

# UC San Diego

## UC San Diego Electronic Theses and Dissertations

**Title**

The challenge of patient safety and the remaking of American medicine

**Permalink**

<https://escholarship.org/uc/item/38s4s7v9>

**Author**

Van Rite, Eric

**Publication Date**

2011

Peer reviewed|Thesis/dissertation

UNIVERSITY OF CALIFORNIA, SAN DIEGO

The Challenge of Patient Safety and the Remaking of American Medicine

A dissertation submitted in partial satisfaction of the requirements for  
the degree Doctor of Philosophy

in

Sociology

by

Eric Van Rite

Committee in charge:

Professor Jeffrey Haydu, Chair  
Professor Steven Epstein  
Professor Edwin Hutchins  
Professor Andrew Lakoff  
Professor Charles Thorpe

2011

Copyright

Eric Van Rite, 2011

All rights reserved.

The Dissertation of Eric Van Rite is approved, and it is acceptable in quality and form for publication on microfilm and electronically:

---

---

---

---

---

Chair

University of California, San Diego

2011

## TABLE OF CONTENTS

|                                                                                             |         |
|---------------------------------------------------------------------------------------------|---------|
| Signature Page.....                                                                         | iii     |
| Table of Contents.....                                                                      | iv      |
| List of Tables.....                                                                         | v       |
| Acknowledgments.....                                                                        | vi      |
| Vita.....                                                                                   | ix      |
| Abstract.....                                                                               | x       |
| <br>CHAPTER 1 –<br>Introduction: The Patient Safety Challenge.....                          | <br>1   |
| <br>CHAPTER 2 –<br>From Risk to Reform: Changing the Concept of Medical Error.....          | <br>42  |
| <br>CHAPTER 3 –<br>From Tragedy to Advocacy: Patient Stories of Transformation.....         | <br>91  |
| <br>CHAPTER 4 –<br>Making the Case for Patient Safety: Organizational Leaders & Advocacy... | <br>140 |
| <br>CHAPTER 5 –<br>Conclusion: The Politics of Patient Safety and Healthcare Reform.....    | <br>192 |
| <br>Appendix: Chronology of Major Events Related to Patient Safety .....                    | <br>215 |
| Bibliography.....                                                                           | 216     |

## LIST OF TABLES

|                                                                                                                         |     |
|-------------------------------------------------------------------------------------------------------------------------|-----|
| Table 1: Historically Significant Reports on Medical Error .....                                                        | 90  |
| (Medical Insurance Feasibility Study,<br>Harvard Medical Practice Study,<br>and To Err is Human)                        |     |
| Table 2: Prominent Medical Error Narratives.....                                                                        | 139 |
| (Advocacy Stories of Betsy Lehman,<br>Sorrel King, and Dennis Quaid)                                                    |     |
| Table 3: Major Patient Safety Advocacy Organizations.....                                                               | 191 |
| (National Patient Safety Foundation,<br>Institute for Healthcare Improvement,<br>and World Alliance for Patient Safety) |     |

## ACKNOWLEDGEMENTS

Jeff Haydu has been my primary advisor since I first entered the Sociology program at UCSD. My initial interest in the comparative-historical sociology of labor lined up very well with his work. For various reasons, however, I decided to embark on a contemporary project on US healthcare for my dissertation. I can't say how much I appreciate Jeff's dedicated mentorship. He has kindly and graciously helped me to overcome numerous professional challenges, and has always done so with practical assistance and good-natured humor. It is no exaggeration to say that I would not have completed this dissertation without Professor Haydu's extensive support.

My sincere thanks go out to my committee members – Andy Lakoff, Steve Epstein, Charlie Thorpe and Ed Hutchins. Andy Lakoff's seminars – 'Contemporary Theory,' 'Technology and the Human,' and 'Sociology of Risk' – played a significant role in the theoretical perspective, derived from Foucault's concepts, that guide this dissertation project. I have benefited greatly from Andy's careful approach to teaching dense (and often convoluted) concepts like 'governmentality.' Steve Epstein's meticulous scholarship, intersecting with such research fields as Science Studies and Medical Sociology, has provided an inspirational model to follow. This dissertation is still very far from attaining that model, but I aspire to Steve's commitment with both his scholarship and his teaching. Charlie Thorpe was a late addition to the committee, and I am very grateful for his time and contribution to a student that he did not know so well beforehand. While the dissertation has taken quite a different direction from where it first began, I thank Ed Hutchins for his continuous support and interest in the project.

Finally, in addition to my current committee members, I also wish to thank Michael Schudson for his initial service on my committee - for suggesting Ed as another member, and then for his continued interest in the project after he left UCSD.

Besides my committee members, I'd also like to thank other members of the Sociology department who have helped me along in the program. Rick Biernacki supported my application, sold me on the program, and ultimately helped to guide me into Sociology at UCSD. John Skrentny has provided crucial support with my teaching in Law and Society Courses, a field of instruction that has become a major teaching interest of mine. I also thank John Evans, Isaac Martin and Kwai Ng for supporting my work through various venues (such as the Culture and Society Workshop). The staff at the Sociology Main Office has always been immensely helpful. Specifically for the trials and tribulations of a PhD student, the grad coordinators during my time – Rafael Acevedo for the first couple of years and then Manny dela Paz since then – have both been crucial allies. I especially extend my thanks to Manny for his help with navigating the pitfalls of advanced 'ABD' territory over the last couple of years.

I'm thankful for the friends and colleagues, among the grad students in Sociology and in other programs, which I made at UCSD. I want to give very special thanks to Rob Fargo, Raquel Jacob-Almeida, Brian Lindseth and Kevin Moseby for their supportive company, so invaluable in so many ways, over the years. I am fortunate for a grad cohort of brilliant colleagues and good friends – my thanks to Michael Evans, Stephanie Chan, Gordon Chang, Tom Waidzunas, and Alper Yalcinkaya. Of course, grad school camaraderie spreads beyond 'the cohort.' At different times during my grad school career, I've benefited from knowing the likes of April Huff, Katie Kenny, Kris Kohler,



Leslie Lewis, Martha Poon, Cindy Schairer, Jon Shafran, Matt Shindell, and Sabrina Strings. This list could go on – there’s not enough space to name all those that have been helpful in both personal and professional support over the years – so I thank all the kindred souls and fellow travelers that I was lucky to meet during my time at UCSD.

Last but certainly not least, my sincere and humblest appreciation to my family. My thanks to my wife’s parents, Jean and David Hitchcock for first welcoming me in to their home as their son-in-law, and then for much-appreciated babysitting help. In addition, my thanks to Jean, for many leads in understanding healthcare organizations. My gratitude also extends to Bernie DeRuyter, who is no longer here to share in this accomplishment, but who helped me enormously when I was growing up. My brother, Adam, can also attest to the warmth of Bernie’s gentle and kind soul. His lasting imprint is apparent whenever Adam and I get together. To my mother, Mary Gagnon, for buying me that set of encyclopedias way back in grade school, which began an educational journey that has passed many years since I spent hours reading those volumes. Your hard work at the ‘Mill’ gave me an opportunity to pursue a love of learning - my deepest thanks for establishing the foundation for my lengthy educational goals. Without my daughter, Kora, this project would likely have already been completed. But from infancy through ‘terrible twos,’ I would not trade all that time spent on the playground and at the zoo for anything else. Finally, to my wife, Kathryn – we finally (almost) made it! I cannot fully express my gratitude for your love, support, and especially for your patience. While it’s been a bumpy ride at times, the destination, with this project as with anything else, would mean much, much less without you and Kora along for the journey.

## VITA

|             |                                                                                                                          |
|-------------|--------------------------------------------------------------------------------------------------------------------------|
| 2001        | B.A., Sociology, University of Wisconsin – Madison                                                                       |
| 2001-2003   | Library Assistant, Social Sciences and Humanities Library, University of California, San Diego                           |
| 2004, 2005  | Research Assistant (for Professor Haydu and Professor Martin), Sociology Department, University of California, San Diego |
| 2005        | M.A., Sociology, University of California, San Diego                                                                     |
| 2004 – 2007 | Teaching Assistant, Dimensions of Culture Writing Program, Marshall College, University of California, San Diego         |
| 2007 – 2009 | Teaching Assistant & Associate-In, Sociology Department, University of California, San Diego                             |
| 2008 – 2009 | Senior Teaching Assistant, Sociology, University of California, San Diego                                                |
| 2009 – 2010 | Teaching Assistant, Urban Studies and Planning Program, University of California, San Diego                              |
| 2011        | Associate-In, Sociology Department, University of California, San Diego                                                  |
| 2011        | Ph.D., Sociology, University of California, San Diego                                                                    |

## ABSTRACT OF THE DISSERTATION

The Challenge of Patient Safety and the Remaking of American Medicine

by

Eric Van Rite

Doctor of Philosophy in Sociology

University of California, San Diego, 2011

Jeffrey Haydu, Chair

This dissertation accounts for the ‘patient safety challenge,’ which developed over the course of 1990s, gained prominence in the early 2000s, and now occupies a significant place in healthcare reform. Positioning medical error as a significant, wide-ranging, and entrenched problem in need of attention, the patient safety challenge is a reform discourse. Patient safety reformers challenge the healthcare industry to take action to better manage medical error, and in so doing call for a major transformation in the structure of care delivery.

Charting major aspects of patient safety reform discourse, this dissertation addresses three overarching questions. First, what constitutes patient safety discourse and who are the leading advocates for patient safety reform? Next, what are advocates, and their associated discourse, attempting to change about understandings of medical error specifically, and about the organization and delivery of healthcare more generally? Finally, what are the consequences of patient safety advocacy for the medical profession and for healthcare reform?

In seeking to reconstitute the medical profession with an ethos of shared responsibility and collective improvement, patient safety advocates attempt to remake the profession by redefining its culture and conduct. This dissertation examines three major aspects of patient safety discourse: how the concept of medical error has become an object of research and target for advocacy, how patient stories of medical error transform both patients and providers, and how leading advocates and organizations attempt to change notions of culture and responsibility in the organization of healthcare work.

These dimensions contribute to changes in the medical profession's political role in healthcare reform, in the wake of recent comprehensive legislation. Federal reform efforts call for a significant restructuring of care delivery, influenced by a rationality of patient safety that constructs medical error as a preventable risk, asserts patients as partners in error prevention, and makes safety culture a central organizational goal. With high stakes in the shape that the US healthcare system takes over the next decade, the medical profession has been challenged, by a discourse of patient safety that the Federal government now also promotes, to join in efforts at remaking American medicine.

## CHAPTER 1 – Introduction: The Patient Safety Challenge

Easily overlooked within a very detailed campaign pamphlet on health care reform, then-presidential candidate Barack Obama’s “Plan for a Healthy America” includes an interesting discussion of patient safety. In a section entitled “ensuring providers deliver quality care,” the plan states, “Obama will require providers to report preventable medical errors, and support hospital and physician practice improvement to prevent future occurrences.”<sup>1</sup> Such mention of medical error is significant for a plan that focuses largely upon the problems of cost and access, which tend to dominate political discussions of health care reform in the United States.<sup>2</sup> Elsewhere in the pamphlet, concern for medical error returns in a section on malpractice reform. After echoing long-standing calls for limitations on malpractice insurance premiums, a general conclusion states, “Obama will also promote new models for addressing physician errors that improve patient safety, strengthen the doctor-patient relationship, and reduce the need for malpractice suits.”<sup>3</sup> A subtle, yet consequential, prioritizing of patient safety over medical malpractice, Obama’s campaign promises, as well as subsequent presidential policies,<sup>4</sup> shed light upon a shift in health care reform efforts around the issue of medical

---

<sup>1</sup> “Barack Obama’s Plan for a Healthy America: Lowering health care costs and ensuring affordable, high-quality health care for all”, pg.7, document downloaded from [www.barackobama.com](http://www.barackobama.com).

<sup>2</sup> Especially after passage of sweeping reform legislation – the Patient Protection and Affordable Care Act – in March of 2010, the issues of cost and access continue to dominate debates on health care in the US. Though quality improvement was included in the legislation, which will be discussed in the conclusion.

<sup>3</sup> Ibid., pg. 8.

<sup>4</sup> Such as with funding for electronic medical records in the stimulus bill, officially known as the American Recovery and Reinvestment Act of 2009.

error. Beginning in the early 1970s, medical malpractice reform garnered significant attention during various periods of political activity, when crises in liability insurance markets resulted in calls for changing malpractice laws.<sup>5</sup> Starting in the mid-1990s, and gaining prominence in the 2000s, patient safety discourse imagines an alternative arena for dealing with medical error, resting upon the goal of preventing harm to patients.

In nearly any mention of patient safety, widespread attention toward medical error is most often linked to an influential Institute of Medicine (IOM) report from late 1999, entitled *To Err is Human: Building a Safer Health System*, which estimated that between 44,000 and 98,000 Americans die every year as a result of preventable medical errors. Through this publication, the IOM reported that the lethal consequences of medical mistakes ranks higher than the yearly deaths attributable to such prominent causes of death as AIDS, breast cancer, or automobile accidents. At the higher, 98,000 estimate, medical error results in more deaths than the combined total of those three more well known causes.<sup>6</sup> When such stark statistical representations are matched with the individual tragedies that the numbers can only attempt to signify, the resulting publicity of medical mistakes has marked the emergence of a patient safety challenge to the health care industry, triggering various calls for reform.

As the conventional story in health care, the IOM's 1999 *To Err is Human* report marks the watershed moment when suddenly medical error was recognized as a problem and patient safety was placed upon the national reform agenda. The IOM report,

---

<sup>5</sup> According to Richard Bucilla, an underwriter for AIG who spoke at the closing plenary of the 2007 National Patient Safety Association Congress (May 4, 2007 in Washington DC) the 'significant times' for malpractice reform were 1975-77, 1985-87 and 2001-2003 (qualifying that "tort reform generally lacks permanence.")

<sup>6</sup> Institute of Medicine (2000), Statistics can be found in the Executive Summary.

however, rests upon a series of other reports, along with patient stories and nascent organizational campaigns, which all contributed to a revised conceptualization of medical error. Focusing upon error prevention rather than financial restoration, patient safety advocates produce a discourse of error that challenges the traditional medical liability system as inefficient for managing safety in health care. Patient safety discourse repositions the assumptions of how a medical error is understood and determined - from resting upon a legal standard of negligence and guiding ethic of individual accountability to a safety standard of prevention and guiding ethic of collective improvement. Pursuing an expansive agenda based upon the guiding principle of prevention, patient safety advocacy develops in a context of other major changes in health care reform, such as evidence-based medicine, consumer-centered care and quality improvement.

Safety concerns have been a part of health care delivery for decades.<sup>7</sup> In addition to challenging the malpractice system, what is significant about patient safety discourse is how ubiquitous it has become – issues that were previously distinct, such as infection control, product liability, or staffing levels, are now usually discussed in relation to promoting patient safety.<sup>8</sup> Given the complex and fragmented structure of US health care, the challenge of patient safety is precisely in an attempted reform project of reorganization, bringing competing models of delivery to follow a more unified paradigm through appeals to patient safety. Following the growing reach of patient safety

---

<sup>7</sup> Schimmel (1964) provides a mid-20<sup>th</sup> century example of research in health care safety. See Guarnieri (1992) and Chassin (1998) for general discussions of safety and quality in health care history and policy. Ilan & Fowler (2005) and Small & Barach (2002) provide early accounts of the patient safety movement.

<sup>8</sup> For examples of patient safety texts that draw such links see Hurwitz & Sheikh (2009) and Reynard, Reynolds & Stevenson (2009).

discourse over the last two decades, in this dissertation I explore the ways in which the field of patient safety research and advocacy promotes alternative models for understanding medical error and organizing the delivery of health care.

In charting the emergence and development of a patient safety reform discourse, my analysis is directed toward answering three overarching questions. First, what constitutes patient safety discourse and who are the leading advocates for patient safety reform? Next, what are advocates, and their associated discourse, attempting to change about understandings of medical error specifically, and about the organization and delivery of health care more generally? Finally, what are the consequences of patient safety advocacy for the medical profession and for health care reform? The remainder of this introductory chapter sets the stage for how these questions will be answered over the course of the dissertation. In the next section, I review research on medical error and patient safety from Sociological and Social Science perspectives. Then, I provide a more detailed review of research on the medical profession, and link that to theoretical work in the area of governmentality studies, in order to explain the dissertation's overall theoretical contribution regarding patient safety and the medical profession. While each chapter draws upon distinct academic literatures, the general contribution of the research is presented in this chapter. I follow the theoretical review and contribution with a discussion of research methods. My analysis of patient safety is guided by open-ended and interpretive versions of qualitative discourse analysis, such as genealogical approaches to discourse and Critical Discourse Analysis. Finally, I give brief summaries of the three substantive chapters, as well as of the concluding chapter, in order to provide a preview of the rest of the dissertation.



## **Background: From Medical Error to the Patient Safety Challenge**

Patient safety initiatives encompass a wide variety of issues in medical care, ranging from detailed guidelines for avoiding mistaken use of pharmaceuticals to strategies for limiting hospital-based infections. Though the term ‘patient safety’ did not come in to widespread use until the 1990s (especially so after the late 1999 IOM report), the study of medical error in health care delivery has a longer history,<sup>9</sup> including in research conducted by Sociologists.<sup>10</sup> In the late 1970s, ethnographic accounts by Marcia Millman and Charles Bosk examined how doctors and other health care professionals made sense of mistakes and dealt with anxieties over medical malpractice. More recently, social science researchers have taken note of the growing emphasis on patient safety to study what the relatively new field entails. This section reviews both Millman and Bosk, along with some of the more recent Social Science research on patient safety, in order to build a background for a longer explanation of the dissertation’s main theoretical contribution, related to the medical profession, in the subsequent section.

Millman’s research on medical mistakes offers a critical perspective on the organization of health care delivery in the late 1970s. She explains that when mistakes occur, “they are perpetuated and ignored by physician-colleagues, and furthermore, that this response is built into the organization of hospital life and the professional training

---

<sup>9</sup> See Footnote #7 of this chapter for some of that history.

<sup>10</sup> Bosk (1979) and Millman (1977) are the most widely noted that specifically address medical mistakes. A related discussion of iatrogenesis comes from Illich (1976). While interesting, Illich does not deal strictly with medical error, and has been critiqued for being overly polemical. See Horrobin (1977) for one such extensive criticism.

and outlook of physicians.”<sup>11</sup> As a result, Millman shows that physicians, similar to other professional occupations, “will construct collective rationalizations and defenses to help them through their mistakes and to protect themselves from the reactions of the lay world.”<sup>12</sup> Millman explains how this happens through what she calls neutralization, defined as “the various processes by which medical mistakes are systematically ignored, justified, or made to appear unimportant or inconsequential by the doctors who have made them or those who have noticed that they have been made.”<sup>13</sup> By calling attention to the way that error is pushed aside, Millman’s concept of ‘neutralization’ actually identifies an overriding sentiment, that of minimizing the significance of error, which patient safety reformers will attempt to transform over two decades later. Millman’s argument can be seen as a Sociological precursor to similar sorts of criticisms that patient safety advocates will later make, in imploring for a change to the medical culture that hides errors from being disclosed. Although from a vantage point more firmly within the health care industry, such critiques are no less challenging.

With a less critical tone, Bosk’s research on medical mistakes instead focuses more extensively upon the medical profession. Bosk explains that, “our lack of understanding of how physicians detect, categorize, and punish error is fatal to our understanding of social control in the medical profession,” such that “we do not know how to interpret a profession’s claim to be self-regulating.”<sup>14</sup> Through ethnography of a teaching hospital, Bosk finds the answer to the puzzle of control and regulation in the

---

<sup>11</sup> Millman (1977), pp. 9-10.

<sup>12</sup> Ibid., p. 90.

<sup>13</sup> Ibid., p. 91.

<sup>14</sup> Bosk (1979), p. 27.

medical profession through a contrast between what he terms as ‘moral errors’ and ‘technical errors’:

Moral error breaches a professional’s contract with his client. He has not acted in good faith. He has done less than he should have. Such conduct is not honest and defensible but undercuts all the presumptions on which the professional-client relationship is based. For this reason moral errors are treated more seriously than technical ones. They undercut the very fabric of client-professional and professional-professional relationships. Hence the control of technical performance is subordinated to the control of moral performance; without the overarching moral system, the technical system is not amenable to control.<sup>15</sup>

The significance of this distinction for control is that “professionals forgive errors that are defined as involving techniques,” while “professionals punish errors that are defined as moral.”<sup>16</sup> The result, according to Bosk, is that “professionals interpret their mandate to control performance as an injunction to maintain a community of high moral standards.”<sup>17</sup> While Millman criticizes the medical profession for neutralizing mistakes in a way that makes the medical profession appear unaccountable, Bosk shows how self-regulation of the profession is intimately tied to how errors are classified, establishing the bounds of morality for the professional community. But like Millman, Bosk’s compelling distinction between technical errors and moral errors also previews one of the significant challenges of patient safety reform. With patient safety discourse, advocates position medical error as both a technical problem and moral dilemma, directing research toward the problem of error reduction and advocacy toward changing how responsibility is organized in delivery.

---

<sup>15</sup> Bosk (1979), p. 171.

<sup>16</sup> Ibid., p. 181.

<sup>17</sup> Ibid., p.181.

Of course, the landscape of health care has changed remarkably since Millman and Bosk provided their vivid accounts of medical error in the 1970s. Advances in biological research and medical technology make contemporary health care delivery vastly more complicated than it was only a few decades ago. Medical interventions that were once unthinkable or impossible now offer promise for restoring and maintaining health, but can also pose substantial risks to patients. The apparent tension between progress and risk is one of the most compelling challenges confronting wealthy, developed democracies,<sup>18</sup> exemplified in advanced health care systems by the emergence and rapid development of patient safety discourse. Despite significant attention within the health care industry, patient safety has not yet been extensively investigated by social scientists, though interest has been growing.<sup>19</sup> Recent social science research on patient safety has covered the dimensions of communication and teamwork,<sup>20</sup> the role of narrative in patient safety reporting and learning,<sup>21</sup> the significance of an organizational culture directed toward patient safety,<sup>22</sup> and worker participation in incident reporting.<sup>23</sup> While much of this work is intriguing, it tends to follow the lead of health care researchers' agenda on improving patient safety, rather than taking an analytical approach more in line with Millman's critical stance on health care organization or Bosk's theoretical distinctions related to professional regulation.

---

<sup>18</sup> See, for example, Beck (1992).

<sup>19</sup> For support of this, see review articles by Idedema (2009) and Ovretveit (2009), both from a special issue on patient safety in *Social Science & Medicine* 69 (2009).

<sup>20</sup> Hewett, et al. (2009); Kerr (2009); Whyte, et al. (2009).

<sup>21</sup> Iedema, et al. (2006); Iedema, et al. (2009); Waring (2009).

<sup>22</sup> Waring (2005); Waring (2007a); Weiner, et al. (2008); Collins, et al. (2009).

<sup>23</sup> Macrae (2008).

Given that social science research on patient safety is still in its infancy, there is debate over how researchers should proceed. Vincent bluntly asks “do we approach patient safety simply as critics or do we aspire to be contributors?”<sup>24</sup> Not only raising the question, Vincent implores social scientists to not only criticize, but also find ways that research may actually contribute effectively to advancing patient safety.<sup>25</sup> On the other hand, Zuiderent-Jerak, Strating, Nieboer, and Bal claim that social science research needs to shift from “uncovering barriers to implementation,” which would help promote effectiveness of patient safety interventions; to “unpacking how patient safety is done and which possibilities and problems this produces,”<sup>26</sup> which is essentially a critical perspective on the patient safety project. Either side in this debate seems to disagree on the starting point (‘simply as critics’ versus ‘uncovering barriers’), as well as what should be the goal of social science research on patient safety (‘contributors’ versus ‘unpacking patient safety’). Since the field is still in formation, such discord is not unexpected.

As this debate continues in a relatively new area of research for social science, my approach to studying patient safety does not fall firmly upon one side, as either critical or contributory. Instead, I view this dissertation project as descriptive of the rise of patient safety discourse, and historical in explaining how that discourse relates to changes in the medical profession and health care delivery. I have not found any descriptive-historical study of patient safety discourse that has been undertaken to explain the significance of patient safety ideas in the context of changes to health care delivery and the medical profession over the past couple of decades. To account for emergence and growth of

---

<sup>24</sup> Vincent (2009), p. 1779.

<sup>25</sup> Ibid, p. 1779.

<sup>26</sup> Zuiderent-Jerak, Strating, Nieboer, and Bal (2009), p. 1720.

patient safety, I develop a history that explains how medical error reports, patient stories, and organizational campaigns constitute a particular patient safety discourse, which fits within a broader story of the shifting character of the medical profession. In a sense, this project serves as an update to Millman and Bosk's late 1970s work on medical error, but in light of the contemporary patient safety reform movement, which has only recently become a topic of study for social science.<sup>27</sup>

Through a descriptive-historical study, I am accounting for the rise of what I describe as 'the patient safety challenge,' which emerged and developed over the course of 1990s, gained prominence in the early 2000s, and now occupies a significant place in health care reform efforts. Positioning medical error as a significant, wide-ranging, and entrenched problem in need of political and organizational attention, the patient safety challenge is a discourse of reform. This reform discourse includes both an alternative to the medical malpractice model for understanding medical mistakes, as well as a research and advocacy orientation for transforming the organization of health care delivery. Resting upon a conceptualization of human error borrowed from research in psychology and human factors engineering, patient safety reformers challenge the health care industry to take action to better manage medical error, and in so doing call for a major transformation in health care delivery.

What is at stake in the patient safety challenge? While significant in its own right, and discussed throughout the dissertation, the transformational orientation of patient safety discourse is not only about challenging a particular conception of medical

---

<sup>27</sup> Though medical error has been a significant topic within health care research since at least the early 1990s, the patient safety movement can be identified as taking hold with the IOM's 1999 publication *To Err is Human*.

error. As a discourse that promotes an alternative rationality for understanding and managing medical error, the patient safety challenge also speaks to changes in the medical profession over the last couple of decades. To tackle what they see as an unacceptable problem, patient safety reformers recognize that the medical profession will have to change. For instance, leading patient safety advocates Lucian Leape and Don Berwick state, “creating cultures of safety requires major changes in behavior, changes that professionals easily perceive as threats to their authority and autonomy.”<sup>28</sup> This recasting of professional behavior relies upon a unified rationality governing health care delivery – with medical error as a preventable risk, with patients as partners in the prevention of error, and with safety culture (along with system redesign) as the organizational model for transforming health care delivery. These three major changes are the subject of each substantive chapter of the dissertation (chapter previews follow the upcoming contributions and methods sections), and all contribute to the contemporary remaking of the medical profession. While this chapter began with contrasting medical malpractice and patient safety in Barack Obama’s 2008 campaign materials to introduce the significance of medical error, that distinction will take a secondary role until the next chapter. As prompted by the research reviewed in this section, I turn now to looking at what patient safety implies about changes to the medical profession, and by connection to health care organization, over the last two decades.

---

<sup>28</sup> Leape and Berwick (2005), p. 2387.

## **Theoretical Contribution: Remaking the Medical Profession**

“A theory of professions should be centrally concerned with the conditions under which knowledge is produced and applied in ways that make a difference for the life of others.”<sup>29</sup>

Within medical sociology, accounting for the rise and fall of medicine’s professional dominance has been a central topic of inquiry and debate. This dissertation research seeks to contribute to that research by incorporating an analytical approach, derived largely from Foucault’s concept of governmentality, which has yet to be extensively utilized in accounting for changes to the medical profession. In this section, I first provide a general overview of some major works and ideas in medical sociology about the rise and decline of the medical profession. Then, I provide some links between the professions literature and Foucault’s ideas, mostly through the work of Magali Sarfatti Larson, in order to transition to the concept of governmentality. Finally, I explain how building further links between the professions literature and governmentality studies, resting upon recent scholarship on patient safety by Justin Waring, can better inform our understanding of the contemporary remaking of the medical profession, illustrated throughout the dissertation by the case of patient safety reform.

Sociological accounts concerning the status and power of the medical profession<sup>30</sup> can be traced to the profession’s heyday in the mid-20<sup>th</sup> century. The legacy of Eliot

---

<sup>29</sup> Larson (1990), p. 32.

<sup>30</sup> Initial guidance for this discussion of the status of the medical profession comes from Kevin M. Moseby’s unpublished paper “The Sociology of Medicine, and the Sociology of Biomedicine: Two Analytic Categories Defined,” as well as from Marjorie Banks, et al.



Freidson's work on the professions still plays a very strong role in how the medical profession is understood; in fact, the grounds for debate are based upon concepts and arguments first advanced by Freidson in the early 1970s.<sup>31</sup> Responding to the assumption that the medical profession was defined by institutional altruism,<sup>32</sup> Freidson shifted the sociological study of medicine to a more critical view of the profession. According to Freidson, the concept of autonomy, defined as "control over the content and the terms of work,"<sup>33</sup> is the most significant factor in considering professional power. Accordingly, Freidson argues, "The only occupation that is truly autonomous is medicine itself. It has the authority to direct and evaluate the work of others without in turn being subject to formal direction and evaluation by them. Paradoxically, its autonomy is sustained by the *dominance* of its expertise in the division of labor."<sup>34</sup> This dominance within the division of labor gave the medical profession a vast amount of political power, of cultural and social status, and of economic wealth, lasting throughout most of the middle decades of the twentieth century.

How the medical profession came to attain such a privileged position has been carefully described in Paul Starr's extensive history of the profession. Starr describes medicine's unique power in this way - "among the professions, medicine is both the paradigmatic and the exceptional case: paradigmatic in the sense that other professions emulate its example; exceptional in that none have been able to achieve its singular

---

(1996), who review the debate over professional power to shed light upon 1990s medical malpractice discourse.

<sup>31</sup> Freidson (1970a) and Freidson (1970b).

<sup>32</sup> Talcott Parsons is the theorist most identified with this functionalist explanation.

<sup>33</sup> Freidson (1970b), p. 134.

<sup>34</sup> Ibid., p. 136.

degree of economic power and cultural authority.”<sup>35</sup> According to Starr, “power, at the most rudimentary personal level, originates in dependence”, such that “the power of the professions primarily originates in dependence upon their knowledge and competence.”<sup>36</sup> As a result of these definitions then, “professional authority can be defined, in part, by a distinctive type of dependency condition – the dependence on the professional’s superior competence.”<sup>37</sup> As with Freidson, Starr also asserts the power of the medical profession as a result of the privileged status of its knowledge. Although accounting for the rise of the medical profession from the late 19<sup>th</sup> to the 20<sup>th</sup> century, Starr sees a profound change underway as he describes the unfolding history of medical care. From the early 1980s, only a decade after Freidson’s publications on professional dominance, Starr could see the ‘coming of the corporation.’ He describes the approaching shift as “the rise of the corporate ethos in medical care,” a potential revolution that “is already one of the most significant consequences of the changing structure of medical care.”<sup>38</sup>

With this transformation on the horizon, the terms of debate regarding the professional power of medicine began to radically shift in the 1980s, spawning arguments that the medical profession was in a state of decline. Descriptions of professional decline came in various flavors - deprofessionalization, proletarianization, corporatization, and bureaucratization<sup>39</sup> - emphasizing distinct but often complementary processes. Coming

---

<sup>35</sup> Starr (1982), p. 29.

<sup>36</sup> Ibid., p. 4.

<sup>37</sup> Ibid., p. 15.

<sup>38</sup> Starr (1982), p. 448.

<sup>39</sup> See Light and Levine (1988) and Haug (1988) for discussion of deprofessionalization; Murphy (1990) for discussion of proletarianization; McKinlay and Stoeckle (1990) for discussion of corporatization; and Conrad and Schneider (1990) for discussion of bureaucratization.

toward the end of the 1980s, the major premise of each of these arguments was in describing, and accounting for, the decline of the medical profession's status and power from its mid-century golden era. Also around this time, Abbott's influential work on the 'system of professions' shifted attention away from the power of any particular profession and instead focused upon professional competition and jurisdictional battles over control of work tasks.<sup>40</sup> He explains that "professions make up an interacting system" such that "professions compete within this system, and a profession's success reflects as much the situations of its competitors and the system structure as it does the profession's own efforts."<sup>41</sup> While Abbott does not focus upon the decline of medicine per se, his thorough analysis places professions in competition within a system, lessening the emphasis upon dominance of any particular profession. This systems perspective, along with the more explicit professional decline arguments from the late 1980s to the early 1990s, sets off a continuing debate over the trajectory of status and power of the medical profession.

More recently, conclusions about the professional decline of medicine have not relinquished, though with some qualification. Staking a claim for continued decline, Leicht and Fennell observe that for medicine "there is plenty of evidence that control over professional work is moving firmly in the direction of corporate and bureaucratic control," which is "driven by pressure for revenue generation, accountability to the state, and actions to avoid lawsuits."<sup>42</sup> Scott and colleagues characterize the contemporary health care environment as an "era of managerial control and market mechanisms" in

---

<sup>40</sup> Abbott (1988).

<sup>41</sup> Abbott (1988), p. 33.

<sup>42</sup> Leicht and Fennell (2001), p. 14.

which “beginning in the early 1980s, governmental policies shifted toward deregulation and a reliance on market forces, and large corporate groups entered the field. The central value governing institutional practice during this period is *efficiency* of service provision.”<sup>43</sup> Recognition that the so-called ‘golden age’ of the medical profession has long since elapsed is now commonly observed.<sup>44</sup> For example, Boyer and Lutfey contrast the medical profession of the 1950s as having “Scientific and financial autonomy; Professional dominance of physicians; Cultural authority of medicine,” with that of the profession in 2009 as being characterized by “Decreased scientific and financial autonomy; Physicians as “double agents” to patients and insurance companies; Erosion of public trust.”<sup>45</sup> For a perspective outside of medical sociology, Burnham confirms, in a review of medical history, that, “by the closing years of the twentieth century, great social forces were shifting physicians somewhat away from the privileged recognition that society had once accorded them,” so that “physician professionals were particularly unhappy as their collective social position eroded with demedicalization.”<sup>46</sup> While not giving up completely on his concept of professional dominance, Freidson would step back from the extensive reach that the idea once had, due to the various arguments and observations noting the decline of the medical profession’s power and status.<sup>47</sup> Although dominance no longer provides an accurate description of the medical profession’s status and power, Light warns against over-simplifying decline and instead

---

<sup>43</sup> Scott, et al. (2000), p. 22.

<sup>44</sup> McKinlay and Marceau (2002) make one such argument.

<sup>45</sup> Boyer and Lutfey (2010), p. S80.

<sup>46</sup> Burnham (1998), p. 158.

<sup>47</sup> See Freidson (1994) for a collection of essays on reassessing the medical profession. See Freidson (2001) for a continued reassessment amidst a general theory of the significance of the professions.

looks at power shifts as a pendulum swing among institutional actors.<sup>48</sup> Even with such qualifications, for a variety of observers, the medical profession does not have the same unified position of dominance and authority that it was once considered to have during its height in the middle decades of the 20<sup>th</sup> century.

In light of this direction of scholarship on the medical profession, it would seem as though the patient safety challenge, in disclosing an epidemic of medical mistakes and questioning the culture of medical practice, fits with the overall story of professional decline. On top of continual medical malpractice concerns – consider the growth of defensive medicine - patient safety erodes practitioner control and autonomy since safety protocols are generally imposed with managerial guidance and under administrative pressures. With the contemporary status of the medical profession less certain than it once was, the story of patient safety could also be told along the lines of professional decline. Such a story might be compelling when considering resistance, but it would not completely account for the rapidly expanding field of patient safety, which has also been embraced by many in the medical profession. In a 2010 review of the professions literature, Timmermans and Oh warn, “strong pressures do not necessarily herald the end of organized, professional medicine. Professions form political alliances, rally allies, and then fight back in courts, the media, and at various policy levels. The ultimate trump card in these fights is that professionals have expertise that may keep patients alive.”<sup>49</sup> At a time when the power and status of the medical profession has diminished from its mid-20<sup>th</sup> century peak, patient safety discourse encompasses a new field of knowledge

---

<sup>48</sup> Light (2001).

<sup>49</sup> Timmermans and Oh (2010), p. S97.

governing the organization of health care. Given its privileged expertise in care delivery, the medical profession is not just forced to adhere to patient safety mandates but also actively constructs what those principles mean and how they will be practiced.<sup>50</sup>

The main theoretical contribution of this dissertation research, then, is to explore how a new form of knowledge, patient safety, contributes to the changing character of the medical profession, ultimately influencing the profession's more recent, and more active, participation in health care reform. Keeping in mind Randall Collins' comment that "it is not the existence of knowledge that is crucial, but how it is socially organized,"<sup>51</sup> I take cue from Freidson as way of building this contribution. Freidson observed that "the question of the influence of the knowledge and concepts of professions on human consciousness and state policy has been given too little attention by sociologists."<sup>52</sup> In coming to such a conclusion, Freidson cites the importance of Magali Larson's work on professional knowledge, which brings together Foucault's ideas on discourse with the professions literature. Derived from Larson's engagement with Foucault, I build upon her work in establishing a stronger link between Foucault's discourse analysis and the professions literature, using the case of patient safety to investigate how the political role of the medical profession has recently changed, despite the assumed decline of the status and power of the profession.

Often identified with her book *The Rise of Professionalism*, Larson takes a conflict-based assessment of the history of professions. She claims that "the emergence

---

<sup>50</sup> Evidence of this is presented throughout the dissertation, but particularly in chapter 4, which covers organizational patient safety efforts, such as lead by the two leading US safety advocates, Dr. Lucian Leape and Dr. Donald Berwick.

<sup>51</sup> Collins (1990), p. 18.

<sup>52</sup> Freidson (1994), p. 7.

of the professional model in the liberal phase of capitalism as the outcome of a project tending toward market control.”<sup>53</sup> In terms of how professionals secure power, for Larson that “goes far beyond mere technical autonomy”, and instead “derives from monopoly: a monopoly of competence legitimized by officially sanctioned “expertise,” and a monopoly of credibility with the public.”<sup>54</sup> In other work, Larson would develop a broader theoretical approach encompassing her earlier historical analysis of competence and credibility, while asserting the added significance that knowledge plays in theorizing professions. Restating the quote that introduced this section, Larson proposes that, “a theory of professions should be centrally concerned with the conditions under which knowledge is produced and applied in ways that make a difference for the life of others.”<sup>55</sup> I take this statement as a guiding theoretical approach to patient safety – to study the conditions under which patient safety knowledge is produced, and then the ways that patient safety knowledge is applied – in order to develop an argument about the contemporary status of the medical profession.

The emphasis on professional knowledge is a major contribution of Larson’s work on the professions. For example, Larson makes a connection between the established concept of autonomy to her highlighting of professional knowledge as: “autonomy, which has occupied a special analytical place in the sociology of professions, is justified in principle by the professionals’ claim of possessing a special and superior knowledge, which should therefore be free of lay evaluation and protected from inexpert

---

<sup>53</sup> Larson (1977), p. 38.

<sup>54</sup> Ibid., p. 38.

<sup>55</sup> Larson (1990), p. 32.

interference.”<sup>56</sup> Overall, her perspective on the concept of profession is summarized in the following extensive declaration:

Profession should be seen as a complex programme of research rather than a readily usable and unproblematic concept. *Structurally*, profession is a link between codified knowledge and practice, in a world of non-knowers or of less knowing laity. As a structural link between the hierarchic educational system and the hierarchic occupational order, profession seeks in both orders institutional guarantees which only the state can offer. Profession can thus become, structurally, a *material link between the state and the deployment of specialized knowledge in the civil society*. By their structural characteristics, professions are a necessary part in any theory of the *modern* state. But this would be a state that resembles Foucault’s conception...: a state that equips society and is presented to all its citizens as a *positive* agency.<sup>57</sup>

In deriving guidance from Larson, my use of ‘profession’ is with the complex and contradictory aspects of the concept in mind, rather than assuming any easily accessible applications of the concept. Patient safety knowledge is produced and applied with complex and contradictory consequences for the medical profession. Still, the end goal of such an analysis is to investigate the connection that forms ‘between the state and the deployment of specialized knowledge in civil society.’ With patient safety being the specialized knowledge developed in civil society, I argue how it has contributed to remaking the medical profession in line with recent political attempts at reforming health care. By the dissertation’s conclusion, I suggest that the medical profession, not necessarily in complete unity but still with consistency, now has the opportunity to play a more active role in state interventions in health care delivery (notably, Federal reform). Using Larson as a bridge between the professions literature and Foucault’s analytical approach, the conditions of patient safety knowledge production, along with how that

---

<sup>56</sup> Larson (1990), p. 31.

<sup>57</sup> Ibid., p. 44, (italics in original).



knowledge becomes part of the medical profession through state interventions in health care delivery, serve as the main theoretical contribution for the dissertation.

That the concept of profession encompasses both conditions of knowledge production (related specifically to patient safety) and a link to the state (through the medical professions expanded role in health care reform) can be further explained through incorporating Foucault's concept of governmentality. Developed toward the end of the 1970s, Foucault's notion of governmentality provides a theoretical basis for reassessing knowledge in the medical profession. Built around a series of lectures and unpublished works from late in his career, Foucault sketched out the historical development of an analytically distinct 'governmental rationality' (or 'governmentality') as "the institutions, procedures, analyses and reflections, the calculations and tactics...which has as its target population, as its principal form of knowledge political economy, and as its essential technical means apparatuses of security."<sup>58</sup> The concept of governmentality places emphasis upon the 'population' as an object of study, and all the forms of knowledge and techniques of intervention (such as risk assessment and management) that are associated with it.<sup>59</sup> In conceptualizing governmentality, Foucault uses a unique understanding of power, theorizing, "the exercise of power consists in guiding the possibility of conduct and putting in order the possible outcome. Basically power is less a confrontation between two adversaries or the linking of one to the other than a question of government."<sup>60</sup> This notion of power is what Larson was referring to in the above extensive quote about using Foucault's conception of the state. From this

---

<sup>58</sup> Foucault (1991), p. 102.

<sup>59</sup> Foucault (1994).

<sup>60</sup> Foucault (1982), p. 221.

notion of power (and related conception of the state), government is understood as “the way in which the conduct of individuals or of groups might be directed: the government of children, of souls, of communities, of families, of the sick.”<sup>61</sup> The concept of ‘government’ is fairly open since “it did not only cover the legitimately constituted forms of political or economic subjection, but also modes of action, more or less considered and calculated, which were destined to act upon the possibilities of action of other people,” such that “to govern, in this sense, is to structure the possible field of action of others.”<sup>62</sup> While the state is crucial in governing, the concept refers to all the ways in which the ‘actions of others’ might be directed towards certain proscribed ends, though not necessarily through coercion.<sup>63</sup>

Later followers and interpreters of Foucault’s ideas would elaborate on the major aspects of governmentality, providing definitions and other applications of the concept. Gordon describes how Foucault “proposed a definition of the term ‘government’ in general as meaning ‘the conduct of conduct’: that is to say, a form of activity aiming to shape, guide, or affect the conduct of some person or persons.”<sup>64</sup> Dean provides a similar general definition of government “as the ‘conduct of conduct’ – the more or less deliberate attempt to shape the actions of others or of oneself.”<sup>65</sup> Further expansion from Gordon concerns how “a rationality of government will thus mean a way or system of thinking about the nature of the practice of government (who can govern; what governing

---

<sup>61</sup> Foucault (1982), p. 221.

<sup>62</sup> Ibid., p. 221.

<sup>63</sup> For more about the concept of governmental rationality and its relation to the state, see Lakoff (2005), p. 136.

<sup>64</sup> Gordon (1991), p. 2.

<sup>65</sup> Dean (1999), p. 198.

is; what or who is governed), capable of making some form of that activity thinkable and practicable both to its practitioners and to those upon whom it was practised.”<sup>66</sup> Again, in related terms, Dean explains government “...as an assemblage of practices, techniques, and rationalities for the shaping of the behaviour of others and of oneself,” such that “our study of government does not amount to a study of politics or power relations in general; it is a study only of the attempts to (more or less) rationally affect the conduct of others and ourselves.”<sup>67</sup> Dean then helpfully summarizes the theoretical approach - “An analytics of government is thus a way of thinking about how we conduct ourselves and others, and how we think about ourselves and others while we are doing this. It is thus an attempt to gain clarity about the conditions under which we think and act in the present.”<sup>68</sup> As will be shown throughout the dissertation, patient safety knowledge is a form of governmentality – ‘a way of thinking about how we conduct ourselves and others’ when it comes to medical errors, and ‘how we think about ourselves and others while we are doing this’ when it comes to the organization of responsibility in health care delivery. If patient safety discourse has remade the medical profession, or at least attempts to do so, it is through a form of knowledge and advocacy that is focused upon governing the conduct of physicians.

Governmentality, when matched with Foucault’s at-times related concept of problematization, provides an analytical approach to how patient safety discourse constitutes changes to the medical profession – questioning how conduct in medicine is, both formally and informally, regulated. Using Collier and Lakoff’s definition,

---

<sup>66</sup> Gordon (1991), p. 3.

<sup>67</sup> Dean (1999), p. 198.

<sup>68</sup> Ibid., p. 36.

“Problematization is a term that suggests a particular way of analyzing an event or situation: not as a given but as a question.”<sup>69</sup> Following Dean, then, a problematization of government concerns the “calling into question of how we shape or direct our own and others’ conduct.”<sup>70</sup> If we look at the recent history of patient safety with the analytical guidance of problematizing government, I argue that patient safety is directly about questioning the contemporary medical profession – specifically in terms of what constitutes its professional culture and conduct – in order to make the case for transforming health care delivery, redistributing care responsibility, and building an overall improvement ethos. So what is at stake with the patient safety challenge is a questioning of the profession that has the potential implication of remaking medicine. The questioning of conduct that is brought on by patient safety discourse disrupts the profession’s conservative inclinations (such as was historically seen with professional dominance) and moves the profession toward pursuit of comprehensive health care reform (albeit in an incremental manner).

By remaking the medical profession, in theoretical terms, I mean ‘problematizing government’ of the medical profession. I ultimately argue that, in practical terms, evaluation of the medical profession has shifted through the incorporation of patient safety knowledge, with the profession’s relationship to the state then taking a more active role in health care reform. Professional dominance and decline assumes a particular concept of profession, resting upon a possessive conceptualization of power and a more static notion of status. If the concept of profession, via Larson and then Foucault, is

---

<sup>69</sup> Collier and Lakoff (2008), p. 11.

