

The National Clinical Care Commission Report to Congress: Leveraging Federal Policies and Programs to Improve Diabetes Treatment and Reduce Complications

M. Carol Greenlee, Shari Bolen, William Chong, Ayotunde Dokun, Jasmine Gonzalvo, Meredith Hawkins, William H. Herman, Ellen Leake, Barbara Linder, and Paul R. Conlin

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The National Clinical Care Commission			
Leveraging federal policies and programs to more effectively prevent and treat diabetes			
Foundational recommendations	All-of-government approach	Health equity	Access to care
Subcommittee	General population	Population at risk	People with diabetes
Focus	All of government	Public health/clinical care delivery	Clinical care delivery
Social factors and environmental exposures	Education/schools, agriculture/food, housing, transportation, commerce, green spaces, neighborhoods, drinking water, environmental exposures	Agriculture/food, housing, green spaces, neighborhoods, drinking water, environmental exposures	Agriculture/food, housing, green spaces, neighborhoods, drinking water, environmental exposures
Public health	Food labeling, sugar-sweetened beverages (SSB), marketing to children, paid maternity leave, breastfeeding	Increase awareness and diagnosis of prediabetes, food labeling, SSB	Food labeling, SSB
Health care	Access and affordability	Harmonize National Diabetes Prevention Program (DPP) and Medicare Diabetes Prevention Program recognition programs, approve metformin for diabetes prevention	Diabetes self-management education and support/training, improve access to diabetes devices, team-based care, workforce training, technology-enabled mentoring, virtual care
Policy	Health-in-all policies, food labeling, tax on SSB, marketing to children, paid maternity leave, establish Office on National Diabetes Policy (ONDP)	Coverage of HbA _{1c} for screening; increase availability of, referral to, and insurance coverage for effective diabetes prevention interventions; insurance coverage for all effective modes of DPP delivery; mandate insurance coverage for the National Diabetes Prevention Program under the Affordable Care Act, ONDP	Marketplace health plan subsidies, Medicaid expansion, insulin access and affordability, improve access to diabetes devices, quality measurement and reporting, preeductible coverage for secondary and tertiary prevention, improved payment models, ONDP
Research	Evaluate and optimize the impact of non-health-related federal agency policies and programs on diabetes prevention and control, train and fund the workforce to perform such research	Benefit-based tailored treatment, better elucidate the causes and prevention of type 1 diabetes	Address barriers to diabetes self-management education and support/training, explore methods to improve team-based care, digital connectivity as a social determinant of health
Agencies	Department of Education, Department of Agriculture, Department of Housing and Urban Development, Department of Transportation, Federal Trade Commission, Federal Communications Commission, Food and Drug Administration, Environmental Protection Agency, Office of the Assistant Secretary for Health	Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, Veterans Affairs, Indian Health Service, Department of Housing and Urban Development, Internal Revenue Service, Food and Drug Administration, National Institutes of Health	Centers for Medicare and Medicaid Services, Veterans Affairs, Indian Health Service, Department of Defense, Health Resources and Services Administration, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, National Institutes of Health, Office of Minority Health



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The Treatment and Complications subcommittee of the National Clinical Care Commission focused on factors likely to improve the delivery of high-quality care to all people with diabetes. The gap between available resources and the needs of people living with diabetes adversely impacts both treatment and outcomes. The Commission's recommendations are designed to bridge this gap. At the patient level, the Commission recommends reducing barriers and streamlining administrative processes to improve access to diabetes self-management training, diabetes devices, virtual care, and insulin. At the practice level, we recommend enhancing programs that support team-based care and developing capacity to support technology-enabled mentoring interventions. At the health system level, we recommend that the Department of Health and Human Services routinely assess the needs of the health care workforce and ensure funding of training programs directed to meet those needs. At the health policy level, we recommend establishing a process to identify and ensure pre-deductible insurance coverage for high-value diabetes treatments and services and developing a quality measure that reduces risk of hypoglycemia and enhances patient safety. We also identified several areas that need additional research, such as studying the barriers to uptake of diabetes self-management education and support, exploring methods to implement team-based care, and evaluating the importance of digital connectivity as a social determinant of health. The Commission strongly encourages Congress, the Department of Health and Human Services, and other federal departments and agencies to take swift action to implement these recommendations to improve health outcomes and quality of life among people living with diabetes.

