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## Using Clinical Practice Guidelines and Knowledge Translation Theory to Cure the Negative Impact of the National Hospital Peer Review Hearing System on Healthcare Quality, Cost, and Access

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# Using Clinical Practice Guidelines and Knowledge Translation Theory to Cure the Negative Impact of the National Hospital Peer Review Hearing System on Healthcare Quality, Cost, and Access

Katharine Van Tassel\*

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## I. INTRODUCTION

According to an estimate by the Institute of Medicine made over a decade ago, treatment errors in hospitals alone caused as many as 98,000 deaths yearly.<sup>1</sup> This Institute of Medicine report is proving to be very conservative. A recent Consumer Reports investigation came to the conclusion that “[m]ore than 2.25 million Americans will probably die from medical harm this decade . . . . ‘That’s like wiping out the entire populations of North Dakota, Rhode Island, and Vermont. It’s a man-made disaster.’”<sup>2</sup> Thus, it appears that the three major systems in the United States designed to improve the quality of patient care—the state medical malpractice and licensure systems and the private hospital peer review hearing system—are all failing at their task.

To date, most of the attention of academics, legislators, and lawyers has been on critiquing the medical malpractice and licensure systems, while the far more important hospital peer review hearing system has gone almost unnoticed. In light of the astonishing number of patients killed in hospitals each year and the soaring costs of healthcare, it is time to begin a critical review of the hospital peer review hearing system.

Private hospital peer review is “a self-policing system where physicians

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1. INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000).

2. *How Safe Is Your Hospital? Our New Ratings Find That Some Are Riskier than Others*, CONSUMER REPS. (Aug. 2012), <http://www.consumerreports.org/cro/magazine/2012/08/how-safe-is-your-hospital/index.htm>.

informally evaluate each other and sanction those physicians who are allegedly failing to provide quality patient care.”<sup>3</sup> This system is based on the old, and now discredited, “bad apples” approach to quality improvement that is grounded in the view that medical errors were caused by incompetent physicians. This approach is sometimes referred to as the “name, blame, shame” model.<sup>4</sup> A large body of research demonstrates that, in fact, most medical errors are not the result of incompetent physicians but instead are due to the faulty systems that the hospitals are relying upon to provide care. According to the Institute of Medicine, “improving safety for patients require[s] a systems approach in order to modify the conditions that contribute to errors.”<sup>5</sup> Reflecting this understanding, modern empirically driven error prevention measures rely on a systems approach developed using the same continuous quality improvement theory relied upon in the airline industry.<sup>6</sup>

Moreover, the “bad apples” approach used by the hospital peer review hearing process fosters an environment of secrecy about errors, undermining efforts to discover and fix the root causes of the errors.<sup>7</sup> As the systems that hospitals do implement to avoid errors are only as good as the data they are based upon, faulty or insufficient data means faulty or insufficient systems. It is important to note that the threat of becoming the target of hospital peer review is a far greater deterrent to disclosure of medical errors than the threat of being sued for malpractice. As many physicians have medical malpractice insurance, a physician can recover from the payment of damages pursuant to a lawsuit and can continue to practice medicine. On the other hand, as this Article will explain, the possibility that a physician’s career can be completely destroyed by hospital peer review is very real.<sup>8</sup> Thus, the “bad apples” approach is ill-conceived as it not only fails to deal with the main cause of medical errors, it also works to perpetuate the root causes of those errors by discouraging disclosure.

Compounding the problem associated with the overall structure of the hospital peer review hearing process are the standards relied upon during the

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3. Katharine Van Tassel, *Harmonizing the ACA with State Tort and Licensure Systems and Hospital Peer Review*, HEALTH AFF. BLOG (July 3, 2012), <http://healthaffairs.org/blog/2012/07/03/harmonizing-the-aca-with-state-tort-and-licensure-systems-and-hospital-peer-review/> [hereinafter Van Tassel, *ACA*]; see generally Katharine Van Tassel, *Hospital Peer Review Standards and Due Process: Moving from Tort Doctrine to Contract Principles Based on Clinical Practice Guidelines*, 36 SETON HALL L. REV. 1179 (2006) [hereinafter Van Tassel, *Due Process*].

4. See *infra* notes 127–37 and accompanying text.

5. INST. OF MED., *supra* note 1, at 49.

6. See *id.* at 71–73.

7. See *infra* Part III.

8. See *infra* notes 143–51.

process to measure physician competency.<sup>9</sup> There are two main categories of standards that hospitals use to measure quality of care during the hearing process: customary care standards and standards that place complete discretion in the hands of hospital administrators to sanction a physician for the good of the hospital. Both of these standards can have a negative impact on healthcare quality, cost, and access.

The customary care, or eminence-based, category of standards for measuring physician competence is based upon treatment choices that are subjective and are based upon the predilections of particular physicians based upon tradition, opinion, or clinical experience.<sup>10</sup> This choice is not being made based upon objective, scientific evidence. This reliance in peer review on customary care standards is in direct contrast with the new national push to move the United States to a modern, evidence-based model of medical practice through major changes in government-provided healthcare, including the care provided under the Patient Protection and Affordable Care Act<sup>11</sup> (ACA, also known as ObamaCare), Medicare, and Medicaid.<sup>12</sup> The evidence-based model for making treatment choices is grounded in empirical data generated by clinical outcomes and effectiveness research that suggests the optimum treatment for a rapidly growing number of clinical conditions. This use of empirical data generated through scientific methodology to make medical decisions shows great promise for enhancing quality of care while decreasing the cost of care. This Article asserts that the hospital peer review hearing process encourages the perpetuation of custom-based practices through the use of customary care standards, undermining the national efforts to improve the quality and cost of healthcare through the practice of evidence-based treatment choices.

The second category of standards, those that place complete discretion in the hands of hospital administrators to sanction a physician for the good of the hospital, contain no limit on the discretion of decision-makers. These standards create a significant risk that decisions to exclude certain physicians could be made based on reasons having nothing to do with the

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9. *See infra* Part IV.

10. *See infra* Part IV. A.

11. Pub. L. No. 111-148, 124 Stat. 119 (2010), amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (codified in scattered sections of the U.S. Code).

12. Katharine Van Tassel, *Harmonizing the Affordable Care Act of 2010 with the Three Main National Systems for Healthcare Quality Improvement: The State Tort and Licensure Systems and the Hospital Peer Review System*, 72 BROOK. L. REV. (forthcoming 2013), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2150825](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2150825) [hereinafter Van Tassel, *Harmonizing*].

interests of patient safety. These reasons could be economic, personal, or discriminatory in nature. Importantly, there is a growing concern that peer review is being used to silence whistleblowers who are trying to call attention to poor quality of care or risky practices that could cause patient harm.

Finally, there is the very real possibility that the “bad apples” approach relied upon in the hospital peer review hearing process adversely impacts access to healthcare, with a particularly negative potential impact on minority physicians and minority and low-income patients.<sup>13</sup>

Together, these problems mean that the hospital peer review hearing process can actually act to negatively impact healthcare quality, cost, and access. In light of the serious due process violations inherent in the processes adopted by most hospitals,<sup>14</sup> these processes should be revamped to comport with the current scientific understanding of medical error prevention and quality improvement methodology, while at the same time protecting the due process rights of physicians and the rights of patients to access to healthcare.

This Article starts with a history of the growth of hospital peer review and then examines the merits of the rationales that motivated the passage of the Health Care Quality Improvement Act of 1986<sup>15</sup> (“HCQIA”), which catapulted peer review into the national system that exists today.<sup>16</sup> The Article next explains how the peer review hearing process works and how HCQIA turns private hospitals into small, individual quasi-regulatory agencies. The Article goes on to critique the “bad apples” approach taken by hospital peer review in light of the growing body of empirical research that supports a systems improvement approach to dealing with the problem of medical error.<sup>17</sup> Next, the Article explains how the choice of standards that hospital peer review relies upon to measure physician competence negatively impacts quality and cost.<sup>18</sup> Finally, the Article raises questions regarding the possible impact that hospital peer review has on access to healthcare, with a particularly negative potential impact on minority physicians as well as minority and low-income patients.<sup>19</sup>

This Article proposes that hospital peer review be completely

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13. See *infra* Part V.

14. For a complete discussion see Katharine A. Van Tassel, *Blacklisted: The Constitutionality of the Federal System for Publishing Reports of “Bad” Doctors in the National Practitioner Data Bank*, 33 CARDOZO L. REV. 2031 (2012) [hereinafter Van Tassel, *Blacklisted*].

15. Health Care Quality Improvement Act of 1986, Pub. L. No. 99-660, 100 Stat. 3743 (codified at 42 U.S.C. §§ 11101–11152 (2006)).

16. See *infra* Part II.

17. See *infra* Part III.

18. See *infra* Part IV.

19. See *infra* Part V.

restructured to comport with the current scientific understandings of the methodologies that best act to prevent medical errors.<sup>20</sup> A new system should be developed that relies on the application of a blend of knowledge translation theory with continuous quality improvement research to integrate evidence-based treatment choices using clinical practice guidelines into physician practice. Based on the libertarian paternalism theory developed by Professors Cass Sunstein and Richard Thaler, this proposed system relies upon “gold standard” clinical practice guidelines as the default treatment choice, but then allows for individual physician choice in deviating from this choice if it is reasonable to do so. This exception allows for the currently high level of scientific uncertainty that exists when it comes to many medical conditions, particularly in the realm of the treatment of outliers. As the practice of evidence-based medicine (population-based medicine, or the treatment of “norm”) grows through the greater understanding of optimal treatment choices for the majority of people, and later transitions to personalized medicine based on the treatment of individuals according to their unique genetic profiles, this currently high degree of scientific uncertainty will steadily diminish over the next several decades, reducing the use of this exception. This proposed system also looks to the future of medicine as it allows for, and facilitates, the ultimate transition of the practice of medicine to the personalized medicine model.

In order to optimize this systems approach to error prevention, this new proposed system should be coupled with the adoption of a version of the anonymous third-party error reporting system successfully utilized by the airline industry that has been long advocated by the healthcare quality improvement movement.

Finally, this proposal recognizes that the hospital is both the best and least cost avoider when it comes to medical errors by allowing physicians to use a comparative negligence type of defense during the peer review hearing process. The use of this defense, coupled with reporting to an anonymous third-party error reporting system, acts to conditionally insulate the physician from National Practitioner Data Bank (NPDB) reporting.

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20. See *infra* Part VI.



## II. THE HOSPITAL PEER REVIEW HEARING PROCESS

### A. *The Rationales for the Passage of the Health Care Quality Improvement Act*

Hospital peer review is a private process whereby physicians evaluate each other's performance and sanction those who are found to have provided poor patient care.<sup>21</sup> Prior to 1986, hospital peer review was a process that only some hospitals utilized on a relatively infrequent basis to sanction physicians who allegedly provided poor quality patient care.<sup>22</sup> Then, the 1980s brought what many thought was a crisis in the cost of medical malpractice insurance.<sup>23</sup> At the time, insurance costs were rising at rates that were causing some physicians to abandon their practices, while insurance companies were walking away from some markets. Stories from the press about this perceived crisis abounded.<sup>24</sup>

The usual suspects, the tort system and lawyers, were blamed. President Ronald Regan and Attorney General Edwin Meese agreed with this assessment and touted tort reform as the answer to the problem.<sup>25</sup> Others asserted that the answer was to encourage the adoption by hospitals of the use of the peer review process to weed out the "bad apples."<sup>26</sup> The latter viewpoint resulted in the passage of the Health Care Quality Improvement Act of 1986.<sup>27</sup> HCQIA gave a congressional stamp of approval to the peer review hearing process by granting conditional immunity from suit for those involved in the process.<sup>28</sup> Thereafter, the rate of adoption of peer review processes by hospitals across the country increased dramatically. Today, every hospital in the country has some form of peer review hearing process in place.

The following sections discuss the merits of the three problems that motivated the passage of HCQIA. The three alleged problems were: (1) the threat of lawsuits allegedly discouraging physicians from participating in peer review; (2) the large number of incompetent physicians allegedly moving from state to state to avoid being barred from the practice of medicine; and, (3) the alleged crisis over the cost of medical malpractice insurance coverage.

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21. Van Tassel, *Due Process*, *supra* note 3, at 1186–89.

22. *Id.*

23. See *infra* notes 75–89 and accompanying text.

24. See David J. Nye et al., *The Causes of the Medical Malpractice Crisis: An Analysis of Claims Data and Insurance Company Finances*, 76 GEO. L.J. 1495, 1496–98 (1988).

25. *Id.*

26. See *infra* notes 125–53 and accompanying text.

27. S. 1744, 99th Cong., 100 Stat. 3743 (1986).

28. Van Tassel, *Due Process*, *supra* note 3, at 1194–97.

## 1. Did the Threat of Lawsuits Chill Physician Participation in Peer Review?

For many, the cause of the mythical malpractice insurance crisis of the 1980s was simple: there were too many “bad doctors.”<sup>29</sup> Those who held this belief argued for mechanisms to purge the system of incompetent physicians.<sup>30</sup> Based on this belief, in the early to mid-1980s:

[S]tates and health care accrediting bodies stepped up their promotion of peer review—the process by which physicians judge the competence of their fellow professionals and recommend disciplinary action for those found dangerously incompetent. As this process gathered force, physicians aggrieved by the results of peer review increasingly appeared in federal court claiming that the actions of their peers were anti-competitive and violated federal antitrust laws. Although hospitals and peer review participants generally prevailed in these lawsuits, the victories entailed costly and time-consuming litigation.<sup>31</sup>

One of the narratives that added fuel to the fire was the case of Dr. Timothy Patrick, a matter that went all the way to the United States Supreme Court in *Patrick v. Burget*.<sup>32</sup> The *Patrick* case involved a physician, Dr. Timothy Patrick, who started his career at the Astoria Medical Clinic (“Astoria Clinic”). The Astoria Clinic was located in the town of Astoria, Oregon, population 10,000.<sup>33</sup> During the relevant time period, Columbia Memorial Hospital (“CMH”) was the only hospital in town and a majority of the physicians at the CMH were either employees or partners of the Astoria Clinic.<sup>34</sup>

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29. Health Care Quality Improvement Act of 1986, H.R. REP. NO. 99-903, pt. 1, at 2 (1986), reprinted in 1986 U.S.C.A.N. 6384, 6385 [hereinafter H.R. REP. NO. 99-903, pt. 1] (“This bill is needed to deal with one important aspect of the medical malpractice problem in this country—incompetent and unprofessional physicians.”).

30. *Id.* (“This legislation would do much to reduce the damage committed by this small, but very destructive, group of doctors. It would require organizations that discipline doctors to report their disciplinary actions to a central location and would require hospitals to seek this information before hiring doctors. It would also require the reporting and dissemination of paid malpractice claims.”).

31. *Manion v. Evans*, 986 F.2d 1036, 1037 (6th Cir. 1993).

32. 486 U.S. 94 (1988).

33. *Id.* at 95–96.

34. *Id.* at 96.

After working at the Astoria Clinic for one year, Dr. Patrick decided not to stay on as a partner.<sup>35</sup> He began his own general surgery practice<sup>36</sup> in competition with the Astoria Clinic.<sup>37</sup>

After he left their practice, the physicians at the Astoria Clinic filed two separate complaints at separate times against Dr. Patrick with the executive committee of the only local hospital, CMH, alleging poor patient care.<sup>38</sup> In both matters, the hospital began the hospital peer review hearing process allowing members of the Astoria Clinic to be involved in both the investigation and decision-making process.<sup>39</sup> The first complaint was eventually dismissed.<sup>40</sup>

At the private hospital hearing on the second complaint, the same Astoria Clinic partner who filed the first complaint sat as the chair of the five member ad hoc committee that heard the charges and defense.<sup>41</sup> Rather than risk termination, Dr. Patrick resigned his staff privileges before the committee reached its decision.<sup>42</sup>

Dr. Patrick filed suit alleging that the Astoria Clinic's physicians violated antitrust laws by bringing a sham hospital peer review proceeding in order to destroy his practice and eliminate him as a competitor.<sup>43</sup> The jury agreed, awarding him \$650,000 in antitrust damages that the district court trebled to \$2.2 million under the antitrust laws. In addition, the court awarded \$228,600 in attorney's fees.<sup>44</sup> Importantly, on appeal, the Ninth

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35. *See id.*

36. *Id.*

37. *Id.*

38. *Id.* at 96–97. As the relationship soured, the Astoria Clinic doctors began to criticize Dr. Patrick for failing to obtain adequate backup coverage and outside consultations for his patients admitted to the hospital. *Id.* Then, in 1979, Dr. Boelling, a partner in the Astoria Clinic, filed the first complaint against Dr. Patrick with the executive committee of CMH's medical staff. *Id.* According to Dr. Boelling, Dr. Patrick had allegedly left a patient in the care of a new associate. *Id.* The new associate left the patient unattended. *Id.*

39. *Id.* The person who chaired the investigation of this first complaint was a partner in the Astoria Clinic, Dr. Russell. *Id.* As a result of the investigation, the complaint was referred to the State Board of Medical Examiners (BOME) by the executive committee. *Id.* at 97. In addition, other cases of Dr. Patrick's were referred to the BOME. *Id.* The same Dr. Russell, who chaired the investigation at the hospital, drafted the letter of reprimand that was issued by the BOME. *Id.* This letter was eventually withdrawn. *Id.* Then, only two years later, another Astoria Clinic partner filed a second complaint against Dr. Patrick with CMH. *Id.*

40. *Id.*

41. *Id.* Dr. Patrick attempted to get the members of the ad hoc committee to testify about their personal bias against him, but they refused. *Id.*

42. *Id.*

43. *Id.* at 98. Two of the defendants in the case were partners in the Astoria Clinic, Dr. Gary Boelling and Dr. Franklin Russell. Another defendant was a surgeon working at the Astoria Clinic, Dr. Richard Harris.

44. *Id.* The Ninth Circuit later reversed, finding that the trial court did not properly instruct the jury on the state-created antitrust immunity to peer review activities. *See id.* Ultimately, the United States Supreme Court reversed the Ninth Circuit Court of Appeals, holding that Oregon's peer

Circuit Court of Appeals made the specific finding that “there was substantial evidence that respondents had acted in bad faith in the peer-review process.”<sup>45</sup>

The press, and later Congress, appeared to ignore the important sham peer review aspects of the case.<sup>46</sup> Instead, the sensationalized press spin that caught national attention was that an incompetent physician was allowed to opt-out of a peer review proceeding to avoid a decision on his competence.<sup>47</sup> Then, that same incompetent physician turned around and filed a lawsuit and won millions against the honest, hard-working members of the peer review committee who were just trying, altruistically, to improve the quality of patient care.<sup>48</sup>

Adding to the hype, it was claimed that the *Patrick* case was causing alarm among physicians because it raised the specter of retaliatory litigation for good faith involvement in peer review.<sup>49</sup> Members of Congress speculated, with no empirical evidence in support, that this alleged apprehension discouraged doctors from volunteering to be a part of the peer review process in order to steer clear of the possibility of facing a court case that could cost millions.<sup>50</sup> To lessen these unconfirmed fears, Congressman Ron Wyden of Oregon (Dr. Patrick’s home state where the case was litigated) played good politics by introducing a bill to provide immunity from lawsuits filed by targeted physicians against those who engaged in “good faith” peer review.<sup>51</sup> This bill later became HCQIA.<sup>52</sup> Thus, it

review statute did not provide for active supervision as necessary to establish antitrust immunity under the state-action doctrine. *Id.* at 98–99, 105.

45. *Id.* at 98 (footnote omitted).

46. The Ninth Circuit Court of Appeals specifically found that:

[T]here was substantial evidence that respondents had acted in bad faith in the peer-review process. The court held, however, that even if respondents had used the peer-review process to disadvantage a competitor rather than to improve patient care, their conduct in the peer-review proceedings was immune from antitrust scrutiny. The court reasoned that the peer-review activities of physicians in Oregon fall within the state-action exemption from antitrust liability because Oregon has articulated a policy in favor of peer review and actively supervises the peer-review process.

