

# **A NOVEL APPROACH TO DETERMINING BEST MEDICAL PRACTICES: LOOKING AT THE EVIDENCE**

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## I. PREFACE

The practice of medicine in America is changing. Our population is growing, partially as a result of advancing medical knowledge and technology that saves and prolongs lives that would have been lost fifty years ago. With a growing number of patients to serve and the increased cost of treatment that has accompanied these advances, America has reached a critical time in which access to quality health care is a significant concern for nearly everyone. The good news is that we now have answers to questions once thought unanswerable and methods of sharing and applying those answers that many never dreamed possible. Using these resources in a way that makes health care more efficient, accessible, and successful will require expertise as well as commitment to medical practice based on evidence, transparency, and the ability to track our progress and adapt. We are at the threshold of an era of medicine based in

information rather than individual experience. As evidence based practice becomes the standard in the medical profession, the judiciary and state and federal legislators will fulfill their role and adapt the law to meet the requirements of changed circumstances. Evidence based medicine has been around for some time, but the technology to share evidence instantly and easily is only now being developed. By integrating high quality evidence with technology, the healthcare industry can lead the way to better outcomes in the emergency room and the courtroom.

## II. INTRODUCTION

The healthcare industry has utilized clinical practice guidelines for decades.<sup>1</sup> This paper will explore the future of clinical practice guidelines as a tool for improving the delivery of healthcare to a growing population with more limited financial resources and their use as evidence in medical malpractice litigation.

Part I begins with an explanation of the development and organization of scientific knowledge and how healthcare providers have applied that knowledge as medicine has transitioned from superstition to educated guesswork to evidence-based practice. Next, this section discusses what guidelines are, why they work, the deficiencies and drawbacks of current guidelines, and a strategy to improve the quality and delivery of guidelines to health care providers. Finally, Part I explores implementation of a nationwide guideline delivery system that integrates guidelines into clinician workflow and strategies for enforcement of adherence to that system.

Part II first discusses the legal implications of the development of an integrated guideline delivery system. The section begins by examining the development of tort law as applied to professional negligence in medicine, followed by a discussion of the weaknesses inherent in the current judicial approach. Part II then discusses evidentiary issues, comments on current awareness and utilization of

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<sup>1</sup> See Anthony M. Napoli & Andy Jagoda, *Clinical Policies: Their History, Future, Medical Legal Implications, and Growing Importance to Physicians*, 33 J. EMERGENCY MED. 425, 425-26 (2007).

guidelines by malpractice attorneys, and highlights previous legislative experiments encouraging the use of guidelines in malpractice litigation. The paper concludes with a discussion of the inevitability of wider utilization of guidelines and proposes a path for their expedient integration into regular medical and legal practice.

### III. PART I

#### A. Evolution of Medical Evidence

Early medicine was based on the barest and most undeveloped of evidence. In ancient cultures, medicine men were the keepers of magic secrets—those who could communicate with the gods and procure relief from what early civilizations considered signs of divine displeasure.<sup>2</sup> Hippocrates, often thought of as the father of modern medicine,<sup>3</sup> was “one of the first to declare that illness was caused, not by gods or evil spirits, but for biological reasons. . .”<sup>4</sup> As a physician and philosopher in ancient Greece, his evidence was the changes he observed in the human body, and his concept of prognosis was an attempt to predict these changes.<sup>5</sup> Galen, perhaps the greatest medical mind of the ancient world, was forbidden by law to dissect humans.<sup>6</sup> Therefore, much of his groundbreaking work discovering the separate functions of arteries and veins and mapping the human circulatory system was based on his work dissecting pigs, dogs, apes, and even elephants.<sup>7</sup>

By the Middle Ages, medicine had become a creature of

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<sup>2</sup> See JOHN CAMP, *MAGIC, MYTH AND MEDICINE* 16 (Taplinger Publ'g Co. 1973).

<sup>3</sup> See ROGER FRENCH, *MEDICINE BEFORE SCIENCE: THE RATIONAL AND LEARNED DOCTOR FROM THE MIDDLE AGES TO THE ENLIGHTENMENT* 9 (Cambridge Univ. Press 2003).

<sup>4</sup> CAMP, *supra* note 2, at 17.

<sup>5</sup> See FRENCH, *supra* note 3, at 11-12.

<sup>6</sup> PAUL STRATHERN, *A BRIEF HISTORY OF MEDICINE FROM HIPPOCRATES TO GENE THERAPY* 22, 24 (1st Carroll & Graf ed., Carroll & Graf Publishers 2005).

<sup>7</sup> See *id.* at 29-33.

superstition, closely tied to religious dogma.<sup>8</sup> Sickness was thought of as a punishment for sinfulness, and the sick were often ostracized from society.<sup>9</sup> These attitudes were exacerbated by a lack of scientific knowledge and preserved by a societal impetus against its development, fueled by fear among religious leaders of the belief that nature, not God, held the ultimate power over life and death.<sup>10</sup>

With the Renaissance came an explosion of scientific thought and innovation,<sup>11</sup> fueled in part by the fall of Constantinople in 1453, which allowed for the recovery of many ancient texts.<sup>12</sup> People had a new hunger for knowledge about the natural world that could be tested and recorded.<sup>13</sup> The study of alchemy bred a closer look at the small parts that make up our bodies and our world, and the foundation began to be laid for a base of human knowledge about how our bodies work.<sup>14</sup> Throughout this time, physicians relied on their experience, on what they observed in individual patients.

Physicians and scientists have done their best over the centuries to compile what evidence was available, but until relatively recently the ability to track, record, and apply evidence was severely limited by technology. The ability to travel quickly across great distances, to speak by telephone and fax, and the technological miracle of electronic communication has allowed development of more advanced and reliable clinical trials, lower rates of error, and an enhanced ability to develop and compare higher quality evidence. As a result, the amount of high quality evidence being created today is far greater than it was even twenty years ago.<sup>15</sup> Instead of relying solely on their experience, doctors now have the benefit of scientific

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<sup>8</sup> See FRENCH, *supra* note 3, at 66.

<sup>9</sup> See STRATHERN, *supra* note 6, at 69-70.

<sup>10</sup> See FRENCH, *supra* note 3, at 66-67.

<sup>11</sup> See PHILIP RHODES, *AN OUTLINE HISTORY OF MEDICINE* 42-43 (Cambridge Univ. Press 1985).

<sup>12</sup> See GEORGE OSTROGORSKY, *HISTORY OF THE BYZANTINE STATE* 571-72 (Joan Hussey trans., Rutgers Univ. Press, rev. ed. 1969).

<sup>13</sup> See RHODES, *supra* note 11, at 42.

<sup>14</sup> See STRATHERN, *supra* note 6, at 75-77.

<sup>15</sup> See Simon C. Mathews & Peter J. Pronovost, *Physician Autonomy and Informed Decision Making: Finding the Balance for Patient Safety and Quality*, 300 *JAMA* 2913, 2913-14 (2008).

evidence to guide their decision making.<sup>16</sup> So why is it that even where there is evidence of the highest quality, many doctors still ask the oldest doctor in the room? It would be overly simplistic and likely unfair to accuse doctors of being unwilling to change or unwilling to accept scientific evidence because of some fear that they will lose their special status in society. More likely the problem has its roots in the current guidelines themselves. Surveys show that most physicians agree with the idea of guidelines,<sup>17</sup> so how can we manage the development and delivery of guidelines so that physicians will actually use them in practice?

## B. Guideline Basics

Clinical practice guidelines (CPGs) are recommended clinical approaches to specific healthcare issues.<sup>18</sup> Guidelines can be directed to physicians, nurses, allied health professionals, or even to health care administrators.<sup>19</sup> They can address particular interventions meant to be applied to the individual patient or systems measures meant to improve overall patient safety at an institution.<sup>20</sup> A guideline comes into play once a physician has made a diagnosis or a hospital has identified a systematic problem.<sup>21</sup> Once the problem is identified, the guideline is employed to incorporate the most recent and relevant evidence and recommendations based on that evidence into the care delivered to the individual patient.<sup>22</sup>

Thousands of guidelines have been written, including multiple

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<sup>16</sup> See *id.* at 2914.

<sup>17</sup> Sean R. Tunis et al., *Internists' Attitudes about Clinical Practice Guidelines*, 120 ANNALS INTERNAL MED. 956, 959 (1994).

<sup>18</sup> Ash Samanta et al., *The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the Bolam Standard?*, 14 MED. L. REV. 321, 321 (2006) (citation omitted).

<sup>19</sup> See generally National Guideline Clearinghouse, Guideline Index, [http://www.guideline.gov/browse/guideline\\_index.aspx](http://www.guideline.gov/browse/guideline_index.aspx) (last visited Sept. 18, 2009).

<sup>20</sup> *Id.*

<sup>21</sup> See Samanta et al., *supra* note 18, at 321.

<sup>22</sup> See *id.* at 321-22.

guidelines on the same subjects.<sup>23</sup> Because a system has not yet been developed to effectively certify guidelines based on highest quality methodology that could reject those that do not meet explicit standards, many guidelines are of poor quality<sup>24</sup> and may even contradict one another.<sup>25</sup> Guidelines are developed by many different groups with various agendas and goals.<sup>26</sup> Managed care organizations have long used guidelines as a way to limit expenditures.<sup>27</sup> On the other hand, guidelines from patient safety groups on hand hygiene in hospitals have drastically reduced the incidence of hospital-acquired infection, saving thousands of lives.<sup>28</sup> Guidelines may be based on evidence of varying quality, from randomized, double-blind clinical trials—evidence of the highest quality—to consensus based guidelines developed from the opinions and experience of experts—evidence of the lowest quality.<sup>29</sup> Variations in the methodology currently employed in the development of these guidelines may cause physicians to view them with a jaundiced eye.<sup>30</sup>

There is now a large and growing bio-medical evidence base, and evidence developed from high quality studies is added every day.<sup>31</sup> The speed at which technology has developed over the last quarter-

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<sup>23</sup> See Richard E. Moses & Andrew D. Feld, *Legal Risks of Clinical Practice Guidelines*, 103 AM. J. GASTROENTEROL. 7, 8 (2008).

<sup>24</sup> See Mathews & Pronovost, *supra* note 15, at 2915.

<sup>25</sup> Allan D. Sniderman & Curt D. Furbert, *Why Guideline-Making Requires Reform*, 301 JAMA 429, 430 (2009).

<sup>26</sup> Napoli & Jagoda, *supra* note 1, at 425.

<sup>27</sup> See Moses & Feld, *supra* note 23, at 8.

<sup>28</sup> See Ctrs. Disease Control and Prevention, *Guideline for Hand Hygiene in Health-Care Settings*, <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm> (last visited Sept. 25, 2009).

