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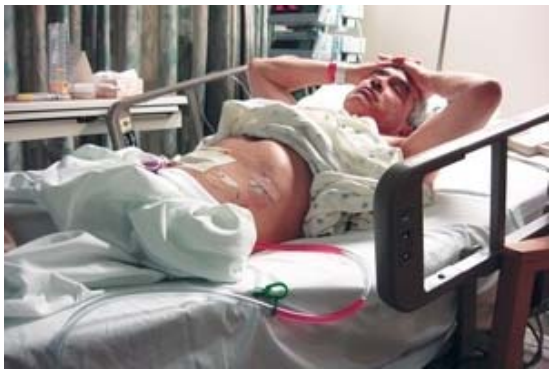
Cleveland Clinic cases highlight safety oversight flaws



Retired Air Force Col. David Antoon became a patient-safety advocate after he says was gravely injured during surgery at the Cleveland Clinic. He says no one is held accountable in the U.S. healthcare system.

By Joe Carlson
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Nearly four years ago, government inspectors investigating a complaint by retired Air Force Col. David Antoon threatened to cut off Cleveland Clinic from receiving Medicare payments after being stonewalled by hospital officials. The Vietnam combat veteran had accused the hospital of failing to fully investigate his charge that someone other than his authorized surgeon had performed prostate cancer surgery and left him gravely injured.

Hospital officials refused to show the inspectors all of the notes in Antoon's complaint file, and the doctor who claimed to have done the procedure declined to talk to surveyors about how the hospital handled the case, CMS inspection reports show.

Antoon, a commercial 747 pilot in civilian life until the operation left him incontinent, is baffled that medicine has no organization like the National Transportation Safety Board to address safety failures. “You cannot keep things concealed in aviation,” he said. But in healthcare, “They're just gathering data points from patient complaints. And every data point is a damaged life or a death.”

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Early 2010 wasn't the last time the flagship hospital of the prestigious Cleveland Clinic Health System was threatened with the ultimate sanction by CMS-backed state inspectors for not addressing problems initially brought to light by patient complaints. In 2012, inspectors threatened to shut off its nearly $1 billion per year in Medicare payments after hospital officials admitted they hadn't fully investigated a complaint that doctors had implanted a heart stent without first getting the patient's consent.

And last July, Ohio hospital inspectors again threatened to suspend Cleveland Clinic's participation in Medicare after hospital officials told a patient they had no evidence that a surgeon neglected to remove a suture needle after surgery. It was only under questioning by a government inspector that a hospital ombudsman later admitted having an X-ray on file showing the left-in needle, according to inspection reports on file with the CMS.

Cleveland Clinic officials did not make any top-ranking officials available to comment on the issues raised by its responses to these and other patient complaints. “Cleveland Clinic sees more than 5 million outpatient visits per year, has nearly 160,000 admissions and the highest acuity of patients in the country (meaning the sickest of the sick),” hospital spokeswoman Eileen Sheil wrote in an e-mail. “We are committed to providing the best care and safest environment for our patients.” Cleveland Clinic officials also say quirks in the state's inspection system lead to a higher number of CMS deficiencies.

A three-month Modern Healthcare analysis of hundreds of pages of federal inspection reports reveals the 1,268-bed hospital spent 19 months on “termination track” with Medicare between 2010 and 2013 as a result of more than a dozen inspections and follow-up visits triggered by patient complaints.

The Cleveland Clinic is far from alone in facing the only sanction the CMS can apply to hospitals when serious safety problems and violations of informed consent rules are brought to light by patient complaints. An analysis of Medicare inspection data found that between 2011 and 2014 there were at least 230 validated serious incidents—dubbed “immediate jeopardy” complaints—that led the agency to threaten hospitals with losing their ability to serve Medicare patients unless they immediately fixed the problems.

Overall, there were at least 9,505 CMS complaints lodged in that time against 1,638 hospitals, which included low-severity “standard level” violations; midlevel “condition level” violations; and the less common but most serious “immediate jeopardy” complaints. Only the most serious and condition-level complaints can lead to threats of being cut off from government funding.

Only in very rarest of circumstances has the CMS followed through on the threat. The CMS' ultimate goal with hospital inspections “is to ensure compliance with Medicare rules, not close down hospitals that are essential to local communities,” a CMS spokeswoman said.


