

## Patient Safety

# What Does It Take? A Case Study of Radical Change Toward Patient Safety

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**H**uman factors engineering has been repeatedly proposed as key to improving patient safety.<sup>1,2</sup> For example, medical devices designed with insufficient attention to human needs and capabilities can lead to errors, increasing the likelihood of adverse events, whereas devices designed using human factors engineering techniques can reduce errors and improve patient safety.<sup>3-5</sup>

Although the potential contributions of human factors engineering to health care are compelling, adopting such an approach requires a radical behavioral shift from a “blame and shame” approach, which emphasizes added training to a systems approach that also emphasizes improved design.<sup>1,2,6</sup> These two world views are based on an equally deep desire to improve patient safety, but they differ markedly in terms of the primary interventions they suggest to achieve that aim. The importance of organizational change to patient safety has been well documented,<sup>7,8</sup> but there do not appear to be any longitudinal case studies investigating why and when organizations make this radical shift.

This article presents a case study of a medical device manufacturer that exhibited the traditional approach for years, but then, within a relatively short period, initiated a companywide transition to a human factors approach. By framing the findings of the case study within generalizable theories of organizational change, an understanding of the factors contributing to radical reform may help foster analogous changes in organizations within health care and elsewhere and thereby improve patient safety.

### Theory

According to *punctuated equilibrium theory*, organizations can experience long periods of resistance to

## Article-at-a-Glance

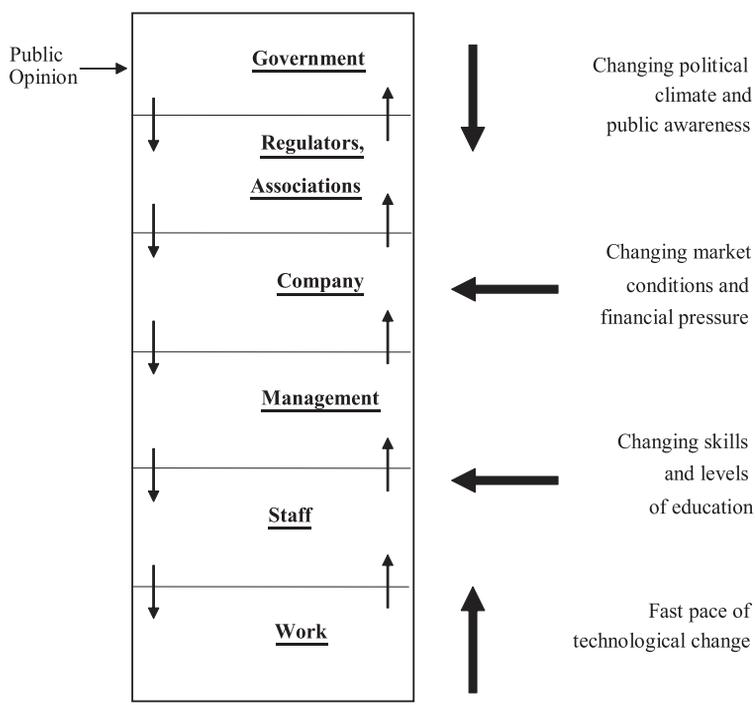
**Background:** Adopting a human factors engineering approach to patient safety requires a radical behavioral shift from “blame and shame,” which emphasizes further training, to systems thinking, which also emphasizes improved system design. A medical device manufacturer appeared to initiate this radical shift after exhibiting the traditional approach for years.

**Methodology:** The research focused on a patient-controlled analgesia device. A qualitative case study methodology was used to study events in the period from the device’s introduction (1988) until the start of the behavioral change (May 2001). Data on 50 relevant events were analyzed. The tabular summary was analyzed for evidence of the prerequisites predicted by punctuated equilibrium theory, and the graphical time line was analyzed for evidence of vertical alignment across levels.

**Results:** Radical behavioral change was preceded by a critical 9.5-month period with three characteristics: new corporate leadership, perceived poor corporate performance, and aligned disruptions occurring within a relatively short time at almost every level in the external environment in which the company operated.

**Discussion:** These findings are consistent with punctuated equilibrium theory, according to which organizations can experience long periods of resistance to change followed by fast revolutionary change (approximately two years). The findings also have implications for when and how to introduce patient safety policy interventions to “tilt the playing field” and thereby increase the likelihood that such reforms will succeed.

## Rasmussen's Framework for Risk Management



**Figure 1.** Various levels of a complex sociotechnical system are involved in risk management (work, staff, management, company, regulators and professional associations, government, and public opinion). These levels are subject to disruptive forces, shown by the arrows on the right, that stress the system as a whole. Adapted from Rasmussen J.: *Risk management in a dynamic society: A modelling problem*. *Safety Science* 27:183–213, Nov. 1997 and reprinted with permission from the BMJ Publishing Group from Vicente K.J.: *From patients to politicians: A cognitive engineering view of patient safety*. *Qual Saf Health Care* 11:302–304, Dec. 2002.

To assess this last precondition, a systematic framework for representing a company's external environment is useful. Rasmussen's framework for risk management, shown in Figure 1 (left), describes complex sociotechnical systems as a hierarchy of individuals and organizations.<sup>11</sup> (The number of levels and their labels can vary across industries.) Under this view, safety is an emergent property affected by the decisions of all—journalists, politicians, regulators, CEOs, and managers—not just front-line staff.<sup>12</sup> Thus, adverse events can be caused by a lack of vertical alignment (that is, mismatches) between a company and any of its surrounding levels.

