American Diabetes Association®

Dear ADA Professional Member:

One of the American Diabetes Association's (ADA's) core mission goals is to improve the lives of all people affected by diabetes. It's what we do every day across all areas of the organization, and it's what our people are passionate about. At the ADA, we recognize that therapeutic inertia is a substantial barrier to that goal, but 2019 is the year when we all start to do something about it. Despite the availability of 40 new branded medications developed in the past 20 years, as well as a wealth of education and information resources for people who have the disease, the hard truth we must face is that the average A1C in the United States has not substantially changed in the past decade. We cannot allow this to continue.

As an important starting point to addressing barriers to accelerating care, the ADA hosted a full-day summit on Overcoming Therapeutic Inertia and invited more than 130 professionals from across the spectrum of care, including clinicians, diabetologists/endocrinologists, primary care providers, researchers, patients, payors, and representatives from health systems, industry, diabetes nonprofit organizations, technology companies, and more. More than 98% of invited attendees participated in the summit, demonstrating an incredible level of interest in finding solutions to this perplexing problem. Not only was attendance high, but interaction was even higher. For every session, there were more questions than the speakers had time to answer. Well over 200 comments were submitted throughout the day.

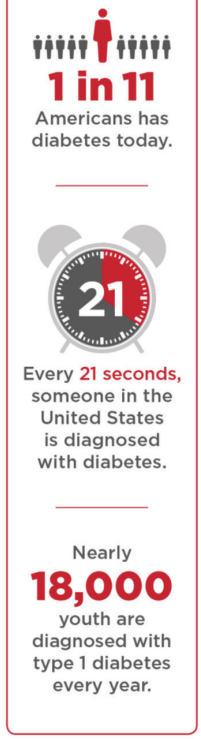
A steering committee representing many of the key stakeholders in attendance met the following day and discussed the presentations and all of the feedback received. After this thorough review, several key themes began to emerge, and some gaps in stakeholder representation were identified. This Summary of Proceedings includes brief recaps of the main issues discussed by each stakeholder group, major needs identified, steering committee recommendations, and a high-level timeline for next steps. The Summit was an incredible first step toward our goal of developing disruptive strategies to eliminate the problem of therapeutic inertia.

One thing we can be sure of: this problem is too big for any one stakeholder to address, and we can only achieve a successful solution by working together. The problem won't be solved with only pockets of participation or with some stakeholders left out of the discussion. We all need to be in this for the long haul, and all stakeholders need to do their part.

I want to thank all of the summit participants for making their time and expertise available to this cause, and especially our steering committee members, who have devoted many additional hours to finalizing this summary and leading the way forward. I also want to thank our sponsors for their generous contributions, which allowed this meeting to take place. We have included a list of those sponsors on the inside back cover of this summary.

If you wish to lend your expertise to our efforts by participating in a future work group, are interested in being a sponsor of our continued efforts, or just want to be informed of our progress, please reach out by sending an email to therapeuticinertia@diabetes.org. You can also receive the latest information and updates by visiting professional.diabetes.org/therapeuticinertia, where we will post significant updates. We have already posted a roster of summit attendees and the presentations given at the summit on the site.

All of us at the ADA are thrilled with this strong start to addressing this huge unmet need in clinical care. By working together and leveraging resources, we can overcome therapeutic inertia and truly improve the lives of individuals with diabetes. We look forward to having you join us to help millions of people live longer, better lives through our combined efforts.



Sincerely,

William T. Cefalu, MD

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Summary of Proceedings of the American Diabetes Association Summit "Overcoming Therapeutic Inertia: Accelerating Diabetes Care FOR_LIFE"

Despite comprehensive treatment recommendations, the continuous introduction of new medications that address unmet clinical needs, and significant advances in medical device technologies, a substantial percentage of individuals with diabetes are not achieving their treatment goals, resulting in poor health outcomes (1,2). A recent study by Carls et al. (1) compared data from 2,677 adults with self-reported diabetes from the National Health and Nutrition Examination Survey (NHANES) 2007–2010 and 2011–2014 survey periods and found that achievement of individualized glycemic targets declined from 69.8% in the earlier period to 63.8% in the later period, and the percentage of individuals with an A1C >9.0% increased from 12.6 to 15.5% over that interval.

The term clinical inertia, defined as "failure of health care providers [HCPs] to initiate or escalate therapy when indicated," has been in use for nearly two decades (3), and numerous studies have focused on clinician and patient behavior, as well as health system factors (4,5), as reasons for suboptimal glycemic control. However, inertia in the management of diabetes is a serious, multifactorial problem involving all stakeholders in the diabetes ecosystem: patients, clinicians, health systems, payors, and industry. Thus, the term therapeutic inertia has been adopted to encompass all forces and factors that contribute to delay in implementing the most effective care for each person with diabetes. This term emphasizes the breadth of the problem and the need for cooperation among all stakeholders to develop solutions.

Although glycemic control is the most frequently considered and measured variable for assessing therapeutic inertia, numerous other factors are important to ensuring optimal health for people with diabetes; these include lipid and blood pressure control, medication adherence, healthy eating, physical activity, behavioral health, smoking cessation, and routine examinations.

Recognizing that all stakeholders must play a role in addressing this important health concern, the American Diabetes Association (ADA) convened a summit titled "Overcoming Therapeutic Inertia: Accelerating Diabetes Care FOR_LIFE" on 28 November 2018, in Arlington, VA, to identify and assess issues related to therapeutic inertia, discuss barriers, and develop solutions and next steps that will have a significant impact on long-term outcomes. Funded by the ADA's industry partners, the summit brought together more than 100 members of the diabetes health care ecosystem, including interprofessional primary care providers (PCPs), diabetes specialists, and representatives from health systems, payor organizations, and patient advocacy groups. A list of participants is included in Appendix 1, and the summit agenda is presented in Appendix 2.

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Representatives from each of these stakeholder groups presented scientific evidence and their personal and professional perspectives on the impact of, barriers leading to, and possible solutions for therapeutic inertia. Summit participants provided input after each group of presentations through moderated discussion sessions. Specific feedback requested during the opening presentation can be found in the "word cloud" figures in Appendix 3. Comments submitted by participants throughout the summit (edited for spelling and punctuation only) are included in Appendix 4.

This report provides a summary of stakeholders' key concerns and proposed solutions and outlines the summit Steering Committee's recommendations for developing the objectives, strategies, and performance metrics that will guide implementation of the ADA's "Overcoming Therapeutic Inertia" campaign.

Summary And Recommendations

The invited lecturers' presentations and input from summit participants served as the basis for the following summary of proceedings.

"OVERCOMING THERAPEUTIC INERTIA" CAMPAIGN

"Overcoming Therapeutic Inertia" will be a multiyear campaign to reduce therapeutic inertia in the management of type 1 and type 2 diabetes in adults. The ADA has accepted leadership responsibility for the campaign as an expansion of its mission to improve the lives of people affected by diabetes. In addition to its established collaborations with stakeholders, industry partners, and health care delivery systems, the ADA has several platforms and channels to reach crucial audiences and is well-positioned with the tools necessary to execute meaningful and sustainable change.

Although therapeutic inertia affects all populations, the campaign will initially target adults with type 2 diabetes as its first priority, focusing on PCPs, who are the principal providers of diabetes care to this population. Lessons learned will apply moving forward with the campaign to address type 1 diabetes, gestational diabetes, and prediabetes in adults.

The campaign will be executed in three phases:

- **Phase 1.** Convene a summit to obtain input from stakeholders and develop recommendations for implementation. This is a summary of the proceedings of the Phase 1 summit.
- **Phase 2.** Develop and strengthen partnerships and collaborations with additional stakeholder groups, determine priorities, and begin to devise solutions to therapeutic inertia.
- **Phase 3.** Implement solutions, measure results, and accelerate diabetes management globally to improve outcomes based on ADA's Standards of Medical Care in Diabetes (6).

PREVALENCE AND COST OF DIABETES

***William T. Cefalu, MD,** Chief Science, Medical & Mission Officer, American Diabetes Association, Arlington, VA, summarized the prevalence and costs of diabetes in the U.S.*

The Centers for Disease Control and Prevention (CDC) estimates that 30.3 million people of all ages (9.4% of the U.S. population) had diabetes in 2015, and that diabetes reached a high of 25.2% among those ≥65 years of age (7). It was also estimated that 84.1 million Americans had prediabetes (7). Diabetes results in 277,000 annual premature deaths, and more than 300 million work days are lost every year because of diabetes (8).

In 2017, the estimated total cost of diagnosed diabetes in the U.S. was $327 billion; one in every four health care dollars was spent for the care of people with diabetes (8). This includes $237 billion spent on direct medical costs and $90 billion in reduced productivity (8). Approximately $31 billion are spent annually directly on diabetes medications, $15 billion of which is for insulin (8). From 2012 to 2017, the cost of diabetes medications increased by 45% (adjusted for inflation) (8). The increase in costs can be attributed to both the rising prevalence of diabetes and the increased cost per person affected.

