National Clinical Care Commission Webinar Meeting 9
Tuesday, November 17, 2020
1:00 pm — 5:30 pm EST

Meeting Summary

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Welcome, Review of Agenda, and Introduction

Dr. Clydette Powell, Designated Federal Office for the National Clinical Care Commission (NCCC), welcomed everyone to the meeting and conducted roll call (see Appendix for Commission members). The meeting started with a quorum.

Dr. William (Bill) Herman, Chair of the NCCC welcomed everyone and briefly reviewed the Commission's Charge and duties. Dr. Herman explained that the Commission's activities have been performed by three Subcommittees: the Prevention—General Population Subcommittee, the Prevention—Targeted Population Subcommittee, and the Treatment and Complications Subcommittee. He noted that there is also a Work Group focusing on access to care and promising models for integrated service delivery and payment, and that all of the three subcommittees address crosscutting issues related to health equity, social determinants of health, and research need.

Dr. Herman explained that today the Commission will hear updates from the three Subcommittees, discuss the Subcommittees' draft recommendations, and hear public comments.

Dr. Herman introduced Dr. Dorothy Fink, Deputy Assistant Secretary for Women's Health, Director of the Office on Women's Health (OWH), Office of the Assistant Secretary for Health.

Dr. Fink expressed her appreciation for the opportunity to greet the Commission. She stated that it is a privilege to support the Commission, and the OWH is well positioned to ensure a smooth transfer of support from the Office of Disease Prevention and Health Promotion (ODPHP) to OWH. Dr. Fink noted that the Commission's efforts synergize with the OWH's work, and that the OWH team is looking forward to the Subcommittee's updates, their second round of draft recommendations, and public comments.

Treatment and Complications Subcommittee Update

Introduction and Update

Dr. Carol Greenlee, co-chair of the Treatment and Complications Subcommittee, briefly reviewed the Subcommittee's focus and work process. She explained that they have divided the Subcommittee into four priority area groups, including:

- Diabetes Self-Management Education and Support (DSMES)
- Team-based Care
- Diabetes Technology
- Virtual Care

Health Equity

Dr. Greenlee then reviewed the Subcommittee's first mature draft recommendation on health equity.

Draft recommendation 1: (the Centers for Medicare & Medicaid Services [CMS] and other departments and agencies including the U.S. Department of Veterans Affairs [VA], the Health Resources and Services Administration [HRSA], the Indian Health Service [IHS], the U.S. Department of Defense [DoD], and the Federal Bureau of Prisons [BoP]):
"Health equity as a component of any new or revised policy related to diabetes"

- For any new or revised policy related to diabetes, the relevant federal agency will consider and evaluate the impact on health disparities.
- Federal agencies will ensure collection of appropriate and relevant data and will use such data to assess and improve the impact of their policies and/or regulations on health disparities among persons with diabetes.

Diabetes Education and Support

Dr. Jasmine Gonzalvo, team lead of the DSMES Priority Area Group explained that the group had additional calls with the American Diabetes Association (ADA) and the American Association of Diabetes Educators (ADCES) and received written comments. She then briefly reviewed the following six draft recommendations that the group first presented at the Commission's last meeting (Meeting 8).

Draft recommendation 1: Expand access and reduce barriers to delivery of Diabetes Self-Management Training (DSMT).

Draft recommendation 2: Reduce administrative burden regarding standards and documentation requirements for DSMES programs.

Draft recommendation 3: Create a task force with the authority to update the Medicare Quality Standards (1997) that govern DSMT.

Draft recommendation 4: Establish a process for ongoing timely review, updating and revision with input from external stakeholders.

Draft recommendation 5: Develop processes to utilize Quality Innovation Network-Quality Improvement Organization (QIN-QIO) data to generate CMS policies that support community-based diabetes education programs.

Draft recommendation 6: Prioritize funding for innovative research to explore factors that affect referrals to and patient uptake of DSMES, such as patient, clinician, and systemic-level barriers, quality measures and incentives, and patient reported outcomes and perspectives.

Dr. Gonzalvo noted that the group is drafting content to support these draft recommendations.

Diabetes Technology

Dr. Bill Chong, team lead of the Diabetes Technology Group, explained that the group conducted additional stakeholder calls, refined their draft recommendations based on the

additional information gathered through the calls and public comments, and are developing additional recommendations. He then presented the group's three draft recommendations that have been refined since the last Commission meeting.

Draft recommendation 1: Continue to allow for virtual visits to minimize disruption of care and reduce unnecessary patient burden.

Draft recommendation 2: Update current eligibility requirements for different diabetes technologies and establish a process for regular re-evaluation of the eligibility requirements.

Draft recommendation 3: Establish a process to ensure clarity and consistent application of eligibility and reimbursement requirements across all parties involved, including Medicare Administrative Contractors and Auditors.

Team-Based Care

Dr. Shari Bolen, team lead of the Team-based Care Group, explained that since the last Commission meeting, the group has broadened the concept of team-based care and revised their draft recommendations. She briefly reviewed the group's focus areas and highlighted the key barriers to implementing team-based care. Dr. Bolen then presented the group's draft recommendations intended to address issues related to health care workforce shortages, reimbursement for team-based care, and technical assistance.

Clinician Workforce

Dr. Bolen shared what the group has learned from stakeholder calls regarding clinician workforce shortage and presented draft recommendations that the group is still working on.

- Global assessment of health care workforce (not just specific subgroups such as physicians) is needed. Currently there are not coordinated data collection efforts to show the effectiveness of the training programs in addressing the workforce needs.
- Congress established the National Health Care Workforce Commission under Section 5101 of the Affordable Care Act to provide data on the health care workforce and policy advice to Congress and the administration, but the Commission has not been funded.
- The Workforce Commission is charged to:
    - Communicate and coordinate with different government agencies over workforce policies
    - Develop and commission evaluations of workforce education and training programs
    - Identify barriers to improve coordination of federal, state, and local workforce policies
    - Encourage workforce innovations to address population health needs
    - Produce two reports annually on key workforce issues

Draft recommendations (under development): The National Health Care Workforce Commission (or a similar committee) should be funded to assess health care workforce needs, and relevant government agencies (i.e. CMS, HRSA, DoD, VA) should act on this information by affecting policies to align clinician workforce policies to meet national needs.

Dr. Bolen explained that such a recommendation has been proposed in the past; however no actions were taken. She noted that additional steps may be needed to achieve the stated goals.

Reimbursement for Team-Based Care (under development)
Dr. Bolen shared that all stakeholders that the group has spoken with suggested

- Incorporating the utilization of community health workers, pharmacists, and integrated (or collaborative) behavioral health specialists into existing Medicare and Medicaid value-based payment models through incentives,
    - The incentives could be additional or not fully accrued without the use of specific team members.
    - The incentives are needed at the provider and team levels as well as the system level.

Technical Assistance (under development)
Dr. Bolen shared that most stakeholders mentioned the need to consult experts on how to integrate team members. She explained that the stakeholders offered the following two suggestions.

- Fund Primary Care Extension Programs listed in the Affordable Care Act Section 5405.
- Provide support for primary care practices to hire consultants.

Next Steps
Dr. Bolen stated that the group will 1) refine the draft recommendations that are under development and 2) determine additional recommendations.

Discussion
Dr. Dean Schillinger asked Dr. Bolen if the Subcommittee will make specific recommendations regarding increasing primary care-related workforce needed to meet the needs.

Dr. Bolen agreed there are areas of need. She explained that the Subcommittee may not go to that level of detail. She noted that the Subcommittee does not have a good sense regarding how to fully address all the health care workforce needs beyond the physician level, and they do not have assessment of different groups of the health care workforce to help fill the need. She explained that the Subcommittee is trying to recommend funding the Workforce Committee to review the issue broadly.

