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Harmonizing the Affordable Care Act with the Three Main National Systems for Healthcare Quality Improvement: The Tort, Licensure, and Hospital Peer Review Hearing Systems

Katharine Van Tassel[†]

INTRODUCTION

In 1999, an Institute of Medicine report revealed the startling news that treatment errors in hospitals were the cause of up to 98,000 deaths annually.¹ In a recent 2012 update on this situation, a Consumer Reports investigation concluded that approximately 2.25 million people in the United States will likely die from medical harm in the next decade.² Thus, the Institute of Medicine report and the follow-up Consumer

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

² *How Safe Is Your Hospital? Our New Ratings Find That Some Are Riskier than Others*, CONSUMER REPORTS (Aug. 2012), <http://www.consumerreports.org/cro/magazine/2012/08/how-safe-is-your-hospital/index.htm>. (“More than 2.25 million Americans will probably die from medical harm this decade That’s like wiping out the entire populations of North Dakota, Rhode Island, and Vermont. It’s a manmade disaster.”). In the decade since the IOM Report was published, this situation has not improved. A new study by the Department of Health and Human Services estimates that one in seven Medicare patients (thirteen and a half percent) experience an adverse event each month in American hospitals, and some 15,000 die every month as a result. Deborah Huso, *Medical Errors Kill 15,000 Medicare Patients a Month*, DR. HANSEN CHIROPRACTIC (Nov. 17, 2010), http://drhansenchiropractic.com/blog/b_3884_medical_errors_kill_15000_medicare_patients__month.html. This makes medical errors in hospitals one of the leading causes of death in the nation. A recent *Healthgrades* study estimates that more than 230,000 hospital deaths from 2007 to 2009 could have been prevented within the Medicare population alone. KRISTEN REED & RICK MAY, HEALTHGRADES, THE THIRTEENTH ANNUAL HEALTHGRADES HOSPITAL QUALITY IN AMERICA STUDY 2 (2010), available at <http://www.healthgrades.com/business/img/HealthGradesHospitalQualityInAmericaStudy2010.pdf>.

Reports investigation published over a decade later suggest that the three main systems in the United States tasked with improving the quality of patient care—the state medical malpractice and licensure systems and the private hospital peer review hearing system—are all failing at their missions.

A large and rapidly growing group of empirical studies suggests that the current normative practice of custom-based medicine in the United States may be partly to blame. Custom-based medical practice can have a profoundly negative impact on the quality and cost of healthcare. This is the same standard that the three main U.S. quality improvement systems rely upon to measure physician competence. The customary care (or eminence-based) model of medical practice is based on physician preference grounded in tradition, opinion, or clinical experience and not on objective, scientific evidence.

The quality and cost problems with the customary care model of medical practice have led to new national initiatives to move the United States to a contemporary, evidence-based model of medical practice. These initiatives have led to major changes in government-provided healthcare. These changes appear in the Veterans Administration (VA) Hospital System, Medicare, and in the major new rules governing private healthcare insurance sold over Health Benefit Exchanges pursuant to the Patient Protection and Affordable Care Act of 2010 (also known as the ACA or “Obama Care”). The evidence-based model of medical practice is grounded in empirical data created by clinical outcomes and effectiveness research. This empirical data can recommend the best treatment for a steadily increasing number of clinical disorders. This use of evidence-based medical practice shows great promise for improving quality of care while reducing its cost.³

This article addresses the question of whether the three main systems for improving healthcare quality in the United States are following the government’s lead by encouraging the adoption of evidence-based medical practice. Unfortunately, the short answer is no.

Reflecting an understanding of the benefits of evidence-based treatment choices, a minority of state tort systems have

³ Katharine A. Van Tassel, *Hospital Peer Review Standards and Due Process: Moving from Tort Doctrine Toward Contract Principles Based on Clinical Practice Guidelines*, 36 SETON HALL L. REV. 1179, 1194-97 (2006); see also Ronen Avraham, *Private Regulation*, 34 HARV. J.L. & PUB. POLY (2009) (advocating this same use of CPGs by hospitals but adding a proposal of providing immunity from suit for those who apply CPGs).

stepped away from using customary care as the exclusive proxy for quality of care in medical malpractice actions. These tort systems are allowing the introduction of risk–benefit analysis grounded in empirical science as evidence of what constitutes reasonable care. Thus, this article argues that these minority state tort systems are operating instrumentally to encourage the transition away from custom-based medical practice and toward evidence-based medical practice. By virtue of applying their own state law, the state licensure systems of this minority group of states will follow suit. On the other hand, the majority of state tort systems continue to rely on customary care to measure quality, with their licensure systems mirroring this choice. This means that the ACA, and other federal programs such as Medicare, are on a collision course with the majority of state tort and licensure systems over the practice of evidence-based medicine.

The third major system for improving quality of care is the private hospital peer review system. Private hospital peer review is a self-policing system where physicians informally evaluate each other and sanction those physicians who are allegedly failing to provide quality patient care. This article asserts that hospital peer review, like the tort and licensure systems, encourages the perpetuation of custom-based practices and undermines national efforts to improve the quality and cost of healthcare through the practice of evidence-based treatment choices. However, the hospital peer review system provides an even stronger disincentive to the adoption of evidence-based medicine than the other quality systems because the outcome of hospital peer review could be the loss of a physician's entire career.

Unfortunately, while the ACA has at least some provisions addressing the need to make changes in the medical malpractice and licensure systems to encourage the use of evidence-based standards of care, the ACA completely ignores the hospital peer review system. This article makes specific suggestions for how to revise all three major systems so that they can work in tandem with federal law to encourage physicians to adopt the evidence-based model of medical practice in order to improve healthcare quality, cost, and access.

This article starts by explaining the difference between customary care treatment choices and evidence-based treatment choices. Next, the article explains how customary care can be poor quality care, how the customary treatment choice of a particular region can be more related to geography than to quality, and how customary treatment can be costly

treatment. This article then outlines how federally provided healthcare pursuant to the ACA, as well as Medicaid and the VA Hospital System, have adopted evidence-based treatment choices that show great promise for enhancing quality of care while decreasing the cost of care. The article goes on to explain how the three U.S. systems for improving quality of care—the state medical malpractice and licensure systems, and the private hospital peer review hearing system—are acting instrumentally to thwart national efforts to move to modern, evidence-based healthcare. This article accomplishes this by citing empirical research and providing a working example of how a physician risks medical malpractice liability, or the loss of the ability to practice medicine entirely through hospital peer review, by choosing the evidence-based treatment choice rather than adhering to the customary treatment choice.

Finally, this article proposes specific solutions to this disconnect between federally provided healthcare pursuant to the ACA, Medicaid, and the VA Health System, and the other three systems for improving health care quality, cost, and access. These solutions involve both top-down and bottom-up strategies. In the context of the tort and licensure systems, the solution is top-down because it requires action on the part of state legislatures or court systems. It is up to legislators or judges to change the scope of the admissible evidence in medical malpractice and licensure cases, either by statute or case law, to allow risk-benefit analysis based on empirical evidence to become admissible on the issue of the standard of care.

On the other hand, the solution is bottom-up when it comes to hospital peer review. This article proposes that hospital peer review be completely restructured through the application of a blend of knowledge translation theory with continuous quality improvement research. This blended approach will put knowledge into action by integrating into physician practice evidence-based treatment choices using clinical practice guidelines. Relying on the paternalistic libertarian theory developed by Professors Cass Sunstein and Richard Thaler, this proposed system relies upon “gold standard” clinical practice guidelines as the default treatment choice, but then allows for individual physician choice in deviating from this default choice if it is reasonable to do so. This exception allows for the high level of scientific uncertainty that exists currently when it comes to many medical conditions, particularly in the realm of the treatment of outliers. As the practice of evidence-based medicine (also

known as population-based medicine or the treatment of “norm”) grows through the greater understanding of optimal treatment choices through big data techniques to establish comparative effectiveness—and later transitions to personalized medicine based on the treatment of individuals according to their unique genetic profiles—the currently high degree of scientific uncertainty will steadily diminish and reduce the use of this exception.

I. THE NEGATIVE IMPACT OF CUSTOMARY CARE PRACTICES ON THE QUALITY AND COST OF HEALTHCARE

A. *Evidence-Based Versus Custom-Based Care*

As a general matter, *customary care* is care that would customarily be given by other physicians under the same or similar circumstances. Customary care is subjective and is based on physician preference (grounded on tradition, opinion, or clinical experience⁴) and not on objective, scientific evidence. In contrast, the evidence-based model for medical practice is grounded on empirical data created through the use of clinical outcomes and effectiveness research. This empirical data can recommend the best treatment for a steadily increasing number of clinical disorders.

The practice of providing customary care (also referred to by many as “eminence-based medicine”) is the normative practice in the United States. Unfortunately, a steadily growing group of studies demonstrates that many customary treatment choices can have a negative impact on the quality of care. Another large group of studies indicates that there is a wide variation in custom for the same medical condition across the country and that the choice of customary treatment can be related more to geography than to quality. Finally, there are a rapidly mounting number of studies that show the significant negative impact of some customary care choices on the cost of healthcare.

⁴ See THE IOWA CONSORTIUM FOR SUBSTANCE ABUSE RESEARCH & EVALUATION, EVIDENCE-BASED PRACTICES: AN IMPLEMENTATION GUIDE FOR COMMUNITY-BASED SUBSTANCE ABUSE TREATMENT AGENCIES 3 (2003), available at <http://www.uiowa.edu/~iowapic/files/EBP%20Guide%20-%20Revised%205-03.pdf> (The Iowa Consortium for Substance Abuse Research and Evaluation is based at the University of Iowa).

These problems with customary care have, over time, become well documented by the Dartmouth Atlas of Health Care.⁵ The Dartmouth Atlas describes itself as follows:

For more than 20 years, the Dartmouth Atlas Project has documented glaring variations in how medical resources are distributed and used in the United States. The project uses Medicare data to provide information and analysis about national, regional, and local markets, as well as hospitals and their affiliated physicians. This research has helped policymakers, the media, health care analysts and others improve their understanding of our health care system and forms the foundation for many of the ongoing efforts to improve health and health systems across America.⁶

In a special report issued by the Dartmouth Atlas Project (DAP), three categories of customary care were distinguished: failure to provide necessary care, preference-sensitive care, and supply-sensitive care.⁷ This article adds an additional category: misuse of medical care.

The DAP defines the first category of customary care as the failure to provide needed care.⁸ The failure to provide needed, or necessary, care is referred to in this article as the underuse of care. Examples of the types of customary care that fall into the category of underuse of care are provided in Part

⁵ *The Dartmouth Atlas of Healthcare*, <http://www.dartmouthatlas.org/> (last visited Apr. 11, 2013) [hereinafter *Dartmouth Atlas*].

The Dartmouth Atlas Project (DAP) began in 1993 as a study of health care markets in the United States, measuring variations in health care resources and their utilization by both geographic areas. More recently, the research agenda has expanded to reporting on the resources and utilization among patients at specific hospitals. DAP research uses very large claims databases from the Medicare program and other sources to define where Americans seek care, what kind of care they receive, and to determine whether increasing investments in health care resources and their use result in better health outcomes for Americans. The Dartmouth Atlas is a product of the Center for the Evaluative Clinical Sciences at Dartmouth Medical School.

Press Release, Geisel Sch. of Med. at Dartmouth, New Study Shows Need for a Major Overhaul of How United States Manages Chronic Illness (May 16, 2006), *available at* http://geiselmed.dartmouth.edu/news/2006_h1/16may2006_overhaul.shtml [hereinafter Dartmouth Press Release].

⁶ *Dartmouth Atlas*, *supra* note 5.

⁷ ELLIOT S. FISHER ET AL., REGIONAL AND RACIAL VARIATION IN HEALTH CARE AMONG MEDICARE BENEFICIARIES: A BRIEF REPORT OF THE DARTMOUTH ATLAS PROJECT 24 (Kristen K. Bronner ed., 2008), *available at* http://www.dartmouthatlas.org/downloads/reports/AF4Q_disparities_Dec2008.pdf.

⁸ *Id.* The DAP describes effective care as “consist[ing] of evidence-based services such as HemoglobinA1c testing for diabetics. Variations in effective care reflect failure to deliver needed care.”

I.B. Also discussed in Part I.B is the second category of customary care: the misuse of medical care. While underuse is an omission error, misuse is the wrong choice of medical care and therefore represents a commission error.

The third category of customary care is preference-sensitive care, which includes care for medical conditions for which there are multiple treatment options, each with its own benefits and trade-offs.⁹ The broad geographical variations in the use of preference-sensitive customary care, referred to in this article as an unwarranted variation in care, are set forth in Part I.C.

The fourth category of customary care is supply-sensitive care, which represents care for which the supply of a specific resource (for example, the number of physicians, hospital beds, or specialized testing equipment) heavily influences the customary amount of care provided.¹⁰ With supply-sensitive care, the amount of spending on the same condition also varies widely depending on where the patient lives.¹¹ Supply-sensitive customary care is also referred to as the overuse of medical care in this article. These broad variations in the use of medical care are discussed in Part I.D.

B. Customary Care Can Be Poor Quality Care: Misuse and Underuse

The last several decades of public health research have revealed that customary care can actually be “bad” patient care. Customary care can lead to misuse and underuse of the delivery of healthcare. Misuse occurs when the wrong care is provided. Underuse is the failure to deliver necessary healthcare; in other words, care for which the benefits clearly outweigh the risks.¹²

The 1980s brought the first group of studies that revealed that many customary treatment choices resulted in the misuse of healthcare. These studies exposed “serious weaknesses in the scientific underpinnings of many customary practices.”¹³ For example, the use of certain respiratory

⁹ *Id.*

¹⁰ *Id.*

¹¹ *See id.*

¹² Minal S. Kale et al., *Trends in the Overuse of Ambulatory Health Care Services in the United States*, ARCH. INTERN. MED. E1, E1-E2 (2012).

