Beneath the Surface of Unnecessary Surgery: A Case Study on the Limits of Existing Protections

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Abstract Unnecessary surgery has been a focus of health policy concern for decades. Such events are supposed to be prevented by the (a) self-policing of hospital medical staffs, (b) oversight of state medical boards, (c) third-party restrictions on payment, and (d) threat of malpractice lawsuits. While critics may point to failures of will on the part of those responsible for such policing, this case study points to more fundamental problems. The case involved an extension of the diagnosis of Chiari malformation to justify surgery to help relieve symptoms of individuals previously identified as suffering from chronic pain or fatigue syndrome. It illustrates how strenuous efforts to reduce what other members of the medical profession perceived as unnecessary surgery were overcome by (a) uncertainty concerning appropriate diagnosis and treatment, (b) patient desperation-driven self-referrals unrestricted by professional oversight or geographic boundaries, (c) the ambition of a surgeon determined to practice as he or she desired, (d) a business-focused national hospital chain insulated from direct clinical accountability, and (e) the highly profitable nature of the surgery itself.

Keywords quality, regulation, malpractice, medical licensure, the Joint Commission

Unnecessary surgery involves interventions that are either not indicated or not in the patient's best interest when weighed against more conservative alternatives. Both excess costs and deaths or injuries from surgery deemed unnecessary have been a focus of public policy concern since the 1950s (US Subcommittee on Interstate and Foreign Commerce 1976; Institute of Medicine 2010).

Research in this area has looked at surgical differences between service areas (Wennberg 2014) and explored the effects on surgical rates of tissue

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committee reports, second opinion programs, and educational initiatives focused on both physicians and consumers (Raffensperger 1969; Lindsey and Newhouse 1990; Wolfson, Santa, and Slass 2014). I review here a specific controversy that helps illustrate the limits of existing protections.

Most would acknowledge that these protections, largely reliant on medical self-regulation, are awkward and often ineffective. No surgeons believe what they do is unnecessary, and colleagues hesitate to criticize those decisions (Leape 1992). When hospital medical staff colleagues become patient safety problems, interventions tend to be delayed (Gawande 2002). State medical licensure boards exhibit a similar reticence. In 2015 those boards suspended the licenses of only 706 of 953,695 actively licensed physicians in the United States—a figure out of line with even the most conservative estimates of the prevalence of abuse through unnecessary procedures (Federation of State Medical Boards 2016; Young et al. 2016). Typical insurance company payment incentives and the threat of malpractice suits also would seem to do more to encourage than discourage unnecessary procedures (Emanuel and Fuchs 2008; Sloan and Chepke 2008).

The case involved a protracted struggle alleging unnecessary surgeries for chronic pain. Almost all of my account is based on press coverage and publicly accessible documents.[1] It took place as part of a larger controversy concerning the appropriate diagnosis and treatment of Chiari malformations: the abnormal presence of cerebellar tonsils in the spinal canal rather than in the posterior fossa (National Institute of Neurological Disorders and Stroke 2018). The case involved liberalizing the criteria for the diagnosis of Chiari malformation to justify the surgery on patients suffering from chronic pain and fatigue.[2]

Desperate Patients, an Ambitious Surgeon, and Hospital Staff Regulation

Chronic pain syndrome (generalized pain that persists longer than 3 months) affects as many as 100 million people in the United States (Institute of Medicine 2011). Chronic fatigue syndrome affects a more devastated subset of as many as 2.5 million persons (Centers for Disease Control and Prevention 2017). The plight and quest for relief of those suffering from

1. I also served as an expert witness under a confidentiality agreement with the law firm representing several of the plaintiffs.

2. For information on the traditional diagnosis standards, see Doberstein et al. 2017. The relative efficacy of this surgery or its alternatives has not been resolved by randomized clinical trials (Sousa et al. 2018).

chronic fatigue syndrome have been powerfully portrayed in the recent documentary *Unrest* by Jennifer Brea (Bentley 2017). There are no known cures and only modest success in managing the symptoms (Arnold et al. 2016). The sufferers and their families scour the Internet for advice from other sufferers and service providers.

Dr. A offered hope to such patients. He had recently been promoted to full professor with tenure in the Department of Neurosurgery at a prominent medical school. Dr. A paid more attention than was typical for a neurosurgeon to patients who complained of chronic fatigue and pain. Those with such vague complaints are usually cut short and either referred to a psychiatrist or told nothing could be done for them.

Chiari malformation, a rare congenital skull malformation, could generate similar complaints. Dr. A suspected it was not as rare as believed, because the evidence was too subtle for most neurosurgeons to detect through magnetic resonance imaging and other diagnostic procedures. He came to believe that expanding the criteria for diagnosing the condition justifying surgery represented a major breakthrough in treatment.

