COMMENTARY

Trends in the Evidence Level for the American Diabetes Association's "Standards of Medical Care in Diabetes" From 2005 to 2014

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In the January Supplement of *Diabetes Care*, the American Diabetes Association (ADA) has published the newest version of the "Standards of Medical Care in Diabetes" (1). These Standards provide guidelines to help clinicians in the management of their patients with diabetes or at risk for diabetes. Published in one form or another since 1989, the Standards cover multiple aspects of clinical care, such as screening and diagnosis, glycemic management, and cardiovascular risk reduction. Over the past decade, the ADA has made a concerted effort to be transparent and evidence-based in its guideline development as recommended by the Institute of Medicine for guideline-setting organizations (2). We reviewed the ADA recommendations from the past decade to assess trends in the quality of evidence cited to support these recommendations.

Each year, the recommendations in the Standards are reviewed and revised in light of emerging and changing evidence. We examined the total number and evidence level for all bulleted recommendations made by the Standards of Care each year from 2005 to 2014. Recommendations are assigned ratings of A, B, C, or E depending on the quality of evidence (Table 1). For our analyses of trends over the past decade, we combined A- and B-level recommendations into a "higher-level evidence" category and combined C- and E-level recommendations into a "lower-level evidence" category. We then calculated the proportion of overall recommendations that were based on higher-level evidence each year. We also examined trends in the recommendations within the following four mutually exclusive clinical domains: *1*) glycemic management and related issues (e.g., diabetes screening and diagnosis, microvascular complications); *2*) cardiovascular-related care (e.g., blood pressure and lipid assessment and management); *3*) general recommendations related to lifestyle, nutrition, and self-management; and *4*) pediatric- or obstetric-related diabetes care.

From 2005 to 2014, the total number of annual bulleted recommendations increased by 51% (from 154 to 232). During this time, the proportion of recommendations per year that were based on higher-level evidence increased from 39 to 51%, and 2014 was the first year in which the majority of recommendations were based on this higher evidence level (Fig. 1). This increasing proportion of recommendations based on higher-level evidence, together with the increase in total number of recommendations, reflected both the higher evidence quality of new recommendations and the publication of higher-level evidence to support existing recommendations. These results compare favorably with similar analyses of guideline evidence quality conducted in cardiology and oncology (3,4).

To investigate which care domains had the highest quality of supporting evidence, we repeated our analyses within each of the four mutually exclusive care domains (Fig. 2). Of these four clinical domains, cardiovascular-related recommendations had the highest quality of evidence, with the proportion of higher-level recommendations increasing from 51% in 2005 to 69% in 2014. Recommendations related to glycemic management and to lifestyle, nutrition, and self-management had similar proportions of higher-level recommendations in 2014 (57% and 59%, respectively). Recommendations related to pediatric or obstetric diabetes care had

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Table 1—ADA evidence grading system for the "Standards of Medical Care in Diabetes"

Level of evidence	Description
A	Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including ● Evidence from a well-conducted multicenter trial ● Evidence from a meta-analysis that incorporated quality ratings in the analysis Compelling nonexperimental evidence; i.e., "all or none" rule developed by the Centre for Evidence-Based Medicine at the University of Oxford Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including ● Evidence from a well-conducted trial at one or more institutions ● Evidence from a meta-analysis that incorporated quality ratings in the analysis
B	Supportive evidence from well-conducted cohort studies ● Evidence from a well-conducted prospective cohort study or registry ● Evidence from a well-conducted meta-analysis of cohort studies Supportive evidence from a well-conducted case-control study
C	Supportive evidence from poorly controlled or uncontrolled studies ● Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results ● Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls) ● Evidence from case series or case reports Conflicting evidence with the weight of evidence supporting the recommendation
E	Expert consensus or clinical experience

the lowest proportion of high-level recommendations, increasing from a paltry 4% for most of the decade to 36% in 2014.

Our findings indicate that the recommendations are increasingly based on higher-quality evidence, although nearly half of recommendations continue to reflect expert opinion or conflicting or limited evidence from smaller studies. These findings reflect the reality that *1*) randomized clinical trials or similar high-quality research studies do not exist for every clinical care decision and *2*) there remain areas that lag behind in the quality of evidence to guide care recommendations, especially in pediatric and obstetric care. Recommendations with C- or E-level evidence can help to identify areas that require further research.

The positive trends seen over the past decade in the quality of evidence supporting the Standards should be considered in light of two significant developments in diabetes care. First, the quality of diabetes care within the U.S., while improving, frequently falls short of the recommended goals set out in these Standards. Recent data indicate that up to 49% of people with diabetes still did not meet the targets for glycemic control, blood pressure, and/or LDL cholesterol level (5). Professional organizations such as the ADA can play a key role in supporting more effective clinical care (6). One promising development within the Standards beginning in 2012 has been the inclusion of a Strategies for Improving Care section. This section provides practical strategies to optimize provider and team behavior, support patient behavior change, and improve systems of care. The most recent standards include four recommendations, all based on A- or B-level evidence, to help providers and care systems recognize and overcome barriers to effective care delivery.

