

2013

## Mistake-Proofing Medicine: Legal Considerations and Healthcare Quality Implications

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### Recommended Citation

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# Mistake-Proofing Medicine: Legal Considerations and Healthcare Quality Implications

John R. Grout\*, John W. Hill\*\*,  
Arlen W. Langvardt\*\*\*

## ABSTRACT

*In 1999, the Institute of Medicine estimated that approximately 98,000 deaths resulted annually from medical errors. This shocking number does not appear to have lessened during the intervening years. Mistake-proofing techniques similar to those that have proven useful in the product liability context hold great promise for reducing the number of medical errors. However, the adoption of such techniques in healthcare settings is more limited than expected.*

*This article examines potentially useful mistake-proofing techniques, explores the largely unsound reasons why healthcare professionals have been slow to adopt such techniques, and explores the implications of mistake-proofing adoption (or lack thereof) for malpractice litigation and liability. Along the way, this article considers the undesirable effects of misperceptions on the part of healthcare professionals regarding their risks of being held liable in a malpractice case. This article also proposes ways of encouraging greater adoption of mistake-proofing techniques and other error-reduction practices in healthcare contexts.*

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## I. INTRODUCTION

Issues of healthcare access and affordability have received

considerable media attention in recent years and have been the subjects of political debate, regulatory action, and judicial decisions.<sup>1</sup> Although the focus on access and affordability has not kept healthcare *quality* issues from also being noted, the problem of how to improve healthcare quality remains a troublesome one.<sup>2</sup> An “unconscionable error rate”<sup>3</sup> documented in a landmark study in 1999 by the Institute of Medicine (IOM) shocked many, as the IOM estimated that up to 98,000 deaths

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1. Most notably, huge numbers of media reports dealt with controversies preceding and following the 2010 enactment of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in scattered sections of 26 U.S.C. & 42 U.S.C.). *See, e.g.*, Kirk Johnson, *States’ Rights Is Rallying Cry of Lawmakers*, N.Y. TIMES, Mar. 26, 2010, at A1 (providing examples of states’ legislative reactions asserting states’ rights); Kevin Sack, *In Partisan Battle, Governors Clash With Attorneys General Over Lawsuits*, N.Y. TIMES, Mar. 28, 2010, at A25 (highlighting states with partisan battles relating to the decision to join the federal health care mandate litigation); *see also* James Osborne, *Tenth Amendment Movement Aims to Give Power Back to the States*, FOX NEWS (May 26, 2009), <http://www.foxnews.com/politics/2009/05/26/tenth-amendment-movement-aims-power-states> (noting that at least 35 states asserted Tenth Amendment rights within the year). In the high-profile 2012 decision on the constitutionality of the Affordable Care Act, the U.S. Supreme Court held that the statute’s individual mandate—the requirement that all individuals have health insurance in force in 2014 and thereafter or else incur an obligation to make a shared responsibility payment, 26 U.S.C. §5000A (2012)—was a valid exercise of the congressional power to tax. *Nat’l Fed’n of Indep. Bus. v. Sebelius*, Nos. 11-393, 11-398 and 11-400, slip op. at 33–44 (U.S. June 28, 2012); *see also* U.S. CONST. art. I, § 8, cl. 1 (providing Congress with the “power to lay and collect taxes”). The Court, however, held that Congress exceeded its constitutional powers in providing that a state risked losing all existing Medicaid funding if it declined to participate in a Medicaid expansion that Congress initially would fully fund but that later would lead to an obligation on the part of the state to pay ten percent of the added costs. *Nat’l Fed’n of Indep. Bus.*, slip op. at 49–50. The Court resolved the constitutional problem by holding that states could decide whether to participate in the Medicaid expansion without risking the loss of existing Medicaid funding if they said “no” to the expansion. *Id.* at 55–58.

2. *See, e.g.*, John W. Hill, Arlen W. Langvardt & Anne P. Massey, *Law, Information Technology, and Medical Errors: Toward a National Healthcare Information Network Approach to Improving Patient Care and Reducing Malpractice Costs*, 2007 U. ILL. J.L. TECH. & POL’Y 159, 159–65 (noting the growing role that information technology should play in reducing medical errors); Phillip T. Powell & Ron Laufer, *Promises and Constraints of Consumer-Directed Healthcare*, 53 BUS. HORIZONS 171, 171–72, 177 (2010) (arguing that consumer-directed healthcare will not only lower costs, but also increase quality).

3. David Ahern, *Patient-Centered Computing and eHealth: Transforming Healthcare Quality*, Introductory Remarks at Harvard Medical School Seminar (Mar. 28–30, 2008) (on file with authors).

per year resulted from medical errors.<sup>4</sup> There are indications that the incidence of errors has not abated in the years since the IOM's study, and may even be increasing.<sup>5</sup> Accounts of serious medical errors continue to abound.<sup>6</sup>

A 2006 report by the IOM identified quality problems so serious that, on average, a hospital patient would be subjected to at least one medication error per day.<sup>7</sup> In a "national report card" on American healthcare, the Rand Corporation concluded

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4. Inst. of Med., *To Err Is Human: Building a Safer Health System* 31 (Linda T. Kohn et al. eds., 2000) [hereinafter IOM, *TO ERR IS HUMAN*].

5. See David L. Classen et al., "*Global Trigger Tool*" Shows That Adverse Events in Hospitals May Be Ten Times Greater Than Previously Measured, 30 HEALTH AFF. 581, 581–82, 586 (2011) (implementing a new method for detecting adverse events in a hospital setting); Christopher P. Landrigan et al., *Temporal Trends in Rates of Patient Harm Resulting from Medical Care*, 363 NEW ENG. J. MED. 2124, 2130, 2133 (2010) (reporting the results of a study of ten North Carolina hospitals); *U.S. Hospital Errors Continue to Rise*, WASH. POST (Apr. 2, 2007), <http://www.washingtonpost.com/wp-dyn/content/article/2007/04/02/AR2007040200813.html> (reporting the results from an examination of Medicare hospitalization records); see also *A National Survey of Medical Error Reporting Laws*, 9 YALE J. HEALTH POL'Y L. & ETHICS 201, 202 (2008) [hereinafter *National Survey*] (extrapolating the error rate from the IOM study to the population numbers in 2006).

6. See, e.g., Charles R. Denham et al., *An NTSB for Health Care—Learning From Innovation: Debate and Innovate or Capitulate*, 8 J. PATIENT SAFETY 3, 5 (2012) (sharing story of heparin overdose to twin infants); Liz Kowalczyk, *Mass. Patient Death Rate a Concern*, BOS. GLOBE, Dec. 6, 2007, at B1 (stating that the Massachusetts patient death rate is higher than the national average); Liz Kowalczyk, *Surgical Mistakes Persist in Bay State*, BOS. GLOBE, Oct. 26, 2007, at A1 (highlighting various surgical errors at a Massachusetts hospital); Jordan Rau, *Hospital Mistakes Go Public*, L.A. TIMES, June 30, 2008, at A1 (providing examples of hospital errors in California); *Family Sues Geisinger Over Newborn's Death*, PENNLIVE.COM (Jan. 11, 2008), [http://www.pennlive.com/midstate/index.ssf/2008/01/family\\_sues\\_geisinger\\_over\\_new.html](http://www.pennlive.com/midstate/index.ssf/2008/01/family_sues_geisinger_over_new.html) (reporting that an overdose of antibiotics by the hospital led to the death of one infant and permanent brain injury in another); *Family Sues Hospital After Man's Tonsil Surgery Death*, FOX NEWS (Aug. 28, 2008), <http://www.foxnews.com/story/0,2933,412222,00.html> (alleging that an incorrectly adjusted breathing tube caused suffocation); *Tape Shows Woman Dying on Waiting Room Floor*, CNN (July 1, 2008), <http://www.cnn.com/2008/US/07/01/waiting.room.death/index.html>.

7. Michael Brophy, *The July 2006 IOM Report on Medication Errors*, MED. MALPRACTICE L. & STRATEGY (ALM Media Properties, L.L.C., New York, N.Y.), Sept. 2006, available at [http://www.lawjournalnewsletters.com/issues/ljn\\_medlaw/23\\_12/news/147223-1.html](http://www.lawjournalnewsletters.com/issues/ljn_medlaw/23_12/news/147223-1.html). The 2006 IOM report estimated that at least 1.5 million preventable medication errors occur each year in hospitals and similar medical facilities. INST. OF MED., PREVENTING MEDICATION ERRORS 124 (Philip Aspden et al. eds., 2006) [hereinafter IOM, *PREVENTING MEDICATION ERRORS*].

that over time, almost everyone in the United States is at risk of receiving poor healthcare.<sup>8</sup> An estimated four percent of all patients entering hospitals experience some type of adverse incident, approximately half of which are preventable and twenty-five percent of which stem from negligence.<sup>9</sup>

Healthcare systems have become more complex as they have evolved.<sup>10</sup> Various healthcare providers (HCPs)—for instance, hospitals, clinics, physicians, nurses, other medical professionals, and staff persons—all play roles in the furnishing of care to patients. For institutional HCPs, there are dual lines of authority for clinical and administrative staff and powerful subcultures that may often clash.<sup>11</sup> As a result, it may not be clear where the ultimate responsibility for reducing healthcare errors resides in a given HCP.<sup>12</sup> Healthcare processes also tend to be insufficiently connected to one another in any real-time fashion,<sup>13</sup> leading to gaps in information flow and resulting in uneven delivery of care.<sup>14</sup> If the error rates in intensive care

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8. RAND HEALTH, THE FIRST NATIONAL REPORT CARD ON QUALITY OF HEALTH CARE IN AMERICA 3 (2006), available at [http://www.rand.org/pubs/research\\_briefs/2006/RAND\\_RB9053-2.pdf](http://www.rand.org/pubs/research_briefs/2006/RAND_RB9053-2.pdf) (finding that there is little variation in receiving recommended medical care, even when looking at race, gender, or financial status of individuals); see also Denham et al., *supra* note 6, at 3–4 (stating that healthcare harm is the third leading cause of death in the United States). Perhaps one of the most glaring indications of underlying systemic problems is that the United States, despite its higher healthcare expenditures, has a higher infant mortality rate than any other industrialized nation belonging to the Organization for Economic Co-operation and Development (OECD). JULIUS B. RICHMOND & RASHI FEIN, THE HEALTH CARE MESS: HOW WE GOT INTO IT AND WHAT IT WILL TAKE TO GET OUT 93 (2005).

9. Jonathon Todres, *Toward Healing and Restoration for All: Reframing Medical Malpractice Reform*, 39 CONN. L. REV. 667, 679 (2006).

10. Brad Broberg, *Medical Errors Going Under the Microscope*, PUGET SOUND BUS. J., (Oct. 28, 2007, 9:00 PM), <http://www.bizjournals.com/seattle/stories/2007/10/29/focus1.html> (focusing on the impact that variability has on whether the complex system works smoothly).

11. R. Nat Natarajan & Amanda Hoffmeister, *Do No Harm: Can Health Care Live Up to It?*, TENN. TECH. U., <http://www.tntech.edu/mayberry/noharm/> (last visited Oct. 8, 2012).

12. See *id.* (noting that the different entities involved in healthcare may use different definitions for error and quality in healthcare).

13. See Hill, Langvardt & Massey, *supra* note 2, at 197–204 (analyzing the role that electronic medical records can play in reducing medical errors).

14. Ahern, *supra* note 3; Sidney Taurel, Chairman & CEO Eli Lilly & Co., *The Health Care Conundrum: A Call for Leadership*, Remarks at the Indiana University Kelley School of Business Annual Business Conference (Mar. 8, 2006) (on file with authors). A lack of understanding of patterns of error and lack of communication is often the culprit in causing medical errors, as opposed to purely individual human mistakes. Tom Murphy, *Clarian Plans*

units were acceptable, for example, in the airline and banking industries, the result would be two dangerous landings per day at O'Hare International Airport and 32,000 checks deducted from the wrong accounts every hour.<sup>15</sup> When one considers what is at risk, the high medical error rates in the United States become especially difficult to excuse. Yet those high rates persist.

In order to slash the "unconscionable" rate of medical errors and thereby improve healthcare quality, HCPs should make greater use of mistake-proofing regimens that feature, among other things, the application of lean-manufacturing techniques borrowed from industry.<sup>16</sup> Mistake-proofing is defined as "the use of process or design features to prevent errors or the negative impact of errors."<sup>17</sup> It has been employed in domains other than healthcare with significant success.<sup>18</sup> With most serious medical errors likely resulting from systems failures as opposed to the failure of single individuals,<sup>19</sup> devising means of preventing process errors would be a logical course of

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*Training Center*, INDIANAPOLIS BUS. J., Apr. 3, 2006, at A3 (supporting the opening of a simulation training center for health care professionals).

15. Ahern, *supra* note 3. For another instructive comparison, consider that in the era of total-quality management (TQM) and Six-Sigma thinking, many business organizations strive to limit errors to 3.4 defects per million opportunities. See *What is Six Sigma?*, ISIXSIGMA MAG., [http://www.isixsigma.com/sixsigma/six\\_sigma.asp](http://www.isixsigma.com/sixsigma/six_sigma.asp) (last visited Oct. 8, 2012) (identifying Six Sigma as a quality measure that "strives for near perfection").

16. John R. Grout & John S. Toussaint, *Mistake-Proofing Healthcare: Why Stopping Processes May Be a Good Start*, 53 BUS. HORIZONS 149, 150 (2010) (recognizing the ability of an assembly line to stop at the push of a button is sometimes the best reaction to a problem). Other possible approaches to reducing the number of medical errors include a changed delivery model, better-crafted incentives for HCPs, a modified tort liability system, and greater use of health information technology. See John W. Hill, Angela N. Aneiros & Paul R. Hogan, *Law and the Healthcare Crisis: The Impact of Medical Malpractice and Payment Systems on Physician Compensation and Workload as Antecedents of Physician Shortages—Analysis, Implications and Reform Solutions*, 2010 U. ILL. J.L. TECH. & POL'Y 91, 132–50. Except to the extent that such other approaches complement or otherwise constitute a component of a sound mistake-proofing program, discussion of them is beyond the scope of this article.

17. JOHN GROUT, MISTAKE-PROOFING THE DESIGN OF HEALTH CARE PROCESSES 1 (2007), available at <http://www.ahrq.gov/qual/mistakeproof/mistakeproofing.pdf>.

