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Arlen W Langvardt, Indiana University

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MISTAKE-PROOFING MEDICINE: LEGAL CONSIDERATIONS AND HEALTHCARE QUALITY IMPLICATIONS

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

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* Dean and David C. Garrett, Jr. Professor in Business Administration, Campbell School of Business, Berry College

** Arthur M. Weimer Chair in Business Administration and Life Sciences Research Fellow, Kelley School of Business, Indiana University

*** Professor of Business Law, Eveleigh Professor of Business Ethics, and Life Sciences Research Fellow, Kelley School of Business, Indiana University
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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. Although 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, the adoption of such techniques in healthcare settings has not occurred to the extent it should have.

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, the article considers the undesirable effects of misperceptions on the part of healthcare professionals regarding their risks of being held liable in a malpractice case. The article also proposes ways of encouraging greater adoption of mistake-proofing techniques and other error-reduction practices in healthcare contexts.
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.¹ Although this 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.² An “unconscionable error rate”³ documented in a landmark study in 1999 by the Institute

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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
of Medicine (IOM) shocked many, as the IOM estimated that up to 98,000 deaths per year resulted from medical errors. There are indications that the incidence of errors has not abated in the years since the IOM’s study, and may even be increasing. Accounts of serious medical errors continue to abound.


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. In a “national report card” on American healthcare, the Rand Corporation concluded that over time, almost everyone in the United States is at risk of receiving poor healthcare. An estimated 4 percent of all patients entering hospitals experience some type of adverse incident, approximately half of which are preventable and 25 percent of which stem from negligence.


7 Brophy, supra note 4. The 2006 IOM report estimated that at least 1.5 million preventable medication errors occur each year in hospitals and similar medical facilities. INSTITUTE OF MEDICINE, PREVENTING MEDICATION ERRORS 112 (Philip Aspden et al., eds. 2006) [hereinafter IOM, PREVENTING MEDICATION ERRORS].

8 RAND HEALTH, THE FIRST NATIONAL REPORT CARD ON QUALITY OF HEALTH CARE IN AMERICA 3 (2006), http://www.rand.org/pubs/research_briefs/2006/RAND_RB9053-2.pdf. See Denham et al., supra note 6, at 3-4. 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. JULIUS B. RICHMOND & RASHI FEIN, THE HEALTH CARE MESS: HOW WE GOT INTO IT AND WHAT IT WILL TAKE TO GET OUT 93 (2005).

Healthcare systems have become complex as they have evolved. 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. As a result, it may not be clear where the ultimate responsibility for reducing healthcare errors resides in a given HCP. Healthcare processes also tend to be insufficiently connected to one another in any real-time fashion, leading to gaps in information flow and resulting uneven delivery of care. If the error rates in intensive care units were acceptable in the airline and banking industries, for example, 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. When one considers what is at risk, the high medical error rates in the U.S. become especially difficult to excuse. Yet those high rates persist.

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13 Ahern, *supra* note 3; Sidney Taurel, Chairman & CEO, Eli Lilly & Co., Remarks at the Indiana University Kelley School of Business Annual Business Conference, “The Health Care Conundrum: A Call for Leadership,” March 8, 2006 (notes on file with authors). A lack of understanding of patterns of error resulting from shared information is often the culprit in causing medical errors, as opposed to purely individual human mistakes. Tom Murphy, *Clarian Plans Training Center*, INDIANAPOLIS BUS. J., Apr. 3-9, 2006, at 46A.

14 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.
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.\textsuperscript{15} Mistake-proofing is defined as “the use of process or design features to prevent errors or the negative impact of errors.”\textsuperscript{16} It has been employed in domains other than healthcare with significant success.\textsuperscript{17} With most serious medical errors likely resulting from systems failures as opposed to the failure of single individuals,\textsuperscript{18} devising means of preventing process errors would be a logical course of 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

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\textsuperscript{15} John R. Grout & John S. Toussaint, \textit{Mistake-Proofing Healthcare: Why Stopping Processes May Be a Good Start}, 53 \textit{Bus. Horizons} 149, 150 (2010). 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, \textit{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 \textit{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.


\textsuperscript{17} Grout & Toussaint, \textit{supra} note 15.

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face. 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.

Despite mistake-proofing’s desirability, HCPs have tended to adopt such processes at a less-than-speedy pace. 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. In assigning that grade, Consumers Union noted the problematic example that most hospitals had not adopted systems and procedures known to prevent medication errors.

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19 See, e.g., Hill, Langvardt & Massey, supra note 2, at 159-60. HCPs often tend not to be shy about voicing their concerns over the supposed prevalence of malpractice lawsuits. See, e.g., id. 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 181-82. But it is true that an error prevented is a potential lawsuit prevented.

20 GROUT, supra note 16, at 14-16.

21 See id. at 17-18, 19, 20, 23. See also id., preface (noting that “we still have much more to do to improve patient safety, “ that mistake-proofing is a “little-known but very promising approach to preventing medical errors,” and that even though certain mistake-proofing processes have been adopted by HCPs, “[w]e have only scratched the surface” in terms of discovering and implementing useful devices and applications of that nature) (comments of preface author Carolyn M. Clancy, Director, Agency for Healthcare Research and Quality).

22 CONSUMERS UNION, TO ERR IS HUMAN--TO DELAY IS DEADLY 12-13 (2009). In 2000, the IOM suggested a goal of reducing healthcare errors by 50 percent over five years. IOM, TO ERR IS HUMAN, supra note 4, at 4. That goal went unachieved. 2007 NATIONAL HEALTHCARE QUALITY REPORT, AGENCY FOR HEALTHCARE RESEARCH & QUALITY, U.S. DEPT. OF HEALTH & HUM. SERVS., AHRQ Pub. No. 08-0040, at iv, 2 (2008).