Dr. Schillinger highlighted HRSA's grant programs designed to produce primary care physicians. He asked if the Subcommittee would recommend scaling up those successful programs.

Dr. Bolen agreed that there might be an opportunity at HRSA. She explained that the group plans to learn more from additional stakeholders and may make a separate recommendation.

Dr. Carol Greenlee added that the Subcommittee recognizes there is a disconnect between the needs assessment and where the funding goes regarding Graduate Medical Education. She explained that the Subcommittee is hoping that if a National Workforce Commission is funded, they might also have some authority to increase the accountability around meeting the needs. However, the challenge is that the National Workforce Commission was never funded, she said, even though it was recommended by many organizations. Dr. Greenlee shared that in addition to making a recommendation around funding the National Workforce Commission, the Treatment and Complications Subcommittee is exploring other options to address the needs.

Dr. Paul Colin added that the Subcommittee welcomes input from other Subcommittees when making recommendations in overlapping areas.

Dr. Don Shell asked if the Subcommittee members are aware of the metrics used to evaluate the outcome/effectiveness of the existing training programs.

Dr. Bolen replied that there is a lot of success in HRSA's training programs in terms of meeting the needs of local areas; however, the programs do not measure health outcomes.

Dr. Schillinger added that HRSA's training programs do not track changes in preventable hospitalization rates by region because they do not have control over where the graduates practice.

Dr. Colin commented that CMS is a larger funder than HRSA; however, there is little accountability as to how they allocate training funds for physicians (primary or sub-specialties). He shared his view that global changes will be needed, not just specific programs funded by HRSA.

Virtual Care

Ms. Ellen Leake, team lead of the Virtual Care Group, shared that the group conducted additional stakeholder calls and developed a few draft recommendations. Ms. Leake provided background information and highlighted the key issue(s) for each draft recommendation.

VA/DoD Virtual Medical Center

Background: In 2019, VA/DoD Joint Incentive Fund supported the development and implementation of a national virtual information technology platform, which uses a bidirectional avatar-to-avatar exchange to deliver virtual care and education.

Issue: A common barrier to the completion of DSMES is access to a certified program. Remote and rural locations can mean long travel times to a certified center, and traditional class times can conflict with work schedules. For example, both the IHS and HRSA have high rates of

diabetes among their beneficiaries and encounter some of the same problems with access and staff and program availability. Increased levels of collaboration and access facilitated between the federal agencies regarding DSMES/DSMT will contribute to increased access for all covered lives in federal health programs.

Draft presentation: Provide funding to design and implement a pilot program that leverages the VA/DoD Virtual Medical Center in order to increase access to DMSES/DSMT for beneficiaries/ people with diabetes in additional federal health programs.

E-consultations

Background: E-consultations (virtual clinician-to-clinician consultations) offer an opportunity to get needed specialty care assistance for people with diabetes with

- Less delay (wait time)
- Access for those who might not otherwise have it available (location or payer type)
- Less cost to the system for the encounter (as well as for delayed or missed care)
- Less risk of fragmentation
- Less patient burden and personal cost
- A mechanism to transfer new evidence and expertise into the practice of primary care physicians effectively and efficiently

Issue: Confusion and burden to practices and patients around coding and billing often discourage utilization of e-consultations and threaten program integrity.

Draft recommendation: CMS should take the following steps to increase program integrity and utilization of virtual asynchronous interprofessional consultations (i.e. e-consults)

- Require that billing code 99452 be submitted only after treating providers act on recommendations provided by a consultant.
- Clarify language within the CPT descriptor for billing codes 99451 and 99452 that indicates treating providers should not use these codes if a transfer of care or other face-to-face service is generated by the e-consultant.
- Clarify that 7 and 14-day limits on single use of 99451 and 99452 should apply per-patient per-specialty. Consultations with more than one specialty during the time windows should allow use of such codes for each discrete request.
- Pursue pathways to waive co-insurance requirements for billing codes 99451 and 99452 to reduce complexity and incentivize use of e-consultations.

Project ECHO

Background: Project ECHO (the ECHO model) increases the capacity of health workers in rural and underserved areas to provide best-practice specialty care to their patients, in the communities where they live. The ECHO model uses videoconference technology to connect providers in underserved communities (“spokes”) with teams of specialists at regional and national medical centers (“hub”) for long-term tele-mentoring, collaboration, and case-based learning on urgent health topics and conditions. The ECHO model is not “telemedicine,” in

which specialists assume care of the patient. Instead, participation in ECHO programs gives local providers the knowledge and self-efficacy to better care for their own patients, in the communities where they live.

Issue: Funding for operational costs are inadequate and limit the reach and sustainability and thus the benefit (impact) of these programs. Medications, technology or other treatment modalities do not benefit patients with diabetes if care providers are unfamiliar or uncomfortable with how to prescribe, implement, and monitor these modalities.

Draft recommendation (under development): Identify funding mechanisms to advance the use of technology-enabled collaborative learning and capacity-building models (e.g., Project ECHO).

- Expand grant programs under HRSA and possibly other federal agencies to use the ECHO model to improve access to specialty care in rural or medically underserved areas.

Telehealth Waivers (under development)

Ms. Leake explained that the Subcommittee is waiting to see whether or not the telehealth waivers will be continued, and that they will decide what to do next accordingly.

Next Steps

Ms. Leake noted that the Subcommittee wants to make sure that any recommendations will not further exacerbate the digital divide, and the group will develop more draft recommendations around waivers and the digital divide before the Commission's February 2021 meeting.

Discussion

Dr. John Boltri expressed his support for the draft recommendation around Project ECHO because in his view it helps primary care physicians working in rural areas. He, however, also raised concern over the draft recommendation on e-consultation, particularly the billing code 94452. He pointed out that if the Subcommittee recommends that primary care physicians get paid only if they act upon the consultants' advice, it would discourage primary care physicians to consult with specialists because of the large amount of paperwork and the small amount of reimbursement. He suggested either wording the draft recommendation differently or recommending reimbursing the primary care physicians more to increase the utilization. Dr. Boltri also noted that he was not sure if requiring the primary care physician to act on the consultant's advice would help increase the utilization.

Dr. Greenlee replied that the Subcommittee developed the draft recommendation based on the input from the Association of American Medical Colleges, and the Subcommittee has sent a follow-up request for further clarification. She explained that the copays can discourage both the primary care physician and the specialist to utilize e-consultation, and that the Subcommittee is trying to find a way to get rid of the copays. She stated that the Subcommittee will revise the wording to improve clarity.

Dr. Boltri agreed with Dr. Greenlee on waiving the copays. He reiterated that adding additional documentation burden to primary physicians for the already small amount of reimbursement would discourage primary physicians from using e-consultation.

Dr. Bill Herman asked Ms. Leake to provide some specifics in the legislation around Project ECHO.

Ms. Leake explained that the bill is in the house but it has never gone to the Senate. Overall, it is about long-term sustainable funding, she said.

Dr. Greenlee clarified that the funding was to HRSA. She added that in the bill, there are also CMS-related elements about participation in ECHO, providing credits to NIPS, and how CMS can further promote the use of Project ECHO. She explained that the Subcommittee's rationale is that the increased funding would help enhance the capacity of the agencies (e.g., HRSA and IHS) to meet the patients' needs and to generate a big return of investment.

Dr. Naomi Fukagawa asked about the Workforce Commission. She commented that the Workforce Commission's charge seems to be in line with the National Clinical Care Commission's charge. She wanted to know how that addresses reducing redundancy, which is one of the tasks the NCCC is charged to do.

Dr. Bolen explained that the scope of globally assessing workforce shortages is large, and she was concerned that the National Clinical Care Commission may not have the capacity to address the large issue.