Dr. Toby Cosgrove

Unlike with nursing homes, the CMS lacks the power to levy fines against hospitals that violate the rules. The absence of meaningful sanctions provides a loophole for officials at some hospitals to engage in prolonged negotiations with CMS inspectors when confronted with patient-safety complaints, which typically conclude with the hospital promising to revamp policies and beef up staff training. The result, safety advocates say, is a regulatory system unable to respond to problems in a manner that ensures the problems won't happen again once the inspectors have left the premises.

“There's a lack of a kind of a graded set of consequences,” said Dr. John Santa, medical director for Consumer Reports' health division. “One of the challenges in the system is there isn't much in between. It's either a traffic ticket or a felony.”

One of the most heavily cited hospitals in the country over the three years of CMS records reviewed by Modern Healthcare was the well-known research-oriented UC San Diego Medical Center, which racked up 73 deficiencies in that time period. The 25-bed critical-access hospital Atoka (Okla.) County Medical Center had 70 deficiencies over the three years.

The Cleveland Clinic, with 36 deficiency complaints, ranked 20th on the list of hospitals with deficiencies stemming from patient complaints. Other high-prestige medical centers ranked significantly lower. Johns Hopkins Hospital in Baltimore, for instance, received six deficiency notices during the three-year period.

CEO is VA candidate

The largest private employer headquartered in Ohio, the Cleveland Clinic over the years has built a stellar reputation for being “patient-centered” and has consistently earned high rankings from some ratings groups. Last week, sources confirmed that CEO Dr. Toby Cosgrove, who has headed the Cleveland Clinic since 2004, is under consideration by the White House to become the next secretary of Veterans Affairs, a job that would have him running the scandal-wracked, $55 billion national health system for military veterans.

His nomination will likely bring closer scrutiny of his hospital system's overall safety and quality record on Capitol Hill. The business-backed Leapfrog Group, for instance, gave the Cleveland Clinic a D when it expanded its safety grades in 2012 to include failing grades. The grade improved to C last year.

“We have been continually disappointed by their patient-safety scores, although we have seen improvements,” said Leah Binder, CEO of the group.

Safety experts note serious incidents and responses to individual cases rarely affect hospitals' overall ranking in patient-satisfaction surveys and appear to have little impact on accreditation by the Joint Commission, a voluntary organization funded by hospitals whose only enforcement power is to withdraw accreditation. Like the CMS, the Joint Commission very rarely uses its ultimate punishment. The commission, whose inspection reports are not made public, has consistently awarded the Cleveland Clinic good quality-of-care ratings.

Yet the high level of patient complaints leading to CMS deficiency reports at Cleveland Clinic and other well-known hospitals is raising alarm bells. “If you have these events in a place that has this kind of reputation, it makes you wonder about your average community or teaching hospital,” said Dr. William Jessee, a former executive of the Joint Commission and CEO of the Medical Group Management Association who is now a professor of health systems management at the University of Colorado.

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Patient-safety experts say that individual violations can happen in any hospital. But patterns of repeated types of violations are rarer and more concerning because they may be a sign that a hospital is failing to do the deep analysis required to prevent future occurrences of the same problems. But neither the federal hospital inspection system nor the accreditation process is designed to track or punish recurrent violations.

For each case the CMS cited at the Cleveland Clinic, hospital officials eventually corrected the problems to the satisfaction of state surveyors, who inspect hospitals on Medicare's behalf. All of the violations were reported to the hospital's board of governors and to Cosgrove, who in at least one case was personally cited for systemic management failure. They cited him for failing to enforce an adequate informed-consent system after he admitted some patients were not told a robot would be used in their procedure.

The threatened funding terminations also covered a series of six operating-room fires dating to 2009 and 2010 that left three patients with physical injuries, including second-degree burns to a patient with a cerebral hemorrhage and another getting a small-bowel transplant. “Although a root-cause analysis was done on the first fire in April of 2009, the hospital continued to have fires caused by the same type of ignition,” inspectors wrote.

They concluded electric surgical tools were setting skin antiseptics on fire, possibly because operating-room humidity wasn't being monitored according to federal hospital fire codes. “A review of the humidity readouts revealed that many of the readings were lower than what is required,” according to the report.

Safety experts say repeat violations are a warning flag.