EVIDENCE AND IMPACT OF THERAPEUTIC INERTIA

***Kamlesh Khunti, FMedSci, FRCGP, FRCP, MD, PhD,** Professor, Leicester Diabetes Centre-Bloom, Leicester, U.K., presented an overview of the scope and impact of therapeutic inertia.*

Large randomized controlled trials have demonstrated that achievement of target glucose levels early in the course of diabetes leads to better microvascular outcomes in the short term and better cardiovascular outcomes in the long term (5,9–13). This suggests that there is a positive legacy effect (i.e., "metabolic memory") associated with early achievement of near-normal glucose levels. Achieving target glucose levels early in the disease trajectory is also associated with maintaining lower A1C levels for longer periods and with a shorter time to the attainment of stable glycemic management (14,15).

Although national and international clinical guidelines recommend that treatment should be escalated if individualized glycemic targets are not met within 3–6 months of initiation of treatment (16,17), intensi-

fication of treatment when clinically indicated is often not occurring (2), and a significant number of patients are not meeting the generally recommended A1C target of <7% A1C (15,16,18–20). Although intensification has been the primary focus of clinical inertia discussions, overtreatment and failure to de-intensify therapy when appropriate is another facet of therapeutic inertia that must be addressed, particularly in older adults with type 2 diabetes who are at increased risk for hypoglycemia (21,22).

Several barriers to therapy intensification have been cited (23–26). For patients, perceptions of medication efficacy, cost constraints, medication side effects, regimen complexity, nonadherence, weight gain, lack of appropriate education and training, diminished quality of life due to the burden of daily self-management regimens, and concerns about hypoglycemia create barriers to desired self-management behaviors. Clinicians are challenged to intensify therapy by different barriers, including restrictions on time and resources, lack of training and education, suboptimal patient medication-taking behavior, perceptions about patients' ability and willingness to follow treatment protocols, concerns about hypoglycemia, and management of patients' comorbidities. Importantly, there is a significant disconnect between what patients believe and what clinicians think patients believe regarding their concerns about weight gain, hypoglycemia, pain from injections, and pain from fingerstick blood glucose monitoring (27).

Patient Perspective

*The patient perspective on therapeutic inertia was provided by **Felicia Hill-Briggs, PhD,** 2018 ADA President, Health Care & Education and Professor of Medicine and Senior Director of Population Health Research and Development, Johns Hopkins University and School of Medicine, Baltimore, MD.*

Dr. Hill-Briggs shared her personal story of living with type 1 diabetes. When diagnosed at the age of 9 years, Dr. Hill-Briggs lived in a segregated Baltimore, MD, neighborhood that was predominantly African American. She was treated by a family practice physician who had privileges at a segregated hospital. Because type 1 diabetes was so rare in African Americans, she was the first person with type 1 diabetes her physician had seen and the first person diagnosed with type 1 diabetes at the segregated hospital. No diabetes education program was available, and when she was discharged, it was difficult for her parents to find a physician who would treat her.

Dr. Hill-Briggs credited the ADA for playing a major role in providing education (e.g., through its magazine *Diabetes Forecast*) and support to her and her family during the early years after her diagnosis. As she transitioned into adulthood, she experienced what she described as the "health care perils" of having a preexisting medical condition. While earning her doctorate in clinical psychology, she was under-insured and unable to afford her diabetes supplies. Her solution was to seek out and enroll in diabetes research studies to receive medical care and supplies at no cost. Not surprisingly, when she finished graduate school, she started her own clinical practice and focused her research on underserved and high-risk populations. Dr. Hill-Briggs shared key lessons learned from her experience.

Social determinants such as socioeconomic status and geographic location significantly affect access to medical care, availability of health care resources, and social and educational support for disease self-management. The impact is compounded when clinicians who provide care to patients living in economically challenged communities are, themselves, under-resourced in their practices. Additionally, appropriate initiation and intensification of therapies cannot be achieved without a focus on self-management. Dr. Hill-Brings also cited a disconnect between what patients and their families are actually willing to do to ensure their well-being when resourced appropriately and clinicians' perceptions, which tend to ascribe self-management challenges to suboptimal patient and family motivation.

Dr. Hill-Briggs urged summit participants to think of ways to empower and effectively communicate with patients and families as they collaborate on solutions to address therapeutic inertia.

Clinician Perspectives

ENDOCRINOLOGIST PERSPECTIVE

***M. Sue Kirkman, MD,** Professor of Medicine and Medical Director, Diabetes Clinical Trials Unit, University of North Carolina, Chapel Hill, outlined the key clinical concerns she and her colleagues experience at their clinic and how they are addressing those challenges.*

The inability to efficiently coordinate and fully use the multidisciplinary diabetes health care team poses significant challenges for patients and the clinic. Because certified diabetes educators (CDEs), pharmacists, and physicians have their own schedules, it is difficult for patients to consult with all of them on the same day unless these visits are scheduled in advance. This puts a significant burden on patients, many of whom must travel 2–3 hours for clinic visits.

Restricted patient access to diabetes education is

also a significant concern. Under the current system, diabetes education must be provided at the clinic to be eligible for reimbursement. This requirement severely limits access to diabetes education offerings because many patients are unable or unwilling to travel long distances to receive education. Although the clinic offers education in group classes, this service is under-utilized, with only one to four patients attending each month.

Because of time constraints and a limited number of CDEs, diabetes education resources are focused primarily on patients with type 1 diabetes, a group that requires additional time for training due to their use of medical devices (i.e., insulin pumps and continuous glucose monitoring [CGM] systems) and complex insulin regimens. Very little time is available for patients with type 2 diabetes. Time constraints are compounded by the clinic's large population of patients who have low health literacy, are under- or uninsured, or both.

Clinicians at University of North Carolina Diabetes Clinical Trial Unit do not have ready access to accurate formulary information for patients. Often a clinician will prescribe a specific medication for a patient and then learn that the medication is not on formulary or requires pre-authorization. This not only requires additional clinician time, but also creates additional barriers for patients.

Lowering A1C continues to be a priority for clinicians; however, achieving A1C goals must be balanced against patients' priorities (e.g., avoiding hypoglycemia), which takes additional time. This problem is exacerbated when patients' priorities are in conflict with the goals their endocrinologist or other specialists believe they should focus on.

Clinicians are overburdened with unnecessary referrals because many patients with type 2 diabetes who are referred to the clinic do not need specialist intervention. In many cases, they primarily need diabetes self-management education and support (DSMES) services. These unnecessary referrals contribute to provider burnout, which in turn contributes to therapeutic inertia.

To address these challenges, the clinic has taken steps to improve the practice workflow. Triage staff download data from patients' devices (i.e., insulin pumps, CGM systems, and blood glucose meters). These data are immediately available to clinicians and patients, which enhances the patient-provider interaction. The clinic now makes extensive use of their pharmacist and pharmacy residents, who are available for more frequent follow-up with patients and can spend more time consulting with them regarding their medications and other components of their self-management regimen.

PHARMACIST PERSPECTIVE

***Sandra Leal, PharmD, MPH, CDE,** Chief Executive Officer, SinfoníaRx, Tucson, AZ, discussed medication optimization, outlining key barriers and solutions related to intensifying therapy.*

Individualizing therapy has become increasingly complicated given the large number of oral and injectable medications now available. Inadequate or nonexistent coverage for medications remains an obstacle to adequate patient medication-taking behaviors and is an ongoing challenge for HCPs. However, the practice of nonmedical switching by many insurers also creates medication access barriers for patients. This may contribute to therapeutic inertia in one of two ways: patients' current medication or medical device may be removed from their insurer's formulary, or insurers may increase patients' copayment for their medications or devices and supplies. In either scenario, patients must choose between continuing their current therapy despite increased out-of-pocket expenses or switching to a therapy that may not be as effective, may be unfamiliar, or may put them at increased risk of adverse health outcomes, any of which can intensify diabetes-related distress. Additionally, the administrative burden of navigating these insurance issues often creates gaps in care for patients who are trying to be adherent.

Many patients with diabetes have comorbidities that require multiple medications and complex regimens. Often, older adults may be prescribed as many as 20 different medications to take each day (28). Managing these patients not only requires pharmacists to spend additional time assessing and addressing complicated drug interactions, but also creates significant financial burdens for patients who cannot easily afford the copayments for all of their medications.

Increasing evidence shows that suboptimal medication-taking behavior is not the leading reason for treatment failures. A recent survey showed that inadequate therapy—defined as "dose too low," "different or additional drug needed," or "wrong drug"—accounts for approximately 57% of failures to achieve treatment goals (28). Unnecessary therapy and "dose too high" instances accounted for approximately 14% of failures to achieve treatment goals (28).

The use of comprehensive medication management (CMM), with pharmacists included as part of a team-based care model, has the potential to address many contributors to therapeutic inertia. CMM is a standard of care that ensures that each patient's medications are individually assessed to determine that each is appropriate for the patient, effective for the clinical need, and safe given the patient's comorbidities and other medications and can be taken by the patient as intended (28).

CMM offers potential benefits for all stakeholders. Patients benefit from increased clinical support and improved outcomes for patients. Clinicians can dedicate more time to assessing patient needs and determining appropriate treatment regimens. Payors and health plans benefit when they pay only for medications that are safe, appropriate, and effective for patients, and are used as intended. The average return on investment in medication management services ranges from 3:1 to 5:1 per dollar spent and has been reported to be as high as 12:1 per dollar spent (28).

