

# Getting (Along) With the Guidelines: Reconciling Patient Autonomy and Quality Improvement Through Shared Decision Making

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## Abstract

In past decades, stark differences in practice pattern, cost, and outcomes of care across regions with similar health demographics have prompted calls for reform. As health systems answer the growing call for accountability in the form of quality indices, while responding to increased scrutiny on practice variation in the form of pay for performance (P4P), a rift is widening between the system and individual patients. Currently, three areas are inadequately considered by P4P structures based largely on physician adherence to guidelines: diversity of patient values and preferences; time

and financial burden of therapy in the context of multimorbidity; and narrow focus on quantitative measures that distract clinicians from providing optimal care. As health care reform efforts place greater emphasis on value-for-money of care delivered, they provide an opportunity to consider the other “value”—the values of each patient and care delivery that aligns with them.

The inherent balance of risks and benefits in every treatment, especially those involving chronic conditions, calls for engagement of patients in decision-

making processes, recognizing the diversity of preferences at the individual level. Shared decision making (SDM) is an attractive option and should be an essential component of quality health care rather than its adjunct. Four interwoven steps toward the meaningful implementation of SDM in clinical practice—embedding SDM as a health care quality measure, “real-world” evaluation of SDM effectiveness, pursuit of an SDM-favorable health system, and patient-centered medical education—are proposed to bring focus back to the beneficiary of health care accountability, the patient.

**F**orty-two years after evidence of variability in health service utilization in Vermont was first published in *Science* to a lukewarm reception,<sup>1</sup> the American and Canadian health care systems are now in the midst of a rapid changeover. Quality has become the central theme of the entire industry, and the *raison d'être* of a burgeoning number of organizations. A major target for quality has been variability in physicians' practice patterns,<sup>2,3</sup> with efforts in recent years involving the use of pay for

performance (P4P), whereby adherence to clinical guidelines is increasingly tied to reimbursement. The benefits of this practice remain unproven,<sup>4</sup> but perhaps more importantly our “progress” has introduced new issues: Does marrying quality and reimbursement inadvertently pit financial incentives against patient autonomy and trust, the cornerstones of physician–patient relationships? More fundamentally, can health care providers negotiate their obligations to individual patients against their P4P incentives? As jurisdictions embark on the quest to provide value-based health care by rigorous determination of clinical and health economic end points, there is a necessity to consider the other “value”—values of individual patients at their point of care and treatment decisions that align with them. In the same way in which application of research evidence to the bedside cannot occur without consideration of the specific clinical contexts,<sup>5</sup> diversity of patient values and preferences often cannot be fully encapsulated in population-based guideline recommendations. In this article, we illustrate the unintended consequences associated with current performance evaluation, including circumstances where incentives generated from these approaches diverge from priorities of patients and their frontline clinicians. Furthermore,

we propose measures that uphold shared decision making (SDM) as a vital addition to provider-centric indices in our effort to achieve higher quality of care for all.

## The Diversity of Patient Values and Preferences

In health care, benign paternalism is giving way to patient-centered care as the new norm.<sup>6</sup> However, ongoing tension exists between quality measures, centered on providers' adherence to practice recommendations, and the enshrinement of patient self-determination in medical decision making. It is recognized that the threshold of clinical benefit at which patients agree to undergo the burden, cost, and adverse effects of medical therapy may not align with those perceived by their treating physicians or advocated in practice guidelines. For example, proportion of patients with atrial fibrillation who undergo oral anticoagulation is a quality metric commonly used to evaluate the effectiveness of stroke prevention.<sup>7,8</sup> However, a decision-aid-based interview involving patients at high risk of developing this common arrhythmia reported wide variability in their risk thresholds for initiating anticoagulation should they develop the disease; in fact, the number-needed-to-treat

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to prevent one stroke at which respondents would agree to warfarin therapy ranged from 9 to 100.<sup>9</sup> Similarly, a study on treatment of hypertension, another commonly used quality metric,<sup>7</sup> revealed not only patients' general requirement of higher clinical benefit prior to therapy compared with their clinicians but also subgroups who accepted varying degrees of minimum effect size in cardiovascular protection.<sup>10</sup> In another evaluation of preferences among cardiovascular patients, perception of mortality as an important clinical end point decreased fourfold among those  $\geq 85$  years compared with those aged 18 to 44; gradients across race and income were also observed.<sup>11</sup> In the examples above, the uniform implementation of P4P based on homogenous application of practice guidelines would inadvertently penalize a proportion of the target population who legitimately do not deem the clinical benefit of the recommended therapy to offset its treatment burden and adverse effects. Patient-centeredness begins with recognition of patients as individuals, each with personal values that cannot be adequately captured by guidelines derived from population-based evidence. Indeed, in-depth interviews of British health care providers working under the Quality and Outcomes Framework, the main P4P program of its National Health Service, identified loss of patient-centeredness and patient choice as important concerns.<sup>12</sup> Even as health systems aim to demonstrate value through an emphasis on practice pattern and quality, any acceptable measure ought to respond to and reflect the diversity of the individual patients they serve.

