

# DISCLOSING DEVIATIONS: USING GUIDELINES TO NUDGE AND EMPOWER PHYSICIAN-PATIENT DECISION MAKING

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*Americans fail to receive recommended care roughly half the time, reflecting poor decision making that threatens their health. This Article offers an innovative solution: require physicians to disclose clinical practice guideline recommendations to patients during informed consent. Behavioral economics suggests that insisting physicians and patients discuss guidelines, before deviating from them, could be surprisingly effective at nudging more rational care choices. At the same time, such disclosure should also educate and empower patients, serving autonomy.*

*Previous scholarship on unwarranted variances in care has focused primarily on malpractice reforms, largely ignoring the role of cognitive bias and the importance of patients receiving empirically based, consensus recommendations. This Article provides important new analysis of the connection between cognitive bias in physician decision making and practice guidelines. It offers key insights on aligning informed consent with patient autonomy and begins an important dialogue on elevating the salience of guidelines, thereby improving physician-patient decision making practices.*

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#### INTRODUCTION

“We’re literally dying, waiting for the practice of medicine to catch up with medical knowledge . . . [A] thousand Americans die each week because

the care they get is not consistent with the care that medical science tells us they should get.”<sup>1</sup> Americans fail to receive recommended health care almost half of the time, and these shortcomings reflect serious problems with the decision making of both physicians and patients.<sup>2</sup> Better adherence to clinical practice guidelines (“Guideline(s)”) would improve quality of care.<sup>3</sup> Yet, physicians are frequently unfamiliar with Guideline recommendations and almost never

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<sup>1</sup> Martin Sipkoff, *9 Ways to Reduce Unwarranted Variation*, MANAGED CARE (Nov. 1, 2003), <https://www.managedcaremag.com/archives/2003/11/9-ways-reduce-unwarranted-variation> [<https://perma.cc/5WTC-MF5S>] (quoting NAT’L COMM. FOR QUALITY ASSURANCE, THE STATE OF HEALTH CARE QUALITY 2003 (2003)).

<sup>2</sup> Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635, 2641 (2003) (“[P]articipants received 54.9 percent of recommended care.”).

<sup>3</sup> INST. OF MED. OF THE NAT’L ACADS., CLINICAL PRACTICE GUIDELINES WE CAN TRUST, REPORT BRIEF 1, 4 (2011) [hereinafter 2011 IOM STANDARDS: REPORT BRIEF] (stating these guidelines optimize care by providing the information necessary for “selecting the best care for a unique patient based on his or her preferences” and “aid clinicians and patients alike in determining the best treatment options”); M. Hassan Murad, *Clinical Practice Guidelines: A Primer on Development and Dissemination*, 92 MAYO CLINIC PROC. 423, 431 (2017) (“Empirical evidence shows that guidelines improve patient outcomes.”); see also Julie M. Fritz et al., *Does Adherence to the Guideline Recommendation for Active Treatments Improve the Quality of Care for Patients with Acute Low Back Pain Delivered by Physical Therapists?*, 45 MED. CARE 973 (2007) (concluding adherence to guideline for low back pain leads to better clinical outcomes and lower costs); Kimberly A. Hepner et al., *The Effect of Adherence to Practice Guidelines on Depression Outcomes*, 147 ANNALS INTERNAL MED. 320 (2007) (finding that guideline adherence in depression care is linked to better outcomes); Marco Proietti et al., *Adherence to Antithrombotic Therapy Guidelines Improves Mortality Among Elderly Patients with Atrial Fibrillation: Insights from the REPOSI Study*, 105 CLINICAL RES. CARDIOLOGY 912 (2016) (concluding that guideline adherence was associated with lower mortality among elderly atrial fibrillation patients); M.H. Wilke et al., *Guideline-Adherent Initial Intravenous Antibiotic Therapy for Hospital-Acquired/Ventilator-Associated Pneumonia is Clinically Superior, Saves Lives and is Cheaper than Non Guideline Adherent Therapy*, 16 EUR. J. MED. RES. 315 (2011) (finding that guidelines for pneumonia saved lives, money, and were overall superior); Zachary I. Willis et al., *Effect of a Clinical Practice Guideline for Pediatric Complicated Appendicitis*, 151 JAMA SURGERY 1 (2016) (finding that guidelines for the management of pediatric complicated appendicitis improved patient outcomes); Achim Wöckel et al., *Effects of Guideline Adherence in Primary Breast Cancer—A 5-year Multi-Center Cohort Study of 3976 Patients*, 19 BREAST 120 (2010) (finding less guideline adherence tracked lower survival in breast cancer patients); Charlotte Z. Woods-Hill et al., *Association of a Clinical Practice Guideline with Blood Culture Use in Critically Ill Children*, 171 JAMA PEDIATRICS 157 (2017) (finding guidelines improve laboratory results for critically ill children). But see Cynthia M. Boyd et al., *Clinical Practice Guidelines and Quality of Care for Older Patients with Multiple Comorbid Disease: Implications for Pay for Performance*, 294 JAMA 716 (2005) (finding that guidelines did not provide the best care for elderly patients with comorbidity).

Guidelines are statements developed by multi-disciplinary expert panels that include recommendations, based on a systematic review of evidence and an assessment of the benefits and harms of alternative care options. See 2011 IOM STANDARDS: REPORT BRIEF, *supra*, at 1.

tell patients about them.<sup>4</sup> Even when aware of Guidelines, cognitive biases lead physicians to discount them.<sup>5</sup>

Existing legal scholarship on unwarranted care variance has focused primarily on malpractice reforms.<sup>6</sup> This Article will propose an innovative solution: require physicians to disclose Guideline recommendations to patients as part of informed consent, prior to any deviation. Behavioral economics suggests that by countering cognitive biases, informed consent discussion could be a surprisingly effective nudge toward guideline adherence.

Part I of this Article will describe widespread, unwarranted variances in care. Part II will highlight the comparative advantage guidelines offer over ad hoc physician-patient decision making. Next, Part III will explain how insufficient knowledge of Guidelines, cognitive biases, and lack of legal disclosure obligation all contribute to current guideline under-adherence.<sup>7</sup> Together, Parts

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<sup>4</sup> Michael D. Cabana et al., *Why Don't Physicians Follow Clinical Practice Guidelines? A Framework for Improvement*, 282 JAMA 1458, 1463 (1999); Donald E. Casey, Jr., *Why Don't Physicians (and Patients) Consistently Follow Clinical Practice Guidelines*, 173 JAMA INTERNAL MED. 1581, 1581–82 (2013); Naomi Fearn et al., *What Do Patients and the Public Know About Clinical Practice Guidelines and What Do They Want from Them? A Qualitative Study*, BMC HEALTH SERVS. RES., Feb. 24, 2016, at 1, 11 (finding in a Scotland study that “[t]he public is generally unaware of the existence of guidelines, though people are enthusiastic about them once they are made aware of them”).

<sup>5</sup> See *infra* Section III.B.

<sup>6</sup> See Ronen Avraham, *Overlooked and Underused: Clinical Practice Guidelines and Malpractice Liability for Independent Physicians*, 20 CONN. INS. L.J. 273, 278 (2014); Mark A. Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, 54 L. & CONTEMP. PROBS. 119, 121 (1991); Marshall B. Kapp, *Getting Physicians and Patients to Choose Wisely: Does the Law Help or Hurt?*, 46 U. TOL. L. REV. 529, 536–37 (2015); Maxwell J. Mehlman, *Professional Power and the Standard of Care in Medicine*, 44 ARIZ. ST. L.J. 1165, 1169 (2012); Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 648 (2001). *But see* Wendy Netter Epstein, *Nudging Patient Decision-Making*, 92 WASH. L. REV. 1255, 1283–85, 1301 (2017) (analyzing patient instability of preferences and systematic decision making biases and mistakes and recommending that physicians frame defaults for care instead of providing a menu of options to patients); John E. Wennberg & Philip G. Peters, Jr., *Unwarranted Variations in the Quality of Health Care: Can the Law Help Medicine Provide a Remedy/Remedies?*, 37 WAKE FOREST L. REV. 925, 938 (2002) (proposing malpractice reforms but also recommending that physicians use informed choice rather than consent to elicit patient values for preference-sensitive care).

<sup>7</sup> Generally, cognitive bias in physician decision making remains an under-explored area of legal scholarship. *But see* Thomas L. Greaney, *Economic Regulation of Physicians: A Behavioral Economics Perspective*, 53 ST. LOUIS U. L.J. 1189, 1189–90 (2009) (applying behavioral economics to physician decision making to consider how to structure financial incentives); Russell B. Korobkin & Thomas S. Ulen, *Law and Behavioral Science: Removing the Rationality Assumption from Law and Economics*, 88 CAL. L. REV. 1051, 1090 (2000) (seminal law and economics article, briefly analyzing physician decision making); Jessica Mantel, *The Myth of the Independent Physician: Implications for Health Law, Policy, and Ethics*, 64 CASE W. RES. L. REV. 455, 501–05 (2013) (discussing the impact of organization culture in light of physicians' use of cognitive schema). *But cf.* Epstein, *supra* note 6, at 1260, 1284 n.166, 1289 (focusing on patient bias but also acknowledging that physicians

II and III will present an important new legal analysis of the connection between cognitive bias in physician decision making and guidelines. Part IV will argue that requiring physicians to disclose guideline recommendations to patients would improve decision making, without limiting physician discretion or patient choice. Then, it will offer a normative perspective on why this prescriptive remedy better aligns decision making practices with the ethical principles underlying healthcare: autonomy, beneficence, non-maleficence, and justice. Part IV will include significant new insights on reforming informed consent to incorporate empiric evidence from health literacy and behavioral economics.

#### I. POOR DECISION MAKING UNDERMINES QUALITY OF CARE AND THREATENS HEALTH

For decades, scholars have recognized substantial, unjustified variances in care approaches between physicians for patients with similar diagnoses.<sup>8</sup> For example, a patient with diabetes in Chicago is half as likely to receive a test monitoring blood lipids as a similar patient in Fort Lauderdale, despite overwhelming evidence that such test should be performed.<sup>9</sup> A patient with heart disease in Bloomington is three times more likely to undergo bypass surgery than a similar patient in Albuquerque.<sup>10</sup> These wide variances exist not only between geographic regions but also between individual physicians in a single hospital.<sup>11</sup> While some of these variations may be explained by differences in clinical need or patient preference, a significant percentage do not appear to be

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suffer biases); Barbara A. Noah, *The (Ir)rationality of (Un)informed Consent*, 34 QUINNIPIAC L. REV. 691, 697–98 (2016) (essay briefly discussing cognitive bias in the context of necessary fallibility in medical decision making); Victoria A. Shaffer, *Nudges for Health Policy: Effectiveness and Limitations*, 82 MO. L. REV. 727, 728–35 (2017) (short discussion of successful physician nudges).

<sup>8</sup> See generally John E. Wennberg, *Unwarranted Variations in Healthcare Delivery: Implications for Academic Medical Centres*, 325 BMJ 961 (2002).

<sup>9</sup> THE DARTMOUTH ATLAS OF HEALTH CARE, THE QUALITY OF MEDICAL CARE IN THE UNITED STATES: A REPORT ON THE MEDICARE PROGRAM 120–21 (John E. Wennberg & Megan McAndrew Cooper eds., 1999).

<sup>10</sup> *Id.* at 156.

<sup>11</sup> JONATHAN SKINNER & ELLIOTT S. FISHER, THE DARTMOUTH INST. FOR HEALTH POLICY & CLINICAL PRACTICE, REFLECTIONS ON GEOGRAPHIC VARIATIONS IN U.S. HEALTH CARE 1 (2010) (“some primary care physicians order more than twice as many CT scans as their colleagues in the same practice”); Yusuke Tsugawa et al., *Variation in Physician Spending and Association with Patient Outcomes*, 177 JAMA INTERNAL MED. 675, 681 (2017) (care spending varies more across individual physicians than across hospitals and is not associated with better outcomes); *Key Issues: Racial Disparities*, DARTMOUTH ATLAS HEALTH CARE, <http://archive.dartmouthatlas.org/keyissues/issue.aspx?con=2942> [<https://perma.cc/Y6FK-F5BZ>] (last visited Apr. 1, 2019) [hereinafter *Dartmouth—Racial Disparities*] (recognizing “both unequal treatment within a hospital or by a given provider, and unequal treatment because of where people live”).

so justified.<sup>12</sup> Too often, medical practice remains divorced from scientific method and empiric evidence.<sup>13</sup>

In fact, physicians commonly (but unintentionally) undertreat, overtreat or mistreat patients, and the resulting costs to patients and to the U.S. healthcare system are staggering.<sup>14</sup> Failure to provide the recommended care contributes to thousands of preventable deaths each year and poses a serious threat to the health of the American public.<sup>15</sup> In addition, this lack of adherence wastes \$260 to \$380 billion per year, more than the federal government spends on education, housing, and transportation combined.<sup>16</sup> Unwarranted variance in care re-

<sup>12</sup> Tsugawa et al., *supra* note 11, at 681 (demonstrating larger variation in spending across physicians than across hospitals and arguing that “policies that target physicians within hospitals may be more effective in reducing wasteful spending than policies focusing solely on hospitals”); Wennberg, *supra* note 8, at 962 (stating patient preferences cannot explain many variations in practice); John E. Wennberg & Peggy Y. Thomson, *Time to Tackle Unwarranted Variations in Practice*, 342 *BMJ* 687, 687 (2011) (“[M]uch of the variation . . . is unwarranted because it isn’t explained by illness or patient preference.”). *But see* AM. C. OBSTETRICIANS & GYNECOLOGISTS OPINION NO. 629, CLINICAL GUIDELINES AND STANDARDIZATION OF PRACTICE TO IMPROVE OUTCOMES 1–2 (2015), available at <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Patient-Safety-and-Quality-Improvement/co629.pdf?dmc=1&ts=20190401T1916341474> [https://perma.cc/8BY3-MPUR] [hereinafter ACOG GUIDELINE OPINION] (contrasting necessary clinical variation based on “age, ethnicity, weight, medical history, and desired outcome” with unwarranted variations in care); Matthew Mercuri & Amiram Gafni, *Examining the Role of the Physician as a Source of Variation: Are Physician-Related Variations Necessarily Unwarranted?*, 24 *J. EVALUATION CLINICAL PRAC.* 145, 146 (2017) (describing the view that such variation is problematic as unsubstantiated by empirical evidence).

<sup>13</sup> “Our medicine is run by cowboys today, where everyone is riding the range doing whatever they’re wanting to do . . . . It’s a failure at all levels . . . .” describes Dr. Steven Clark, a professor and childbirth safety expert. Alison Young, *Hospitals Know How to Protect Mothers. They Just Aren’t Doing It*, USA TODAY (July 27, 2018, 1:54 PM), <https://www.usatoday.com/in-depth/news/investigations/deadly-deliveries/2018/07/26/maternal-mortality-rates-pre-eclampsia-postpartum-hemorrhage-safety/546889002/> [https://perma.cc/B35B-CUG8].

<sup>14</sup> INST. OF MED. OF THE NAT’L ACADS., VARIATION IN HEALTH CARE SPENDING: TARGET DECISION MAKING, NOT GEOGRAPHY 1–2 (2013) [hereinafter 2013 IOM REPORT] (finding “[u]nderuse, misuse, and overuse of various services often put patients in danger;” geographic variations in care are substantial, pervasive, and persistent over time); Isaac D. Buck, *Overtreatment and Informed Consent: A Fraud-Based Solution to Unwanted and Unnecessary Care*, 43 *FLA. ST. U. L. REV.* 901, 905, 908 (2016) (describing over \$750 billion in wasted healthcare spending due to overtreatment and proposing civil False Claims Act enforcement to reduce unnecessary care).

<sup>15</sup> McGlynn et al., *supra* note 2, at 2635 (stating that failure to adhere to Guidelines “pose[s] serious threats to the health of the American public”); see also *Health Care Quality*, RAND CORP., <http://www.rand.org/topics/health-care-quality.html> [https://perma.cc/8BSA-KQSE] (last visited Apr. 1, 2019) (“The gap between the care patients should get and what they actually receive likely contributes to thousands of preventable deaths each year . . .”).

<sup>16</sup> Donald M. Berwick & Andrew D. Hackbarth, *Eliminating Waste in U.S. Health Care*, 307 *JAMA* 1513, 1513–14 (2012) (estimating failure to follow best practices in care delivery wastes \$102 billion to \$154 billion and overtreatment wastes an additional \$158 billion to \$226 billion per year); see also *Federal Spending: Where Does the Money Go*, NAT’L PRIORITIES PROJECT, <https://www.nationalpriorities.org/budget-basics/federal-budget-101/spe>

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flects serious and costly shortcomings in the decision making of physicians and patients.<sup>17</sup>

## II. INCREASING THE SALIENCE OF CLINICAL PRACTICE GUIDELINES COULD IMPROVE PHYSICIAN AND PATIENT DECISION MAKING

### A. *Guidelines Recommend the Best Care Approach for Most Patients*

Clinical practice guidelines can help solve unwarranted variance in care by improving the decision making of physicians and patients.<sup>18</sup> Professional recommendations regarding appropriate care have existed in one form or other as long as medicine has been practiced.<sup>19</sup> The emphasis on formally adopted Guidelines gained more salience, however, after John Wennberg's groundbreaking research revealed unwarranted geographic disparities in care.<sup>20</sup> The desire to ensure rational, scientifically based medical care and to contain costs led to increased funding of and emphasis on formal Guidelines and the comparative effectiveness research upon which they rely.<sup>21</sup> Recently, under the Affordable Care Act, taxpayers made a \$4 billion investment in these quality improvement initiatives.<sup>22</sup>

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nding/ [https://perma.cc/M92P-34WN] (last visited Apr. 1, 2019) (showing the government spent \$102.3 billion on education, \$85 billion on transportation, and \$61.5 billion on housing and community).

<sup>17</sup> Many factors appear to contribute to unjustified variations in care, including lack of knowledge of the recommended approach, poor physician and patient decision making, poor care processes, misaligned payment systems, and uncoordinated care. INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 1–2 (2001) [hereinafter IOM CROSSING THE QUALITY CHASM]; 2013 IOM REPORT, *supra* note 14, at 3–4; Casey, *supra* note 4, at 1582 (recommending the use of checklist-based algorithms); *Effective Care*, DARTMOUTH ATLAS HEALTH CARE, <http://archive.dartmouthatlas.org/keyissues/issue.aspx?con=2939> [https://perma.cc/L7Z3-XLWK] (last visited Apr. 1, 2019) [hereinafter *Dartmouth—Effective Care*]; *Supply-Sensitive Care*, DARTMOUTH ATLAS HEALTH CARE, <http://archive.dartmouthatlas.org/keyissues/issue.aspx?con=2937> [https://perma.cc/48V3-LS3J] (last visited Apr. 1, 2019) [hereinafter *Dartmouth—Supply Sensitive*].

<sup>18</sup> Even with the substantial new investment in Comparative Effective Research and Guidelines over the last decade, well-developed Guidelines do not exist for many care decisions. Further, developing reliable scientific data to test everything that physicians do out of custom and practice is almost certainly cost prohibitive. When reliable Guidelines are unavailable, individual physician-patient decision making remains the best available approach.

<sup>19</sup> David M. Eddy, *Practice Policies: Where Do They Come From?*, 263 JAMA 1265, 1265 (1990).

<sup>20</sup> John Wennberg & Alan Gittelsohn, *Small Area Variations in Health Care Delivery*, 182 SCI. 1102, 1107 (1973); *see also* Mello, *supra* note 6, at 649 (recognizing the connection between Wennberg's scholarship and emphasis on clinical practice guidelines); Wennberg, *supra* note 8, at 964.

<sup>21</sup> *See, e.g.*, Mehlman, *supra* note 6, at 1190–91.

<sup>22</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-18-311, COMPARATIVE EFFECTIVENESS RESEARCH: ACTIVITIES FUNDED BY THE PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND (2018) [hereinafter 2018 GAO REPORT].