DIABETES EDUCATOR PERSPECTIVE

***Gretchen Youssef, MS, RD, CDE,** Program Director, MedStar Diabetes Institute, MedStar Health, Washington, DC, and 2019 ADA President, Health Care & Education, discussed the challenges and underlying causes of therapeutic inertia as they relate to providing diabetes education services.*

Although the value and outcomes of DSMES and medical nutrition therapy (MNT) are proven, these services are grossly underutilized (29,30). Low referral rates, "no-shows," and poor reimbursement are affecting the long-term viability of many education programs.

Often, patients lack the skills, knowledge, and support needed for effective self-management of diabetes, resulting in frustration and dissatisfaction with their care. Social determinants (e.g., availability of safe places to exercise, availability and affordability of healthy foods, affordability of medications, and adequate transportation), diabetes distress, and health literacy and numeracy also affect medication-taking behavior and patients' ability to maintain lifestyle therapy.

Poor access to DSMES is a key reason for these deficits. Only 5% of newly diagnosed Medicare beneficiaries use DSMES services, largely due to a limited number of providers who refer and limited numbers of CDEs. There are fewer than 20,000 CDEs in the US, which means there are more than 1,500 patients with diabetes per diabetes educator (31). Other factors affecting access include a limited number of education hours covered by Medicare, coverage restrictions (e.g., on where education can be provided), prohibition against providing DSMES and MNT services on the same day, and unaffordable copayments.

Providers often do not "meet the person where they are"—meaning either in their community or at their stage of readiness to receive education and treatment. In addition to the limited number of CDEs, low reimbursement rates, fee-for-service models, and fragmented and siloed health systems are also affecting clinicians' ability to provide quality diabetes care. Moreover, many providers have expressed feelings of burnout and dissatisfaction when working within health systems that do not provide comprehensive support for the management of chronic diseases.

Although using risk stratification strategies to identify patients with the greatest need for comprehensive care and education can relieve some of the burden, the bigger issue of patient access to education can only be addressed through advocacy efforts. DSMES and MNT must be positioned as a treatment and included in diabetes quality metrics, including HEDIS (Healthcare Effectiveness Data and Information Set) measures. Advocacy initiatives such as the Congressional Expanding Access to DSMES Act proposed by the Diabetes Advocacy Alliance (32,33); efforts to publicize this legislative initiative are underway.

Health System Perspectives

HEALTHPARTNERS HEALTH SYSTEM

***Beth Averbeck, MD,** Senior Medical Director of Primary Care, HealthPartners Medical Group, Minneapolis, MN, discussed how HealthPartners is addressing therapeutic inertia.*

HealthPartners is a consumer-governed, nonprofit health system in Minneapolis, MN. The system's providers see 1.2 million patients each year, half of whom are covered by the system's health plan.

The system uses a team-based approach to address all patient health care needs during each clinic visit. Protocols are based on evidence-based guidelines and built into the workflow with the role of each care team member clearly defined and integrated into the electronic health record (EHR) system to provide a consistent experience for patients. Medical staff meet regularly with health plan staff and occasionally with staff from the system's research institute to discuss best practices. A positive rating is based on achieving targets in all measures.

To provide education and training to its PCPs, the system uses a collaborative model of medical education and care management (from Project ECHO [Extension for Community Healthcare Outcomes], developed at the University of New Mexico School of Medicine [34]), which involves having endocrinologist/educator teams share their expertise and best practices with their primary care colleagues through video conferencing.

In 2017, among HealthPartners' 41,488 members with diabetes, there were 361 fewer heart attacks, 20 fewer leg amputations, and 954 fewer eye complications than in 2000.

The system's research institute developed a "Diabetes Wizard" EHR dashboard tool that identifies, for each patient, the modifiable risk factors by which

optimal diabetes care is assessed (e.g., lipids, blood pressure, A1C, BMI, tobacco use status, and aspirin/anticoagulant use). This allows physicians to prioritize patients' most significant risk factors for discussion. The tool also includes a decision-support function, which presents clinical recommendations for addressing risks and a patient portal, which enhances patient-provider communication.

Because the patient population is racially and culturally diverse, the system has compiled a statewide cultural database, derived from patient-reported race, country of origin, and preferred language. This database assists staff in discussing various subjects with patients in a manner that is congruent with their cultural beliefs and preferences.

PARKLAND HEALTH AND HOSPITAL SYSTEM

***Luigi Meneghini, MD, MBA,** Professor at UT Southwestern Medical Center and Executive Director of the Global Diabetes Program, Parkland Health & Hospital System, Dallas, TX, discussed how his system initiated a quality improvement (QI) program focusing on diabetes outcomes.*

Parkland Health & Hospital System serves as the county health system for Dallas, TX, with a network of 12 adult primary care centers located in underserved areas of the county; more than half of its patient population is "uncovered" (having no insurance and receiving unpaid or self-paid care). Among Parkland's more than 33,000 patients with diabetes who completed at least one office visit, approximately 50% were Hispanic, 30% were African American, and the remaining 20% of patients were white or Asian.

Parkland created the Global Diabetes Program (GDP) in 2014 to address the patient population with diabetes within its system. One of the early initiatives of the GDP was to partner with the ADA's Diabetes INSIDE on a QI program. Diabetes INSIDE is a national, multi-sector QI framework that leverages ADA's expertise in diabetes and strength as a trusted convener to sustain long-term engagement by health care stakeholders to improve diabetes population health.

An assessment of glycemic control and use of medications among the Parkland diabetes population found that 82% of patients with and A1C ≥9% were not on insulin. Parkland formed a multidisciplinary committee of health professionals from the 12 primary care centers to address the specific issue of insulin inertia through shared medical appointments. Key targets for improvements that can be made by providers were primary care education, practice change, information access, and workflow support. Based on the implementation of the QI program, from 2014 to 2017, there was an increase of approximately 130% in the number of patients with and A1C ≥9% who were prescribed insulin therapy and a decrease of approximately 15% in the proportion of system patients with and A1C ≥9%.

To address medication adherence, system pharmacists, information technology professionals, and the GDP partnered to develop the Parkland Score for Adherence to Medication, which calculates the proportion of days covered for each patient's medications. A percentage adherence score is now available at the point of care (POC) for clinicians while they are seeing patients and is available on the Diabetes Overview dashboard, which was created to streamline and facilitate diabetes information-gathering from the EHR system. The dashboard includes all key information on a single screen and is accessed at the POC, enabling clinicians to quickly assess patients' clinical status, including overall risk, vital signs, metabolic laboratory values, medications, screening results, immunizations, outpatient visits, emergency department visits, hospitalizations, and upcoming health maintenance appointments. The dashboard also provides information about patients' access to health behavior services (e.g., most recent diabetes education class or nutrition visit) and goals. This information facilitates meaningful discussions with patients regarding their health status, lifestyle behaviors, and any obstacles they may have regarding treatment and medication-taking behavior.

The system uses remote electronic consultations, combined with bi-weekly video conferencing, to specifically address knowledge and practice gaps in primary care. This combination approach has been effective at improving PCPs' understanding of diabetes management, including the appropriate use of newer therapies with cardiovascular benefits.

The system is now actively exploring ways to increase its engagement with the community and address social determinants of health such as housing instability, homelessness, unsafe environments, and poverty.

Payor Perspective

UNITEDHEALTHCARE

***Sanford Cohen, MD,** Chief Medical Officer, Employer and Individual, UnitedHealthcare Islandia, NY, provided an overview of UnitedHealthcare's approach to therapeutic inertia.*

UnitedHealthcare remains focused on expanding its value-based care relationships with providers, moving away from the fragmented fee-for-service model to value-based arrangements with varying levels of risk-sharing for QI and patient outcomes.

Using the UnitedHealthcare provider portal, clinicians can access important information about their UnitedHealthcare patients to help identify issues

and close gaps in care, such as whether a patient has been admitted through the emergency department or whether a medication should be refilled. Using predictive analytics, UnitedHealthcare provides clinicians with information to help them better address barriers to treatment in patients with prediabetes and diabetes. In addition, a care manager may reach out to patients and their provider and support them in their treatment plan. Recognizing the need to address depression and other behavioral health comorbidities, UnitedHealthcare also has integrated behavioral health screening and referrals into its programs.

The company is also working with accountable care organizations (ACOs), designing support teams to work with them. For example, when the company learns that one of the ACO members was in the emergency department or discharged from the hospital, the ACO is notified so that follow-up and additional coordination can be provided. Because of UnitedHealthcare's value-based care approach in the employer-sponsored and individual network, ACOs have up to 17% fewer hospitals admissions than non-ACOs.

UnitedHealthcare also offers benefit designs that include certain classes of medications such as diabetes medications, statins, and blood pressure medications at a copayment before the deductible is met to improve patient medication-taking behavior with medications that may prevent comorbidities associated with chronic diseases such as diabetes and high cholesterol. The company is also working on tools to assist with POC decision-making.

The company has developed a diabetes health plan that offers incentives to members to comply with evidence-based preventive care guidelines, perform certain health actions, and follow-up with their clinicians, by reducing or eliminating patient copayments for certain types of diabetes-related care. This has resulted in improved quality of care and increased patient satisfaction by removing financial barriers to care and has slowed disease progression to diabetes or other related conditions. (The diabetes health plan progression analysis is based on 48,252 continuously enrolled members from the third quarter of 2016 to the third quarter of 2017, compared to populations without the diabetes health plan.)