<sup>29</sup> Steering Comm. on Quality Improvement and Mgmt., Am. Acad. of Pediatrics, *Classifying Recommendations for Clinical Practice Guidelines*, 114 PEDIATRICS 874, 875 (2004) [hereinafter *Steering Comm., Classifying Recommendations*].

<sup>30</sup> See Napoli & Jagoda, *supra* note 1, at 427.

<sup>31</sup> See Mathews & Pronovost, *supra* note 15, at 2914; see also Wendy E. Gerhardt et al., *Putting Evidence-Based Clinical Practice Guidelines into Practice: An Academic Pediatric Center's Experience*, 33 JOINT COMM'N J. ON QUALITY & PATIENT SAFETY 226, 226 (2007).

century has fueled an expansion in the field of clinical research, and those in the field have responded with a greater volume of higher quality data. As a result, we are now in a position to identify healthcare interventions that have been proven to benefit public health on a macro level, a pursuit that has at times had our leaders at each other's throats over the merits of a fully privatized or fully government-run healthcare system. Putting aside the politico-ideological struggles over the final form of our approach, as stakeholders in our health care system we must recognize that science demands evidence. Once the evidence has been developed and the methodology behind it tested and proven, we should, if we are serious about our commitment to improve public health, demand that it be applied in practice.

### C. The Role of Guidelines in Improving Healthcare

One of the most important goals of CPGs is to reduce unwarranted variations in care.<sup>32</sup> In other words, CPGs are part of an effort to standardize medicine in America. "Standardization is among the best methods available to improve quality and reduce costs of care."<sup>33</sup> We have a national curriculum in our medical schools, yet hospitals, even within the same region, can have vastly different approaches to the same condition.<sup>34</sup> For example, the administration of aspirin to patients presenting with symptoms of a heart attack, outside of a small percentage for whom aspirin is contra-indicated, has been shown to have substantial benefit with minimal risk of harm.<sup>35</sup> As a result, aspirin is recommended for

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<sup>32</sup> Napoli & Jagoda, *supra* note 1, at 426.

<sup>33</sup> Mathews & Pronovost, *supra* note 15, at 2914.

<sup>34</sup> See Dartmouth Institute, Dartmouth Atlas of Health Care, [http://www.dartmouthatlas.org/data\\_tools.shtml](http://www.dartmouthatlas.org/data_tools.shtml) (last visited Sept. 18, 2009) (From this page you can link to maps that can be queried to show variations in care based on treatment and geographical region); Karen C. Lee et al., *Pediatricians' Self-reported Clinical Practices and Adherence to National Immunization Guidelines After the Introduction of Pneumococcal Conjugate Vaccine*, 158 ARCHIVES PEDIATRIC ADOLESCENT MED. 695, 695 (2004) (discussing self-reported low adherence rates to generally accepted immunization schedules by pediatricians).

<sup>35</sup> See Cari R. Levy et al., *Acute Myocardial Infarction in Nursing Home Residents: Adherence to Treatment Guidelines Reduces Mortality, But Why Is Adherence So Low?*, 10 J. AM. MED. DIR.

nearly every patient presenting with such symptoms. Yet, adherence to this guideline is as low as fifty percent in some hospitals.<sup>36</sup> There is no purpose behind withholding that inexpensive little pill; it just is not given.<sup>37</sup> This type of unwarranted variation in care between hospitals creates a problem that confounds the medical professionals who strive to track and understand physician and hospital error.<sup>38</sup>

A system that allows for unwarranted treatment variations naturally results in random errors, which are not capable of organization or comparison; nothing is learned from the pain and suffering these errors cause. Standardization of health care, even if only for interventions backed by the strongest of evidence, will result in a drastic reduction of random error. Once random error is reduced, what is left is systematic error, which can be tracked, evaluated, and corrected.

Opponents of standardization of medicine cite the uniqueness of each patient and the resulting need for individualized approaches.<sup>39</sup> The argument is that data derived from the study of groups of people will often not be applicable to the individual patient with unique circumstances.<sup>40</sup> In actual practice standardized medicine allows for and even encourages varied approaches where patient characteristics or desired outcomes provide a valid basis for variation.<sup>41</sup> Standardized medicine is not a mechanization of healthcare requiring doctors to become technicians or automatons. Rather, it is a powerful tool to deliver a limited amount of healthcare to the greatest number of people in the most effective way.

Another positive aspect of guidelines, if they are created and

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ASSOC. 56, 56-58 (2009).

<sup>36</sup> See *id.* at 56.

<sup>37</sup> See *id.* at 60.

<sup>38</sup> See Mathews & Pronovost, *supra* note 15, at 2914.

<sup>39</sup> See John R. Hampton, *Guidelines – for the Obedience of Fools and the Guidance of Wise Men?*, 3 CLINICAL MED. 279, 280-81 (2003).

<sup>40</sup> See Finlay A. McAlister et al., *How Evidence-Based Are the Recommendations in Evidence-Based Guidelines?*, 4 PLOS MED. 1325, 1329 (2007).

<sup>41</sup> Mathews & Pronovost, *supra* note 15, at 2914; see also Steering Comm., *Classifying Recommendations*, *supra* note 29, at 876.

implemented thoughtfully, is the level of patient participation they engender. Patient compliance with doctors' instructions, or more accurately their lack of compliance, is cited as a major reason for the apparent ineffectiveness of many treatments.<sup>42</sup> The legal doctrine of informed consent, which has developed into an indispensable aspect of health care in the United States, was a rejection of the concept that "doctor knows best." The doctrine recognized that patients need to play a role in their own health care to obtain their desired outcomes and avoid uncomfortable risks. CPGs can inform patients as well as doctors by indicating not only the recommended course of treatment but also the risks, alternatives, and evidence that underlie those recommendations.<sup>43</sup> CPGs can facilitate conversations between patient and doctor, as well as help bridge the gap between the mysterious world of diagnostics and the real and tangible world of treatment.<sup>44</sup> Informing the individual patient is paramount both for legal reasons and to fully involve patients in their own health care. The latter increases the likelihood that patients will truthfully disclose necessary information to physicians and comply fully with physician instructions. Any high quality guideline should have the input not only of the health care specialties that touch on the interventions involved but also patients who can represent the concerns of the individual receiving the care.<sup>45</sup>

#### **D. Room for Improvement**

Despite the near universal understanding that reducing unwarranted variations in care is the best approach to improving overall patient outcomes and reducing costly and often detrimental overtreatment, physicians are still wary of CPGs.<sup>46</sup> One survey of

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<sup>42</sup> See R. Brian Haynes et al., *Helping Patients Follow Prescribed Treatment: Clinical Applications*, 288 JAMA 2880, 2880 (2002).

<sup>43</sup> Steven H. Woolf et al., *Potential Benefits, Limitations, and Harms of Clinical Guidelines*, 318 BRIT. MED. J. 527, 527-28 (1999).

<sup>44</sup> *Id.*

<sup>45</sup> M. Hassan Murad et al., *Incorporating Patient Preferences in Evidence-Based Medicine*, 300 JAMA 2483, 2483 (2008).

<sup>46</sup> Monika Pogorzelska & Elaine L. Larson, *Assessment of Attitudes of Intensive Care Unit Staff*

health care providers showed that while over 60% of internists agreed that guidelines are good educational tools and likely to improve the quality of health care, only 18% reported that their practice had changed in the past year as a result of guideline use.<sup>47</sup> Two factors were most prominent among these providers' reasons for distrust of CPGs.

First, they do not always trust the source of the guidelines.<sup>48</sup> Guidelines come from many sources. They are often based on low quality evidence, which is compiled based on poor methodology.<sup>49</sup> Sometimes they are promulgated for reasons other than improved patient care, such as cost control or health care rationing.<sup>50</sup> Many are not transparent as to the selection of the drafting panel, the interests of the panel members/organization developing the guideline, or the evidence upon which recommendations are based.<sup>51</sup> Physicians tend to trust guidelines that are transparent, as well as those that come from a professional association with which the physician is associated.<sup>52</sup> Second, physicians fear that CPGs represent a step toward reliance on "cookbook" medicine and the beginning of the end of physician autonomy and discretion.<sup>53</sup> In addition, there are legitimate concerns about whether CPGs are sufficiently current and how often they need to be updated in order to maintain their value.<sup>54</sup>

The concerns of health care providers about the sources and quality of the guidelines with which they are presented are well founded. There are thousands of guidelines presently in use in

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*Toward Clinical Practice Guidelines*, 27 DIMENSIONS CRITICAL CARE NURSING 30, 30 (2008).

<sup>47</sup> Tunis, *supra* note 17, at 959-60.

<sup>48</sup> *Id.* at 961.

<sup>49</sup> *Id.*

<sup>50</sup> Woolf, *supra* note 43, at 529; see also Jodi M. Finder, *The Future of Practice Guidelines: Should They Constitute Conclusive Evidence of the Standard of Care?*, 10 HEALTH MATRIX 67, 74 (2000).

<sup>51</sup> Sniderman & Furbert, *supra* note 25, at 429-30.

<sup>52</sup> Tunis, *supra* note 17, at 961.

<sup>53</sup> *Id.* at 959.

<sup>54</sup> Paul G. Shekelle et al., *Validity of the Agency for Healthcare Research and Quality Clinical Practice Guidelines: How Quickly Do Guidelines Become Outdated?*, 286 JAMA 1461, 1461 (2001).

American health care institutions,<sup>55</sup> often covering the same subjects, with some even directly contradicting one another.<sup>56</sup> Many are consensus based, as opposed to evidence-based guidelines.<sup>57</sup> Consensus-based means that the identifying symptoms, relevant considerations, and recommendations contained in the guideline are based on a consensus of the experience based opinions of the practitioners who authored it.<sup>58</sup> Experience is the most unreliable form of evidence for the same reason that guidelines and standardization are powerful tools to improve health care: because the most useful information in health care is derived on the basis of what is most likely to happen to an individual patient based on what happens to large groups of similar patients that receive similar treatment.<sup>59</sup> In other words, one individual patient case may contain variables or anomalies not found in most patients, so that a doctor's experience with a particular patient may seem to indicate one approach, when in fact that approach diverges from what would be proper treatment for the vast majority of patients. The highest quality evidence available is derived from fully randomized, double-blind trials with enough participants to make the results statistically significant.<sup>60</sup> Few, if any, guidelines are based completely on such high quality evidence.<sup>61</sup> Indeed, the evidence necessary to codify every approach in every situation does not exist, and it may never exist.<sup>62</sup> The highest quality clinical practice guidelines are based on the highest quality *available* evidence, coupled with transparency as to the makeup of the panel, the organization developing the guideline, the interests of all parties involved, the quality of evidence

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<sup>55</sup> Napoli & Jagoda, *supra* note 1, at 425.