Comparative effectiveness research (“CER”) compares outcomes between existing health interventions to determine which provides the most benefit and least harm, in an effort to determine the most effective practices.<sup>23</sup> CER studies “which standard interventions work best for whom.”<sup>24</sup> In doing so, CER seeks to assist physicians, patients, and policy makers to “make informed decisions to improve health care.”<sup>25</sup> Guidelines typically rely on CER to form recommendations for care.<sup>26</sup>

The Institute of Medicine<sup>27</sup> (“IOM”) defines clinical practice guidelines as “statements that include recommendations intended to optimize patient care. They are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.”<sup>28</sup> Guidelines reflect the recommended care approach of an expert panel, based on systematic review of empiric evidence and judgments regarding the weight to give potential harms and benefits.<sup>29</sup> Typically, multi-disciplinary experts draft proposed Guidelines with patient participation or input.<sup>30</sup> Before Guidelines are adopted, they are peer reviewed and, when necessary, revised.<sup>31</sup> If utilized effectively, Guidelines

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<sup>23</sup> INST. OF MED. OF THE NAT’L ACADS., INITIAL NATIONAL PRIORITIES FOR COMPARATIVE EFFECTIVENESS RESEARCH 41 (2009) (“Comparative effectiveness research (CER) is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care.”).

<sup>24</sup> Lois Shepherd, *Informed Consent for Comparative Effectiveness Research Should Include Risks of Standard Care*, 45 J.L. MED. & ETHICS 352, 352 (2017) (quoting R.R. Faden et al., *Informed Consent, Comparative Effectiveness, and Learning Health Care*, 370 NEW ENG. J. MED. 766, 766 (2014)).

<sup>25</sup> 2018 GAO REPORT, *supra* note 22, at 1.

<sup>26</sup> INST. OF MED. OF THE NAT’L ACADS., CLINICAL PRACTICE GUIDELINES WE CAN TRUST 7 (2011) [hereinafter 2011 IOM STANDARDS].

<sup>27</sup> The IOM was renamed the Health and Medicine Division (“HMD”) on March 15, 2016. *About Us*, HEALTH & MED. DIVISION, [www.nationalacademies.org/hmd/About-HMD](http://www.nationalacademies.org/hmd/About-HMD) [<https://perma.cc/U23T-3NBP>] (last updated Jan. 16, 2018, 4:13 PM). The IOM was, and the HMD is, part of the National Academies of Science, Engineering and Medicine (“National Academies”).

The National Academies are private, nonprofit institutions that provide independent, objective analysis and advice to the nation and conduct other activities to solve complex problems and inform public policy decisions related to science, technology, and medicine. The Academies operate under an 1863 congressional charter to the National Academy of Sciences, signed by President Lincoln.

*Id.*

<sup>28</sup> 2011 IOM STANDARDS, *supra* note 26, at 25–26.

<sup>29</sup> *Id.* at 26.

<sup>30</sup> K. De Boeck et al., *Medical Consensus, Guidelines, and Position Papers: A Policy for the ECFS*, 13 J. CYSTIC FIBROSIS 495, 497 (2014); Murad, *supra* note 3, at 425.

<sup>31</sup> Yvonne D’Arcy, *Practice Guidelines, Standards, Consensus Statements, Position Papers: What Are They, How They Differ*, AM. NURSE TODAY (Oct. 2007), <https://www.americannurses.com/practice-guidelines-standards-consensus-statements-position-papers-what-they-are-how-they-differ/> [<https://perma.cc/WP6R-8Z28>].



have the potential to make care more scientifically-based, more rational.<sup>32</sup> Given the magnitude of the problem with unwarranted variance in care and recent refinements in the quality of Guidelines, Guidelines present an enormous opportunity to improve healthcare in the United States.<sup>33</sup>

Well-developed Guidelines have significant advantages over traditional, ad hoc physician-patient decision making.<sup>34</sup> First, they typically provide the best available information.<sup>35</sup> Guidelines stem from a systematic review of the latest empiric research.<sup>36</sup> They include easily accessible summaries of up-to-date information that can help align medical decision making with evidence from CER.<sup>37</sup> While some have criticized Guidelines for “freezing” a care recommendation based on then-available research, this criticism is both overstated and largely avoidable.<sup>38</sup> It is avoidable if Guidelines are regularly updated.<sup>39</sup> It is overstated in that it ignores that individual physicians are far more likely to rely on outdated or incomplete information without Guidelines than with them.<sup>40</sup> After all, given the volume of new studies published monthly, practicing physicians cannot and do not read most of them.<sup>41</sup> Certainly for the over-

<sup>32</sup> Murad, *supra* note 3, at 425.

<sup>33</sup> *Id.* at 431 (“Empirical evidence shows that guidelines improve patient outcomes . . .”); Proietti et al., *supra* note 3, at 917 (concluding that guideline adherence was associated with lower mortality among elderly atrial fibrillation patients); Wöckel et al., *supra* note 3, at 125 (discussing how less guideline adherence tracked lower survival in breast cancer patients).

<sup>34</sup> Countries around the world utilize Guidelines to improve quality of care. See GUIDELINES INT’L NETWORK, <http://www.g-i-n.net> [<https://perma.cc/MQ8X-B4G4>] (last updated Nov. 18, 2016).

<sup>35</sup> Dan Bang & Chris D. Frith, *Making Better Decisions in Groups*, ROYAL SOC’Y OPEN SCI., Aug. 16, 2017, at 1, 6 (“As a statistical rule of thumb, pooling information across independent individuals leads to more reliable information.”).

<sup>36</sup> See *NGC and NQMC Inclusion Criteria*, AGENCY FOR HEALTHCARE RES. & QUALITY, <http://www.ahrq.gov/gam/summaries/inclusion-criteria/index.html> [<https://perma.cc/U4BK-HLQ5>] (last updated Oct. 2018) [hereinafter *Inclusion Criteria*].

<sup>37</sup> Significantly, Guidelines include recommendations as well as evidence summaries. *Id.*

<sup>38</sup> Mehlman, *supra* note 6, at 1209 (describing how guidelines can freeze the standard of care).

<sup>39</sup> When a physician does read of a new study that suggests a different care approach, he or she would also need to conduct a systematic review of all evidence in order to reach a care recommendation based on the same quality of information as contained in Guidelines. It would be grossly inefficient to encourage each individual physician to try to keep up with the clinical knowledgebase this way, rather than using Guidelines.

<sup>40</sup> This article describes out-of-date guidelines as an overstated problem in comparison to individual physician knowledge, but it readily acknowledges that it would be unwise to increase the salience of guidelines without also ensuring adequate updating procedures. See *infra* Part IV. Studies suggest that most guidelines need to be updated every three to five years. See, e.g., 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, 1466 (2001).

<sup>41</sup> In fact, a study estimated that journals published “7,287 articles monthly that would need to be considered to comprehensively and systematically update the primary care knowledgebase.” Brian S. Alper et al., *How Much Effort is Needed to Keep Up with the Literature Rel-*

whelming majority of physicians and patients, paying more attention to Guidelines would considerably improve the information used to make care decisions.<sup>42</sup>

Second, Guidelines often provide superior expertise and perspective when compared to individual physician decision making.<sup>43</sup> Studies show that groups typically have a greater number of different ideas and bring more specializations to decision making than individuals.<sup>44</sup> Groups are also more likely to make rational decisions than individuals.<sup>45</sup> Guidelines reflect these comparative advantages.<sup>46</sup> They are drafted and reviewed by a group of multi-disciplinary experts.<sup>47</sup> They also often benefit from representative patient input in formation.<sup>48</sup> These manifold viewpoints enable Guidelines to reflect thoughtful consideration of diverse perspectives and expertise.

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*evant for Primary Care?*, 92 J. MED. LIBR. ASS'N 429, 433 (2004). It would take 3.6 physicians reading full-time just to keep up. *Id.*

<sup>42</sup> Nothing in this proposal would prevent a physician who did have more up-to-date knowledge from acting on that superior information. While this article contends that physician should be required to disclose Guidelines before deviating from them, deviating remains cheap and easy.

<sup>43</sup> Bang & Frith, *supra* note 35, at 6 (“[S]tudies show that, by adopting the decision favoured by the majority of independent dermatologists, the accuracy of skin and breast cancer diagnosis can be improved over and above the single-best individual.”).

<sup>44</sup> Jeffery B. Schmidt et al., *New Product Development Decision-Making Effectiveness: Comparing Individuals, Face-to-Face Teams, and Virtual Teams*, 32 DECISION SCI. 575, 591–92 (2001). Thus, for close to 500 years, it has been commonly accepted wisdom that two heads are better than one. *See, e.g.*, JOHN HEYWOOD, A DIALOGUE CONTEINYN THE NOMBER IN EFFECT OF ALL THE PROVERBES IN THE ENGLISHE TONGUE: COMPACTE IN A MATTER CONCERNYNG TWO MANER OF MARIAGES, MADE AND SET FOORTH (1546). On balance empiric research supports this proverb. Bang & Frith, *supra* note 35, at 7 (“Groups have been shown to outperform individuals for many problems of probability and reasoning.”). However, studies do also show that groups can suffer from “groupthink,” conformity pressure that stifles divergent ideas. IRVING L. JANIS, GROUPTHINK 174 (2d ed. 1982).

<sup>45</sup> Tamar Kugler et al., *Are Groups More Rational Than Individuals? A Review of Interactive Decision Making in Groups*, 3 WIRES COGNITIVE SCI. 471, 478 (2012).

<sup>46</sup> Groups tend to raise the quality of the decision making of the majority. They benefit equally qualified participants and lower qualified participants. They may, however, paradoxically lower the decision making of any superior group members. Bahador Bahrami et al., *Optimally Interacting Minds*, 329 SCI. 1081, 1084–85 (2010).

<sup>47</sup> Murad, *supra* note 3, at 425; *Inclusion Criteria*, *supra* note 36.

<sup>48</sup> Guidelines have improved recently as a result of increased attention to patient preferences and patient centered outcomes. The ACA introduced new funding for Patient-Centered Outcome Research Institute (PCORI), and the benefits of this new emphasis are only beginning to be realized. 2018 GAO REPORT, *supra* note 22, at 1–2. *But see* Melissa J. Armstrong & Joshua A. Bloom, *Patient Involvement in Guidelines is Poor Five Years After Institute of Medicine Standards: Review of Guideline Methodologies*, RES. INVOLVEMENT & ENGAGEMENT, Oct. 2, 2017 (showing patient and public involvement with guideline development remains low five years after publication of 2011 IOM Standards). The new PCORI funding and patient focus should help ameliorate prior concerns regarding a mismatch between research measures and patient-centered outcome goals. *See* Mehlman, *supra* note 6, at 1214–17 (highlighting concerns).

Third, the process of Guideline creation, peer review, and adoption allows for careful consideration of benefits, risks, and alternatives. This sort of slower, more deliberate thinking tends to be more rational and reliable than the “thinking fast” required by individual physicians making care recommendations in real time in exam rooms.<sup>49</sup> Because Guidelines rest on a systemic review of empiric evidence, include collective wisdom from a group of learned experts and representative patients, and are formed only after a thoughtful deliberative process, Guidelines should reflect the best care approach for most patients most of the time.<sup>50</sup>

While skeptics often compare Guidelines to perfect decision making highlighting shortcomings, such analysis is inapposite.<sup>51</sup> The alternative to Guideline adherence is not an idealized decision making process—it is decidedly more flawed ad hoc individual physician and patient decision making.<sup>52</sup> When evaluating the importance and value of Guidelines, the proper question is not whether Guidelines have challenges, but whether or not Guidelines can improve decision making *vis a vis* physicians and patients alone.<sup>53</sup> The answer is clearly yes.<sup>54</sup>

<sup>49</sup> DANIEL KAHNEMAN, THINKING, FAST AND SLOW 28, 79 (2011) (discussing how time pressure and unfamiliarity make heuristic mistakes more likely); Evangelia Tsiga et al., *The Influence of Time Pressure on Adherence to Guidelines in Primary Care: An Experimental Study*, 3 BMJ OPEN 1, 1 (2013) (finding “most medical decisions are taken in a context of pressure and uncertainty” and suggesting that “experts use intuitive decision-making strategies rather than structured approaches.”).

<sup>50</sup> 2011 IOM STANDARDS: REPORT BRIEF, *supra* note 3, at 1, 4 (showing guidelines optimize care by providing the information necessary for “selecting the best care for a unique patient based on his or her preferences” and “aid clinicians and patients alike in determining the best treatment options”); Murad, *supra* note 3, at 431 (“Empirical evidence shows that guidelines improve patient outcomes . . .”); *see also* Fritz et al., *supra* note 3 (concluding adherence to guideline for low back pain leads to better clinical outcomes and lower costs); Hepner et al., *supra* note 3 (finding that guideline adherence in depression care is linked to better outcomes); Proietti et al., *supra* note 3 (concluding that guideline adherence was associated with lower mortality among elderly atrial fibrillation patients); Wilke et al., *supra* note 3, at 315, 321 (finding that guidelines for pneumonia saved lives, money, and were overall superior); Willis et al., *supra* note 3 (finding that guidelines for the management of pediatric complicated appendicitis improved patient outcomes); Wöckel et al., *supra* note 3 (finding less guideline adherence tracked lower survival in breast cancer patients); Woods-Hill et al., *supra* note 3 (finding guidelines improve laboratory results for critically ill children). *But see* Boyd et al., *supra* note 3, at 720 (finding that guidelines did not provide the best care for elderly patients with comorbidity).

<sup>51</sup> To be clear, these criticisms can be very useful in helping Guidelines to develop and improve. It is only when they are used to justify discounting or underfunding Guidelines that they merit reconsideration.

<sup>52</sup> Noah, *supra* note 7, at 698 (highlighting “necessary fallibility” in physician-patient decision making).

<sup>53</sup> One common criticism of Guidelines is that committees form them based on empiric evidence from studies that have very narrow participation criteria, typically eliminating patients with co-morbidities or other complicating factors. This creates challenges when applying Guidelines in the real world where patients often present with multiple medical issues that

*B. Physician Decision Making Suffers from Structural Limitations and Cognitive Biases*

The comparative strength of Guidelines contrasts with systematic shortcomings in physician and patient decision making. Despite being held in high regard, as compared to Guidelines, physician decision making suffers from lower quality information, fewer viewpoints, time pressure, and cognitive biases.<sup>55</sup> Patients receive recommended care only half of the time.<sup>56</sup> As a result of practice constraints, when physicians make care recommendations, they typically do so in a matter of seconds or minutes, without research, and without

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may need to be factored into the determination of appropriate care. The ACA provides new funds to begin addressing this concern, and the proposed remedy intentionally allows cheap and easy deviations from Guidelines when physicians have a rational basis to recommend a different care approach. 2018 GAO REPORT, *supra* note 22, at 1. However, given the magnitude and cost of the current problem with unjustified variances in care, the need for patient differentiation should not be overstated nor should physicians disregard Guideline recommendations lightly.

<sup>54</sup> Guideline criticisms relating to bias or conflict of interest illustrate this point. Some Guidelines skeptics point out that there is seldom wholly impartial funding for the creation of Guidelines. *See, e.g.*, Mehlman, *supra* note 6, at 1214. While often true, there are still several reasons to believe that Guidelines are less likely to be biased or suffer conflicts of interest than an individual physician's recommendation. First, Guidelines must be based on a systematic review of empiric evidence. *Inclusion Criteria*, *supra* note 36. In contrast, an individual physician typically supplies no evidence to support his or her recommendation. Second, Guidelines are also formed by multi-disciplinary panels, which tend to combat bias and discrimination better than individuals. Bang & Frith, *supra* note 35, at 7 ("While our own biases are often hidden from ourselves, we are remarkably good at detecting others' biases."). In individual physician decision making, there is no such check on the individual's biases. Third, an individual physician often has a direct personal financial interest in a care recommendation given. Multi-disciplinary panelists may have some financial interest in Guidelines, but that interest is usually far more attenuated than the individual physicians'. Moreover, diverse panelists would tend to have diverse interests, and as a result, the final Guideline recommendation should be less subject to special interest capture than any one individual. So, while imperfect, Guidelines should be markedly better on average than individual physicians at combatting bias or conflict of interest.

<sup>55</sup> Tsiga et al., *supra* note 49, at 1 (stating most medical decisions are made under time pressure). While this article highlights flaws in physician decision making, it is written with the utmost respect for physicians, the work that they do, and the effort they expend trying to make the best possible healthcare recommendations. We are all human and all utilize heuristics. So, illustrating these intuitive rather than rational decision making strategies is not intended as criticism, only as necessary empiric evidence that greater deference to scientifically based, carefully considered, consensus recommendations is warranted. Physicians also predominantly create the very Guidelines that this article suggests deserve increased prominence.

<sup>56</sup> McGlynn et al., *supra* note 2, at 2641–42. This is a fairly crude statistic, and the exact percentage of variances that are neither clinically supported nor based on patient preference may be lower. Nonetheless, it is overwhelmingly clear that the percentage of patients who are over-treated, undertreated or mistreated is far too high.

consultation with anyone other than, at times, the patient.<sup>57</sup> While individual physician decision making varies both by physician and by circumstance, in general, it lacks the reliability of Guidelines.<sup>58</sup>

The first shortcoming of physician decision making, at least as compared to Guidelines, stems from inferior information. As discussed above, physicians typically are not, and realistically cannot be, familiar with all of the latest empiric evidence bearing on care.<sup>59</sup> In fact, studies show that physicians have at least one question for every two patients that they see and leave roughly two-thirds of these questions unanswered.<sup>60</sup> So, when they make a recommendation, it is not usually based on the best available data.<sup>61</sup>

Even if familiar with the latest research, individual physician decision making lacks the benefit of a slower deliberative process and multiple viewpoints.<sup>62</sup> To be successful, physicians must learn to make care decisions quickly and without collaboration with other experts.<sup>63</sup> While perhaps necessary, the speed and isolation of individual physician decision making render mistakes more likely.<sup>64</sup>

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<sup>57</sup> Tsiga et al., *supra* note 49, at 1 (stating most medical decisions are made under time pressure).

<sup>58</sup> Studies show that many factors such as gender, experience, and training impact individual physician decision making. *See, e.g.*, Karen E. Lutfey et al., *Physician Cognitive Processing as a Source of Diagnostic and Treatment Disparities in Coronary Heart Disease: Results of a Factorial Priming Experiment*, 51 J. HEALTH & SOC. BEHAV. 16, 22 (2010) (finding that physician gender and level of experience influence clinical decision making); *see also* Daniel Kahneman, *Maps of Bounded Rationality: Psychology for Behavioral Economics*, 93 AM. ECON. REV. 1449, 1469 (2003) (“What is natural and intuitive in a given situation is not the same for everyone . . .”).

<sup>59</sup> Alper et al., *supra* note 41, at 436.

<sup>60</sup> Guilherme Del Fiol et al., *Clinical Questions Raised by Clinicians at the Point of Care: A Systematic Review*, 174 JAMA INTERNAL MED. 710, 710, 712, 715–16 (2014) (“Unanswered questions may lead to suboptimal patient care decisions.”).

<sup>61</sup> As discussed below, many physicians also lack knowledge or familiarity with Guidelines.

<sup>62</sup> Casey, *supra* note 4, at 1582 (identifying under-adherence with Guidelines as possibly explained by reduced time for “detailed, systematic, and, hence, consistent evaluation and treatment”); Tsiga et al., *supra* note 49, at 1 (discussing that most medical decisions are made under time pressure).

<sup>63</sup> Physicians also poorly predict patient preferences in on the spot care decisions. Benjamin Moulton & Jaime S. King, *Aligning Ethics with Medical Decision-Making: The Quest for Informed Patient Choice*, 38 J.L. MED. & ETHICS 85, 89–90 (2010) (stating how studies show wide variation in patient preferences and that physicians predict such variation poorly).

<sup>64</sup> Tsiga et al., *supra* note 49, at 3–5 (stating time pressure and uncertainty make physician heuristic mistakes more common). At the same time, heuristics like overconfidence can cause physicians “to spend insufficient time accumulating evidence and synthesizing it before action.” Pat Croskerry, *Achieving Quality in Clinical Decision Making: Cognitive Strategies and Detection of Bias*, 9 ACAD. EMERGENCY MED. 1184, 1193 (2002).