Unlike for drugs, which require rigorous documentation of safety and efficacy before general use, for surgical procedures deference is given to the independent judgment of surgeons. Surgical innovation has often, despite the discomfort of medical critics, followed a more flexible, informal path (Cochrane 1972; Wennberg and Cooper 1996). Dr. A's surgery for these particular patients could have been defined as an experimental treatment not normally reimbursed by insurers and requiring approval and oversight by the medical school's institutional review board (IRB). Instead, his surgeries were paid for routinely, and there was no IRB review.

Dr. A and the university medical center were, however, sued for unnecessary surgery by four patients. These four cases received confidential settlements. In addition, 14 local physicians signed a letter to the chairman of the Department of Neurosurgery of the medical school expressing concerns about the rates of seemingly unnecessary surgery. A bitter test of wills in the department followed, which was resolved through a negotiated settlement. Dr. A received a "terminal sabbatical" year at full pay with additional funds for his expenses, on the condition that he would not do surgery during that year and would resign from his tenured position at the university at its end.

The National Hospital Chain

Despite the lawsuits and complaints from colleagues, more positive views of Dr. A's surgery had reached patients through more sympathetic physician

and Internet website referrals. He tried to set up his practice in a metropolitan area of an adjoining state but was largely blocked from obtaining full privileges at the hospitals in the area. He found support to perform his surgeries at R hospital, run by a national hospital chain (NHC), a facility with 62 acute-care beds in a rural area.

Although it is a nonprofit, church-affiliated system, the NHC had long before been spun off into a separate corporate entity to protect the church from the financial risks of its hospitals. It currently consists of about 45 hospitals and more than 8,200 beds spread across nine states. The NHC's structure and the compensation of its executives are similar to those of for-profit chains. In 2015, according to its 990 form filed with the Internal Revenue Service, 15 of the NHC's top executives received total compensation of over $1 million. All of the top executives in each of its facilities are directly employed by corporate headquarters, and a centralized management information system handles payroll, keeping track of financial activity and the contribution of each individual medical staff member to the corporation's bottom line. In contrast, at least on paper, the selection of hospital medical staff members, review of their performance, and determination of the limits of their hospital privileges are left to the discretion of the local hospital's affiliated medical staff.

Dr. A paid a visit to the hospital and its CEO in June 1999. It had a relatively low occupancy rate of about 50%. Although it was still profitable, even a "cash cow" for capital improvements at some of NHC's larger, urban facilities, many smaller rural hospitals had been losing profitable specialty services to large regionalized medical centers, and this must have been a concern of R hospital's managers. Dr. A explained his plan to do surgery at the hospital that, while not unusual, would be performed on patients who did not fit the traditional profiles for that treatment.

No red flags appear to have been raised. The bulk of the hospital's medical staff were primary care physicians, there was no neurosurgeon on the staff of the hospital, and no help from outside experts was requested for the review. The standard questionnaire was apparently sent to each of the hospitals where Dr. A previously had privileges. More detailed information concerning the medical staff's deliberations is privileged and unavailable. Dr. A's application, however, met no delays, and the hospital board granted him privileges in October 1999.

Consequences and State Regulatory Processes

Dr. A's surgical practice grew as he predicted. The number of admissions for Chiari malformations rose from 0 in 1998 to a total of 964 by the end

of 2002. The number of craniotomies and laminectomies rose from 33 in 1998 to total 1,298 by the end of 2002. With reimbursements estimated at $30,000 for each, Dr. A had generated almost $40 million in gross practice revenues ($30,000 per procedure × 1,298 procedures). For calendar years 2000–2002 his practice generated an estimated profit of $4,682,000, a quarter of the profits generated by R hospital's entire medical staff of more than 150 physicians during this period.[3]

The hospital and its administrator featured Dr. A's practice on its website, proclaiming that "Dr. A offers an existing surgical procedure simply not yet applied to a condition traditionally not treated surgically. With a relatively short hospital stay, most patients awoke from surgery with noticed decrease in previous symptoms. . . . This is wonderful news for both the general public and the medical community in that over 10 million people suffer from fibromyalgia and chronic fatigue syndrome in the United States alone." They paid for a media consultant to prep Dr. A for an interview on a weekly national news show that aired in March 2000. Inquiries from chronic pain and fatigue sufferers jumped after its airing. If NHC management had any doubts about the decision to support Dr. A's practice, those doubts did not prevent them from soon afterward promoting R hospital's CEO to run one of their larger hospitals, at a substantial increase in pay.