The Treatment and Complications subcommittee of the National Clinical Care Commission evaluated federal programs and policies that impact the care of people with diabetes. We collected information to inform recommendations to optimize individualized care, improve health outcomes, and reduce health disparities. We recognized that despite increasing numbers of medications and nonpharmacologic treatments for people with diabetes and the continuously updated standards of

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care to inform clinicians, only about a third of people with diabetes receive recommended standards of care, leaving many at risk for experiencing harm (1). Thus, we focused on the gap between available resources and the use of those resources by people with diabetes with the goal of developing specific recommendations to narrow this gap.

The Treatment and Complications subcommittee initially constructed a framework to guide its work.

Achieving and maintaining optimal health and well-being while living with diabetes requires that patients and their caregivers:

- Have access to and understand information about diabetes, its management, and its potential complications.
- Participate collaboratively with health care providers in selecting treatments that are consistent with their unique characteristics and goals of care.
- Have the skills, confidence, and psychosocial and material support to perform the necessary self-management tasks.

In addition, health systems must proactively deliver high-quality individualized diabetes care, and community resources must align with the self-management needs of these individuals.

From this, the Treatment and Complications subcommittee established six focus areas that, through their impact on federal policies and programs, are most likely to improve care of people with diabetes. These are diabetes education, diabetes devices, team-based care, virtual care, diabetes care delivery, and research needs. Our rationale and recommendations are described below within each of these focus areas and are summarized in Table 1.

FOCUS AREA 1: DIABETES EDUCATION

Reducing Administrative Barriers to Diabetes Self-Management Training

Diabetes self-management education and support (DSMES) facilitates the acquisition of knowledge and skills necessary for people with diabetes and/or their caregivers to successfully manage diabetes. DSMES is designed to help people with diabetes integrate and maintain these vital

behaviors as part of their treatment program.

Diabetes self-management training (DSMT) is the Medicare benefit that covers DSMES services for Medicare beneficiaries. Despite robust evidence demonstrating the effectiveness of DSMT, less than 5% of Medicare beneficiaries with a new diagnosis of diabetes receive DSMT. There is strong evidence that increased participation in DSMT reduces health care spending by preventing emergency and urgent care visits and inpatient hospitalizations (2). Several factors have been associated with reduced access to DSMT, including social and economic conditions and the unavailability of DSMT providers in certain areas. This limited access to diabetes education can further exacerbate health disparities (3).

Underutilization of DSMT by those who may benefit is affected by many factors. These include outdated Centers for Medicare and Medicaid Services (CMS) standards, burdensome administrative requirements, and inconsistent auditing processes that make it difficult and costly for DSMT programs to be reimbursed and remain financially viable. There is a shortage of diabetes care and education specialists and a striking lack of programs in both urban and rural areas that have a high prevalence of diabetes (4).

Recommendation 1

We recommend that the CMS update the 2000 Medicare Quality Standards that govern DSMT and establish a process for ongoing review, updating, and revision, with broad input from people and parties affected by these standards. The CMS should ensure that eligibility, documentation, and reimbursement requirements are clearly defined and that they are consistently applied across all parties involved in accreditation, billing, and reimbursement, including Medicare Administrative Contractors and auditors. Updates should include a reduction in administrative burden regarding standards, documentation, and reimbursement requirements for DSMT programs.

Enhancing Access to Community-Based Diabetes Education Programs

Although some community-based diabetes education programs are not accredited DSMT programs due to the administrative burden required to implement the

Medicare Quality Standards, they use evidence-based curricula to adapt to and meet the unique needs and preferences of the communities they serve. These programs are commonly offered in group settings and in diverse locations such as schools, work sites, community centers, and places of worship. Programs are often led by trained public health workers who self-identify as community health workers (CHW) or community health advisors (5). These programs are not intended to replace formal DSMT but can increase access to diabetes education and other health care resources.

Evidence supports the effectiveness of community-based diabetes education programs, including programs for minority Medicare beneficiaries (6–8). However, these programs are often supported by grant funding and may not have sustainable sources of reimbursement (7,9). Innovative collaborations between community-based diabetes education programs and accredited/recognized DSMT programs (10) may be complementary and help improve health equity for people with diabetes residing in underserved communities (11).

Recommendation 2

We recommend that the CMS develop reimbursement mechanisms for community-based diabetes education programs, as a complement to existing accredited/recognized DSMT programs, when evidence shows that these programs improve diabetes outcomes.