¹³ Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, 54 LAW & CONTEMP. PROBS. 87, 88-89 & n.6 (1991) (citing, for

techniques and gastric freezing of ulcers, which were quickly adopted as “standard practice,” were ultimately discredited by scientific studies.¹⁴ More recently, the practice of prescribing a choice among a broad array of antibiotics for uncomplicated urinary tract infections was identified as misuse—only the prescription of nitrofurantoin, trimethoprim-sulfamethoxazole, or quinolone is appropriate.¹⁵ Another study disclosed that medications are customarily misused in elderly patients 7.2% of the time.¹⁶ Other common practices that have been discredited are the routine use of antiarrhythmic drugs for all patients with irregular heartbeats after a heart attack¹⁷ and the long-held, but erroneous, belief that hormone replacement therapy prevents heart disease in women.¹⁸ It has also been established that lumbar discectomy, the most common surgical treatment for those with back and leg pain, is largely unnecessary.¹⁹ And in 2011, a study was published that

example, David M. Eddy & John Billings, *The Quality of Medical Evidence: Implications for Quality of Care*, HEALTH AFF., Spring 1988, at 19, 20 (“For at least some important practices, the existing evidence is of such poor quality that it is virtually impossible to determine even what effect the practice has on patients, much less whether that effect is preferable to the outcomes that would have occurred with other options.”); David M. Eddy, *Clinical Policies and the Quality of Clinical Practice*, 307 NEW ENG. J. MED. 343, 343 (1982) (“[T]here is reason to believe that there are flaws in the process by which the profession generates clinical policies.”).

¹⁴ See, e.g., Havighurst, *supra* note 13, at 88-89 & n.6; Eddy, *supra* note 13, at 343.

¹⁵ Kale et al., *supra* note 12, at E1-E2 (“[U]se of antibiotics other than nitrofurantoin, trimethoprim-sulfamethoxazole or quinolone” is the incorrect treatment for “uncomplicated urinary tract infections.”).

¹⁶ *Id.* at E5.

¹⁷ Christine Gorman, *Are Doctors Just Playing Hunches*, TIME (Feb. 15, 2007), <http://www.time.com/time/magazine/article/0,9171,1590448,00.html>. The long-followed, customary practice of physicians has been to prescribe antiarrhythmia drugs to every patient who experiences irregular heartbeats after a heart attack. *Id.* A surprising study showed that patients with only mild arrhythmias are more likely to die if they take antiarrhythmia drugs. *Id.* Based on this empirical evidence, some physicians have modified their practice and adopted the evidence-based choice, and give the medication only to those with severe cardiac arrhythmias post heart attack. *Id.* But some still have not. *Id.*

¹⁸ Mark A. Hlatky et al., *Quality-of-Life and Depressive Symptoms in Postmenopausal Women After Receiving Hormone Therapy: Results From the Heart and Estrogen/Progestin Replacement Study (HERS) Trial*, 287 JAMA 591, 591 (2002) (finding that in 2763 postmenopausal women with pre-existing coronary artery disease who were randomly assigned to take either estrogen/progestin HRT or a placebo, researchers found no overall reduction in the rate of coronary heart disease events among the women receiving HRT compared to those receiving the placebo). This new reality altered the risk-benefit calculus that was formerly used to recommend hormone replacement therapy to tens of thousands of women. See generally *id.*

¹⁹ James N. Weinstein et al., *Surgical v. Non-Operative Treatment for Lumbar Disc Herniation*, 296 JAMA 2441, 2445, 2447 (2006). Those who had surgery and those who were provided with more conservative treatment, such as physical therapy, reached the same level of recovery. *Id.*

estimated that the choice to surgically implant cardioverter-defibrillators (ICDs) was incorrect 20%–40% of the time.²⁰

On the other hand, a large group of physicians stick to customary practices of *not* providing important medical care, even in the face of empirical evidence that those treatments would greatly benefit their patients, in many cases placing their patients at a significantly increased risk of death. These customs represent *underuse* of healthcare.²¹ A major study was released in 2005²² that surprised many. This study uncovered the unfortunate failure of both physicians and hospitals to provide treatments that were essential for saving the lives of those who suffered from the most common causes of death—pneumonia, heart attack, and heart failure.²³

A major study published on December 24, 2012, suggests that there has been little improvement on the part of individual physicians in this underuse problem in the seven years since the 2005 study.²⁴ For example, physicians fail to provide antithrombotic treatment for atrial fibrillation 28.1% of the time.²⁵ This treatment, when provided, decreases the risk of stroke for these patients.²⁶ Physicians fail to provide aspirin 35.5% of the time, beta-blockers 44.8% of the time, and statins 41.4% of the time for patients with coronary heart disease.²⁷ Aspirin reduces the occurrence of vascular events in patients with coronary artery disease, including myocardial infarction

²⁰ Sana M. Al-Khatib et al., *Non-Evidence-Based ICD Implantations in the United States*, 305 JAMA 43, 43 (2011). The use of implantable cardioverter-defibrillators (ICDs) can prevent sudden cardiac death. *Id.* In the study, over 20% of patients were given surgically implanted ICDs inappropriately. *Id.* at 45. The percentage of inappropriate implantation of ICDs was as high as 40%. *Id.* at 48.

²¹ See Kale et al., *supra* note 12, at E1.

²² Ashish K. Jha et al., *Care in U.S. Hospitals—The Hospital Quality Alliance Program*, 353 NEW ENG. J. MED. 265, 265 (2005).

²³ See Ford Fessenden, *It's the Simple Things, but Some Hospitals Don't Do Them*, N.Y. TIMES, Aug. 21, 2005, § 4, at 43, available at http://www.nytimes.com/learning/teachers/featured_articles/20050822monday.html. For example, patients who are prescribed aspirin within the first twenty-four hours after a heart attack have up to a thirty percent improvement in their rate of survival. *Id.* However, many physicians fail to provide this very simple, life-saving treatment.

²⁴ Kale et al., *supra* note 12.

²⁵ *Id.* at E2.

²⁶ N.A. Mark Estes III et al., *ACC/AHA/Physician Consortium 2008 Clinical Performance Measures for Adults With Nonvalvular Atrial Fibrillation or Atrial Flutter: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and the Physician Consortium for Performance Improvement (Writing Committee to Develop Clinical Performance Measures for Atrial Fibrillation)*, 117 CIRCULATION 1101-20 (2008), available at <http://circ.ahajournals.org/content/117/8/1101.full.pdf+html> (“Atrial fibrillation is associated with an increased risk of stroke, heart failure, and all-cause mortality, especially in women.”).

²⁷ Kale et al., *supra* note 12, at E2.

and death.²⁸ Failure to prescribe beta-blockers “can be associated with a broad range of adverse outcomes, including all-cause and cardiovascular mortality, cardiovascular hospitalizations, and the need for revascularization procedures.”²⁹ “The use of statins reduces [the] risk of cardiovascular events.”³⁰

Physicians also fail to provide beta-blockers in patients with congestive heart failure 40.3% of the time³¹ (beta-blockers improve symptoms and significantly improve mortality³²) and fail to use statins in patients with diabetes mellitus 63.8% of the time³³ (statins produce a 19%–55% reduction in cardiovascular disease events in patients with diabetes mellitus—a major cause of mortality).³⁴ In addition, there is a failure by physicians to use ACE inhibitors in congestive heart failure 58.4% of the time. ACE inhibitors, combined with standard treatment, slow the progression of heart failure in patients with mild symptoms, and their use has shown “beneficial effects on mortality, morbidity, and quality of life.”³⁵ Finally, physicians fail to use antiplatelets in stroke patients 51.3% of the time (antiplatelets significantly decrease risk of secondary stroke, myocardial infarction, and death³⁶) and fail to use the pharmacologic treatment of osteoporosis 54.9% of the time³⁷

²⁸ AM. COLL. OF CARDIOLOGY FOUND. ET AL., CHRONIC STABLE CORONARY ARTERY DISEASE: PERFORMANCE MEASUREMENT SET 55 (Jan. 2011), available at <http://www.ama-assn.org/ama1/pub/upload/mm/pcpi/cadminisetjune06.pdf>.

²⁹ *Id.* at 61.

³⁰ *Id.* at 29.

³¹ Kale et al., *supra* note 12, at E2.

³² William E. Chavey II, *The Importance of Beta Blockers in the Treatment of Heart Failure*, 1 AM. FAM. PHYSICIAN 2453, 2453-62 (2000), available at <http://www.aafp.org/afp/2000/1201/p2453.html>.

³³ Kale et al., *supra* note 12, at E2.

³⁴ John Buse, *Statin Treatment in Diabetes Mellitus*, 21 CLINICAL DIABETES 168, 171 (2003).

Since the 1970s, there have been substantial epidemiological data demonstrating that cardiovascular diseases (here defined as ischemic heart disease, stroke, and peripheral vascular disease) constitute the primary cause of morbidity and mortality in patients with diabetes. In fact, at least 60% and arguably 80% of people with diabetes will eventually succumb to cardiovascular disease (CVD).

Id. at 168.

³⁵ M.K. Davies et al., *ABC of Heart Failure Management: Diuretics, ACE Inhibitors, and Nitrates*, 320 BMJ 428, 429 (2000).

³⁶ Dawn Meyer, *Antiplatelets and Stroke Outcomes: State of the Science*, 21 CRIT. CARE NURS. CLIN. N. AM. 517-28 (2009).

³⁷ Kale et al., *supra* note 12, at E2.

(pharmacologic treatment can “prevent fractures in men and women with low bone density or osteoporosis”³⁸).

All of these studies, taken together, demonstrate that following customary care can actually negatively impact quality of care by either suggesting that a physician provide the wrong treatment or fail to provide a lifesaving treatment. Thus, following customary care may mean that a patient’s condition may not only fail to improve, it may worsen, while also exposing that patient to unnecessary risks, long-term disability, or death.

C. *Customary Care Is Related More to Location than to Quality: Unwarranted Variation*

In the 1980s, an entirely separate series of surprising empirical studies raised the question of whether patients receive very different care depending on where they live, suggesting that customary care might have a stronger link to geography than to quality.³⁹ It appeared from these studies that the choices physicians make when treating the identical clinical conditions vary widely from region to region.⁴⁰ These

³⁸ Amir Qaseem et al., *Pharmacologic Treatment of Low Bone Density or Osteoporosis to Prevent Fractures: A Clinical Practice Guideline from the American College of Physicians*, 149 ANNALS INTERNAL MED. 404, 405 (2008).

³⁹ See generally John Wennberg & Alan Gittelsohn, *Small Area Variations in Health Care Delivery*, 182 SCI. 1102 (1973) [hereinafter Wennberg I]; John E. Wennberg et al., *Professional Uncertainty and the Problem of Supplier-Induced Demand*, 16 SOC. SCI. MED. 811, 812-17 (1982) [hereinafter Wennberg et al., *Professional Uncertainty*] (detailing differences in surgical practices); John E. Wennberg, *Dealing With Medical Practice Variations: A Proposal For Action*, HEALTH AFF., Summer 1984, at 6, 7 [hereinafter Wennberg II] (variations in surgical procedures and medical treatments were documented); David M. Eddy, *Variations in Physician Practice: The Role of Uncertainty*, HEALTH AFF., Fall 1984, at 74, 77-80 (detailing physician variations in choice of diagnosis and of procedure); Mark R. Chassin et al., *Variations in the Use of Medical and Surgical Services by the Medicare Population*, 314 NEW ENG. J. MED. 285, 287 (1986) (measuring variation in rates of use by Medicare beneficiaries).

⁴⁰ See generally Wennberg I, *supra* note 39. For example,

In Maine, by the time women reach seventy years of age in one hospital market the likelihood they have undergone a hysterectomy is 20 percent while in another market it is 70 percent. In Iowa, the chances that male residents who reach age eighty five have undergone prostatectomy range from a low of 15 percent to a high of more than 60 percent in different hospital markets. In Vermont, the probability that resident children will undergo a tonsillectomy has ranged from a low of 8 percent in one hospital market to a high of 70 percent in another.

Id. at 9; see also Mark A. Hall & Michael D. Green, *Introduction*, 37 WAKE FOREST L. REV. 663, 670-71 (2002) (citing Bruce E. Landon et al., *Personal, Organizational, and Market Level Influences on Physician Practice Patterns: Results of a National Survey of Primary Care Physicians*, 39 MED. CARE 889, 889 (2001) (failing to find, through the use of clinical vignettes, any evidence of “a consistent practice style” for certain

studies prompted the creation of The Dartmouth Atlas of Health Care so that these issues could be intensely investigated.⁴¹ The Dartmouth Atlas Project (DAP) has confirmed what the initial studies suggested: there is a wide variation of treatments for the same condition from region to region across the entire United States.⁴²

For example, a patient is five times more likely to be treated with a lower extremity bypass if that patient lives in Baltimore, Maryland than if that patient lives in Temple, Texas. Patients with prostate cancer are three times more likely to be treated with a radical prostatectomy if they live in Salt Lake City, Utah than if they live in San Francisco, California.⁴³

An infrequent, but devastating, complication of diabetes and peripheral vascular disease is amputation. A patient's chances of leg amputation can change by a factor of ten depending on where that patient lives.⁴⁴ Other examples include the rates of hip, knee, and shoulder replacements. A patient who lives in Ogden, Utah is four times more likely to receive a hip replacement than a patient who lives in Bryan, Texas.⁴⁵ Similarly, a patient living in Lincoln, Nebraska is almost four times more likely to receive a knee replacement than a patient living in New York, New York.⁴⁶ And a patient living in

common discretionary medical decisions)); see also James F. Blumstein, *The Legal Liability Regime: How Well Is It Doing In Assuring Quality, Accounting for Costs, and Coping with an Evolving Reality In The Health Care Marketplace*, 11 ANNALS HEALTH L. 125, 137 (2002) (Thus, "to ask an expert . . . what the 'customary practice' is [for a particular condition] on a national basis . . . is to ask a question to which there cannot be, for many diagnosis and treatment decisions, a coherent answer.").

⁴¹ *Dartmouth Atlas*, *supra* note 5.

