American Diabetes Association's Standards of Care: A Paradigm Shift in the Dissemination of Information

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Diabetes Care 2018;41:387–388 | https://doi.org/10.2337/dci17-0064

It is well understood that diabetes is a complex, chronic illness in which glycemic control reduces the development and progression of macrovascular and microvascular complications. Achieving risk reduction requires continuous medical care and self-management, with multifactorial risk-management strategies beyond just glycemic control, including lifestyle changes and cardiovascular risk reduction. Given the current knowledge of what is required to reduce complications, improve quality of life, and prevent progression to overt disease states, it is important that providers caring for people with diabetes have the latest and most updated clinical translation of the evidence as they consider the day-to-day management of their patients. In this regard, the American Diabetes Association (ADA) has been actively involved in the development and dissemination of diabetes care standards, guidelines, and related documents to support and improve patient care for over 25 years. Specifically, the ADA's "Standards of Medical Care in Diabetes," referred to as the Standards of Care, has always been intended to provide clinicians, patients, researchers, payers, and other interested individuals with evidence-based information on all aspects of diabetes care, general treatment goals, and tools to evaluate the quality of care (1).

The recent acceleration of the pace of new information being released regarding diabetes care and research has been startling. To put this in perspective, the first ADA Standards of Care, published in 1989, provided recommendations based on the available evidence at that time and filled only four pages in *Diabetes Care* (2). In the most recent update, 28 years later, the document is well over 170 pages! Over 40 new type 2 diabetes treatment options have been approved since 2005 (3), not even counting advances in technology, such as continuous glucose monitoring. In the last year alone, there have been many significant changes to the Standards of Care, and the 2018 version incorporates new information on cardiovascular disease risk management, diabetes management technology, the appropriate use of A1C, and risk factors for type 2 diabetes in youth (4). With this rapid pace of new information, releasing new recommendations on an annual basis is no longer sufficient. Thus, beginning in 2018, the ADA will update and revise the online version of the Standards of Care throughout the year, making necessary additions and annotations as new evidence and regulatory changes merit immediate incorporation. Some theoretical examples of updates that may be considered "event driven" and "update worthy" could include the following:

- The U.S. Food and Drug Administration makes a decision to approve metformin for prevention in people with prediabetes
- A major clinical trial provides evidence that a particular therapy is substantially better (or worse) than conventional therapy
- A new drug is approved
- New or updated consensus definitions or positions of the ADA are released

The living Standards of Care represent a paradigm shift that reflects the ADA's goal and desire to get the latest information into the hands of providers as soon as possible to meet our mission objective to "improve the lives of all people living with diabetes." Potential updates may be suggested by ADA staff, members of the diabetes community, or members of the Professional Practice Committee (PPC), the ADA expert committee tasked with updating the Standards of Care. In every case, the option to update the Standards of Care during the year will be the decision of the PPC, who will determine whether new evidence or regulatory changes merit immediate incorporation.

The changes to the Standards of Care described above will ensure that they provide clinicians, patients, researchers, and health plan and policy makers with the most up-to-date information on diabetes care. To underline the need for a living Standards of Care, two specific examples faced the PPC in December 2017, just days after the 2018 Standards of Care was publicly released. First, semaglutide was approved for use in type 2 diabetes on December 5, just days prior to the release of the Standards of Care. Semaglutide is a glucagon-like peptide 1 receptor agonist with apparent cardiovascular benefits for people with type 2 diabetes. As this

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was not an approved agent at the time the PPC reviewed the data for 2018, a recommendation could not be made in the 2018 Standards of Care. Second, a consensus report on clinically meaningful outcome measures beyond A1C for type 1 diabetes representing a consensus from the diabetes community (including the ADA) was published in the December issue of *Diabetes Care* (5), again too late to be incorporated into the Standards of Care by the PPC.

Such topics in the past would have to wait until the following year to be incorporated into the Standards of Care. However, as the Standards of Care are now a "living" document, there is an opportunity for this type of information to be incorporated throughout the year after PPC review and approval. Thus, while the Standards of Care will continue to be updated annually, it may also be updated more frequently online should the PPC determine that new evidence or regulatory changes (e.g., drug approvals, label changes) merit immediate incorporation.