However, in November 2002 the state medical board summarily suspended Dr. A's license, automatically triggering suspension of his hospital privileges. Nine surgical cases had come to the attention of the board. Dr. A would mount a vigorous defense of his decisions over the next decade. It included expert witness testimony of neurosurgeons from prominent medical centers who shared many of his views concerning the diagnostic criteria of Chiari malformations. His medical board licensure adverse action file grew to 65 separate notifications of legal actions and board decisions.

After a lengthy first hearing in February 2003, the board concluded that in eight of these cases Dr. A had performed surgery that was not medically indicated, and it suspended his license indefinitely. Many of his former patients rose to his defense, circulating an Internet petition that claimed more than 500 signatures. One even wrote the governor demanding that members of the board be fired.

In July 2004, Dr. A received a second hearing and presented evidence that a minority of neurosurgeons believed the majority view was incorrect, and that a measurable amount of cerebellum tonsils descending through the hole in the skull through which the spinal cord passes, known as the foramen

3. Based on an analysis performed by NHC used by a plaintiff as an exhibit at trial. Citation to quote and data have been withheld to protect confidentiality.

magnum, was not needed to support an operable diagnosis. The board in response extended a temporary license with two conditions: no such surgery would be done by Dr. A without the patient first receiving a second opinion from a neurosurgeon approved by the board (after which the patient could choose), and Dr. A could perform that surgery only when included in a formal research project overseen by an IRB. Dr. A requested that this requirement be modified since it would force every patient to participate in a research project and not freely choose to do so. Eight months later the board relented, specifying that Dr. A should "conduct research on the effect of surgery for hyperplastic posterior fossa on one or more comorbid conditions" as part of a formal project under the auspices of an IRB, but allowing surgical candidates to receive the surgery without participating in the research. This exemption arguably accepted that the surgery was not experimental. No further questioning of the appropriateness of the IRB and its oversight, or of the design, methods, and results of this research, appears in Dr. A's transactions with the board.

A laminectomy procedure brought on a new set of hearings and sanctions beginning in 2008. The board charged that Dr. A's diagnosis of cervical stenosis with myelopathy was not supported by the radiological evidence. It was recommended that he be reprimanded and placed on probation with stipulations. Dr. A presented evidence from the research literature and expert witnesses in a February 2009 hearing, but the board concluded the surgery was unnecessary, suspended Dr. A's license for 2 months, and provided a temporary license for 4 months that did not allow spinal surgery. In exchange for this temporary license Dr. A agreed to dismiss all pending litigation against the board and acknowledged that the board was under no obligation to extend his license further.

That temporary license expired at the end of September 2009. In August 2010 the board denied reinstatement, stating that "you have not indicated in any of your interviews with the Board members that you would practice any differently, or modify your practice as to alleviate any of the Board's concerns set forth in its 2003 and 2009 Orders of Discipline."

After a third hearing in November 2010, Dr. A was again granted a full undated medical license but with conditions that he (a) not perform the surgery on anyone under age 18; (b) not do the surgery on any patient until the patient receives an independent neurological examination by a board-certified neurologist, and the record of that examination must be included

as part of Dr. A's patient record; (c) provide these records to the board; (d) have his patients sign an informed consent form that discloses his past history with the board; and (e) meet with members of the board a year later to discuss and review his practice.

A chart review of the records he submitted to the board then revealed that Dr. A was performing surgeries on patients for whom the independent neurologists did not find appropriate indications, and the board-appointed radiologist found no evidence of need. It ordered a fourth disciplinary hearing, but that was canceled after a consent agreement was finalized on December 12, 2013.

The consent agreement, either through mutual reconciliation or exhaustion, appears to have provided a final resolution of the dispute. It specified an independent second opinion for Chiari malformation by a neurosurgeon will be required only when the reviewing radiologist concludes the radiological evidence shows less than 0.5 millimeters of cerebellar tonsillar herniation below the foramen magnum. Dr. A, however, will do surgery on such patients only if the independent second opinion agrees. All previous restrictions on Dr. A's practice of surgery of the cervical spine were waived.

The final agreement provided the board some modest control over when the surgery in question could be performed by Dr. A. Yet, for the most part, Dr. A, the hospital, and the NHC had successfully overcome all the major medical staff credentialing and state medical board obstacles to performing the surgery. Review was required only in those cases where the radiological evidence showed less than 0.5 millimeters of herniation instead of the 10-fold higher 5 millimeters previously used to justify the surgery.