The complexity, uncertainty, and time pressure of physician decision making creates an environment where cognitive bias thrives.<sup>65</sup> Cognitive biases are systematic errors in judgment; they illustrate how actual human decision making differs from rational-agent models.<sup>66</sup> Rational-agent models assume that people will weigh the costs and benefits of their choices based on the information available to them and pick the choice that maximizes expected utility.<sup>67</sup> Behavioral economists have shown that these models often fail to predict actual human behavior.<sup>68</sup> Humans' ability to make rational decisions is limited by the complexity, novelty and costs of the decision, the cognitive limits of their minds, and the time available to decide.<sup>69</sup>

Real decision makers are not purely or perhaps even predominantly rational.<sup>70</sup> They make decisions using two systems simultaneously, System 1 and System 2.<sup>71</sup> System 1 is an "automatic mode" that involves fast thinking "with little or no effort and no sense of voluntary control."<sup>72</sup> System 2 is an "effortful mode" that requires slower thinking and attention and is used for complex reasoning.<sup>73</sup> System 1 suffers from biases and error-prone heuristics, rule of thumb shortcuts.<sup>74</sup> System 2 is more rational, but also slower, effortful, and of limited capacity.<sup>75</sup> To conserve effort and optimize performance, System 1 and System 2 regularly interact. System 1 continuously and unconsciously generates suggestions that System 2 either endorses or rejects.<sup>76</sup> System 1 "cannot be turned

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<sup>65</sup> Croskerry, *supra* note 64, at 1192; Greaney, *supra* note 7, at 1194–95 (showing limited information and complexity tend to increase cognitive bias; bias "is endemic in health care decisionmaking"); Noah, *supra* note 7, at 701–02 ("both physicians and patients also regularly employ biases and heuristic shortcuts . . ."); *see also* KAHNEMAN, *supra* note 49, at 36, 79, 85. Some Guideline skeptics point to the intractable uncertainty of medicine to discount Guidelines, but such uncertainty is one of the reasons Guidelines are so important. When faced with uncertainty, decision making is more likely to reflect heuristics and biases.

<sup>66</sup> *See* Kahneman, *supra* note 58, at 1449 (describing the "systematic biases that separate the beliefs that people have and the choices they make from the optimal beliefs and choices assumed in rational-agent models"); *see also* KAHNEMAN, *supra* note 49, at 7.

<sup>67</sup> Kahneman, *supra* note 58, at 1459.

<sup>68</sup> *Id.*

<sup>69</sup> *See generally* KAHNEMAN, *supra* note 49; Judith H. Hibbard & Ellen Peters, *Supporting Informed Consumer Health Care Decisions: Data Presentation Approaches that Facilitate the Use of Information in Choice*, 24 ANN. REV. PUB. HEALTH 413, 415 (2003) (recognizing increased use of heuristics when information is complex or requires comparisons on multiple variables).

<sup>70</sup> Greaney, *supra* note 7, at 1194–95; Kahneman, *supra* note 58, at 1469.

<sup>71</sup> KAHNEMAN, *supra* note 49, at 24. We are not conscious of System 1, which operates automatically and too quickly for awareness.

<sup>72</sup> *Id.* at 20.

<sup>73</sup> *Id.* at 21.

<sup>74</sup> System 1 "sometimes answers easier questions than the one it was asked," without the person realizing that this substitution has occurred. *Id.* at 25. Use of heuristics simplifies choice but compromises accuracy. It leads to predictable mistakes. *Id.*

<sup>75</sup> *Id.* at 21, 25, 35.

<sup>76</sup> *Id.* at 25.

off[,]” nor should it be.<sup>77</sup> People need System 1 because System 2 would be overwhelmed if asked to make all decisions.<sup>78</sup> When decisions must be made quickly, are unfamiliar, or involve uncertainty, System 1 plays a larger role in decision making and, as a result, these choices reflect biases and heuristics more often.<sup>79</sup>

Physicians tend to be highly educated, hard-working, well-intended decision makers, but they are still human. As humans, their decision making remains subject to cognitive biases.<sup>80</sup> Accordingly, when they face complex, novel, and uncertain decisions, with limited information and time, like which health care alternative has fewer risks and more benefits for a particular patient, they may rely more on their automatic system when deciding, rather than the more deliberate and rational System—System 2.<sup>81</sup> This predictably increases the risk of biases and systematic errors in decision making.<sup>82</sup>

Medical scholars have catalogued thirty biases or failed heuristics that impair physician decision making.<sup>83</sup> This Article uses three to illustrate common, but unconscious, mistakes in physician decision making: status quo bias, overconfidence bias, and availability bias.<sup>84</sup>

Status quo bias refers to the natural tendency to approach a problem the same way one has in the past, even after receiving information that suggests a new approach would be better.<sup>85</sup> The status quo serves as a “default” and is “sticky,” meaning people will continue to follow it even when a purely rational decision maker would use the new information to update their beliefs about the

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<sup>77</sup> *Id.*

<sup>78</sup> *Id.* at 35; Bang & Frith, *supra* note 35, at 14 (“Biases are the reality of our cognitive system. It is the cost we pay for efficiency.”).

<sup>79</sup> See KAHNEMAN, *supra* note 49, at 79.

<sup>80</sup> Noah, *supra* note 7, at 701–02; *see also* Kahneman, *supra* note 58, at 1469.

<sup>81</sup> KAHNEMAN, *supra* note 49, at 105; Jessica S. Ancker & David Kaufman, *Rethinking Health Numeracy: A Multidisciplinary Literature Review*, 14 J. AM. MED. INFORMATICS ASS’N 713, 715 (2007) (“[T]ime pressures can cause people to base decisions on rapid and automatic affective responses”); J.S. Blumenthal-Barby & Hadley Burroughs, *Seeking Better Health Care Outcomes: The Ethics of Using the “Nudge”*, 12 AM. J. BIOETHICS 1, 1 (2012) (stating how behavioral economics explains how “decision making [is] flawed and biased in predictable ways”); Greaney, *supra* note 7, at 1194–95; Mantel, *supra* note 7, at 479–81.

<sup>82</sup> Greaney, *supra* note 7, at 1197–99; Korobkin & Ulen, *supra* note 7, at 1085; *see also* Mantel, *supra* note 7, at 480–84.

<sup>83</sup> Croskerry, *supra* note 64, at 1186.

<sup>84</sup> This article highlights cognitive mistakes in individual physician decision making to demonstrate why Guidelines should be elevated in medical decision making, but as compared to patients, physicians likely have fewer cognitive errors. As experts with skill and experience, physicians on balance make fewer heuristic mistakes. KAHNEMAN, *supra* note 49, at 11.

<sup>85</sup> William Samuelson & Richard Zeckhauser, *Status Quo Bias in Decision Making*, 1 J. RISK & UNCERTAINTY 7, 8 (1988).

best approach.<sup>86</sup> Physicians appear to suffer from “status quo bias.”<sup>87</sup> As a result, physicians often recommend the same care they have in the past, even after empiric evidence indicates that another alternative is more beneficial or less risky.<sup>88</sup> Adopting a new method takes more cognitive work and does not intuitively feel right, even when rationally it is the superior course. Status quo bias can be so strong that “it takes an average of 17 years for evidence from randomized clinical trials to be incorporated into practice . . .”<sup>89</sup>

Stent implantation illustrates this problem.<sup>90</sup> By 2007, clinical trials had revealed that stents neither prevent heart attacks nor extend lives in stable patients.<sup>91</sup> Because “one in [fifty patients] will suffer a serious complication or die as a result of the implantation procedure[,]” the evidence indicated that implanting stents not only lacked benefit but also unjustifiably risked serious harm.<sup>92</sup> An updated Guideline followed by 2011.<sup>93</sup> Nonetheless, five years lat-

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<sup>86</sup> This problem can be especially common when considering more than two treatment options. Croskerry, *supra* note 64, at 1192 (“[M]ultiple alternatives bias,” a variant of status quo bias, suggests that if there are more than two care options, physicians will be even more likely to stick with the status quo); Ezekiel J. Emanuel et al., *Using Behavioral Economics to Design Physician Incentives that Deliver High-Value Care*, 164 ANNALS INTERNAL MED. 114, 115 (2016) (describing how “[c]hoice [o]verload” can reinforce status quo bias for physicians); In medical literature, a contradicted claim can continue to persist in citations for a decade after being disproven. See Athina Tatsioni et al., *Persistence of Contradicted Claims in the Literature*, 298 JAMA 2517 (2007).

<sup>87</sup> Bang & Frith, *supra* note 35, at 2 (describing physician performance of tonsillectomies decades after evidence showed such procedures were ineffective); Croskerry, *supra* note 64, at 1192; Greaney, *supra* note 7, at 1197–98 (discussing how physicians exhibit status quo bias, continuing a practice even after knowledge of peer-reviewed literature demonstrating a better care approach).

<sup>88</sup> Bang & Frith, *supra* note 35, at 2; Cabana et al., *supra* note 4, at 1458, 1462; Richard G. Frank, *Behavioral Economics and Health Economics*, in BEHAVIORAL ECONOMICS AND ITS APPLICATIONS 195, 199 (Peter Diamond & Hannu Vartiainen eds., 2007) (noting physician have been slow to adopt effective drugs like beta blockers and to switch to prescribing generics despite compelling evidence); Greaney, *supra* note 7, at 1198; Sandra H. Johnson, *Polluting Medical Judgment? False Assumptions in the Pursuit of False Claims Regarding Off-Label Prescribing*, 9 MINN. J.L. SCI. & TECH. 61, 74–82 (2008) (describing how physicians continue to rely on habit even when the practice is contrary to peer-reviewed literature raising serious safety concerns).

<sup>89</sup> Casey, *supra* note 4, at 1581. This lag time may also reflect confirmation bias.

<sup>90</sup> David Epstein & ProPublica, *When Evidence Says No, but Doctors Say Yes*, ATLANTIC (Feb. 22, 2017), <https://www.theatlantic.com/health/archive/2017/02/when-evidence-says-no-but-doctors-say-yes/517368/> [<https://perma.cc/BRM9-RZNS>]; see also Epstein, *supra* note 6, at 1311 (discussing stents as an example where physician reliance on custom and practice rather than data undermines the quality of care).

<sup>91</sup> William E. Boden et al., *Optimal Medical Therapy with or without PCI for Stable Coronary Disease*, 356 NEW ENG. J. MED. 1503, 1504 (2007); see also Kathleen Stergiopoulos & David L. Brown, *Initial Coronary Stent Implantation with Medical Therapy vs Medical Therapy Alone for Stable Coronary Artery Disease: Meta-Analysis of Randomized Controlled Trials*, 172 ARCHIVES INTERNAL MED. 312 (2012) (stating that later systematic review of clinical trials on stent implantation reconfirming lack of benefit).

<sup>92</sup> Epstein & ProPublica, *supra* note 90.



er, nearly half of all stents implanted in stable patients were still inappropriate.<sup>94</sup> Despite strong evidence and significant risk of serious harm, many physicians continued to follow outdated implantation practices.<sup>95</sup> Status quo bias impedes physicians from quickly integrating innovation into practice, often at great cost.<sup>96</sup>

“Overconfidence bias” may also impair physician decision making.<sup>97</sup> This bias reflects the reality that people often think they know more than they actually do and place far too much confidence in their own opinions and skills.<sup>98</sup> Overconfidence bias appears to be endemic in medicine.<sup>99</sup> In fact, in a study comparing autopsy results with diagnosis, physicians who were “completely certain” of their diagnosis turned out to be completely wrong 40 percent of the time.<sup>100</sup> Overconfidence leads to unwarranted care variances because when physicians systematically overestimate their own knowledge and skill, they are substantially less likely to change care recommendation in response to evidence

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<sup>93</sup> Glenn N. Levine et al., *2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention*, 58 J. AM. C. CARDIOLOGY e44, e48, e91 (2011).

<sup>94</sup> Frederick A. Masoudi et al., *Trends in U.S. Cardiovascular Care: 2016 Report from 4 ACC National Cardiovascular Data Registries*, 69 J. AM. C. CARDIOLOGY 1427, 1433, 1436 (2017) (stating, even after the new guideline, half of stents implanted in stable patients were definitely or possibly inappropriate).

<sup>95</sup> Over-implantation of stents also almost certainly reflects physician commission bias. Commission bias makes humans want to take action once a problem has been identified, even if no action would be more likely to maximize utility. See, e.g., Ian Scott, *Errors in Clinical Reasoning: Causes and Remedial Strategies*, 339 BMJ 22, 24 (2009) (describing commission bias as the “[t]endency to do something . . . even if intended actions are not supported by robust evidence and may in fact do harm”). It also likely reflects confirmation bias.

<sup>96</sup> While innovation usually eventually trickles into custom and practice, the proposed remedy would speed this process by improving physician education and by nudging physician decision making, thus improving the quality of care.

<sup>97</sup> KAHNEMAN, *supra* note 49, at 262–63 (explaining that emotional, cognitive, economic, and social pressures all contribute to physician overconfidence); Bang & Frith, *supra* note 35, at 1; Eta S. Berner & Mark L. Graber, *Overconfidence as a Cause of Diagnostic Error in Medicine*, 121 AM. J. MED. S2, S2 (2008); Croskerry, *supra* note 64, at 1193; Pat Croskerry & Geoff Norman, *Overconfidence in Clinical Decision Making*, 121 AM. J. MED. S24, S24 (2008) (stating overconfidence is one of the most significant cognitive biases in physician decision making); Greaney, *supra* note 7, at 1197.

<sup>98</sup> KAHNEMAN, *supra* note 49, at 260–63.

<sup>99</sup> *Id.* at 263 (describing how social, economic, cognitive and emotional factors lead physicians to overconfidence); Croskerry & Norman, *supra* note 97, at S27 (describing physician overconfidence as common, part of the culture of medicine).

<sup>100</sup> KAHNEMAN, *supra* note 49, at 263 (discussing how, perversely, patients and organizations tend to prefer confident physicians; recognizing uncertainty is frowned upon). An example of this bias outside medicine is that 93 percent of people report that they are “above average” drivers. Ola Svenson, *Are We All Less Risky and More Skillful Than Our Fellow Drivers?*, 47 ACTA PSYCHOLOGICA 143, 146 (1981). Of course, almost half of them are wrong.

of a better approach.<sup>101</sup> When overconfidence bias interacts with status quo bias, the effect is compounded, and physicians may find it very challenging to respond rationally to CER or Guidelines that suggest a different treatment method would improve care.<sup>102</sup>

Physicians may also experience an “availability bias.”<sup>103</sup> This bias refers to the tendency to overestimate the significance of information or experiences that readily come to mind.<sup>104</sup> The evidence that is the most “available” is mistaken for being the most “relevant.”<sup>105</sup> In physicians, this means that they may overvalue the significance of their recent or dramatic clinical experience in decision making and under-appreciate more scientifically sound, empiric research on a broader population.<sup>106</sup> So, for example, when a physician’s last three patients failed to respond to smoking cessation counseling, the physician may stop counseling smokers because he or she considers it fruitless.<sup>107</sup> The physician may do so despite knowledge of empiric evidence from large, well-controlled public health studies that physician-led smoking cessation counseling materially improves the chances that a patient will stop smoking.<sup>108</sup> The empiric evidence simply does not resonate the way the physician’s own available experiences do.<sup>109</sup> Especially when coupled with overconfidence bias, this can cause physicians to subconsciously discount evidence of the best care recommenda-

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<sup>101</sup> Bang & Frith, *supra* note 35, at 4–5; Croskerry, *supra* note 64, at 1193 (“Overconfidence may result in significant errors of both omission and commission and result in unwarranted interventions, costly delays, or missed diagnoses.”); Croskerry & Norman, *supra* note 97, at S27.

<sup>102</sup> Unfortunately, these unconscious, cognitive biases may also be reinforced by a more conscience risk/benefit analysis that under the current malpractice system acting consistent with prior practice is safer, at least when such prior practice reflects the customary approach. See Michael Frakes, *The Impact of Medical Liability Standards on Regional Variations in Physician Behavior: Evidence from the Adoption of National-Standard Rules*, 103 AM. ECON. REV. 257, 275–76 (2013) (concluding that malpractice law may discourage physician deviations from customary practice).

<sup>103</sup> Croskerry, *supra* note 64, at 1187; Greaney, *supra* note 7, at 1198–99; Korobkin & Ulen, *supra* note 7, at 1090 (recognizing the distorting impact of the availability heuristic on physician decision making); Tsiga et al., *supra* note 49, at 4.

<sup>104</sup> See generally Amos Tversky & Daniel Kahneman, *Availability: A Heuristic for Judging Frequency and Probability*, 5 COGNITIVE PSYCHOL. 207 (1973).

<sup>105</sup> *Id.*

<sup>106</sup> KAHNEMAN, *supra* note 49, at 130 (stating personal experience tends to be more available than statistical evidence); see also *id.* at 249 (“‘Pallid’ statistical information is routinely discarded when it is incompatible with one’s personal impressions of a case.”).

<sup>107</sup> See Tsiga et al., *supra* note 49, at 4.

<sup>108</sup> See McGlynn et al., *supra* note 2, at 2641 (counseling has the lowest rates of adherence).

<sup>109</sup> KAHNEMAN, *supra* note 49, at 111 (showing small sample size bias causes humans to suggest a more coherent explanation for extreme outcomes when none in fact exists); see also *id.* at 130, 249 (recognizing common physician error of viewing patient as exception or unique, ignoring evidence to the contrary).

tion. These and other cognitive biases undermine purely rational decision making in even the best-intended physicians.<sup>110</sup>

Given the risk of cognitive bias in physician decision making, critics of Guidelines who favor a more individualized care approach may want to reconsider. It is true that individuals with the same diagnosis can and do respond differently to the same care.<sup>111</sup> However, if there is a predictable basis for such response, it should be reflected in the Guidelines.<sup>112</sup> If there is not an established basis to predict which individual will respond differently, evidence demonstrates that most patients will benefit from following Guideline recommendations.<sup>113</sup> While physicians should remain free to deviate from Guidelines based on professional judgment, they should exercise that discretion far more cautiously. After all, evidence suggests that physicians overestimate their ability to personalize care appropriately and cognitive biases mislead physicians regarding the significance of their clinical experiences and personal impressions.<sup>114</sup>

### C. Patient Decision Making Suffers from Lack of Understanding and Cognitive Biases

Having shown how physician decision making suffers from imperfect information, limited time and perspective, and cognitive biases, it is worth examining how these same factors impact patient decision making. Unsurprisingly, similar weaknesses exist.<sup>115</sup> These shortcomings are greatly compounded in pa-

<sup>110</sup> There may be ways that physicians can counter cognitive biases. This article suggests using Guideline recommendations as defaults for care and discussing as well as documenting any reason for deviating from Guidelines. For other suggestions, see, for example, Croskerry, *supra* note 64, at 1187.

<sup>111</sup> See, e.g., Daniel C. Malone et al., *The Good, the Bad, and the Different: A Primer on Aspects of Heterogeneity of Treatment Effects*, 20 J. MANAGED CARE PHARMACY 555, 555–56 (2014).

<sup>112</sup> The next generation of guidelines will likely include more nuanced recommendations based on reliable individualized risk prediction and response to therapy estimates. David M. Eddy et al., *Individualized Guidelines: The Potential for Increasing Quality and Reducing Costs*, 154 ANNALS INTERNAL MED. 627, 633 (2011) (stating individualized guidelines, applying readily available characteristics in a scientific way, increased quality and reduced cost in the context of blood pressure management); Murad, *supra* note 3, at 429.

<sup>113</sup> KAHNEMAN, *supra* note 49, at 249; Murad, *supra* note 3, at 431 (“Empirical evidence shows that guidelines improve patient outcomes . . .”).

<sup>114</sup> KAHNEMAN, *supra* note 49, at 111, 130, 249, 263. While this article highlights biases and failed heuristics, under circumstances involving a regular environment and prolonged practice, physician’s System 1 intuitive decision making can be accurate. *Id.* at 11, 185, 240–41. The challenge, of course, is that too often physician decisions are not made in this sort of environment. This insight does, however, help to explain why physicians who perform a single procedure hundreds or even thousands of times a year have substantially better outcome statistics than physicians who perform the same procedure infrequently.