“If there was no additional investigation or actions taken after the first root-cause analysis failed to prevent subsequent fires, that would appear to be an indictment of management and leadership,” said Dr. Jim Bagian, a former astronaut and nationally known hospital-safety expert at the University of Michigan. “That would indicate there is no robust safety system, which (raises) the question, if there was no system for these fires in the OR, is there a safety system that operates anywhere in the hospital?” said Bagian, who was founding director of the National Center for Patient Safety at the Veterans Health Administration.

Photo credit: Stan Bullard

The fires triggered a two-day “immediate jeopardy” warning by the CMS. Eventually, the Cleveland Clinic responded by making operating room policy changes and conducting staff training sessions, the reports show.

Jessee, the former Joint Commission executive, said healthcare experts believe incidents that affect patient safety are far more common than reported. A series of recent reports by HHS' Office of the Inspector General also concluded the nation's reporting system for patient-safety incidents was inadequate.

“The industry has been wrestling with the patient-safety issue for at least 15 years,” Jessee said. “It's been a high-visibility policy issue since 1999, and yet you hear about events and you wonder how much progress has been made.”

Antoon, the military vet and former commercial pilot, has since gone on to become a patient-safety advocate well-known in the hallways of healthcare regulators across the country for his aggressive inquiries. He has an ongoing medical-malpractice case against the Cleveland Clinic and his physicians there, but he says no amount of money will repair his physical or emotional damage.

“This stopped being about me a long time ago. This is about a fraudulent, broken medical system where patients are injured and nobody is accountable,” he said. “The airplanes are still crashing. Doesn't anybody care?”

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In This Issue

Given rapid changes under way and on the horizon for the nation's healthcare system, most hospitals and health systems are closely evaluating their desired position in the future value-based business model. Nearly 80 percent of hospital organizations are currently involved in or actively exploring partnership opportunities, according to a recent report.[1] To meet the various requirements ahead, many providers are pursuing partnerships as a means of building infrastructure, economies of scale, and market essentiality.

While much media and industry attention has focused on traditional healthcare mergers and acquisitions, different types of innovative partnerships have emerged in recent years. In the Fall 2012 *Kaufman Hall Report*, we focused on new partnerships between different types of players, including insurers and providers. In this issue, we take a close look at the "next generation" of partnership arrangements between hospitals and health systems. Many of these new relationships are among organizations that historically were competitors. Partnership models described in this article include:

- Purchasing and "Best Practice" Collaboratives
- Management Services Agreements
- Accountable Care Collaboratives
- Health Plan Co-Ownerships
- Joint Operating Agreements

These models are at the "low end" of the integration continuum, where organizations typically retain their current governance and control structures, but collaborate on a selected group of common objectives. In some cases, hospitals and health systems are entering into these relationships with the thought that they could evolve into a more integrated partnership in the future, after "testing the waters" for cultural compatibility and organizational congruence. Other organizations enter into these agreements as a way to achieve some of the advantages of a fully integrated partnership, without giving up their independence.

One common factor among these different types of partnerships is the close geographic proximity of the member organizations. Being located near one another reduces logistical challenges and makes it easier for partners to derive financial value and greater synergies. Neighboring organizations typically are familiar with their potential partner and often serve the same or similar patient populations. Over time, such partnerships establish a potential platform for wider geographic, or even statewide, networks.

Form must follow function in any partnership. The structure of the arrangement must be driven by the goals and objectives of the organizations. To achieve success, the partnership design must align with the long-term vision of the organizations involved.

Leveraging Purchasing Efficiencies and Extending Best Practices

Purchasing Collaboratives are contractual agreements between multiple parties that create a new entity in order to achieve greater efficiencies and economies of scale in purchasing arrangements. The partnering systems maintain an ownership interest in the purchasing collaborative, but ownership and governance of their other operations remain independent.

For example, the MNS Supply Chain Network was announced in November 2011 as a partnership between MedStar Health in Columbia, Md., Novant Health in Winston-Salem, N.C., and Sentara Healthcare in Norfolk, Va. The Network is designed to lower costs of medical supplies and services, such as transcription, pharmacy support, and cardiology devices.[2] Network officials projected that prices on $50 million to $80 million of the $1 billion the three hospitals spend annually on medical supplies could be lowered to benchmark pricing.[3] The MNS Supply Chain Network is managed by a board which includes a senior executive from each of the three systems. The board chairmanship rotates annually among the three systems.[4]

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