<sup>70</sup> Dean (1999), p. 27.

viewed from a different light – not in terms of evaluating a profession regarding dominance or decline, but instead through ‘problematizing government’ as a way of questioning conduct in the profession – we can see how a new form of professional knowledge has emerged and how the profession’s relation to the state has then shifted. Patient safety discourse questions the culture and conduct of medicine that had defined an earlier era and continues to this day despite observations of professional decline. In seeking to reconstitute the profession with a revised politics of shared responsibility and ethos of collective improvement, patient safety advocates attempt to remake the profession by redefining its culture and conduct. I tell a story of how patient safety discourse remakes the medical profession in three iterations: how the concept of medical error has become an object of research and target for advocacy (discussed in chapter 2), how patient stories of medical error transform both patients and providers (chapter 3), and how leading advocates and organizations attempt to change notions of culture and responsibility in the organization of the healthcare workplace (chapter 4). These three dimensions together account for changes in the medical profession’s political role in health care reform and the ongoing state interventions that result from recent comprehensive legislation (chapter 5). At the end of the concluding chapter, I also suggest where this project may be taken with future research, in hopes of building upon the dissertation to construct a detailed history of patient safety discourse and politics. Before providing a brief preview of these arguments in each of the chapters, I first discuss the research methods used throughout the dissertation.

### **Research Method: Text and Discourse Analysis**

“Discourse is a practice not just of representing the world, but of signifying the world, constituting and constructing the world in meaning.”<sup>71</sup>

With the proliferation of discourse around medical error, safety and the profession, the method I rely upon to investigate the patient safety challenge is text and discourse analysis. Discourse analysis encompasses a very large field of methods from both the humanities and social sciences. Influenced by the theoretical guidance of Foucault’s analytics of government, the methods that I employ in the dissertation do not follow a strict methodological recipe. Instead, I rely upon a set of concepts and tools from areas of discourse analysis that utilize flexible, interpretive methodologies. Given my analytical emphasis upon the concept of governmentality, I draw upon the methodological tradition of Foucault, as described by Dreyfus and Rabinow, but also with general influence from Dean and Nadesan.<sup>72</sup> In addition to Foucauldian analytics, I rely upon methodological guidance from Fairclough’s Critical Discourse Analysis.<sup>73</sup> In this section I begin with general discussion of discourse, followed by attention toward the importance of interpretation and meaning in discourse analysis. Then, I look more closely at Foucault’s genealogical project and Fairclough’s critical discourse analysis. Finally I provide a description of the specific types of patient safety discourse I examined, in order to provide details as to how I conducted my analysis.

---

<sup>71</sup> Fairclough (1992), p. 64.

<sup>72</sup> Dreyfus and Rabinow (1983); Also see Dean (1999) and Nadesan (2008) for other discussions of methods that have been based upon Foucault’s concepts.

<sup>73</sup> Fairclough (1992).

Though not encompassing all types, much of discourse analysis is inseparable from the theoretical perspective that is taken. For studying language, Gee states this general point emphatically as: “Method and theory cannot be separated, despite the fact that methods are often taught as if they could stand alone. Any method of research is a way to investigate some particular domain. In this case, the domain is language-in-use. There can be no sensible method to study a domain, unless one also has a theory of what the domain is.”<sup>74</sup> If method is derived from theory, then it also stands to reason that such a perspective on discourse does not easily lend toward a formulaic method. Fairclough expresses this notion by saying, “...there is no set procedure for doing discourse analysis; people approach it in different ways according to the specific nature of the project, as well as their own views of discourse.”<sup>75</sup> Thus, discourse analysis is a more open and variable type of method, heavily dependent upon one’s theoretical perspective, topic of study, and conception of discourse.

Given such methodological variance resulting from theoretical differences, it is not surprising that the term ‘discourse,’ and then subsequently ‘discourse analysis,’ are generally also given open-ended definitions. Avoiding a definition of discourse, Power sees a “range of different and competing interpretations of what counts as discourse.”<sup>76</sup> Speaking specifically about Foucault’s analytics, Mills also observes the open-ended character of discourse, “The term discourse is not rooted within a larger system of fully worked-out theoretical ideas, but is one element in Foucault’s work. This lack of system

---

<sup>74</sup> Gee (1999), p. 5; See also Edwards and Potter (1992), p. 11 for a similar discussion in the shift to discursive psychology.

<sup>75</sup> Fairclough (1992), p. 225.

<sup>76</sup> Power (2000), p. 105.

sometimes causes difficulty for theorists and may be one of the reasons that there are so many different definitions of the term discourse, and so many modifications of the meaning of the term. However, this lack of general system is also what makes for a certain flexibility when theorists are trying to use Foucault's work to fit changing social circumstances."<sup>77</sup> While such lack of precision may be considered a weakness, Mills points out the advantage that comes with a methodological flexibility of not being tied to fixed terms. Nonetheless, Mills does derive a working, though loose, definition as: "Discourses are sets of sanctioned statements which have some institutionalised force, which means that they have a profound influence on the way that individuals act and think."<sup>78</sup> She goes on to clarify, "What constitutes the boundaries of a discourse is very unclear. However, we can say that discourses are those groupings of statements which have similar force – that is, they are grouped together because of some institutional pressure, because of a similarity of provenance or context, or because they act in a similar way."<sup>79</sup> This notion of discourse as having 'institutionalised force,' despite unclear boundaries, is what drives my approach to studying patient safety discourse. In reviewing statements in technical reports, medical error narratives, and organizational campaigns, I have identified claims and concepts that amount to 'institutionalised force' - efforts to influence a shift in professional conduct of medicine, based upon principles promoting patient safety.

Fundamental to understanding how the term 'discourse' gets used has to do with assumptions about language – that talk and text are constitutive of reality, rather than

---

<sup>77</sup> Mills (2004), p. 15.

<sup>78</sup> Ibid., pp. 55-56.

<sup>79</sup> Ibid., pp. 55-56.



purely representational. For example, Wood and Kroger state, “the major assumption of discourse analysis is that the phenomena of interest in social and psychological research are constituted in and through discourse.”<sup>80</sup> Fairclough offers a similar rendering as “discourses do not just reflect or represent social entities and relations, they construct or ‘constitute’ them; different discourses constitute key entities (be they ‘mental illness’, ‘citizenship’ or ‘literacy’) in different ways, and position people in different ways as social subjects (e.g. as doctors or patients).”<sup>81</sup> Fairclough and Wodak expand upon the idea of constitutive in proposing the dialectical nature of discourse as, “...socially *constitutive* as well as socially shaped: it constitutes situations, objects of knowledge, and the social identities of and relationships between people and groups of people. It is constitutive both in the sense that it helps to sustain and reproduce the social status quo, and in the sense that it contributes to transforming it.”<sup>82</sup> As discourse constitutes objects and concepts, along with being shaped by them, the methodological approach to language must necessarily be flexible to account for such a dynamic process. An emphasis on the constitutive significance of discourse offers a contrast to more traditional research perspectives, which Wood and Kroger describe in terms of three major shifts: “(a) from a distinction between talk (discourse) and action to an emphasis on talk *as* action, (b) from a view of talk (discourse) as a route to internal or external events or entities to an emphasis on talk as the event of interest, and (c) from a view of variability as anomalous feature of action to an appreciation of variability both within and between people.”<sup>83</sup>

---

<sup>80</sup> Wood & Kroger (2000), p. 4.

<sup>81</sup> Fairclough (1992), pp. 3-4.

<sup>82</sup> Fairclough and Wodak (1997), p. 258, italics in original.

<sup>83</sup> Wood & Kroger, (2000), p. 4, italics in original.

With patient safety reform, I look to talk of safety and error as the central driving force in efforts at reforming health care delivery and remaking the medical profession. Discourse does not just represent such efforts, but actively constitutes them, while at the same time being shaped by the shifting political and cultural environment.

With the constitutive significance of language as discourse, interpretation and meaning play central roles in discourse analysis. Connecting definition to meaning, Torfing theorizes how, “a discourse is a differential ensemble of signifying sequences in which meaning is constantly negotiated,”<sup>84</sup> such that “all actions have meaning, and to produce and disseminate meaning is to act.”<sup>85</sup> Fairclough also draws upon meaning in reiterating that “discourse is a practice not just of representing the world, but of signifying the world, constituting and constructing the world in meaning.”<sup>86</sup> Speaking of Foucault’s work, Dreyfus and Rabinow find that “the more one interprets the more one finds not the fixed meaning of a text, or of the world, but only other interpretations. These interpretations have been created and imposed by other people, not by the nature of things.”<sup>87</sup> The lack of fixed meaning justifies an open and variable approach to discourse, so that, methodologically, “the resulting interpretation is a pragmatically guided reading of the coherence of the practices of society... yet it is not a general method.”<sup>88</sup> While not explicitly addressing discourse analysis, McCarthy derives the implications that a focus on meaning and interpretation has for method:

---

<sup>84</sup> Torfing (1999), p. 85.

<sup>85</sup> Ibid., p. 94.

<sup>86</sup> Fairclough (1992), p. 64.

<sup>87</sup> Dreyfus and Rabinow (1983), p. 107.

<sup>88</sup> Ibid., pp. 124-125.

interest in the problem of meaning is linked to a methodological framework that is neither causal nor explanatory but *semiotic*. The semiotic study of culture is directed toward the study of symbolic and signifying systems through which a social order is communicated and reproduced. These signifying systems and social practices are what make up a culture and its structures of meaning.<sup>89</sup>

Examining patient safety discourse is thus a project in examining the professional culture of medicine, exploring the problem of meaning through interpretation of such concepts and practices as medical error, patient stories, and patient safety organizations and campaigns. Citing Clifford Geertz's famous assertion, McCarthy elaborates that the analysis of culture is "not an experimental science in search of law but an interpretive one in search of meaning."<sup>90</sup> By interpreting discourse, I am in search of the various meanings of patient safety ideals, in order to explain how such concepts and claims problematize the medical profession, and through that questioning then work to constitute a new form of conduct and culture in medicine.

From these considerations about discourse, along with the significance of interpretation and meaning, I supplement a mix of Foucauldian genealogical analysis with Fairclough's Critical Discourse Analysis. In rather direct fashion, Dreyfus and Rabinow exhort what the genealogist does and does not do:

The genealogist does not seek to discover substantial entities (subjects, virtues, forces) or to reveal their relationships with such other entities. Rather, he studies the emergence of a battle which defines and clears a space. Subjects do not first preexist and later enter into combat or harmony. In genealogy subjects emerge on a field of battle and play roles, there and there alone. The world is not a play which simply masks truer reality that exists behind the scenes. It is as it appears.<sup>91</sup>

---

<sup>89</sup> McCarthy (1996), p. 20, italics in original.

<sup>90</sup> Geertz (1973), p. 5 [quoted in McCarthy (1996)].

<sup>91</sup> Dreyfus and Rabinow (1983), p. 109.

Similarly, I do not assume that patient safety discourse masks any reality to be uncovered. The discourse constitutes subjects who behave, with practices that follow, in terms of patient safety. Thus it can also be said that “instead of origins, hidden meanings, or explicit intentionality, Foucault the genealogist finds force relations working themselves out in particular events, historical movements, and history.”<sup>92</sup> In the following chapters, I look to identify what those particular events or historical movements are that construct the patient safety project, as it emerges in the 1990s and develops over the past decade. Recalling the methodological flexibility of discourse analysis, Tamboukou explains that, “Foucault’s genealogies do not offer methodological ‘certainties’; they persistently evade classification, but they do encourage and inspire the making of new questions to interrogate the truths of our world.”<sup>93</sup> Ultimately then, according to Dreyfus and Rabinow, “drawing from these disparate components, one seeks to establish a set of flexible relationships, and merge them into a single apparatus in order to isolate a specific historical problem.”<sup>94</sup> In terms of genealogical analysis, I investigate the relationship among concepts and subjects that play out through the broad field of patient safety discourse, in order to identify discussions of the problem of professional conduct in medicine.

However, this endeavor is not strictly a genealogical project, as I hope to not only describe the emergence of patient safety but also derive a sense of the direction and shape

---

<sup>92</sup> Dreyfus and Rabinow (1983), p. 109.

<sup>93</sup> Tamboukou (1999), p. 215.

<sup>94</sup> Dreyfus and Rabinow (1983), p. 121.

of power relations that the discourse constructs.<sup>95</sup> For that effort, I draw upon Fairclough's Critical Discourse Analysis (CDA) to supplement Foucauldian analytics. Not an uncomplimentary pairing, it is clear that Fairclough draws from Foucault in statements such as: "the immediate origins and motivations of change in the discursive event lie in the problematization of conventions for producers or interpreters, which can happen in a variety of ways."<sup>96</sup> Day Slater also notes the affinities between Foucault and CDA when it comes to the linkage between power and discourse: "for [Foucault], power is not confined to institutions or to the powerful, and does not act just to repress, but is multiple and productive and dispersed across a range of discursive sites. Discursive structures therefore act to express, legitimate and maintain particular power relations. But discourses cannot, ultimately, be determining, as they are always more less open to contest and change, and oppositional discourses can and do emerge to challenge the dominant and privileged ones."<sup>97</sup> It is in the connection between power and discourse, specifically from any oppositional discourses that arise, which links Foucault to the work of prominent CDA scholars like Fairclough.

I follow in the path of CDA by subscribing to the notion that "describing discourse as social practice implies a dialectical relationship between a particular discursive event and the situation(s), institution(s) and social structure(s) which frame it."<sup>98</sup> This assertion is qualified by saying, "it is important that the relationship between discourse and social structure should be seen dialectically if we are to avoid the pitfalls of

---

<sup>95</sup> This comes to fruition in chapter 4, about redesigning control in the healthcare workplace, and chapter 5, with discussion of the politics of healthcare reform.

<sup>96</sup> Fairclough (1992), p. 96.

<sup>97</sup> Day Slater (2000), p. 131.

<sup>98</sup> Fairclough and Wodak (1997), p. 258.

overemphasizing on the one hand the social determination of discourse, and on the other hand the construction of the social in discourse.”<sup>99</sup> As a result of such a dialectical discourse analysis, the broader implications concern how “CDA sees itself not as dispassionate and objective social science, but as engaged and committed” but which “does not imply that CDA is less scholarly than other research: standards of careful, rigorous and systematic analysis apply with equal force to CDA as to other approaches.”<sup>100</sup> Like the CDA approach, I am committed to understanding the dialectical relationship between discourse and social structure when accounting for the patient safety challenge. As a cautious observer, I see that patient safety holds both promise and peril in its connection to remaking the medical profession. I hope that the outcome of this research can actively participate in debates over the direction of professional care throughout the contemporary reform wave of the American health care system.

Based upon these guiding methodological influences in discourse analysis, specifically from Foucault’s genealogical approach and Fairclough’s CDA, the specific way in which I analyzed patient safety discourse now follows. Overall, the majority of my research material is written text. I placed these textual documents in three (not mutually exclusive) categories that comprise patient safety discourse: (1) scientific-technical discourse (for example, research reports on medical error), (2) popular-ethical discourse (for example, media narratives of patient injury), and (3) policy-political discourse (for example, organizational advocacy campaigns). Though not exclusive to each chapter, the scientific-technical discourse tended to structure chapter 2 on the

---

<sup>99</sup> Fairclough (1992), p. 65.

<sup>100</sup> Fairclough and Wodak (1997), pp. 258-259.

shifting concept of medical error; popular-ethical discourse guided chapter 3 on patient stories; and policy-political discourse informed chapter 4 on safety culture standardization in the health care industry. Recalling Mills, “discourse analysis of written text aims to make explicit those implicit norms and rules for the production of language.”<sup>101</sup> Thus, I extracted repeated notions, arguments, sentiments, premises and assumptions from these documents, trying to make explicit the norms and rules of patient safety discourse. In making sense of patient safety discourse, it is also crucial to bring forth those ideas that underlie explicit statements, but which are necessary for the discourse to bear logical coherence and consistency. Getting at such implicit assumptions can be tricky, but I have tried to call attention to them wherever possible.

As a supplement to the documents collected, I also conducted some participant observation, along with informal conversational interviews. This supplemental data collection was somewhat more limited in scope compared to the document analysis. However, I did attend the 2007 National Patient Safety Foundation Annual Congress in Washington, DC (reported mostly in chapter 4). There I attended various professional panels, and observed patient safety presentations, and conversed with some attendees and exhibitors in the exhibit hall (the bibliography lists the panels that I attended). Informal conversations with local contacts at the UCSD School of Medicine, and Scripps Healthcare System, also provided general direction for my analysis.

There is a vast amount of patient safety discourse, but the most prominent voices and texts became apparent based upon repeated reference over time and across various sources. Over the course of nearly four years, I searched for materials related to patient

---

<sup>101</sup> Mills (2004), p. 124.

safety and medical error, coming to observe those documents and names that get mentioned over and over (reports such as the Institute of Medicine's *To Err is Human*, for example, is mentioned in nearly every discussion of patient safety, and names like Don Berwick and Lucian Leape are ubiquitous). Other key perspectives on patient safety for analysis would include: researchers and policymakers in the field of health care quality; patient safety advocates; patients who were victims; patient safety organizations and advocacy groups; state and federal government health and welfare agencies. Sources for these figures include: reports and scientific articles; policy statements; media accounts; presentations, websites, pamphlets of organizations; governmental documents. From these perspectives and sources, I created lists of prominent moments, compiled in analytical terms as discursive shifts, which constitute a conceptual transition about error and safety, establishing the contours of discourse on patient safety. To analyze all the documents, I did close reading, took notes, re-read, pulled out significant quotes, re-read and then organized quotes based upon themes that help construct a historical description. Ultimately this method helped to build a theoretical case for the remaking of professional conduct as exemplified in patient safety discourse.

The analysis of patient safety discourse is used to present a narrative of the politics of patient safety, particularly related to how the debate over the problem of medical error is both questioning and redefining the medical profession. According to patient safety advocates, the health care industry needs to undergo a massive transformation - from a traditional culture of secrecy and mistakes to a new patient safety culture of openness and learning. Resting upon an ideal of safety improvement, a discourse of patient safety has become ubiquitous in health care, referenced in regard to



nearly any issue that can be connected to questions of safety. Based upon the overall theoretical review and methods of discourse analysis, the following chapter previews provide a brief account of how a new discourse emerges in health care, the ways that we see it substantiated in public documents, and how certain consequences (unintended or not) follow from such a novel field of discourse.

## **Chapter Previews - risk, narrative, & safety culture**

### *Chapter 2 – Redefining the Concept of Medical Error*

Out of the medical malpractice insurance crisis of the 1970s, the California Medical Insurance Feasibility Study (MIFS) was the first systematic attempt to assess the statistical rate of medical error. Taking guidance from the MIFS, the more robust Harvard Medical Practice Study (HMPS) garnered broader national attention for the study of medical error, at least within the field of health care research, due to its dissemination in the prestigious *New England Journal of Medicine*. The watershed moment for awareness of medical error, though, came from the US Institute of Medicine's (IOM) *To Err is Human* report. Published in late 1999, the IOM's groundbreaking report marks a significant turning point in the development of the movement for patient safety. This report, along with the publicity it received, is widely credited with securely placing patient safety on the agenda of any (and every) health care organization. Much of the attention and fervor circling the IOM report results from its most famous statistical assertion, an estimate of between 45,000 and 98,000 Americans

deaths every year as a result of preventable medical mistakes. Largely from the power and publicity of that number, the problem of medical error, and the developing patient safety movement, would jump from the confines of a relatively narrow health care constituency to a prominent spot on the national health care reform agenda. Starting with the MIFS in 1977, advanced by the HMPS in 1991 and culminating in IOM reports of 2000 (and also of 2004), I explain how the risk-based understanding of medical error came about, both challenging the liability model of medical error and forming the basis of the patient safety interventions discussed in subsequent chapters. As the upper estimate of the annual number of US deaths due to medical error, '98,000' is repeated again and again in nearly any discussion of patient safety. As a method from 1977 inspired a study in 1991 that is eventually made popular in 2000, this chapter follows the circuitous path of how medical error is redefined, from an object of risk research to a target of policy reform, through the discourse of scientific-technical reports.

### *Chapter 3 – Narratives of Patient Tragedy and Empowerment*

Where is the patient in the story of medical error and patient safety? When given a spotlight by the popular media, patient tragedies bring significant public attention to the concern over medical error. One of the most well known stories of patient tragedy is that of the Boston Globe Health reporter Betsy Lehman, who died in 1994 from an accidental overdose of a chemotherapy drug. Adding to the shock of a deadly error happening to a health reporter and highly-educated patient, was the fact that the mistake occurred at one of the most respected hospitals in the nation, the Dana Farber Cancer Institute in Boston. Tragedies such as Betsy Lehman's death are a stark reminder that medical error is a not

only a technical problem understood in terms of research reports and statistics, but is also one of patient tragedy and public response. Besides Betsy Lehman's death, this chapter also reviews the medical error narratives of Sorrel King, who lost her daughter Josie to a series of medical errors at Johns Hopkins (Baltimore) in 2001, as well as the Actor Dennis Quaid, whose newborn twins narrowly survived an accidental overdose of a blood-thinning drug at Cedars Sinai (Los Angeles) in 2007. Although patient deaths from medical error have not translated into a massive patient-led movement, patient stories and advocacy are linked, through the stories of Lehman, King and Quaid, to the prevention politics of the patient safety reform agenda. Patients are taking a more active role in national (and even transnational) patient safety advocacy, and I explore how medical error narratives imagine the patient role as not simply a passive victim of error but rather as an active agent for change. In collaboration with patient safety experts who also argue that patients themselves are among the best safety advocates, Sorrel King and Dennis Quaid each share their transformational story, told to promote the argument that patients are fundamental partners in the prevention of unnecessary harm.

#### *Chapter 4 – Work System, Safety Culture, and the Reorganization of Medical Work*

Facing pressure from such sources as the IOM's rousing report and media coverage of patient tragedies, a series of health care advocacy campaigns emerged to take the lead on patient safety - setting priorities, goals, and further shaping the patient safety reform agenda. Among the massive field of health care advocacy organizations, the National Patient Safety Foundation (NPSF) and the Institute for Healthcare Improvement (IHI) are the two main organizational players in US patient safety advocacy. In the wake

of the IOM report, both organizations launched extensive campaigns to raise awareness and garner support for the patient safety cause, including the inauguration of the NPSF's annual meetings and the commencement of the IHI's 100,000 lives campaign. Promoting these advocacy campaigns are leading figures such as Lucian Leape and Donald Berwick, who disseminate a growing science of patient safety and quality improvement to justify and rationalize the massive (attempted) changes such initiatives bring about within the health care industry. The NPSF and the IHI push an organizational commitment to safety cultures in the health care workplace, along with the complementary idea of designing safety systems, as the major methods for reducing the risk of medical error and limiting patient harm. Outside of the US, the World Health Organization has gotten involved by forming the World Alliance for Patient Safety, which seeks to spread the message to health systems across the globe. For any of these advocacy efforts, an organizational culture committed to safety, a recognition of the inevitability of human error, and specific techniques such as reporting systems are all asserted as necessary changes that health care systems, along with the medical profession, must take for patient safety. Within the health care workplace, a tension between individual accountability and system improvement belies the assumed easy implementation of a standardized safety culture. As a force of consensus-building, patient safety advocacy campaigns have the effect of institutionalizing a conception of medical error as an urgent risk. Particularly when pushing for an alternative politics of responsibility, these campaigns seek to pressure the health care industry to reorganize work culture and organization towards the goals of patient safety (and quality improvement).

### *Chapter 5 – Patient Safety and Health Care Reform*

In a brief concluding chapter, I consider how my discussion of medical error and patient safety encompasses broader health care reform by returning to the theoretical argument about the remaking of the medical profession and its relationship to the state. Beginning with an overview of some important ways that patient safety has entered health care reform at the federal level, I then contemplate how the link between patient safety and health care reform matters for remaking the medical profession. Amidst remarkable advancements in medicine over the last decade, the political debate over quality and safety has potentially arrived at a significant moment of transformation. Though it remains to be seen how major this transition will be in the coming years, a conceptual and organizational shift in the delivery of health care, as witnessed by the story of patient safety, is already under way. With high stakes in the shape that health care delivery takes in the next decade, the medical profession has become more collaborative regarding comprehensive reform, through the discourse of patient safety and quality, to join the federal government in reorganizing American medical care. Finally, at the end of this concluding chapter, I look to what the future holds – both for the ongoing politics of patient safety and for an expansion of this project. At the conclusion, and in pursuing future work, I suggest that the federal government and the medical profession have a shared interest in advancing patient safety and quality improvement. For the government, this comes through as an avenue for reform and for reducing health care costs; while for the profession, it provides a way to re-establish a social position that has been undermined by managed care.

## CHAPTER 2 – From Risk to Reform: Changing the Concept of Medical Error

The public has been led to expect that doctors ‘do good,’ and when they don’t, it is because of personal negligence or bad practice. The public (and even much of the medical profession) has not been sufficiently educated to realize that there is some measurable risk in every medical intervention, and when that risk is spread over thousands or millions of persons subject to intervention, it results in countable numbers of individuals paying the whole price for the benefit provided to the larger population.<sup>102</sup>

--Gelfand, Quoted in *Medical Insurance Feasibility Study*, 1977

...at least 44,000 Americans die each year as a result of medical errors...the number may be as high as 98,000. Even when using the lower estimate, deaths due to medical errors exceed the number attributable to the 8<sup>th</sup>-leading cause of death. More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).<sup>103</sup>

--From the preface of the IOM’s *To Err is Human*, 2000

From the late 1970s to the early 2000s, the conceptualization of medical error underwent a significant change. ‘Countable numbers’ of deaths from medical error was not known in the late 1970s, as the quote above argues that error should be considered a necessary risk for the benefits of medical intervention. By the early 2000s, although the exact toll was still not precisely known, estimates painted a shocking picture of up to 98,000 annual US deaths due to medical error.<sup>104</sup> Especially when matched with stories

---

<sup>102</sup> Gelfand, H.M. quoted in *Medical Insurance Feasibility Study* (1977), p. xiii (original source - *Science* 195:728-9, 1977).

<sup>103</sup> Institute of Medicine (2000), p.1.

<sup>104</sup> An April 2011 report estimates the rate to be even higher than what was used to calculate the 98,000 statistic. See Classen (2011).

of individual tragedy,<sup>105</sup> statistical estimates of error mortality garnered widespread publicity, marking the emergence of a safety and quality challenge to any notion of ‘acceptable risk.’ Over the course of about two decades between the above quotes, the concept of medical error shifts from being described as an acceptable risk of medical intervention to a target of reform policies centered upon prevention.

In this chapter, I explore this transition in understanding of error in medicine, as witnessed by analyzing influential reports on medical error. The Medical Insurance Feasibility Study, published in 1977, takes a tempered response to its findings on the rate of error, with an interpretation that risk is inseparable from medical intervention. Over a decade later, the Harvard Medical Practice Study, published in 1991, would come to mostly similar findings on the rate of error, but with a distinct interpretation of pursuing risk reduction and establishing an agenda of further research on error prevention in health care delivery. Attention toward medical error, though, is most prominently connected to the US Institute Of Medicine’s *To Err is Human* report, released in late 1999 and published in early 2000. With the famous statistic of 98,000 annual deaths attributable to error, the conventional story in health care marks the Institute of Medicine report as a watershed, when medical error became an issue of national public concern. The report, however, actually represents the culmination of a shift toward thinking about medical error in terms of risk reduction and error prevention. Over the course of these three reports, medical error becomes an object of research and policy, forming a distinct patient safety discourse that challenges the medical malpractice system as inefficient, adversarial and ultimately counterproductive for ensuring medical care is safe.

---

<sup>105</sup> Patient Stories are discussed in the next chapter.

Patient safety discourse shifts medical error outside of a strict medical liability model, instead conceptualizing error as preventable and subject to collective interventions. Whereas the malpractice system views mistakes as negligent and subject to financial restoration, patient safety discourse instead describes errors as inevitable byproducts of a complex system that should instead be subject to preventive measures for mitigating harm. A keystone in the development of patient safety discourse has to do with creating a conceptual space outside of the malpractice system for understanding medical error, which is accomplished through scientific-technical reports that construct error as a distinct object of research and preventive intervention. Patient safety, as a growing field of health care research and reform, offers another avenue, at times complimentary but ultimately in competition, for the understanding of medical error. The conceptual change in medical error is significant not only for challenging the dominance of the medical malpractice system, but also sets the stage for how the medical profession is remade (which becomes more apparent in the following chapters).

From an analysis of scientific-technical reports on medical error, in this chapter I construct a history of how medical error was transformed into an object of research and target for prevention policies. Starting with the Medical Insurance Feasibility Study in 1977, advanced by the Harvard Medical Practice Study in 1991 and culminating in Institute of Medicine reports of 2000 and 2004, I explain how medical error came to be understood in terms of risk and eventually as an objective for reform in health care. Much of the shift from risk to reform is derived from the power of a number. As the upper estimate of the annual number of US deaths due to medical error, '98,000' is repeated again and again in nearly any discussion of patient safety, from assertions by



staunch advocates of quality assessment to casual mentions by neutral observers in the media. As a method from 1977 inspired a study in 1991 that is eventually made popular by the IOM in 2000, this chapter traces the circuitous path of how that prominent number came to be constructed. Ultimately, following the reports in this way shows how safety advocates and reformers attempt to convince both the public and policymakers that medical error is a serious risk that will require transformational reform of health care delivery. To tell this story, I begin with a brief review of research on risk (along with some on classification), which will serve as a theoretical guide for the case studies of three medical error reports that take up the bulk of the chapter, before finally concluding with a discussion that both compares the three reports and assesses their significance for establishing a broader discourse on patient safety.

### **Risk and Medical Error**

The modern ideologies of prevention are overarched by a grandiose technocratic rationalizing dream of absolute control of the accidental, understood as the irruption of the unpredictable. In the name of this myth of absolute eradication of risk, they construct a mass of new risks which constitute so many new targets for preventive intervention.<sup>106</sup>

The proliferation of risk has been a significant historical development, leading scholars to examine risk as its own area of study. As noted by Castels in the above quote, the relationship between risk and preventive intervention is an uneasy one, as the ‘modern ideologies of prevention’ seem to constitute the very risks that they seek to

---

<sup>106</sup> Castels (1991), p. 289.

manage. This chapter focuses upon changing ideas of medical error, on one level in terms of what error is but more fundamentally for how conceptions of error relate to conceptions of risk. How error is defined and counted rests upon assumptions about the role of risk in medicine. I argue that the three reports reviewed over the course of the chapter signify a transition in the relationship between the concepts of error and risk. As a theoretical guide for analysis of the case studies, in this section I draw upon major theories of risk, especially interested in how risks are treated as ‘real’ or ‘constructed.’

One framework for studying risk has been derived from Foucault’s work on governmentality and biopower, which provide a theoretical basis for later work specifically on the concept of risk. Built around a series of lectures, interviews and unpublished writings from late in his career, Foucault sketched out the historical development of an analytically distinct ‘governmental rationality’ (or ‘governmentality’) as “the institutions, procedures, analyses and reflections, the calculations and tactics...which has as its target population, as its principal form of knowledge political economy, and as its essential technical means apparatuses of security.”<sup>107</sup> Discussed in more detail in the previous chapter, Foucault’s concept of governmentality has also been influential in spawning a tradition in Risk Studies that places emphasis on the various of forms of knowledge employed to study populations. Descending from his emphasis on governmental rationality and population,<sup>108</sup> subsequent historical work by other scholars continued with more specific reference to risk.<sup>109</sup> For example, Hacking traces the rise of

---

<sup>107</sup> Foucault (1991), p. 102.

<sup>108</sup> Foucault (1994).

<sup>109</sup> In addition to governmentality, Foucault’s concept of ‘problematization,’ understood as “what has made possible the transformations of the difficulties and obstacles of a

statistical thinking in the 19<sup>th</sup> century, as the so-called ‘avalanche of numbers’ provided the basis for determining risks related to crime, accidents, and poverty.<sup>110</sup> Statistical techniques formed an essential basis in calculating risk for the purposes of insurance. In Ewald’s terms, insurance is a ‘technology of risk’ - the central political technology for the early 20<sup>th</sup> century development of social welfare models.<sup>111</sup> According to Ewald, risks are not given, but are constituted through an historical process of knowledge construction, political intervention and economic justification.<sup>112</sup> Based upon risk sharing over the population, welfare policies expanded over the mid-20<sup>th</sup> century with the rise of actuarial techniques, which Simon argues has had lasting ideological consequences.<sup>113</sup> More recently, Rose has argued that we find ourselves in a phase he calls ‘advanced liberalism,’ a governmental rationality that asserts the primacy of market mechanisms, leading to more privatized notions of risk.<sup>114</sup> Renaming a similar shift as ‘prudentialism,’ O’Malley asserts that a new combination of actuarial techniques is forming, such that a collectivized risk model is losing ground to a privatized one.<sup>115</sup>

Reviewing the governmentality approach to risk, O’Malley summarizes that “...risks are not regarded as intrinsically real, but as a particular way in which problems

---

practice into a general problem for which one proposes diverse practical solutions,” is also related (and discussed in chapter 1). For more on problematization see Foucault (1994), p. 118; and Collier, Lakoff, et al. (2004).

<sup>110</sup> Hacking (1991).

<sup>111</sup> Ewald (1991).

<sup>112</sup> Ibid.

<sup>113</sup> Simon (1988).

<sup>114</sup> Rose (1996).

<sup>115</sup> O’Malley (1996).

are viewed or ‘imagined’ and dealt with.”<sup>116</sup> With more detail, Dean offers this explanation of how governmentality theorists conceive of risk:

There is no such thing as risk in reality. Risk is a way – or rather, a set of different ways – of ordering reality, of rendering it into a calculable form. It is a way of representing events so they might be made governable in particular ways, with particular techniques, and for particular goals. It is a component of diverse forms of calculative rationality for governing the conduct of individuals, collectivities and populations.<sup>117</sup>

Taken together, governmentality theories provide a framework for understanding the emergence of new rationalities governing risk. According to Silbey, one of the key perspectives within this disparate field of work, “embracing risk means to ‘conceive and address social problems in terms of risk.’”<sup>118</sup> Once something is understood in terms of risk then that leads to specific ways of managing it in terms of risk. In contrast to malpractice reform (which is associated with tort reform), patient safety reform assumes medical error as a risk, which then organizes solutions through prevention policies. From the perspective of governmentality theories, the history of patient safety provides an example of the social construction of risk, with ways of thinking about the problem as a risk (such as statistical rates of error in patient populations), and then setting up ways for managing it in terms of prevention (such as reporting systems that monitor error).

In contrast to the constructivist perspective of Governmentality theorists, other theoretical approaches do in fact regard risk as more ‘intrinsically real.’ German

---

<sup>116</sup> O’Malley (2008), p. 57. For an extended analysis of the theories and methods of the governmentality approach, with a chapter on risk, see Dean (1999a).

<sup>117</sup> Dean (1999b), p. 131.

<sup>118</sup> Silbey (2009), p. 345.

Sociologist Ulrich Beck has advanced one of the most well known realist positions.<sup>119</sup> According to Beck's influential 'Risk Society' thesis, social organization in the 20<sup>th</sup> century has become increasingly structured based upon responses to very real threats to humanity, such as nuclear war and environmental degradation. Beck asserts the provocative claim that risk has eclipsed traditional categories, such as class, in organizing politics and society.<sup>120</sup> Joined in part by British sociologist Anthony Giddens, Beck has also developed the concept of reflexive modernization, claiming that risks are an inevitable condition of complex, modern technological systems.<sup>121</sup> Thus, risks cannot be eliminated, but rather must be acknowledged as inherent consequences of these systems. From the perspective of American Sociology, Perrow and Vaughan put forth arguments with similarities to Beck and Giddens' reflexive modernization, in writing about how risk becomes normalized – as an inevitable product of complex organizations for Perrow and as result of organizational culture for Vaughan. Despite best intentions, according to Perrow complex organizations (many disparate, specialized parts make up the whole) with tight coupling (close connection between parts or events in the organization) cannot completely assure that an accident will not happen. Perrow's analysis attempts to prioritize acceptable risks, thus allowing for some choice in how to mitigate the reality and inevitability of system accidents.<sup>122</sup> Vaughan's research traces how the 'normalization of deviance' in NASA's organizational culture resulted in the decision to

---

<sup>119</sup> This separation between, roughly, Foucault-influenced risk theories and Beck-influenced risk theories is confirmed in Dean (1999b). For an expanded discussion of comparing a broader range of theories of risk, see Zinn (2008).

<sup>120</sup> Beck (1992).

<sup>121</sup> Beck and Giddens (1994).

<sup>122</sup> Perrow (1984).

launch the Challenger, when risk was known to exist. Vaughan shows how work culture can lead to the acceptance of certain risks, such that ‘risky’ decisions, and eventually accidents themselves, can occur without ever breaking any rules.<sup>123</sup> According to these theories from European and American Sociologists, risk has a real occurrence with any social advancement, complex organization or technological endeavor. Interestingly, patient safety advocates have themselves been influenced by such theories, specifically using ideas from Perrow and Vaughan –both Sociologists are cited in the Institute of Medicine’s *To Err is Human* Report for their work on organizational culture.

Seemingly divergent perspectives on the reality of risk, the historical grounding of the interdisciplinary Governmentality approach (such as Rose, Simon and O’Malley) can actually complement the political and organizational imperative of prominent Sociological accounts (like that of Beck, Perrow and Vaughan). Recalling Castels’ quote from the beginning of this section, whether an emerging discourse of risk (in this case, related to patient safety) identifies a novel and real danger may actually be secondary to the organizational, political, and technological imperative to assess and manage everything as a risk. O’Malley observes the power that risk conveys, “the model of risk itself – the use of predictive statistical knowledge linked to techniques of harm prevention – overwhelmingly has been regarded as one of the benefits bestowed by science.”<sup>124</sup> Leaving aside the constructivist versus realist debate that hangs over much scholarship on risk, allows research to concentrate on the proliferation of risk itself, and investigate how such discourses on risk change over time. As noted by Dean, “the

---

<sup>123</sup> Vaughan (1996).

<sup>124</sup> O’Malley (2010), p. 3.

significance of risk does not lie with risk *itself* but with what risk gets attached to,”<sup>125</sup> implying that what risk is conceptually related to will be what makes risk consequential. With shifting interpretations of medical error leading to different methods for understanding and managing it as a risk, the scientific-technical reports on medical error in this chapter are part of a broader story of the proliferation of risk.

As will be seen over the course of the reports, when risk reduction gets attached to medical error, the focus of reform becomes advancing prevention policies in health care delivery. This chapter traces a historical process in which governmentality theories on the construction of risk can work together with the political-institutional emphasis of risk society and organizational approaches to risk. Through an emerging scientific-technical discourse of patient safety, understandings of risk and medical error are at first seen in a state of flux – continually redefined in terms of a changing context. As patient safety discourse becomes more established, though, the connection between risk and medical error takes on a more settled relationship, most notably as a result of the influential Institute of Medicine report. As a consequence of that report, ways of thinking about error as a risk (in terms of a system property to mitigated) are connected to ways of managing error (for example, through reporting based upon improvement rationales). Guided by a loose synthesis of major theories on risk, the three reports on medical error constitute a crucial link in the development of patient safety discourse. As a scientific-technical discourse that defines the problem of medical error, each of the three reports offers a distinct interpretation of how to approach medical error as a risk, signifying changes in both the concepts of error and risk over the course of the decades between

---

<sup>125</sup> Dean (1999b), p. 131 (*italics in original*).

each report. I handle each report chronologically, starting with the next section on the Medical Insurance Feasibility Study (1977), followed by a section on the Harvard Medical Practice Study (1991), and ending with analysis of the Institute of Medicine Reports (2000 and 2004).

## **Medical Error as Object of Study and Acceptable Risk**

### **- Medical Insurance Feasibility Study (1977)**

National concern in the US over rising medical costs can be traced back to the 1970s, as health care expenditures rapidly increased. Political pressure for reforming malpractice, and thus understanding the incidence of medical error, develops within a context of cost considerations, but can be more specifically traced to cyclical malpractice insurance crises. As insurance rates drastically increase (problem of affordability) or insurers drop out of the liability insurance market altogether (problem of availability), political urgency for reforming the medical malpractice system quickly takes shape.<sup>126</sup> From 1972 until about 1975, a medical malpractice crisis hit nationwide, with particular pressure in the state of California. As liability insurance became increasingly unavailable or unaffordable for many physicians, the California Medical Association and the California Hospital Association commissioned a study to determine the incidence of medical injury in the course of health care delivery.

---

<sup>126</sup> See Richmond and Fein (2005) for more on the history of rising costs and malpractice reform in health care.



Published in 1977, the Medical Insurance Feasibility Study (MIFS)<sup>127</sup> was the first effort to establish a statistical analysis of the rate of medical error.<sup>128</sup> Lead by principal investigators Don Harper Mills, John S. Boyden, Jr. and David S. Rubsamen,<sup>129</sup> the goal of the MIFS was to assess the scope of medical error, as a basis for providing policymakers with an empirical foundation for considering alternative compensation systems. As stated in the report, “the purpose of this Study was to accumulate data adequate to determine the cost feasibility of almost any non-fault compensation system, the reported data include the type, frequency, and severity of patient-disabilities caused by health care management in California, without regard to legal fault.”<sup>130</sup> While a malpractice crisis may have been a significant contextual factor for conducting the study, “the statistical data on [medical error] incidences and characteristics were primarily developed for actuarial employment to determine the costs of alternative compensation systems.”<sup>131</sup> Consequently, the MIFS did not evaluate the malpractice system, nor did the report provide any specific policy recommendations for liability reform. The research objective was strictly to provide statistical data on the incidence of medical error, which could then be used by policymakers to consider alternative compensation systems.

Reviewing a sample of approximately 21,000 hospital records from 28 California hospitals during calendar year 1974, Mills and colleagues recognize that “most

---

<sup>127</sup> Besides published as a stand-alone report in 1977, the California MIFS was released as a technical summary, focused upon methods and results, in the *Western Journal of Medicine* 128:360-365, April 1978.

<sup>128</sup> Institute of Medicine (1978), p. 75.

<sup>129</sup> Mills is the principal author of the report, listed as administrator, editor and contractor of the MIFS.

<sup>130</sup> California Medical Insurance Feasibility Study (1977), p. 2.

<sup>131</sup> *Ibid.*, p. 107.

admissions were for diseases and conditions for which no one had causative responsibility...[but] sprinkled among these hospitalizations were patients who incurred disabilities from the very medical management they sought.”<sup>132</sup> A complicated research dilemma, as will reoccur in the subsequent studies on the incidence of medical error, is what exactly constitutes the object of analysis when reviewing thousands of hospital records. As a technical problem of definition, what exactly is a medical error? From a common sense viewpoint, what makes for a medical error may seem to be obvious. However, for any statistics to be produced, medical errors must be first identified into categories and then classified accordingly. Research in the social construction of knowledge (specifically, from the interdisciplinary field of Science Studies) has established that classification, and related processes like commensuration and standardization, are not straightforward endeavors. For example, Wynne has argued, “classification is not simple or absolute. What we are doing is choosing for practical purposes to emphasize a certain constellation of attributes of these individual entities in some contexts, and another in others.”<sup>133</sup> In the process of classification, seemingly distinct medical issues and events are made commensurable to one another when placed under the same category of medical error. Espeland and Stevens have argued that commensuration “offers standardized ways of constructing proxies for uncertain and elusive qualities.”<sup>134</sup> In the MIFS, as well as subsequent reports, classification and commensuration are part of the process of defining events as errors.

---

<sup>132</sup> California Medical Insurance Feasibility Study (1977), p. xiii.

<sup>133</sup> Wynne (1989), p. 24.

<sup>134</sup> Espeland and Stevens (1998), p. 316.

When the MIFS was undertaken, guidance in defining medical error could not be gleaned from any previous research on the issue, as Mills and colleagues lament that, “...defining appropriate compensable events is a difficult task.”<sup>135</sup> As a result, the MIFS established the first working classification system for medical error, having to make all the information seen in hospital records standardized into a framework of whether an error took place. To accomplish this, Mills and colleagues argue the focus should be on outcomes analyses, not process, such that “data reported here may stimulate further investigation of identified patterns of disabilities for prevention purposes, but the development of those patterns ought not to be biased by antecedent conceptions of preventability.”<sup>136</sup> In other words, the authors propose that any conceptualization of medical error should derive from patterns in the data, as opposed to coming from an assumed theoretical notion of prevention. Given the politics of malpractice reform, it would appear that Mills and colleagues did not want to be criticized for reading any assumptions into their data. While subsequent reports would not explicitly contradict such a proscription, assumptions would not be so neatly ignored or dismissed. What constitutes a medical error, as with all of the reports discussed in this chapter, is intimately tied up with perspectives on the rational organization of healthcare delivery, understood through an emerging discourse on quality and patient safety in health care.

Based upon a context of malpractice crisis and reform, an important assumption behind the data collection task of the MIFS is to assess, using the wording in the study’s title, the feasibility of alternative compensation systems. As a result, more common

---

<sup>135</sup> California Medical Insurance Feasibility Study (1977), p. 5.

<sup>136</sup> Ibid., p. 7.

terms like medical error, accident, or mistake would be conceptually ambiguous. To be more analytically precise, the MIFS uses the technical term “potentially compensable event (PCE),” defined as “a disability caused by health care management.”<sup>137</sup> In turn, each component of this initial, basic definition is also defined: disability is considered “a temporary or permanent impairment of physical or mental function (including disfigurement) or economic loss in the absence of such impairment,” causation is determined “when the disability is more probably than not attributable to health care management,” and finally health care management “includes both affirmative actions (commission) and inactions (omission) of any health care provider or attendant, whether or not such actions or inactions constitute legal fault.”<sup>138</sup> Such a careful definition is made even more rigorous through a complex methodology that includes five criteria for determining the minimum threshold for what makes a disability countable, all of which is then organized into six classes of Potentially Compensable Events.<sup>139</sup> As the concept of medical error had very scant research history before the MIFS, the process of establishing and defining a term for study is a significant contribution. Even though future studies would depart from use of the technical term ‘Potentially Compensable Event,’ definitions of error, as well as methodologies for studying it, can be traced back to groundwork laid by Mills and colleagues in the MIFS.<sup>140</sup>

---

<sup>137</sup> California Medical Insurance Feasibility Study (1977), p. 8.

<sup>138</sup> *Ibid.*, p. 8.

<sup>139</sup> The very extensive criteria for what makes a disability countable are found on pp. 8-9 of the MIFS, with all six of the classes of PCEs found on pp. 10-15.

<sup>140</sup> More on definitions and methodology can be found in MIFS section 3 (‘Potentially Compensable Events’), section 6 (‘Data Collection Methods’), and section 7 (‘Sample Design’).