23 CONSUMERS UNION, TO ERR IS HUMAN--TO DELAY IS DEADLY 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 141-47, 200-01.
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. Moreover, there is not a true national system of accountability with sufficient quality transparency to enable healthcare consumers and regulators to identify those HCPs that commit abnormally large numbers of errors and to create pressure for change.

In addition, fear of legal liability serves as an impediment to more 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. As will be seen, that concern is largely unwarranted because of a key rule of evidence. But to the extent 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 for fear that such disclosure will result in enhanced expectations of quality and an attendant greater propensity for patients to bring malpractice lawsuits. That fear, too, is largely off the mark but still serves as an impediment to broader use of mistake-proofing measures.

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24 See infra text accompanying notes 94-101, 203-07.
25 See infra note 95; infra text accompanying notes 203-07.
26 GROUT, supra note 16, at 17.
27 See infra text accompanying notes 151-75.
29 See infra text accompanying notes 151-75, 181-82.
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. Section II examines the nature, frequency, and severity of medical errors and provides background on the legal treatment extended to them. Section III focuses on the causes of medical errors. In Section IV, the article discusses mistake-proofing approaches and principles and outlines particular applications to healthcare.

Section V examines impediments to the use of mistake-proofing techniques in healthcare. As preliminarily noted above and as will be addressed in more depth in Section V, some of these impediments stem from a misunderstanding among healthcare providers about whether taking mistake-proofing steps would somehow be damaging to their interests and positions in litigation over alleged medical errors. In Section VI, the 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 any medical error was committed.\textsuperscript{30} What, then, is a medical error, and when does it furnish the basis for legal liability?

\textit{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 . . . .”\textsuperscript{31} Liability may be imposed on the HCP (or HCPs) when the error caused the patient to experience a harmful outcome.\textsuperscript{32} The immediately preceding statements regarding actionable medical errors contemplate the controlling effect of negligence principles, which govern most instances of liability in the healthcare arena and many instances of liability in other professional or business-oriented contexts.\textsuperscript{33}

A. \textit{Negligence and the Reasonable Care Focus}

\begin{itemize}
\item\textsuperscript{30} \textit{E.g.}, \textsc{Kenneth R. Wing, Law and the Public’s Health} 291-92 (6\textsuperscript{th} ed. 2003). Although medical errors are a leading cause of adverse events, a bad outcome for a patient may result even when no error occurred. \textit{Id}. The flipside is also true—i.e., not all medical errors result in harm to the patient.
\item\textsuperscript{31} Albert W. Wu et al., \textit{To Tell the Truth: Ethical and Practical Issues in Disclosing Medical Mistakes to Patients}, 12 J. Gen. Internal Med. 770, 775 (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.” \textsc{John D. Banja, Medical Errors and Medical Narcissism} 3, 6 (2005).
\item\textsuperscript{32} \textit{E.g.}, \textit{Wing, supra} note 30, at 291-92; \textsc{J. Stuart Showalter, The Law of Healthcare Administration} 40-41 (4\textsuperscript{th} ed. 2004). 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 \textit{preventable} adverse events.
\item\textsuperscript{33} \textit{See Showalter, supra} note 32, at 39-77; \textsc{Restatement (Second) of Torts} § 299A & cmts. a-c (1977) [hereinafter \textsc{Restatement (Second)}].
\end{itemize}
Negligence cases center 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.\[^{34}\] 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. 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.\[^{35}\] 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.\[^{36}\]

The basic negligence principles outlined in the preceding paragraph receive application in a very broad range of settings. The myriad potential applications of negligence principles\[^{37}\] 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 have adopted.\[^{38}\] Similarly, negligence liability may follow if a manufacturer utilized a production process that a

\[^{34}\] Restatement (Second), supra note 33, §§ 281, 282, 283, 284, 289A, 298, 299, 328A, 328B.

\[^{35}\] Id. §§ 282, 283, 284, 299A.

\[^{36}\] Id. §§ 281, 282, 283, 328A, 328B.

\[^{37}\] 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.

\[^{38}\] See id., §§ 298 cmt. b, 299 & cmt. e, 299A & cmts. a-e, 300 & cmt. c; Restatement (Third) of Torts: Product Liability §§ 1 cmt. a, 2(b)-(c) cmts. a, b (1997) [hereinafter Restatement (Third)].
reasonable manufacturer would not have employed, and the process led to an injury-causing product defect.  

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 healthcare provider (HCP) or when an aggrieved client sues an attorney, negligence is the legal theory that nearly always controls the case. In the healthcare context, the key questions are whether the HCP acted as a reasonable HCP 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. 

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 have adopted. 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

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39 See RESTATEMENT (SECOND), supra note 32, §§ 298 cmt. b, 299 & cmt. e, 299A & cmts. a-e, 300 & cmt. c; RESTATEMENT (THIRD), supra note 38, § 1 cmt. a.


41 The previously noted definition of medical error, see supra text accompanying note 31, 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. Wu et al., supra note 31, at 775; Hill, Langvardt, & Massey, supra note 2, at 165.

42 Hill, Langvardt, & Massey, supra note 2, at 165-68.

43 E.g., SHOWALTER, supra note 32, at 40-43.
diagnosis. 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. So might the nurse who failed to pick up on obvious signs of patient distress even though a reasonable nurse would have noted such signs and reacted accordingly. Of course, individual HCPs other than doctors and nurses may be at risk of negligence liability under the same principles just outlined if they cause harm to patients through actions or inactions that fall below the due care standard appropriate to their position.

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. After all, the HCPs may have provided the nature and type of treatment that was reasonable under the circumstances. In such a situation, there was no breach of duty and thus no basis for negligence liability, the bad outcome notwithstanding.

