It's All About Access!

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My childhood friend, Melissa Burns, was diagnosed with type 1 diabetes at the age of 5 years. She did not have access to the medications of today, nor to quality health care. Although she and her family worked hard to manage her diabetes, in 2002, she died in her early 30s of diabetes complications.

Melissa is one reason why I am passionate about diabetes care, education, and research and the main reason I want to focus here on the issue of access to diabetes care. I will focus specifically on areas that I see affecting quality of life and health outcomes for people with diabetes, from the perspective of a diabetes educator working in population health management in a 10-hospital health care system in Maryland and Washington, DC.

“Access” is defined as “the ability to use, enter, or get near [something] (1).” But what does access really mean to people with diabetes (PWD), to society, and to the U.S. health care system? It means *everything*.

For PWD, access is the foundation of optimal health outcomes, quality of life, and affordable medical costs. For society and the health care system, adequate access is one way to help control the health impacts and rising cost burden of diabetes.

Health Policy: Building a Foundation

The first area I would like to focus on is policy, which supports each aspect of access that I will discuss subsequently. The World Health Organization defines “health policy” as “decisions, plans, and actions that are undertaken to achieve specific health care goals within a society (or population) (2). Herein, my use of this term aligns with this definition.

The American Diabetes Association (ADA) is working hard to effect health policy change. The ADA's Government Affairs and Advocacy team tackles the everyday realities that challenge people with diabetes and the diabetes ecosystem. Among the many things they work on are:

- Improving access to diabetes self-management education and support (DSMES)
- Securing diabetes research funding
- Ensuring access to insulin
- Expanding access to health care
- Eliminating various forms of workplace discrimination

The ADA's proactive health policy initiatives provide support for efforts to improve access for PWD on a variety of fronts.

Access to Prevention Services

I am sure most readers of this article are familiar with the National Institutes of Health–funded Diabetes Prevention Program (DPP) (3) and its follow-up DPP Outcomes Study, which is still ongoing after more than 2 decades (4,5). Earlier in my career, I had the opportunity to work as the program manager at the MedStar Health Research Institute's DPP site in Washington, DC. The DPP study demonstrated that intensive lifestyle intervention reduced the incidence of type 2 diabetes by 58%, whereas metformin therapy reduced the incidence of diabetes by 31% (3).

More than one-third (33.9%) of U.S. adults, representing 84.1 million people, have prediabetes. Thus, there is an ever-increasing need for diabetes prevention services to help stem the rising burden of diabetes on people with the disease, their health care providers, and the larger health care system (6). To address this need, the Centers for

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Disease Control and Prevention launched the National Diabetes Prevention Program (National DPP) in 2010. And in 2018, the Centers for Medicare & Medicaid Services began covering participation in related Medicare DPP programs for Medicare recipients (7).

Early results from the National DPP have been promising, but they also highlight the challenges of translating interventions from randomized controlled trials into real-world settings. We need to learn from successful participants and programs which practices facilitated their success. Conversely, we must learn from those who did not meet the program's lifestyle change goals what can be done differently to improve success rates, particularly in high-risk communities. In addition, we need to continue advocating for increased payer reimbursement for participation in and payment for the provision of National DPP and Medicare DPP programs.

Access to Affordable Medications

Access to and affordability of insulin are pressing public health issues in the United States at present. This year, it has been hard to open a newspaper or turn on a radio without hearing about the staggering cost of insulin and the impact that cost is having on the lives of PWD (8). In the most extreme cases, there have been deaths, particularly among young PWD, who have rationed their insulin because of its high price.

PWD not only are challenged by the omnipresent daily demands of diabetes self-care, but also must often face the reality of not being able to afford the medications they need to live well and adequately manage their disease. Shockingly, the average price of insulin has more than tripled since 2002, causing some PWD to have to choose between paying for insulin or paying for other necessities such as food, utilities, and rent (8,9). Today, a vial of rapid-acting insulin can cost from \$203 to \$343 using a GoodRx coupon (10). Compare that to the Veterans Administration's contracted cost of a vial of rapid-acting insulin, which is as low as \$21–56 (11). The retail cost is 15 times higher than the VA contracted price. What is still not clear is why insulin is so expensive and what happens to increase its retail cost between the day it is manufactured and the day someone picks it up at a pharmacy.

Currently, 7.4 million Americans with diabetes use insulin, including 24% of adults with diabetes whose income is less than the federal poverty level, making them particularly vulnerable in the face of high insulin prices (9).

