Patient Safety, Public Safety and Certain Medical Malpractice Proceedings
July 17, 2008

News/Event: The widespread public and patient safety movement has resulted in expanded reporting of preventable serious events in healthcare.

Analysis: Patient safety, public safety and some malpractice actions now intersect with issues concerning the investigation of serious reportable events in healthcare.

Application: Forensic psychiatrists evaluating cases of alleged medical malpractice must have a working knowledge of serious reportable events and an understanding of statutory and common law protections to the release of some related documents. Some types of records are not protected from disclosure.

Patient safety is now a well-established national movement within the larger framework of public safety. In the last twenty years, the media has played an important role in sounding various alarms concerning problems related to the safety of medical devices, prescription drugs and the adverse events of medication error, serious mishaps, suicide, escape from mental health facilities, etc. As this article is being written, the story continues to unfold concerning the tragic consequences of tainted heparin.

The purpose of this short article is to demonstrate how issues pertaining to patient safety, public safety, and medical malpractice proceedings are intersecting. First, we will examine a clinical vignette of a tragic event within a Veterans Administration Medical Center (VAMC), which set into motion a sequence of events. The facility where it occurred has present and future concerns regarding patient safety. The national Veterans Administration has need to study and to investigate. The public at large has important concerns regarding the reporting of preventable events and the keeping of statistical records that will serve to minimize future harm. Injured patients and the families of deceased patients have rights to pursue civil remedies and financial compensation.

Vignette:

Mr. W. was a disabled veteran in his early forties. In 2006, newspapers printed the story of his death and followed its aftermath. The patient was known to a particular Veterans Administration Medical Center (VAMC) for having severe chronic mental illness. On the day he died, he required psychiatric hospitalization and was admitted to a psychiatry ward. Mr. W. produced a very minor altercation with another patient over a mealtime beverage. A nursing assistant and several patients intervened to physically restrain Mr. W. on the floor of the dining area. During the restraint, Mr. W. died and medical examiners determined that asphyxia and cardiac arrhythmia contributed to his death. This, by definition, was a serious reportable healthcare event. The family of Mr. W. filed a large wrongful death suit in federal court alleging medical malpractice as well as a Bivens action having to do with the alleged deprivation of civil liberties during the restraining of Mr. W. (The U.S. Supreme Court ruling in Bivens v. Six

Unknown Federal Narcotics agents dealt with issues relating to the Fourth Amendment to the U. S. Constitution, which states, "The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures shall not be violated….")

In response to the tragic event, the VAMC was required to report the event to appropriate governmental agencies and to conduct a Root Cause Analysis. Furthermore, in anticipation of a lawsuit, the VAMC conducted physician and nursing peer review activities designed to address professional issues within the context of the specific tragedy. The local police, the specific VMAC police and the National VA Office of Inspector General were required to investigate whether a crime had been committed.

The attorneys representing Mr. W.'s family sought to acquire documents from the VAMC regarding the Root Cause Analysis, the medical and nursing peer review records, and documents generated by the VA Office of Inspector General concerning Mr. W.'s death. The U.S. attorneys representing the VAMC and its professional employees claimed that all three categories of written record were privileged. The federal district court considered the controversy and ruled that the Root Cause Analysis documents were statutorily protected from disclosure to the plaintiffs. It ruled that the medical and nursing peer review documents were protected from discovery under the attorney work product rule because these documents had been prepared at the request of the VAMC's local attorney in response to an anticipated lawsuit. However, the court concluded that the written record of the investigation by the VA Office of Inspector General was not privileged and would be turned over to the plaintiffs. Almost immediately following the court's ruling, the lawsuit settled.

The first lesson is obvious but bears mention. Minor events do not require restraint and/or seclusion. Furthermore, when truly needed, restraints must be applied carefully so as not to cause significant harm or death. Next, Root Cause Analysis records are protected by federal statute and certain types of peer review documents are protected from discovery if they have been properly declared to be attorney work product. Other records, including those of official investigative bodies, may be discoverable, as in this case, if the investigation has been concluded.