B. Imputed Liability and Direct Liability

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44 E.g., Jones v. Speed, 577 A.2d 64, 65 (Md. 1990).

45 See James Walker Smith, Hospital Liability §§ 4.04[1], 10.05[1][a], 11.02[2], [3], 11.04[1] (rev. ed. 2005).

46 See id. § 11.02[2], [3].

47 WING, supra note 30, at 291-92. 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 50-57.

48 See WING, supra note 30, at 291-92.

49 Id. See Restatement (Second), supra note 33, §§ 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.
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. Either of two grounds--and sometimes both grounds--may come into play: 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; and direct liability, under which the organizational HCP is held liable for its own failure to use reasonable care.

Consider, for instance, the previously noted examples of negligence on the part of a nurse in caring for a patient. Assuming that the nurse was the 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. 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.

50 SMITH, supra note 45, §§ 3.01, 3.02. The same rule applies with regard to employers generally. RESTATEMENT (THIRD) OF AGENCY § 2.04 (2006).
51 Hill, Langvardt, & Massey, supra note 2, at 166 & n.40.
52 SMITH, supra note 45, §§ 3.01, 3.02. 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, because nurses are typically employees whereas physicians usually are independent contractors even though they have 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.
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. If a reasonable hospital would have adopted a different procedure that would have substantially reduced the risk of harm to patients, the hospital is likely to be held directly liable for negligence. 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.

The above discussion suggests two important and often related characteristics of many instances of negligence liability in 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. To take an example of an egregious error, consider the surgeon who amputates the patient’s right leg when the amputation was to have been of the left leg. 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 leg

54 See SMITH, supra note 45, § 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). Id.; SHOWALTER, supra note 32, at 129. 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 SMITH, supra note 45, §§ 3.01, 3.02, 3.03[1].

55 See SMITH, supra note 45, § 3.03[1]; SHOWALTER, supra note 32, at 129.

56 See infra text accompanying notes 138-47.
amputated would be the correct one. In that sense, the medical mistake was a group error. Depending on the facts, it may also have been a system error. If, for instance, the hospital where the surgery was performed did not have in place a simple policy requiring clear pre-surgery marking of the body part or area to be operated on (or some other policy setting up appropriate safeguards), we can add to the mix a system error that would make the hospital directly liable in addition to individual HCPs who were negligent.  

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. But HCPs have not adopted such processes on as widespread a basis as might be expected. Later sections 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 section 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 intertwined considerations are notable. First, most errors are

57 See SMITH, supra note 45, §§ 3.01, 3.02, 3.03[1]; SHOWALTER, supra note 32, at 129. See also supra notes 52, 54 (discussing respondeat superior liability and direct liability for corporate negligence).

58 See infra text accompanying notes 126-37.
multi-factorial and often involve both cognitive/knowledge and system/process failures.\textsuperscript{59} 

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. These considerations lead to variability in the quality of delivery.\textsuperscript{60} Third, medicine involves both art and science and requires subjective judgment, especially in the art component. Given that subjectivity, the predominant culture influences both behaviors and outcomes.\textsuperscript{61} Underlying medical culture is a host of behavioral issues that contribute to medical errors through various psychological and epistemological influences.\textsuperscript{62} 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 attended by defenses against failure. After “repeated experiences with failure . . . [,] system designers and operators [usually] implement layers of defenses or redundancy so that an error will be intercepted and its trajectory halted” before harm results.\textsuperscript{63} Nonetheless, no matter how well-designed processes are, some latent errors will still occur.\textsuperscript{64} A key question that surfaces is whether the error was

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\textsuperscript{59} Gordon Schiff, Presentation, Understanding Diagnostic Errors, Harvard Seminar Nov. 2008, \textit{supra} note 18 (notes on file with authors).

\textsuperscript{60} GROUT, \textit{supra} note 16, at 19.

\textsuperscript{61} RICHMOND \\ & FEIN, \textit{supra} note 8, at 69.

\textsuperscript{62} BANJA, \textit{supra} note 31, at 16.

\textsuperscript{63} \textit{Id.} at 11.

\textsuperscript{64} Weingart, \textit{supra} note 32.
\end{flushleft}
systemic or, instead, one person failing in some essential respect (“single-point failure”). In the healthcare context, such 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. 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 providing care. 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. They also may come from different disciplines and educational backgrounds. 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. It may also be haphazard. For example, physicians frequently do not have a good grasp of how hospitals function.

At a more macro level, the focus of many hospitals has not been upon error prevention. One hospital chief executive officer reportedly stated that patient safety was not “on his radar

65 BANJA, supra note 31, at 12.
67 See id.
68 Leape, supra note 18. 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 32 (floor comment during presentation).
screen” and described his job as “feeding the beast” (i.e., generating revenues). 69 Noting this lack of focus on error prevention and reduction, a study that gave rise to a New England Journal of Medicine article revealed that an estimated 3.7 percent of patients admitted to hospitals experience an adverse event, 70 that 27.6 percent of these adverse events result from negligence, and that in approximately 25 percent of the negligently caused adverse events, the patient dies. 71 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 substandard care.” 72 Further, the problem of patient safety outside the hospital setting is said to be as great as inside hospitals. 73

B. Medical Error and Behavioral Underpinnings

No discussion of the nature of medical error would be complete without some recognition of its behavioral underpinnings. 74 In examining the physiology 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. Skilled-based performance involves often-unconscious, rapid, and sometimes-effortless responses to demands. Rule-based performance involves the

69 Weingart, supra note 32.


71 Id.

72 Id. at 370.


74 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, 193-204 (2004).
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.\textsuperscript{75}

Skill-based errors generally fall within the category of what might be termed \textit{slips}. 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), and loss of activation (actor forgets purpose of the behavior).\textsuperscript{76} Rule- and knowledge-based errors are often termed \textit{mistakes}. Rule-based errors occur when the wrong rule is applied. 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

\textsuperscript{75} See \textit{id}.