18. See Grout & Toussaint, *supra* note 16 (showing how Toyota implements these concepts).

19. Lucian L. Leape, *The Patient Safety Imperative*, Presentation at Harvard Medical School Seminar: Progress in Patient Safety (Nov. 3–4, 2008) [hereinafter Leape Harvard Seminar Nov. 2008] (on file with authors).

action. Doing so should also be highly desirable from the perspective of HCPs, given that medical errors may lead to malpractice lawsuits—something no HCP wants to face.<sup>20</sup> This desirability is enhanced by evidence that mistake-proofing techniques and technologies in many cases can be implemented inexpensively and can hold the potential to improve return on investment.<sup>21</sup>

Despite mistake-proofing's desirability, HCPs tend to adopt such processes slowly.<sup>22</sup> Improvements in U.S. healthcare quality have likewise been slow—so slow that in 2009, Consumers Union assigned a failing grade to the quality improvement efforts.<sup>23</sup> In assigning that grade, Consumers Union noted the problematic example that most hospitals did not adopt systems and procedures known to prevent medication errors.<sup>24</sup>

What accounts for the slow adoption of mistake-proofing processes in the healthcare setting? Inadequate regulatory efforts serve as one reason. For example, there is no national entity specifically charged with coordinating, tracking, and meaningfully encouraging patient safety improvements. The current fragmented efforts along these lines fall short.<sup>25</sup> Moreover,

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20. See, e.g., Hill, Langvardt & Massey, *supra* note 2, at 159–60 (pointing out the high cost of medical malpractice claims). HCPs often tend not to be shy about voicing their concerns over the supposed prevalence of malpractice lawsuits. See, e.g., *id.* (identifying malpractice liability as a “crisis” and a focal point of the 2004 presidential campaign). In reality, the vast majority of medical errors—even those that result in harm to a patient—do not lead to malpractice litigation. See *infra* text accompanying notes 264–265. But it is true that an error prevented is a potential lawsuit prevented.

21. GROUT, *supra* note 17, at 14–16.

22. See *id.* at 17–20, 23 (providing list of reasons why it is difficult to implement these processes in the healthcare setting). See also *id.* at iii (“[W]e still have much more to do to improve patient safety . . . a little-known but very promising approach to preventing medical errors . . . We have only scratched the surface . . . as many other devices and applications are still in the pipeline or have yet to be discovered and disseminated.”).

23. CONSUMERS UNION, TO ERR IS HUMAN—TO DELAY IS DEADLY 12–13 (2009) [hereinafter CONSUMERS UNION]. In 2000, the IOM suggested a goal of reducing healthcare errors by fifty percent over five years. IOM, TO ERR IS HUMAN, *supra* note 4, at 4. That goal went unachieved. AGENCY FOR HEALTHCARE RESEARCH & QUALITY, U.S. DEP’T OF HEALTH & HUM. SERVS., AHRQ Pub. No. 08-0040, 2007 NATIONAL HEALTHCARE QUALITY REPORT, at iv, 2 (2008).

24. CONSUMERS UNION, *supra* note 23, at 5–7. As will be seen, a sound mistake-proofing program should include procedures and techniques designed to prevent medication errors, which occur with surprising frequency. See *infra* text accompanying notes 197–203, 256–257.

25. See *infra* text accompanying notes 114–121, 259–263.



there is no true national system of accountability with sufficient quality transparency to enable healthcare consumers and regulators to identify HCPs that commit abnormally large numbers of errors and to create pressure for change.<sup>26</sup>

In addition, fear of legal liability serves as an impediment to widespread adoption of mistake-proofing processes. The concern is that the implementation of mistake-proofing might be used as evidence that such actions were possible but that HCPs delayed in their implementation, with harm coming to the patient in the meantime.<sup>27</sup> As will be seen, that concern is largely unwarranted because of a key rule of evidence.<sup>28</sup> But to the extent that the concern is there, it serves as an obstacle. Further, even when mistake-proofing has been implemented, HCPs may be reluctant to acknowledge the use of mistake-proofing and share knowledge gained through its use with other HCPs.<sup>29</sup> The fear is that such disclosure will result in enhanced expectations of quality and an attendant greater propensity for patients to bring malpractice lawsuits.<sup>30</sup> That fear, too, is largely off the mark<sup>31</sup> but still serves as an impediment to broader use of mistake-proofing measures.

This article addresses the key role that mistake-proofing processes would play in medical error reduction if such processes were widely adopted. It also proposes ways in which obstacles to broad adoption may be ameliorated or eliminated. Part II examines the nature, frequency, and severity of medical errors and provides background on the legal treatment extended to them. Part III focuses on the causes of medical errors. In Part IV, the article discusses mistake-proofing approaches and principles and outlines particular applications to healthcare.

Part V examines impediments to the use of mistake-proofing techniques in healthcare. Some of these impediments stem from a misunderstanding among healthcare providers

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26. See *infra* note 115; *infra* text accompanying notes 259–263.

27. GROUT, *supra* note 17, at 17.

28. See *infra* text accompanying notes 207–231.

29. See GROUT, *supra* note 17, at 18 (highlighting the presence of many examples of mistake-proofing solutions and approaches in the manufacturing arena but the lack of available examples of mistake-proofing in the healthcare field).

30. See *id.* at 17–18 (explaining that the contributors to the article of mistake-proofing examples wanted to remain anonymous, so as to not create liability).

31. See *infra* text accompanying notes 207–231, 237–238.

about whether taking mistake-proofing steps somehow damages their interests and positions in litigation over alleged medical errors. In Part VI, this article offers recommendations for increasing the use of mistake-proofing innovations in healthcare and for overcoming the impediments to their broad adoption.

## II. NATURE OF MEDICAL ERRORS AND LEGAL TREATMENT THEREOF

This section considers fundamental legal principles that must be grasped if the desirability of mistake-proofing medicine is to be fully understood. Any discussion of medical errors and the legal treatment they receive must begin with the recognition that the occurrence of an adverse medical event—an instance in which treatment administered to a patient yielded a bad outcome—does not necessarily mean that a medical error was committed.<sup>32</sup> What, then, is a medical error, and when does it furnish the basis for legal liability?

*Medical error* may be defined as an HCP's act of "commission or . . . omission . . . that would have been judged wrong by skilled and knowledgeable peers at the time it occurred."<sup>33</sup> Liability may be imposed on the HCP (or HCPs) when the error caused the patient to experience a harmful outcome.<sup>34</sup> The immediately preceding statements regarding actionable medical errors contemplate the controlling effect of negligence principles, which govern most instances of liability in the healthcare

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32. See e.g., KENNETH R. WING, LAW AND THE PUBLIC'S HEALTH 291–92 (6th ed. 2003) (pointing out that very few adverse events implicate the *res ipsa loquitar* doctrine). The flipside is also true—i.e., not all medical errors result in harm to the patient.

33. Albert W. Wu et al., *To Tell the Truth: Ethical and Practical Issues in Disclosing Medical Mistakes to Patients*, 12 J. GEN. INTERNAL MED. 770, 770 (1997). Given the process nature of healthcare, the key question for liability purposes will often be whether an HCP's actions or omissions deviated so much from those that are usual and customary as to constitute a "process variation." JOHN D. BANJA, MEDICAL ERRORS AND MEDICAL NARCISSISM 6 (2005).

34. E.g., J. STUART SHOWALTER, THE LAW OF HEALTHCARE ADMINISTRATION 40–41 (4th ed. 2004) (illustrating the deference given to decisions by medical professionals); WING, *supra* note 32, at 291–92 (stating that a patient must be able to show both actual and proximate causation for the harmful outcome to establish liability for negligence). Because legal principles focus on the intersection of an error and an adverse event in which patient harm occurs, it may be useful to characterize potential liability-triggering instances as *preventable* adverse events. Saul N. Weingart, *The Nature of Error in Health Care*, Presentation at Harvard Medical School Seminar: Progress in Patient Safety (Nov. 2008) (notes on file with authors).

arena and many instances of liability in other professional or business-oriented contexts.<sup>35</sup>

#### A. NEGLIGENCE AND THE REASONABLE-CARE FOCUS

Negligence cases revolve around the proposition that the defendant failed to fulfill a duty of reasonable care owed by the defendant to the plaintiff, with the plaintiff suffering harm as a result.<sup>36</sup> The reasonable-care concept calls for the actions or inactions of the defendant to be measured against those of the hypothetical reasonable person of ordinary prudence.<sup>37</sup> The plaintiff will seek to demonstrate that a reasonable person would not have done what the defendant did, or would have done what the defendant failed to do.<sup>38</sup> If the plaintiff proves such a breach of duty on the part of the defendant and demonstrates the existence of a sufficient causation link between the defendant's failure to use reasonable care and the harm experienced by the plaintiff, the defendant will be held liable for negligence.<sup>39</sup>

The basic negligence principles outlined in the preceding paragraph are applied in a very broad range of settings.<sup>40</sup> The myriad of potential applications of negligence principles include, for instance, the product liability context. Manufacturers may face liability if they adopted a product design that substantially increased the risk of harm to product users (including the injured plaintiff) and was a design that reasonable manufacturers would not adopt.<sup>41</sup> Similarly, negligence liability

35. See RESTATEMENT (SECOND) OF TORTS § 299A & cmts. a-c (1965) ("[O]ne who undertakes to render services in the practice of a profession or trade is required to exercise the skill and knowledge normally possessed by members of that profession or trade in good standing in similar communities.").

36. RESTATEMENT (SECOND) OF TORTS, *supra* note 35, §§ 281 cmt. c, illus. 1-3, cmt. e, 283 cmts. b-c, 284 cmt. a, 285 cmts. e-f, cmt. g & illus. 1-7, 289 cmt. j, illus. 5-6, cmt. k, illus. 7-8, cmt. m, illus. 9-14.

37. WING, *supra* note 32, at 290-91.

38. RESTATEMENT (SECOND) OF TORTS, *supra* note 35, §§ 282-83, 284, 299A (defining the standard for reasonable behavior, which may include either an act or a failure to act).

39. *Id.* §§ 281-83, 328A-B.

40. See, e.g., *id.* §§ 281 cmt. c, illus. 1-3, cmt. e, 283 cmts. b-c, 284 cmt. a, 285 cmts. e-f, cmt. g & illus. 1-7, 289 cmt. j, illus. 5-6, cmt. k, illus. 7-8, cmt. m, illus. 9-14, 299A cmts. a-e.

41. See *id.* §§ 298 cmt. b, 299 & cmt. e, 299A & cmts. a-e, 300 & cmt. c; see also RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §§ 1 cmt. a, 2(b)-

may follow if a manufacturer utilized a production process that a reasonable manufacturer would not employ, and the process led to an injury-causing product defect.<sup>42</sup>

The professional liability context is another one of the many settings to which negligence principles are applied. Although the term “malpractice” is often used when a harmed patient sues a physician or other HCP, or when an aggrieved client sues an attorney, negligence is the legal theory that nearly always controls the case.<sup>43</sup> In the healthcare context, the key questions are whether the HCP acted as a reasonable HCP<sup>44</sup> would have under the circumstances, and if not, whether that failure to exercise due care caused—or helped to cause—the harm suffered by the plaintiff.<sup>45</sup>

For example, assuming the existence of the causation link just noted, a physician could be at risk of liability if she adopted a course of treatment that a similarly situated reasonable physician would not adopt.<sup>46</sup> The same would be true if the physician failed to diagnose a patient’s serious illness until long after a reasonable physician would have made the diagnosis.<sup>47</sup> Consider, too, the example of the nurse who failed to follow a physician’s orders regarding a patient’s treatment (something the reasonable nurse would not do, absent extraordinary and compelling circumstances). If the patient suffered harm as a result, the nurse could face negligence liability.<sup>48</sup> So might a nurse who fails to pick up on obvious signs of patient distress when a

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(c) cmts. a, b (1998).

42. See RESTATEMENT (SECOND) OF TORTS, *supra* note 35, §§ 298 cmt. b, 299 & cmt. e, 299A & cmts. a–e, 300 & cmt. c; see also RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 cmt. a (1998).

43. *E.g.*, WING, *supra* note 32, at 290–91. Seldom do malpractice cases present claims of intentional or reckless wrongdoing, as opposed to negligence. John C.P. Goldberg, *The Constitutional Status of Tort Law: Due Process and the Right to a Law for the Redress of Wrongs*, 115 YALE L.J. 524, 621 (2005) (discussing implications of caps on damages in medical malpractice cases).

44. The previously noted definition of *medical error*, see *supra* text accompanying note 33, applies this “reasonable HCP” concept by comparing what the HCP under scrutiny did or did not do to what “skilled and knowledgeable peers” would or would not have done. Hill, Langvardt & Massey, *supra* note 2, at 165–66; Wu et al., *supra* note 33, at 770.

45. Hill, Langvardt & Massey, *supra* note 2, at 165–68.

46. *E.g.*, SHOWALTER, *supra* note 34, at 40–43 (reviewing the reasonable physician standard, the locality rule, the school rule, and reasonable prudence standard).

47. *E.g.*, Jones v. Speed, 577 A.2d 64, 67–70 (Md. 1990) (brain tumor).

48. See JAMES WALKER SMITH, HOSPITAL LIABILITY §§ 4.04[1], 10.05[1][a], 11.02[2]–[3], 11.04[1] (rev. ed. 2005).

reasonable nurse would have noted such signs and reacted accordingly.<sup>49</sup> Of course, these same principles apply to individual HCPs other than doctors and nurses if they cause harm to patients through actions or inactions that fall below the due-care standard appropriate to their position.<sup>50</sup>

It is important to recall, however, that the mere proof of a bad outcome for a patient is not by itself sufficient for the imposition of negligence liability on HCPs involved in the patient's care.<sup>51</sup> After all, the HCPs may have provided the nature and type of treatment that was reasonable under the circumstances. In such a situation, there is no breach of duty and thus no basis for negligence liability, despite the bad outcome.<sup>52</sup>

#### B. IMPUTED LIABILITY AND DIRECT LIABILITY

The previously noted examples of malpractice liability involved individual defendants such as doctors and nurses. Of course, hospitals and other organizational HCPs may also face liability. One of two grounds, and sometimes both grounds, may be used to establish liability. The first method is imputed liability under *respondeat superior*, a doctrine that calls for the hospital or other organizational defendant to be held liable for the negligence of its employees if that negligence occurred within the scope of employment.<sup>53</sup> The other method is direct liability, under which the organizational HCP is held liable for its own failure to use reasonable care.<sup>54</sup>

Consider, for instance, the previously noted examples of negligence on the part of a nurse in caring for a patient. As-

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49. *See id.* § 11.02[2]–[3].

50. WING, *supra* note 32, at 289–91 (explaining the different standard of conduct that is applied to medical professionals). As will be seen, an institutional HCP such as a hospital may face liability as well in some such instances. *See infra* text accompanying notes 53–60.

51. *See* WING, *supra* note 32, at 291–93 (emphasizing that the patient must be able to show a breach of the duty of care by the HCP and also must show both actual and proximate causation).

52. *Id.*; RESTATEMENT (SECOND) OF TORTS, *supra* note 35, §§ 281, 283, 328A. Of course, a lawsuit may still be filed in such an instance—particularly if the outcome is extremely bad—but there should be no liability if there was no failure to use reasonable care.

53. SMITH, *supra* note 48, § 3.01–02. The same rule applies with regard to employers generally. RESTATEMENT (THIRD) OF AGENCY § 2.04 (2006).