⁴² See CTR. FOR THE EVALUATIVE CLINICAL SCI., DARTMOUTH ATLAS OF HEALTH CARE: STUDIES OF SURGICAL VARIATION SPINE SURGERY, *available at* http://www.dartmouthatlas.org/downloads/reports/Spine_Surgery_2006.pdf (last updated Apr. 15, 2010). For example, a patient is twenty times more likely to have surgery if that patient lives in Idaho Falls, Missoula, or Mason City than if that patient lives in Newark, Bangor, or Terre Haute. *Id.* at 7. Other examples: A patient living in Bradenton, Florida is seventy-five percent more likely to have spinal surgery than a patient living in Tampa, Florida, *id.*, and a patient is fifty percent more likely to have hip surgery if that patient lives in Fort Lauderdale than in neighboring Miami, ELLIOTT S. FISHER ET AL., TRENDS AND REGIONAL VARIATION IN HIP, KNEE, AND SHOULDER REPLACEMENT 17 (Apr. 6, 2010), *available at* http://www.dartmouthatlas.org/downloads/reports/Joint_Replacement_0410.pdf.

⁴³ ANITA ARORA ET AL., WHAT KIND OF PHYSICIAN WILL YOU BE? VARIATION IN HEALTH CARE AND ITS IMPORTANCE FOR RESIDENCY TRAINING 10 (Oct. 30, 2012), *available at* http://www.dartmouthatlas.org/downloads/reports/Residency_report_103012.pdf.

⁴⁴ Philip P. Goodney et al., *Variation in the Use of Lower Extremity Vascular Procedures for Critical Limb Ischemia*, 5 CIRC. CARDIOVASC. QUAL. OUTCOMES 1, 2 (2012), *available at* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3281555/>.

⁴⁵ FISHER ET AL., *supra* note 42, at 6.

⁴⁶ *Id.* at 8.

Provo, Utah is ten times more likely to receive a shoulder replacement than someone living in Syracuse, New York.⁴⁷

Another study demonstrated that the amount and type of care for chronically ill patients at the end of life differed greatly at academic medical centers located in different regions across the country.⁴⁸ The authors point out that “[t]he degree of variation . . . suggests . . . that patients are receiving care and resident physicians are receiving training that reflects the local practice style of their teaching hospital.”⁴⁹

These studies indicate that what constitutes customary care can be based on physician preferences (referred to in one major study as “local practice style[s]”⁵⁰) unlinked from best practices and that these preferences can be highly dependent on the region in which the physician practices.

D. Customary Care Can Be Costly Healthcare: Overuse

Customary care can also result in overuse of healthcare. Of the estimated \$700 billion wasted every year by the U.S. healthcare system, “over use, or the delivery of services for which the risks exceed the benefits, has been identified as a significant component, equaling roughly 280 billion.”⁵¹ Overall, “[r]esearch on appropriateness indicates that from one quarter to one third of medical services may be of no value to patients.”⁵² For example, 11.3% of screening EKGs, 25.3% of screening urine analyses, 7.0% of screening x-rays, and 37.9% of complete blood counts are unnecessarily ordered as part of a general medical exam.⁵³ Antibiotics are unnecessarily prescribed for upper respiratory tract infections 40.2% of the time, for acute bronchitis 58.8% of the time, and for asthma 6.8% of the time.⁵⁴

A 2012 study from the Stanford University School of Medicine revealed that an invasive heart test, used routinely to

⁴⁷ *Id.* at 10.

⁴⁸ ARORA ET AL., *supra* note 43, at 7.

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ Kale et al., *supra* note 12, at E2 (citing THOMSON REUTERS, WHERE CAN \$700 BILLION IN WASTE BE CUT ANNUALLY FROM THE US HEALTH-CARE SYSTEM? (2009), available at <https://healthleadersmedia.com/content/241965.pdf>).

⁵² See BARRY R. FURROW ET AL., HEALTH LAW § 7-1, at 34 (5th ed. 2004) (citing Robert Brook & Kathleen Lohr, *Will We Need to Ration Effective Medical Care?*, 3 ISSUES IN SCI. & TECH., no. 1, at 68 (Fall 1986)).

⁵³ Kale et al., *supra* note 12, at E5.

⁵⁴ *Id.*

measure heart function, is being dramatically overused.⁵⁵ This test is called a left ventriculography, or left ventriculogram, and it measures the percentage of blood that gets squeezed out with each heartbeat for a cost of \$300.⁵⁶ Out of 37,000 Aetna patients studied who underwent this test in 2007, 88% had already received another, more effective test that provided the same (and in many cases, better) data to the physician.⁵⁷ These patients received the left ventriculogram test inappropriately, exposing them to the risks of side effects from injecting the dye, increased radiation exposure, and an increased risk of heart arrhythmias and stroke with no resulting benefit,⁵⁸ wasting \$976,800 in just this one group of patients in one year.

The DAP suggests that much of this overuse occurs because these are supply-sensitive services. The care of chronically ill, elderly patients provides a good example of how these supply-sensitive services lead to overuse.⁵⁹ Popular, customary belief is

⁵⁵ Ronald M. Witteles et al., *Use and Overuse of Left Ventriculography*, 163 AM. HEART J. 617 (2012).

⁵⁶ *Invasive Heart Test Being Dramatically Overused, Study Shows*, SCIENCE DAILY (Apr. 6, 2012), <http://www.sciencedaily.com/releases/2012/04/120406234519.htm>.

⁵⁷ *Id.*

⁵⁸ *Id.* In 2011, the National Physicians Alliance through its Good Stewardship project identified the top five overused ambulatory care practices in internal medicine, family medicine and pediatrics and then began a campaign to educate physicians in how to avoid these overuses. Good Stewardship Working Grp., *The "Top 5" Lists in Primary Care: Meeting the Responsibility of Professionalism*, 171 ARCH. INTERN. MED. 1385-90 (2011). The "Choosing Wisely" campaign was started the following year by the American Board of Internal Medicine Foundation in coordination with nine physician specialty groups to identify tests or procedures that are commonly used but are not always appropriate. *Choosing Wisely: An Initiative of the ABIM Foundation*, <http://choosingwisely.org> (last visited Mar. 12, 2013).

⁵⁹ Dartmouth Press Release, *supra* note 4 (press release summarizing the study findings: "Almost One-Third of Medicare Spending for Chronically Ill Unnecessary, According to Dartmouth Atlas of Health Care; Improving Care Could Also Lower Costs") (referring to ELLIOT FISHER ET AL., *THE CARE OF PATIENTS WITH SEVERE CHRONIC ILLNESS: AN ONLINE REPORT ON THE MEDICARE PROGRAM BY THE DARTMOUTH ATLAS PROJECT* (2006), available at http://www.dartmouthatlas.org/downloads/atlas/2006_Chronic_Care_Atlas.pdf). This

Dartmouth Atlas Project studied the records of 4.7 million Medicare enrollees who died from 2000 to 2003 and had at least one of 12 chronic illnesses. The study demonstrates that even within this limited patient population, Medicare could have realized substantial savings—\$40 billion or nearly one-third of what it spent for their care over the four years—if all U.S. hospitals practiced at the high-quality/low-cost standard set by the Salt Lake City region. The report comes on the heels of a report by Medicare's trustees that the insurance program will exhaust its trust fund in 2018, two years earlier than previously forecast.

Dartmouth Press Release, *supra* note 4.

that more services—that is, using every available resource such as specialists, hospital and ICU beds, diagnostic tests and imaging etc.—produces better outcomes. Based on this assumption, the supply of resources—not the incidence of illness—drives utilization of the services. In effect, the supply of hospital beds, ICU beds, and specialty physicians creates its own demand, so areas with more resources per capita have higher costs per capita.⁶⁰

One of the DAP’s groundbreaking studies released in 2006 investigating the amount of care provided to chronically ill, elderly patients reviewed data from the top academic medical centers in the country and discovered that

the average number of hospitalized days during the last six months of life ranged from 12.9 days per decedent at St. Mary’s Hospital (the principal hospital of the Mayo Clinic in Rochester, Minn.) to 23.9 at New York-Presbyterian Hospital. The University of California at Los Angeles teaching hospital had the highest average number of days in intensive care units during the last six months of life (11.4 days per decedent), a rate 3.5 times higher than the rate for patients treated at the University of California teaching hospital in San Francisco (3.3 days per decedent). Medicare enrollees who were patients of the New York University Medical Center had an average of 76.2 physician visits during their last six months of life, almost one-third more than patients at the next-highest rate academic medical center, the Robert Wood Johnson University Hospital (57.7 visits per decedent). Patients of the University of Kentucky Hospital had slightly more than half as many (18.6) physician visits as the national average (33.5).⁶¹

Importantly, the study debunked the “more is better” myth in health care,” as hospitals that provided more intensive care and spent more did not get better results.⁶² On the other

⁶⁰ Dartmouth Press Release, *supra* note 4.

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

Id.

⁶¹ *Id.*

⁶² *Id.*

The researchers studied patients with chronic illnesses because about 30 to 35 percent of Medicare dollars are spent on people with these conditions during the last two years of their lives. Two-thirds of those in the study were diagnosed with cancer, congestive heart failure and/or chronic lung disease. “The majority of acute care hospitals are applying their standard forms of ‘rescue medicine’ to people who are in advanced stages of diseases that can’t be cured,” said Wennberg. “Patients don’t benefit—they can’t be rescued—and the costs of such care are very high, both in dollars spent and in providing care that the majority of chronically-ill

hand, those “with the best quality and [best] outcomes used far fewer resources.”⁶³ For example, “[p]atients in low-cost, high-quality regions such as Salt Lake City, Utah, Rochester, Minn., and Portland, Ore., are admitted less frequently to hospitals, spend less time in intensive care units and see fewer specialists.”⁶⁴ What this demonstrates is that the hospitals that are making low-cost choices are not withholding needed care.⁶⁵ They are simply more efficient by providing better outcomes while using fewer resources.⁶⁶ The authors of the study recommend that “[t]hese organizations offer a benchmark of performance toward which other systems should strive.”⁶⁷ This study agreed with other estimates that 30%–35% of the cost of Medicare could be saved if the overuse generated by regional customs was avoided.⁶⁸

In a recent *New Yorker* article on the issue of the overuse of medical services, Harvard Professor Atul Gawande examined the reasons that McAllen, Texas is one of the most expensive markets in the country, second only to Miami, Florida.⁶⁹ He opined that “[t]he cause of McAllen’s extreme costs was, very simply, across-the-board overuse of medicine.” In his article, Professor Gawande pointed out that Medicare spends two times the national average on Medicare enrollees in McAllen. This totaled fifteen thousand dollars per patient, per year.⁷⁰ He observed that,

[b]etween 2001 and 2005, critically ill Medicare patients received almost fifty percent more specialist visits in McAllen than in El Paso, and were two-thirds more likely to see ten or more specialists in a six month period. In 2005 and 2006, patients in McAllen received twenty percent more abdominal ultrasounds, thirty percent more bone-density studies, sixty percent more nerve-conduction studies to diagnose carpal-tunnel syndrome, and five hundred and fifty percent more urine-flow studies to diagnose prostate troubles. They received one-fifth to two-thirds more gall bladder operations, knee replacements, breast biopsies, and bladder scopes. They

patients might not want, such as admissions to intensive care and being sent to specialist after specialist.”

Id.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *See id.*

⁶⁶ *See id.*

⁶⁷ *Id.*

⁶⁸ *See id.*

⁶⁹ Atul Gawande, *The Cost Conundrum*, NEW YORKER (June 1, 2009), http://www.newyorker.com/reporting/2009/06/01/090601fa_fact_gawande?currentPage=all.

⁷⁰ *Id.*

received two to three times as many pacemakers, implantable defibrillators, cardiac-bypass operations, carotid endarterectomies, and coronary artery stents. And Medicare paid for five times as many home-nurse visits.⁷¹

And yet, compared to neighboring El Paso, a similar community, the hospitals in McAllen did not provide better quality of care.⁷² On the twenty-five metrics that Medicare uses to measure quality, El Paso performed better than McAllen on each metric.⁷³ Importantly, a patient is exposed to unnecessary risk each time that patient has an unwarranted invasive test or surgery. These risks could include the possibility of physical disability or death.

II. GOVERNMENT PROGRAMS PROVIDING HEALTHCARE HAVE ADOPTED EVIDENCE-BASED MEDICINE

A. *Veterans Administration Hospitals, Medicare, and Medicaid*

The quality and cost problems with the customary care model have led to new national initiatives to move the United States toward a modern, evidence-based model of medical practice through major changes in government-provided healthcare. Together, government programs provide healthcare for over 80 million people.⁷⁴ The VA Hospital System is a good example of a system that works well in coordinating care and improving outcomes through evidence-based medicine.⁷⁵ The Centers for Medicare & Medicaid Services (CMS) has also taken steps through Medicare to encourage healthcare providers to use

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Health insurance is now primarily provided by the government in the public sector, with 60-65% of healthcare provision and spending coming from programs such as Medicare, Medicaid, TRICARE, the Children's Health Insurance Program, and the Veterans Health Administration. U.S. CENSUS BUREAU, DEP'T OF COMMERCE, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2007 (2008). Before ACA, around 84.7% of Americans had some form of health insurance; either through their employer or the employer of their spouse or parent (59.3%), purchased individually (8.9%), or provided by government programs (27.8%; there is some overlap in these figures). All government health care programs have restricted eligibility, and there is no government health insurance company which covers all Americans. Before ACA, Americans without health insurance coverage totaled 15.3% of the population, or 45.7 million people. *Id.*

⁷⁵ PHILLIP LONGMAN, BEST CARE ANYWHERE: WHY VA HEALTH CARE IS BETTER THAN YOURS 1-10 (2007) (describing the VA system and its practice of evidence-based medicine resulting in well-coordinated care that results in good outcomes).

best practices grounded in evidence-based guidelines to improve outcomes through several major programs.⁷⁶

The first program adopted by CMS that focuses on best practices deals with “never events.” Never events are preventable medical errors that would not occur if best practices were followed.⁷⁷ Oddly enough, before the never events initiative, healthcare providers could bill for the additional services required to treat patients for the injuries caused by these mistakes.⁷⁸ These additional payments amounted to a bonus for bad patient care. Under the never events approach, CMS will not reimburse healthcare providers for these costs, forcing the healthcare providers to bear the cost of their mistakes⁷⁹ and encouraging the adoption of best practices to avoid making them. This program also requires that hospitals report never events to state officials to allow for outcome tracking. The public shaming that comes with publishing this data also encourages best practices to avoid

⁷⁶ For a detailed overview of these quality of care measures, see JAMES T. O'REILLY, *HEALTHCARE RULEMAKING GUIDE: ADMINISTRATIVE RULES IMPLEMENTING THE NEW HEALTH CARE LAWS* (2012) (a treatise on all of the provisions in ACA), and Barry Furrow, *Regulating Patient Safety: The Patient Protection and Affordable Care Act*, 159 U. PENN. L. REV. 1727, 1737 (2011) (providing an overview of the quality of care provisions contained in both ACA and other government provided healthcare programs).