FOCUS AREA 2: DIABETES DEVICES

Many technological advances have emerged to facilitate real-time diabetes self-management and improve quality of life for people with diabetes. These include insulin pumps that provide more precise insulin delivery and continuous glucose monitors (CGM) that allow individuals to modify lifestyle choices and diabetes medications and receive alerts when hypoglycemia is imminent. Newer insulin pumps that integrate with CGM devices can automatically adjust insulin delivery without direct patient input.

Growing evidence suggests that these devices provide a wide range of benefits to people with diabetes, including improved glucose control, reduced glucose variability, and less frequent hypoglycemia.

Table 1—Treatment and Complications subcommittee recommendations

Focus area	Recommendations
Diabetes education	<p>The CMS should update the 2000 Medicare Quality Standards that govern DSMT and establish a process for ongoing review, updating, and revision, with broad input from people and parties affected by these standards. The CMS should ensure that eligibility, documentation, and reimbursement requirements are clearly defined and that they are consistently applied across all parties involved in accreditation, billing, and reimbursement, including Medicare Administrative Contractors and auditors. Updates should include a reduction in administrative burden regarding standards, documentation, and reimbursement requirements for DSMT programs.</p> <p>The CMS should develop reimbursement mechanisms for community-based diabetes education programs, as a complement to existing accredited/recognized DSMT programs, when evidence shows that these programs improve diabetes outcomes.</p>
Diabetes devices	<p>The CMS should use existing processes to update and regularly reevaluate (at least every 3 years) eligibility requirements for various diabetes devices, leading to appropriate coverage determinations when there is sufficient evidence to support such national determinations. The CMS should ensure that, to the extent there are national requirements established, eligibility, documentation, and reimbursement requirements are clearly defined, and that they are consistently applied across all parties involved, including Medicare Administrative Contractors and auditors. In evaluating the data to revise eligibility requirements, the CMS should evaluate the current evidence, including published, peer-reviewed evidence, and consider both glycemic benefits and nonglycemic benefits (including patient-reported outcomes, which may include quality of life and diabetes distress).</p>
Team-based care	<p>Steps should be taken to ensure an adequate workforce and to enhance and sustain team-based care to improve outcomes for people with diabetes.</p> <ul style="list-style-type: none"> ● Establish a process within HHS to routinely assess and identify all health care workforce needs and ensure that training program funding across agencies is directed to meet these needs. ● Ensure the HRSA training programs are designed to meet unmet needs in the team-based health care workforce. <ul style="list-style-type: none"> ○ Evaluate and address regulatory or statutory limitations on HRSA training programs that affect the agency's ability to meet the needs of team-based care and new care models. ○ Increase funding for exemplary HRSA programs that support training health care professionals in team-based care in medical shortage areas, such as the HRSA National Health Services Corps. ● Identify and implement mechanisms for involvement of community health workers, clinical pharmacists, and integrated (or collaborative) behavioral health services in existing and future value-based models of care (alternative payment models). ● Enhance funding to AHRQ through Primary Care Extension Programs and other mechanisms to provide technical assistance to medical practices to implement team-based care. <p>Steps should be taken to enhance implementation and sustainability of community health workers as critical members of the diabetes care teams.</p> <ul style="list-style-type: none"> ● The CMS should clarify and build on the 2013 final rule, expanding the scope of Medicaid-reimbursable services by CHW to include social, behavioral, and economic supports as part of covered services. <ul style="list-style-type: none"> ○ Clarify that Medicaid funding is available for CHW to address SDOH, building on the 7 January 2021 CMS SDOH road map. ○ Clarify that CHW qualifications should focus on life experience, interpersonal skills as natural helpers, community membership, and formal education or clinical training. ○ Develop policies that require CHW services be delivered in accordance with evidence-informed standards for CHW programs such as those developed by the National Committee for Quality Assurance, the CDC CHW Core Consensus (C3) Project, the Community Guide, and the National Association of Community Health Workers. ● Increase funding to CDC to expand programs to assist all states in infrastructure development and processes to integrate CHW services in a comprehensive, whole-person approach that includes economic, behavioral, and social supports as well as clinical and preventive services.
Virtual care	<p>Congress should support use of virtual care modalities.</p> <ul style="list-style-type: none"> ● Remove geographic and originating site restrictions so that CMS can provide access to telehealth services as appropriate. ● Make permanent the ability for Federally Qualified Health Centers and Rural Health Centers to provide services by telehealth. ● Make permanent the telehealth waiver for DSMES/DSMT. ● Maintain coverage for audio-only visits to comply with the Executive Order on Advancing Racial Equity and Support for Underserved Communities. <p>The Centers for Medicare & Medicaid Innovation should fund a demonstration project with HRSA and the IHS that utilizes an ECHO-type model to support uptake and implementation of diabetes care best practices among primary care providers and care teams. The project should include training of community health workers, payment for both hub-and-spoke participants' time, collection and analysis of interim data, utilization of a shared services approach for training on the telementoring model, infrastructure, and data collection to inform broader implementation.</p> <ul style="list-style-type: none"> ● In collaboration with the HRSA, provide diabetes-related telementoring to small or rural health clinics (spokes) to include focus on SDOH and behavioral health issues that impact diabetes outcomes and leverage existing academic center hubs to support uptake and implementation of diabetes care best practices. ● In collaboration with the IHS and tribal and urban Indian clinics, create supportive learning and mentorship relationships to assist in implementing diabetes care best practice and leverage the existing Tribal Epidemiology Centers and academic center hubs.