\textsuperscript{76} Weingart, \textit{supra} note 32. See Human Factors MD, The Psychology of Error, http://www.humanfactorsmd.com/hfandmedicine_reducerror_nature.html. The latter source offers this explanation:

Slips and lapses are errors in the performance of skill-based behaviors, typically when our attention is diverted. A common mechanism for a slip is "capture," in which a more frequently performed behavior "takes over" a similar, but less familiar one. For example, a capture error is made 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. Description errors are slips that occur when the objects of different actions are close together or visually similar, as when the wrong control on an EKG is adjusted because it's close to other controls that look the same. Loss of activation errors are lapses where the goal is forgotten in the middle of a sequence of actions (e.g., a radiologists forgetting what he is looking for after retrieving and displaying a comparison study), or we omit a step in a routine sequence (e.g., the failure to complete a "double-check" for blood-type in an organ transfer protocol).

\textit{Id}.
(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). 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. Evidence indicates that between 8 and 15
percent of providers are impaired in one or more of the senses just noted (a figure similar to what
would be found in the general population). Substance abuse problems and behavioral
disorders 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 then
eventual harm to the patient, as well as to severe compromising of the affected HCP’s ability to
exercise sound medical judgment. Disruptive behaviors can adversely affect morale and create

77 Weingart, supra note 32; Human Factors MD, supra note 76.

(notes on file with authors).

79 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.

80 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, Presentation, Fatigue and Error: Achieving Evidence-Based
workplace frictions. 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 that may have been adopted.\(^8^1\)

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. Such breaches often occur because failures to comply with safeguards go undetected for extended periods of time. 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.\(^8^2\) The causes of such normalization of corrupted practices are found in the phenomena of socialization,

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\(^8^1\) Bush, supra note 78.

\(^8^2\) John Banja, The Normalization of Deviance in Health Care Delivery, 53 BUS. HORIZONS 139, 139-40, 141 (2010).
institutionalization, and rationalization. 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. Institutionalization exposes newcomers to deviant behaviors, often performed by authority figures. 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.\(^83\)

\(^83\) Id. at 141. 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

the 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.
Earlier discussion noted that negligence liability may be imposed when a medical error resulted from a failure to use reasonable care.\(^8^4\) Despite this prospect of liability, the tort system has not had the effect of coercing 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 acceptance of the notion that compliance rules should apply to physicians. Long recognized as the most dominant players in care delivery,\(^8^5\) physicians are also very much in a position to dominate the culture of care delivery. This power, if coupled with a narcissism tendency, may lead to feelings of arrogance and being “special.”\(^8^6\)

In addition, physicians are trained in a culture in which disclosure of errors--even to peers--is regarded as an indication of weakness. This makes admission of errors difficult.\(^8^7\) Physicians are naturally inclined to import their feelings and proclivities into practice settings. 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. He saw the same tendencies, beliefs, and behaviors in other physicians.\(^8^8\) Given the gravity and high stakes often associated with the healthcare setting,

\(^8^4\) See supra text accompanying notes 34-49.


\(^8^6\) BANJA, supra note 31, at 50.

\(^8^7\) Id. at 29.

\(^8^8\) Id. at 54.
rationalizing and not acknowledging their mistakes may offer physicians a relief from the angst that error disclosure could create.\textsuperscript{89} 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.

Although 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, concern about potential liability has prompted 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.\textsuperscript{90} Defensive medicine has been estimated to cause, on a national basis, $70 billion per year in unnecessary treatment costs.\textsuperscript{91} 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’

\textsuperscript{89} Id. at 47.


\textsuperscript{91} MASSACHUSETTS MEDICAL SOCIETY, \textit{INVESTIGATION OF DEFENSIVE MEDICINE IN MASSACHUSETTS} 1 (2008).
overestimation of their chances of being sued, let alone being held liable.\textsuperscript{92} 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.\textsuperscript{93}

The failure of medicine to make substantial progress in reducing medical errors across most of its disciplines\textsuperscript{94} can also 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.\textsuperscript{95} More than half of the states require reporting of medical errors.\textsuperscript{96}

\textsuperscript{92} See infra text accompanying notes 181-82.

\textsuperscript{93} See infra text accompanying notes 183-85.

\textsuperscript{94} However, anesthesiology serves as an example of mistake-proofing being applied in a medical discipline with great success. See Hyman & Silver, supra note 90, at 895, 899, 927. Anesthesia safety improved significantly after a professional body promulgated patient monitoring guidelines and anesthesiologists implemented them. As a further result, anesthesiologists’ insurance premiums remained relatively flat (unlike those of other specialties). Id. 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 1-3. 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 90, at 991.

\textsuperscript{95} 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 to develop a “national strategy to improve the delivery of health care services, patient health outcomes, and population health.” 42 U.S.C. § 280j (2012). 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 Agency for Healthcare Research and Quality, Advancing
but meaningful reduction in the number of errors remains an elusive goal.\textsuperscript{97} The usefulness of the information obtained through the state error-reporting systems that do exist is impaired by chronic under-reporting of errors.\textsuperscript{98} Moreover, there is no comprehensive national system of

Excellence in Healthcare, http://www.ahrq.gov/. \textit{See also, e.g., AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, NATIONAL HEALTHCARE QUALITY REPORT 2011, http://www.ahrq.gov/quality/nhqr11/hrqr11.pdf. (example of an annual report issued by AHRQ); GROUT, supra note 16 (example of an AHRQ-sponsored report regarding useful safety measures); Agency for Healthcare Research and Quality, AHRQ Innovations Exchange, http://www.innovations.ahrq.gov/ (example of AHRQ-provided tips for improving healthcare quality). The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §§ 299b-21 \textit{et seq.} (2012), calls for an AHRQ-administered process by which public or private organizations may choose to form patient safety organizations (PSOs). \textit{Id.} §§ 299b-21, 299b-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. \textit{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. \textit{Id.} §§ 299b-23, 299b-24. \textit{See generally} Patient Safety and Quality Improvement, 42 C.F.R. Part 3 (2009) (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.