Prevention—Targeted Population Subcommittee Update

Introduction and Overall Update

Dr. John Boltri, co-chair of the Prevention—Targeted Population Subcommittee, announced that Subcommittee Co-Chair Ann Albright will retire after this meeting, and that he and Dr. Howard Tracer will be co-chairs of the Subcommittee.

Work Progress

Dr. Boltri explained that the Subcommittee carries out its work through four Focus Area Groups, which have gathered additional information through stakeholder calls and literature search.

Team leads of the Focus Area Groups one by one presented their draft recommendations. For each recommendation, they provided background information and highlighted the issue(s) to be addressed.

Focus Area 1: Screening/Diagnosis for Prediabetes/Diabetes

Dr. David Strogatz, team lead of the Focus Area 1 Group, presented four draft recommendations.

TOPIC: Raising public awareness about prediabetes and the National Diabetes Prevention Program

Background: Since 2016 CDC has collaborated with the Ad Council on a national public service campaign to raise awareness about prediabetes. The campaign website has links for a brief self-administered test for the risk of prediabetes and zip code locations where the National Diabetes Prevention Program (National DPP) is offered. More than 3.4 million people have visited the website and completed the prediabetes risk test, and more than 124,000 people visited the National DPP website to find the location of a program.

Issue: Gaps in awareness for those with prediabetes and familiarity with the National DPP is still significant. The 2020 National Diabetes Statistics Report showed that only 15.3% of adults with prediabetes (based on fasting glucose 100-125 mg/dL or HbA1c 5.7-6.4%) reported having been told they have prediabetes by a health professional.

Draft recommendation 1: Increase support to the CDC for its role in the continuation of the campaign. The increased support could enhance the specific strategies within CDC cooperative agreements with state/local health departments (DP18-1817) and affiliates of national organizations (DP17-1705) to increase awareness of prediabetes and the National DPP in high-burden populations and underserved areas.

TOPIC: Expanded coverage for screening/diagnostic tests used to confirm prediabetes

Background: Criteria for abnormal blood glucose in the diagnosis of prediabetes have established for fasting blood glucose, glucose tolerance test, and hemoglobin A1c. However, Medicare does not cover hemoglobin A1c for prediabetes screening.

Issue: The two tests that are covered present logistical complications (that is, required fasting state of the patient, extended length of the clinic visit) that do not apply to the test of hemoglobin A1c levels. The 2015 United States Preventive Services Task Force (USPSTF) recommendations and the 2018 American Diabetes Association (ADA) guidelines for standards of medical care cite fasting blood glucose, oral glucose tolerance test, and hemoglobin A1c as equally appropriate tests for clinicians to consider screening and testing for prediabetes and diabetes.

Draft recommendation 2: CMS should provide coverage of hemoglobin A1c testing when used to screen for prediabetes.

TOPIC: A new clinical quality measure for screening of abnormal blood glucose

Background: In 2019 the American Medical Association (AMA) proposed three new electronic clinical quality measures for review by the National Quality Forum to monitor and improve

quality of care for patients with prediabetes. The measure that is specific to screening and diagnosis is "The percentage of patients aged 40 years and older with a BMI greater than or equal to 25 who are seen for at least two office visits or at least one preventive visit during the 12 month period who were screened for abnormal blood glucose at least once in the last three years." The measure was derived from the 2015 USPSTF guidelines and 2018 ADA guidelines; both sets of guidelines indicate use of fasting blood glucose, oral glucose tolerance test, or hemoglobin A1c for screening purposes.

Issues: Analyses of data from the National Health and Nutrition Examination Survey (NHANES) showed that a high percentage of adults meeting screening criteria proposed in USPSTF and ADA guidelines reported not being screened for diabetes in the past three years. Guidance therefore is needed on the interpretation and follow-up of random (non-fasting) blood glucose tests when results are not available for the recommended screening modalities.

Draft recommendation 3: Endorsement and promotion of this clinical quality measure by all federal agencies that directly deliver or influence the delivery of care.

TOPIC: Use of existing administrative data to identify patients meeting the criteria for prediabetes

Background: Analyses of electronic medical records and laboratory claims data have shown that testing for abnormal blood glucose or HbA1c levels has become more common in middle-aged and older adults. However, the opportunity to identify a patient with prediabetes and refer the patient to a prevention program may be missed during an acute or routine visit because of the clinician's competing priorities or incomplete information gathered at the time.

Issue: Administrative data could be queried to create a registry of patients meeting the criteria for prediabetes (e.g., on the basis of BMI and abnormal blood glucose or HbA1c). Patients in the registry could be contacted by clinic staff to discuss prediabetes and opportunities to enroll in the National DPP or Medicare DPP. The patient's medical record could be flagged for reinforcement of these messages at future visits.

Draft recommendation 4: Federal agencies that deliver care (e.g., VA, DoD, IHS) should systematically use administrative data to identify patients already meeting criteria for prediabetes and to confirm appropriate follow-up.

Focus Area 2: Improve Access to and Utilization of Evidence-based Effective Type 2 Diabetes Prevention Interventions

Dr. Shannon Idzik, team lead of the Focus Area 2 Group, presented the refined draft recommendations and provided background information.

TOPIC: Metformin and FDA Approval

Background: There is a body of clinical evidence to support the use of metformin in delaying the onset of diabetes. However, metformin does not have an FDA approved indication for prediabetes.

Issue: FDA has not approved metformin for the treatment of prediabetes. Lack of an FDA approval affects coverage and payment for metformin. Prescribing metformin for prediabetes is currently considered "off-label" use.

Draft recommendation 1: FDA approve metformin for the delay of type 2 diabetes.

TOPIC: Interagency Coordinating Body

Background: Originally mandated by Public Law 93-354 and established in 1974, the Diabetes Mellitus Interagency Coordinating Committee (DMICC) is chaired by the National Institute of Diabetes and Digestive and Kidney Diseases and includes other members of the Department of Health and Human Services (HHS) and other federal agencies that support diabetes-related activities. The DMICC facilitates cooperation, communication, and collaboration on diabetes among these government entities. This approach helps ensure that federal diabetes activities are coordinated and not duplicated, as well as stimulates collaborations where appropriate.

Issue: There is a lack of understanding of how the statutory authority and scope of the DMICC aligns with the recommendation of the NCCC around a federal interagency coordinating body within HHS to review, support, promote, and implement proven evidence-based programs.

Draft recommendation 2: Identify or establish a federal interagency coordinating body within HHS to review, support, promote, and implement proven evidence-based programs shown to be effective in preventing or delaying type 2 diabetes.

TOPIC: Delivery of Evidence-based Interventions

Background: Various modes have been used across federal agencies to deliver evidenced-based interventions to delay/prevent type 2 diabetes. However, there is variation in coverage by private and public payers of delivery modes that have evidence of successful patient outcomes in delaying or preventing type 2 diabetes.

Issue: There are barriers to access to evidence-based type 2 diabetes delay/prevention interventions. Offering these interventions through a variety of delivery modes may increase access; however, coverage for alternative delivery modes varies across payers.

Draft recommendation 3: Coverage for all proven modes of delivery for evidence-based interventions that produce successful patient outcomes consistent with the National DPP quality standards in delaying or preventing type 2 diabetes.

