MEDICINE AND SOCIETY: PEER-REVIEWED ARTICLE
Should Clinical Guidelines Incorporate Cost Pathways for Persons With Financial Hardship?
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Abstract

The American Diabetes Association 2020 Standards of Care for the treatment of hyperglycemia in type 2 diabetes includes a treatment pathway when "cost is a major issue." This pathway recommends use of 2 generic drug classes, thereby codifying differential treatment for those with financial hardship. This article explores 4 implications of incorporating the cost pathway into clinical recommendations: (1) the presence of a cost pathway might create the appearance of an evidence-based quality difference through activation of implicit bias; (2) screening for financial hardship to guide therapy has potential harms for patients; (3) concern that financial hardship warrants differing care might impact overall quality of care and patient-clinician relationships; and (4) applying the guidelines when caring for patients with financial hardship might demoralize clinicians.

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Recommendations and Pathways

In December 2018, the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) published recommendations for the treatment of hyperglycemia in type 2 diabetes for persons failing metformin monotherapy.[1] These recommendations are incorporated in the ADA 2020 Standards of Care.[2] This essay considers 4 ethical concerns about including patients' financial hardship as part of a treatment pathway (algorithm),[1] a component of the algorithm I call a *social pathway* since it relies on assessing medication affordability. The social pathway is distinct from the 4 *clinical pathway* components of the algorithm, which depend on assessing clinical parameters for persons with type 2 diabetes. Two of these clinical pathways involve assessment of patients for atherosclerotic cardiovascular disease (ASCVD) or for either chronic kidney disease (CKD) or heart failure (HF). When ASCVD, CKD, or HF are not present, there are 2 additional clinical pathways for a "compelling need to minimize hypoglycemia" or a "compelling need to minimize weight gain or promote weight loss."[1] The social pathway, which is indicated when "cost is a

major issue,"[1] represents a third choice for those without ASCVD, CKD, or HF. The 2 drug classes in common for avoidance of hypoglycemia and weight-related risks in these groups are patented sodium-glucose cotransporter (SGLT2) inhibitors and patented glucagon-like peptide 1 (GLP-1) analogues. Dipeptidyl peptidase 4 inhibitors and thiazolidinediones are also included as medication options to avoid hypoglycemia. The social pathway recommends generic sulfonylureas and thiazolidinediones.[1,3]

Evidence and Representation
The 2 clinical pathways for persons with ASCVD or either CKD or HF are supported by a number of placebo-controlled trials for individual SGLT2 and GLP-1 medications.[4,5,6] By contrast, the literature guiding treatment of persons with type 2 diabetes without ASCVD, CKD, or HF is relatively weak. Most studies comparing drug classes to one another are of short duration, rely on surrogate outcomes, and are industry funded. In a 2016 review of comparative effectiveness studies, only 4% of 177 studies had a duration of greater than 2 years and 12% of 162 studies explicitly reported receiving no industry sponsorship.[7] Although outcomes such as weight gain and rates of hypoglycemia are well suited to studies of short duration, for persons without cardiovascular or renal disease, we do not have comparative effectiveness studies with microvascular, macrovascular, or mortality outcomes to guide treatment preferences.[7,8] The text of the 2020 ADA Standards of Care recognizes the weakness of the data in stating: "For patients without established ASCVD, indicators of high ASCVD risk, HF, or CKD, the choice of a second agent to add to metformin is not yet guided by empiric evidence."[3] The ADA treatment algorithm graphic, however, does not convey the poor-quality evidence and lack of certainty guiding medication choices for persons without ASCVD, HF, or CKD.