<sup>56</sup> See Sniderman & Furbert, *supra* note 25, at 430.

<sup>57</sup> See Napoli & Jagoda, *supra* note 1, at 426.

<sup>58</sup> *Id.*

<sup>59</sup> GEOFFREY R. NORMAN & DAVID L. STREINER, PDQ EPIDEMIOLOGY 123 (2nd ed., B.C. Decker, Inc. 1998).

<sup>60</sup> See Steering Comm., *Classifying Recommendations*, *supra* note 29, at 875.

<sup>61</sup> See *id.*

<sup>62</sup> See Sniderman & Furbert, *supra* note 25, at 430.

underlying each recommendation, and consideration of patient preferences.<sup>63</sup>

On the scale of quality between pure consensus based guidelines and those based only on the highest quality, double-blind, randomized trial evidence are guidelines considered by many to be the most insidious: those promulgated by managed care organizations.<sup>64</sup> Such guidelines could be seen as mechanisms used by these organizations to avoid paying for certain procedures for patients with whom they contract to provide health care.<sup>65</sup> Of course, for the doctor concerned with delivering the highest quality care or the patient concerned with receiving such care, the issue with managed care organization produced guidelines should be less with the source of those guidelines than it is with the quality of the guideline itself.<sup>66</sup> One might assume these organizations have a greater interest in cost control than in quality of care. Against that backdrop, such guidelines should be suspect if they are ambiguous as to the quality of evidence behind their recommendations or as to the viable alternatives that are available to the patient. Perceptions aside, the quality of a guideline is a product of transparency in the methodology used in the development of the guideline combined with the clarity of the recommendations with respect to the underlying evidence, the available treatment alternatives, and the patient outcomes envisioned by the authors in constructing the specific recommendations.<sup>67</sup> Shortcomings in these areas are characteristic of many of the guidelines currently available, and without a systematic approach to reviewing and approving guidelines based on these criteria, physician distrust of guideline content is inevitable and even appropriate.

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<sup>63</sup> See *id.* at 429; see also Steering Comm., *Classifying Recommendations*, *supra* note 29, at 875.

<sup>64</sup> See Am. Coll. of Emergency Physicians, *Clinical Guidelines in a Managed Care Env't* 7 (June 1998), <http://www.acep.org/workarea/DownloadAsset.aspx?id=8944>.

<sup>65</sup> See Heidi Grisson, *Practice Guidelines: The Physician's Friend or Foe?*, 57 *CURRENT SURGERY* 158, 158 (2000).

<sup>66</sup> See *id.*

<sup>67</sup> Steering Comm., *Classifying Recommendations*, *supra* note 29, at 877.

## E. The "Cookbook" Medicine Myth

The issue of loss of discretion by doctors in favor of "cookbook" medicine controlled solely by guidelines is one that causes consternation among health care providers.<sup>68</sup> This issue, like the issue of questionable guideline sources, can be addressed by regulating what guidelines are approved for use and how those approved guidelines must be constructed. Non-transparent guidelines, those that fail to identify the evidence that underlies each recommendation, may seem to present each recommendation as the understood proper approach. In fact, a recommendation backed by the highest quality evidence with a positive risk/benefit ratio is the proper approach in most situations. However, it is well understood that particular patients may have characteristics that remove them from the group for whom a particular recommendation is applicable.<sup>69</sup> It is within the discretion of the treating physician, and further is her duty, to decide whether a particular patient fits the profile in the guideline.<sup>70</sup> It is as irresponsible to apply a guideline recommendation to a patient to whom it does not apply as it is to fail to apply a high quality guideline recommendation to a patient to whom it does.<sup>71</sup> The lower the strength of the recommendation, the more discretion a treating physician has to determine the proper course of treatment. A high quality guideline, which identifies the evidence underlying each recommendation, does not eliminate physician discretion, but it instead bounds that discretion in accordance with the best available clinical evidence.<sup>72</sup> The result is that if only high quality guidelines were available, physicians would be allowed whatever discretion necessary to fill in the gaps left in the available evidence. Any exercise of discretion beyond that would be

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<sup>68</sup> See Mathews & Pronovost, *supra* note 15, at 2914; see also Tunis, *supra* note 17, at 959.

<sup>69</sup> See Ole Frithjof Norheim, *Healthcare Rationing – Are Additional Criteria Needed for Assessing Evidence Based Clinical Practice Guidelines?*, 319 *BMJ* 1426, 1427 (1999).

<sup>70</sup> See T. S. Cheah, *The Impact of Clinical Guidelines and Clinical Pathways on Medical Practice: Effectiveness and Medico-legal Aspects*, 27 *ANNALS ACAD. MED. SING.* 533, 536 (1998).

<sup>71</sup> See *id.*

<sup>72</sup> See Steering Comm., *Classifying Recommendations*, *supra* note 29, at 876.

irresponsible. One would assume that responsible doctors do not seek such discretion.

That is not to say that no guidelines have a negative effect on the discretion afforded reasonable and responsible doctors. In the context of managed care organization guidelines, physicians may be restricted from taking an approach that, while not supported by the highest quality evidence, does have some evidentiary support and is both the physician and patient's choice for treatment.<sup>73</sup> In such a situation, physicians have a legitimate reason to fear an unreasonable restriction of their discretion, at least from a medical perspective.

## F. Caring for the Individual Patient

Beyond the issue of physician discretion, where there is a choice of treatment, and beyond those situations where certain avenues of treatment are foreclosed for economic reasons, there is the legitimate cause for concern among treating physicians that clinical trial evidence is based on evidence derived from randomized clinical trials that informs the effect of pre-existing circumstances and treatments on *groups* of patients.<sup>74</sup> In actual practice, a treating physician deals with what has happened or what will happen to an individual. This question is likely more relevant to private practice physicians, especially in rural settings, who deal with the same few patients over a long period of time. For the majority of treating physicians who are concerned with the delivery of effective healthcare to a large and growing population, basing treatment decisions on what has been shown in unbiased studies to be most effective on the largest number of people is the approach that should deliver the best likelihood of positive patient outcomes. Again, even when working with the highest quality evidence, physicians are not bound to follow a guideline without exercising their professional discretion. However, the prudent physician ignores these recommendations at her own risk.

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<sup>73</sup> See Wendy K. Mariner, *What Recourse? – Liability for Managed-care Decisions and the Employee Retirement Income Security Act*, 343 NEW ENG. J. MED. 592, 594 (2000).

<sup>74</sup> See NORMAN & STREINER, *supra* note 59, at 123; see also McAlister, *supra* note 40, at 1329.

## G. Guideline Expiration Dates

The value of CPGs largely derives from the fact that more high quality evidence than ever is available and is being incorporated into guidelines.<sup>75</sup> The other side of that coin is that as more evidence is developed, previous guidelines, even those of the highest quality, become outdated and must be supplemented or rewritten. A study of this issue published by a team of researchers led by Paul Shekelle, MD, PhD, showed that the average shelf life of most CPGs is between three and six years.<sup>76</sup> In other words, no matter how high the quality of the CPG, if it is more than six years old it is likely out-of-date. While this concern represents a key weakness of CPGs, it also validates the reasoning behind them. We are developing new evidence every day, and health care providers have a professional obligation to apply it. CPGs, if their quality can be regulated and monitored, are a formidable tool to accomplish this task. That it becomes outdated is a defining characteristic of any document that purports to deliver the best known evidence. Because the need to be updated is a characteristic of CPGs, a process for updating is essential to any scheme designed to control which CPGs are approved and which are rejected.

## H. Guidelines and Healthcare Rationing

Though this paper will not discuss healthcare rationing in depth, it is a subject that merits separate and serious discussion. Healthcare rationing is not an idea up for debate. It is a reality of our time. Limited resources, a growing and ever more densely situated population, rapidly advancing technology and the associated rise in cost for medical procedures mean that rationing must occur in order to provide basic health services to our communities. Transparent and high quality CPGs designed to reduce unnecessary treatments and identify the medically proper treatments lend medical legitimacy to

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<sup>75</sup> See Mathews & Pronovost, *supra* note 15, at 2914.

<sup>76</sup> Shekelle, *supra* note 54, at 1466.

rationing decisions.<sup>77</sup> If we must ration health care, it is paramount that we do so rationally.

## I. Solving the Problem

CPGs are valuable tools to aid healthcare providers in delivering the proper care to patients while eliminating costly and often dangerous overtreatment, reducing unwarranted variations in care from one hospital to another, and improving patient outcomes.<sup>78</sup> Unfortunately, despite their positive potential, the sheer numbers of CPGs currently in circulation, their varying quality, and concerns over the motives of the authors have created a stigma that has hindered widespread acceptance and use of high quality guidelines.<sup>79</sup> With the advancing ability to gather and develop evidence of the highest quality, increasing use of guidelines, both in education and in practice, seems inevitable. With that in mind, what is needed now is a plan to reduce not only the negative perception of CPGs, but more importantly to address the substantive weaknesses in many current guidelines that fuel this perception.<sup>80</sup> This section will briefly describe a proposal to accomplish these goals, and then it will explore each aspect of that proposal in detail.

In much the same way that standardization of health care will improve outcomes, tracking, and accountability, standardization of the method by which CPGs are reviewed and approved will improve both their actual and their perceived value. Taking the concept from theory to practice requires support, participation, and implementation on a large scale. The Agency for Healthcare Research and Quality (AHRQ) currently supports efforts to control the quality of CPGs by sponsoring committees that produce

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<sup>77</sup> Norheim, *supra* note 69, at 1427.

<sup>78</sup> See Cheah, *supra* note 70, at 534; see also Jeremy M. Grimshaw & Ian T. Russell, *Effect of Clinical Guidelines on Medical Practice: A Systematic Review of Rigorous Evaluations*, 342 THE LANCET 1317, 1321 (1993).

<sup>79</sup> Woolf et al., *supra* note 43, at 530.

<sup>80</sup> See Sniderman & Furber, *supra* note 25, at 430-31.

guidelines based on transparent and high quality methodology.<sup>81</sup> Taking this concept a step further, the AHRQ is in a position to establish a professional task force that will be responsible, first, for promulgating the methodological basis for analysis of proposed guidelines as well as for applications to challenge or update previously approved guidelines and, second, for actually administering the analyses and approvals.<sup>82</sup> Once a significant body of approved guidelines was assembled, this task force would also be responsible for disseminating those guidelines to hospitals so that they can be put to use on a national scale. This step would require establishment of a centralized database containing the approved guidelines<sup>83</sup> that would interface with clinical information systems (CISs) already in place in local hospitals. The interface would allow the guideline matrix to pull in specific patient information contained in the clinical information system and create a patient-specific recommendation set. Physicians and nurses treating a particular patient could then interface with the system to retrieve and review recommendations as well as receive reminders to administer drugs, check vital signs, or complete other routine patient care tasks. This integration into physician workflow is the key to accomplishing the goal of reducing unwarranted variations in care and ensuring that aspects of treatment are not overlooked.<sup>84</sup>

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<sup>81</sup> Agency for Healthcare Research and Quality, <http://www.ahrq.gov/about/whatis.htm> (last visited Oct. 19, 2003).