I was recently talking with Robert Eckel, ADA's 2020 President, Medicine & Science, about his two sons, Clark and Peter, both of whom have type 1 diabetes. The Eckels

have faced an additional cost issue affecting access to medications: high insurance deductibles. For Dr. Eckel's sons, these deductibles have ranged from \$7,500 to \$10,000 for the past 2 years. While at a professional meeting in Paris, France, in 2018, Dr. Eckel went shopping, not to buy a bottle of Chanel perfume for his wife, but rather to buy insulin for his two sons. His bill came to \$385 USD, but the same amount of the same type of insulin would have cost him more than \$1,900—five times as much—back in the United States (10).

Unfortunately, purchasing insulin in another country is not a realistic strategy for most PWD, and it certainly is not a viable long-term solution to the current high cost of insulin here in the United States. The ADA is focused on continuing to work with members of Congress and all stakeholders to find solutions that can help reduce these unreasonably high costs for all Americans who use insulin. Listed below are some programs that offer options for PWD who do not meet the requirements of coupon or other insulin assistance programs because of their income or insurance status.

- Sanofi's Valyou savings program. People living in the United States who have no prescription drug coverage can purchase a month's supply of one or two different Sanofi insulin products for a total of \$99 per month with valid prescriptions (12).
- Lilly's authorized generic version of Humalog. The company in 2019 released a lower-priced version of Humalog that sells for \$137.35 per vial or \$265.20 for 5 pens—50% lower than the usual list price for Humalog (13).
- Novo Nordisk's Novolin ReliOn insulins at Walmart. NPH, regular, and 70/30 formulations of ReliOn human insulin (not insulin analogs) sell for about \$25 per vial at Walmart and Sam's Club pharmacies and can be purchased without a prescription (14).

Some of these discount prices may still seem high, and using human insulin products such as those sold at Walmart poses more challenges than using newer-generation analog insulin products. However, by decreasing out-of-pocket monthly insulin costs from more than \$1,000 to \$99, such programs provide options for people who otherwise could not afford insulin at all. Interestingly, based on a national telephone-based survey of Walmart and chain pharmacies across the United States, it has been estimated that Walmart sells up to 18,000 vials of ReliOn insulin per day (15).

The ADA has made insulin access and affordability one of its highest-priority advocacy issues. In 2017, the

Association's board of directors convened an Insulin Access and Affordability Working Group led by former ADA Chief Scientific, Medical & Mission Officer William T. Cefalu. This group examined the full scope of the issue and met with more than 20 stakeholders in the insulin supply chain, publishing its conclusions and recommendations in *Diabetes Care* in 2018 (9).

Since May 2018, there have been 12 hearings on Capitol Hill regarding prescription affordability. Although these hearings are a step in the right direction, no policy has yet emerged, and no laws have been enacted. So, what can Congress do to make insulin more affordable, and what should your "elevator speech" be when advocating for people who depend on insulin? The following four goals have been identified as key legislative actions to address this problem on a national level (9):

- Increasing pricing transparency throughout the insulin supply chain
- Lowering or removing patient cost-sharing for insulin
- Streamlining the approval process for lower-cost biosimilar insulins
- Increasing access to health care coverage for people with diabetes

What else can you do?

- Get mad. We have been dealing with this dire situation far too long.
- Sign the ADA insulin petition, and ask your patients to do the same. You can find the petition at makeinsulinaffordable.org. To date, about a half million persons have signed. With more than 7 million PWD using insulin, we need every one of them to sign, as well as their friends and relatives.
- Contact your Congressional representatives, send letters, and respond when you receive calls to action from the ADA, the American Association of Diabetes Educators (AADE), and other stakeholder organizations.

Access to DSMES Programs

The ADA's Education Recognition team is responsible for assisting about 3,800 DSMES sites across the United States in obtaining and maintaining their ADA recognition. The AADE also offers accreditation for DSMES programs. Both organizations are national accrediting organizations for Medicare, and the programs they certify follow the National Standards of DSMES (16) and Medicare requirements (17).

Numerous studies have demonstrated the benefits of DSMES (18–20); however, these programs continue to be grossly underutilized, with <5% of Medicare beneficiaries

and <7% of individuals with private insurance receiving DSMES within the first year of diagnosis (21,22).

In 2012, only 1.7% of Medicare beneficiaries with diabetes had a Medicare claim for DSMES (23).

Poor access to diabetes education continues to be a major impediment to PWD gaining the skills and knowledge they need to effectively manage this complicated chronic medical condition. One problem is that the Medicare reimbursement rules have not caught up with the changing landscape of the current health care environment, resulting in cost barriers for DSMES participants and for DSMES provider programs, both of which hinder the timely delivery of these important services.