*Id.* at 98–99 (footnotes omitted).

47. See Nicholas Kadar, *How Courts Are Protecting Unjustified Peer Review Actions Against Physicians by Hospitals*, 16 J. AM. PHYSICIANS & SURGEONS 17, 20 (2011).

48. *Id.*

49. *Id.* at 20; see also H.R. REP. NO. 99-903, pt. 1, at 3 (1986), reprinted in 1986 U.S.C.C.A.N. 6384.

50. Kadar, *supra* note 47, at 20; H.R. REP. NO. 99-903, pt. 1, at 3.

51. Kadar, *supra* note 47, at 20; H.R. REP. NO. 99-903, pt. 1, at 3.

52. H.R. REP. NO. 99-903, pt. 1, at 1.

appears that there was little real evidentiary support for the proposition that the threat of lawsuits was chilling participation in peer review and that HCQIA was needed to deal with this problem.

## 2. Were Large Numbers of Incompetent Physicians “State Hopping” to Avoid Sanctions?

While the sensationalized and highly slanted version of the *Patrick* case played out in the national press, another, more gruesome narrative captured the attention of the nation. The story of Dr. Frederick Huffnagle hit the pages of the *Boston Globe* in 1986,<sup>53</sup> chronicling how the doctor was able to move his medical practice from state to state, leaving a series of horribly mangled patients in his wake.

After performing unauthorized experimental replacement hip surgery in one hospital in Connecticut,<sup>54</sup> Dr. Huffnagle moved to another hospital that was not aware of his malpractice in the same state.<sup>55</sup> There, he implanted in a patient an artificial knee that was the wrong size.<sup>56</sup> When he removed it, he fractured one of the patient’s bones and ruptured a tendon, leaving the patient permanently disabled.<sup>57</sup> Altogether, Dr. Huffnagle was successfully sued five times for malpractice that occurred in Connecticut.<sup>58</sup> In 1981, Dr. Huffnagle moved to California and obtained staff privileges at a hospital by lying about his past malpractice cases.<sup>59</sup> In the one year he practiced in California, four more malpractice lawsuits were filed against him.<sup>60</sup> Dr.

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53. *Small Percentage of Doctors Responsible for Surge in Malpractice Suits, Rates*, BOS. GLOBE, June 15, 1986, at M1.

54. *Id.* Within two years of obtaining staff privileges at Beverly Hospital in Danvers, Connecticut, Dr. Huffnagle was placed on probation for performing experimental hip replacement surgery without the proper equipment in 1970. *Id.* Dr. Huffnagle had never performed the surgery before, nor had anyone else at the hospital where the surgery was performed. *Id.* Due to this incident, among “other serious continuing difficulties,” Beverly Hospital declined to renew his staff privileges. *Id.*

55. *Id.* Dr. Huffnagle also had staff privileges at nearby Hunt Memorial. *Id.* In spite of the problems at Beverly Hospital, Dr. Huffnagle continued to perform surgeries at Hunt Memorial, including several surgeries on Beatrice Higgins. *Id.* Although she had osteoarthritis, Beatrice could still walk to the grocery store to get her groceries when she first met Dr. Huffnagle. *Id.* The good doctor implanted an artificial knee in Beatrice which was the wrong size. *Id.* When he removed it, he fractured a bone and ruptured a tendon. *Id.* Five years later, Beatrice was still confined to a nursing home and could only leave in a wheelchair. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.* One of those patients, twenty-nine-year-old Roger Lucas, was a bindery supervisor who pulled a muscle in his back when stacking crates. *Id.* Four years after a botched surgery by Dr. Huffnagle, Roger Lucas was left seriously disabled and in constant pain. *Id.* According to the story, he was unable to ever work again. *Id.*

Huffnagle next transferred to Massachusetts to yet another position treating patients.<sup>61</sup>

Along with the *Patrick* and Huffnagle cases, the perceived medical malpractice insurance crisis was utilized by the press to inflame the public, giving Congress the incentive to adopt the Health Care Quality Improvement Act of 1986.<sup>62</sup> It appears that emotion ruled the day, prompting action without any follow-up research into whether the *Patrick* and Huffnagle cases were representative of a large number of other, similar, situations. HCQIA's legislative history describes the sentiment of the times:

Unfortunately, groups such as state licensing boards, hospitals and medical societies that should be weeding out incompetent or unprofessional doctors often do not do so. Even when such bodies do act against bad physicians, these physicians find it easy to move to different hospitals or states and continue their practices in these new locations.

The result has been a series of highly visible situations in which physicians with a long history of incompetence or unprofessional conduct have continued to cause needless deaths and injury for years after their damaging behavior was noticed.<sup>63</sup>

In the findings of the Act itself, Congress explained the purposes behind the legislation:

The Congress finds the following:

(1) The increasing occurrence of medical malpractice and the need to improve the quality of medical care have become nationwide problems that warrant greater efforts than those that can be undertaken by any individual State.<sup>64</sup>

As discussed in the next section, there was, and still is, a quality of care crisis in the form of preventable medical errors that kill tens of thousands of

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61. *Id.*

62. Health Care Quality Improvement Act of 1986, Pub. L. No. 99-660, 100 Stat. 3743 (codified at 42 U.S.C. §§ 11101–11152 (2006)).

63. H.R. REP. NO. 99-903, pt. 1, at 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6384.

64. 42 U.S.C. § 11101(1) (2006). For a more complete discussion of HCQIA see Van Tassel, *Due Process*, *supra* note 3, at 1194–97.

people in hospitals every year.<sup>65</sup> Therefore, this finding is supported by empirical evidence.<sup>66</sup> However, the other findings appear to be based on mere speculation. For example, the next congressional finding that supported the passage of HCQIA was that “[t]here is a national need to restrict the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician’s previous damaging or incompetent performance. . . . This nationwide problem can be remedied through effective professional peer review.”<sup>67</sup>

A search of the legislative record reveals that no studies were cited to support this conclusion. Research also indicates that the problem of physicians “state hopping” after injuring patients in one state to start practice with a clean slate in another state was not common.<sup>68</sup>

The last congressional finding in support of the peer review section of HCQIA is also suspect: “The threat of private money damage liability under Federal laws, including treble damage liability under Federal antitrust law, unreasonably discourages physicians from participating in effective professional peer review. . . . There is an overriding national need to provide incentive and protection for physicians engaging in effective professional peer review.”<sup>69</sup>

There is no evidence cited in the legislative record that physicians were chilled from reporting their inept colleagues or were discouraged from participating in peer review by the threat of suit. To the contrary, the more likely cause of any reluctance on the part of physicians to report their colleagues to hospital administration is the culture prevalent in most hospitals.<sup>70</sup>

In order to ameliorate this speculative problem of a reluctance to participate in peer review, provisions were written into HCQIA to broadly insulate peer review participants, including hospitals, from liability in

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65. See *infra* Part II.A.3.

66. See *infra* notes 80–86.

67. 42 U.S.C. § 11101(2)–(3).

68. Charlotte L. Rosenberg, *How Bad Doctors Dodge Discipline*, 62 MED. ECON. 241, 241–54 (1985) (reporting on thirty-three physicians who engaged in state hopping after negative state licensure proceedings and pointing out that less than 1% of physicians have problems that lead to licensure sanctions); U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-84-53, REPORT TO THE SECRETARY OF HEALTH AND HUMAN SERVICES: EXPANDED FEDERAL AUTHORITY NEEDED TO PROTECT MEDICARE AND MEDICAID PATIENTS FROM HEALTH PRACTITIONERS WHO LOSE THEIR LICENSES, at iii (1984) (identifying thirty-nine doctors who relocated to new states after losing their license in another state).

69. 42 U.S.C. § 11101(4)–(5).

70. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-01-130, NATIONAL PRACTITIONER DATA BANK: MAJOR IMPROVEMENTS ARE NEEDED TO ENHANCE DATA BANK’S RELIABILITY 7 (2000), available at [www.gao.gov/assets/240/230998.pdf](http://www.gao.gov/assets/240/230998.pdf) [hereinafter MAJOR IMPROVEMENTS ARE NEEDED].

monetary damage.<sup>71</sup> The goal was to prevent physicians from challenging the results of peer review in court and winning damages, like the case of Dr. Patrick.<sup>72</sup> HCQIA also established the National Practitioner Data Bank, discussed in Part II.C of this Article, in order to prevent physicians like Dr. Huffnagle from “mov[ing] from State to State without disclosure or discovery of the physician’s damaging or incompetent performance.”<sup>73</sup>

As described in Part III, this early day “bad apples” approach has proven to have negative effects on the quality of care movement, and, on the federal level, has been replaced by a systems approach that uses continuous quality improvement theory.<sup>74</sup>

### 3. Was There a Medical Malpractice Insurance Crisis?

The reality is that there was not a crisis in medical malpractice *insurance* during the 1980s, as Professor Thomas Baker points out in his popular and highly regarded book *The Medical Malpractice Myth*.<sup>75</sup> Professor Baker persuasively debunks “the beliefs that undergird the call for tort ‘reform’ and impede the ability of the polity to focus on, and respond constructively to, the real problems of health care in twenty-first century America.”<sup>76</sup> The insurance cycle was the real cause of the rise in insurance

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71. Van Tassel, *Due Process*, *supra* note 3, at 1194–97.

72. This immunity does not extend to civil rights claims or government antitrust prosecutions. See 42 U.S.C. § 11112(a); see also H.R. Rep. No. 99-903, pt. 1, at 2–3 (1986) (“[I]t is essential to provide some legal immunity to doctors and hospitals that engage in peer review activities, as noted above, under current law and practice, physicians who engage in incompetent or unprofessional acts find it very convenient to move to another jurisdiction and resume practice. . . . [F]aced with the certainty that they can no longer hide their past records, physicians facing disciplinary action will feel compelled to challenge vigorously any action taken against them. Based on recent experience, the Committee believes that many of these physicians will file antitrust lawsuits.”). It is important to note that at no point was the goal of HCQIA to bar the ability of physicians to challenge a sham peer review and gain injunctive relief from sham peer review sanctions unrelated to quality of care. For this reason, the Act does not actually use the term “immunity.” Instead, it provides that if a “professional review action” meets the Act’s standards, the peer reviewers “shall not be liable in damages under any law of the United States or of any State . . . with respect to the [professional review] action.” 42 U.S.C. § 11111(a)(1)(D).

73. 42 U.S.C. § 11101(1).

74. See *infra* notes 125–53 and accompanying text.

75. See generally TOM BAKER, *THE MEDICAL MALPRACTICE MYTH* (2005) [hereinafter BAKER, MYTH].

76. Mary Coombs, *The Medical Malpractice Myth*, 27 J. LEGAL MED. 243, 243 (2006) (reviewing TOM BAKER, *THE MEDICAL MALPRACTICE MYTH* (2005)).



rates in the 1980s.<sup>77</sup> Moreover, there was no real relationship between “bad” doctors and the perceived insurance crisis.<sup>78</sup>

On the other hand, there is no doubt that there was, and still is, a medical malpractice crisis.<sup>79</sup> Importantly, Professor Baker points out what many, until recently, have ignored—that an astonishing amount of malpractice occurs in the United States.<sup>80</sup> In 1999, the Institute of Medicine issued the ground-breaking report on medical errors in hospitals called *To Err Is Human*.<sup>81</sup> The nation was shocked to learn that between 44,000 and 98,000 patients die each year in hospitals due to preventable medical mistakes.<sup>82</sup> And then, in 2010, a follow-up study of ten North Carolina hospitals revealed that the hospital peer review processes institutionalized by HCQIA are ineffective, as “harms remain common, with little evidence of widespread improvement.”<sup>83</sup>

The problem of medical error prompted Consumer Reports to issue the first-ever safety ratings of hospitals in July of 2012.<sup>84</sup> According to the Consumer Reports investigation, medical errors

contribute to the deaths of 180,000 hospital patients a year, according to projections based on a 2010 report by the Department of Health and Human Services. Another 1.4 million are seriously

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77. *Id.*; see also Tom Baker, *Medical Malpractice and the Insurance Underwriting Cycle*, 54 DEPAUL L. REV. 393 (2005) [hereinafter Baker, *Cycle*] (providing a primer on the liability insurance underwriting cycle that draws on the research prompted by the mid-1980s insurance hard market).

78. *Id.* at 393.

79. Christopher P. Landrigan et al., *Temporal Trends in Rates of Patient Harm Resulting from Medical Care*, 363 NEW ENG. J. MED. 2124, 2130 (2010) (“In a study of 10 North Carolina hospitals, we found that harm resulting from medical care was common, with little evidence that the rate of harm had decreased substantially over a 6-year period ending in December 2007.”).

80. BAKER, MYTH, *supra* note 75, at 24. For example, the California Medical Insurance Feasibility Study was the first major study that came out in the mid-1970s. See Don Harper Mills, *Medical Insurance Feasibility Study: A Technical Summary*, 128 W.J. MED. 360 (1978). This study discovered that one out of every twenty patients was injured by physicians and one out of every ten of these patients died as a result. See *id.* at 363–64. Of these injuries, one out of every six was the result of malpractice. See *id.* at 363–65. This translated into physicians injuring 140,000 patients and killing 14,000 patients in California in 1974 alone. See *id.* Then, there was the famous Harvard Medical Practice Study that came out in the mid-1980s during the second medical malpractice insurance “crisis.” See T.A. Brennan, *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study*, 13 QUALITY & SAFETY HEALTH CARE 145 (2004). This study was commissioned and paid for by the State of New York and was performed by researchers from Harvard. *Id.* The Harvard Medical Practice Study rocked the country when it published its findings that doctors injured one out of twenty-five patients and one out of every four of these cases was caused by negligence. *Id.* There were 27,000 injuries from medical malpractice in New York in 1984. *Id.* at 29. This study suggests that there are 140,000 patients who die from medical malpractice every year. *Id.* at 30.

81. See generally INST. OF MED., *supra* note 1.

82. *Id.*

83. Landrigan et al., *supra* note 79, at 2124.

84. CONSUMER REPS., *supra* note 2.

hurt by their hospital care. And those figures apply only to Medicare patients. What happens to other people is less clear because most hospital errors go unreported and hospitals report on only a fraction of things that can go wrong.<sup>85</sup>

The Consumer Reports article goes on to point out that “[m]ore than 2.25 million Americans will probably die from medical harm this decade . . . . ‘That’s like wiping out the entire populations of North Dakota, Rhode Island, and Vermont. It’s a man-made disaster.’”<sup>86</sup>

The question then becomes how to deal with the problem of medical error? Are these failures of human beings or of systems?<sup>87</sup>

This medical malpractice crisis means that hospital peer review is actually a good idea. However, as discussed below,<sup>88</sup> the dated “bad apples” approach of the current peer review system, which has been discredited by empirical research, must be replaced with a modern peer review system. Updating the peer review system can be accomplished using knowledge translation theory to implement a systems approach for avoiding medical error using continuous quality improvement methodology grounded in empirical outcomes research.<sup>89</sup>

#### *B. How Does the Hospital Peer Review Hearing Process Work?*

Private peer review “is a self-policing system [conducted in hospitals] where physicians informally evaluate each other and sanction those physicians who are allegedly failing to provide quality patient care.”<sup>90</sup> This commonly triggers an investigation and, if the targeted physician contests the results of the investigation, she or he can request a hearing.<sup>91</sup> The hearing is a highly informal affair conducted by the hospital with the

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85. *Id.*

86. *Id.*

87. What has gone unnoticed is that there are relatively few medical malpractice lawsuits, especially compared to the amount of medical malpractice. BAKER, MYTH, *supra* note 75, at 25–26. For every one medical malpractice lawsuit, there are between seven and twenty-five injuries. Compare this with car accident cases: almost everyone who gets injured by a negligent driver files an auto lawsuit or claim. *See id.*

88. *See infra* notes 125–53 and accompanying text.

89. *See* Part VI.B.

90. Van Tassel, *ACA*, *supra* note 3; *see also* DEBORA A. SLEE, VERGIL N. SLEE & H. JOACHIM SCHMIDT, *SLEE’S HEALTH CARE TERMS* 439 (5th ed. 2008).

91. *See* Van Tassel, *Due Process*, *supra* note 3, at 1191–92.

physician permitted to engage in very limited discovery.<sup>92</sup> If a physician is found to have provided poor quality of care after a hearing conducted by the hospital,<sup>93</sup> that physician may be penalized in a variety of ways. The ultimate sanction is the termination of the physician's hospital staff privileges.<sup>94</sup> The investigation and hearing are conducted pursuant to the process described in the institution's medical staff bylaws.<sup>95</sup> While hospitals differ in the exact processes they adopt, most have a few common features. First, medical staff bylaws are viewed as enforceable contracts between the hospital and members of the medical staff.<sup>96</sup> These bylaws outline who can make a complaint.<sup>97</sup> The medical staff executive committee usually decides, based on the complaint, whether an investigation should be initiated or whether the matter should be dropped<sup>98</sup>—unless there is an emergency, in which case the chief of staff decides.<sup>99</sup>

If a decision is made to investigate a complaint, as a general rule, the physician will be notified.<sup>100</sup> Either the executive committee will conduct the investigation itself, or they will appoint an ad hoc committee made up of members of the general medical staff to do so.<sup>101</sup> Beyond the possibility of

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92. AM. HEALTH LAWYERS ASS'N, PEER REVIEW GUIDEBOOK: CREDENTIALING AND PEER REVIEW PRACTICE GROUP OF THE AMERICAN HEALTH LAWYERS ASSOCIATION 60 (3d ed. 2003) [hereinafter PEER REVIEW GUIDEBOOK].

93. Hospital peer review is conducted pursuant to the obligations of the hospital medical staff to ensure "the quality of the professional services provided by individuals with clinical privileges . . ." JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGS., COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS: THE OFFICIAL HANDBOOK, ch. PMS.1, at MS-2 (1999 ed. 1999) [hereinafter CAMH].

94. See PEER REVIEW GUIDEBOOK, *supra* note 92; see CAMH, *supra* note 93, at MS-7.

95. For a detailed explanation of this process, see Van Tassel, *Due Process*, *supra* note 3, at 1194–97.

96. See MICHAEL A. CASSIDY, IMMUNITY FOR CREDENTIALING DECISIONS UNDER FEDERAL AND STATE LAW 38 (2003).

97. Also called a request for corrective action. See PEER REVIEW GUIDEBOOK, *supra* note 92, at 30. The bylaws also describe the person who, or group that, decides whether to commence an investigation based on the complaint. *Id.* at 23.

98. In *Pulido v. St. Joseph Memorial Hospital*, 547 N.E.2d 1383 (Ill. App. Ct. 1989), the court granted summary judgment against a physician who pointed out that the same four-member executive committee conducted the investigation and found that summary suspension of staff privileges was warranted. The Illinois Court of Appeal also heard the appeal of their own decision, which they affirmed. *Id.* at 1387–88. The hospital board of trustees then affirmed. *Id.*

99. *Id.* When the situation poses "immediate danger" to patients warranting immediate summary suspension of the physician's staff privileges, one individual can be designated as the decision-maker—commonly the chief of staff—or the decision can be made by the executive committee. *Id.*

100. The *Peer Review Guidebook* advocates giving the physician the full details of the complaint. PEER REVIEW GUIDEBOOK, *supra* note 92, at 23. See, e.g., *Campbell v. St. Mary's Hosp.*, 252 N.W.2d 581, 584 (Minn. 1977) (physician notified of investigation). It is not always the case that physicians are given notice that an investigation is being undertaken. See *Islami v. Covenant Med. Ctr., Inc.*, 822 F. Supp. 1361, 1365 (N.D. Iowa 1992) (physician was not informed of investigation).