54. Hill, Langvardt & Massey, *supra* note 2, at 166 & n.40 (explaining the corporate negligence doctrine that provides for direct liability of hospitals).

suming that the nurse was an employee of a hospital or another organizational HCP, the nurse would not be the only liable party. The hospital or other organizational HCP serving as the nurse's employer would also be liable on an imputed basis under *respondeat superior*.<sup>55</sup> In such scenarios, the employer is not really at fault; the employee is. However, the public policy considerations underlying *respondeat superior* support a rule that the employer—normally the recipient of the benefit of an employee's service—may have to bear some of the burdens associated with the employee's mistakes.<sup>56</sup>

In other situations, the hospital or other organizational HCP may be at fault and therefore may face direct liability for its own negligence. Assume, for example, that a hospital's established procedure regarding administration of narcotics proves inadequate to prevent a dosage error and the resulting harm to a patient. The hospital is likely to be held directly liable for negligence if a reasonable hospital would have adopted a different procedure that substantially reduced the risk of harm to patients.<sup>57</sup> The "would have adopted a different [procedure]" statement is important, because it underscores the key role that the failure to take certain precautionary actions may play in furnishing the basis for negligence liability.<sup>58</sup>

The above discussion suggests two important and often related characteristics of many instances of negligence liability in

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55. SMITH, *supra* note 48, § 3.01–02. The *respondeat superior* rule is more likely to serve as a basis for the hospital to be held liable when the negligent person was a nurse than when he or she was a physician. *Id.* Nurses are typically employees, whereas physicians usually are independent contractors with hospital admission privileges. If the physician is an independent contractor, *respondeat superior* would not make the hospital liable. *Id.* Of course, a physician who is a hospital employee (e.g., a hospitalist), *respondeat superior* would come into play and would expose the hospital to liability in the event of the employee's negligence. *See id.*

56. *See* RESTATEMENT (SECOND) OF AGENCY §§ 219, 228–229 (1958) (limiting the employer's liability to actions performed by the employee within the scope of employment).

57. *See* SMITH, *supra* note 48, § 3.03[1]. The "corporate negligence" contemplated here may take a variety of forms, with the hospital being held liable for its own failure to use reasonable care (not, as in the *respondeat superior* setting, for its employees' negligence). SHOWALTER, *supra* note 34, at 129; SMITH, *supra* note 48, § 3.03[1]. Of course, depending upon the facts of the particular case, it is possible that a hospital could face both direct liability for its own negligence and *respondeat superior* liability because its employees were negligent as well. *See id.* §§ 3.01–02, 3.03[1].

58. SHOWALTER, *supra* note 34, at 129 (focusing on failures to provide adequate accommodations and facilities); SMITH, *supra* note 48, § 3.03[1].

healthcare settings: the group errors characteristic and the system errors characteristic. Medical errors that give rise to negligence liability often involve the actions of more than one party, as opposed to a single HCP who fails to exercise reasonable care.<sup>59</sup> To take an example of an egregious error, consider the surgeon who amputates the patient's right leg instead of the left. The surgeon presumably failed to use reasonable care. But other HCPs involved in the patient's care during the pre-operative stage may well have failed to take reasonable steps to help ensure that the correct leg was amputated. In that sense, the medical mistake was a group error. Depending on the facts, it may also be a system error. If, for instance, the hospital did not have a simple policy requiring clear pre-surgery marking of the body part, we can add to the mix a system error that makes the hospital directly liable in addition to individual HCPs who were negligent.<sup>60</sup>

Because negligence liability is premised on harm-causing mistakes that fall below the standard of due care, mistake-proofing efforts of the sort discussed in this article make a great deal of sense in the healthcare environment. They are designed to lessen the likelihood of harm-causing medical errors, and they relate directly to the individual-error, group-error, and system-error aspects of the negligence liability environment faced by HCPs. Moreover, they typically do not carry a hefty price tag and are relatively easy to implement.<sup>61</sup> But HCPs have not adopted such processes as broadly as might be expected. Later parts of the article will address reasons for this state of affairs and propose ways to expand the use of mistake-proofing processes. First, however, we devote further attention in the following part to the causes of medical errors.

### III. CAUSES OF MEDICAL ERRORS

#### A. THREE INTERTWINED CONSIDERATIONS

Given the high cost of healthcare in the United States, why do medical errors occur with such frequency? Three often inter-

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59. See *infra* text accompanying notes 194–203.

60. See SHOWALTER, *supra* note 34, at 129 (including institutional errors as a basis for negligence); SMITH, *supra* note 48, §§ 3.01–02, 3.03[1]; see also *supra* notes 55, 57 (discussing *respondeat superior* liability and direct liability for corporate negligence).

61. See *infra* text accompanying notes 172–193.

twined considerations are notable. First, most errors are multifactorial and often involve both cognitive/knowledge and system/process failures.<sup>62</sup> Second, most care is delivered through a series of frequently complex processes that are often plagued with a lack of consistency and a cultural dependence upon individuals.<sup>63</sup> These considerations lead to variability in the quality of delivery.<sup>64</sup> Third, medicine involves both art and science and requires subjective judgment, especially in the art component.<sup>65</sup> Given that subjectivity, the predominant culture influences both behaviors and outcomes.<sup>66</sup> Underlying the medical culture is a host of behavioral issues that contribute to medical errors through various psychological and epistemological influences.<sup>67</sup> When combined with the customary defensive responses by HCPs to systemic failure and the absence of a comprehensive, centralized system for measuring, tracking, and reporting errors, the three considerations identified above operate as barriers to reducing the incidence of medical errors. We now examine those considerations in more depth.

Most systems of complex, intrinsically hazardous processes are accompanied by defenses against failure. After “repeated experiences with failure . . . [,] system designers and operators . . . [usually] implement layers of defense[s] or redundancy so that an error will be intercepted and its trajectory halted” before harm results.<sup>68</sup> Nonetheless, no matter how well-designed processes are, some latent errors will still occur.<sup>69</sup> A key question that surfaces is whether the error was systemic or, instead, the result of one person failing in some essential respect (“single-point failure”).<sup>70</sup> In the healthcare context, such

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62. Gordon Schiff, Understanding Diagnostic Errors, Presentation at Harvard Medical School Seminar: Progress in Patient Safety (Nov. 2008) (on file with authors).

63. GROUT, *supra* note 17, at 19 (calling the reliance on individual perfection a perpetuation of a “myth of infallibility”).

64. *Id.* (lacking consistent processes inhibits the implementation of mistake-proofing).

65. See RICHMOND & FEIN, *supra* note 8, at 68 (stating that discretion is involved in medical decisions).

66. *Id.*

67. BANJA, *supra* note 33, at 15–16 (analogizing the topic of medical errors to a spider web).

68. *Id.* at 11.

69. *Id.* at 12.

70. See *id.* (distinguishing between system failures and individual errors will not only establish liability, but it will also provide more focused correction).



determinations become important for legal purposes because of the manner in which teams providing medical care are structured.

In most settings, teams make fewer mistakes than do individuals, especially when all members of a team are cognizant of each individual member's responsibilities.<sup>71</sup> It is important to note that medical teams are often formed temporarily from various sources for single episodes of care. Some who become part of the team for a given episode may be independent contractors rather than employees of the healthcare facility where care is provided. Physicians in a particular medical practice may furnish services as team members in a number of diverse contexts. The members of these teams, however, are rarely trained together.<sup>72</sup> They also may come from different disciplines and educational backgrounds.<sup>73</sup> Further, team training in the medical profession tends to be limited and insufficiently grounded in a scientific understanding of the human factors that influence effective teamwork.<sup>74</sup> It may also be haphazard.<sup>75</sup> For example, physicians frequently do not have a good grasp of how hospitals function.<sup>76</sup>

At a more macro level, many hospitals have not focused on error prevention. One hospital chief executive officer reportedly stated that patient safety was not "on his radar screen" and described his job as "feeding the beast" (i.e., generating revenues).<sup>77</sup> Noting this lack of focus on error prevention and reduction, a study that gave rise to a *New England Journal of Medicine* article revealed troubling statistics. An estimated 3.7% of patients admitted to hospitals experience an adverse event, 27.6% of these adverse events result from negligence, and in approximately 25% of the negligently caused adverse

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71. D.P. BAKER ET AL., MEDICAL TEAMWORK AND PATIENT SAFETY: THE EVIDENCE-BASED RELATION 29 (2005).

72. *Id.*

73. *Id.*

74. *Id.* at 43.

75. *See id.* at 47 (calling for either a national error reporting system or requiring participation in team training programs).

76. Leape, *supra* note 19. A floor comment by one physician during a medical seminar regarding the absence of teamwork is telling: "As someone working in the hospital, I don't know what is going on. So much of the time no one knows what is going on." Weingart, *supra* note 34 (floor comment during presentation).

77. Weingart, *supra* note 34.

events, the patient dies.<sup>78</sup> These results led to the conclusion that “there is a substantial amount of injury to patients from medical management, and many injuries are the result of sub-standard care.”<sup>79</sup> Further, the problem of patient safety outside the hospital setting is said to be as great as inside hospitals.<sup>80</sup>

#### B. MEDICAL ERROR AND BEHAVIORAL UNDERPINNINGS

No discussion of the nature of medical error would be complete without some recognition of its behavioral underpinnings.<sup>81</sup> In examining the psychology of medical error, insights can be gleaned from a triad of cognitive models of human performance. Performance can be skill-based, rule-based, or knowledge-based.<sup>82</sup> Skilled-based performance often involves unconscious, rapid, and effortless responses to demands.<sup>83</sup> Rule-based performance involves the application of some algorithm or finite sequence of instructions, such as “if X occurs, then do Y.” Knowledge-based performance involves the use of novel problem-solving skills.<sup>84</sup>

Skill-based errors generally fall within the category of what might be termed *slips*.<sup>85</sup> Slips can be subcategorized to errors involving capture (familiarity with a similar behavior overrides the appropriate behavior), description (similarity in physical appearance or proximity of a wrong object to the correct object causes the wrong choice of behavior), associative activation (actor becomes distracted from task at hand), or loss of activation (actor forgets purpose of the behavior).<sup>86</sup> Rule-based

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78. T.A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of Harvard Medical Practice Study*, 324 NEW ENG. J. MED. 370, 371, 373 (1991) (reporting results of a study analyzing randomly sampled hospital records from New York hospitals).

79. *Id.* at 370.

80. David W. Bates, Welcoming Remarks at Harvard Medical School Seminar: Progress in Patient Safety (Nov. 3–4, 2008) (on file with authors).

81. For a detailed discussion of the cognitive influences on preventable adverse events, see Jiajie Zhang et al., *A Cognitive Taxonomy of Medical Errors*, 37 J. BIOMEDICAL INFORMATICS 193, 193–202 (2004).

82. *The Psychology of Human Error*, HUM. FACTORS MD (June 8, 2010), <http://www.humanfactorsmd.com/psychology-of-human-error/>.

83. *See id.* (classifying skills as automatic).

84. *Id.*

85. *Id.* (occurring typically when an individual’s attention is diverted).

86. Weingart, *supra* note 34. An example of a capture error is “when a nurse misprograms a new infusion pump because the sequence of steps is similar, but not identical to the pump he is most familiar with.” *The Psychology of Human Error*, *supra* note 82. “[W]hen the wrong control on an EKG is adjust-

and knowledge-based errors are often termed *mistakes*.<sup>87</sup> Rule-based errors occur when the wrong rule is applied.<sup>88</sup> Knowledge-based mistakes may occur because of various common thinking tendencies. These include: memory biases (including such ones as choice-supportive bias, the recall of prior options chosen over options rejected); availability heuristics (predicting the frequency of an event based upon how easily an example can be brought to mind); confirmation bias (a tendency to search for or interpret new information in a way that confirms one's prior preferences or attitudes); and overconfidence (having greater faith in one's knowledge or ability than is warranted).<sup>89</sup> Each of these factors can lead to erroneous decisions and actions in the healthcare setting.

The problem of impaired providers sometimes also contributes to the causation of preventable adverse events. Impaired providers are those physicians or other medical personnel who are unable to fulfill their professional responsibilities properly because of physical or psychological illness or because of substance abuse.<sup>90</sup> Evidence indicates that between eight and fifteen percent of providers are impaired in one or more of the senses just noted (a figure similar to what is found in the general population).<sup>91</sup> Substance abuse problems and behavioral disorders<sup>92</sup> can interfere with healthcare quality in various ways. For example, an HCP's substance abuse can lead to a failure to record important information in a patient's chart and eventual harm to the patient, as well as severely compromising the affected HCP's ability to exercise sound medical judg-

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ed because it's close to other controls that look the same" is an example of a descriptive error. *Id.* When a "radiologist[] forget[s] what he is looking for after retrieving and displaying a comparison study" qualifies as a loss of activation error. *Id.*

87. *The Psychology of Human Error*, *supra* note 82.

88. *Id.*

89. Weingart, *supra* note 34.

90. Booker T. Bush, *The Physician Who Becomes Impaired*, Presentation at Harvard Medical School Seminar: Progress in Patient Safety (Nov. 2008) (on file with authors).

91. *Id.*

92. These may include, for instance, boundary violations such as selling drug samples or engaging in sexual relations with co-workers, disruptive behaviors such as throwing scalpels and yelling at other members of the medical team, and even outright dishonesty such as taking advantage of patients for financial gain. *Id.*

ment.<sup>93</sup> Disruptive behaviors can adversely affect morale and create workplace frictions.<sup>94</sup> The result may be an unhealthy culture that enhances the risk of error on the part of distracted or intimidated individuals or, as the following discussion indicates, undermines checks against error.<sup>95</sup>

### C. OTHER CAUSES OF MEDICAL ERRORS

Contemporary research suggests that catastrophic patient-care adverse events usually involve various people “committing multiple, often seemingly innocuous, mistakes that . . . breach an organization’s fail-safe mechanisms.”<sup>96</sup> In an environment such as the frequently chaotic team setting in healthcare, the likelihood of errors increases because the lack of a sound organizational culture results in compliance failures becoming normalized.<sup>97</sup> The causes of such normalization of corrupted prac-

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93. In other instances, there may have been no substance abuse on the part of a provider of medical services but the provider may be similarly impaired for a simple reason: fatigue. The problem of provider fatigue may help to answer a question posed by a physician commentator: “Why are so many mistakes made doing things that are routine in medicine?” Christopher P. Landrigan, *Fatigue and Error: Achieving Evidence-Based Schedule Improvements*, Presentation at Harvard Medical School Seminar: Progress in Patient Safety (Nov. 2008) (on file with authors). There is empirical evidence that physicians’ often exhaustive work schedules contribute to the incidence of medical errors. See Njib T. Ayas et al., *Extended Work Duration and the Risk of Self-Reported Percutaneous Injuries in Interns*, 296 JAMA 1055, 1059–60 (2006) (finding that extended work hours were associated with an increased risk of percutaneous injuries); Christopher P. Landrigan et al., *Effect of Reducing Interns’ Work Hours on Serious Medical Errors in Intensive Care Units*, 351 NEW ENG. J. MED. 1838, 1838–39, 1842–44 (2004) (finding that interns made thirty-five percent more medical errors of a serious nature, and five times more diagnostic errors, on a traditional work schedule than on a schedule reflecting reduced work hours). Despite promulgation of standards for work hours by the Accreditation Council for Graduate Medical Education (ACGME), there is far from universal compliance with the standards. Christopher P. Landrigan et al., *Interns’ Compliance with Accreditation Council for Graduate Medical Education Work-Hour Limits*, 296 JAMA 1063, 1063–64, 1065–66 (2006) (“83.6% of participating interns reported working hours that were noncompliant with the ACGME duty-hour standards . . .”). Given the busy schedules of many physicians, it seems likely that fatigue may also be a problem well after they complete their training.