Serious Reportable Healthcare Events

Upon reviewing the vignette it becomes clear that lots of diverse attention follows a tragic inpatient event. In 2002 the National Quality Forum (NQF) published a list of twenty-seven serious "never" events and recommended nationwide reporting of those events for the purpose of enhancing patient and public safety. In 2003, the American Psychiatric Association (APA) reviewed, through its Task Force, the twenty-seven events and found that six were particularly applicable to psychiatry. The six are:

1. Patient death or serious disability associated with patient elopement for more than four hours

2. Patient death or serious disability associated with medication error
3. Patient death or serious disability associated with the use of restraints or bedrails while being care for in a healthcare facility
4. Sexual assault on a patient within or on the grounds of a healthcare facility
5. Death or significant injury of a patient or staff member resulting from a physical assault
6. Patient suicide or attempted suicide resulting in a serious disability while being cared for in a healthcare facility

In 2002/2003, the APA had concerns about whether written information found within Root Cause Analysis documents, etc. would be protected from subsequent use in malpractice case actions. The U.S. Congress passed the Patient Safety and Quality Improvement Act of 2005, which required the reporting of serious adverse healthcare events, and protections were placed concerning Root Cause Analysis documents. These protections in combination with the overall growth of patient safety/public safety movement led to an astounding increase in NQF membership from 2002 to 2006. Initially, only a handful of states and organizations were members. By 2006, twenty-five states required licensed healthcare facilities to report various kinds of serious adverse events. Other states are considering similar reporting requirements. Presently, eighty million lives are covered under the present reporting structures. NQF's list of members and board of directors is impressive and includes most national subspecialty medical organizations.

In 2006 the NQF published an update (Serious Reportable Events in Healthcare 2006 Update: A Consensus Report c. 2007, National Quality Forum, www.qualityforum.org , Washington, D.C.). NQF took the twenty-seven events, added one and gave guidance concerning application of the list to the investigation of tragic events in the healthcare setting. The most recent list follows:

Serious Reportable Events in Healthcare

1. SURGICAL EVENTS
   A. Surgery performed on the wrong body part
   B. Surgery performed on the wrong patient
   C. Wrong surgical procedure performed on a patient
   D. Unintended retention of a foreign object in a patient after surgery or other procedure
   E. Intraoperative or immediately postoperative death in an ASA Class I patient

2. PRODUCT OR DEVICE EVENTS
   A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
   B. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
   C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

3. PATIENT PROTECTION EVENTS
   A. Infant discharged to the wrong person
   B. Patient death or serious disability associated with patient elopement (disappearance)

C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility

4. CARE MANAGEMENT EVENTS
   A. 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)
   B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
   C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
   D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
   E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
   F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
   G. Patient death or serious disability due to spinal manipulative therapy
   H. Artificial insemination with the wrong donor sperm or wrong egg

5. ENVIRONMENTAL EVENTS
   A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
   B. 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
   C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
   D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility
   E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

6. CRIMINAL EVENTS
   A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
   B. Abduction of a patient of any age
   C. Sexual assault on a patient within or on the grounds of a healthcare facility
   D. Death or significant injury of a patient or staff member resulting from a physical assault (e.g., battery) that occurs within or on the grounds of a healthcare facility

Reporting, Reimbursement, and Professional Practice

The reporting movement continues to grow and to have important effects in a variety of areas. First, beginning on October 1, 2008, it is proposed that Medicare and Medicaid dollars will not cover a number of hospital-acquired conditions: Foreign object retained after surgery, air embolism, blood incompatibility, type III and IV pressure ulcers, falls and trauma-fractures, dislocations, intracranial bleeding, injuries, crushing injuries and burns, catheter associated urinary tract infections, vascular catheter associated infections, and surgical site infection-mediastinitis after CABG. (Federal Register, Volume 73, No. 84 Wednesday, April 30, 2008. The change was made in response to the Deficit Reduction Act of 2005 and the Medicare Improvements and

Extension Act, Division B, etc.) The changes were largely in response to the work of the NQF, more recently in collaboration with the Centers for Disease Control, etc. Major health insurance carriers are considering implementing similar policies of non-payment for avoidable events (B.A. Gabriel, Uncle Sam's New Scrutiny, Physicians Practice, May 2008).

More implications of the reporting movement will become evident. Serious reportable healthcare events will begin to represent de facto institutional malpractice. The extent to which this will reach to individual physicians concerning their professional duties to patients in specific adverse events will soon become evident. One wonders whether state licensing boards of medicine and nursing will soon become automatically notified about specific serious preventable healthcare events not previously sent to those boards as complaints. State boards of medicine may one day be included in the notification process and will be investigating alongside other relevant agencies as the public and patient safety movement grows. If so, it will impact physician hospital privileges and licensing.

Forensic psychiatrists might wish to take note that the logic is powerful: Bad medical/psychiatric results have now become publicly declared to be reportable medical mistakes because they are serious, rare and held to be avoidable. One day, easily envisioned legislation may make medical malpractice cases stemming from serious reportable healthcare events carry sufficient force to shift the burden of proof to the defendant doctor and institution. If so, the ancient descriptor, Res ipsa loquitur, "the thing speaks for itself," may apply to these cases. Recall that the APA Task Force report found that six of the NQF's twenty-eight "never" events applied to psychiatry. Everything considered, public and patient safety will soon become the larger topic under which medical and legal issues of medical malpractice are discussed.