



Alleged Failure to Recognize and Restrain Patient that Presented Elopement Risk Leads to \$900,000 Settlement

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NEWS: An 88-year-old woman was taken to a local hospital after being found sitting outside her son's home, apparently confused. She was then transferred to a nursing facility, where she was diagnosed with altered levels of consciousness and inability to perform activities of daily living. The woman was again admitted to the hospital and fitted with a vest-restraint system. Based on an interdisciplinary plan of care with regard to the restraints, the woman's vest and wrist restraints were discontinued three days after her admission. The next day, the woman was visited by her son. Soon after her son left, the woman went missing and was found on the hospital roof approximately 14-16 hours after disappearing, dead of hypothermia. The parties settled for \$900,000 prior to trial.

BACKGROUND: A woman was found sitting outside of her son's home apparently confused and was taken to a local hospital. After remaining in the hospital for approximately one week, the woman was transferred to a nursing facility, where she remained for two months and was diagnosed with altered levels of consciousness and an inability to perform the activities of daily living. During her stay at the nursing facility, the woman began experiencing an unsteady gait and a continued altered level of consciousness. She was admitted to another local hospital with diagnoses of prior stroke, dementia, and normal pressure hydrocephalus, all causally linked to altered levels of consciousness. A note was entered into the

woman's chart that read, "pt. becoming agitated, not wanting to stay in bed." Another notation stated that the patient was an "imminent risk to self" and that she had been found trying to remove the Hep-Lock and attempting to climb out of her bed. In light of these observations, the woman was fitted with a vest-restraint system and moved to a patient room.

A couple of days later, an interdisciplinary plan of care with regard to the restraints was prepared. With respect to the vest restraint and wrist restraints, the plan noted that the woman was "attempting to discontinue therapeutic interventions," as the woman had been found trying to remove the restraints. The defendant alleged that despite the plan of care, the restraints were ultimately removed.

The next day, a physical therapist made a notation on the woman's chart that read, "[patient] sitting in recliner at nursing station due to increased tendency to wander and not tolerating Posey vest." At 10:30 a.m. that same day, an occupational therapist noted that the woman was in her room. Later that day, the woman's son came to visit her for four hours and alleged that the woman recognized him and was able to effectively converse with him. Some time after the visit ended, the woman went missing in the hospital. She was later found dead from hypothermia on the hospital's roof.

The woman's son sued the hospital claiming wrongful death on behalf of his mother's estate. The plaintiff alleged that while his mother was

in the hospital, he observed numerous staffers at the facility observing the woman wandering and that none of them took steps to address the elopement/disappearance risk. Furthermore, the plaintiff brought forth evidence that the woman traveled through a fire door without an alarm, through stairs above her room, through a door in the boiler room that should have been locked and through yet another door that should have been locked before reaching the roof, where she ultimately died. Documentation was introduced that confirmed that a mechanical room that the woman traveled through to reach the roof should have been locked, but that the lock had been broken for at least a few months prior to the woman's admission to the facility. Plaintiff's counsel also alleged that the facility had received numerous continuing violations of care-planning regulations, and that an unreasonable number of patient elopements had occurred at the facility in the two years preceding the woman's death. Despite having knowledge of these issues, argued the plaintiff, the facility took no steps to update its policies or provide training or emergency drills.

The defendants denied any wrongdoing, and a settlement was reached between the parties prior to trial in the amount of \$900,000.

REFERENCE

Court of Common Pleas of Pennsylvania, Fifth Judicial Circuit, Allegheny County, No. GD-08-026648

WHAT THIS MEANS TO YOU: This case perfectly illustrates several key principles of safety science that help to explain how errors like this occur. In his work on complex systems failure, James Reason posits that every accident is the result of multiple and sometimes seemingly small and unrelated system failures. By themselves, none of these small or latent failures are sufficient to produce a major accident. It is only when the failures aggregate — when the holes in Reason's "Swiss Cheese" model line up — that serious events with disastrous consequences occur. Such was the case here. This patient's death occurred because of multiple latent failures in two seemingly unrelated systems — clinical judgment and routine maintenance. None of these failures by themselves would have resulted in the death of the patient. It was the confluence of these latent defects — the failure of the staff to employ adequate clinical judgment in preventing elopement, combined with lapses in routine maintenance that left several

doors unalarmed and unlocked — that produced the disastrous outcome.