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Table 1—Continued

Focus area	Recommendations
Diabetes care delivery	<p>The CMS should develop and implement a quality measure to assess potential overtreatment, inappropriate treatment, or risk of harm among Medicare beneficiaries with diabetes and life-limiting conditions to reduce the incidence of severe hypoglycemia and improve patient safety.</p> <p>We recommend that federal policies and programs remove cost barriers to ensure that insulin is affordable for all people with diabetes and that no one with diabetes who needs insulin cannot get it because of cost.</p> <p>We recommend that the HHS establish a process to determine and regularly reevaluate high-value diabetes services and treatments to be fully covered (pre-deductible) by health insurance based on their ability to prevent development or progression of diabetes complications.</p>
Diabetes research	<p>The NIH should prioritize funding for research to identify and address factors that affect referrals to and patient uptake of DSMES such as patient-, clinician-, and system-level barriers, quality measures and incentives, and patient-reported outcomes and perspectives.</p> <p>Increase funding for implementation research across federal agencies (for example, AHRQ, NIH, CMS, HRSA, IHS, CDC, Department of Veterans Affairs, and Department of Defense) to better translate team-based care into practice and test new team-based care models to improve diabetes care and outcomes.</p> <p>Digital connectivity should be investigated as an SDOH affecting the development and progression of diabetes.</p> <ul style="list-style-type: none"> • The FCC, the U.S. Department of Agriculture, and the HHS should expand the scope of an interagency memorandum of understanding beyond the Rural Telehealth Initiative or establish another mechanism to bring together the appropriate federal agencies to share information on and investigate 1) the relationship between digital connectivity and health; and 2) the types of digital services and the level of adoption of digital services needed to make a positive impact on health. • The FCC should conduct research to better understand the associations of digital connectivity, diabetes prevalence, and improved diabetes health outcomes.

Patient-reported outcomes indicate that use of these devices leads to a better understanding of and control of glucose levels and reduced fear of hypoglycemia. Additionally, use of these devices may be associated with reduced burden of diabetes-related care, diabetes distress, and acute diabetes complications (12–14).

Nonetheless, newer diabetes devices are underutilized. Administrative requirements make it difficult to obtain and maintain insurance coverage for these devices. The CMS’s eligibility requirements are not interpreted or applied uniformly across the various parties involved in eligibility review and approval. The CMS’s coverage of glucose testing supplies is not aligned with eligibility requirements for diabetes devices. More importantly, eligibility requirements and coverage lag behind the evolving evidence of their effectiveness (15,16).

There is a National Coverage Determination (17) for insulin pumps and a Local Coverage Determination (18) for CGM. Stakeholders report that the eligibility criteria for the National Coverage Determination and Local Coverage Determination are outdated and do not reflect current evidence for whom access to diabetes devices will provide benefits. The CMS’s eligibility requirements for diabetes devices should be updated to better reflect the current scientific

evidence, thereby expanding the population for whom these technologies are “medically reasonable and necessary.” In addition, hypoglycemia avoidance and quality of life should be considered in the coverage determination for these devices.

Recognizing that evidence is rapidly evolving, the CMS should also regularly reevaluate and revise its coverage determinations through an established process that can be initiated internally or by external requests. From the perspectives of patients and providers, the review process is not applied at sufficiently regular intervals to keep the CMS’s eligibility criteria current. The CMS can ensure that appropriate patients receive access to diabetes devices by using existing processes to regularly evaluate new data. At the same time, data on longer-term clinical benefits and cost-effectiveness are needed to support the CMS in considering whether to establish new or to modify existing coverage determinations. Where available data are insufficient to support use of these devices among people with diabetes, identifying gaps in evidence will be important to inform future research.