101. Van Tassel, *Due Process*, *supra* note 3, at 1189–94.

being interviewed, which may or may not happen, the physician has no role in the investigation phase.<sup>102</sup>

Once the investigation is complete, the next step depends on whether the medical executive committee or an ad hoc committee of the medical staff has conducted the investigation.<sup>103</sup> If the investigation has been undertaken by an ad hoc committee, that committee will draft the set of charges and make recommendations for corrective action. The recommended corrective action of the ad hoc committee will be sent to the targeted physician, who can file an appeal with the executive committee. The executive committee will have a summary, highly informal “hearing” in order to reach a decision.<sup>104</sup> This decision can then be appealed to the board of directors.<sup>105</sup> However, the board of directors is commonly comprised of laypersons who are likely to concur with the medical judgments of the medical executive committee.<sup>106</sup> As mentioned previously, in 1986 Congress passed HCQIA, giving a congressional stamp of approval to the hospital peer review process by providing conditional immunity from suit to those who participate in the process.<sup>107</sup>

### C. The National Practitioner Data Bank Reporting and Query Mandates

In addition to creating “immunity” from suit, HCQIA also set up the National Practitioner Data Bank (“NPDB”).<sup>108</sup> Under the Act and its regulations, multiple different organizations are required to report

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102. *Id.*

103. *Id.* If the medical staff executive committee has conducted the investigation, it will draw up the list of charges and its recommended corrective action. *Id.* This judgment can then be appealed by the physician to the governing body of the hospital. *Id.* The appeal is not de novo but is based on the record created by the hearing in front of the executive committee. PEER REVIEW GUIDEBOOK, *supra* note 92, at 28. After a highly informal “hearing” on the matter, the decision of the board of directors then constitutes a final action of the hospital that the physician can appeal to a trial court. *Id.* at 28.

104. *Id.*

105. *Id.*

106. See John H. Colteaux, Note, *Hospital Staff Privileges: The Need for Legislation*, 17 STAN. L. REV. 900, 907 (1965).

107. See Van Tassel, *Due Process*, *supra* note 3, at 1194–97.

108. See 42 U.S.C. § 11101 (2006). The Health Resources and Services Administration (HRSA) has the federal responsibility of oversight for the NPDB. MAJOR IMPROVEMENTS ARE NEEDED, *supra* note 70, at 7. HRSA completed the regulations that established the operation of the NPDB in October of 1989. *Id.* While HRSA is responsible for ensuring compliance with these regulations, a private operator performs the actual day-to-day operation of the NPDB. *Id.*

information that allegedly reflects poor quality patient care by physicians.<sup>109</sup> For example, insurance companies must report malpractice payments and settlements on behalf of physicians to the NPDB.<sup>110</sup> State licensing boards must report disciplinary actions<sup>111</sup> and health care providers<sup>112</sup> must report peer review actions that restrict a physician's clinical privileges for more than thirty days.<sup>113</sup>

Hospitals must also check the NPDB every two years on every physician who already has staff privileges and for each physician applying for staff privileges.<sup>114</sup> Organizations such as professional societies and state licensure boards are allowed to query the NPDB, but they are not required to do so.<sup>115</sup> Individual physicians may only query for information about themselves.<sup>116</sup>

### 1. Recent Expansion to Include All Healthcare Practitioners in the NPDB Reporting System

In 2010, the passage of new regulations expanded the list of healthcare professionals that the NPDB reports on from only physicians and dentists to all healthcare practitioners.<sup>117</sup> In addition, the list of entities that can query the NPDB has expanded to include "private sector hospitals, nursing homes, and other organizations so that they may be used when making employment, affiliation, certification, or licensure decisions."<sup>118</sup>

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109. MAJOR IMPROVEMENTS ARE NEEDED, *supra* note 70, at 7.

110. *Id.*

111. *Id.*

112. *Id.* For example, hospitals and health plans. *Id.*

113. *Id.* Even private professional societies such as the American Dental Association and the American Medical Association must report sanctions that impact membership. *Id.* Some federal agencies, such as the Department of Veterans Affairs, must report to the NPDB any negative actions involving physicians they insure, employ, or regulate. *Id.* at 8. Practitioners excluded from participating in the Medicare and Medicaid programs must also be reported if they either default on federal loan agreements or engage in fraud or abuse. *Id.* at 8–9.

114. *Id.* at 9.

115. *Id.*

116. *Id.*

117. HHS National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners, 45 C.F.R. pt. 60, §§ 60.1–60.16 (2012).

118. U.S. Dep't. of Health & Human Servs., DATA BANK, <http://www.npdb-hipdb.hrsa.gov/resources/section1921.jsp> (last visited Aug. 11, 2011). Thus:

Hospitals and their human resource departments and nurse recruitment offices now have access to licensure actions on all types of health care professionals. They may query the Data Bank on all types of health care professionals including nurses, nurse aides, and other allied health care professionals when making their hiring decisions. The ability to perform pre-employment screenings of potential health care employees is an invaluable resource that can enhance the hiring process and increase an organization's efforts towards patient safety.

*Id.*

These new regulations bring the states into the picture by requiring hospitals to send reports of all action “that adversely affects the clinical privileges of a physician [or dentist] for a period longer than 30 days”<sup>119</sup> to the state licensure board. The state licensure boards are then required to report this information to the NPDB.<sup>120</sup>

As more fully discussed below,<sup>121</sup> the fact that hospitals must check the NPDB for negative reports before granting staff privileges to a physician<sup>122</sup> means that a negative NPDB report can mean the end of a physician’s career.<sup>123</sup> This is because it is highly unlikely, if not impossible, to find a new position after a negative NPDB report.<sup>124</sup>

### III. THE MERITS OF THE “REMOVING BAD APPLES” APPROACH USED BY PEER REVIEW VERSUS THE CONTINUOUS QUALITY IMPROVEMENT APPROACH OF THE NATIONAL PATIENT SAFETY MOVEMENT FOR DEALING WITH MEDICAL ERRORS

Previously, the assumption was that the majority of medical errors were caused by incompetent or lazy physicians.<sup>125</sup> The hospital peer review system is based on this “bad apples” approach, which posits that the quality of healthcare can be improved by identifying the “bad apples” and removing them from the system.<sup>126</sup> This is called the “name, blame, shame” model.<sup>127</sup> One of the important goals of the national patient safety movement is to teach providers about the substantial flaws in this “bad apples” approach.<sup>128</sup>

119. 42 U.S.C. § 11133 (2006).

120. See HHS National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting on Adverse and Negative Actions, 45 C.F.R. pt. 60, § 60.5(d) (2012).

121. See *infra* notes 143–51 and accompanying text.

122. See 42 U.S.C. § 11135 (2006).

123. See Van Tassel, *Blacklisted*, *supra* note 14, at 2057–62.

124. See *infra* notes 143–51 and accompanying text; see also Sheree Lynn McCall, *A Hospital’s Liability for Denying, Suspending and Granting Staff Privileges*, 32 BAYLOR L. REV. 175, 175 (1980) (“A physician’s livelihood is dependent on acquiring and maintaining hospital staff privileges.”).

125. See Donald M. Berwick, *Continuous Improvement as an Ideal in Health Care*, 320 NEW ENG. J. MED. 53 (1989).

126. *Id.*

127. David C. Hsia, *Medicare Quality Improvement: Bad Apples or Bad Systems?*, 289 JAMA 354 (2003).

128. Kelly Fryer-Edwards, *Talking about Harmful Medical Errors with Patients*, TOUGH TALK: HELPING DOCTORS APPROACH DIFFICULT CONVERSATIONS, <http://depts.washington.edu/toolbox/errors.html> (last visited July 10, 2012).

Based on lessons drawn from other high-risk industries such as aviation and nuclear power, the Institute of Medicine instructs that the broad and diverse nature of medical errors means that the “bad apples” approach was ill-conceived; rather, it is the health care systems themselves that must be changed.<sup>129</sup> The report emphasizes that “although some of these cases [of preventable adverse events] may stem from incompetent or impaired providers, the committee believes that many could likely have been avoided had better systems of care been in place.”<sup>130</sup>

In the time since the Institute of Medicine report was issued, patient safety experts have come to agree with the Institute of Medicine that the majority of medical errors are not the result of incompetent physicians but are due to faulty systems that hospitals are relying upon to provide care.<sup>131</sup>

Health care delivery for any one patient involves a variety of complex interlinked systems. Different individual providers and teams of providers are often involved in the care of a single patient; those providers are governed by interwoven regulations emanating from provider groups, facilities, states and the federal government. Factors at every level of these systems affect the incidence of medical errors and the responses that they provoke. From this perspective, it is clear that preventing errors does not entail simply “getting rid of bad apples.” Rather, “improving safety for patients require[s] a systems approach in order to modify the conditions that contribute to errors.” After reviewing the successful systems-based safety improvements in the airline industry and in workplace safety, the IOM noted, “[A]ccidents can be prevented through good organizational design and management.”<sup>132</sup>

The patient safety movement not only asserts that the “bad apples” approach is not the solution to the problem of medical errors, but also that the “bad apples” approach actually has a negative impact on the quality of healthcare since it promotes secrecy about errors.<sup>133</sup> It is human nature to avoid disclosure of mistakes if it means not only the potential loss of hospital staff privileges, but also the real possibility of the loss of a physician’s entire career practicing medicine.<sup>134</sup> As discussed in the next

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129. INST. OF MED., *supra* note 1, at 30.

130. *Id.*

131. Feature, *A National Survey of Medical Error Reporting Laws*, 9 YALE J. HEALTH POL’Y L. & ETHICS 202 (2009) (the editorial staff of the *Yale Journal of Health Policy, Law, and Ethics* conducted a national survey of medical error reporting laws).

132. *Id.* at 203 (alterations in original) (footnotes omitted).

133. *See id.* at 213.

134. For a complete discussion see Van Tassel, *Blacklisted*, *supra* note 14, at 2057–62.

section, this can be the result of many hospital peer review proceedings.<sup>135</sup> The Institute of Medicine acknowledged that many, if not most, physicians were likely to be hesitant to report their own mistakes and those of others.<sup>136</sup> Underreporting was already recognized as a serious problem at the time of the Institute of Medicine report.<sup>137</sup>

*A. Underreporting Negatively Impacts the Identification of the Root Causes of Medical Errors*

Underreporting is a serious hurdle that must be overcome before the problem of medical error can be remedied. This is because health care administrators and policymakers need accurate data on the different types of errors and how often they occur in order to diagnose the root causes of medical errors.<sup>138</sup> Once the causes of the errors are identified, system reforms can be implemented.<sup>139</sup>

As such, the secrecy surrounding errors prevents proper analysis of the root causes of errors and inhibits efforts to prevent recurrences of those errors.<sup>140</sup> The systems that hospitals implement to avoid errors are only as good as the data they are based upon. Faulty or insufficient data means faulty or insufficient systems. Thus, the “bad apples” approach is ill-conceived as it not only fails to deal with the main cause of medical errors, it also works to perpetuate the root causes of those errors by discouraging disclosure. More open communication among healthcare workers about errors, as well as decreasing the “culture of blame” in healthcare around errors, are both seen as prerequisites to understanding why errors really happen and how they can be prevented.<sup>141</sup>

*B. A Negative Peer Review Report Can Be a “Career-Ender,” Chilling Error Reporting*

The patient safety movement has identified the fear of lawsuits as one of the causes of medical error underreporting.<sup>142</sup> What is missing from the

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135. *See id.*

136. *See A National Survey of Medical Error Reporting Laws, supra* note 131, at 213.

137. *Id.*

138. *See id.* at 203.

139. *Id.*

140. *See id.* at 213–14.

141. *Id.* at 213.

142. *See id.* at 218.



literature is the fact that hospital peer review is likely to be a far more muscular deterrent of error reporting as it involves the exponentially greater sanction of the loss of the ability to practice medicine entirely. For example, for a surgeon, the loss of hospital staff privileges in one hospital as the result of a negative peer review report can mean the end of that physician's career.<sup>143</sup> For a surgeon, lack of access to hospital facilities to perform surgeries is, in effect, the end of that physician's practice.<sup>144</sup> The most obvious situation where this will occur is when there is only one hospital facility in the community.<sup>145</sup> Loss of clinical privileges at that sole hospital means being barred from the practice of medicine in that community.<sup>146</sup>

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143. See BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 378 (5th ed. 2001) (explaining that a precondition to the practice of medicine is access to hospitals); see also McCall, *supra* note 124, at 175 (“A physician’s livelihood is dependent on acquiring and maintaining hospital staff privileges. This access to hospital facilities is necessary for most physicians to adequately treat and care for patients, to maintain their medical practice, and to pursue their medical career.”); Note, *The Physician’s Right to Hospital Staff Membership: The Public-Private Dichotomy*, 1966 WASH. U.L.Q. 485, 510–11 (asserting that a successful doctor must have access to hospitals).

144. See McCall, *supra* note 124, at 175; see also FURROW ET AL., *supra* note 143, at 378 (explaining that precondition to the practice of medicine is access to hospitals).

145. *Kiracofe v. Reid Mem’l Hosp.*, 461 N.E.2d 1134, 1142 (Ind. Ct. App. 1984) (noting that when a hospital is the only one in a community, “its economic impact is great, and the denial of hospital privileges, in many cases, is tantamount to denying a physician the opportunity to practice his or her chosen profession”). In *Greisman v. Newcomb Hosp.*, 192 A.2d 817, 824–25 (N.J. 1963), the court described the situation as follows:

The Newcomb Hospital is the only hospital in the Vineland metropolitan area and it is publicly dedicated, primarily to the care of the sick and injured of Vineland and its vicinity . . . . Doctors need hospital facilities and a physician practicing in the metropolitan Vineland area will understandably seek them at the Newcomb Hospital. Furthermore, every patient of his will want the Newcomb Hospital facilities to be readily available. It hardly suffices to say that the patient could enter the hospital under the care of a member of the existing staff, for his personal physician would have no opportunity of participating in his treatment; nor does it suffice to say that there are other hospitals outside the metropolitan Vineland area, for they may be too distant or unsuitable to his needs and desires. All this indicates very pointedly that, while the managing officials may have discretionary powers in the selection of the medical staff, those powers are deeply imbedded in public aspects, and are rightly viewed, for policy reasons . . . as fiduciary powers to be exercised reasonably and for the public good.

*Id.* at 824.

146. See *Kiracofe*, 461 N.E.2d at 1142; see also *Greisman*, 192 A.2d at 824–25. What many seem to lose sight of is that a physician’s inability to practice has a ripple effect—when a physician can no longer practice medicine, all of that physician’s patients lose access to healthcare. This situation could impact hundreds of people. The loss of their physician is especially hard on those who are dependent on Medicaid and Medicare; it could be years before they are able to find a new physician willing to take on new Medicaid or Medicare patients. One in three physicians are currently turning away new Medicaid patients. See Robert Lowes, *Almost 1 in 3 Physicians Turn Away New Medicaid Patients*, MEDSCAPE TODAY NEWS (Aug. 7, 2012), <http://www.medscape.com/viewarticle/76876>. This situation will grow exponentially worse as the physician shortage grows and millions of new ACA patients and aging baby boomers flood the system. See *id.*

While taking a bit more time to occur, an adverse peer review finding will ultimately impact the physician who practices in a very large community with multiple hospitals in the same disastrous way. When the hospital does its mandatory check of the NPDB for physicians applying for staff privileges for the first time, or the once-every-two-year check for physicians already on staff, the negative report will become known.<sup>147</sup> A termination or limitation of staff privileges at one hospital is likely to trigger a second hospital to follow suit to avoid placing itself at risk of being sued for negligent credentialing.<sup>148</sup> A national survey revealed that in 2007 alone, 48,075 licensure, credentialing, or memberships decisions were impacted by NPDB reports.<sup>149</sup>

Dr. Edward Dench, Jr., former president of the Pennsylvania Medical Society, opines that a data bank report “can essentially make you unemployable, and it can be the difference between getting insurance and

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147. See *supra* note 118 and accompanying text.

148. In a GAO report on the problems with the accuracy of the data contained in the NPDB, the agency acknowledged that the information contained in the databank “can affect a practitioner’s reputation and livelihood . . . .” MAJOR IMPROVEMENTS ARE NEEDED, *supra* note 70, at 3. An HRSA survey revealed that NPDB users, including credentialing committees, chiefs of the medical staff, department chairs, and the chief executive officers, found the reports to be an important part of the credentialing process. See Teresa M. Waters et al., *The Role of the National Practitioner Data Bank in the Credentialing Process*, 21 AM. J. MED. QUALITY 30, 34 (2006).

149. ALAN LEVINE ET AL., STATE MEDICAL BOARDS FAIL TO DISCIPLINE DOCTORS WITH HOSPITAL ACTIONS AGAINST THEM, 6 & n.7 (2011), available at <http://www.citizen.org/documents/1937.pdf>. The Levin report reached this conclusion based upon data from TERESA M. WATERS ET AL., INST. FOR HEALTH SERVICES RESEARCH & POL’Y STUDIES, NATIONAL PRACTITIONER DATA BANK USER AND NON-USER SURVEYS: FINAL REPORT, tbl. IV.C.94. Levin, et al., *supra*. The authors of the Levin report explained that they reached this conclusion based on Waters’s “survey question which was ‘Would your decision regarding the practitioner have been different if you had not received the NPBD response?’ 9.04% of the responses answered ‘yes.’ Applying this percentage to the 531, 802 matches for 2007 results in an estimated 48,075 decisions that were affected by an NPBD report.” *Id.* Adding to the cascade of negative effects a physician faces from a negative peer review report is the loss of both medical insurance and the termination of managed care contracts. See generally McCall, *supra* note 124. In most states, a physician cannot practice without liability insurance. And the loss of managed care contracts alone can destroy a physician’s practice, even without all of the other negative consequences of being blacklisted. See *id.* The amazing growth of managed care compels the participation of almost all health care providers in managed care contracts. See *id.* Physicians who are not part of a practice group with managed care contracts, or who are not preferred providers with multiple managed care organizations, have a difficult time maintaining a practice. See *id.* In order to be considered for, or maintain, these contracts, health care providers must work to stay in good standing with these managed care organizations. See *id.* Physicians who lose hospital staff privileges for quality of care reasons are highly likely to face the immediate termination of managed care contracts. See *id.*

not getting insurance . . . .”<sup>150</sup> A far-reaching and comprehensive study commissioned by the State of California into the reasons for the low and declining level of reporting of negative peer review actions to the NPDB supports Dr. Dench by revealing that:

[P]hysicians who have been the subject of a [negative peer review action] report state that it is difficult or impossible to find a new position, their professional lives are ruined, other entities will not grant privileges even if they have fulfilled the terms of the discipline, and they spend years and hundreds of thousands of dollars in court trying to clear their professional names and reputations.

. . . .

. . . Physicians who had experienced [having a negative peer review report state that it] . . . was a “career ender.”<sup>151</sup>

Thus, like the tort and licensure systems, the threat of a hospital peer review action provides a powerful disincentive to error reporting. Arguably, the hospital peer review system, with its career-ending potential, is an even greater obstacle.

### *C. Error Reporting Statutes Provide Confidentiality from Disclosure in Civil Lawsuits, But Not in Private Peer Review Actions*

Of the twenty-seven states that have implemented mandatory medical error reporting systems, twenty-one have express provisions that bar the production of the error reports in any civil litigation in order to encourage error reporting.<sup>152</sup> However, none of these states protect the physician who has reported his or her own error from being targeted by the hospital peer review process.<sup>153</sup> As many physicians have medical malpractice insurance,

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150. Steve Twedt, *A Negative Data Bank Listing Isn't Easy to Erase*, PITTSBURGH POST-GAZETTE (October 27, 2003, 12:00 AM), <http://www.post-gazette.com/stories/news/us/a-negative-data-bank-listing-isnt-easy-to-erase-520674/>.

151. LUMETRA, COMPREHENSIVE STUDY OF PEER REVIEW IN CALIFORNIA: FINAL REPORT, 65, 94 (2008), available at [http://www.mbc.ca.gov/publications/peer\\_review.html](http://www.mbc.ca.gov/publications/peer_review.html) (Physicians with negative peer review reports “described not being able to find any position or job after having an [negative] report filed and spending three to five years in [peer review] hearings and other procedures to fight for their reputations, even after the [licensure board] found no wrongdoing on their part. They reported spending thousands of dollars to fight the charges so they could again practice as physicians.”).

152. *Id.* at 214.