An examination of the clinical judgments made in this case reveals several shortcomings. The decision to apply the vest restraint at the hospital was made after multiple observations by the staff of the patient's altered mental status. Specifically, staff noted that the patient was agitated, was attempting to climb out of bed, was an imminent danger to herself, and had been trying to pull out her Hep-Lock. While this initial decision might have been well-reasoned, it was poorly documented. An interdisciplinary plan of care addressing the use of the vest restraint was not prepared for "a couple of days," and when the plan was finally developed, the staff employed circular reasoning to justify the need for the vest restraint — the patient needed the vest restraint because she kept trying to remove the vest restraint. This raises the question of whether the staff had a clear understanding of the patient's risk factors and indications for restraint use, and may have led to the subsequent erroneous decision to discontinue use of the vest restraint without employing alternative methods to ensure the patient's safety.

The day after the vest restraint was discontinued, a physical therapist clearly documented the patient's tendency to wander and also her inability to "tolerate" the vest restraint. This created the duty on the part of the staff to address the potential safety risk of elopement, especially after prior observations that the patient was an imminent danger to herself. The staff initially and appropriately addressed this risk by positioning the patient in a chair near the nurses' station. However, this protective measure was not maintained, and the patient wandered off the unit and to her death later that day. The staff apparently did not consider other alternatives to the vest restraint, which might have included assigning a sitter to the patient.

Also, it appears that the staff did not recognize that the patient's mental state fluctuated during the course of the day. On the day the patient wandered from the unit, a physical therapist noted that the patient had a tendency to wander and that she was positioned in a recliner near the nurses' station. Later that day, the patient's son reported that his mother had recognized him and had conversed with him. While this report from the patient's son may have been reassuring, it did not mean that the patient was no longer an elopement risk. This is particularly true in light

of the fact that providers had related the patient's altered mental status to underlying clinical diagnoses of dementia, prior stroke, and normal pressure hydrocephalus. Thus, the staff may have been erroneously reassured by the son's report of the patient's behavior, and as such failed to maintain the proper level of vigilance necessary to prevent her from eloping and harming herself.

An important strategy in guarding against complex systems failure is the implementation of critical redundancies — layers of safety strategies that guard against each other's failure. Interestingly, the hospital had a system of critical redundancy in place — two locked doors and one door with an alarm — but failure to properly maintain the doors defeated this important safety measure.

The many failures of the maintenance system illustrate yet another important safety principle — normalization of deviance. This is a phenomenon whereby system failures that go unaddressed over a period of time are no longer seen as deviations and become the organizational norm. Information developed by the plaintiff in this case showed that the lock on one of the doors had been broken for several months. It is clear that lapses in maintenance had become normalized at this organization — it is the way the organization routinely operated.

In addition to highlighting key safety principles, this case illustrates several important safety lessons for healthcare risk managers:

- Protective measures for confused, disoriented, or wandering patients must be implemented based on clear evidence of safety risks and may be discontinued only if the safety risks are no longer present or if the measure is being replaced with another, equally effective measure.
- Patients who are a danger to themselves because of altered mental status or due to any other cause must be assessed regularly to determine safety measures needed to prevent harm. Transient improvements in mental status must not be interpreted as resolution of the underlying causes of previously observed mental status changes.
- Routine maintenance plays a critical role in maintaining a safe environment for patients. Environment-of-care rounds are a critical component of the organization's safety program and should serve as the "canary in the coal mine" when routine maintenance and upkeep is being neglected.

REFERENCE

Reason J. *Human Error*. Cambridge, UK: Cambridge University Press, 1990. ■

Alleged Negligence Causes Oxygen to Ignite: \$1.2M Verdict

NEWS: A woman was admitted to the hospital after suffering a heart attack. The woman was a high fall risk and eventually fell and fractured her nose and cut her forehead. The woman was fitted with an oxygen mask. Shortly thereafter, the electrocautery combined with oxygen from the mask, sparking a fire and leaving the woman with first and second degree burns. A jury returned a verdict of \$1,215,000 in Michigan.

BACKGROUND: A 75-year-old woman suffering from deafness and blindness and unable to speak English was admitted to the hospital suffering from heart attack. She was immediately placed in the ICU, and although her condition was improving, she was medicated, agitated, and pulling at her breathing tubes and IV lines. Once the woman's condition improved, she was to be scheduled for cardiac bypass surgery. Due to the woman's high fall risk, she was fitted with restraints. Five days after being admitted, the restraints were removed by a nurse, causing the woman to fall and suffer a fractured nose and a cut on her forehead. While a resident was being called to care for the woman, she was placed back into a bed and fitted with an oxygen mask. The resident utilized a cauterization tool on the woman which emitted thermal energy. The electrocautery in the device mixed with the oxygen, a highly flammable element, from the mask, causing a spark and igniting a fire. The fire department was called to the scene, but the fire had been extinguished by the time they arrived. The woman lost consciousness during the ordeal and was resuscitated by hospital staff and was later placed into a medically induced coma for several weeks. The fire caused the woman to suffer first and second degree burns on her face and shoulders. Due to the injuries sustained during her hospital stay, the woman was forced to move out of her family home and into a nursing home.

