3:26 doi:10.1186/1754-9493-3-26

a southern state recently told me that he had always attended an annual meeting of 400 of the best college students in southern universities. He told me of a recent meeting he attended in which he asked his usual question of how many in the audience were pre-med, only one hand went up in that room of 400 students. He then said that, 10 years ago, half the students in the room would have raised their hands. I will close with another well-known quote: "So shall ye reap the whirlwind" (Table 2.2).

## Selected Readings

1. "Preventable Hospital-Acquired Conditions (HACs), Including Infections," Federal Register 75, no. 157 (Aug 2010):50080.
2. Lembitz A, Clarke TJ. Clarifying "never events" and introducing "always events". Patient Saf Surg. 2009;3:26–31.
3. Inouye SK, Brown CJ, Tinetti ME. Medicare nonpayment hospital falls and unintended consequences. N Engl J Med. 2009;360:2390–3.
4. Carr JM, de la Torre R. Implementing tight glucose control after coronary artery bypass surgery. Ann Thorac Surg. 2005;80(3):902–9.