94. Bush, *supra* note 90.

95. *Id.*

96. John Banja, *The Normalization of Deviance in Health Care Delivery*, 53 BUS. HORIZONS 139, 139 (2010).

97. See *id.* at 139–41 (noticing that the normalized behavior may not directly cause harm, but potentially creates a weakness in the system when a future error does occur).

tices are found in the phenomena of socialization, institutionalization, and rationalization.<sup>98</sup> Socialization, usually mediated by an informal system of rewards and punishments, operates to determine when an organizational newcomer is fully accepted into a particular group.<sup>99</sup> Institutionalization exposes newcomers to deviant behaviors, often performed by authority figures.<sup>100</sup> Rationalization enables participants in care delivery systems to convince themselves and others that departures from compliant practices are not only legitimate but often even necessary to ensure proper care.<sup>101</sup>

Earlier discussion noted that negligence liability may be imposed when a medical error results from a failure to use reasonable care.<sup>102</sup> Despite this prospect of liability, the tort system has not effectively coerced HCPs into creating, implementing, and enforcing the effective use of mistake-proofing principles and techniques. One reason may be a characteristic of some physicians' psyche: a narcissism that blocks full ac-

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98. *Id.* at 141.

99. *Id.*

100. *Id.*

101. *Id.* Common noncompliant practices in patient care settings include: "not washing or sanitizing hands sufficiently; not gowning up or skipping some other infection-control procedures; not changing gloves when appropriate; failing to check armbands; not performing safety checks; using abbreviations; not getting required approval before acting; and violating policies on storing or dispensing medications." *Id.* at 140. In an example of normalization of a departure from standard practice in a surgical setting, a medical student observing a surgery reported that:

[T]he surgeon inadvertently touched the tip of the instrument he was using to his plastic face mask. Instead of his requesting or being offered a sterile replacement, he just froze for a few seconds while everyone else in the operating room stared at him. The surgeon then continued operating. Five minutes later he did it again and still no one did anything.

*Id.* When the medical student later asked a nurse about what had happened, the nurse called it "no big deal" and added that "[w]e'll just load the patient with antibiotics and he'll do fine." *Id.* The patient was given antibiotics and did recover well. *Id.* However, tragic results—a patient's death—occurred in an instance involving a combination of an individual's mistake and a noncompliant act by others. After turning off a surgical patient's ventilator because the surgeon wanted to take an x-ray, an anesthesiologist forgot to turn the ventilator back on for significantly longer than the few seconds the ventilator was to be off. *Id.* at 140–41. It was later discovered that an alarm meant to alert the anesthesiologist regarding the ventilator problem had been disabled, "possibly because the operating room staff found the constant beeping [of the alarm] irritating and annoying." *Id.* at 141.

102. See *supra* text accompanying notes 36–52.

ceptance of the notion that compliance rules apply to physicians. Long recognized as the most dominant players in care delivery,<sup>103</sup> physicians are also very much in a position to dominate the culture of care delivery. This power, if coupled with a narcissistic tendency, may lead to feelings of arrogance and being “special.”<sup>104</sup>

In addition, physicians are trained in a culture in which disclosure of errors—even to peers—is regarded as an indication of weakness.<sup>105</sup> This makes admission of errors difficult. Physicians are naturally inclined to import their feelings and proclivities into practice settings.<sup>106</sup> When this tendency is combined with physicians’ dominant positions in care delivery, there emerges fertile ground for a culture that resists error admission and causal identification. One physician has stated that narcissism led him to believe he had total control, to attribute his mistakes to others, to refuse to resolve tensions with others, to reject new ideas, and to cling rigidly to his original attitudes.<sup>107</sup> He saw the same tendencies, beliefs, and behaviors in other physicians.<sup>108</sup> Given the gravity and high stakes often associated with the healthcare setting, rationalizing and not acknowledging their mistakes may offer physicians a relief from the angst that error disclosure could create.<sup>109</sup> It therefore stands to reason that the threat of legal liability is somewhat limited in its ability to curb mistakes and cause behavioral changes in people who externalize blame rather than admit mistakes.

The prospect of avoiding negligence liability has not had the seemingly logical effect of spurring HCPs to adopt mistake-proofing processes on a wider scale. However, concern about po-

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103. See Andrew K. Dolan, *Antitrust Law and Physician Dominance of Other Health Practitioners*, 4 J. HEALTH POL’Y 675, 679 (1980) (discussing the dominant position physicians are in when controlling the approval of applications for hospital privileges); see also Atul Gawande, *The Cost Conundrum*, NEW YORKER, June 1, 2009, at 44 (noting the incentive doctors have to prioritize financial gains over patient-centered care).

104. BANJA, *supra* note 33, at 50 (listing the DSM-IV traits for the narcissistic personality disorder).

105. *Id.* at 29.

106. *Cf. id.* at 15 (acknowledging that doctors’ thoughts and feelings impact their communication with patients).

107. *Id.* at 54.

108. See *id.* (suggesting that similar behavior is encouraged in other doctors).

109. *Id.* at 47 (attempting to avoid liability).

tential liability prompts many physicians to engage in what they call “defensive medicine”—ordering tests and procedures they would not otherwise order because of the fear of being sued if they do not order those tests and procedures.<sup>110</sup> Defensive medicine has been estimated to cause, on a national basis, seventy billion dollars per year in unnecessary treatment costs.<sup>111</sup> As will be seen in later analysis, the actual need to engage in such defensive medicine likely is not as great as many physicians perceive it to be. This erroneous perception may result from a misunderstanding concerning what negligence law really provides and from physicians’ overestimation of their chances of being sued, let alone being held liable.<sup>112</sup> Rather than being preoccupied with the supposed need to engage in defensive medicine, HCPs would do far more to protect themselves against liability by making greater use of mistake-proofing processes and techniques.<sup>113</sup>

The failure of medicine to make substantial progress in reducing medical errors across most of its disciplines<sup>114</sup> can also

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110. David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609, 2609 (2005) (differentiating between “positive” and “negative” defensive medicine). Various commentators have noted the defensive medicine concerns held by critics of the current legal regime. *E.g.*, William P. Gunnar, *Is There an Acceptable Answer to Rising Medical Malpractice Premiums?*, 13 ANNALS HEALTH L. 465, 476–77 (2004) (“Physicians have come to believe that every patient is a potential lawsuit.”). Other commentators regard the defensive medicine concerns as overblown. *E.g.*, Kenneth C. Chessick & Matthew D. Robinson, *Medical Negligence Litigation Is Not the Problem*, 26 N. ILL. L. REV. 563, 570, 574 (2006) (emphasizing that “insurance companies are paying out less in claims each year, despite charging more in premiums” and that defensive medicine is not a shield from liability); David A. Hyman & Charles Silver, *The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?*, 90 CORNELL L. REV. 893, 937–38 (2005) (“The difficulty in proving the causal link between malpractice exposure and higher levels of defensive medicine arises from the multitude of motives providers may have for performing ‘unnecessary’ tests and procedures . . .”). For further analysis of the supposed defensive medicine problem, see *infra* text accompanying notes 232–241.

111. MASS. MED. SOC’Y, INVESTIGATION OF DEFENSIVE MEDICINE IN MASSACHUSETTS 1 (2008).

112. See *infra* text accompanying note 237.

113. See *infra* text accompanying note 239.

114. However, anesthesiology serves as an example of mistake-proofing being applied in a medical discipline with great success. See Hyman & Silver, *supra* note 110, at 917–23. Anesthesia safety improved significantly after a professional body promulgated patient monitoring guidelines and anesthesiologists implemented them. See *id.* at 920. As a further result, anesthesiologists’

be attributed, in part, to the absence of a national entity sufficiently empowered to engage in comprehensive tracking of HCPs' adoption, or lack of adoption, of safety measures.<sup>115</sup> More than half of the states require reporting of medical errors,<sup>116</sup> but meaningful reduction in the number of errors remains an

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insurance premiums remained relatively flat (unlike those of other specialties). *See id.* at 918. This suggests that mistake-proofing can be helpful in reducing HCPs' oft-voiced complaints about the costs of malpractice insurance. *See Hill, Langvardt & Massey, supra* note 2, at 159. There remains a question, however, about why other medical specialties have not embraced mistake-proofing principles and techniques to achieve similar results. Hyman & Silver note that "[m]any providers have failed to adopt patient safety measures of proven effectiveness, and they have similarly failed to use information already in their possession to protect patients from harm." Hyman & Silver, *supra* note 110, at 991.

115. This is not to say that the federal government has ignored patient safety issues. Federal law calls for the Secretary of Health and Human Services (HHS) to develop a "national strategy to improve the delivery of health care services, patient health outcomes, and population health." 42 U.S.C. § 280j (2006). Ways of improving healthcare quality are among the matters to be addressed in that strategy. *Id.* An agency housed within HHS, the Agency for Healthcare Research and Quality (AHRQ), engages in educational efforts consistent with its name and seeks to promote quality enhancements through reports and recommendations. *See Advancing Excellence in Healthcare*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.ahrq.gov/> (last visited Sept. 29, 2012); *see also, e.g.*, AGENCY FOR HEALTHCARE RES. & QUALITY, NATIONAL HEALTHCARE QUALITY REPORT (2012), available at <http://www.ahrq.gov/qual/nhqr11/nhqr11.pdf> (annual report issued by AHRQ); GROUT, *supra* note 17, at 1 (AHRQ-sponsored report); *AHRQ Innovations Exchange*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.innovations.ahrq.gov/> (last visited Sept. 29, 2012) (AHRQ-provided tips). The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §§ 299b-21 to 26 (2006), calls for an AHRQ-administered process by which public or private organizations may choose to form patient safety organizations (PSOs). *Id.* §§ 299b-21, 24. HCPs participating in PSOs may choose to provide the PSOs confidential reports on medical errors and events that bear adversely on patient safety, with such reports being barred from discovery and evidentiary use in cases in which plaintiffs attempt to have the HCPs held liable for the alleged errors. *Id.* § 299b-22. The PSOs then report such information for inclusion, on an anonymous basis, in databases designed to lead to the enhancement of health quality and patient safety. *Id.* §§ 299b-23 to 24. *See generally* Patient Safety Organizations and Patient Safety Work Product, 42 C.F.R. § 3 (2009) (listing regulations promulgated pursuant to Patient Safety and Quality Improvement Act of 2005 in order to implement statute). These efforts are both useful and commendable, but the voluntary nature of both PSO creation and error-reporting by HCPs means that the information acquired by the AHRQ and available for inclusion in the databases is less complete, and therefore less useful, than it might be.

116. *See National Survey, supra* note 5, at 207, 213. For discussion of such statutes, their similarities, and their differences, *see id.* at 213–22. Details of the state error-reporting systems are beyond the scope of this article.



elusive goal.<sup>117</sup> The usefulness of the information obtained through the state error-reporting systems that do exist is impaired by chronic under-reporting of errors.<sup>118</sup> Moreover, there is no comprehensive national system of mandatory error-reporting,<sup>119</sup> despite recommendations by the IOM and commentators that such a system be adopted.<sup>120</sup> It therefore becomes difficult to track progress in error reduction even if such progress is being made.<sup>121</sup>

As the foregoing discussion has revealed, medical errors stem from various causes, including complex processes, chaotic team environments, behavioral factors, and imperfect defensive measures. Moreover, those measures fail because of several factors, including flawed institutional cultures that undermine safeguards, physician narcissism that may create a resistance to quality improvements, and the absence of a well-coordinated, centralized system of error reporting and safety improvement tracking. What, then, can be done to improve healthcare quality? The following section turns to the potentially efficacious remedy of applying mistake-proofing theory and techniques to reduce the incidence of preventable adverse events.

#### IV. MISTAKE-PROOFING: ATTRIBUTES AND APPLICATIONS TO HEALTHCARE

Citing examples of “normalized-deviance” situations in

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117. *See id.* at 202, 206–07.

118. *Id.* at 213–14. Likely reasons for the under-reporting include lenient failure-to-report penalties in some states, budgetary constraints that limit the resources devoted by the state to checking on whether errors were reported, and fears on the part of HCPs that their reporting of an error could be used against them in malpractice litigation, despite the liability protections typically present in the states’ laws. *Id.* at 215–19.

119. As noted earlier, federal law generally contemplates a voluntary reporting regime. *See supra* note 115. In the Medicare and Medicaid contexts, however, hospitals must report on numerous measures of quality, including certain types of medical errors, in order to receive a full updated payment from the government in the following fiscal year. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., FISCAL YEAR 2009 QUALITY MEASURE REPORTING FOR 2010 PAYMENT UPDATE 1 (2010), available at <http://www.cms.hhs.gov/HospitalQualityInits/Downloads/HospitalRHQDAPU200808.pdf> [hereinafter QUALITY MEASURE REPORTING].

120. *See* IOM, TO ERR IS HUMAN, *supra* note 4, at 86–87; *see also, e.g.*, Lucian L. Leape & Donald M. Berwick, *Five Years After To Err Is Human: What Have We Learned?*, 293 JAMA 2384, 2384 (2005).

121. CONSUMERS UNION, *supra* note 23, at 6–8.

which seemingly innocuous process failures and mistakes become commonplace, some commentators advise erecting as many barriers as possible to errors.<sup>122</sup> The reason is not that holes in the defensive barriers to error are unavoidable; rather the holes are an artifact of institutional rigidity and the organization's failure to learn from experience because of the factors enumerated in the previous section.<sup>123</sup> Such organizations have been called "slow learners, slow improvers, slow innovators, and ultimately sluggish competitors."<sup>124</sup> Given the complexities associated with such causes of error as chaotic team environments and physician narcissism, defenses based on changing human nature are often less effective than mistake-proofing. Speaking in regard to an industry other than healthcare but offering a useful suggestion for the medical context, one commentator asserts:

The old way of dealing with human error was to scold people, retrain them, and tell them to be more careful . . . My view is that you can't do much to change human nature, and people are going to make mistakes. If you can't tolerate [error,] you should remove the opportunities for error.<sup>125</sup>

In healthcare, this means changing the design of care delivery. The IOM has stated that "[h]ealth care has safety and quality problems because it relies on outmoded systems of work. Poor designs set the workforce up to fail, regardless of how hard they try. If we want safer, higher-quality care, we will need to have redesigned systems of care."<sup>126</sup> Both the United States and

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122. See, e.g., STEVEN J. SPEAR, CHASING THE RABBIT 49 (2009).

