EDITORIAL (SEE INZUCCHI ET AL., P. 1364)

American Diabetes Association–European Association for the Study of Diabetes Position Statement: Due Diligence Was Conducted

Almost everyone has heard the saying, "If you want to keep a friend, never talk about religion or politics." In regard to the specific management of type 2 diabetes, we can alter this phrase somewhat and suggest, "If you want to keep a colleague, never talk about diabetes guidelines!" Most providers of diabetes care will readily admit that a forum for intense debate revolves around the issue of what is the best approach to manage individuals with diabetes. A provider can justify his decision for treatment based solely on a wide range of management strategies available in the literature. For example, if you really care to do the exercise by searching on PubMed, you will note that the search term "diabetes management" will result in >24,000 citations. The use of "diabetes guidelines" or "diabetes algorithm" as search terms will yield >8,900 and 3,100 citations, respectively. In addition to the debate based on publications, this topic also evokes considerable emotion. With the release of the latest statement on the management of hyperglycemia in type 2 diabetes, the debate will continue unabated. Specifically, this issue of *Diabetes Care* reports on the position statement from the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Titled "Management of Hyperglycemia in Type 2 Diabetes: A Patient-Centered Approach," this effort results from a joint request of the ADA and EASD executive committees and represents the final product of years of work (1). As it has been the case when prior guidelines have been published, not only from these two organizations but also from other societies and federations, this position statement will generate considerable interest, heated debate, and published commentaries, editorials, and letters on the strengths and weaknesses of the approach.

In regard to the message delivered from previously published guidelines, there are providers who strongly feel that given the overall scope of the diabetes burden worldwide and the fact that data continue to state inadequate glycemic control today, an algorithm-based approach should not only be emphasized but also justified. Additional justification for this approach is that it provides a consistent management plan and serves an important purpose to guide providers who may not be as versed in diabetes management. Given the fact that most diabetic patients are not seen in specialized centers, the argument is made that an algorithm-based approach may provide the most feasible management plan that can be applied to the greatest number of subjects. A more defined prescriptive approach is also supported by those who feel that we should reserve the newer therapies only after the traditional agents have failed. In support of this position, the available cost-effectiveness data are cited (although, admittedly, we have very little to date). In addition, the cost of the medication and expense involved in monitoring may be provided as compelling reasons for choosing the specific management approach. On the opposite end of this argument, there is the camp of providers who feel strongly that so much data has accumulated on the pathophysiology of type 2 diabetes that a specific pharmaceutical approach is warranted in that direction. In reality, however, the majority of providers seem to fall squarely between the two management approaches described above. Basing their decision on a number of important factors, they would suggest the use of all agents. This latter approach essentially selects a particular therapy after carefully considering all relevant factors (e.g., comorbidities, disease duration, resources, etc.) that contribute to the ultimate success or failure of the therapy. The approach to consider all factors and individualize therapy is the approach taken in the ADA-EASD position statement. In this regard, the position statement definitely achieves its objectives.

The most attractive aspect of the new position statement is that, more than any other previously reported guidelines to date, it clearly emphasizes that "one size does not fit all." As stated, the recommendations were "less prescriptive than and not as algorithmic as prior guidelines" (1). Given the varied phenotype, genotype, stage of the patient in the natural history of the disease, and current metabolic state of the patient, we, as providers, fully understand that concept. However, if you are a provider, member of a medical care facility, or representative of a health plan and your goal is to address glycemic control issues in your patient population based on an algorithm approach that provided guidance for every step in management, you would certainly not endorse the approach taken by the writing group. Instead, we are provided with recommendations for treatment based on a knowledge and understanding of many patient and clinical factors as required before deciding to implement an individualized treatment plan. The need to pursue "individualized" therapy was clearly accelerated from the findings of the Action to Control Cardiovascular Risk in Diabetes (ACCORD), Action in Diabetes and Vascular Disease: Preterax and Diamicron MR Controlled Evaluation (ADVANCE), and Veterans Affairs Diabetes Trial (VADT) studies when evaluating cardiovascular end points (2–4). As described, not every subject benefited from intensive glycemic management, although there were suggestions that subsets of patients did benefit.

Another area emphasized in the position statement was the need to consider patient preferences in this process. As specifically stated, "Patient involvement in the medical decision making constitutes one of the core principles of evidence-based medicine, which mandates the synthesis of best available evidence from the literature with the clinician's expertise and patient's own inclinations." As such, I really liked the concept emphasized by Fig. 1 in the position statement, and I feel that this graph alone is an incredible teaching tool. This simple graphic provides considerable understanding of the

overall approach and can be especially valuable to primary care providers, medical students, and house officers. Essentially, Fig. 1 depicts the elements of decision making used to determine appropriate efforts for achieving glycemic control. As outlined, this approach encompasses consideration of patient attitudes, risks of therapy, disease duration, life expectancy, comorbidities, presence of complications, and the resources and support systems available. Such a comprehensive approach to care is not addressed by simple algorithms and also argues against the current move to mandate quality indicators for A1C as a determinant in judging how skilled a provider may be in delivering diabetes care. Specifically, the position statement is very clear in arguing for less stringent A1C goals if patients are predisposed to hypoglycemia and have limited life expectancy, advanced complications, extensive comorbidities, or a glycemic target that is difficult to control despite intensive education, counseling, and effective doses of glucose-lowering agents. Yet, one can argue that certain provider practices may have a patient population for which these clinical characteristics are the norm; thus, such a quality indicator as percent of subjects achieving an A1C $<7\%$, as stated by the writing group, in this case, would not adequately reflect the actual standard of care provided by the clinician.