153. *Id.* at app., available at [http://www.mbc.ca.gov/publications/peer\\_review.html](http://www.mbc.ca.gov/publications/peer_review.html) (the appendix sets forth the language of the statutes in place in each state; a review of this language reveals no

a physician can recover from payment of damages pursuant to a lawsuit and can continue to practice medicine. As such, the loss of a medical malpractice lawsuit is less threatening than the loss of a physician's entire career that can occur from a negative hospital peer review proceeding. This creates the possibility that the threat of hospital peer review discourages error reporting and nullifies any positive effect of provisions that bar production of error reports in civil litigation.

#### IV. DOES THE HOSPITAL PEER REVIEW HEARING SYSTEM NEGATIVELY IMPACT QUALITY OF CARE?

There are two main categories of standards that hospitals rely upon in peer review to measure quality of care: customary care standards and standards that place complete discretion in the hands of hospital administrators to sanction a physician for the good of the hospital. As discussed in the next sections, both sets of standards can have a negative impact on the quality and cost of healthcare.

##### A. *The Impact of Customary Care Standards on Healthcare Quality and Cost*

Unfortunately, one of the two main standards that hospital peer review relies upon to measure physician competence consists of the same customary care standards that many state tort systems are starting to walk away from based on concerns about their negative impact on quality of care.<sup>154</sup> Examples of the standards that fall into this category of customary care include those which hold physicians to a standard of care as measured by the “[hospital’s] standard of competence”<sup>155</sup> or “the general standards of the surgical community”<sup>156</sup> or the “standard of the hospital or the medical staff .

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mention of private hospital peer review actions).

154. See Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 170 (2000) (explaining that many states are moving away from custom as the exclusive proxy for quality).

155. *Adkins v. Sarah Bush Lincoln Health Ctr.*, 544 N.E.2d 733, 736 (Ill. 1989) (physician's treatment of patients failed to conform to “the Center's standard of competence”).

156. *Rhee v. El Camino Hosp. Dist.*, 247 Cal. Rptr. 244, 246, 248–49 (Cal. Ct. App. 1988). In *Rhee*, a newly minted surgeon who had excellent credentials and training evaluations during his residency ran afoul of a group of surgeons in the hospital where he started his practice. *Id.* Members of this group of physicians both served on the peer review panels charged with judging whether the new surgeon met this in-house standard and testified that the new surgeon “did not ‘meet the general standards of the surgical community at El Camino Hospital . . . .’” *Id.* at 248–49.

. . .”<sup>157</sup> As is the case with the use of customary care standards in medical malpractice litigation, the reliance in peer review on customary care acts to entrench custom-based decision making at the cost of quality of care.<sup>158</sup>

As a general matter, “customary care” is the type of care that is typically given by other physicians under comparable circumstances. Customary care is subjective and is based on the predilections of particular physicians based upon tradition, opinion, or clinical experience<sup>159</sup> and not on objective, scientific evidence. The practice of providing customary care, also referred to by many as “eminence-based medicine,”<sup>160</sup> is the normative practice in the United States.

In comparison, the evidence-based model of medical practice is centered on empirical data created by comparative effectiveness research and outcomes analysis. As this body of research grows, evidence-based treatment guidelines are being developed using this empirical data. These evidence-based practice guidelines, called clinical practice guidelines (“CPGs”), can be used to recommend optimal treatments for a steadily increasing number of clinical disorders.<sup>161</sup> CPGs reflect the “well-considered opinions of expert panels, based upon reviews of the best available data, as to how physicians should approach certain clinical problems.”<sup>162</sup>

### 1. The Four Different Categories of Customary Care Practice

The customary care model of medical practice is currently the dominant model for the provision of healthcare in the United States. Unfortunately, a steadily growing group of studies demonstrate that many customary treatment choices can have a negative impact on the quality and cost of

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157. *Campbell v. St. Mary’s Hosp.*, 252 N.W.2d 581, app., at 588 (Minn. 1977) (describing the bylaws which state that corrective action is appropriate when “professional conduct of any member of the staff shall be considered to be lower than the standard of the hospital or the medical staff . . . .”); see *Helling v. Carey*, 519 P.2d 981, 983 (Wash. 1974); see also DAN B. DOBBS, *THE LAW OF TORTS* § 242, at 633 (1st ed. 2000).

158. See *infra* notes 235–43 and accompanying text.

159. IOWA CONSORTIUM FOR SUBSTANCE ABUSE RESEARCH & EVALUATION, *EVIDENCE-BASED PRACTICES: AN IMPLEMENTATION GUIDE FOR COMMUNITY-BASED SUBSTANCE ABUSE TREATMENT AGENCIES* (2003), available at <http://www.uiowa.edu/~iowapic/files/EBP%20Guide%20-%20Revised%205-03.pdf> (The Iowa Consortium for Substance Abuse Research and Evaluation is based at the University of Iowa).

160. A term first used by David Eddy. See David M. Eddy, *Evidence-Based Medicine: A Unified Approach*, 24 *HEALTH AFF.* 9, 9 (2005).

161. CPGs are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” INST. OF MED., *CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM* 8 (Marilyn Field & Kathleen N. Lohr eds., 1990).

162. Richard R. Leahy, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines*, 77 *CALIF. L. REV.* 1483, 1506 (1989).

healthcare. These problems with the customary care model of medical practice have, over time, become well-documented by the Dartmouth Atlas Project.<sup>163</sup> Research conducted under the auspices of the Dartmouth Atlas Project<sup>164</sup> “uses very large claims databases from the Medicare program and other sources to define where Americans seek care, what kind of care they receive, and to determine whether increasing investments in health care resources and their use result in better health outcomes for Americans.”<sup>165</sup> In a special report issued by the Dartmouth Atlas Project, three different categories of customary care practices were identified that can have a significant, negative impact on healthcare quality and cost: failure to provide necessary care, preference-sensitive care, and supply-sensitive care.<sup>166</sup> This Article also adds an additional category—*misuse* of medical care.

These four categories of customary care practices, and their impact on healthcare quality and cost, are explained in the next subsections. The first category of customary care practices are those that give rise to the *misuse* of care. Examples of these customary care practices are provided in Section IV.A.1.a. The second category of customary care is described by the Dartmouth Atlas Project as the failure to provide needed care;<sup>167</sup> in other words, care for which the benefits clearly outweigh the risks.<sup>168</sup> This Article

163. *Understanding the Efficiency and Effectiveness of the Health Care System*, DARTMOUTH ATLAS OF HEALTH CARE, <http://www.dartmouthatlas.org/> (last visited Apr. 2, 2013). The Dartmouth Atlas describes itself as follows:

For more than 20 years, the Dartmouth Atlas Project has documented glaring variations in how medical resources are distributed and used in the United States. The project uses Medicare data to provide information and analysis about national, regional, and local markets, as well as hospitals and their affiliated physicians. This research has helped policymakers, the media, health care analysts and others improve their understanding of our health care system and forms the foundation for many of the ongoing efforts to improve health and health systems across America.

*Id.*

164. The Dartmouth Atlas Project is a “product of the Center for the Evaluative Clinical Sciences at Dartmouth Medical School.” Press Release, Geisel School of Medicine at Dartmouth, New Study Shows Need for a Major Overhaul of How United States Manages Chronic Illness (May 16, 2006), available at [http://geiselmed.dartmouth.edu/news/2006\\_h1/16may2006\\_overhaul.shtml](http://geiselmed.dartmouth.edu/news/2006_h1/16may2006_overhaul.shtml) [hereinafter Dartmouth Press Release].

165. *Id.*

166. ELLIOT S. FISHER, DAVID C. GOODMAN & AMITABH CHANDRA, REGIONAL AND RACIAL VARIATION IN HEALTH CARE AMONG MEDICARE BENEFICIARIES: A BRIEF REPORT OF THE DARTMOUTH ATLAS PROJECT 24 (Kristen K. Bronner ed., 2008), available at [http://www.dartmouthatlas.org/downloads/reports/AF4Q\\_disparities\\_Dec2008.pdf](http://www.dartmouthatlas.org/downloads/reports/AF4Q_disparities_Dec2008.pdf).

167. *Id.* The Dartmouth Atlas Project describes effective care as “consist[ing] of evidence-based services such as Hemoglobin A1c testing for diabetics” and further states that “[v]ariations in effective care reflect failure to deliver needed care.” *Id.*

168. Minal S. Kale et al., *Trends in the Overuse of Ambulatory Health Care Services in the United States*, 173 JAMA: INTERNAL MED. 142, 142–43 (2013) (“... underuse represents the failure

refers to failure to provide needed, or necessary care as the *underuse* of care. While *misuse* is the incorrect choice of medical care and so is an error of commission, *underuse* is an error of omission. Examples of customary care practices that can result in the underuse of care are provided in Section IV.A.1.b.

The third category of customary care is preference-sensitive care. The Dartmouth Atlas Project explains that preference-sensitive care occurs when a condition has multiple possible treatment options, each with its own benefits and risks.<sup>169</sup> The Dartmouth Atlas Project has, in great detail, described the broad geographical variations in the provision of the type and invasiveness of care that has arisen in the use of preference-sensitive customary care. This Article refers to these broad geographical variations in the delivery of care as the *unwarranted variation* in care. Examples of this type of care are set forth in Section IV.A.1.c.

The fourth category of customary care is supply-sensitive care. The Dartmouth Atlas Project describes supply-sensitive care as care for which the supply of a specific resource (for example, number of physicians, hospital beds or specialized testing equipment) heavily influences the customary amount of care provided.<sup>170</sup> With supply-sensitive care, the amount of spending on the same condition can vary widely depending on where the patient lives.<sup>171</sup> This Article refers to supply-sensitive customary care as the *overuse* of medical care. Examples of these broad variations in the use of medical care are discussed in Section IV.A.1.d.

#### *a. Customary Care Can Be Poor Quality Care—Misuse*

Public health research into comparative effectiveness has revealed that customary care can actually be “bad” patient care. Customary care choices can lead to both *misuse* and *underuse* of healthcare. The delivery of the wrong care is the *misuse* of care. The failure to deliver necessary healthcare is the *underuse* of care—in other words, care for which the benefits of the treatment clearly outweigh the potential risks associated with that treatment.<sup>172</sup>

With regard to misuse, scientific studies have identified numerous customary care practices that show little to no evidence of benefit, but which can actually put patients in danger of harm, that are still practiced on a daily

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to deliver healthcare for which the benefits outweigh the risks (e.g. use of an aspirin in patients with coronary disease); and misuse is the delivery of the wrong care (e.g. the use of an antibiotic other than nitrofurantoin, trimethoprim-sulfamethoxazole or quinolone is the incorrect treatment for uncomplicated urinary tract infections.”).

169. *Id.*

170. *Id.*

171. *Id.*

172. *Id.* at 142–43.

basis. This problem with the integration of evidence-based treatment choices into physician practice is a well-studied problem. Scores of studies have revealed that physicians are being exposed to evidence-based medicine in the form of CPGs on a regular basis—they go to seminars, listen, agree, then go back to practice and ignore the new information.<sup>173</sup> In an initiative to change entrenched medical practices, seventeen major medical specialty groups issued recommendations that physicians stop using ninety different unnecessary, but frequently used, tests and procedures, many of which are harmful to patients.<sup>174</sup>

This list of “don’ts” adds to a prior list of forty-five previous recommendations made in “an educational initiative called Choosing Wisely, directed at both patients and physicians, under the auspices of the American Board of Internal Medicine Foundation and in partnership with Consumer Reports.”<sup>175</sup> Examples of a few of the many practice customs that

173. See e.g., Lee A. Green et al., *Translation of Research into Practice: Why We Can't "Just Do It,"* 18 J. AM. BRD. FAMILY PRAC. 541, 541(2005) (There is “widespread agreement that physicians and healthcare systems simply do not put new knowledge about how to improve our patients’ outcomes into practice nearly quickly enough. . . . For example, consider the guideline that “congestive heart failure patients should be evaluated for use of beta-blockers.” An expert physician may be aware of this recommendation and may wholeheartedly accept it as good practice, but may still fail to adopt it when they happen to see an elderly patient in the clinic who could benefit from beta-blockage. Knowledge of evidence can remain separate from, and not integrated into, the physician’s extensive database of procedures that guides their decision and actions. This makes the likelihood of recognizing that the new knowledge is appropriate and incorporating it into these well-rehearsed procedures very uncertain.”); Illaria Baiardini et al., *Why Do Doctors and Patients Not Follow Guidelines?*, 9 CURRENT OPINION ALLERGY CLINICAL IMMUNOLOGY 228, 228 (2009) (“During the last few years, different studies and theories have tried to explain the reason why doctors and patients do not follow guidelines. . . . [A]lthough the efforts to develop and divulge evidenced-based guidelines, results of studies conducted in the United States and the Netherlands suggest that most of the time, guidelines are not applied; about 30-40% of patients do not benefit from a cure programme based on scientific evidence, whereas 20-25% of therapeutic choices may be unnecessary and sometimes even harmful.”); Michael D. Cabana et al., *Why Don't Physicians Follow Clinical Practice Guidelines?*, 282 JAMA 1458, 1458 (1999) (“Despite wide promulgation, clinical practice guidelines have had limited effect on changing physician behavior.”); Justin Timbie et al., *Five Reasons That Many Comparative Effectiveness Studies Fail to Change Patient Care and Clinical Practice*, 31 HEALTH AFF. 2168, 2168 (2012) (“[D]ecades of experience suggest that translating evidence into changes in clinical practice is rarely rapid . . . .”); David A. Davis et al., *Translating Guidelines Into Practice: A Systematic Review of Theoretic Concepts, Practical Experience and Research Evidence in the Adopting of Clinical Practice Guidelines*, 15 CAN. MED. ASS’N J. 408, 408 (1997) (“The evidence shows serious deficiencies in the adoption of CPGs in practice”).

174. Laurie Tarkan, *Doctor Groups Issue Lists of Overused Medical Tests*, N.Y. TIMES (Feb. 21, 2013, 12:52 PM), <http://well.blogs.nytimes.com/2013/02/21/doctor-groups-issue-list-of-overused-medical-tests/>.

175. Roni Caryn Rabin, *Doctor Panels Urge Fewer Routine Tests*, N.Y. TIMES (April 4, 2012), [http://www.nytimes.com/2012/04/04/health/doctor-panels-urge-fewer-routine-tests.html?\\_r=0](http://www.nytimes.com/2012/04/04/health/doctor-panels-urge-fewer-routine-tests.html?_r=0):

United States specialty societies representing more than 500,000 physicians developed



involve the misuse of care that are on the Choosing Wisely list of “don’ts” follow.

The Society of Nuclear Medicine and Molecular Imaging recommends against the use of routine annual stress testing using a nuclear heart scan after coronary artery surgery as this exposes a patient to a level of radiation that is the equivalent of 2,000 chest x-rays.<sup>176</sup> The American College of Obstetricians and Gynecologists recommends against the induction of labor or the performance of a C-section as a matter of convenience before a woman’s 39th week of pregnancy, unless it is medically necessary, as it can lead to an increased risk of learning disabilities, respiratory problems and other risks to the baby.<sup>177</sup> The American Academy of Neurology recommends against the prescription of opioid or butalbital drugs to treat migraine headaches, except when no other treatment is effective, as frequent use of these drugs can worsen migraines.<sup>178</sup> The Society of Hospital Medicine—Pediatric Hospital Medicine recommends against the routine use of anti-reflux treatment for infants who suffer from acid reflux as this treatment can cause significant adverse effects.<sup>179</sup> The American Geriatrics Society recommends against the prescription of benzodiazepines or other sedative hypnotics in older adults as a first choice for insomnia, agitation, or delirium because the use of these medications doubles the risk of car accidents, falls and hip fractures in older adults.<sup>180</sup>

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lists of *Five Things Physicians and Patients Should Question* in recognition of the importance of physician and patient conversations to improve care and eliminate unnecessary tests and procedures. These lists represent specific, evidence-based recommendations physicians and patients should discuss to help make wise decisions about the most appropriate care based on their individual situation. Each list provides information on when tests and procedures may be appropriate, as well as the methodology used in its creation.

In collaboration with the societies, Consumer Reports has created resources for consumers and physicians to engage in these important conversations about the overuse of medical tests and procedures that provide little benefit and in some cases harm.

*Lists*, CHOOSING WISELY: AN INITIATIVE OF THE ABIM FOUNDATION, <http://www.choosingwisely.org/doctor-patient-lists/> (last visited on Mar. 16, 2013).

176. SOC’Y OF NUCLEAR MEDICINE & MOLECULAR IMAGING, *Five Things Physicians and Patients Should Question*, CHOOSING WISELY, <http://www.choosingwisely.org/doctor-patient-lists/society-of-nuclear-medicine-and-molecular-imaging/> (last visited on Mar. 16, 2013).

177. AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *Five Things Physicians and Patients Should Question*, CHOOSING WISELY, <http://www.choosingwisely.org/doctor-patient-lists/american-college-of-obstetricians-and-gynecologists/> (last visited on Mar. 16, 2013).

178. AM. ACAD. OF NEUROLOGY, *Five Things Physicians and Patients Should Question*, CHOOSING WISELY, <http://www.choosingwisely.org/doctor-patient-lists/american-academy-of-neurology/> (last visited on Mar. 16, 2013).

179. SOC’Y OF HOSP. MED.—PEDIATRIC HOSP. MED., *Five Things Physicians and Patients Should Question*, CHOOSING WISELY, <http://www.choosingwisely.org/doctor-patient-lists/society-of-hospital-medicine-pediatric-hospital-medicine/> (last visited on Mar. 16, 2013).

180. AM. GERIATRICS SOC’Y, *Five Things Physicians and Patients Should Question*, CHOOSING WISELY, <http://www.choosingwisely.org/doctor-patient-lists/american-geriatrics-society/> (last visited on Mar. 16, 2013).

*b. Customary Care Can Be Poor Quality Care—Underuse*

A correspondingly large group of physicians adhere to customary practices of *not* providing critical treatments, even in the face of repeated, empirically sound studies that these treatments are of great benefit to their patients. The failure to provide these treatments can, in many situations, expose patients to a significantly increased risk of death. These customary care practices represent *underuse* of healthcare.<sup>181</sup> A major 2012 study suggests that underuse continues to be a major problem in spite of efforts to integrate CPGs into daily physician practice.<sup>182</sup> For example, physicians are failing to provide antithrombotic treatment for atrial fibrillation in 28.1% of these cases.<sup>183</sup> Prescribing antithrombotic drugs decreases the risk of stroke for these patients.<sup>184</sup> For patients with coronary heart disease, doctors are failing to provide aspirin 35.5% of the time, beta-blockers 44.8% of the time, and statins 41.4 % of the time.<sup>185</sup> Aspirin can reduce the occurrence of vascular events, including myocardial infarction and death.<sup>186</sup> Beta-blockers can decrease all cause and cardiovascular mortality, cardiovascular hospitalizations, and the need for revascularization procedures.<sup>187</sup> Statins can reduce the risk of cardiovascular events.<sup>188</sup>

Doctors also fail to prescribe beta-blockers in congestive heart failure patients 40.3% of the time<sup>189</sup> (beta-blockers ameliorate symptoms and greatly improve mortality<sup>190</sup>) and fail to prescribe statins in diabetes patients

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181. Ashish K. Jha et al., *Care in U.S. Hospitals—The Hospital Quality Alliance Program*, 353 NEW ENG. J. MED. 265, 265 (2005) (uncovering the unfortunate failure of both physicians and hospitals to provide treatments that were essential for saving the lives of those who suffered from the most common causes of death, pneumonia, heart attack, and heart failure).

182. Kale et al., *supra* note 168, at 142–43 (describing a study that suggests there has been little improvement on the part of individual physicians in this underuse problem in the seven years since the 2005 Jha study, *supra* note 181).