The Real Appeal program, provided as a preventive medical benefit at no cost to members, is an online coaching program targeting weight and weight-related health conditions. It is modeled after the CDC-recognized Diabetes Prevention Program. Results show that the average participant loses 10 pounds, with 80% of participants losing weight, and 42% decreasing their BMI by 5% or more. Furthermore, Real Appeal's data show that participants have saved up to 16% in annual medical costs compared to nonparticipants.

UnitedHealthcare is also addressing social determinants of health. Identifying barriers to care may result in referrals to community-based programs for assistance.

Industry Perspectives

SANOFI

***Rachele Berria, MD, PhD,** Global Vice President and Medical Head, Diabetes at Sanofi, Bridgewater, NJ, presented an overview of approaches Sanofi is taking to address therapeutic inertia in terms of scientific research and engagement, critical insights, and innovations.*

The Micro-Learning Cloud was a pilot program developed by Sanofi in collaboration with Columbia University, MedStar, and Duke University. The program featured a series of 56 short videos (1–4 minutes each) specifically designed to support outreach and increase patient engagement in ethnically and racially diverse populations and reflecting "cultural humility" in how information was presented to a diverse population of people with type 2 diabetes. This was reflected in the language, topics discussed (e.g., dietary issues), and health priorities unique to each ethnic or racial group. Animated cartoons and videos were used, with on-demand, self-paced, self-directed learning modules accessible through various platforms. The Micro-Learning Cloud program led to significant improvements in self-care, with patients being much less worried about insulin therapy and the stigma related to it after watching the videos.

In collaboration with the American Association of Clinical Endocrinologists, Sanofi surveyed 1,000 patients with type 2 diabetes and 1,000 HCPs to assess their perceptions regarding diabetes management. Patients were asked if they would be willing to do more to achieve their A1C targets; 60% said they were willing to do more to achieve A1C targets, but only 20% of HCPs believed that was the case. Importantly, 22% of patients reported that they stopped taking their medications without telling their HCP, and among those patients, 38% reported discontinuing their medication due to frustration in not meeting their A1C targets.

In an effort to continue exploring the provider-patient communication disconnect, especially in hard-to-treat patients, another survey was conducted of individuals with type 2 diabetes who were treated with basal insulin and HCPs. Patients reported improved long-term A1C, staying healthy, and avoiding weight gain as their top three priorities. HCPs reported avoidance of side effects, affordability, and long-term A1C control as their top three priorities.

Sanofi developed a coaching tool to assist patients starting insulin glargine 300 units/mL (a second-generation basal insulin formulation), using key lessons learned from other successful behavioral modification programs. Offered free to patients, the web-based tool provides 24/7 access to qualified nurses. Assessments of patients who participated in the program showed improvement in their medication-taking behavior and persistence with their insulin regimen at the end of 1 year.

Sanofi has also entered into a joint venture called Onduo with Google and the life sciences research company Verily. The Onduo coaching platform is designed to connect patients with a variety of tools to support their daily self-management through a virtual clinic that is available to patients 24/7. Onduo is also working in partnership with Dexcom to incorporate CGM into coaching, and pilot programs are underway in several US states, leveraging the power of connection, support, and empowerment.

ABBOTT DIABETES CARE

***Karmeen Kulkarni, MS, RD, BC-ADM, CDE,** Director, Scientific Affairs, Abbott Diabetes Care, Alameda, CA, provided a brief overview of CGM technology and functionality and discussed factors that likely contribute to therapeutic inertia relative to CGM use.*

When used properly, CGM can be a useful tool for people with type 1 diabetes or for people with type 2 diabetes on intensive insulin therapy (35). Many PCPs may be unaware of the benefits of CGM and lack knowledge about how to interpret CGM data to adjust therapy. Additionally, many primary care practices may not be structured to incorporate new technologies into their workflow; for example, downloading data from devices (CGM systems, blood glucose meters, and insulin pumps) can occupy too much office staff time. From an administrative standpoint, HCPs find the insurance coverage process for CGM systems to be cumbersome (e.g., the need for pre-authorizations), and their perception of the cost to patient due to coinsurance or lack of coverage is limiting use. Finally, differences in professional guidelines (e.g., the recent American College of Physicians recommendation for a higher A1C threshold than is recommended by diabetes professional organizations [36]) and lack of timely updates of professional guidelines may be further limiting CGM adoption.

A key challenge in addressing these barriers is providing education and training to nondiabetes specialists that is tailored to each provider's depth of diabetes knowledge, clinic type, and support staff. Given the number of HCPs in the US—209,000 PCPs vs. 8,000 diabetes specialists (37,38)—scalability of education and training remains an obstacle.

CGM manufacturers can assist in overcoming these obstacles by integrating standardized CGM data presentation software into their product offerings and supporting educational programs to promote understanding of CGM. Additionally, manufacturers should assume a strong role in working directly with payors and health systems to improve access to CGM. Working with professional organizations, patient advocacy groups, and government agencies can also be effective.

MERCK

***Swapnil N. Rajpathak, MD, MPH, DrPH,** Executive Director for the Center for Observational and Real-World Evidence, Merck, Kenilworth, NJ, presented a series of studies demonstrating the prevalence and clinical and economic impact of therapeutic inertia and discussed Merck's external research collaborations with payors and health systems.*

Merck has conducted several studies on the topic of therapeutic inertia. Some were conducted as part of research collaborations with external organizations, including the Cleveland Clinic, Harvard Medical School, Carolinas Healthcare System, and Aetna. Findings from US studies showed that a large proportion of patients with type 2 diabetes were not meeting their glycemic targets on metformin, had no or delayed treatment intensification, and, among those whose medication regimen was intensified, had a median time to intensification of more than 1 year (39,40). Furthermore, timely treatment intensification positively affects glycemic target attainment (41,42). Similar results on suboptimal glycemic control and therapeutic inertia were also observed in studies conducted in other countries. A recent study conducted in collaboration with Aetna showed that factors associated with conformance to guidelines can help to improve clinical outcomes in high-risk subgroups and potentially lead to lower health care costs (43).

Continued and expanded data-sharing and collaboration with clinicians, health systems, and payors are needed to generate additional evidence about the causes and impacts of therapeutic inertia and to evaluate the effectiveness of solutions designed to address it.

MAJOR NEEDS IDENTIFIED

INITIAL PERCEPTIONS OF NEEDS RELATED TO THERAPEUTIC INERTIA: WORD CLOUDS

During the first presentation, participants were asked to give their perceptions of the causes and impacts of therapeutic inertia using one-word responses. The frequency of responses was calculated and the results were presented as "word clouds." Word clouds

are graphic representations of the words provided by participants; the size of each word is proportional to the word's frequency. The word clouds developed from participants' responses during the summit can be found in Appendix 3.

For the first word cloud, "time" was the most common word used to describe the top contributor to therapeutic inertia, followed by "cost," "fear," "apathy," and "overwhelmed." For the second word cloud, which asked how participants perceived therapeutic inertia as affecting their organizations, "cost," "frustration," and "complications" were the top three words identified. For the third word cloud, participants identified "education" followed by "time" as the top two words to describe the solutions to address therapeutic inertia. Interestingly, the much wider variety of words provided in the third word cloud may suggest that participants perceive therapeutic inertia as a multifactorial problem and that a wide range of solutions must be considered when addressing the issue.

HOLISTIC APPRACH

Comprehensive diabetes management requires a multidisciplinary team and an interprofessional approach. Access to more diabetes specialists and education are needed to support PCPs. Strategies to overcome therapeutic inertia must address all aspects of patient self-management, including medication-taking behavior, healthy eating, physical activity, use of available technology, smoking cessation, routine examinations (e.g., ophthalmology, neurology, and dental), mental and behavioral health, and social determinants. Greater utilization of the team-based, chronic care model and seamless data-sharing among all stakeholders is needed.

CHANGES IN REGULATORY AND REIMBURSEMENT POLICIES

Regulatory, coverage, and reimbursement policies that improve patient access and support all components of chronic care are needed. This will require the development of appropriate metrics to assess patient status and care team performance. These metrics can then be used to support government advocacy efforts at the state and national levels and provide guidance to payors to facilitate the development of national coverage and reimbursement policies.

DECISION-SUPPORT TOOLS AND RESOURCES

Participants identified a need for decision support in primary care. Many diabetes HCPs lack adequate knowledge in prescribing medications, and the publication of multiple clinical guidelines with differing metrics and recommendations is causing confusion among HCPs about treatment options. Addressing this issue would first involve developing simplified, more user-friendly recommendations and simplified tools for medication selection, therapy intensification, and self-management education based on ADA *Standards of Medical Care in Diabetes* (6), and then providing training and education that support the use of these recommendations in primary care settings.

Development of more advanced EHR systems that employ analytics and artificial intelligence would further support shared clinical decision-making involving both patients and providers. Essential components of these EHR systems include simple dashboard presentations of data that facilitate risk stratification and interpretation of current patient status, presentation of recommendations for specific therapy regimens to consider based on each patient's medical and psychosocial status and insurance coverage, up-to-date formulary information for each patient, and real-time measurement of each patient's medication-taking behavior.

In addition, diabetes HCPs need ready access to up-to-date information about the financial assistance programs, care management services, self-management education resources, and social support services patients can access in their communities.