⁷⁷ The concept of “never events” was first developed by the National Quality Forum (NQF) to describe gross medical errors, “errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a health care facility.” Press Release, Ctrs. for Medicare & Medicaid Servs., *Eliminating Serious, Preventable, and Costly Medical Errors—Never Events* (May 18, 2006), available at <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1863>; Agency for Healthcare Research & Quality, *Patient Safety Primers*, <http://www.psnet.ahrq.gov/primer.aspx?primerID=3> (last visited on Mar. 29, 2013) (“The term ‘Never Event’ was first introduced in 2001 by Ken Kizer, MD, former CEO of the National Quality Forum (NQF), in reference to particularly shocking medical errors (such as wrong-site surgery) that should never occur.”). Some examples of never events are: “surgery on the wrong body part; foreign body left in a patient after surgery; mismatched blood transfusion; major medication error; severe ‘pressure ulcer’ acquired in the hospital; and preventable post-operative deaths.” *Id.* A reporting requirement for “never events” has been adopted by over twenty states. These reporting requirements force providers to disclose adverse outcomes to the appropriate state department, with the goal of improving their operations. *Id.*

⁷⁸ Lucian L. Leape & Donald M. Berwick, *Five Years After To Err Is Human: What Have We Learned*, 293 JAMA 2384, 2388 (2005).

⁷⁹ CTRS. FOR MEDICARE & MEDICAID SERVS. FISCAL YEAR 2009 QUALITY MEASURE REPORTING FOR 2010 PAYMENT UPDATE, available at <http://www.cms.gov/HospitalQualityInits/downloads/HospitalRHQDAPU200808.pdf>.

errors.⁸⁰ As a follow-on program, CMS also recently began to refuse reimbursement for hospital-acquired infections.⁸¹

A second program, the Premier Quality Initiative, started in 2002 when CMS began ranking hospitals by performance, based on patient outcomes that can be positively affected by the adoption of best practices.⁸² Depending on a hospital's ranking, it can receive a bonus or a reduced payment.⁸³ This program includes a reporting incentive by giving those hospitals that report certain quality data a higher annual increase in their payment rates. This data is then used to rank participating hospitals,⁸⁴ and these rankings are available on the consumer-friendly Hospital Compare website.⁸⁵ Consumers can decide which hospital to use to decrease their risk of death or complications from, for example, a particular surgical procedure. Finally, CMS has issued a proposed rule⁸⁶ to integrate overall patient experience of care into its reward system.⁸⁷ This gives weight to the goal of establishing patient-centered care by giving patients a place at the table so their voices can be heard. Hospitals that score well in both quality of care provided *and* patient experience of care would receive higher payments under this proposed rule.⁸⁸

A third program, the Physician Quality Reporting System (PQRS), is targeted at physicians and provides

⁸⁰ Press Release, Ctrs. for Medicare & Medicaid Servs., *supra* note 77.

⁸¹ Centers for Medicare & Medicaid—CMS, PREMIER, <http://www.premierinc.com/quality-safety/tools-services/safety/topics/guidelines/cms-guidelines-4-infection.jsp> (last visited Mar. 12, 2013).

⁸² ALLIANCE FOR HEALTH REFORM, REWARDING SUPERIOR QUALITY CARE: THE PREMIER HOSPITAL QUALITY INCENTIVE DEMONSTRATION: CENTERS FOR MEDICARE & MEDICAID SERVICES FACT SHEET (2006), *available at* <http://www.allhealth.org/BriefingMaterials/HospitalPremierFS200602-175.pdf> (outlining the methods used to score and rank hospitals based on quality measures); *see also* Ctrs. for Medicare & Medicaid Servs., *Premier Hospital Quality Incentive Demonstration*, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalPremier.html> (last updated Jan. 9, 2013, 9:25 AM) (same, along with setting forth some of the results of the project).

⁸³ ALLIANCE FOR HEALTH REFORM, *supra* note 82.

⁸⁴ Press Release, Ctrs. for Medicare & Medicaid Servs., CMS Updates the National Hospital Quality Measure Acute Myocardial Infarction Set for Discharges as of April 1, 2009 (Dec. 31, 2008), *available at* www.cms.gov/HospitalQualityInits/Downloads/HospitalAMI-6FactSheet.pdf.

⁸⁵ *Hospital Compare*, MEDICARE, <http://www.medicare.gov/hospitalcompare/> (last visited Mar. 12, 2013).

⁸⁶ Hospital Inpatient Value-Based Purchasing Program, 76 Fed. Reg. 2454 (proposed Jan. 13, 2011) (to be codified at 42 C.F.R. pts. 422 and 480).

⁸⁷ Press Release, Ctrs. for Medicare & Medicaid Servs., Affordable Care Act to Improve Hospital Care for Patients (Jan. 7, 2011), *available at* <http://www.cms.gov/apps/media/press/release.asp?Counter=3893>.

⁸⁸ *Id.*

increased reimbursement for physicians who report information on quality measures. These measures are focused on patient outcomes for services covered by the Physician Fee Schedule under Medicare Part B.⁸⁹ PQRS was expanded in 2011 to add twenty new reporting measures. Starting in 2015, physicians will be docked for failing to report data on patient outcomes.⁹⁰ Of special interest is the bonus that physicians received starting in 2011 for writing prescriptions electronically.⁹¹ In 2012, physicians who fail to do so will have their reimbursements docked.⁹² The goal of this initiative is to prevent the millions of medication errors that occur in the United States every year. It also will provide the ability to track the prescription practices of physicians.

B. The Patient Protection and Affordable Care Act of 2010

The Patient Protection and Affordable Care Act of 2010 (the ACA) was signed into law by President Obama on March 23, 2010.⁹³ Almost all of the press to date has focused on the ACA's goal of improving access to health care by increasing the number of people who qualify for Medicaid and by changing the private insurance market with the advent of the individual mandate. However, improving the quality and cost of healthcare is also a major goal of the Act. There are several major initiatives contained in the ACA that reflect this goal and which all work to encourage the practice of evidence-based medicine by building on the already strong CMS efforts described in the previous section.

Importantly, in conjunction with the American Recovery and Reinvestment Act of 2009 (the Recovery Act),⁹⁴ the ACA

⁸⁹ The Medicare Improvements and Extension Act of 2006, sec. 101(b), § 1848, 120 Stat. 2975, 2975-77, established the PQRS. The PQRS was originally called the PQRI (Physician Quality Reporting Initiative). Press Release, Ctrs. for Medicare & Medicaid Servs., Physician Quality Reporting System and E-Prescribing Program (Nov. 3, 2010), available at <http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3858>.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ Pub. L. No. 111-148, 124 Stat. 119 (2010) (to be codified as amended in scattered sections of Titles 21, 25, 26, 29, and 42 of the United States Code).

⁹⁴ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, tit. VIII, 123 Stat. 115, 175-77 (2009); see also *Comparative Effectiveness Research Funding*, HHS.GOV, <http://www.hhs.gov/recovery/programs/cer/index.html> (last visited Mar. 12, 2013) (showing research funding allocation among government entities). The Recovery Act created the Federal Coordinating Council for Comparative Effectiveness Research to organize such research across the federal government. Recovery Act § 804, 123 Stat. at 187-88; reflected in 42 U.S.C.A. § 299b-8.

will be providing hundreds of millions of dollars of funding for research to develop evidence-based clinical practice guidelines that will be used to define the best practices that the Act promotes.⁹⁵ For example, under § 10303 of the ACA, these best practices⁹⁶ will be used to create more of the same types of patient outcome measures that are already being utilized in Medicare.⁹⁷ The ACA creates a new oversight entity, the Patient-Centered Outcomes Research (PCOR) Institute, to direct the Comparative Effectiveness Program that will create data banks⁹⁸ comparing the effectiveness of two or more treatments.⁹⁹ These databanks will provide much needed

⁹⁵ See, e.g., 123 Stat. at 176-78.

The Agency for Healthcare Research and Quality (AHRQ) has opportunities under the American Recovery and Reinvestment Act of 2009 (Recovery Act) to provide patients, clinicians, and others evidence-based information to make informed decisions about health care. The Recovery Act contains \$1.1 billion for comparative effectiveness research. Of the total, \$300 million is for AHRQ to build on its existing collaborative and transparent Effective Health Care program.

AHRQ and the Recovery Act, <http://www.ahrq.gov/fund/ceferra.htm> (last updated Nov. 2011). The National Guideline Clearinghouse is sponsored by the ARHQ. The National Guideline Clearinghouse reviews all clinical practice guidelines for the quality of the evidence supporting them. NAT'L GUIDELINE CLEARINGHOUSE, <http://www.guideline.gov/about/index.aspx> (last visited Jan. 14, 2012) (providing a "public resource for evidence based clinical practice guidelines").

⁹⁶ Section 6301 mandates patient-centered outcomes research as a part of the larger goal of developing comparative clinical effectiveness research (CER). The section defines "comparative clinical effectiveness research" to mean "research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments [and] services . . ." Recovery Act § 1181(a)(2)(A). ACA further defines medical treatments and services broadly, to include the provision of care as well as the use of medical devices, pharmaceuticals, and "integrative health practices." *Id.* § 1181(a)(2)(B). CER is well funded, with \$1.1 billion provided by the Recovery Act divided among the AHRQ (\$300 million), the National Institutes of Health (\$400 million), and the Office of the HHS Secretary (\$400 million). Agency for Healthcare Research & Quality, *Overview of the American Recovery and Reinvestment Act*, <http://www.ahrq.gov/legacy/fund/ceferraover.htm> (last visited Mar. 29, 2013).

⁹⁷ Patient Protection and Affordable Care Act (ACA) § 10303(a), amending § 931(f), 42 U.S.C.A. § 299b-31(f) (2010) (giving the Secretary of Health and Human Services two years to develop at least ten outcome measurements for acute and chronic diseases, including the five most prevalent and resource-intensive conditions and three years to develop ten primary and preventative care measurements for distinct populations).

⁹⁸ Once the research is completed, Section 6301 creates a system for distributing and posting in a database the results of this research through AHRQ's Office of Communication and Knowledge Transfer. ACA § 6301(b), amending § 937(a)(1).

⁹⁹ The PCOR Institute is not a government agency; instead, it is a non-profit institute. ACA § 6301(a), § 1181(b)(1). The PCOR website describes its goals as follows:

Patient-Centered Outcomes Research (PCOR) helps people . . . make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as: 1. "Given my personal characteristics, conditions and preferences, what should I expect will happen to me?" 2. "What are my options and what are the benefits and harms of those options?" 3. "What can I do to improve the outcomes that

decision-making tools for both healthcare providers and consumers in light of the multiple medications and treatments that are marketed to deal with the same health condition.¹⁰⁰

Adding another layer to this push for the nationwide adoption of evidence-based medical practice is the ACA's creation of the Center for Quality Improvement and Patient Safety (CQIPS).¹⁰¹ This center will develop tools to facilitate the adoption of best practices by healthcare providers.¹⁰² CQIPS will award grants and provide technical assistance in order to help providers adopt best practices.¹⁰³ With the addition of this center, the ACA now has a system for the development of best practices (AHRQ¹⁰⁴), a system for publicizing these best practices (PCOR), and a system for integrating these best practices (CQIPS) into the everyday practices of hospitals and physicians.

Central to the ACA are the Health Benefit Exchanges. In keeping with the ACA's theme of improving quality and cost of care, these exchanges also work instrumentally to move the ball forward in these areas.¹⁰⁵ In order to qualify to sell

are most important to me?" 4. "How can [the health care system] help me make the best decisions about my health and healthcare?"

PATIENT-CENTERED OUTCOMES RESEARCH INST., PATIENT-CENTERED OUTCOMES RESEARCH DEFINITION REVISION: RESPONSE TO PUBLIC INPUT (Feb. 15, 2012), <http://www.pcori.org/assets/PCOR-Definition-Revised-Draft-and-Responses-to-Input.pdf>.

To answer these questions, PCOR . . . [a] Assesses the benefits and harms of preventive, diagnostic, therapeutic, . . . or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people; [b] Is inclusive of an individual's preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health-related quality of life; [c] Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and [d] Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, resource availability, and other stakeholder perspectives.

Id.

¹⁰⁰ Priorities in research will be set according to gaps in the evidence over clinical outcomes, areas of variation in medical practice, and areas of practice where there are pressing quality concerns. These priorities will be delineated as part of the national strategy for quality care. Recovery Act § 1181(d)(1)(A). The institute must also release its research findings to clinicians, patients, and the public within ninety days of receiving them. *Id.* § 1181(d)(8)(A). These findings will be made available on the Institute's website. *Id.* § 1181(h)(3).

¹⁰¹ ACA § 3501, § 933(a).

¹⁰² Recovery Act § 933(b)(2)-(5).

¹⁰³ *Id.* § 934(a)(1).

¹⁰⁴ See *supra* note 93.

¹⁰⁵ Part II, Subtitle D of ACA, "Consumer Choices and Insurance Competition Through Health Benefit Exchanges" contains important quality components. ACA § 1311 (spelling out the form of the American Health Benefit Exchanges).

insurance to consumers through these exchanges,¹⁰⁶ insurers must evaluate providers by the same quality benchmarks that CMS uses to rate providers,¹⁰⁷ as described above.¹⁰⁸ As with the CMS reimbursements under Medicare, the higher the rating, the greater the private insurance reimbursement will be for healthcare services.¹⁰⁹ Continuing the parallel, just like Medicare, the insurance companies must also publish the quality of care and patient satisfaction data that they gather.¹¹⁰ In a major change to private insurance practices, the ACA¹¹¹ turns private insurers into mini regulatory agencies by requiring private insurers to:

(A) improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, . . . for treatment or services under the plan or coverage;

(B) implement activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional;

(C) implement activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and

(D) implement wellness and health promotion activities.¹¹²

¹⁰⁶ Subsection (c) details the criteria that health plans must meet to be “qualified” to be sold on the exchanges. *Id.* § 1311(c).

