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The 2013 American Association of Clinical Endocrinologists' Diabetes Mellitus Management Recommendations:

Improvements Needed

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For more than 20 years, the American Association of Clinical Endocrinologists (AACE) has been an authoritative source of advocacy and expertise in endocrinology. In line with its mission, the AACE recently introduced an update to their 2009 diabetes mellitus (DM) management algorithm,[1] issuing an algorithm (April 2013),[2] followed by a consensus statement (July2013).[3]

Management recommendations can be useful if they are based on evidence, developed through a readily understood process, and respectful of patients' life circumstances and goals. A process that is easily understood is essential for physicians; other health care providers, such as physician assistants, nurse practitioners, and pharmacists; and patients to adequately judge the validity of management recommendations. Inclusion of patients' values and preferences is important if the recommendations are to inform patient-centered care. In

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our view, the AACE's DM algorithm and consensus statement do not meet these expectations and should not be used to guide clinical care in their current form.

Algorithms and clinical guidelines should offer an assessment of the likely benefits and harms of treatments, and evaluate the quality of all of the relevant literature. The Institute of Medicine (IOM) has therefore proposed 8 standards for developing clinical practice guidelines to ensure "scientifically valid, transparent, and reproducible results."[4(p4)] Although the AACE's algorithm and consensus statement were not explicitly labeled as "guidelines," they were "developed to provide clinicians with a practical guide"[3(p3)] to the management of type 2 DM, making them subject to the same general principles. The algorithm and consensus statement fall short on several of the 8 IOM standards. We are particularly concerned about the following.

Standard 1: Establishing Transparency

Users of guidelines should understand how recommendations were developed and who was involved.[4] Although the AACE's consensus statement includes references to systematic reviews, there is no explicit statement of how evidence, expertise, and values were considered in determining the recommendations, whether by a systematic review of the literature or a systematic process of consensus. In addition, there is no information on how the development of the consensus statement was funded. In particular, users might want to know whether parties that could benefit from the recommendations directly, or indirectly, underwrote the salaries of AACE staff, the meetings of the panel, or other expenses. Without adequate disclosure of funding sources, users are unable to judge whether the recommendations were developed based on the best available evidence and are free from avoidable bias.

Standard 2: Management of Conflict of Interest

Users of guidelines should have confidence that patients' needs and scientific evidence served as the basis for the proposed recommendations. The IOM therefore recommended that the authors of guidelines report and eliminate or reduce their financial conflicts of interest[4] because financial relationships may consciously or unconsciously influence behavior and recommendations.[4–7] Members with financial conflicts of interest should represent a minority of the group that develops a guideline, with the chair of the group having no such conflicts.

In the consensus statement, the AACE panel members reported their financial relationships. Public records show that between 2009 and 2012, 16 of the 19 members of the group had financial associations of more than $100 with industry (range, $2600–$488 000).[8] Seven task force members, including the chair, had financial relationships of more than $250 000. Many of the financial associations were with companies that sell DM medications that figure prominently in the algorithm and consensus statement. It is impossible to know the specific effects of these relationships on the development of the recommendations. Nonetheless, these substantial financial conflicts of interest may undermine users' trust.[4]

Standard 3: Guideline Development Group Composition

To address the needs of clinicians and patients, the guideline group should be balanced, multidisciplinary, and include a patient, patient advocate, or patient-consumer organization representative.[4] Primary care physicians care for most patients with type 2 DM[9] and are the primary intended users of the algorithm and consensus statement. However, 18 of the 19 members of the AACE panel were endocrinologists; a cardiologist was the sole nonendocrinologist.

Admittedly, patient engagement in the development of guidelines is not yet widespread. However, such engagement might have improved several aspects of the AACE's algorithm and consensus statement, as these documents do not fully address the challenges of being a patient with DM. Panel members acknowledged the need to individualize treatments and to consider the patient as a whole. However, neither assessment of the patient's values and preferences nor shared decision making were explicitly discussed in either document. Patient context, goals, values, and preferences play a prominent role in patient-centered care and guide the selection of medications to treat hyperglycemia. Given the lack of comparative effectiveness data for long-term clinical outcomes in DM, therapeutic decisions are often based on short-term side effect profiles, safety, cost, treatment burden, and expected glucose reduction. The panel chose to emphasize 3 adverse effects of antihyperglycemic agents: hypoglycemia, weight gain, and cardiovascular morbidity. Although these adverse effects are important, other aspects of treatment may be more consequential for particular patients, such as flexibility and intensity of treatment regimens, gastrointestinal tract intolerance, cost, and other attributes that may affect quality of life. Some patients, in fact, prioritize medication cost and the burden and intensity of treatment over efficacy.

Standard 5: Establishing Evidence Foundations for and Rating the Strength of Recommendations

Users of guidelines should understand how the evidence was derived and the level of confidence for each recommendation.[4] Neither the algorithm nor the consensus statement included a rating of the task force's confidence in the evidence supporting each recommendation. A table rating the level of confidence in the evidence and the strength of each recommendation, in accordance with the Grading of Recommendations Assessment, Development and Evaluation Working Group's framework,[10] would have clarified which steps in the algorithm are based on high-quality, complete, and consistent data. This is particularly important given the paucity of data that directly compare antidiabetic agents, define the optimal glycemic control targets, and allow for individualization of treatment based on clinical characteristics. In addition, the users of these recommendations would benefit from greater insight into how the panel weighed the benefits and potential harms, costs, burden, and inconveniences of the recommended therapies and interventions. For patients with DM, treatment burden and cost are often important considerations, and sometimes the most important considerations. For medications to have a chance to benefit patients, they have to be able to afford them, to obtain them, and to be willing and able to take them.

Conclusions

Guidelines and algorithms are important tools that can help physicians, physician assistants, nurse practitioners, and pharmacists deliver effective care to their patients. A multidisciplinary panel with independent funding and with members who have no substantial financial and intellectual conflicts of interest is essential, as is an explicit and readily understandable development process that clearly incorporates patients' values and preferences into recommendations.

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