<sup>82</sup> For a list of suggested reforms for clinical practice guidelines from commentators in the field, see Sniderman & Furbert, *supra* note 25, at 430-31. Multiple tools are currently available to assess the quality of guidelines by evaluating the methodology used in their development. The most widely recognized of these tools is the AGREE instrument. For a review of available tools including the AGREE instrument, see generally Joan Vlayen et al., *A Systematic Review of Appraisal Tools for Clinical Practice Guidelines: Multiple Similarities and One Common Deficit*, 17 INT'L. J. QUAL. HEALTH CARE 235 (2005).

<sup>83</sup> The National Guideline Clearinghouse already has compiled, through its website, thousands of guidelines from various medical organizations. It differs from the database proposed here in that there is no rigorous review methodology (though there is a submission process), and it is not designed for interaction with local clinical decision support systems. See National Guideline Clearinghouse, <http://www.guideline.gov> (last visited Aug. 31, 2009).

<sup>84</sup> See Gerhardt, *supra* note 31, at 232 (emphasizing that use of guidelines by physicians will aid in providing consistent care).

## J. Methodology: Defining the Standard

The quality of the methodology behind a guideline is the determining factor in the quality of the guideline itself.<sup>85</sup> In defining the role of a task force charged with review and approval of guidelines, development of useful and transparent standards by which guidelines are judged is crucial.<sup>86</sup> The reviewing body must consider (1) the patient outcomes envisioned by the authors, (2) the method by which the evidence was identified, (3) the method by which the evidence was graded and controlling evidence was selected, (4) the method by which recommendations based on lower quality evidence were decided, (5) the transparency of the guideline as to underlying evidence, and (6) the grading of recommendations reflecting the boundaries of physician discretion in applying the guideline.<sup>87</sup> The GRADE standard is an example of a widely accepted and utilized standard for transparent grading of CPG recommendations.<sup>88</sup>

## K. Guideline Fundamentals

The highest quality guidelines should follow a defined and transparent methodology. Professional associations may employ their own structure, but transparency of the standards used is an essential component of any quality guideline. Generally, a research question is identified and a panel is chosen to collaborate on the project.<sup>89</sup> The panel should consist of all appropriate stakeholders,<sup>90</sup>

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<sup>85</sup> See Yoon K. Loke et al., *Systematic Reviews of Adverse Effects: Framework for a Structured Approach*, 7 BMC MED. RES. METHODOLOGY 32, 33 (2007) (cautioning against guidelines based only on favorable outcomes); see also Steering Comm., *Classifying Recommendations*, *supra* note 29, at 874.

<sup>86</sup> See Loke et al., *supra* note 85, at 32; see also Steering Comm., *Classifying Recommendations*, *supra* note 29, at 874; Steering Comm. on Quality Improvement and Mgmt., Am. Acad. of Pediatrics, *Policy Statement Toward Transparent Clinical Policies*, 121 PEDIATRICS 643, 643-44 (2008) [hereinafter Steering Comm., *Policy Statement*], available at <http://aappolicy.aappublications.org/cgi/reprint/pediatrics;121/3/643.pdf>.

<sup>87</sup> See Steering Comm., *Classifying Recommendations*, *supra* note 29, at 874-77.

<sup>88</sup> See Gordon H. Guyatt et al., *Going from Evidence to Recommendations*, 336 BMJ 1049-51 (2008).

<sup>89</sup> Loke et al., *supra* note 86, at 33.

which may include physicians whose specialty is involved in managing the condition being addressed, nursing, ancillary services, respiratory therapy, pharmacy, nutrition, as well as representatives of other interested parties, including patient representatives and, at times, hospital administrators or managed care representatives.<sup>91</sup> A search of the available evidence is conducted using biomedical information sources, such as Medline, EMBase, CINAHL, and other relevant databases.<sup>92</sup> It is worth mentioning that databases have only recently been developed to catalog the vast resources of biomedical research and offer an accessible format that facilitates this kind of comprehensive evidence search. When the search is complete, the evidence is reviewed for relevance, both in terms of how closely it fits the subject and how recently it was produced.<sup>93</sup> Once the irrelevant or outdated evidence has been removed, articles and studies are selected on the quality of the evidence.<sup>94</sup> The panel then reviews the "anticipated balance between benefits and harms" to the patient of potential recommendations.<sup>95</sup> The recommendations are then graded according to strength of evidence and benefit-to-harm ratio.<sup>96</sup> Recommendations based on the strongest evidence with the greatest benefit-to-harm ratio are designated and identified with the highest grade.<sup>97</sup> A physician would have little discretion to reject such a recommendation absent a strong reason why the recommendation

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<sup>90</sup> Ira Madan et al., *Methodology for the Developing of NHS Plus Evidence-Based Guidelines*, 57 OCCUPATIONAL MED. 304, 305 (2007).

<sup>91</sup> Sniderman & Furbert, *supra* note 25, at 429.

<sup>92</sup> See Loke et al., *supra* note 86, at 35; see also Madan et al. *supra* note 90, at 305.

<sup>93</sup> See Madan et al., *supra* note 90, at 305; see also Steering Comm., *Classifying Recommendations*, *supra* note 29, at 875.

<sup>94</sup> See Steering Comm., *Classifying Recommendations*, *supra* note 29 at 875; see also Loke et al., *supra* note 86, at 36-37.

<sup>95</sup> Steering Comm., *Classifying Recommendations*, *supra* note 29, at 875.

<sup>96</sup> *Id.*

<sup>97</sup> *Id.* at 875-76; see also Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group, [www.gradeworkinggroup.org](http://www.gradeworkinggroup.org) (last visited Aug. 31, 2009) [hereinafter GRADE].

should not apply to a particular patient.<sup>98</sup> Recommendations based on lower quality evidence are then graded accordingly (e.g., B for recommend, C for no recommendation, D for do not recommend, I for insignificant evidence against).<sup>99</sup> The discretion of the physician is greater for the lower graded recommendations.<sup>100</sup> Though this is not the only grading system in use, it is reflective of the logic generally employed.<sup>101</sup>

## L. Quality of Evidence vs. Strength of Recommendation

There is an important and often misunderstood distinction between strength of recommendation and quality of evidence.<sup>102</sup> Double-blind randomized trials are the gold standard for evidence, but sometimes a recommendation will be supported by multiple double-blind randomized trials which show a near balance between risk and benefit for the patient.<sup>103</sup> A recommendation based on that evidence, despite the fact that the evidence is of the highest quality, would receive a low grade because the evidence shows that there is generally little benefit to the intervention. Conversely, a recommendation could receive a very high grade based on low quality evidence like observational studies, where the risks are known to be so small and the benefits known to be so high that the strength of the recommendation is obvious. In simplistic terms, you do not need a randomized trial on the effectiveness of parachutes to know you should put one on before jumping out of a plane.<sup>104</sup>

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<sup>98</sup> Steering Comm., *Classifying Recommendations*, *supra* note 29, at 876-77.

<sup>99</sup> See AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, GUIDE TO CLINICAL PREVENTIVE SERVICES: RECOMMENDATIONS OF THE U.S. PREVENTIVE SERVICES TASK FORCE, viii-ix (2009), vii, <http://www.ahrq.gov/clinic/pocketgd09/pocketgd09.pdf>

<sup>100</sup> *Id.*

<sup>101</sup> For a more thorough understanding of the technical aspects of recommendation grading systems, see GRADE, *supra* note 97.

<sup>102</sup> See AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, *supra* note 99, at 44-45; see also Guyatt et al., *supra* note 88, at 1049-50.

<sup>103</sup> For a discussion of the practical limitations of randomized clinical trial evidence, see McAlister, *supra* note 40, at 1325.

<sup>104</sup> *But see* Gordon C. S. Smith & Jill P. Pell, *Parachute Use to Prevent Death and Major Trauma*

## M. Passing Muster

A guideline should not pass muster with the proposed reviewing body, even if it is compiled according to the process described above, if it is not transparent in all respects. That means not only identifying who was on the panel and what their expertise and input was, but also what the goal of the panel was in authoring the guideline. Further, each recommendation should be graded on both the quality of evidence underlying it and how closely linked it is to the actual evidence used in formulating the recommendation. In this way, the panel does not ask physicians to rely on the expertise and discretion of the panel over their own. Instead, the panel presents the physician with the best possible evidence on the treatment she is contemplating. The panel provides the physician with the same evidence that it reviewed and requires that the physician, if she does not follow the guideline, must at the very least acknowledge the evidence and substantiate any deviation. The amount of substantiation required would be proportional to the strength of the recommendation: to deviate from a strong recommendation would require convincing substantiation, whereas deviation from a weak recommendation or option would require little or no substantiation.

Any body responsible for approving guidelines and, by extension, treatment standards, must include a process for challenging and updating already approved guidelines. The speed at which medical research exposes previously unknown or misunderstood data necessarily means that whatever guidelines are created will become outdated with time. Further, physicians who feel as though their approach is warranted, even if it contradicts a guideline, should have the opportunity to appeal the guideline, so long as their appeal is based on evidence and not on experience-based conjecture. A comprehensive guideline program must be able to respond and adjust to new evidence, especially if the program itself, through integration with a nationally accessible database that works with local CISs, is to become a tool to improve the very guidelines upon which it is based.

## **N. The Carrot and the Stick**

Change as fundamental as shifting physicians from treatment based on personal experience and “what I learned in medical school” to reliance on a dynamic and evolving body of medical evidence is likely simpler in theory than in practice. For implementation of a national database integrated with CISs to be successful, there must be both a carrot and a stick. For the concept of guideline models integrated into clinician workflow to succeed in terms of reduction in unwarranted variations in care, standardization of care, patient tracking, and the dissemination of valuable public health data, hospital administrators and physicians must have a reason to comply. Two subjective reasons for compliance are the reduction in paperwork and related strain on doctors responding to insurance company denials and the increased likelihood of payment. A third is the possible effect on predictability in medical malpractice litigation. However, these concerns do not affect all physicians, and some will naturally interpret their effects differently from others, so they cannot be counted on as sufficient motivators for compliance with the proposed system.