183. Kale et al., *supra* note 168, at 143.

184. N. A. Mark Estes III et al., *ACC/AHA/Physician Consortium 2008 Clinical Performance Measures for Adults with Nonvalvular Atrial Fibrillation or Atrial Flutter: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and the Physician Consortium for Performance Improvement*, 117 CIRCULATION 1101, 1104 (2008), available at <http://circ.ahajournals.org/content/117/8/1101.full> (“Atrial fibrillation is associated with an increased risk of stroke, heart failure, and all-cause mortality, especially in women.”).

185. Kale et al., *supra* note 168, at 143.

186. AM. COLL. OF CARDIOLOGY ET AL., CHRONIC STABLE CORONARY ARTERY DISEASE: PERFORMANCE MEASUREMENT SET 55 (2005), available at <http://www.ama-assn.org/ama1/pub/upload/mm/pcpi/cadminisetjune06.pdf>.

187. *Id.* at 61.

188. *Id.* at 29.

189. Kale et al., *supra* note 168, at 143.

190. William E. Chavey, II, *The Importance of Beta Blockers in the Treatment of Heart Failure*,

63.8% of the time<sup>191</sup> (statins can decrease cardio-vascular disease events by 19% to 55%—a major cause of mortality in diabetes patients).<sup>192</sup> Adding to this surprising picture, physicians fail to prescribe ACE inhibitors in congestive heart failure patients 58.4% of the time. ACE inhibitors can, when prescribed in conjunction with standard treatment, slow heart failure progression in patients with mild symptoms, and can have a beneficial impact on mortality, morbidity, and quality of life.<sup>193</sup> Finally, physicians are failing to prescribe antiplatelets for stroke patients 51.3% of the time (the use of antiplatelets can significantly decrease the risk of secondary stroke, myocardial infarction, and death<sup>194</sup>) and are failing to prescribe drugs for the treatment of osteoporosis 54.9 % of the time<sup>195</sup> (the use of pharmacologic treatments can “prevent fractures in women and men with osteoporosis or low bone density”).<sup>196</sup>

Also of great concern are the widespread flaws recently found in the treatment of ovarian cancer.<sup>197</sup> A new study whose results were announced in March of 2013 focused on 13,321 women with ovarian cancer who were diagnosed from 1999 to 2006 in California.<sup>198</sup> The study revealed that only 37% of the women studied received the treatment recommended in CPGs promulgated by the National Comprehensive Cancer Network, a consortium of twenty-one major cancer treatment centers.<sup>199</sup> This means that two-thirds of the physicians who treat ovarian cancer patients ignored CPGs that significantly impact mortality.<sup>200</sup>

The number of studies that suggest that customary care can actually negatively impact quality of care by either suggesting that a physician

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62 AM. FAM. PHYSICIAN 2453, 2453–62 (2000), available at <http://www.aafp.org/afp/2000/1201/p2453.html>.

191. Kale et al., *supra* note 168, at 143.

192. John Buse, *Statin Treatment in Diabetes Mellitus*, 21 CLINICAL DIABETES 168 (2003) (“Since the 1970s, there have been substantial epidemiological data demonstrating that cardiovascular diseases (here defined as ischemic heart disease, stroke, and peripheral vascular disease) constitute the primary cause of morbidity and mortality in patients with diabetes. In fact, at least 60% and arguably 80% of people with diabetes will eventually succumb to cardiovascular disease (CVD).”).

193. M. K. Davies et al., *ABC of Heart Failure: Management: Diuretics, ACE Inhibitors, and Nitrates*, 320 BRIT. MED. J. 428, 429 (2000).

194. Dawn Meyer, *Antiplatelets and Stroke Outcomes: State of the Science*, 21 CRITICAL CARE NURSING CLINICS N. AM. 517, 517–28 (2009).

195. Kale et al., *supra* note 168, at 143.

196. Amir Qaseem et al., *Pharmacologic Treatment of Low Bone Density or Osteoporosis to Prevent Fractures: A Clinical Practice Guideline from the American College of Physicians*, 149 ANNALS OF INTERNAL MED. 404, 405 (2008).

197. Denise Grady, *Widespread Flaws Found in Ovarian Cancer Treatment*, N.Y. TIMES (Mar. 11, 2013), available at <http://www.nytimes.com/2013/03/12/health/ovarian-cancer-study-finds-widespread-flaws-in-treatment.html?pagewanted=all>.

198. *Id.*

199. *Id.*

200. *Id.*

provide the wrong treatment or fail to provide a life-saving treatment are steadily growing. These studies demonstrate that following customary care may mean that a patient's condition may not only fail to improve, it may worsen through their exposure to unnecessary risks of harm, including long-term disability or death.

*c. Customary Care Is Related More to Location Than to Quality—  
Unwarranted Variation*

Through a long series of large empirical studies, the Dartmouth Atlas Project has documented that patients receive very different care depending on where they live—from region to region across the entire United States—suggesting that customary care might have a stronger links to geography than quality.<sup>201</sup> For example, a patient is five times more likely to undergo a lower extremity bypass if that patient lives in Baltimore, Maryland than if that patient lives in Temple, Texas.<sup>202</sup> Another example deals with patients with prostate cancer. It is three times more probable that a patient will undergo a radical prostatectomy if that patient lives in Salt Lake City than if that patient lives in San Francisco.<sup>203</sup>

Leg amputation is an infrequent, but shattering, complication of diabetes and peripheral vascular disease.<sup>204</sup> Depending where a patient with diabetes lives, that patient's chances of leg amputation can change by a factor of ten times.<sup>205</sup>

Other illustrations involve the rates of shoulder, hip, and knee replacements. A person with chronic shoulder pain living in Provo, Utah is

201. CTR. FOR THE EVALUATIVE CLINICAL SCI., DARTMOUTH ATLAS OF HEALTH CARE: STUDIES OF SURGICAL VARIATION SPINE SURGERY, [http://www.dartmouthatlas.org/downloads/reports/Spine\\_Surgery\\_2006.pdf](http://www.dartmouthatlas.org/downloads/reports/Spine_Surgery_2006.pdf) (last updated Apr. 15, 2010). For example, a patient is 20% more likely to have spine surgery if that patient lives in Idaho Falls, Missoula or Mason City than if that patient lives in Newark, Bangor or Terre Haute. *Id.* Other examples: a patient living in Bradenton, Florida has a 75% greater chance of spinal surgery than a patient living in its neighbor to the north, Tampa, Florida, *id.*, and a patient is 50% more likely to have hip surgery if that patient lives in Ft. Lauderdale than in neighboring Miami. ELLIOTT S. FISHER ET AL., TRENDS AND REGIONAL VARIATION IN HIP, KNEE, AND SHOULDER REPLACEMENT (Apr. 6, 2010), [http://www.dartmouthatlas.org/downloads/reports/Joint\\_Replacement\\_0410.pdf](http://www.dartmouthatlas.org/downloads/reports/Joint_Replacement_0410.pdf).

202. Anita Arora et al., *What Kind of Physician Will You Be? Variation in Health Care and Its Importance for Residency Training* (Oct. 30, 2012), available at <http://www.dartmouthatlas.org/pages/residency>.

203. *Id.*

204. Philip P. Goodney et al., *Variation in the Use of Lower Extremity Vascular Procedures for Critical Limb Ischemia*, 5 CIRCULATION: CARDIOVASCULAR QUALITY OUTCOMES 94, 94 (2012), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3281555/>.

205. *Id.* at 10.

ten times more likely to undergo a shoulder replacement than someone living in Syracuse, New York.<sup>206</sup> For a person with chronic hip pain, if that person lives in Ogden, Utah, that person is four times more likely to undergo a hip replacement than a person who lives in Bryan, Texas.<sup>207</sup> Correspondingly, a person with chronic knee pain living in Lincoln, Nebraska is almost four times more likely to undergo a knee replacement than a person living in Manhattan, New York.<sup>208</sup>

In the context of chronically ill patients, another study demonstrated that the amount and type of care for those at the end of life varied a great deal between academic medical centers located in different regions across the country.<sup>209</sup> The authors of the study explain that “[t]he degree of variation suggests . . . that patients are receiving care and resident physicians are receiving training that reflects the local practice style of their teaching hospital.”<sup>210</sup>

Collectively, these studies suggest that customary care choices can be based on physician preferences (referred to in one major study as “local practice styles”<sup>211</sup>) unlinked from best practices and that these preferences are more influenced by the region in which a physician practices medicine than by quality of care.

#### *d. Customary Care Can Be Costly Healthcare—Overuse*

Following customary care can also lead to the overuse of healthcare. It is estimated that \$700 billion is wasted every year by the United States healthcare system. The overuse of healthcare “has been identified as a significant component [of this waste], equaling roughly 280 billion.”<sup>212</sup> Studies on the appropriateness of care suggest that “from one quarter to one third of medical services may be of no value to patients.”<sup>213</sup> For example, 7.0% of screening x-rays, 11.3% of screening EKGs, 25.3% of screening urine analyses, and 37.9% of complete blood counts are unnecessarily

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206. FISHER ET AL., *supra* note 201, at 6.

207. *Id.*

208. *Id.* at 8.

209. Arora et al., *supra* note 202, at 7.

210. *Id.*

211. *Id.*

212. Kale et al., *supra* note 168, at 143.

213. Robert H. Brook & Kathleen N. Lohr, *Will We Need to Ration Effective Medical Care?*, ISSUES SCI. & TECH., Fall 1986, at 68. Another study found a “seventeen-fold variation in lab use among internists dealing with clinical patients.” Steven A. Schroeder et al., *Use of Laboratory Tests and Pharmaceuticals: Variation Among Physicians and Effect of Cost Audit on Subsequent Use*, 225 JAMA 969 (1973) (There are wide variations in the use of “laboratory tests, prescription drugs, X-rays, return appointments, and telephone consultations among similarly trained doctors in a wide variety of practice settings.”).

ordered as part of a general medical exam.<sup>214</sup> The overuse of antibiotics is of particular concern in light of the rapidly growing number of antibiotic resistant infections in the United States.<sup>215</sup> Antibiotics are unnecessarily prescribed for acute bronchitis 58.8% of the time, for upper respiratory tract infections 40.2% of the time, and for asthma 6.8% of the time.<sup>216</sup>

Another example comes from a 2012 study completed by researchers at the Stanford University School of Medicine which revealed that an invasive heart test, used routinely to measure heart function, is being dramatically overused.<sup>217</sup> This test is called a left ventriculography (or left ventriculogram) and it measures the amount of blood that gets squeezed out with each heartbeat. This test costs \$300.<sup>218</sup> In 2007, 37,000 Aetna patients underwent this test. Eighty-eight percent of these patients had already undergone another, more effective test that provided the equivalent (and in many cases, better) information to the physician.<sup>219</sup> These patients should not have received this test as they were exposed to the risks associated with injecting the dye, such as increased radiation exposure and an increased risk of heart arrhythmias and stroke without any benefit,<sup>220</sup> wasting \$976,800 every year.

Studies performed under the auspices of the Dartmouth Atlas Project suggest that a significant portion of this overuse is because these are supply-sensitive services. The care of chronically ill, older adult patients is a good

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214. Kale et al., *supra* note 168, at 146.

215. Peter Eisler, *Deadly 'Superbugs' Invade U.S. Health Care Facilities*, USA TODAY (Mar. 6, 2013, 4:40 PM), <http://www.usatoday.com/story/news/nation/2012/11/29/bacteria-deadly-hospital-infection/1727667/> (finding that deadly CRE bacteria are showing up in hospitals and other health care facilities across the country and there is virtually nothing to stop these "superbugs" at this point); *Antibiotics: Misuse Puts You and Others at Risk*, MAYO CLINIC (Feb. 4, 2012), <http://www.mayoclinic.com/health/antibiotics/FL00075> ("Antibiotics can be lifesavers, but misuse has increased the number of drug-resistant germs.").

216. Kale et al., *supra* note 168, at 146.

217. Ronald M. Witteles et al., *Use and Overuse of Left Ventriculography*, 163 AM. HEART J. 617, 617–23 (2012).

218. *Invasive Heart Test Being Dramatically Overused, Study Shows*, SCI. DAILY (April 6, 2012), <http://www.sciencedaily.com/releases/2012/04/120406234519.htm>.

219. *Id.*

220. *Id.* In 2011, the National Physicians Alliance through its Good Stewardship project identified the top five overused ambulatory care practices in internal medicine, family medicine and pediatrics and then began a campaign to educate physicians in how to avoid these overuses. Good Stewardship Working Grp., *The "Top 5" Lists in Primary Care: Meeting the Responsibility of Professionalism*, 171 ARCHIVES INTERNAL MED. 1385, 1385–90 (2011). The "Choosing Wisely" campaign was started the following year by the American Board of Internal Medicine Foundation in coordination with nine physician specialty groups to identify tests or procedures that are commonly used but are not always appropriate. CHOOSING WISELY: AN INITIATIVE OF THE ABIM FOUNDATION, <http://choosingwisely.org> (last visited Apr. 2, 2013).

example of how these supply-sensitive services can lead to overuse.<sup>221</sup>

Common, customary belief is that:

[M]ore services—that is, using every available resource such as specialists, hospital and ICU beds, diagnostic tests and imaging, and more—produces better outcomes. Based on this assumption, the supply of resources—not the incidence of illness—drives utilization of the services. In effect, the supply of hospital beds, ICU beds, and specialty physicians creates its own demand, so areas with more resources per capita have higher costs per capita.<sup>222</sup>

A study investigating the amount of care provided to chronically ill, elderly patients in their last six months of life<sup>223</sup> discredited the ‘more is better’ myth in healthcare as hospitals that provided more exhaustive care and spent more did not get better results.<sup>224</sup> On the other hand, those “with

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221. Dartmouth Press Release, *supra* note 164 (summarizing the study findings that “[a]lmost One-Third of Medicare Spending for Chronically Ill Unnecessary, According to Dartmouth Atlas of Health Care; Improving Care Could Also Lower Costs” (referring to John E. Wennberg et al., *The Care of Patients with Severe Chronic Illness: An Online Report on the Medicare Program by the Dartmouth Atlas Project* (2006), available at [http://www.dartmouthatlas.org/downloads/atlas/2006\\_Chronic\\_Care\\_Atlas.pdf](http://www.dartmouthatlas.org/downloads/atlas/2006_Chronic_Care_Atlas.pdf)) and stating that this Dartmouth study “studied the records of 4.7 million Medicare enrollees who died from 2000 to 2003 and had at least one of 12 chronic illnesses. The study demonstrates that even within this limited patient population, Medicare could have realized substantial savings—\$40 billion or nearly one-third of what it spent for their care over the four years—if all U.S. hospitals practiced at the high-quality/low-cost standard set by the Salt Lake City region. The report comes on the heels of a report by Medicare’s trustees that the insurance program will exhaust its trust fund in 2018, two years earlier than previously forecast.”).

222. Dartmouth Press Release, *supra* note 164 (“The financial incentives used by Medicare and most other payers encourage the overuse of acute care hospital services and the proliferation of medical specialists. The care of people with chronic illness accounts for more than 75 percent of all U.S. health care expenditures, indicating that overuse and overspending is not just a Medicare problem—the health care system as a whole has not developed efficient, effective ways of caring for people with severe chronic illnesses.”).

223. This study reviewed data from the top academic medical centers in the country and discovered that:

[T]he average number of hospitalized days during the last six months of life ranged from 12.9 days per decedent at St. Mary’s Hospital (the principal hospital of the Mayo Clinic in Rochester, Minn.) to 23.9 at New York-Presbyterian Hospital. The University of California at Los Angeles teaching hospital had the highest average number of days in intensive care units during the last six months of life (11.4 days per decedent), a rate 3.5 times higher than the rate for patients treated at the University of California teaching hospital in San Francisco (3.3 days per decedent). Medicare enrollees who were patients of the New York University Medical Center had an average of 76.2 physician visits during their last six months of life, almost one-third more than patients at the next-highest rate academic medical center, the Robert Wood Johnson University Hospital (57.7 visits per decedent). Patients of the University of Kentucky Hospital had slightly more than half as many (18.6) physician visits as the national average (33.5).

*Id.*

224. *Id.* (“The researchers studied patients with chronic illnesses because about 30 to 35 percent of Medicare dollars are spent on people with these conditions during last two years of their lives.

the best quality and ‘best’ outcomes utilized far fewer resources.”<sup>225</sup> Illustratively, “patients in low-cost, high-quality regions such as Salt Lake City, Utah, Rochester, Minn., and Portland, Ore., are admitted less frequently to hospitals, spend less time in intensive care units and see fewer specialists.”<sup>226</sup> Thus, hospitals making low cost choices are not withholding needed care;<sup>227</sup> they are providing more efficient care that produces better outcomes while using fewer resources.<sup>228</sup> The authors of the study explain that “[t]hese organizations offer a benchmark of performance toward which other systems should strive.” This study comports with other estimates that Medicare could save 30% of its costs if the over-use created by adherence to regional customs was rectified.<sup>229</sup>

## 2. An Increasing Number of State Tort Systems Are Shifting to Evidence-Based Care as the Standard of Care

In contrast to the hospital peer review hearing system, state tort systems are gradually shifting away from what is presently the majority rule that relies upon customary practice as conclusive evidence of the standard of care.<sup>230</sup> It appears that the courts in these states recognize the problems that come with the use of custom—as discussed above—as the exclusive proxy for quality.<sup>231</sup> For instance, in a medical malpractice case, in order to meet the standard of care, a physician must “possess and use the care, skill and knowledge ordinarily possessed and used under like circumstances . . . .”<sup>232</sup>

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Two-thirds of those in the study were diagnosed with cancer, congestive heart failure and/or chronic lung disease. ‘The majority of acute care hospitals are applying their standard forms of ‘rescue medicine’ to people who are in advanced stages of diseases that can’t be cured,’ said Wennberg. ‘Patients don’t benefit—they can’t be rescued—and the costs of such care are very high, both in dollars spent and in providing care that the majority of chronically-ill patients might not want, such as admissions to intensive care and being sent to specialist after specialist.’”)

225. *Id.*

226. *Id.*

227. *Id.*

228. *Id.*

229. *Id.*

230. See generally Philip G. Peters, Jr., *The Role of the Jury in Modern Malpractice Law*, 87 IOWA L. REV. 909 (2002) (discussing the merits of the role of custom as conclusive evidence of the standard of care in malpractice litigation and the movement by many states to use custom as only some evidence of the standard of care).

231. *Id.*

232. *Burns v. Metz*, 513 N.W.2d 505, 509 (Neb. 1994) (internal quotation marks omitted); see *Vergara v. Doan*, 593 N.E.2d 185, 188 (Ind. 1992) (judging the physician’s conduct by a “minimum standard of care for the particular practice” (internal quotation marks omitted)). For an excellent overview of medical malpractice law, see DOBBS, *supra* note 157, at § 342, 634–35.



Instead of restricting the scope of evidence that is admissible to show what constitutes reasonable care to what is customarily done under the circumstances, a growing minority of state courts are permitting the introduction of into evidence of risk-benefit analysis grounded in empirical science to show what is reasonable care under the circumstances.<sup>233</sup>

By transitioning away from custom as an exclusive proxy for quality, parts of the tort system appear to be acting instrumentally to benefit both the quality and cost of healthcare by encouraging evidence-based medical practice.<sup>234</sup> Regrettably, as explained below, a large part of the tort system and the entire hospital peer review system are lagging behind and acting to thwart that transition.

*a. Empirical Evidence of the Positive Impact on Quality of Healthcare of Rejecting Customary Care as the Exclusive Proxy for Quality*

Can using an evidence-based standard of care in medical malpractice cases and in the hospital peer review hearing process have a positive impact on the quality and cost of care? The answer appears to be “yes.” A recent empirical study employing data kept by the National Hospital Discharge Surveys on treatment utilization rates from 1977 to 2005 showed that there was “a 30–50 percent reduction in the gap between state and national utilization rates of various treatments and diagnostic procedures [including obstetric, cardiac and diagnostic procedures] following the adoption of a rule requiring physicians to follow national, as opposed to local, standards.”<sup>235</sup> Professor Michael Frakes of the Cornell Law School, who is the author of the study, found that:

[C]ustom-based liability standards may indeed encourage the perpetuation of customary practices and likewise discourage deviations from custom. . . .