The plaintiff alleged that the hospital's resident was negligent in failing to remove the oxygen mask. The resident, who had been on the job for only a few months, admitted he was fatigued when he committed the mistake. The case triggered a renewed discussion in Michigan regarding the number of resident per-shift hours worked and

increased supervision of first-year residents. However, the defendant denied liability. The parties disagreed on what injuries triggered the need for the woman's move to the nursing home. The defendant alleged that it was the underlying heart attack and the woman's pre-existing conditions, including deafness and blindness.

The plaintiff filed two suits — one for negligence and one for medical malpractice. The jury verdict of \$1.2 million was returned only on the medical malpractice claim.

REFERENCE

Circuit Court of Michigan, Case No.: 2008-004622-NM

WHAT THIS MEANS TO YOU: This case presents multiple areas of concern: the decision to remove the vest restraint in the presence of ongoing fall risk factors, impaired judgment on the part of the resident due to fatigue, and lack of supervision of this relatively new resident.

This patient was injured shortly after use of a vest restraint was discontinued. This raises the question of whether an adequate fall risk assessment was done prior to deciding to discontinue restraint use. It is also unknown whether staff considered alternative means of addressing fall risk. The patient was described as being blind, deaf, and unable to speak English. In an unfamiliar environment and without the ability to comprehend instructions or make her needs known, this patient should have been assessed as being at high risk for falling. Despite this, the vest restraint was removed, and it is unclear that any alternative means of protecting the patient were implemented in its place.

Resident fatigue is a significant threat to patient safety that has been well documented in the literature. It has been shown that 17 hours of sustained wakefulness impairs performance to the same degree as a blood level alcohol of 0.05%, the legal definition of intoxication in many industrialized countries. Thus, in this case, if the resident had been awake for 17 hours or more at the time of the incident, it was as if he had been intoxicated while caring for this patient. Given this, it is not hard to understand why he failed to discontinue the oxygen while using the cautery.

In 2003, the Accreditation Council of Graduate Medical Education (ACGME) introduced duty limits that restricted resident work weeks to 80 hours averaged over a 4-week period. However, interns and residents routinely worked more than the specified 80-hour limit. But even if residents' work hours adhered to the ACGME guidelines but included extended shifts, they were eight times more likely to

commit a preventable medical error and four times more likely to commit a fatal medical error.

In 2008, the Institute of Medicine (IOM) recommended that further measures be taken to safeguard patients from fatigue-related errors on the part of medical trainees. These measures included alleviating fatigue and loss of sleep among trainees by further reducing work schedules and providing five-hour periods of uninterrupted sleep during shifts of 16 hours or more, increasing resident supervision, and improving handoffs among trainees. In June of 2010, the ACGME released for comment new duty limit standards, with special focus on PGY-1 trainees. Under these new standards, PGY-1 work weeks cannot exceed 80 hours per week or 16 hours per shift, averaged over 4 weeks. More senior residents are also limited to 80 hours per week, averaged over four weeks, but may be scheduled for 24-hour shifts, with an additional four hours for patient handoffs. Although the ACGME rejected the IOM's recommendation of a period of five hours of uninterrupted sleep for residents working shifts longer than 16 hours, it did recommend "strategic napping" for such residents. The new standards are to take effect in July 2011.

Lack of adequate resident supervision is another well-documented threat to patient safety. Lack of technical competence and errors in judgment are common among trainees and can be easily counteracted with adequate supervision from more senior physicians. In addition, better supervision of medical trainees has also been shown to counteract the effects of fatigue in medical trainees.

This case highlights important lessons about the effects of fatigue on medical trainees and the ultimate impact on patients. In light of research evidence showing the effects of fatigue on medical trainees and the resulting injuries to patients, it is no longer acceptable to deploy fatigued medical trainees to care for patients. Even though the revised ACGME guidelines will not take effect until July 2011, organizations with residency programs would be well-advised to begin making the proposed changes now.

In addition, organizations must address resident supervision, particularly for PGY-1 residents. In addition to counteracting the deficiencies in judgment and technical skill among inexperienced residents, increased supervision is also a recognized countermeasure for fatigue among those residents. With increased national attention being focused on the role of fatigued and unsupervised medical trainees in medical errors, organizations that do not address these issues proactively do so at their own peril — and that of their patients. ■