Vertical alignment is becoming more important and yet more difficult to achieve. As shown on the right side of Figure 1, health care systems are increasingly subject to external stressors that are stronger and change more frequently than in the past. When various levels of the system are experiencing different pressures, a company should coordinate its actions with the dynamic constraints imposed by other levels to remain viable and competitive—an impetus for organizational change.

change followed by fast revolutionary change (approximately two years).<sup>9,10</sup> The long (and successful) periods of equilibrium “operate to maintain status quo, often in spite of clear dysfunctional consequences.”<sup>9(p. 180)</sup>

The theory postulates three preconditions for revolutionary change:

1. A new chief executive officer (CEO) facilitates radical shifts because new leaders do not have a vested interest in the old way of doing things
2. A severe crisis in perceived performance encourages a company to question and modify its modes of operation
3. Major environmental jolts “that dramatically alter the competitive and operating conditions of an environment”<sup>10(p. 1145)</sup> demand change for survival and success

## Methodology

A qualitative case study methodology was used to test the theoretical predictions just described. This particular case was chosen because it was rich in information and provided an opportunity to study a phenomenon that had never been investigated. The scope of investigation included a particular medical device, its manufacturer, and the manufacturer's external environment. Consequently, two interacting systems akin to the one shown in Figure 1 were relevant, one for device manufacturing and another for device usage. The analysis was used to investigate the top of the manufacturing system—public opinion, government, regulators and associations, and company (that is, the device manufacturer)—but not the company's lower management, staff, and work levels because detailed insider information was not available. Conversely, the analysis

**Table 1. Definitions of Levels Based on Rasmussen's Framework\* Used to Classify the Events Shown in Table 2 and Figure 2<sup>†</sup>**

1. **Work:** A change in the technology that health care providers use to deliver care
2. **Staff:** An erroneous or a correct decision or action made by a health care provider (e.g., nurse or physician) in the process of delivering care
3. **Company:** A decision, an action, or a policy made by the device manufacturer
4. **Regulators and Professional Associations:** A decision, an action, or a policy made by a government regulator (e.g., FDA) or by a nongovernmental professional association (e.g., AAMI, ECRI, ISMP)
5. **Government:** A decision, an action, or a policy made by a branch of the U.S. Federal Government (e.g., Congress, Department of Justice)
6. **Public Opinion:** The public dissemination of written information, in the form of a newspaper article, a scientific article, a report, or a book

\* Rasmussen J.: Risk management in a dynamic society: A modelling problem. *Safety Science* 27:183-213, Nov. 1997.

<sup>†</sup> FDA, U.S. Food and Drug Administration; AAMI, Association for the Advancement of Medical Instrumentation; ISMP, Institute for Safe Medication Practices.

was used to investigate the bottom of the device usage system—hospital staff and work—but not any of its higher levels because almost all the reported patient deaths do not name the hospital. Using these criteria, six categories of events, as identified in Table 1 (above), were adopted.

The researcher has never had a financial relationship with the manufacturer or any of its competitors but had some knowledge of the case, having authored a few relevant documents. Data were collected primarily during May 2000 through January 2003, from the scientific literature, the trade literature, the Internet, and an online education research system database, using two criteria: (1) the period from which the device was introduced (1988) until the corporate change was started (May 2001) and (2) the categories in Table 1.

As data were collected and classified, a (paper) case database was developed by creating a file for each category. Fifty events were identified, each classified into one category, and then assembled into a tabular summary and graphical time line. If an event could be classified

in multiple categories, preference was given to the most salient fit. A blind expert reviewer independently categorized all events, resulting in 94% agreement.

Data were analyzed using a double-pronged, theory-driven approach: The tabular summary was analyzed for evidence of the prerequisites predicted by punctuated equilibrium theory, and the graphical time line was analyzed for evidence of the vertical alignment predicted by Rasmussen's framework.

## Results

Table 2 (pages 601-603) summarizes the event sequence, and Figure 2 (page 604) illustrates these events as a time line. Some general constraints or trends do not have specific dates and thus are only described below in the relevant level.

### Work

Patient-controlled analgesia (PCA) pumps were developed to improve pain management for patients and reduce work load for nurses by using automation to help patients self-administer more frequent but smaller doses of analgesia.<sup>13</sup> A nurse programs the pump using a human-computer interface consisting of displays and a keypad. The parameters entered by the nurse govern how much analgesic is delivered. There is no way for the pump to verify independently if the settings are correct because it cannot sense the concentration or type of analgesic. Thus, a programming error can lead to an under- or overdelivery of analgesic. An overdelivery can lead to patient injury or death. The PCA pump investigated in this case study was introduced in 1988 (event 1 in Table 2).<sup>14</sup>

### Staff

Several drug-concentration programming errors in the use of this PCA pump have been associated with reported deaths, beginning in 1995 (events 6, 9, 14, 17, 24, and 31).<sup>15</sup> A recent epidemiological analysis (factoring in underreporting rates) conservatively estimated that the total number of deaths with this device which occurred solely from such errors may be between 65 and 667, with a known denominator of more than 22 million, leading to a mortality likelihood of 1 in 33,000 to 1 in 338,800.<sup>15</sup>

On June 11, 1997, an anonymous source submitted a voluntary report about this PCA pump to the U.S.

**Table 2. Chronology of Events, Classified According to Levels Defined in Table 1 (see Figure 2 for Time Line Illustration)\***

Event	Date	Level	Description
1	1988	Work	PCA pump introduced into marketplace
2	1988	Reg., Assoc.	ANSI/AAMI HE: 1988 human factors guidelines published
3	1985-89	Reg., Assoc.	FDA compiles data showing that 45% to 50% of all medical device recalls from 1985 to 1989 stemmed from poor product design
4	Nov. 28, 1990	Gov't.	Congress passes Safe Medical Devices Act
5	Sep. 1993	Reg., Assoc.	ANSI/AAMI HE: 1993 human factors guidelines published
6	Oct. 16, 1995	Staff	Reported death from concentration programming error
7	May 8, 1996	Reg., Assoc.	ISMP makes first mention of susceptibility to programming errors
8	Jun. 19, 1996	Company	Manufacturer agrees to make software change in upcoming year
9	Jul. 1, 1996	Staff	Reported death from concentration programming error
10	Oct. 9, 1996	Company	Manufacturer has yet to make promised changes
11	Dec. 18, 1996	Company	FDA publishes primer to explain human factors engineering to medical device manufacturers
12	Dec. 1996	Reg., Assoc.	Manufacturer creates warning labels to distinguish different concentrations and continues to investigate software changes
13	Mar. 11, 1997	Reg., Assoc.	FDA publishes design control guidance for medical device manufacturers
14	Mar. 25, 1997	Staff	Reported death from concentration programming error
15	Jun. 1, 1997	Reg., Assoc.	Revised FDA regulations (21 CFR 820.30), including implicit reference to human factors, become effective
16	Jun. 11, 1997	Staff	Voluntary report warning of potentially lethal safety threat due to programming errors
17	Sep. 1997	Reg., Assoc.	ECRI issues hazard report involving three deaths due to programming errors
18	Oct. 29, 1997	Company	Manufacturer sends Dear Clinician letter, implying that ECRI report is inaccurate and advocating training; no mention of redesign
19	May 1998	Public Opinion	Article published in <i>Journal of Clinical Monitoring and Computing</i> shows that human factors redesign leads to improved performance
20	May 29, 1998	Reg., Assoc.	FDA publishes guidance relating to premarket submissions for software contained in medical devices
21	Jun. 17, 1998	Reg., Assoc.	ISMP issues generic warning about safety problems with PCA pumps
22	Nov. 1998	Public Opinion	Letter to editor published in <i>Journal of the American Medical Association</i>
23	Jan. 1999	Company	Manufacturer led by new and more aggressive CEO and top management team
24	Jul. 28, 1999	Staff	Reported death from concentration programming error