TOPIC: CDC Recognition and CMS Payment

Background: In response to the increasing incidence of diabetes and prediabetes in the U.S., Congress authorized CDC to establish the National DPP in 2010. The National DPP is a partnership of public and private organizations working together to build a nationwide delivery system for a lifestyle change program proven effective to prevent or delay the onset of type 2 diabetes in adults with prediabetes. The National DPP provides a framework for type 2 diabetes prevention efforts in the U.S. based on: 1) a trained workforce of lifestyle coaches; 2) national quality standards supported by the CDC Diabetes Prevention Recognition Program; 3) a national network of program delivery organizations sustained through public/private payer coverage; and 4) participant referral and engagement. The Center for Medicare and Medicaid Innovation and CDC are collaborating to meet joint agency priorities related to the Medicare Diabetes Prevention Program (Medicare DPP) expanded model. The CY 2017 Physician Fee Schedule final rule, published on Nov. 15, 2016, established a framework for the expanded model, enabling National DPP program delivery organizations with CDC full or preliminary recognition to enroll as Medicare DPP suppliers effective January 1, 2018 in anticipation of the April 1, 2018 start date for furnishing Medicare DPP services. CDC revises its Diabetes Prevention Recognition Program Standards and Operating Procedures every 3 years in response to changes in the scientific literature, data from organizations participating in the recognition program, and public comments. There are additional requirements for programs to bill Medicare.

Issue: Some organizations in rural and underserved areas experience challenges in achieving preliminary or full CDC recognition and applying to become Medicare DPP suppliers.

Draft recommendation 4: Streamline CDC recognition process, ongoing data collection/record keeping, and CMS payment process for the Nation DPP/Medicare DPP while maintaining quality

TOPIC: Medicare DPP Restriction

Background: Section 1115A of the Social Security Act (SSA) established the CMMI to test innovative payment techniques and service delivery models. The Medicare DPP is one of the models currently being tested. Section 1115A of the SSA states “The Secretary shall elect models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title.” “The Secretary shall conduct an evaluation of each model tested under this subsection. Such evaluation shall include an analysis of

- the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centered criteria determined appropriate by the Secretary; and
- the changes in spending under the applicable titles by reason of the model.”

The Medicare DPP continues as an expanded model test. There will be a final evaluation as described above. It is covered service under the model demonstration. In the current CMMI Medicare DPP, there is a once-in-a-lifetime limit on the Medicare DPP service.

Based on findings from the original DPP research trial, subsequent translation studies demonstrating the program's effectiveness in non-clinical settings, and the 15-year results of the DPP Outcomes Study, this intervention has been studied extensively and has substantial evidence supporting its effectiveness across settings and populations.

Issue: The future of the Medicare DPP as a covered service will be determined by the outcome of the CMMI model demonstration evaluation. Full virtual delivery of the Medicare DPP is not currently included under the expanded model; this may limit CMS's ability to enroll a sufficient number of Medicare beneficiaries required to evaluate the expanded model. Virtual delivery of make-up sessions is part of the Medicare DPP expanded model (as described in the 2018 Physician Fee Schedule). There may be variables that affect participants' ability to fully engage in or complete the program that may warrant additional intervention. There may be a dose-related impact.

Draft recommendations 5:

- Approve Medicare DPP as a covered benefit (not just a model expansion service)
- Lift the once-in-a-lifetime limit on Medicare DPP as a covered service

TOPIC: Medicare DPP Reimbursement Rates

Background: The CY2017 and 2018 Physician Fee Schedule final rules established the benefit structure and payment rates for the Medicare DPP based on a Diabetes Prevention Progress model test conducted from 2013 to 2015. The payments are adjusted annually.

Issues: Current Medicare DPP payment rates may not be sufficient to cover the expenses of many program delivery organizations. Currently, only a limited number of eligible organizations with preliminary or full CDC recognition have applied to become Medicare DPP suppliers. Reimbursement rates may have a disproportionate impact on smaller and rural programs.

Draft recommendation 6: Increase the reimbursement rate for the Medicare DPP.

TOPIC: Medicaid Coverage

Background: Medicaid coverage for the National DPP is a state-level decision. The National DPP is delivered in various evidence-based delivery methods. Since 2012, 17 states have achieved varying levels of Medicaid coverage of the National DPP through Medicaid State Plans, 1115 waivers, pilots with Medicaid Managed Care Organizations (MCOs), and additional mechanisms. State Medicaid Agencies—or MCOs in the case of voluntary coverage—determine the types of delivery modes (in-person and/or virtual) that would be covered.

Issue: Medicaid coverage for the National DPP vary from state to state. Covered delivery modes and the level of reimbursement authorized differ across states. The risk for developing diabetes is higher in the Medicaid population than other populations.

Draft recommendations 7:

- Increase the number of states that choose to cover the National DPP and other evidence-based interventions that produce successful patient outcomes consistent with the National DPP quality standards in delaying or preventing type 2 diabetes within their Medicaid programs.
- Promote state Medicaid coverage of all proven modes of delivery for evidence-based interventions that produce successful patient outcomes consistent with the National DPP quality standards in delaying or preventing type 2 diabetes.

Discussion

Awareness

Dr. Bill Herman commented that the first and the fourth draft recommendations in Focus Area 1 appear to be about increasing awareness. He suggested broadening the efforts to increase awareness in the general population.

Dr. David Strogatz responded that one of the CDC cooperatives he mentioned goes to all states to improve awareness and familiarity with the National DPP for the general population, and that the two cooperatives highlighted in the first draft recommendation have a specific charge for extending outreach to underserved and highly burdened populations.

Dr. Ann Albright added that CDC's public awareness campaign is for the entire population. She explained that the Ad Council Campaign is aired for the entire population, but they have alternated the targeted audiences over the years to ensure the message resonates. She further explained that the funding provided through the specific cooperative agreements goes to the states or national organizations to raise awareness and program uptake by those populations; however, there are also efforts to reach the entire population. Additionally, CDC also has efforts focusing on adults at high risk, she said.

Quality measures

Dr. Carol Greenlee asked for clarification about the AMA quality measures.

Dr. Ann Albright clarified that those three measures are intended to be used by all entities including CMS, health care organizations, and commercial payers. Currently, only one measure is on CMS's MUC list (referral to National DPP or national nutrition therapy).

Dr. David Strogatz added that in Focus Area 1, the Subcommittee mentioned only one of the three measures that is related to screening.

Participation in Medicare DPP
Dr. Greenlee commented that one of the biggest barriers to participation in Medicare DPP is the upfront cost. She asked Dr. Idzik if the Subcommittee plans to address the issue in the repot.

Dr. Idzik responded that they have not discussed upfront cost yet.

Dr. Ann Albright explained that most payers require organizations to demonstrate value before they pay. CDC has helped a number of community-based programs to demonstrate value through various mechanisms (e.g., provide funding, and help them connect to other resources or networks). She pointed out that it would be challenging if these organizations cannot demonstrate long-term capability and sustainability. She noted that CDC encourages organizations to explore multiple resources to sustain.

Dr. Dean Schillinger, referencing the DPP study results, wondered if the Subcommittee could make a recommendation around conducting research to identify people with a specific type of prediabetes that would lead to diabetes. He wondered if new research is needed to also identify people who would benefit from the intensive prevention programs such as the National DPP.

Dr. David Strogatz responded that Dr. Schillinger's suggestion/comment would be a good topic for Focus Area 4 (research). He noted that evidence suggests that prediabetes is associated with increased risk of various health conditions (e.g., cardiovascular diseases and other subclinical measures). For those with prediabetes who may not develop diabetes, lifestyle prevention programs may still be beneficial, he said.

Dr. Howard Tracer stated that the best predicator of prediabetes is high A1c and glucose level. He added that Dr. John Boltri will address heterogenicity and other approaches in Focus Area 4.

Focus Area 3: Sustainability of Type 2 Diabetes Prevention

Dr. Howard Tracer, team lead of the Focus Area 3 Group, first provided an overall background and evidence, then presented draft recommendations.

TOPIC: Identify "booster" doses through research
Background: In the DPP study, Intensive Lifestyle Intervention and metformin were both effective in reducing the risk of developing diabetes over 2.8 years (Intensive Lifestyle Intervention: 58%; metformin: 31%).

Issue: However, the optimal strategy to sustain the reduced risk over the longer term is unknown, and the effects of lifestyle interventions and metformin on the risk of cardiovascular disease and other diabetes-related health outcomes in people with prediabetes have not been well studied.