\textsuperscript{96} \textit{National Survey, supra} note 5, at 207, 213. For discussion of such statutes, their similarities, and their differences, see \textit{id.} at 213-22. Details of the state error-reporting systems are beyond the scope of this article.

\textsuperscript{97} \textit{See id.} at 202, 206-07.

\textsuperscript{98} \textit{Id.} at 213, 214. 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. \textit{Id.} at 215-19.
mandatory error-reporting.\textsuperscript{99} despite recommendations by the IOM and commentators that such a system be adopted.\textsuperscript{100} It therefore becomes difficult to track progress in error reduction even if such progress is being made.\textsuperscript{101}

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.

\textbf{IV. Mistake-Proofing: Attributes and Applications to Healthcare}

Citing examples of “normalized-deviance” situations in which seemingly innocuous process failures and mistakes become commonplace, some commentators advise erecting as

\textsuperscript{99} As noted earlier, federal law generally contemplates a voluntary reporting regime. \textit{See supra} note 95. 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. \textit{See} CTRS. FOR MEDICARE \& MEDICAID SERVS., FISCAL YEAR 2009 QUALITY MEASURE REPORTING FOR 2010 PAYMENT UPDATE, http://www.cms.hhs.gov/HospitalQualityInits/Downloads/HospitalRHQDAPU200808.pdf. [hereinafter QUALITY MEASURE REPORTING].

\textsuperscript{100} IOM, \textit{TO ERR IS HUMAN}, \textit{supra} note 4, at 86-87. See, e.g., Lucian L. Leape & Donald M. Berwick, \textit{Five Years After} To Err Is Human: \textit{What Have We Learned?}, 293 JAMA 2384, 2834 (2005).

\textsuperscript{101} CONSUMERS UNION, \textit{supra} note 22, at 6-8.
many barriers as possible to errors. 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. Such organizations have been called “slow learners, slow improvers, slow innovators, and ultimately sluggish competitors.”

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.

In healthcare, this means changing the design of care delivery. The IOM has stated that "[h]ealthcare has safety and quality problems because it relies on outmoded systems of work.

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

103 Id.

104 Lindsay Chappell, The Pokayoke Solution, 5 AUTOMOTIVE NEWS INSIGHTS, Aug. 5, 1996, at 24i. 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 Errors, AERO MAG., July 1998, http://www.boeing.com/commercial/aeromagazine/aero_03/textonly/m01txt.html. 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, Presentation, Root Cause and Failure Mode/Effects Analysis, Harvard Seminar Nov. 2008, supra note 18 (notes on file with authors).
Poor designs set the work force up to fail regardless of how hard they try. If we want safer, higher quality health care, we need to redesign systems of care.”105 Both the United States and United Kingdom governments have called for improving the safety of healthcare through changing the physical design of hospitals and other similar healthcare facilities.106

Redesigning care systems promises to be no small task, however, especially considering that design changes in physical environments are relatively infrequent. Redesign, after all, is usually not a consideration in environments saturated with designed objects.107 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.108 Mistake-proofing furnishes a systems design framework that

105 INSTITUTE OF MEDICINE, 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 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.


107 See Berwick, supra note 105, at 251.

meets these criteria. Often referred to as “error-proofing,”¹⁰⁹ “poka-yoke,”¹¹⁰ and “fail-safing,”¹¹¹ 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.¹¹²

A. A Typology of Approaches

As a starting point for understanding the potential for mistake-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.¹¹³

Mistake prevention in the work environment involves making design changes that stop activities if an error is in process.¹¹⁴ Such prevention reduces complexity, ambiguity, vagueness,

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¹¹⁴ Shingo, supra note 110, at 99.
and uncertainty. 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. Humans normally perform moderately wide and deep tasks reasonably well, but the likelihood of mistakes increases as task width and depth increases.115 Similarly, visual systems, also known as 5 Seiri (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.116

Mistake detection identifies process errors found by inspection after actions have been taken. Although 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. 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. Other mistake-detection techniques include successive checks, inspections of previous steps when a mistake is found at a subsequent step,

115 Grout, supra note 16, at 5-6.

116 Gwendolyn D. Galsworth, Visual Systems: Harnessing the Power of a Visual Workplace 14 (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. Consider some examples of visual systems. Glidden EZ Tracks ceiling paint is pink when wet but dries white. Since painting a ceiling almost always involves painting over old white paint, the pink color makes obtaining uniform coverage easier and prevents mistakes. Dipstick handles on Toyota vehicles have distinctive shapes and colors, with the oil dipstick being a yellow, circular shape and the transmission dipstick an orange “T” shape. See id.
and self-checks that allow process participants to assess the quality of their own work.\(^{117}\)

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

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 table saw use. Fifteen percent of these instances resulted in amputations and related costs of approximately $2.13 billion.\(^{118}\) An important mistake-proofing device is featured on SawStop\textsuperscript{TM} 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. The voltage drops when flesh contacts the blade, causing an aluminum brake to be deployed. This stops the blade within five milliseconds. The

\(^{117}\) GROUT, supra note 16, at 5-6. Consider the example of Applied Bolting Technology’s direct-tension-indicating washers. These washers are used to detect when bolts have been torqued to the correct tension. Each washer has small indentations that are filled with orange polymer. As the bolt is tightened, the indentations are flattened, squeezing the polymer to the edge of the washer. Properly tightened washers have a distinctive pattern of orange polymer around them. Visual inspection of the tightness can easily be accomplished. More importantly, since the tightness criterion is apparent, workers continue to tighten the bolt until proper tightness is achieved. This makes defects and rework very unlikely.

safety device mounted on a table saw that is of high quality on other respects has allowed the SawStop™ saw to become the market’s best-seller despite a several hundred dollar price premium.  