*continued*

**Table 2. Chronology of Events, Classified According to Levels Defined in Table 1 (see Figure 2 for Time Line Illustration)\* (continued)**

Event	Date	Level	Description
25	Sep. 29, 1999	Company	Manufacturer states that it has been notified by government that it is not in compliance with FDA regulations and that it is negotiating a proposed consent decree
26	Oct. 5, 1999	Company	Manufacturer appoints new vice president of corporate regulatory and quality science
27	Oct. 7, 1999	Reg., Assoc.	FDA officials state that manufacturer's corporate culture must change
28	Oct. 9, 1999	Company	Manufacturer's CEO states that he is concentrating on changing corporate culture
29	Nov. 2, 1999	Gov't.	U.S. Department of Justice signs consent decree with manufacturer, who agrees to pay \$100,000,000 for repeated manufacturing problems with in-vitro diagnostic tests
30	Nov. 29, 1999	Public Opinion	IOM report released, with tremendous impact on public awareness of patient safety
31	Feb. 28, 2000	Staff	Death of 19-year-old Florida woman from concentration programming error
32	May 6, 2000	Public Opinion	<i>Tallahassee Democrat</i> reports on death (front page)
33	May 12, 2000	Public Opinion	<i>Tallahassee Democrat</i> reports hospital plans extra nurse training (front page)
34	May 25, 2000	Public Opinion	<i>Tallahassee Democrat</i> reports evidence in death missing (front page)
35	May 28, 2000	Public Opinion	<i>Tallahassee Democrat</i> publishes 2,611-word, front-page article, stating that death likely due to concentration programming error that may have been preventable
36	May 28, 2000	Public Opinion	Abbreviated version of same article appears in <i>New Orleans Times-Picayune</i>
37	May 28, 2000	Public Opinion	Abbreviated version of same article appears in <i>Orlando Sentinel</i>
38	May 28, 2000	Public Opinion	Abbreviated version of same article appears in <i>Ventura County Sunday Star</i>
39	May 29, 2000	Public Opinion	Abbreviated version of same article appears in <i>Denver Post</i>
40	May 31, 2000	Reg., Assoc.	ISMP reports on same death
41	Jun. 1, 2000	Public Opinion	<i>Tallahassee Democrat</i> publishes editorial, urging lawmakers to act
42	Jul. 12, 2000	Reg., Assoc.	ISMP publishes follow-up article on death with clarification
43	Jul. 18, 2000	Reg., Assoc.	FDA publishes guidance document to help manufacturers incorporate human factors engineering into medical device design process
44	Oct. 2000	Public Opinion	Article published in <i>Anesthesia Patient Safety Foundation (APSF) Newsletter</i> , summarizing reported deaths and human factors design issues
45	Oct. 2000	Company	Manufacturer responds in <i>APSF Newsletter</i> , stating that new device will be available in 2001

**Table 2. Chronology of Events, Classified According to Levels Defined in Table 1 (see Figure 2 for Time Line Illustration)\* (continued)**

Event	Date	Level	Description
46	Oct. 2000	Public Opinion	Human factors consultant responds in <i>APSF Newsletter</i> , taking side of manufacturer
47	Mar. 2001	Public Opinion	Rebuttal to manufacturer and human factors consultant published in <i>APSF Newsletter</i>
48	Mar. 6, 2001	Public Opinion	Letter to editor published in <i>Canadian Medical Association Journal (CMAJ)</i>
49	Mar. 6, 2001	Company	Manufacturer responds in <i>CMAJ</i>
50	May 1, 2001	Company	Manufacturer places job ad for program manager—human factors engineering, initiating corporatewide human factors initiative

\* PCA, patient-controlled analgesia; Reg., regulatory; Assoc., association; Gov't, government; ANSI, American National Standards Institute; AAMI, Association for the Advancement of Medical Instrumentation; FDA, U.S. Food and Drug Administration; ISMP, Institute for Safe Medication Practices; CEO, chief executive officer; IOM, Institute of Medicine.

Food and Drug Administration (FDA; event 16), stating the following:

Due to the way the pump programming is set up, it increases the risk of programming error. . . . Reporter's opinion is that [the manufacturer] should be required to change the pump programming options to prevent potentially fatal medication errors. . . . This problem has been forwarded to [the manufacturer] without any satisfactory resolution. Reporter is hoping that the FDA can require a change that can potentially prevent a fatality.<sup>16</sup>