Draft recommendation 1 (NIH, CDC): The NCCC recommends more research on the number, frequency, and content of "booster" doses (i.e., lifestyle intervention sessions) needed, to effectively sustain weight loss and type 2 diabetes prevention in the longer term, after successful completion of a (1 year) diabetes prevention intervention.

- Studies on the effectiveness of metformin and combined approaches to prevent diabetes in the longer term are also needed.
- Studies on sustaining type 2 diabetes prevention over the longer term should also capture the effect of these interventions on the risk of diabetes-related health outcomes such as cardiovascular disease and microvascular disease.

TOPIC: Ensure insurance coverage and reimbursement
Background: Insurance coverage of benefits to a large degree determines the implementation and availability of the type 2 diabetes prevention programs.

Issue: Lack or insufficient reimbursement hinders the availability and implementation of diabetes prevention interventions in the longer term.

Draft recommendation 2 (CMS): The NCCC recommends ensuring that coverage and reimbursement are included in the Medicare and Medicaid payment system for evidence-based strategies that sustain long-term diabetes prevention.

TOPIC: Maintain a continued commitment to prediabetes and diabetes prevention
Background: The overall incidence of type 2 diabetes is increasing in the United States. Reducing the incidence of type 2 diabetes will require a sustained focus on diabetes prevention.

Issue: Funding priorities of federal agencies often shift over time, and federal grants designed to improve community health may not specify diabetes prevention as a priority.

Draft recommendation 3 (NIH, CDC, HRSA, [VA, DoD]): Federal agency initiatives and programs targeting type 2 diabetes prevention should maintain a continued commitment to prediabetes and preventing type 2 diabetes.

Discussion
Dr. Shari Bolen commented on challenges associated with Medicaid coverage, and she asked if one of the Subcommittee's draft recommendations addresses Medicaid coverage across states.

Dr. Howard responded that the Subcommittee did discuss how to get more states to cover Medicaid DPP in Focus Area 2. He stated that the Subcommittee will need to work out more details, and the Subcommittee does intend to address the topic.

Dr. Bolen shared that the Treatment and Complications Subcommittee is making a draft recommendation for DSME, which also has varied coverage by Medicaid. She asked if the

Prevention—Targeted Population Subcommittee has figured out how best to increase Medicaid coverage.

Dr. Idzik shared that one possibility mentioned in one of the Subcommittee's conversations is using federal level incentives to encourage states to make it happen.

Dr. Ann Albright shared that CDC has done demonstration projects with states.

Ms. Pat Schumacher added that part of that effort is about lessons learned, through which CDC is able to document what works. She noted that it was a valuable opportunity to learn from states that have gone that path.

Dr. Shari Bolen suggested that the Prevention—Targeted Population Subcommittee and the Treatment and Complications Subcommittee make a combined recommendation around the topics or ensure alignment if the two subcommittees are to make separate recommendations.

Dr. Ann Albright agreed. She anticipated that a number of recommendations will overlap, and will need to be worked out across all three subcommittees.

Other Commission members agreed.

Focus Area 4: Develop New and More Effective Preventive Strategies for Type 1 and Type 2 Diabetes

Dr. John Boltri, team lead of the Focus Area 4 Group, provided overall background information, highlighted the key issues, and presented draft recommendations addressing type 2 and type 1 diabetes.

Type 2 Diabetes Research

Background: The National DPP was created in 2010 with the CDC-lifestyle change program as its foundation. This lifestyle change program is based on the NIH-sponsored DPP study showing that people with prediabetes who complete a structural lifestyle change program can reduce the risk of developing type 2 diabetes by 58%.

Issues: The DPP developed proven effective methods for preventing type 2 diabetes, yet participation in diabetes prevention programs is low. There are disparities in implementation and uptake of diabetes prevention programs, and social determinants of health may further exacerbate the disparities. Additionally, medications proven to prevent or delay the onset of type 2 diabetes are limited, and most people who achieve weight loss from diabetes prevention programs regain the weight.

Draft recommendation 1: The NCCC recommends funding to

- Promote widespread implementation of the most effective in-person and virtual diabetes prevention programs.

- Study impediments to participation in effective diabetes prevention programs for the communities of greatest need.
- Disseminate new knowledge about effective diabetes prevention programs both in-person and virtually.

Draft recommendation 2: The NCCC recommends funding to support research to better define the heterogeneity of prediabetes and type 2 diabetes to understand intervention response and develop personalized medicine approaches.

Draft recommendation 3: The NCCC recommends funding for behavioral research to understand barriers to long-term maintenance of weight loss achieved in diabetes prevention programs and methods to help people maintain long-term weight loss.

Type 1 Diabetes Research
Background:

1. It is not well understood why people develop type 1 diabetes. Current research indicates that some interventions (e.g., immune modulators and monoclonal antibodies) may delay or prevent type 1 diabetes.
2. Approximately 30% of patients with new onset of type 1 diabetes present with diabetic ketoacidosis, which is a serious condition that can lead to diabetic coma and even death.
3. In 1988, Congress passed the Special Statutory Funding Program for type 1 diabetes research (also known as the Special Diabetes Program), which has led to significant progress in type 1 diabetes research and the creation of innovative collaborative research consortia and clinical trials networks.
4. The TEDDY (Environmental Determinants of Diabetes in the Young) study screens newborns for increased genetic risk for type 1 diabetes and studies treatment to prevent type 1 diabetes. The TrialNet studies the risk for diabetes in close relatives with type 1 diabetes.

Issues:

1. We need to better understand why people develop type 1 diabetes so that they can be identified before developing type 1 diabetes symptoms. Research is needed to figure out how best to leverage emerging data to develop precise and effective screening programs that could be used to identify people at high risk who might benefit from interventions.
2. The Special Diabetes Program was originally funded for five years but the program has most recently been funded only on an annual basis. Annual funding, however, inhibits the research programs' opportunities because many research projects require multiyear funding to be successful.

Draft recommendation 4: The NCCC recommends funding the Special Diabetes Program in five-year increments so that new, innovative research can effectively be developed.

Discussion
Dr. John Boltri noted that he will revise the draft recommendation to incorporate Dr. Dean's Schillinger's comment.

Dr. Dean Schillinger offered to share more information.

After a short break, Dr. Clydette Powell conducted roll call, and the Commission resumed the meeting with a quorum.

Prevention—General Population Subcommittee Update

Introduction and Overall Update

Dr. Dean Schillinger, co-chair of the Prevention—General Population Subcommittee, briefly reviewed the Subcommittee's scope of work and explained the rationale for the Subcommittee's focus and approach. He noted that while Prevention—General Population Subcommittee is making recommendations targeting the general population, the Subcommittee's population-level interventions to prevent type 2 diabetes will also benefit individuals living with prediabetes, type 1 and type 2 diabetes, as well as diabetes-related complications. Dr. Schillinger stated that the recommendations will be harmonized across the three Subcommittees later.

Dr. Schillinger shared clinicians' viewpoints on social and environmental factors as barriers to optimal care for people with diabetes, reviewed the NCCC Diabetes Prevention and Care Model, and highlighted federal agencies whose policies and/or activities affect diabetes prevention and treatment.

Dr. Schillinger also updated the Commission on the Subcommittee's progress, including developing six draft recommendations that were presented at the last Commission meeting, conducted literature search, and heard 10 key informant presentations following the last Commission meeting.

Presentation of Draft Recommendations

Members of the Prevention—General Population Subcommittee then presented their draft recommendations.

TOPIC: Support more robust efforts to change the food supply
Dr. Aaron Lopata then presented the Subcommittee's draft recommendations 7 and 8. (The Subcommittee presented its first six draft recommendations at the last Commission meeting).