RESEARCH

Funding for demonstration projects, pragmatic trials, and registry efforts, focusing on both clinical trials and real-world data, is needed to further elucidate the causes and impacts of therapeutic inertia and evaluate the effectiveness of specific solutions designed to address these problems.

PARTNERSHIPS AND COLLABORATIONS

The ADA's Overcoming Therapeutic Inertia campaign will require greater participation by more representatives from health systems and insurers, as well as representatives from other stakeholder groups such as EHR developers, community health workers, primary care organizations, technology companies (e.g., Google and Apple), life sciences companies, device manufacturers, pharmacy benefit management companies, retail pharmacy chains, and patients.

STEERING COMMITTEE RECOMMENDATIONS

WORKING GROUPS

Based on summit participants' input on needs and potential solutions to overcome therapeutic inertia, the

Steering Committee recommends the formation of four working groups. Each group will address specific aspects of therapeutic inertia, working in close coordination with other stakeholders when appropriate.

1. **Practice Optimization Group.** This group would address the full range of barriers affecting therapy decision-making, specifically focusing on enhancements to current EHR systems and strategies for integrating all members of the health care team. An important task for the group will be to identify and partner with relevant companies and organizations (e.g., payors, EHR developers, and health systems) in furthering these initiatives. A key objective would be to develop strategies for eliminating silos and integrating all health care team members (e.g., diabetes educators, dietitians, pharmacists, diabetes specialists, and community health workers) into primary care protocols and workflow.
2. **Patient Access Group.** This group would focus on identifying barriers to access (e.g., cost, reimbursement, regulatory issues, and social determinants) and developing strategies to improve patient access to clinical care, medications, devices, diabetes education, and community resources. It is anticipated that this group would work closely with the Policy & Partnership group described below to support initiatives to improve reimbursement policies and eliminate restrictive regulations regarding where and how diabetes education can be provided.
3. **Research Group.** This group would focus on several topics relevant to advancing the ADA's campaign objectives. A first priority would be to develop metrics and milestones for assessing campaign progress and successes. Other priorities would include investigating the use of large data sets and registries to develop metrics for assessing performance of health care systems and patient status and needs and identifying and collating best practices from successful models both from within the diabetes care community and from other disease care communities.
4. **Policy & Partnership Group.** This group would work to identify and establish collaborations with additional stakeholders and relevant organizations that could assist in the development of solutions and advocacy efforts. This group will focus on developing recommendations and lobbying strategies to promote reimbursement and regulatory policies that fully support appropriate management of chronic diseases. This would include the following collaborations with the other working groups:
   - *Patient Access Group:* to improve reimbursement for HCPs, improve and expand coverage of all components of patient care, and eliminate regulatory obstacles.
   - *Practice Optimization Group:* to formulate recommendations to payors regarding their preauthorization policies for medications and devices not on formulary. The goals are to ensure that patients receive the most appropriate medications and devices and to lessen the administrative burden on clinicians and medical office staff.
   - *Practice Optimization and Research Groups:* to promote more effective use of and appropriate reimbursement for alternative delivery approaches for education and treatment (including telemedicine and eHealth technologies) that can meet the needs of patients where they live and increase the frequency and quality of patient-provider interactions during and between clinic visits.

IMPLEMENTATION

The Steering Committee outlined the following tasks and timetable for campaign implementation:

February—June 2019

- Revise objectives, recommendations, and scope of working groups based on input from summit participants.
- Identify and recruit individuals to participate in working groups. The recruitment pool would include summit participants and individuals from additional stakeholder groups, including PCPs, allied health providers, patients, EHR system developers, payors, representatives from the Centers for Medicaid& Medicare Services and the U.S. Department of Health and Human Services, community health workers, technology companies (e.g., Apple and Google), pharmacy benefit management companies, and pharmacy chains.
- Coordinate initial meetings of working groups.

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- Facilitate ongoing meetings and activities of working groups.
- Compile findings and recommendations from working groups.
- Publish findings and recommendations from the working groups in Diabetes Care, detailing specific strategies and initiatives for the campaign.

CONCLUSIONS

Therapeutic inertia is a significant barrier to adequate diabetes management in the U.S. Given the increasing prevalence of diabetes (7) and the costs (both to patient health and well-being and to the economy) associated with inappropriately managed diabetes (8), effectively addressing therapeutic inertia must be viewed as the uppermost priority within

the diabetes health care ecosystem. This summit was the first step in a strategic effort by the ADA to ensure that it is recognized as such and to develop and implement constructive solutions in partnership with all stakeholders.

The scope and causes of therapeutic inertia extend far beyond patients' medication-taking behaviors and inadequate intensification of therapy; rather, it is a multifactorial problem involving a wide range of stakeholders, including patients, clinicians, health systems, payors, and industry. Because underlying obstacles to providing access to quality diabetes care are present in all stakeholder groups, each group must address these obstacles internally and externally through partnerships and cooperation with other stakeholders. As part of the medical community, the ADA's goal is to improve patient outcomes. Its Overcoming Therapeutic Inertia campaign is a crucial first step in achieving this goal.

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APPENDIX 2 Summit Agenda

7:00am–8:00am	Check-In and Breakfast
8:00am–8:30am	**Introduction to the Campaign** WILLIAM T. CEFALU, MD Chief Science, Medical and Mission Officer American Diabetes Association Arlington, Virginia
8:30am–9:15am	**Magnitude and Assessment of Therapeutic Inertia** KAMLESH KHUNTI, FMEDSCI, FRCGP, FRCP, MD, PhD Professor, Leicester Diabetes Centre - Bloom Leicester General Hospital Leicester, United Kingdom
9:15am–9:30am	**Patient Mission Moment** FELICIA HILL-BRIGGS, PHD, ABPP President, American Diabetes Association, Health Care and Education Professor of Medicine; Physical Medicine and Rehabilitation; Health, Behavior and Society; and Acute and Chronic Care Johns Hopkins University Senior Director of Population Health Research and Development Johns Hopkins HealthCare LLC Baltimore, Maryland
9:30am–10:00am	Break
10:00am–10:30am	**Clinician- Primary Care + Specialist Perspective** M. SUE KIRKMAN, MD Professor of Medicine and Medical Director, Diabetes Clinical Trials Unit University of North Carolina Chapel Hill, North Carolina SANDRA LEAL, PHARMD, MPH, CDE Member, American Diabetes Association's Primary Care Advisory Group Chief Operating Officer SinfoníaRx Tucson, Arizona GRETCHEN YOUSSEF, MS, RD, CDE President-Elect, American Diabetes Association, Health Care and Education Program Director, MedStar Diabetes Institute MedStar Health Washington, District of Columbia
10:30am–11:15am	*Moderated discussion to follow*
11:15am–11:30am	**Health System Perspective** BETH AVERBECK, MD Senior Medical Director of Primary Care HealthPartners Medical Group Minneapolis, Minnesota LUIGI MENEGHINI, MD, MBA Professor and Executive Director of the Global Diabetes Program Parkland Health and Hospital System

Department of Internal Medicine, Division of Endocrinology
University of Texas Southwestern Medical Center
Dallas, Texas

11:30am–12:15pm *Moderated discussion to follow*

12:15pm–1:30pm Lunch

1:30pm–1:45pm **Payor Perspective**

SANFORD COHEN, MD
UnitedHealthcare
Islandia, New York

1:45pm–2:30pm *Moderated discussion to follow*

2:30pm–3:00pm **Industry Perspective**

RACHELE BERRIA, MD, PhD
Global Vice President
Medical Head, Diabetes
Sanofi
Bridgewater, New Jersey

KARMEEN KULKARNI, MS, RD, BC-ADM, CDE
Director, Scientific Affairs
Abbott Diabetes Care
Officer Emeritus, American Diabetes Association
Alameda, California

SWAPNIL N. RAJPATHAK, MD, MPH, DrPH
Executive Director for the Center for Observational and Real-World Evidence
Merck
Kenilworth, New Jersey