Amidst an array of statistical data on medical error, the central finding of the MIFS, much to the surprise of Mills and colleagues, is that Potentially Compensable Events occurred in a relatively small percentage of total hospitalizations. As stated by the researchers, “only 4.65% of hospitalized patients were found to have incurred PCEs and less than 1% of all hospitalized patients had PCEs due to legal fault [which would satisfy the legal standard of negligence].”<sup>141</sup> For research driven by a context of malpractice crisis, the percentage classified as due to negligence, at less than 1% of hospitalizations, was unexpected for Mills and colleagues. Suggesting the inefficiency of the malpractice system for compensating medical injury, they would explain that “only those few with the more severe permanent disabilities have better than even chances of successful lawsuits, but most of these individuals are probably already in the litigation arena, if they are to enter at all.”<sup>142</sup> Whatever expectations might be reasonable regarding the success or failure of litigation, Mills and colleagues ultimately conclude that the risk of error has to be accepted as part of medical interventions, stating:

This study should leave everyone with the realization that there are finite risks associated with health care management, most of which are unrelated to conduct characterized as legal fault. Society deserves the right to nourish great expectations from the advances in modern medicine, but *no one* should remain unaware that benefits and adverse risks are inseparable. When considering the circumstances under which these risks arise, their incidence rates are remarkably low.<sup>143</sup>

The assumption, as stated outright, is that “benefits and adverse risks are inseparable,” which forms a basis for the interpretation that medical error “rates are remarkably low.”

---

<sup>141</sup> California Medical Insurance Feasibility Study (1977), p. 105.

<sup>142</sup> *Ibid.*, p. 105.

<sup>143</sup> California Medical Insurance Feasibility Study (1977), p. 105 (*italics in original*).

Given this assumption and interpretation of the data, Mills and colleagues seem to suggest, from their detailed analysis of the data, that medical error presents an acceptable risk. If the benefits of medical intervention are desired, then the risk of error and possible injury has to be accepted as well. From the perspective of the authors of the MIFS, the ratio of high benefits from modern medicine compared to a ‘remarkably low’ rate of injury found by the study, yields the conclusion that medical error should be considered an acceptable risk.

An interpretation of ‘acceptable risk,’ matched with the fact that the national malpractice crisis had largely subsided by the time the MIFS was published in 1977, meant that little specific change would result directly from the study’s findings. In addition, the methodology of using hospital records to assess the rate of medical injury was considered a limitation in the wake of the study. From a more hesitant position than what the Institute will take a couple of decades later, a 1978 Institute of the Medicine report entitled *Beyond Malpractice* asserts that “the reliability of estimates of injury incidence based on patient records is questionable.”<sup>144</sup> The IOM explains this critique by saying that “such records are admissible as evidence in malpractice suits: thus, if providers are sensitive to situations of potential liability, they may produce patient records that tend to under-report the incidence of medical injuries, whether or not induced by provider fault.”<sup>145</sup> According to this criticism, the MIFS relies upon a data source that carries a bias to under-report error and injury. Recognizing the “limitations of hospital records as a data source,” the IOM nonetheless commends the MIFS as “the best estimate

---

<sup>144</sup> Institute of Medicine (1978), p. 3.

<sup>145</sup> Ibid., p. 3.

to date of the incidence of medical injuries.”<sup>146</sup> The IOM confers that the lack of reliable statistics on the incidence of medical injury is due to the problem of defining medical error, since “there is no consensus on the definitions of medical injury or compensable injury,” then, “effective data collection and analysis are difficult and of questionable value.”<sup>147</sup> A stubborn challenge, widespread consensus over the definition of medical error would remain elusive beyond the 1970s.

In the malpractice system, a practitioner’s liability for a medical injury is decided by a court’s determination of negligence. Outside of the courtroom, the definition for what constitutes medical injury would continue to evolve through a scientific-technical discourse on error that emerges with the MIFS. An investigative project of assessing the statistical incidence of medical injury made the MIFS unique amidst a context of malpractice crisis in the 1970s. More directly, the problem of medical error was completely surrounded by the political pressure of malpractice reform, leaving little space for an understanding of error separate from the liability system. While the MIFS marks the origin of research focused upon medical error as an object of analysis, further investigations carrying forward the study of error would not occur until the 1990s. Despite having little direct influence, the historical significance of the MIFS is in providing an early analysis using hospitals records in order to determine statistical rates of medical injury. Asserting the inevitability of risk in any medical intervention, the authors interpret the rate of error as low. Working past the problem of defining medical

---

<sup>146</sup> Ibid., p. 75.

<sup>147</sup> Ibid., p. 67.

injury, similar data would come to be viewed in a new light by researchers asserting a distinctive understanding of the relationship between risk and medical error.

## **Medical Error as Agenda for Research and Risk Reduction**

### **– Harvard Medical Practice Study (1991)**

When malpractice insurance underwriting cycles leave the crisis stage and return to some form of normalcy, political pressure to reform malpractice wanes, and then so does the associated interest in assessing rates of medical injury. The 1970s malpractice crisis, as the impetus for the California Medical Insurance Feasibility Study, subsided a couple of years before the end of the decade. A few years of relative stasis in the liability insurance market would be shaken by the return of another malpractice crisis in the mid-1980s. Even more significant for the ongoing story of medical error, the landscape of health care delivery undergoes remarkable change as managed care gains momentum throughout, but especially ramping up toward the end, of the 1980s.<sup>148</sup> Managed care refers to a general trend within health care organization that emphasizes cost containment, leading to innovative, and often controversial, strategies for shifting financial risks and incentives in the delivery of care.<sup>149</sup> Types of plans vary widely, and in extremely complex ways, but ultimately managed care employs methods for assessing the efficient utilization of medical resources. Managed care typically relies upon the use of a market model to control cost, and also has the effect of expanding efforts in the

---

<sup>148</sup> Again, see Richmond & Fein (2005) for more on the history of rising healthcare costs.

<sup>149</sup> See Bodenheimer and Grumbach (2009), p. 43-70, for more on managed care and the organization of health care in the US.



evaluation of quality (and performance) in health care. From a market perspective, cost and quality go hand-in-hand when evaluating any good or service. Whether the encroachment of market forces, as brought about by managed care, is beneficial continues to be hotly contested.<sup>150</sup> The shift to managed care and the market model, though, provides a significant context for the expansion of a scientific-technical discourse about medical error.

The hiatus in the study of medical error would come to a permanent end in 1991, with the publication of the Harvard Medical Practice Study in the February 7<sup>th</sup> edition of *The New England Journal of Medicine*. Published in two parts,<sup>151</sup> and with funding acknowledged from the New York Department of Health and the Robert Wood Johnson Foundation,<sup>152</sup> the authors of the study include up to 11 faculty members of Harvard University – drawing from the School of Public Health, School of Medicine, Kennedy School of Government and Law School. Among the authors, Lucian Leape of the Department of Health Policy and Management at the Harvard School of Public Health, along with Troyen Brennan of Brigham and Women’s Hospital and Harvard Medical School, would become two of the most well-known figures in the expanding field of patient safety research and policy.<sup>153</sup>

---

<sup>150</sup> Public discourse from 2009-2010 regarding Congressional comprehensive health care reform legislation is one such example.

<sup>151</sup> There was also a third part of the HMPS published in the Jul. 25, 1991 edition of the *NEJM*, which examined malpractice claims. Focusing specifically on rates of medical error, the two parts reported in the Feb. 7, 1991 edition of the *NEJM* are more relevant for the discussion of risk and error in this chapter.

<sup>152</sup> Harvard Medical Practice Study II (1991), p. 377.

<sup>153</sup> Besides LL Leape and TA Brennan, the other authors involved in the HMPS include AR Localio, AG Lawthers, NM Laird, LE Hebert, LM Peterson, JP Newhouse, PC Weiler, HH Hiatt, and BA Barnes.

With influential authors and a prestigious venue for disseminating findings, the Harvard Medical Practice Study (HMPS) would update, and indeed reinvigorate, the research on medical error that began with the California Medical Insurance Feasibility Study. Leape, Brennan and colleagues clearly reference the MIFS as “the most widely quoted estimates of the incidence of iatrogenic injury and substandard care,” noting that research on medical error has since been largely dormant.<sup>154</sup> Given more than a decade of such dormancy, the main purpose of study, as stated by the authors of the HMPS, was “to develop more current and more reliable estimates of the incidence of adverse events and negligence in hospitalized patients.”<sup>155</sup> Using a distinct term for medical error, Leape, Brennan and colleagues “defined an adverse event as an injury that was caused by medical management (rather than underlying disease) and that prolonged the hospitalization, produced a disability at the time of discharge, or both,” and “defined negligence as care that fell below the standard expected of physicians in their community.”<sup>156</sup> Though the MIFS report was very much concerned with technical aspects of classification and coding, the general definitions found in the HMPS do not depart radically from the earlier study. Similarly, the findings of the HMPS would not differ remarkably from that which was found by the MIFS. Derived from a sample of New York hospital records, the HMPS cites comparable results to what the MIFS found,<sup>157</sup> with rates of medical error within one percentage point - 3.7% of

---

<sup>154</sup> Harvard Medical Practice Study I (1991), p. 370.

<sup>155</sup> *Ibid.*, p. 370.

<sup>156</sup> *Ibid.*, p. 370.

<sup>157</sup> Again, despite different terminology (MIFS used category of ‘potentially compensable events’ while HMPS used category of ‘adverse events’), both studies use fairly similar definitions of medical error.

hospitalizations in the HMPS, while 4.6% in the MIFS.<sup>158</sup> The finding for hospitalizations due to negligence is even closer, at 1.0% in the HMPS versus 0.8% in the MIFS.<sup>159</sup> Given similarities in definitions and results with an older study, then what makes the HMPS so consequential for an emerging scientific-technical discourse on medical error?

Produced under time constraints in order to advise on policy options for the 1970s malpractice crisis, the MIFS did not employ a random sampling strategy. In contrast, the HMPS was conducted with more time,<sup>160</sup> allowing for a robust, random sample. Consequentially, a population estimate can be reliably derived from a random sample. Leape, Brennan and colleagues are thus able to determine from the results of their random sample that when, “extrapolating to the state of New York in 1984, we estimated that 2550 patients suffered permanent total disability and that 13,451 died at least in part as a result of adverse events.”<sup>161</sup> While definitions and results may be similar, a population estimate carries much more weight when reporting statistics on medical error. Rates and percentages, while important as technical data, do not have the same power to grab public attention and call for urgent action in the way that a generalizable mortality number does. Although the number reported in the HMPS would gain, at least upon its release, only modest attention outside of the health care industry, the study’s use of a random sample will later become very consequential for the watershed *To Err is Human*

---

<sup>158</sup> Harvard Medical Practice Study I (1991), p. 373

<sup>159</sup> Ibid., p. 373 lists comparison data with the MIFS.

<sup>160</sup> And, not to be overlooked, the HMPS had a larger, prestigious source of funding (namely, the Robert Wood Johnson Foundation) and a prominent team of authors with the vast institutional resources of Harvard University.

<sup>161</sup> Harvard Medical Practice Study I (1991), p. 371.

report, as a distinct interpretation of the data takes hold. To say that a specific number of deaths can be attributed to error makes for a powerful rhetorical strategy in rallying for wider industry support and in awakening public attention. The methodological improvement of the HMPS will bear more significance as it is used to construct a national population estimate in the *To Err is Human* report (discussed later in this chapter).

Where the HMPS breaks completely from the MIFS is in a new interpretation of risk and medical error, building a foundation for patient safety research and policy as a separate field of study and advocacy, distinct from malpractice reform. Casting medical error in a new conceptual light, the agenda for patient safety research and policy develops alongside the quality movement that was gaining ground in health care during the time that the HMPS was conducted and published. Quality is a major focus for the authors of the HMPS, which was not the case over a decade earlier with the MIFS. The new interpretation of medical error and risk, as found in the HMPS, runs parallel to a context of growing attention to quality assurance in health care delivery. Leape, Brennan and colleagues question how quality is connected to the liability system, stating that “malpractice litigation should in theory be linked to quality assurance,” since “malpractice litigation is intended in part to promote better-quality care by fixing economic sanctions on those who provide substandard care that leads to injuries.”<sup>162</sup>

Given the adverse events discovered by research team of the HMPS, such noble intentions of how the malpractice system should work to assure quality, regrettably, often fall short in practice. Describing “the burden of iatrogenic injury” as “large,” the authors

---

<sup>162</sup> Harvard Medical Practice Study I (1991), p. 372.

of the HMPS assert that “even more disturbing was the number of adverse events caused by negligence,” tallied as 27,179 injuries, 6895 deaths and 877 cases of permanent and total disability.<sup>163</sup> This is taken even further - “medical records are probably a poor source of information on negligence that does not cause injury,” such that the HMPS findings “reflect not the amount of negligence, but only its consequences.”<sup>164</sup> That the numbers of adverse events caused by negligence were described as ‘disturbing,’ matched with the admission that the study did not catch negligence if no injury resulted, implies that Leape, Brennan and colleagues find the malpractice system lacking in its quality assurance capabilities.<sup>165</sup> Any separation between defining error and providing solutions will only become further blurred in subsequent patient safety advocacy that rests upon the foundation laid by this research.<sup>166</sup> Also dispelling a related justification of the liability system, tied to the variation in malpractice rates of different medical sub-specialties, “our data suggest that variations among specialties in rates of litigation do not reflect differing levels of competence, but rather differences in the kinds of patients and diseases for which the specialist cares.”<sup>167</sup> Based upon such findings, the authors of the HMPS question how effective the medical malpractice system actually can be for assuring quality in health care delivery.

The tenuous connection between the malpractice system and quality assurance leads Leape, Brennan and colleagues to assert a new interpretation of medical error in the

---

<sup>163</sup> Ibid., p. 373.

<sup>164</sup> Ibid., p. 373.

<sup>165</sup> This is also supported by Harvard Medical Practice Study III (1991), which asks “whether malpractice litigation promotes high quality in medical care” (p. 249).

<sup>166</sup> Discussed further in chapter 4, in the context of Lucian Leape’s advocacy.

<sup>167</sup> Harvard Medical Practice Study I (1991), p. 374.

context of their results. Citing research and court cases that define negligence, they are more emphatic than the authors of the MIFS that, “error is not the same as negligence. In tort law, medical negligence is defined as failure to meet the standard of practice of an average qualified physician practicing in the specialty in question.”<sup>168</sup> From the basis of those referenced statements, follows the original claim that “negligence occurs not merely where there is an error, but when the degree of error exceeds an accepted norm. The presence of error is a necessary but not sufficient condition for the determination of negligence.”<sup>169</sup> In order to improve quality, attention needs to be focused first and foremost upon error itself, along with the norms that govern them. That there is a conceptual distinction between negligence and error is a significant contribution that started with the MIFS, but when reinterpreted through the lens of quality assurance, justifies targeting medical error as a field of research and policy. The HMPS, arising from a different context than the MIFS, advances the consequential idea that error itself provides an agenda for research and policy. What makes the HMPS distinct is that this agenda can be considered independent, and perhaps even supersede the significance of,<sup>170</sup> research and policy on negligence and the malpractice system.

Given the ongoing political and intellectual stakes in debates over liability reform,<sup>171</sup> Leape, Brennan and colleagues are careful to provide some caveats and further explanation regarding the idea of medical error as a distinct concept for research and

---

<sup>168</sup> Ibid., p. 381.

<sup>169</sup> Ibid., p. 381.

<sup>170</sup> As will be developed later with the *To Err is Human* report.

<sup>171</sup> Not only with medical malpractice reform, but this also relates to tort reform in general. See Haltom and McCann (2004) for an excellent discussion of the recent history tort reform in the United States.

policy. Just as medical error does not automatically align with negligence, “adverse events do not, of course, necessarily signal poor-quality care; nor does their absence necessarily indicate good-quality care.”<sup>172</sup> This is, in part, because “with the present state of medical knowledge,” some adverse events “are unavoidable.”<sup>173</sup> As a result, “perfection can never be the standard of practice, since the vagaries of biology and human behavior make perfection unattainable, in either execution or outcome, for any form of treatment,” such that, “standards of practice must always include an acceptance of some degree of error.”<sup>174</sup> Following the axiom that some degree of risk is always present in any activity,<sup>175</sup> the authors of the HMPS similarly affirm, though not with the same implications as the acceptable risk notion of the MIFS, that it is not possible to eliminate every single medical error.<sup>176</sup> Citing Sociologist Charles Perrow’s influential book *Normal Accidents*,<sup>177</sup> Leape, Brennan and colleagues justify this by explaining “...some degree of error is inherent in all human activity. In highly technical, complicated systems, even minor errors may have disastrous consequences. Medicine is no exception; errors in the performance of highly technical procedures, such as brain or open-heart surgery, can also have catastrophic results.”<sup>178</sup> If error cannot be completely avoided, and if the consequences of error can be a matter of life and death, then the public may have to look beyond the malpractice system for advancing safety.

---

<sup>172</sup> Harvard Medical Practice Study I (1991), p. 372.

<sup>173</sup> Harvard Medical Practice Study II (1991), p. 381.

<sup>174</sup> *Ibid.*, p.381.

<sup>175</sup> This is still distinct, at least in consequences, from the assertion found in the MIFS that risk (of injury) and benefit (of medical care) are inseparable.

<sup>176</sup> While every medical error cannot be prevented, the key difference between the logic of the MIFS and that of the HMPS is that harm to patients can be prevented.

<sup>177</sup> Perrow (1984) is cited in HMPS II (1991).

<sup>178</sup> Harvard Medical Practice Study II (1991), pp. 380-381.

Focused upon the improvement of health care quality, an emphasis on error prevention - rather than error elimination - is a central tenet of the HMPS. Leape, Brennan and colleagues are careful to make a distinction between “preventable” and “unpreventable” adverse events, with the former (“preventable”) subject to intervention based upon current knowledge, while the latter (“unpreventable”) would be the subject of future interventions that “require advances in biomedical knowledge.”<sup>179</sup> Explained further, “as knowledge increases, in theory more adverse events will become preventable,” because it has been historically the case that “the safety and effectiveness of many current medical treatments result from the earlier reduction or elimination of complications similar, or identical to, those we have identified as adverse events here.”<sup>180</sup> Despite the distinction between ‘preventable’ and ‘unpreventable,’ as well as the caveat about the impossibility of totally eliminating error, the authors of the HMPS declare that “most adverse events are preventable...particularly those due to error or negligence.”<sup>181</sup> The findings of the study are couched within a forthright assertion that, “preventing medical injury will require attention to the systemic causes and consequences of errors, an effort that goes well beyond identifying culpable persons.”<sup>182</sup> Approaches to preventing error from resulting in disaster “...have paid off handsomely in other highly technical and complicated enterprises, such as aviation” so that “a similar strategy may work in medicine as well.”<sup>183</sup> The suggestion to borrow ideas from other industries is

---

<sup>179</sup> Harvard Medical Practice Study II (1991), p. 380.

<sup>180</sup> Ibid., p. 383.

<sup>181</sup> Ibid., p. 380.

<sup>182</sup> Ibid., p. 383.

<sup>183</sup> Ibid., p. 383.



taken from leading quality advocate Dr. Donald Berwick,<sup>184</sup> who argues that the health care industry has been (and even continues to be) decades behind other industries in terms of innovative and effective quality assurance.

While the 1977 Medical Insurance Feasibility Study did not include an explicit set of recommendations, no such reservations are present in the 1991 Harvard Medical Practice Study. Prevention of adverse events requires more than ‘identifying culpable persons,’ as the medical malpractice system attempts. Instead, a better understanding of the ‘systemic causes and consequences of errors’ is needed in order to prevent injury. This conceptual transformation is evident in the following agenda-setting statement from the authors of the HMPS:

Our description of adverse events represents an agenda for research on quality of care. Adverse events result from the interaction of the patient, the patient’s disease, and a complicated, highly technical system of medical care provided not only by a diverse group of doctors, other care givers and support personnel, but also by a medical-industrial system that supplies drugs and equipment. Reducing the risk of adverse events requires an examination of all these factors as well as of their relation with each other.<sup>185</sup>

In contrast to the MIFS, risk is not understood as an inseparable consequence of medical intervention. Rather, the authors of the HMPS, while not advocating for the outright elimination of risk, posits risk reduction as a goal for further research on medical error (or adverse events, the technical term used in the study). The malpractice system, with a focus on determinations of liability and financial compensation, is largely irrelevant to risk reduction. In the decade since the MIFS was released, another malpractice insurance

---

<sup>184</sup> See Berwick (1989) for an early and influential statement on importing industrial quality ideas to medicine.

<sup>185</sup> Harvard Medical Practice Study II (1991), pp. 383-384.

crisis emerged in the mid-1980s to provide an impetus for the HMPS to revisit the question of how much medical error was occurring. If insurance crises come and go, yet rates of medical error remain similar from the MIFS to the HMPS, then the malpractice system must not be the sole target of reform. The HMPS promotes further research on the quality of the health care delivery system - so that with a better understanding of medical error, the harm to patients can be prevented or mitigated. A research agenda targeting error prevention, then, marks a discursive shift toward risk reduction.

With a new conceptualization of medical error and risk, the authors of the HMPS list some limitations to the study, and offer some recommendations and future directions for “an agenda for research on quality of care.”<sup>186</sup> As noted above with the MIFS, hospital record reviews carry an underreporting bias, since records can be subpoenaed in a malpractice suit there is then an incentive to hide any possible mistakes. Relying upon hospital records, the authors of the HMPS recognize this potential source of error underreporting.<sup>187</sup> As a review of hospital records, the HMPS does not include any data on outpatient visits, which greatly outnumber hospital admissions, and therefore could be another source of underreporting of error.<sup>188</sup> The scope, prevalence, and significance of error in an outpatient setting could be explored in future research.<sup>189</sup> Unlike with the interpretation of ‘acceptable risk’ found in the MIFS, underreporting need not be weakness of the HMPS. With Leape, Brennan and colleagues trying to call attention to

---

<sup>186</sup> Harvard Medical Practice Study II (1991), p. 383.

<sup>187</sup> Ibid., p. 383.

<sup>188</sup> Ibid., p. 383.

<sup>189</sup> To my knowledge, this data still does not exist. Given that hospital record reviews have established the problem of medical error, the methodological issues (such as sampling strategy and obtaining access) would seem to forestall efforts at conducting a thorough review of error in an outpatient setting.

the problem of medical error, any sources of underreporting would mean that the rate of error is actually larger than what can be determined through a hospital record review.

Besides limitations related to underreporting, the HMPS contains research recommendations toward advancing quality and safety. At first glance a possible shortcoming, the physician-reviewers of the hospital records were general internists and surgeons, rather than specialists, potentially leading to discrepancies on what constitutes an adverse event.<sup>190</sup> The possibility of such understandable differences, though, leads directly to the recommendation that “norms for acceptable levels of various adverse events need to be established.” Once set in place, “hospitals can then target their quality-assurance activities to the areas most likely to respond to such efforts.”<sup>191</sup> Advancing quality assurance will ultimately rest upon bolstering research into medical error and then education of all health care workers:

Future reductions in the occurrence of adverse events also depend in part on research into causes. In the case of adverse events that are currently unpreventable, progress will come from scientific advances...in the case of events due to error, control will require scientific advances in some instances, but we believe that progress will also depend heavily on systems analysis, education, and the development and dissemination of guidelines and standards of practice.<sup>192</sup>

The research agenda, and associated educational campaign, put forth in the HMPS sets out an ambitious ideal for assuring safety in health care delivery. As a conceptual shift, error has a distinct existence outside of the field of negligence. Established as an object of analysis for research and policy, reducing the risk of medical error now becomes a new avenue for health care reform.

---

<sup>190</sup> Harvard Medical Practice Study II (1991), p. 383.

<sup>191</sup> *Ibid.*, p. 382.

<sup>192</sup> *Ibid.*, p. 383.

Among the authors of the HMPS, Lucian Leape has become the most recognizable advocate for new ways of thinking about medical error. His campaign for redesigning health care delivery to be more sensitive about error begins with the HMPS, and is followed with an influential article “Error in Medicine” from the December 21, 1994 issue of the *Journal of the American Medical Association*. Leape argues that “the literature of medical error is sparse,” since, like the HMPS, most studies focus upon injuries rather than specifically upon error itself.<sup>193</sup> The lack of attention to error, according to Leape, is not because physicians and nurses do not experience error, as “they have a great deal of difficulty in dealing with human error when it does occur.”<sup>194</sup> Leape argues the problem is with the culture of medicine, centered upon perfection in a way that makes physicians ask: “How can there be an error without negligence?”<sup>195</sup> The way forward is “if it were recognized that both systems and individuals contribute,”<sup>196</sup> so that “prevention efforts must focus on root causes – system errors in design and implementation.”<sup>197</sup> The conceptual shift that detaching error from negligence, and thus seeking to reduce the risk that medical error poses means that “errors must be accepted as evidence of system flaws not character flaws.”<sup>198</sup> As a fundamental departure from how medical error has been understood, Leape argues that the way forward for making health care safer is in changing the culture of medicine itself.<sup>199</sup>

---

<sup>193</sup> Leape (1994), p. 1851.

<sup>194</sup> Ibid., p. 1851.

<sup>195</sup> Ibid., p. 1851.

<sup>196</sup> Ibid., p. 1852.

<sup>197</sup> Ibid., p. 1854.

<sup>198</sup> Ibid., p. 1857.

<sup>199</sup> This line of reasoning, along with Leape’s other work, will be discussed in more detail in chapter 4 of this dissertation.

Providing an intellectual context through which error can be separated from negligence, the HMPS serves as a foundational report for the emerging field of patient safety. Though the term ‘patient safety’ is not used at all in the report itself, the significance of the HMPS lies in developing a new understanding of error in medicine. Using a scientific-technical justification to establish a new research agenda, the concept of medical error takes on a different form and consequence in the HMPS. When a number of influential studies on the scope and prevalence of medical error were subsequently published throughout the 1990s, medical malpractice began eroding as the predominant lens for understanding medical accidents,<sup>200</sup> with a patient safety discourse emerging to rearticulate medical error instead in terms of risk and prevention. No longer would error be strictly associated with medical malpractice reform, but instead would become connected to the growing quality movement in health care, and specifically to the notion of changing the culture of the medical profession. However, action would be gradual,<sup>201</sup> and not extend beyond discussions within health care policy circles for much of the 1990s. It would take stronger public recognition from the influential Institute of Medicine for the problem of medical error to gain widespread, national notice, and jumpstart efforts to remake safety in health care delivery.

---

<sup>200</sup> See Baker (2005) for some of the other studies, and how that research undermines arguments made in support of medical malpractice crises.

<sup>201</sup> Some of the early efforts, such as the response to Betsy Lehman’s death from medical error and the founding of the National Patient Safety Foundation, are covered in chapters 3 and 4, respectively.

## Medical Error as Call to Action and Target for Reform

### - *To Err is Human* (2000) & Patient Safety (2004)

In the wake of the failure of political reform of the health care system in the early 1990s,<sup>202</sup> efforts to change the organization of care delivery would have to find new avenues in the national policy agenda. Within a context of the developing quest for quality in health care, transitioning from an emphasis on quality assurance to quality improvement,<sup>203</sup> a report by the Institute of Medicine (IOM) would considerably raise the profile of medical error as a major problem in health care. First released in late 1999 and published in early 2000, the IOM's *To Err is Human: Building a Safer Health System* marks a watershed moment in the promotion of patient safety as a field of policy action, extending beyond the research focus on medical error found in the HMPS. The *To Err is Human* report, along with the publicity it received, is widely credited with securely placing patient safety on the agenda of every health care organization.<sup>204</sup> With financial support from the National Research Council and the Commonwealth Fund, *To Err is Human* was created by the 'Committee on Quality of Health Care in America,' comprised of 19 influential members,<sup>205</sup> from a diverse array of health-related institutions.<sup>206</sup> Under

---

<sup>202</sup> Again, Richmond and Fein (2005) provide an excellent history of the US health care system, which includes discussion of the failure of President Clinton's plan. See also Skocpol (1997) for a more specific explanation of the Clinton failure.

<sup>203</sup> See Wiener (2000) for an extensive account of the Quality Movement.

<sup>204</sup> Almost any text on patient safety will cite *To Err is Human* as the impetus for action on medical error. See, for example, Hurwitz and Sheikh (2009).

<sup>205</sup> Including Lucian Leape and Donald Berwick, discussed in the previous section on the HMPS (as well as later in this section, and in Chapter 4 of this dissertation).

<sup>206</sup> Committee members hailed from wide-ranging stakeholder groups: universities (e.g., Harvard) and academic medical centers (e.g., Mount Sinai School of Medicine), health

its congressional charter (as part of the National Academics), this 2000 IOM publication, which was produced to publicize the problem of medical error in American health care delivery, fits with the Institute's larger mission to provide advisement upon matters of public health and identify issues of general medical concern.<sup>207</sup> As the first in a series of reports investigating safety and quality issues in the US health care system, *To Err is Human* was followed in 2001 by a broader report entitled *Crossing the Quality Chasm*,<sup>208</sup> and then in 2004 by another publication focused specifically upon safety, *Patient Safety: Achieving a New Standard for Care*.<sup>209</sup>

Much of the attention generated by *To Err is Human* derives from its most famous statistical assertion - an estimate that up to 98,000 Americans die every year as a result of preventable medical mistakes.<sup>210</sup> This astounding number is derived from extrapolating the HMPS data (based upon the review of New York hospital records) to the US population as a whole. Estimates from another study based in Colorado and Utah<sup>211</sup> would be less, with the IOM offering a lower range of 44,000. Despite this seemingly divergent estimate, such numbers would prove powerful in obtaining public attention, and securing political urgency, about the problem of medical error. Even at the lower estimate of 44,000, deaths attributable to medical error would rank higher than the 8<sup>th</sup>

---

policy groups (e.g., Institute for Health Care Improvement), health plans (e.g., Blue Cross Blue Shield), employers (Delta Airlines).

<sup>207</sup> Institute of Medicine (2000); For a self-sponsored history of the Institute of Medicine, written before *To Err is Human*, see Berkowitz (1998), who describes the IOM mission as "to educate the general public and health policy decision-makers on important aspects of health science and health practice" (p. 274).

<sup>208</sup> Institute of Medicine (2001).

<sup>209</sup> Institute of Medicine (2004).

<sup>210</sup> Institute of Medicine (2000).

<sup>211</sup> Studdert, et al. (2000).

leading cause of death in the US, more than such prominent, well-known sources of mortality as AIDS, breast cancer and automobile accidents.<sup>212</sup> The IOM cites the total national cost of medical error as estimated between 17 billion and 29 billion dollars.<sup>213</sup> Morbidity, mortality, and economic output can be estimated, but according to the IOM, “not all the costs can be directly measured. Errors are also costly in terms of loss of trust in the system by patients and diminished satisfaction by both patients and health professionals.”<sup>214</sup> Despite the seemingly obvious severity of medical error, “silence surrounds this issue,” since “for the most part, consumers believe they are protected” and because “media coverage has been limited to reporting of anecdotal cases.”<sup>215</sup> Almost a decade after the HMPS, the IOM questions why “must we wait another decade,” asserting “a call to action to make health care safer for patients.”<sup>216</sup> From its organizational complexity, presentation of statistics, and outright call for action, the IOM report departs significantly from the relatively more subdued tone of the MIFS and HMPS reports.

The IOM’s *To Err is Human* report would garner wide publicity on account of such differences, though, especially from the use of statistics and the urgent call to action. Rather than disseminate original data, like the MIFS and HMPS did, the IOM report reviews research in order to set a national policy agenda for health care quality. The

---

<sup>212</sup> Institute of Medicine (2000), p. 1.

<sup>213</sup> Ibid., pp. 1-2. It is also important to note that the HMPS data shows that elderly, and often very ill, patients are most at risk of injuries from medical error, such that the estimates reported by the IOM may not be directly comparable in terms of the economic significance. See Harvard Medical Practice Study I (1991), pp. 373-75.

<sup>214</sup> Institute of Medicine (2000), p. 2.

<sup>215</sup> Ibid., p. 3.

<sup>216</sup> Ibid., p. 5.



committee “has focused its initial attention on quality concerns that fall into the category of medical errors” for these five specific reasons:

First, errors are responsible for an immense burden of patient injury, suffering and death. Second, errors in the provision of health services, whether they result in injury or expose the patient to the risk of injury, are events that everyone agrees just shouldn’t happen. Third, errors are readily understandable to the American public. Fourth, there is a sizable body of knowledge and very successful experiences in other industries to draw upon in tackling the safety problems of the health care industry. Fifth, the health care delivery system is rapidly evolving and undergoing substantial redesign, which may introduce improvements, but also new hazards.<sup>217</sup>

The blunt nature of these statements is a clear departure in tone from the earlier reports.

Asserting that errors are “an immense burden,” “shouldn’t happen,” and “are readily understandable to the American public,” takes a position on the problem in a way that elicits action on behalf of the audience or reader. Neither the MIFS nor the HMPS, in attempting to maintain legitimacy through scientific objectivity, had such outright proscriptions for policy change. The political ambitions of the IOM report are explicitly stated as:

The goal of this report is to break this cycle of inaction. The status quo is not acceptable and cannot be tolerated any longer. Despite the cost pressures, liability constraints, resistance to change and other seemingly insurmountable barriers, it is simply not acceptable for patients to be harmed by the same health care system that is supposed to offer healing and comfort.<sup>218</sup>

The IOM report is marked as a watershed because of this unwavering call to action.

After medical error has been targeted as an object of research through the MIFS and

---

<sup>217</sup> Institute Of Medicine (2000), p. x.

<sup>218</sup> Ibid., p. 3.

especially due to the HMPS, medical error takes on a political dimension as a target for policy reform through the IOM's *To Err is Human* report.

While the HMPS and the MIFS established the empirical basis of medical error, with some implications for health care reform, the significance of the IOM report is in how its call to action makes a case for the reorganization of health care delivery. The IOM report has similar definitions for what constitutes error as was found in the HMPS,<sup>219</sup> but adds a distinct definition of safety as “freedom from accidental injury.”<sup>220</sup> From this definition, “we must systematically design safety into processes of care,”<sup>221</sup> a connection that draws together a way of thinking about error with how to manage it. This is spelled out in the IOM report as:

Preventing errors means designing the health care system at all levels to make it safer... The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system. This does not mean that individuals can be careless. People must still be vigilant and held responsible for their actions. But when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.<sup>222</sup>

Shifting responsibility is at the forefront of *To Err is Human*. As opposed to the MIFS, prevention is asserted as fundamental and there is little notion of acceptable risk in such statements. Instead, witness the implied reference to quality improvement, which gained prominence in health care over the course of the 1990s, when advocates began looking to other industries for new management models. Rather than target individuals, quality

---

<sup>219</sup> The IOM follows the definition of ‘adverse event’ used in the HMPS, and also follows, like the HMPS, from James Reason’s distinction between errors of omission and commission, as well as the inevitability of error. See Institute of Medicine (2000), p. 4.

<sup>220</sup> Institute of Medicine (2000), p. 4.

<sup>221</sup> Ibid., p. ix.

<sup>222</sup> Ibid., pp. 4-5.

improvement places emphasis on the system as a whole, shifting from an individual focus and negative sanctions to collective effort and system improvement.<sup>223</sup> Errors are prevented and safety results when the system is robust, rather than when individual physicians, or any other professional, are perfect. This shift toward the system means, according to the IOM, that “errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing.”<sup>224</sup>

The IOM’s *To Err is Human* challenges the health care industry to improve quality and safety through reforming the system and culture of medical practice. In order to make reform effective, the IOM committee “seeks to strike a balance between regulatory and market-based initiatives, and between the roles of professionals and organizations.”<sup>225</sup> This balance will be accomplished by targeting factors in the external environment, including “availability of knowledge and tools to improve safety, strong and visible professional leadership, legislative and regulatory initiatives, and actions of purchasers and consumers to demand safety improvements,” as well as factors inside health care organizations, identified as “strong leadership for safety, an organizational culture that encourages recognition and learning from errors, and an effective patient safety program.”<sup>226</sup> Through developing these factors in the external environment and within organizations, the IOM sets a goal of 50% error reduction in 5 years.<sup>227</sup> The stakes that justify this lofty goal, amidst such an ambitious reform agenda, are found in the medical error mortality statistic. The power of the number 98,000 (annual deaths due

---

<sup>223</sup> Chapter 4 discusses more about quality improvement. See also Wiener (2000).

<sup>224</sup> Institute of Medicine (2000), p. ix.

<sup>225</sup> Ibid., p. 6.

<sup>226</sup> Ibid., p. 6.

<sup>227</sup> Ibid., p. 4.

to error) is what the IOM report is known for and what is continually used to mobilize action.<sup>228</sup> The risk related to medical error is no longer acceptable when matched with a statistic so alarming. Instead, medical error, classified and counted, becomes a target for preventive intervention in the name of patient safety.

As stated early in *To Err is Human*, “unsafe care is one of the prices we pay for not having organized systems of care with clear lines of accountability.”<sup>229</sup> Traditionally, error reporting is seen as a method for securing accountability from health care providers. State health departments, federal agencies, health care accreditation organizations, and individual hospitals each serve as repositories of various types of reporting. But in order to more effectively prevent medical error, the IOM pushes for using reporting not only for accountability purposes but also for system improvement. As one of the main reform recommendations of *To Err is Human*, the committee proposes “identifying and learning from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be make safer for patients.”<sup>230</sup> While an array of error reporting efforts are found across the health care industry, the IOM reports, *To Err is Human* along with a subsequent publication entitled *Patient Safety: Achieving a New Standard for Care*,<sup>231</sup> focus upon making error reporting a major tool for developing patient safety ideals into practice.

---

<sup>228</sup> In many ways similar to how the number of uninsured, at about 47 million, becomes powerful for mobilizing action in support of the comprehensive health care reform legislation of 2009-10.

<sup>229</sup> Institute Of Medicine (2000), p. 3.

<sup>230</sup> Ibid., p. 6.

<sup>231</sup> Institute of Medicine (2004).

Among explanations of the problem of medical error and recommendations for patient safety policy, the Committee on Quality of Health Care in America dedicates nearly a quarter of the *To Err is Human* report<sup>232</sup> to the discussion of error reporting. Reporting is classified into two broad categories, based upon a system's main justification. According to the IOM report, "reporting systems whose primary purpose is to hold providers accountable are 'mandatory reporting systems,'" while "reporting systems that focus on safety improvement are 'voluntary reporting systems.'" Mandatory systems typically target major errors that result in serious harm or death, while voluntary systems address more minor mistakes (sometimes called 'near-misses') that do not generally result in harm.<sup>233</sup> The IOM's categorization makes a clear distinction based upon injury outcome. On the one hand, providers and institutions are held accountable for major harm through the requirement of reporting.<sup>234</sup> On the other hand, mistakes that do not result in major harm are subject to voluntary submission for data analysis and review for improvement of delivery systems. Ultimately, the 2000 IOM report claims that this diversity of reporting cannot just be classified via the two major intentions of accountability and improvement, but can also be structured in a complementary fashion. The far fewer errors that result in serious injury necessitate mandatory reporting and public disclosure (for accountability), while the more numerous minor errors and minimal injuries are subject to voluntary reporting and kept confidential (for improvement).<sup>235</sup>

---

<sup>232</sup> This amounts to 2 chapters, out of the 8 chapters of *To Err is Human*.

<sup>233</sup> Institute of Medicine (2000), pp. 86-87.

<sup>234</sup> Importantly, though, this is still distinguished from legal liability. One of the main hurdles to reporting based upon accountability is the fear of legal discovery that would place providers subject to malpractice suits.

<sup>235</sup> Institute of Medicine (2000), p. 101.

Spurned by the impassioned recommendations and extensive publicity that the 2000 IOM report generated, most health care organizations reassessed their medical error policies, resulting in guidelines that would be explicitly formulated in the name of patient safety. In a similar spirit, many states passed regulations attempting to provide further oversight of the health care industry in regards to patient safety issues. Ethically, patient safety disturbs customary norms that have traditionally managed relations between care providers and their patients, as trust and responsibility are thrown into doubt and flux. Such a diverse mixture of reporting policies and regulations, couched in a revised safety ethos, has proved difficult to implement with the unified vision of patient safety that the IOM, and other safety policy advocates, would hope to realize. As a result, a 2004 follow-up report from the IOM, *Patient Safety: Achieving a New Standard for Care*, places significant attention upon the need for standardization of reporting systems. In calling for more data to study patient safety, the IOM recognizes that "...researchers need standard, nationally accepted ways of defining, classifying, and characterizing adverse events and near misses."<sup>236</sup> Not only for the sake of researchers, but also to effectively enroll health care providers to actively participate in improving care through reporting, the IOM states "[the] lack of standardization imposes unnecessary burdens and is a major disincentive to reporting adverse events."<sup>237</sup>

More generally, standardization is one of the most significant objectives of patient safety reform, with advocates arguing that lives are saved and costs are reduced when care is standardized along best practices. In tracing the rising prevalence of evidence-

---

<sup>236</sup> Institute of Medicine (2004), p. 248.

<sup>237</sup> Ibid., p. 248.

based medicine, Science Studies scholars Timmermans and Berg emphasize the investigation of “...both the form and content of standardization: to look at what is standardized, how it is standardized, what is included and what is excluded, what novel configurations of things and people are brought into being, and how much uniformity is actually achieved.”<sup>238</sup> Since standards often bring an assumption of objectivity, the politics behind standardization are often overlooked. Timmermans and Berg call our attention to the assumptions, interests and justifications behind standardization.<sup>239</sup>

As with *To Err is Human*, reporting is justified with the rationales of accountability and improvement; however, the language of ‘improvement’ is modified to ‘learning’ or ‘system redesign.’ More significantly, the previously formal distinction between accountability and learning from the 2000 report is subsequently represented as existing along a continuum of practices in the 2004 publication.<sup>240</sup> IOM advocacy in this updated report is summarized as: “the health system has under-invested by a large margin in learning approaches. The American health care system will continue to lack sufficient capacity to deliver excellent care to all patients without fundamental change in the overall level of performance of the system as a whole.”<sup>241</sup> In the roughly five years between the two IOM publications, a further push towards error reporting in the name of learning and system redesign is regarded as the most effective intervention. Ostensibly, the accountability rationale behind reporting does not advance patient safety as much as reporting for the purposes of learning and system redesign does, since this fragmented

---

<sup>238</sup> Timmermans and Berg (2003), p. 24.

<sup>239</sup> Continued theoretical discussion of standardization is in chapter 4.

<sup>240</sup> Institute of Medicine (2004), p. 253

<sup>241</sup> Ibid., p. 273

array of systems suffers from a lack of standardization. Thus, the IOM proposes further development and standardization of the learning and improvement end of the reporting continuum, as opposed to the already established accountability side. Recommended as a necessary objective for progress in patient safety, the IOM states, “standardization of data will enable the evolution of a new knowledge base of patient safety information and system improvements that can be readily incorporated into the practice of evidence-based medicine.”<sup>242</sup>

As a primary example of patient safety reform, the overall goal of medical error reporting centers upon the disclosure of medical errors, sometimes for the sake of holding health care accountable, other times justified as safety improvement by way of learning from mistakes. Given potentially competing rationales of accountability and improvement, error reporting can have contradictory implications as a strategy for reducing the risk of medical error. Further openness and teamwork may be a welcome change, but also must be accepted with the consequence of more extensive oversight, assessment, and standardization. Error reporting that centers upon accountability as its primary justification tends to focus upon the individual as its target of intervention, while reporting with improvement or learning as its motivation seeks to assess and rationalize health care delivery systems. In reporting as accountability, responsibility for error is specified - individuals are held culpable for the mistakes that they make. In contrast, the premise of learning and improvement approaches to reporting is risk as a collective (system) responsibility, with promoting standards as the panacea of progress. A push towards the standardization of reporting is at the same time an effort to implement

---

<sup>242</sup> Ibid., p. 314



effective ‘improvement/ learning/ system redesign’ approaches to error monitoring. As promoted in the IOM reports, the standardized, rational system is thus seen as the target of intervention for the advancement of patient safety, rather than the behavior modification of individual practitioners through punishment.

While medical error data, such as that found in the HMPS, and patient safety reform efforts, including error reporting, date back years and even decades before the IOM reports of 2000 and 2004, it took the institutional prestige and media publicity brought to bear by IOM publications to garner explicit, widespread attention from both the health care industry and the general public.<sup>243</sup> The Harvard Medical Practice Study’s ambitious call did indeed serve to elicit further research on medical error, but policy adoption is slow until almost a decade later when the Institute of Medicine would release the *To Err is Human* report. The effect of the IOM reports, specifically *To Err is Human*, is a permanent change to the landscape of research and policy on medical error. According to patient safety and quality advocates Lucian Leape and Donald Berwick after *To Err is Human* “research in error prevention and patient safety became a legitimate academic pursuit” and “few individuals now doubt that preventable medical injuries are a serious problem.”<sup>244</sup> Describing medical error as “one of the major public health issues of our time,”<sup>245</sup> Leape and Berwick also express limitations in the years after report, commenting that “building a culture of safety is proving to be an immense

---

<sup>243</sup> As one indicator of this widespread attention, the online tool ‘Google Books Ngram Viewer’ (<http://ngrams.googlelabs.com/>), which “displays a graph showing how [selected] phrases have occurred in a corpus of books (e.g., “British English”, “English Fiction”, “French”) over the selected years” shows that the term ‘patient safety’ jumps significantly after the 2000 publication of *To Err is Human*.

<sup>244</sup> Leape and Berwick (2005), p. 2385.

<sup>245</sup> Ibid., p. 2384.

task and the barriers are formidable.”<sup>246</sup> Concerning the goal of developing reporting systems, they also find that “no comprehensive nationwide monitoring system exists for patient safety,”<sup>247</sup> a goal which was a central recommendation of *To Err is Human*. Even though “critics have pushed back against viewing safety as a problem...of system design” and “public support for improving patient safety often turns instead on fixing blame,”<sup>248</sup> Leape and Berwick see the work ahead as one of instilling continual motivation, stating that the main lessons of the IOM report “is that we will not become safe until we choose to become safe.”<sup>249</sup> The question of choice and motivation marks the transition that the concept of medical error had undergone as a result of the IOM reports. As its status has been confirmed as a real problem, the existence of error as a risk to the patient population is no longer in doubt, but rather, the more difficult task of mobilizing action to do something about the problem is what remains to be accomplished. After establishing medical error as a risk, the work ahead is an undertaking in politics and policy – of reform - that is still unfolding in the decade after *To Err is Human* was first published.<sup>250</sup>

### **Changing the Concept of Medical Error**

Out of the medical malpractice insurance crisis of the 1970s, the California Medical Insurance Feasibility Study was the first systematic attempt to assess the

---

<sup>246</sup> Leape and Berwick (2005), p. 2385.

<sup>247</sup> Ibid., p. 2384.

<sup>248</sup> Ibid., p. 2384.

<sup>249</sup> Ibid., p. 2390.