. . . .

. . . [T]he results of this study more generally suggest that a malpractice rule that bases standards of care on customary physician practices may indeed incentivize the perpetuation of those customary practices and, at the same time, discouraging deviations

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233. See generally Peters, *supra* note 230 (discussing the minority of courts that have shifted away from customary practice analysis and the effect of risk-benefit evidence on juries).

234. See *infra* Part IV.A.2.a.

235. Michael Frakes, *The Impact of Medical Liability Standards on Regional Variations in Physician Behavior: Evidence from the Adoption of National-Standard Rules*, 103 AM. ECON. REV. 257, 257 (2013).

from custom.

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. . . The employment of custom-based standards, moreover, carries a number of important policy implications, particularly with respect to the possible role that they may play in discouraging cost-reducing innovations in delivery practices. Legal scholars have long recognized that the effectiveness of managed care and related strategies may be blunted by a medical liability system that holds physicians to a standard of care determined according to customary physician practices, where those practices were developed in a predominantly fee-for service environment that may have encouraged excessive practice styles.<sup>236</sup>

Professor Frakes further explains that,

By arguably establishing the empirical relevancy of the customary component to malpractice standards, this study validates these concerns and thereby lends support to proposals that call for a relaxation of customary-standard requirements, including those that argue for a stronger role for “reasonableness” in malpractice-standard determinations or, as above, a more definitive role for clinical practice guidelines<sup>237</sup> in malpractice proceedings.<sup>238</sup>

Just as the use of customary care standards in medical malpractice litigation may be acting to entrench custom-based decision making at the cost of quality of care, a similar result is likely to occur when the hospital peer review process employs the same customary care standard. In fact, this deterrence effect is likely to be more significantly felt as the result of a negative peer review decision could mean the loss of a physician’s entire

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236. See Van Tassel, *Harmonizing*, *supra* note 12 (manuscript at 17–18) (on file with author); see Michael Frakes, *The Impact of Medical Liability Standards on Regional Variations in Physician Behavior: Evidence from the Adoption of National-Standard Rules* (Working Paper, 2010) (on file with author).

237. See Frakes, *supra* note 236. The study done by Professor Frakes lends empirical support for arguments made in my 2006 article for a greater role for evidence based medicine, in the form of clinical practice guidelines, in the hospital peer review process. See Van Tassel, *Harmonizing*, *supra* note 12 (manuscript at 18 n.89); see also Van Tassel, *Due Process*, *supra* note 3, at 1241–55.

238. See Van Tassel, *Harmonizing*, *supra* note 12 (manuscript at 17–18); see Michael Frakes, *The Impact of Medical Liability Standards on Regional Variations in Physician Behavior: Evidence from the Adoption of National-Standard Rules* (Working Paper, 2010) (on file with author).

career rather than just the need to pay money damages or increased insurance premiums.

Support for this conclusion can be found in a study of ten hospital systems performed in 2010.<sup>239</sup> This study was disturbing in that it revealed that avoidable physician errors are giving rise to the same rate of patient deaths as was reported over ten years ago in the IOM report.<sup>240</sup> This death rate remains unchanged in spite of multiple initiatives to improve quality.<sup>241</sup> There are still approximately 98,000 people who die each year from preventable physician mistakes.<sup>242</sup> One of the important findings of the 2010 study is that “the penetration of evidence-based safety practices has been quite modest. . . . Compliance with even simple interventions such as hand washing is poor in many centers.”<sup>243</sup>

This Article suggests that one reason for the failure of evidence-based practices to penetrate into daily medical practice may be the continued use of customary care as the exclusive proxy for quality of care by the tort, licensure, and hospital peer review systems.<sup>244</sup>

#### *B. The Impact of Standards That Vest Complete Discretion in Hospital Administrators on Healthcare Quality*

The second category of standards most commonly used in hospital peer review are those that vest complete discretion to hospital administrators to sanction physicians. The most obvious example of this kind of standard is one that gives a hospital’s governing body “the right to remove any member of the medical staff or to deprive any physician or surgeon of the privileges of the hospital whenever in their sole judgment the good of the hospital or the patients therein may demand it.”<sup>245</sup> Other bylaws in this category are less obvious but are just as subjective when applied. These “beauty is in the eye of the beholder” standards define the required level of competence as achieving “high quality medical care”<sup>246</sup> or providing “adequate” medical

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239. Landrigan et al., *supra* note 79, at 2130 (“In a statewide study of 10 North Carolina hospitals, we found that harm resulting from medical care was common, with little evidence that rate of harm had decreased substantially over a 6-year period ending in December 2007.”).

240. *See id.*

241. *See id.*

242. *See id.*

243. *Id.*

244. *See infra* Part V.

245. *N. Broward Hosp. Dist. v. Mizell*, 148 So. 2d 1, 2–5 (Fla. 1962) (internal citations omitted); *see also Tasher v. St. Tammany Parish Hosp.*, No. 87-1139, 1988 U.S. Dist. LEXIS 1018, at \*5 (E.D. La. 1988) (“[E]xecutive Committee has been given [complete discretion] to summarily suspend privileges ‘whenever action must be taken immediately in the best interest of patient care in the hospital;’” this same broad standard was applied at the post-deprivation hearing).

246. *Gaenslen v. Bd. of Dirs. of St. Mary’s Hosp. & Med. Ctr.*, 232 Cal. Rptr. 239, 242 (Cal. Ct.

care<sup>247</sup> or the “best possible care.”<sup>248</sup> These standards supply little to no limitation on the discretion of the decision-makers resulting in a high risk of capricious and arbitrary decision-making.<sup>249</sup>

Without limits on the discretion of the decision-makers, physicians could be excluded for economic,<sup>250</sup> personal,<sup>251</sup> or discriminatory<sup>252</sup> reasons unrelated to patient safety.<sup>253</sup> Some are concerned that there is a growing use of peer review to silence whistleblowers calling an alarm on poor quality or high-risk practices.<sup>254</sup> Another problem with these vague standards is that they fail to provide notice of what conduct will trigger an investigation and reporting to the NPDB.<sup>255</sup>

Of import is that the catalogue of process protections provided by most

App. 1985) (describing standard that excluded physicians who did not provide “high quality” care from staff privileges); *see also* Huffaker v. Bailey, 540 P.2d 1398, 1399–1401 (Or. 1975) (describing how hospitals may require that physicians provide a higher quality of medical care).

247. Koelling v. Bd. of Trs. of the Mary Frances Skiff Mem’l Hosp., 146 N.W.2d 284, 296–97 (Iowa 1966) (failure to provide “adequate” medical care); *see also* Bock v. John C. Lincoln Hosp., 702 P.2d 253, 255 (Ariz. Ct. App. 1985) (recounting that physician’s staff privileges were terminated because executive committee determined that physician “failed to demonstrate to the Medical Committee that [he was] qualified to practice as an Internal Medicine specialist”).

248. Wyatt v. Tahoe Forest Hosp. Dist., 345 P.2d 93, 95 (Cal. Ct. App. 1959) (only physicians and surgeons who, in the judgment of the board, would provide the “best possible care and professional skill” were granted staff privileges); *see also* DUBY v. Jordan Hosp., 341 N.E.2d 876, 880 (Mass. 1976) (“[The hospital,] in judging the [physician’s] professional competence required that he give his patients the ‘best possible care.’”); Huffaker, 540 P.2d at 1399 (physician must provide to patients “a high quality of medical care”).

249. Van Tassel, *Due Process*, *supra* note 3, at 1209–10.

250. *See generally* John D. Blum, *Economic Credentialing: A New Twist in Hospital Appraisal Processes*, 12 J. LEGAL MED. 427 (1991); John D. Blum, *Hospital-Medical Staff Relations in the Face of Shifting Institutional Business Strategies: A Legal Analysis*, 14 U. PUGET SOUND L. REV. 561 (1991); Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431 (1988); Judith E. Orie, Article, *Economic Credentialing: Bottom-Line Medical Care*, 36 DUQ. L. REV. 437 (1998).

251. *See generally* PEER REVIEW GUIDEBOOK, *supra* note 92, at app. B.

252. *See generally id.*, at app. A.

253. The immunity protections put into place by both HCQIA and state immunity legislation result in a loss of access to the judicial system by these aggrieved physicians. *See supra* Parts II–III. If peer review is being used for purposes unrelated to quality of care, then this loss of legal recourse is unjustified. Since HCQIA immunity was put into place to encourage peer review that enhanced the quality of patient care while at the same time protecting physicians’ interests, it is questionable whether peer review proceedings that act merely to protect hospital autonomy in decision-making should enjoy HCQIA protections. This type of standard coupled with HCQIA immunity unjustifiably cuts off a physician’s ability to challenge staffing decisions unrelated to quality of care concerns through a judicial appeal.

254. *See infra* notes 258–62.

255. *See* Moore v. Bd. of Trs. of Carson-Tahoe Hosp., 495 P.2d 605, 607–09 (Nev. 1972) (discussing bylaw that allowed for termination for “unprofessional conduct”).

hospitals under HCQIA as a condition for judicial immunity, such as the right to counsel and some kind of hearing, are empty formalities if, at the conclusion of the hearing, the decision-makers can follow their unfettered personal predilections in deciding the merits.<sup>256</sup>

A major implication is the impact that the current NPDB process is having on whistleblowers and what this means to quality of care.<sup>257</sup> Veteran reporters Steve Twedt and John Beale of the *Pittsburgh Post-Gazette* wrote a whole series of excellent articles detailing the stories of physician whistleblowers who claim that they were punished for pointing out quality of care problems through the use of, or the threat of the use of, hospital peer review.<sup>258</sup>

‘It is clear that we are hearing of more cases of these kind of really difficult conflicts occurring between hospitals, and, in some instances, hospital boards, and the medical staff,’ said Dr. Paul M. Schyve, senior vice president of the Joint Commission on Accreditation of Healthcare Organizations, which accredits most U.S. hospitals. Schyve said one factor driving these disputes is the economic pressure hospitals face to keep costs down and maintain a

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256. Tying into this consideration is the fact that these vague standards raise questions about the meaningfulness of judicial review. As one court described, absent clearly articulated criteria, “it is impossible for any reviewing body to objectively and independently determine if an applicant has established ‘competence.’” *Kiester v. Humana Hosp. Alaska, Inc.*, 843 P.2d 1219, 1226 (Alaska 1992). Thus, courts will be unable to determine whether the peer review result was driven by considerations unrelated to the quality of patient care.

257. The story of Dr. Ulrich is a good example of how the current vague standards, coupled with the broad judicial interpretation of HCQIA immunity, can have a negative impact on quality of patient care. *Ulrich v. City & Cnty. of S.F.*, No. C-99-05003-THE, 2004 WL 1635542 (N.D. Cal. Jul. 12, 2004); see also Steve Twedt, *The Cost of Courage: How the Tables Turn on Doctors*, PITTSBURGH POST-GAZETTE (Oct. 26, 2003, 12:00 AM), <http://www.post-gazette.com/stories/news/us/the-cost-of-courage-how-the-tables-turn-on-doctors-520650/>. Dr. Ulrich raised red flags about the negative impact that staffing cuts would have on quality of patient care. See *Ulrich*, 2004 WL 1635542. Within two weeks of making his complaints, Dr. Ulrich learned that he was being investigated for alleged clinical incompetence. *Id.* After he resigned, he was reported to the state licensure board and the NPDB. *Id.* This story is being repeated across the country, with whistleblowers who protest problems with quality of patient care being threatened with peer review investigation and NPDB reporting to silence their criticisms. See Twedt, *supra* (“In medical centers as small as Centre Community Hospital in State College and as prestigious as Yale and Cornell, doctors who step forward to warn of unsafe conditions or a colleague’s poor work say they have been targeted by hospital administrations or boards.”).

258. An excellent and well-researched series on the number of physicians who have been targeted by abusive uses of peer review is detailed in an extensive series of articles written by Steve Twedt and John Beale of the *Pittsburgh Post-Gazette*. See, e.g., Twedt, *supra* note 257 (first of the series). Additionally, there are a growing number of organizations that support physicians in their allegations against “sham peer review,” such as: the Center for Peer Review Justice, the Semmelweis Society, the Association of American Physicians and Surgeons, and the Alliance for Patient Safety.

good imagine.<sup>259</sup>

Physician whistleblowers are uniquely vulnerable. If a physician whistleblower is labeled as a disruptive physician, the whistleblower can “face sanctions and effective banishment from the profession. That gives hospitals considerable leverage when conflicts occur.”<sup>260</sup>

The negative impact that peer review may be having on whistleblowers raises the question of whether the broad judicial interpretation of HCQIA immunity for hospital peer review has an unintended effect of silencing those who are most able to identify quality of care problems.<sup>261</sup> Before the creation of the NPDB Reporting System, physicians were in the unique position of being able to speak up without fear of retribution when hospital practices placed patients at risk of harm. These voices may now be silenced by the threat of peer review.

#### V. DOES THE HOSPITAL PEER REVIEW HEARING SYSTEM NEGATIVELY IMPACT ACCESS TO HEALTHCARE?

According to physicians, the termination of staff privileges triggered by a negative peer review report that is also filed with the NPDB can be a “career ender” because it is highly unlikely, if not impossible, to obtain staff privileges in another hospital or a new position that does not require staff privileges thereafter.<sup>262</sup> What many seem to lose sight of is that a

259. Twedt, *supra* note 257.

260. *Id.* A University of Baltimore study was ordered by the Maryland General Assembly on credentialing. The study found that whistleblower physicians who alienate hospital officials are vulnerable to having their admitting privileges taken away, with devastating effects on their practices. See Twedt, *supra* note 257. In an extreme example, one physician faced exactly this situation as a result of pushing for an investigation into a nurse allegedly murdering patients night after night. Steve Twedt, *Doctors Pay for Reporting Suspicions: Statistics Linked Deaths to a Single Nurse, but Hospital Officials Didn't Want to Hear about It*, PITTSBURG POST-GAZETTE (Oct. 28, 2003, 12:00 AM), <http://www.post-gazette.com/stories/news/us/doctors-pay-for-reporting-suspicions-520698/>. In one survey of 448 emergency room physicians across the U.S., 23% reported that they had lost a job, or had been threatened with job loss, when they had raised quality of care concerns. *Id.*

261. Twedt, *supra* note 257.

‘We’re the only people who can stand up for patients,’ said Dr. Scott Plantz, an emergency medicine specialist who headed the survey of emergency physicians. ‘The nurses can’t, because they’re employees of the hospital. But doctors aren’t, or at least they weren’t in the past. With managed care and doctors working for hospitals, it gets worse and worse and worse.’

*Id.*

262. See *supra* notes 143–51 and accompanying text; see also McCall, *supra* note 124, at 175 (“A

physician's inability to practice has a ripple effect—when a physician can no longer practice medicine, all of that physician's patients lose access to healthcare. This situation could impact hundreds of people for every physician who is forced out of practice.

The loss of their physician is especially hard on those who are dependent on Medicaid and Medicare; it could be years before they are able to find a new physician willing to take on new Medicaid or Medicare patients. This situation will grow exponentially worse as the physician shortage grows and millions of new ACA patients and aging baby boomers flood the system. The loss of the ability to practice medicine and its ripple effect may have a particularly negative potential impact on minority physicians and minority and low-income patients.

#### *A. The Impact of the Hospital Peer Review System on the Physician Shortage Crisis*

The reliance by the hospital peer review hearing process on the ill-advised “bad apples” approach and on faulty standard of care provisions to eliminate physicians from the practice of medicine could not come at a worse time—a time when the United States is facing a crisis over the shortage of physicians. The United States is undoubtedly already in the midst of a medical malpractice crisis.<sup>263</sup> What is missing from the ObamaCare plan under ACA is a strategy to provide enough doctors to care for the approximately thirty million new or expanded-care patients who will enter our Medicaid, Medicare, and insured-payment medical system in the next few years.<sup>264</sup> According to a recent study by the Association of American Medical Colleges, there already is a shortage of physicians in a large number of states.<sup>265</sup> Many rural and urban areas have no primary care doctors or necessary specialists.<sup>266</sup> When an estimated thirty million Americans flood into the system, many will not be able to find a physician who is willing to take on new patients.<sup>267</sup> Add to this mix the fact that one-

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physician's livelihood is dependent on acquiring and maintaining hospital staff privileges.”)

263. See *supra* notes 75–89 and accompanying text.

264. See Lisa Clemans-Cope et al., *The Affordable Care Act's Coverage Expansions Will Reduce Differences in Uninsurance Rates by Race and Ethnicity*, 31 HEALTH AFF. 920, 920 (2012).

265. See Ass'n. Am. Med. Colls., *Recent Studies and Reports on Physician Shortages in the U.S.* ASS'N AM. MED. COLLEGES (Oct. 25, 2012), <https://www.aamc.org/download/100598/data/recentworkforcestudies.pdf>.

266. See Ass'n. Am. Med. Colls., *2011 State Physician Workforce Data Book*, ASS'N AM. MED. COLLEGES (Nov. 2011), <https://www.aamc.org/download/263512/data/statedata2011.pdf>.

267. Mike Alberti, *Warnings of Doctor Shortage Go Unheeded*, REMAPPING DEBATE (Feb. 17, 2011), <http://www.remappingdebate.org/article/warnings-doctor-shortage-go-unheeded> (“As of September 2009, at least 80 million Americans lived in areas with a shortage of medical practitioners in at least one field, according the Health Resources and Services Administration. Many of those

third of all current doctors are expected to retire by 2020.<sup>268</sup>

It appears that there are no solutions immediately forthcoming. The number of physician training residencies and the number of doctors entering the workforce through U.S. residence training have been frozen for decades at 100,000 by Medicare.<sup>269</sup> And only 900 residency positions (an increase of approximately 1%) have been funded to deal with the physician shortage.<sup>270</sup> Unfortunately, Medicare funding to teaching hospitals is likely to be cut, creating uncertainty over whether even the present number of residency positions will be funded.<sup>271</sup> Even the American Medical Association is urging the government to increase funding for residency training.<sup>272</sup>

Adding to this looming crisis, the cost-cutting measures of the new ObamaCare program under ACA will drastically cut reimbursement of Medicare and Medicaid to cover the costs of the expansion of care.<sup>273</sup> In 2009, it was reported that an estimated one-fourth of all doctors refused to take Medicare patients, and one-half refused Medicaid patients.<sup>274</sup> A new report issued in 2012 reveals that the number of physicians turning away

areas have a lack of access to primary care doctors, dentists, or mental health professionals. In 2006, 30 percent of U.S. counties lacked a single surgeon, according to the American College of Surgeons. Shortages have also been reported in several other fields in recent years, including pediatrics, radiology, and endocrinology.”).

268. See Mark J. Perry, *There's a Coming Doctor Shortage: But Why?*, CARPE DIEM (Jan. 24, 2011), <http://www.mjerry.blogspot.com/2011/01/theres-coming-doctor-shortage-but-why.html>; see also Alberti, *supra* note 267.

269. See Ass'n. Am. Med. Colls., *U.S. Medical School Applicants and Students 1982–83 to 2010–2012*, ASS'N AM. MED. COLLEGES (Sept. 17, 2012), <https://www.aamc.org/download/153708/data/charts1982to2012.pdf> (illustrating the flat medical student enrollment since 1980).

270. Shawn Tully, *Health Care Reform Can't Work Without More Doctors*, CNN MONEY (Apr. 6, 2011, 1:08 PM), [http://money.cnn.com/2011/04/06/news/doctor\\_shortage\\_healthcare.fortune/index.htm](http://money.cnn.com/2011/04/06/news/doctor_shortage_healthcare.fortune/index.htm).