Because of widespread cost-cutting and restructuring efforts, the practice of nursing underwent important changes during the 1990s.<sup>17,18</sup> First, the average age of the workforce increased (for example, in the United States, from 37.4 years in 1983 to 41.9 years in 1998).<sup>19,20</sup> Although older nurses have more experience, they may have a more negative attitude toward computers.<sup>21</sup> Second, there appears to be a trend toward greater use of part-time or contingent nurses, sometimes from temporary employment agencies.<sup>22</sup> For example, 45% of the nurses in Canada worked on a part-time basis in 2001.<sup>19</sup> Medical devices are frequently not standardized within or across hospitals, so temporary nurses may have little or no familiarity with the technology they encounter when working at each new hospital. Furthermore, because part-time nurses work fewer hours, they will have fewer on-the-job opportunities to use new devices than full-time nurses. Finally, a shortage of nurses began in the late 1990s and has expanded

such that the mean job vacancy rate for registered nurses (RNs) in hospitals in the United States was 13% in 2001.<sup>18</sup> Lower RN staffing levels have been linked with lower quality of care and increased patient mortality.<sup>23,24</sup>

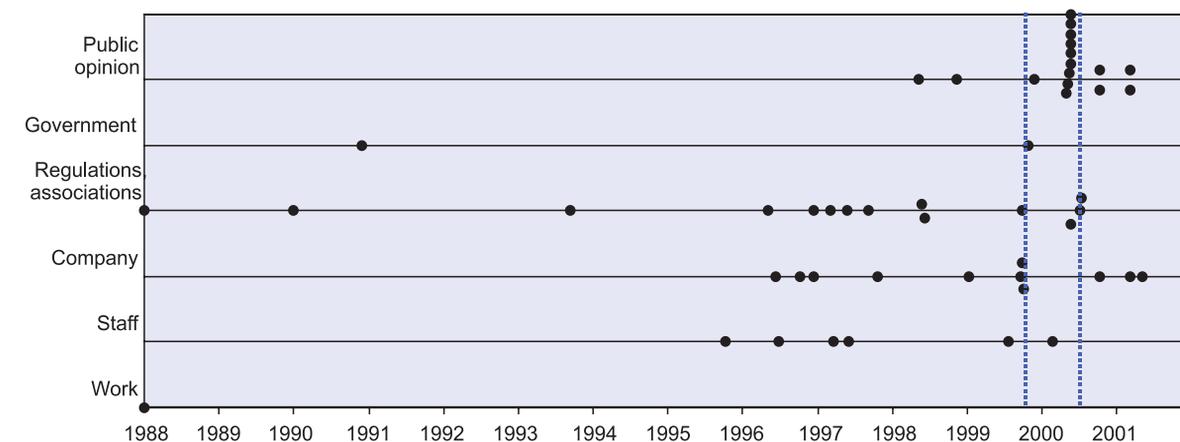
### Regulator and Professional Associations

The FDA compiled data showing that 45% to 50% of all medical device recalls from 1985 to 1989 stemmed from poor product design (event 3).<sup>25</sup> During the 1990s several guidance documents for device design were published, but these either made only passing reference to human factors issues (events 13 and 20) or merely provided a very basic introduction to the discipline (event 11).<sup>26-28</sup>

The revised FDA Good Manufacturing Practice and Quality System Regulations, which became effective June 1, 1997 (event 15),<sup>29</sup> implicitly refer to human factors: "Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient." This wording is ambiguous because a manufacturer could argue that human errors fall outside "the intended use of the device."

On October 7, 1999, FDA officials stated, referring to this PCA pump manufacturer, that "a 'systems' approach is needed, [which] requires the commitment of highest corporate management; in other words, the corporate culture must change" (event 27).<sup>30</sup>

## Time Line Illustration of Event Chronology (Refer to Table 2)



**Figure 2.** The events are classified according to categories defined in Table 1. The dashed lines represent a critical 9.5-month period during which changes occurred at almost all levels of the system, each encouraging the adoption of a human factors approach.

On July 18, 2000, the FDA published a guidance document to help medical device manufacturers incorporate human factors considerations (event 43).<sup>31</sup> This guidance was the most detailed provided to date and came at a time when manufacturers were more aware of human factors engineering. Also, the document provided advice on how to integrate human factors into existing risk management processes, making it more likely that the guidance would be embraced.

As for professional associations, in September 1997 ECRI (then the Emergency Care Research Institute) issued a hazard report on this PCA pump (event 17), stating that it believed the pump is “prone to misprogramming resulting in narcotic overinfusions.”<sup>32(p. 389)</sup> ECRI attributed these difficulties to insufficient attention to human factors engineering design principles: “the user interface and programming logic of the pump are particularly complex and tedious. We believe that the likelihood of user error is increased by the repetitive and time-consuming programming process required by this pump.”<sup>32(p. 389)</sup>

Previously, on May 8, 1996, the Institute for Safe Medication Practices (ISMP) had pointed out this PCA pump’s susceptibility to drug concentration programming errors, stating: “A small group of hospital pharmacists in Chicago has asked [the manufacturer] to address a problem involving programming of [this pump]” (event 7).<sup>33(p. 1)</sup> ISMP reiterated these concerns in several articles

during the next few years (events 21, 40, and 42).<sup>34–36</sup> The Association for the Advancement of Medical Instrumentation published two versions of human factors design guidelines for medical devices (events 2 and 5).<sup>37,38</sup>

### Government

U.S. product liability law places a contradictory pressure on companies deliberating whether to make design changes to a product after an accident. On the one hand, “In a products liability action based on negligence, evidence of postaccident remedial measures undertaken by the defendant [i.e., a manufacturer] with regard to the product in question is generally ruled *inadmissible* to prove the defendant’s negligence” (emphasis added).<sup>39(p. 55)</sup> The intent of this law is not to punish manufacturers for making product improvements after an accident. On the other hand, the law also states that “evidence of postaccident design changes is . . . *discoverable* where it is reasonably likely to lead to discovery of admissible evidence” (emphasis added).<sup>39(p. 59)</sup> Thus, anyone suing a manufacturer may obtain documentation about product improvements made after an accident. Such evidence is *admissible* to “prove the feasibility of precautionary measures. . . . [or] establish a condition existing at the time of the accident.”<sup>39(p. 62)</sup> Thus, information that is inadmissible to prove a manufacturer’s negligence can be made available to a jury to prove that a remedy was feasible. Although jurors

may be instructed to interpret the evidence only for admissible reasons, when jurors learn that improvement was technically feasible but was only introduced after an accident, they may nevertheless infer negligence, regardless of how or why such evidence was introduced.<sup>39</sup>

To return to the event chronology—the U.S. Congress passed the Safe Medical Devices Act of 1990 (event 4) in response to the FDA device recall data from the 1980s (event 3).<sup>40</sup> This law gave the FDA authority to require good manufacturing practices to ensure proper device design, but it took almost seven years before these changes led to revised regulations (event 15).