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. Facilitating correction is accomplished through planned responses when mistakes occur in a manner analogous to auto-correct functions used in computers. Decoupling involves separately error-prone activities at points where errors become irreversible. An example is the deletion of email messages that can be later retrieved if needed.

Both mistake prevention and mistake detection require what are known as setting and control functions. Setting functions differentiate between safe and unsafe conditions; therefore, they are the mechanisms for determining that an error has occurred or is about to occur. The more precise the setting functions, the more extensive mistake-proofing can be. Once a setting function determines that an error has occurred or is imminent, a control function signals the error.

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121 Id. at 8-9. 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. Control and regulatory functions are also of four types: (1) forced--physical size and shape or electronic controls detect and
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.”\textsuperscript{122} 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. These signs were to be moved by the user upon entering and leaving the facility. Berwick found the sign in the correct position 61 percent of the time, with the most prevalent error being the sign indicating “occupied” when the restroom was actually vacant. The result was that ignoring the sign often led to better outcomes than acting based on what the sign actually indicated. In an effort to solve this problem, he placed on the door a handwritten sign that stated “Please flip the sign.” After that sign was ignored, he placed on the door an additional sign stating “Please read the sign (below) about flipping the sign.” That effort, too, failed. Signs that relied upon humans to remember to change their signal simply did not work. The replacement tool Berwick proposed was an automatic vacant/occupied sign of the sort used in aircraft lavatories to provide an extremely accurate indication of restroom status.\textsuperscript{123} This proposed replacement tool was an

\textsuperscript{122} Donald M. Berwick, President, Institute for Healthcare Improvement, Escape Fire: Designs for the Future of Health Care, Plenary Address, Institute for Healthcare Improvement, 11\textsuperscript{th} Annual National Forum on Quality Improvement in Health Care (Dec. 9, 1999), in DONALD M. BERWICK, ESCAPE FIRE: DESIGNS FOR THE FUTURE OF HEALTH CARE 34-35 (2002).

\textsuperscript{123} Id. at 35-37.
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.\textsuperscript{124}

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.”\textsuperscript{125} 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\textsuperscript{126} in comparison with the extraordinary human and financial cost associated with medical errors.\textsuperscript{127} It can therefore result in substantial returns on investment when applied to healthcare.\textsuperscript{128} 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.\textsuperscript{129} Nonetheless, one can obtain a sense

\begin{footnotes}
\item[124] Id. at 37. See GROUT, supra note 16, at 8-9.
\item[125] ROBERT CHALICE, STOP RISING HEALTHCARE COSTS USING THE TOYOTA LEAN PRODUCTION METHODS 25 (2d ed. 2005).
\item[126] GROUT, supra note 16, at 14.
\item[128] GROUT, supra note 16, at 15-16.
\end{footnotes}
of mistake-proofing’s potential by examining some success stories using Tsuda’s typology in simplified healthcare settings before turning to more complex systems.\textsuperscript{130}

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. The pole is equipped with colored lights to illuminate each bag in semi-dark rooms. 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.\textsuperscript{131}

Hand hygiene is a critical factor in reducing the large numbers of nosocomial infections.\textsuperscript{132} One hundred percent compliance with hand hygiene is very difficult to achieve.\textsuperscript{133}

\textit{See infra} text accompanying notes 131-46. For discussion of a more extensive set of examples, see GROUT, supra note 16, at 117-46.

\textsuperscript{130} See Tsuda, supra note 113, at 80.

\textsuperscript{131} Vitaid, IV Illuminators, http://www.vitaid.com/usa/embo-optics/faq.htm. 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. Product Directory, SURGICAL PRODS. MAG. June 1, 2008, http://www.surgicalproductsmag.com/Scripts/ShowPR-PUBCODE-OSO-ACCT-0000100-0608-RELTYPE-PR-PRODCODE-1070-PRODLETT-A.asp.

\textsuperscript{132} Hygreen: The Intelligent Hand Hygiene System, http://www.xhale.com/hygreen/index.asp. Infections acquired in hospitals take the lives of 25 patients per day at a cost of $30 billion. \textit{Id.}
In an example of mistake detection, Xhale Corporation has developed a high technology monitoring system to detect mistakes in hand hygiene. The system utilizes a device that senses hand-washing by individual healthcare workers, who are identified by an electronic badge they wear. The date, time, and location of the hand-washing are recorded in a centralized database and a green light on the badge is illuminated. 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. The green light turns off after coming in proximity with the bed’s sensor. Xhale’s website listed a system cost of $250,000 for a 100-bed hospital but estimated the payback period to be less than a year.\textsuperscript{134}

More than 100,000 wheelchair-related injuries are treated annually,\textsuperscript{135} with 167 deaths being recorded during the period from 1997 through 1999. Many of these injuries occur when patients are entering or leaving the wheelchair. 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. A hand release allows an attendant to move unoccupied wheelchairs.\textsuperscript{136}


\textsuperscript{134} Hygreen: The Intelligent Hand Hygiene System, supra note 132.


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. In an example of preventing the influence of mistakes, non-toxic materials are now substituted for the mercury.  

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.  

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. 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.

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138 Kim, supra note 104. See GROUT, supra note 16, at 26-35.