### The Patient-Centeredness of Quality Indicators

Contemporary performance indices are typically focused on provider behavior, their spotlight fixed on rates of service delivery by practitioners. Although our professional sphere is focused on health, a patient's medical journey must also incorporate personal, vocational, and financial burden associated with managing one's condition. It has been estimated that adhering to the American Diabetes Association guideline requires 122 minutes per day for an average patient,<sup>13</sup> and that a guideline-adherent elderly with type 2 diabetes and chronic obstructive pulmonary disease must take at least five medications, engage in six lifestyle changes, make five to eight additional primary care

visits per year, and attend numerous appointments for smoking cessation and pulmonary rehabilitation.<sup>14</sup> Despite the proportion and extent of multimorbidity becoming increasingly prevalent in the typical patient population,<sup>15,16</sup> current guidelines and P4P incentives remain largely disease-centric, with inadequate consideration for the interaction of multiple coexisting chronic conditions.<sup>17,18</sup> In their current form, quality measures do not capture the 40% of patients discharged from emergency departments who do not adhere to their medications, or the 20% who do not fill their prescription at all<sup>19</sup>; they do not recognize the one in three Medicare beneficiaries in the United States whose pharmaceutical copayments were prohibitive to maintenance of therapy<sup>20</sup>; they do not address the rural patients who must access specialized care in urban centers without travel support. External pressures from an unchecked focus on performance measures are far-reaching: they are not only felt by patients, who are deprived of their own priorities in self-management of chronic conditions, but also by care providers, who must contend with potentially adverse influences.

### Unintended Impact on Clinical Decision Making

Critically, the singular pursuit of quantitative targets contributes to a narrow focus by providers which may displace the primary goal of better patient care. The hospital standardized mortality ratio (HSMR) in Canada provides a case study: A metric used to evaluate quality of care by assessing in-hospital mortality rates after adjustment for demographic factors, diagnosis, and admission status, HSMR has been publicly reported by the Canadian Institute for Health Information since 2007.<sup>21</sup> As HSMR became public, however, the proportion of admissions coded as "palliative," which excludes the case from the score calculation, has risen rapidly while HSMRs began a sharp decline. Furthermore, hospitals publicly reporting HSMRs had a higher proportion of coding as "palliative" compared with those not required to go public with the data, reversing observed trends prior to public disclosure and prompting concerns that many patients may be classified before end-of-life discussion had taken place.<sup>22</sup> Similarly, following the implementation of public reporting of patient outcomes for percutaneous coronary intervention

(PCI) in the United States, lower PCI use in acute myocardial infarction was reported among states with mandatory outcome reporting compared with nonreporting states, particularly for high-risk patients.<sup>23</sup> In addition, an overwhelming majority of interventional cardiologists in a 2005 survey reported publication of mortality statistics to have affected their decision to proceed with PCI, with 85% of respondents not confident in techniques used to adjust for patient risk profile.<sup>24</sup> The physician-patient relationship thrives on a foundation of trust that is based on the shared understanding of a mutual objective: improving the well-being of the patient. This sacred bond may become irreparably threatened by a provider's need to meet a specific target under the P4P scheme.

### SDM: Toward System-Wide Adoption

It is important to recognize the invaluable benefits to recording and reporting outcomes data in health care: A learning health care system that rewards quality of care and process improvement begins with understanding its current performance, while enabling iterative changes informed by the data it collects. Comparisons of indicators at the international level help identify best practices from high-achieving systems,<sup>25,26</sup> while data transparency has been associated with improved outcomes and lower costs in many clinical conditions.<sup>27</sup> However, as Hartzband and Groopman<sup>28</sup> remind us, "There is more to life than death." In medical school, trainees learn the definition of health, codified in the Constitution of the World Health Organization, as "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."<sup>29</sup> Despite this, guidelines and system performance measures continue to emphasize clinical outcomes<sup>30</sup> at the expense of assessing concordance with patient values, often with important sequelae. For example, a 2009 study evaluated the effect of 96 hospitals in Ontario, Canada, participating in a public quality report card program, in which each hospital was evaluated by 12 process-of-care indicators for acute myocardial infarction and 6 measures for congestive heart failure.<sup>31</sup> While the original hospital rankings did not consider patient preferences, a recent reanalysis incorporating patients' goals-of-care designations at the time

of admission revealed significant shifts in hospital performance standing as a result: 22 of 39 hospitals ranking in the highest or lowest quintiles moved out of their respective categories.<sup>32</sup> The pursuit of higher-quality health care must involve bifocal vision: a relentless drive to improve population-based, system-wide outcomes combined with a firm commitment to patient-centeredness grounded in diversity and individuality.