3:00pm–3:30pm *Moderated discussion to follow*

3:30pm–4:00pm Break

4:00pm–4:45pm **Summary and Wrap-Up**

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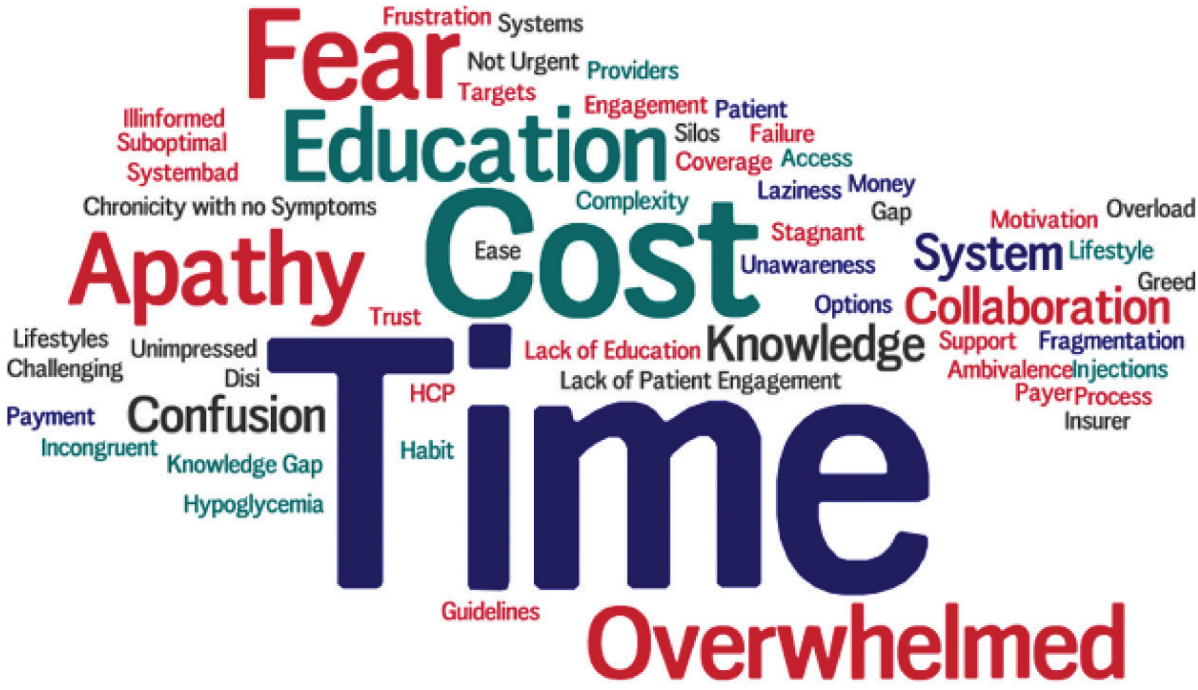
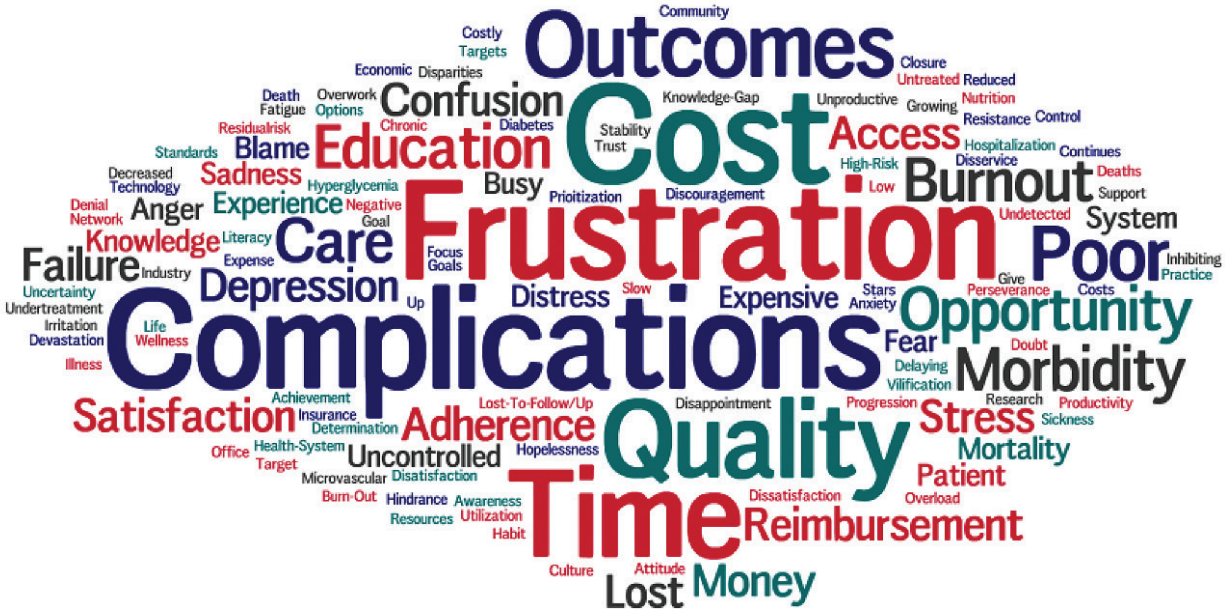
4:45pm–5:00pm **Next Steps**

The following are word clouds that resulted from three feedback requests made during the summit. For each request, attendees were asked to provide words that best described their thinking on a particular topic. The larger words are those that were used most frequently.

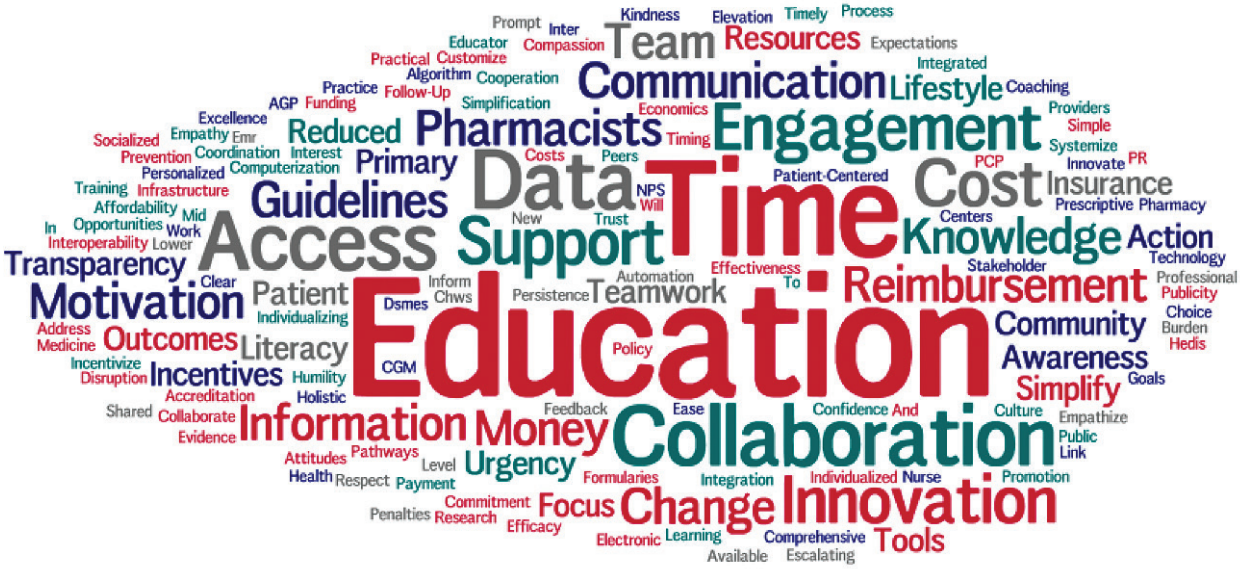
"List the one word that best describes the top contributor to therapeutic inertia."



"List the top three words that best describe the impact of therapeutic inertia on your practice/organization."



"List the top three words that describe potential solutions to therapeutic inertia."



- We need to stop working in silos. Integrate professional CGM in primary care and a diabetes educator who can help the provider and patient reach successful outcomes. Ongoing support is critical and CCM and remote monitoring is there. The DE can coordinate all of this. Clinical and behavioral management needs to be integrated.
- Shouldn't we advance a bundled payment for year one that includes all education screening for mental health etc.?
- While the focus has been on HbA1C and medication compliance measures, should we not also be looking at patient function at work, home, other areas and overall quality of life. Perhaps measures that could be used for all adults who have chronic medical conditions.
- Not a question, but some comments for the writing group. Please remember that therapeutic inertia is more than just not advancing meds. Not dealing with poor diet and lack of exercise is a huge part, and changing behavior there is more difficult than prescribing or taking meds. Also, please remember hypoglycemia. Both people with diabetes and HCPs often downplay this risk or these episodes.
- When the data show DSME works, how do we get it to where the patient is? This is a solution that works. Too often, those 19,500 CDEs are not where the patient is. Not in primary care and frequently being cut from hospitals.
- How do we make "new" medication not be defined as drugs that have been on the market more than 10 years? Exenatide was approved in 2005 and was just called a new medication in this room.
- How do we change the trajectory of getting newer efficacious drugs (proven) in the hands of the primary care providers? The comment on GLP-1s being newer drug for PCs demonstrates this problem.
- Who pays for pharmacists in clinic? Can they get reimbursed for services? Do they have full EPIC access?
- When will rebates be passed on to patients?
- Are there focus group data regarding what can motivate providers and patients to want to reach the goals? For people with cancers and heart failure, they are more driven.
- Why do most T2DM not on insulin need CGM? The additional cost can be used for lifestyle changes.
- What is the impact of a model of treating diabetes versus a mindset of promoting wellness on getting it done in a provider-centric world?
- Since provider time with patient is so limited, what strategies can increase non clinician supportive touch points?
- How do we move forward to make DSMES a metric?
- How does the not allowing of T2D not on insulin with A1C >9 message the PCP about the serious nature of t2d?
- It sounds like your health plan has a lot of member info, and you have talked about sharing that with physicians. However, that has not been my experience with other insurance programs. Is there an easier way to convey and share this information on a regular basis?
- Can Gretchen discuss the details of real-time BG results? Is her clinic the provider of the service? How do they provide staff for call back?
- Quality measures need to be met in a very limited time encounter with a patient. However, because of the constant formulary changes, I now refer to myself as a prescription medication advisor. Not what is best but what is the least expensive regimen. This does not allow me time to address the other key issues like eye care, foot care, lifestyle, etc. markers that need to be discussed at routine visits.
- Role of nonendocrinologist diabetologists should be promoted to supplement endocrinologists, not to replace them, to overcome therapeutic inertia due to access to provider.
- ADA should collaborate with ABFM and ABIM to update diabetes curriculum on education and skill.
- How accurate is "formulary search" information? If ADA can compile and provide info of insurance coverage info, it will be very helpful for PCP.
- General suggesions: 1) Residency education: on top of ADA primary care group's effort in educating PCPs, focusing on primary care residencies may help sustainable long-term effect. In our experience, primary care residency diabetes training needs to be updated, including skill training. If ADA can cooperate with ACGME and primary care medical boards on updating curriculum, including adding diabetes tech training, this will have a huge impact on tackling clinical inertia. 2) Role of

nonendocrinology diabetes specialists: all the talks today further confirmed the proven fact that "comprehensive diabetes management is a multidisciplinary approach." It will not be easy to have support for all PCP offices for comprehensive diabetes managment. But if there is a diabetes center in the area, all PCPs will be able to get support. That means we need more diabetes specialists. ADA should promote the role of nonendocrinologist diabetes specialists to supplement endocrinologists.