<sup>250</sup> An April 2011 issue of *Health Affairs* questions the status of patient safety and quality progress, ten years after the IOM’s famous *To Err is Human* and *Crossing the Quality Chasm* reports. See Dentzer (2011) for an overview of the issue.

statistical rate of medical error. Taking guidance from the MIFS, the more robust Harvard Medical Practice Study garnered broader national attention for the study of medical error, at least within the field of health care research, due to its dissemination in the prestigious *New England Journal of Medicine*. The watershed moment for awareness of medical error, though, came from the US Institute of Medicine's (IOM) *To Err is Human* report. Released in late 1999, the IOM's groundbreaking report marks the culmination of a shift in the concept of medical error. As a significant turning point in the development of the movement for patient safety, the IOM report, along with the publicity it received, is widely credited with positioning patient safety as an essential obligation in health care delivery. All the attention circling the IOM report can be derived from its most famous statistical assertion, an estimate that between 45,000 and 98,000 Americans die every year as a result of preventable medical mistakes. Largely from the power and publicity of that number, the problem of medical error, and the developing patient safety movement, would jump from the confines of a relatively narrow health care constituency to a prominent spot on the national health care agenda. After this section, a summary chart (*Table 1* on page 90) compares key dimensions of the three major reports analyzed in this chapter.

Over the course of the major reports, medical error becomes connected to risk and given its own statistical regularity (*Medical Insurance Feasibility Study*), making error an object for research (*Harvard Medical Practice Study*), and a target for policy proposals and intervention (*To Err is Human* and *Patient Safety*). Through these shifts, medical error takes on a new conceptual status, distinct from an association with negligence that characterizes the medical malpractice model. Through the redefinition of error, from a

legal standard to a scientific standard, providers are implored to reassess what they think constitutes an error, and thus how medical injury is prevented. As opposed to blaming individuals for mistakes, errors are now conceived as a consequence of a highly complex healthcare delivery system. The solution to the problem of error in medicine, then, lies at the level of the system. Reformers seek to standardize error prevention and thus rationalize safety practice. The resulting patient safety model does not necessarily supplant the malpractice model. However, due to the emphasis on prevention as reform policy, patient safety does significantly challenge the legitimacy of the established malpractice system. Given health care providers' ambivalence and wariness toward medical malpractice, a shift in the understanding of risk and responsibility of error has a receptive audience in the medical profession. Despite sympathetic medical professionals, as well as a concerned public, consensus over how to define the problem, and manage the risk, of medical error remains elusive.<sup>251</sup>

Nonetheless, medical error has developed into both an object of analysis (conceived in terms of risk, though it varies across the reports), to also being a target for preventative interventions (conceived in terms of patient safety reform policy). The transition in understanding of error in medicine occurs based upon a scientific-technical discourse (from both the MIFS and HMPS), which then forms the foundation for a more expansive and influential policy-action discourse (IOM reports). Through an analysis of major reports on medical error, this chapter examined the relationship between medical error and risk, and how error prevention eventually came to form a basis of patient safety reform. Such a transformation falls in line with O'Malley's general observation that, "by

---

<sup>251</sup> Again, as in footnote #149, see Dentzer (2011).

the end of the twentieth century, risk had become a predominant way of governing all manner of problems. Prevention is better than cure. Of course it is true that even with respect to governing health through risk techniques there are political and moral dilemmas.”<sup>252</sup> Risk has become predominant in thinking about medical error, with prevention as the guiding reform policy for patient safety. However, this shift also makes clear that the scientific-technical dimensions of error and safety are not all there is to the story. A similar explanation also follows from the perspective of risk society theories, as Adam and van Loon claim that “even the most restrained and moderate-objectivist account of risk implications involve a hidden politics, ethics and morality.”<sup>253</sup> The problem of medical error resonates with such sentiments across theories of risk – medical error is now conceived in terms of risk, but not without political and moral dilemmas. Moral dilemmas come to the forefront in the next chapter, reviewing medical error narratives and the role of the patient in patient safety, where the stories of patient tragedy bring an urgency that statistics cannot accomplish alone. Political dilemmas, then, are referenced in chapters four (and five), which covers safety culture as the primary solution of advocacy campaigns that seek to manage medical error. It is through such moral and political dilemmas that patient safety discourse challenges the medical profession.

---

<sup>252</sup> O’Malley (2010), p.3.

<sup>253</sup> Adam & van Loon (2000), p. 1.

*TABLE 1: HISTORICALLY SIGNIFICANT REPORTS ON MEDICAL ERROR –*

*Medical Insurance Feasibility Study (MIFS), Harvard Medical Practice Study (HMPS), and To Err is Human (TEH)*

|                  | <u>MIFS (1977)</u>                                                          | <u>HMPS (1991)</u>                                                  | <u>TEH (2000)</u>                                                     |
|------------------|-----------------------------------------------------------------------------|---------------------------------------------------------------------|-----------------------------------------------------------------------|
| MAJOR IMPETUS    | 1970s Malpractice crisis                                                    | 1980s Malpractice crisis & quality movement                         | Quality movement & failure of 1990s reform                            |
| KEY DEFINED TERM | Potentially Compensable Event (p. 8)                                        | Adverse event (p. 370)                                              | (Patient) Safety (p. 4)                                               |
| DATA SOURCE      | California hospital records (non-random)                                    | New York hospital records (random)                                  | No new data - review of previous studies                              |
| CENTRAL FINDING  | 4.6% due to error, 0.8% due to negligence                                   | 3.7% due to error, 1.0% due to negligence                           | Estimates 44,000 to 98,000 deaths due to error                        |
| APPROACH TO RISK | Acceptable - given benefits of intervention                                 | Reduction - Agenda for research on quality                          | Prevention - policy for building safer system                         |
| SUBSEQUENT STUDY | HMPS (1991)                                                                 | Studdert, et al. (2000) – Utah and Colorado Study                   | “Crossing the Quality Chasm” (2001)                                   |
| SIGNIFICANCE     | First empirical study on rate of medical error, but little long-term effect | Agenda for research on quality; influential in health care industry | Watershed for error - leading to national attention on patient safety |

### CHAPTER 3 – From Tragedy to Advocacy: Patient Stories of Transformation

Facts, figures and statistics reach the head, but nothing happens unless we reach the heart.<sup>254</sup>

--Dennis Quaid, narrating the Discovery Channel Documentary  
*Chasing Zero: Winning the War on Healthcare Harm*)

Narratives rather than numbers are the primary data of the safety sciences.<sup>255</sup>

--James Reason, quoted in *Safety and Ethics in Health Care*

As discussed in the previous chapter, technical reports are important for emphasizing that the issue of medical error requires dedicated research and reform. Notwithstanding the famous statistic from the Institute of Medicine's *To Err is Human*, technical reports alone are not typically sources of deeply arousing reactions. On the contrary, such reports are often unknown beyond the specific research communities that study them, unless there is a compelling story that goes along with the scientific-technical discourse. The introductory quotes above suggest the very significant role that narratives play in broader patient safety discourse. As a narrative tool for patient safety advocacy within the health care industry, patient tragedies are often used to raise awareness and encourage change in the behavior of professionals. When patient deaths are given media spotlight, medical error gains more widespread public attention, beyond researchers, reformers and providers. Within the health care industry, as well as from the broader

---

<sup>254</sup> *Chasing Zero* Documentary (2010), time: 52:30 until 52:38.

<sup>255</sup> James Reason quoted in the foreword to Hurwitz and Sheikh (2009), p. 17.

national media, medical error stories often become moralistic, as patient tragedies quickly become public scandals with heated and emotional responses.

Consider the story of *Boston Globe* health reporter Betsy Lehman, whose death in 1994 from an accidental overdose helped to catalyze the emerging patient safety movement. Lehman died during cancer treatment at one of the most respected hospitals in United States, the Dana Farber Cancer Institute in Boston. Tragedies such as Betsy Lehman's death are a stark reminder that medical error is a not only a technical problem understood in terms of research reports and regulatory reform but is also one of heartbreaking loss. Had Betsy Lehman survived the accidental overdose, she might have become a prominent patient safety advocate, given that her work in health reporting centered upon informing patients. Still, her death put a tragic face to the numbers reported in the Harvard Medical Practice Study just a couple of years earlier, and so helped to ignite patient safety efforts until *To Err is Human* captured broader, sustained national attention.

When the watershed *To Err is Human* report was published in early 2000, the landscape of patient safety completely changed, making for a new context in which stories of medical error would be connected to the movement for reform. Just over a year after the report came out, in February of 2001, Tony and Sorrel King lost their 18-month old daughter to a series of medical errors at one of the most respected hospitals in the world, Johns Hopkins in Baltimore. In the wake of their tragedy, Tony and Sorrel started a foundation in the name of the daughter, Josie. Working through *The Josie King Foundation*, Sorrel King has become an accomplished public speaker, telling Josie's story at health care conferences and hospital meetings. In recounting the series of errors



that lead to her daughter's death, Sorrel King spreads a patient safety lesson that open communication between care providers, patients, and their families can prevent patient harm.

The patient safety movement gained a celebrity voice when, in November of 2007, the newborn twins of Hollywood actor Dennis Quaid were accidentally given the adult dosage of a blood thinner at Los Angeles' Cedars Sinai Hospital. After nearly two frantic days spent reversing the effect of the overdose, both twins stabilized, and then were released from the hospital 12 days after the mishap with no signs of permanent damage. Though his children did not die, Dennis Quaid experienced an emotional transformation and activist awakening not unlike Sorrel King's. The Quaid family also started a foundation to raise awareness of the problem of preventable medical error. Sharing the story of his twin's accidental overdose, Dennis Quaid provides a celebrity voice for the patient safety movement.

Although the problem of medical error has not resulted in an extensive patient-led movement, patient stories and advocacy are linked to the prevention politics of the patient safety agenda. While still mostly limited to prominent cases, such as those discussed in this chapter, patients are taking a more active role in national, and even transnational, patient safety advocacy than what was seen in the past. More than just victims of error, advocates like Sorrel King and Dennis Quaid see patients as fundamental partners in the prevention of unnecessary harm, forming collaborations with health care professionals who agree that patients themselves are among the best safety advocates. Through their stories of medical error, such advocacy attempts to move beyond seeing patients as only victims, to incorporating how patients themselves can be given a voice in formulating

safety policies. One of the major morals of such patient stories is to convince health care providers that patients can be active and equal partners in the promotion of patient safety. This dual transformation – of both patients and providers as equal partners in patient safety advocacy - occupies a central place in medical error narratives, and thus is an important aspect of broader patient safety discourse.

This chapter begins with a brief overview of narrative analysis, of social science research on narrative in patient safety, and of scholarship on health social movements. Together, this literature informs an approach to the role of narrative in the patient safety movement. With that theoretical background, the majority of this chapter closely examines three case studies of medical error narratives – the media response to Betsy Lehman’s death in 1994, Sorrel King’s transformation to patient safety advocate after the death of her daughter in 2001, and Dennis Quaid’s influential celebrity voice after the accidental overdose of his newborn twins in 2007. Returning to narrative analysis and health social movements, the case studies are then followed by a discussion of the transformational significance of medical error stories, both for how individuals become activists as well as for how the larger medical profession responds to such challenges.

### **The Significance of Error Narratives for Patient Safety as a Health Movement**

While the previous chapter looked at scientific-technical reports on medical error, Larson reminds us that “a discursive field is therefore something broader than a scientific field, since discourses are produced in areas of social practice that include both

unauthorized and non-authoritative speakers.”<sup>256</sup> It is thus important to also look outside of the field of scientific experts, to where a different kind of discourse can be found. For bringing public attention to the cause of patient safety, error narratives can be very effective aspect of the discourse. To explore the role of narrative in patient safety, I draw upon narrative analysis, first in rather general methodological terms, then specifically as related to social science research on patient safety. With that basis in narrative, I explore how work on health social movements and patient groups can be helpful in assessing the significance of medical error stories for the patient safety movement.

Just as with discourse analysis in general (see chapter 1), it is difficult to find a standardized definition of what constitutes narrative and narrative analysis. Nonetheless, I find a guiding set of interpretations from Daiute and Lightfoot:

Narrative analysis is a mode of inquiry based in narrative as a root metaphor, a genre, and discourse. As a metaphor, narrative analysis involves explaining psychological phenomena as meanings that are ordered from some theoretical perspective, like that of a storyteller, and consist of information and comments about the significance of that information... Narratives are also genres, that is, culturally developed ways of organizing experience and knowledge... Narratives are also specific discourse forms, occurring as embodiments of cultural values and personal subjectivities.<sup>257</sup>

This definition of narrative as metaphor, genre and discourse calls attention to the variety of interpretive angles through which one can analyze a story. Medical error narratives serve as metaphors in terms of attributing responsibility through morality lessons. As a genre, error narratives have taken on a particular cultural form as tragedy and scandal, especially in the popular media. Finally, error narratives are part of a larger patient safety

---

<sup>256</sup> Larson (1990), p. 34.

<sup>257</sup> Daiute and Lightfoot (2004), p. x.

discourse that seeks to motivate action on behalf of improving health care quality and performance. It is through narrative as a specific form of patient safety discourse that I will focus upon in this chapter.

Also similar to the open-ended methodological basis of discourse analysis, narrative research also tends to favor a less strict methodology. In comparison to other methods, “narrative research offers no automatic starting or finishing points.”<sup>258</sup> Like other interpretive endeavors, the researcher must go back and forth between the narrative under investigation and the insights drawn from it, which can lead to many dead-ends in analysis. According to Gergen, then, “narratives [need not] be true or false in any absolute sense,” but viewed as “renditions of events, cohering to certain cultural standards, which made sense of life to someone in a particular context,” so that “a narrative was almost always created to give meaning to events in the past.”<sup>259</sup> The importance of analyzing narrative is not to evaluate its accuracy, but to use it for understanding how the storyteller makes sense of past events. For medical error narratives, the process of looking back to give meaning to the tragedy is precisely what is powerful about the stories. Returning to Daiute and Lightfoot, they elaborate that, “narrative discourses are cultural meanings and interpretations that guide perception, thought, interaction, and action. Narrative discourse organizes life – social relations, interpretations of the past, and plans for the future.”<sup>260</sup> By examining the narrative discourse of medical error stories, we get a picture of a distinct set of meanings, much more emotional in tone and motivational in effect, than other aspects of patient safety

---

<sup>258</sup> Squire, Andrews and Tamboukou (2008), p. 1.

<sup>259</sup> Gergen (2004), p. 270.

<sup>260</sup> Daiute and Lightfoot (2004), p. x-xi.

discourse, such as the more dry and technical policy reports found in the previous chapter.

Social science research on patient safety has only begun to address the role of narrative. For example, Iedema and colleagues assert “the importance of dialogic narration currently goes unrecognized in how we practice patient safety and in our approaches to studying how patient safety is achieved and maintained.”<sup>261</sup> Waring has looked at narrative in terms of lessons for healthcare workers that are “amenable to management exploitation in the pursuit of organisational learning.”<sup>262</sup> In other work, Iedema and colleagues emphasize the role of emotion – “thanks to these techniques [of incident reporting], employees can, and are increasingly expected to, express and share feelings, norms and values about what they do, to better organize and manage what they do themselves.”<sup>263</sup> While Waring provides a critique of the use of narrative for management purposes and Iedema, et al show the importance of affect in incident narratives, this research examines narratives as told by doctors and other healthcare workers. Perhaps this follows in line with research on narrative in medical journals, which also tends to focus upon provider’s stories. For example, Rowe finds that “doctors’ [narrative] responses [to medical error] are a product of the temperaments of those who choose to go into the profession, of medical training and medical practice as taught and as practiced, of the organization and funding of health care, of the law, and of doctor–patient relationships.”<sup>264</sup> An exception to the focus upon providers in narrative

---

<sup>261</sup> Iedema, et al. (2009), p. 1756.

<sup>262</sup> Waring (2009), p.1722.

<sup>263</sup> Iedema, et al. (2006), p.137.

<sup>264</sup> Rowe (2004), p. 159.

research, Ocloo has recently published work on two patient support groups in the UK. With a similar conclusion to Waring's work on provider narrative, Ocloo finds that, "the experiences of harmed patients are considered to provide an important source of data in looking at how issues of power and conflict impact upon safety in organisational contexts."<sup>265</sup> In a guiding statement that will be revisited later in this chapter, Ocloo "suggests that the dominance of a medical model is still a powerful determinant in constructing the context of medical harm and patient safety reforms."<sup>266</sup> While the medical model dominates in the US as well, error narratives, like overall patient safety discourse, offer a critique of the model's shortcomings when it comes to the issue of mistakes. Still, patient stories may not completely undermine the medical model. With only Ocloo's work in the UK thus far, the burgeoning field of social science research on patient safety could be improved with further study on the discursive role of patient stories of medical error.

In order to expand the study of narrative in social science research on patient safety, I suggest exploring how patient stories fit within the larger history of patient safety as a health social movement. My argument in this chapter is that narratives are transformational – not only for the specific individuals involved but also, and even more importantly, for how emotional stories are employed as motivation and justification for action on behalf of patient safety. In support of this claim, the contemporary push for patient safety can be grounded in a growing literature on health movements and patient groups, which has sought to understand various social processes of contestation over

---

<sup>265</sup> Ocloo (2010), p. 515.

<sup>266</sup> Ibid, p. 515.

health issues and care delivery.<sup>267</sup> By establishing this distinct field of research, scholars have proposed bringing together insights from social movements theory, medical sociology, and the sociology of science.<sup>268</sup> While many recent studies in this area of research tend to focus upon the experience of disease or illness, the field's general orientation to questions of authority and expertise can be applied to the case of patient safety. As other health movements seek to variously challenge or collaborate with the vast apparatus of science and medicine, so too does patient safety advocacy aim to reshape how safety is conceived and promoted within the health care industry.

How patient safety is categorized as a health social movement (HSM) can be derived from a guiding definition of the term by Brown and Zavestoski, who “define HSMs as collective challenges to medical policy, public health policy and politics, belief systems, research and practice which include an array of formal and informal organisations, supporters, networks of cooperation and media. HSMs make many challenges to political power, professional authority and personal and collective identity.”<sup>269</sup> As will be seen in the case studies of this chapter, the message of medical error narratives constitute a significant challenge to medical policy, politics, and belief systems, as part of a broader patient safety reform effort. Brown and Zavestoski elaborate, “Medical authority has always involved varying alliances between health

---

<sup>267</sup> For an extensive review of the many dimensions of the growing literature on health movements and patient groups, see Epstein (2008).

<sup>268</sup> For bridges between social movements and medical sociology, see Brown and Zavestoski (2004); and Brown, Zavestoski, McCormick, Mayer, Fosch, and Altman (2004). For filling the theoretical gap between medical sociology and the sociology of science, see Hess (2004).

<sup>269</sup> Brown and Zavestoski (2004), p. 679; A similar definition can be found in Brown, et al. (2004), p. 52.

professionals, state agencies, corporate actors, scientists and citizen-activists. As in any dialectic relationship, increasing medical authority has occurred alongside increasing challenges to this authority. HSMs represent the transformation of sporadic and relatively unorganised challenges into formal and institutionalised opposition.”<sup>270</sup> The transformational discourse of error narratives exhibits such a transition from a seemingly random challenge of medical authority to a more unified alternative conception of safety in care delivery. Using the more specific term embodied health movement (a term with a conceptual distinction that focuses more squarely upon disease experience but need not be fleshed out here), Brown, et al. emphasize “organised efforts to challenge knowledge and practice,” which “arises from the recent trend towards the empowerment of patients and more active involvement in their healthcare.”<sup>271</sup> In line with Brown, et al.’s point about embodied health movements, patient safety discourse, as represented by error narratives, can “blur boundaries between lay and expert knowledge.”<sup>272</sup>

The trend towards empowering patients, which can blur the line between lay and expert knowledge, develops in connection to the consumer movement in health care. Allsop, Jones and Baggott agree that, from the growing focus on patient as a consumer, “there is evidence of a shared discourse and values across the groups that promote and represent the interests of healthcare users,” which, “have contributed to the development of participative and consultative processes.”<sup>273</sup> As a result, Allsop, Jones and Baggott continue, “collaboration between health consumer groups within the same condition area

---

<sup>270</sup> Brown and Zavestoski (2004), p. 682.

<sup>271</sup> Brown, et al. (2004). p. 54.

<sup>272</sup> Brown, et al (2004), p. 75-76; See also Epstein (1996) for an extensive analysis of this point about the blurring of lay and expert knowledge.

<sup>273</sup> Allsop, Jones, and Baggott (2004), p. 738.



and across the sector, has increased to a degree where it is possible to point to a health consumer movement. Member groups provide the basis for collective action in the social and political sphere.”<sup>274</sup> Evidence of the consumer movement in patient safety advocacy is most explicit in the name of one of the major patient-led organizations - Consumers Advancing Patient Safety (CAPS).<sup>275</sup> “The evolving nature of [the doctor-patient] relationship,” according to Boyer and Lutfey, means that “where previously we talked of patients, we now refer to consumers, clients, or survivors, and this linguistic change reveals a shifting balance of power as individuals have become more empowered in health care choices, decision-making, and communication.”<sup>276</sup> While the CAPS organization is discussed elsewhere,<sup>277</sup> the error narratives in this chapter also do support the notion of an educated, health care consumer (particularly in the background of Betsy Lehman, but also from King and Quaid, who both push for educating patients in the prevention of medical errors).

The use of narrative has not been neglected by research on health social movements. For example, an article by Klawiter, “uses the narrative of one woman, Clara Larson, to explore changes over time in the experiences of illness available to women diagnosed with breast cancer,” in order to “acknowledge that experiences of disease are shaped not only by the individual circumstances of disease sufferers and the particular character of their pathologies, but by culturally, spatially and historically

---

<sup>274</sup> Ibid, p. 738.

<sup>275</sup> Consumers Advancing Patient Safety - <http://www.patientsafety.org/>.

<sup>276</sup> Boyer and Lutfey (2010), p. S81.

<sup>277</sup> See Chapter 4 for a discussion of CAPS, in the context of The World Alliance for Patient Safety’s Patients for Patient Safety organization.

specific regimes of practices.”<sup>278</sup> Medical error narratives are also shaped by changes to ‘regimes of practices’ – most notably, from the development of patient safety interventions (such as error reporting) and the transformational discourse that support such practices (such as sharing stories to justify learning through error reporting). In my review of three prominent error narratives, the individual story will provide some necessary background, but the analytical focus will be upon how the story is transformational – for colleagues, the victim or their family.

Beyond transforming colleagues, victim or family into a public speaker or activist, I also explore how the stories themselves take on a larger significance, related to what an audience is meant to learn after hearing the story. Along with further reference to narrative analysis and health social movements research, this idea of dual transformation will be revisited in the discussion, following the case studies of Betsy Lehman, Sorrel King and Dennis Quaid. With each of the case studies in this chapter, I provide some details about the error itself to provide background. However, the majority of analysis will be directed toward what happens in the aftermath of tragedy. The emotional process of sharing the story of medical error not only changes the individual involved, but also contributes to an emphasis upon narrative transformation as a crucial motivational slice of the growing patient safety movement. Patients are taking a more active role in national (and even transnational) patient safety advocacy, and medical error narratives imagine the patient role as not simply a passive victim of error but rather as an active agent for change.

---

<sup>278</sup> Klawiter (2004), p. 846.

## Medical Error as Public Scandal

### -- The Death of Betsy Lehman

Betsy Lehman died at the age of 39, leaving behind a husband and two young daughters. Several months later, it was discovered that the cause of her death had been an accidental overdose, when the *Boston Globe* disclosed “that its famed health columnist Betsy Lehman died of heart failure on December 3, 1994 while undergoing chemotherapy at renowned Dana-Farber Cancer Institute in Boston, Mass, [from] a huge overdose of two drugs;” and when just “two days before Lehman's death, another woman reportedly sustained serious, irreversible heart damage from the same overdose.”<sup>279</sup> According to various reports, “at least a dozen doctors, nurses and pharmacists at the Dana Farber Cancer Institute overlooked the error for four days while Lehman continued to receive an overdose of cyclophosphamide and a four-fold overdose of another drug meant to shield her from side effects.”<sup>280</sup> According to reporting by the *Associated Press*, the deadly mistake was only later “discovered by a records clerk on Feb. 13, more than two months after Ms. Lehman died.”<sup>281</sup> Combining Lehman’s occupation as a health reporter at a large and influential media outlet, with an egregious error occurring at a prestigious institution, the story was ripe for public scandal.

Not surprisingly, where the scandal plays out, and in rather harsh terms, is through the pages of the *Boston Globe*. Responding to the tragedy of Lehman’s death, a fellow *Globe* columnist laments that, “Betsy should be alive today, watching the bulbs

---

<sup>279</sup> *Miami Herald* (March 24, 1995).

<sup>280</sup> Rosen, Marty. (April 9, 1995).

<sup>281</sup> *Associated Press*. (May 12, 1995).

she planted last fall push their heads up through the crusty soil, sitting at her cluttered desk at the Globe getting out another health column for her readers, cheering at her daughter's soccer games, making Passover plans, exchanging advice and gossip with her friends, sweetly savoring another season of life as only survivors of serious illness can do.”<sup>282</sup> Globe columnist Bella English’s vivid prose quickly turns from grief to anger, in her response that, “young women do not ordinarily die of cardiac arrest. Through an appalling series of errors that would make The Three Stooges look like brain surgeons, staff members at this world-renowned, elite institution gave Betsy and another patient a massive overdose of a toxic anticancer drug, causing cardiac damage in both. Betsy died; the other woman remains a cardiac cripple.”<sup>283</sup> After brief caveats about the inexact nature of medicine and the fallibility of doctors, the attack continues, “in all the layers of pedigreed professionals who sent Betsy to an early grave, someone should have smelled a skunk. This wasn't just a one-time overdose; the two women were overdosed for four days running,” with an even more tragic admission that “an autopsy showed that Betsy had no visible signs of cancer remaining in her body, which could mean that she had years of life ahead of her.”<sup>284</sup> The error should not have gone on the way that it did, according to English, and that Betsy Lehman had seemingly been cured of her cancer makes it all the more tragic.

Turning back to qualities of the victim, English describes Lehman’s role as a patient - “Betsy was not just your average health care consumer. She had sources and contacts and a lively curiosity about health matters. When she became a patient, she

---

<sup>282</sup> English, Bella. (March 25, 1995).

<sup>283</sup> Ibid.

<sup>284</sup> Ibid.

asked questions, then asked more. She got second opinions. She read the research. She and her husband Bob, a scientist who works at Dana-Farber, had thoroughly acquainted themselves with her illness, with her treatment, with her chances. In the end, she placed her trust in Dana-Farber, which proved woefully unworthy of that trust. Betsy knew that one day, the cancer might take her. But she never expected to be killed by her caregivers.”<sup>285</sup> From all these details about her, Betsy Lehman is held up as a model patient – educated, empowered, active and trusting. Quite the contrary to Lehman’s venerated role as ideal patient, English sees Dana-Farber as not holding up to their end of the relationship, falling short on their primary responsibility in providing care. She declares, “If there’s one lesson we should take away from this, it’s that all the brilliant research in the world doesn’t matter a hoot if it isn’t applied correctly to patients. It’s obvious that Dana-Farber is more interested in research - for which it receives millions in federal funds - than in patient care. Shouldn’t the two coexist in a seamless marriage? What is the research ultimately for, anyway? The grants? The glory? The Nobel Prize? Doctors must remember that behind every protocol there is a patient; not a lab animal but a human being.”<sup>286</sup> Losing sight of the patient – in Betsy’s case leads to an accusation that scientific medicine overlooks patient care - will be a general theme in all three of the error narratives in this chapter.

In summing up the stakes of Lehman’s death, English points her finger right at the top, “one can only hope that the right people are listening, starting with Dana-Farber president Chris Walsh, who referred to Betsy and the other woman debilitated by the

---

<sup>285</sup> English, Bella. (March 25, 1995).

<sup>286</sup> Ibid.

overdose as ‘one incident, two people. I wouldn't like that to indict a whole program.’ And David Livingston, physician-in-chief, who called the systemic breakdown ‘an isolated incident.’”<sup>287</sup> The problem with such a defensive response by Dana-Farber comes when English bluntly exhorts, “Gentlemen, you just don't get it. And it is precisely your type of arrogance that Betsy would have loved to have written about, if only that arrogance hadn't killed her first.”<sup>288</sup> More than what descriptive, factual reporting of the tragedy could do alone, such a heartfelt, well-written commentary makes the leaders of Dana-Farber look foolish and insensitive. And now they have a full-blown public scandal on their hands.

The discovery of the error that killed Betsy Lehman emerged through a context of other errors being reported at the same time (Winter-Spring 1995), leading to a cycle of discovery and disclosure fueled by media coverage of the scandalous nature of medical error. For example, “in other recent, publicized medical mistakes, a surgeon at a Tampa, Fla., hospital on Feb. 20 amputated the healthy leg of a 51-year-old diabetic instead of the diseased one. At the same hospital on March 3, a 77-year-old man died after a technician mistakenly disconnected him from a breathing machine. At a hospital in Grand Rapids, Mich., a surgeon performing a mastectomy on a cancer patient last month removed the wrong breast, a television station reported.”<sup>289</sup> That string of errors was reported in an article in the *Philadelphia Inquirer* that then draws upon the Harvard Medical Practice Study, “there is little information on how frequently patients in hospitals are given incorrect doses of medicine, either through prescription or dispensing error. But a 1991

---

<sup>287</sup> English, Bella. (March 25, 1995).

<sup>288</sup> Ibid.

<sup>289</sup> The Philadelphia Inquirer (March 25, 1995).

Harvard Medical School study found about 7.5 cases of adverse events due to negligence for every single malpractice claim in the courts, concluding there may be far more malpractice occurring than patients or the public realize.”<sup>290</sup> Media coverage then leads to other patients disclosing errors, such as in the case of Jourdann Moore, whose mother “reportedly came forward after seeing reports about Betsy Lehman, a Globe columnist who died of heart failure after she and another woman received overdoses of an anticancer drug at the Dana-Farber Cancer Institute last year.”<sup>291</sup> How media exposure and Lehman’s death fits in with others is also captured in the following observation from Reporter Marty Rosen of the *St. Petersburg Times*:

And problems do not come to light unless someone is maimed or killed, as in the UCH cases or the Dec. 3 death of Boston Globe health reporter Betsy Lehman, who accidentally was given four times the maximum safe dosage of a potent drug during chemotherapy for breast cancer. If the mistake slipped past Lehman, an award-winning health reporter, and her husband, a scientist at the cancer center, what does that mean for patients not educated in health care? Shindul-Rothschild, the Boston professor who knew Lehman as a savvy health expert, said it underscores the importance of reinstituting the often redundant - and more costly - safeguards in the traditional health care system.<sup>292</sup>

Reiterating sentiments from Lehman’s *Boston Globe* colleague about her role as a model patient, this statement also speaks to how public scandal caused by media reporting of medical error can have a snowball effect. Through shocking stories of mishaps in care, an expanding cycle of media discovery and public disclosure places medical error under a wider spotlight, and with more intense scrutiny.

---

<sup>290</sup> Ibid.

<sup>291</sup> Bai, Matt. (April 6, 1995).

<sup>292</sup> Rosen, Marty. (April 9, 1995).

Amidst this context of the discovery and disclosure of medical errors leading to scandal and scrutiny of health care, comes another compelling response from one of Lehman's colleagues at the *Boston Globe*. In a similar heartbroken tone as Bella English, fellow Globe writer Ellen Goodman wonders, "How do you react to a medical horror story? What is the proper etiquette of emotions that rush up from your gut to greet such a tale?"<sup>293</sup> After referring to the medical errors in Tampa and Michigan (alluded to above), Goodman recognizes, "but this time, it's happened to one of us, to Betsy Lehman of all people. A friend, a colleague at The Boston Globe, a 39-year-old mother of two young daughters who had reached for the promise of a breast cancer cure in bone marrow transplant, writing, 'I'm resigned to the idea of going through hell for the hope of a chance.' A chance she didn't get."<sup>294</sup> She says, "Betsy Lehman was given a fatal overdose of the anticancer medication. She was given four times the right dosage. She was given it for four days in a row," wondering "What are we to say? Accidents happen?"<sup>295</sup> After grieving when she first died, "to those of us who count ourselves her friends, this second mourning is compounded by anger. For those who didn't know Betsy, it should be compounded by fear."<sup>296</sup> Goodman wrestles with how to reconcile the discovery of the fatal error months after grieving through Lehman's death.

In her piece, Goodman ponders almost philosophical dilemmas about the nature of misfortune and accidents. She says that, "these are stories that elicit anger as deep as our own vulnerability. Yet even anger wars with the truths wrapped inside cliches:

---

<sup>293</sup> Goodman, Ellen. (March 29, 1995).

<sup>294</sup> Ibid.

<sup>295</sup> Ibid.

<sup>296</sup> Ibid.



Accidents happen, no one is perfect, the "human factor" includes a capacity for the most terrible of mistakes."<sup>297</sup> By considering such inevitability, Goodman carries a somewhat resigned tone when considering the more widespread context of medical error occurring in various ways, at different places. Despite her position as an educated health columnist, being treated at Dana-Farber where her husband worked, Goodman recognizes that "it [still] happened to her; she was still killed by carelessness. By the human errors that adds up to a system's error. By a hospital whose own self-confidence may have been a fatal flaw. By an institution that never installed the computer program that might have flagged this mistake."<sup>298</sup> Again, Goodman wonders rhetorically, "Accidents happen? No one is perfect?" Referring to Lehman's admirable ability to weigh both sides of a story, Goodman affirms, "I haven't a doubt that the people who mishandled her case, her life, are in their own pain. In journalism, Betsy's profession and mine, the worst errors we make can destroy a reputation. In medicine they destroy people. It's the stakes that differ; not the fallibility."<sup>299</sup> Goodman speculates how Lehman would have reacted to a medical error such as her own, "If this had happened to anyone else, Betsy would have been mad as hell. Mad, without forgetting that no system is really mistake-proof, no hospital human-error-proof. Mad anyway."<sup>300</sup> By the end of the commentary, Goodman exhibits a rather extensive transformation in emotion over the discovery of the error; "So what do you say? In December, when Betsy died without a trace of cancer left in her body, the world lost her generosity. In March we lost something else in short supply. A huge

---

<sup>297</sup> Goodman, Ellen. (March 29, 1995).

<sup>298</sup> Ibid.

<sup>299</sup> Ibid.

<sup>300</sup> Ibid.

portion of trust.”<sup>301</sup> The question of trust is precisely what drives the theme of Betsy Lehman’s error narrative – public scandal results when trust in an institution is shaken. Patient safety advocates would use such stories as a wake-up call, to call attention to the problem of error in order to promote change in health care organization and delivery systems.

With the patient safety movement not yet formally organized in 1995, the public scandal resulting from Betsy Lehman’s death, and other mistakes around that time, ends up reasserting traditional solutions of provider disclosure and individual accountability. For example, one article sees the problem as a lack of consumer information about doctors, “when the push for health-care reform fell flat last year, so too did measures aimed at helping patients find out more about hospitals. Much of the information that could help consumers make informed choices is kept secret. Doctors disciplined in one state can set up shop somewhere else. Problems at hospitals become public only when something goes wrong.”<sup>302</sup> Such sentiment implies, then, that the problem lies with individual providers, rather than as a result of systems that do not effectively prevent errors from leading to harm, which would be the major claim behind *To Err is Human* in early 2000.

In the aftermath of the discovery of error in Lehman’s death, the response from Dana-Farber would also follow in a traditional, punitive direction. According to an *Associated Press* article, “the Dana-Farber Cancer Institute said today that it was bringing disciplinary proceedings against two doctors involved in the care of two patients who

---

<sup>301</sup> Ibid.

<sup>302</sup> Sharp, Deborah. (March 27, 1995).

received chemotherapy overdoses.”<sup>303</sup> The Institute’s Chief Physician and Director, Dr. David Livingston would be unable to stem the scandal that had erupted, eventually resigning from his post in order to put forth “a signal that this institution means what it said when it indicated it was going to the bottom of these tragic incidents.”<sup>304</sup> In terms of resource allocation, “Dana-Farber said it would spend \$1.3 million to educate doctors, nurses, pharmacists and other employees about drug protocol and documentation of medical records,” but that remedy was actually only done under the threat of the Joint Commission on the Accreditation of Healthcare Organizations, which “gave the institute six months to correct unspecified problems related to the overdoses or risk losing reimbursement for Medicaid and Medicare patients.”<sup>305</sup>

Besides the fallout for the Dana-Farber Cancer Institute, the doctor who was blamed for Lehman’s death would spend years in court trying to combat the consequences of the public scandal. Reported in the *Boston Globe*, Dr. Lois Ayash was eventually awarded “\$4.2 million for lost wages and emotional distress for the way she was treated by The Boston Globe and the Dana-Farber Cancer Institute following two chemotherapy overdoses in a medical experiment she designed and oversaw.”<sup>306</sup> “Ayash designed and ran the experimental breast cancer treatment in which,” Betsy Lehman had been treated, but “another doctor accidentally ordered the overdoses, which were not discovered for 10 weeks.”<sup>307</sup> Nonetheless, “after an investigation, the hospital reprimanded Ayash for not finding the overdoses sooner” and “a year later, Ayash was

---

<sup>303</sup> Associated Press. (April 2, 1995).

<sup>304</sup> Associated Press. (May 12, 1995).

<sup>305</sup> Ibid.

<sup>306</sup> Dembner, Alice. (February 13, 2002).

<sup>307</sup> Ibid.

laid off.”<sup>308</sup> In response to the jury award, though, Dana-Farber spokesman Steven Singer said that “the real victims of the tragic overdoses were the patients involved and their loved ones,” continuing with the claim that “the institute’s actions in 1995 and 1996 were taken to help ensure patient safety.”<sup>309</sup> Eight years after Lehman’s death, the spokesman’s use of the term ‘patient safety,’ is particularly noteworthy, as it was not in widespread use when the media discourse, and resulting public scandal, erupted in 1995 right after the discovery that Lehman’s death was from an accidental overdose.

The main legacy of Betsy Lehman’s story is not through such court decisions, though, but in how she was honored after her death. In the immediate aftermath, The American Cancer Society’s Massachusetts division “awarded its first Lifetime Achievement Award for excellence in cancer communications to Betsy A. Lehman, who created The Boston Globe’s Health Sense column.”<sup>310</sup> While a worthy honor, the longer-term representation of Lehman’s legacy would come almost a decade after her death. According the *Boston Globe*’s Alice Dembner, “more than nine years after Boston Globe health columnist Betsy Lehman died from a chemotherapy overdose, state officials will memorialize her today by opening a center dedicated to reducing medical errors.”<sup>311</sup> The intent of the ‘Betsy Lehman Center for Patient Safety and Medical Error Reduction’ is “to coordinate patient safety efforts by state and private health agencies and to educate health-care providers about the best ways to prevent errors.”<sup>312</sup> A discourse centering upon patient safety is evident in a quote from Christine Ferguson, commissioner of public

---

<sup>308</sup> Dembner, Alice. (February 13, 2002).

<sup>309</sup> Ibid.

<sup>310</sup> *The Boston Globe*. (April 7, 1995).

<sup>311</sup> Dembner, Alice. (January 12, 2004).

<sup>312</sup> Ibid.

health, who states, "We are going to go great guns and pursue this issue and get the rate of medical errors down and make Massachusetts number one in the country for patient safety."<sup>313</sup> Given that efforts to create the center had been in the works for years, leading Patient Safety advocate Lucian Leape had this to say now that the proper state funding been secured to support it, "Up until now, it's been symbolic, the fact that they're willing to start funding is a very encouraging sign."<sup>314</sup>

Four years after the Harvard Medical Practice Study elicited academic interest in the study of medical error (see Chapter 2), Betsy Lehman's shocking death gave the dangers of medical harm a tragic, public face. The institution in which she was being treated, the Dana-Farber Cancer Institute (affiliated with Harvard Medical School), is a prestigious, cutting-edge research facility that focuses exclusively upon the treatment of cancer. The fact that her husband worked as a cancer researcher at the very institution where she would be killed only added to the tragedy of her death. As a respected health columnist for the *Boston Globe*, Lehman was a popular advocate for informing and educating the public about all matters related to health and medical care. The reaction to Lehman's death, especially the loss of trust in medicine dictated by Lehman's colleagues at the *Boston Globe*, calls attention to Hess's observation that "the accumulation of reports of iatrogenic disease, hospital errors, and capture of medical science by profit motives has led to increased scepticism and civil society mobilisation."<sup>315</sup> While the mobilization into a patient safety movement was still several years away, Lehman's death

---

<sup>313</sup> Dembner, Alice. (January 12, 2004).

<sup>314</sup> Ibid.

<sup>315</sup> Hess (2004), p. 698.

made her colleagues at the *Boston Globe*, as well as media observers of other medical errors, into skeptics out of the health care system.

The significance of Betsy Lehman's death comes from a context of disparate stories of medical error being brought into a broader narrative of public scandal, which would eventually feed into a patient safety discourse that seeks to include patients in the delivery of safe medical care. While the patient safety movement was only just emerging in the mid-1990s when she died, Betsy Lehman's death provides a tragic, emotional story of medical error to go along with the technical statistics of the 1991 Harvard Medical Practice Study in 1991. If that study did not receive the widespread attention beyond academic medicine that was hoped for, it would be the incorporation of stories of error that eventually did. Following on the heels of Leape's influential "Error in Medicine" article in 1994, the discovery of the error that led to Betsy Lehman's death became a public scandal that brought attention to the problem of medical error. With a similar connection between story and report, the next case study of error narrative follows closely after the IOM's *To Err is Human* report, which is largely seen as the turning point for patient safety reform in the US.

### **Medical Error as Inspiration for Advocacy**

#### **— Sorrel King and Josie's Story**

Sorrel King lost her 18-month old daughter Josie to a series of medical errors at one of the most respected hospitals in the world, Johns Hopkins in Baltimore. As described on the website of the Josie King Foundation, "in January of 2001 Josie was

admitted to Johns Hopkins after suffering first and second degree burns from climbing into a hot bath. She healed well and within weeks was scheduled for release. Two days before she was to return home she died of severe dehydration and misused narcotics.”<sup>316</sup>

Johns Hopkins admitted mistakes in the care of Josie, and offered a settlement that the King family decided to put to use for the cause of patient safety. With her husband Tony, Sorrel King started the Josie King foundation, which is best known for distributing a DVD entitled *Josie’s Story*. The DVD airs an emotional speech that Sorrel King gave not long after Josie died, recounting the series of events that lead to the tragedy and urging health care providers to communicate with families to prevent harm to patients. The DVD of *Josie’s Story* has spread to over a thousand health care institutions, not only across the United States but also branching out around the globe. As with Betsy Lehman’s story, the details of how medical error lead to a patient death provides background for a transformational narrative coming in the wake of tragedy.<sup>317</sup>

To hear Sorrel King tell the story of Josie’s death, particularly its immediate aftermath, elicits a range of emotions – grief, anger, shock. In her book, entitled *Josie’s Story*, Sorrel King painstakingly describes the events leading to Josie’s death, and then traces her subsequent transformation to patient safety advocate. Her powerful prose is exhibited in this account of the moment in which her daughter was taken off of life support: “I held her, and then Tony and I held her together, Tony’s arm around me and the other draped under mine as we clung to her and to each other. The minutes ticked by.

---

<sup>316</sup> From the Josie King Foundation website: <http://www.josieking.org/>.

<sup>317</sup> While the main source for this section is Sorrel King’s 2009 book, an outside description of what happened to Josie can be found in Niedowski (December 14, 2003): “How medical error took a little girl’s life,” which was the first of a two part series entitled “A Mother’s Promise.”

Amal [Josie's Doctor] laid the stethoscope on her chest again. He looked at us and nodded. She died in our arms and my heart exploded into a million pieces."<sup>318</sup> Anger and frustration had already set in before Josie was taken off of life support. Sorrel recounts, "Within hours of Josie's cardiac arrest Hopkins began scrambling to collect information. Blood cultures were sent to the lab for testing as they searched for signs of a massive infection. They were searching for something to blame other than themselves. It had to be the fault of the imperfect human body."<sup>319</sup> The rapid turn-of-events lead to a sudden shock, since "in forty-eight hours, we had gone from planning a welcome home celebration to planning a funeral. God, or whoever created us, was very clever when He programmed into our system a mechanism called shock. Shock is a fabulous narcotic."<sup>320</sup> In the immediate aftermath of the tragedy, Doctors from Johns Hopkins would admit the mistake, following in line with patient safety leaders' suggestion to "tell the patient everything they know when they know it,"<sup>321</sup> even driving to the King's home to apologize in person. However, an investigation into the cause of the tragedy would follow, with the potential of derailing any initial cooperation that the King family had received from Johns Hopkins.

Sorrel King explains how Johns Hopkins defined, in unemotional and technical terms, the tragic death of her daughter, "Josie's death was a sentinel event: an event in which there has been an unexpected outcome resulting in death or serious injury."<sup>322</sup>

Millman's work on medical mistakes calls to mind the divergent interpretation of error

---

<sup>318</sup> King (2009), p. 57.

<sup>319</sup> Ibid., p. 52.

<sup>320</sup> Ibid., p. 58.

<sup>321</sup> Leape and Berwick (2005), p. 2388.

<sup>322</sup> King (2009), p. 65.



between patients and providers, “the very definition of what constitutes a medical mistake is carefully controlled by doctors. What would probably be viewed as a mistake by the patient may not be interpreted as a mistake by the physician, and the doctor usually has the power to control the identification of mistakes.”<sup>323</sup> In the aftermath of patient harm, the differential power to define what can be categorized as a medical error contributes to turning any previous cooperation into a more adversarial relationship between patient and provider. Sorrel King certainly felt the power imbalance in her frustration with Johns Hopkins in the weeks and months after Josie’s death. Knowing that a malpractice case would likely appear favorable to a jury, and at the very least bring forth unwanted media scrutiny that would be hard to defend, Hopkins offered a settlement to the King family. Sorrel King explains how the settlement offer felt, as “it was a concept that was difficult to comprehend – money for the death of our daughter. The thought of us accepting it was almost as appalling as them offering it. We didn’t want their money and felt that by accepting it we would be letting them off the hook. We didn’t want it be so easy for them.”<sup>324</sup> Though she admits her initial reaction was a desire to destroy the reputation of Johns Hopkins, Sorrel and Tony King, with help and advice from family as well as from medical and legal professionals, eventually “decided we’d start a foundation. Its mission would be to prevent patients from being harmed or killed by medical errors. We would name it after Josie, and we would begin with Johns Hopkins.”<sup>325</sup>

---

<sup>323</sup> Millman (1977) p. 91.

<sup>324</sup> King (2009), p. 91.

<sup>325</sup> Ibid., p. 117.