<sup>115</sup> Epstein, *supra* note 6, at 1274–85 (providing an excellent analysis of how patients suffer from decision making bias and lack stable preferences).

tients, however, by lack of understanding and the novelty and stress of medical decision making.<sup>116</sup>

Turning first to information, patients receive most of the information they use to make care decisions from their individual physician.<sup>117</sup> As such, physicians pass down any deficiency in information to their patients.<sup>118</sup> Unfortunately, physicians also tend to exacerbate information insufficiencies because they often fail to convey important information they do have to patients.<sup>119</sup> Physicians underestimate the information patients desire and also face time pressures in conveying information.<sup>120</sup>

Patients in turn make these information inadequacies worse because they frequently fail to understand the information their physicians do provide.<sup>121</sup> Conveying information does not ensure comprehension, and evidence suggests that patients routinely have trouble absorbing medical information.<sup>122</sup> In fact, the United States reports widespread prevalence of low health literacy.<sup>123</sup> The Institute of Medicine defines health literacy as “the degree to which individuals have the capacity to obtain, process, and understand basic health information

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<sup>116</sup> Ada C. Stefanescu Schmidt et al., *Boundedly Rational Patients? Part 1: Health and Patient Mistakes in a Behavioral Framework*, 1 J. BEHAV. ECON. FOR POL’Y 11, 11 (2017).

<sup>117</sup> Interestingly, the Internet has greatly increased the number of patients who seek information independently. See, e.g., Jessica Berg, *The E-Health Revolution and the Necessary Evolution of Informed Consent*, 11 IND. HEALTH L. REV. 589, 589, 595 (2014) (“80 percent of US internet users have searched for [medical] information online[.]” arguing that ethical and legal evaluation of informed consent need to catch up to the e-health revolution) (quoting Lygeia Ricciardi et al., *A National Action Plan to Support Consumer Engagement Via E-Health*, 32 HEALTH AFF. 376, 378 (2013)). However, such searches tend to supplement rather than supplant physician disclosures. Most patients lack the knowledge, education, and experience necessary to conduct effective medical research, and many also lack access to the necessary databases.

<sup>118</sup> Scholars have long recognized the information asymmetry between physician and patient, but the information asymmetry between individual physicians and Guidelines merits more attention. See, e.g., Greaney, *supra* note 7, at 1191 (describing physician-patient information asymmetry).

<sup>119</sup> Moulton & King, *supra* note 63, at 87, 89–90 (demonstrating how studies show a “consistent pattern of inadequate information disclosure”).

<sup>120</sup> *Id.* at 85 (“most physicians still undervalue disclosure”); Tsiga et al., *supra* note 49, at 4.

<sup>121</sup> INST. OF MED. OF THE NAT’L ACADS., HEALTH LITERACY: A PRESCRIPTION TO END CONFUSION 1–2 (2004) [hereinafter HEALTH LITERACY]; *Fact Sheet: Health Literacy Basics*, U.S. DEP’T HEALTH & HUM. SERVS., <https://health.gov/communication/literacy/quickguide/factsbasic.htm> [<https://perma.cc/5AXX-3JCN>] (last visited Apr. 2, 2019) [hereinafter *Literacy Basics*]; see also Thaddeus Mason Pope, *Certified Patient Decision Aids: Solving Persistent Problems with Informed Consent Law*, 45 J.L. MED. & ETHICS 12, 17 (2017) (discussing how patients often do not understand the information disclosed).

<sup>122</sup> Pope, *supra* note 121, at 17.

<sup>123</sup> *Literacy Basics*, *supra* note 121 (“[o]nly 12 percent of adults have Proficient health literacy”).

and services needed to make appropriate health decisions.”<sup>124</sup> Nearly half of all adults lack the health literacy necessary to make appropriate health decisions.<sup>125</sup>

Even those patients with above average health literacy may be missing critical points.<sup>126</sup> 90 percent of patients report that they are not able to grasp some health information provided to them.<sup>127</sup> In particular, patients lack numeracy and the ability to process comparative risks and benefits data.<sup>128</sup> So, due to inadequate information provided to patients and to gaps in understanding, the information patients actually utilize for medical decision making is demonstrably less reliable than the information underlying Guidelines.

Limited time and viewpoint likewise weaken patient decision making. Patients, like physicians, typically (although not always) make healthcare decisions on the spot, without more time to think slowly and critically. Quick decision making can impair decision making results.<sup>129</sup>

Similarly, traditional physician-patient decision making lacks the diversity of perspectives and expertise provided by the panels that draft Guidelines. The only voice of experience and expertise patients receive, if any, is their individual physician’s, whose view may be weakened by lack of research and time to reflect, as well as cognitive biases.<sup>130</sup> The richness of thoughtfully considered, multi-disciplinary perspectives and the rationality of empirically based recom-

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<sup>124</sup> HEALTH LITERACY, *supra* note 121, at 2; *see also* Patient Protection and Affordable Care Act of 2010, 42 U.S.C. § 295p(21) (2012) (“The term ‘health literacy’ means the degree to which an individual has the capacity to obtain, communicate, process, and understand health information and services in order to make appropriate health decisions.”). Many factors can impact health literacy, such as education, culture, language, and cognitive ability of the patient or how well the provider conveys the information.

<sup>125</sup> HEALTH LITERACY, *supra* note 121, at 1.

<sup>126</sup> *Literacy Basics*, *supra* note 121.

<sup>127</sup> *Id.* (“[N]early nine out of ten adults may lack the skills needed to manage their health and prevent disease.”).

<sup>128</sup> Ancker & Kaufman, *supra* note 81, at 713, 715 (“[M]any patients get lost in numbers . . .” and “[m]any patients lack basic probability skills . . .”); Epstein, *supra* note 6, at 1283–84 (discussing how patients struggle with numeracy, exacerbating cognitive biases); Hibbard & Peters, *supra* note 69, at 415–16; Russell Korobkin, *Comparative Effectiveness Research as Choice Architecture: The Behavioral Law and Economics Solution to the Health Care Cost Crisis*, 112 MICH. L. REV. 523, 540 (2014) (discussing how cognitive bias heavily influences patient decision making because patients struggle to process complex, novel, comparative information); Ellen Peters et al., *Numeracy Skill and the Communication, Comprehension, and Use of Risk-Benefit Information*, 26 HEALTH AFF. 741 (2007) (stating many patients cannot perform the basic numeric tasks required to make health care decisions effectively); Lisa M. Schwartz et al., *The Role of Numeracy in Understanding the Benefit of Screening Mammography*, 127 ANNALS INTERNAL MED. 966, 969 (1997) (showing only 16 percent of women demonstrated numeracy; most did not accurately apply information about risks and benefits of mammography).

<sup>129</sup> KAHNEMAN, *supra* note 49, at 79.

<sup>130</sup> *See supra* Section II.B; *see also infra* Section III.B.

mendations are simply missing from the traditional individual physician-patient process.

Given limited time and the complicated, stressful, and novel nature of patient decision making, cognitive bias also flourishes.<sup>131</sup> Scholars have identified numerous biases and heuristics that distort patient choice.<sup>132</sup> This Article selects three to exemplify how patient decision making predictably and systematically reflects mistakes and biases: framing effects, single factor bias, and authority bias.

First, patients suffer from framing effects.<sup>133</sup> This means that their decision will often be swayed by *how* physicians present information, rather than an objective analysis of that information.<sup>134</sup> An example of this bias is that patients are more likely to pick a care approach if its risks are described as “9 out of 10 patients recover” rather than “1 out of 10 patients die.”<sup>135</sup> Rationally, the treatment has the same odds under either description, but the different descriptions trigger different responses.<sup>136</sup> Because patients struggle with numeracy and tend to be loss averse, inconsequential variations in description can determine preference.<sup>137</sup>

Patients may also suffer from single factor or “lexicographic” bias, in which they make healthcare decisions based on one factor, ignoring all other variables, to simplify the decision.<sup>138</sup> For example, a low risk patient who has been treated for breast cancer in one breast may focus only on decreasing the risk of future breast cancer when opting for a prophylactic double mastecto-

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<sup>131</sup> Hibbard & Peters; *supra* note 69, at 415–16; Schmidt, et al., *supra* note 116, at 11–13; Daniel Young, *Curing What Ails Us: How the Lessons of Behavioral Economics Can Improve Health Care Markets*, 30 YALE L. & POL’Y REV. 461, 467–68 (2012) (showing patients’ “abilities to make ‘rational’ choices are predictably constrained, especially in situations involving complex calculations and probabilistic trade-offs.”).

<sup>132</sup> See Epstein, *supra* note 6, at 1281 (using behavioral economics to describe systematic and predictable flaws in patient decision making); Korobkin, *supra* note 128, at 540; Noah, *supra* note 7, at 701–02.

<sup>133</sup> Epstein, *supra* note 6, at 1276–77 (discussing how patient preferences may be constructed by frames); Greaney, *supra* note 7, at 1195 (recognizing the impact of framing effects); Korobkin, *supra* note 128, at 534–35 (discussing that preference may be constructed in response to context, especially for novel decisions like healthcare).

<sup>134</sup> Kahneman, *supra* note 58, at 1458; Ada C. Stefanescu Schmidt et al., *Boundedly Rational Patients? Part 2: Health and Patient Mistakes in a Behavioral Framework*, 1 J. BEHAV. ECON. FOR POL’Y 17, 20 (2017).

<sup>135</sup> See, e.g., Epstein, *supra* note 6, at 1276 (describing similar interplay between loss aversion and framing effects on patients).

<sup>136</sup> See Kahneman, *supra* note 58, at 1458.

<sup>137</sup> Needless to say, the fact that patient decision making may turn on phrasing raises serious concerns. Framing effects in literature can also influence physician decision making.

<sup>138</sup> Korobkin, *supra* note 128, at 533–34 (describing lexicographic decision making in patients, especially when faced with the complex and multivariable healthcare decisions); see also Hibbard & Peters, *supra* note 69, at 416 (patients facing burdensome cognitive processes like risk and benefit trade-offs may rely on shortcuts like using a single factor to decide).

my.<sup>139</sup> This single factor focus may ignore increased aggregate risks of an invasive surgery. Aggregate risks include far more common but less available risks like infection, bleeding, and psychological side effects.<sup>140</sup> By focusing on a single factor, the patient simplifies decision making but at times at the cost of accuracy.<sup>141</sup>

Many patients also experience authority bias.<sup>142</sup> This bias causes them to attribute accuracy to their individual physician's recommendation, independent of its merit.<sup>143</sup> It leads patients to over-estimate the validity of their physician's recommendation, and it is one explanation for patients' frequent deference to physicians' recommendations.<sup>144</sup> Authority bias encourages patients to simplify choice by relying on physicians' recommendations.<sup>145</sup>

In summary, patients are often overwhelmed by medical information they struggle to understand. They lack numeracy and, in particular, have trouble comprehending probabilities, which are necessary to evaluate risk and benefit information.<sup>146</sup> Even aside from probabilities, they struggle with evaluability itself and poorly differentiate acceptable from unusual risks.<sup>147</sup> Patients flounder when asked to apply different weights to several variables across multiple options.<sup>148</sup> This sort of novel and complex decision making strains and often exceeds patients' cognitive capacity.<sup>149</sup> As a result, patients commonly employ

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<sup>139</sup> This example is intended to help explain single factor bias but not to weigh in on the propriety of prophylactic double mastectomy. While there is ample reason to be concerned about bias in decision making for prophylactic double mastectomies in low risk patients, there is also considerable basis to view this choice as preference sensitive care. For some patients, emotional wellbeing may recommend the more aggressive approach, even if biomedical risks do not.

<sup>140</sup> See *Surgery to Reduce the Risk of Breast Cancer*, NAT'L CANCER INST., <https://www.cancer.gov/types/breast/risk-reducing-surgery-fact-sheet> [<https://perma.cc/N3MM-NDLJ>] (last updated Aug. 12, 2013). Such choice also may reflect affective bias, basing a decision on an emotional reaction.

<sup>141</sup> Physicians may also fall prey to single factor or lexicographic decision making.

<sup>142</sup> In general, physicians are better decision makers than patients. Physicians have more education and experience and are less emotionally involved. So, some deference is rational, but blind deference is not.

<sup>143</sup> See Stanley Milgram, *Behavioral Study of Obedience*, 67 J. ABNORMAL & SOC. PSYCHOL. 1, 1, 7 (1963) (describing authority bias and its impacts).

<sup>144</sup> See Carl E. Schneider, *Bioethics with a Human Face*, 69 IND. L.J. 1075, 1097 (1994) (stating patients want to be informed but "a quite substantial number of them did not want to make their own medical decisions").

<sup>145</sup> Hibbard & Peters, *supra* note 69, at 419.

<sup>146</sup> Ancker & Kaufman, *supra* note 81, at 715; Epstein, *supra* note 6, at 1284; Schwartz et al., *supra* note 128, at 969. Because patients respond differently to care, risks and benefits in medicine are often presented as probabilities. Yet, patients struggle to comprehend this presentation.

<sup>147</sup> Hibbard & Peters, *supra* note 69, at 415–16; Korobkin, *supra* note 128, at 536, 539.

<sup>148</sup> Hibbard & Peters, *supra* note 69, at 415–16; Korobkin, *supra* note 128, at 536, 539.

<sup>149</sup> Hibbard & Peters, *supra* note 69, at 415–16; see also KAHNEMAN, *supra* note 49, at 36, 59, 79 (stating efforts to analyze several attributes, to process complex or novel information,

biases and heuristics when deciding, which simplify healthcare decisions but compromise accuracy.<sup>150</sup>

*D. From Dyad to Triad: The Ideal Role for Guidelines in Physician-Patient Decision Making*

Recognizing predictable and pervasive shortcomings in physician and patient decision making and the impact those failures have on quality of care, as well as the potential for Guidelines to improve the process, it is time for a sea change in how healthcare decision making occurs.<sup>151</sup> Both physicians and patients need to reorient decision making to provide substantially more attention and deference to the scientifically based, thoughtfully considered consensus reflected in Guidelines. Guidelines should be treated as the third leg to the stool of healthcare decision making, bolstering traditional physician recommendation and patient choice. The current largely ad hoc approach to medical decision making results in over-treatment, under-treatment, and mistreatment.<sup>152</sup> To stabilize this shaky process, physicians should incorporate Guideline recommendations as the default care approach and patients should accord Guidelines equal respect as their individual physician's recommendation.<sup>153</sup>

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especially with limited time, causes cognitive strain and make heuristic mistakes more likely); Ancker & Kaufman, *supra* note 81, at 715.

<sup>150</sup> Ancker & Kaufman, *supra* note 81, at 715; Epstein, *supra* note 6, at 1281–82; Korobkin, *supra* note 128, at 534.

<sup>151</sup> See, e.g., ATUL GAWANDE, THE CHECKLIST MANIFESTO: HOW TO GET THINGS RIGHT 46 (2010) (arguing for a wholesale revision in the role of the individual doctor in a complex, information-overloaded society and championing checklists and protocols as individual physicians come to see themselves as part of a larger health care team). Without question, checklists and protocols improve patient care and should be part of the holistic response to unwarranted care variances. This article endorses guideline disclosure to empower patients because checklists and protocols alone would leave all power in the hands of physicians. See Epstein, *supra* note 6 (sounding the alarm that the law of healthcare decision making has failed to respond adequately to behavioral economics insights). In June 2018, Amazon, JP Morgan, and Berkshire Hathaway announced that Dr. Gawande would serve as CEO of their new joint venture to cut healthcare costs and improve quality. Angelica LaVito et al., *Amazon's Joint Health-Care Venture Finally Has a Name: Haven*, CNBC (Mar. 6, 2019, 4:05 PM), <https://www.cnbc.com/2019/03/06/amazon-jp-morgan-berkshire-hathaway-health-care-venture-named-haven.html> [<https://perma.cc/SJG4-B5NJ>].

<sup>152</sup> 2013 IOM REPORT, *supra* note 14, at 1.

<sup>153</sup> A default is a pre-set course of action to follow, unless the decision maker affirmatively specifies differently. See RICHARD H. THALER & CASS R. SUNSTEIN, NUDGE: IMPROVING DECISIONS ABOUT HEALTH, WEALTH, AND HAPPINESS 83 (2008); see also *infra* Section IV.B. While this article suggests using informed consent to reach this goal, other vehicles could also be utilized to accomplish this end.

In 2008, Richard Thaler and Cass Sunstein published a groundbreaking book, NUDGE: IMPROVING DECISIONS ABOUT WEALTH, HEALTH, AND HAPPINESS, that applied behavioral economics studies to demonstrate that most people systematically and predictably exercise biases and mistakes in healthcare decision making. THALER & SUNSTEIN, *supra*, at 7–8, 19 (2008). In light of these biases and mistakes, they argued that “choice architecture” should



Of course, patients should still play a critical role in healthcare decision making.<sup>154</sup> Their active participation is an end in itself, and no one else can provide the patient's personal values and preferences.<sup>155</sup> Moreover, aside from

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be used to help people make better health choices, without controlling those choices. *Id.* at 6, 10–11. People should be “nudged,” but such interventions should remain “easy and cheap to avoid.” *Id.* at 6. While discussing dozens of nudges, Thaler and Sunstein particularly extolled the value and benefit of setting good defaults. *Id.* at 8, 12, 83, 85.

In 2017, Wendy Netter Epstein published a significant article arguing that the law of healthcare decision making had failed to respond adequately to such behavioral economic insights. Epstein, *supra* note 6, at 1258. Providing a thorough and detailed analysis of patient biases and preference instability, she challenged current emphasis on patient autonomy, and she recommended “patient[s] be presented the default treatment for their condition, with the default being as personalized as possible given available data.” *Id.* at 1301. Epstein criticized neutral presentation of all treatment options without a recommendation and highlighted the importance of an evidence-based approach, but she did not mention Guidelines. *Id.* at 1260.

This article builds off the work of Thaler, Sunstein, Epstein and many others who have advocated for using defaults to nudge better healthcare decision making with a specific, practical proposal that could be immediately implemented. The certified Guidelines prescribed in this Article are materially different than other evidence-based defaults. First, as discussed above, the amount of new evidence available to physicians is staggering, and it would be literally impossible for physicians to stay abreast of all evidence of best practices relevant to their practice. Alper et al., *supra* note 41, at 436. It would similarly be unwise (and arguably a violation of due process) to impose a legal obligation on physicians to obtain and disclose available data without specifying to a reasonable degree of certainty the contours of that data. Physicians need notice of what they are legally required to disclose. This proposal limits the scope of required knowledge and disclosure to a manageable one and defines the disclosure obligation.

Moreover, available evidence is not of equal quality, and the difference between basing a recommendation on available data and basing it on the consensus reached after a systematic review of the latest evidence is dramatic. To quantify this difference in a way that still understates its magnitude, the number of Guidelines listed in the National Guideline Clearinghouse dropped 50 percent after implementation of new Inclusion Criteria in 2014, requiring that Guidelines be based on a systematic review of the evidence. Paul G. Shekelle, *Clinical Practice Guidelines: What's Next?*, 320 *JAMA* 757, 757 (2018). That number would decrease still more if only certified Guidelines complying with the 2011 IOM Trustworthiness Standards were counted (and the initial numbers were Guidelines—not all available data). Certified Guidelines are critical to ensure that any new physician disclosure obligation is realistic, fair, and serves its intended purpose.

<sup>154</sup> Berg, *supra* note 117, at 593–94 (discussing four benefits to patient participation in informed consent); see also *infra* Section IV.C.

<sup>155</sup> Moulton & King, *supra* note 63, at 89, 94 (showing physicians poorly predict patient preferences which vary widely); Shaffer, *supra* note 7, at 733–34 (showing when patients use decision aids for preference sensitive care, they are more likely to select treatment); *Preference Sensitive Care*, DARTMOUTH ATLAS HEALTH CARE, <http://archive.dartmouthatlas.org/keyissues/issue.aspx?con=2938> [https://perma.cc/Q8SP-NRNB] (last visited Apr. 2, 2019) [hereinafter *Dartmouth—Preference Sensitive*] (“studies show that when patients are fully informed about their options, they often choose very differently from their physicians”).

cost, health care decisions primarily impact the patients and generally do not harm others.<sup>156</sup>

Likewise, individual physicians also remain vital, even when well-developed Guidelines exist.<sup>157</sup> Physicians answer questions and help tailor care to a particular patient. The individual physician determines when a Guideline applies to a particular patient and in contrast, when co-morbidities or other biologic factors may justify a deviation.<sup>158</sup>

Guidelines are equally imperative, however. They prompt physicians and patients to select rational, scientifically based medical care, something physicians and patients have struggled to accomplish using a traditional physician-patient approach.