271. See Robert Pear, *Reshaping Medicare Brings Hard Choices*, N.Y. TIMES (Apr. 12, 2011), [http://www.nytimes.com/2011/04/13/us/politics/13medicare.html?\\_r=0](http://www.nytimes.com/2011/04/13/us/politics/13medicare.html?_r=0). At the debate over last year's health plan, Pear noted that Republicans accused Obama of “raiding Medicare” to pay for the new program providing insurance for people under 65. See *id.* Senator Jim Risch of Idaho said, “We are talking about a half-trillion dollars that is being stolen from Medicare.” See *id.* Senator Charles E. Grassley of Iowa said the cuts “threatened seniors” access to care. See *id.*

272. AM. MED. ASS'N, *LIFTING THE CAP ON MEDICARE-FUNDED RESIDENCY SLOTS REDUCES THE SHORTAGE OF PHYSICIANS*, available at <http://www.ama-assn.org/resources/doc/mss/lobby-day-gme.pdf> (last visited Feb. 1, 2013).

273. See Julie Connelly, *Doctors Are Opting Out of Medicare*, N.Y. TIMES (Apr. 1, 2009), <http://www.nytimes.com/2009/04/02/business/retirementspecial/02health.html>; see also Tully, *supra* note 270.

274. Tully, *supra* note 270; see also Alberti, *supra* note 267; *Recent Studies and Reports on Physician Shortages in the U.S.*, *supra* note 265; Kevin Sack, *As Medicaid Payments Shrink, Patients Are Abandoned*, N.Y. TIMES (Mar. 16, 2010), <http://www.nytimes.com/2010/03/16/health/policy/16medicaid.html?pagewanted=all>.



Medicaid patients has increased to one in three physicians.<sup>275</sup>

### *B. Consequences of the Loss of Their Physician on Low-Income Patients*

When physicians lose their ability to practice medicine through a negative peer review report in the NPDB, there can be a large ripple effect. All of a physician's hundreds of patients lose access to their physician of choice. And, for many low-income Medicaid and Medicare patients, the loss of their physician can mean the loss of access to health care entirely for a substantial period of time, up to several years, as they search for a replacement physician who is willing to take on new Medicaid or Medicare patients.<sup>276</sup> The looming physician shortage, coupled with the growing number of physicians who already refuse to take on Medicare (25%) and Medicaid (33%) patients, means that this problem will become exponentially worse.

Adding yet another negative element to this problem is the possibility that a hospital will engage in the practice of economic credentialing, which favors granting hospital staff privileges to physicians whose patients are self-payors or who are covered by private insurers. The practice of economic credentialing disfavors physicians who have practices made up of low-income patients covered by low-reimbursement public insurance such as Medicaid.<sup>277</sup>

These problems make a compelling case that HCQIA should be amended to require the NPDB to gather data on the makeup of the patient populations of the physicians targeted by the hospital peer review hearing process.

### *C. Are Minority Physicians at the Highest Risk for Career Destruction?*

Those physicians who have a high-minority practice evidence significantly more reporting of problems providing quality of care.<sup>278</sup> Importantly, these physicians report that inability to pay, language barriers, a high proportion of Medicaid patients, and increased patient volume to compensate for lower revenue flows are the root causes of these problems.<sup>279</sup>

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275. See Lowes, *supra* note 146.

276. Stephen Zuckerman et al., *Changes in Medicaid Physician Fees, 1998–2003: Implications for Physician Participation*, 28 HEALTH AFF. w510 (June 23, 2004), <http://content.healthaffairs.org/content/suppl/2004/06/17/hlthaff.w4.374.DC1>.

277. See generally Blum, *Economic Credentialing*, *supra* note 250; Blum, *Hospital-Medical Staff Relations*, *supra* note 250; Hall, *supra* note 250; Orie, *supra* note 250.

278. James D. Reschovsky & Ann S. O'Malley, *Do Primary Care Physicians Treating Minority Patients Report Problems Delivering High-Quality Care?*, 27 HEALTH AFF. w222 (Apr. 22, 2008), <http://content.healthaffairs.org/content/27/3/w222.long>.

279. *Id.*

This suggests that the answer is not to terminate these physicians through negative peer review reporting, thereby contributing to the growing physician shortage, but, instead, to find solutions to deal with these root causes that this population of physicians are experiencing in their struggle to provide quality care.

Most of the physicians who have high-minority practices are themselves minorities.<sup>280</sup> By inference, this may mean that minority physicians are likely to have a higher level of problems with the provision of quality of care, making it possible that they are being targeted more often by the hospital peer review process. This could have serious unintended consequences to access to healthcare by minorities, as discussed in the next section.<sup>281</sup> HCQIA should be amended to collect data on the minority status of the physicians who receive negative reports that are published by the NPDB in order to determine if this is, in fact, happening.

*D. Are Minority Patients at the Highest Risk for Loss of Access to Healthcare?*

Minority physicians are more likely to have high-minority practices.<sup>282</sup> If minority physicians with high-minority practices are more likely to be targeted by the hospital peer review hearing process, then these minority patients are more likely to lose their physicians, and furthermore, to lose access to healthcare for the ever growing number of years that it takes to find a new healthcare provider.<sup>283</sup> There is already a significant disparity of minority access to healthcare in this country, a problem that several provisions of the new ObamaCare legislation under ACA are designed to address.<sup>284</sup> If minority patients are losing access to healthcare as a result of the hospital peer review process, then the hospital peer review system is undermining yet another one of the goals of ACA.

Currently, 14.8% of the white population, 32.2% of the black population, and 28.9% of the Hispanic population are covered by

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280. *Id.* at w224.

281. *See infra* Part V.D.

282. *See* Reschovsky & O'Malley, *supra* note 278, at w.226.

283. *HHS Action Plan to Reduce Racial and Ethnic Health Disparities*, U.S. DEPT. HEALTH & HUMAN SERVS. (Apr. 2011), [http://minorityhealth.hhs.gov/npa/files/Plans/HHS/HHS\\_Plan\\_complete.pdf](http://minorityhealth.hhs.gov/npa/files/Plans/HHS/HHS_Plan_complete.pdf).

284. Clemans-Cope, *supra* note 264, at 926–27. Currently, 21.6% of blacks and 33.3% of Hispanics are uninsured. *Id.* exhibit 2, at 925. By 2019, under ACA, 9.8% of blacks and 21.1% of Hispanics will be uninsured. *Id.*

government provided health insurance under Medicaid, CHIP (Children's Health Insurance Program), Medicare, and other public coverage.<sup>285</sup> Consequently, the black and Hispanic populations are already disproportionately feeling the effect of loss of access to healthcare through the refusal of physicians to take on new Medicaid and Medicare patients.<sup>286</sup> These effects will exponentially worsen with the influx of thirty million people into the medical system under ACA starting in 2014 and the additional influx of baby boomers into Medicare over the coming years. Add to this picture the likely negative effect of the hospital peer review hearing process on minority physicians and their minority patient populations made up of a substantial number of Medicaid patients, and the access problem becomes one of access to physicians, not insurance.

The question of whether the hospital peer review system is having serious unintended consequences by negatively impacting access to healthcare by minorities gives more strength to the argument that HCQIA should be amended to collect data on the minority status of the physicians who receive negative reports that are published by the NPDB.<sup>287</sup>

## VI. SOLUTIONS

The hospital peer review hearing system should be completely restructured to comport with the current scientific understandings of the methodologies that best act to prevent medical errors.<sup>288</sup> The “bad apples” approach that currently drives hospital peer review actually has a negative effect on healthcare quality.<sup>289</sup> This “bad apples” approach should be jettisoned and a new systems approach should be developed that relies on the application of a blend of knowledge translation theory with continuous quality improvement research to integrate evidence-based treatment choices using clinical practice guidelines into physician practice. In order to optimize this systems approach to error prevention, this new system should be coupled with the adoption of a version of the anonymous third-party error reporting system long advocated by the healthcare quality improvement movement and successfully utilized by the airline industry.

### *A. Removing the Customary Care Malpractice Standard Roadblock to Adoption of Evidence-Based Standards*

To date, initiatives designed to integrate evidence-based treatment

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285. *Id.* exhibit 2, at 925.

286. *See* Connelly, *supra* note 273; Tully, *supra* note 270; *see also* Alberti, *supra* note 267.

287. *See infra* Part VI.

288. *See supra* Part III.A.

289. *See supra* Part III.

choices into day-to-day physician practice have been largely unsuccessful.<sup>290</sup> Many studies show that physicians are being introduced to evidence-based medicine in the form of clinical practice guidelines on a consistent basis—they go to continuing medical education seminars, pay attention, agree that changing practice habits is a good idea, then go back to practice and disregard the new information.<sup>291</sup> As mentioned earlier, one study of ten hospital systems found that, in the decade since the seminal Institute of Medicine report that initially revealed that 98,000 patients die in hospitals every year from avoidable medical errors, “the penetration of evidence-based safety practices has been quite modest. For example, . . . [c]ompliance with even simple interventions such as hand washing is poor in many centers.”<sup>292</sup>

One of the two most likely reasons for this disappointing situation is the use of customary care standards to gauge medical malpractice liability in the majority of states. If Professor Frakes is correct that medical practice is, in part, shaped by liability standards,<sup>293</sup> then the first step in cutting this Gordian Knot is for all states to adopt the minority rule that allows evidence-based choices to be introduced as evidence of reasonable care in medical malpractice litigation and licensure review. Top-down initiatives<sup>294</sup> and social media efforts<sup>295</sup> will be needed to educate legislators, judges, and lawyers regarding this much needed change to the scope of evidence that is relevant on the issue of the standard of care.

At the same time, hospitals must make the same changes as the tort system in the standards they use in hospital peer review. This change can be encouraged by amending HCQIA to condition immunity from suit for peer review participants, including the hospital, upon modifications of their standards to allow evidence-based choices to be introduced as evidence of

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290. See *supra* Part IV.A.2, Part IV.B.

291. See generally Michael D. Cabana et al., *Why Don't Physicians Follow Clinical Practice Guidelines?*, 282 JAMA 1458 (1999); see also authorities cited *supra* note 173.

292. Landrigan et al., *supra* note 79, at 2130.

293. See generally Frakes, *supra* note 235.

294. Initiatives such as: preparation of a Continuing Legal Education (“CLE”) class for judges and lawyers that can be distributed nationally to state bar associations; articles that can be placed in bar association newsletters; drafts of proposed legislation sent to legislators; and other efforts of this kind.

295. See, e.g., Van Tassel, *ACA*, *supra* note 3; *Healthcare Reform Could Impact Medical Malpractice and Peer Review: The Supreme Court Ruling on ACA Reinforces a Transition to Evidence-Based Care, but Malpractice Liability Currently Favors Custom-Based Medicine*, CREDENTIALING & PEER REV. LEGAL INSIDER, (Credentialing & Peer Review Legal Insider, Danvers, Mass.), Sept. 1, 2012 (detailing an interview with Professor Katharine Van Tassel).

reasonable care.

## *B. Translating Knowledge into Action*

### 1. The Seven Phases of Knowledge Translation Theory

The second most likely reason that physicians are not integrating evidence-based treatment choices into their practices is the failure to use the large body of empirical research generated by behavioral scientists that deals with the well-studied problem of how to translate new knowledge into action. This research has led to the creation of what many call “knowledge translation theory” or “research implementation theory.”<sup>296</sup> According to knowledge translation theory, the successful translation of knowledge into action occurs in seven separate action phases:

- (1) Specifically identifying the problem;
- (2) Identifying, reviewing, and selecting the knowledge to implement;
- (3) Adapting or customizing the knowledge to the local context;
- (4) Assessing the determinants of knowledge use;
- (5) Selecting, tailoring, implementing, and monitoring knowledge translation interventions and knowledge uptake;
- (6) Evaluating outcomes or impact of using the knowledge; and,
- (7) Determining strategies for ensuring sustained knowledge use.<sup>297</sup>

These seven action steps can occur in sequence or simultaneously.<sup>298</sup> In addition, the process is meant to be dynamic, with the knowledge steps changing the action phases at any point in the process.<sup>299</sup> The goal of the action phases is to use planned action theories to consciously engineer change in healthcare systems and groups.<sup>300</sup> An important part of the theory is to actively consider the context in which the physicians are working to be

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296. See generally Sharon E. Straus, Jacqueline M. Tetroe & Ian D. Graham, *Knowledge Translation Is the Use of Knowledge in Health Care Decision Making*, 64 J. CLINICAL EPIDEMIOLOGY 6 (2011).

297. *Id.* at 8–9.

298. *Id.* at 9.

299. *Id.*

300. *Id.*

sure that barriers to knowledge assimilation as well as barriers to implementation are always considered and addressed.<sup>301</sup>

## 2. Using Knowledge Translation Theory to Integrate Evidence-Based Treatment Choices into Physician Practice

In addition to the top-down initiatives mentioned above, bottom-up, grass roots efforts must also be made. The bottom-up portion of the solution that this Article proposes is the use of knowledge translation theory to incorporate knowledge about empirically tested treatment choices into everyday physician practice. The knowledge that this proposal focuses on is the use of evidence-based guidelines called clinical practice guidelines (CPGs) to guide treatment choices.<sup>302</sup> CPGs identify optimum treatment choices which are derived from clinical outcomes and effectiveness research.<sup>303</sup> CPGs reflect the “well-considered opinions of expert panels, based upon reviews of the best available data, as to how physicians should approach certain clinical problems.”<sup>304</sup> The use of CPGs to guide clinical decision-making shows great promise for improving quality of care through the use of what are called “best practices,”<sup>305</sup> as well as for decreasing costs through the use of less costly choices that result in the same or better outcomes as higher cost alternatives.<sup>306</sup>

301. *Id.*

302. CPGs are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” INST. OF MED., CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM 8 (Marilyn J. Field & Kathleen N. Lohr eds., 1990).

303. Van Tassel, *Due Process*, *supra* note 3, at 1242.

304. Leahy, *supra* note 162, at 1506.

305. See Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369, 384–95 (1995); see also AM. MED. ASS’N, LEGAL IMPLICATIONS OF PRACTICE PARAMETERS (1990); PHYSICIAN PAYMENT REVIEW COMM’N, 1989 ANNUAL REPORT TO CONG. 219–36 (recommending federal support for effectiveness research and development of practice guidelines); Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, 54 LAW & CONTEMP. PROBS., Spring 1991, at 87. See generally David M. Eddy, *Clinical Decision Making: Theory vs Practice-Reply*, 264 JAMA 1534, 1534 (1990); Clark C. Havighurst, *Practice Guidelines for Medical Care: The Policy Rationale*, 34 ST. LOUIS U. L.J. 777 (1990) [hereinafter Havighurst, *Policy Rationale*]; Eleanor D. Kinney & Marilyn M. Wilder, *Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities*, 22 U.C. DAVIS L. REV. 421 (1989); Leahy, *supra* note 162; William L. Roper et al., *Effectiveness in Health Care: An Initiative to Evaluate and Improve Medical Practice*, 319 NEW ENG. J. MED. 1197 (1988) (authored by officials of the Health Care Financing Administration proposal); Joint Comm’n on Accreditation of Hosps., Symposium, *Getting It Right: The Making of Practice Guidelines*, 16 QUALITY REV. BULL. 38, 40 (1990).

306. See Rosoff, *supra* note 305, at 370.

*a. Applying Steps One Through Three of Knowledge Translation Theory*

The first step in this process is for each specific practice area within a hospital to set up a working committee. This working committee will be tasked with identifying an initial set of CPGs that are appropriate to adopt into that particular practice context, taking into consideration the resources of the hospital, the particular characteristics and needs of that particular hospital's patients, as well as the skill sets of the physicians who are part of the practice area. Ultimately, this working committee will propose to the entire practice area a set of CPGs that have been tailored to fit the clinical care expectations of the practice group as a whole.

For instance, the working committee of the cardiology practice group of a hospital could start with the CPGs published by the American College of Cardiology (ACC).<sup>307</sup> The CPG working committee will then evaluate and modify these CPGs,<sup>308</sup> taking into consideration the proposed changes of the entire practice area to tailor the CPGs to collective practice style and professional judgments of all of the physicians in the practice area. In order to obtain modifications that are both relevant and feasible, the working committee will first have to educate all of the physicians in the practice area regarding the science behind the CPGs and how the CPGs could improve the quality of patient care. Once there is a consensus on which suggested

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307. There are two main questions that a CPG committee should investigate when choosing the appropriate CPGs. First, who created the CPGs? And second, what scientific methods were used in the creation of the CPG? It is advisable for physicians to rely upon CPGs created by groups with "auspice legitimacy," in other words, those developers with excellent reputations for accuracy and technical expertise. See Rosoff, *supra* note 305, at 384-95. These are most likely to be large, national groups that represent practice specialties, such as the American College of Cardiology or the American Heart Association. It is also recommended that physicians avoid CPGs promulgated by payors, referred to by some as "boundary guidelines." Boundary guidelines "are used by payers [sic] to define the range of practice options within which physicians could act without incurring financial or other sanctions." Havighurst, *Policy Rationale*, *supra* note 305, at 777-78 & n.3 (quoting LEWIN & ERICKSON, LEADERSHIP IN THE DEVELOPMENT OF PRACTICE GUIDELINES: THE ROLE OF THE FEDERAL GOVERNMENT AND OTHERS 3 (rev. ed. 1989) (prepared for the Physician Payment Review Commission's Conference on Practice Guidelines, Washington, D.C., Oct. 11, 1988)). These CPGs are based on cost-benefit choices motivated by profit. See *id.* CPGs that call for the provision of less care could increase the risk of malpractice exposure.

308. In addition, the CPG committee must evaluate the scientific basis for the CPG in great detail. Was the patient population that made up the clinical practice database sufficiently large? Were the results grounded on well-accepted scientific outcomes research? Were the methodologies used appropriate for the context and were they used under the guidance of qualified medical professionals? If any of these questions are answered in the negative, the CPG should be avoided. On the other hand, if the CPG was created to optimize quality of care by competent scientists based on careful analysis of an appropriately large database and the results were controlled for confounding, bias, and probability issues, the CPG could be a candidate for adoption, taking into consideration the nature of the specific practice. See Rosoff, *supra* note 305, 384-95. Thus, the CPG committee should only choose to adopt gold standard CPGs—which are those promulgated by groups with auspice authenticity and created using good scientific techniques.

modifications should be made, the working committee will integrate these changes into the CPGs. At this point, the working committee will then recommend the modified CPGs to the entire group for adoption.<sup>309</sup>

The process described so far relies on steps one through three of knowledge translation theory. These initial steps have specifically identified the problem (particular instances of conflicts between treatment choices suggested by customary practice versus evidence-based practice), will have identified, reviewed, and selected the knowledge to implement (which CPGs to adopt), and will have adapted or customized the knowledge for the local context (modification of the CPGs to reflect the collective practice style and professional judgments of all of the physicians in the practice area).

*b. Applying Steps Four Through Seven of Knowledge Translation Theory*

To be sure that the initial set of CPGs are reviewed and modified on a yearly basis, a CPG standing committee must be appointed every year. For example, the CPG standing committee will review all of the yearly distributions from the ACC (or another appropriate group which has auspice authenticity and promulgates gold standard CPGs<sup>310</sup>) and then make recommendations to the cardiology practice group—for adoption, revision,

309. The amount of time, duplication of effort, and expense associated with this CPG review enterprise is a legitimate criticism of this proposal. One solution to these concerns is to follow the lead of the institutional review boards (IRBs) of medical institutions which conduct multicenter trials during clinical investigations of drugs and devices.

[S]ometimes the IRB at each center of a multicenter trial conducts a complete review of the protocol and informed consent. Such multiple reviews by multiple IRBs can result in unnecessary duplication of effort, delays, and increased expenses in the conduct of multicenter clinical trials. Greater reliance on a centralized IRB review process, in appropriate circumstances, could reduce IRB burdens and delays in the conduct of multicenter trials.

U.S. DEPT. OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY USING A CENTRALIZED IRB REVIEW PROCESS IN MULTICENTER CLINICAL TRIALS pt. II, at 2 (Mar. 2006) (footnotes omitted), available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127013.pdf>. For example, central IRBs have been created to review multicenter trials dealing with a particular type of condition. “[T]he National Cancer Institute (NCI) has created a freestanding central IRB (NCI central IRB) to provide the option for centralized IRB review for the many multicenter cancer trials conducted by NCI.” *Id.* pt VII.B, at 10. Similarly, CPG committees with comparable practice specialties could contract with a centralized CPG review group to perform a continuous review of CPGs to reflect scientific developments. The recommendations of this centralized CPG group could then be submitted to the CPG committee of the local institution for adoption, adoption with modification, or rejection. This pooling of resources is one way to deal with the concerns of duplication of effort, delay, and expense.