On November 2, 1999, the U.S. Department of Justice signed a consent decree with the manufacturer to stop making and distributing in-vitro diagnostic tests until it corrected manufacturing problems (event 29).<sup>41</sup> The FDA had inspected one of the manufacturer's facilities every year since 1993 and continually found a lack of compliance with regulations, despite warnings from the FDA and assurances by the manufacturer that the problems would be fixed; eventually, a court order was sought.<sup>42</sup> The consent decree required that the manufacturer pay \$100 million to the U.S. Treasury—the largest fine ever paid by a company for violating the Federal Food, Drug and Cosmetic Act.<sup>42</sup> This event is not directly related to the manufacturer's PCA pump, but it is relevant to the manufacturer's relationship with the Department of Justice and FDA, as well as its financial performance (see page 606).

## Public Opinion

With one exception, there are no direct, relevant measures of public opinion, so we rely instead on coverage of events in the lay and scientific press. In 1998 an article that happened to have used this PCA pump as a test bed to investigate the impact of human factors design principles on the usability of medical devices was published in the *Journal of Clinical Monitoring and Computing* (event 19; the authors were unaware of the reported patient deaths at that time).<sup>4</sup> A redesign of the human-computer interface was undertaken using human factors principles to make it easier to program and was then evaluated experimentally with nursing students. The new interface significantly reduced task completion times and cut programming errors in half. These findings were later replicated with professional nurses who had an average

of five years of experience with the commercially available design and half an hour with the new design.<sup>5</sup>

In November 1998 a letter to the editor published in the *Journal of the American Medical Association* reported deaths with this PCA pump and pointed to the importance of a human factors design approach (event 22).<sup>43</sup> A year later, the Institute of Medicine (IOM) report *To Err Is Human* was published, bringing the problem of medical errors to the attention of the highest levels of government (event 30).<sup>2</sup> A few weeks later, a Kaiser Family Foundation poll showed that 51% of the public was closely following coverage of the report, making it the most influential health policy story of 1999.<sup>44</sup>

Beginning in May 6, 2000, the *Tallahassee Democrat* published a sequence of newspaper articles, culminating in a front-page article stating that a 19-year-old woman using this PCA pump had died from a morphine overdose after delivering a girl, that the death was not the first of its kind, that it was likely due to a programming error, and that it may have been preventable (events 32–35 and 41).<sup>45–49</sup> Abbreviated versions were published elsewhere (events 36–39).<sup>50–53</sup>

In October 2000 an article published in the *Anesthesia Patient Safety Foundation Newsletter* brought the human factors limitations of this PCA pump and their implications for patient safety to the attention of the anesthesia community (event 44).<sup>54</sup> The manufacturer replied, as did a self-employed human factors consultant who sided with the manufacturer (event 46).<sup>55</sup> A rebuttal was published later, stating that the manufacturer had said it would change the design of the device in 1996 (event 8) and that the human factors consultant did not disclose a conflict of interest (event 47).<sup>56</sup>

On March 6, 2001, a letter to the editor was published in the *Canadian Medical Association Journal*, bringing this PCA pump's susceptibility to programming errors to the attention of the medical community (event 48).<sup>57</sup>

Table 3 (page 606) shows the circulation figures for the media cited in this section as a surrogate measure of their comparative potential impact on public opinion.

## Company

On June 19, 1996, the manufacturer was cited as stating that it would make software changes to the pump “in the coming year” (event 8).<sup>58</sup> However, by October 9,

**Table 3. Approximate Circulation Numbers for Cited Media\***

- *Anesthesia Patient Safety Foundation Newsletter*: 60,475
- *Canadian Medical Association Journal*: 65,000
- *Denver Post*: 610,000
- *Journal of Clinical Monitoring and Computing*: 300-400
- *Journal of the American Medical Association*: 350,000
- *New Orleans Times-Picayune*: 1.5 million
- *Orlando Sentinel*: 257,400 (weekdays)/378,200 (Sundays)
- *Tallahassee Democrat*: 49,000 (weekdays)/65,000 (Sundays)
- *Ventura County Star*: 96,800 (weekdays)/109,200 (Sundays)

\* Data obtained directly from publishers.

1996, it had yet to do so (event 10).<sup>50</sup> By December 18, 1996, it was continuing to investigate software changes and had created warning labels for the drug syringes to help distinguish different concentrations (event 12).<sup>60</sup>

On October 29, 1997 the manufacturer wrote a “Dear Clinician” letter that implied that the ECRI hazard report (event 17) was inaccurate and that added training was one of the keys to error prevention; no mention was made of redesigning the device interface (event 18).<sup>61</sup>

By January 1, 1999, the manufacturer was led by a new and more aggressive CEO and top management team (event 23).<sup>62</sup> On September 29, 1999, the manufacturer stated that it had been notified by the government of alleged noncompliance with the FDA’s Quality System Regulation but that it believed it was in “substantial compliance” and that it was in discussions with the government about a proposed consent decree (event 25).<sup>63</sup> On October 5, 1999, about a month before it signed the \$100 million consent decree (event 29)—the manufacturer appointed a former 20-year employee of the FDA as its new vice president for Corporate Regulatory and Quality Science (event 26).<sup>64</sup> On October 9, 1999—two days after FDA officials stated that the manufacturer needed to change its corporate culture (event 27)—the manufacturer’s CEO stated that he was concentrating on cultural changes in the organization (event 28).<sup>65</sup>

The manufacturer’s stock price was compared with the Standard and Poor’s (S&P) 500 and the S&P 500 Pharmaceuticals Price indices. Before the consent

decree, the manufacturer’s stock price was comparable to these benchmarks. But afterward, the manufacturer’s stock price declined substantially compared to both indexes, its shareholders filed class actions lawsuits against it, its planned acquisition of another drug manufacturer fell through, it feared that it would fall prey to a hostile takeover bid, and it was still being monitored closely by the FDA.<sup>66,67</sup>