The decision to take the settlement money, and use it to make something better come out of her daughter's death, lead Sorrel King down the path toward becoming a patient safety advocate. Her introduction to the field started with meeting Dr. Peter Pronovost, "an anesthesiologist whose father had died from medication errors," and thus "patient safety was his passion."<sup>326</sup> From the beginning of their collaboration, Pronovost, as discussed in his recent book entitled *Safe Patients, Smart Hospitals*, recognizes the significance of patient stories for eliciting action on behalf of patient safety. He states, "I knew the best way to engage Hopkins in this [patient safety] work was to have Sorrel share her powerful story. Her tragedy made the statistics about the number of people who died from medical errors hauntingly real. The name Josie King could be the mnemonic touchstone that would inspire Hopkins to really focus on patient safety."<sup>327</sup> Together, Sorrel King and Peter Pronovost would become a well-known, influential team, who "worked to change the hospital, she from outside its walls and he from within. They began on the two floors where Josie had been a patient. But their goal became something grander, something that had never been done. They wanted to transform the culture of America's hospitals."<sup>328</sup> The working relationship of King and Pronovost brings to light a theoretical point from Allsop, Jones and Baggott, that "health consumer groups have a situated knowledge which draws on personal experience, but incorporates other forms of expertise. The people who represent groups may themselves speak from personal experience but they also legitimate their position through drawing on the experience of their members and this is achieved by operating consultative and participatory

---

<sup>326</sup> Ibid., p. 117.

<sup>327</sup> Pronovost and Vohr (2010), p. 11.

<sup>328</sup> Niedowski (12/15/2003).

practice.”<sup>329</sup> Sorrel King’s personal story, matched with Peter Pronovost’s expertise and experience, will turn out to be a very powerful alliance, as their collaborative relationship grows.

Sorrel King’s transformation to patient safety advocate is the result of her ability to communicate both a tragic story and a passion for change in riveting public speeches. Josie’s story would become a flashpoint for translating patient safety science and statistics into something real, engaging and emotional. Sorrel details her very first speaking engagement, at Hopkins Grand Rounds, in the following paragraphs.

I had never given a speech before, but today I was addressing some of the very people who had contributed to Josie’s death. I had worked hard to craft my message. I so wanted to scream at them and tell them how much it hurt, but I knew if I told them how I really felt, they would leave the room, shake their heads, and say that Sorrel King had lost her mind. Besides, there were no words that could describe my pain.

Instead, I shared with them exactly what happened to Josie and how her care had fallen apart. I broke it down for them like a science experiment and kindly asked them to listen to each other, listen to patients, and listen to the parents. I asked them to partner with me. I asked them to help me.<sup>330</sup>

Again, in her very engaging prose, this passage exhibits Sorrel’s transformation from grief and anger to using Josie’s story as a source of inspiration - to compel her listeners with a sense of urgency and support for patient safety. In giving that first speech, Sorrel King found a calling as a public advocate for patient safety.

---

<sup>329</sup> Allsop, Jones and Baggott (2004), pp. 752-53.

<sup>330</sup> King (2009), p. 120-121.

A few weeks later, an even more significant speaking engagement would occur in Boston, at an Institute for Healthcare Improvement (IHI) conference.<sup>331</sup> Sorrel remembers how fulfilling the experience was, recalling how “standing on the stage that day felt like a good grief-therapy session. I talked and they listened. Not only did they listen, but they showed me they cared. They stood up and applauded. As I walked off the stage, people shook my hand and said thank you. They hugged me as they whispered their own stories of medical errors in my ear: the loved ones they, too, had lost, and the mistakes they had witnessed at patients’ bedsides. I did not cry alone that day.”<sup>332</sup> Since she was speaking before a room full of quality and safety leaders in the health care industry, Sorrel’s story of transformation reached a very receptive, as well as very influential, audience. In particular, Dr. Charles Denham, a patient safety advocate with the Texas Medical Institute of Technology, a quality and safety research organization, had filmed the speech (Dr. Denham will be discussed again later in this chapter). Sorrel describes what happened after her speech at IHI: “A few days after the conference he [Dr. Denham] sent me a box. I opened it and there they were: twenty DVDs of my speech, titled *Josie’s Story* and with Josie’s picture on each one. He told me to give them to any hospital that asked for one and in return I should suggest that they make a donation to the Josie King Foundation.”<sup>333</sup> Within the health care industry, Sorrel King is well known for her speech at IHI, as the DVD *Josie’s Story* rapidly spread around health care institutions across the United States, and even beyond. According to the Josie King Foundation website, “Over 1,200 healthcare institutions around the world use “The Josie

---

<sup>331</sup> This IHI conference was in 2002.

<sup>332</sup> King (2009), p. 122.

<sup>333</sup> Ibid., p. 123.

King Story” as a training tool to emphasize the importance of communication and teamwork in patient safety.”<sup>334</sup>

The patient safety movement needs inspirational figures like Sorrel King for it to grow beyond experts in the field. Peter Pronovost explains how Sorrel King’s storytelling is so motivational for the cause of patient safety:

At Hopkins and all over the world, we too often fall into the habit of looking at patient safety through the cold eyes of a statistician; lives become numbers and deaths becomes [sic] risk ratios. When you begin to understand how this work touches real people, when you can see the face behind the numbers, when you can feel the human suffering, it’s powerful, and it changes everything. In the past my talks were laden with statistics, odds ratios, and confidence intervals. Today when I give a talk I come prepared with the facts, I know the statistics. But I have learned that it’s real stories that move people, not numbers or facts. There is no question you need to provide proof for your theories. But without the story, without emotion, there is not context, it’s just words.<sup>335</sup>

Without Sorrel King’s story, Dr. Pronovost’s patient safety work would be unlikely to gain as large of an audience. Likewise, Sorrel King describes how important it was to have Dr. Pronovost as a collaborator in her crusade for patient safety. She sates, “Dr. Pronovost was proving to be a valuable ally. He was an amazing public speaker, humble and charismatic. A few weeks after my speech in Boston, he and I spoke before the NPSF, the National Patient Safety Foundation, in Washington, DC. We talked about the need for a culture of safety in the health care industry. I spoke from the patient’s perspective, Peter from an institutional perspective. We were a good team.”<sup>336</sup> Their work together was mutually respectful and enlightening. From Peter Pronovost’s perspective, “Sorrel King taught us, [that] a physician can learn a lot about a patient by

---

<sup>334</sup> Josie King Foundation website (<http://www.josieking.org/page.cfm?pageID=23>).

<sup>335</sup> Pronovost and Vohr (2010), pp. 14-15.

<sup>336</sup> King (2009), p. 126.

listening to the family. Physicians and nurses need to stop seeing families as interference, but as an opportunity to improve patient care. It has been shown that patient outcomes improve when patients and their families more actively participate. It's also a moral imperative to involve patients and their families in the care. It's the right thing to do.”<sup>337</sup> In other words, Dr. Pronovost asserts that providers “need to balance our technical training with emotional and social training.”<sup>338</sup>

By involving patients in care, Pronovost argues that changing the culture of health care delivery, more specifically of the medical profession, is necessary for improving patient safety. He states that “Hopkins is one of the best medical centers; we have some of the best surgeons in the world. Errors like this are not generally made from lack of technical expertise but rather from bad teamwork and a toxic hospital culture, something that is endemic to the entire health care system.”<sup>339</sup> So in order “to improve health care, we need to examine how culture affects the systems and structures within which we do our work. Culture influences how we deliver care, how we interrelate with our colleagues, and how we treat our patients. Similarly, the systems in which we work and live, in turn, affect culture – they are interconnected. Whether in a clinic in Africa or in the halls of an American hospital, culture and systems must be reevaluated in order for patient safety to be achieved.”<sup>340</sup> Sorrel King’s hand in changing the culture of health care came as a result of her own transformation, away from being just a victim and potential legal adversary and toward becoming an advocate and a partner. Her personal

---

<sup>337</sup> Pronovost and Vohr (2010), p. 239.

<sup>338</sup> Ibid., p. 266.

<sup>339</sup> Ibid., p. 35.

<sup>340</sup> Ibid., p. 39.

transformation parallels the attempted changes to hospital culture brought on by patient safety reforms – in motivating healthcare professionals to transform their outlook on medical error, and specifically to partner with patients, providers thus become more actively involved in promoting patient safety ideals and practice.

Sorrel King has had numerous speaking engagements, has been featured in documentaries on medical error, and has published a book (with a supporting book tour that included media coverage like an appearance on NBC's *Today* show). How Sorrel expresses her emotional transformation is described in the following way: "I was busy working with Hopkins and other hospitals. I was sharing Josie's story and I was seeing the effect it was having on people. Something had changed in me. My obsession with the destruction of Hopkins had transformed into an obsession with the construction of a safer Hopkins, a safer health care industry. I no longer wanted to fight."<sup>341</sup> Instead, Sorrel King has become focused upon raising awareness and fixing the problem of medical error, saying "that families who have lost loved ones to medical mistakes want hospitals to do three things in the aftermath: Apologize. Tell the truth. And take steps to fix the problem."<sup>342</sup> Sorrel King did get the first two of those three things from Johns Hopkins in the aftermath of Josie's death, and ever since has worked with Dr. Pronovost to ensure that the third continues to be actively pursued.

Coming shortly after the influential Institute of Medicine report from early 2000, Sorrel King's storytelling gives a public face to the issue of medical error. The Kings not only received a financial settlement for the hospital's role in the death of their daughter,

---

<sup>341</sup> King (2009), p. 147-48.

<sup>342</sup> Niedowski (12/15/2003).

but also attained a commitment from Johns Hopkins to implement policy changes promoting patient safety. As described in the PBS documentary *Remaking American Medicine*, Johns Hopkins instituted a series of policies to bolster staff communication and to consider the systematic dimensions of work design.<sup>343</sup> In reviewing policies, standardizing clinical practices and improving the flow of communication, the goal of patient safety interventions is to prevent errors from resulting in patient harm. The common goal of catching errors before they result in harm thus allows patients to take a more active and collaborative role with providers in care delivery. The significance of Sorrel King's story is in her transformation from a victim of error and possible adversary in a lawsuit against a specific institution, in to a public speaker and patient safety partner for national health care improvement. In a context of rapid growth of patient safety since early 2000, Sorrel King has teamed with Dr. Peter Pronovost, who has also become a national leader on patient safety. Dr. Pronovost's status is confirmed in a commentary published in the *Journal of the American Medical Association*, where he argues that "efforts to improve patient safety have progressed to a point that requires national leadership to develop formal processes and policies to establish priorities for patient safety efforts."<sup>344</sup> As he attributes much of his motivation and success to Sorrel King's incessant drive to improve the safety of care, Dr. Pronovost's influence as a patient safety expert is surely helped by teaming up with a patient advocate like Sorrel, witnessing her ascent as an inspirational public speaker for the cause of patient safety.

---

<sup>343</sup> *Remaking American Medicine* program information can be found at: <http://www.pbs.org/remakingamericanmedicine/>.

<sup>344</sup> Pronovost and Faden (2009), p. 891.



## Medical Error as a Celebrity Cause

### --Dennis Quaid's Recognizable Voice

In November of 2007, the newborn twins of Dennis and Kimberly Quaid were accidentally given the adult dosage of the blood-thinning drug, Heparin, at Los Angeles' Cedars Sinai Hospital. The overdose caused the twins' blood to turn to water, and ooze out of their pores. After nearly two days of medical interventions to reverse the effects of the overdose, both twins stabilized, and were released from the hospital 12 days after the mishap with no signs of permanent damage. Though his children did not die, Dennis Quaid experienced an emotional transformation and activist awakening not unlike Sorrel King's. The Quaid family also started a foundation to raise awareness of the problem of preventable medical error. However, in becoming a patient safety advocate, Dennis Quaid not only had a compelling story, but also had the power of his celebrity status to gain attention. With the support of a nationally recognized patient safety expert, Dennis Quaid provides an influential, celebrity voice for the patient safety movement.

Given the celebrity status of a well-known actor, Dennis Quaid shared the story of his twin's near-fatal overdose, while discussing the problem of medical error, in various television appearances - including *The Oprah Winfrey Show*<sup>345</sup>, CNN's *Anderson Cooper 360*<sup>346</sup>, and CBS's *60 Minutes*<sup>347</sup> and *The Early Show*.<sup>348</sup> As the one of the first media

---

<sup>345</sup> "Medical Mistakes: Dr. Oz Talks to Actor Dennis Quaid," *Oprah Winfrey Show*, March 10, 2009. ([http://www.oprah.com/showinfo/Medical-Mistakes-Dr-Oz-Talks-to-Actor-Dennis-Quaid\\_1](http://www.oprah.com/showinfo/Medical-Mistakes-Dr-Oz-Talks-to-Actor-Dennis-Quaid_1)).

<sup>346</sup> "360° Big Interview: Dennis Quaid speaks out," *AC 360*, April 22nd, 2010 (<http://ac360.blogs.cnn.com/2010/04/22/photo-gallery-dennis-quaid-speaks-out/>).

outlets to cover the story, the *60 Minutes* broadcast can be found in video clips on numerous websites and blogs.<sup>349</sup> In the *60 Minutes* story, correspondent Steve Kroft reports, “chances are you probably know someone who has died, or nearly died, because of medical mistakes in a hospital. It's much more common than most people realize, and if it can happen to the children of a movie star, at one of the finest hospitals in the country, it can happen to anyone.”<sup>350</sup> In his words, Dennis Quaid states, “these mistakes that occurred to us are not unique. And they're not unique even to Cedars. They happen in every hospital, in every state in this country. And 100,000 people, that I've come to find out, there's 100,000 people a year are killed every year in hospitals by a medical mistakes.”<sup>351</sup> Quaid quickly adopted some of the main facets of patient safety discourse, such as reference to the famous ‘100,000’ annual deaths statistic from the Institute Of Medicine’s *To Err is Human* (98,000 is the upper estimate used in the report).

Just over six months after the medical mishap, on May 14, 2008, Quaid appeared before a Congressional hearing, testifying that patients should be allowed to sue drug

---

<sup>347</sup> “Dennis Quaid Recounts Twins' Drug Ordeal,” CBS *60 Minutes*, August 24, 2008 (segment was originally broadcast on March 16, 2008, updated on August 22, 2008).([http://www.cbsnews.com/stories/2008/03/13/60minutes/main3936412\\_page4.shtml?tag=contentMain;contentBody](http://www.cbsnews.com/stories/2008/03/13/60minutes/main3936412_page4.shtml?tag=contentMain;contentBody)).

<sup>348</sup> “Dennis Quaid: Medical Errors Happen “Too Often,” CBS *Early Show*, April 12, 2010. (<http://www.cbsnews.com/stories/2010/04/12/earlyshow/health/main6387793.shtml>).

<sup>349</sup> For example, *The Huffington Post* carried the *60 Minutes* story, along with references in the health blogs of the *New York Times* and the *Wall Street Journal*, among others.

<sup>350</sup> “Dennis Quaid Recounts Twins' Drug Ordeal,” CBS *60 Minutes*, August 24, 2008 (segment was originally broadcast on March 16, 2008, updated on August 22, 2008).([http://www.cbsnews.com/stories/2008/03/13/60minutes/main3936412\\_page4.shtml?tag=contentMain;contentBody](http://www.cbsnews.com/stories/2008/03/13/60minutes/main3936412_page4.shtml?tag=contentMain;contentBody)).

<sup>351</sup> “Dennis Quaid Recounts Twins' Drug Ordeal,” CBS *60 Minutes*, August 24, 2008 (segment was originally broadcast on March 16, 2008, updated on August 22, 2008).([http://www.cbsnews.com/stories/2008/03/13/60minutes/main3936412\\_page4.shtml?tag=contentMain;contentBody](http://www.cbsnews.com/stories/2008/03/13/60minutes/main3936412_page4.shtml?tag=contentMain;contentBody)).

manufacturers in State Courts, even if the FDA had already approved the drug being litigated. According to reporting from ABC News, “the actor is arguing for the right to sue the maker of the blood-thinner heparin after his twins almost died from an overdose shortly after their birth.”<sup>352</sup> Quaid testified that “like many Americans, I have always believed that a big problem in this country has been frivolous lawsuits,” and continued that, “But now I know that the courts are often the only path that families have that are harmed by drug companies’ negligence.”<sup>353</sup> In appearing as a witness before Congress, Quaid was not speaking directly as a patient safety advocate. His story, and the publicity that would arise from a Hollywood actor testifying at a Congressional hearing, was caught up in a legal challenge that had already been scheduled before the Supreme Court. The upcoming case, *Wyeth v. Levine*, eventually supported the principle that Quaid had argued for – that patients be allowed to sue for harm caused by FDA-approved drugs in state courts.<sup>354</sup> Though some advocates might argue that improved drugs (as well as medical devices) ultimately improve patient safety, in this instance Quaid’s testimony had not yet squarely aligned with the patient safety movement.

Still, the result of both media coverage and an appearance before Congress shows that Dennis Quaid experienced an individual transformation from victim to advocate. As described in a story on the consumer medical information website, *WebMD*, “He’s no longer just Dennis Quaid, actor, husband, father. He’s added ‘health activist’ to that list,

---

<sup>352</sup> Jaffe, Barrett, and Shine (May 14, 2008).

<sup>353</sup> *Ibid.*

<sup>354</sup> The case considered the question of federal pre-emption – whether FDA regulatory approval pre-empts liability under state law. Ultimately, the Supreme Court, in a 2009 decision, determined that Federal regulatory approval of medication does not protect drug manufacturers from liability through state legal proceedings.

and he takes his new role seriously. He and [wife] Kimberly have since founded The Quaid Foundation ...dedicated to helping minimize the kind of medical mistakes in hospitals that befell their newborn twins.”<sup>355</sup> His work as health activist is crucially supported by an affiliation with the Texas Medical Institute of Technology (TMIT), which describes itself as “a medical research organization, founded in 1984, dedicated to accelerating performance solutions that save lives, save money, and build value in the communities we serve and ventures we undertake,” in which, “TMIT applies the Institute of Medicine's (IOM) design principles of patient-centeredness, evidence-based medicine, and systems performance improvement.”<sup>356</sup> The collaboration between Quaid and TMIT is formalized by the fact that “the Quaid Foundation eventually was merged with Charles Denham’s organization, TMIT,” in order, “to raise public awareness about our broken medical system, to eliminate human error, and to make caregivers aware that patients have the right to know all information that could have an impact on their health and well-being, with major focus on increasing awareness of the dangers of medication errors.”<sup>357</sup> The initial media coverage and Congressional appearance were not fleeting efforts for Dennis Quaid, as his collaboration with TMIT shows a continued dedication to improving safety.

Like Sorrel King’s teaming up with Peter Pronovost, Quaid’s health activism is incorporated into the patient safety world through teaming up with long-standing work of

---

<sup>355</sup> “Dennis Quaid, Health Activist: Actor Dennis Quaid Takes on Medical Errors – and Life with Twins,” August 8, 2008, *WebMD the Magazine*. (<http://www.webmd.com/parenting/features/dennis-quaid-health-activist>).

<sup>356</sup> SafetyLeaders.org - TMIT: About Us. (<http://www.safetyleaders.org/templates/idPage.jsp?ID=1616>).

<sup>357</sup> SafetyLeaders.org - Dennis Quaid: Our New SafetyLeaders TMIT Teammate. (<http://www.safetyleaders.org/Quaid/>).

TMIT and Dr. Charles Denham. With Dr. Denham, as well as Julie Thao, a nurse patient safety advocate,<sup>358</sup> Quaid actually wrote an article on patient safety entitled “Story Power.” This is how Quaid, Thao and Denham describe what the term ‘story power’ means:

Whether you are a physician in training, reciting a patient’s history at rounds, an actor playing the part of a hero in a movie, a parent telling a bedtime story, or a chief executive officer (CEO) inspiring the troops in a hospital, the power of your words rests on telling a story. The art and even the science of storytelling are core to living, learning, and leading. “Story power” lies in the ability to change or reinforce the behavior of others. The relatedness of rhetoric can change a person’s destiny, drive the success of a team, and even define the history of a nation.<sup>359</sup>

Clearly, it is rhetorical piece, written with the intention of persuasion rather than in a tone of neutrality. The article was published in the *Journal of Patient Safety*, a publication affiliated with the National Patient Safety Foundation. The *Journal of Patient Safety* states that it “is dedicated to presenting research advances and field applications in every area of patient safety,” but with a “mix of research and real-world findings.”<sup>360</sup>

Given Sorrel King’s prominent position as patient safety advocate, the assertion of ‘story power’ would be incomplete without mention of Josie King’s story. Also, remember that Dr. Denham was the audience member who recorded Sorrel King’s 2002 speech in Boston at the Institute for Healthcare Improvement

---

<sup>358</sup> Julie Thao is a TMIT Patient Advocate Team Member, whose bio is “After the death of a patient in her care at St. Mary’s Hospital in Madison due to a medical error caused in part by fatigue and systems failures, Julie was invited to become a Patient Safety Fellow at TMIT.”

(<http://www.safetyleaders.org/CareMoms/home.jsp?step=2#tabs>)

<sup>359</sup> Quaid, Thao, and Denham. (2010). P. 5

<sup>360</sup> *The Journal of Patient Safety* website: About the Journal.

(<http://journals.lww.com/journalpatientsafety/pages/aboutthejournal.aspx>)

conference, helping her to distribute the initial copies of the DVD *Josie's Story*.

The article recounts the events that lead to Josie's death, in order to provide background for asserting the significance of the *Josie's Story* DVD. Quaid, Thao and Denham claim the significance of the DVD is through its storytelling, "as a new weapon in the war on medical harm, attacking the real enemy of improvement- fear."<sup>361</sup>

Along with referring to Sorrel King's storytelling, the article also describes the transformation of Dennis Quaid. Their version of the story goes like this: "A movie actor and his wife, thrown into the world of patient safety, are now aware that the suffering of their little twins can save the lives of others if their story and other stories can be leveraged to create change. Having originally formed a family foundation to pursue this goal, they have now teamed with TMIT and the other characters to write a new story about the hearts of health care leaders."<sup>362</sup> The repeated mention of 'story' highlights the significance of Quaid's own transformation to advocacy, which aligns with the emotional and transformational discourse of the error narratives discussed in the article. The following passage shows how transformation is not just limited to the storyteller, but is, perhaps most notably, also directed to the audience of health care providers:

The story characters of this article are no longer satisfied with being wheeled out onto a stage to make you cry at a meeting, then return home, take days to recover, and hope that someone acts. They are getting ready help you do battle with your Goliath by developing media that will help you win the minds and hearts of your teams, so that we can put their hands to work and bring to their lips the sharing of hope that all of us need to tackle the unknown and untried. Like a magnifying glass or even a laser,

---

<sup>361</sup> Quaid, Thao, and Denham (2010), p. 6.

<sup>362</sup> Ibid., p. 11.

they will combine their stories and focus their light into heat, making it too hot for Goliath to survive.<sup>363</sup>

According to the authors, the ‘Goliath’ referred to in this passage is fear. Standing up for patient safety requires one to summon their inner ‘David,’ in order to overcome the fear that results in sticking with the status quo. Stories, then, are considered a weapon for slaying the ‘Goliath’ of fear. Quaid, Thao and Denham “want you to see yourself as a hero. It is time to write your own story. Turn that light into heat and focus it on your villain: the villain that protects the status quo- the way we have always done things. A best friend of this villain is survival centered, blind cost-cutting that drives enormous safety risk and harm to patients.”<sup>364</sup> The reader is encouraged to transform into a hero, to resist the pull of inaction. The article concludes by trumpeting, “time is wasting, people are dying, and children are suffering in your communities and your hospitals. Please do not be the last action hero to step up and be counted. In the years to come, do not be a victim of your past. Do not ignore your inner David. Do not risk knowing that an error harming a loved one or a child could have been prevented if you had acted when you put down this article and read this last word.”<sup>365</sup> In no uncertain terms, statements like those above seek to motivate action by tugging on the emotions of the reader. At least in theory, the reader will then be compelled to transform their behavior, to actively stand up for the cause of patient safety.

Dennis Quaid has been busy as a patient safety advocate in 2010. Along with the ‘Story Power’ article that he co-wrote, he also hosted a documentary on medical error

---

<sup>363</sup> Quaid, Thao, and Denham (2010), p. 12.

<sup>364</sup> Ibid., p. 13.

<sup>365</sup> Ibid., p. 13.

entitled *Chasing Zero: Winning the War on Healthcare Harm*, co-produced by TMIT and the Discovery Channel. The 53 minute program “highlights “extraordinary impact through ordinary things” that patients and caregivers can do to improve patient safety,” specifically emphasizing “improvements in leadership, medication management, healthcare-associated infections, health-information technologies, and high performance solutions.”<sup>366</sup> A telling concluding statement from the documentary reiterates the crucial role of stories and storytellers in patient safety advocacy. Filmed with a close-up shot, Quaid concludes, “facts, figures and statistics reach the head, but nothing happens unless we reach the heart.”<sup>367</sup> Numbers clearly have a certain power to persuade the rational mind, according to statements like this, but it is the emotional connection made through narrative that actually leads to change.

In a review of research on the medical profession, Timmermans and Oh argue, “as consumerist practices emerge and threaten the authority of the medical profession, physicians have thus mobilized to diminish these threats and to seek out new ways to regain the trust of their patients.”<sup>368</sup> While medical error narratives can diminish trust, as was clear with the public scandal surrounding the case of Betsy Lehman, stories can also be told in an attempt to regain and build trust in the medical profession. The productive collaboration between patients, like Sorrel King and Dennis Quaid, and patient safety leaders, like Dr. Peter Pronovost and Dr. Charles Denham, seeks to raise awareness in the

---

<sup>366</sup> Discovery Patient Safety Documentary – International Premiere April 22, 2010.

(<http://www.safetyleaders.org/Quaid/>). More about *Chasing Zero* can be found at:

(<http://www.safetyleaders.org/pages/chasingZeroDocumentary.jsp>);

(<http://discoveryhealthcme.discovery.com/zero/zero.html>);

(<http://dsc.discovery.com/videos/chasing-zero-part-1.html>).

<sup>367</sup> *Chasing Zero* Documentary (2010), time: 52:30 until 52:38.

<sup>368</sup> Timmermans and Oh (2010), p. S98.



public about medical error and to motivate health care providers for the cause of patient safety. 'Reaching the heart,' via the lessons of medical error stories, is an element of patient safety discourse that attempts to overcome any adversarial relations between patients and providers. Instead, this discourse places patients in collaboration with physicians, along with other health care professionals, in a common goal of preventing medical error.

### **Error Narratives, Transformation, and the Medical Profession**

While the stories take place across over a decade, the error narratives of Betsy Lehman, Sorrel King and Dennis Quaid bear similarities. Each involves patients from affluent backgrounds, with medical errors committed at prestigious institutions. Both the class position of Lehman, King and Quaid, as well as the high status of the hospitals, are significant because mistakes are not supposed to happen to people with access to world-class institutions. Patient affluence matters because each occupies a social position where they cannot only assert that mistakes should not have happened, but also actually obtain a response to such assertions. The power of narrative to produce emotional transformation, from stories that ultimately seek to establish motivation for the patient safety movement, would not occur without the combination of affluent victims and high-prestige institutions.

Advanced health care delivery in the United States generates expectations that medical care is, at least for those with access, extremely safe. But when a preventable mistake results in a heartbreaking patient injury or death, media coverage of the story can

turn into a public scandal, eliciting popular outrage. This was evident in each of the three medical error narratives discussed in this chapter. Leading patient safety advocates Leape and Berwick question, “can public outrage provide the pressure needed for change? Although surveys continue to show the public is concerned about medical errors and sensational cases provoke bursts of outrage, public concern is evanescent and thus an inadequate motivator for change.”<sup>369</sup> According to Leape and Berwick, public outrage does not provide sustained motivation for patient safety reform. If public attention is a fleeting motivator, what happens to error stories after media attention subsides?

The case studies of Betsy Lehman, Sorrel King and Dennis Quaid each show how error narratives were translated into patient safety advocacy. Each of their stories recounts how potentially acrimonious relations with particular healthcare institutions were eventually, though unevenly, transcended to pursue more comprehensive reform in the name of patient safety. The narratives of transformation (particularly in the cases of King and Quaid) – from error victim and potential adversary to patient partner and safety activist – form a discourse that is used to elicit an emotional transformation in the audience or reader. Error is transformed from personal tragedy to common cause. With all three stories, the emotional transformation is not just for those directly involved in the tragedy. Instead, the stories are repeated, over and over, in order to elicit a transformation in readers and audiences – most significantly directed toward physicians and other health care professionals. A summary chart (*Table 2* on page 139) compares the major aspects of the three medical error narratives analyzed in this chapter.

---

<sup>369</sup> Leape and Berwick (2005), P. 2389.

The transformational error narratives of Lehman, King and Quaid form a crucial component of patient safety discourse, through which patient safety advocacy can be regarded as a health social movement. The publicity that patient safety receives from public figures such as Sorrel King and Dennis Quaid lends support to Beard's claim that "in the United States, the rise of activism in other arenas has proved that structural trends change when 'patient' advocates become visible, often forging new types of clinical research and practice."<sup>370</sup> In the case of patient safety, patient advocates (King and Quaid) provide crucial partners to professional experts (Dr. Pronovost and Dr. Denham), such that patients themselves are considered essential partners in the quest for quality and safety improvement. Besides patient visibility and partnerships, medical error narratives contribute to including patient safety as a health social movement (HSM) in other ways. "HSMs have successfully leveraged their embodied experience of illness and forged a new path for how social movements can effectively engage in scientific knowledge production," Brown and Zavestoski claim, and "thus, HSMs serve as a critical counter-authority aimed at democratising and reshaping social policy and regulation in a way that transforms the socioeconomic and political conditions that underlie distributions of health and disease among populations."<sup>371</sup> Patient stories bring another set of voices to the discussion of patient safety, asserting a fundamental right, as well as responsibility, for patients to stand with providers in improving the quality and safety of health care.

It is through a context of medical progress and risk that patient safety, as a health movement, has emerged and developed. Regarding the publicity and awareness that

---

<sup>370</sup> Beard (2004), p. 798.

<sup>371</sup> Brown and Zavestoski (2004), p. 692.

results from a health social movement, Beard concludes how the Alzheimer's disease movement "is credited for encouraging the emergence of AD [Alzheimer's Disease] as a social problem that recast the disease from a relatively rare phenomenon to the fourth or fifth leading cause of death in the United States in just one decade."<sup>372</sup> In the case of the patient safety movement, patient stories play a particularly important role in raising the profile of medical error as a significant problem in health care delivery, leading to increased attention upon the safe organization of medical care. Since patient safety reform is focused upon changing delivery organization, though, the movement may actually counter Kolker's observation of "a significant shift," where "Previously, HSMs had focused primarily on problems of patient care, including access to healthcare and health services. More recently, HSMs have turned from 'the clinic' to 'the lab.'"<sup>373</sup> Patient stories of error redirect attention toward clinical care – specifically the organization of health care and the culture of medicine. Efforts to instill an organizational and professional dedication to safety in the delivery of care are at the heart of error narratives, and thus for patient safety as a health social movement.

Each of the error narratives pursues patient empowerment, so that patients can play a role along with medical professionals in preventing unnecessary harm. Such an egalitarian vision of patient partnerships with providers, however, is not without significant tensions. With the role of the patient reconceived from an object of clinical intervention to a partner in care provision, the traditional relationship between provider and patient is destabilized. Patient stories, in attempting to transform and motivate

---

<sup>372</sup> Beard (2004) p. 814.

<sup>373</sup> Kolker (2004), p. 820.

providers to follow with patient safety, challenge the role of the medical profession. In theoretical terms, the error narratives are a part of a larger patient safety discourse that seeks to govern conduct in the medical profession. Iedema, et al.'s discussion of narrative explains how an "intensity of feeling [is] transmuted into a concern to pro-actively (re)organize the work," which, they argue, "is at the heart of a novel shift that sees clinicians assuming governmentality"<sup>374</sup> (where "governmentality is defined as transacting personal and intimate aspects of the work such that they become available for scrutiny and intervention by self and others"<sup>375</sup>). The error narratives are meant to motivate providers to govern their own clinical practice – to become self-conscious of safety in ways that seem very innocuous but also bring to bear a form of control. As a conceptual direction for investigating control, Ocloo "suggests that the dominance of a medical model is still a powerful determinant in constructing the context of medical harm and patient safety reforms. This raises important questions about the power, dominance and control of the medical profession, as well as broader organisational systems that support these processes."<sup>376</sup> Patient stories signify the construction of partnership as a component of patient safety reform, imploring providers to consider the patient and advising patients to speak up. Partnership, however, is not the only discursive consequence in challenging the medical profession. A philosophy of transformation – patients are transformed into advocates, and in so doing providers are then also asked to become agents of change – is what makes patient safety centered upon remaking the

---

<sup>374</sup> Iedema, et al. (2006), p.141.

<sup>375</sup> Ibid., pp.141-42.

<sup>376</sup> Ocloo (2010), p. 515.

medical profession. Since it is courageous and righteous, providers are asked to partner with patients in monitoring themselves for the safe delivery of care.

Though not explicit, power and control are implicated in the stories told about patient safety. According to Waring, “although sense-making is often collective, it can also be a source of conflict as different groups compete to establish particular constructions of knowledge,” so that stories “about safety can act as a source of power through informing shared responses, delineating or reinforcing social boundaries or acting as a vehicle for control.”<sup>377</sup> This depiction reiterates Ocloo’s recommendation, that a “wider approach is seen as vital in identifying the range of social processes associated with medical harm that are also to do with medical dominance and wider issues of power and control,” whereby “these issues have been largely ignored or downplayed in the wholesale adoption of a ‘no-blame culture’ in patient safety.”<sup>378</sup> While this chapter mostly left out any issues of power and control arising from the transformational error narratives, the next chapter analyzes organizational advocacy for patient safety, touching upon such questions via arguments made by reformers for reorganizing health care delivery.

---

<sup>377</sup> Waring (2009), p. 1722.

<sup>378</sup> Ocloo (2010), p. 515.

TABLE 2: PROMINENT MEDICAL ERROR NARRATIVES – Advocacy Stories of Betsy Lehman, Sorrel King & Dennis Quaid

|                         | <u>Betsy Lehman</u>                                                                                      | <u>Sorrel King</u>                                                                                                        | <u>Dennis Quaid</u>                                                                                                         |
|-------------------------|----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| YEAR of ERROR           | 1994 (discovered 1995)                                                                                   | 2001                                                                                                                      | 2007                                                                                                                        |
| TYPE of ERROR           | Medication Error                                                                                         | Missed Diagnosis                                                                                                          | Labeling Error                                                                                                              |
| NATURE of INJURY        | Betsy Lehman died from heart failure caused by a chemotherapy overdose during cancer treatment           | Sorrel King’s daughter died from severe dehydration during treatment for burns                                            | Quaid’s newborn twins survived critical overdose after given adult dosage of a blood-thinning drug                          |
| HOSPITAL (CITY)         | Dana Farber Cancer Institute (Boston)                                                                    | Johns Hopkins (Baltimore)                                                                                                 | Cedars Sinai (Los Angeles)                                                                                                  |
| EXPERT PARTNER          | N/A                                                                                                      | Dr. Peter Pronovost                                                                                                       | Dr. Charles Denham                                                                                                          |
| ASSOCIATED ORGANIZATION | Betsy Lehman Center–founded in 2004 by gov’t of MA to coordinate patient safety efforts                  | Josie King Foundation – founded in 2002 using settlement; mission of preventing medical error                             | Quaid Foundation – founded in 2007 by Quaid family; merged with Dr. Denham’s TMIT in 2010                                   |
| NARRATIVE SIGNIFICANCE  | Public Scandal – Lehman’s death, along with other 1995 errors, lead to media scrutiny and public scandal | Inspiration for Advocacy – Sorrel King has become a key advocate in the industry for inspiring providers to pursue safety | Celebrity Cause – Quaid lends a recognizable celebrity voice, and added media coverage, to field of patient safety advocacy |

**CHAPTER 4 –  
Making the Case for Patient Safety:  
Organizational Leaders, Advocacy and Campaigns**

But it is apparent that the most fundamental change that will be needed if hospitals are to make meaningful progress in error reduction is a cultural one...Errors must be accepted as evidence of system flaws not character flaws.<sup>379</sup>

--Lucian Leape, 1994

The combination of complexity, professional fragmentation, and tradition of individualism, enhanced by a well-entrenched hierarchical authority structure and diffuse accountability, forms a daunting barrier to creating the habits and beliefs of common purpose, teamwork, and individual accountability for successful interdependence that a safe culture requires.<sup>380</sup>

--Lucian Leape and Donald Berwick, 2005

Among the extensive field of health care advocacy organizations, the National Patient Safety Foundation (NPSF) and the Institute for Healthcare Improvement (IHI) are the two most significant organizational players in patient safety advocacy in the US, with Drs. Lucian Leape and Donald Berwick as the two leading figures in the push for patient safety (Leape works with the NPSF and Berwick founded the IHI). Introducing this chapter, the above two quotes represent one of the primary goals of patient safety advocacy (culture change, as stated by Leape in the first quote) and some of the challenges of patient safety reform (the professional culture of medicine, as described by Leape and Berwick in the second quote). The work of organizations like the NPSF and IHI, along

---

<sup>379</sup> Leape (1994), p. 1857.

<sup>380</sup> Leape and Berwick (2005), p. 2387.



with their associated advocacy campaigns, is to disseminate a growing discourse of patient safety – to convince health care professionals that the creation of standardized work systems with an organizational culture committed to safety is fundamental to reducing medical errors and improving the overall quality of care delivery.

Leape and Berwick argue that the problem of medical error is due to “the culture of medicine, a culture that is deeply rooted, both by custom and by training, in high standards of autonomous individual performance and a commitment to progress through research.”<sup>381</sup> They continue, “creating cultures of safety requires major changes in behavior, changes that professionals easily perceive as threats to their authority and autonomy,” which is exacerbated by trying to overcome the complexity of care delivery along with fear and anxiety from organizational change.<sup>382</sup> Alongside technical reports and patient stories, the advocacy work of the NPSF and the IHI solidifies patient safety as an issue that health care organizations must consider. As a force of consensus-building, patient safety advocacy campaigns institutionalize a conception of medical error as an urgent problem. Particularly when pushing for an alternative politics of responsibility, these campaigns seek to pressure all within the health care industry to reorganize delivery systems towards the goals of patient safety.

Since the Institute of Medicine’s groundbreaking *To Err is Human* report in 1999, significant academic, industry, and public attention has turned to the problem of medical error.<sup>383</sup> An appeal for the creation and extension of ‘safety culture’ in health care settings has been, and continues to be, a major solution promoted by the IOM, as well as

---

<sup>381</sup> Leape and Berwick (2005), p. 2387.

<sup>382</sup> Ibid., p. 2387.

<sup>383</sup> Institute of Medicine (2000).

of US advocacy organizations like the NPSF and the IHI. Concern for patient safety encompasses a wide variety of issues, ranging from the standardization of work procedures, such as uniform guidelines for using particular drugs or medical devices, to rather broad national (and even international) health policy campaigns that seek, through a series of patient safety goals, to reduce the number of deaths or injuries attributable to medical errors. As the patient safety movement has grown since the IOM report, safety culture has been a unifying solution across health care organizations and agencies. Emboldened by the reports, statistics and campaigns that position medical error as a risk, patient safety advocacy imagines a redesigned organizational model for managing responsibility in health care delivery. The NPSF and the IHI push the building of safety cultures, along with the complementary idea of designing safety systems, as the major methods for reducing the risk of medical error and limiting patient harm.

Combining personal stories of medical tragedy with statistics about rates of error, the discourse around patient safety has been a powerful impetus for industry and governmental action to understand the scope of medical error, in order to subsequently improve the safety and quality of health care delivery. Since the late 1990s, national efforts to understand error and improve safety have been gaining momentum in most countries with advanced health care systems. Contemporary discourse about patient safety is distinctive not only for the extensive national efforts, but also for international health policy campaigns that seek to reduce the burden of medical harm worldwide. In addition to analyzing the work of the NPSF and IHI in the US, in this chapter I also explore patient safety advocacy promoted by the World Health Organization's (WHO) World Alliance for Patient Safety (WAPS). The Chair of the World Alliance for Patient

Safety is Sir Liam Donaldson, formerly a Senior Official with the UK's National Health Service, who was recognized as a leader in patient safety.<sup>384</sup> US organizations such as the National Patient Safety Foundation or the Institute for Healthcare Improvement and international partnerships like the World Alliance implore health care professionals, petition policymakers and engage the general public in the cause of patient safety. Each of these organizations, and their associated leading advocates, have to sell a notion of what should be done about medical error – in other words, these groups and leaders need to make the case for patient safety.

Looking at the three case studies of the NPSF, the IHI and the WAPS, this chapter is about how that argument for patient safety is made through organizational advocacy and campaigns. Across the three advocacy organizations, the case for patient safety is complex and varied, but nonetheless I center upon two conceptual themes in the discourse: (1) standardizing and rationalizing work organization and (2) building cultures of safety that collectivize responsibility for medical error. The purpose of this chapter is to explore how these themes play out in the advocacy work of the NPSF, the IHI and the WAPS. In the next section, I provide an eclectic review of research - ranging from standardization to workplace control and rationality, to safety culture and responsibility – that can serve to guide the analysis of the conceptual themes in patient safety advocacy discourse. This review is followed by an analysis of major leaders and campaigns for each of the organizations (the National Patient Safety Foundation, the Institute for

---

<sup>384</sup> According to the WHO's WAPS website: "Professor Sir Liam Donaldson, has been presented with a 2006 Picker Award for Excellence in recognition of his achievements in the field of patient-centred care and patient safety."  
[http://www.who.int/patientsafety/news/picker\\_award/en/](http://www.who.int/patientsafety/news/picker_award/en/)

Healthcare Improvement and the World Health Organization's World Alliance for Patient Safety). I conclude with a brief discussion of the much broader field of quality and safety advocacy in the health care industry, in order to call attention to the wide range of activities falling under the purview health care advocacy organizations, as well as to provide a bridge to the concluding chapter's discussion of health care reform, the medical profession and patient safety politics.

### **Theorizing Work Organization and Safety Culture in Patient Safety Discourse**

Patient safety advocacy organizations like the National Patient Safety Foundation, the Institute for Healthcare Improvement and the World Alliance for Patient Safety make a case for standardizing work systems and building safety culture as solutions to the problem of medical error. In this section, I review a varied mix of scholarship that can help make sense of such discourse advocating those broad patient safety solutions. Similar to the two conceptual themes mentioned above, I cover two theoretical avenues in scholarship for how advocates and organizations make the case for patient safety: (1) concerns related to work organization – standardization, control, and rationalization of work and (2) concerns related to organizing responsibility for medical error – building safety culture in health care delivery. Derived from research on standardization, control, rationalization, safety culture and responsibility, this eclectic review provides guidance for addressing how work organization and culture are developed through organizations and advocates that promote patient safety reform.

In discussions of reducing medical error, standardization of health care work processes and protocols is an avowed aspiration of patient safety advocates. According to Timmermans and Epstein's comprehensive Sociological review of the concept, standardization can be viewed "as a process of constructing uniformities across time and space, through the generation of agreed-upon rules," such that "the standards thereby created tend to span more than one community of practice or activity site; they make things work together over distance or heterogeneous metrics; and they are usually backed up by external bodies of some sort, such as professional organizations, manufacturers' associations, or the state."<sup>385</sup> Based upon this definition, "standardization is an active process that aspires to stability and order," and "any order is a hard-won achievement that requires the submission of diverse actors."<sup>386</sup> The result, as is the case with patient safety, is in constructing a working environment "around a standard with an implied script that brings people and things together in a world already full of competing conventions and standards."<sup>387</sup> The challenge of standardization is precisely in its task of bringing a diverse array of actors and interests to follow a more unified paradigm of workplace organization in order to assure patient safety. But when that happens, Timmermans and Epstein explain, "once standards are established, they render invisible the work required to make them possible and the uncertainty and ad hoc tinkering that accompanied standard implementation."<sup>388</sup> For the purposes of patient safety,

---

<sup>385</sup> Timmermans and Epstein (2010), p. 71.

<sup>386</sup> Ibid., p. 84.

<sup>387</sup> Ibid., p. 84.

<sup>388</sup> Ibid., p. 83.

standardization is made possible through changing assumptions among health care professionals about how safe medical care is delivered.

To remake care delivery to be safer, advocates develop arguments about how to best organize health care work. Scholarship on work organization, specifically related to issues of workplace control and rationality, thus provides guidance in understanding assumptions and efforts made related to modifying health care delivery in the name of patient safety. Maintaining a focus upon control, while offering a critical evaluation of changes over time, Edwards argues that work organization has developed in order to control conflict.<sup>389</sup> As small firms expanded to larger corporations in the early twentieth century, control developed into more structured forms, in order to accommodate worker resistance and institute more stable control over workers. Technical control offered a manner of organizing the workplace along the lines of the physical structure of the labor process, while bureaucratic control rested upon social structure of the workplace.<sup>390</sup> While Edwards' historical explanation of control is not focused upon the professions, the discussion of control broadly resonates with Freidson's estimation that, "the crucial issue for the evaluation of any kind of work is its outcome in quantity and quality."<sup>391</sup> "For professional workers," Freidson explains, "the issue is whether they are able to exercise control over their work and its outcome, and what methods of control they use," recognizing that "control over work performance is of course the basic prize over which occupation and administration contend in particular work settings."<sup>392</sup> The question of

---

<sup>389</sup> Edwards (1979).

<sup>390</sup> Ibid.

<sup>391</sup> Freidson (1994), p. 71.

<sup>392</sup> Ibid., p. 71.

control over work is significant to making the case for patient safety, as advocates ask healthcare professionals to subsume the traditional organization of care delivery, resting upon individual clinical judgment, to a universalizing goal of safety and quality improvement, using such techniques as standardized clinical protocols.

Promoted under this guise of improvement, and in tandem with considerations of work control, an associated guiding concept of workplace structure concerns rationality and rationalization in work organization. In tracing the rise of the engineering profession, Noble assesses the transformation and consolidation of the American corporation, which he argues cannot be understood without the related transformation and consolidation of American scientific technology.<sup>393</sup> Noble calls attention to the inextricable links between corporate capitalism and engineering rationality, noting the historical development of this form of rationality as constructed via professionalization and academic accreditation, as opposed to purely descending from universal principles.<sup>394</sup> In re-assessing the professionalization of engineering, Shenhav looks back at the main tenets of early management theory and the subsequent establishment of management ideology as dominant workplace structure in the 20<sup>th</sup> century.<sup>395</sup> Shenhav's contribution concerns tracing the universalization of management ideology, as promoted by the engineering profession, through a process that masked political conflicts and subsequently established a set of mechanical principles by which work organization would be constructed. Utilizing a discourse-analytic strategy, Shenhav argues for the constructed nature of workplace rationality as based not upon universal principles, but

---

<sup>393</sup> Noble (1977), p. 19.

<sup>394</sup> Noble (1977).