¹⁰⁷ These bench marks are similar to the ones used by CMS including patient experience ratings, clinical quality measures, quality assurance, utilization management, provider credentialing, complaints and appeals, patient information programs and network adequacy and access. *Id.* § 1311(c)(1)(D).

¹⁰⁸ See *supra* notes 89-90 and accompanying text.

¹⁰⁹ In the “Rewarding Quality Through Market-Based Incentives” sections of ACA, reimbursement is required to be based upon quality and health outcome scores. ACA § 1311(g); *id.* § 1311(g)(1)(C) (payments must include incentives for “the implementation of activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage.”).

¹¹⁰ Subsection (c)(1)(E) requires the plans to “implement a quality improvement strategy,” *id.* § 1311(c)(1)(E), and subsection (c)(1)(H) requires disclosure of quality measures to enrollees and prospective enrollees. *Id.* § 1311(c)(1)(H).

¹¹¹ *Id.* § 1001, § 2717(a)(1).

¹¹² *Id.* § 1001, § 2717(a)(1)(A)-(D). With regard to hospitals specifically, for plans to be “qualified” to be sold on the health exchanges, § 1311(h), “Quality Improvement,” specifies that the plan may contract with a hospital with more than fifty beds only if the hospital “utilizes a patient safety evaluation system” and has a

Together, the quality improvement provisions under the ACA and CMS create a powerful regulatory engine that will work to move the United States from a system that follows the customary care model of medical care toward a modern, evidence-based system of medical care.

III. THE GROWING NUMBER OF STATE TORT SYSTEMS ADOPTING EVIDENCE-BASED CARE AS THE STANDARD OF CARE

State tort systems are slowly moving away from the current majority rule, which uses customary practice as conclusive evidence of the standard of care,¹¹³ as judges and lawyers begin to recognize the problems with using custom (as discussed above) as the exclusive proxy for quality.¹¹⁴ For example, in order to meet the standard of care in a medical malpractice case, a physician must “possess and use the care, skill and knowledge ordinarily possessed and used under like circumstances”¹¹⁵ Instead of limiting the scope of admissible evidence in defining reasonable care to what is customarily done under the circumstances, some state tort systems are also allowing the introduction of risk-benefit analysis grounded in empirical science as evidence of what is reasonable quality care under the circumstances. This transition away from the tort system’s use of custom as the exclusive proxy for quality appears to benefit both the quality and cost of healthcare. Thus, the tort systems of some states are operating instrumentally to encourage the transition away from custom-based medical practice to evidence-based medical practice. Unfortunately, as discussed below, the majority of state tort systems are acting to thwart that transition.

mechanism in place “to ensure that each patient receives a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional.” *Id.* § 1311(h)(1)(A).

¹¹³ See generally Philip G. Peters, Jr., *The Role of the Jury in Modern Malpractice Law*, 87 IOWA L. REV. 909 (2002) (discussing the merits of the role of custom as conclusive evidence of the standard of care in malpractice litigation and the movement by many states to use custom as only some evidence of the standard of care).

¹¹⁴ *Id.* at 909.

¹¹⁵ *Burns v. Metz*, 513 N.W.2d 505, 509 (Neb. 1994); *Vergara v. Doan*, 593 N.E.2d 185, 188 (Ind. 1992) (judging the physician’s conduct by a “minimum standard of care for the particular practice”). For an excellent overview of medical malpractice law, see DAN B. DOBBS, *THE LAW OF TORTS* § 242, 631-34 (2000).

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

The positive impact that an evidence-based standard of care in medical malpractice cases can have on quality and cost of care is borne out by a recent empirical study that used data on treatment utilization rates from 1977 to 2005 compiled by the National Hospital Discharge Surveys. This study estimated that there was “a 30 – 50% reduction in the gap between the state and national utilization rates of various obstetric, cardiac and diagnostic procedures following the abandonment of a rule requiring physicians to meet the standards set by local physicians and the contemporaneous adoption of a national-standard rule.”¹¹⁶ The author of the study, Professor Michael Frakes of Cornell Law School, finds that in the context of medical malpractice, “custom-based liability standards may indeed encourage the perpetuation of customary practices and likewise discourage deviations from custom”¹¹⁷ Professor Frakes concludes that

the results of this study more generally suggest that a malpractice rule that bases standards of care on customary physician practices may indeed incentivize the perpetuation of those customary practices and, at the same time, discourage deviations from custom. . . .

The employment of custom-based standards, moreover, carries a number of important policy implications, particularly with respect to the possible role that they may play in discouraging cost-reducing innovations in delivery practices. Legal scholars have long recognized that the effectiveness of managed care and related strategies may be blunted by a medical liability system that holds physicians to a standard of care determined according to customary physician practices, where those practices were developed in a predominantly fee-for-service environment that may have encouraged excessive practice styles.¹¹⁸

Professor Frakes goes on to state that,

[b]y arguably establishing the empirical relevancy of the customary component to malpractice standards, this study validates these concerns and thereby lends support to proposals that call for a

¹¹⁶ Michael Frakes, *The Impact of Medical Liability Standards on Regional Variations in Physician Behavior: Evidence from the Adoption of National-Standard Rules 1* (Aug. 2010) (unpublished manuscript) (on file with author).

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 37-38.

relaxation of customary-standard requirements, including those that argue for a stronger role for “reasonableness” in malpractice-standard determinations or, as above, a more definitive role for clinical practice guidelines in malpractice proceedings.¹¹⁹

As is the case with the use of customary care standards in medical malpractice litigation, the reliance on the customary care proxy for quality in licensure proceedings and hospital peer review is also likely to entrench custom-based decision making at the cost of quality of care. This conclusion finds support in several studies. First, a study was released in 2005 that demonstrated that physicians fail to provide simple, yet essential, healthcare for common, serious conditions.¹²⁰ Another study, released in December of 2012, revealed that the intervening seven years since the 2005 study have brought little change in these failures, demonstrating that physicians are surprisingly slow to adopt evidence-based care.¹²¹ In a recent *New Yorker* article, quality-of-care expert and Harvard Professor Atul Gawande noted that there is a disconcerting fifteen-year average lag time in the adoption by physicians of evidence-based practice choices.¹²² Another study released in 2010 demonstrated that the rate of injuries in hospitals from physician errors remained unchanged in the ten years since the IOM Report. This status quo exists in spite of multiple initiatives to improve quality.¹²³ Importantly, the study found that “the penetration of evidence-based safety practices has been quite modest. For example, . . . [c]ompliance with even simple interventions such as hand washing is poor in many centers.”¹²⁴

This article suggests that one reason for the failure of evidence-based practices to penetrate into daily medical practice may be the continued use of customary care as the

¹¹⁹ *Id.* at 38 (footnote omitted). The study done by Professor Frakes lends empirical support for my arguments for a greater role for evidence based medicine, in the form of Clinical Practice Guidelines, in the hospital peer review process made in my 2006 article. See Van Tassel, *supra* note 3, at 1241-55.

¹²⁰ Jha, *supra* note 22; see also *supra* notes 23-37 and accompanying text.

¹²¹ Kale et al., *supra* note 12.

¹²² Atul Gawande, *Big Med*, NEW YORKER (Aug. 12, 2012), http://www.newyorker.com/reporting/2012/08/13/120813fa_fact_gawande; see also *infra* note 162.

¹²³ Christopher P. Landrigan et al., *Temporal Trends in Rates of Patient Harm Resulting from Medical Care*, 363 NEW ENG. J. MED. 2124, 2130 (2010) (“In a statewide study of 10 North Carolina hospitals, we found that harm resulting from medical care was common, with little evidence that rate of harm had decreased substantially over a 6-year period ending in December 2007.”).

¹²⁴ *Id.* at 2125.

exclusive proxy for quality of care by the tort, licensure, and hospital peer review systems.

B. How Does the Conflict Between Evidence-Based Medicine and Custom-Based Medicine Play Out in a Malpractice Action?

An example of how the conflict between custom-based and evidence-based medicine manifests itself in a medical malpractice action occurs when a physician chooses whether to use a stent to treat a patient who has blocked coronary arteries and stable coronary heart disease.

It is part of customary practice to prop open blocked arteries with a stent, a practice called percutaneous coronary intervention or “PCI.”¹²⁵ With PCI, a physician implants a mesh tube into an artery to hold it open when it is narrowed by accumulated plaque. This tube allows blood to flow more freely.¹²⁶ The total cost for the placement of a stent is between 30 and 50 thousand dollars and more than one million of these procedures are performed every year.¹²⁷ This means a total cost to the healthcare system of between 30 to 50 billion dollars.¹²⁸ In addition, there are risks associated with this procedure which include the possibility of a heart attack, stroke, serious allergic reactions, bleeding, and kidney damage.¹²⁹ When these risks are manifested, the cost to the system of this treatment expands exponentially.

A recent meta-study of randomized trials published in early 2012 (the 2012 Stent Study) demonstrates that an inexpensive treatment with a handful of prescription drugs—a mix of ACE inhibitors, statins, beta-blockers, and daily aspirin—provides the same treatment benefits as stents for the

¹²⁵ This is a procedure called percutaneous coronary intervention (or “PCI”) in which a surgeon inserts a mesh tube made of metal into an artery that has become narrowed by accumulated plaque. The [mesh] tube [is] threaded through an artery in the leg or arm[.] [Then it] expands to hold the artery open at the point where blood flow is restricted [by accumulated plaque].

Nicholas Bakalar, *No Extra Benefits Are Seen in Stents for Coronary Artery Disease*, N.Y. TIMES, Feb. 28, 2012, at D7, available at <http://www.nytimes.com/2012/02/28/health/stents-show-no-extra-benefits-for-coronary-artery-disease.html>.

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

prevention of chest pain, heart attacks, and death.¹³⁰ The authors of the study conclude that, “In the context of controlling rising health care costs in the United States, this study suggests that up to 76% of patients with stable CAD [coronary artery disease] can avoid PCI [percutaneous coronary intervention (such as stenting)] altogether if treated with optimal medical therapy”¹³¹ Evidence-based medicine would involve incorporating this meta-study into daily practice choices and trying drug therapy before resorting to implantation of a stent.

One of the authors of the study, Dr. David Brown of the Stony Brook University Medical Center in New York, doubts that this study will change the behavior of many physicians.¹³² He explains that,

In many hospitals, the cardiac service line generates 40 percent of the total hospital revenue, so there’s incredible pressure to do more procedures. . . . When you put in a stent, everyone is happy—the hospital is making more money, the doctor is making more money—everybody is happier except the health care system as a whole, which is paying more money for no better results.¹³³

The 2012 Stent Study provides an opportunity to explain how the conflict between a custom-based medicine treatment choice and an evidence-based treatment choice might play out in a medical malpractice action. If a patient with stable coronary heart disease dies as the result of the insertion of a stent (for example, the surgery causes a heart attack) and that patient was treated in one of the majority of states where customary care is conclusive evidence of the quality of care,¹³⁴ that patient’s estate would be unlikely to persuade a malpractice attorney to take the case in the first instance. The duty of care is fairly consistent in most states,

¹³⁰ Kathleen Stergiopoulos & David L. Brown, *Less Is More: Initial Coronary Stent Implantation with Medical Therapy vs Medical Therapy Alone for Stable Coronary Artery Disease: Meta-Analysis of Randomized Controlled Trials*, 172 ARCH. INTERN. MED. 312, 312-18 (2012) (analysis included results on more than 7200 patients enrolled in eight studies between 1997 and 2005 comparing stents with medical therapy in stable heart patients with narrowed sections in their heart arteries). Over half of those with stable coronary artery disease were implanted with stents before they tried drug treatment. Julie Steenhuisen, *Pills as Good as Stents for Some Patients: Study*, REUTERS (Feb. 28, 2012), <http://www.reuters.com/article/2012/02/28/us-pills-stents-idUSTRE81R24520120228>.

¹³¹ Stergiopoulos & Brown, *supra* note 130, at 318.

¹³² Steenhuisen, *supra* note 130.

¹³³ Bakalar, *supra* note 125.

¹³⁴ See DOBBS, *supra* note 115, § 243, at 634-35.

which is to provide the kind of care used by a reasonable physician, who has like education, training, and expertise, under the circumstances.¹³⁵ Here, the issue is the kind of treatment that a reasonable cardiologist would provide for a person with stable coronary artery disease and a blocked coronary artery.¹³⁶ In a customary care state, the only relevant evidence on this issue is evidence of what the customary treatment by a cardiologist would be for a patient with this condition.¹³⁷ The evidence will show that the custom is to implant a stent. The physician complied with the custom and, therefore, did not breach the standard of care, even though the patient died. Based on these facts, this case has little chance of success.

The 2012 Stent Study, described above, would not be relevant and therefore would be inadmissible. The study could not be admitted to show that the risks of stent implantation far outweighed the benefits and that, therefore, it was unreasonable to implant the stent. This study is not relevant evidence in a customary care state because it does not help answer the question of what constitutes customary care for patients with stable coronary artery disease and blocked coronary arteries. For this reason, the physician is rewarded by the tort system for following the custom, even though evidence-based medical practice suggests a different treatment choice.

The situation changes dramatically if the cardiologist did not place a stent and, instead, prescribed the far less expensive, less risky, and equally effective treatment—using medications to treat the patient—and the patient died of a heart attack from a blocked artery. This physician, although making the choice encouraged by evidence-based medical practice, would not be able to use the 2012 Stent Study to protect herself or himself from liability by showing that the decision not to place the stent was reasonable. The study, once again, would be inadmissible. Unlike the first scenario, where it is unlikely that a plaintiff's lawyer would even take the case in the first place, a plaintiff's lawyer would be likely to take this case because the custom is to implant a stent and the cardiologist did not do so. The plaintiff's lawyer could easily find an expert to testify that the custom is to implant a stent and that, if the stent would have been implanted, the blockage would have been bypassed and the patient would have been

¹³⁵ *Id.*

¹³⁶ Assuming there were no other confounding conditions.