In May 2000 the manufacturer told the *Tallahassee Democrat* that its PCA pump had no design flaws and that it was safe if used as directed and that instead of device redesign, the manufacturer advocated better nurse training (event 35).<sup>48</sup> In October 2000 the manufacturer responded to the *Anesthesia Patient Safety Foundation Newsletter* article, stating that a new device was supposed to become available in 2001 (event 45).<sup>68</sup> A few months later, it made the same statement in a reply to the letter to the *Canadian Medical Association Journal* (event 49).<sup>14</sup>

In May 2001 the manufacturer placed a job advertisement for a human factors engineering program manager in its corporate regulatory and quality science unit, which operated to reflect a remarkable behavioral change. The manufacturer did the following:

In May 2001 the manufacturer placed a job advertisement for a human factors engineering program manager in its corporate regulatory and quality science unit, which operated to reflect a remarkable behavioral change. The manufacturer did the following:

- Set up a human factors council at corporate headquarters with representatives from each of its divisions;
- Injected human factors input into existing medical device design projects
- Created a human factors process for designing all future medical devices
- Put on training courses throughout the company to educate employees about the importance of human factors engineering (event 50)

## Discussion

The behavioral changes documented in this article are consistent with punctuated equilibrium theory and Rasmussen’s framework. Virtually all the major trends in nursing during the past decade seem to increase the likelihood of errors with computer-based devices, pointing to a growing misalignment between staff and technology, as reflected in the growing number of reported deaths due to errors in programming of PCA pumps. Yet, like

many other health care organizations, the manufacturer continued to exhibit the traditional approach to medical error for years, with an emphasis on better nurse training. This long period was followed by a comparatively abrupt shift toward human factors design.

All three prerequisites for radical change were observed. First, the manufacturer had a new and more aggressive CEO and management team in January 1999 and appointed a new vice president of corporate regulatory and quality science—the unit that later hired the human factors engineering program manager—in October 1999. These changes occurred about 2.3 and 1.5 years before the radical shift was initiated, respectively, putting them within the ballpark criterion of two years for fast revolutionary change. Second, the manufacturer experienced a profound performance crisis after the consent decree. Third, during the 9.5-month period from November 2, 1999, to July 18, 2000, changes occurred at almost every level of the external environment in which the company operated (Figure 2). Before this critical period, events tended to be sparsely distributed across time and levels; this was the first cluster of vertically aligned events.

All the events in this critical cluster provided the manufacturer with reasons for adopting a human factors approach. About a year later, the manufacturer initiated a radical behavioral reform. The theoretical explanation for this case and experiences with change in health care suggest that this type of radical change is generalizable.<sup>69</sup>

This research appears to be the first longitudinal case study of a corporate shift toward a human factors approach to patient safety. The findings suggest that this shift can begin when there is new leadership, a perception of poor organizational performance, and a disruption of the operating environment by alignment at multiple levels of a complex sociotechnical system—in this case, the IOM report and nine newspaper articles at the public-opinion level, the \$100 million consent decree at the government level, detailed FDA guidance and two ISMP articles at the regulatory and association level, and a reported death due to device misprogramming at the staff level. These factors encourage an organization to change to achieve vertical alignment with its external environment—a particular form of punctuated equilibrium theory.

Several limitations should be noted. Internal company documents were not accessible, and because the manufacturer is engaged in legal action, it declined our request for additional information. Consequently, this account of events should not be considered definitive. Also, although the process of radical change has begun, whether and when it will take hold across the organization are unknown. Finally, the events in the chronology do not seem to be of equal importance, but we do not know of any valid method for weighting the relative influence of events on cultural change.

### Implications for Patient Safety Reform: "Tilting the Playing Field"

The theoretical explanation for this case is only one of many mechanisms for organizational change, but it has implications for improving patient safety in other settings. Given the importance of economic performance, hospitals should create market forces that reward corporate change by conducting human factors evaluations before purchasing medical devices, products, and services, and by feeding back the evaluation results to every manufacturer, not just the one that was selected, so that all can improve their designs.<sup>5,70</sup> This, in turn, requires that hospitals hire, train, and reward personnel to build in-house human factors expertise.<sup>71</sup>

Given the importance of an aligned landscape, hospitals should partner with other stakeholders identified by Rasmussen's framework to encourage reform. For example, hospitals can build relationships with news media to raise awareness about the urgent need for a human factors approach to patient safety. In the Tallahassee death described earlier in this article, the hospital initially did not explain to the family why the patient died and only provided a "cursory explanation of the incident" to the media.<sup>72</sup> Were it not for the journalist's persistence, this event would not have reached the public, and the corporate change described here may not have occurred. Public policy research in other sectors shows that such adverse events "provide an opportunity for advocacy in the guise of analysis,"<sup>73(p. 133)</sup> but only if they are widely publicized. The profound improvements spurred by the Betsy Lehman and Libby Zion cases—two tragic medical error deaths that involved a journalist or a journalist's relative—show that hospitals should seek to publicize, not

cover up, tragic adverse events to improve patient safety. Analogous types of vertically aligned linkages should be built with politicians, government regulators, professional associations, and corporations to induce major environmental jolts that tilt the playing field, thereby encouraging radical change toward patient safety. **1**