Background: The Farm Bill ($86B) is a powerful, underutilized tool for (1) preventing and controlling diabetes and (2) curbing health care spending and reducing disparities.

- The USDA Special Crop Block Grant Program aims to enhance the competitiveness of specialty crops (fruits, vegetables, tree nuts, dried fruits, horticulture, and nursery crops; $85M, 0.1% of the Farm Bill).

- The USDA Specialty Crop Research Initiative attempts to address the critical needs of the specialty crop industry in sustaining all components of food and agriculture, including conventional and organic food production systems (85M, 0.1% of the Farm Bill).
- The Healthy Food Financing Initiative (HFFI) provides grants and loans to improve access to healthy foods by financing grocery stores, farmers' markets, food hubs, co-ops etc. in urban or rural areas. Evidence shows that HFFI-financed programs increase food security and reduce intake of added sugars (~$25M, 0.03% of Farm Bill).

Draft recommendation 7 (USDA): The NCCC recommends that the USDA support more robust efforts to change the food supply in the U.S. so as to promote the prevention and control of diabetes by significantly

- expanding and increasing funding for the Specialty Crop Block Grants to increase specialty crop production, support food safety, and drive demand through education for specialty crops (fresh fruits and vegetables) to increase dietary diversity as an aid to help people achieve the Dietary Guidelines for Americans; and
- increasing funding for Specialty Crop Research Initiative grants for research on how to improve specialty crop production efficiency, handling and processing, productivity, and profitability over the long term (including specialty crop policy and marketing).

Draft recommendation 8 (USDA): The NCCC recommends that the USDA support more robust efforts to improve healthy food access in the U.S. so as to promote the prevention and control of diabetes by significantly expanding and increasing funding for the evidence-based Healthy Food Financing Initiative, a federal effort to improve food access in low-income, underserved communities and communities of color in urban and rural areas that support farmers and healthy food retailers to improve access to nutritious, affordable, and fresh food.

Discussion

Dr. Bill Herman commented that it makes sense to scale up these programs, and he expressed support for the draft recommendations.

TOPIC: Support robust efforts to improve healthy food access

Dr. Lopata went on to present draft recommendations related to USDA non-SNAP nutrition programs (the Subcommittee presented draft recommendations around the SNAP program at the Commission's last meeting). Dr. Lopata provided background information about the programs and highlighted the opportunities to enhance the impact of the programs.

Background, Issues, and Opportunities

The USDA provides nutritional assistance ($146B) through several programs besides SNAP. Such programs not only reduce food insecurity but also have tremendous potential to prevent and control diabetes, with a focus on pregnancy and early childhood.

- The National School Lunch and Breakfast Programs (30M children per day): Since the inception of the Healthy, Hunger-Free Kids Act (HHFK), the incidence of obesity among

children of low-income families who were enrolled in the program declined by 47%. However, schools face many challenges related to food costs, availability of foods, staff training, and infrastructure. As a result, the HHFK nutritional standards are at risk of being undermined.

- The Summer Nutrition Programs (3M children): The enrollment rate is only about 10% compared to those eligible for school lunch program.

- The Fresh Fruit and Vegetable Program : The program introduces and provides children with a wide variety of fresh fruits and vegetables to prevent diabetes; it increases fresh fruit and vegetable intake by 1/3 cup per day without increasing calories. The demand for this program is much greater than the supply of funds.

- The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) (7M participants per month): Since the revision of its food package in 2009, WIC has been shown to help reduce the excess weight gain in women, improve birthweight of infants, and reduce childhood obesity. However, prescriptive food package is at risk of being undermined. Additionally, breastfeeding support is insufficient, and the technology infrastructure is adequate.

TOPIC: Enhance nutrition assistance programs that focus on the peripartum/childhood periods

Background and Rationale: The NCCC finds that USDA's nutrition assistance programs that focus on the peripartum period and childhood—a critical time in the life course that influences the risk of developing diabetes—are effective in preventing diabetes and should receive additional support.

Draft recommendation 9 (USDA): Th NCCC recommends:

- Maintaining the nutrition standards found to be salutary (HHFK Act).
- Providing adequate funding for: (a) schools to purchase, prepare, and serve healthy, quality foods and beverages for school meals and snacks to meet nutrition standards; and (b) USDA to deliver training and technical assistance to support maintenance and attainment of nutrition standards, and skills to run a program to effectively prevent diabetes.
- Strengthening, increasing funding for, and improving access to and participation in summer feeding programs, including partnerships and collaboration between the public and private sectors to promote innovation in rural or remote areas and other high-risk areas where participation has been low.
- Strengthening and expanding the reach of the successful Fresh Fruit and Vegetable Program for elementary students from economically disadvantaged families to support a reduction in diabetes through improved dietary quality.
- Further strengthening the WIC program by sustaining the evidence-based, prescriptive WIC food package; expanding funding for breastfeeding, peer counseling services; and

improving information systems and technology to provide better access, better serve WIC participants, and prevent diabetes.

Discussion
Dr. Meredith Hawkins asked for clarification about the term "undermined."

Dr. Lopata clarified that the term is used in the sense of budgetary. He explained that the rationale of the recommendation is to give schools the resources needed to meet the nutritional standards, not lower the standards, and that those successful programs need to be scalped up to serve a large number of people.

Dr. Paul Conlin commented on that the last part of the 2nd bullet of draft recommendation 9 (i.e., "to run a program to effectively prevent diabetes") could be interpreted as running the National DPP program in schools.

Dr. Lopata agreed the language needs to be revised to improve clarity.

Dr. Naomi Fukagawa commented that the specific recommendations are great. She suggested the Subcommittee make broader recommendations to transform the food system.

Dr. Lopata agreed that they could definitely broaden the draft recommendations. He explained that draft recommendation 7 addresses Dr. Fukagawa's suggestion. He added that the Subcommittee could consider combining some more specific draft recommendations.

Dr. Schillinger agreed that it makes sense to include the specific draft recommendations in an overarching draft recommendation. He asked Dr. Naomi Fukagawa to help make a recommendation to catalyze a change in the food system.

TOPIC: Institute a graded federal tax on sugar-sweetened beverages
Dr. Bill Herman presented recommendations around sugar-sweetened beverages. Dr. Herman first provided background information, presented evidence, and explained the rationale for the draft recommendations.

Background
Sugar-sweetened beverages comprise the largest single source of added sugar in diets (30-40%) in the United State. The highest intake levels are among younger age groups with lower social economic status, and among non-Hispanic Blacks and Hispanics. Evidence shows that consumption of sugar-sweetened beverages is associated with type 2 diabetes, cardiovascular disease, and all-cause mortality. Evidence also suggests a causal relation between overconsumption of empty calories and lack of compensatory satiety, greater insulin resistance, hepatic metabolic dysfunction, and generation of inflammatory biomarkers.

At least 9% of diabetes cases are attributable solely to the consumption of sugar-sweetened beverages (1.8 million of 21 million expected diabetes cases over 10 years in the U.S.). Sugar-

sweetened beverage also is a significant contributor to diabetes disparities. Studies have shown that one sugar-sweetened beverage per day increases the risk of type 2 diabetes by 18%.

Increasing the price of sugar-sweetened beverages via excise tax of about one cent per ounce (about 10%) has been shown to reduce the consumption by at least 10-20% and raise significant revenue that can be used to fund health promotion activities. Such taxation would provide significant health and economic benefits. For example, a volume tax would prevent 1.1 million lifetime cardiovascular diseases and diabetes cases and save the United States $53.2B; and a tiered tax based on sugar content would prevent 2.2 million cases and save $105B.

Currently seven cities in the U.S. and 40 countries in the world levy an excise tax on sugar-sweetened beverages. However, the American Beverage Association has succeeded in lobbying four states to pass preemptive legislation barring taxation on sugar-sweetened beverages.