What about the potential obstacles from third-party payers and malpractice suits? Insurance companies could refuse to pay for unnecessary or experimental surgery. Yet it is hard to come up with a completely defensible definition of unnecessary surgery, particularly given the uncertainties concerning many diagnoses. One can usually find a few experts who will argue the surgery was a reasonable decision. So instead, fraud and abuse units focus on low-hanging fruit that can be plucked more easily to recover money. When physicians or hospitals fraudulently bill for services they have not performed, incorrectly bill for services that they have, or engage in kickback arrangements, collection is less difficult for third-party payers. NHC itself had to pay Medicare over $100 million in a settlement for False Claims Act allegations brought by three

whistle blowers involving overutilization and kickbacks to physicians financially tied to NHC hospitals. Dr. A, however, had no direct financial ties to NHC. His surgery, whether or not it was necessary, was performed competently and properly billed.[4]

Competently performed but "unnecessary" surgery is also a poor prospect for malpractice suits. That it has been performed often and not prevented becomes part of its defense. Indeed, malpractice suits involving harm overwhelmingly seem to focus on what was not done rather than what was done but unnecessary (Sloan et al. 1993). Of the more than 30 malpractice suits that alleged unnecessary surgery and poor outcomes for surgery Dr. A performed before he first lost his license in 2002, none have reached a satisfactory resolution from the perspective of the plaintiffs.[5] In these cases the defense for the hospital was essentially that it had complied fully with all the standards required by the Joint Commission and for Dr. A was that he had conducted himself within the boundaries of acceptable and prevailing medical practice. Only one case has gone to trial, and while Dr. A was found negligent due to improper care, neither the hospital nor NHC was judged to have behaved improperly. Given such a track record, why would the hospital and chain choose to stop providing a place for such profitable procedures?

Implications

As the case of Dr. A demonstrates, the failure of individual review processes to prevent unnecessary surgery can't simply be ascribed to a lack of will. Dr. A's peers at the university hospital and on the state medical board persisted despite cost in time and personal discomfort. A system of peer protection against unnecessary surgery, however, is only as strong as its weakest link, as the marriage of convenience between Dr. A and NHC demonstrates. In addition, a system governed by formal procedures and strong evidence standards provides many opportunities for resistance, as the saga of state medical board responses shows. Informal peer controls have also probably been further weakened by an Internet-enhanced lay referral system that helps insulate specialist practice from dependence on the good opinions of local colleagues for referrals.

4. Here I am indebted to the insights provided by Karen Lessin, former chief compliance officer for Independence Blue Cross in Philadelphia, in a telephone conversation in May 2017.

5. Some of these suits precipitated the board's action, and others followed. Dr. A's license was subsequently restricted, and I report here only the cases of surgery prior to his first licensure suspension.

One must be cautious about making broader generalizations from this case study, but the cautions suggest conclusions. Few surgical decisions involve as much ambiguity and uncertainty as those described in this case. Diagnosis is difficult because of patients' complex array of imprecise symptoms. The safety and efficacy of the surgery are uncertain. Just as there is less geographic variation in use of surgeries for conditions for which indications are clearer (Wennberg and Cooper 1996; Wennberg 2014), peer review processes have been more successful at reducing unnecessary procedures such as appendectomies for which the standards for surgery are more certain and easily documented. Yet to say it is harder to restrict unnecessary surgery when there is less certainty that it is unnecessary should give readers pause.

This case focused on a small rural hospital that is part of a large national chain, but that does not imply that such organizations are the only source of such possibly unnecessary surgery. Neurosurgeons at some medical-school-affiliated regional systems have also pushed the boundary of surgery for Chiari malformations, with some similar controversy (e.g., Evans 2009). The uncertainty in the appropriateness of the surgery and the certainty related to its profitability both probably played some role in all of these cases.

Why not just demand a greater degree of certainty to justify surgeries? Surgeons do not live within the same constraints that pharmaceutical firms do in releasing new drugs. Surgeons also are not subject as individuals to anything resembling the periodic drug and proficiency testing requirements imposed on commercial airline pilots by the Federal Aviation Administration. They are held, ostensibly, to the more modest standard of "acceptable and prevailing medical practice." We have seen in this case how ambiguous that standard can be, and it certainly does not depend on strong evidence of safety and efficacy.

Yet to ask the question may also help answer it. Public concern and demands for action have never reached the level of intensity for surgery that helped create the US Food and Drug Administration and Federal Aviation Administration requirements for pharmaceutical firms and commercial airline pilots. Nothing similar to the thalidomide tragedy or massive and visible fatalities from airline crashes has happened. Instead, patients and their surgeons continue to search for solutions in situations where the lack of solutions well supported by evidence is too hard to accept. Protecting patients suffering from chronic pain from unnecessary surgery, despite any strength of commitment to such a goal, will continue to be an awkward and often ineffective process.

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