The ADA/EASD treatment algorithm is not aligned with best practices of guideline presentation.[9] There are other guidelines commonly used in primary care that more rigorously evaluate and display the evidence. For example, the American Heart Association and American College of Cardiology 2018 Cholesterol Guideline categorizes each evidence statement based on the class (strength) of the recommendation and level (quality) of evidence.[10] Their recommendations include value statements when treatments might be supported by high-quality outcomes evidence but do not meet thresholds for cost effectiveness. Unlike the ADA recommendations, the graphic display of the treatment algorithms includes color codes for the strength of the recommendation or value of each branch point.[10]

Implicit Bias
How will clinicians read the treatment algorithm graphic? Specifically, for persons without ASCVD, CKD, or HF, will the juxtaposition of the 2 clinical pathways and the social pathway encourage the perception that there is an evidence-based quality difference between the choices for the clinical and social pathways? To understand how the algorithm might be communicating a quality difference between the clinical and social pathways, we must consider the nature of implicit bias and how the ADA/EASD treatment algorithm embeds implicit bias.

Research on implicit bias has described the tendency of people to see social groups through the lens of *us* and *them*, accentuating differences and thereby distancing the 2 groups. The negative attributes of "them" and their circumstances affirm the positive attributes of "us" and our station. Implicit bias is activated when a socially held bias is anchored to a second set of preferred-less preferred dichotomous elements, such that

the bias and second set of value judgments reinforce one another. Although some individuals may not believe in the bias and the differences between "us" and "them," the strength of the anchoring of the social bias to a second set of value judgments can influence perception.[11]

There are long-standing biases against the poor that are reinforced by narratives that the poor are responsible for their status, are prone to dependence, and deserve less.[11,12,13] In the ADA/EASD recommendations, the financially able (deserving) are anchored to the clinical pathways (a form of decision making preferred by clinicians) while the people with financial hardship (less deserving) are anchored to decision making that is less clinically grounded (and therefore less preferred by clinicians). The anchoring reinforces the social hierarchy. The anchoring also differentially frames perceptions of medication options: the patented medication options (SGLT2 inhibitors and GLP-1 analogues) in common for the 2 clinical pathways when ASCVD, CKD, or HF is not present are framed as more preferred, higher quality care, and the generic medication options in the social pathway are framed as less preferred, lower quality care, despite the absence of evidence regarding macrovascular and microvascular outcomes and death for this patient population. We come to perceive and value high-quality care for "us" in part by defining and segregating a socially less deserving "other." The social pathway of the ADA/EASD recommendations functions like a fun house mirror. On one side, it makes the medication options of the clinical pathways look larger and better, because on the other side are poorer people with diminutive care options. The "mirror" can prevent us from seeing gaps and biases in the literature, deviations of the ADA/EASD from best practices in writing guidelines, overreliance on expert opinion, absence of population assessment of costs and benefits of new therapeutics, and our collective failure to provide universal access to care.

More About Ethics and Justice
Here, I discuss 3 additional implications for patient care of incorporating the ADA/EASD social pathway in clinical recommendations.

Potential harms of screening for financial hardship. The social pathway is aligned with efforts to promote cost-of-care discussions. Yet research on cost-of-care discussions is at best formative with respect to screening methods, clinician resistance, interventions, and outcomes.[14,15,16,17,18] Screening for social determinants of health has shown promise,[19,20,21,22] but potential harms have been acknowledged.[23] Some patients might find the screening questions intrusive, disrespectful, stigmatizing, or undermining of trust. However, the purpose of screening for social determinants is to mitigate their impact through structural change,[21] a different intent than the ADA/EASD social pathway. Screening for financial hardship to guide diabetes therapy is untested, and absent an evidence base, it raises ethical questions: Should clinicians inform patients that they are asking about ability to afford medications in order to prescribe presumably "lesser" therapy? Will patients feel devalued by being relegated to the social pathway?[24] What should clinicians do when they learn that patients' financial hardship goes beyond paying for diabetes medications?