Draft recommendation 10 (Treasury): The NCCC recommends that, similar to the federal tobacco tax, the U.S. Treasury Department impose an excise tax on sugar-sweetened beverages to create at least a 10% increase in their shelf prices.

- Calculations regarding the amount of tax should employ a graded taxation model based on the amount of added sugar to stimulate reformulation by industry.
- The revenues generated should be reinvested in a manner that promotes the health of those communities that bear a disproportionate burden of type 2 diabetes.
- The Office of the U.S Trade Representative should ensure that all international trade agreements allow for the taxation of sugar-sweetened beverages and front-of-package health advisory labels.

Dr. Herman explained that the Subcommittee is still exploring the last bullet point of the draft recommendation. He then presented a second draft recommendation related to limiting the consumption of sugar-sweetened beverages.

TOPIC: Prohibit the sale of sugar-sweetened beverages in federal government-owned or -leased offices, workplaces, healthcare facilities, and public space

Background

In response to evidence linking consumption of sugar-sweetened beverages to type 2 diabetes and cardiovascular disease, many organizations have recommended limiting the intake of sugar-sweetened beverages. Previous attention has focused on restricting sales of sugar-sweetened beverages in schools; less attention has been paid to worksite bans.

A study of a workplace sugar-sweetened beverage sales ban in a health system found that reductions in consumption of sugar-sweetened beverage correlated with improvements in waistline circumference and insulin sensitivity. The intervention was also found to be cost saving to the employer.

Draft recommendation 11 (trans-agency): Federal agencies should adopt policies to prohibit the sale of sugar-sweetened beverages in federal government-owned or -leased offices, workplaces, healthcare facilities, and public spaces. Federal agencies should ensure onsite access to safe, clean water and healthy beverage alternatives.

Discussion

Dr. Ann Albright shared that some federal agencies (e.g., CDC's diabetes prevention center) has healthy food and drink options. She asked Dr. Herman's thoughts on beverage and food options in vending machines.

Dr. Herman responded that they could add banning sales of sugar-sweetened beverages in vending machines in the draft recommendation. Regarding food options sold in different vending machines, Dr. Herman explained that the focus of the draft recommendation is on sugar-sweetened beverages, and that they have not taken on other items sold in vending machines.

Dr. Bill Chong asked for clarification about public spaces. For example, would private vendors be banned to sell sugar-sweetened beverages in the public areas?

Dr. Herman responded that the intent of the draft recommendation is to be all inclusive, and public areas could include public park facilities as well. He acknowledged that he was not sure how to handle food trucks in public places, and that the Subcommittee needs to think about the specifics and practicality.

Dr. Chong also asked about if there are data showing benefits from related experiences.

Dr. Herman explained that there are data showing positive effects, and the analyses have been assuring. He further explained that the Subcommittee specifies excise tax instead of sales tax, so that people would be aware of the price increase.

TOPIC: Create a trans-agency diabetes entity to promote trans-sectoral efforts

Dr. Dean Schillinger presented the Subcommittee's recommendation around leveraging efforts across federal agencies, and he explained the rationale.

Background

To prevent and control type 2 diabetes and to reduce extant disparities, significant changes need to take place in the social and environmental contexts. Fostering such change requires not only efforts of conventional health care agencies but also strategies of federal agencies that are considered to be "non-health"-focused because these non-health agencies' policies help shape the social and environmental contexts that heavily influence the incidence and complications of diabetes.

While most developed nations are affirmatively addressing type 2 diabetes through trans-sectoral governmental entities and associated activities, the U.S. has no such entity to enable trans-agency collaboration to prevent and control type 2 diabetes. As a result, the U.S. engages in little to no trans-sectoral work, and what little work has been done has been of a pilot nature and lacks scale. This represents an untapped opportunity to better leverage the efforts of federal agencies and to increase coordination among them to achieve the outcomes specified in the Commission's charter.

Draft recommendation 12: The NCCC recommends that a new federal entity be created to foster broad, trans-agency collaborative work aimed at positively changing the social and environmental contexts that are promoting the type 2 diabetes epidemic. In addition to involving departments and agencies within HHS, this entity should include, but not be limited to, the Departments of Agriculture, Transportation, Education, Justice, Defense, Labor, Veterans Affairs, the Federal Trade Commission, the Environmental Protection Agency, and the Bureau of Indian Affairs.

- The NCCC recommends that this entity would have as its primary responsibilities to (1) facilitate coordination among federal agencies with respect to trans-agency approaches to preventing and controlling type 2 diabetes; and (2) make recommendations to the executive and legislative branches regarding actions they can take to prevent and control type 2 diabetes.
- The NCCC recommends that this entity be positioned at the Secretary level (e.g. Secretary of HHS).

Dr. Schillinger explained that such an entity (the National Prevention Council) existed for 5 years (2011-2016), compromised of 20 federal agencies, was chaired by the Surgeon General, and shared similar objectives although the Council was not specific to diabetes.

Discussion
Dr. Shari Bolen asked why the National Prevention Council was stopped.

Dr. Dean Schillinger explained that based on his understanding the Council was stopped because of the Administration change and because it was linked to the Affordable Care Act. He shared that the Subcommittee plans to find someone from the Council to share insights.

Dr. Ann Albright pointed out that each agency has its own charge and mission. She remined the Subcommittee to be careful about the wording to avoid unintended consequences (e.g., added oversight and burden to the agencies); and to ensure that the entity would help facilitate the agencies' work.

TOPIC: Expand federal housing assistance
Dr. Bill Cook presented the Subcommittee's draft recommendation around housing.

Background
Homelessness, housing instability, and the quality of and context of housing, pose a risk for incident diabetes and impair diabetes management among those with diabetes. Families that need to spend more than 30% of their income on housing have difficulty affording food, medications, and medical services.

The federal government currently influences housing through two agencies: HUD and IRS. While HUD subsidizes housing via public authority-owned housing (>2 million people) and the housing voucher program (~5 million people) for privately owned subsidized housing, the IRS manages the Low-income Housing Tax Credit Program (LIHTC) that gives tax credits to developers for low-income/subsidized or mixed housing.

Data support the importance of housing for health outcome. Evidence also show that smoking restrictions in public housing improves health. Additionally, programs such as the Support and Services at Home in Vermont have demonstrated better health outcomes because of the use of wellness nurses and care coordinators in public housing. However, fewer than 1 in 5 families (17%) eligible for a public or subsidized housing ever receive these services.

Draft recommendation 13 (HUD and IRS): The NCCC recommends that, in order to reduce type 2 diabetes incidence and diabetes complications and reduce costs to the government and society:

- HUD expand its federal housing assistance programs to allow access for more qualifying families, such that over a 20-year period, all qualifying families can access subsidized or public housing.
- IRS further incentivize developers to place units in low-poverty areas, where it has been shown to be most beneficial to prevent the development of obesity and diabetes.
- IRS integrate neighborhood health parameters into the Qualified Allocation Plan process in their scoring systems in all states using the LIHTC program, leaving latitude for states to exercise some local control to allow for local conditions. These health parameters would include, but not be limited to, embedded or nearby healthcare service, transportation, employment opportunities, education opportunities, food availability, and recreation and physical activity availability.
- HUD establish a mechanism to fund or subsidize the cost of embedding health services (if needed) in developments so as to incentivize committing space or employing unused space for such services in their plans.

TOPIC: Reduce secondhand smoke exposure in public/subsidized housing
Dr. Schillinger then presented the Subcommittee's last draft recommendation and explained the rationale.

Background
Consumption or exposure to tobacco smoke elevates the risk of incident of type 2 diabetes and amplifies the risk of complications and death among people living with diabetes. Diabetes

prevalence is higher among people living in public housing (17.6%) than the general population (9.4%). Smoking rates and rates of exposure to secondhand smoke are even higher among people living with diabetes and prediabetes, especially among those who are poor, have limited education, and are Black. As such, socioeconomic and racial disparities in diabetes incidence, complications, and death, in part, exist as a result of inequitable access to tobacco control interventions.