123. See *id.*

124. *Id.*

125. George Labar, *Can Ergonomics Cure 'Human Error'?*, OCCUPATIONAL HAZARDS, Apr. 1996, at 48. It is common to blame employees individually for error and assume that experienced employees need additional training because they have forgotten what should be done. *Human Factors Process for Reducing Maintenance Errors*, AERO MAG., [http://www.boeing.com/commercial/aeromagazine/aero\\_03/textonly/m01txt.html](http://www.boeing.com/commercial/aeromagazine/aero_03/textonly/m01txt.html) (last visited Nov. 20, 2012). Boeing has termed this phenomenon the "blame and training" cycle, in which workers learn nothing new and errors are therefore likely to recur. *Id.* Other commentators have termed this the "blame, shame, and train" cycle which helps cause well-intentioned professionals who are placed in poorly designed systems to commit the same errors redundantly. See, e.g., Hans Kim, *Root Cause and Failure Mode/Effects Analysis*, Presentation at Harvard Medical School Seminar: Progress in Patient Safety (Nov. 2008) (on file with authors); Leape Harvard Seminar Nov. 2008, *supra* note 19.

126. INST. OF MED., CROSSING THE QUALITY CHASM 4 (2001). Recommending changing the design of health care systems to improve patient safety, a commentator notes:

Being careful helps, but it brings us nowhere near perfection . . . . The

United Kingdom governments have called for improving the safety of healthcare through changing the physical design of hospitals and other similar healthcare facilities.<sup>127</sup>

Redesigning care systems promises to be no small task, however, especially considering that design changes in physical environments are relatively infrequent. Consequently, a framework is necessary to guide systems redesign. The solution needs to employ diverse tools that help ensure healthcare workers know what to do differently and that provide a vocabulary of error-avoidance responses.<sup>128</sup> Mistake-proofing furnishes a systems design framework that meets these criteria. Often referred to as “error-proofing,”<sup>129</sup> “poka-yoke,”<sup>130</sup> and “fail-safing,”<sup>131</sup> mistake-proofing consists of concepts that help formulate design changes to reduce human error and that involve the use of process and design features. There is evidence that healthcare organizations are beginning to discover the benefits of lean-manufacturing techniques, such as those used by Toyota as part of its mistake-proofing efforts.<sup>132</sup>

#### A. A TYPOLOGY OF APPROACHES

As a starting point for understanding the potential for mis-

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remedy is in changing systems of work. The remedy is in design . . . . The goal should be extreme safety. I believe we should be as safe in our hospitals as we are in our homes. But we cannot reach that goal through exhortation, censure, outrage, and shame. We can reach it only by commitment to change, so that normal, human errors can be made irrelevant to outcome, continually found, and skillfully mitigated.

Donald Berwick, *Not Again! Preventing Errors Lies in Redesign—Not Exhortation*, 322 *BRIT. MED. J.* 247, 247–48 (2001).

127. J. B. Battles, *Quality and Safety by Design*, 15 *QUALITY & SAFETY IN HEALTH CARE* (Supp. 1) i1, i1-3 (2006); *see also* DESIGN COUNCIL, DEP’T OF HEALTH, DESIGN FOR PATIENT SAFETY (2003), [http://www.designcouncil.org.uk/Documents/Documents/Publications/Health/Design%20for%20Patient%20Safety\\_Design\\_Council.pdf](http://www.designcouncil.org.uk/Documents/Documents/Publications/Health/Design%20for%20Patient%20Safety_Design_Council.pdf).

128. *See* Grout & Toussaint, *supra* note 16, at 150.

129. MARK GRABAN, LEAN HOSPITALS: IMPROVING QUALITY, PATIENT SAFETY, AND EMPLOYEE SATISFACTION 139 (2009).

130. SHIGEO SHINGO, ZERO QUALITY CONTROL: SOURCE INSPECTION AND THE POKA-YOKE SYSTEM 45 (1986); Grout & Toussaint, *supra* note 16, at 151.

131. Richard B. Chase & Douglas M. Stewart, *Make Your Service Fail-Safe*, 35 *SLOAN MGMT. REV.* 35, 35–43 (1994).

132. *See* Grout & Toussaint, *supra* note 16, at 150; *see also* Mark Graban, *Open Source “Lean Healthcare” Google Map*, LEAN BLOG (Aug. 12, 2009), <http://www.leanblog.org/2009/08/open-source-lean-healthcare-google-map/>.

take-proofing to improve healthcare quality, we now briefly examine the various approaches that represent a general framework for its application. Professor Tsuda has developed a typology of approaches that, although not exhaustive, provides a vocabulary for discussing mistake-proofing design. The approaches are: “(1) mistake prevention in the work environment; (2) mistake detection; (3) mistake prevention” focused on detecting mistake sources; and (4) curtailment of the influence of mistakes.<sup>133</sup>

Mistake prevention in the work environment involves making design changes that stop activities if an error is in process.<sup>134</sup> Such prevention reduces complexity, ambiguity, vagueness, and uncertainty.<sup>135</sup> Two basic design principles guide mistake prevention in the work environment. The first is moderation of “wide and deep” task structures, with “wide” meaning multiple alternatives for a given decision and “deep” meaning a protracted series of choices.<sup>136</sup> Humans normally perform either moderately wide and deep tasks reasonably well, but the likelihood of mistakes increases if tasks are both wide and deep.<sup>137</sup> Similarly, visual systems, also known as 5S (organization, orderliness, cleanliness, standardization, and discipline), involve visually sharing information in work environments in order to allow participants to know something important at a glance.<sup>138</sup>

“Mistake detection identifies process errors found by inspecting the process after actions have been taken.”<sup>139</sup> Alt-

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133. Yoshikazu Tsuda, *Implications of Fool Proofing in the Manufacturing Process*, in 16 *QUALITY THROUGH ENGINEERING DESIGN* 79, 80 (Way Kuo & Marcia Martens Pierson eds., 1993).

134. SHINGO, *supra* note 130, at 99.

135. GROUT, *supra* note 17, at 5.

136. *Id.*

137. *Id.* at 6.

138. See GWENDOLYN D. GALSWORTH, *VISUAL SYSTEMS: HARNESSING THE POWER OF A VISUAL WORKPLACE* 4 (1997). The visual systems principle includes removing unneeded items from the workplace, arranging needed items so that they are easy to find, reducing visual “noise,” institutionalizing improvements once made, and avoiding a return to past practices. *Id.* Consider some examples of visual systems. Glidden EZ Tracks ceiling paint is pink when wet but dries white. *Glidden EZ Track Ceiling Paint*, GLIDDEN, <http://www.glidden.com/pro/products/ez-track-ceiling-paint-pro.do> (last visited Oct. 19, 2012). Since painting a ceiling almost always involves painting over old white paint, the pink color makes obtaining uniform coverage easier and prevents mistakes. *Id.*

139. GROUT, *supra* note 17, at 7.

though obviously not as effective as mistake prevention, knowledge that a mistake has been made will often permit remedial actions to be taken soon enough to avoid some of the most undesirable results of the mistake.<sup>140</sup> Data acquired from inspections can also be used to reduce the occurrence of incorrect actions using a technique known as statistical process control, which indicates when processes are out of control.<sup>141</sup> Other mistake-detection techniques include successive checks, inspections of previous steps when a mistake is found at a subsequent step, and self-checks that allow process participants to assess the quality of their own work.<sup>142</sup>

Mistake prevention of the source-detection variety identifies problems found through process inspections before harm-causing errors can occur.<sup>143</sup> Once a human has initiated a process, the process may perform an inspection itself.<sup>144</sup> Design changes that reduce or eliminate the consequences of the errors are introduced.<sup>145</sup> Airbags and guardrails are examples of preventing the influence of mistakes.<sup>146</sup> These design features do not stop automobile accidents from happening but are usually preferable to the alternative that may result in their absence.<sup>147</sup>

A useful example of a mistake-prevention safety feature is a device that reduces injuries from table saws. The Consumer Product Safety Commission estimated that in 2001, there were 55,300 medically treated blade-contact injuries associated with

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140. *Id.*

141. *Id.*

142. *Id.* Consider the example of Applied Bolting Technology's direct-tension-indicating washers. See *Direct Tension Indicator*, APPLIED BOLTING TECH., <http://www.appliedbolting.com/direct-tension-indicator-bolting-method.html> (last visited Oct. 18, 2012). These washers are used to detect when bolts have been torqued to the correct tension. *Id.* Each washer has small indentations that are filled with orange polymer. *Id.* As the bolt is tightened, the indentations are flattened, squeezing the polymer to the edge of the washer. *Id.* Properly tightened washers have a distinctive pattern of orange polymer around them. *Id.* Visual inspection of the tightness can easily be accomplished. *Id.* More importantly, since the tightness criterion is apparent, workers continue to tighten the bolt until proper tightness is achieved. *Id.* This makes defects and rework very unlikely.

143. GROUT, *supra* note 17, at 9.

144. *Id.*

145. *Id.*

146. See *id.* at 13.

147. See *id.*

table saw use.<sup>148</sup> Fifteen percent of these instances resulted in amputations and related costs of approximately \$2.13 billion.<sup>149</sup> An important mistake-proofing device is featured on SawStop™ table saws, which employ an electrically charged blade monitored by a signal processing unit in order to detect human flesh coming in contact with the table saw blade.<sup>150</sup> The voltage drops when flesh contacts the blade, causing an aluminum brake to be deployed.<sup>151</sup> This stops the blade within five milliseconds.<sup>152</sup> The safety device mounted on a table saw that is of high quality in other respects has allowed the SawStop™ saw to become the market's best-selling cabinet saw despite a several hundred dollar price premium.<sup>153</sup>

SawStop™ also illustrates the use of purposeful design to prevent the influence of mistakes because it dramatically reduces the severity of any resulting injury. Preventing the influence of mistakes involves either facilitation of mistake correction or decoupling of processes.<sup>154</sup> Facilitating correction is accomplished through planned responses when mistakes occur in a manner analogous to auto-correct functions used in computers.<sup>155</sup> Decoupling involves separating error-prone activities at points where errors become irreversible.<sup>156</sup> An example is the deletion of email messages that can be later retrieved if needed.<sup>157</sup>

Both mistake prevention and mistake detection require what are known as *setting* and *control* functions.<sup>158</sup> Setting functions differentiate between safe and unsafe conditions; therefore, they are the mechanisms for determining that an er-

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148. Memorandum from Page C. Faulk, Gen. Counsel, Jeffrey R. Williams, Assistant Gen. Counsel for Enforcement and Info., and Hyun S. Kim, Attorney Office of the Gen. Counsel, to Consumer Prod. Safety Comm'n (June 28, 2006), available at <http://www.cpsc.gov/library/foia/foia06/brief/tablesaw.pdf>.

149. *Id.*

150. *SawStop Table Saws are the Most Advanced Saws in the World, Setting the Standard for Table Saw Safety*, SAWSTOP, [http://www.sawstop.com/howitworks/sawstop\\_whitepaper.pdf](http://www.sawstop.com/howitworks/sawstop_whitepaper.pdf) (last visited Oct. 1, 2012).

151. *Id.*

152. *Id.*

153. *SawStop*, SAWSTOP, <http://www.sawstop.com> (last visited Oct. 18, 2012).

154. GROUT, *supra* note 17, at 9.

155. *Id.* at 10.

156. *Id.* at 13.

157. *Id.*

158. *Id.* at 7, 9.

ror has occurred or is about to occur.<sup>159</sup> The more precise the setting functions, the more extensive mistake-proofing can be.<sup>160</sup> Once a setting function determines that an error has occurred or is imminent, a control function signals the error.<sup>161</sup>

In 1999, Donald Berwick, then the president of the Institute for Healthcare Improvement, delivered an address in which he discussed a need for new tools to improve healthcare quality. Making a statement that remains true today, he noted that “[o]ur current tools can’t do the job. We can’t get where we need to go by stressing the current system.”<sup>162</sup> Berwick then offered an instructive example from a setting other than healthcare. Restrooms in his workplace had signs that slide in order to indicate whether the restroom was occupied or, instead, vacant.<sup>163</sup> These signs were to be moved by the user upon entering and leaving the facility. Berwick found the sign in the correct position 61% of the time, with the most prevalent error being the sign indicating “occupied” when the restroom was actually vacant.<sup>164</sup> The result was that ignoring the sign could lead to better outcomes than acting based on what the sign actually indicated.<sup>165</sup> In an effort to solve this problem, he placed on the door a handwritten sign that stated “Please flip the sign.”<sup>166</sup> After that sign was ignored, he placed on the door an additional sign stating “Please read the sign (below) about flip-

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159. *Id.* at 7.

160. *Id.*

161. *Id.* at 9. Setting functions are of four types: (1) physical—checks to ensure that physical attributes of a process are correct; (2) sequencing—checks the precedence relationship of the process to ensure steps are in the correct order; (3) grouping or counting—checks to ensure that matched sets of resources are available or that the correct number of repetitions has occurred; and (4) information enhancement—assures that information required in the process is available at the correct time and place and is salient to the user in noisy environments. *Id.* Control and regulatory functions are also of four types: (1) forced—physical size and shape or electronic controls detect and interdict the mistakes before it can occur, (2) shutdown—the entire process is automatically stopped; (3) warning—a mistake is signaled but the process is allowed to continue unless stopped by an operator; and (4) sensory alert—some sensory cue signals ex post that a mistake has occurred or been acted upon. *Id.* at 10.

162. DONALD M. BERWICK, *ESCAPE FIRE: DESIGNS FOR THE FUTURE OF HEALTH CARE* 34–35 (2002).

163. *Id.* at 35.

164. *Id.*

165. *Id.*

166. *Id.* at 36.

ping the sign.”<sup>167</sup> That effort, too, failed. Signs that relied upon humans to remember to change their signal simply did not work.<sup>168</sup> The replacement tool Berwick contrasted was an automatic vacant/occupied sign of the sort used in aircraft lavatories to provide an extremely accurate indication of restroom status.<sup>169</sup> This tool was an example of a forcing function, borrowed from mistake-proofing, to create a situation in which the actions are constrained so that failure at one stage prevents the next step from happening.<sup>170</sup>

Another commentator expresses this problem more globally: “It is not sufficient to address excessive medical errors by just adding more staff and more costs. Rather, it is important to get at the root causes of errors and to design systems that make the errors impossible to occur.”<sup>171</sup> In the following subsection, we consider ways in which particular mistake-proofing techniques can address causes of errors and thereby enhance healthcare quality.

#### B. APPLICATIONS OF MISTAKE-PROOFING IN HEALTHCARE SETTINGS

Mistake-proofing is typically inexpensive<sup>172</sup> in comparison with the extraordinary human and financial cost associated with medical errors.<sup>173</sup> It can therefore result in substantial returns on investment when applied to healthcare.<sup>174</sup> Opportunities for mistake-proofing abound in healthcare, and, despite some progress, many of these opportunities go unrealized. Enhanced understanding of why errors persist should lead to the identification of mistake-proofing techniques capable of preventing or correcting the errors.<sup>175</sup> Nonetheless, one can obtain

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167. *Id.*

168. *Cf. id.* at 37.

169. *Id.* at 37.

170. *Id.* at 37; *see also* GROUT, *supra* note 17, at 8–9.

171. ROBERT CHALICE, STOP RISING HEALTHCARE COSTS USING THE TOYOTA LEAN PRODUCTION METHODS 25 (2d ed. 2005).

172. GROUT, *supra* note 17, at 14.

173. *See* AGENCY FOR HEALTHCARE RES. & QUALITY, MEDICAL ERRORS: THE SCOPE OF THE PROBLEM 1 (2003) (explaining that medical errors cost the country \$37.6 billion per year).