Diversity of individual patient preference must no longer be grouped with undesirable practice variability as issues to be conquered but, rather, as an essential fabric to be interwoven into a high-functioning health care system. Although there has been an important and welcome trend of increasing patient participation in guideline deliberations, the views of select individuals on a panel may not adequately represent the full array of preferences experienced by all patients in every clinical encounter. Expanding the evaluation of provider performance based on SDM to facilitate dialogue related to risks and benefits of a treatment, at the level of the individual encounter, is therefore an important approach. Although data from a recent *Cochrane Systematic Review* support the efficacy of decision aids in improving patient knowledge and empowerment in decision making,<sup>33</sup> adoption of SDM has been hampered by several concerns, in particular a perceived passivity on the part of clinicians in the face of patient demands in such discussions.<sup>34</sup> However, it bears noting that recent literature suggests that clinically inappropriate patient demands are more rare than generally appreciated.<sup>35</sup> For example, a review of 5,050 cancer-related clinical encounters revealed only 1% to have involved an inappropriate patient request.<sup>36</sup> Furthermore, the role of providers in SDM extends much beyond providing information about treatment options: Active engagement with patients in eliciting personal values, aligning unrealistic expectations, and identifying external decision pressures are also essential aspects.<sup>37,38</sup>

We believe SDM implementation requires four linked strategies. First, SDM should be embedded into quality indices, with a focus on patient-reported outcomes rather than provider-documented checklists. The performance metric in the Physician Quality Reporting System

in the United States, which captures SDM as a component, is guided by clinician reporting.<sup>4</sup> As most providers do not have formal training in SDM, outcomes reported by the patient using validated tools would provide an improved feedback loop that enables targeted education while reducing the reporting burden of clinicians. Not only are a wide array of validated patient-reporting tools for SDM available (e.g., CollaboRATE and COM-RADE tools),<sup>39,40</sup> several jurisdictions in the United States, United Kingdom, and Canada are actively using patient-reported outcomes in their primary care and elective surgical pathways,<sup>41</sup> providing infrastructure that facilitates the integration of SDM quality reporting.

Second, quality measures need to be responsive to SDM effectiveness in real-world clinical practice. Although high-quality evidence on the benefits of decision tools exist, translation of this knowledge from a research setting into widespread routine practice is a process that is context dependent: Provider time, continuity of care, team composition, and patient characteristics can all play a role.<sup>42</sup> Currently, implementation strategies to enable SDM uptake in routine practice suffer from low quality of evidence base.<sup>40</sup> With availability of real-world outcomes through the use of patient-reported measures, clinicians, researchers, administrators, and policy makers can perform rigorous evaluation to determine subgroups in which SDM may be inappropriate and situations where its costs outweigh its benefits. Patient perspectives should be actively incorporated in these policy discussions to determine the operational impact of SDM measures and to inform necessary modifications. These findings “from the trenches,” in turn, should iteratively refine the direction of implementation strategy.

Third, a health care system amenable to adoption of SDM needs to be actively pursued across the spectrum, from health services delivery to clinical research. System-level prerequisites to sustaining SDM at the bedside, including ready access to decision aids at point-of-care through integration with electronic medical records,<sup>43</sup> as well as alternatives to fee-for-service reimbursement that currently rewards volume over value, are urgently needed. Promising novel payment structures exist, such as the

Medicare Shared Savings Program for Accountable Care Organizations, using patient-reported surveys that include questions on quality of SDM (Consumer Assessment of Healthcare Providers and Systems).<sup>39,44</sup> Nonetheless, rigorous evaluation is needed to ensure that these novel payment structures are providing their anticipated outcomes of long-term SDM uptake. As sound medical decisions are predicated on accurate estimates of disease progression, improvements are also required in prognosis research. The inadequate quality of risk models for some diseases and the proliferation of multiple predictive tools for others emphasize the need for quality control and harmonization.<sup>45</sup>

Finally, the training of future medical professionals must place greater emphasis on patient-oriented approaches. Although enthusiasm for the uptake of critical appraisal skills in medical education has accompanied the rise of evidence-based medicine, it is critical to combine the objective results of population-based medical literature with the subjective experience of illness and individual patient goals.<sup>46</sup> Narrative-based pedagogy has been established as a viable approach to improving patient-centered communication through exposure to outcome-based literature<sup>47</sup> and has been successfully implemented at select medical institutions.<sup>48</sup> Furthermore, a focus on teaching the current understanding of human psychology as it relates to health-related behaviors<sup>49</sup> will equip future practitioners with tools to provide long-term support and encouragement as their patients embark on their path of disease management facilitated through SDM.

In the end, medicine is not only an exacting science that requires precise measurement of traces on an electrocardiogram to diagnose an arrhythmia but, more importantly, a *humanistic* art that notices the discolored eyebrows of a patient who denies a smoking history. In our quest for personalized medicine, we have long recognized the role that genetic variability plays on disease prognosis and treatment response. It is time that we also embrace the diversity of patient perspectives, as our motivations for practicing this ever-evolving profession are renewed when we see individuals as more than dots on a Kaplan–Meier curve.



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