<sup>395</sup> Shenhav (1999)

rather upon a contingent incorporation of engineering doctrine into management ideology and practice. After battles for supremacy in the early 20<sup>th</sup> century, this engineering approach to management was eventually institutionalized over the course of five decades.<sup>396</sup> From both Noble and Shenhav, rationality is not seen as an independent, purely technical, property of workplace organization, as is often assumed by theories of management and engineering. Instead, the design of work occurs through a historical process of rationalization, replete with conflicts that are later forgotten or erased. In forming “specific niches of their own,” Murphy argues more directly that professions rely upon “the development of the formal legal system and bureaucratic organization: that is, on the more general process of formal rationalization.”<sup>397</sup> Concerning changes specifically to the medial profession, Freidson confirms such notions that “rationalization will also be an important part of continuing efforts to control the quality of care and the accountability of those who provide it,”<sup>398</sup> in the context of the growth of managed care. While not as explicitly stated as the committed push for standardization, patient safety advocates implicitly promote rationalization of work as a related way in which healthcare professionals can make care delivery safer. Scholarship on standardization and rationalization are useful when taken together to inform both the explicit and implicit arguments made for the case of patient safety. Bringing standardization and rationalization together, with an undercurrent of tensions over control of health care work, makes for a unique combination of scholarly influences for the analysis of work organization in the case studies of patient safety advocacy.

---

<sup>396</sup> Shenhav (1999), p. 196.

<sup>397</sup> Murphy (1990), p. 93

<sup>398</sup> Freidson (1989), p. 200.



While questioning the structure of work organization is a significant element of patient safety advocacy efforts, those seeking to transform health care delivery more directly advance the concept of safety culture as their major point of emphasis. A relevant review article on the concept of safety culture by Susan Silbey, asserts that, “since the 1990s, identifying broken or otherwise damaged safety culture has become a familiar explanation for organizational and technological failures.”<sup>399</sup> Although “largely absent from sociological scholarship,” Silbey observes that “the term safety culture is invoked with increasing frequency.”<sup>400</sup> She defines the term ‘safety culture’ as referring to “a commonly shared, stable set of practices in which all members of an organization learn from errors to minimize risk and maximize safety in the performance of organizational tasks and the achievement of production goals”<sup>401</sup> a definition that resonates with patient safety advocacy. To clarify this conceptualization, Silbey utilizes a definition of culture that “is understood to be emergent and indeterminate, an indissoluble dialectic of system and practice,” such that “the consequences of safety culture cannot be engineered and only probabilistically predicted with high variation from certainty.”<sup>402</sup> Such a notion of culture aligns with the overall theoretical and methodological perspective of this dissertation, focused upon the complex and contested, yet emergent and influential, nature of public discourse on medical error and patient safety. Silbey states, “what is specifically missing from accounts of safety culture is attention to the mechanisms and processes that produce systemic meanings, including understandings of

---

<sup>399</sup> Silbey (2009), p. 342.

<sup>400</sup> Ibid., p. 342.

<sup>401</sup> Ibid., p. 343.

<sup>402</sup> Ibid., p. 356.

risk, safety, authority, and control. A reflexive, historically grounded, empirical research agenda should address these issues.”<sup>403</sup> This chapter attempts to follow along with such recommendations from Silbey for how to study safety culture – I look particularly to how patient safety advocates produce understandings of what needs to be changed in medical care, merging an overarching concern about safety culture with various efforts underway to standardize and rationalize health care delivery.

Both work organization and safety culture encompass questions about responsibility within the workplace. With overtones of control and rationalization of work, the result of promoting safety culture is tensions in the workplace over a reconstitution of responsibility in health care. Based upon these observations, Silbey’s argument suggests that “the endorsement of safety culture can be usefully understood as a way of encouraging and allocating responsibility - one response to the dangers of technological systems.”<sup>404</sup> This could be applied more specifically to health care by saying that the dangers of medical error, once recognized, lead to the reallocation of responsibility through patient safety discourse. Further conceptualization of responsibility comes from Heimer and Staffen’s ethnographic research of two neonatal intensive care units. In their theoretical review, they define responsibility as “high-quality compliance with norms – thoughtful compliance oriented toward achieving the objective of the norm or meeting one’s obligations to others rather than toward avoidance of blame or superficial conformity.”<sup>405</sup> From the discourse of patient safety advocates, they would follow such a definition of responsibility. The sociological value of studying

---

<sup>403</sup> Silbey (2009), p. 360.

<sup>404</sup> Ibid., p. 343.

<sup>405</sup> Heimer and Staffen (1998), p. 7.

responsibility, according to Heimer and Staffen, is that “choices and agency are “responsible” only when they are social.”<sup>406</sup> From this theorization, Heimer and Staffen ultimately argue that “when we study the taking of responsibility, the use of human rationality and generosity to live up to obligations to others, many traditional problems of moral theory become clearer,” such that “the key question is not when people should be held accountable but rather what social arrangements encourage them to hold *themselves* accountable.”<sup>407</sup> Following this theoretical guidance in the sociology of responsibility, I examine how advocates and organizations ask health care professionals to “hold themselves accountable” through ‘high-quality compliance’ to patient safety norms. What results is a reform effort aimed at realigning responsibility so that health care work is founded upon an explicit ethic of safety and quality improvement, rather than one based upon “avoidance of blame or superficial conformity.”<sup>408</sup>

Returning to safety culture, Heimer and Staffen’s theory of responsibility is related to what Silbey calls ‘responsibilization.’ Silbey claims “because the propagation and inculcation of safety culture is only one approach to enhancing the reliability and safety of complex technologies, it is not unreasonable to wonder whether safety culture, focused on individual participants’ self-determined contributions to the system as a whole, might not be described as an expression of responsibilization, this neoliberal technique of governance.”<sup>409</sup> As opposed to assumptions of coercive domination

---

<sup>406</sup> Heimer and Staffen (1998), p. 13.

<sup>407</sup> Ibid., p. 373, italics in original.

<sup>408</sup> Heimer and Staffen (1998), p. 7.

<sup>409</sup> Silbey (2009), p. 348

underlining some theories of work organization,<sup>410</sup> Silbey's 'responsibilization' argument lines up with a governmentality approach,<sup>411</sup> following the ways in which conduct is aligned to pursue the prerogatives of patient safety reform.

Using the three case studies in this chapter, I analyze institutional organizations, with a focus upon leading figures, as they sell an idea of patient safety reform – redesigning work systems and building safety culture as the solutions to the problem of medical error. The assorted research reviewed in this section corresponds with the divergent influences and reach of patient safety discourse. As a unifying theme, though, patient safety advocacy combines efforts to increase the efficiency of health care delivery (such as standardization) with concerns over responsibility for medical error (such as safety culture). While overlooking potential tensions over work control, patient safety advocates assert that efficiency and safety can exist in unison, secured by reorganizing health care work through concepts such as standardization and safety culture.

## **Making the Case for Safety Culture**

### **-- The National Patient Safety Foundation**

"The main change that will be needed is a change in our culture."<sup>412</sup>

Three years after the Harvard Medical Practice Study was published in 1991,<sup>413</sup> Lucian Leape's seminal article, "Error in Medicine,"<sup>414</sup> played a path-breaking role in

---

<sup>410</sup> This is a tone struck by some of the Control Theories, such as Edwards (1979).

<sup>411</sup> Foucault (1991), and discussed in the dissertation's introduction (Chapter 1).

<sup>412</sup> Leape, et al. (1998), p. 1447.

positioning medical error as a major problem and setting out early principles of patient safety. In the article, he argues that “the important point is that successful accident prevention efforts must focus on root causes – system errors in design and implementation,” with “the primary objective of system design for safety is to make it difficult for individuals to err,” while also recognizing “that errors will inevitably occur and to plan for their recovery.”<sup>415</sup> Such reasoning rests upon an assumption that, “because it is impossible to prevent all error, buffers should be built into each system so that errors are absorbed before they can cause harm to patients,” such that “systems should be designed so that errors can be identified in time to be intercepted.”<sup>416</sup> With the Harvard Medical Practice Study providing statistics to show the extensive problem of medical error and then setting an agenda for further research, Lucian Leape’s “Error in Medicine” article advocated a focus upon the design of care delivery, when error was reconceived as due to system failures rather than resulting from individual shortcomings.

Two years after Leape’s influential 1994 article, the foundation for patient safety organizational advocacy started with an October 1996 conference put together by the American Association for the Advancement of Science, the American Medical Association, the Annenberg Center for Health Sciences and the Joint Commission on the Accreditation of Healthcare Organizations. The conference was titled “Examining Errors in Healthcare: Developing a Prevention, Education and Research Agenda.” Described as “a first-time-ever cooperative effort,” the conference sought “to develop a prevention,

---

<sup>413</sup> Harvard Medical Practice Study I and II (1991).

<sup>414</sup> This article is also discussed in chapter 2.

<sup>415</sup> Leape (1994), p.1854.

<sup>416</sup> Ibid., p.1856.

education and research agenda for healthcare errors,” and it “attracted interest from researchers, healthcare leaders and error-prevention experts representing a broad range of perspectives, disciplines and specialties including non-healthcare related industries.”<sup>417</sup> Topics of the conference included “education and training, communication, legal issues, organizational processes, human factors, fatigue, drug use, anesthesia, surgery, and medication errors,” as well as, “a panel examining an actual instance of error [which] highlighted the emotional, legal, ethical and professional issues that arise when an error is made that causes or contributes to injury.”<sup>418</sup>

The first day of the conference began with an announcement that the American Medical Association would establish a National Patient Safety Foundation.<sup>419</sup> Early funding of 1 million dollars was provided by a grant from the 3M Corporation in February of 1997.<sup>420</sup> From that initial start-up, “the funds for its estimated \$2-million annual budget come from the AMA and corporate sponsorship by pharmaceutical, insurance, and healthcare management firms.”<sup>421</sup> The National Patient Safety Foundation

---

<sup>417</sup> From The American Association for the Advancement of Science website, Scientific Freedom, Responsibility and Law Program (SFRL), which focuses on the ethical, legal, and social issues associated with the conduct of research and with advances in science and technology: <http://www.aaas.org/spp/sfrl/projects/errors.htm>

<sup>418</sup> From The American Association for the Advancement of Science website, Scientific Freedom, Responsibility and Law Program (SFRL): <http://www.aaas.org/spp/sfrl/projects/errors.htm>

<sup>419</sup> National Patient Safety Foundation Press Release (October 13, 1996): <http://npsf.org/pr/pressrel/pr1096.htm>.

<sup>420</sup> National Patient Safety Foundation Press Release (February 1997): <http://npsf.org/pr/pressrel/pr297.htm>.

<sup>421</sup> Goldsmith (1997), p. 1561.

(NPSF) was first modeled after the Anesthesia Patient Safety Foundation,<sup>422</sup> but has since grown to be a much larger organization, with an annual Congress every year since 1998, a competitive Research Grants Program, and publication of the *Journal of Patient Safety*.<sup>423</sup> As Lucian Leape and colleagues describe it, “the NPSF is dedicated to serving as a community forum and leading the transition from a culture of blame to a culture of safety,” with the foundation’s mission centered upon promoting “the safety of the healthcare system by catalyzing action and supporting a fresh and honest discussion about the notions of risk, error, blame, and accountability.”<sup>424</sup> As illustration of its role as the catch-all advocacy group for patient safety, an overview of the NPSF, written by Goldsmith just a year after its founding, states that “its organizational structure encourages the interaction of safety experts, public health advocates, patient representatives, medical ethicists, physicians and other healthcare practitioners, managed care organizations, government, researchers, employers, lawyers, and liability insurers, among others.”<sup>425</sup>

The NPSF’s mission is developed through four core strategies of promoting research, implementing knowledge, fostering communication, and developing educational approaches; all of which makes the Foundation “dedicated to serving as a community forum and leading the transition from a culture of blame to a culture of

---

<sup>422</sup> In an earlier article, Leape mentioned the role of Anesthesiology (1994), p. 1856 – “Anesthesiologists have led the medical profession in recognizing system factors as causes of errors, in designing fail-safe systems, and in training to avoid errors.”

<sup>423</sup> National Patient Safety Foundation website: <http://www.npsf.org/>.

<sup>424</sup> Leape, et al. (1998), p. 1445.

<sup>425</sup> Goldsmith (1997), p. 1561

safety.”<sup>426</sup> According to Leape and colleagues, the approach that NPSF takes overcomes the “deterrent approach to safety, and the extensive legal and regulatory structures that support it,” which “has had limited impact on reducing patient injuries.”<sup>427</sup> Instead, they continue that “it is now clear that an additional approach is needed that continues to hold healthcare providers accountable, but moves beyond blame in investigating why healthcare accidents happen and how the risks of future accidents can be identified.”<sup>428</sup> This sentiment is elaborated with an assertion by Leape and colleagues that, “The medical imperative is clear: to make healthcare safe we need to redesign our systems to make errors difficult to commit and create a culture in which the existence of risk is acknowledged and injury prevention is recognized as everyone’s responsibility. A new understanding of accountability that moves beyond blaming individuals when they make mistakes must be established if progress is to be made.”<sup>429</sup> This description of the NPSF and its mission, as stated by the most prominent leaders identified with patient safety, shows the main tenet of the movement – changing the culture of medicine, to shift healthcare delivery from a ‘blaming’ to a ‘learning’ model of error prevention.

At the 2007 National Patient Safety Congress, this discourse of culture and systems improvement was central to the panels, posters and presentations. For example, posters of the NPSF-sponsored Patient Safety Fellows each emphasized the importance of ‘Culture of Safety,’ ‘Systems Approach,’ and ‘Shared Communication,’<sup>430</sup> with one of posters defining “culture of safety” as “an environment that supports candid discussion of

---

<sup>426</sup> Leape, et al. (1998), p. 1445.

<sup>427</sup> Ibid., p. 1445.

<sup>428</sup> Ibid., p. 1445.

<sup>429</sup> Ibid., p. 1444.

<sup>430</sup> 2007 NPSF Congress Field Notes.



errors, their causes and ways to prevent them.”<sup>431</sup> At a presentation panel within the “Engagement Towards a Shared Vision” track, the audience heard about the ‘Minnesota Model’ from the Minnesota MAPS program – Minnesota Alliance for Patient Safety.<sup>432</sup> From the 2007 NPSF Congress program, the panel discusses “Minnesota’s shared vision toward a statewide culture of learning, justice and accountability will be highlighted,” where participants will “learn how the safety coalition, a large healthcare organization, and the regulatory boards embarked upon a journey to create consensus and establish a common philosophy regarding behavior and accountability.”<sup>433</sup> According to the presentation, the goal of the MAPS program is to “foster learning and focus on changing behavior, rather than outcomes,” with mantra of “Commitment, Collaboration, Communication.” The health care organizations that commit to the MAPS program resolve to “strive for a culture that balances the need for a non-punitive learning environment with the equally important need to hold persons accountable for their actions.”<sup>434</sup>

One of the founders and leading advocates of the Minnesota MAPS program, Alison Page of Fairview Health Services in Minneapolis, received the 2007 National Patient Safety Foundation (NPSF) Chairman's Medal.<sup>435</sup> Awarded at the Congress Plenary Address, the Chairman’s Medal is given “in recognition of emerging leadership

---

<sup>431</sup> 2007 National Patient Safety Foundation (NPSF) Congress Field Notes.

<sup>432</sup> 2007 NPSF Congress: Thursday, May 3, 2007, 1:30pm, Engagement Towards a Shared Vision 304: “Creating a Just Culture – A Statewide Change.”

<sup>433</sup> NPSF Congress Program (2007), p. 19.

<sup>434</sup> 2007 NPSF Congress Field Notes.

<sup>435</sup> 2007 NPSF Congress Field Notes.

in the patient safety field.”<sup>436</sup> After praising the work of the Minnesota MAPS and Alison Page’s leadership, the plenary continued with the “Fourth Annual Distinguished Advisors Town Hall Meeting,” which included Donald Berwick and Jim Conway of the Institute for Healthcare Improvement, Carolyn Clancy of the Agency for Healthcare Research and Quality, David Lawrence of Kaiser Permanente, Lucian Leape from Harvard School of Public Health and the National Patient Safety Foundation, Dennis O’Leary from the Joint Commission on the Accreditation of Healthcare Organizations, and Sir Liam Donaldson from the UK’s National Health Service and the WHO’s World Alliance for Patient Safety.<sup>437</sup> In an open question-and-answer discussion format, the various distinguished advisors gave their perspective on the goals, successes and challenges of the patient safety movement. While each ‘Distinguished Advisor’ offered distinct comments, there seemed to be agreement over Lucian Leape’s closing words, an assessment that a “values-based approach to culture is the secret to cultural change and fundamental to the practice of safety.”<sup>438</sup>

Lucian Leape’s role as a leading figure in Patient Safety advocacy was institutionalized at the 2007 National Patient Safety Congress, with an announcement of the founding of the Lucian Leape Institute. As described on the NPSF website “The Lucian Leape Institute at the National Patient Safety Foundation, launched in 2007, functions as a think tank to define strategic paths and issue calls to action for the field of patient safety and is intended to provide vision and context for the many efforts underway within the healthcare system,” with its work coming in the form of “reports that guide the

---

<sup>436</sup> NPSF Press Release (May 3, 2007): [http://npsf.org/pr/pressrel/2007-05-3\\_3.php](http://npsf.org/pr/pressrel/2007-05-3_3.php).

<sup>437</sup> Ibid., and NPSF Congress Program (2007).

<sup>438</sup> 2007 NPSF Congress Field Notes.

work of the field and challenge the system to address the issues critical to making the system safer.”<sup>439</sup> The tangible culmination of Leape’s repeated efforts, going back to when the Harvard Medical Practice Study was initiated in the late 1980s, is in the NPSF Institute named in his honor.

As of 2011, “the Institute has focused on identifying and framing vital transforming concepts that require system-level attention and action,” with “six concepts identified to date include: Medical education reform; Active consumer engagement in all aspects of healthcare; Transparency as a practiced value in everything we do; Integration of care within and across healthcare delivery systems; Restoration of joy and meaning in work; The safety of the healthcare workforce.”<sup>440</sup> Accordingly, “fulfilling the objectives embodied in these six concepts is critical to moving the national patient safety agenda forward; it is clear that this will require profound changes in the culture and structure of our healthcare system.”<sup>441</sup> As he had been saying for over a decade and a half, and now institutionalized in his namesake Institute, the central focus of patient safety advocacy is in reforming the culture of health care.

Going back to Leape’s 1994 article, “Error in Medicine,” technical points about system design to prevent errors are challenging, but not the most significant barrier to change. Leape claimed “the most important reason physicians and nurses have not developed more effective methods of error prevention is that they have a great deal of difficulty in dealing with human error when it does occur. The reasons are to be found in

---

<sup>439</sup> Lucian Leape Institute at National Patient Safety Foundation: <http://www.npsf.org/au/>.

<sup>440</sup> Lucian Leape Institute at the National Patient Safety Foundation: <http://www.npsf.org/lli/>.

<sup>441</sup> Lucian Leape Institute at the National Patient Safety Foundation: <http://www.npsf.org/lli/>.

the culture of medical practice.”<sup>442</sup> Health care systems need to be redesigned, but ultimately this rests upon a foundation of transforming the culture of medicine to be focused upon safety. The answer to what needs to be changed about the culture of the medical profession can be found in Lucian Leape’s description of what constitutes a culture of safety. Building such a culture is a complex process, but Leape simplifies it to these five steps: “make safety a management priority,” “create a learning organization,” “value the employees,” “think in terms of systems,” and “safety is everyone’s responsibility.”<sup>443</sup> Each of these steps is simple in principle, but profound in effect. It requires a fundamental change to how medical care is organized and managed – a shift in thought that is directed in large part to the medical profession, though it applies to all employees within any health care organization. With safety as a top priority, a focus upon learning means that employees must feel invested in organizational goals. When safety is perceived in terms of a system feature, rather than solely an individual responsibility, then pursuing patient safety becomes a collective effort. As components of safety culture, system design, organizational goals, and collective learning are all meant to challenge the traditional culture of medicine that emphasizes individual physicians as centerpiece of care delivery. Instead, physicians are part of a broader organizational effort, at least in ideal terms, working together to prevent error from leading to patient harm.<sup>444</sup>

---

<sup>442</sup> Leape (1994), p. 1851.

<sup>443</sup> Leape (2007), pp. 63-64.

<sup>444</sup> From the standpoint of the traditional culture of medicine, such changes bring, however, a potential loss of professional autonomy and status.

Such a fundamental change in medical culture brings steep challenges. For guidance in developing safety culture in health care, patient safety advocates have looked to other industries for assistance, in hopes of efficiently importing techniques and expertise that are deemed successful elsewhere. According to Leape's 1994 article, "By contrast [to aviation], accident prevention has not been a primary focus of the practice of medicine."<sup>445</sup> Four years later, Leape asserts that "patient safety has come to the healthcare agenda," but "we have failed to design our systems for safety relying instead on requiring individual error-free performance enforced by punishment, a strategy abandoned long ago by safer industries such as aviation and nuclear power."<sup>446</sup> Cited for its high reliability and admirable safety record, the aviation industry has been a very influential model for the development of patient safety in the health care industry. From the viewpoint of health care, the aviation industry can serve as an ideal model because of its organizational commitment to safety and collective responsibility for managing risk. In other words, aviation is considered a model because of its safety culture, providing lessons for patient safety reform in health care.

As patient safety has attained significant media attention, popular notice has also been given to the comparison between aviation safety and health care safety. For example, an October 2006 *New York Times* article followed how pilots are serving as consultants for hospital safety programs. The article recounts how a catastrophic 1977 runway collision on the Canary Islands, resulting in 583 deaths, lead to a series of changes in the Aviation industry focusing on communication, leadership and decision-

---

<sup>445</sup> Leape (1994), p. 1855.

<sup>446</sup> Leape, et al. (1998), p. 1444.

making. In the aftermath of the tragedy, a focus upon the potential for human errors significantly shifted conceptions of safety in aviation to accommodate for crew limitations. According to the article, a general lesson about managing human error through safety design and safety culture produced safer flying, lessons that advocates are trying to export to health care.<sup>447</sup>

An organizational culture committed to safety, a recognition of the inevitability of human error, and specific techniques such as reporting systems are all asserted as useful lessons that patient safety advocates say health care can learn from aviation. Experts from the Aviation industry meet with health care audiences, such as at the NPSF Annual Congresses, to demonstrate how these techniques can be successfully implemented, resulting in what is considered an effective culture of safety.<sup>448</sup> According to Leape, Berwick and Bates, aviation safety “relied on the widespread implementation of hundreds of small changes in procedures, equipment, training, and organization that aggregated to establish an incredibly strong safety culture and amazingly effective practices. These changes made sense; were usually based on sound principles, technical theory, or experience; and addressed real-life problems.”<sup>449</sup> While tensions between individual accountability and system improvement may persist, patient safety advocates push the

---

<sup>447</sup> Murphy (2006).

<sup>448</sup> For example, a panel at the 2007 NPSF Congress (Friday, May 4, 1:00p, Medication and Device Safety Track 501) had a consultant with experience in the Aviation industry.

<sup>449</sup> Leape, Berwick and Bates (2002), p. 505.

idea that a more uniform organizational culture centered upon improvement, an ideal found in aviation, is key to reducing medical error.<sup>450</sup>

Along with taking guidance from other industries, the NPSF ultimately seeks to professionalize the patient safety activities of any individual charged with such responsibilities in health care organizations. Just started on Feb 15, 2011, “the American Society of Professionals in Patient Safety (ASPPS) at NPSF is the first and only individual membership program for the patient safety field. ASPPS was established to advance patient safety as a unique and vital healthcare discipline, and to build an engaged, focused community of individuals committed to accelerating the delivery of safe patient care. The Society’s multi-disciplinary membership reflects a commitment to teamwork as a pre-condition for patient safety, critical work for which all share responsibility.”<sup>451</sup> This recent effort by NPSF calls to mind Taylor and Zald’s observation that “segments of professions may start new professional organizations or lobby extant groups to change healthcare policies or programs.”<sup>452</sup> NPSF’s general work as the preeminent organization for patient safety advocacy then also confirms Taylor and Zald’s overall assessment: “Some institutional movements may even resemble elite-driven campaigns, as senior personnel identify with a movement’s goals and use their positions, authority, and expertise to press for change. Such would seem to be the case with the movement to reduce medical errors, which has used dramatic cases of error and

---

<sup>450</sup> From a critical perspective, one could argue that the aviation model is simply a metaphor used for persuasion. However, for the purposes of this chapter, I take advocate’s ideations of the aviation model as sincere.

<sup>451</sup> American Society of Professionals in Patient Safety (ASPPS) at NPSF: <http://www.npsf.org/hp/ASPPS.php>. See also NPSF Press Release on ASPPS: <http://www.npsf.org/pr/pressrel/2011-02-22.php>.

<sup>452</sup> Taylor and Zald (2010), p. 314.

statistical assessment of aggregate case analysis to pressure medical chiefs of staff to place the problem of medical error on organizational agendas.”<sup>453</sup> The NPSF’s main mission has been precisely about placing the problem of error on the agenda of any and every health care organization. As exemplified by leading figure Lucian Leape, the NPSF has promoted system design as a major technical solution to error reduction, but ultimately rests upon changing the culture of medicine. In its publications, websites, leadership and conferences, the NPSF promotes safety culture as the most important intervention to reduce the burden of medical error.

The challenge comes from what is overlooked by such idealistic discourse on the powers of safety culture. While “one is hard-pressed to find a reference to power, group interests, conflict, or inequality in the literature promoting safety culture,” Silbey explains that “the proponents of safety culture recognize the greater authority and resources of top-level management and recommend using it to institute organizational change from the top down, mandated by organizational leaders, even if designed by hired consultants.”<sup>454</sup> According to Silbey, “the consistent valorization of clear lines of hierarchy accompanies a surprising failure to see how this same hierarchy undermines communication and self-reflection about hazards,” which means that advocates then “fail to adequately recognize the diminished power of those in subordinate positions.”<sup>455</sup> Patient safety leaders like Leape, and organizations like the NPSF, take pains to diminish the hierarchy and subordination in health care workplaces. For example, in his seminal article from 1994, Leape notes that “elimination of fear and the creation of a supportive

---

<sup>453</sup> Taylor and Zald (2010), p. 314.

<sup>454</sup> Silbey (2009), p. 361.

<sup>455</sup> Ibid., p. 361.



working environment are other potent means of preventing errors.”<sup>456</sup> While Leape’s recognition of potential problems in the workplace dates early in discussions of error reduction, such focus on work organization comes into sharper relief through theories of quality improvement, which establishes some vital links with patient safety advocacy.

## **Making the Case for Continuous Improvement**

### **-- The Institute for Healthcare Improvement**

“Some is not a Number. Soon is not a Time.”<sup>457</sup>

The Institute for Healthcare Improvement (IHI) has its roots in the National Demonstration Project on Quality Improvement in Healthcare (NDP), which was launched in 1986 “to explore the application of modern quality improvement methods to healthcare.”<sup>458</sup> While founded earlier than the NPSF - the IHI was formed in 1991 - the organization’s major patient safety campaigns came in the wake of the IOM’s *To Err is Human* report. “As an independent, nonprofit organization whose aim is to improve healthcare quality in the United States and Canada by fostering collaboration instead of competition among healthcare organizations,”<sup>459</sup> the IHI describes its mission of improving healthcare as “its promise, and its daily work.”<sup>460</sup> The result of the IHI’s work

---

<sup>456</sup> Leape (1994), p. 1857.

<sup>457</sup> Slogan for IHI’s *5 Million Lives Campaign*:  
<http://www.ihi.org/IHI/Programs/Campaign/>.

<sup>458</sup> From “A History of IHI” Timeline available at <http://www.ihi.org/ihi/about>.

<sup>459</sup> Voelker (1997), p. 1560.

<sup>460</sup> “Closing the Quality Gap: An Introduction to IHI,” p. 4 (available at [www.ihi.org](http://www.ihi.org)).

is that “Quality Improvement is no longer a fringe philosophy in healthcare. It is now the mainstream approach for ensuring that the best possible care is delivered to every patient every day – and it is rapidly taking its rightful place in the core business strategy for institutions trying to survive in an increasingly competitive marketplace.”<sup>461</sup> This notion can be expanded to include both patient safety and quality improvement – neither of which is considered fringe any longer, as both have become part of the mainstream discourse of health care reform.

While Lucian Leape is closely connected to the NPSF through his namesake Institute, the leadership behind the IHI is even more directly the result of the work of its founding figure, Dr. Donald Berwick. After his leading role with the NDP in the late 1980s, Berwick founded the IHI to provide an organizational outlet to spread the message of quality improvement in health care. In a recent article in *The New York Times*, reporter Robert Pear describes Berwick as “a man with a mission, a preacher and a teacher who has been showing hospitals how they can save lives and money by zealously adhering to clinical protocols for the treatment of patients.”<sup>462</sup> With Don Berwick’s leadership, the IHI has been one of the most significant players in the quality movement since the Institute’s founding in 1991. According to Berwick, though, the environment changed remarkably when “in 1999 [*To Err is Human*] and 2001 [*Crossing the Quality Chasm*], the Institute of Medicine published 2 landmark reports on the evidence for quality failures and called urgently for redesign of care systems to achieve

---

<sup>461</sup> “Closing the Quality Gap: An Introduction to IHI,” p. 4 (available at [www.ihl.org](http://www.ihl.org)).

<sup>462</sup> Pear (June 22, 2010).

improvements.”<sup>463</sup> With these IOM reports bringing widespread attention upon safety and quality in the US health care system, Berwick and the IHI now had a crucial opportunity with which to redouble their efforts upon spreading the message, and implementing the lessons, of continuous improvement.

From the interest generated in the wake of the IOM reports, the centerpiece of the IHI’s patient safety work is in two campaigns started by Berwick: the ‘100,000 Lives Campaign’ began in 2004, and then the ‘5 million Lives Campaign’ in 2006. In laudatory terms, the 100,000 Lives Campaign is described by the IHI as “a national effort to reduce preventable deaths in US hospitals,” in which “no one could have imagined the strength of the response” because “what happened was truly exhilarating: an extraordinary resurgence of spirit and an unprecedented commitment to change and collaboration across the healthcare industry.”<sup>464</sup> According to the IHI, “the 3,100 hospitals that participated in this initiative achieved a remarkable goal. Through their work on the Campaign’s interventions, combined with other national and local improvement efforts, these facilities saved an estimated 122,000 lives in 18 months. Along the way, nothing less than new standards of care began to emerge. Healthcare will never be the same – and the work continues.”<sup>465</sup> Building upon such inspirational rhetoric from the first campaign, the 5 Million Lives sought to “protect patients from five million incidents of medical harm over the next two years (December 2006 – December

---

<sup>463</sup> Berwick (2008), p. 1182.

<sup>464</sup> IHI website: <http://www.ihi.org/IHI/Programs/Campaign/>.

<sup>465</sup> Ibid.

2008)” by enlisting “at least 4,000 US hospitals in a renewed national commitment to improve patient safety faster than ever before.”<sup>466</sup>

At the 2007 NPSF Congress, in a presentation entitled “The IHI 5 Million Lives Campaign: A Nation Writes a Great Story,”<sup>467</sup> Jim Conway, Senior Vice President of the IHI explained both of the signature campaigns of his organization. According to the 2007 NPSF Congress program, “since the stirring Call to Action by Don Berwick in December of 2004, all segments of the US healthcare industry have focused in partnership on saving lives and reducing harm, raising the profile of the problem and our proactive response, and building a reusable national infrastructure for change. This session will focus on the successes, challenges, and learning to date and the go-forward plan for the 5 Million Lives Campaign.”<sup>468</sup> Some of the issues Conway discussed in his presentation included, “‘Sharing stories – narrative learning & lessons learned’; ‘disconnect between stories and data’; ‘extraordinary stories in the campaign’; ‘getting patients involved in interventions,’ ‘build a reusable national infrastructure for change’; and ‘set a goal – some is not a number, soon is not a time’.”<sup>469</sup> The 5 Million Lives Campaign defined “medical harm” as: “unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment), that requires additional monitoring, treatment or hospitalization, or that results in death.” While this definition is a fairly mundane one, the more radical aspect of the Campaign had to do with the fact that “such injury is considered harm whether or not it is

---

<sup>466</sup> IHI website: <http://www.ihi.org/IHI/Programs/Campaign/>.

<sup>467</sup> 2007 NPSF Congress: Friday, May 4<sup>th</sup>, 10:30 am, Engagement toward a Shared Vision 404: “The IHI 5 Million Lives Campaign: A Nation Writes a Great Story.”

<sup>468</sup> NPSF Congress Program (2007), p. 24.

<sup>469</sup> 2007 NPSF Congress Field Notes.

considered preventable, resulted from a medical error, or occurred within a hospital.”<sup>470</sup>

The IHI takes a far-reaching perspective when it comes to quality and safety improvement – any harm to patients, over the course of medical management, is considered something that the industry needs to take very seriously, making every effort to avoid. Among other things, Conway mentioned that even drug side effects would be included within the category of harm to patients that should also fall under the purview of quality and safety improvement efforts.<sup>471</sup>

Both of the IHI’s patient safety campaigns have ended (and with no additional campaigns in the works). Despite the close of the campaigns, “the support hospitals have come to expect from IHI’s Campaigns will not end. IHI will continue to help hospitals until patients everywhere receive the best care possible, every time.”<sup>472</sup> Beyond such continued assistance the “IHI’s next frontier of hospital work is the IHI Improvement Map. Building on many years of hard work in hospitals and the momentum of the 100,000 Lives and 5 Million Lives Campaigns, IHI will now help hospitals improve patient care by focusing on an essential set of process improvements designed to achieve high levels of performance in areas that matter most to patients. The map will make sense of many complex and competing demands, making it possible for hospitals to find reliable routes to success.”<sup>473</sup> Through the Improvement Map, the IHI offers “the rich content and support that was offered in the Campaigns, including How-to Guides, tools,

---

<sup>470</sup> For more information on how the Campaign defines medical harm see the FAQs tab in the Campaign area of IHI.org at:

<http://www.ihl.org/IHI/Programs/Campaign/Campaign.htm?TabId=6>.

<sup>471</sup> 2007 NPSF Congress Field Notes.

<sup>472</sup> Improvement Map FAQs:

<http://www.ihl.org/IHI/Programs/ImprovementMap/ImprovementMap.htm>.

<sup>473</sup> Ibid.

and introductory calls, at no cost, and they will also be able to access new, vibrant forms of support.”<sup>474</sup> So while the IHI has not continued its patient safety work with another campaign beyond 5 Million lives, the organization has attempted to institutionalize its resources and assistance through the online tool of the Improvement Map.

Given the prevalence of monitoring and assessment in both of the IHI’s signature campaigns, the patient safety work of the IHI has been connected to other efforts in developing error reporting in health care. The primary goal of reporting is generally defined as the disclosure of errors, which is then used for purposes of safety improvement by way of learning from mistakes. Disclosure, though, has both accountability and improvement justifications. Error reporting that centers upon accountability as its primary justification tends to focus upon the individual as its target of intervention, while reporting with improvement and learning as its motivation seeks to assess and rationalize health care delivery systems. In reporting as accountability, responsibility for error is specified - individuals are held culpable for the mistakes that they make. In contrast, the premise of learning or improvement approaches to reporting is risk as a collective (system) responsibility, with promoting standards as the panacea of progress. While many regulatory agencies (mostly at the state level) tend toward accountability justifications, work such as the IHI campaigns and Improvement Map push monitoring efforts toward the goal of improvement. When standardization of reporting is couched with patient safety justifications, that often translates to an effort at implementing effective ‘improvement/ learning/ system redesign’ approaches to error monitoring. As

---

<sup>474</sup> Improvement Map FAQs:  
<http://www.ihi.org/IHI/Programs/ImprovementMap/ImprovementMap.htm>.

promoted by the IHI, the standardization of safety reporting toward improvement justifications should be a major goal for the pursuit of patient safety. But as Timmermans and Epstein observe, “the trick in standardization appears to be to find a balance between flexibility and rigidity and to trust users with the right amount of agency to keep a standard sufficiently uniform for the task at hand.”<sup>475</sup> For the case of patient safety, the trick with standardizing error monitoring is to reconcile more rigid reporting systems focused upon behavior modification of the individual (accountability) with relatively flexible reporting systems centered upon sharing and disseminating information on medical errors (improvement). The dream of reformers like Berwick (and organizations like the IHI) is that the standardization of reporting systems towards the goal of improvement - in which disclosure and analysis of errors is used for collective learning rather individual punishment - will have dual consequences of redesigning health care systems to be safer and building a workplace culture of safety.

The IHI’s reporting campaigns, as part of Berwick’s larger reform project, are meant to transform health care workplaces. In contrast to other industries, Berwick argues that health care has yet to fully move beyond an outdated, Taylorist conception of work design. As an influential paradigm in early-20<sup>th</sup> century industrial management, Frederick Taylor’s *Principles of Scientific Management* attempted to find the most efficient way to manage workers, based upon certain principles of scientific design in the workplace. Taylor’s scientific management introduced a system of attempted cooperation and assumed shared interests between workers and management, all resting upon scientific methodology - organizing the workplace, and the objects within it

---

<sup>475</sup> Timmermans and Epstein (2010), p. 81.

(including the workers), in a configuration determined and controlled by the work design expert.<sup>476</sup> However influential Taylor's scientific management was to industrial management in the early decades of the 20<sup>th</sup> century, Berwick states "healthcare came late to the Taylorist party," only incorporating such ideas in the 1980s with the development of standardized protocols.<sup>477</sup> Up until then, he says, "the model for healthcare delivery was very much a craft model."<sup>478</sup>

While Berwick's abridged version of work history may be oversimplified, he utilizes that overview of theories of work organization in order to prove the value of quality improvement in health care. Berwick assumes a vast potential for continuous improvement in the health care workforce. He claims that, "nearly everyone comes to work wanting to do a good job and to feel proud of what they do. Most would probably like to learn a little something as well. And so the energy behind the scientific pursuit of change, behind continuous improvement, is latent in the employees. When leaders and managers tap that energy by providing people the opportunity to improve work, they are tapping into a powerful force."<sup>479</sup> Berwick sees quality improvement initiatives as "a way to take control, a way for the demoralized, frustrated doctor to get back in the loop. When that happens, it is really compelling."<sup>480</sup>

As a result of such assumptions about the motivational power of quality improvement, Berwick imagines that "in a post-Taylorist workplace, the workforce has to

---

<sup>476</sup> Taylor (1912).

<sup>477</sup> Berwick (2007), p. 53.

<sup>478</sup> Ibid., p. 53.

<sup>479</sup> Ibid., p. 54.

<sup>480</sup> Berwick quoted in Voelker (1997), p. 1560.



develop the skill of *identifying and agreeing on what they are going to make better*.”<sup>481</sup>

Or more directly relevant toward the medical profession, he argues that “physicians have been taught to do their work well, but not necessarily to help their work improve.”<sup>482</sup>

Quality improvement assumes working environments can be made so that physicians and other health care professionals are dedicated to continually improving processes and outcomes – to make healthcare work more effective and safe, and thus lower costs while improving quality. As applied to health care, quality and safety are improved when the workforce together seeks better outcomes and fewer errors. Rather than focusing upon individuals (either in terms of punishment or promotion), the key to improvement is collective responsibility whereby all professionals work together to accomplish organizational goals. Berwick has been pushing for this notion of quality since 1989, when he advanced an argument that, “modern theories of quality improvement in industry are persuasive largely because they focus on the average producer, not the outlier, and on learning, not defense,”<sup>483</sup> implicating health care as decades behind other industries in terms of implementing theories of quality improvement.

The quest for quality improvement arises in a context of the growth of evidenced-based medicine, but with distinct implications for patient safety. Timmermans and Epstein describe that context in terms of how “the healthcare field is engaged in a massive standardization movement called evidence-based medicine whereby professional organizations and regulatory entities make the scientifically best evidence available to clinicians in the form of meta-reviews of the literature, practice guidelines, assessment

---

<sup>481</sup> Berwick (2007), p. 54, italics in original.

<sup>482</sup> Berwick quoted in Voelker (1997), p. 1560.

<sup>483</sup> Berwick (1989), p. 54.

tools, and standardized outcome measures.”<sup>484</sup> Harking back to the seminal 1994 article “Error in Medicine,” Leape affirmed such standardization efforts in claiming that “one of the most effective measures of reducing error is standardizing processes wherever possible.”<sup>485</sup> While standardization is significant in patient safety and quality, there is a crucial distinction when it comes to evidenced-based medicine. In discussing the uncertainties and limits of supportive evidence for certain protocols, Berwick has said, “the rhetoric and tone of comment on work in the field of day-to-day healthcare affect the pace of improvement. Academic medicine has a major opportunity to support the redesign of healthcare systems; it ought to bear part of the burden for accelerating the pace, confidence, and pervasiveness of that change.”<sup>486</sup> As evidence-based medicine has become more established, Berwick warns that, “Healthcare researchers who believe that their main role is to ride the brakes on change—to weigh evidence with impoverished tools, ill fit for use—are not being as helpful as they need to be. “Where is the randomized trial?” is, for many purposes, the right question, but for many others it is the wrong question, a myopic one. A better one is broader: “What is everyone learning?” Asking the question that way will help clinicians and researchers see further in navigating toward improvement.”<sup>487</sup> While both patient safety and evidenced-based medicine are movements that rest upon standardization, Berwick is concerned that progress will be forestalled by a competing criteria for evidence between each movement. This concern calls to mind Hess’ observation that “evidence-based medicine and science become the

---

<sup>484</sup> Timmermans and Epstein (2010), p. 80.

<sup>485</sup> Leape (1994), p. 1856.

<sup>486</sup> Berwick (2008), p. 1184

<sup>487</sup> *Ibid.*, p. 1184.

points of reference in resolving disputes over how medicine is to be integrated and which therapies are to be accepted or rejected.”<sup>488</sup> As Berwick’s push for continuous improvement has entered patient safety advocacy, the higher standard of evidence that academic medicine places upon evaluating clinical practice, according to Berwick, should not get in the way of a dedication to continuous improvement in health care delivery.

## **Making the Case for Patient Safety as a Global Concern**

### **– The World Alliance for Patient Safety**

“Patient Safety is truly becoming a global issue.”<sup>489</sup>

As the chair of the World Health Organization’s World Alliance for Patient Safety, Sir Liam Donaldson offers a stark declaration of the potentially dangerous shortcomings of health care delivery. He states, “Time and time again, investigation of patient deaths as a result of health-care errors – and the stories of their families – show people whose fate seemed to have been determined from the moment they entered the health facility for care... Their deaths resulted from a chain of system failures in which repeated opportunities to stop the inevitable outcome were missed, with tragic consequences.”<sup>490</sup> Like the discourse of the NPSF and IHI in the United States, Donaldson sees such tragic patient deaths as a motivational impetus to improve the safety of care delivery on a global scale. “Challenging the very idea that these patient deaths

---

<sup>488</sup> Hess (2004), pp. 698-99.

<sup>489</sup> World Health Organization (2005a), p. 3.

<sup>490</sup> Ibid., p. 3.

from unsafe care are inevitable,” Donaldson says, “is a powerful element of the drive behind the World Alliance for Patient Safety.”<sup>491</sup>

With patient safety policy and organization expanding in many Developed nations, World Health Assembly Resolution 55.18 was adopted in May 2002, urging “Member States to pay the closest possible attention to the problem of patient safety and to establish and strengthen science-based systems necessary for improving patient safety and the quality of healthcare.”<sup>492</sup> Two years later, the World Alliance for Patient Safety (WAPS) was created to “facilitate the development of patient safety policy and practice in all Member States and act as a major force for improvement internationally.”<sup>493</sup> What had begun as a problem within advanced, national health care systems in the late 1990s and early 2000s, patient safety has subsequently been converted into an issue of global concern and international action, via the agendas and initiatives of the World Alliance.

A major rallying point on the patient safety agenda, especially at the international level, is the development and sponsorship of universal standards for safe medical care. As noted with the NPSF and IHI in the US, patient safety advocacy promotes standardization, particularly crucial if the movement is to succeed in reaching beyond national borders. Standardization efforts are apparent in the World Alliance’s Global Patient Safety Challenges, *Clean Care is Safer Care* and *Safe Surgery Saves Lives*. From 2005 through 2006, the first Global Challenge, *Clean Care is Safer Care* focused upon medical hygiene and sanitation. On the heels of ostensible success with *Clean Care is Safer Care*, the second Global Patient Safety Challenge, *Safe Surgery Saves Lives*, began

---

<sup>491</sup> World Health Organization (2005a), p. 3.

<sup>492</sup> World Health Organization (2006), p. iii.

<sup>493</sup> Ibid., p. iii.

in 2007 to seek a reduction in the variability of surgical care. The two Global Challenges provide insight into the “form and content”<sup>494</sup> of international safety standardization, helping to assess how the World Alliance establishes itself on the global stage.

Simplicity, commitment, action and improvement describe the major thrust of the *Clean Care is Safer Care* campaign, with infection as the main target and hygiene as the primary solution. As World Alliance Chair Donaldson explains, “the world has the knowledge and resources to dramatically reduce the impact of healthcare-associated infection. What is needed is commitment and action at all levels, to ensure that every patient’s right to the cleanest and safest care is achieved.”<sup>495</sup> This sentiment is echoed by Professor Didier Pittet, who as the Global Patient Safety Challenge campaign leader declares, “promoting ‘Clean Care is Safer Care’ is not a choice. It is our duty to patients, their families, and health-care workers. Let us move forward together. Each of us can make a small difference; significant improvement requires an effort from all of us.”<sup>496</sup> The problem is clear and the solution is simple, so that concerted effort and commitment to action are what is necessary for unified improvement. From this premise, the campaign seeks to raise general awareness, gain Member State involvement, and implement specific clean care guidelines.

While the specific content of *Clean Care is Safer Care* involves blood safety, injection practices, sanitation, and clinical procedures, the central intervention revolves around hand hygiene. In order to promote this as a solution to healthcare-associated infections, WHO’s World Alliance for Patient Safety developed a set of hand hygiene

---

<sup>494</sup> Timmermans and Berg (2003), p. 24 (see Chapter 2 for full quote).

<sup>495</sup> World Health Organization (2005b), p. 1.

<sup>496</sup> Ibid., p.25.

recommendations. Along with indications for when to wash hands and how to use gloves, the guidelines carefully instruct a ‘hand hygiene technique with alcohol-based formulations’ (7 steps, 20-30 seconds), as well as a ‘handwashing technique with soap and water’ (10 steps, 40-60 seconds).<sup>497</sup> In their simplicity, these specific techniques, and the general guidelines that support them, provide an accessible global standard for hand hygiene. Derived from the guidelines of the World Alliance’s *Clean Care* campaign, international safety standardization, in the particular form of hand hygiene, is key to reducing infections and thus advancing patient safety.

Initiated in 2007, the second Global Patient Safety Challenge is *Safe Surgery Saves Lives*. As announced quite explicitly by Atul Gawande, the *Safe Surgery* campaign leader, “surgical care has been an essential component of public health systems worldwide for a century. The quality and safety of that care has been dismayingly variable in every part of the world. The *Safe Surgery Saves Lives* campaign aims to change that by raising the standards that people everywhere can expect.”<sup>498</sup> Following the overall standardization impulse of the WAPS, the *Safe Surgery* campaign’s orientation does not stray far from the groundwork laid by the *Clean Care* Global Patient Safety Challenge. Campaign leader for *Safe Surgery Saves Lives*, Gawande, is a recognized advocate for the use of checklists in health care delivery,<sup>499</sup> and so the specific standardized form that organizes the campaign’s major intervention is a Surgical

---

<sup>497</sup> World Health Organization (2005c), pp. 17-19.