- Can you share timelines for the different phases?
- What is being done to increase the importance of looking beyond HbA1c for diabetic patients with all the new data?
- Will there be a recommendation paper on clinical application of new evidence? Study results are good, but how do we incorporate them in my practice to better patient outcomes?
- How many people have a regimen for titrating people to goals that has worked and is functional to provide in positive results?
- Does anyone have a diabetes protocol?
- It's possible to make visits fun, something the patient looks forward to.
- Clinical practice guidelines from various organizations tend to parallel conceptually in regard to care planning and treatment recommendations. It would be helpful to have a collective consensus of the treatment guidelines for PCPs and clinicians to use at the point of care. This will lessen the burden of having to navigate a plethora of opinions that ultimately arrive at the same general conclusion in terms of best practice. All in keeping with the tenets of evidence-based medicine.
- To address the question of personalized care. Through community engagement via spending more time with patients, the impact of establishing meaningful relationships with patients cannot be overstated. It is through this engagement that we will ultimately change the way health care is delivered and patient outcomes will be transformed.
- I agree that an area we should explore would be to have medical office assistants work at the top of their license and provide more education and support. This is not a group of health care providers ADA typically works with. How can we provide more training and resources to help with that?
- There are so many guidelines! As part of the process, we should review what's out there adapt/adopt -- instead of necessarily only relying on ADA guidelines.
- There are guidelines for education referrals (4 critical times). Two questions: (1) Can ADA fund research to validate this algorithm? (2) How can these be better disseminated and implemented?
- So much of the focus has been on inertia related to medications. While I appreciate meds are an important component, this initiative also needs to address the inertia seen when it comes to using and advancing lifestyle therapies - DSMES, MNT, and behavioral medicine.
- What are some of your best practices for coordinating with the patients' other providers - managing their other conditions, particularly behavioral health?
- How do you define A1C success? Speakers have presented less than 7, 8, and 9.
- How do we address siloed care between specialists, urgent care, and ER/hospitals? Data from EHR doesn't interface.
- Primary care is responding to lack of specialist access (i.e., hep c treatment, HIV care, response to the opioid epidemic via MAT, and preventative care across the lifespan). Reimbursement needs to value complexity of managing chronic illness with comorbid conditions. How do we shift this?
- How do health systems facilitate communication between specialists? Is this the same with urgent care reimbursements (if paying for visits, is there a responsibility to facilitate data/info sharing)?
- Is the DM Wizard available regardless of EHR company? Who updates algorithms and mapping? Can it interface from multiple sources (i.e. bi-directional from payor or lab?)
- How do we facilitate "upstream" communication early in hospitalization (after acute stabilization) to PCP to align care prior to dc (not as patient leaving hospital)?
- What is the response to the system approach when a patient achieves goal and is "discharged" then returns to an elevated A1C in 3-6 months? What happens then?
- Can we scale what's going well in systems more broadly WITHOUT a single-payor system or universal access?
- How do we deal with variability in EHR capacity? Epic is amazing, but many FQHCs and CHC practices can't afford the price tag. Poorer practices (and poorer patients) need more, not less.
- Care gap reports give some information, however we lose the opportunity to capture referrals/specialist care or satellite system care (urgent care) when it happens to capture records. What is the barrier to sharing with PCPs about what and who is reimbursed for care?

- What resources are available to activate payor resources that are identified in the office? How can we utilize these resources more comprehensively?
- Do you see a role in advocating for employers to offer paid sick time, as it is a barrier for patients to access preventative or medical home care during scheduled work hours and subsequently impact ER utilization?
- Do any EHRs have a triage function to send PWD to appropriate services (e.g., education or specialist care)?
- Guidelines need to be based on SRs, but this is expensive and time consuming. How do we have increased multidisciplinary, multiorganizational guidelines that are measured for implementability and effectiveness?
- How important is it that the guidelines you use are based on systematic reviews?
- Therapeutic inertia also includes instituting interventions that have minimal chance of success. Please address this, because of time constraints providers will increase dose of insulin by 5 units (when current dose is 50 units) or increase oral therapy slightly (double glimepiride from 1 mg to 2mg) even though these will have zero chance of success in a patient with A1C of 9%.
- We need EHR reps as part of this summit/working group like EPIC, All-scripts, Cerner, etc. They need to help facilitate the management of diabetes. EHR documentation and workflow issues need to improve. Just being able to know what is covered by a patient's insurance and cutting down on prior authorizations a bit should be HUGE!
- This summit also needs CMS and HHS reps and point of views as they make rules that serve as direct barriers to A1C goal attainment, reimbursement, and benefits coverage like education.
- The guidelines have become too academic for primary care, this needs addressed. How can we make these more basic and simple?
- How can we change paradigm of disease management, refer to specialist early for aggressive and fast intensification, and then return to PCP when A1C is at goal? When you have a heart attack, you don't see cardiologist 15 years later. Why then, when we are diagnosed with T2D don't we see a diabetes specialist for 10 years? My schedule as a specialist is overwhelmed with follow-up patients at goal who are reluctant to return to primary care. This results in huge access problem.
- Can the panel address the MANY guidelines that give opposing messages? Historically, AACE vs ADA/EASD and now ACP vs. the world? Primary care is confused as to what to do and what should be the goal. This is a huge driver of inertia!
- How is the pharmacist in the practice getting reimbursed? As a CDE? Something else?
- How many PCP offices have access to a diabetes educator?
- Here are some innovative thoughts for therapeutic inertia 1. Bundle payments for diabetes education visits. 2. Increase the number of visits based on A1C level (and/or other metrics) to better evaluate the effectiveness of treatments (including lifestyle changes). 3. Create a diverse workforce dedicated to diabetes care. This helps with some of the trust issues inherent to diverse patients and HCPs. 4. Increase HCP training for new trainees (may need to back up and suggest new accreditation criteria to assure students get what they need) and existing providers. Instead of HCPs relying on education from pharma reps, who could be biased, it'd be great to have education from ADA, AADE, etc., that is evidence-based and nonbiased. 5. Campaign to increase public awareness to decrease stigma. 6. Limit advertisement of unhealthy foods and behaviors. 7. Consider providing education to providers that is specific to those with special needs and often underserved. Those with disability (deaf, cognitive decline, etc.) do not always have access to tools that work for them. All education videos to patients must have closed captioning available. 8. Decrease cost of meds. I spend at least 20% of my time talking about access to care. This time could be better spent.
- You mentioned UHC helping with transportation. How exactly are you doing that? How can the prior-authorization process be streamlined?
- When physician payment is reduced by prescribing expensive superior drugs, you are changing therapeutic decisions from what is best for the patient to what is best for the physicians.
- I worry that over-emphasis on medication management will lead us to miss the behavioral aspects of diabetes care. How can we be sure that pharmacists always consider the impact of changes in food and activity on how the medications the patient takes control glycemia?
- We have Essential Health Benefits for children through congressional action and rule making. Should we not have Essential Health Benefits for all individuals with T2D?
- B2H Brownfields to Healthfields can link the PCP to community resources and federal resources that can improve access to care and prevention. Should the stakeholder community in diabetes also include environment stakeholders i.e. reduced environmental exposure endocrine disrupters and leverage through community sustainability?
- In the Lipska study, was there a disproportionate number of underinsured or impoverished patients in the complex/poor category? That might explain the higher use of SUs.