One potential solution would be to use Medicaid and Medicare payments from the federal government as an incentive for compliance. Once the CDSS is in place, hospitals could be provided a grace period for implementation, customization, education, and compliance training. Once the grace period expires, hospitals would be required to assure adherence to the system. Again, adherence does not imply following every guideline in every situation. Instead, adherence would mean complying with the electronic documentation procedures, responding to alerts and recommendations created by the system, and applying CPGs where appropriate. Much like the possible response of private insurers, Medicaid and Medicare would pay for treatments for which the system was employed and guidelines were either followed or permissibly deviated from, and there would be no payment where it was not. In this way the scheme would be less a punitive measure for non-compliance than an opportunity to qualify for federal payment for treatments that comply with the federally recognized standard.

## O. Information Technology and Evidence-Based Practice

Creating a centralized database of approved guidelines that can assimilate patient information from existing CISs and integrate dynamic and individualized patient care models into physician workflow sounds like a daunting task. However, multiple information technology applications of this concept are currently in development. This section will focus on three groups: the GLIDES project at the Yale Center for Medicine Informatics;<sup>105</sup> the Clinical Decision Support Consortium (CDSC), which is comprised of a group of investigators from Brigham and Women's Hospital, Harvard Medical School, and Partners HealthCare Information Systems (in partnership with researchers from several other institutions);<sup>106</sup> and the SAGE project, which was administered by a consortium from GE Health Care, the University of Nebraska Medical Center, Intermountain Health Care, Apelon, Inc., Stanford University, and the Mayo Clinic.<sup>107</sup>

## P. The GLIDES Project

The focus of the GLIDES project is on developing methods of integrating clinical decision support (CDS) into health care delivery.<sup>108</sup> CDS Systems (CDSSs) are "information systems designed to improve clinical decision making."<sup>109</sup> The system has to be easily accessible before, during, and after the physician interacts with the patient.<sup>110</sup> GLIDES is pioneering the implementation of CDS

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<sup>105</sup> Guidelines Into Decision Support (GLIDES) Project, <http://gem.med.yale.edu/glides/> (last visited Oct. 19, 2009).

<sup>106</sup> Clinical Decision Support Consortium (CDSC), <http://www.partners.org/cird/cdsc/> (last visited Oct. 19, 2009).

<sup>107</sup> Samson W. Tu et al., *The SAGE Guideline Model: Achievements and Overview*, 14 J. AM. MED. INFORM. ASSOC. 589 (2007).

<sup>108</sup> GLIDES Project Objectives and Goals, <http://gem.med.yale.edu/glides/objectives.htm> (last visited Oct. 19, 2009).

<sup>109</sup> Amit X. Garg et al., *Effects of Computerized Clinical Decision Support Systems on Practitioner Performance and Patient Outcomes*, 293 JAMA 1223 (2005).

<sup>110</sup> GLIDES Project Objectives and Goals, *supra* note 108.

into two systems, the GE Centricity system and the EPIC Epicare system.<sup>111</sup> The systems chosen for implementation are only two of many in use currently to manage clinical information.<sup>112</sup> Current use of different IT systems between hospitals for information management underscores one of the difficulties of large-scale implementation of national collections of encoded CPGs: creating a method of communicating with systems that employ different programming, especially clinical language recognition. Without going into too much technical detail, different vendors of IT solutions for health care institutions each use proprietary language programming. Creating a database of responsive CPGs that can communicate with different systems is a difficult undertaking as long as vendors refuse to share such programming information. The GLIDES program seeks to “demonstrate cross-platform utility and will help to establish a wide range of best practices useful to the health IT vendor community.”<sup>113</sup>

### **Q. The CDS Consortium**

The CDS Consortium was organized to “assess, define, demonstrate, and evaluate best practices for knowledge management and clinical decision support in healthcare information technology that scale—across multiple ambulatory care settings and . . . technology platforms.”<sup>114</sup> The key to the success of CDSS is integration into the workflow of physicians at the point of care.<sup>115</sup> The CDS Consortium approach is broken down into six research objectives.

The first objective is to address “best practices for the entire knowledge management lifecycle from clinical practice guidelines to

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<sup>111</sup> *Id.*

<sup>112</sup> For a website comparing clinical information system vendor products, see <http://www.klasresearch.com/Klas/Site/News/NewsLetters/2008-08/CIS2008.aspx>.

<sup>113</sup> GLIDES Project Objectives and Goals, *supra* note 108.

<sup>114</sup> CDSC Goals and Objectives, [http://www.partners.org/cird/cdsc/goals\\_objectives.asp](http://www.partners.org/cird/cdsc/goals_objectives.asp) (last visited Oct. 19, 2009).

<sup>115</sup> Tu, *supra* note 107, at 589.

actionable clinical decision support.”<sup>116</sup> The second focuses on knowledge specification, creating a communication method for knowledge that can be human readable and suitable for web implementation.<sup>117</sup> Third, the Consortium seeks to build a knowledge portal and repository, creating an accessible database of collaborative knowledge of implementation strategies for CDS demonstration projects.<sup>118</sup> Fourth, a public web service that provides human readable CDS content for actual clinical use to reduce the short term need for local hospitals to transition to electronic health records in order to benefit from the knowledge base.<sup>119</sup> The fifth objective seeks to create an evaluation process to assess “satisfaction, performance, and efficiency of collaborative knowledge engineering.”<sup>120</sup> Finally, the sixth research objective is to provide dissemination of knowledge both to AHRQ, which funds the project, as well as specifically targeting information to “physicians in small office environments considering adoption of, or using, electronic records.”<sup>121</sup> As a whole, the project looks to establish that implementation of CPGs through the use of CDS can begin to move forward without being preceded by a complete national transition to electronic medical records.<sup>122</sup> This idea addresses one of the major issues with projects such as the SAGE Guideline Model, which sought to integrate a centralized database of encoded CPGs into workflow in hospitals across the nation.<sup>123</sup>

## R. The SAGE Guideline Model

The SAGE Guideline Model was a project which sought to address many of the daunting technical deficiencies in our electronic

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<sup>116</sup> CDSC Goals and Objectives, *supra* note 114.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> *Id.*

<sup>123</sup> Tu, *supra* note 107, at 589-90.

medical record infrastructure which currently make national implementation of projects like GLIDES and the CDSC project so difficult. The SAGE project was funded by the National Institute of Standards and Technology (NIST) Advanced Technology Program.<sup>124</sup> At this point GE Healthcare, the owner of the intellectual property right for the SAGE execution engine, has not developed the technology commercially.<sup>125</sup> However, a Korean group at Inha University has taken the SAGE model, “which is freely available, and developed their own execution engine.”<sup>126</sup>

A major concern in developing a guideline integration program that can be applied effectively to existing CISs is workflow models for certain interventions that already exist in many hospitals. A generalized approach to guideline modeling would undoubtedly conflict with hospital specific models already in place. “SAGE DSS does not control the host system’s workflow. Rather, it responds to opportunities for decision support in the care process. . . .”<sup>127</sup> In this way it “enable[s] clinical and administrative events to trigger SAGE DSS and for it to then deliver appropriate recommendations through CIS facilities,” what the creators of SAGE term an event-driven system.<sup>128</sup> In simple terms, the SAGE system is triggered by patient information that either already exists, or is input into the CIS, combined with additional information, such as admitting diagnosis. When a triggering event occurs, SAGE DSS responds with an appropriate guideline model which is dynamic in that it includes all variations that have not been precluded by the information already in the system.<sup>129</sup> Clinicians can query the system for specific feedback based on further information, as well as accessing the data

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<sup>124</sup> Email from Samson W. Tu, swt@stanford.edu, Senior Research Engineer, Stanford University, to John Tucker, jttucker@central.uh.edu, JD Candidate 2010, University of Houston Law Center (March 22, 2009, 4:58pm CST) (on file with the recipient).

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*; see also Kim et al., *Knowledge Translation of SAGE-Based Guidelines for Executing with Knowledge Engine*, 2008 AMIA ANNUAL SYMPOSIUM PROCEEDINGS 1008 (2008).

<sup>127</sup> Tu, *supra* note 107, at 590.

<sup>128</sup> *Id.*

<sup>129</sup> *Id.* at 591.

underlying any recommendations.<sup>130</sup> "SAGE-CIS interactions may originate as events in the Patient Care process, be generated by a SAGE guideline action, or be driven by the clock. . . ."<sup>131</sup> The model would therefore not only identify, for example, what severity level and therefore what treatment model should be applied to a patient presenting with a particular condition, but they would also trigger automatic reminders for maintenance and surveillance actions such as administration of drugs, drug interactions, monitoring of vital signs, and other periodic checks.<sup>132</sup>

Though this discussion will not dig too deeply into the technical aspects of the system, one of the difficulties in widespread application of the SAGE system is variation in expression language used in CISs, both for input of information and for expression of recommendations.<sup>133</sup> The SAGE model uses language bases from SNOMED CT, LOINC, and National Drug File-Reference Terminology.<sup>134</sup> In addition, concepts can be merged or differentiated using Boolean combinations.<sup>135</sup> The model also allows for the use of terminology identified as *primitive*, meaning not pre-defined within the system.<sup>136</sup> At the point at which the guidelines are encoded, meaning when they are taken from a document of synthesized evidence and recommendations to a dynamic computer model, "a terminology server should support post-coordination of new concepts when supported by the terminology or via Boolean concept expressions."<sup>137</sup> When the guideline is then used to support a patient care decision, SAGE queries the terminology server and translates the guideline into the local expression language.<sup>138</sup>

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<sup>130</sup> *Id.* at 596.

<sup>131</sup> *Id.* at 591.

<sup>132</sup> Tu, *supra* note 107, at 591.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

<sup>135</sup> *Id.* at 592.

<sup>136</sup> *Id.*

<sup>137</sup> Tu, *supra* note 107, at 592.

<sup>138</sup> *Id.*

Further challenges arise from duplication of information available in queries performed by SAGE. Information may be available from encoded guidelines, from local CIS, or from reliable alternative sources.<sup>139</sup> Because where patient data is limited, recommendations may appear to contradict, and in order to prevent the SAGE CDS from eliminating conflicting data, the SAGE project introduced the concept of *Evidence Statements* into the model.<sup>140</sup> “The evidence statements are declarative in that they include no implied actions or prescribed behaviors.”<sup>141</sup> Instead, they are available to assist the clinician in further refining their patient record in order to make the right patient care decision.<sup>142</sup>

The greatest obstacles to implementing systems like SAGE are “developing and maintaining comprehensive guideline knowledge bases and a lack of comprehensive integrated standards.”<sup>143</sup> The first of these concerns would be addressed directly by the creation of a national task force to review and approve proposed guidelines based on high quality methodology integrated with a data collection project that catalogues, updates and makes such information available to CDS solutions such as the SAGE model. The second is addressed by the SAGE developers directly. The problem is that many hospitals have developed their own protocols and workflow models.<sup>144</sup> In addition, some interventions, for example those calling for prescription of antibiotics could require a choice between equally valid options. In such a scenario, one antibiotic is as good as the other, but within one hospital only one should be prescribed. These discretionary variations present a problem for any plan that proposes application of a generalized workflow model to all hospitals.<sup>145</sup>

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<sup>139</sup> This is especially true in the case of drug information, especially drug interaction data. See *id.* at 596.