<sup>498</sup> World Health Organization (2006), p. 15.

<sup>499</sup> See Gawande (2010), about the power of using checklists in medicine, as well as in aviation, the military, construction and an array of other fields and businesses.

Safety Checklist.<sup>500</sup> As with the hand hygiene guidelines, the simplicity of the checklist provides an accessible global standard for surgery. Although the specific content differs in seeking to reduce the complications from various types of surgery, the *Safe Surgery* campaign takes a similar form as the *Clean Care* campaign - raising awareness, attaining commitment and setting standards.

While the World Alliance's patient safety advocacy is organized heavily around international standardization, it does so in the context of efforts to include and empower patients in the process of standardizing health care systems.<sup>501</sup> With the flurry of activity around various health movements, new categorizations of what it means to be a patient are being developed.<sup>502</sup> An important new role of the changing patient category is to seek inclusion in medical decision-making as a health consumer.<sup>503</sup> Shifting the patient from passive receiver of medical wisdom to active consumer of health care services, the World Alliance also provides space for patient-consumers to voice and publicize concerns regarding safety. Through its Patients for Patient Safety initiative, the WASP attempts to include patient stories and to empower patients to take part in safety policy, so that they too may promote international standardization and join in advancing the global health movement around patient safety.<sup>504</sup>

---

<sup>500</sup> English version of the Surgical Safety Checklist is available at:  
[http://whqlibdoc.who.int/publications/2009/9789241598590\\_eng\\_Checklist.pdf](http://whqlibdoc.who.int/publications/2009/9789241598590_eng_Checklist.pdf)

<sup>501</sup> This context is also discussed in the previous chapter (3).

<sup>502</sup> Landzelius, Kyra (2006), and also see previous chapter (3).

<sup>503</sup> Allsop, Judith, Kathryn Jones, and Rob Baggott (2004).

<sup>504</sup> This is vividly on display in 16 minute DVD – “Patient Safety; Patient Voices” - produced by the World Alliance for Patient Safety, which looks at perspective of various patient advocates from across the world (from the US, Zambia, Ireland, Ukraine). Patient stories are also on prominent display throughout WAPS publication *A Year of Living Less*

One of the primary functions of Patients for Patient Safety (PFPS) has been organizing workshops that bring patients from across the globe together with health care providers and policymakers to rally for patient safety. The first workshop took place in London in 2005, resulting in a pronouncement that: “We, Patients for Patient Safety, envision a different world in which health care errors are not harming people. We are partners in the effort to prevent all avoidable harm in health care. Risk and uncertainty are constant companions. So we come together in dialogue, participating in care with providers. We unite our strength as advocates of care without harm in the developing as well as the developed world.”<sup>505</sup> The declaration continues by resolving that patients should take a central place in devising safety programs, building dialogue among stakeholders, defining best safety practices, and instituting systems for dealing with harm. Ultimately, the guiding framework of PFPS is reflected in the organization’s statement of case, which says that “Patients for Patient Safety will assist and support efforts to develop a collective voice for consumers, citizens, patients or lay caregivers who are interested in sharing their experience and lessons learned in order to improve safety.” The push for partnership is illustrated by an assertion that the PFPS “will foster the role of consumers as partners in the delivery of care who are owed honesty and respect, and who have responsibility for respectfully contributing to policymaking activities that seek to advance systems-based, patient-centered care.”<sup>506</sup> Using phrases like ‘Partners in the delivery of

---

*Dangerously* – See for example, World Health Organization (2005a), p. 8, p. 14, p. 18, p. 22, p. 26, p. 30, p. 32.

<sup>505</sup> From the “London Declaration,” Patients for Patient Safety, WHO World Alliance for Patient Safety ([http://www.who.int/patientsafety/patients\\_for\\_patient/](http://www.who.int/patientsafety/patients_for_patient/)).

<sup>506</sup> From the Patients for Patient Safety Statement of Case,



care,’ and ‘systems-based, patient-centered care’ aligns closely with patient safety discourse in the US.

According to PFPS, patients need an organized and collective voice, in order to promote their interests as active partners in health care policymaking. Rather than only sharing their tragic stories of loss due to medical errors, patients are seen as fundamental to safety promotion. This is not just owed to them. Patients themselves bear responsibility to actually take part in health care safety, through their inclusion in efforts to make health care safer. The extent of collective responsibility does not end with care providers, but expands the reach of healthcare work organization to include the patient’s voice in securing safety.

Patients for Patient Safety is heavily influenced, and in many ways outright managed, by US-based Consumers Advancing Patient Safety (CAPS).<sup>507</sup> In its mission statement, CAPS “envision[s] a partnership between consumers and providers to create global healthcare systems that are safe, compassionate, and just,”<sup>508</sup> which resonates with, and thus helps to explain, the language of PFPS. The founder of CAPS, Sue Sheridan, is also the leader of PFPS.<sup>509</sup> The explicit role of CAPS in PFPS is further elaborated in the following statement.

---

WHO World Alliance for Patient Safety:  
[http://www.who.int/patientsafety/patients\\_for\\_patient/statement/index.html](http://www.who.int/patientsafety/patients_for_patient/statement/index.html)).

<sup>507</sup> In some ways, this is similar to the World Alliance for Patient Safety as a whole, which takes its major organizational guidance and support from a grant by the UK National Health Service, and is managed by many from the NHS administration.

<sup>508</sup> From Consumers Advancing Patient Safety website ([www.patientsafety.org](http://www.patientsafety.org)).

<sup>509</sup> More on Sue Sheridan’s background and work in patient safety reform can be found in Quaid, Thao, and Denham. (2010), p. 11.

From the beginning, the role of real patients and their family caregivers was deemed to be a crucial component of the World Alliance. A first step was the invitation made to CAPS Co-founder and President, Susan E. Sheridan, an American whose family has experienced the impact of medical error, to lead the PFPS consumer action area. Under the aegis of the World Alliance, CAPS leadership led in the development of the PFPS statement of case and proposed an international event to recruit and convene consumer champions who can contribute to better, safer healthcare systems world-wide.<sup>510</sup>

In both its title and statements, CAPS frames the role of the patient as a consumer of health care, justifying its mobilization of patients and demands for safety reform around that category. Using this conceptual shift, national and global patient safety movements have the effect of redefining patients from the object of intervention in health care to an active agent for changing delivery systems.

Bolstered by consistent health care and media attention, a diverse set of patient safety projects ostensibly seeks to reduce, and even eliminate, an array of risks to patients. Where the hierarchy of medical decision-making traditionally rests exclusively with doctors, the patient safety agenda has questioned such a structure, seeking the standardization of safety practices and the inclusion of patients in safety policies. The standardization push brought forth by the World Alliance's global patient safety challenges, as well as the inclusion demands of Patients for Patient Safety, all under the umbrella of the WHO, seems to bear out Liam Donaldson's statement that "Patient Safety is truly becoming a global issue."<sup>511</sup> With its global reach, sociological research on organizational similarity and diffusion can provide some understanding into the work of the World Alliance for Patient Safety. The global diffusion model of Meyer and

---

<sup>510</sup> From Consumers Advancing Patient Safety website (<http://www.patientsafety.org/page/94877/>)

<sup>511</sup> World Health Organization (2005a), p. 3.

colleagues proposes that “worldwide models define and legitimate agendas for local action,” as these models have developed from global cultural and associational processes.<sup>512</sup> As national advocacy provides a background for the World Alliance for Patient Safety, the patient safety movement now has transnational networks and global implications, continuing to take shape as the push for international standardization and patient empowerment is advanced. In related fashion, DiMaggio and Powell’s theory of institutional isomorphism calls attention to the homogeneity of organizational forms, and hypothesizes some methods through which similarity occurs.<sup>513</sup> Understood alongside standardization, the concepts of global diffusion and institutional isomorphism also serve to explain how a dominant safety model takes on a certain standard form, as in the WAPS, as it spreads worldwide.

Placed under the unified banner of patient safety advocacy, the World Alliance provides clear, simple, and precise solutions ostensibly applicable to every health care setting. While reducing the burden of unsafe health care is clearly a laudable goal, it may have distinct consequences for local systems. As Timmermans and Epstein observe, “somewhere between glorified globalization and dark dehumanization, each standard achieves some small or large transformation of an existing social order. Again, the specificity of the actual standard matters: Different standards will generate different outcomes for different users.”<sup>514</sup> In its efforts to promote international safety standardization, the WHO and the World Alliance for Patient Safety overlook continued debates about both the problem of medical error and what constitutes standard safety

---

<sup>512</sup> Meyer, et al. (1997).

<sup>513</sup> DiMaggio and Powell (1983).

<sup>514</sup> Timmermans and Epstein (2010), p. 83

solutions. The largest healthcare accreditation organization in the US, the Joint Commission, has drawn criticism for its plans to team with the WHO. As *Modern Healthcare* reports, some experts wonder “...whether it’s a legitimate effort to reduce patient errors, or an opportunity to raise the commission’s profile overseas at a time when its reputation at home has taken some knocks.”<sup>515</sup> In the arena of discourse and agenda-setting, patient safety is relatively easy to agree upon. However, when it comes to categorizing medical error, implementing patient safety standards, and including patients as consumers, competing interests start to become more readily apparent. Also, the World Alliance provides mostly recommendations, rather than resources, to apply safety standards or develop patient networks. As new international partnerships are devised and developed, though, it remains to be seen what role the WHO’s World Alliance and Patients for Patient Safety, will play in further efforts at standardizing safety and reorganizing responsibility in global health care.

### **The Field of Organizational Advocacy for Patient Safety**

Just as patient safety research has rapidly expanded over the last decade, so too have avenues for patient safety advocacy. As the only major organization dedicated specifically to the cause in the US, the National Patient Safety Foundation (NPSF) is the advocacy group most connected to selling patient safety, with its associated leading figure, Lucian Leape, as one of the most well-known national advocates. Its activities are

---

<sup>515</sup> Lubell (2007), p. 6-7, 16.

wide-ranging, but of particular note is the focus upon building safety culture as a panacea for safety progress, as well as its recent move to professionalize patient safety through the American Society of Professionals in Patient Safety (ASPPS) at NPSF. With an overlapping push for patient safety, the Institute for Healthcare Improvement (IHI) has taken the interest in medical error to advance its primary mission for advancing quality improvement in health care. The founder of IHI, Don Berwick has been recognized as a charismatic leader of the quality movement, as evidenced by the success of the IHI's signature '100,000 Lives' and '5 Million Lives' Campaigns. With the advent of health care reform, the profile of the IHI has risen in the last couple of years, especially for Don Berwick (who will be discussed further in the next chapter). Such attention given to medical error and patient safety by national advocacy groups, such as efforts in the US by the NPSF and IHI, have been transformed into global advocacy. The World Alliance for Patient Safety (WAPS) follows along with national efforts in such endeavors as standardizing best practices for safety, as well as giving patients an active voice and equal role in patient safety reform. While the leader of the WAPS, Liam Donaldson, asserts that patient safety has 'gone global,' it remains to be seen how such a widespread effort will translate to local implementation beyond advanced health care systems that already had national patient safety organizations. As the case studies for this chapter and three of the most significant patient safety advocacy organizations, a summary chart (*Table 3* on page 191) compares the major elements of the NPSF, IHI and WAPS.

However influential the NPSF, IHI, and WAPS are for selling safety reform, there are many other groups and agencies that are working in and around the large field of patient safety. For example, The Leapfrog Group was started in 1998 when "a group of

large employers came together to discuss how they could work together to use the way they purchased healthcare to have an influence on its quality and affordability.”<sup>516</sup> As with many organizations, the “1999 report by the Institute of Medicine gave the Leapfrog founders an initial focus – reducing preventable medical mistakes.”<sup>517</sup> The group’s mission is described in that “the founders realized that they could take ‘leaps’ forward with their employees, retirees and families by rewarding hospitals that implement significant improvements in quality and safety.”<sup>518</sup> Besides the Leapfrog Group, the Joint Commission and the National Quality Forum also play significant roles in promoting patient safety policy and practice. The Joint Commission seeks “to continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value,”<sup>519</sup> and the National Quality Forum, which seeks to build consensus over national performance standards.<sup>520</sup>

The central United States government agency dealing with patient safety is the Agency for Healthcare Research and Quality (AHRQ), which has been involved in facilitating and analyzing patient safety practices. For example, the agency has supported research and evaluation into state patient safety reporting systems,<sup>521</sup> and a “Web-based resource that provides practical information on the patient safety dimensions used in

---

<sup>516</sup> The Leapfrog Group: About us - [http://www.leapfroggroup.org/about\\_us](http://www.leapfroggroup.org/about_us).

<sup>517</sup> Ibid.

<sup>518</sup> Ibid.

<sup>519</sup> The Joint Commission: About us - [http://www.jointcommission.org/about\\_us/about\\_the\\_joint\\_commission\\_main.aspx](http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx)

<sup>520</sup> The National Quality Forum: About us - [http://www.qualityforum.org/About\\_NQF/About\\_NQF.aspx](http://www.qualityforum.org/About_NQF/About_NQF.aspx).

<sup>521</sup> Rand Technical Report (2006).

AHRQ's Hospital Survey on Patient Safety Culture (HSOPS),”<sup>522</sup> as well as “a list of general resources from leading public and private groups involved in patient safety.”<sup>523</sup> Finally, the WHO's World Alliance for Patient Safety is not the only example of the global push for patient safety. Connected to Dr. Charles Denham's organization,<sup>524</sup> “the Global Patient Safety Forum is the convening organization of the world's leading patient safety organizations, whose mission is to save lives, save money, and build value in the community communities we serve by accelerating solutions in patient safety from suppliers through providers to purchasers of healthcare including consumers.”<sup>525</sup> Along with their representative leaders, each of these institutional organizations - the NPSE, the IHI and the WAPS - attempts to promote change in health care delivery systems related to securing safety and advancing quality.

Since the focus of this chapter was the discourse of organizations and leaders, it remains to be seen how much of the case for patient safety – how such concepts as work standardization and safety culture - has been received and adopted. In their review article, Timmermans and Epstein recognize, “the power of standardization depends on whether standards are actually implemented.”<sup>526</sup> As a major effort behind changing work organization, standardization in patient safety remains uncertain in its implementation and uneven in its application. Regardless of how the message of safety culture has been taken up, one of Silbey's central conclusions holds: “as the phenomena continually

---

<sup>522</sup> AHRQ HSOPS:

<http://www.ahrq.gov/qual/patientsafetyculture/hospcult1.htm#Dimensions>.

<sup>523</sup> AHRQ Resource List:

<http://www.ahrq.gov/qual/patientsafetyculture/hospimpptsaf.htm>.

<sup>524</sup> Dr. Denham and TMIT are discussed in chapter 3.

<sup>525</sup> The Global Patient Safety Forum: <http://www.globalpatientsafetyforum.org/#>.

<sup>526</sup> Timmermans and Epstein (2010), p. 79.

recede before efforts to control them, research advocating safety culture seems, in the end, to suggest that responsibility for the consequences of complex technologies resides in a cultural ether, everywhere or nowhere.”<sup>527</sup> Relevant for discourse on health care quality and safety, such nebulous use of culture “as both the explanation and remedy,” according to Silbey then “obscures the different interests and power relations enacted in complex organizations.”<sup>528</sup> As patient safety advocacy combines efforts to increase the efficiency of health care delivery (through standardization) with concerns over responsibility for medical error (through safety culture), the resulting tensions over work control and organizational power may contribute to an uncertain and uneven implementation of patient safety solutions.

Studying patient safety in the UK, Waring provides some indication of how patient safety has been actually implemented. He states that “over the last 20 years, developments in health service management have seemingly challenged medical autonomy and self-regulation, yet the eventual impact has often been small or incremental, as managers have lacked the capacity to engage in the technical areas of medicine and doctors have been able to reinforce their monopoly through blocking or capturing managerial initiatives.”<sup>529</sup> While control and rationality often seem to be directed unilaterally, Waring warns that management initiatives do not always capture their intended targets. Derived from a Foucauldian analytical approach, Waring discusses a concept he calls ‘adaptive regulation,’ a “tendency towards regulatory

---

<sup>527</sup> Silbey (2009), p. 363.

<sup>528</sup> Ibid., p. 343.

<sup>529</sup> Waring (2007b), p. 175.



modification and capture,”<sup>530</sup> in which “any form of regulation is rarely static or fixed but contested and negotiated in the context of social change, professional groups must be able to adapt their regulatory practices to meet changing social expectations, new forms of knowledge and also the cultural needs of the profession.”<sup>531</sup> Patient safety discourse, as new form of knowledge and model of regulation in health care, seeks to shift the culture of medicine, from what advocates see as a toxic one of ‘blame and shame’ to a more effective environment of ‘openness and improvement.’ As a result of patient safety initiatives, professional conduct in medicine has come under scrutiny through desires to change medical culture. Waring’s analysis of patient safety in the UK suggests that “rather than analysing the outward changes in management or accounting for the overt methods by which professionals resist management, we need to look more deeply at the changes within professional practice and culture to understand how resistance or adaptation lead to new forms of governmentality and a convergence between professionalism and managerialism.”<sup>532</sup> Though patient safety reformers attempt to sell certain notions of workplace organization, of course that does not necessarily mean such ideas are taken up without resistance or modification.

Placed in a tenuous position relative to the wave of privatization brought on by managed care, notions such as safety culture are a novel reform response - an assertion (and in some ways, re-assertion) of collective concerns and interventions, in the face of massive changes in health care delivery. Attempting to move beyond models of error that blame and discipline individuals, patient safety advocacy seeks to govern health care

---

<sup>530</sup> Waring (2007b), p. 175

<sup>531</sup> Ibid., p. 175.

<sup>532</sup> Ibid., p. 177.

workplaces with aspirations for the development of a successful, and standardized, safety culture. In order to change organizational culture of health care and the professional culture of medicine, patient safety advocacy seems to undermine aspects of the traditional professional culture of medicine. However, in affirming an organizational culture centered upon safety and quality improvement, adhering to patient safety principles translates into a stronger position for political reform of health care. As Mechanic has observed, “hospitals are not particularly safe place to be, and their lack of adequate quality-assurance systems would be an acute embarrassment to most other large industries,” noting that “many organizations and government agencies have begun to address the issue, although progress has been slow.”<sup>533</sup> Advocacy groups have responded to that ‘embarrassment,’ agreeing with how Mechanic links safety and quality of care issues to the need for general reform of the US health care system. How patient safety has been connected to, and has become significant for, health care reform and the medical profession, will be discussed next, in the concluding chapter of the dissertation.

---

<sup>533</sup> Mechanic (2006), p. 10.

**TABLE 3: MAJOR PATIENT SAFETY ADVOCACY ORGANIZATIONS -**  
*National Patient Safety Foundation, Institute for Healthcare Improvement, and World Alliance for Patient Safety*

|                              | <u>NPSF</u>                                                                                        | <u>IHI</u>                                                                             | <u>WAPS</u>                                                                                |
|------------------------------|----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| YEAR STARTED                 | 1997                                                                                               | 1991                                                                                   | 2004                                                                                       |
| FOUNDING IMPETUS             | Annenberg Conference<br>“Examining Errors”                                                         | National Demonstration<br>Project (late 1980s)                                         | National patient safety<br>programs (2000s)                                                |
| HEADQUARTERS                 | Boston, MA                                                                                         | Cambridge, MA                                                                          | Geneva, Switzerland                                                                        |
| PROMINENT<br>LEADER          | Lucian Leape                                                                                       | Donald Berwick                                                                         | Liam Donaldson                                                                             |
| ACTIVITIES &<br>CAMPAIGNS    | NPSF Annual Congress;<br>Lucian Leape Institute;<br>Society for Professionals<br>in Patient Safety | ‘100,000’ & ‘5 Million’<br>Lives Campaigns; IHI<br>Improvement Map; IHI<br>Open School | Global PS Challenges;<br>Patients for Patient<br>Safety; Education &<br>Training Workshops |
| AGENDA                       | Improve safety of care -<br>dedicated solely to<br>patient safety advocacy<br>& reform             | Wide-ranging reform<br>agenda pursuing quality<br>methods in healthcare                | Improve patient safety<br>worldwide; Involve<br>WHO member states                          |
| SIGNIFICANCE for<br>ADVOCACY | First US organization<br>dedicated specifically to<br>patient safety advocacy                      | Major US organization<br>for advancement of<br>safety & quality<br>improvement         | International effort to<br>advance safety – patient<br>safety becomes global               |

## CHAPTER 5 – CONCLUSION

### The Politics of Patient Safety and Health Care Reform

During a Congressional recess in July 2010, patient safety advocate and founder of the Institute for Healthcare Improvement, Dr. Donald Berwick, was appointed by President Obama to head the Centers for Medicare and Medicaid Services (CMS). With the federal government's responsibility in financing the Medicare and Medicaid programs, Berwick's appointment as director of CMS is a very influential position in the US health care system. Even more so now, since CMS is set to play a pivotal role in the implementation of the comprehensive health care reform bill, the Patient Protection and Affordable Care Act, that was passed into law in March of 2010.<sup>534</sup> According to an article in *The New York Times*, "the agency [CMS] must write and enforce dozens of regulations to expand Medicaid, trim Medicare and test new ways to deliver care."<sup>535</sup>

Given the tense political battle over health care, and his role as a care delivery reformer, Berwick's nomination came with criticism from Republican opponents of the Affordable Care Act. Robert Pear's article in the *Times* states, "Republicans are using the nomination to revive their arguments against the new health care law," in which "Dr. Berwick has given them plenty of ammunition."<sup>536</sup> Most of the fodder for Republican criticism comes from comments that Berwick has made regarding health care rationing, as well as for his unapologetic appreciation of the United Kingdom's government-run

---

<sup>534</sup> The Patient Protection and Affordable Care Act – promoted more generally by supporters in the shortened form of Affordable Care Act. See *The Washington Post* (2010) for a helpful overview of the Law's passage and immediate implications.

<sup>535</sup> Pear (June 22, 2010).

<sup>536</sup> Ibid.

National Health Service. Senate Republican leader, Mitch McConnell, describes Dr. Berwick as an “expert on rationing,” and Senator Pat Roberts, Republican of Kansas, calls him “the perfect nominee for a president whose aim has always been to save money by rationing health care.”<sup>537</sup> Senator Charles Grassley of Iowa, the senior Republican on the Finance Committee, referring to, as well as inciting, the pervasive fear of more extensive government involvement in health care, has said that “It doesn’t help him to say good things about the British health care system.”<sup>538</sup>

Despite all the criticism from Republicans, though, Pear’s article continues, “whatever doubts might exist in Washington, Dr. Berwick has fans in hospitals around the country.”<sup>539</sup> For example, Dr. Frank Davidoff, a former editor of the *Annals of Internal Medicine* said, “Don Berwick preaches revolution,”<sup>540</sup> in which “He is trying to overthrow ‘a stupid system’ that serves the needs of doctors, administrators and insurers rather than patients.”<sup>541</sup> Another of Berwick’s supporters, Theodore E. Townsend, president of St. Luke’s Hospital in Cedar Rapids, Iowa, said: “Dr. Berwick has inspired me and this community. He has used his charisma and his leadership ability to improve the quality of care at hundreds and hundreds of hospitals. I can’t think of anyone else who has had that kind of impact.”<sup>542</sup> Berwick’s charismatic dedication to improving health care, as exalted by supporters that see him as a dynamic leader of the quality movement, makes him an inspiring choice to head CMS during a time of reform.

---

<sup>537</sup> Quoted in Pear (June 22, 2010).

<sup>538</sup> Quoted in Pear (June 22, 2010).

<sup>539</sup> Pear (June 22, 2010).

<sup>540</sup> Quoted in Pear (June 22, 2010).

<sup>541</sup> Pear (June 22, 2010).

<sup>542</sup> Ibid.

Berwick's role in the politics of health care actually goes back over a decade before his involvement in the Obama administration. In April 1997, "President Clinton appointed him [Berwick] to the Advisory Commission on Consumer Protection and Quality in the Healthcare Industry, which is charged with developing a broader understanding of issues facing the changing health care delivery system and with building consensus on ways to ensure and improve quality in health care."<sup>543</sup> While advisory roles do not have the same policymaking consequence as directing an administrative agency, Berwick is thus no stranger to participating in the federal government's activities around health care reform. The stakes, though, are much higher given the successful passage of sweeping reform in 2010, as opposed to the failure of Clinton's comprehensive reform effort in 1993-1994. In addition to the Affordable Care Act, the Medicare and Medicaid programs have become the target of intense discussions over how to cope with growing US government debt, bringing up the politically contentious issue of entitlement reform.

After Berwick's recess appointment in July 2010, the political controversy has continued into his temporary tenure as director of CMS. Pear's *New York Times* article reports that "Members of Congress, including Democrats, have urged the Obama administration to search for another Medicare chief after concluding that the Senate is unlikely to confirm President Obama's temporary appointee, Dr. Donald M. Berwick."<sup>544</sup> This is because, "In a letter to the White House last week, 42 Republican senators urged Mr. Obama to withdraw the nomination of Dr. Berwick to head the Centers for Medicare and Medicaid Services, which runs insurance programs for more than 100 million people.

---

<sup>543</sup> Voelker (1997), p. 1560.

<sup>544</sup> Pear (March 7, 2011).

If those senators stick together, they could block confirmation.”<sup>545</sup> According to Pear, “He became caught up in the partisan battle over the new health law,” noting Republican criticism of his statements on rationing, the UK’s NHS, and end-of-life procedures.<sup>546</sup> Despite his supporters outside of Washington, “several people who work with Dr. Berwick at the Medicare agency said they were disappointed that the White House had not done more to promote him,” leaving his staff at CMS with little optimism that Berwick would be permanently appointed.<sup>547</sup>

While it seems unlikely that Berwick’s role as head of CMS will continue much longer, the politics of his nomination and appointment show how the movement for patient safety and quality improvement connects to more general considerations about comprehensive health care reform. Given Berwick’s (albeit temporary) tenure as leader of CMS, a champion of patient safety has reached a position of high institutional significance within the Federal government. As a leading advocate of the patient safety (and quality) challenge, Berwick lends a strong voice for transforming health care delivery in the US. Dr. Don Berwick’s position at CMS provides one indication that the challenge to the status quo of American medicine has been taken up by the Federal government. Returning to the theoretical terms used in the dissertation’s introduction, the patient safety challenge – understood conceptually as questioning the (traditional) culture and conduct of the medical profession - has found its way, at least through one of the movement’s most recognizable figures, to a leadership position in the most significant Federal health care financing agency (CMS).

---

<sup>545</sup> Pear (March 7, 2011).

<sup>546</sup> Ibid.

<sup>547</sup> Ibid.

In order to examine the patient safety challenge, I have attempted to answer three overarching questions in this dissertation (these were also stated in the introduction). First, what constitutes patient safety discourse and who are the leading advocates for patient safety reform? Next, what are advocates, and their associated discourse, attempting to change about understandings of medical error specifically, and about the organization and delivery of health care more generally? Finally, what are the consequences of patient safety advocacy for the medical profession and for health care reform? Answers to the first two questions were at the forefront of analysis throughout the case studies on: discourse around medical error reports (chapter 2); patient stories of medical error (chapter 3); and patient safety advocacy organizations and campaigns (chapter 4). For this concluding chapter, I return more closely to answers for the third question, which was developed as the theoretical focus of the introduction (chapter 1).

As a conclusion to the dissertation, this chapter briefly explores how quality and patient safety are now firmly on the health care reform agenda. First, I cover some important ways that patient safety has entered health care reform at the federal level, beyond the example of Berwick's temporary appointment to head CMS. From that overview, I then consider how the link between patient safety and health care reform matters for remaking the medical profession (again, in theoretical terms of questioning the conduct and culture of medicine). Finally, I look to what the future holds – both for the ongoing politics of patient safety and for an expansion of this project. At the end, and in pursuing future work, I suggest that the Federal government and the medical profession have a shared interest in advancing patient safety and quality improvement. For the government, this comes through as an avenue for both comprehensive health care



reform as well as for curtailing Medicare and Medicaid costs; while for the profession, it provides a way to re-establish status that has been undermined by managed care.

### **Patient Safety and Health Care Reform**

In an address to physicians at the 2009 meeting of the American Medical Association House of Delegates, President Obama said “we need to explore a range of ideas about how to put patient safety first, let doctors focus on practicing medicine, and encourage broader use of evidence-based guidelines. That's how we can scale back the excessive defensive medicine reinforcing our current system of more treatment rather than better care.”<sup>548</sup> As with his presidential campaign materials discussed in the introduction, these statements also exhibit a prioritization of patient safety reform over medical malpractice (tort) reform. The key to reducing defensive medicine, according to President Obama, is in focusing on safety and quality improvement (as opposed to, say, making changes to the malpractice system). The extension of that logic is that our health care system improves when we move beyond ‘our current system of more treatment’ toward one premised upon quality (‘better care’).

Given the very large number of uninsured in the US compared to other advanced democracies, public attention toward health care reform is often directed toward expanding access, rather than lowering costs or advancing quality. According to the director of the White House Office of Management and Budget from 2009 to 2010, Peter

---

<sup>548</sup> President Obama’s speech available at:  
<http://www.ama-assn.org/ama/pub/about-ama/our-people/house-delegates/2009-annual-meeting/speeches/president-obama-speech.page>

Orszag, states, “In health care reform, there’s always an underlying tension between those who are more concerned about expanding coverage and those who are more concerned about containing costs and improving quality. The House bill tilted toward coverage; the Senate bill, toward cost-effectiveness and quality.”<sup>549</sup> Since the political maneuvering needed to pass health care reform ended up adopting much of the Senate bill, Orszag asserts, “the health care law starts the arduous process of shifting the medical payment system away from an emphasis on quantity of care and toward an emphasis on quality.”<sup>550</sup> Providing an example related to patient safety, Orszag says, “it [the health care law] creates penalties for hospitals with high rates of readmission and hospital-acquired infections.”<sup>551</sup> Another effect of the Accountable Care Act, according to Orszag, is that it “creates an Innovation Center to experiment with new strategies. Successful pilot programs can be ramped up to national scale without the need for additional legislation.”<sup>552</sup> However, the law has come under attack from Republican efforts to repeal it, and, even more precarious for its lasting legality, from various court challenges lead by Republican Attorney Generals of different states.<sup>553</sup> Given contradictory decisions at the District Court level, and with the likelihood of competing outcomes from different US Circuit Courts of Appeals, the various legal challenges now seem destined to reach a divided Supreme Court.<sup>554</sup>

---

<sup>549</sup> Orszag (November 4, 2010).

<sup>550</sup> Ibid.

<sup>551</sup> Ibid.

<sup>552</sup> Ibid.

<sup>553</sup> See Sack and Pear (November 26, 2010), for reporting on the first of the court challenges to the Affordable Care Act.

<sup>554</sup> See Liptak (April 26, 2011), for reporting on the reform law’s likely path to the Supreme Court.

Even with fierce political opposition and impending court challenges, the federal government is proceeding with efforts to develop the administrative rules and agencies that will implement the law. For example, the Agency for Healthcare Research and Quality reports that “The Affordable Care Act called on the Secretary of Health and Human Services to establish a National Strategy for Quality Improvement in Health Care. This National Strategy is a strategic plan for improving the delivery of health care services, achieving better patient outcomes, and improving the health of the U.S. population. The plan will be updated continually as the Affordable Care Act is implemented.”<sup>555</sup> A report to Congress about the National Strategy, states that “The Affordable Care Act seeks to increase access to high-quality, affordable health care for all Americans,” and is developed through “the National Quality Strategy that sets priorities to guide this effort and includes a strategic plan for how to achieve it.”<sup>556</sup> Besides the National Quality Strategy, “The Affordable Care Act also called for the establishment of an Interagency Working Group on Health Care Quality. This group of senior officials represents 23 Federal agencies with major responsibility for health care quality and quality improvement. Its function is to provide a platform for collaboration, cooperation, and consultation among relevant agencies regarding quality initiatives, as a means to ensure alignment and coordination across Federal efforts and with the private sector.”<sup>557</sup> The language of quality is pervasive in this sample of administrative work in the first year since the health care reform law passed. Through such efforts, quality

---

<sup>555</sup> From the AHRQ website: <http://www.ahrq.gov/workingforquality/>.

<sup>556</sup> From the DHHS website:  
<http://www.healthcare.gov/center/reports/quality03212011a.html/>.

<sup>557</sup> From the AHRQ website: <http://www.ahrq.gov/workingforquality/>.

improvement is guiding Federal departments, agencies, and commissions, all of which produce strategic plans and reports, in order to implement the Affordable Care Act.

Amidst all the talk and text of quality improvement, there is discussion of medical error and patient safety. Consider such statements from Healthcare.gov (Federal communication website from the DHHS about healthcare reform):

Health care providers should be relentless in their efforts to reduce the risk for injury from care, aiming for zero harm whenever possible and striving to create a system that reliably provides high-quality health care for everyone. This isn't easy. Such a system requires, for example, the design of standard operating procedures, a workforce with diverse yet complementary skills, workloads that allow enough time for errors to be corrected or mitigated and leadership that promotes continuous improvement. But this kind of system can also make a big difference in improving care, whether it's by preventing serious medication events or eliminating healthcare associated infections and other preventable conditions.<sup>558</sup>

Ideas such as 'aiming for zero,' 'standard operating procedures,' and 'preventable conditions,' all resonate with claims found in medical error reports (such as the IOM report, *To Err is Human*) or of advocacy campaigns (like the IHI's '100,000 Lives' Campaign). Couched in a motivational rhetoric, the statements above thus fit alongside other examples of patient safety discourse that also attempt to transform care delivery.

With these efforts targeting quality improvement, patient safety has become more directly part of the administrative implementation of the Affordable Care Act. According to a press release on April 12, 2011, "Health and Human Services Secretary Kathleen Sebelius, joined by leaders of major hospitals, employers, health plans, physicians, nurses, and patient advocates, today announced the Partnership for Patients, a new

---

<sup>558</sup> From the DHHS website:  
<http://www.healthcare.gov/center/reports/quality03212011a.html/>.

national partnership that will help save 60,000 lives by stopping millions of preventable injuries and complications in patient care over the next three years.”<sup>559</sup> Immediately after the claim of saving lives, comes an assertion that “The Partnership for Patients also has the potential to save up to \$35 billion in health care costs, including up to \$10 billion for Medicare. Over the next ten years, the Partnership for Patients could reduce costs to Medicare by about \$50 billion and result in billions more in Medicaid savings. Already, more than 500 hospitals, as well as physicians and nurses groups, consumer groups, and employers have pledged their commitment to the new initiative.”<sup>560</sup> The potential to save thousands of lives and billions of dollars are positioned as the leading justifications for the initiative, along with the hundreds of groups supporting it within the health care industry. According to the DHHS website, “The Obama Administration has launched the *Partnership for Patients: Better Care, Lower Costs*, a new public-private partnership that will help improve the quality, safety, and affordability of health care for all Americans. The Partnership for Patients brings together leaders of major hospitals, employers, physicians, nurses, and patient advocates along with state and federal governments in a shared effort to make hospital care safer, more reliable, and less costly.”<sup>561</sup> As with the quotes above, this language resembles other aspects of patient safety discourse, particularly that of leading advocates and organizations. Though still rather vague and general in form, patient safety discourse is apparent in Federal efforts to implement, as well as to publicly advertise, the Affordable Care Act. In addition to having a leader like

---

<sup>559</sup> From DHHS website: <http://www.hhs.gov/news/press/2011pres/04/20110412a.html/>.

<sup>560</sup> From DHHS website: <http://www.hhs.gov/news/press/2011pres/04/20110412a.html/>.

<sup>561</sup> Available at the DHHS communication website:  
<http://www.healthcare.gov/center/programs/partnership/index.html/>.

Don Berwick appointed to head CMS, the language of patient safety has considerably structured initial implementation projects from the comprehensive health care law.

From an insider perspective, Bob Wachter specifically claims that patient safety is a leading avenue for pursuing the administration of the health care reform law. A Professor of Medicine at the University of California, San Francisco, and leading patient safety researcher, Wachter provides this insight about how the ‘Partnership for Patients’ initiative came together, “I suggested that the topic of patient safety remained compelling and scary, and that it might be at a tipping point – with new success stories in reducing infections and improving surgical safety, more hospitals possessing the infrastructure to improve safety, and increasing penetration of IT systems due to federal support through the meaningful use standards.” Referencing Don Berwick’s role as director of CMS and thus leader in implementing quality reform in the Affordable Care Act, Wachter says that “he’d [Berwick] be looking to do Something Big – an initiative aimed at capturing hearts and minds, a federal version of his IHI 100,000 Lives and 5 Million Lives campaigns. What better target than patient safety?”<sup>562</sup> He continues, though, “The devil will be in the details, but there is a lot to like in this initiative: a national spotlight on the issues of patient safety, an ambitious but achievable improvement goal, an effort to harmonize measures across various stakeholders, a focus on skill building and learning networks, a broad-based partnership, and significant resources both to do the work and to create incentives for improvement.”<sup>563</sup> As witnessed by Wachter’s insight and Berwick’s

---

<sup>562</sup> Wachter (2011). <http://thehealthcareblog.com/blog/2011/04/12/the-partnership-for-patients-the-inside-scoop-on-a-game-changing-safety-initiative/>

<sup>563</sup> Wachter (2011). <http://thehealthcareblog.com/blog/2011/04/12/the-partnership-for-patients-the-inside-scoop-on-a-game-changing-safety-initiative/>

leadership, then, patient safety is a guiding principle for implementing the most comprehensive reform to the US health care system in decades.

These efforts by the Federal government come with some urgency, as recent studies have expressed a lack of progress in safety. According to a front-page article in *The New York Times*, “efforts to make hospitals safer for patients are falling short, researchers report in the first large study in a decade to analyze harm from medical care and to track it over time.”<sup>564</sup> Published in a November 2010 issue of the *New England Journal of Medicine*, the research team did not find evidence of widespread reduction in harm to patients, and concluded that “achieving transformational improvements in the safety of health care will require further study of which patient-safety efforts are truly effective across settings and a refocusing of resources, regulation, and improvement initiatives to successfully implement proven interventions.”<sup>565</sup> An April 2011 issue of *Health Affairs* also questions the status of patient safety and quality progress, ten years after the IOM’s famous *To Err is Human* and *Crossing the Quality Chasm* reports.<sup>566</sup> So while patient safety discourse is now centrally implicated in federal health care reform efforts, it comes at a time when doubt is being raised as to how much progress has been made from, up to this point at least, mostly industry initiatives and advocacy campaigns. The lack of progress in patient safety may provide further opening for Federal efforts to proceed in remaking health care delivery, both for the sake of saving lives and reducing costs (as illustrated through the *Partnership for Patients* initiative).

---

<sup>564</sup> Grady, Denise. (November 24, 2010).

<sup>565</sup> Landrigan, et al. (2010), p. 2133.

<sup>566</sup> See Dentzer (2011) for an overview of the issue.

### Safety Discourse, Federal Reform and the Medical Profession

What do such emergent links, between patient safety discourse and federal health care reform, say about changes to the medical profession? As a discourse that promotes an alternative rationality for understanding and managing medical error, reformers have used the patient safety challenge to encourage changes in the medical profession over the past decade. Professional culture and conduct in medicine are measured up against a unified rationality governing health care delivery – with medical error as a preventable risk, with patients as partners in the prevention of error, and with safety culture and standardized work systems as the organizational models for transforming health care delivery. While not exhaustive of patient safety discourse, these elements have been taken up through Federal health care reform efforts. For example, the name of the initiative *Partnership for Patients*, speaks to the significance of collaboration and partnership. Quadagno provides some context for how the medical profession “attempted to compensate for the loss of political influence by forming new partnerships, notably with consumer groups.”<sup>567</sup> However, she continues, “these alliances were more fragile, their members more fickle, and making their power base less secure. Thus, the struggle for control of the health care system continued into the twenty-first century, with organized medicine weakened but not vanquished.”<sup>568</sup> While patient safety principles, such as partnering with patients, do not automatically re-establish the medical

---

<sup>567</sup> Quadagno (2004), pp. 831-832.

<sup>568</sup> Ibid., pp. 831-832.



profession's diminished status, such endeavors can be seen as a form of leverage for realigning the profession's position within a changing health care system.

Now that patient safety discourse has been taken up through Federal health care reform, the relationship between profession and state may also be undergoing significant change, with implications for the autonomy and authority of the medical profession. As Freidson famously asserted, "the most strategic and treasured characteristic of the profession - its autonomy - is... owed to its relationship to the sovereign state from which it is not ultimately autonomous."<sup>569</sup> Explaining this bonded connection between professions and the state, Freidson writes:

...in widely diverse political contexts the state uniformly leaves in the hands of the profession control over the technological side of its work. What varies as relations with the state vary is control over the social and economic organization of work....so long as a profession is free of the technical evaluation and control of other occupations in the division of labor, its lack of ultimate freedom from the state, and even its lack of control over the socio-economic terms of work do not significantly change its essential character as a profession.<sup>570</sup>

Patient safety advocates have fundamentally redefined the meaning of medical error, emphasizing harm prevention over individual perfection in care delivery. Patient safety discourse, as promoted by reformers, offers an alternative rationality for guiding the medical profession, pushing for shared responsibility among a team of health care professionals as a driving force for improving the safety and quality of medical care. Safety and quality directives, such as standardized protocols and checklists, routinely guide clinical practice. Coming out of a 1990s context of health care privatization and

---

<sup>569</sup> Friedson (1970a), pp. 23-24.

<sup>570</sup> Ibid., pp. 24-25.

the failure of political reform, the patient safety movement has grown by merging with other health care reform efforts, such as accountability and quality improvement, to ultimately envision an organizational transformation in health care delivery that has implications for the technical, social and economic organization of medicine.

In theoretical terms, the ‘problematizing government’ of the medical profession that was discussed in the introduction can be connected to the ‘problematizing government’ of the health care system. Evaluation of the medical profession has shifted through the incorporation of patient safety knowledge, with the profession’s relationship to the state being restructured as a result of health care reform. Patient safety discourse questions the culture and conduct of medicine, but targets a traditional notion of the profession that had defined an earlier era. In a retrospective essay to Starr’s *Social Transformation of American Medicine*, White says that, “the growth of the “total quality improvement” (TQI) movement and events such as the publication of the recent Institute of Medicine (IOM) reports *To Err Is Human* (2000) and *Crossing The Quality Chasm* (2001) reflect a new prominence [for quality considerations],” which “make a forceful case for reassessing medicine’s underlying performance.”<sup>571</sup> But in questioning and reassessing medicine’s culture and performance, patient safety reformers do not simply undermine the profession’s status, but instead attempt to assert a progressive and transformational role for the medical profession within a redesigned health care system.

Guided by a dedication to patient safety and quality improvement, advocates would argue that changing the culture of the medical profession is necessary if the health care system is going to be transformed. This requires modifying expectations of what it

---

<sup>571</sup> White (2004), p. 861.

means to safely deliver effective medical care. The focus is no longer upon the individual clinician with expertise and autonomy, but upon teams of care providers, with varying specializations, who all work together to deliver safe and effective care in collaboration with the patient and their family. This rests upon an ideal of teamwork, which may seem to undermine the individual physician's autonomy, but brings the medical profession as a whole upon the leading edge of reforming health care delivery. With such a leading role, the medical profession can be viewed as staking a claim to the contemporary remaking of American health care. Patient safety challenges American medicine to reform itself (culture and conduct) as the health care system is also being reformed. Such a dual transformation has the potential to give the profession a considerable voice in the shape that health care will take in the next decade. While this challenge is by no means completely or uniformly adopted, it may be a better alternative than clinging to the professional dominance that defined an earlier era, and which has been largely dismantled through managed care and other forms of privatized oversight.

Through patient safety discourse, and associated ideas about quality improvement, reforming the medical profession has become part of health care reform. With control over the Medicare and Medicaid programs, the Federal government plays an important role as the largest payer of health care in the US. These programs, especially Medicare as the US population ages, are going to bankrupt the Federal government from rising health care costs. Patient safety (and quality improvement) discourse falls in line with the cost-conscious interests within certain frameworks for reform. Advocates target a transformation in the professional conduct of medicine as a major route to improving the safety, quality and cost of health care. At least according to advocates, this

orientation is considered both collaborative and progressive for reforming the US health care system to be more safe, efficient and effective. Other avenues for dealing with the problem of medical error do not lead to such collaboration. For example, medical malpractice is seen as overly adversarial and inefficient in its quality assurance functions. So while medical malpractice reform was the initial impetus for analyzing the scope and prevalence of medical error (see chapter 2), it is no longer the primary objective of patient safety reform. Instead, patient safety discourse has been incorporated into comprehensive Federal health care reform, with the medical profession and the state now linked in changing the system. Though this linkage is a potential threat to traditional professional autonomy, patient safety advocates would argue that it is a better option than leaving the profession's fate up to the whims of a market model of care delivery. Since the private sector has been unable to significantly modify the cost and quality of the system on its own, the Federal government and the medical profession share an interest in changing the US health care industry. For the government, this results from pressures for both general reform and for cutting (or curtailing) the crushing cost of Medicare and Medicaid; while for the profession, it provides a way to re-establish a social position that had been undermined by managed care. This could result in a new configuration of state and profession, as implicated through patient safety (and closely associated quality improvement) directives in health care reform. The sway of market forces that has been guiding the health care system since the 1980s (and as predicted by Starr's observation of the 'coming of the corporation') may be eclipsed as the profession and the state develop a proposed partnership with which to remake the structure of medical care delivery in the US. With contemporary health care reform in flux from various political and legal

challenges, though, the consequences and implications of how that alliance comes together are still uncertain and unfolding.

In this dissertation, I have explored major aspects and events<sup>572</sup> of what I describe as ‘the patient safety challenge.’ As a discourse of reform, the patient safety challenge emerged and developed over the course of 1990s, gained prominence in the early 2000s, and now occupies a significant place in health care reform efforts. Positioning medical error as a significant, wide-ranging, and entrenched problem in need of political and organizational attention, the reform discourse includes both an alternative to the medical malpractice model for understanding medical mistakes, as well as a research and advocacy orientation for transforming the organization of health care delivery. Patient safety reformers challenge the health care industry to take action to better manage medical error, and in so doing call for a major transformation in the US health care system. With a revised politics of shared responsibility and ethos of collective improvement, patient safety advocates attempt to remake the profession by redefining its culture and conduct along those lines. I have explored how patient safety discourse remakes the medical profession in three iterations: how the concept of medical error has become an object of research and target for advocacy (discussed in chapter 2), how patient stories of medical error transform both patients and providers (chapter 3), and how leading advocates and organizations attempt to change notions of culture and responsibility in the organization of the health care workplace (chapter 4). These three dimensions together lay a basis for medicine’s potential new role (and relation to the

---

<sup>572</sup> A chronology in the Appendix provides a list of the major events covered.

state) in the implementation of health care reform, through recent initiatives arising from comprehensive legislation passed in 2010 (as briefly discussed in this chapter).