Recommendation 3

The National Clinical Care Commission recommends that the CMS use existing

processes to update and regularly reevaluate (at least every 3 years) eligibility requirements for various diabetes devices, leading to appropriate coverage determinations when there is sufficient evidence to support such national determinations. The CMS should ensure that, to the extent there are national requirements established, eligibility, documentation, and reimbursement requirements are clearly defined and that they are consistently applied across all parties involved, including Medicare Administrative Contractors and auditors. In evaluating the data to revise eligibility requirements, the CMS should evaluate the current evidence, including published, peer-reviewed evidence, and consider both glycemic benefits and nonglycemic benefits (including patient-reported outcomes, which may include quality of life and diabetes distress).

FOCUS AREA 3: TEAM-BASED CARE
Increase the Health Care Workforce and Support Team-Based Care

Person-centered team-based care is essential to improving the lives of people with diabetes. As an example, team-based care may include a clinician, a pharmacist who titrates medications and checks for drug–drug interactions, a nurse who supports diabetes education and behavior change, a social worker

who addresses social needs, and a care coordinator who helps with referrals and appointments. Managing coexisting medical and behavioral health conditions, multiple medications, preventive care, social factors, and/or other life stressors often impedes the ability of people with diabetes to effectively manage their diabetes (19,20). These complexities also interfere with a single health care provider's ability to offer high-quality, guideline-recommended care. One of the most effective approaches to address these gaps in diabetes care and improve diabetes outcomes is to integrate nonphysician providers into interprofessional care teams (21–25).

We focused on key aspects of person-centered team-based care that may be influenced by federal agencies and have the greatest potential to improve diabetes outcomes, improve patient and provider experiences, and reduce health care costs.

To implement team-based care, clinical practices need access to an appropriately trained workforce, adequate reimbursement to support the team, and assistance and support in incorporating the team into patient care.

Several deficiencies and barriers in federal efforts impede the development, implementation, and sustenance of an appropriate workforce for team-based care:

- Lack of a global assessment of primary health care work force needs
- Lack of standardized data collection to demonstrate the impact of training programs on health care work force needs
- Failure to require agencies that support training programs to address health care workforce needs identified by the Health Resources and Services Administration (HRSA)
- Limits on the types of health care professional trainees that are allowed in certain HRSA training programs, making it challenging to provide interprofessional training

Reimbursement for team members is unreliable, which also limits practices' abilities to develop and implement team-based care. This is especially problematic for CHW, clinical pharmacists, and behavioral health specialists, all of whom can improve outcomes for people with diabetes as part of team-based

care. Value-based payment models, which offer health care providers incentive payments for the quality of care they offer to patients, may help support the inclusion of additional team members.

Implementing team-based care also requires changes in the approach to and design of care delivery. Primary care practices, especially small- and medium-sized practices, often do not have the expertise and/or resources for this transformation. Technical assistance (or practice consultation and coaching) can facilitate practice transformation and the adoption of evidence-based practices, quality improvement, and system changes (26–30). The Primary Care Extension Program was established by the Affordable Care Act to provide this type of technical assistance but currently lacks sufficient funding to accomplish its mandate.

Recommendation 4

We recommend that steps be taken to ensure an adequate workforce and to enhance and sustain team-based care to improve outcomes for people with diabetes:

- Establish a process within the U.S. Department of Health and Human Services (HHS) to routinely assess and identify all health care workforce needs and ensure that training program funding across agencies is directed to meet these needs
 - Ensure the HRSA training programs are designed to meet unmet needs in the team-based health care workforce
 - Evaluate and address regulatory or statutory limitations on HRSA training programs that affect the agency's ability to meet the needs of team-based care and new care models
 - Increase funding for exemplary HRSA programs that support training health care professionals in team-based care in medical shortage areas, such as the HRSA National Health Services Corps
- Identify and implement mechanisms for involvement of CHW, clinical pharmacists, and integrated (or collaborative) behavioral health services in existing and future value-based models of care (alternative payment models)
- Enhance funding to the Agency for Healthcare Research and Quality (AHRQ) through Primary Care Extension Programs and other mechanisms to provide technical assistance to medical

practices to implement team-based care.