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## References

1. Leape L.L.: Error in medicine. *JAMA* 272:1851-1857, Dec. 21, 1994.
2. Institute of Medicine: *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press, 2000.
3. Association for the Advancement of Medical Instrumentation (AAMI): *Human Factors Design Process for Medical Devices* (ANSI/AAMI HE48:2001). Arlington, VA: AAMI, 2001.
4. Lin L., et al.: Applying human factors to the design of medical equipment: Patient-controlled analgesia. *J Clin Monit Comput* 14:253-263, May 1998.
5. Lin L., Vicente K.J., Doyle D.J.: Patient safety, potential adverse drug events, and medical device design: A human factors engineering approach. *J Biomed Inform* 34:274-284, Aug. 2001.
6. Vicente K.J.: *The Human Factor: Revolutionizing the Way People Live with Technology*. Toronto: Knopf Canada, 2003.
7. Gaba D.: Structural and organizational issues in patient safety: A comparison of health care to other high-hazard industries. *California Management Review* 43:83-102, Fall 2000.
8. Carroll J.S., Edmondson A.C.: Leading organizational learning in health care. *Qual Saf Health Care* 11:51-56, Mar. 2002.
9. Tushman M.L., Romanelli E.: Organizational evolution: A metamorphosis model of convergence and reorientation. In Cummings L.L., Staw B.M. (eds.): *Research in Organizational Behavior*, vol. 7. Greenwich, CT: JAI Press, 1985, pp. 171-222.
10. Romanelli E., Tushman M.L.: Organizational transformation as punctuated equilibrium: An empirical test. *Academy of Management Journal* 37:1141-1166, Oct. 1994.
11. Rasmussen J.: Risk management in a dynamic society: A modelling problem. *Safety Science* 27:183-213, Nov. 1997.
12. Vicente K.J.: From patients to politicians: A cognitive engineering view of patient safety. *Qual Saf Health Care* 11:302-304, Dec. 2002.
13. Heath M.L., Thomas V.J.: *Patient-Controlled Analgesia: Confidence in Postoperative Pain Control*. Oxford, UK: Oxford University Press, 1993.
14. McLeskey C.H.: Patient-controlled analgesia. *Can Med Assoc J* 164:620-621, Mar. 6, 2001.
15. Vicente K.J., et al.: Programming errors contribute to death from patient-controlled analgesia: Case report and estimate of probability. *Can J Anesthes* 50:328-332, Apr. 2003.
16. U.S. Food and Drug Administration: *Medical Device Reporting*. [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI\\_ID=97571](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=97571) (accessed Aug. 22, 2003).
17. Aiken L., et al.: Nurses' reports on hospital care in five countries. *Health Aff (Millwood)* 20:43-53, May-Jun. 2001.
18. Steinbrook R.: Nursing in the crossfire. *New Engl J Med* 346:1757-1766, May 30, 2002.
19. Canadian Nursing Advisory Committee: *Our Health, Our Future: Creating Quality Workplaces for Canadian Nurses*. Ottawa: Advisory Committee on Health Human Resources, 2002. [http://www.hc-sc.gc.ca/english/for\\_you/nursing/cnac\\_report/index.html](http://www.hc-sc.gc.ca/english/for_you/nursing/cnac_report/index.html) (accessed Aug. 22, 2003).
20. Buerhaus P.I., et al.: Implications of an aging registered nurse workforce. *JAMA* 283:2948-2954, Jun. 14, 2000.
21. Simpson G., Kenrick M.: Nurses' attitudes toward computerization in clinical practice in a British general hospital. *Comput Nurs* 15:37-42, Jan.-Feb. 1997.
22. Manion J.: Emergence of the free agent nurse workforce. *Nurs Adm Qu* 26:68-78, Fall 2002.
23. Needleman J., et al.: Nurse-staffing levels and the quality of care in hospitals. *New Engl J Med* 346:1715-1722, May 30, 2002.
24. Aiken L., et al.: Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. *JAMA* 288:1987-1993, 2002.
25. U.S. Food and Drug Administration: *Human Factors Implications of the New GMP Rule Overall Requirements of the New Quality System Regulation*, Apr. 22, 1998. <http://www.fda.gov/cdrh/humfac/hufacimp.html> (accessed Aug. 25, 2003)
26. U.S. Food and Drug Administration, Center for Devices and Radiological Health: *Design Control Guidance for Medical Device Manufacturers*, Mar. 11, 1997. <http://www.fda.gov/cdrh/comp/designgd.html> (accessed Aug. 25, 2003).
27. U.S. Food and Drug Administration, Center for Devices and Radiological Health: *Guidance for FDA Reviewers and Industry: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, May 29, 1998. <http://www.fda.gov/cdrh/ode/57.html> (accessed Aug. 25, 2003).
28. Sawyer D.: *Do It by Design: An Introduction to Human Factors in Medical Devices*. Rockville, MD: U.S. Food and Drug Administration, Center for Devices and Radiological Health, 1996. <http://www.fda.gov/cdrh/humfac/doi.html> (accessed Aug. 25, 2003).
29. U.S. Food and Drug Administration: 21 CFR 820.30, 1997. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf CFRsearch.cfm?FR=820.30> (accessed Aug. 7, 2003).
30. Ferdic, Inc.: FDA skeptical of Abbott's new man to fix quality problems, FDA Webview reports. *PR Newswire*, Oct. 7, 1999.