139 Kim, supra note 104. See GROUT, supra note 16, at 26-35.
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.\footnote{Kim, supra note 104. See GROUT, supra note 16, at 26-35.}

Consider, for example, the process of prescribing medicine for patients. This deceptively simple process too often results in prescription errors, which are costly occurrences.\footnote{See Lauran Neergaard, Report Finds Drug Errors Hurt 1.5 Million, Associated Press, Jul. 20, 2006, http://abcnews.go.com/Health/wireStory?id=2216059. It has been estimated that “a preventable drug error can add more than $5,800 to the hospital bill of a single patient. Assuming 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.” Id.} One hospital 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.\footnote{Interview with C. Lynne Rover-Willoughby, Director of Medical Informatics, Community Health Network, in Indianapolis, IN (Oct. 19, 2004).} 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.\textsuperscript{143}

Computer-assisted prescribing furnishes a partial answer to the problem of medication error. Such prescribing has been estimated to result in a 50 percent or greater reduction in errors.\textsuperscript{144} The imposition of information technology on flawed processes, however, has been analogized to paving over cart paths.\textsuperscript{145} 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.\textsuperscript{146} In the medication-error example, mistake-proofing might involve the

\textsuperscript{143} Kim, supra note 104.

\textsuperscript{144} CONSUMERS UNION, supra note 22, at 6.

\textsuperscript{145} Interview with Ronald W. Dollens, former President and CEO, Guidant Corp., and past Chairman, Healthcare Leadership Council, in Bloomington, IN (Feb. 1, 2006). See Naresh Khatri et al., Medical Errors and Quality of Care, 48 CAL. MGMT. REV. 115, 134-135 (2006).

\textsuperscript{146} Kim, supra note 104. Evanston Northwestern Healthcare executives report that implementation of its EMR system led its hospitals to engage in a streamlining of healthcare processes, with substantial savings in time and money resulting from process improvements considered 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, National Committee for Quality Healthcare), Jeffrey H. Hillebrand (Chief Operating Officer, Evanston Northwestern Healthcare), Thomas H. Hodges (Chief Financial Officer, Evanston Northwestern Healthcare), Joseph Golbus (President, ENH Medical Group), Peggy King (Senior Vice President, Quality and Risk Management, Evanston Northwestern Healthcare), and Dr. Ned Wagner (Medical Director of Medical Informatics, Evanston Northwestern Healthcare), in Evanston, IL (April 19, 2006).
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,\textsuperscript{147} one might expect HCPs to wholeheartedly embrace mistake-proofing because of its low cost and reliance upon fail-safe techniques. Despite mistake-proofing’s potential to enhance healthcare quality in a relatively inexpensive fashion\textsuperscript{148} and despite the identification of many specific mistake-proofing processes of a beneficial nature,\textsuperscript{149} 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.\textsuperscript{150} So why would HCPs resist implementation of mistake-proofing processes? A key reason appears to be the same one

\textsuperscript{147} See supra text accompanying notes 59-89.

\textsuperscript{148} See GROUT, supra note 16, at 14-16.

\textsuperscript{149} See id. at 117-46.

\textsuperscript{150} See supra text accompanying notes 126-27.
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. 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. This evidentiary rule is usually referred to as the “subsequent remedial measures” rule because it is so titled. 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. For diversity jurisdiction to exist, the plaintiff and the defendant(s) must be from different states and the amount in

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151 The concern is that “[i]n claiming the ‘after,’ one must own up to the ‘before.’” GROUT, supra note 16, 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).

152 FED. R. EVID. 407.

153 Id. See, e.g., C. Paul Carver, Subsequent Remedial Measures 2000 and Beyond, 27 WM. MITCHELL L. REV. 583, 584 (2000).

controversy—the damages sought by the plaintiff—must be at least $75,000.\textsuperscript{155} 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 many of them are,\textsuperscript{156} state rules that match or closely resemble FRE 407 normally will apply.\textsuperscript{157}

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.\textsuperscript{158}


\textsuperscript{156} See Showalter, supra note 32, at 39-77; Wing, supra note 30, at 287-92.

\textsuperscript{157} See Carver, supra note 153, at 584, 587-88, 589; 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); Chris Guthrie, Misjudging, 7 Nev. L.J. 420, 422 (2007);

\textsuperscript{158} Fed. R. Evid. 407. This version of the rule took effect in December 2011. Id. (Legislative History Links). The version in effect from 1997 to December 2011 read as follows:
An evidentiary rule of similar content and effect exists in most states. 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 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. 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

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 results in any ruling on evidence admissibility.” Id.

See Carver, supra note 153, at 584, 587-88, 589; Henderson, supra note 157, at 4; Guthrie, supra note 157, at 422. Details of the respective state rules are beyond the scope of this article.

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.\textsuperscript{161}

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.\textsuperscript{162} 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.\textsuperscript{163}

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.\textsuperscript{164} Among HCPs, however, insufficient awareness that the subsequent remedial measures rules may

\textsuperscript{161} Hoffman & Zuckerman, supra note 160, at 508. See Henderson, supra note 157, at 5-6; Carver, supra note 153, at 610; Guthrie, supra note 157, at 423.

\textsuperscript{162} See Hoffman & Zuckerman, supra note 160, at 508; Carver, supra note 153, at 610; Guthrie, supra note 157, at 423.

\textsuperscript{163} See Hoffman & Zuckerman, supra note 160, at 508-09; Carver, supra note 153, at 610-11.

\textsuperscript{164} See Hoffman & Zuckerman, supra note 160, at 508-09; Carver, supra note 153, at 610-11.
be applied to their activities could help explain why the adoption of mistake-proofing techniques has not been more widespread in the healthcare field.\textsuperscript{165}

B. \textit{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.\textsuperscript{166} 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.”\textsuperscript{167} 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

\textsuperscript{165} See GROUT, \textit{supra} note 16, at 17.