310. See *supra* Part II.B–C.



or rejection.

The CPGs adopted by the practice area will then become the performance expectations for that practice area and every physician who is a member of that department will be expected to comply with the CPGs except in situations where, in the judgment of the physician, they are not appropriate.<sup>311</sup> If the CPGs are not appropriate—and all agree that not every patient fits the norm—the physician will be expected to engage in documentation of the reasons for deviating from the CPGs. A physician who fails to comply with the CPGs without a well-documented rationale should be subject to corrective action. This process tracks the libertarian paternalism theory advanced by Professor Richard Thaler of the University of Chicago and Professor Cass Sunstein of Harvard University.<sup>312</sup> Like the libertarian paternalism theory, this proposal starts with a default position that assumes the adoption of the best practice under the circumstances that is derived from empirical evidence but then allows for the physician to make an individual choice in deviating from this default if it is reasonable to do so.<sup>313</sup> This proposal has no room for an irrational or thoughtless choice to deviate from the default. Similar to the evaluation process that a reasonable person should use before crossing the street—“stop, look, and listen”—CPGs request that physicians stop and think before deciding not to follow

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311. As Professor Rosoff explains:

The goal of . . . CPGs is not, despite what some physicians may believe, to remove all elements of discretion and professional judgment from medical care. There will always be the need—and, one would hope, the latitude—for the exercise of professional judgment. Still, as the body of what is knowable and what is known grows, the degree of latitude will inevitably be impacted by the extant knowledge base. When one does not know what is right or wrong, everything is fair game to do. Knowledge brings limitations, or at least, the basis for limitations to be imposed. As an Institute of Medicine committee on Practice Guidelines has stated, the formal recognition of the practice guidelines movement ‘can be seen as part of a significant cultural shift, a move away from unexamined reliance on professional judgment toward more structured support and accountability for such judgment.’

Rosoff, *supra* note 305, at 375 (footnotes omitted).

312. Cass R. Sunstein & Richard H. Thaler, *Libertarian Paternalism Is Not an Oxymoron*, 70 U. CHI. L. REV. 1159, 1159 (2003).

313. *Id.*

The idea of libertarian paternalism might seem to be an oxymoron, but it is both possible and desirable for private and public institutions to influence behavior while also respecting freedom of choice. Often people’s preferences are unclear and ill-formed, and their choices will inevitably be influenced by default rules, framing effects, and starting points. In these circumstances, a form of paternalism cannot be avoided. Equipped with an understanding of behavioral findings of bounded rationality and bounded self-control, libertarian paternalists should attempt to steer people’s choices in welfare-promoting directions without eliminating freedom of choice. It is also possible to show how a libertarian paternalist might select among the possible options and to assess how much choice to offer. Examples are given from many areas, including savings behavior, labor law, and consumer protection.

*Id.*

the CPG. Next, the physician must document the rationale for the decision to reject the CPG. This documentation provides data for compliance review and CPG evaluation by risk management.

Applying the paternalistic libertarian model acknowledges that much of medical practice still operates in an area of scientific uncertainty, where one size does not fit all and the art of medicine must come into play. This model permits physicians to work from a more uniform starting point in the decision-making tree that is grounded upon empirical data for the treatment of “norm,” while allowing for the freedom required by scientific uncertainty to employ the medical arts to make a different choice if reasonable.

However, allowing for a “safe harbor” from tort liability just because a physician mechanically follows a CPG is not wise. Not every patient fits the norm. There continues to be a great deal of scientific uncertainty when it comes to the best treatment for many conditions, most particularly when it comes to the treatment of outliers. As the practice of evidence-based medicine (population-based medicine, or the treatment of “norm”) grows through the greater understanding of optimal treatment choices for the majority of people, and later transitions to personalized medicine based on the treatment of individuals according to their unique genetic profiles, this currently high degree of scientific uncertainty will steadily diminish over the next several decades, reducing the use of this exception. This proposed system also looks to the future of medicine as it allows for, and facilitates, the ultimate transition of the practice of medicine to the personalized medicine model.

Updates on an ongoing basis to the set of CPGs must be done by the cardiology standing committee to keep pace with scientific developments. The practice norm for all of the cardiology practice group’s physicians should be to apply the CPGs adopted by the cardiology practice. Data on the actual implementation of the CPGs should be gathered by the risk management department. If a CPG was not followed, collecting information on the reasons why the CPG was not followed will allow for further modifications by the standing committee to fit the needs of the practice and its patients. This fine-tuning will allow improved adherence to the CPG.

The process described in this section relies on steps four through seven of knowledge translation theory. A continuous assessment of the determinants of knowledge use (when the CPGs have been followed or not and why) will be made by risk management pursuant to step four. If further education regarding the CPGs is needed, problem solving can be done and strategies for teaching can be created pursuant to step five. Steps six through seven for translating knowledge into action are fulfilled through a

continuing assessment of the success in implementing the CPGs and their impact on healthcare quality and cost.

*c. A Working Example of the Application of Knowledge Translation Theory*

A simple example of how this process can work is the practice of the prescription of aspirin after a heart attack. Providing aspirin to a patient within twenty-four hours of a heart attack is well known to increase that patient's chances of survival by 30%, and this increased survival rate is well supported by scientific evidence.<sup>314</sup> In spite of this evidence, 50% of physicians fail to provide this simple, life-saving treatment.<sup>315</sup> This proposal envisions that the CPG committees of all of the hospital cardiology departments across the country propose that their practice area adopt the CPG of the American College of Cardiology<sup>316</sup> recommending this treatment. Thus, this CPG would become an expectation of performance for the medical staff of the hospital's cardiology department.

If, in fact, a heart attack patient is admitted to the hospital with a condition that contradicts the provision of this treatment, the physician must document this fact as the reason why the CPG was not followed. With this documentation, the failure to provide the treatment will not constitute a violation of the performance expectation as set forth in the adopted CPG. Rather, because the physician made a reasoned decision not to follow the CPG, the performance failure would be the failure to document this reason. This documentation exception should avoid a rigid expectation that the CPG be followed in all circumstances. It recognizes that patient care does not always follow the norm and allows for flexibility to adjust to a patient's unique needs. Risk management would then follow-up with the physician to investigate why the CPG was not followed.

This committee system allows for physician choice among CPGs,<sup>317</sup>

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314. UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES, HOSPITALS COMPARE, available at <http://www.hospitalcompare.hhs.gov/Hospital/Static/Data-Professionals.asp>

315. *Id.*

316. The American College of Cardiology and the American Heart Association publish their guidelines for the management of patients with acute myocardial infarction ("MI," more commonly known as "heart attack"); updates to the guidelines are published in the *Journal of the American College of Cardiology*. Am. Coll. Cardiology & Am. Heart Assoc., 1999 Update: ACC/AHA Guidelines for the Management of Patients with Acute Myocardial Infarction, 34 J. AM. COLL. CARDIOLOGY 890, available at <http://content.onlinejacc.org/data/Journals/JAC/22905/03514.pdf>. The American Heart Association also publishes jointly-authored guidelines in their journal *Circulation: Journal of the American Heart Association*. Am. Coll. Cardiology & Am. Heart Assoc., 1999 Update: ACC/AHA Guidelines for the Management of Patients with Acute Myocardial Infarction, 100 CIRCULATION 1030, available at <http://circ.ahajournals.org/content/100/9/1016.full.pdf+html>.

317. Clinical Practice Guidelines are based on empirical data generated by clinical outcomes and

which act to suggest treatment choices based on best outcomes derived from empirical studies.<sup>318</sup> Two models have already been implemented and demonstrate how this is already working: the integrated practice models adopted by the Mayo Clinic<sup>319</sup> and the VA Hospital System.<sup>320</sup>

### C. Adopting the Third-Party Error Reporting System Used by the Airline Industry

While there are systems in place that require *hospitals* to report medical errors to regulatory agencies, there is no system in place that encourages physicians, nurses, and other hospital employees to report medial errors or near misses. As discussed earlier, underreporting is a serious hurdle that must be overcome before the problem of medical error can be remedied. Health care administrators and policymakers need accurate data on error types and frequency in order to diagnose their root causes.<sup>321</sup> Recognizing the cause of the errors allows system reforms to be developed and implemented.<sup>322</sup>

The culture of blame—and the fear of sanctions it triggers—creates an environment of secrecy surrounding medical errors.<sup>323</sup> The creation of an error reporting system that short-circuits this blame game is a prerequisite to understanding why errors really happen and how they can be prevented. Members of the quality improvement movement have long advocated the adoption of the system for error reporting created by the Federal Aviation Administration (FAA) and National Aeronautics and Space Administration (NASA). This system relies on anonymous mechanisms for error reporting, which encourages voluntary, confidential, and non-punitive reporting for

effectiveness research that suggests the optimum treatment for a rapidly growing number of clinical conditions. See Leahy, *supra* note 162, at 1506.

318. See *id.* This use of empirical data generated through scientific methodology to make medical decisions shows great promise for enhancing quality of care while decreasing the cost of care. See Van Tassel, *Due Process*, *supra* note 3, at 1241–55.

319. See Douglas McCarthy et al., *Mayo Clinic: Multidisciplinary Teamwork, Physician-Led Governance, and Patient-Centered Culture Drive World-Class Health Care*, 27 COMMONWEALTH FUND PUB., Aug. 2009, at 13–14, available at [http://www.commonwealthfund.org/~media/Files/Publications/Case%20Study/2009/Aug/1306\\_McCarthy\\_Mayo\\_case%20study.pdf](http://www.commonwealthfund.org/~media/Files/Publications/Case%20Study/2009/Aug/1306_McCarthy_Mayo_case%20study.pdf) (describing the structural and cultural pillars undergirding the Mayo Clinic's integrated model of health care delivery).

320. See Van Tassel, *Harmonizing*, *supra* note 12.

321. See *supra* notes 138–41 and accompanying text.

322. See *supra* notes 138–41 and accompanying text.

323. See *supra* Part III.

pilots,<sup>324</sup> aviation mechanics,<sup>325</sup> and air traffic controllers,<sup>326</sup> as well as other aviation professionals. Importantly, the FAA “has also chosen to waive fines and penalties, subject to certain limitations, for unintentional violations of federal aviation statutes and regulations which are reported to ASRS [Aviation Safety Reporting System].”<sup>327</sup>

Adopting a similar system for reporting medical errors or near misses in hospitals will allow hospital risk management teams access to data essential to identifying error types and frequency in order to diagnose their root causes so that system reforms can be developed and implemented.<sup>328</sup> The seven-step translation of knowledge theory described above should be used in educating physicians and other medical personnel in the use of these systems.<sup>329</sup>

*D. Allowing a “Comparative Negligence” Type of Defense in Physician Peer Review in Order to Encourage Continuous Quality Improvement Element*

In addition to continuously gathering information on why some best practices are adopted and some are not, the hospital’s risk management department must continuously institute new error avoidance processes, and adapt those hospital processes to optimize uptake of error avoidance systems based on this data. Adding to this responsibility, risk management should be tasked with using the data generated by the anonymous third-party medical error reporting system described above.

Another failure of the hospital peer review hearing process is its refusal to acknowledge that it is the hospital, not the physician, which has the power to use this data to institute new, system-wide processes for avoiding errors. Thus, the hospital is in the best position to avoid medical errors at the least cost—otherwise known as the “best cost avoider.”<sup>330</sup>

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324. See generally AVIATION SAFETY REPORTING SYS., <http://asrs.arc.nasa.gov/index.html> (last visited Aug. 16, 2012).

325. See FED. AVIATION ADMIN., A PRACTICAL GUIDE TO MAINTENANCE ASAP PROGRAMS (2009), available at [http://www.faa.gov/about/initiatives/asap/reports\\_presentations/media/Maintenance\\_ASAP\\_DOT-FAA-AR-9-28.pdf](http://www.faa.gov/about/initiatives/asap/reports_presentations/media/Maintenance_ASAP_DOT-FAA-AR-9-28.pdf).

326. See Alan Levine, *FAA Error-Reporting Program Reveals Hazards, Yields Fixes*, USA TODAY (Apr. 5, 2010, 9:38 AM), [http://www.usatoday.com/news/washington/2010-04-04-faa-error-reports\\_N.htm](http://www.usatoday.com/news/washington/2010-04-04-faa-error-reports_N.htm).

327. *Confidentiality and Incentives to Report*, AVIATION SAFETY REPORTING SYS., available at <http://asrs.arc.nasa.gov/overview/confidentiality.html> (last visited Aug. 16, 2012).

328. See *id.*

329. See *supra* Part VI.B.1.

330. Katharine Van Tassel, *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645, 1688–89 (2004) [hereinafter Van Tassel, *Biotech*]. In this article, I explain the enterprise liability doctrine as follows:

“[I]mproving safety for patients require[s] a systems approach in order to modify the conditions that contribute to errors.” After reviewing the successful systems-based safety improvements in the airline industry and in workplace safety, the IOM noted, “[A]ccidents can be prevented through good organizational design and management.”<sup>331</sup>

Enterprise liability theory counsels that the hospital peer review system, like the personal injury recovery system, should place the cost of injuries on the best cost avoider since they are in the best position to take steps to avoid the injury.<sup>332</sup> This theory explains that one of the goals of the hospital peer review system should be to act instrumentally to encourage the best cost avoider to institute safety measures to avoid liability for future errors.<sup>333</sup> The Institute of Medicine points out that “although some of these cases [of

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The prime objective of the tort system is to compensate innocent victims harmed by faulty conduct. However, shifting the cost of these injuries onto the wrongdoers is arguably instrumental in achieving many other equally laudatory objectives. Forcing a manufacturer to bear the costs of injuries incurred from its products that are faulty in their manufacture or design may deter future misconduct and may tacitly encourage more careful behavior, such as increasingly diligent testing and product design. The cost of injuries from the use of a product may also then be built into the price of the product and passed on to the consumer. If these effects are realized, several goals that commonly fall under the rubric of “enterprise liability” may be accomplished. First, the cost of the risk will be borne by society generally, instead of the innocent victim alone. Second, the price of the product will reflect its true social cost. This price will then mediate consumer choice, resulting in optimum levels of production and purchase. As the price of the product increases as a result of internalizing the cost of injuries, the consumption of the product will decline as consumers switch to less costly alternatives, resulting, ultimately, in a decrease in injuries due to the use of the product. Thus, through enterprise liability, the tort system arguably insulates against the overuse and overconsumption of relatively risky products. Moreover, enterprise liability may place the cost of injury avoidance on the least-cost accident avoider. The manufacturer is often in the best position to accurately assess the various ways of avoiding costs of injuries through redesign, quality control, and other safety measures. As a result of its level of access, the manufacturer is also often in the best position to insure against future injuries. Internalizing all of these costs, as well as the costs associated with injuries, into the price of the product may ultimately force a manufacturer to consider the true cost of certain products when making its choices of which products to produce. It is hoped that the end result of enterprise liability is a socially efficient output.

Finally, placing the cost of the injury from the product onto the manufacturer that reaps the profits from the sales of the product is morally the right and fair outcome.

*Id.* (footnotes omitted).

331. *A National Survey of Medical Error Reporting Laws*, *supra* note 131, at 203 (citation omitted).

332. *See* Van Tassel, *Biotech*, *supra* note 330.

333. *See id.*

preventable adverse events] may stem from incompetent or impaired providers, the committee believes that many could likely have been avoided had better systems of care been in place.”<sup>334</sup> Thus, hospitals are in the best position to prevent medical errors.

Under the enterprise liability theory, it should be recognized that a hospital owes a duty of care to its physicians to create a safe practice environment that optimizes error avoidance. This is similar to the duty of care that factories owe their workers to provide a safe work environment. To properly recognize who is in the best position to avoid the risks of many errors, the physician should be able to assert a form of the defense of comparative negligence by the hospital in a hospital peer review action. In order to make out this defense, the physician must establish that: (1) the hospital could have implemented a feasible error avoidance system, (2) the hospital failed to implement this system, and (3) the error would not have happened if the system had been in place.<sup>335</sup> This also allows for a proper apportionment of fault based upon who is in the best position to avoid the risk of error according to the extensive body of research on the systems approach to error avoidance.

Just as in the case of the airline pilot who has committed an error who is not punished if that pilot has self-reported, if the physician is successful in this defense, in addition to having reported to the anonymous third party reporting system, any sanction should be limited to error avoidance training, and this sanction should not be reported to the NPDB. The self-report should also be barred from being used as evidence in the hospital peer review process to ensure that the physician’s self-report cannot be used against that physician. These protections provide strong incentives to the physician to self-report their errors.

Importantly, just as with the airline error reporting system, the physician will not be entitled to this defense if the physician has engaged in reckless or intentional conduct. This preserves the appropriate level of physician accountability.<sup>336</sup> Creating this exemption to the reporting requirement will require an amendment to HCQIA.

Allowing this defense in hospital peer review will encourage hospitals to buy into the anonymous third party error reporting system described above. In addition, it will encourage hospitals to use the data generated by this error reporting system in their continuous quality improvement

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334. INST. OF MED., *supra* note 1, at 30.

335. This is similar in many respects to a product liability cause of action. *See* Van Tassel, *Biotech*, *supra* note 330.

336. *See, e.g.*, ROBERT M. WACHTER, UNDERSTANDING PATIENT SAFETY 349–53 (2d ed. 2012) (proposing a model for balancing “no blame” and accountability by looking at degrees of fault as well as alluding to the idea of collective responsibility that includes the physician, the healthcare team and, importantly, the hospital).

processes in accord with the weight of the evidence on what works to prevent medical errors.

## VII. CONCLUSION

In light of the astonishing number of patients killed in hospitals each year and the soaring costs of healthcare, it is time to begin a critical review of the hospital peer review hearing system. This Article starts the dialogue by pointing out some of the more obvious problems with this system, including: the “bad apples” approach, the choice of standards that the hospital peer review hearing system relies upon to measure physician competence, and the possible negative impact that the hospital peer review hearing system has on access to healthcare—particularly the potential negative impact on minority physicians as well as minority and low-income patients.<sup>337</sup> All of these problems negatively impact overall healthcare quality, cost, and access.

In order to deal with these problems, this Article proposes that hospital peer review be completely restructured to comport with the current scientific understanding of the methodologies that best act to prevent medical errors.<sup>338</sup> A new system that relies upon the application of knowledge translation theory—along with continuous quality improvement—to integrate evidence-based treatment choices using clinical practice guidelines into physician practice should be developed. Relying on the libertarian paternalism theory developed by Professors Cass Sunstein and Richard Thaler, this proposed system relies upon “gold standard” clinical practice guidelines as the default treatment choice, but then allows for individual physician choice in deviating from this default choice if it is reasonable to do so. This exception allows for the currently high level of scientific uncertainty that exists when it comes to many medical conditions, particularly in the realm of the treatment of outliers. As the practice of evidence-based medicine (population-based medicine, or the treatment of “norm”) grows through the greater understanding of optimal treatment choices for the majority of people, and later transitions to personalized medicine based on the treatment of individuals according to their unique genetic profiles, this currently high degree of scientific uncertainty will steadily diminish over the next several decades, reducing the use of this exception. This proposed system also looks to the future of medicine as it allows for, and facilitates, the ultimate

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337. *See supra* Parts III–V.

338. *See supra* Part VI.



transition of the practice of medicine to the personalized medicine model. In order to optimize this systems approach to error prevention, this Article proposes that this new system be coupled with the adoption of a version of the anonymous third-party error reporting system successfully utilized by the airline industry and long-advocated by the healthcare quality improvement movement. Finally, this proposal recognizes that the hospital is both the best and least cost avoider when it comes to medical errors by allowing physicians to use a form of the comparative negligence defense during the peer review hearing process, that, coupled with reporting to an anonymous third-party error reporting system, acts to conditionally insulate the physician from NPDB reporting.