174. *See* GROUT, *supra* note 17, at 15–16.

175. *See* Kelly M. Pyrek, *Can Medicine Be Made Mistake-Proof?*, INFECTION CONTROL TODAY (Apr. 1, 2008), <http://www.infectioncontroltoday.com/articles/can-medicine-be-made.html>. Later discussion will provide examples. *See infra* text accompanying notes



a sense of mistake-proofing's potential by examining some success stories using Tsuda's typology in simplified healthcare settings before turning to more complex systems.<sup>176</sup>

Typically, several bags of intravenous fluids are hung from IV poles in intensive care units. Tubes run out of the IV bags and into infusion pumps that carefully measure the amount delivered to the patient's bloodstream. Hooks holding the bags are arrayed in four directions, in the manner of a compass. Many infusion pumps are thus designed to handle up to four fluids concurrently. Embo-Optics provides an improved IV pole that allows the bags to be hung side-by-side and physically lined up above the section of the infusion pump that is controlling the relevant fluid.<sup>177</sup> The pole is equipped with colored lights to illuminate each bag in semi-dark rooms.<sup>178</sup> Color coding at the other end of the IV tubes matches the colored lighting of the IV fluids. Besides making the monitoring of the IVs easier, these changes prevent mistakes and thus furnish an example of mistake prevention in the work environment.<sup>179</sup>

Hand hygiene is a critical factor in reducing the large numbers of nosocomial infections.<sup>180</sup> One hundred percent compliance with hand hygiene is very difficult to achieve.<sup>181</sup> In an

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179–202. For discussion of a more extensive set of examples, see GROUT, *supra* note 17, at 117–46.

176. See Tsuda, *supra* note 133, at 80.

177. See *Vitaid Anesthetic Products*, IPV MED., <http://www.ipvmedical.com/vitaid.html> (last visited Oct. 7, 2012).

178. *Id.*

179. See *IV Illuminators*, MERCURY MED., [http://mercurymed.com/catalogs/RDR\\_IVIlluminators.pdf](http://mercurymed.com/catalogs/RDR_IVIlluminators.pdf) (last visited Nov. 28, 2012); *Vitaid Anesthetic Products*, *supra* note 177. In another example of mistake prevention in the work environment (an example analogous to achieving more uniform coverage of ceiling with pink paint that dries white), adding dye that changes the antiseptic Chlorhexidine from clear to blue-green made it far more popular with doctors who could see where they had missed. *Surgical Products*, SURGICAL PRODS. MAG. (June 1, 2008), <http://www.surgicalproductsmag.com/scripts/default.asp> (follow “Digital Edition” hyperlink; then follow “2008” under “Back Issues” hyperlink; then follow “June 2008” hyperlink) (last visited Oct. 6, 2012).

180. *Hand Hygiene Recording and Reminding System*, HYGREEN, <http://hygreen.com/index.asp> (last visited Oct. 6, 2012) [hereinafter HYGREEN]. Infections acquired in hospitals take the lives of 270 patients per day. *Id.*

181. The narcissism discussed earlier in the article, see *supra* Part III.C, can play a role in something as simple as hand hygiene. See Mark Todd, *Doctors Don't Have Germs, Nurse Told*, SYDNEY MORNING HERALD (June 21, 2005), <http://www.smh.com.au/news/national/doctors-dont-have-germs-nurse->

example of mistake detection, Hygreen, Inc. has developed a high technology monitoring system to detect mistakes in hand hygiene.<sup>182</sup> The system utilizes a device that senses hand-washing by individual healthcare workers, who are identified by an electronic badge they wear.<sup>183</sup> The date, time, and location of the hand-washing are recorded in a centralized database and a green light on the badge is illuminated.<sup>184</sup> When a worker approaches a patient's bed, a sensor near the bed verifies that hand-washing has occurred or causes the badge to vibrate if hand-washing has not occurred.<sup>185</sup> The green light turns off after coming in proximity with the bed's sensor.<sup>186</sup>

More than 100,000 wheelchair-related injuries are treated annually,<sup>187</sup> with 167 deaths being recorded during the period from 1997 through 1999.<sup>188</sup> Many of these injuries occur when patients are entering or leaving the wheelchair.<sup>189</sup> If the patient forgets to engage the brake while transferring, the wheelchair can roll, toppling the patient. In an example of mistake prevention through source inspection, there has been development of a mistake-proofing device that avoids this problem by automatically locking the wheels whenever weight is not applied to the seat of the chair.<sup>190</sup> A hand release allows an attendant to move unoccupied wheelchairs.<sup>191</sup>

In the past, blood pressure cuffs and thermometers contained potentially toxic mercury, which could be released if either item were damaged or not disposed of properly.<sup>192</sup> In an example of preventing the influence of mistakes, non-toxic ma-

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told/2005/06/20/1119250928025.html.

182. See HYGREEN, *supra* note 180.

183. *HyGreen and Hand Hygiene: How it Works*, HYGREEN, <http://hygreen.com/HandHygieneMonitor/How.asp> (last visited Oct. 18, 2012).

184. *Id.*

185. *Id.*

186. *Id.*

187. H. Xiang et al., *Wheelchair-Related Injuries Treated in U.S. Emergency Departments*, 12 INJ. PREVENTION 8, 8 (2006).

188. John Grout, *Examples 41-50*, MISTAKEPROOFING.COM, <http://www.mistakeproofing.com/example5.html> (last visited Oct. 6, 2012).

189. See Julie A. Braun, *Legal and Medical Aspects of Long-Term Care Litigation*, in 1 THE ELDER LAW PORTFOLIO SERIES 13-1, 13-183 to -184 (Harry S. Margolis ed., 2007).

190. GROUT, *supra* note 17, at 56.

191. *Id.*

192. See *Recommended Management and Disposal Options for Mercury-Containing Products*, U.S. ENVTL. PROTECTION AGENCY, [http://www.epa.gov/hg/mgmt\\_options.html](http://www.epa.gov/hg/mgmt_options.html) (last updated Feb. 7, 2012).

terials are now substituted for the mercury.<sup>193</sup>

### C. MISTAKE-PROOFING AND COMPLEX HEALTHCARE PROCESSES

The foregoing examples of mistake-proofing involve simple solutions to rather simple, low-level problems. Mistake-proofing in healthcare is not limited to problems of this nature, however. It can also be applied to more complex processes. Problem diagnosis in more complex settings, however, often requires root cause and failure/mode effects analysis (RCA). RCA adheres to the mistake-proofing tenets that systems can be made safer by design and that analysis of adverse events can guide this design.<sup>194</sup>

In more complex systems settings, there are almost always multiple factors contributing to mistakes. No one of these factors alone is the root cause. Errors are a function of natural weaknesses in human cognition and behavior (human factors) interacting with systems errors (latent errors), with the result that any well-intentioned professional who is placed in a poorly designed system is likely to commit an error. Hence, in these settings RCA might be better termed “contributing factors analysis.” Contributing factors include such influences as management decisions, organizational processes, work conditions, workload, supervision, knowledge, ability, and barriers.<sup>195</sup> RCA counters the tendency to focus on what appear to be the obvious causes proximate to an adverse event and looks beyond to the underlying causes. Information is gathered from a variety of sources regarding broader, systemic factors. Structured inquiry examines not only the active failure but work conditions, management decisions, and organizational processes, using such techniques as cause-and-effect (“fishbone”) diagrams, process flow charting, and multidisciplinary meetings.<sup>196</sup>

Consider, for example, the process of prescribing medicine for patients. This deceptively simple process too often results in prescription errors, which are costly occurrences.<sup>197</sup> One hospi-

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193. *See id.*

194. Kim, *supra* note 125; *see* GROUT, *supra* note 17, at 26–35.

195. Kim, *supra* note 125; *see* GROUT, *supra* note 17, at 26–35.

196. Kim, *supra* note 125; *see* GROUT, *supra* note 17, at 26–35.

197. *See* Lauran Neergaard, *Medication Errors Injure More Than 1.5m*, BOSTON.COM, (July 21, 2006), [http://www.boston.com/news/nation/articles/2006/07/21/medication\\_errors\\_injure\\_more\\_than\\_15m/](http://www.boston.com/news/nation/articles/2006/07/21/medication_errors_injure_more_than_15m/) (“[A] serious drug error can add more than \$5,800 to the hospital bill of a single patient. Assuming

tal reported that medication errors frequently stemmed from the combination of pharmacists being unable to read prescriptions written by physicians, the need for immediate administration of medication when waiting presented risks, and the unavailability of physicians to clarify the prescriptions due to other commitments.<sup>198</sup> An RCA of a medication error in a hospital revealed that the following factors contributed to the error's occurrence: (1) containers containing the correct and incorrect medications looked similar; (2) the error occurred on a Friday (patients prefer to be treated on Fridays and hospital management liked to accommodate patients, leading to high volume and the consequence that the pharmacist was hurried); (3) staffing was inadequate on Fridays because there was not enough room in the pharmacy to accommodate more pharmacists; and (4) the lack of room resulted from a building design that could only accommodate two sterile hoods, one of which was reserved for biological agents.<sup>199</sup>

Computer-assisted prescribing furnishes a partial answer to the problem of medication error. Such prescribing has been estimated to result in a fifty percent or greater reduction in errors.<sup>200</sup> The imposition of information technology on flawed processes, however, has been analogized to paving over cart paths.<sup>201</sup> A more efficacious approach involves using failure modes and effects analysis to prospectively identify high-risk processes and create detailed process mapping. Next comes an identification of all the ways in which errors may occur, as well as consideration of the effects of the errors, followed by prioritizing the process steps based on the probability of occurrence and consequences of failure. Mistake-proofing the process would then be the final step.<sup>202</sup> In the medication-error exam-

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that hospitals commit 400,000 preventable drug errors each year, that's \$3.5 billion—not counting lost productivity and other costs—from hospitals alone . . . .”).

198. Interview with C. Lynne Rover-Willoughby, Dir. of Med. Informatics, Cmty. Health Network, in Indianapolis, Ind. (Oct. 19, 2004).

199. Kim, *supra* note 125.

200. CONSUMERS UNION, *supra* note 23, at 6.

201. Interview with Ronald W. Dollens, former President and Chief Exec. Officer, Guidant Corp., in Bloomington, Ind. (Feb. 1, 2006); see Naresh Khatri et al., *Medical Errors and Quality of Care*, 48 CAL. MGMT. REV. 115, 134–35 (2006).

202. Kim, *supra* note 125. Evanston Northwestern Healthcare executives report that implementation of its Electronic Medical Record (EMR) system led its hospitals to engage in a streamlining of healthcare processes, with substantial savings in time and money resulting from process improvements con-

ple, mistake-proofing might involve the following actions: drug containers could be designed so that medicines that are similar in appearance are segregated in markedly different containers; computerized physician-order entry systems could be employed to remove the issue of illegibility and automatically signal drug interactions; and scheduling could be managed to better balance prescription volume.

Given the previously discussed roles of complex processes, chaotic team environments, and behavioral dysfunctions in causing medical errors, one might expect HCPs to wholeheartedly embrace mistake-proofing because of its low cost and reliance upon fail-safe techniques.<sup>203</sup> Despite mistake-proofing's potential to enhance healthcare quality in a relatively inexpensive fashion<sup>204</sup> and despite the identification of many specific mistake-proofing processes of a beneficial nature,<sup>205</sup> mistake-proofing adoption has not occurred on as widespread basis as it should have. In the following section, we consider a likely reason for that state of affairs.

#### V. IMPEDIMENTS TO WIDESPREAD ADOPTION OF MISTAKE-PROOFING IN HEALTHCARE FIELD

Because negligence liability is premised on harm-causing mistakes that fall below the standard of due care, mistake-proofing efforts of the sort discussed in this article make a great deal of sense in the healthcare environment. They are designed to lessen the likelihood of harm-causing medical errors, and they relate directly to the individual-error, group-error, and system-error aspects of the negligence liability environment faced by HCPs. Moreover, they typically do not carry a hefty price tag and are relatively easy to implement.<sup>206</sup> So why

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sidered to be a necessary prerequisite to fully successful EMR implementation. Interviews with Mark R. Neaman, CEO, Evanston Northwestern Healthcare, past Chairman, Healthcare Leadership Council, and past Chairman, Nat'l Comm. for Quality Healthcare, Jeffrey H. Hillebrand Chief Operating Officer, Evanston Northwestern Healthcare, Thomas H. Hodges Chief Fin. Officer, Evanston Northwestern Healthcare, Joseph Golbus President, ENH Med. Grp., Peggy King Senior Vice President, Quality and Risk Mgmt., Evanston Northwestern Healthcare, and Dr. Ned Wagner Med. Dir. of Med. Informatics, Evanston Northwestern Healthcare, in Evanston, IL (Apr. 19, 2006).

203. See *supra* text accompanying notes 62–109.

204. See GROUT, *supra* note 17, at 14.

205. See *id.* at 117–46.

206. See *supra* text accompanying notes 172–173.

would HCPs resist implementation of mistake-proofing processes? A key reason appears to be the same one encountered in regard to mistake-proofing efforts in the manufacturing context: concern that adoption of a mistake-proofing process after harm has come to a patient (or a product user, in the product liability setting) could be used against the defendant in the harmed party's attempt to have negligence liability imposed on the defendant.<sup>207</sup> In other words, HCPs are concerned about falling victim to this argument: "Your adoption of the mistake-proofing process after I was harmed suggests that you should have implemented it sooner in order to protect me—and others like me—against being harmed. Therefore, your failure to adopt the mistake-proofing process earlier indicates negligence on your part." But is this concern on the part of HCPs well-founded? We turn to that question in the following discussion.

#### A. THE SUBSEQUENT REMEDIAL MEASURES RULES: CONTENT AND RATIONALE

In order to determine whether the above-described concern of HCPs is soundly based, we must address Federal Rule of Evidence (FRE) 407.<sup>208</sup> This evidentiary rule is usually referred to as the "subsequent remedial measures" rule because it is so titled.<sup>209</sup> Although the negligence principles that govern malpractice cases exist as part of state law, such cases may be pursued in federal court if the requirements of diversity jurisdiction are met.<sup>210</sup> For diversity jurisdiction to exist, the plaintiff and the defendant(s) must be from different states and the amount in controversy—the damages sought by the plaintiff—must exceed \$75,000.<sup>211</sup> Because some malpractice cases may be litigated in federal court under the right set of conditions, FRE 407 is of considerable potential relevance to the issues addressed in this article. Although FRE 407 does not apply when malpractice cases are brought in state courts, as

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207. The concern is that "[i]n claiming the 'after,' one must own up to the 'before.'" GROUT, *supra* note 17, at 17. *Cf. National Survey*, *supra* note 5, at 218–19 (noting similar fear that may cause some HCPs not to fulfill their obligation to report medical errors even if the relevant state's law requires such a report).

208. FED. R. EVID. 407 (2006).

209. *Id.*; *see also, e.g.*, C. Paul Carver, *Subsequent Remedial Measures 2000 and Beyond*, 27 WM. MITCHELL L. REV. 583, 584 (2001).