Historically, the ad hoc physician-patient decision making model made sense. Empirically based recommendations did not exist for the overwhelming majority of care decisions.<sup>159</sup> Even when Guidelines did exist, they were sometimes of limited trustworthiness and could be difficult to access during decision making.<sup>160</sup> More recently, however, with the investment in CER and Guideline improvement and the enormous expansion of computer use in everyday medical practice, Guidelines are ready to help revolutionize care.<sup>161</sup> To realize the promise of Guidelines, physician-patient decision making practices will have to change, giving Guidelines a more central role.

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<sup>156</sup> Melissa Ballengee Alexander, *Autonomy and Accountability: Why Informed Consent, Consumer Protection, and Defunding May Beat Conversion Therapy Bans*, 55 U. LOUISVILLE L. REV. 283, 303 (2017) (discussing the importance of patient autonomy).

<sup>157</sup> Trustworthy Guidelines still do not exist for many care decisions, but the quality of Guidelines is increasing and should increase further as research and Guidelines funded by the ACA's \$4 billion investment bear fruit. 2018 GAO REPORT, *supra* note 22, at 2.

<sup>158</sup> Without question, there are valid reasons to deviate from Guidelines. Patient preference may result in a different care approach, especially for preference-sensitive care. *Dartmouth—Preference Sensitive*, *supra* note 155 (defining “preference-sensitive care” as treatment involving significant outcome trade-offs between different options). Moreover, at times, a Guideline that ostensibly applies to a patient may not be appropriate given co-morbidities or other biologic factors. The proposed remedy intentionally allows cheap and easy deviation from Guidelines at the physician's recommendation or the patient's preference. This recognizes the importance of allowing deviations that are thoughtfully considered.

<sup>159</sup> Murad, *supra* note 3, at 423–24 (discussing the history of formal guidelines).

<sup>160</sup> *Id.* at 424, 429; see also Tamara Kredon et al., *Guide to Clinical Practice Guidelines: The Current State of Play*, 28 INT'L J. QUALITY HEALTH CARE 122, 122 (2016) (showing over time guidelines “have shifted from opinion-based to evidence-informed, including increasingly sophisticated methodologies . . .”).

<sup>161</sup> See, e.g., *Electronic Medical Records/Electronic Health Records*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/nchs/fastats/electronic-medical-records.htm> [<https://perma.cc/6YG4-CMQ5>] (last updated Mar. 31, 2017) (showing 86.9 percent of office-based physicians use an electronic medical records system).

### III. EXPLAINING CURRENT GUIDELINE UNDER-ADHERENCE: LACK OF KNOWLEDGE, BEHAVIORAL ECONOMICS, AND CURRENT LAW

Why haven't Guidelines already dramatically improved care? The answer, like our healthcare system more generally, is complicated. Multiple factors continue to impede progress at both the macro and micro levels. At the macro level, organizations need to develop and implement better care processes, in particular incorporating effective use of information technologies and knowledge and skill management.<sup>162</sup> Payment systems need reform to incentivize appropriate care and improve value.<sup>163</sup> Organizations need to create effective teams and better coordinate care across conditions, services, sites, and time.<sup>164</sup> These reforms should be part of a holistic solution but are beyond the scope of this Article, which focuses at the micro level on individual physician and patient decision making.<sup>165</sup> At the micro level, the first step to improving the salience of Guidelines will be to dramatically improve knowledge and familiarity with Guidelines.<sup>166</sup>

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<sup>162</sup> IOM CROSSING THE QUALITY CHASM, *supra* note 17, at 9; Casey, *supra* note 4, at 1582 (recommending the use of checklist-based algorithms). Such changes could greatly facilitate Guideline adherence.

<sup>163</sup> 2013 IOM REPORT, *supra* note 14, at 3–4. Fee for service care contributes to over-treatment. Supply-sensitive care, “where the supply of a specific resource has a major influence on utilization rates,” reflects another aspect of these payment system problems. *Dartmouth—Supply Sensitive*, *supra* note 17. Even with better payment structures, however, financial incentives may unavoidably leave at least some conflict of interest between physician and patients that contributes to waste and to sub-optimal care.

<sup>164</sup> IOM CROSSING THE QUALITY CHASM, *supra* note 17, at 12; *see also Dartmouth—Effective Care*, *supra* note 17.

<sup>165</sup> While beyond the scope of this article, organizational culture can also influence physicians' clinical decision making. *See generally* Mantel, *supra* note 7. Similarly, insurance coverage can influence both physician and patient decision making (and distort the healthcare market). Some who oppose a heightened reliance on Guidelines do so at least in part because of concern over improper use of Guidelines for insurance coverage determinations. While improper use is possible, it is not inherent in Guideline disclosure. After all, the use of Guidelines as a default for care decisions differs materially from the use of Guidelines for coverage decisions. *See, e.g.*, Ira Mark Ellman & Mark A. Hall, *Redefining the Terms of Health Insurance to Accommodate Varying Consumer Risk Preferences*, 20 AM. J.L. & MED. 187, 191–92 (1994) (identifying practical problems with using Guidelines to define insurance contracts). This article recognizes that there are valid reasons to deviate from Guidelines. While it proposes structuring choice to encourage Guideline adherence, it also intentionally allows cheap and easy deviations.

<sup>166</sup> Adherence varies greatly between Guidelines and between specific recommendations within Guidelines. Marjolein Lugtenberg et al., *Why Don't Physicians Adhere to Guideline Recommendations in Practice? An Analysis of Barriers Among Dutch General Practitioners*, 4 IMPLEMENTATION SCI. 1, 4 (2009). Some Guidelines have high adherence, but for many Guidelines, adherence remains low.

A. *Inadequate Knowledge and Familiarity Hinders Guideline Adherence*

All too often physicians lack knowledge or familiarity with Guidelines.<sup>167</sup> It is axiomatic that a Guideline cannot improve physician decision making if the physician is not aware that the Guideline exists. Even when aware of a Guideline's existence, if the physician lacks familiarity with the Guideline's specific recommendations, the Guideline cannot significantly influence decision making.<sup>168</sup> Any solution must incentivize improved physician knowledge and familiarity.

Patient decision making presents the same challenge, in more pronounced form. Even more so than physicians, patients are largely unaware of the existence of Guidelines.<sup>169</sup> They often do not realize that empiric evidence from comparative effectiveness research exists or that there may be carefully considered national consensus recommendations available.<sup>170</sup> Physicians seldom disclose Guidelines to patients.<sup>171</sup> They may discuss risks and benefits in a way that mirrors the evidence summary contained in Guidelines, in whole or in part, but they do not typically mention the Guidelines themselves. Most significantly, they do not usually relay the consensus recommendation contained in

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<sup>167</sup> ACOG GUIDELINE OPINION, *supra* note 12 (“implementation of protocols and guidelines often is delayed because of lack of health care provider awareness”); Cabana et al., *supra* note 4, at 1458, 1461 (“[F]or 78% of the guidelines, more than 10% of physicians are not aware of their existence.”); Lugtenberg et al., *supra* note 166, at 6.

<sup>168</sup> Cabana et al., *supra* note 4, at 1461 (showing that, often, lack of familiarity with guidelines was more of an issue than lack of awareness); Lugtenberg et al., *supra* note 166, at 4 (finding, in a Dutch study, general practitioners lacked familiarity with 46 percent of key recommendations in Guidelines).

<sup>169</sup> Melissa J. Armstrong et al., *Recommendations for Patient Engagement in Guideline Development Panels: A Qualitative Focus Group Study of Guideline-Naïve Patients*, PLOS ONE, Mar. 20, 2017, at 2 (“public awareness of guidelines is low”); Fearn et al., *supra* note 4, at 11 (finding in a Scotland study that “[t]he public is generally unaware of the existence of guidelines, though people are enthusiastic about them once they are made aware of them.”).

<sup>170</sup> Armstrong et al., *supra* note 169, at 2–3 (“[I]ndividuals aware of guidelines have only a vague understanding of what they are and how they are developed.”).

<sup>171</sup> See K. Schipper et al., *Strategies for Disseminating Recommendations or Guidelines to Patients: A Systematic Review*, 11 IMPLEMENTATION SCI. 1, 2 (2016) (“patients are not aware of the existence of recommendations,” discussing the failure to inform patients of Guidelines and recommendations). Moreover, as physicians begin disclosing Guidelines to patients, patients will be taught to ask for them. In this way, better disclosure practices by one physician should beget new patient expectations and demands, which should in turn help ensure that other physicians likewise make better Guideline disclosures.

Guidelines.<sup>172</sup> Until physicians routinely disclose them, Guidelines cannot and will not improve patient decision making.<sup>173</sup>

*B. Cognitive Biases Explain Systematic Guideline Under-Adherence*

Solving this lack of knowledge is a necessary first step in improving decision making and thereby quality of care, but it is not sufficient alone. As empiric studies have shown, even after becoming familiar with Guidelines, physicians under-adhere to them.<sup>174</sup> Cognitive biases help to explain this systematic and predictable under-adherence.<sup>175</sup>

The same three cognitive biases discussed previously can also explain why physicians discount Guidelines in decision making. Status quo bias leads physicians to instinctually want to approach care the same way they have in the past, even after becoming familiar with Guidelines that would cause a purely rational decision maker to change treatment method.<sup>176</sup> Status quo bias makes physicians slow to innovate and encourages physicians to undervalue or even ignore new Guidelines that suggest a different practice.<sup>177</sup>

Other biases explain how physicians may justify under-adherence, even when it is not empirically warranted. When physicians who are familiar with Guidelines deviate, they report two primary reasons (aside from macro-barriers and patient preference): (1) belief that their own judgment is superior, at least for a particular patient, or (2) belief that the Guideline is biased or otherwise

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<sup>172</sup> *Id.* Physicians may indirectly relay a Guideline recommendation if that recommendation accords with their own recommendation, but that is not as informative as also relaying the consensus. For patients, the evidence-based, consensus recommendation of experts reflected in Guidelines may have special weight.

<sup>173</sup> For efficiency and to set a more traditional default, this proposal does not require disclosure of Guidelines unless care will deviate from the Guideline recommendation. This limited reform directly targets unjustified care variances. However, there may also be good reasons to disclose Guidelines even when they accord with physician recommendation and patient preference. More routine Guideline disclosure seems likely to reduce anxiety and simplify patient decision making.

<sup>174</sup> See, e.g., Catherine L. Chen et al., *Preoperative Medical Testing in Medicare Patients Undergoing Cataract Surgery*, 372 NEW ENG. J. MED. 1530, 1535 (2015) (citing “no difference in the prevalence of testing as compared with 20 years ago, before the introduction of guidelines stating that routine preoperative testing for cataract surgery was not necessary,” to conclude that publishing Guidelines alone does not necessarily change individual physician behavior).

<sup>175</sup> Deepika Mohan et al., *Assessing the Validity of Using Serious Game Technology to Analyze Physician Decision Making*, PLOS ONE, Aug. 25, 2014, at 6 (stating heuristics play an important role in physician decision making and can help explain failure to follow Guidelines).

<sup>176</sup> See Chen et al., *supra* note 174, at 1535; Croskerry, *supra* note 64, at 1192; Emanuel et al., *supra* note 86, at 115.

<sup>177</sup> Casey, *supra* note 4, at 1581 (stating it takes seventeen years for evidence to be incorporated into practice).

not sound.<sup>178</sup> Overconfidence bias and availability bias explain why these rationales often reflect heuristic mistakes rather than sound scientific reasoning.<sup>179</sup>

Overconfidence bias leads physicians to greatly overestimate their own skill and knowledge as compared to Guidelines.<sup>180</sup> At least on average, physicians are wrong about having superior judgment.<sup>181</sup> Better information, multiple perspectives, and a more deliberative process all suggest that Guidelines usually provide higher quality care recommendations than an individual physician can. Yet, overconfidence causes physicians to question Guidelines and to overestimate their own judgment for care.<sup>182</sup>

Similarly, “availability bias” causes physicians to doubt the soundness of Guidelines, without adequate scientific basis. Because physicians naturally treat available memories as most relevant, they often overestimate the importance of their recent clinical experience.<sup>183</sup> This leads them to question Guidelines, even when empirically Guidelines rest on sounder scientific foundation than the individual physician’s random clinical outcomes or impression.<sup>184</sup> So, even when physicians are familiar with robust evidence supporting a Guideline, they may intuitively and unconsciously discount that evidence if it contradicts their personal experiences. This causes them to systematically undervalue Guidelines.

Bounded rationality also significantly impacts patient decision making, but in a different way. Unlike physicians, most patients are not ignoring or discounting Guidelines, they are wholly unaware of them.<sup>185</sup> Not told that an empirically based, consensus recommendation exists and overwhelmed by the complexity and novelty of medical decision making, most patients employ the

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<sup>178</sup> See *id.* at 1582; see also Cabana et al., *supra* note 4, at 1459–61.

<sup>179</sup> Guidelines are imperfect and sometimes change when better evidence comes to light or physicians discover a reliable basis for predicting more individualized risk. Nonetheless, empiric evidence establishes that guideline adherence improves patient outcomes and that physicians overestimate their own ability to determine appropriate individual deviations. See Murad, *supra* note 3, at 429.

<sup>180</sup> KAHNEMAN, *supra* note 49, at 263; Berner & Graber, *supra* note 97, at S2; Croskerry, *supra* note 64, at 1193; Croskerry & Norman, *supra* note 97, at S27 (stating overconfidence is one of the most significant cognitive biases in physician decision making).

<sup>181</sup> See KAHNEMAN, *supra* note 49, at 249 (showing that physicians discount known base rates when inconsistent with their impression of a particular patient on the basis that the patient is unique, despite evidence that belies this exceptionalism).

<sup>182</sup> Berner & Graber, *supra* note 97, at S2; Croskerry, *supra* note 64, at 1193; Croskerry & Norman, *supra* note 97, at S27; Greaney, *supra* note 7, at 1197; see KAHNEMAN, *supra* note 49, at 262–63.

<sup>183</sup> See KAHNEMAN, *supra* note 49, at 111, 130, 249.

<sup>184</sup> See *id.* at 249.

<sup>185</sup> Armstrong et al., *supra* note 169, at 2–3 (showing that “public awareness of guidelines is low and that individuals aware of guidelines have only a vague understanding of what they are and how they are developed”); Fearn et al., *supra* note 4, at 11 (“The public is generally unaware of the existence of guidelines, though people are enthusiastic about them once they are made aware of them.”).

decision simplification heuristics of adopting whatever their physician recommends.<sup>186</sup> This approach enables the patient to simplify (or even avoid) taxing and often emotionally costly medical decisions.<sup>187</sup>

Physicians do not always make recommendations, however, and when they do not, patients may rely on other, often even less accurate heuristics.<sup>188</sup> If patients had a better decision simplification tool available, like Guideline recommendations, they could use it.<sup>189</sup> Increasing knowledge of this more reliable decision simplification tool and at the same time nudging the physicians' recommendations should have a significant impact on patient decision making.

### C. Current Law Does Not Require Guideline Adherence or Disclosure

Knowing that physicians and patients systematically under-adhere to Guidelines, the question becomes whether the law can help increase the salience of Guidelines. To answer this question, one must first understand how Guidelines interact with laws governing malpractice and informed consent.<sup>190</sup>

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<sup>186</sup> *Dartmouth—Preference Sensitive*, *supra* note 155 (“patients commonly delegate decision-making to physicians”); Korobkin, *supra* note 128, at 540 (“a large number of patients employ the simple heuristic of adopting their physician’s recommendation”); *see also* THALER & SUNSTEIN, *supra* note 153, at 157 (“Doctors are crucial choice architects . . .”); Schneider, *supra* note 144, at 1097 (stating many patients “did not want to make their own medical decisions”).

<sup>187</sup> Korobkin, *supra* note 128, at 537–38 (discussing how trading off attributes can be difficult emotionally).

<sup>188</sup> Physicians are not legally obligated to make care recommendations. Am. Med. Ass’n, *The AMA Code of Medical Ethics’ Opinions on Informing Patients*, 14 VIRTUAL MENTOR 555, 555 (2012) [hereinafter *AMA Ethics Opinion*] (encouraging physicians to “make recommendations” but only recognizing an “ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice”); *see also* Moulton & King, *supra* note 63, at 88–89. Many physicians choose to do so, but some do not or do not always. *See* Epstein, *supra* note 6, at 1301 (“nothing in the law requires that physicians promote any particular option over another”).

<sup>189</sup> Since physicians are authority figures and most patients trust and respect their physicians, some patients may continue to defer to their physicians’ recommendation, if any, even after being told of Guidelines. This significant and, at times, blind deference to physician recommendations explains why the law may treat the physician-patient relationship as a fiduciary one and restrict physicians’ ability to limit liability based on agreement. *See, e.g.,* Tunkl v. Regents of the Univ. of Cal., 383 P.2d 441, 448 (Cal. 1963).

<sup>190</sup> Malpractice creates potential tort liability for physicians who cause harm when they breach the standard of care. While states vary in the exact approach, most define the standard of care by what a reasonably prudent or minimally competent physician would have done under similar circumstances. *See, e.g.,* Locke v. Pachtman, 521 N.W.2d 786, 791 (Mich. 1994) (stating that the standard of care is determined by what a “reasonably prudent” physician would have done); McCarty v. Mladineo, 636 So. 2d 377, 381 (Miss. 1994) (stating that the standard of care is set by what a “reasonably prudent, minimally competent” physician would have done); McCourt v. Abernathy, 457 S.E.2d 603, 607 (S.C. 1995) (stating that the standard of care is “determined by what an ordinary careful and prudent physician would have done”).

In malpractice cases, the enforceability of Guidelines varies by state and, to some extent, by practice area.<sup>191</sup> However, most courts have held that Guidelines regarding a practice are probative, but not dispositive, evidence of the standard of care.<sup>192</sup> There are outlier cases; some courts have excluded evidence of Guidelines altogether and others have treated Guidelines as dispositive.<sup>193</sup> Nonetheless, most courts treat Guidelines as “some evidence” of the standard of care.<sup>194</sup> So, most physicians need not adhere to Guidelines to avoid malpractice liability, and conversely, adhering to Guidelines does not generally provide a safe harbor from such liability.<sup>195</sup>

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This standard, heavily influenced by custom and practice, relies on expert testimony and does not typically include survey or other empiric evidence of what other similar practitioners are doing (or have done). See Tim Cramm et al., *Ascertaining Customary Care in Malpractice Cases: Asking Those Who Know*, 37 WAKE FOREST L. REV. 699, 711–12 (2002); see also Mehlman, *supra* note 6, at 1184–86.

In some cases, courts have held that, if a physician can establish that he acted in accordance with generally recognized and accepted practice, the plaintiff cannot prevail even if the plaintiff proves that the prevailing practice is ineffective or otherwise undesirable. See, e.g., *Doe v. Am. Red Cross Blood Servs.*, 377 S.E.2d 323, 326 (S.C. 1989) (finding that a professional has no liability for failure to screen blood for HIV when screening was not customary practice). Recently, however, many states have moved from a purely custom-based standard of care to incorporate more of a reasonable physician standard, asking not just what physicians ordinarily do but also what they should do. MARK A. HALL ET AL., *HEALTH CARE LAW AND ETHICS* 292 (9th ed. 2018).

<sup>191</sup> Mehlman, *supra* note 6, at 1220–21, app. at 1233–35; see also *Conn v. United States*, 880 F. Supp. 2d 741, 747 (S.D. Miss. 2012) (holding that experts may rely on clinical practice guidelines).