Patient-clinician relationship. Other quality of care factors can be affected by reinforcing tiers of care. Patient-clinician communication and trust may be impaired, eroding the foundations of just relationships. In a seminal study, Lisa Cooper and colleagues demonstrated that measures of clinicians' implicit race bias were associated with potentially harmful communication patterns between clinicians and patients and with

poor care ratings among African-American patients.[25] In addition, clinicians might make assumptions about who should receive less expensive, lower-quality care based on their "poor" appearance, diction, or behavior. In making such assumptions, they might inadvertently contribute to the burden of discrimination and resultant risk of adverse health effects among those with financial hardship.[26]

Clinician demoralization. Finally, clinicians are torn between their professional ethics to provide quality care to all patients and real-world financial constraints on practice. A colleague in a safety net practice, reflecting on the type 2 diabetes treatment algorithm, said to me, "The longer I work here, the further I fall behind the rest of primary care practice." Every prescription for a "bad" generic sulfonylurea (perceived by clinicians as of lesser quality based on their interpretation of the ADA/EASD treatment algorithm) and institutional formulary restrictions for expensive patented medication become demoralizing. Clinicians react negatively to their home institutions as opposed to the expert panel that recommended the generic therapies for people with financial hardship or the health system that structures care as a privilege. Clinicians know their home institutions are imperfect, so it is easy to ascribe blame to them. Given their need for guidance in navigating the complex terrain of medical care, clinicians regard experts as having principled authority. They have difficulty discerning that experts' enthusiasm for progress and the appeal of innovation may perpetuate bias in medical practice. They may not perceive the marginalization and stigmatization of persons with financial hardship and how practice patterns might be promoted, in part, on the backs of the poor.

A Bigger Picture

Although I am critical of the function of a cost-of-care pathway in the ADA/EASD recommendation statement, financial hardship is a staggering issue. Prior to the coronavirus pandemic, nearly 41 million Americans lived below the federal poverty line, and nearly 140 million Americans (43%) were either poor or low income under the Supplemental Poverty Measure.[27] Nearly 40% of Americans could not afford a $400 emergency,[28] and 27.5 million Americans did not have health insurance.[29] Among the insured, 43% reported that they "struggled" to meet their deductible, and 40% assumed debt from medical bills.[27] Low income is part of the web of social determinants of health that also affects diabetes risk.[30,31,32,33] Survey data indicate that nearly 1 in 4 adults and seniors reported difficulty affording medications.[34] Low income, poor health status, and being prescribed 4 or more medications were risk factors for difficulty affording medications[34]; each factor is associated with type 2 diabetes. Difficulty affording medications leads patients to make unpalatable decisions, such as taking medications less frequently than prescribed, buying less nutritious food to afford medication, or choosing between the needs of family members or their own needs.[35]

Furthermore, people with low income are subject to structural forces that suppress wages, create dangerous work environments, undermine social services, limit affordable and stable housing, create food deserts, contribute to disproportionate rates of incarceration or control by judicial systems, threaten the social fabric of early childhood, make health care less accessible, expose people to pollutants, undercut the quality of primary and secondary education, and limit access to higher education, thereby maintaining a skewed playing field.[9] As described above, the poor are blamed for their poverty.[11,12,13] Poverty is often racialized or gendered, strengthening the biases that harm persons of color, women, and the poor.[12,36,37,38,39]

The ethical concerns described here are predicated on understanding poverty or financial hardship as an individual characteristic warranting individual intervention. Alternatively, poverty can be understood as being rooted in the socioeconomic system—as being a feature of the economy and the degree of social cohesion.[40] That the ADA/EASD recommendations created a pathway for individual patients for whom "cost is a major issue"[1] is one more indicator of a broken system in need of repair.[41,42] Instead of devoting a pathway in a treatment algorithm to the poor, we should bring urgency to eliminating cost as a barrier to high-value, cost-effective care.

It could be different. Imagine more of our health professional societies demanding universal access to care and single-payer health insurance.[43,44] Imagine expert panels applying best practices to writing clinical guidelines in the context of universal access to care, without conflicts of interest with the pharmaceutical industry, and sensitive to patient-centered and population health perspectives. Imagine our medical societies becoming advocates and allies for the elimination of poverty. Engaging issues of poverty and rooting out manifestations of bias within and outside our medical societies, while no doubt challenging, will make our medical societies more relevant and stronger.

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