Enhance Access to CHW

Social determinants of health (SDOH), including socioeconomic position, health literacy, the food environment, and the built and ambient environments, affect outcomes for people with diabetes. Overcoming these barriers requires connections between providers and community resources. Enhancing trust and cultural competence is particularly relevant given the health disparities that exist in communities of color. CHW serve as liaisons between health and social services and the community.

CHW interventions have been shown to be effective and cost-effective in improving diabetes knowledge, lifestyle behaviors, and health outcomes, especially in disadvantaged populations (31,32). Given substantial health disparities among people with diabetes, implementing effective strategies to aid disadvantaged communities is particularly important to improving diabetes care. However, uptake of CHW has been low because of limited reimbursement and barriers to implementation.

The 2013 CMS Final Rule allowed Medicaid agencies to reimburse community-based preventive services, including those provided by CHW (33). However, most states have narrowly interpreted this rule, concluding that it only applies to medical preventive services and not to social, economic, and behavioral services. The "road map" issued to state health officials by the CMS on 7 January 2021 was designed to further drive the adoption of strategies that address SDOH in Medicaid and the Children's Health Insurance Program (34), but CHW were not specifically mentioned in the road map. In addition, organizations need assistance to integrate CHW into team-based care. The Centers for Disease Control and Prevention (CDC) offer grants, toolkits, and online resources to assist health care organizations, community organizations, and states in implementing and sustaining a CHW workforce. Increased funding to this program will accelerate implementation and sustainability of CHW by addressing system- and policy-level barriers to their integration at the state level.

Recommendation 5

We recommend that steps be taken to enhance implementation and sustainability of CHW as critical members of the diabetes care teams.

- The CMS should clarify and build on the 2013 Final Rule, expanding the scope of Medicaid-reimbursable services by CHW to include social, behavioral, and economic supports as part of covered services.
 - Clarify that Medicaid funding is available for CHW to address SDOH, building on the 7 January 2021 CMS SDOH road map
 - Clarify that CHW qualifications should focus on life experience, interpersonal skills as natural helpers, community membership, and formal education or clinical training
 - Develop policies that require CHW services be delivered in accordance with evidence-informed standards for CHW programs such as those developed by the National Committee for Quality Assurance, the CDC CHW Core Consensus (C3) Project, the Community Guide, and the National Association of Community Health Workers
- There should be an increase in funding to the CDC to expand programs to assist all states in infrastructure development and processes to integrate CHW services in a comprehensive, whole-person approach that includes economic, behavioral, and social supports as well as clinical and preventive services.

FOCUS AREA 4: VIRTUAL CARE**Increase Access to Virtual Care**

“Virtual care” is a broader term than telemedicine and encompasses 1) use of web-based portals for communication between patients and their care teams; 2) electronic consultations between primary care and specialty clinicians; 3) telephone and video clinic visits; 4) data sharing between patients and their care teams; 5) diabetes education classes for patients using technology-based platforms; and 6) real-time, peer-to-peer consultations and mentoring for clinicians and care teams. Increased use of virtual care has the potential to improve patients’ access to high-quality care

as well as reduce the burden and costs of care for many people with diabetes (35).

During the COVID-19 public health emergency, the CMS issued waivers to allow use of virtual care modalities to facilitate data sharing, the delivery of diabetes care and education, and the continued use of diabetes devices without in-person visits. These waivers were well received by both the medical community and patients. Since they continue to help patients receive needed care without in-person visits, these services should be continued and expanded. Telephone clinic visits (i.e., audio only) remain particularly important for individuals with limited digital literacy or access.

Recommendation 6

We recommend that Congress support use of virtual care modalities.

- Remove geographic and originating site restrictions so that CMS can provide access to telehealth services as appropriate
- Make permanent the ability for Federally Qualified Health Centers and Rural Health Centers to provide services by telehealth
- Make permanent the telehealth waiver for DSMES/DSMT
- Maintain coverage for audio-only visits to comply with the Executive Order on Advancing Racial Equity and Support for Underserved Communities

Telementoring to Improve Access to High-Value Care for People With Diabetes

Technology-enabled collaborative learning and capacity building (i.e., telementoring) is a program that has seen limited use by federal agencies. It has the potential to improve access to high-value care for many people with diabetes, especially those who lack access to specialty care. The Extension for the Community Healthcare Outcomes (ECHO) Program is an example of a successful telementoring program. Its hub-and-spoke structure enables capacity building through regular knowledge sharing between specialty care experts (hubs) and geographically dispersed care teams (spokes).