In addition to making the Standards of Care a living document, the ADA is also revising and clarifying the other types of scientific and medical reports that it produces. Moving forward, the ADA will publish Standards of Care, ADA statements, consensus reports, and scientific reviews as outlined below (1). The Standards of Care is an official ADA position authored by the ADA and overseen by the PPC that provides ADA's current clinical practice recommendations. The PPC is a multidisciplinary team of approximately 12 leading experts in the field of diabetes care and includes physicians, diabetes educators, registered dietitians, and others whose experience includes adult and pediatric endocrinology, epidemiology, public health, lipid research, hypertension, preconception planning, and pregnancy care. This group performs an extensive clinical diabetes literature search, supplemented with input from ADA staff and the medical community at large, and synthesizes all new, pertinent information into the Standards of Care. The final document is reviewed and approved by the ADA's Board of Directors and traditionally appears as a supplement to the January issue of *Diabetes Care*.

In the past, in addition to the Standards of Care, the ADA has also published topic-specific position statements, which represented an official ADA point of view or belief on advocacy, policy, economic, or medical issues related to diabetes. By their nature, many of these position statements contained recommendations for clinical practice (1). The ADA is now moving away from this paradigm, to avoid a situation in which recommendations in a position statement are out of sync with those in the Standards of Care. The Standards of Care will now be the sole source of official ADA clinical practice recommendations.

The ADA will continue to publish consensus reports, which represent an expert consensus opinion and generally contain a comprehensive examination of a particular topic. Consensus reports, in contrast to the Standards of Care, are authored by an ad hoc expert panel, and the reports represent the panel's collective analysis, evaluation, and opinion but are not an official ADA position. The need for an expert consensus report arises when clinicians, scientists, regulators, and/or policy makers desire guidance and/or clarity on a medical or scientific issue related to diabetes for which the evidence is contradictory, emerging, or incomplete.

The ADA will also now publish scientific reviews: in-depth, balanced reviews and analyses of the literature on a scientific or medical topic related to diabetes. A scientific review is also not considered an ADA position and does not contain official clinical practice recommendations but, again, is produced under the auspices of the ADA by invited experts. Importantly, however, a scientific review or consensus report may provide a scientific rationale for clinical practice recommendations that will end up informing the Standards of Care. Members of the medical and scientific community are encouraged to submit proposals for consensus reports and scientific reviews at professional.diabetes.org/soc.

Finally, the ADA will periodically publish ADA statements that represent an official ADA point of view or belief that does not contain clinical practice recommendations and may be issued on advocacy, policy, economic, or medical issues related to diabetes (e.g., the Economic Costs of Diabetes report that ADA produces every 5 years). ADA statements undergo a formal review process, including a review by the appropriate national committee, ADA mission staff, and the Board of Directors.

As we move into this new paradigm, the Standards of Care will supersede all previous ADA position statements, and the Standards of Care will represent the one document containing all official clinical recommendations of the ADA. Previously published ADA position statements, while still containing valuable analyses, will not be considered the ADA's current official position.

In addition to the paradigm shift of new data being incorporated into the Standards of Care on an ongoing basis, the Standards of Care will also be available as a user-friendly and interactive app for both web and mobile devices. The app allows clinicians access to the most up-to-date information and includes convenient tools, such as a diabetes risk calculator and interactive diabetes treatment algorithm.

These changes underline the intent of the ADA to innovate and refine the Standards of Care to ensure that they are as current and user-friendly as possible for clinicians, and health plan and policy makers who rely on them as the most authoritative and current guidelines for diabetes care. As we move forward, the Standards of Care will continue to promote an "individualized" approach to diabetes management based on current evidence and will continue to support the use of technology to improve diabetes care and self-management. Thus, with the reinvention of the Standards of Care as a living document and a new interactive app, users of the Standards of Care will have the absolute latest information on diabetes care and research at their fingertips. All this is part of our mission effort "to prevent and cure diabetes and to improve the lives of all people affected by diabetes."

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

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