<sup>140</sup> *Id.*

<sup>141</sup> *Id.*

<sup>142</sup> *Id.*

<sup>143</sup> Tu, *supra* note 107, at 597.

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

Instead, the SAGE model would allow for customization through workflow-specific encoding, within certain limits.<sup>146</sup> Where systematic discretion is called for, local hospitals would have the choice of altering their workflow to fit the CDS model, or vice versa.<sup>147</sup>

Leading researchers in the field of guideline development and implementation of CDSS have studied the effectiveness of CDSS in practice.<sup>148</sup> These researchers performed two studies, the first published in 1998 and the second in 2005.<sup>149</sup> The studies reviewed "randomized and nonrandomized controlled trials that evaluated the effect of a CDSS compared with care provided without a CDSS on practitioner performance or patient outcomes."<sup>150</sup> The results showed that CDSSs generally improve the rate at which practitioners perform in accordance with time based and intervention based recommendations.<sup>151</sup> The studies also found some improvement in patient outcome, but the final conclusions of the 2005 study stated that "effects on patient outcomes remain understudied and, when studied, inconsistent."<sup>152</sup> The widespread implementation of CDSS will likely require more definitive study of the effects of the use of such systems on patient outcomes.

## S. Making Doctors' Lives Easier

The benefits of CDSSs, if they are conveniently integrated into workflow, are not limited to reduction in variation in patient care, better informed decision making, and higher compliance rate for

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<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> Though the details of these studies will not be discussed here, for a thorough explanation of the methodology and conclusions, of these studies see Dereck L. Hunt, MD et al., *Effects of Computer-Based Clinical Decision Support Systems on Physician Performance and Patient Outcomes*, 280 JAMA 1339 (1998); see also Garg et al., *supra* note 109, at 1223.

<sup>149</sup> *Id.*

<sup>150</sup> Garg et al., *supra* note 109 at 1223.

<sup>151</sup> Hunt et al., *supra* note 148, at 1344-45; Garg et al., *supra* note 109, at 1229-31.

<sup>152</sup> Garg et al., *supra* note 109, at 1223.

routine patient care such as administration of drugs or monitoring. They can also ease the strain on physicians from the huge volume of paperwork that currently burdens them and decreases the amount of time they have available to actually interact with patients.<sup>153</sup> The bulk of this paperwork is either documentation of care or administrative insurance related forms, especially those related to denials of payment.<sup>154</sup> For a physician using a CIS integrated with CDS which requires input of patient data in real time, as well as providing tracking for interventions and patient outcome based on guideline recommendations, the information requested by insurance companies would already be contained within the system. A plug-in that allowed reports to be generated from the CIS-CDS system could not only free up doctors to spend more time with patients, but also accelerate and simplify the payment process. A report documenting compliance with an accepted treatment guideline submitted to an insurance company along with a request for payment could foreclose the opportunity of the insurer to refuse payment, eliminating the need for doctors to respond to payment denials in such cases.

## T. Maximizing the Value of CDSS

The value of a CDSS to a health care institution is a product of how the administrators implementing the system and the clinicians utilizing it change the way they work to maximize the tool.<sup>155</sup> Like with cellular phones or high-speed internet, the constant advance of technology makes IT solutions like CDSSs more user friendly and therefore more valuable as time goes on.<sup>156</sup> While this technological reality is what makes these tools so useful, it also can be a detriment if end users are not accustomed to them. To maximize the utility of these systems, it is imperative that clinicians, administrators, insurers, managed care organizations, and even courts become

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<sup>153</sup> The Physicians' Working Group for Single-Payer National Health Insurance, *Proposal of the Physicians' Working Group for Single-Payer National Health Insurance*, 290 JAMA 798-99 (2003).

<sup>154</sup> *Id.*

<sup>155</sup> Basit Chaudhry, *Computerized Clinical Decision Support: Will it Transform Healthcare?*, 23 J. GEN. INTERNAL MED. 85 (2007).

<sup>156</sup> *Id.* at 86.

familiar and comfortable with their use.

## **U. Nothing Wasted**

Application of a CDSS similar to SAGE, in addition to improving care and saving physicians and hospitals from mountains of paperwork, could provide a valuable resource for healthcare tracking and surveillance. Because presenting symptoms, initial diagnoses, recommendations, interventions and patient outcomes are all recorded in the electronic system, the resulting data would be a ready resource for researchers. HIPAA already prescribes the process by which researchers can request and receive health care data without threatening patient privacy.<sup>157</sup> In accordance with the statute, personal information could be stripped from data, which could then be mined for valuable information applicable to one research question or another.<sup>158</sup> Extrapolated to its fullest extent, researchers compiling the very same evidence upon which high quality guidelines are based could pull data based on certain medical characteristics from variable geographical locations or age groups, providing a ready source of valuable data. In such a scenario, no treatment, approach, intervention, or outcome would be wasted. The knowledge base that would build as an incident to the guideline integration system could then be applied to improvement of guidelines, disease research, and even further study of the effectiveness of the guideline implementation itself.

## **IV. PART II**

### **A. Tort Law and the Medical Standard of Care**

Medicine has long held a special place in tort law, its duty of care distinct from that of the reasonably prudent person.<sup>159</sup> When asked

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<sup>157</sup> Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320 d-6(1996).

<sup>158</sup> *Id.*

<sup>159</sup> Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163 (2000).

to decide whether a doctor acted negligently in treating a patient, a jury is asked not whether the doctor's conduct was reasonably prudent in the situation, but instead whether it comported with what other doctors in similar situations normally do.<sup>160</sup> In this way, "tort law allows physicians to set their own standard of care."<sup>161</sup> Though this approach is still the law in most jurisdictions today, over the past half century there has been a subtle erosion of the complete deference afforded the medical community in defining the medical standard of care.<sup>162</sup>

## B. Informing the Patient

In the 1950's, it was not common practice for doctors to inform patients about details of a procedure, its risks, or its possible alternatives.<sup>163</sup> Doctors were considered to be the experts, owning an understanding of things medical which the common person did not have the capacity to grasp, and therefore had no reason to be told. The doctrine of informed consent changed that conception, requiring doctors to explain a treatment to a patient in detail, along with risks, alternatives, and likelihood of success.<sup>164</sup> Courts across the country adopted this common law doctrine, signaling judicial recognition of "a patient's fundamental right to make medical decisions."<sup>165</sup> This recognition indicated the societal realization that doctors were neither magicians nor intellectuals on such a scale that the common man could not comprehend their knowledge or reasoning. Doctors, as it turned out, were just people with specialized but limited knowledge; the patient, as the one whose health was on the line, should have all the information that the doctor has, as well as the final say in what happens to his body.

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<sup>160</sup> *Id.* at 165.

<sup>161</sup> *Id.* at 163.

<sup>162</sup> *Id.* at 164.

<sup>163</sup> Ben A. Rich, *Medical Custom and Medical Ethics: Rethinking the Standard of Care*, 14 CAMBRIDGE Q. HEALTHCARE ETHICS 27, 29 (2005).

<sup>164</sup> *Id.*

<sup>165</sup> *Id.*

### C. The Nationwide Standard of Care

Perhaps as important as the doctrine of informed consent and more pertinent to this discussion is the gradual adoption by the common law courts of the nationwide standard of care.<sup>166</sup> This transition to a nationwide standard is a signal of the abandonment of the concept that the medical care a patient should expect within the United States depends on where you are in the country. The major reasoning behind this concept was that rural communities do not have access either to the equipment or the medical talent that urban areas do.<sup>167</sup> As a result, in the simplest terms, there is only so much they can do for you. The development of the ability to travel quickly and easily, to communicate, and the advance in the technological capabilities of rural clinics, would all seem to dispel the need for local standards. Finally, medical school curricula now all include six required competencies, including evidence-based medicine, which all medical students must achieve before being licensed to practice.<sup>168</sup> Therefore patients can legitimately claim an expectation that doctors who trained in that nationwide system should treat patients according to their standardized education. The nationwide standard of care conflicts with the prevailing approach to medical malpractice in that courts that apply it continue to decide the standard of care by jury on an ad hoc basis.

Both the doctrine of informed consent and the nationwide standard of care are examples of how advances in the medical evidence base have changed the way that we view medical professionals, and therefore changed the expectation to which they are legally subject. CPGs are another product of this progression. As such, it is likely that they will permeate medical malpractice litigation in the same way they are permeating medical practice. The question is how the courts will allow CPGs to be used as evidence in a

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<sup>166</sup> 61 AM. JUR. 2D *Physicians, Surgeons, Etc.* § 202 (2008).

<sup>167</sup> *See id.*

<sup>168</sup> *See* General competencies required for completion of medical residency, approved by the Accreditation Council for Graduate Medical Education (ACGME), <http://www.acgme.org/outcome/comp/compMin.asp> (last visited September 28, 1999).

courtroom.

The deference to medical expertise that characterized the legal approach to medical malpractice for most of the twentieth century resulted in the definition of the standard of care as customary practice, i.e., what other doctors usually do in a similar situation.<sup>169</sup> Instead of asking what a reasonably prudent doctor would do, the court simply asks what other doctors are doing. In the face of mounting empirical evidence as to the proper medical approach in many situations it would seem that requiring only that medical professionals adhere to what everybody else is doing in order to avoid negligence liability, especially where common practice is contradicted by the available evidence, is an increasingly irresponsible proposition.

The transition being signaled organically by the development of high quality evidence and the creation of high quality guidelines has been adopted judicially by the courts of England.<sup>170</sup> Until recently, the medical standard of care in England was defined by the *Bolam*<sup>171</sup> case, decided in 1957.<sup>172</sup> Under the *Bolam* test, “a doctor is not negligent if what he has done would be endorsed by a responsible body of medical opinion in the relevant specialty at the material time.”<sup>173</sup> *Bolam* was the standard for forty years, until it was abrogated by the House of Lords’ ruling in *Bolitho* in 1997.<sup>174</sup> Under this new standard, “Clinical practice, however prevalent within the medical profession, would perhaps be unlikely to withstand logical scrutiny if that practice is contrary to a clear consensus emerging from the evidence base.”<sup>175</sup> Further, a lack of risk analysis as a factor in reaching a clinical conclusion may not be considered a responsible

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<sup>169</sup> See *United Blood Services v. Quintana*, 827 P.2d 509, 520 (Colo. 1992).

<sup>170</sup> See Ash Samanta et al., *The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the Bolam Standard?*, 14 MED. L. REV. 321, 322-23 (2006).