Clinical practices affiliated with the Indian Health Service (IHS) and HRSA serve patients with a high prevalence of diabetes (36,37). These same patients are likely to have difficulty accessing specialty care

(38–40). Primary care clinicians are often responsible for delivering ongoing care but may not have the required tools and specialty expertise. Improving access to telementoring programs would expand their skill sets and help them to deliver high-value care to patients in traditionally underserved settings.

Recommendation 7

We recommend that the Centers for Medicare and Medicaid Innovation fund a demonstration project with the HRSA and the IHS that utilizes an ECHO-type model to support uptake and implementation of diabetes care best practices among primary care providers and care teams. The project should include training of CHW, payment for hub-and-spoke participants’ time, collection and analysis of interim data, and utilization of a shared-services approach for training on the telementoring model, infrastructure, and data collection to inform broader implementation.

- In collaboration with HRSA, provide diabetes-related telementoring to small or rural health clinics (spokes) to include focus on SDOH and behavioral health issues that impact diabetes outcomes and leverage existing academic center hubs to support uptake and implementation of diabetes care best practices.
- In collaboration with IHS and tribal and urban Indian clinics, create supportive learning and mentorship relationships to assist in implementing diabetes care best practice and leverage the existing Tribal Epidemiology Centers and academic center hubs.

FOCUS AREA 5: DIABETES CARE DELIVERY**Preventing Hypoglycemia**

Quality measures for diabetes have primarily focused on treating hyperglycemia because the degree and duration of hyperglycemia are directly related to the risk of long-term diabetes complications. However, intensive treatment goals may have only modest benefits but carry increased risk in older adults with diabetes and advanced complications and/or comorbidities and in people with limited life expectancy.

Severe hypoglycemia is an important risk for people treated with insulin or

insulin secretagogues. The risk of attendant harm from severe hypoglycemia (e.g., falls, fractures, hospitalizations, and death) is increased in older adults (41). Therefore, less intensive glucose targets and medication deprescribing are appropriate for 1) older adults taking medications that increase risk of hypoglycemia who may be unable to recognize and/or appropriately treat hypoglycemia (e.g., people with cognitive impairment or dementia); and 2) individuals across the life span with clinical conditions that limit life expectancy (e.g., patients with metastatic cancer). In these and other subsets of patients, the risks from hypoglycemia, treatment burden, and costs may outweigh any potential benefits. Such potential overtreatment lies at the intersection of low-value practices and patient safety and should be discouraged.

Current federal quality measures focus solely on avoiding hyperglycemia. However, treatment approaches that relax targets for glucose control in some older adults or those with limited life expectancy are widely considered to be appropriate diabetes care. Nonetheless, clinicians often treat such patients with more intensive glycemic goals as an unintended consequence of current quality measures. Therefore, a quality measure should be developed and applied that focuses on the subset of patients with diabetes in whom the risks of hypoglycemia outweigh any potential benefits.

Recommendation 8

We recommend that CMS develop and implement a quality measure to assess potential overtreatment, inappropriate treatment, or risk of harm among Medicare beneficiaries with diabetes and life-limiting conditions to reduce the incidence of severe hypoglycemia and improve patient safety.

Insulin Affordability

At least 7 million people in the U.S. use insulin to manage their diabetes, and for many of these people, including all of those with type 1 diabetes, insulin is life-sustaining. However, the cost of insulin has increased dramatically and at a rate that far exceeds the rate of inflation, making insulin unaffordable for many people with diabetes. The cost of a vial of insulin glargine (Lantus) rose from \$47 in 2002 to

\$340 in 2022 (42). This high cost of insulin poses a tremendous barrier to optimal diabetes treatment. At least one in four individuals treated with insulin report rationing their insulin (43), while even more make significant trade-offs in other aspects of their lives (e.g., food, housing, transportation, etc.) to purchase insulin.

Recommendation 9

We recommend that federal policies and programs remove cost barriers to ensure that insulin is affordable for all people with diabetes and that no one with diabetes who needs insulin cannot get it because of cost.

Insurance Coverage for Secondary Prevention

Diabetes treatment goals are directed at maintaining health and preventing complications such as cardiovascular disease, retinopathy, nephropathy, and neuropathy. Indeed, diabetes complications are the greatest cause of morbidity and mortality and the largest contributor to the cost of diabetes in the U.S. (44). When diabetes complications are present, the cost of care is three times higher than when there are no complications (45).