Amidst remarkable advancements in medical care over the last several decades, the political debate over quality and safety has potentially arrived at a significant moment of transformation. Patient safety discourse highlights a reorganization of both medicine and health care delivery in the United States. Though it remains to be seen how major this transition will be in the coming years, a conceptual and organizational shift in the delivery of health care, as witnessed by the story of patient safety, is already under way. As prodded by patient safety discourse and advocates, the medical profession has become incorporated into comprehensive reform. With high stakes in the shape that health care delivery takes in the next decade, the medical profession has been targeted, by a discourse of patient safety and quality, to join the Federal government in reorganizing American health care. As the political and legal battles of this reorganization continue to be fought, it is through such struggles that American medicine will be remade.

### **A History of Patient Safety Politics**

Writing in 1989, Freidson said, “I do not see changes that will actually transform rather than merely alter the position of the medical profession in either the nation or the health care system.”<sup>573</sup> While his position might have changed in the years since that statement and when he passed away in 2005, I would suggest that the recent history of patient safety reform makes a solid case for the (at least attempted) transformation of the

---

<sup>573</sup> Freidson (1989), p. 201.

American medical profession. In terms of discourse, patient safety seeks a significant change to the culture of medicine, striking a challenge to the professional dominance that Freidson so eloquently described was the defining feature of medicine for most of the middle part of the 20<sup>th</sup> century. In order to further support this argument of professional transformation, my goal is to develop this project into a more extensive history of patient safety in the context of health care reform politics.

In a brief review of the history of patient safety, Lucian Leape has claimed, “Patient safety has finally ‘‘arrived.’’ Every hospital now has a patient safety officer and many have implemented meaningful changes in policy and practice that are reducing errors and injuries to patients.”<sup>574</sup> He continues “Creating a safe environment in our incredibly complex health care system requires a major culture change. As such, it will be frustratingly slow and halting. But that change is occurring and beginning to show results. The possibility of injury-free care no longer seems inconceivable.”<sup>575</sup> According to Leape, Berwick and Bates, “The Institute of Medicine (IOM) Report *To Err is Human* converted an issue of growing professional awareness to one of substantial public concern in a manner and pace unprecedented in modern experience with matters of healthcare quality.”<sup>576</sup> They continue “In short order, the US Congress initiated hearings and the president ordered a government-wide feasibility study, which led to a subsequent directive to governmental agencies to implement the recommendations of the IOM report,” in which “The IOM called on all parties to make improving patient safety a

---

<sup>574</sup> Leape (2008), p. 8.

<sup>575</sup> Ibid., p. 8.

<sup>576</sup> Leape, Berwick and Bates (2002), p. 501.

national priority.”<sup>577</sup> This dissertation project has traced important movements within the history that is described by Leape and by Leape, Berwick and Bates – providing context from before the IOM report, as well as about what happened after – to explain how medical error become an issue of concern and how patient safety discourse became part of everyday talk in health care organizations. Further work on the history of patient safety will encompass additional aspects of the politics of patient safety, specifically concerning how the Federal government became involved, which would expand upon the discussion from this concluding chapter (looking at Congressional hearings and other legislative action is one such avenue for expansion).

In building upon the analysis of the dissertation, it could be developed by merging the specific consideration of patient safety politics with Silbey’s more general research recommendation that “future research on safety in complex systems should explore just those features of complex systems that are elided in the talk of safety culture: normative heterogeneity and cultural conflict, competing sets of interests within organizations, and inequalities in power and authority.”<sup>578</sup> Following such a recommendation would also resonate with Ocloo’s suggestion, noted in earlier chapters, that, “a more holistic approach is needed in developing new patient safety reforms,” where “adopting this wider approach is seen as vital in identifying the range of social processes associated with medical harm that are also to do with medical dominance and wider issues of power and control. It is argued that these issues have been largely ignored or downplayed in the

---

<sup>577</sup> Leape, Berwick and Bates (2002), p. 501.

<sup>578</sup> Silbey (2009), p. 343.



wholesale adoption of a ‘no-blame culture’ in patient safety.”<sup>579</sup> For both Silbey and Ocloo, questions of power, authority and control are important considerations for both safety culture generally and patient safety specifically. I have tried to touch upon some of those considerations in the last two chapters, but future work would benefit from more extensive analysis of power, control and authority in patient safety discourse and politics.

Looking back across decades, the structure of the American health care system has changed dramatically. For example, Boyer and Lutfey list some contrasting characteristics in US healthcare systems over the last 60 years – where 1950 as based upon “medical authority; solo practice; fee for service,” by 2009 healthcare is characterized by “Managed care organizations; Dispersion of authority; Utilization review; Case management.”<sup>580</sup> In discussing changes across time, Scott and colleagues assert that we have entered “The era of *managerial control and market mechanisms*,” where “beginning in the early 1980s, governmental policies shifted toward deregulation and a reliance on market forces, and large corporate groups entered the field. The central value governing institutional practice during this period is *efficiency of service provision*.”<sup>581</sup> It is under these more recent renderings by Boyer and Lutfey and by Scott and colleagues that patient safety develops within a health care system undergoing major changes. In tracing the broader history of patient safety, besides more in-depth discussion of politics and power, I hope to explore how quality and safety fit within long-term changes to the US healthcare system. This is perhaps a more complicated task, but one in which patient safety (and quality improvement) do play important parts.

---

<sup>579</sup> Ocloo (2010), p. 515.

<sup>580</sup> Boyer and Lutfey (2010), p. S80.

<sup>581</sup> Scott, et al. (2000), p. 22.

In future work, I also aim to develop the claim that the federal government and the medical profession have a shared interest in advancing patient safety and quality improvement. Much of this collaboration is currently unfolding as health care reform is being implemented. For the government, such collaboration provides an opportunity for reforming the entire health care system along with being a hopeful attempt at curtailing Medicare and Medicaid costs. For the medical profession, a renewed association with the state potentially provides a way to reassert a social position that has been undermined by managed care and other market-based initiatives. If such linkages unfold, then it would culminate in an altered configuration of state and profession, as first initiated and then made possible by patient safety and quality directives in health care reform. What this project will become, then, is a history of patient safety discourse and politics, within the context of major changes in the US health care delivery system. With a basis in this dissertation, I anticipate following further developments in patient safety discourse and reform politics, in order to track how such developments continue to shape efforts at remaking medicine and the health care system in the United States.

## Appendix: Chronology of Events Related to Patient Safety Discourse

| YEAR  | – EVENT –                                               | CHAPTER   |
|-------|---------------------------------------------------------|-----------|
| ===== |                                                         |           |
| 1977  | – Medical Insurance Feasibility Study published –       | Chapter 2 |
| 1991  | – Harvard Medical Practice Study published –            | Chapter 2 |
| 1991  | – Institute for Healthcare Improvement founded –        | Chapter 4 |
| 1994  | – Betsy Lehman dies during treatment for cancer –       | Chapter 3 |
| 1995  | – Reporting of Lehman’s death and other errors –        | Chapter 3 |
| 1996  | – Annenberg Conference on “Examining Errors” –          | Chapter 4 |
| 1997  | – National Patient Safety Foundation founded –          | Chapter 4 |
| 2000  | – IOM’s <i>To Err is Human</i> published –              | Chapter 2 |
| 2001  | – IOM’s <i>Crossing the Quality Chasm</i> published –   | Chapter 2 |
| 2001  | – Josie King dies at Johns Hopkins in Baltimore –       | Chapter 3 |
| 2002  | – Josie King Foundation started by Sorrel King –        | Chapter 3 |
| 2004  | – IOM’s <i>Patient Safety</i> published –               | Chapter 2 |
| 2004  | – Betsy Lehman Center founded by Mass. Government –     | Chapter 3 |
| 2004  | – World Alliance for Patient Safety founded by WHO –    | Chapter 4 |
| 2007  | – Dennis Quaid’s twins hurt; Quaid Foundation started – | Chapter 3 |
| 2010  | – Quaid Foundation merged with Dr. Denham’s TMIT –      | Chapter 3 |
| 2010  | – Patient Protection and Affordable Care Act passed –   | Chapter 5 |
| 2011  | – <i>Partnership for Patients</i> Initiative Created –  | Chapter 5 |

## BIBLIOGRAPHY

### I. Books, Articles, Reports

- Abbott, Andrew. (1988). *The System of Professions: An Essay on the Division of Expert Labor*. Chicago: The University of Chicago Press.
- Adam, Barbara and Joost van Loon. (2000). "Introduction: Repositioning Risk; the Challenge for Social Theory." In *The Risk Society and Beyond: Critical Issues for Social Theory*, Edited by Barbara Adam, Ulrich Beck and Joost Van Loon. London: Sage Publications.
- Allsop, Judith, Kathryn Jones, and Rob Baggott. (2004). "Health Consumer Groups in the UK: A New Social Movement?," *Sociology of Health and Illness* 26(6): 737-56.
- Associated Press. (April 2, 1995). "Disciplinary Proceedings Begun in Cancer Drug Overdose Cases." *The New York Times*. Section 1; Page 28; Column 1; National Desk.
- Associated Press. (May 12, 1995). "Hospital Official Resigns over Drug Overdoses." *The New York Times*. Section A; Page 16; Column 1; National Desk.
- Bai, Matt. (April 6, 1995). "Children's Hospital Admits Giving Wrong Drug to Child." *The Boston Globe*. METRO/REGION; Pg. 33.
- Baker, Tom. (2005). *The Medical Malpractice Myth*. Chicago: University of Chicago Press.
- Beard, Renée L. (2004). "Advocating voice: organisational, historical and social milieux of the Alzheimer's disease movement." *Sociology of Health & Illness* 26 (6): 797-819.
- Beck, Ulrich. (1992). *Risk Society: Towards a New Modernity*. London: Sage Publications.
- Beck, U., A. Giddens and S. Lash (1994). *Reflexive Modernization: Politics, Tradition and Aesthetics in the Modern Social Order*. Cambridge: Polity Press.
- Berkowitz, Edward D. (1998). *To Improve Human Health: A History of the Institute of Medicine*. Washington, DC: National Academy Press.

- Berwick, Donald M. (1989). "Continuous Improvement as an Ideal in Health Care." *The New England Journal of Medicine* 320: 53-56.
- Berwick, Donald M. (2007). "Building Quality in the Healthcare Environment." In *The Trust Crisis in Healthcare: Causes, Consequences, and Cures*, Ed. by David A. Shore. New York: Oxford University Press.
- Berwick, Donald M. (2008). "The Science of Improvement." *Journal of the American Medical Association* 299(10): 1182-1184.
- Bodenheimer, Thomas S. and Kevin Grumbach. (2009). *Understanding Health Policy: A Clinical Approach, Fifth Edition*. San Francisco: McGraw Hill.
- Bosk, C.L. (1979). *Forgive and Remember: Managing Medical Failure*. Chicago: University of Chicago Press.
- The Boston Globe*. (April 7, 1995). "3 From Globe are Honored by Cancer Society." METRO/REGION; Pg. 29.
- Boyer, Carol A. and Karen E. Lutfey. (2010). "Patient -Provider Relationships and Help-seeking Behaviors: Examining Critical Health Policy Issues within and beyond the Clinical Encounter." *Journal of Health and Social Behavior* 51: S80.
- Bowker, G. and S.L. Star. (1999). *Sorting Things Out: Classification and its Consequences*. Cambridge, MA: MIT Press.
- Brown, Phil and Steven Zavestoski. (2004). "Social Movements in Health: An Introduction." *Sociology of Health and Illness* 26(6): 679-694.
- Brown, Phil, Stephen Zavestoski, Sabrina McCormick, Brian Mayer, Rachel Morello Fosh, and Rebecca Gasior Altman. (2004). "Embodied Health Movements: New Approaches to Social Movements in Health." *Sociology of Health & Illness* 26(1): 50-80.
- Burnham, John C. (1998). *How the Idea of Profession Changed the Writing of Medical History*. (*Medical History*, Supplement No. 18). London: Wellcome Institute for the History of Medicine.
- California Medical Insurance Feasibility Study: California Medical Association and California Hospital Association. (1977). *Report on the Medical Insurance Feasibility Study*. San Francisco: Sutter Publications.
- Castel, R. (1991). "From Dangerousness to Risk" In *The Foucault Effect: Studies In Governmentality*, Edited by G.Burchell, C. Gordon and P. Miller. Chicago: The University of Chicago Press.

- Chassin M. (1998). "Is Health Care Ready for Six-Sigma Quality?" *Milbank Quarterly* 76(4): 565-1.
- Classen, David C., Roger Resar, Frances Griffin, Frank Federico, Terri Frankel, Nancy Kimmel, John C. Whittington, Allan Frankel, Andrew Seger and Brent C. James. (2011). "'Global Trigger Tool' Shows That Adverse Events In Hospitals May Be Ten Times Greater Than Previously Measured." *Health Affairs* 30 (4):581-589.
- Collier, S.J., A. Lakoff, et al. (2004). "Biosecurity: Toward an Anthropology of the Contemporary." *Anthropology Today* 20 (5): 3-7.
- Collier, Stephen J. and Andrew Lakoff. (2008). "The Problem of Securing Health." In *Biosecurity Interventions: Global Health and Security in Question*, Edited by Andrew Lakoff and Stephen J. Collier. New York: Columbia University Press.
- Collins, Molly E., Susan D. Block, Robert M. Arnold, and Nicholas A. Christakis. (2009). "On the prospects for a blame-free medical culture." *Social Science & Medicine* 69: 1287–1290.
- Conrad, Peter, and Joseph W. Schneider. (1990). "Professionalization, monopoly, and the structure of medical practice." In *The sociology of health and illness: Critical perspectives, 3<sup>rd</sup> ed.* Edited by Peter Conrad and Rochelle Kern. New York: St. Martin's Press, 141-147.
- Daiute, Colette and Cynthia Lightfoot. (2004). "Editors' Introduction: Theory and Craft in Narrative Inquiry." In *Narrative Analysis: Studying the Development of Individuals in Society*, Edited by Colette Daiute and Cynthia Lightfoot. London: Sage Publications.
- Day Sclater, Shelley. (2000). "Introduction." In *Lines of Narrative: Psychosocial Perspectives*, Edited by Molly Andrews, Shelley Day Sclater, Corinne Squire and Amal Treacher. New York: Routledge.
- Dean, Mitchell. (1999a). *Governmentality: Power and Rule in Modern Society*. London: SAGE Publications.
- Dean, Mitchell. (1999b). "Risk, calculable and incalculable." In *Risk and Sociocultural Theory: New Directions and Perspectives*, Edited by Deborah Lupton. Cambridge, UK: Cambridge University Press.
- Dembner, Alice. (February 13, 2002). "Doctor Awarded \$4M from Globe, Cancer Institute." *The Boston Globe*. METRO/REGION; Pg. B1.

- Dembner, Alice. (January 12, 2004). "Push for Patient Safety Honors Writer." *The Boston Globe*. METRO/REGION; Pg. B3.
- Dentzer, Susan. (2011). "Still Crossing The Quality Chasm--Or Suspended Over It?" *Health Affairs*, 30 (4): 554-555.
- DiMaggio, Paul J. and W.M. Powell. (1983). "The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields." *American Sociological Review* 48 (2): 147-160.
- Doheny, Kathleen. (August 8, 2008). "Dennis Quaid, Health Activist: Actor Dennis Quaid Takes on Medical Errors – and Life with Twins." *WebMD the Magazine*. ([http://www.webmd.com/parenting/features/dennis-quaid\\_health-activist](http://www.webmd.com/parenting/features/dennis-quaid_health-activist)).
- Dreyfus, Hubert L. and Paul Rabinow. (1983). *Michel Foucault: Beyond Structuralism and Hermeneutics*, 2<sup>nd</sup> edition. Chicago: The University of Chicago Press.
- Edwards, Richard. 1979. *Contested Terrain: The Transformation of the Workplace in the Twentieth Century*. New York: Basic Books.
- Edwards, Derek and Jonathan Potter. (1992). *Discursive Psychology*. London: Sage Publications.
- English, Bella. (March 25, 1995). "A Lesson Learned too Late for Betsy." *The Boston Globe*, Metro/ Region, pg. 17.
- Epstein, Steven. (1996). *Impure Science: AIDS, Activism and the Politics of Knowledge*. Berkeley, CA: University of California Press.
- Epstein, Steven. (2007). "Patient Groups and Health Movements." In *The Handbook of Science and Technology Studies*, 3<sup>rd</sup> Edition. Edited by E. Hackett, O. Amsterdamska, M. Lynch, and J. Wajcman. Cambridge: MIT Press.
- Espeland, Wendy Nelson and Mitchell L. Stevens. (1998). "Commensuration as a Social Process." *Annual Review of Sociology* 24: 313-343.
- Ewald, F. (1991). "Insurance and Risk." In *The Foucault Effect: Studies in Governmentality*, Edited by G. Burchell, C. Gordon and P. Miller. Chicago, The University of Chicago Press.
- Fairclough, Norman. (1992). *Discourse and Social Change*. Cambridge, UK: Polity Press.

- Fairclough, Norman and Ruth Wodak. (1997). "Critical Discourse Analysis." In *Discourse as Social Interaction*, Edited by Teun A. van Dijk. London: Sage Publications.
- Foucault, Michel. (1978). *The History of Sexuality, Volume I: An Introduction*. New York: Vintage.
- Foucault, Michel. (1983). "The Subject and Power." In *Michel Foucault: Beyond Structuralism and Hermeneutics, 2<sup>nd</sup> Edition*, by H. Dreyfus and P. Rabinow. Chicago: The University of Chicago Press.
- Foucault, Michel. (1991). "Governmentality." In *The Foucault Effect: Studies in Governmentality*. Edited by G. Burchell, C. Gordon and P. Miller. Chicago, The University of Chicago Press.
- Foucault, Michel. (1994). *Ethics, Subjectivity and Truth: Essential Works of Foucault, 1954-84, Volume 1*. New York: the New Press.
- Foucault, M. (1994). *Power: Essential Works of Foucault, 1954-1984, Volume 3*. New York: The New Press.
- Freidson, Eliot. (1970a). *Profession of Medicine: A Study in the Sociology of Applied Knowledge*. New York: Dodd, Mead & Company.
- Freidson, Eliot. (1970b). *Professional Dominance: The Social Structure of Medical Care*. New York: Atherton Press.
- Freidson, Eliot. (1989). *Medical Work in America: Essays on Healthcare*. New Haven: Yale University Press.
- Freidson, Eliot. (1994). *Professionalism Reborn: Theory, Prophecy, and Policy*. Chicago: The University of Chicago Press.
- Freidson, Eliot. (2001). *Professionalism: The Third Logic*. Chicago: The University of Chicago Press.
- Gawande, Atul. (2010). *The Checklist Manifesto: How to Get Things Right*. New York: Metropolitan Books.
- Gee, James Paul. (1999). *An Introduction to Discourse Analysis: Theory and Method*. New York: Routledge.
- Geertz, Clifford. (1973). *The Interpretation of Cultures; Selected Essays*. New York: Basic Books.



- Gergen, Mary. (2004). "Once Upon a Time: A Narratologist's Tale." In *Narrative Analysis: Studying the Development of Individuals in Society*, Edited by Colette Daiute and Cynthia Lightfoot. London: Sage Publications.
- Goldsmith, Marsha F. (1997). "National Patient Safety Foundation Studies Systems." *Journal of the American Medical Association* 278 (19): 1561.
- Goodman, Ellen. (March 29, 1995). "A Second Mourning Compounded by Anger." *The Boston Globe*. Op-ed, pg. 11.
- Gordon, Colin. (1991). "Governmental Rationality: An Introduction." In *Foucault Effect: Studies in Governmentality*, Edited by G. Burchell, C. Gordon and P. Miller. Chicago: The University of Chicago Press.
- Grady, Denise. (November 25, 2010). "Study Finds No Progress in Safety at Hospitals." *The New York Times*: A1.
- Guarnieri, M. (1992). "Landmarks in the History of Safety." *Journal of Safety Research* 23: 151-8.
- Hacking, Ian. (1991). "How Should We Do the History of Statistics?" In *The Foucault Effect: Studies in Governmentality*, Edited by G. Burchell, C. Gordon and P. Miller. Chicago: The University of Chicago Press.
- Haltom, William and Michael McCann. (2004). *Distorting the Law: Politics, Media, and the Litigation Crisis*. Chicago: The University of Chicago Press.
- Harvard Medical Practice Study I: Troyen A. Brennan, Lucian L. Leape, Nan M. Laird, Liesi Hebert, A. Russell Localio, Ann G. Lawthers, Joseph P. Newhouse, Paul C. Wieler, and Howard H. Hiatt. (1991). "Incidence of Adverse Events and Negligence in Hospitalized Patients." *The New England Journal of Medicine* 324 (6): 370-376.
- Harvard Medical Practice Study II: Lucian L. Leape, Troyen A. Brennan, Nan Laird, Ann G. Lawthers, A. Russell Localio, Benjamin A. Barnes, Liesi Hebert, Joseph P. Newhouse, Paul C. Weiler and Howard Hiatt. (1991). "The Nature of Adverse Events in Hospitalized Patients." *The New England Journal of Medicine* 324 (6): 377-384.
- Harvard Medical Practice Study III: A. Russell Localio, Ann G. Lawthers, Troyen A. Brennan, Nan M. Laird, Liesi E. Hebert, Lynn M. Peterson, Joseph P. Newhouse, Paul C. Weiler, and Howard H. Hiatt. (1991). "Relation Between Malpractice Claims and Adverse Events Due to Negligence." *The New England Journal of Medicine* 325 (4): 245-251.

- Haug, Marie. (1988). "A re-examination of the hypothesis of physician deprofessionalization." *Milbank Quarterly* 66 (supplement 2):48-56.
- Heimer, Carol A. and Lisa R. Staffen. (1998). *For the Sake of the Children: The Social Organization of Responsibility in the Hospital and the Home*. Chicago: the University of Chicago Press.
- Hess, David J. (2004) "Medical Modernisation, Scientific Research Fields and the Epistemic Politics of Health Social Movements," *Sociology of Health & Illness* 26(6): 695-709.
- Hewett, David G., Bernadette M Watson, Cindy Gallois, Michael Ward, and Barbara A Leggett. (2009). "Intergroup communication between hospital doctors: Implications for quality of patient care." *Social Science & Medicine* 69: 1732–1740.
- Horrobin, David F. (1977). *Medical Hubris: A Reply to Ivan Illich*. Montreal: Eden Press.
- Hurwitz, Brian and Aziz Sheikh. (2009). *Health Care Errors and Patient Safety*. West Sussex, UK: Wiley-Blackwell.
- Iedema, Rick, Arthas Flabouris, Susan Grant, Christine Jorm. (2006). "Narrativizing errors of care: Critical incident reporting in clinical practice." *Social Science & Medicine* 62: 134–144.
- Iedema, Rick and Christine Jorm, Martin Lum. (2009). "Affect is central to patient safety: The horror stories of young anaesthetists." *Social Science & Medicine* 69: 1750–1756.
- Iedema, Rick. (2009). "New approaches to researching patient safety." *Social Science & Medicine* 69: 1701–1704.
- Ilan, R. and R. Fowler. (2005). "Brief History of Patient Safety Culture and Science." *Journal of Critical Care* 20(1): 2-5.
- Illich, Ivan. (1976). *Medical Nemesis: The expropriation of health*. New York: Pantheon Books.
- Institute of Medicine. (1978). *Beyond Malpractice: Compensation for Medical Injuries*. Division of Legal, Ethical, and Educational Aspect of Health. Washington, DC: National Academy of Sciences.
- Institute of Medicine. (2000). *To Err is Human: Building a Safer Health System*. Linda

- T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, editors. Washington, DC: National Academy Press.
- Institute of Medicine. (2001). *Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century*. Committee on Quality Health Care in America, Institute of Medicine. Washington, DC: National Academy Press.
- Institute of Medicine. (2004). *Patient Safety: Achieving a New Standard of Care*. Committee on Data Standards for Patient Safety, Board on Health Care Services. Washington, DC: National Academy of Sciences.
- Jaffe, Matthew, Kate Barrett, and Tom Shine. (May 14, 2008). "Actor Calls Courts 'Only Path' to Justice for Patients Harmed by Drugs." *ABC News Online*. (<http://abcnews.go.com/Health/story?id=4848865&page=1>).
- Kerr, Anne. (2009). "A problem shared? Teamwork, autonomy and error in assisted conception." *Social Science & Medicine* 69: 1741–1749.
- King, Sorrel. (2009). *Josie's Story: A Mother's Crusade to Make Medical Care Safe*. New York: Atlantic Monthly Press.
- Klawiter, Maren. (2004). "Breast cancer in two regimes: the impact of social movements on illness experience." *Sociology of Health & Illness* 26 (6): 845–874.
- Kolker, Emily S. (2004). "Framing as a cultural resource in health social movements: funding activism and the breast cancer movement in the US 1990–1993." *Sociology of Health & Illness* 26 (6): 820–844.
- Lakoff, Andrew. (2005). *Pharmaceutical Reason: Knowledge and Value in Global Psychiatry*. New York: Cambridge University Press.
- Landrigan, Christopher P., Gareth J. Parry, Catherine B. Bones, Andrew D. Hackbarth, Donald A. Goldmann, and Paul J. Sharek. (2010). "Temporal Trends in Rates of Patient Harm Resulting from Medical Care." *The New England Journal of Medicine* 363: 2124–34.
- Landzelius, Kyra (2006) "Introduction: Patient Organization Movements and New Metamorphoses in Patienthood," *Social Science & Medicine* 62(3): 529–37.
- Larson, Magali Sarfatti. (1977). *The Rise of Professionalism: A Sociological Analysis*. Berkeley: University of California Press.

- Larson, Magali Sarfatti. (1990). "In the matter of experts and professionals, or how impossible it is to leave nothing unsaid." In Rolf Torstendahl and Michael Burrage, editors, *The Formation of Professions: Knowledge, State and Strategy*. London: Sage Publications.
- Leape, Lucian L. (1994). "Error in Medicine." *Journal of the American Medical Association* 272 (23): 1851-1857.
- Leape, Lucian L., David D. Woods, Martin J. Hatlie, Kenneth W. Kizer, Steven A. Schroeder, George D. Lundberg. (1998). "Promoting Patient Safety by Preventing Medical Error." *Journal of the American Medical Association* 280 (16): 1444-1447.
- Leape, Lucian L., Donald M. Berwick and David W. Bates. (2002). "What Practices Will Most Improve Safety? Evidence-Based Medicine Meets Patient Safety." *Journal of the American Medical Association* 288 (4): 501- 507.
- Leape, Lucian and Donald Berwick (2005). "Five Years after *To Err is Human*: What Have We Learned?" *Journal of the American Medical Association* 293 (19): 2384-2390.
- Leape, Lucian L. (2007). "Medical Errors and Patient Safety." In *The Trust Crisis in Healthcare: Causes, Consequences, and Cures*, Ed. by David A. Shore. New York: Oxford University Press.
- Leape, Lucian L. (2008). "Scope of Problem and History of Patient Safety." *Obstetrics and Gynecology Clinics of North America* 35: 1-10.
- Liecht, Kevin T. and Mary L. Fennell. (2001). *Professional Work: A Sociological Approach*. Malden, MA: Blackwell Publishers.
- Light, Donald W., and Sol Levine. (1988). "Changing character of the medical profession: A theoretical overview." *Milbank Quarterly* 66 (supplement 2):10-32.
- Light, Donald W. (2001). "Countervailing Power: The Changing Character of the Medical Profession in the United States." In *The Sociology of Health and Illness: Critical Perspectives, Sixth Edition*, Edited by Peter Conrad. New York: Worth Publishers.
- Liptak, Adam. (April 26, 2011). "Supreme Court Rejects Virginia's Request to Speed Challenge to Health Care Law." *The New York Times*: A18.
- Lubell, Jennifer. (2007). "Foreign Adventures: As the Joint Commission teams with the WHO to encourage patient safety worldwide, some wonder what's behind the move." *Modern Healthcare*. May 7, 2007: 6-7, 16.

- Macrae, Carl. (2008). "Learning from patient safety incidents: Creating participative risk regulation in Healthcare." *Health, Risk & Society* 10(1): 53 – 67.
- Marjoribanks, Timothy, Mary-Jo Delvecchio Good, Ann G. Lawthers, and Lynn M. Peterson. (1996). "Physicians' Discourses on Malpractice and the Meaning of Medical Malpractice." *Journal of Health and Social Behavior* 37 (2): 163-178.
- McCarthy, E. Doyle. (1996). *Knowledge as Culture: The New Sociology of Knowledge*. New York: Routledge.
- McKinlay, John B., and John D. Stoeckle. (1990). "Corporatization and the social transformation of doctoring." In *The sociology of health and illness: Critical perspectives, 3<sup>rd</sup> ed.* Edited by Peter Conrad and Rochelle Kern. New York: St. Martin's Press, 161-172.
- McKinlay, John B., and Lisa D. Marceau. (2002). "The end of the golden age of doctoring." *International Journal of Health Services* 32(2): 379-416.
- Mechanic, David. (2006). *The Truth About Health Care: Why Reform is Not Working in America*. New Brunswick, NJ: Rutgers University Press.
- Meyer, J. W., and J. Boli. (1997). "World Society and the Nation-State." *The American Journal of Sociology* 103 (1): 144-181.
- Miami Herald*. (March 24, 1995). "Another Fatal Error, this Time at Revered Boston Hospital." Section A; Page 1, Column 4.
- Millman, M. (1977). *The Unkindest Cut: Life in the Backrooms of Medicine*. New York: Morrow Quill Paperbacks.
- Mills, Sara. (2004). *Discourse*. London: Routledge.
- Murphy, Katie. (2006). "What Pilots Can Teach Hospitals About Patient Safety." *The New York Times*: D6, D10.
- Murphy, Raymond. (1990). "Proletarianization or bureaucratization: the fall of the professional?" In *The Formation of Professions: Knowledge, State and Strategy*. Edited by Rolf Torstendahl and Michael Burrage. London: Sage Publications.
- Nadesan, Majia. (2008). *Governmentality, Biopower and Everyday Life*. New York: Routledge.

- National Patient Safety Foundation. (2007). Congress Program: *Learning from the Past, Creating the Future*.
- Niedowski, Erika. (December 14, 2003). "How medical error took a little girl's life." *The Baltimore Sun*: 1.A.
- Niedowski, Erika. (December 15, 2003). "From Tragedy, a Quest for Safer Care." *The Baltimore Sun*: 1.A.
- Noble, David. (1977). *America by Design: Science, Technology and the Rise of Corporate Capitalism*. New York: Knopf.
- Ocloo, Josephine Enyonam. (2010). "Harmed patients gaining voice: Challenging dominant perspectives in the construction of medical harm and patient safety reforms." *Social Science & Medicine* 71:510-516.
- O'Malley, Pat. (1996). "Risk and Responsibility." In *Foucault and Political Reason: Liberalism, neo-liberalism and rationalities of government*, Edited by A. Barry, T. Osbourne, N. Rose. Chicago: The University of Chicago Press.
- O'Malley, Pat. (2008). "Governmentality and Risk." In *Social Theories of Risk and Uncertainty: An Introduction*, Edited by Jens O. Zinn. Malden, MA: Blackwell Publishing.
- O'Malley, Pat. (2010). *Crime and Risk*. London: Sage Publications.
- Orszag, Peter. (November 4, 2010). "To Save Money, Save the Health Care Act." *The New York Times*: A29.
- Ovretveit, John. (2009). "The contribution of new social science research to patient safety." *Social Science & Medicine* 69: 1780–1783.
- Pear, Robert. (June 22, 2010). "Health Agency Nominee Faces Confirmation Battle." *The New York Times*: A18.
- Pear, Robert. (March 7, 2011). "Rising Calls to Replace Top Man at Medicare." *The New York Times*: A12.
- Perrow, C. (1984). *Normal Accidents: Living with High-Risk Technologies*. New York: Basic Books.
- The Philadelphia Inquirer* (March 25, 1995). "Cancer Center Admits Role in a Death Patient was Mistakenly Given Four Times a Recommended Dosage." National, A04.

- Power, Richenda. (2000). *A Question of Knowledge*. Essex, UK: Pearson Education Limited.
- Pronovost, Peter J. and Ruth R. Faden. (2009). "Setting Priorities for Patient Safety: Ethics, Accountability, and Public Engagement." *Journal of the American Medical Association*. 302(8):890-891.
- Pronovost, Peter and Eric Vohr. (2010). *Safe Patients, Smart Hospitals: How One Doctor's Checklist Can Help Us Change Health Care From the Inside Out*. New York: Hudson Street Press.
- Quadagno, Jill. (2004). "Physician Sovereignty and the Purchasers' Revolt." *Journal of Health Politics, Policy and Law* 29 (4-5): 815-834.
- Quaid, Dennis, Julie Thao, and Charles R. Denham. (2010). "Story Power: The Secret Weapon." *Journal of Patient Safety* 6: 5-14.
- Rand Technical Report - Beckett, Megan K., Donna Fossum, Connie S. Moreno, Jolene Galegher, and Richard S. Marken. (2006). *A Review of Current State-Level Adverse Medical Event Reporting Practices: Toward National Standards*. Rand Technical Report prepared for the Agency for Healthcare Research and Quality. Santa Monica, CA: Rand.
- Reynard, John, John Reynolds and Peter Stevenson. (2009). *Practical Patient Safety*. Oxford: Oxford University Press.
- Richmond, Julius B. and Rashi Fein. (2005). *The Health Care Mess: How We Got Into It and What It Will Take to Get Out*. Cambridge, MA: Harvard University Press.
- Rose, Nikolas. (1996). "Psychiatry as a Political Science: Advanced Liberalism and the Administration of Risk." *History of the Human Sciences* 9 (1): 1-23.
- Rosen, Marty. (April 9, 1995). "Staff Cuts Alarm Hospital Experts." *St. Petersburg Times*. TAMPA BAY AND STATE; Pg. 1B.
- Rowe, Michael. (2004). "Doctors' responses to medical errors." *Critical Reviews in Oncology/Hematology* 52:147-163.
- Sack, Kevin and Robert Pear. (November 26, 2010). "Health Law Faces Threat of Undercut from Courts." *The New York Times*: A11.
- Schimmel, E.M. (1964). "The Hazards of Hospitalization." *Annals of Internal Medicine* 60:100-10.

- Scott, W. Richard, Martin Ruef, Peter J. Mendel, and Carol A. Caronna. (2000). *Institutional Change and Healthcare Organizations: From Professional Dominance to Managed Care*. Chicago: The University of Chicago Press.
- Sharp, Deborah. (March 27, 1995). "Errors Renew the Call for Doctor Review." *USA Today*. NEWS; Pg. 1A
- Shenhav, Yehouda. 1999. *Manufacturing Rationality: The Engineering Foundations of the Managerial Revolution*. New York: Oxford University Press.
- Skocpol, Theda. (1997). *Boomerang: Health Care Reform and the Turn Against Government*. New York: W.W. Norton and Company.
- Silbey, Susan S. (2009). "Taming Prometheus: Talk About Safety and Culture" *Annual Review of Sociology* 35: 341–69.
- Simon, Jonathan. (1988). "The Ideological Effects of Actuarial Practices." *Law and Society Review* 22 (4): 771-800.
- Small, S.D. and P. Barach (2002). "Patient Safety and Health Policy: A History and Review." *Hematology/ Oncology Clinics of North America* 16(6): 1463-82.
- Squire, Corinne, Molly Andrews and Maria Tamboukou. (2004). "Introduction: What is Narrative Research?" In *Doing Narrative Research*, Edited by Molly Andrews, Corinne Squire, and Maria Tamboukou. London: Sage.
- Studdert, David M., Eric J. Thomas, Helen R. Burstin, Brett I.W. Zbar, E. John Orav, and Troyen A. Brennan. (2000). "Negligent Care and Malpractice Claiming Behavior in Utah and Colorado." *Medical Care* 38 (3): 250-260.
- Tamboukou, Maria. (1999). "Writing Genealogies: An Exploration of Foucault's Strategies for Doing Research." *Discourse* 20 (2): 201-18.
- Taylor, Frederick. 1912. *Principles of Scientific Management*. New York: Norton.
- Taylor, Verta and Mayer N. Zald. 2010. "Conclusion: The Shape of Collective Action in the U.S. Health Sector." In Jane C. Banaszak-Holl, Sandra R. Levitsky, Mayer N. Zald, Eds, *Social Movements and the Transformation of American Healthcare*. New York: Oxford University Press.
- Timmermans, Stefan and Marc Berg. (2003). *The Gold Standard: The Challenge of Evidence-Based Medicine and Standardization in Health care*. Philadelphia: Temple University Press.



- Timmermans, Stefan and Steven Epstein. (2010). "A World of Standards but not a Standard World: Toward a Sociology of Standards and Standardization." *Annual Review of Sociology* 36: 69-89.
- Timmermans, Stefan and Hyeyoung Oh. (2010). "The Continued Social Transformation of the Medical Profession." *Journal of Health and Social Behavior* 51: S94.
- Torring, Jacob. (1999). *New Theories of Discourse: Laclau, Mouffe, and Zizek*. Oxford, UK: Blackwell Publishers.
- Vaughan, D. (1996). *The Challenger Launch Decision: Risky Technology, Culture, and Deviance at NASA*. Chicago: University of Chicago Press.
- Vincent, Charles. (2009). "Social scientists and patient safety: Critics or contributors?" *Social Science & Medicine* 69: 1777–1779.
- Voelker, Rebecca. (1997). "IHI Views Collaboration vs Competition in Quality." *Journal of the American Medical Association* 278 (19): 1560.
- Waring, Justin J. (2005). "Beyond blame: cultural barriers to medical incident reporting." *Social Science & Medicine* 60: 1927–1935.
- Waring, Justin J. (2007a). "Doctors' thinking about 'the system' as a threat to patient safety." *Health: An Interdisciplinary Journal for the Social Study of Health, Illness and Medicine* 11(1): 29-46.
- Waring, Justin. (2007b). "Adaptive regulation or governmentality: patient safety and the changing regulation of medicine." *Sociology of Health & Illness* 29 (2): 163–179.
- Waring, Justin J. (2009). "Constructing and re-constructing narratives of patient safety." *Social Science & Medicine* 69: 1722–1731.
- The Washington Post*. (2010). *Landmark: The Inside Story of America's New Health-Care Law and What It Means for Us All*. New York: Public Affairs.
- Weiner, Bryan Jeffrey, Cherri Hobgood, and Megan A. Lewis. (2008). "The meaning of justice in safety incident reporting." *Social Science & Medicine* 66: 403–413.
- White, William D. (2004). "Reason, Rationalization, and Professionalism in the Era of Managed Care." *Journal of Health Politics, Policy and Law* 29 (4-5): 853-868.
- Whyte, Sarah, Carrie Cartmill, Fauzia Gardezi, Richard Reznick, Beverley A Orser, Diane Doran, and Lorelei Lingard. (2009). "Uptake of a team briefing in the

- operating theatre: A Burkean dramaturgical analysis.” *Social Science Medicine* 69: 1757–1766.
- Wiener, Carolyn L. (2000). *The Elusive Quest: Accountability in Hospitals*. Hawthorne, NY: Aldine De Gruyter.
- Wood, Linda A. and Rolf O. Kroger. (2000). *Doing Discourse Analysis: Methods for Studying Action in Talk and Text*. London: Sage Publications.
- World Health Organization. (2005a). *A Year of Living Less Dangerously. World Alliance for Patient Safety Progress Report 2005*. Geneva, Switzerland: WHO Press.
- World Health Organization. (2005b). *World Alliance for Patient Safety. Global Patient Safety Challenge, 2005-2006*. Geneva, Switzerland: WHO Press.
- World Health Organization. (2005c). *World Alliance for Patient Safety. WHO Guidelines on Hand Hygiene in Healthcare (Advanced Draft): A Summary*. Geneva, Switzerland: WHO Press.
- World Health Organization. (2006). *World Alliance for Patient Safety: Forward Programme, 2006-2007*. Geneva, Switzerland: WHO Press.
- Wynne, Brian. (1989). “Establishing the Rules of Laws: Constructing Expert Authority.” In R. Smith and B. Wynne, Editors, *Expert Evidence: Interpreting Science in the Law*. London: Routledge.
- Zinn, Jens O. (2008). “A Comparison of Sociological Theorizing on Risk and Uncertainty.” In *Social Theories of Risk and Uncertainty: An Introduction*, Edited by Jens O. Zinn. Malden, MA: Blackwell Publishing.
- Zuiderent-Jerak, Teun, Mathilde Strating, Anna Nieboer, and Roland Bal. (2009). “Sociological refigurations of patient safety; ontologies of improvement and ‘acting with’ quality collaboratives in healthcare.” *Social Science & Medicine* 69: 1713–1721.

## II. Websites and Internet References

### A. *Websites for Organizations, Agencies, Campaigns*

Agency for Healthcare Research and Quality –  
National Strategy for Quality Improvement in Health Care.  
<http://www.ahrq.gov/workingforquality/>

American Society of Professionals in Patient Safety (ASPPS) at NPSF:  
<http://www.npsf.org/hp/ASPPS.php>.

Consumers Advancing Patient Safety  
<http://www.patientsafety.org/>

The Global Patient Safety Forum:  
<http://www.globalpatientsafetyforum.org/#>

Institute for Healthcare Improvement  
<http://www.ihl.org/>

The Joint Commission:  
<http://www.jointcommission.org/>

The Josie King Foundation  
<http://www.josieking.org/>

The Leapfrog Group:  
<http://www.leapfroggroup.org/>

Lucian Leape Institute at the National Patient Safety Foundation:  
<http://www.npsf.org/lli/>

National Patient Safety Foundation:  
<http://www.npsf.org/>

National Quality Forum:  
<http://www.qualityforum.org/>

National Strategy for Quality Improvement in Health Care  
 From <http://www.healthcare.gov/center/reports/quality03212011a.html>

Partnership for Patients Program Website  
<http://www.healthcare.gov/center/programs/partnership/index.html>

World Health Organization – Patients for Patient Safety:  
[http://www.who.int/patientsafety/patients\\_for\\_patient/en/](http://www.who.int/patientsafety/patients_for_patient/en/)

World Health Organization – World Alliance for Patient Safety:  
<http://www.who.int/patientsafety/en/>

## *B. Internet References*

“Barack Obama’s Plan for a Healthy America: Lowering health care costs and ensuring affordable, high-quality health care for all”, document downloaded from [www.barackobama.com](http://www.barackobama.com) (accessed 9/15/08).

“Obama Addresses Physicians at AMA Meeting: Transcript of President Obama's Remarks” (June 15, 2009)  
 2009 Annual Meeting of the AMA House of Delegates  
 Hyatt Regency Hotel Chicago, Ill.  
<http://www.ama-assn.org/ama/pub/about-ama/our-people/house-delegates/2009-annual-meeting/speeches/president-obama-speech.page>

TMIT – Charles Denham and Dennis Quaid  
[\(http://www.safetyleaders.org/Quaid/\)](http://www.safetyleaders.org/Quaid/)  
 SafetyLeaders.org: TMIT About Us.  
<http://www.safetyleaders.org/templates/idPage.jsp?ID=1616>).  
 TMIT – Care Moms  
<http://www.safetyleaders.org/CareMoms/home.jsp?step=2#tabs>

Discovery Patient Safety Documentary – *Chasing Zero*  
 (<http://discoveryhealthcme.discovery.com/zero/zero.html>);  
 (<http://dsc.discovery.com/videos/chasing-zero-part-1.html>).

Dennis Quaid's Television appearances:

Medical Mistakes: Dr. Oz Talks to Actor Dennis Quaid," *Oprah Winfrey Show*,  
 March 10, 2009 ([http://www.oprah.com/showinfo/Medical-Mistakes-Dr-Oz-Talks-to-Actor-Dennis-Quaid\\_1](http://www.oprah.com/showinfo/Medical-Mistakes-Dr-Oz-Talks-to-Actor-Dennis-Quaid_1))

"360° Big Interview: Dennis Quaid speaks out," *AC 360*, April 22nd, 2010  
 (<http://ac360.blogs.cnn.com/2010/04/22/photo-gallery-dennis-quaid-speaks-out/> )

"Dennis Quaid Recounts Twins' Drug Ordeal," *CBS 60 Minutes*, August 24, 2008  
 (segment was originally broadcast on March 16, 2008, updated on August 22, 2008)  
 ([http://www.cbsnews.com/stories/2008/03/13/60minutes/main3936412\\_page4.shtml?tag=contentMain;contentBody](http://www.cbsnews.com/stories/2008/03/13/60minutes/main3936412_page4.shtml?tag=contentMain;contentBody))

"Dennis Quaid: Medical Errors Happen "Too Often," *CBS Early Show*, April 12, 2010  
 (<http://www.cbsnews.com/stories/2010/04/12/earlyshow/health/main6387793.shtml>)

For example, *The Huffington Post* carried the *60 Minutes* story, along with references in the health blogs of the *New York Times* and the *Wall Street Journal*, among many others.

"Dennis Quaid Recounts Twins' Drug Ordeal," *CBS 60 Minutes*, August 24, 2008 (segment was originally broadcast on March 16, 2008, updated on August 22, 2008)  
 ([http://www.cbsnews.com/stories/2008/03/13/60minutes/main3936412\\_page4.shtml?tag=contentMain;contentBody](http://www.cbsnews.com/stories/2008/03/13/60minutes/main3936412_page4.shtml?tag=contentMain;contentBody))

Partnership for Patients Press Release  
<http://www.hhs.gov/news/press/2011pres/04/20110412a.html>

Wachter, Bob. (2011). "The Partnership for Patients: The Inside Scoop on a Game Changing Safety Initiative" Available on *The Health Care Blog*  
<http://thehealthcareblog.com/blog/2011/04/12/the-partnership-for-patients-the-inside-scoop-on-a-game-changing-safety-initiative/>

### **III. 2007 National Patient Safety Congress - May 3-4, Washington DC**

*Field Notes derived from attendance at the following panels:*

|                          |                                                    |
|--------------------------|----------------------------------------------------|
| Thursday, May 3, 10:00am | Research Future - 105                              |
| Thursday, May 3, 11:15am | Tension, Trust, Transparency - 208                 |
| Thursday, May 3, 1:30pm  | Engagement Towards a Shared Vision - 304           |
| Thursday, May 3, 3:30pm  | Plenary Address: Distinguished Advisors Town Hall  |
| Friday, May 4, 10:30am   | Engagement toward a Shared Vision - 404            |
| Friday, May 4, 1:00pm    | Medication and Device Safety - 501                 |
| Friday, May 4, 2:45pm    | Closing Plenary: Tort Reform from Key Stakeholders |