210. *E.g.*, *Leazer v. Kiefer*, 821 P.2d 957, 960 (Idaho 1991); *Darling v. Charleston Mem'l Hosp.*, 211 N.E.2d 253, 256–57 (Ill. 1965).

211. 28 U.S.C. § 1332 (2006).

many of them are,<sup>212</sup> state rules that match or closely resemble FRE 407 normally will apply.<sup>213</sup>

FRE 407 reads as follows:

When measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove:

- negligence;
- culpable conduct;
- a defect in a product or its design; or
- a need for a warning or instruction.

But the court may admit this evidence for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures.<sup>214</sup>

An evidentiary rule of similar content and effect exists in most states.<sup>215</sup> In the following discussion, we will often refer to FRE 407 and its state law counterparts as the “subsequent remedial measures rules.”

The subsequent remedial measures rules rest on the policy determination that steps to improve safety and minimize future

212. See SHOWALTER, *supra* note 34, at 39–77; WING, *supra* note 32, at 287–92.

213. See Carver, *supra* note 209, at 584, 587–89; Chris Guthrie, *Misjudging*, 7 NEV. L.J. 420, 422 (2007); Roger C. Henderson, *Product Liability and Admissibility of Subsequent Remedial Measures: Resolving the Conflict By Recognizing the Difference Between Negligence and Strict Tort Liability*, 64 NEB. L. REV. 1, 4 (1985).

214. FED. R. EVID. 407. This version of the rule took effect in December 2011. *Id.* The version in effect from 1997 to December 2011 read as follows:

When, after an injury or harm allegedly caused by an event, measures are taken that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product’s design, or a need for a warning or instruction. This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as proving ownership, control, or feasibility of precautionary measures, if controverted, or impeachment.

*Id.* (superseded by revised version effective Dec. 1, 2011). The 2011 version was “part of the general restyling of the Evidence Rules to make them more easily understood and to make style and terminology consistent throughout the rules.” *Id.* (Committee Notes on Rules—2011 Amendment). Because the changes effected by the 2011 version were meant to be “stylistic only,” there was “no intent to change any result in any ruling on evidence admissibility.” *Id.*

215. See Carver, *supra* note 209, at 584, 587–89; Guthrie, *supra* note 213, at 422; Henderson, *supra* note 213, at 4. Details of the respective state rules are beyond the scope of this article.

harm are in the obvious interest of the public, and that their implementation should therefore be encouraged. If, however, evidence of a defendant's post-harm-to-the-plaintiff adoption of a safety measure could be used by the plaintiff to help make his case against the defendant, there would be a disincentive to adopt such measures.<sup>216</sup> Under a regime of that nature, the defendant's short-term interest in avoiding liability in a particular case could take priority in the defendant's decision-making, perhaps causing the defendant not to adopt what might otherwise be a perfectly sensible safety measure. Such a decision would undermine the long-term interests in furthering safety and minimizing future defects or errors.<sup>217</sup>

To serve the broader public interests at stake, then, evidentiary rules on subsequent remedial measures become necessary. With the defendant having the subsequent remedial measures rules' assurance that post-harm adoption of the safety measure will not disadvantage him, her, or it in the litigation at hand, the defendant should be more likely to do the right thing and adopt the safety measure.<sup>218</sup> Besides being in the public interest, the measure should operate in the long-term interest of the defendant. If the measure lessens the likelihood of future instances of harm, it should correspondingly reduce the amount of litigation with which the defendant might otherwise have to contend.<sup>219</sup>

Of course, the subsequent remedial measures rules are likely to help achieve their policy objective of encouraging the adoption of safety measures only if defendants and would-be defendants are sufficiently aware of the existence of such evidentiary rules. Such awareness on the part of manufacturers probably has helped to pave the way toward broader adoption of mistake-proofing processes in the manufacturing realm.<sup>220</sup> Among HCPs, however, insufficient awareness that the subsequent remedial measures rules may be applied to their activi-

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216. See Guthrie, *supra* note 213, at 423; Henderson, *supra* note 213, at 5–6; Joseph A. Hoffman & George D. Zuckerman, *Tort Reform and Rules of Evidence: Saving the Rule Excluding Evidence of Subsequent Remedial Action*, 22 TORT & INS. L.J. 497, 498 (1987).

217. Carver, *supra* note 209, at 610; Guthrie, *supra* note 213, at 423; Henderson, *supra* note 213, at 5–6; Hoffman & Zuckerman, *supra* note 216, at 508.

218. See Carver, *supra* note 209, at 610; Guthrie, *supra* note 213, at 423; Hoffman & Zuckerman, *supra* note 216, at 508.

219. See Hoffman & Zuckerman, *supra* note 216, at 508–09.

220. See Carver, *supra* note 209, at 610–11; Hoffman & Zuckerman, *supra* note 216, at 508–09.



ties could help explain why the adoption of mistake-proofing techniques has not been more widespread in the healthcare field.<sup>221</sup>

B. THE SUBSEQUENT REMEDIAL MEASURES RULES:  
HEALTHCARE APPLICATIONS

It is important to note that even though the subsequent remedial measures rules may be applied most often in the context of product liability litigation, their application is not—and should not be—restricted to that context.<sup>222</sup> FRE 407 does say, of course, that evidence of a subsequent remedial measure cannot be used to prove the existence of “a defect in a product or its design; or a need for a warning or instruction.”<sup>223</sup> Although the quoted language directly contemplates product liability cases, earlier language in FRE 407 indicates that the rule can be applied outside the product liability context. The rule states that evidence of subsequent remedial measures cannot be used to prove “negligence [or] culpable conduct” on the part of the defendant.<sup>224</sup> This portion of the rule speaks in terms of failures to use reasonable care more generally, without any language limiting the “negligence [or] culpable conduct” reference to the product liability setting.<sup>225</sup> Subsequent remedial measures rules among the states are to the same general effect.<sup>226</sup> Be-

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221. See GROUT, *supra* note 17, at 17–18.

222. See Henderson, *supra* note 213, at 1–6; see also FED. R. EVID. 407 (Notes of Advisory Committee on Proposed Rules) (noting that “courts have applied this principle to exclude evidence of subsequent repairs, installation of safety devices, changes in company rules, and discharge of employees”). Some states’ formulations of the subsequent remedial measures rules do not contain language specifically mentioning product defects and subsequent corrective measures—a further indication that the rules are not meant to be restricted to the context of product liability litigation. See Carver, *supra* note 209, at 587–89. Although the subsequent remedial measures rules normally are interpreted as having potential applicability to product liability cases regardless of whether the specific formulations expressly mention product safety, there has been some division among the states as to whether the rules apply in all product liability cases (whether negligence-based or brought on a strict liability theory), or only in those product liability cases that are negligence-based. See *id.* at 587–91; Henderson, *supra* note 213, at 3–20. Further exploration of the latter set of issues is beyond the scope of this article.

223. FED. R. EVID. 407.

224. *Id.*

225. See *id.*

226. See Guthrie, *supra* note 213, at 422–23; Henderson, *supra* note 213, at 1–6.

cause malpractice cases against HCPs are based on principles of “negligence” and require proof of “culpable conduct” in the form of a failure to use reasonable care, the subsequent remedial measures rules are applicable in the healthcare realm.<sup>227</sup>

Accordingly, if an HCP being sued by a harmed plaintiff is considering adoption of a mistake-proofing process meant to reduce the likelihood that a future patient would be harmed in the way the plaintiff was, the HCP’s decision on whether to adopt the mistake-proofing process should be made with knowledge of the protection afforded by the subsequent remedial measures rules. Concern of the “they’ll use it against me in the lawsuit” variety is not a well-founded reason for rejecting implementation of such a safety measure when it otherwise seems reasonable and would further a long-term interest that the HCP and its future patients share: the interest in lessening the likelihood of medical errors.

It should be noted, of course, that even though the subsequent remedial measures rules have the above-noted general effect of prohibiting plaintiffs from making evidentiary use of later safety measures in an effort to prove the defendant’s negligence,<sup>228</sup> the rules do not furnish a guarantee that evidence of such measures can never be used. FRE 407, for instance, permits the use of such evidence when it is offered “for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures.”<sup>229</sup> These exceptional instances depend, however, on litigation tactics and/or testimony in which the defendant effectively opens the door to use of evidence of the safety measures.<sup>230</sup> Absent such opening of the door, the defendant’s mere adoption of the safety measure is not enough to justify admission of evidence thereof.<sup>231</sup>

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227. See FED. R. EVID. 407; see also *id.* (Notes of Advisory Committee on Proposed Rules) (noting examples of contexts in which rule applies); Henderson, *supra* note 213, at 1–6 (noting application of federal and state rules in negligence cases).

228. See *supra* text accompanying notes 214–218, 222–227.

229. FED. R. EVID. 407.

230. The “if disputed” language in the rule is the key here. See *id.*

231. In any litigation in which issues may arise under the relevant subsequent remedial measures rule, the mistake-proofing HCP would be well-advised to file a motion *in limine* in an effort to get the evidentiary questions sorted out and ruled upon ahead of trial. The same would be true where the HCP has adopted mistake-proofing processes concerning some of its healthcare services but not regarding the different particular services the

## VI. MISTAKE-PROOFING AND ERROR REDUCTION: WHAT TO DO?

We turn here to recommendations that flow from the article's earlier sections dealing with the need to reduce the rate and number of medical errors, the usefulness in that regard of mistake-proofing techniques, and the impediments to more widespread adoption of such techniques. Some recommendations in the following subsections have a specific mistake-proofing thrust; others speak to error-reduction issues more generally.

### A. ENHANCE HCPs' UNDERSTANDING OF NEGLIGENCE PRINCIPLES AND RELATED CONSIDERATIONS

As earlier discussion revealed, HCPs are not legally liable to a patient every time a bad outcome resulted from medical treatment they ordered or administered. Rather, HCPs are liable only if the bad outcome resulted from medical treatment that reflected negligence because it fell below the standard of reasonable care examined earlier in the article.<sup>232</sup> One presumes—and hopes—that most HCPs are aware of these fundamental principles. Yet even if HCPs have this awareness, they need a realistic understanding of what the reasonable care standard actually contemplates.

For instance, the reasonable care standard does not require the ordering of every conceivable test or procedure that a physician might order for a given patient who displays certain symptoms. If it is quite unlikely that a particular disease or condition would be the cause of the symptoms and much more likely that another explanation is the genuine one, the hypothetical reasonable physician against whom the actual physician is measured might decline to order a test that would rule out the quite unlikely disease or condition. Thus, the physician who does not order that test may well have exercised reasonable care.<sup>233</sup> This is especially apt to be the case if the test for

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plaintiff was receiving when she experienced harm. Evidence of such adoption of mistake-proofing processes by the HCP should not be admissible to prove negligence in failing to mistake-proof the particular services received by the plaintiff. Allowing such evidence to be admitted would violate at least the spirit of the subsequent remedial measures rules. A general lack-of-relevance objection would also be appropriate.

232. See *supra* text accompanying notes 43–52.

233. See *supra* text accompanying notes 43–52, 110–113.

the improbable condition is also very expensive or physically onerous for the patient.<sup>234</sup> Of course, other factors—such as extreme severity of the potentially resulting harm to the patient if she in fact has the improbable condition—could tip the scales the other way on whether a reasonable physician would order the test.<sup>235</sup> Even so, this basic point remains valid: properly applied, negligence law's reasonable care standard does not contemplate a tests-and-procedures arms race in which HCPs who fail to keep up are necessarily doomed to liability.

Physicians and other HCPs frequently invoke the defensive medicine argument in response to the foregoing paragraph's observations. If we do not order this vast array of tests and procedures, the argument goes, we will be sued. Therefore, the argument continues, we end up ordering tests and procedures *that we really do not think are necessary* (or even very desirable) in order to protect ourselves against the litigation that in today's environment almost certainly will follow if we do not take such defensive steps.<sup>236</sup>

Those who make the defensive medicine argument do so with considerable earnestness, but they may suffer from distorted senses of the respective likelihoods of being sued for malpractice and being held liable in such cases. Contrary to the argument's premise that lawsuits and potential liability are a given unless the HCP engages in what amounts to overtreating, the percentage of patients who take legal action over medical errors that harmed them has been shown to be as low as only three to six percent.<sup>237</sup> Moreover, in the small percentage of instances when an error does result in litigation, plain-

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234. See *supra* text accompanying notes 43–52.

235. See *id.*

236. See *supra* text accompanying notes 110–113.

237. Catherine M. Sharkey, *Unintended Consequences of Medical Malpractice Damages Caps*, 80 N.Y.U. L. REV. 391, 399 n.26 (2005). Other estimates put the percentage higher, at ten to fourteen percent. Neil Vidmar, *Medical Malpractice Lawsuits: An Essay on Patient Interests, the Contingency Fee System, Juries, and Social Policy*, 38 LOY. L.A. L. REV. 1217, 1226–27 (2005). Regardless of whether the correct estimate is three to six percent or, instead, ten to fourteen percent, it is clear that the vast majority of harmed patients do not file claims. *Id.* at 1227–28; see also Hyman & Silver, *supra* note 110, at 976; David M. Studdert et al., *Claims, Errors, and Compensation Payments in Medical Malpractice Litigation*, 354 NEW ENG. J. MED. 2024, 2025 (2006). Physicians, however, have been shown to overestimate significantly their actual risk of being sued. One study concluded that physicians perceive the risk of being sued as three times greater than it actually is. Gunnar, *supra* note 110, at 476.

tiffs win their cases only about twenty-five percent of the time.<sup>238</sup> HCPs naturally do not want to be in the groups sued and/or held liable, even if those groups are statistically small. However, a more realistic understanding among HCPs of the likelihood—really unlikelihood—of being sued, let alone being held liable, should work to the benefit of HCPs and the healthcare system by lessening HCPs' tendencies to think extreme defensive medicine is necessary and by reducing the considerable costs that accompany unwarranted tests and procedures.

By ordering tests and procedures they, in the exercise of their professional judgment, would not order if not for their inaccurate sense of the risk of litigation and liability, physicians are not necessarily increasing the quality of care and are doing little or nothing to reduce medical error frequency.<sup>239</sup> Moreover, what they see as an objectionable but necessary litigation risk-mitigation strategy may be a counterproductive self-fulfilling prophecy. If large numbers of physicians operate under the misimpression that they have to order tests and procedures they would not otherwise order, then doing so indeed becomes the norm despite its lack of soundness. It also creates the potential for an unwarranted ratcheting-up of the reasonable care standard, as a plaintiff's attorney can argue that with everybody else ordering this huge battery of tests and procedures, a particular defendant's failure to do so must have been wrong.<sup>240</sup> To the extent that judges and juries buy this view of what should constitute reasonable care, HCPs will continue to feel hamstrung in their attempts to exercise their professional judgment. It is a hamstringing brought on in large part, however, by HCPs' failure to have a realistic sense of their chances of being sued and of being held liable.

Acquiring the realistic understanding that the chances of being sued and of being held liable are small should give HCPs greater confidence that they do not reflexively have to join the unwarranted tests-and-procedures arms race. In the process,

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238. Sharkey, *supra* note 237, at 451–52; Vidmar, *supra* note 237, at 1232.