¹³⁷ See DOBBS, *supra* note 115, § 243, at 634-35.

unlikely to have had a heart attack and died. While the defendant physician will likely have an expert to testify that an equally acceptable custom is to treat with medications,¹³⁸ this

¹³⁸ A brief note on the two schools of thought defense just to be sure that it is clear that this affirmative defense does not ameliorate this conflict: One of the oft-cited cases that describes the two schools of thought defense is the Pennsylvania case of *Jones v. Chidester*, 610 A.2d 964 (Pa. 1992). As the court in *Jones* explains, under this defense, if there are two approaches to treating a particular condition, one is chosen by a majority of physicians and one that is followed by a “considerable number of recognized and respected individuals,” the defendant physician will not be held liable for adopting the treatment choice of this considerable minority. *Id.* at 969. There are multiple reasons why this defense does not alter the conflict described by the stenting hypothetical. First, there is a question regarding whether a particular state has adopted this defense. Second, the relevance of the defense will depend on whether the state has adopted the locality rule, the same or similar locality rule, or the national rule. The defense will not be viable if the evidence-based treatment choice has not garnered enough support to reflect the practice choice of a considerable minority in either the same locality, the same community or a similar locality, or on a national basis under the national rule, depending on which rule the state has adopted. Many evidence-based treatment choices will initially be adopted only in large cities where there are teaching hospitals. Thus, it will not be a practice choice of very many physicians in the vast majority of communities that exist outside the large cities for a considerable number of years, if at all. And, under the national rule, it will take a great deal of time before the number of physicians who have adopted the evidence-based treatment choice reaches a “considerable number” of physicians, especially if the state adopts a proportionality test. In a recent *New Yorker* article, quality of care expert Harvard Professor Atul Gawande noted that there is a disconcerting fifteen year average lag time in the adoption by physicians of evidence-based practice choices. Gawande, *supra* note 122; *see also infra* note 162.

Over and above this problem of relevance, it is important to note that this is an affirmative defense as well as a question of fact. The physician will have to go to trial as the applicability of this defense is a question of fact for the jury to decide. As the physician is faced with going through the emotional turmoil and cost of an entire trial, once again, the physician will be significantly deterred from adopting the evidence-based practice choice. “[P]hysicians consistently report that they often engage in defensive practices and that they feel intense pressure to do so out of fear of becoming the subject of a malpractice suit.” Emily R. Carrier et al., *Physicians’ Fear of Malpractice Lawsuits Are Not Assuaged by Tort Reforms*, 29 HEALTH AFFAIRS 1585, 1585 (2010) (citing David Studdert et al., *Defensive Medicine and Tort Reform: A Wide View*, 25 J. GEN. INTERN. MED. 380, 380 (2010), and David Studdert et al., *Defensive Medicine Among High Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609, 2609 (2005)). “[I]ndividual physicians’ concerns about their own malpractice risk are pervasive, vary across specialties in ways that are likely to reflect underlying malpractice risk, and reflect objective measures of risk across states to a limited degree.” *Id.* What stands out is that “the level of liability concern reported by physicians is arguably out of step with the actual risk of experiencing a malpractice claim.” *Id.* at 1591. One explanation is the common tendency for most to over-estimate what are called “dread-risks,” which are rare but have devastating outcomes. This tendency

relates to the well-documented human tendencies to overestimate the risk of rare events and to be particularly fearful of risks that are unfamiliar, potentially catastrophic, or difficult to control. Lawsuits are rare events in a physician’s career, but physicians tend to overestimate the likelihood of experiencing them. . . . Severe, unpredictable, uncontrollable events are associated with a feeling of dread that triggers a statistically irrational level of risk aversion. . . . Physicians may be subject to this phenomenon when it comes to malpractice suits. Because of the rarity of the

“battle of the experts” is likely to create a reasonable question of fact, and the case will be likely to survive a motion for summary judgment and go to a jury. Thus, the physician will not avoid litigation and will be “punished” for adopting evidence-based practice and failing to follow the custom in this case.

As the Frakes Study suggests, physicians are very motivated to avoid litigation. Consequently, until the majority of the states adopt the minority rule and allow the introduction of risk-benefit analysis grounded in empirical science as evidence of what is reasonable care under the circumstances, the customary care rule will be a road block in the federal government’s quest to transition away from custom-based medical practice to evidence-based medical practice.

IV. HOSPITAL PEER REVIEW

Private peer review is a self-policing system conducted in hospitals where physicians informally evaluate each other and report on those physicians who are allegedly failing to provide quality patient care to hospital administration.¹³⁹ If, after an investigation and hearing conducted by the hospital,¹⁴⁰ a physician is found to have provided poor quality of care, that physician may be penalized in a variety of ways, including the termination of the physician’s hospital staff privileges.¹⁴¹

suits, most physicians have little familiarity with them. The consequences of being sued are perceived as potentially disastrous to one’s medical reputation, psychological well-being, and financial stability. Finally, physicians tend to view lawsuits as random events, unpredictable and uncontrollable, because they are not viewed as related to the quality of care provided. These factors may lead to a fear of suits that seems out of proportion to the actual risk of being sued.

Id.; see also David Studdert et al, *Medical Malpractice*, 350 NEW ENG. J. MED. 283 (2004); A.G. Lawthers, *Physicians Perceptions of the Risk of Being Sued*, 17 J. HEALTH POL. POL’Y L. 463 (1992). Finally, the two schools of thought rule was developed to deal with two different customs of care that existed in light of scientific uncertainty over which choice was the most effective with the least associated risk. It should not be relevant, as a public health matter, when there is a reasonable degree of scientific certainty over treatment choice, especially if one treatment choice is especially risky or just plain ineffective.

¹³⁹ VIRGIL SLEE ET AL., *SLEE’S HEALTHCARE TERMS* 439 (5th ed. 2008). For a detailed explanation of this process, see Van Tassel, *supra* note 3, at 1194-97.

¹⁴⁰ Hospital peer review is conducted pursuant to the obligations of the hospital medical staff to ensure “the quality of the professional services provided by individuals with clinical privileges” JOINT COMM’N ON ACCREDITATION OF HEALTHCARE ORGS., *COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS: THE OFFICIAL HANDBOOK*, MS.1, at MS-2 (1999) [hereinafter CAMH].

¹⁴¹ CREDENTIALING AND PEER REVIEW PRACTICE GROUP OF THE AM. HEALTH LAWYER’S ASS’N, *PEER REVIEW GUIDEBOOK* 60, MS-7 (3d ed. 2003) [hereinafter PEER REVIEW GUIDEBOOK]; CAMH, *supra* note 140, at MS-7.

In 1986, Congress passed the Health Care Quality Improvement Act (HCQIA) in response to a perceived crisis over the costs for insurance coverage for medical malpractice.¹⁴² HCQIA gave a Congressional stamp of approval to the hospital peer review process by providing conditional immunity from suit to those who participated in the process.¹⁴³ After the passage of HCQIA, the rate of hospital adoption of peer review processes increased dramatically until today all of the nation's hospitals have adopted some form of peer review.

HCQIA also set up the National Practitioner Data Bank (NPDB).¹⁴⁴ Under the Act and its regulations, multiple different organizations are required to report information involving physicians that allegedly reflects the provision of poor quality patient care. For example, insurance companies must report malpractice payments and settlements on behalf of physicians to the NPDB,¹⁴⁵ state licensing boards must report disciplinary actions to the NPDB,¹⁴⁶ and healthcare providers¹⁴⁷ must report

¹⁴² 42 U.S.C. §§ 11101-11152 (2006). For a complete history of HCQIA, see Katharine Van Tassel, *Using Clinical Practice Guidelines and Knowledge Translation Theory to Cure the Negative Impact of the Hospital Peer Review Hearing System on Healthcare Quality, Cost and Access?*, 40 PEPP. L. REV. 911 (2013).

¹⁴³ Van Tassel, *supra* note 3, at 1194-97; see MICHAEL A. CASSIDY, IMMUNITY FOR CREDENTIALING DECISIONS UNDER FEDERAL AND STATE LAW 38 (2003).

¹⁴⁴ 42 U.S.C. § 11101. The Health Resources and Services Administration (HRSA) has "federal oversight responsibility for [the] NPDB." U.S. GEN. ACCOUNTING OFFICE, GAO-01-130, NATIONAL PRACTITIONER DATA BANK: MAJOR IMPROVEMENTS ARE NEEDED TO ENHANCE DATA BANK'S RELIABILITY 7 (2000) [hereinafter MAJOR IMPROVEMENTS], available at <http://www.gao.gov/new.items/d01130.pdf>. HRSA completed the regulations that established the operation of the NPDB in October of 1989. *Id.* While HRSA is responsible for ensuring compliance with these regulations, the actual day-to-day operation of the NPDB is performed by a private operator. *Id.* In 2010, the list of healthcare professionals that the NPDB reports on was expanded from just physicians and dentists to *all* healthcare practitioners by the passage of new regulations. In addition, the list of entities that can query the NPDB has expanded to include "private sector hospitals, nursing homes, and other organizations so that they may be used when making employment, affiliation, certification, or licensure decisions." *Legislation and Regulations: Why Is Section 1921 Important?*, DATA BANK, <http://www.npdb-hipdb.hrsa.gov/resources/section1921.jsp> (last visited Feb. 14, 2013). Thus,

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

Id.

¹⁴⁵ 42 U.S.C. § 11101.

¹⁴⁶ *Id.*

peer review actions to the NPDB that restrict a physician's clinical privileges for more than thirty days.¹⁴⁸

Hospitals must also check the NPDB for negative reports on each physician applying for staff privileges and must check the NPDB for negative reports every two years for every physician who already has staff privileges.¹⁴⁹

A. *Hospital Peer Review Relies Upon Customary Care Standards*

Unfortunately, one of the main standards¹⁵⁰ that hospital peer review relies upon to measure physician competence

¹⁴⁷ For example, hospitals and health plans. These new regulations bring the states into the picture by requiring hospitals to send reports of all actions "that adversely affect[] the clinical privileges of a physician or dentist for a period of longer than 30 days," 42 U.S.C. § 11133 (2000), to the state licensure board. The state licensure boards are then required to report this information to the NPDB. National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting on Adverse and Negative Actions, 75 Fed. Reg. 4677, § 60.5(d) (Jan. 28, 2010).

¹⁴⁸ MAJOR IMPROVEMENTS, *supra* note 144, at 7. Even private professional societies such as the American Dental Association and the American Medical Association must report sanctions that impact membership. *Id.* Some federal agencies, such as the VA, must report to the NPDB any negative actions that involve physicians whom they insure, employ, or regulate. *Id.* at 7-8. Practitioners who are excluded from participating in the Medicare and Medicaid Programs must also be reported if they either default on federal loan agreements or engage in fraud or abuse. *Id.* at 8-9.

¹⁴⁹ *Id.* at 9. There are also organizations which are allowed to query the NPDB, such as professional societies and state licensure boards, but they are not required to do so. *Id.* Individual physicians may only query for information about themselves. *Id.*

¹⁵⁰ The other major category of standards commonly used in hospital peer review is one that expressly vests complete and unfettered discretion in decision makers is one which gives a hospital's governing body "the right to remove any member of the medical staff or to deprive any physician or surgeon of the privileges of the hospital whenever in their sole judgment the good of the hospital or the patients therein may demand it." *N. Broward Hosp. Dist. v. Mizell*, 148 So. 2d 1, 2 (Fla. 1962); *see also Tasher v. St. Tammany Parish Hosp.*, No. 87-1139, 1988 U.S. Dist. LEXIS 1018, at *5 (E.D. La. 1988) (The executive committee had complete discretion to summarily suspend privileges "whenever action must be taken immediately in the best interest of patient care in the hospital"; this same broad standard was applied at the post-deprivation hearing.). Also included in this category are those by-laws that are less blatant but, in application, still call for a purely subjective determination. These standards define the required level of competence as that which the decision makers determine is the "best possible care," *Wyatt v. Tahoe Forest Hosp. Dist.*, 345 P.2d 93, 95 (Cal. Ct. App. 1959) (only physicians and surgeons who, in the judgment of the board, would provide the "best possible care and professional skill" were granted staff privileges); *see also DUBY v. Jordan Hosp.*, 341 N.E.2d 876, 880 (Mass. 1976) (hospital, "in judging the [physician's] professional competence[,] required that he give his patients the 'best possible care'"); *Huffaker v. Bailey*, 540 P.2d 1398, 1399 (Or. 1975) (physician must provide to patients "a high quality of medical care"), or "adequate medical care," *Koelling v. Bd. of Trs. of Mary Francis Skiff Mem'l Hosp.*, 146 N.W.2d 284, 296-97 (Iowa 1966) (failure to provide "adequate" medical care); *see also Bock v. John C. Lincoln Hosp.*, 702 P.2d 253, 255 (Ariz. Ct. App. 1985) (physician's staff privileges were terminated because Executive Committee determined that the

consists of the same customary care standards that many state tort systems are starting to eschew based on concerns about their impact on quality of care.¹⁵¹ As is the case with the use of customary care standards in medical malpractice litigation, the reliance on customary care in peer review acts to entrench custom-based decision making at the cost of quality of care. However, the hospital peer review system provides an even stronger disincentive to the adoption of evidence-based medicine than the other quality systems. As discussed more fully in the next section, according to physicians, the termination of staff privileges triggered by a negative peer review report that is also filed with the NPDB can be a “career ender” because it is highly unlikely, if not impossible, to obtain staff privileges in another hospital or a new position that does not require staff privileges thereafter.¹⁵²

physician “failed to demonstrate to the Medical Committee that [he was] qualified to practice as an Internal Medicine specialist.” (internal quotation marks omitted), or “high quality medical care,” *Gaenslen v. Bd. of Dir. of St. Mary’s Hosp. & Med. Ctr.*, 232 Cal. Rptr. 239, 242 (Ct. App. 1985) (standard that excluded physicians from staff privileges who did not provide “high quality” care); *Huffaker*, 540 P.2d at 1399-401 (requirement that physicians provide a “high quality of medical care”). For a complete explanation of why these standards supply few limitations on the discretion of the decision makers which lead to a high risk of arbitrary and capricious decision making, see Van Tassel, *supra* note 3, at 1197-1241.