In 2019, the ADA, in partnership with the Diabetes Advocacy Alliance, introduced a bill to the U.S. House of Representatives and the U.S. Senate to try to solve this problem (24). The Expanding Access to Diabetes Self-Management Training (DSMT) Act, if enacted into law, would remove barriers to DSMES (or DSMT, as it is called for Medicare beneficiaries), by:

- Allowing providers who are not directly involved in managing diabetes to refer their patients with diabetes to DSMT services
- Allowing carryover of the 10 hours now approved in year 1 (the first year the benefit is used) to future years, as well as six additional hours of DSMT services if needed initially
- Increasing from 2 to 6 the number of hours of DSMT covered in subsequent years
- Eliminating copayments for DSMT and excluding DSMT costs from deductible requirements
- Allowing DSMT services to be provided in community-based locations
- Establishing a 2-year demonstration project for electronic provision of DSMT, potentially paving the way for future Medicare coverage of virtual services

Access to Diabetes Education

When the many barriers to DSMES are removed, other important issues related to access will also need to be addressed. These include the question of whether there will be enough programs and educators to accommodate all people with diabetes and whether existing programs are located in the areas of greatest need.

As shown in Figure 1, there are >30 million people with diabetes in the United States (25) and just over 6,000 DSMES sites certified as of May 2019 (G.A.Y., personal communication). At current numbers, each site would need

FIGURE 1 Access to DSMES programs as of May 2019. *Source: author's personal communication with ADA and AADE DSMES program directors.

to serve ~5,000 PWD per year, which is well beyond the capabilities of most existing sites.

Figure 2 shows the distribution of DSMES sites across the United States as of April 2018. Jayapaul-Philip et al. (26) developed this map of county-level DSMES program availability data superimposed on diabetes prevalence rates. Based on these data, only 48% of the 4,200 programs included in this effort have at least one DSMES site; only 39% of the counties in the highest diabetes prevalence tertile have DSMES programs, compared with approximately half

of the counties in the middle and lowest tertiles, which have lower diabetes prevalence rates. This geo-information dramatically highlights the lack of access to DSMES in many communities throughout the country.

Addressing this shortage of educators and DSMES programs will be key to ensuring optimal outcomes for PWD. As shown in Figure 3, there are currently ~20,000 certified diabetes educators (CDEs) in the United States, most of whom are registered nurses or registered dietitians. Pharmacists, mental health providers, physical therapists, exercise physiologists, and others make up the balance (27). Compounding the shortage, not all of these CDEs work full time, and they also often have other job responsibilities, such as case management and research. Conversely, there are diabetes educators practicing in the field without the CDE credential. At present, there is just one CDE for every 1,500 PWD. A full-time CDE working in an education center could theoretically see each of 1,500 PWD for only 1 hour each a year. Clearly, there are not enough of us.

According to current recommendations, there are four crucial times when PWD should receive DSMES: at diagnosis, for an

FIGURE 2 Counties with at least one DSMES service location as of April 2018, by diabetes prevalence. Data sources: Centers for Disease Control and Prevention, 2016, www.cdc.gov/diabetes/data/countydata/statecountyindicators.html; ADA and AADE program data. Reprinted with permission from ref. 26.

FIGURE 3 Access to DSMES providers (25,27).

annual assessment, when complicating factors occur, and during transitions in care (20). Unfortunately, in my experience, most PWD may receive DSMES at diagnosis if they are lucky and after that only if or when complicating factors arise.

I would like to make the case that it is time for the diabetes health care provider community to look differently at how we provide DSMES and diabetes management services across the care continuum. We also need to explore how best to optimize the integration of DSMES at each health care and community touch point with PWD. As educators, we need to find ways to expand the services we offer and to better integrate our services within existing systems to increase the number of PWD who we can reach. Diabetes educators need to be where the patients are. This may mean offering diabetes education in primary care offices, in emergency rooms and hospitals, and in community-based locations such as recreation centers and senior housing facilities to improve ease of access.

We also need strategies to improve the cost-effectiveness of diabetes education delivery. For example, skills such as how to use a blood glucose meter can be taught by a clinic's medical assistant, whereas the more specialized task of interpreting blood glucose results can be taught by the diabetes educator.

As the rapidly evolving U.S. health care ecosystem moves from fee-for-service to value-based care, many health care providers find themselves straddling the crevasse between the two systems. Diabetes educators are in a unique position to evolve in their roles and position themselves to meet the needs of their patients, primary care providers, health care systems, population health management teams, and payers as premier providers of quality diabetes care and education across the life continuum. It is time for diabetes educators, working with other health care providers; with organizations such as ADA, AADE, and the National Certification Board for Diabetes Educators; and with other diabetes stakeholders, to step up to realize our full potential to

drive change. With such a renewed effort, I feel strongly that we can help to realize improved outcomes for PWD.