\textsuperscript{166} See Henderson, \textit{supra} note 157, at 1-2, 3-6; Guthrie, \textit{supra} note 157, at 422-23. \textit{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. \textit{See} Carver, \textit{supra} note 153, 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. \textit{See id.} at 587-91; Henderson, \textit{supra} note 157, at 3-20. Further exploration of the latter set of issues is beyond the scope of this article.

\textsuperscript{167} FED. R. EVID. 407.
“negligence [or] culpable conduct” on the part of the defendant. 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. Subsequent remedial measures rules among the states are to the same general effect. Because 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.

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 where 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.

168 Id.
169 See id.
170 See Henderson, supra note 157, at 1-2, 3-6; Guthrie, supra note 157, at 422-23.
171 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 157, at 1-2, 3-6 (noting application of federal and state rules in negligence cases).
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, 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.” 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. Absent such opening of the door, the defendant’s mere adoption of the safety measure is not enough to justify admission of evidence thereof.

VI. Mistake-Proofing and Error Reduction: What to Do?

172 See supra text accompanying notes 158-63, 166-71.

173 FED. R. EVID. 407.

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

175 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 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.
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.176 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.177 This is especially apt to be the case if the test for the improbable condition is also very expensive or physically onerous.

176 See *supra* text accompanying notes 40-49.

177 See *supra* text accompanying notes 40-49, 90-93.
for the patient. 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. 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 don’t 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 don’t 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 don’t take such defensive steps.

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 over-treating, the percentage of patients who take legal action over medical errors that harmed them has been shown to be as low as only 3 to 6 percent. Moreover, in the small percentage of instances

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178 See supra text accompanying notes 40-49.

179 See supra text accompanying notes 40-49.

180 See supra text accompanying notes 90-93.

when an error does result in litigation, plaintiffs win their cases only about 25 percent of the time. 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. 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 to 14 percent, it is clear that the vast majority of harmed patients do not file claims. Id. at 1227-28; Hyman & Silver, supra note 90, 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 90, at 476.

182 Sharkey, supra note 181, at 451-52; Vidmar, supra note 181, at 1232.

183 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, http://www.nytimes.com/2012/08/01/opinion/more-treatment-more-mistakes.html.
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.¹⁸⁴ 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, 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.¹⁸⁵

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.¹⁸⁶

¹⁸⁴ 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 40-49.

¹⁸⁵ See supra text accompanying notes 102-49.

¹⁸⁶ Again, a consideration in the reasonable care standard is what other HCPs are or are not doing. See supra text accompanying notes 40-49; supra note 41.
Wouldn’t the latter effect amount to a ratcheting-up of the reasonable care standard, and wouldn’t 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. 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 there is reliable evidence that it does— 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. 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

187 Hill, Langvardt, & Massey, supra note 2, at 165-68.
188 See supra text accompanying notes 102-49.
189 E.g., WING, supra note 30, at 291-92.
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.\textsuperscript{190}

\textbf{B. \textit{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 Federal Rule of Evidence 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.\textsuperscript{191} 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 establish negligence on the defendant’s part. Thus, if the plaintiff is to establish

\textsuperscript{190} See \textit{supra} text accompanying notes 113-49.

\textsuperscript{191} GROUT, \textit{supra} note 16, at 17. See \textit{supra} text accompanying notes 151, 160-61.
negligence, the plaintiff must do so on the basis of evidence other than the defendant’s later adoption of the safety measure.\(^{192}\)

The subsequent remedial 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.\(^{193}\) 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,\(^{194}\) 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.\(^{195}\) Such reports could

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\(^{193}\) Guthrie, *supra* note 157, at 423; Hoffman & Zuckerman, *supra* note 160, at 498. For further discussion of the subsequent remedial measures rules, see *supra* text accompanying notes 152-75.

\(^{194}\) For a discussion of the federal government’s patient safety efforts, see *supra* note 95.

\(^{195}\) *See* *supra* note 95.
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 federal 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 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

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196 See, e.g., sources cited supra note 1.
more on health outcomes than had been the case in the past.\textsuperscript{197} Reimbursement-related incentives for adopting mistake-proofing processes would 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 medications.\textsuperscript{198} 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.\textsuperscript{199}

D. \textit{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.\textsuperscript{200} Of course, we advocate adoption of those techniques.


\textsuperscript{199} \textit{See} 42 U.S.C. §§ 280g-12, 139jjj (2012); 42 C.F.R. 425.20.

\textsuperscript{200} \textit{See} supra text accompanying notes 125-49.
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.201 Electronic systems have been shown to be highly effective in reducing the numbers of medication errors.202 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 liability 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.203 Although roughly half of the states have medical error-reporting laws, with many of them ostensibly making reporting mandatory,204

201 See supra note 7; supra text accompanying notes 141-46. 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 112 (estimating that at least 1.5 million preventable medication errors occur each year).

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

203 See supra note 95.

204 See National Survey, supra note 5, at 207-10, 213-20.
chronic under-reporting appears to plague the state schemes.\textsuperscript{205} 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 28 “should never happen” errors—a list generally utilized in the present optional reporting systems.\textsuperscript{206} 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 patients’ names. Third, in order to encourage compliance with the reporting requirement, regulations must provide that in a harmed patient’s negligence (or

\textsuperscript{205} See supra note 98 & accompanying text.

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.\textsuperscript{207} 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. \textit{Convince 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.\textsuperscript{208} 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.\textsuperscript{209} The seemingly error-prone therefore end up paying premiums of the same amount paid by the non-error-prone.

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

\textsuperscript{207} Such features are present in the current optional reporting system, see \textit{supra} note 95, and should be continued.

\textsuperscript{208} Gunnar, \textit{supra} note 90, at 471.

\textsuperscript{209} \textit{Id.}; Hyman & Silver, \textit{supra} note 90, at 981-82.
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 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 process. 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.