¹⁵¹ Examples of the standards that fall into this category of customary care include those which hold physicians to a standard of care as measured by the “[hospital’s] standard of competence,” *Adkins v. Sarah Bush Lincoln Health Ctr.*, 544 N.E.2d 733, 736 (Ill. 1989) (physician’s treatment of patients failed to conform to “the Center’s standard of competence”), or the “standard of the hospital or the medical staff,” *Campbell v. St. Mary’s Hosp.*, 252 N.W.2d 581, 588 (Minn. 1977) (corrective action appropriate when “professional conduct of any member of the staff shall be considered to be lower than the standard of the hospital or the medical staff”); *see also* *Helling v. Carey*, 519 P.2d 981, 983 (Wash. 1974); *DOBBS, supra* note 115, § 242, at 633; *Rhee v. El Camino Hosp. Dist.*, 247 Cal. Rptr. 244, 246, 248-49 (Ct. App. 1988) (Newly minted surgeon who had excellent credentials and training evaluations during his residency ran afoul of a group of surgeons in the hospital where he started his practice. Members of this group of physicians both served on the peer review panels charged with judging whether the new surgeon met this in-house standard and testified that the new surgeon “did not ‘meet the general standards of the surgical community at El Camino Hospital . . .”).

¹⁵² *See infra* notes 153-63 and accompanying text; *see also* Sheree Lynn McCall, *A Hospital’s Liability for Denying, Suspending and Granting Staff Privileges*, 32 BAYLOR L. REV. 175, 175 (1980) (“A physician’s livelihood is dependent on acquiring and maintaining hospital staff privileges. The access to hospital facilities is necessary for most physicians to adequately treat and care for patients, to maintain their medical practice, and to pursue their medical career.”).

B. *Peer Review Sanctions Can Be a “Career Ender,”
Chilling the Adoption of Evidence-Based Medicine*

The loss of hospital staff privileges in one hospital as the result of a negative peer review report can mean the end of a physician’s career.¹⁵³ A good example is that of a surgeon. For a surgeon, lack of access to hospital facilities to perform surgeries, in effect, ends that physician’s career.¹⁵⁴ The most obvious situation where this will occur is when there is only one hospital facility in the community.¹⁵⁵ Loss of clinical privileges at that sole hospital is likely to mean being barred from the practice of medicine in that community.¹⁵⁶

¹⁵³ For a detailed discussion of the myriad problems with hospital peer review, including its questionable constitutionality, see generally Katharine Van Tassel, *Blacklisted: The Constitutionality of the Federal System for Publishing Reports of “BAD” Doctors in the National Practitioner Data Bank*, 33 CARDOZO L. REV. 2031 (2012); McCall, *supra* note 152, at 175; Note, *The Physician’s Right to Hospital Staff Membership: The Public-Private Dichotomy*, 1966 WASH. U. L.Q. 485, 510-11 (concluding a successful doctor must have access to hospitals).

¹⁵⁴ See BARRY R. FURROW ET AL., HEALTH LAW: HORNBOOK SERIES § 7-1, 374 (2000) (explaining that precondition to the practice of medicine is access to hospitals).

¹⁵⁵ *Kiracofe v. Reid Mem’l Hosp.*, 461 N.E.2d 1134, 1142 (Ind. 1984) (noting that when a hospital is the only one in a community, “its economic impact is great, and the denial of hospital privileges, in many cases, is tantamount to denying a physician the opportunity to practice his or her chosen profession”). In *Greisman v. Newcomb Hosp.*, 192 A.2d 817, 824 (N.J. 1963), the court described the situation as follows:

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

Id.

¹⁵⁶ *Kiracofe*, 461 N.E.2d at 1142; *Greisman*, 192 A.2d at 824. What many seem to lose sight of is that a physician’s inability to practice has a ripple effect—when a physician can no longer practice medicine, all of that physician’s patients lose access to healthcare. This situation could impact hundreds of people. The loss of their physician is especially hard on those who are dependent on Medicaid and Medicare; it could be years before they are able to find a new physician willing to take on new Medicaid or Medicare patients. One in three physicians are currently turning away new Medicaid patients. Robert Lowes, *Almost 1 in 3 Physicians Turn Away New Medicaid Patients*, MEDSCAPE MED. NEWS (Aug. 7, 2012), <http://www.medscape.com/viewarticle/768763>. This situation will grow exponentially worse as the physician shortage grows and millions of new ACA patients and aging baby boomers flood the system.

While taking a bit more time to occur, an adverse peer review finding will ultimately impact the physician who practices in a very large community with multiple hospitals in the same disastrous way. When the hospitals perform their mandatory check of the NPDB for physicians applying for staff privileges for the first time, or their biennial check for physicians already on staff, the negative report will become known.¹⁵⁷ A termination or limitation of staff privileges at one hospital is likely to trigger a second hospital to follow suit to avoid placing itself at risk of being sued for negligent credentialing.¹⁵⁸ A national survey revealed that in 2007 alone, 48,075 licensure, credentialing, or membership decisions were impacted by NPDB reports.¹⁵⁹

Dr. Edward Dench, Jr., former President of the Pennsylvania Medical Society, opines that a data bank report

¹⁵⁷ See *supra* note 149.

¹⁵⁸ In a GAO Report on the problems with the accuracy of the data contained in the NPDB, the agency acknowledged that the information contained in the databank “can affect a practitioner’s reputation and livelihood.” MAJOR IMPROVEMENTS, *supra* note 144, at 3. A HRSA survey revealed that NPDB users, including credentialing committees, chiefs of the medical staff, department chairs and the chief executive officers, found the reports to be an important part of the credentialing process. Teresa Waters et al., *The Role of the National Practitioner Data Bank in the Credentialing Process*, AM. J. MED. QUALITY 34 (2006).

¹⁵⁹ ALAN LEVINE & SIDNEY WOLFE, HOSPITALS DROP THE BALL ON PHYSICIAN OVERSIGHT 6 & n.7 (2009), available at <http://www.citizen.org/documents/18731.pdf>. The Levine Report reached this conclusion using data from TERESA WATERS ET AL., NATIONAL PRACTITIONER DATA BANK USER AND NON-USER SURVEY FINAL REPORT 169 tbl.IV.C.94 (Apr. 2001). The authors of the Levine Report explained that they reached this conclusion based on Waters’s

survey question which was “Would your decision regarding the practitioner have been different if you had not received the NPDB response.” 9.04 percent of the responses answered “yes.” Applying this percentage to the 531,802 matches for 2007 results in an estimated 48,075 decisions that were affected by an NPDB report.

LEVINE & WOLFE, *supra*, at 6 n.7.

Adding to the cascade of negative effects a physician faces from a negative peer review report is the loss of both medical insurance and the termination of managed care contracts. In most states, a physician cannot practice without liability insurance. . . . And the loss of managed care contracts alone can destroy a physician’s practice, even without all of the other negative consequences of being blacklisted. The amazing growth of managed care compels the participation of almost all health care providers in managed care contracts. Physicians who are not part of a practice group with managed care contracts, or who are not preferred providers with multiple managed care organizations, have a difficult time maintaining a practice. In order to be considered for, or maintain, these contracts, health care providers must work to stay in good standing with these managed care organizations. Physicians who lose hospital staff privileges for quality of care reasons are highly likely to face the immediate termination of managed care contracts.

Van Tassel, *supra* note 153, at 2061-62 (footnote omitted).

“can essentially make you unemployable, and it can be the difference between getting insurance and not getting insurance.”¹⁶⁰ A far-reaching and comprehensive study commissioned by the State of California into the reasons for the low and declining level of reporting of negative peer review actions to the NPDB supports Dr. Dench’s claim, revealing that

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

....

... Physicians who had experienced [having a negative peer review report state that it] ... was a “career ender.”¹⁶¹

Thus, like the tort and licensure systems, the threat of a hospital peer review action provides a powerful disincentive to switching from custom-based to evidence-based practice. Arguably, the hospital peer review system, with its career-ending potential, is an even greater obstacle to this conversion.

V. SOLUTIONS

The solution to this disconnect between the ACA and the other three systems for improving healthcare quality, cost, and access involves both top-down and bottom-up strategies. In the context of the tort and licensure systems, the solution is a top-down one because it requires action on the part of state legislatures or court systems. It is up to legislators or judges to change the scope of the admissible evidence in medical malpractice and licensure cases, either by statute or case law, to allow risk–benefit analysis based on empirical evidence to become admissible on the issue of the standard of care.

¹⁶⁰ Steve Twedt, *A Negative Data Bank Listing Isn’t Easy to Erase*, PITTSBURGH POST-GAZETTE (Oct. 27, 2003), <http://www.post-gazette.com/pg/03300/234532.stm>.

¹⁶¹ LUMETRA, COMPREHENSIVE STUDY OF PEER REVIEW IN CALIFORNIA: FINAL REPORT 65, 94 (2008) (citation omitted), *available at* http://www.mbc.ca.gov/publications/peer_review.pdf (Physicians with negative peer review reports “described not being able to find any position or job after having [a negative] report filed and spending three to five years in [peer review] hearings and other procedures to fight for their reputations, even after the [licensure board] found no wrongdoing on their part. They reported spending thousands of dollars to fight the charges so they could again practice as physicians.”).

On the other hand, the solution is a bottom-up one when it comes to hospital peer review. Of course, because rational physicians are likely to balk at adopting evidence-based treatment choices if it will result in a lawsuit, the laws that make custom the exclusive proxy for quality must first be changed as explained above.

Next, as described below, regulations under the ACA should be formulated to allow for the integration of evidence-based medicine into hospital practice. To date, efforts to integrate evidence-based treatment choices into physician practice have met with little success. Scores of studies have revealed that physicians are being exposed to evidence-based medicine in the form of clinical practice guidelines (CPGs) on a regular basis—they go to seminars, listen, agree, then go back to practice and ignore the new information.¹⁶² The disconnect that these studies evince is a well-studied problem of translating knowledge into action.

¹⁶² See, e.g., Lee A. Green & Colleen M. Seifert, *Translation of Research into Practice: Why We Can't "Just Do It,"* J. AM. BD. FAM. PRAC. 541, 541 (2004) (There is "widespread agreement that physicians and healthcare systems simply do not put new knowledge about how to improve our patients' outcomes into practice nearly quickly enough. . . . For example, consider the guideline that 'congestive heart failure patients should be evaluated for use of beta-blockers.' An expert physician may be aware of this recommendation and may wholeheartedly accept it as good practice, but may still fail to adopt it when they happen to see an elderly patient in the clinic who could benefit from beta-blockade. Knowledge of evidence can remain separate from, and not integrated into, the physician's extensive database of procedures that guides their decision and actions. This makes the likelihood of recognizing that the new knowledge is appropriate and incorporating it into these well-rehearsed procedures very uncertain."); Illaria Baiardini et al., *Why Do Doctors and Patients Not Follow Guidelines,* 9 CURR. OPIN. ALLERGY CLIN. IMMUNOL. 228, 228 (2009) ("During the last few years, different studies and theories have tried to explain the reason why doctors and patients do not follow guidelines. . . . [A]lthough the effort made to develop and divulge evidenced-based guidelines, results of studies conducted in the United States and the Netherlands suggest that most of the time, guidelines are not applied[;] about 30-40% of patients do not benefit from a cure programme based on scientific evidence, whereas 20-25% of therapeutic choices may be unnecessary and sometimes even harmful."); Michael D. Cabana et al., *Why Don't Physicians Follow Clinical Practice Guidelines?*, 282 JAMA 1458, 1458 (1999) ("Despite wide promulgation, [clinical practice] guidelines have had limited effect on changing physician behavior."); Justin W. Timbie et al., *Five Reasons that Many Comparative Effectiveness Studies Fail to Change Patient Care and Clinical Practice,* 31 HEALTH AFFAIRS 2168, 2168 (2012) ("[D]ecades of experience suggest that translating evidence into changes in clinical practice is rarely rapid"); David A. Davis et al., *Translating Guidelines Into Practice: A Systematic Review of Theoretic Concepts, Practical Experience and Research Evidence in the Adopting of Clinical Practice Guidelines,* 15 CAN. MED. ASS'N 408, 408 (1997) ("The evidence shows serious deficiencies in the adoption of CPGs in practice.").

A. *Translating Knowledge into Action*

Behavioral scientists have developed a large body of empirical research on how to effectively put knowledge into action, which has resulted in the creation of what many call “knowledge translation theory” or “research implementation theory.”¹⁶³ Knowledge translation theory teaches that there are seven action phases that are key to translating knowledge into action:

- [1] specific identification of the problem;
- [2] identifying, reviewing, and selecting the knowledge to implement;
- [3] adapting or customizing the knowledge to the local context;
- [4] assessing the determinants of knowledge use;
- [5] selecting, tailoring, implementing, and monitoring knowledge translation interventions and knowledge uptake;
- [6] evaluating outcomes or impact of using the knowledge; and
- [7] determining strategies for ensuring sustained knowledge use.¹⁶⁴

These seven action steps can occur *in seriatim*. In addition, it is important to note that these knowledge steps can change the action phases at any point in the sequence.¹⁶⁵ “The action parts of the cycle are based on planned action theories that focus on deliberately engineering change in health care systems and groups.”¹⁶⁶ An important part of the theory is to actively consider the particular circumstances of the physicians who are the end users of the knowledge that is being assimilated.¹⁶⁷

The solution that this article proposes is the use of knowledge translation theory to integrate knowledge about effective treatment choices that have been developed through empirical science into daily physician practice. The empirically based knowledge that this proposal focuses on is the use of best practices based upon evidence-based guidelines called clinical practice guidelines (CPGs) to guide treatment choices.¹⁶⁸ CPGs

¹⁶³ Sharon E. Straus et al., *Knowledge Translation Is the Use of Knowledge in Health Care Decision Making*, 64 J. CLIN. EPI. 6, 6-10 (Jan. 2011).