- Where does EPIC get the information about formulary coverage and how often is it updated? Agree that often the information is incomplete and not sufficiently accurate/available.
- DSMES/MNT often requires face-to-face interactions, which itself may be a barrier to many patients. How can we promote/test novel solutions (for example using novel technologies and digital platforms) to complement education that is accessible to all patients (especially those in underserved communities)?
- Why is the onus for patient health almost always the final responsibility of the provider instead of a shared responsibility of all stakeholders?
- Is the United tool "Check My Script" embedded into the EMR? While it would be a great tool to have, there are many other plans besides United that providers need to deal with. These tools need to be rolled out with the provider workflows in mind.
- Unless guidelines are converted into algorithms that can be run with the assistance of AI and embedded into the HCP workflow/EMR, the barriers to implementation of evidence-based treatments will continue to loom large.
- What digital tools has United found to be impactful with their patient population?
- How can we include intensification of DSMES and management into our practice?
- How can we expand our definition of therapy? We refer to medications in this regard. How can we include management, DSMES, etc.?
- How can ADA create expectation that food intake is therapy? Include at each step of medication adjustment.
- Expand measures beyond labs, as BobE does include key food and activity metrics. Refer as indicated.
- Please, we need to expand beyond tracking and intensifying medications. i.e. start with basic 'diet' guidelines, then begin to intensify as appropriate.
- Please, when we ask or talk about how do you manage your diabetes let's include more than meds.
- Please, can we be more descriptive about what "lifestyle" is. As currently discussed, it appears to be easily dismissed as too complicated and/or patient "you take care of that on your own." What are the expectations for nutrition therapy and DSMES? Look at the 4 critical times as a guide and setting expectations for care.
- ADA should consider collaborating with Bureau of Primary Care to share best practices.
- Seems like its all about PCP knowledge and systems (e.g., population outreach). Team based care, real-time data, formulary tools, problem-solving on cost, etc. Can we collectively develop programs around this?
- Any thoughts about how to resolve the tension between FFS and value-based payment? A future of capitation by geographic area?
- Can we hear more about how HealthPartners uses the CV Wizard with patients? Is it used during the visit, or do patients access via portal?
- Is there a paper on results of MedStar program for diabetes? Do bundled payments exist for diabetic care?
- How do we ban the routine 3-month follow-up visit?
- Follow-up frequency with clinicians needs to be based on the changes at the visit, not based on a routine or linked to A1C. Patients and clinicians need to look at changes in time in range within weeks of a new therapy, not wait for A1C. How do we change the focus away from A1C?
- Why doesn't UHC cover CGM for people with T2D? Using intensive insulin therapy with risk for severe hypo or markedly elevated A1C?
- Why wasn't cost of meds or devices more discussed? Something needs to happen here.
- The extent to which advanced analytics and AI should be leveraged to overcome inertia and aid in decision-making cannot be emphasized enough. Code can be written and implemented within any local EHR system based on individual patient information to tell an HCP the best choices.
- A study showing how treatment of other clinical comorbidities many contribute to not treating hyperglycemia is a logical next step. It could help highlight the need for a more holistic approach.
- Would a seal or stamp of approval from ADA help to drive payers to update their plans and push it down to HCP? Then patients and others could hold people accountable if it is not being followed.
- It would help if we redefined diabetes into a staged approach to engage with patients earlier, when it may be easier to impact their lifestyle. Like cancer, there could be combinations of drugs used early so that there is an urgency that is lacking in the sequential approach.

- Would the Apple health kit be a more universal system that could provide daily CGM, heart rate, and activity scores?
- Do you base care protocols on the ADA consensus guideline or determine other guidelines to follow? How do you justify changes to guidelines if you choose any?
- Should industry collaborate among themselves to address these issues more broadly beyond individual companies?
- What do you think of the Medicare requirement that pump or CGM users must see their physician at specified intervals?
- How do we integrate CHWs into diabetes care teams?
- How do we develop systems of care that extend to clients' homes and communities?
- What organic community efforts or activities can we integrate diabetes education and tools into?
- There are models of intensive case management teams for HIV, home visitation, and falls clinics (to address senior falls). Can we share models that are out there for diabetes team or community care to share promising practices or areas where we can enhance access to care and services outside the clinic walls? Senior falls clinics provide a time and location for seniors to come in to address their issues around falls prevention and other health issues at the same time.
- Model to explore was the MA Prevention and Wellness Trust Fund. Partnerships across the state made up of clinical and community sites and providers, including CHWs, addressing diabetes at all levels and settings with feedback loops built in between community and clinical partners.
- Incentivizing was mentioned. Do you do this for patients? If yes, can you give a few examples please?
- Why are fixed-dose combination pills or fixed-ratio insulins not used more in practice? Combo therapy has repeatedly been shown to be more cost-effective, gets you to goal quicker, and improves adherence.
- As a payer, what are your views of using fixed-dose combination pills or fixed-ratio combination insulins in diabetes care?
- What percentage of people with diabetes use the online tools? What is the approach for those who do not have digital access?
- In the case of CGM use, is this geared more toward T1 diabetes? How do you move the needle for more T2 to use CGM?
- Can you share more detail on the 3-month prognostication as a risk factor for nonoptimization of metabolic control? Is it for new DM or newly diagnosed DM? Any learning for those beyond the 3 months to improve?
- What do you feel is exactly missing in primary care to take care of the diabetic? Does the practice obtain CGM data in real time, and if so, has it been helpful in type 2?
- Any thought why group classes are not popular?
- Is there a preferred method of interaction with the pharmacy which results in improved outcomes? In person? Virtual? Telephonic? How important is an initial in-person visit?
- Any work on decreasing evidenced-based gaps such as decision-support tools? Is there confusion on which guidelines to follow?
- How effective is your decision support? What guidelines do you use?
- Informed formulary decision-making by payors is a great theoretical concept. Would you expect payors to have more clinical data?
- Access and delivery are constantly ignored as barriers to care. Appreciate your perspective and unfortunate experiences that a lot of our patients have to live with.
- While this was very well planned and there were great presentations, this whole area of concern is far larger than "clinical inertia!" It's way more than just clinical and it's way more than "inertia." It's a huge system issue in which inertia is just a piece of the system. Further, so much of today's discussion focused on medications and clinical indicators-especially A1C. Don't we need to start putting far more emphasis on time in range? I know that we need to start somewhere, but it is very clear to me that we need to better identify the root problem, then identify all of the contributing factors, then identify measures/outcomes overall for each of the parts of the system.
- Are you tracking the impact of nonmedical switching? This is very problematic when switching patients from one insulin to another.
- I think its critical to keep in mind that the emotional and behavioral aspects of care for patients and providers need to be central in all next steps.
- From the PCP perspective, what are some short-term things you would like to see in place that can help you as a provider to address therapeutic inertia? Is there some low-hanging fruit in this regard?

- Formulary issues and nonmedical switching could be argued to contribute to barriers in achieving target goals. Should nonmedical switching be part of a therapeutic inertia plan, or do you believe it is not related?
- Should policy on preauthorization be put on the table in discussion of clinical inertia?
- The discussion tends to focus on the clinical encounter and the provider prescription. As the population continues to shift toward minority representation, we need to place greater emphasis on social determinants of patient health care behaviors.
- To what extent will this initiative focus on reimbursement policy as a strategy to reduce clinical inertia?
- What about the biologic heterogeneity of diabetes? How do we individualize therapy without understanding this?
- Do you think it might be easier to avoid huge costs downstream by helping patients invest in the right therapy early on?
- Where are we learning from other therapeutic areas? Cancer would never use monotherapy! Also, ask patients what they care about. Weight, emotions, hypo all benefit from better therapies. What other therapeutic area would allow most patients to use a class of medicine that would never be approved today? SUs at least teach doctors to use low dose. How about progressive combos? Lobby for better access, in most plans, one is super cheap (Soliqua), one is very expensive (Xultophy). Since access is hard, lobby for common forms for patient access programs.
- Why do you say T2 can't ever get tech like T1? Professional CGM could be useful for many T2s, and it's very cheap. Do we have limits to what is spent on dialysis? No, we don't. But we could try to avoid that spending and invest in better drugs used at the right time, not just when A1Cs get to 9 (or 16!).
- How do you decide on cardioprotective medicine for those with diabetes?
- I am very interested in the comments on eHealth/telehealth. How common is this practice currently in diabetes? What is needed for this to explode to allow us to meet more patients "where they are" and deliver this kind of care via technology?
- Internal cost savings was shown to be a solution as a buy-in for executive support. What about showing cost savings to patients as a "if you did DSMES/DSMT you can save $$$ long-term?" Can this be done?
- What tools are available and in wide use to help patients manage their medication regimen, which seems like it could be overwhelming? (>25 meds!)
- Barrier to clinical inertia is not just making sure a medication is on formulary but if the patient can afford it. Discussion of "are you on a HDHP and what is your deductible?" may uncover nonadherence due to an $800 list price for 30 days or an $80 copay for one med. Are health care professionals equipped to have that discussion?
- I feel that we should not overlook the importance of connecting with patients on a personal-life level to better understand the dynamics of patient noncompliance. We should work to identify the social determinants that influence therapeutic inertia. Patients need to feel intimately connected to the provider and HC system in order to create a more synergistic relationship that could potentially improve patient outcomes.
- Going back to Tracey's "blow my hair back" challenge - a lot of this sounds like better/increased execution of what we're already doing. Is that really going to make a dent in the >100 million patients with diabetes or pre-diabetes?
- We need realistic goals. Oftentimes, more than 3 months is needed to get to goal. One year is more practical.
- Why haven't we taken on cost of meds? I know pharma is here, and they are a big presence, but we need to ask pharma and industry how they can lower costs.
- How does UHC reconcile their value contracts for diabetes devices (exclusive Medtronic pump for people over 18) when HCPs believe another pump may be better?
- Glad to hear you say Real Appeal is modeled after the DPP. Is it part of the National DPP and have CDC recognition?
- What is the role of patient preference with respect to coverage for medications or services?
- We didn't talk enough about hypoglycemia and its role in therapeutic inertia. Hope it is addressed in the white paper.

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