<sup>171</sup> *Bolam v. Friern Hosp. Mgmt. Comm.* (1957) 2 ALL ER 118 (Q.B.D.) (U.K.).

<sup>172</sup> Samanta et al., *supra* note 170, at 321.

<sup>173</sup> *Id.*

<sup>174</sup> *Bolitho v. City and Hackney Health Auth.*(1997) 4 All ER 771 (H.L.) (appeal taken from C.A.) (U.K.).

<sup>175</sup> Samanta et al., *supra* note 170, at 326-27.

conclusion under *Bolitho*.<sup>176</sup> The decision “emphasized that the word ‘responsible’ in the traditional formulation of the *Bolam* test meant that responsible practice is that which withstands the scrutiny of ‘logical analysis’ from a judicial perspective.”<sup>177</sup>

The methodology underlying high quality guidelines—systematic review of evidence, reliance on the best available scientific studies, grading of evidence, input from specialists and stakeholders—qualify them as a product of logical analysis. As a result, in courts adhering to the *Bolitho* standard, practice supported by guidelines would meet the logical analysis test. The use of guidelines in English courts to inform the standard of care has been advanced by legislative acts of the British Parliament, establishing the National Institute for Health and Clinical Excellence (NICE) in 1999 under section 11 of the National Health Service (NHS) Act of 1977.<sup>178</sup> NICE was created by the government to “promote the development and use of guidelines.”<sup>179</sup> As guidelines become increasingly well known and well designed and as the evidence base grows, the efforts of NICE, and of its American counterparts, cannot help but promote the use of guidelines to inform the standard of care in medical malpractice litigation.

### **E. Tort Law, Tradition, and the American Way**

The *Bolitho* decision and the efforts of NICE may have important implications in England; but what is happening in the United States to bring evidence based medicine to bear on the legal standard of care? As it turns out, we have a legal revolution of our own brewing, as more states begin to adopt a stance similar to *Bolitho*.<sup>180</sup> Though they have been widely referenced in legal articles on the topics of

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<sup>176</sup> *Id.* at 327.

<sup>177</sup> *Id.* at 326.

<sup>178</sup> *Id.* at 322; The National Health Service Act, 1977, c. 49 § 11 (Eng.); National Institute for Health and Clinical Excellence website, <http://www.nice.org.uk/aboutnice/> (last visited Oct. 17, 2009).

<sup>179</sup> Samanta et al., *supra* note 170, at 322.

<sup>180</sup> Peters, *supra* note 159, at 171.

standard of care and medical negligence, the words of two of our preeminent American justices seem indispensable to this discussion. Supreme Court Justice Oliver Wendell Holmes, in his opinion in *Texas and Pacific Railroad v. Behymer*, said of the lack of precautions taken by the railroad employer, "What usually is done may be evidence of what ought to be done, but what ought to be done is set by the standards of reasonable prudence, whether it is complied with or not."<sup>181</sup> Decades later Justice Learned Hand from the 2nd court of Appeals in *The T.J. Hooper*, commented on the lack of weather radios aboard tugboats, writing "Courts must in the end say what is required; there are precautions so imperative that even their universal disregard will not excuse their omission."<sup>182</sup> Taken together, these two statements tell us that if something is irresponsible, the fact that it is usually done is no excuse, and if something is necessary, evidence that it is never done is no excuse. In other words, customary practice must yield to reason and logical analysis.

The most famous American case that espouses the view that customary practice alone is not determinative of the standard of care was *Helling v. Carey*.<sup>183</sup> In *Helling*, all evidence supported the conclusion that the ophthalmologist defendant had treated the plaintiff in accordance with the widely recognized and prevailing practice.<sup>184</sup> Plaintiff was under 40 years old when she was under the doctor's care, and was treated over time for chronic eye problems.<sup>185</sup> It was standard practice to test for glaucoma only in patients over 40, and the doctor did not test for it.<sup>186</sup> However, at 32 the plaintiff discovered she did indeed have glaucoma, and she sued the doctor for malpractice, claiming that she had suffered permanent damage as a result of the doctor's failure to diagnose her condition at an early

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<sup>181</sup> Rich, *supra* note 162, at 28 (citing *Tex. & Pac. R.R. v. Behymer*, 189 U.S. 468, 470 (1903)).

<sup>182</sup> *Id.* (citing *The T.J. Hooper*, 60 F.2d 737, 740 (2d Cir. 1932)).

<sup>183</sup> Peters, *supra* note 159, at 170; *Helling v. Carey*, 519 P.2d 981 (1974).

<sup>184</sup> Rich, *supra* note 162, at 31.

<sup>185</sup> *Id.*

<sup>186</sup> *Id.*

stage.<sup>187</sup> The jury in the trial court ruled in favor of the doctor, but that decision was reversed by the Washington Supreme Court.<sup>188</sup> The Court rejected the presumption that adherence to the customary practice was dispositive of meeting the standard of care, and further held that because the test was easy and cheap with no risk associated with it and essential to the diagnosis of a serious condition, failure to perform the test on all patients was negligence per se.<sup>189</sup> The *Helling* decision has been rejected in most jurisdictions, perhaps because further evidence could have been introduced to refute the finding of the Court that the test was simple, inexpensive and without risk;<sup>190</sup> however, it was the first decision by a state supreme court to squarely hold that adherence to the community standard did not meet the standard of care.

## F. Breaking New Ground

The *Helling* case was decided in 1974. Since that time, 17 states have produced appellate decisions “explicitly rejecting the view that mere conformity to the usual custom and practice constitutes conclusive evidence of practice within the standard of care. . . .”<sup>191</sup> In that context, expert testimony, perhaps supported by CPGs with a high quality evidence base, could potentially establish that an accepted practice was wrong, and as a result, “adherence to the prevailing custom and practice, under the circumstances of the case, constituted negligence.”<sup>192</sup> The Colorado Supreme Court addressed this potential squarely in *United Blood Services v. Quintana*, saying, “Negligence cannot be excused on the grounds that others practiced the same kind of negligence. . . the customary or prevailing practice may not be adequate or objectively reasonable in light of all the facts

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<sup>187</sup> *Id.*

<sup>188</sup> *Id.* at 31-32.

<sup>189</sup> *Id.* at 32.

<sup>190</sup> *Id.*

<sup>191</sup> *Id.*

<sup>192</sup> *Id.*

and circumstances.”<sup>193</sup> The substantial minority of states whose appellate decisions reflect this view indicate: 1) there is a growing trend away from the deference to medical custom in assessing negligence liability, and 2) there is an important role in medical negligence litigation for guidelines that reflect best practices supported by high quality empirical evidence.

### G. The Battle of the Experts

The current approach to establishing the standard of care in a medical malpractice case in American courts involves what is often referred to as the “battle of the experts.”<sup>194</sup> Each side calls its expert. The defense expert argues that the defendant’s conduct clearly met the standard, which that expert defines for the jury.<sup>195</sup> The plaintiff’s expert argues that the defendant’s conduct clearly fell below the standard of care, which that expert then defines for the jury.<sup>196</sup> The attorneys take turns attacking the other side’s expert, often based less on the content of their testimony than on some aspect of their past or their experience which tends to render them generally less credible.<sup>197</sup> Within this system, parties can research professionals in the relevant field, often those who have testified numerous times before, and select one whose experience conforms to or contradicts the conduct of the doctor, depending on which side they represent. Once these experts have made their arguments based on their often substantial expertise, jurors are asked to decide which expert is credible and which is not. In other words, jurors are asked, based on conflicting expert testimony, to determine the proper medical approach.<sup>198</sup> The jury system is a great tool for avoiding bias and prejudice and producing just results, but trial advocacy instructors will often say

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<sup>193</sup> *Id.* (citing *United Blood Servs. v. Quintana*, 827 P.2d 509, 525-6 (1992)).

<sup>194</sup> Steven E. Pegalis, *Medical Malpractice: The Art of Advocacy When Engaging In The “Battle of the Experts,”* 23 AM. J. TRIAL ADVOC. 259 (1999).

<sup>195</sup> *Id.* at 261.

<sup>196</sup> *Id.* at 259.

<sup>197</sup> *Id.*

<sup>198</sup> Finder, *supra* note 50, at 78.

that the average juror has less than a high school education. In this context, asking lay jurors to make medical decisions after damage has been done by agreeing with one expert and rejecting the assertions of another is irresponsible if the purposes are to punish true negligence, encourage proper care, and compensate injured parties for damage attributable to improper conduct by a medical professional.

Beyond the unfair position the court puts jurors in when asking them to decide the medical standard of care, the battle of the experts is an odd approach in jurisdictions that have adopted the concept of a nationwide standard of care. If medical school curricula and facilities nationwide have prompted the courts to declare, for the purposes of medical malpractice litigation, that the days of local standards of care are over, and that we now adhere to a nationwide standard, then how can that standard be decided separately and distinctly by a different jury for every claim? That is not to say that individual facts and circumstances have no bearing on malpractice litigation, nor is it to say that such facts could impact whether a doctor's actions were negligent or not. However, just as one cannot ignore the fact that every harm done to a patient is the product of distinct circumstances, one also cannot ignore the fact that the best medical evidence, which becomes the basis for teaching and practice where enough evidence has been gathered, is developed in the context of the effect of health issues and course of treatment on groups of people. Those approaches that have strong evidentiary support are those that work for the largest percentage of subjects. Just as a doctor should be required to examine the evidence and either follow recommendations or deviate from them based on legitimate observations that dictate such action, an expert should not be able to argue in court against the great weight of legitimate medical evidence without an equally legitimate reasoning behind such an argument. Just as opinion evidence has far less value than empirical evidence in medicine, when presented in a case concerned with the proper delivery of medical care; it has far less value in the courts as well.

## **H. Getting Guidelines Admitted**

If it is assumed that CPGs are helpful in the litigation context, the question still remains how best to utilize them. Will they be

admissible as evidence, and if so, what will their role be? The first obstacle to admissibility of CPGs, due to the fact that they are written by people who will most likely not testify in the trial in which their CPGs are used, is overcoming the hearsay rule. Hearsay is an out of court statement by a person not then testifying, offered to prove the truth of the statement.<sup>199</sup> This problem should be easily overcome by recognition of CPGs as learned treatises, an exception to the hearsay rule in every jurisdiction.<sup>200</sup>

Beyond the issue of hearsay is the question of whether or not guidelines are admissible scientific evidence under the *Daubert* standard.<sup>201</sup> Under *Daubert*, in which the Supreme Court held that the Federal Rules of Evidence superseded the long standing *Frye* standard,<sup>202</sup> the Court recognized the two requirements of Rule 702: that before allowing the jury to view scientific evidence the court must determine (1) that the evidence is relevant to the controversy before the court, and (2) that it is reliable.<sup>203</sup> The *Daubert* Court held that reliability depended on whether the evidence was produced using scientific method, whether it was peer reviewed, the known rate of error, and whether the evidence is generally accepted within the relevant scientific community.<sup>204</sup> Clinical practice guidelines developed by professional groups with transparent methodology would be difficult for a court to reject for reliability under this standard. The issue of relevance would of course depend on the individual circumstances of the case and the guideline offered.