<sup>192</sup> Mehlman, *supra* note 6, at 1220–21, app. at 1233–35 (summarizing reported cases from 1995–2011, the overwhelming majority of which treated Guidelines as “some evidence” of the standard of care); Chris Taylor, *The Use of Clinical Practice Guidelines in Determining Standard of Care*, 35 J. LEGAL MED. 273, 279–80 (2014) (stating that most courts have allowed introduction of guidelines as relevant but not as defining the standard of care); see *Jilek v. Stockson*, 796 N.W.2d 267, 275 (Mich. Ct. App. 2010); *Frakes v. Cardiology Consultants*, No. 01-A-01-9702-CV-00069, 1997 WL 536949, at \*5 (Tenn. Ct. App. Aug. 29, 1997).

<sup>193</sup> See, e.g., *Conn*, 880 F. Supp. 2d at 747 (holding that experts may rely on clinical practice guidelines). But see, e.g., *Liberatore v. Kaufman*, 835 So. 2d 404, 405 (Fla. Dist. Ct. App. 2003) (holding trial court abused its discretion by admitting specialty practice bulletin to support expert testimony).

<sup>194</sup> See Mehlman, *supra* note 6, at 1220–21, app. at 1233–35 (summarizing reported cases from 1995–2011, the overwhelming majority of which treated Guidelines as “some evidence” of the standard of care); Taylor, *supra* note 192, at 279–80 (stating that most courts have allowed introduction of guidelines as relevant but not as defining the standard of care); see also *Jilek*, 796 N.W.2d at 275; *Frakes*, 1997 WL 536949, at \*5.

<sup>195</sup> See Avraham, *supra* note 6, at 300–02 (showing only twenty-eight cases of successful guideline use in malpractice cases from 2000 to 2010). From 1989 to 1999, Maine experimented with using guidelines as a defense or safe harbor for malpractice. *Id.* at 305–06. Florida has also tried a more limited safe harbor initiative for caesarian sections. Neither initiative appeared to significantly impact physician behavior. *Id.* at 306–07. Most states do not recognize an express “safe harbor” for guideline compliance.



One might expect nonetheless that, at minimum, physicians would be required to disclose Guidelines to patients given Guidelines' potential value to medical decision making.<sup>196</sup> This does not appear to be the case. While no case has considered this question directly and there is relatively little case law delineating the scope of mandatory informed consent disclosures, existing precedent suggests that physicians are not required to disclose Guidelines.<sup>197</sup>

States define mandatory disclosures through their informed consent laws.<sup>198</sup> Historically, the doctrine of informed consent traces its roots in the United States to *Schloendorff v. Society of New York Hospital*, a 1914 opinion authored by Justice Cardozo holding that patient consent must precede medical care.<sup>199</sup> The decision in *Schloendorff* was based largely on the ethical principle of bodily integrity and the legal principle of avoiding battery.<sup>200</sup> Over time, as physician paternalism has waned and patient autonomy grown, informed consent has evolved and expanded.<sup>201</sup> Today, informed consent rests on the ethical norm of autonomy, as well as bodily integrity, and requires information disclosure as opposed to merely permission to touch.<sup>202</sup>

While all fifty states have informed consent requirements, states vary regarding the scope of disclosures required.<sup>203</sup> Most states have adopted one of two general approaches to determine the scope of the physician's duty to disclose.<sup>204</sup> About half of states follow the traditional "physician-based" standard,

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<sup>196</sup> The standard of care required to avoid medical malpractice cannot generally be altered through informed consent disclosure, and the two doctrines are typically legally distinct. So, a physician may engage in malpractice even after obtaining proper informed consent, or conversely, a physician may be liable for breach of informed consent even if the physician's treatment adhered to the standard of care. HALL ET AL., *supra* note 190, at 409. Some states, however, merge the two legal doctrines and discuss breach of informed consent as a type of medical malpractice. See, e.g., *Bradley v. Sugarbaker*, 809 F.3d 8, 14–15 (1st Cir. 2015) (merging lack of informed consent with malpractice).

<sup>197</sup> Anecdotally, I would add that my physicians have never shared Guidelines with me.

<sup>198</sup> See FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 144 (8th ed. 2018).

<sup>199</sup> *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 92–93 (N.Y. 1914), *abrogated on other grounds by Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957).

<sup>200</sup> *Id.* at 93.

<sup>201</sup> JANET L. DOLGIN & LOIS L. SHEPARD, *BIOETHICS AND THE LAW* 46 (4th ed. 2019).

<sup>202</sup> Today, informed consent typically rests on the legal doctrine of negligence or medical malpractice rather than battery. JESSICA W. BERG ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 46 (2d ed. 2001).

<sup>203</sup> Nadia N. Sawicki, *Mandating Disclosure of Conscience-Based Limitations on Medical Practice*, 42 AM. J.L. & MED. 85, 110–11 (2016). States also differ regarding when physicians are required to obtain informed consent. For example, some states limit informed consent requirements to surgical or other invasive treatments. Most states limit informed consent requirements in an emergency. *Id.* at n.119.

<sup>204</sup> Some scholars argue for adoption of a particular patient standard, which would rely on the expressed values and preferences of the particular patient to determine what constitutes "material" information. See Robert Gatter, *Informed Consent Law and the Forgotten Duty of Physician Inquiry*, 31 LOY. U. CHI. L.J. 557, 559 (2000). So far, only a small number of ju-

which imposes a duty for a physician to disclose what a reasonably prudent physician would customarily disclose to a patient under similar circumstances.<sup>205</sup> This physician-based disclosure standard provides wide deference to physicians to determine for themselves the amount and type of information that should be provided.

The remaining states follow the “reasonable patient” standard.<sup>206</sup> This standard requires physicians to disclose the information that a reasonable patient in the plaintiff’s position would deem material under the circumstances.<sup>207</sup> In 1972 in *Canterbury v. Spence*, the seminal reasonable patient standard case, the court stated that the scope of disclosure required “must be measured by the patient’s need, and that need is the information material to the decision.”<sup>208</sup> The reasonable patient standard with its “materiality” test would eventually be adopted by approximately half of all states.<sup>209</sup>

Under either the physician-based or the reasonable patient standard, the scope and content of the duty to disclosure remains vague and undefined. There is no place to look up what a “reasonable patient” would consider “material” under the circumstances or to definitively establish what a reasonably prudent physician would customarily disclose.<sup>210</sup> Case law in this area remains fact-sensitive and relatively sparse. So, it is hard to draw conclusions with certainty.

### *1. Physician-Based States Almost Certainly Do Not Require Guideline Disclosure*

Nonetheless, it seems unlikely that physicians are legally obligated to disclose Guidelines in physician-based disclosure states.<sup>211</sup> The American Medical

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risdictions have adopted this “particular patient” approach. HALL ET AL., *supra* note 190, at 158.

<sup>205</sup> HALL ET AL., *supra* note 190, at 158; *see also* Culbertson v. Mernitz, 602 N.E.2d 98, 104 (Ind. 1992); Hamilton v. Bares, 678 N.W.2d 74, 79 (Neb. 2004).

<sup>206</sup> Even within the two basic approaches to determining required disclosures, states vary regarding the exact standard and requirements.

<sup>207</sup> *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972).

<sup>208</sup> *Id.* at 786.

<sup>209</sup> *See* Nadia N. Sawicki, *Modernizing Informed Consent: Expanding the Boundaries of Materiality*, 2016 U. ILL. L. REV. 821, 829 (2016) (stating that approximately half of all states follow the reasonable patient standard in informed consent cases); *see also, e.g.*, Miller-McGee v. Wash. Hosp. Ctr., 920 A.2d 430, 443–44 (D.C. 2007).

<sup>210</sup> Guidelines could be instructive, as they discuss principal risks, benefits, and alternatives. They are unlikely to be dispositive, however. Similar to the connection between Guidelines and the standard of care, Guidelines are relevant to informed consent disclosures, but they do not necessarily reflect customary physician practice nor what a reasonable patient may deem material under specific circumstances.

<sup>211</sup> Significantly, informed consent currently takes a “no harm, no foul” approach to disclosure failures. Even if a physician fails to disclose required information, the plaintiff cannot recover unless that failure proximately caused the plaintiff’s injury. *See* FURROW ET AL., *supra* note 198, at 160–61. This requires proof that if the required information had been dis-

Association (“AMA”) Code of Ethics requires physicians to disclose information about: “(i) the diagnosis (when known); (ii) the nature and purpose of recommended interventions; [and] (iii) the burdens, risks, and expected benefits of all options, including foregoing treatment.”<sup>212</sup> Legal scholars sometimes refer to such information as the “standard risk-and-benefit disclosure,” because it is the information typically required by informed consent.<sup>213</sup> Since the consensus recommendation reflected in Guidelines is not a diagnosis, recommended intervention, nor a burden, risk, or benefit of a treatment option, Guidelines appear to fall outside of the standard risk-and-benefit disclosure.<sup>214</sup> As such, they are unlikely to be mandatory disclosures.

Some ambiguity remains regarding this result, however, because the physician-based standard turns in part on custom, typically established by expert testimony.<sup>215</sup> While the AMA Code of Ethics may influence that expert testimony and custom, or even be separately admissible, it is probably not dispositive itself.<sup>216</sup> The Code of Ethics arguably tells what a physician should disclose ra-

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closed, the patient would, more likely than not, have selected a different treatment option. *Id.* The mere failure to provide adequate information for effective decision making is not actionable. *Id.*

Some scholars argue that informed consent should be reformed to provide a dignity-based remedy for disclosure failures. *See, e.g.,* Rita Barnett-Rose, *Informed Consent, Psychotropic Medications, and a Prescribing Physician’s Duty to Disclose Safer Alternative Treatments*, 16 DEPAUL J. HEALTH CARE L. 67, 100 (2014). This article takes no position on remedy reforms, and instead posits that changing the ethical and legal standard of informed consent should have a meaningful impact on physician behavior even if the new duty is only nominally enforceable in tort.

<sup>212</sup> AM. MED. ASS’N, CODE OF MEDICAL ETHICS 29 (2017). The Principles of Medical Ethics and the Opinions of the AMA Council on Ethical & Judicial Affairs together make up the AMA Code of Ethics. *Code of Medical Ethics Overview*, AMA, <https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview> [https://perma.cc/H2U6-6KVK] (last visited Apr. 4, 2019).

<sup>213</sup> Sawicki, *supra* note 203, at 111 (describing these as the “standard risk-and-benefit disclosure” that all jurisdictions require).

<sup>214</sup> To be clear, this article posits that patients should be told that nationally certified Guidelines promulgated by a panel of experts recommend (a particular approach) based on empiric evidence, prior to deviation from the Guideline recommendation. This statement relaying the Guideline’s evidence-based, consensus recommendation differs from any statements relaying the risks, benefits and alternatives themselves.

<sup>215</sup> Cramm et al., *supra* note 190, at 701.

<sup>216</sup> Moreover, another provision of the Code of Ethics injects additional uncertainty into the scope of required disclosures. In Opinion 8.08, the Code of Ethics instructs physicians to disclose “all relevant medical information,” but then caveats that “[t]he quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients.” *AMA Ethics Opinion*, *supra* note 188, at 555. This arguably expands the scope of disclosures but also provides significant physician discretion.

As applied to Guidelines, the existence and content of consensus recommendations seem clearly “relevant.” Nonetheless, this type of guideline recommendation has not traditionally been regarded as required “medical” information. *See, e.g.,* 15 U.S.C. § 1681a(i) (2012) (defining “medical information”). Certainly, physicians do not seem to be disclosing guidelines.

ther than what a reasonably prudent physician customarily would disclose. Still, customary disclosures tend to be laxer, not more expansive, than set forth in the Code of Ethics.<sup>217</sup> So, Guidelines almost certainly are not currently required disclosures in physician-based disclosure states.

2. *Reasonable-Patient States Likely Do Not Require Guideline Disclosure, Even if They Should*

The question is a much closer call in states that have adopted the reasonable patient approach. Guidelines seem to be the type of information that would be “material” to a reasonable patient, as they provide important context and valuable information for decision making. Speaking descriptively, however, most (but not all) courts have interpreted the scope of “material” information as limited to the standard risk-and-benefit disclosure.<sup>218</sup> They apply materiality to delineate *which* risk, benefit and alternative must be disclosed, not to expand disclosures to other types of information.<sup>219</sup> Even in reasonable patient states, few courts have found liability for failure to disclose information beyond the standard risk-and-benefit disclosure.<sup>220</sup> Since Guidelines are not within the

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*See* Fearn et al., *supra* note 4, at 11 (finding that “[t]he public is generally unaware of the existence of guidelines”); *see also* Armstrong et al., *supra* note 169.

<sup>217</sup> Moulton & King, *supra* note 63, at 87–88.

<sup>218</sup> *See* Sawicki, *supra* note 209, at 837 (arguing that “it is increasingly obvious that what counts as ‘material’ information for the average patient may not [sic] captured by the common law disclosure duty.”).

<sup>219</sup> *See* Duffy v. Flagg, 905 A.2d 15, 23 (Conn. 2006) (finding that a patient cannot expand the limited disclosure required by informed consent by asking the provider more questions); Miller-McGee v. Wash. Hosp. Ctr., 920 A.2d 430, 440 (D.C. 2007) (“[A]t a minimum, a physician must disclose the nature of the condition, the nature of the proposed treatment, any alternate treatment procedures, and the nature and degree of risks and benefits inherent in undergoing and in abstaining from the proposed treatment.”) (quoting Crain v. Allison, 443 A.2d 558, 562 (D.C. 1982)) (alteration in original); Duttry v. Patterson, 771 A.2d 1255, 1258 (Pa. 2001). *But see, e.g.*, Dingle v. Belin, 749 A.2d 157, 170 (Md. 2000) (finding that informed consent requires disclosure of who will be conducting or supervising the procedure); Johnson *ex rel.* Adler v. Kokemoor, 545 N.W.2d 495, 506, 509 (Wis. 1996) (finding a breach of informed consent duty because of a failure to disclose inexperience and substantially higher statistical risk with an inexperienced surgeon).

<sup>220</sup> Sawicki, *supra* note 209, at 833. Nadia Sawicki suggests an optimal scope for required informed consent disclosures. She contends that disclosures should include non-medical information that a reasonable patient would consider “material” if within the physician’s knowledge and expertise and not contrary to public policy. *See id.* Guideline recommendations fall within Sawicki’s proposed scope. Most patients would consider them material. They fall within physicians’ expertise, and they are not contrary to public policy.

That being said, outside of Guideline recommendations, this article expresses no opinion on what non-medical information should be considered “material” information for healthcare decision making. It does note, however, that clear disclosure requirements are both more effective and fairer than unpredictable ones, and that the cost of any required disclosures in time, money, and confusion should always be weighed against the alleged benefits.

standard risk-and-benefit disclosure, physicians are probably not legally obligated to disclose them even in reasonable patient states.<sup>221</sup>

#### IV. REFORMING INFORMED CONSENT TO REQUIRE GUIDELINE DISCLOSURE WOULD NUDGE QUALITY CARE AND PROMOTE ETHICS

If the goal is to improve decision making through increasing Guidelines' salience, the law can help by requiring disclosure of Guidelines as part of informed consent.<sup>222</sup> This legal change would improve knowledge and familiarity with Guidelines, and behavioral economics suggests that it should also effectively nudge physician and patient decision making toward quality care.<sup>223</sup> Ethically, disclosure of Guidelines should better align medical decision making practices with autonomy, beneficence, non-maleficence, and justice. At minimum, patients should be told that empirically based, thoughtfully considered consensus recommendations exist before they consent to other care that deviates from such recommendations.

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<sup>221</sup> Some commentators have suggested that the reasonable patient disclosure standard is broader. See, e.g., Hindi E. Stohl, *When Consent Does Not Help: Challenges to Women's Access to a Vaginal Birth After Cesarean Section and the Limitations of the Informed Consent Doctrine*, 43 AM. J.L. & MED. 388, 403 (2017). Prescriptively, I may agree that it should be, but descriptively, courts have seldom enforced it outside the context of the standard risk-and-benefit disclosure. The cases evidence disconnect between broad dicta and narrow holdings, although I readily acknowledge that the fact-sensitive nature of cases in this area makes accurate predictions difficult.

Moreover, the fact that many physicians do not perceive a legal obligation to disclose Guidelines (as they are often unfamiliar with them and almost never disclose them) is far more significant than whether or not the physician-perception is correct. Until physicians feel obligated to disclose Guidelines, Guidelines cannot play the central role they should in healthcare decision making. The law (or AMA ethical opinion) needs to be clarified to ensure that physicians recognize an express obligation to disclose evidence-based, consensus recommendations to patients.

<sup>222</sup> The most efficient and effective way to implement this informed consent change would be to revise AMA Code of Ethics Opinion 2.1.1 to include disclosure of applicable Guideline recommendations as a fourth type of required information. See CODE OF MEDICAL ETHICS, *supra* note 212, at 29. This revision should influence physician practice immediately as an ethical obligation and over time as a legal obligation, as the new standard becomes incorporated into expert testimony of what a reasonably prudent physician would customarily disclose. See William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1770 (1999) (extolling the benefit of using ethical obligations for disclosure obligations in the context of conflicts of interest). Similarly, it may take some time for courts to embrace it when interpreting what information is material to a reasonable patient. Nonetheless, this approach would still probably be faster and at least as efficacious as trying to adopt new laws, regulations, or precedents in all fifty states.

<sup>223</sup> Blumenthal-Barby & Burroughs, *supra* note 81, at 2–3.

*A. Disclosure Improves Physician and Patient Knowledge of Guidelines*

Mandatory disclosure should help alleviate the deficiency in physician and patient knowledge of Guidelines.<sup>224</sup> Physicians would have to become more familiar with Guidelines to satisfy their legal and ethical informed consent obligations.<sup>225</sup> Such increased familiarity alone should improve physician decision making, as physicians have better information from which to make quality care decisions.<sup>226</sup>

Patients would likewise benefit from increased knowledge as they learn of Guidelines from their physicians' disclosures prior to any deviation.<sup>227</sup> The evidence based, consensus recommendation in Guidelines will provide patients with important context with which to critically evaluate their care options. Guidelines tell patients what a majority of experts recommend after a systematic review of empiric evidence. To the extent the Guideline recommendation differs from their individual physician's recommendation or their personal preference, patients need to understand this divergence. Over time, patients should come to expect and to regularly rely on the more rational, scientifically based Guideline recommendations in making care decisions. Improving physician and

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<sup>224</sup> ACOG GUIDELINE OPINION, *supra* note 12 (“Implementation of protocols and guidelines often is delayed because of lack of health care provider awareness . . . .”); Cabana et al., *supra* note 4, at 1461 (“[F]or 78% of guidelines, more than 10% of physicians are not aware of their existence.”); Lugtenberg et al., *supra* note 166, at 4; *see also* Epstein, *supra* note 6, at 1306 (requiring physicians to disclose evidence based “defaults” would educate physicians).

<sup>225</sup> Requiring physician disclosure of the medico-legal recommendation contained in Guidelines arguably raises First Amendment concerns. However, under *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 884 (1992), mandatory disclosure of Guidelines seems more likely to be treated as regulation of professional conduct that incidentally burdens speech, which courts have traditionally upheld. In *Casey*, the court rejected a free-speech challenge to an informed-consent law that required disclosure of gestation age and the availability of printed materials from the State on financial assistance, reasoning that the law should be understood as a regulation of professional conduct that incidentally burdens speech. *Id.* at 884. While *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2375 (2018), held that a different abortion disclosure law was likely a violation of the First Amendment, the court reached this conclusion after affirming the informed consent carve-out in *Casey* and finding that the disclosure law before it was “not an informed-consent requirement or any other regulation of professional conduct.” *Id.* at 2373. Mandatory guideline disclosure looks far more like *Casey* than like *Becerra*, which involved the regulation of pregnancy crisis centers regardless of whether or not the crisis centers offered any medical procedures. For more analysis of the First Amendment and informed consent, see Claudia E. Haupt, *Professional Speech*, 125 YALE L.J. 1238, 1258–60 (2016); David Orentlicher, *Abortion and Compelled Physician Speech*, 43 J.L. MED. & ETHICS 9 (2015); Nadia N. Sawicki, *Informed Consent as Compelled Professional Speech: Fictions, Facts, and Open Questions*, 50 WASH. U. J.L. & POL'Y 11 (2016).

<sup>226</sup> Of course, correcting information shortcomings alone does not counter any cognitive biases that may impede adoption of rational, scientifically based care recommendations, but it should still improve decision making somewhat.