¹⁶⁴ *Id.* at 9.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ CPGs are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” INST. OF MED., *CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM* 8 (Marilyn Field & Kathleen N. Lohr eds., 1990).

identify optimum treatment choices that are derived from clinical outcomes and effectiveness research.¹⁶⁹ CPGs reflect the “well-considered opinions of expert panels, based upon reviews of the best available data, as to how physicians should approach certain clinical problems.”¹⁷⁰ The use of CPGs to guide clinical decision making will improve quality of care by the use of what are called “best practices”¹⁷¹ and will decrease costs through the use of less costly choices that result in the same or better outcomes as higher-cost alternatives.¹⁷²

1. Applying Steps One Through Three of Knowledge Translation Theory

In order to specifically identify an initial set of CPGs that are appropriate to adopt into a particular practice context, the set of physicians who make up a specific practice group within a hospital should set up a working committee. The ultimate task of this working committee will be to propose to the entire practice group a set of CPGs that has been modified to fit the clinical care expectations of the practice group as a whole. An example would be a working committee of the cardiology practice group of a hospital which would likely start

¹⁶⁹ *Id.* at 6.

¹⁷⁰ Richard E. Leahy, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice guidelines*, 77 CALIF. L. REV. 1483, 1506 (1989).

¹⁷¹ Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369, 390-91, 394 (1995); KIRK B. JOHNSON ET AL., AM. MED. ASS'N, LEGAL IMPLICATIONS OF PRACTICE PARAMETERS 1 (1990) (referring to CPGs as “practice parameters” to guide physicians in “deliver[ing] high quality medical care in a fashion that is effective and efficient, thereby enabling the profession to respond to society’s need to assure appropriate utilization of health care services and to control health care expenditures without sacrificing quality of care.”); PHYSICIAN PAYMENT REVIEW COMM'N, 1989 ANNUAL REPORT TO CONGRESS 219-20 & n.1 (recommending federal support for outcome research and creation of practice guidelines based thereon); see also generally Robert H. Brook et al., *Predicting the Appropriate Use of Carotid Endarterectomy, Upper Gastrointestinal Endoscopy, and Coronary Angiography*, 323 NEW ENG. J. MED. 1173, 1173 (1990); David M. Eddy, *Clinical Decision Making: From Theory to Practice*, 263 JAMA 287, 287 (1990) (explaining the challenge that led to the best practices initiatives); Clark C. Havighurst, *Practice Guidelines for Medical Care: The Policy Rationale*, 34 ST. LOUIS U. L.J. 777 (1990); Eleanor D. Kinney & Marilyn D. Wilder, *Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities*, 22 U.C. DAVIS L. REV. 421, 424-27 (1989); Leahy, *supra* note 170; William L. Roper et al., *Effectiveness in Health Care: An Initiative to Evaluate and Improve Health Care*, 319 NEW ENG. J. MED. 1197, 1198 (1988) (describing what will later be labeled as a “best practices” initiative as an “effectiveness initiative” on the part of the Health Care Financing Administration); Steve Berman et al., *Foreword*, in Symposium, *Getting It Right: The Makings of Practice Guidelines*, 16 QUALITY REV. BULL., Feb. 1990, at 40.

¹⁷² Rosoff, *supra* note 171, at 370.

with the CPGs promulgated by the American College of Cardiology (ACC).¹⁷³ The CPG working committee would first evaluate these CPGs,¹⁷⁴ taking into consideration the suggestions of the entire practice group regarding modification of these CPGs to fit the collective practice style and professional judgments of all of the physicians in the practice group. The process of soliciting modifications will include educating the entire group regarding the merits (the strength of the science and the impact on quality) of each CPG at issue. Once these group suggestions are integrated into the CPGs, the working committee will then recommend them to the entire group for adoption.¹⁷⁵

¹⁷³ There are two main questions which a CPG committee should investigate when choosing the appropriate CPGs. First, who created the CPGs? And second, what scientific methods were used in the creation of the CPG? It is advisable for physicians to rely upon CPGs created by groups with “auspice legitimacy”—in other words, those developers with excellent reputations for accuracy and technical expertise. *Id.* at 384-85. These are most likely to be large national groups which represent practice specialties, such as the ACC or the American Heart Association. It is also recommended that physicians avoid CPGs promulgated by payors, referred to by some as “boundary guidelines.” Boundary guidelines “are used by payors to define a range of practice options within which physicians could act without incurring financial or other sanctions.” Havighurst, *supra* note 171, at 778 n.3 (citing L. LEWIN & J.E. ERIKSON, LEADERSHIP IN THE DEVELOPMENT OF PRACTICE GUIDELINES: THE ROLE OF THE FEDERAL GOVERNMENT AND OTHERS 3 (rev. ed. 1989) (prepared for the Physician Payment Review Commission’s Conference on Practice Guidelines, Washington, D.C., Oct. 11, 1988)). These CPGs are based on cost/benefit choices motivated by profit. CPGs that call for the provision of less care could increase the risk of malpractice exposure.

¹⁷⁴ In addition, the CPG committee must evaluate the scientific basis for the CPG in great detail. Was the patient population that made up the clinical practice data base sufficiently large? Were the results grounded on well-accepted scientific outcomes research? Were the methodologies used appropriate for the context and were they used under the guidance of qualified medical professionals? If any of these questions are answered in the negative, the CPG should be avoided. On the other hand, if the CPG was created to optimize quality of care by competent scientists based on careful analysis of an appropriately large data base and the results were controlled for confounding, bias and probability issues, the CPG could be a candidate for adoption taking into consideration the nature of the specific practice. Rosoff, *supra* note 171, at 384-86, 388, 390.

¹⁷⁵ The amount of time, duplication of effort, and expense associated with this CPG review enterprise is a legitimate criticism of this proposal. One solution to these concerns is to follow the lead of the institutional review boards (IRBs) of medical institutions which conduct multicenter trials during clinical investigations of drugs and devices.

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

See U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY USING A CENTRALIZED IRE REVIEW PROCESS IN MULTICENTER CLINICAL TRIALS (Mar. 2006), at Part II, <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm127013.pdf>. For

Thus, steps one through three of knowledge translation theory will have been applied: this initial committee will have specifically identified the problem (the particular instances of conflict between treatment choices suggested by customary practice versus evidence-based practice), will have identified, reviewed, and selected the knowledge to implement (which CPGs to adopt), and will have adapted or customized the knowledge (the CPG) to the local context.

2. Applying Steps Four Through Seven of Knowledge Translation Theory

Once the adoption of the initial set of CPGs has been completed, a CPG committee would be appointed on a yearly basis which could review and update the guidelines. Whenever ACC (or another appropriate group that has auspice authenticity¹⁷⁶) distributes new CPG provisions or revisions of existing CPGs, the CPG committee could make recommendations to the cardiology practice group for adoption (with or without revision) or rejection.

Once the CPGs are adopted by the practice group, each physician who is a member of that department will be expected to comply with the CPGs except in situations where, in the judgment of the physician, they are not appropriate.¹⁷⁷ In those

example, central IRBs have been created to review multicenter trials dealing with a particular type of condition. “[T]he National Cancer Institute . . . has created a freestanding central IRB . . . to provide the option for centralized IRB review for the many multicenter cancer trials conducted by NCI.” *Id.* at Part VII.B. Similarly, CPG committees with comparable practice specialties could contract with a centralized CPG review group to perform a continuous review of CPGs to reflect scientific developments. The recommendations of this centralized CPG group could then be submitted to the CPG committee of the local institution for adoption, adoption with modification, or rejection. This pooling of resources is one way to deal with the concerns of duplication of effort, delay, and expense.

¹⁷⁶ See Rosoff, *supra* note 171, at 384-95.

¹⁷⁷ As Professor Rosoff explains:

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

Id. at 375.

circumstances, the physician will be expected to engage in documentation of the reasons for deviating from the CPGs. A physician who fails to comply with the CPGs without a well-documented rationale should be subject to corrective action.

This process fits with the paternalistic libertarian theory advanced by Harvard Professor Cass Sunstein and University of Chicago Professor Richard Thaler, which starts with a default position based upon empirical evidence of best practices but then allows for individual choice in deviating from this default if it is reasonable to do so.¹⁷⁸ What this system does not allow for is an irrational choice or an “unthinking” choice to deviate from the norm without careful consideration. Just as with crossing a street, when a reasonable person should “stop, look, and listen,” the CPGs ask physicians to stop, think, and make a rational choice to accept or reject the CPG. Then, these physicians must document their reason for a choice to reject the CPG, which creates data for review by risk management.

In the area of scientific uncertainty, where one size does not fit all and the art of medicine must come into play, the paternalistic libertarian model works well. It allows for a starting point in the decision-making tree that is based on empirical data for the treatment of “norm,” with the freedom to make a different choice if reasonable.

To keep the CPGs from falling behind current best practices, the cardiology CPG committee should perform updates on an ongoing basis to keep pace with scientific developments. The CPGs adopted by the cardiology practice group would then become the practice norm for all of the cardiology practice group’s physicians. Data should be gathered by the risk management department on the actual implementation of the CPGs. If a CPG was not followed,

¹⁷⁸ Cass Sunstein & Richard Thaler, *Libertarian Paternalism Is Not an Oxymoron*, 70 U. CHI. L. REV. 1159, 1159 (2003).

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

collecting information on the reasons why the CPG was not followed will allow for further modifications to fit the needs of the practice and its patients. Fine tuning the CPG in this way will improve adherence to the CPG.

Thus, steps four through seven of knowledge translation theory will have been applied. Pursuant to step four, a continuous assessment will be made by risk management of the determinants of knowledge use (when the CPGs have been followed or not, and why). Pursuant to step five, if further education regarding the CPGs is needed, problem solving can be done and strategies for teaching can be created by the cardiology CPG committee in conjunction with risk management. Thus, a continuing assessment of the success in implementing the CPGs and their impact on healthcare quality and cost can be made, fulfilling the requirements of steps six through seven for translating knowledge into action.

3. A Working Example of the Application of Knowledge Translation Theory

The prescription of aspirin after a heart attack provides a simple example of how this process will work. Scientific studies have long established that providing aspirin to a patient within twenty-four hours of a heart attack may increase that patient's chances of survival by thirty percent.¹⁷⁹ Yet fifty percent of physicians in hospitals across the country are failing to provide this simple, lifesaving treatment.¹⁸⁰ Under this proposal, the CPG committees of all of the hospital cardiology departments across the country should propose that the CPG of the American College of Cardiology¹⁸¹ recommending this treatment be adopted as an expectation of performance of the medical staff of each hospital's cardiology department.

To provide an example of how the exception to following the CPG would work, if this CPG on aspirin treatment for heart attack victims has been adopted and a heart attack patient is admitted to the hospital with a condition that contradicts the provision of this treatment, the physician must document this fact. Otherwise, the failure to provide the

¹⁷⁹ Fessenden, *supra* note 23.

¹⁸⁰ Van Tassel, *supra* note 3, at 1245.

¹⁸¹ The ACC/AHA Guidelines for the Management of Patients with Acute Myocardial Infarction, and updates to the guidelines, are published in the *Journal of the American College of Cardiology*, 28 AM. C. CARDIOLOGY 1328, 1374-76 (1996); 34 AM. C. CARDIOLOGY 890, 890-911 (1999) (updates), available at <http://coment.onlinejacc.org/>.

treatment will violate the performance expectation as set forth in the adopted CPG. This documentation exception should avoid a rigid expectation that the CPG be followed in all circumstances. It recognizes that patient care does not always follow the norm and allows for flexibility to adjust to a patient's unique needs.

This exception also allows for the high level of scientific uncertainty that exists currently when it comes to many medical conditions, particularly in the realm of the treatment of outliers. As the practice of evidence-based medicine (also known as population-based medicine or the treatment of "norm") grows through the greater understanding of optimal treatment choices through big data techniques to establish comparative effectiveness—and later transitions to personalized medicine based on the treatment of individuals according to their unique genetic profiles—the currently high degree of scientific uncertainty will steadily diminish and reduce the use of this exception.

This committee system will allow for physician choice among CPGs¹⁸² which will then suggest treatment choices based on best outcomes derived from empirical studies.¹⁸³ An example of how this is already being done is the integrated practice model adopted by the Mayo Clinic¹⁸⁴ and the VA Hospital System.¹⁸⁵

CONCLUSION

As pointed out in this article, a large and rapidly growing group of empirical studies suggests that the current normative practice of custom-based medicine in the United States has a negative impact on the quality and cost of healthcare. The quality and cost problems with the customary care model have led to a national push to move the United

¹⁸² Clinical Practice Guidelines are based on empirical data generated by clinical outcomes and effectiveness research which suggests the optimum treatment for a rapidly growing number of clinical conditions. Leahy, *supra* note 170, at 1506.

¹⁸³ *Id.* This use of empirical data generated through scientific methodology to make medical decisions shows great promise for enhancing quality of care while decreasing the cost of care. Van Tassel, *supra* note 3, at 1245.

¹⁸⁴ See DOUGLAS MCCARTHY ET AL., THE COMMONWEALTH FUND, PUB. NO. 1306, MAYO CLINIC: MULTIDISCIPLINARY TEAMWORK, PHYSICIAN-LED GOVERNANCE, AND PATIENT-CENTERED CULTURE DRIVE WORLD-CLASS HEALTH CARE 13 (2009), available at http://www.commonwealth.org/~media/Files/Publications/Case%20Study/2009/Aug/1306_McCarthy_Mayo_case%20study.pdf (describing the structural and cultural pillars undergirding the Mayo Clinic's integrated model of health care delivery).

¹⁸⁵ See *supra* note 76 and accompanying text.

States to a modern, evidence-based model of medical practice through major changes in government-provided healthcare.

However, the three main systems already in place for improving healthcare in the United States are encouraging the perpetuation of custom-based practices undermining the national efforts to improve the quality and cost of healthcare through the practice of evidence-based treatment choices. This article's specific suggestions for how these systems can be modified to work in tandem with federal law will encourage physicians to adopt the evidence-based model of medical practice in order to improve healthcare quality, cost, and access.