References, *continued*

31. Kaye R., Crowley J.: *Guidance for Industry and FDA Premarket and Design Control Reviewers—Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management*, Jul. 18, 2000. <http://www.fda.gov/cdrh/humfac/1497.html> (accessed Aug. 7, 2003).
32. Emergency Care Research Institute: Abbott PCA Plus II patient-controlled analgesia pumps prone to misprogramming resulting in narcotic overinfusions. *Health Devices* 26:389–391, Sep.–Oct. 1997.
33. Institute for Safe Medication Practices: Safety briefs. *ISMP Medication Safety Alert* 1:1, May 8, 1996.
34. Institute for Safe Medication Practices: Frequently occurring problems noted during ISMP evaluations of hospital medications systems—Part 2. *ISMP Medication Safety Alert* 12:3, Jun. 17, 1998.
35. Institute for Safe Medication Practices: Design flaw predisposes Abbott Lifecare PCA Plus II pump to dangerous medication errors. *ISMP Medication Safety Alert* 5:2, May 31, 2000.
36. Institute for Safe Medication Practices: Safety briefs. *ISMP Medication Safety Alert* 5:2, Jul. 12, 2000.
37. Association for the Advancement of Medical Instrumentation (AAMI): *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* (ANSI/AAMI HE:1988). Arlington, VA: AAMI, 1988.
38. Association for the Advancement of Medical Instrumentation (AAMI): *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* (ANSI/AAMI HE48:1993). Arlington, VA: AAMI, 1993.
39. Anonymous: *American Law of Products Liability, 3rd edition, Part 4: Negligence Liability*. Rochester, NY: The Lawyers Co-operative Publishing, 1987.
40. U.S. Congress: Safe medical devices act, Public Law 101-629 [H.R. 3095], Nov. 28, 1990.
41. U.S. Department of Justice: *Abbott Laboratories to Remedy Deficiencies in Medical Diagnostic Devices and Pay \$100 Million*, Nov. 2, 1999. <http://www.usdoj.gov/opa/pr/1999/November/522civ.htm> (accessed Aug. 25, 2003).
42. U.S. Food and Drug Administration: *Abbott Labs Signs Consent Decree with FDA; Agrees to Correct Manufacturing Deficiencies*, Nov. 2, 1999. [www.fda.gov/bbs/topics/NEWS/NEW00697.html](http://www.fda.gov/bbs/topics/NEWS/NEW00697.html) (accessed Aug. 7, 2003).
43. Weinger M.B., et al.: Incorporating human factors into the design of medical devices. *JAMA* 280:1484, Nov. 1998.
44. Kaiser/Harvard Program on Public and Health Policy: *The Kaiser/Harvard Health News Index* 4(6):1-2, 1999. <http://www.kff.org/content/2000/1565/HNP%20Nov-Dec1999.pdf> (accessed Aug. 25, 2003).
45. St. John P.: Overdose kills mom at TMH. *Tallahassee Democrat*, May 6, 2000, p. A1.
46. St. John P.: TMH plans extra training. *Tallahassee Democrat*, May 12, 2000, p. A1.
47. St. John P.: Evidence gone in TMH death. *Tallahassee Democrat*, May 25, 2000, p. A1.
48. St. John P.: Drug pump's deadly trail. *Tallahassee Democrat*, May 28, 2000, p. A1.
49. Editorial: National solution essential to stop drug pump error. *Tallahassee Democrat*, Jun. 1, 2000.
50. St. John P.: Pump cited in drug overdoses; Some experts seek recall of dispenser. *New Orleans Times-Picayune*, May 28, 2000, p. A32.
51. St. John P.: Bedside aid often deadly 'drug pump' needs recall, redesign, experts allege. *Denver Post*, May 29, 2000, p. A1.
52. St. John P.: Drug pump prone to errors; Many experts want to see the devices recalled and redesigned to eliminate overdoses. *Orlando Sentinel*, May 28, 2000, p. A14.
53. St. John P.: Flawed drug pumps lead to hospital deaths nationwide. *Ventura County Sunday Star*, May 28, 2000, p. A1.
54. Vicente K.J.: Human factors researcher alarmed by deaths during PCA. *Anesthesia Patient Safety Foundation Newsletter* 15(3):36, 2000. <http://www.gasnet.org/societies/apsf/newsletter/2000/fall/06OpinionFumanFactors.htm> (accessed Aug. 7, 2003).
55. Andre A.D.: Human factors consultant rebuts PCA pump danger charges. *Anesthesia Patient Safety Foundation Newsletter* 15:37–38, Fall 2000. <http://www.gasnet.org/societies/apsf/newsletter/2000/fall/08Rebuttal.htm> (accessed Aug. 25, 2003).
56. Vicente K.J.: Patients perceived still at risk with PCA pump. *Anesthesia Patient Safety Foundation Newsletter* 15:60, Winter 2000–2001. <http://www.gasnet.org/societies/apsf/newsletter/2000/winter/20Opinion.htm> (accessed Aug. 25, 2003).
57. Doyle D.J., Vicente K.J.: Patient-controlled analgesia. *C Med Assoc J* 164:620, Mar. 6, 2001.
58. Institute for Safe Medication Practices: Safety briefs. *ISMP Medication Safety Alert* 1(12):2, 1996.
59. Institute for Safe Medication Practices: Safety briefs. *ISMP Medication Safety Alert* 1(20):1, 1996.
60. Institute for Safe Medication Practices: Safety briefs. *ISMP Medication Safety Alert* 1(25):1, 1996.
61. Mayer D.: Dear Clinician letter. Abbott Park, IL: Hospital Products Division, Abbott Laboratories. Oct. 9, 1997.
62. Oloroso A.: New CEO poised to rev up sleepy Abbott's strategy: White's task is boosting growth. *Crain's Chicago Business*, Sep. 21, 1998, p. 4.
63. AFX: Abbott Laboratories diagnostic unit in talks with FDA over compliance issues. *AFX News*, Sep. 29, 1999.
64. Abbott Laboratories: Abbott names executive to lead global quality and regulatory organization. *PR Newswire*, Oct. 5, 1999.
65. Barrett A, Melcher RA: Drugmaker, heal thyself. *Business Week*, Oct. 11, 1999, p. 88.
66. Abbott Laboratories: Abbott announces shareholder rights plan. *PR Newswire*, Nov. 10, 1999.
67. Davidson D.: Painful remedy. *The Daily Deal*, Jul. 10, 2000.
68. McLeskey C.H.: Abbott addresses medication errors through advanced PCA technology. *Anesthesia Patient Safety Foundation Newsletter* 15:36–37, Fall 2000. <http://www.gasnet.org/societies/apsf/newsletter/2000/fall/07OpinionResponse.htm> (accessed Aug. 7, 2003).
69. Ferlie E.B., Shortell S.M.: Improving the quality of health care in the United Kingdom and the United States: A framework for change. *Milbank Q* 79(2):281–315, 2001.
70. Shulkin D: Using a market model to track advances in patient safety. *Jt Comm J Qual Saf* 29:146–151, Mar. 2003.
71. Gosbee J.: Human factors engineering and patient safety. *Qual Saf Health Care* 11:352–354, Dec. 2002.
72. Stark K., et al: *Covering the Quality of Health Care: A Resource Guide for Journalists*. Minneapolis: The Association for Health Care Journalists, 2002. <http://www.ahcj.umn.edu/qualityguide> (accessed Aug. 7, 2003).
73. Birkland T.A.: *After Disaster: Agenda Setting, Public Policy, and Focusing Events*. Washington, DC: Georgetown University Press, 1997.