<sup>227</sup> *See* Armstrong et al., *supra* note 169, at 12–13; Fearn et al., *supra* note 4, at 4.

patient knowledge of Guidelines is an essential first step in improving medical decision making.

*B. Disclosure Should Nudge Decision Making Toward Quality Care*

The next step is nudging decision making to counter cognitive biases and to make Guideline adherence the easiest cognitive path, without limiting physician discretion or patient choice. A nudge is any method of intentionally structuring choice to influence behavior in a predictable way, without controlling that choice.<sup>228</sup> Nudges should be “easy and cheap to avoid.”<sup>229</sup>

*1. Nudging Physicians*

Behavioral economics suggests that informed consent discussion of Guidelines could nudge better physician decision making in four ways.<sup>230</sup> First, requiring disclosure of Guidelines prior to deviation sets a new and better “default” for care.<sup>231</sup> If physicians start from the premise that Guidelines usually provide the appropriate care approach, Guidelines should effectively act as a default.<sup>232</sup> Defaults are sticky, meaning that decision makers tend to defer to them.<sup>233</sup> So, if individual physicians treat Guideline recommendations as the starting point, they will be less likely to recommend unwarranted variations and

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<sup>228</sup> THALER & SUNSTEIN, *supra* note 153, at 6. Choice architecture is the intentional organization of “the context in which people make decisions.” *Id.* at 3.

<sup>229</sup> *Id.* at 6.

<sup>230</sup> Mandatory disclosure imposes a new requirement on physicians, not merely a nudge. The expectation, however, is that this limited disclosure requirement will also nudge physicians’ care recommendations towards greater Guideline adherence.

<sup>231</sup> See THALER & SUNSTEIN, *supra* note 153, at 73; Blumenthal-Barby & Burroughs, *supra* note 81, at 2–3; see also Epstein, *supra* note 6, at 1306 (requiring physicians to make a recommendation instead of being neutral will nudge them to be educated on the best approach). As discussed below, priming, social nudge, and accountability justification all suggest that disclosure could trigger physicians treating Guidelines more like defaults for care.

<sup>232</sup> See Blumenthal-Barby & Burroughs, *supra* note 81, at 3 (“Defaults nudge not only the actions of patients but also those of physicians.”). This default could be reinforced by pre-programmed, automatically generated electronic prompts in accordance with the Guideline approach, which could be manually changed if warranted. See Shaffer, *supra* note 7, at 733 (recognizing the effectiveness of electronic health records preselecting the generic version of a drug). Ideally, this default would also be strengthened by a requirement that physicians briefly document the reason for any deviation from the Guideline in the medical records in order to make the default stickier. See ACOG GUIDELINE OPINION, *supra* note 12, at 2 (suggesting that physicians should “document clearly the rationale for deviation from any recommended practice”); Kapp, *supra* note 6, at 540 (suggesting that physicians should be required to document the reason for any deviation in the medical record).

<sup>233</sup> Epstein, *supra* note 6, at 1294.

more likely to adhere to Guidelines, absent rational justification for deviation.<sup>234</sup>

Second, relaying the consensus view of other physicians, as stated in Guidelines, should serve as a “social nudge,” influencing individual physicians to adopt the Guideline position.<sup>235</sup> Physicians, like most people, respond to peer pressure. They tend to want to act in accordance with their peers, and reminding them when their approach differs from their peers can be quite effective at increasing conformity.<sup>236</sup> Since Guidelines reflect a consensus view, requiring individual physicians to disclose that consensus recommendation prior to deviation should naturally nudge physicians to greater adherence.<sup>237</sup>

Third, the act of discussing Guidelines may also “prime” physicians to give Guidelines greater weight.<sup>238</sup> Studies suggest that our minds are influenced by subconscious cues, and mentioning a concept may influence our behavior to orient more towards that concept.<sup>239</sup> While this area of behavioral economics is more controversial and less well understood, studies suggest that discussing Guidelines may actually subconsciously increase the prominence of Guidelines in physicians’ minds, thereby influencing physicians to choose adherence more often.

Fourth, if a physician still believes that deviating from a Guideline provides the optimal care approach, the process of having to explain why should

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<sup>234</sup> See Emanuel et al., *supra* note 86, at 115–17 (recognizing the need for and effectiveness of new defaults given physician status quo bias and the benefit of setting the right action as the “path of least resistance” given limits of willpower).

<sup>235</sup> *Id.* at 116 (recognizing that physicians are “heavily influenced by their perception of how their performance compares with those around them”); Amol S. Navathe & Ezekiel J. Emanuel, *Physician Peer Comparisons as a Nonfinancial Strategy to Improve the Value of Care*, 316 JAMA 1759, 1759 (2016) (describing social nudges as a “powerful tool to help physicians reduce unnecessary and unjustified variations in care”).

<sup>236</sup> See Mantel, *supra* note 7, at 489–90 (“physicians have a strong propensity to imitate their peers”).

<sup>237</sup> Some critics may worry that physicians would feel too much pressure to adhere to Guidelines, conforming even when there is a valid reason to deviate. This result is possible but unlikely to be common, and given the pervasive and costly under-adherence in the current system, it is a small risk well worth taking.

<sup>238</sup> Along with setting a default and using social nudges, priming is one of the fundamental means of influencing choice in keeping with liberal paternalism. THALER & SUNSTEIN, *supra* note 153, at 5, 69–71 (recognizing information, peer pressure, and priming as ways to influence behavior); Blumenthal-Barby & Burroughs, *supra* note 81, at 8 tbl.1 (recognizing defaults, social nudges, and priming as key tools to nudge and discussing how to utilize such tools ethically).

<sup>239</sup> Blumenthal-Barby & Burroughs, *supra* note 81, at 6 (recognizing the effectiveness of priming as a means to influence healthcare decision making); Patricia S. Groves et al., *Priming Patient Safety Through Nursing Handoff Communications: A Simulation Pilot Study*, 39 W.J. NURSING RES. 1394, 1399, 1407 (2016) (stating early evidence suggests nurses’ behavior could be primed by safety language); Lutfey et al., *supra* note 58, at 16–18, 22–23 (evidencing effectiveness of priming physicians to counter cognitive bias and address unwarranted variations in context of coronary heart disease).



serve as an “accountable justification,” helping to ensure a rational basis for deviation.<sup>240</sup> Studies show that actively considering contrary evidence is one of the most effective de-biasing strategies, especially in countering overconfidence.<sup>241</sup> Moreover, having to account to another for a decision tends to decrease heuristic mistakes.<sup>242</sup> Requiring a physician to acknowledge that the Guideline recommends a different approach and to explain his or her rationale for deviation to the patient should make physician decision making more rational.<sup>243</sup> For these reasons, behavioral economics suggests that informed consent discussion of Guidelines may be surprisingly effective at improving physician decision making.

## 2. *Nudging Patients*

Mandating disclosure of Guidelines should likewise improve patient decision making. Guideline recommendations provide patients with an optimal “default.”<sup>244</sup> They offer an empirically based, thoughtfully considered consensus recommendation that reflects the best choice for most patients. As such, they present patients with a more reliable decision simplification tool and help structure choices so that the easiest cognitive path for patients corresponds to the choice that is most likely to be beneficial. This makes it more likely that patients will make better health choices, without controlling these choices.<sup>245</sup>

In contrast, there may be no default under the current system, as physicians are not legally obligated to provide a care recommendation and can leave patients floundering to decide.<sup>246</sup> Even when physicians choose to make a rec-

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<sup>240</sup> It would be difficult to include all necessary Guideline disclosures in the generic pre-printed informed consent forms patients are sometimes given before seeing a physician because Guidelines address a specific clinical circumstance. However, if physicians found a way to do so and did not engage in any discussion with the patient about the Guidelines, this method of disclosure would not have the same nudge for physicians or for patients.

<sup>241</sup> Croskerry & Norman, *supra* note 97, at S26 (“People’s judgments were better calibrated (there was less overconfidence) when they were obliged to take account of disconfirming evidence . . . . This *consider-the-opposite* strategy appears to be one of the more effective debiasing strategies.”).

<sup>242</sup> *Id.* at S25–26.

<sup>243</sup> See Shaffer, *supra* note 7, at 731 (recognizing the effectiveness of “accountable justification” in the overprescribing of antibiotics).

<sup>244</sup> Their physician would, of course, remain free to explain why he or she believes the Guideline does not offer the best practice under the circumstances. Likewise, patients would remain free to deviate from a Guideline based on their own personal preference.

<sup>245</sup> See THALER & SUNSTEIN, *supra* note 153, at 5. *But see* Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647, 665 (2011) (arguing that required disclosures empirically fail to improve decisions).

<sup>246</sup> See *AMA Ethics Opinion*, *supra* note 188, at 555 (encouraging physicians to “make recommendations” but only recognizing an “ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice”); *see also* Epstein, *supra* note 6, at 1301 (“nothing in the law requires that physicians promote any particular option over another”).

ommendation, their recommendation may be less reliable than Guideline recommendations due to inadequate evidence, insufficient time, limited viewpoint, or cognitive bias.<sup>247</sup> So, Guidelines create a more consistent and trustworthy default for patients.<sup>248</sup>

Mandating disclosure of Guidelines should also nudge patient decision making through a sort of warning function. As discussed previously, having to confront contrary evidence is an effective de-biasing tool.<sup>249</sup> If patients have to acknowledge Guidelines before deviating from them, this process should lead to fewer heuristic mistakes.<sup>250</sup> Addressing a conflict between national consensus Guidelines and an individual physician's contrary recommendation should help to counter authority bias. Similarly, recognizing contrary Guideline recommendations should encourage patients to reconsider how their own decisions may be skewed by single factor bias, emotions, evaluability weaknesses, or other mistake.<sup>251</sup>

It is worth acknowledging, however, that disclosing Guidelines may have a cost for patients who choose to deviate anyway. While some patients will opt for recommended care after being nudged by Guideline disclosure, those patients who still choose to deviate from Guidelines after disclosure may actually feel worse for knowing that they are deviating.<sup>252</sup> For at least some patients, the nudge may evoke negative emotions like guilt or anxiety.<sup>253</sup> Such costs, while possible, are greatly offset by the larger benefit of improving decision making and decreasing unwarranted variance in care.<sup>254</sup>

Requiring disclosure of Guideline recommendations should improve the knowledge and decision making of both physicians and patients, without limit-

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<sup>247</sup> See *supra* Section II.B.

<sup>248</sup> See Moulton & King, *supra* note 63, at 89 (showing that without a recommendation and discussion, patients are “vulnerable to numerous decision-making biases and effectively cheat[ed] . . . out of an accessible expert opinion.”). Moreover, when a physician recommendation and Guideline recommendation agree, this consistency and corroboration generates an even more persuasive default for patients.

<sup>249</sup> Croskerry & Norman, *supra* note 97, at S26; Moulton & King, *supra* note 63, at 88 (“engaging in a treatment discussion with a physician can greatly assist patients to identify any biases or misconceptions”).

<sup>250</sup> See Croskerry & Norman, *supra* note 97, at S25–26; Moulton & King, *supra* note 63, at 88; Shaffer, *supra* note 7, at 733–34.

<sup>251</sup> See Moulton & King, *supra* note 63, at 88.

<sup>252</sup> See Edward L. Glaeser, *Paternalism and Psychology*, 73 U. CHI. L. REV. 133, 150 (2006) (proposing that social comparison nudges may act as an emotional tax on “bad” behavior); Linda Thunström, *Welfare Effects of Nudges: The Emotional Tax of Calorie Menu Labeling*, 14 JUDGMENT & DEC. MAKING 11, 11 (2019) (finding that using calorie information to nudge better eating emotionally taxes those with lower self-control).

<sup>253</sup> *Id.*

<sup>254</sup> Moreover, any increased internal dissonance should be no greater nor more pernicious than a patient currently feels when going against a physician recommendation. Arguably, it will be less because the personal relationship is removed.

ing physician discretion or patient choice. It should also nudge care towards more rational, scientifically based approaches that increase quality.<sup>255</sup>

C. *Requiring Guideline Disclosure Furthers Ethical Goals and Begins Broader Informed Consent Realignment*

Physicians should also be required to disclose Guidelines to patients for ethical reasons. Four primary ethical principles underlie the normative framework of healthcare: autonomy, beneficence, non-maleficence, and justice.<sup>256</sup> Autonomy is the principle that patients should be “free to choose” between appropriate alternative care options, including declining care.<sup>257</sup> Beneficence is the principle that care should “do good” for patients.<sup>258</sup> Non-maleficence is the principle that physicians should first “do no harm.”<sup>259</sup> Justice is the principle that individuals should be treated fairly and resources should be distributed equitably.<sup>260</sup>

1. *Improving Decision Making Enhances Ethics*

Unwarranted variance in care indicates a failure of all four ethical principles. Physicians who over-treat, undertreat, or mistreat patients often provide no benefit, risk harm, and at least from a systemic perspective, fail to treat like patients alike.<sup>261</sup> Such approach is also contrary to meaningful autonomy, unless the patient understands that such care is not supported empirically nor recommended by expert consensus before consenting. Empiric evidence establish-

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<sup>255</sup> Ultimately, whether (or when) requiring disclosure of Guideline recommendations improves knowledge and results in more recommended care poses empiric questions. These questions can and should be answered definitively through empiric research.

<sup>256</sup> See, e.g., TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS *passim* (5th ed. 2001) (arguing that dilemmas in bioethics should be resolved by applying the principles of autonomy, beneficence, non-maleficence, and justice).

<sup>257</sup> See BARRY R. FURROW ET AL., BIOETHICS: HEALTHCARE LAW AND ETHICS 15 (8th ed. 2018).

<sup>258</sup> *Id.*

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

<sup>260</sup> *Id.* at 16.

<sup>261</sup> Unwarranted variations in care cannot be explained by discrimination alone and are common even for privileged groups. See Steven M. Asch et al., *Who Is at Greatest Risk for Receiving Poor-Quality Health Care?*, 354 NEW ENG. J. MED. 1147, 1147 (2006) (concluding that the “differences among sociodemographic subgroups . . . are small in comparison with the gap . . . between observed and desirable quality of health care”). Nonetheless, one clear benefit of greater Guideline adherence should be less discrimination in healthcare. See, e.g., *Dartmouth—Racial Disparities*, *supra* note 11 (describing racial disparities in care as a result of failure to provide recommended care, but also noting geographic, hospital, and provider influence). Studies show that implicit bias impacts the care patients receive. See Chloë FitzGerald & Samia Hurst, *Implicit Bias in Healthcare Professionals: A Systematic Review*, BMC MED. ETHICS, Mar. 1, 2017, at 1, 13. Moving to a more scientifically based approach should decrease this injustice.

es that adherence to Guidelines improves patient outcomes.<sup>262</sup> Since requiring disclosure of Guidelines is expected to improve adherence, such reform should bring healthcare more in line with its underlying ethical goals.

Stents provide a useful illustration.<sup>263</sup> When physicians implant a stent in a stable patient contrary to Guidelines, they likely provide no benefit. Stents do not decrease the risk of heart attack nor do they extend lives.<sup>264</sup> Moreover, because one in fifty patients suffer serious complications or die as a result of stent implantation, contraindicated stent implantation violates the principle of non-maleficence; it may do serious harm.<sup>265</sup> When some stable patients receive stents inappropriately and others do not, this also violates justice, as similarly situated patients do not receive the same treatment.<sup>266</sup> Mandatory disclosure of Guidelines helps to avoid these ethical violations by nudging physicians and patients toward recommended care, enhancing quality of care and core ethical values.<sup>267</sup>

## 2. *Requiring Guideline Disclosure Helps to Align Informed Consent with Autonomy*

Autonomy merits more in depth discussion. In the United States, the ethical and legal doctrine of informed consent seeks to protect patients' autonomy in healthcare decision making. Unfortunately, however, currently required disclosures fail to help patients make decisions that maximize individual utility. Almost twenty-five years ago, Peter Schuck identified the significant gap between the ethical goals and reality of informed consent.<sup>268</sup> This gap exists largely because informed consent laws only mandate information disclosure, while autonomous decision making requires patient understanding.<sup>269</sup> The legal requirements of informed consent track formal and objective disclosure instead

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<sup>262</sup> Murad, *supra* note 3, at 429; Proietti et al., *supra* note 3, at 917 (finding guideline adherence associated with lower mortality among elderly atrial fibrillation patients); Wöckel et al., *supra* note 3, at 120, 126 (showing less guideline adherence tracked lower survival in breast cancer patients).

<sup>263</sup> Autonomy is omitted here so that it can be discussed in greater detail below. *See infra* Section IV.C.2. However, to the extent the patients who receive the contraindicated stent are unaware of the Guideline recommendation, their autonomy has been undermined even if they received the standard risk-and-benefits disclosure and “consented” because they were denied critical context from which to understand their choice.

<sup>264</sup> Stergiopoulos & Brown, *supra* note 91, at 312.

<sup>265</sup> Epstein & ProPublica, *supra* note 90.

<sup>266</sup> *See* Masoudi et al., *supra* note 94, at 1433 tbl.4, 1436.

<sup>267</sup> Nudging patient decision making toward greater Guideline adherence is ethically defensible because it is welfare promoting. *See* Cass R. Sunstein, *The Ethics of Nudging*, 32 YALE J. REG. 413, 450 (2015).

<sup>268</sup> Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 903–05 (1994) (identifying the gap and describing it as structural and intractable).

<sup>269</sup> Pope, *supra* note 121, at 17. Time constraints and economic realities also contribute to the gap. Schuck, *supra* note 268, at 921–22.

of more substantive but subjective understanding. This poses a problem because the disclosure of information is necessary for patient understanding, but it is often not sufficient.

An arguably larger problem, however, stems from *misalignment* between the *type* of information that is legally compelled and patient understanding.<sup>270</sup> Empiric studies have repeatedly shown that patients cannot effectively process the information on risks, benefits, and alternatives informed consent legally compels.<sup>271</sup> Weighing risks and benefits requires numeracy and evaluability that patients lack, and expecting patients to compare risks and benefits of alternate treatment options only compounds the cognitive overload.<sup>272</sup> It is therefore unsurprising that patients often either defer to their physicians or use heuristics to select a “bad” care option that fails to further their individual utility.

For too long the legal doctrine of informed consent has ignored empiric evidence regarding what patients can understand and how they make decisions. This must change. States need to reconsider informed consent requirements with the teachings of health literacy and behavioral economics in mind. This will require reevaluating *how* and *when* patients are provided information and asked to decide, as well as more traditional debates regarding *what* information to provide.<sup>273</sup> The remedy proposed in this Article is only a first step in what should be a much broader reform of informed consent requirements.<sup>274</sup>

Requiring disclosure of Guideline recommendations should help to align informed consent with understanding, however.<sup>275</sup> Guideline recommendations

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<sup>270</sup> To be clear, this article does not necessarily advocate curtailing existing disclosures. Even if most patients cannot understand them, some do. Moreover, dignity may require risk and benefit disclosures, even when the information disclosed exceeds comprehension. Informed consent has ethical value as a process, recognizing the patient as an active agent not merely an object of treatment, as well as for improving outcomes.

<sup>271</sup> Korobkin, *supra* note 128, at 540; see Hibbard & Peters, *supra* note 69, at 415–16.

<sup>272</sup> Ancker & Kaufman, *supra* note 81, at 714–16; Epstein, *supra* note 6, at 1283–84; Hibbard & Peters, *supra* note 69, at 415–16; Korobkin, *supra* note 128, at 540; Peters et al., *supra* note 128, at 741; Schwartz et al., *supra* note 128, at 972.

<sup>273</sup> See generally Schmidt et al., *supra* note 116; Schmidt et al., *supra* note 134. Compelling evidence suggests that well-designed patient decision aids can improve patient understanding. Pope, *supra* note 121, at 13.

<sup>274</sup> There may be good reasons to structure legal informed consent requirements so that they are objective and predictable, even recognizing that this could leave a gap between disclosure and understanding. However, there is no justification for continuing to ignore how patients actually understand and process information. The legal doctrine should at least aim directly at the ethical goal.