The writing group states that the new position statement does incorporate the best available data to date. As also stated, where solid support did not exist, they used the experience and insight of the writing group and incorporated an extensive review by additional experts. Therefore, the process by which this position statement was developed was not a trivial exercise. It represented an extensive, comprehensive, and well-vetted review process. Each of us has experienced the same frustration when trying to get approval and comments on a single manuscript from one institution and from one research group. The effort involved to review suggestions, edit the narrative, obtain consensus on changes, and have final approval from so many individuals is a real challenge. Can any of us possibly begin to appreciate the tremendous effort and time taken to bring this position statement narrative to fruition?

Essentially, the process began in late 2010 with a joint request by the ADA and EASD executive committees. In September 2010, there was the first organizational meeting at the EASD meeting in Stockholm, Sweden, for which the leadership of the two organizations and the writing group co-chairs met for general discussions and an agreement on time lines. From October to November 2010, the committee members (four from each organization in addition to the co-chairs) were selected, invited, and approved. From February to April 2011, there were countless communications from which the scope of the paper was determined, the writing plan and time line were discussed and approved, literature was reviewed, and a bibliography was created. By this point, there was full consensus on the statement's scope and outline. By May 2011, writing assignments were given to each committee member and a first draft was created. From May through September 2011, there were three face-to-face meetings, including one each at the ADA Scientific Sessions in San Diego, California, and EASD meeting in Lisbon, Portugal. During these gatherings, there were line-by-line reviews of the draft, multiple revisions, and creation and approval of the main figures and table. Full consensus on the final draft was not reached until December 2011. At that time, individual experts from North America, Europe, Australia, and Asia were asked to review the available draft. This list included representation from endocrinology, primary care/family medicine, cardiology, nursing, diabetes education, and pharmacy. Feedback, responses, and revisions from 26 individuals were compiled, and the resulting penultimate draft was then submitted to the ADA's Professional Practice Committee, the EASD's Panel for Overseeing Guidelines and Statements, and five sister organizations (including The Endocrine Society, American College of Physicians, and American Association of Diabetes Educators). Final revisions were made based on this input. The final draft was then submitted for endorsement and signoff from the executive committees of the ADA and EASD. In February 2012, a final version was submitted to both *Diabetes Care* and *Diabetologia*. By that time, it had been revised over 45 times! In summary, the proposed "patient-centered approach" highlighted in the new position statement provides not only the most comprehensive management strategy to date but also the most vetted and thoroughly reviewed management strategy for diabetes ever published.

Therefore, it goes without saying that with the publishing of the new ADA-EASD position statement in this month's issue of *Diabetes Care*, we begin a new era of debate for diabetes management. In essence, this narrative will not address every provider's concerns. In a way, it will only "add more fuel the fire" for those who disagree with a specific statement or with the overall approach proposed. As editor in chief, I fully expect to receive many requests for commentaries and letters to the editor to be published and that outline either specific concerns of individuals or, for that matter, opinions strongly endorsing the guidelines. I expect my counterpart at *Diabetologia* to be faced with a similar deluge of communications. These different views will be given consideration for publication in *Diabetes Care*, as these views will also be given a voice in other professional publications. No one would argue that the position 2statement answers all questions. However, as stated, this approach appears to be extremely rational, comprehensive, and very thoughtful in regards to the management of hyperglycemia in type 2 diabetes. This approach put forth by the writing group is the reason many of us have chosen medicine as a career. It is an expansive approach that suggests recommendations considered "within the context of the needs, preferences, and tolerances of each patient." I strongly endorse the statement that "informed judgment and the expertise of experienced clinicians will therefore always be necessary." Thus, the method put forth by the writing group advocates a practice for diabetes care truly based on the art of medicine.

In summary, we now have the new position statement of the ADA-EASD that endorses a patient-centered approach. I am certain that there will be a wide range of opinions and emotions generated with the statements or recommendations put forth by the writing group. However, there is one aspect that no one will disagree with, and that is that "due diligence" for this initiative was clearly conducted and that the findings were clearly vetted. With that being said and with that background, let the debate begin!

William T. Cefalu, MD

From the Joint Program on Diabetes, Endocrinology and Metabolism, Pennington Biomedical Research Center, Louisiana State University (LSU) System, Baton Rouge, Louisiana; and the Louisiana State University Health Sciences Center School of Medicine, New Orleans, Louisiana.

Corresponding author: William T. Cefalu, william.cefalu@pbrc.edu.

DOI: 10.2337/dc12-0564

Acknowledgments—No potential conflicts of interest relevant to this article were reported.

References

1. Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach. Position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 2012;35:1364–1379
2. Turnbull FM, Abraira C, Anderson RJ, et al. Intensive glucose control and macrovascular outcomes in type 2 diabetes. Diabetologia 2009;52:2288–2298
3. Gerstein HC, Miller ME, Byington RP, et al.; Action to Control Cardiovascular Risk in Diabetes Study Group. Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med 2008;358:2545–2559
4. Patel A, MacMahon S, Chalmers J, et al.; ADVANCE Collaborative Group. Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes. N Engl J Med 2008;358:2560–2572