Diabetes Population Health Management: A Case Example

The population health management journey at MedStar Diabetes Health Institute has included an evolving role for our diabetes educators, and many of the program elements we have implemented have improved access for PWD, enhanced support for primary care providers (PCPs) and endocrinologists in their care of patients, and resulted in improved quality of care, health outcomes, and patient and provider satisfaction.

Our team started its journey into population health management in 2012 by completing a needs assessment and identifying all diabetes stakeholders in our system. This was an 18-month process that resulted in leadership and provider buy-in and support of the program. As part of this assessment, our population with diabetes was stratified, as shown in Figure 4.

We developed a Diabetes Boot Camp program focusing on the high-risk, high-cost patients at the top of the risk stratification pyramid—those with an A1C $\geq 9\%$ —to maximize our clinical and economic impact (28). Patients are referred to the Boot Camp by their PCP or endocrinologist to participate in an intensive and concise medication management and education intervention of 12 weeks' duration.

The program begins with two face-to-face intensive DSMES/medical nutrition therapy visits with the CDE. During these visits, an in-depth assessment is completed that covers barriers to self-care, including access to medications and healthful food choices and other social determinants of health that may

FIGURE 4 Risk stratification by A1C level for MedStar's diabetes care pathway. *DSMES and medication nutrition therapy referral. T2DM, type 2 diabetes mellitus.

negatively affect outcomes. Participants commit to checking their blood glucose two times per day using the Biotel blood glucose monitoring system, a technology-enabled system that transmits each blood glucose check via cellular networks to a dashboard in our virtual clinic. After the two in-person visits, participants then move on to 10 weeks of virtual clinic follow-up by diabetes specialty nurse practitioners, who provide access to virtual DSMES and care via phone, text, or email. At 12 weeks, participants return to their PCP for care.

To evaluate this program, our first 366 participants with both pre- and post-program A1C values available were compared with concurrent, matched-chart control subjects who received usual care. The mean age of our participants was about 57 years, 62% were female, 81% were African American, 42% were Medicaid recipients, and 18% were on Medicare. The absolute decrease in A1C was 3.1% in the intervention group compared with 1.4% in the matched control group—a difference of 1.7% between groups. Participants in our Boot Camp also had decreases in 30- and 90-day pre- and post-intervention hospitalization rates of 79 and 77%, respectively, compared with increases of 14 and 58%, respectively, in the matched control group. Finally, participants, referring providers, and the Boot Camp CDEs and nurse practitioners were very satisfied with the program.

This technology-enabled intervention decreased hospital utilization, improved patient outcomes, resulted in high levels of patient and provider satisfaction, and demonstrated to our health care system the value of diabetes educators in population management.

The Boot Camp educators, who are registered dietitians, registered nurses, and pharmacists, took on nontraditional roles, including:

- Facilitating the use of near real-time blood glucose monitoring, which provided teachable moments when high or low blood glucose levels occurred and timely medication and lifestyle adjustments
- Carrying out shared decision-making with participants when adding new diabetes medications, which helped to address medication access issues
- Making adjustments to diabetes medications based on an evidence-based algorithm, with oversight by an endocrinologist and diabetes nurse practitioner
- Providing virtual diabetes education and management, which eased the barrier of attending multiple in-person visits and allowed for the timely provision of care

These nontraditional roles for diabetes educators, as well as the availability of virtual education, improved access to DSMES and to timely care management for PWD. Such an approach could increase reach for clinics with limited CDE support.

Conclusion

When it comes to diabetes care and education, it's all about access. Ensuring access to medications, multidisciplinary diabetes care providers, and evidence-based DSMES programs will provide PWD with the tools they need to meet their individualized diabetes management goals and enjoy good health.

Because health policy drives access, I encourage all diabetes health care professionals to get or stay involved in advocacy, be a voice for diabetes, and support the ADA and those you care for who are living with or at risk for diabetes. Sign up to become a diabetes advocate at diabetes.org/advocatesignup.

The U.S. health care environment is rapidly changing, and all diabetes stakeholders must remain agile and flexible to ensure our success as a community for positive change on behalf of PWD. Diabetes educators must play an integral role in diabetes management as key members of interdisciplinary health care teams. All diabetes care providers must be willing to move beyond traditional roles and traditional care models when necessary to achieve patient-centered goals. On behalf of the ADA and myself, I strongly urge all diabetes health professionals to become agents for change to help break down all barriers to access for PWD.

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