<sup>275</sup> See Shlomo Cohen, *Nudging and Informed Consent*, 13 AM. J. BIOETHICS 3, 6, 8 (2013) (“Not only need nudging not damage autonomy but it can enhance it . . . [It can] assist people in making choices compatible with their own goals.”); Korobkin, *supra* note 128, at 527 (arguing that choice architecture can be used to “increase the likelihood that the individuals will be able to make personally utility-maximizing choices[,]” in proposing an insurance market that he contends could enable consumers to contract for coverage that met or exceeded a certain level of cost-effectiveness); Abraham P. Schwab, *Formal and Effective Autonomy in Healthcare*, 32 J. MED. ETHICS 575, 579 (2006) (“[Effective autonomy] requires for-

are far easier for patients to comprehend than traditional raw data on risks, benefits and options.<sup>276</sup> Recommendations are simply easier to process cognitively. They avoid the problems patients experience with numeracy, probabilities, evaluability, and complex weighing of multi-variable factors in the standard risks-and-benefits disclosure.<sup>277</sup> They provide the bottom line. As a result, disclosing Guideline recommendations should help combat behavioral biases and empower patient decision making.<sup>278</sup>

In addition to being easier to understand, disclosure of Guideline recommendations also serves autonomy by providing critical information for informed decision making.<sup>279</sup> When there is a “right” answer empirically, as with effective care, it is not enough to describe raw risks and benefits to patients, then, present them with options.<sup>280</sup> Patients also need to be told that strong empiric evidence and a national expert consensus supports a single option. Such context is indispensable, and the failure to share it is harmful and arguably misleading.<sup>281</sup> It suggests that all options presented are equal, setting patients up to

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mal autonomy, but goes beyond it by requiring attention to the background conditions in which decision makers will more accurately reflect their desires through their decisions. Effective autonomy is fostered if and only if biases resulting from bounded cognition are identified as risks in the decision-making processes of autonomous people and this followed by appropriate debiasing.”).

<sup>276</sup> In fact, physicians, who have far more education and experience than patients, overwhelmingly prefer to receive Guideline recommendations in addition to evidence summaries of risks and benefits. Ignacio Neumann et al., *Do Clinicians Want Recommendations? A Multicenter Study Comparing Evidence Summaries with and Without GRADE Recommendations*, 99 J. CLIN. EPIDEMIOLOGY 33, 37–38 (2018) (finding 86 percent of physicians preferred recommendations accompany evidence summaries of risks and benefits).

<sup>277</sup> Some might argue that this approach could cause patients to provide too much deference to Guidelines, and that such deference undermines rather than enhances autonomy. I disagree. Patients have so far to go before they provide Guideline recommendations with the weight that they deserve, the risk of blindly following Guidelines is relatively small in comparison to the costs of the current approach. Moreover, providing an optimal default does not undermine autonomy. Like glasses, a good default helps patients see, but it does not limit patient choice any more than glasses limit sight. Patients remain free to deviate from Guidelines, cheaply and easily. They just have better information from which to decide. See Sunstein, *supra* note 267, at 415–16, 427, 438 (showing that ethical nudges promote informed choice, combat behavioral biases, and educate).

<sup>278</sup> While some may argue that nudging the recommendation undermines autonomy by removing agency, this argument misses that patients retain agency, even with a nudge, because they retain choice. See *id.* at 415, 438. Moreover, since so many patients currently defer blindly to their individual physician recommendation, improving the recommendation to which they defer should be welfare enhancing.

<sup>279</sup> This ethical claim is different from the others in that it does not rest on the assumption that disclosure of Guidelines will improve knowledge, understanding, or decision making outcomes. It claims that providing such information to patients is an ethical imperative independent of outcome based on the duty to disclose material information.

<sup>280</sup> See *Dartmouth—Effective Care*, *supra* note 17.

<sup>281</sup> Guidelines help patients evaluate any physician’s recommendation as well as their own initial preferences for care.

pick poorly or to waste significant cognitive effort struggling with what should be an easy decision.<sup>282</sup> While patients with idiosyncratic preferences should remain free to pick the care option that comports with their values and preferences, the failure to disclose Guideline recommendations undermines autonomy by omitting crucial information.<sup>283</sup>

Even when Guidelines relate to preference-sensitive care, they provide patients with better information to decide in a way that is more likely to maximize their individual utility.<sup>284</sup> If a patient understands that the evidence is mixed regarding the best option and that the expert consensus is that patients should decide based on which risk is more important to them, that information aids decision making.<sup>285</sup> It simplifies the decision to a more manageable one and directs

<sup>282</sup> Improved beneficence and non-maleficence with increased Guideline adherence arguably present the most compelling ethical argument for requiring disclosure of Guidelines prior to deviation. However, this benefit depends on disclosure effectively changing the care actually provided. While there is strong reason to believe that this would prove to be the case empirically, this article contends that disclosure is ethically required even if it does not materially change care.

<sup>283</sup> Whether government insurance or other shared cost systems should pay any added costs associated with such care is, of course, a quite different question.

<sup>284</sup> See Sunstein, *supra* note 267, at 431–32.

<sup>285</sup> Similarly, some Guideline skeptics point to conflicting Guidelines to argue that Guidelines should not play a more prominent role. However, only a small number of Guidelines conflict, and the conflict is usually narrow. Moreover, even conflicting Guidelines can still provide helpful information to patients.

For example, there are conflicting Guidelines on breast cancer screening for low risk women between the ages of 40 and 45. Compare U.S. Preventative Services Task Force Guidelines and ACOG Guidelines, AM. COLL. OBSTETRICS & GYNECOLOGISTS, BREAST CANCER RISK ASSESSMENT AND SCREENING IN AVERAGE RISK WOMEN (July 2017), <https://www.acog.org/-/media/Practice-Bulletins/Committee-on-Practice-Bulletins---Gynecology/Public/pb179.pdf?dmc=1&ts=20181105T1829304931> [<https://perma.cc/37MW-W64C>] [hereinafter ACOG]; *Final Recommendation Statement, Breast Cancer: Screening*, U.S. PREVENTATIVE SERVS. TASK FORCE (Jan. 2016), <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/breast-cancer-screening1> [<https://perma.cc/W6QY-G4ZK>] [hereinafter U.S. PREVENTATIVE SERVS.]; Some Guidelines do not recommend routine mammograms. ACOG, *supra*, at 12. Others recommend screening annually, and still others contend that biannual screening is appropriate. *Id.* at 4 tbl.1. Such conflicting advice need not be confusing or unhelpful, however. The Guidelines agree that the risk of breast cancer for this population is relatively small and that false positive screening results, with accompanying anxiety and expense, are fairly common. *Id.* at 5; see also U.S. PREVENTATIVE SERVS., *supra*. They also agree that routine screening can detect a small number of cancers early enough to save some lives. ACOG, *supra*, at 2; U.S. PREVENTATIVE SERVS., *supra*. They disagree only regarding whether the aggregate risk associated with the common problem of false positives outweighs the very small but also very serious risk of not catching the cancer early enough to cure it. See ACOG, *supra*, at 5–6.

Narrowing recommended treatment choices and explaining the competing values should help patients. Physicians simply need to tell patients that, under age 45, even the experts do not agree, and so whatever seems right is an appropriate choice. Having personally been told to get a mammogram yearly, then experienced a follow up mammogram, subsequent ultrasounds, an hour-long MRI, and ultimately a biopsy, I wish I had been told that many experts

the patient to the most important consideration. Guideline disclosure serves an important educational purpose.

Moreover, even if Guideline disclosure does not change the outcome of patient decision making, the process itself has ethical value. It recognizes patients as active agents, not merely objects of treatment.<sup>286</sup> Providing patients the information for optimal decision making accords them dignity and respect.<sup>287</sup>

Some scholars disagree. They contend that, in light of patients' cognitive biases and other limitations, the emphasis on autonomy in healthcare decision making is misplaced.<sup>288</sup> Without question, patients are imperfect decision makers, but it would be wrong to abandon or even to lessen the role of patient decision making. Aside from cost, healthcare decisions primarily impact patients alone. Moreover, only patients can provide insight into their personal values and preferences.<sup>289</sup> Further, studies suggest that the process of being included in decision making may increase patients' knowledge, decrease patients' anxiety, and lead to better treatment adherence.<sup>290</sup> So, for these reasons, patient decision making, like democracy, is the worst form of decision making, except for all the others.<sup>291</sup> Autonomy remains an essential priority, both as an end in itself and for its ability to enhance quality of care. Physicians should be required to disclose Guidelines to empower patient autonomy and to enhance the other fundamental ethical principles underlying healthcare, prior to deviation.

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do not recommend screening because false positives are so common. I wasn't told and only learned of the other Guidelines after several grueling months. While thinking I could have avoided the anxiety of so many tests suggesting cancer and the thousands of dollars in medical co-pays may only be hindsight bias, at least I would have been informed, and it would have been my choice.

<sup>286</sup> This view falls within the right to health approach to health policy and practice, which considers active participation critical to quality and acceptability of care. *See generally* Office of the High Comm'r for Human Rights, CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12), ¶ 11, U.N. Doc. E/C.12/2000/4 (2000); HEALTH AND HUMAN RIGHTS IN A CHANGING WORLD (Michael A. Grodin et al. eds. 2013).

<sup>287</sup> This is not intended to suggest that patients who decline such information should be forced to receive it. Autonomy also allows patients the freedom to choose not to be informed or to participate.

<sup>288</sup> *See, e.g.*, Epstein, *supra* note 6, at 1256–58.

<sup>289</sup> Berg, *supra* note 117, at 594.

<sup>290</sup> *Id.*; Anne E.M. Brabers et al., *What Role Does Health Literacy Play in Patients' Involvement in Medical Decision-Making?*, PLOS ONE, Mar. 3, 2017, at 1–2.

<sup>291</sup> *See The Worst Form of Government*, INT'L CHURCHILL SOC'Y, <https://www.winstonchurchill.org/resources/quotes/the-worst-form-of-government/> [https://perma.cc/5FK4-GFX3] (last visited Apr. 4, 2019) (“Many forms of Government have been tried, and will be tried in this world of sin and woe. No one pretends that democracy is perfect or all-wise. Indeed it has been said that democracy is the worst form of Government except for all those others forms . . . .”) (quoting Winston S. Churchill, Address at the House of Commons, (Nov. 11, 1947)).



*D. A National Entity Should Certify Guidelines to Ensure Reliability*

For mandatory Guideline disclosure to realize these practical and normative goals, a neutral, independent organization will need to delineate which Guidelines merit disclosure. Without question, some Guidelines lack trustworthiness. If there is not a system to certify well-developed Guidelines, poorly formed and unreliable or dated Guidelines could undermine acceptance of and deference to other Guidelines.<sup>292</sup> Or worse, such Guidelines could hurt rather than improve physician and patient decision making. To avoid this, an independent and neutral organization must serve as gatekeeper, and there must be a transparent, fair, efficient, and effective certification process.<sup>293</sup>

The federal government has provided one possible model for certifying Guidelines. Since 1999, the National Guideline Clearinghouse (“NGC”) has published all submitted Guidelines that meet its “Inclusion Criteria” in a single searchable database, available at no charge through the Internet.<sup>294</sup> Since June 2014, the NGC Inclusion Criteria has required that Guidelines contain a care recommendation designed to optimize care for a specific clinical circumstance.<sup>295</sup> The Inclusion Criteria also demands that Guideline recommendations be based on a systematic review of evidence and that the expert panel submit documentation of that review.<sup>296</sup> Guidelines must include an assessment of the benefits and harms of care options, as well as proof that the expert panel developed, reviewed, or revised the Guideline within the past five years.<sup>297</sup> Funding

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<sup>292</sup> See Chih-Ming Liang, *Rethinking the Tort Liability System and Patient Safety: From the Conventional Wisdom to Learning from Litigation*, 12 IND. HEALTH L. REV. 327, 373–74 (2015) (inconsistent quality of guidelines limits their legal use); Mello, *supra* note 6, at 653, 686–88 (describing diversity, multiplicity and unregulated sources of guidelines and the challenges to legal use created thereby, in the context of malpractice liability); Taylor, *supra* note 192, at 290 (showing bias in the development of some guidelines should limit their legal use).

<sup>293</sup> See 2011 IOM STANDARDS, *supra* note 26, at 4–5 (recommending a mechanism to identify trustworthy guidelines); Shekelle, *supra* note 153, at 757–58. Many developed countries utilize a single, centralized entity to issue Guidelines. See, e.g., AUSTL. NAT’L HEALTH & MED. RES. COUNCIL, <https://www.nhmrc.gov.au> [<https://perma.cc/A9SV-38SA>] (last visited Apr. 4, 2019); NAT’L INST. HEALTH & CARE EXCELLENCE, <https://www.nice.org.uk> [<https://perma.cc/H6BJ-EYXP>] (last visited Apr. 4, 2019). While there may be benefits in the United States to allowing multiple groups to issue Guidelines, as per the status quo, the failure to certify reliable Guidelines seems likely to jeopardize the effectiveness and to undermine the benefits of any mandatory disclosure reform.

<sup>294</sup> *About NGC and NQMC*, AGENCY FOR HEALTHCARE RES. QUALITY, <https://www.ahrq.gov/gam/about/index.html> [<https://perma.cc/VNC4-PCZ5>] (last updated July 2018); *Inclusion Criteria*, *supra* note 36. The NGC is a website and database sponsored by the Agency for Healthcare Research and Quality, originally created in partnership with the AMA and the American Association of Plans (now America’s Health Insurance Plans).

<sup>295</sup> *Inclusion Criteria*, *supra* note 36. This requirement contrasts with an evidence summary alone or with more generalized recommendations.

<sup>296</sup> *Id.*

<sup>297</sup> *Id.*

for the NGC expired July 16, 2018, however, and it is not yet clear what new entity may step in to perform a similar role.<sup>298</sup>

Whether it is the NGC or another organization, in order to realize their promise, Guidelines must be accessible in a single database that is freely available and easily searchable.<sup>299</sup> The Guidelines included in that database must meet the minimal NGC Inclusion Criteria and satisfy other appropriate indicia of reliability.<sup>300</sup> Guidelines that fail to adhere to a sufficient threshold of scien-

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<sup>298</sup> Shekelle, *supra* note 153, at 758; *Guidelines and Measures Updates*, AGENCY FOR HEALTHCARE RES. QUALITY, <https://www.ahrq.gov/gam/updates/index.html> [<https://perma.cc/R5VJ-9582>] (last updated Sept. 2018) (stating that in August 2018, AHRQ launched a one year study to “identify new models for disseminating and accessing” Guidelines). The ECRI Institute, a nonprofit organization that previously contracted with the federal government to develop and maintain the NGC is now offering ECRI Guidelines Trust, a website with summarized guidelines and TRUST ratings on how well each guideline meets the IOM Standards. Haifa Kassis, *The National Guideline Clearinghouse Has Closed. What’s Next?*, 33 AM. MED. WRITERS ASS’N J. 133, 133 (2018); *FAQs*, ECRI INST., <http://guidelines.ecri.org/a-sk-us> [<https://perma.cc/P89N-UAW4>] (last visited Apr. 4, 2019). While this organization has experience, their website currently has few guidelines because they were not able to use NGC content. *FAQs, supra*. It is not yet clear whether the ECRI will adequately fill the hole left by the NGC closing.

<sup>299</sup> The medical profession has fought hard to retain professional self-regulation, and some resist increased salience of Guidelines as a threat to this professional autonomy. Guidelines should not be seen as a threat to self-regulation, however, in as much as an evolution. Physicians typically play the leading role in drafting Guidelines, and the NGC was created in partnership with the AMA. *About NGC and NQMC, supra* note 294; *see also* Amir Qaseem et al., *The Development of Clinical Practice Guidelines and Guidance Statements of the American College of Physicians: Summary of Methods*, 153 ANNALS INTERNAL MED. 194 (2010). Guidelines may actually be essential to retaining professional self-regulation. Existing persistent and pervasive unwarranted variances in care are embarrassing and harmful. If physicians do not revise their practices to make care more scientifically based, they could face far more significant challenges to self-regulation.

<sup>300</sup> Guidelines that satisfy the NGC Inclusion Criteria may still vary substantially in quality. This stems primarily from differences in the strength of evidence underlying them, the strength of the recommendation contained therein, and the appropriateness of the development process. To address such differences and to improve the relevance and reliability of Guidelines, in 2011, the Institute of Medicine published eight standards for trustworthy Guidelines (“IOM Standards”). The IOM Standards mandate: (1) transparency, (2) disclosure and management of conflict of interests, (3) group composition, including patient participation and a multi-disciplinary panel, (4) compliance with separate IOM standards for systematic reviews of CER, (5) rating strength of evidence and of recommendation, (6) specific and clear articulation of recommendations, (7) external review, and (8) updating. 2011 IOM STANDARDS, *supra* note 26, at 75–137. The IOM Standards largely overlap with the Grading of Recommendations, Assessment, Development, and Evaluation (“GRADE”) approach developed in 2003 and the Guidelines International Network and the World Health Organization criteria. Murad, *supra* note 3, at 424.

From the end of 2017 until being defunded mid-2018, the NGC published an assessment of the extent to which each new Guideline adhered to IOM Standards (“NEATS Assessment”), rating compliance with each of the eight IOM standards either yes or no or from poor to excellent. U.S. DEP’T HEALTH & HUMAN SERVS., NAT’L GUIDELINE CLEARINGHOUSE, NATIONAL GUIDELINE CLEARINGHOUSE EXTENT ADHERENCE TO TRUSTWORTHY STANDARDS (NEATS) INSTRUMENT (2017), *available at* [https://www.guideline.gov/documents/neats\\_inst](https://www.guideline.gov/documents/neats_inst)

tific basis and trustworthiness would do more harm than good and should not be required disclosures.

#### CONCLUSION

In conclusion, physicians should be required to disclose Guideline recommendations to patients as part of informed consent, prior to any deviation.<sup>301</sup> Unwarranted variations in care reflect pervasive shortcomings in physician and patient decision making that threaten the health of Americans. Better adherence to Guidelines could help alleviate this problem, but Guidelines will not be able to realize their promise as long as physicians discount them and patients lack knowledge of them.

Structuring legal and ethical obligations to nudge physicians and patients to follow Guideline recommendations more often should minimize unjustified variations in care, without limiting professional judgment or patient choice. Disclosure will improve knowledge of Guidelines and help to combat cognitive biases that cause physicians and patients to make poor choices. While disclosure will not result in perfect adherence, elevating the role of evidence-based, consensus Guideline recommendations should improve quality of care and provide better, more understandable information to empower patient choice.<sup>302</sup>

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ument.pdf [[https://web.archive.org/web/20171002200826/https://www.guideline.gov/documents/neats\\_instrument.pdf](https://web.archive.org/web/20171002200826/https://www.guideline.gov/documents/neats_instrument.pdf)]. This NEATS Assessment allowed physicians, patients, and policymakers to quickly and easily determine the trustworthiness of a new Guideline.

Guidelines that rate yes or at least yes or “good” on all eight IOM Standards address most historic criticisms associated with Guidelines. They are transparent regarding the strength of recommendation, as well as the evidence and value judgments underlying that conclusion. *Id.* They minimize and disclose potential conflicts of interest and incorporate patient-preferences and patient-centered outcomes. *Id.* They are updated regularly. *Id.*

Reasonable people could disagree regarding whether or not mandatory disclosure should be limited to Guidelines meeting this rigorous criteria or some lesser one. 81 percent of physicians want to receive recommendations even when based on “poor” strength of evidence. Neumann et al., *supra* note 276, at 38–39. So, there is ample reason to believe that patients might likewise value such information. Nonetheless, there is also reason to be concerned that requiring disclosure of less reliable Guideline recommendations might cause confusion or otherwise undermine broader adherence efforts. This article does not resolve this dispute but instead identifies existing metrics that rate the trustworthiness of Guidelines, and leaves open the question of whether or not to impose additional requirements beyond the NGC Inclusion Criteria, and if so at what exact level, prior to mandatory disclosure.

<sup>301</sup> Other initiatives to address macro reforms and to improve Guideline dissemination should also be adopted to eliminate unwarranted care variances.

<sup>302</sup> “Perfect” adherence should be understood as following the care recommendation contained in a Guideline, absent patient preference or necessary clinical variation.

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