Prevention strategies fall into three categories: primary prevention, to prevent a disease before it occurs; secondary prevention, to reduce the impact of the disease once it has occurred; and tertiary prevention, to reduce disability and restore function in someone with a complication of the disease. Nearly two-thirds of people with diabetes do not receive guideline-recommended care, putting them at risk for avoidable health care utilization and costs (1).

As a provision of the Affordable Care Act, health insurers are required to cover, at no cost to the patient, primary prevention services that the U.S. Preventive Services Task Force recommends as Grade A (strongly recommended) or Grade B (recommended). However, secondary prevention strategies (e.g., DSMES) and tertiary prevention strategies (e.g., eye exams and laser treatment for retinopathy) are not treated similarly even if they are highly cost-effective. For most patients, including Medicare beneficiaries, secondary and tertiary prevention services require cost sharing as part of the coverage. For people with diabetes, and especially those with lower incomes, cost sharing reduces

treatment adherence. Removing cost sharing enhances adherence to prevention services and therapies (46). Providing pre-deductible coverage (i.e., coverage at no cost to the patient) for some of the most critical secondary and tertiary prevention services for diabetes offers an opportunity to help close existing gaps in care and the associated human and financial costs of diabetes complications.

Recommendation 10

We recommend that HHS establishes a process to determine and regularly reevaluate high-value diabetes services and treatments to be fully covered (pre-deductible) by health insurance based on their ability to prevent development or progression of diabetes complications.

FOCUS AREA 6: RESEARCH NEEDS

Evaluation of Barriers to DSMES

The underutilization of DSMES is multifactorial, with barriers at the patient, clinician, and health system levels. Although some barriers have been identified, research is needed to uncover and understand additional barriers (47). In addition, research is needed to test approaches to address these barriers and improve referral to and uptake of DSMES.

Recommendation 11

We recommend that the National Institutes of Health (NIH) prioritize funding for research to identify and address factors that affect referrals to and patient uptake of DSMES, such as patient-, clinician-, and system-level barriers, quality measures and incentives, and patient-reported outcomes and perspectives.

Implementation Research for Team-Based Care

There is a need to better define implementation strategies to accelerate adoption of team-based care to improve diabetes outcomes. Implementation research attempts to close the gap between knowing and doing by identifying and addressing barriers to the uptake of new, proven health interventions (48,49).

Recommendation 12

We recommend increased funding for implementation research across federal agencies (e.g., AHRQ, NIH, CMS, HRSA, IHS, CDC, Department of Veterans Affairs, and Department of Defense) to

better translate team-based care into practice and test new team-based care models to improve diabetes care and outcomes.

Digital Connectivity as an SDOH

Diabetes is highly prevalent in communities with low internet connectivity, lower incomes, lower achieved education levels, and older age. Indeed, there is an inverse relationship between the prevalence of diabetes and the degree of broadband connectivity. Federal programs to improve internet access for people with low income are available (e.g., Lifeline Program), but digital connectivity, or lack of it, is associated with not only access to health care but also education and distance learning, employment (e.g., remote work), job searches, online applications, training, and much more. This suggests that digital connectivity is a “super” SDOH because it amplifies the impact of other social factors (50–53). Further, investigation of the mechanisms of how digital connectivity is associated with health is critical to improving health outcomes.

Recommendation 13

We recommend that digital connectivity be investigated as an SDOH affecting the development and progression of diabetes.

- The Federal Communications Commission (FCC), the U.S. Department of Agriculture, and the HHS should expand the scope of an interagency memorandum of understanding beyond the Rural Telehealth Initiative or establish another mechanism to bring together the appropriate federal agencies to share information on and investigate 1) the relationship between digital connectivity and health; and 2) the types of digital services and the level of adoption of digital services needed to make a positive impact on health.
- The FCC should conduct research to better understand the associations of digital connectivity, diabetes prevalence, and improved diabetes health outcomes.

SUMMARY

The Treatment and Complications subcommittee identified many federal policies and programs that impact diabetes

treatment and complications and targeted six key areas that were felt to have the greatest potential to improve diabetes care in the U.S. The subcommittee’s recommendations direct Congress and several federal departments and agencies to reduce administrative barriers, improve access to high-value patient-centered care, and address knowledge gaps. We believe that implementing these recommendations will benefit the health of people with diabetes and further support clinicians as they advocate for patients’ access to effective diabetes treatments.

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