239. They may even be increasing the risk of errors, as each additional procedure presents a risk of error. Sanjay Gupta, *More Treatment, More Mistakes*, N.Y. TIMES, July 31, 2012, at A21.

240. As earlier discussion suggested, one consideration in the reasonable care standard is what other HCPs are or are not doing. See *supra* text accompanying notes 43–52.

they can free themselves to do what they entered the profession to do: exercise their best judgment in an effort to promote the health of their patients. Rather than being so concerned about the seeming imperative to order unwarranted tests and procedures, HCPs can direct greater attention to the adoption of measures that really can improve healthcare quality, reduce error risk, and lessen the danger of liability: the mistake-proofing processes examined herein.<sup>241</sup>

As noted earlier, adoption of mistake-proofing can have implications for the reasonable care standard's application in negligence cases dealing with medical errors. Just as the use of mistake-proofing processes can serve as evidence that due care was exercised, a defendant's failure to adopt mistake-proofing processes could suggest a failure to use reasonable care—especially if other HCPs begin adopting such techniques on a more widespread basis.<sup>242</sup> Would not the latter effect amount to a ratcheting-up of the reasonable care standard, and would not that be a good reason for HCPs generally to shy away from going the mistake-proofing route (on the theory that if no one is doing it, an individual HCP's failure to do it might not be seen as a failure to use due care)? The first part of this compound question merits a “yes” answer; the second part, a “no.”

One can fairly assume that if mistake-proofing processes became widely adopted, such processes would become part of what constitutes reasonable care. In that event, an HCP's failure to adopt appropriate processes of that sort could suggest a failure to exercise reasonable care and could therefore help support a negligence claim.<sup>243</sup> But that prospect does not furnish a sound reason for HCPs to resist, on an en masse basis, adoption of mistake-proofing processes in order to avoid a situation in which mistake-proofing utilization becomes part of the reasonable care norm (to the possible detriment of certain HCPs who become defendants). Such a strategy on the part of HCPs would miss a far more important point: that adoption of mistake-proofing techniques would greatly benefit HCPs in a liability avoidance sense.

If mistake-proofing prevents many medical errors—and

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241. See *supra* text accompanying notes 122–205.

242. Again, a consideration in the reasonable care standard is what other HCPs are or are not doing. See *supra* text accompanying notes 43–52; *supra* note 44.

243. Hill, Langvardt & Massey, *supra* note 2, at 165–68.

there is reliable evidence that it does<sup>244</sup>—there will be fewer and fewer instances in which error-related bad outcomes for patients occur. If there is no error, there can be no liability.<sup>245</sup> The prevention of errors will also go a long way toward reducing the number of bad outcomes for patients. Of course, it is not possible to eliminate all risks of harms. Bad outcomes sometimes result even when all due care was exercised. But any HCP, regardless of his, her, or its views concerning the legal system and the rules of tort liability, obviously wants to reduce the risks of harms to patients to the extent reasonably possible. Mistake-proofing holds great promise for doing so.<sup>246</sup>

#### B. ENHANCE HCPs' UNDERSTANDING OF FRE 407 AND ITS STATE COUNTERPARTS

As an earlier section explained, a lack of understanding on the part of HCPs concerning FRE 407 and its state counterparts can present an impediment to the adoption of mistake-proofing processes in the healthcare environment. The concern is that HCPs' implementation of a mistake-proofing measure after an incident in which harm came to a patient might be used against the HCPs in litigation over that harm, on the theory that pre-harm implementation of the measure could have prevented the harm and that the failure to adopt the measure earlier was a failure to use reasonable care.<sup>247</sup> To the extent that this concern is widespread, HCPs could perceive a disincentive to adopt mistake-proofing processes and, accordingly, could refrain from taking such sensible steps.

The concern is largely unwarranted, however. The impediment it poses to adoption of mistake-proofing measures can be overcome through educating HCPs on the purposes and effects of FRE 407 and the similar evidentiary rules existing in many states. As previous discussion revealed, these *subsequent remedial measures* rules provide that evidence of safety enhancement measures taken by a defendant to address the type of risk and harm already experienced by a plaintiff cannot generally be used against the defendant in the plaintiff's attempt to es-

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244. See *supra* text accompanying notes 122–205.

245. E.g., WING, *supra* note 32, at 291–92.

246. See *supra* text accompanying notes 133–205.

247. GROUT, *supra* note 17, at 17. See *supra* text accompanying notes 207, 216–217.

establish negligence on the defendant's part. Thus, if the plaintiff is to establish negligence, the plaintiff must do so on the basis of evidence other than the defendant's later adoption of the safety measure.<sup>248</sup>

The subsequent remedial measures rules exist to eliminate a disincentive to the adoption of safety enhancement measures—the disincentive resulting from defendants' concern that the adoption of the measures could come back to haunt them in a negligence case dealing with harm that preceded adoption of the measures.<sup>249</sup> This is the very concern that can operate problematically in the context of medical error-reduction efforts. Hence, achieving greater awareness among HCPs concerning the subsequent remedial measures rules and their purpose of eliminating a disincentive to the adoption of safety enhancement measures should be a key piece of a strategy to encourage more widespread adoption of mistake-proofing processes in healthcare settings.

#### C. ENHANCE NATIONAL TRACKING AND ENCOURAGEMENT OF PATIENT-SAFETY EFFORTS

A national move to track and encourage patient-safety efforts on the part of HCPs should help facilitate expanded utilization of mistake-proofing processes. Although the federal government and private organizations have been somewhat active in promoting patient safety efforts,<sup>250</sup> a more tightly coordinated national program along those lines is needed. Wider adoption of mistake-proofing processes and more extensive reporting by HCPs on those actions (whether to a federal agency or an organization operating under a public-private arrangement) would make even more meaningful best-practices reports possible.<sup>251</sup> Such reports could encourage HCPs to make greater use of mistake-proofing processes by revealing those processes' error-reduction propensities and cost-effective nature.

The goal of increasing the adoption of mistake-proofing measures by HCPs could be furthered, of course, through fed-

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248. FED. R. EVID. 407; *see also* Carver, *supra* note 209, at 584, 587–89; Henderson, *supra* note 213, at 4–6.

249. Guthrie, *supra* note 213, at 423; Hoffman & Zuckerman, *supra* note 216, at 498. For further discussion of the subsequent remedial measures rules, *see supra* text accompanying notes 208–231.

250. For a discussion of the federal government's patient safety efforts, *see supra* note 115.

251. *See supra* note 115.



eral requirements that would mandate such measures as well as periodic reports by HCPs on what they have done in that regard. In today's often gridlocked legislative environment, however, a proposal to impose such requirements by statute could be a non-starter. Imposing such requirements through agency regulations (assuming that previous statutes' delegations of power would be broad enough to permit such regulations) could not only trigger political objections<sup>252</sup> but also involve significant practical obstacles. Regulations requiring the adoption of, and reporting on, mistake-proofing processes would have to be extremely specific and detailed. They would need to address such issues as which HCPs are subject to the requirements, which particular mistake-proofing techniques are mandated, what type and level of implementation by an HCP constitutes compliance, what consequences ensue if the HCP does not comply, and various others. The level of detail that would be necessary in such regulations would make their prompt promulgation very unlikely. Even if the regulations ultimately were promulgated, the problem of medical errors would continue to be insufficiently mitigated during the intervening years.

A more promising avenue would be to have federal regulations that encourage the use of mistake-proofing through providing incentives for doing so. Regulations of the Centers for Medicare and Medicaid Services already call for financial reimbursement to HCPs to be based more on health outcomes than had been the case in the past.<sup>253</sup> Reimbursement-related incentives for adopting mistake-proofing processes would be a logical addition to those regulations. Although the literal application of the regulations would be confined to the Medicare and Medicaid contexts, HCPs that implement mistake-proofing techniques because of Medicare and Medicaid-related incentives would seem likely to employ those techniques more broadly (i.e., even outside the Medicare and Medicaid contexts) once they see the error-reduction values of the techniques.

In addition, the federal government has utilized financial incentives as a way of encouraging the adoption of electronic medical records and electronic systems for prescribing medica-

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252. See, e.g., *supra* note 1.

253. See QUALITY MEASURE REPORTING, *supra* note 119; Kevin Sack, *Medicare Rules Say 'Do No Harm'*, N.Y. TIMES, Sept. 30, 2008, at A1.

tions.<sup>254</sup> With error reduction being a primary goal of those incentives, a similar approach would make sense in regard to mistake-proofing measures. A further possible regulatory avenue could be the addition of incentives for error-reduction measures to the rules governing Accountable Care Organizations, whose creation is encouraged in the 2010 Patient Protection and Affordable Care Act.<sup>255</sup>

#### D. ACCELERATE THE ADOPTION OF ELECTRONIC SYSTEMS FOR PRESCRIBING MEDICATIONS

Earlier discussion in the article noted a number of mistake-proofing techniques that can be very helpful in healthcare contexts.<sup>256</sup> Of course, we advocate adoption of those techniques. We give special emphasis here, however, to the importance of broader utilization of electronic systems for prescribing medications. As noted earlier, the numbers of medication errors remain unreasonably high, with the consequences for patients in too many instances being devastating.<sup>257</sup> Electronic systems have been shown to be highly effective in reducing the numbers of medication errors.<sup>258</sup> Prudent HCPs clearly should be moving in the direction of using such systems.

Because costs obviously can be an issue, the previously noted federal incentives for adopting electronic prescribing systems should be continued and probably enhanced in order to speed the rate at which such adoption takes place. Prudent insurance companies should also reward insureds that adopt electronic prescribing systems by charging them reduced premiums, given that such systems' demonstrated usefulness in reducing or eliminating errors should lead to less risk of liabil-

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254. See 42 C.F.R. § 423.159–160 (2011); Steve Lohr, *Big Medical Groups Begin Patient Data-Sharing Project*, N.Y. TIMES (Apr. 6, 2011, 12:01 AM), <http://bits.blogs.nytimes.com/2011/04/06/big-medical-groups-begin-patient-data-sharing-project/>.

255. See 42 U.S.C. §§ 280g-12, 1395jjj (2011); Medicare Shared Savings Program, 76 Fed. Reg. 67,973 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425).

256. See *supra* text accompanying notes 171–205.

257. See *supra* note 7; *supra* text accompanying notes 197–202. See also Denham et al., *supra* note 6, at 5, 8 (discussing, among other sorts of medical errors, medication errors and the havoc they may wreak); IOM, PREVENTING MEDICATION ERRORS, *supra* note 7, at 113–14 (estimating that at least 1.5 million preventable medication errors occur each year).

258. E.g., Denham et al., *supra* note 6, at 8.

ity for HCPs and their insurers.

#### E. MAKE MEDICAL ERROR-REPORTING A NATIONAL REQUIREMENT

The federal government has taken steps down the medical error-reporting path, but the scheme set up so far makes reporting optional.<sup>259</sup> Although roughly half of the states have medical error-reporting laws, with many of them ostensibly making reporting mandatory,<sup>260</sup> chronic under-reporting appears to plague the state schemes.<sup>261</sup> When the absence of a federal requirement is coupled with the incomplete, patchwork-quilt nature of state reporting requirements and the concerns about under-reporting in states that do have reporting laws, the resulting picture does not capture the full extent of the medical error problem. Only a national reporting requirement can provide a true basis for determining whether the problem is lessening, increasing, or remaining at the same level over time. A national reporting requirement also can lead to a meaningful system of accountability in which HCPs that commit large numbers of errors can be identified by consumers making healthcare purchasing decisions and by government agency personnel determining whether regulatory action may be warranted.

Although the details of a national regulatory regime requiring error-reporting are largely beyond the scope of this article, three key points are worth noting here. First, a useful foundation is already in place in the work of the National Quality Forum. This private organization has compiled a list of twenty-nine “serious reportable events”—a list generally utilized in the present optional reporting systems.<sup>262</sup> This list would be of obvious value in a regulatory switch to mandatory reporting because it would mean that the government would not have to start from scratch in determining what should be on the list of errors to be reported. Second, in order to safeguard the privacy interests of patients, regulations should specify that the information reported by the HCP not contain pa-

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259. See *supra* note 115.

260. See *National Survey*, *supra* note 5, at 213–20.

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

262. See NAT'L QUALITY FORUM, SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE: A CONSENSUS REPORT (2011).

tients' names. Third, in order to encourage compliance with the reporting requirement, regulations must provide that in a harmed patient's negligence (or other malpractice) lawsuit concerning an HCP's supposed error, the fact that the HCP submitted an error report and the content of the HCP's report are both non-discoverable and not subject to evidentiary use.<sup>263</sup> HCPs thus would not need to be concerned that, by complying with the federal reporting requirement, they would be helping the plaintiff make out his or her case.

#### F. CONVINCING LIABILITY INSURERS TO EMPLOY EXPERIENCE RATING

In the automobile insurance setting, a driver whose negligence has caused accidents is very likely to be charged higher premiums than those charged to an otherwise similarly situated driver who does not have a history of accident involvement. One would expect a similar approach to be employed in the realm of medical liability insurance, so that, say, a physician against whom multiple malpractice complaints have been made would pay more in premiums than would a same-practice-area physician against whom no or very few malpractice claims had been lodged. But malpractice insurance rating—the process by which premiums are set—often does not work that way. In setting premiums for physicians, for instance, insurers frequently classify physicians according to specialty and geographic area, and then charge the same premiums to all those of a particular specialty within a certain geographic area.<sup>264</sup> Under this approach, the history or lack of history of malpractice claims against the physician receives little or no consideration when the amount of the premium is determined.<sup>265</sup> The seemingly error-prone physician therefore ends up paying premiums of the same amount paid by the non-error-prone physician.

A switch to experience rating—leading to higher premiums for those with a history of negligence complaints against them and lower premiums for those without such a history—would logically furnish an incentive to HCPs to take steps to minimize the chances of error. The cause of broadening the utilization of mistake-proofing processes could thus be furthered by such a

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263. Such features are present in the current optional reporting system, see *supra* note 115, and should be continued.

264. Gunnar, *supra* note 110, at 471.

265. *Id.*; Hyman & Silver, *supra* note 110, at 981–82.

change in how insurers determine the amounts of premiums.

## VII. CONCLUSION

Although harm-causing errors can never be totally eliminated from our healthcare system, the numbers of errors that continue to occur remain surprisingly high. Mistake-proofing processes afford great promise as error-reduction devices and have the further advantage of being cost-effective. Yet obstacles seemingly have blocked more widespread utilization of such processes. As the article has noted, some of these obstacles have stemmed from HCPs' unclear or flat-out erroneous understanding of relevant legal principles dealing with matters of liability and admissible evidence. Overcoming these impediments in the manner explored in the article and adopting the error-reduction recommendations made here would furnish benefits all around. Patients would benefit through receiving enhanced quality of care and through a reduction in their chances of being harmed by medical error. Society and the healthcare system as a whole would benefit through cost savings associated with many fewer instances of error and through consumers' greater confidence in the quality of the care they receive. HCPs would benefit by having to worry less about liability and by thus being freed-up to focus more on what they entered the healthcare field to do: provide high-quality care that improves patients' lives.