Once they are deemed admissible, there is the question of whether or not CPGs can be admitted into evidence by judicial notice. When a court takes judicial notice of an adjudicative fact, in the context of a civil trial, that fact must be accepted as true by the

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<sup>199</sup> Fed. R. Evid. 801(c).

<sup>200</sup> Fed. R. Evid. 803(18).

<sup>201</sup> *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

<sup>202</sup> *Frye v. U.S.*, 293 F. 1013, 1014 (D.C. Cir. 1923). (holding that expert testimony must be based on ideas “sufficiently established to have gained general acceptance in the particular field in which [they] belong.”)

<sup>203</sup> Fed. R. Evid. 702.

<sup>204</sup> *Daubert*, 509 U.S. at 593-94.

jury.<sup>205</sup> Judicial notice obviates the need for the proponent of the evidence to lay a foundation for the evidence to be admitted.<sup>206</sup> For a fact to be judicially noticed, it must be either generally known in the community in which it is offered or capable of ready and accurate determination by resort to sources whose accuracy cannot reasonably be questioned.<sup>207</sup> The problem for CPGs is that, while some may contain enough high quality empirical evidence to be worthy of judicial notice, many will not contain enough empirical evidence to establish that their accuracy cannot reasonably be questioned. Of course, even if they did rise to that level, as of now there is no resource through which the information in CPGs can be readily and accurately determined. Looking to the future, the creation of a nationwide database of approved CPGs would create a resource capable of providing ready and accurate answers to such queries. As the evidence base grows, more and more CPGs will contain information on best practices whose accuracy cannot reasonably be questioned, but until that time, judicial notice seems out of reach as a method of admitting CPGs as evidence in medical malpractice litigation.

## I. Informing the Standard of Care

Likely the most obvious and useful application of CPGs in the litigation setting is through their use by testifying experts as informing the standard of care.<sup>208</sup> In a classic battle of the experts, the one relying on high quality empirical data would be at an advantage in establishing her position as the true standard of care. As more jurisdictions adopt the position that customary care is not dispositive of the standard of care, and that reasonable prudence in reviewing and utilizing evolving evidence is a necessary factor in determining whether the standard was met, the reliance of testifying medical experts on CPGs will only increase. The development of such a

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<sup>205</sup> Fed. R. Evid. 201.

<sup>206</sup> *Id.*

<sup>207</sup> Fed. R. Evid. 201(b).

<sup>208</sup> Samanta et al., *supra* note 170, at 344.

practice would, of course, rely on the widespread acceptance and use of CPGs by physicians around the country, perhaps spurred by the implementation of integrated systems that make CPGs available and useful to physicians involved directly in patient care. Most authors who have written on the subject come to the conclusion that CPGs would be useful as evidence, placed in context by testifying experts.<sup>209</sup> Their use in this fashion should be a relief to many medical malpractice attorneys from both sides of the bar who struggle with the difficult task of preparing a case and an expert to convince a jury that they should be declared the winner of the battle of the experts. The greater the use of CPGs as evidence in medical malpractice litigation, the more the transparent, reliable, and publicly available medical information will become the basis for determinations of liability, and the more predictable such litigation will become.

## J. Malpractice Guidelines and Clinical Practice Guidelines

CPGs are not an unknown in the world of medical malpractice litigation. A 1996 survey of malpractice attorneys conducted by Andrew Hyams, David Shapiro and Troyen Brennan found that about half were aware of CPGs, and that guidelines were a consideration for many in determining whether or not to accept a case.<sup>210</sup> Guidelines were also found many times to be a factor in settlement negotiations.<sup>211</sup> The study revealed that, currently, CPGs are most often employed on behalf of plaintiffs, and that plaintiffs had a higher success rate when CPGs were employed.<sup>212</sup> This trend may have led to a stronger push for legislation similar to the Maine

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<sup>209</sup> See e.g., Albert Tzeel, *Clinical Practice Guidelines and Medical Malpractice*, 28 THE PHYSICIAN EXECUTIVE 36, 37 (March/April 2002).

<sup>210</sup> Arnold J. Rosoff, *Evidence-Based Medicine and the Law: The Courts Confront Clinical Practice Guidelines*, 26 J. HEALTH POLITICS, POLICY & LAW 327, 341 (2001) (citing Andrew L. Hyams et al., *Medical Malpractice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POLITICS, POLICY & LAW 289-313 (1996)).

<sup>211</sup> *Id.*

<sup>212</sup> *Id.*

experiment, allowing the use of CPGs as shield, but not as sword.<sup>213</sup> The implications of this survey are clear: CPGs are on the radar for attorneys and legislators alike, and important decisions about their use must be made in recognition of the fact that their prevalence in the medical community is clearly increasing.

### **K. Legislative Approaches to Clinical Practice Guidelines**

Gradual acceptance of CPGs as evidence under the common law is one way to integrate them into medical negligence practice. Another is legislative mandate. Several attempts have been made to legislatively promote the use of CPGs in such cases. The various legislative initiatives on the subject have taken widely varied approaches to the application of CPGs in the litigation context.

The approach of the Minnesota legislature was perhaps the most drastic; essentially establishing an irrebuttable presumption that approved CPGs represented the standard of care.<sup>214</sup> In other words, if a doctor followed the guideline, she had met the standard as a matter of law, and if she deviated, she was liable for negligence *per se*.

In 1993, Senator John Chaffee (R-R.I.), among others, proposed the Health Equity and Access Reform Today (HEART) bill.<sup>215</sup> Under that bill, "adherence to state-developed guidelines which had been certified by the secretary of Health and Human Services would raise a rebuttable presumption of appropriate care that would be overcome only by 'clear and convincing evidence.'"<sup>216</sup> Thus, following approved guidelines would satisfy the standard of care unless the plaintiff could show that the recommendations contained in the guideline were clearly improper.

In 1990, Maine unveiled its Medical Malpractice Demonstration

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<sup>213</sup> *Id.* at 342.

<sup>214</sup> *Id.* at 340.

<sup>215</sup> Rosoff, *supra* note 210, at 340; Health Equity and Access Reform Today Bill, S. 1770, 103d Cong. § 4025 (1993).

<sup>216</sup> Rosoff, *supra* note 210, at 340.

Project,<sup>217</sup> a five year experiment, later renewed for another five years, which authorized physicians to use adherence to approved guidelines as a defense to a malpractice claim, but did not allow plaintiffs to use non-adherence as the basis for such a claim.<sup>218</sup> This concept of CPGs as *shield*, but not as *sword*, has raised concerns among some jurists who cite due process concerns.<sup>219</sup> These critics assert that such use of CPGs should be available either to both plaintiffs and defendants, or to neither.<sup>220</sup> Notwithstanding the constitutional issues, the critic's view has been proven accurate in terms of the usefulness of the statute.<sup>221</sup> Only a nominal number of defendants have even bothered to employ the defense, and some commentators surmise that without the threat of suit for not adhering to guidelines, physicians don't see the protection as enough of an incentive to actually use them.<sup>222</sup> However, the small number of cases in which the defense was utilized may also be due to the fact that the same legislation also requires screening and mediation panels to review cases in order to encourage resolution of claims without proceeding to trial.<sup>223</sup> The panel determines whether "the defendant complied with an applicable parameter or protocol establishing the applicable standard of care."<sup>224</sup>

## V. CONCLUSION

The solution to this problem does not lie in a wholesale

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<sup>217</sup> ME. REV. STAT. ANN. tit. 24, §§2971-2978 (2009); for a review of the effectiveness of the Maine legislation on reducing medical malpractice costs, see generally LESLIE G. ARONOVITZ, MEDICAL MALPRACTICE: MAINE'S USE OF PRACTICE GUIDELINES TO REDUCE COSTS, S. REP. NO. 94-8 (1993).

<sup>218</sup> Rosoff, *supra* note 210, at 342.

<sup>219</sup> *Id.*

<sup>220</sup> *Id.*

<sup>221</sup> *See id.* at 343.

<sup>222</sup> *Id.* at 343-44 (speculating that one-side use of guidelines in defense litigation is not needed to ensure use of guidelines).

<sup>223</sup> *Id.*

<sup>224</sup> *Id.* (citing ME. REV. STAT. ANN. tit. 24, § 2855(1)(a-1)).

acceptance of CPGs as the definitive standard of care, nor does it lie in a reversion to total deference to physician discretion. As with most appropriate solutions, this one lies somewhere in the middle. Legislative mandate of the use of CPGs in litigation cannot be the solution if all other avenues are abandoned. Without funding for creation of a national database, as well as success in programs that seek to integrate CPGs into patient care, recognition, use, and understanding of CPGs will not be widespread enough to actually affect the strategy of trial lawyers. For lawyers to rely on them in the courtroom, CPGs must be accepted by medical professionals on a national scale. In order for them to be accepted, they must become the path of least resistance. They must be presented in a way that makes doctors lives easier. To do that, they must (1) represent the best method of achieving the best possible patient outcomes, (2) be promulgated or approved by organizations highly respected in the medical community, (3) be designed, created and approved with total transparency throughout the entire process, (4) be made readily available to physicians and the public, both with respect to the recommendations and to the underlying evidence, (5) be integrated into physician workflow in the context of patient care, and (6) be tied in with incentive and disincentive programs that reward those who use them and punish those who do not. Once the medical profession fully embraces the use of high quality CPGs as a routine aspect of medical practice, medical malpractice attorneys will have no choice but to incorporate them into evidence presented to a jury asked to determine liability. With increased use by attorneys, the common law will develop its own methods of utilizing CPGs as evidence. Such adoption by the courts will signal the legislature as to the way that the medical and legal professions are comfortable with the use of CPGs, making it easier to craft effective legislation.

Modern medicine may well be an art, but it has always been based on scientific evidence. As our evidence base grows, it would be irresponsible and negligent not to adapt our medical practice to incorporate advances in knowledge. Many in the medical community have recognized the gap between knowledge and practice and begun to build the bridges necessary to carry that knowledge into exam rooms, operating rooms, ERs, and nurseries all

over this country. Our population is growing, our economy is declining, and more people than ever before lack access to quality health care. Doctors, lawyers, politicians, businessmen, and patients all have a responsibility to take notice of how our national health care can be improved. As technology evolves and we are presented with new options for sharing knowledge, it is inevitable that evidence-based practice will come to dominate, and perhaps salvage the health care system in this country. The sooner the tort system adapts to these changes, the smoother the transition will be.