A second trend in diabetes care is the growing recognition of the need to tailor population-level recommendations to individual patients with a wide range of concurrent conditions, personal preferences, and health goals. The science and art of medicine come together when the clinician is faced with making treatment recommendations for a patient who would not have met eligibility criteria for the studies on which guidelines were based. Recognizing that one size does not fit all, the Standards moved in 2009 from a single A1C goal for adults to three-tiered recommendations for more or less stringent targets, as well as separate recommendations for older adults (7). Additionally, the Standards now include a diagram (see Fig. 6.1 in ref. 1) suggesting how A1C treatment goals may be made more or less stringent after consideration of individual patient factors, such as risk for hypoglycemia, disease duration, and life expectancy. The complex task of incorporating concepts of individualization into evidence-based population-level guidelines is commendable, and our hope is that the ADA can extend this effort into domains beyond glycemic control.

Patients with diabetes are complex. Continuing therapeutic advances, the aging U.S. population, and the ongoing epidemics of obesity and sedentary lifestyles all present challenges to clinicians, policy makers, and evidence-based guideline makers. These challenges will require careful consideration of the existing evidence, new approaches to tailoring evidence to individual

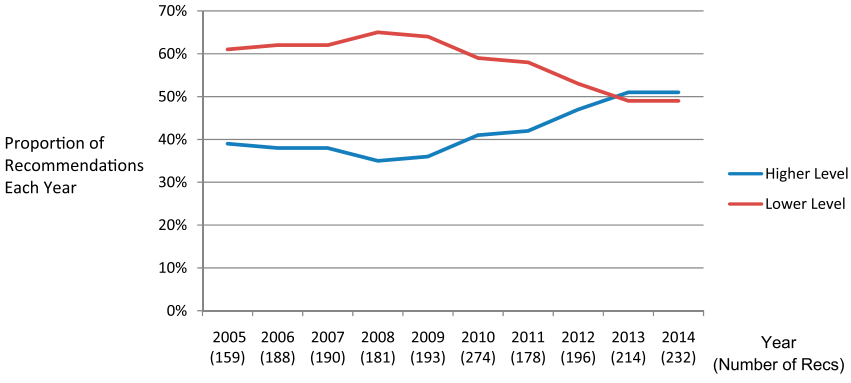

Figure 1—Trend from 2005 to 2014 in number and proportion of recommendations (Recs) made each year in the ADA Standards of Care that were based on higher-level evidence vs. lower-level evidence.

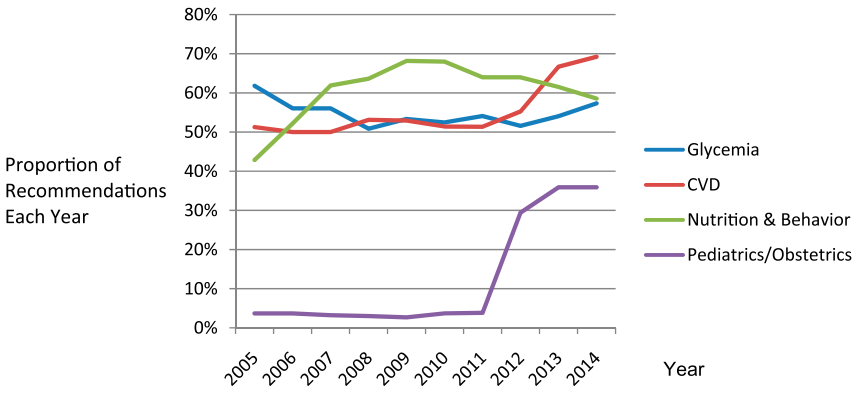

Figure 2—Trends from 2005 to 2014 in annual proportion of recommendations based on higher-level evidence, stratified into four mutually exclusive categories: glycemic management and related issues (e.g., diabetes screening and diagnosis, microvascular complications); cardiovascular-related care (CVD) (e.g., blood pressure and lipid assessment and management); general recommendations related to lifestyle, nutrition, and self-management; and pediatric- or obstetric-related diabetes care.

patients, and expansion of the evidence base in a way that will continue to make diabetes care recommendations more evidence-based and also more widely implemented.

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Duality of Interest. R.W.G. currently serves as the chairperson of the ADA Professional Practice Committee (a volunteer position). He reports no financial conflicts of interest. M.S.K. was employed as staff at the ADA from 2007 to 2012 with oversight of the Standards of Care and other ADA Clinical Practice Recommendations. She also reports no financial conflicts of interest.

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