To mitigate tobacco-related disparities, in July 2018, HUD implemented a mandatory smoke-free policy requiring all public housing authority-owned housing to prohibit combustible tobacco use in indoor dwelling, shared areas, and in outdoor areas within 25 feet of exits and windows. However, this policy does not apply to multi-unit housing including Section 8 federally subsidized housing, leaving these sites unprotected from secondhand smoke unless residents voluntarily make their apartments smoke free.

Expanding HUD's smoke-free policy to federally subsidized housing units could have significant population-level benefits by reducing diabetes incidence, diabetes-related complications, and diabetes-related deaths.

Draft recommendation 14 (HUD): The NCCC recommends that, in order to reduce type 2 diabetes incidence and diabetes complications and reduce costs to the government and to society:

- HUD broaden the implementation of indoor smoke-free policies to include subsidized multi-unit housing, beyond public housing authority housing.
- HUD require multi-unit housing adopting smoke-free policies to also provide access to cessation resources (i.e., referrals to cessation resources).

Discussion

Dr. Bolen asked if HUD has the ability to allocate smoke cessation resources.

Dr. Schillinger responded that his understanding is that HUD does have certain authority. He acknowledged that he was not yet sure about the state-by-state variations and the exact language needed to make the recommendation practical, and that is why the Subcommittee labeled the draft recommendations as under development, he said.

Dr. Ayotunde Dokun voiced concern over the possibility of increasing homelessness, especially for those who may have difficulty quitting smoking.

Dr. Schillinger agreed there is more work to be done and the Subcommittee needs a better understanding of the situation.

Dr. Conlin suggested "smoke free in all common areas or immediate surrounding of multi-dwelling housing units."

Dr. Dokun stated that he was more comfortable with the language.

Next Steps

Dr. Schillinger summarized that the Subcommittee plans to

- Synthesize literature search results in nutrient/diet domains;
- Refine the draft recommendations;
- Conduct additional literature search and key informant calls; and
- Develop additional draft recommendations in other domains.

Access to Care Work Group Update

Update

Dr. Herman noted that people with diabetes and those at risk for diabetes do not always have access to health care, and the Commission needs to make recommendations around access to health care. He explained that access to care to a large degree depends on insurance coverage, but it also requires having enough providers and hospitals to deliver care and individuals' capacity (e.g., health literacy) to properly use the health care resources.

Dr. Herman commented that in the United States, the issue is that the health insurance system is pluralistic. He pointed out the need to think systematically about addressing gaps in these programs, particularly in federal programs such as Medicare and Medicaid and the Health Insurance Marketplaces, to ensure that people have access to care.

Dr. Herman stated that the Work Group strives to make recommendations to federal agencies and departments to primarily

- Expand access to care and affordability of care, and also
- Further implementation of some successful models for integrated service delivery and payment.

Dr. Herman shared that since the Commission's September 2020 meeting, the Work Group has narrowed down the scope and is scheduling conference calls with key informants. He again invited all members to participate in these calls.

Discussion

Dr. Schillinger thanked Dr. Herman for working on the important topics, and he asked if Dr. Herman plans to address both bullet points, or focus on the first bullet point.

Dr. Herman responded that the Work Group will focus on the first bullet point. He explained that some aspects of the second bullet point (e.g., team-based care and other models of care) have been discussed by the Treatment and Complications Subcommittee, and that the Work Group will discuss other topics that have not been systematically looked at.

Dr. Schillinger commented that the model of accountable care organization makes sense in terms of bringing alignment of the Subcommittees' recommendations. He stated that he also recognizes the challenge of reviewing integrated models for delivery and payment.

Dr. Herman explained that they will focus on what the Center for Medicare and Medicaid Innovation has focused on and will ensured that successful models will be discussed across the three Subcommittees.

Public Comment

Ms. Mary Hearns-Ayodele, a public-school teacher in Texas and a member of the Faith Community, commented that the topics of the Commission's meeting is dear to her community and to the students in her school. She noted that Commission's Diabetes Prevention and Care Model is important to everyone. She shared that the food options offered at some public schools are not healthy and are not helping children in the long run. She stated that this Commission meeting is important to people who have difficulty making the ends meet, and to people who do not have access to fresh food. Ms. Hearns-Ayodele said that she will let people in her community know that there are people who care about their health and there are recommendations being developed to help people who do not have access to preventive care.

Public Comment Solicitation

Dr. Powell explained that following this meeting, OWH will set up a mechanism to solicitate public comments and stakeholder input on the Subcommittees' draft recommendations. The public input will help the Subcommittees strengthen their draft recommendations. Currently there are three means for the public to provide input: providing oral comments at public meetings, submitting written comments to the Commission's email address (OHQ@hhs.gov), and providing comments in response to Federal Register Notices on regulations.gov. The new plan is to solicit public input on an open, continuous basis on Regulatons.gov to help the Commission refine and strengthen their draft recommendations through an iterative process.

Dr. Powell explained the following step-by-step process.

- The Subcommittees approve which draft recommendation(s) they would like to post through regulations.gov to seek public comment.
- The OWH team drafts and posts a Federal Register Notice.
- The public can read and submit comments on regulations.gov.
- The OWH team will use the Federal Docket Management System to manage the comments posted.
- The OWH team will periodically update the Subcommittees on the comments received.

Dr. Herman asked if there is a mechanism to inform the key informants of the Federal Register Notices.

Dr. Powell responded that OWH will utilize the synergy between OWH and ODPHP to identify the best way to disseminate and amplify the message, and that in February 2021, they will know how the public is engaged.

Dr. Herman asked again how the Subcommittees' draft recommendations would be posted.

Dr. Powell explained that the posting process will be driven by the Subcommittees and the Commission. The support team (the OWH team and the contractor) will do behind the scenes work, and the Subcommittees will determine when they are ready to post their draft recommendations, and which draft recommendation(s) they would like to post.

Dr. Herman encouraged the Subcommittees' co-chairs to submit draft recommendations for which they would like to receive public input.

Dr. Powell noted that the Subcommittees' co-chairs will discuss details at the next Subcommittees co-chairs call.

Recognition and Appreciation of Service to NCCC

Dr. Herman announced that Dr. Ann Albright will retire in December and CAPT David Wong has been detailed to focus on COVID-related work. He thanked Dr. Albright and CAPT Wong for their contribution to the Commission's work.

Meeting Review and Next Steps

Dr. Herman commented that today's meeting is productive. He noted that the public meetings do stimulate discussion and help with the Commission's progress. He encouraged the Subcommittees to continue their work after today's meeting.

Dr. Herman noted that the Access to Care Work Group will conduct meetings in the following weeks, and he welcomed all Commission members to join the calls and make contributions.

Dr. Powell expressed her gratitude for all the Commission members' work. She announced that the Commission will regroup on February 17, 2021, and she anticipated a lot of activities between now and then.

Additional Discussion

Regarding the Treatment and Complications Subcommittee's work and the draft recommendation around workforce, Dr. Schillinger commented that it might worth highlighting the role of oral health workers in the team-based model.

Dr. Schillinger also asked if the February 2021 meeting will be the Subcommittees' last opportunity to present final set of recommendations.

Dr. Powell explained that the Subcommittee will present their third round of draft recommendations in February 2021 meeting. She noted that it is expected that the Subcommittees will further discuss and tweak the draft recommendations between February and June. She noted that by June 2021, the Commission should be settled upon their recommendations and supporting information so that they could put together the Report in the summer and meet to review and approve the final Report in September 2021.

Dr. Herman commented that the Prevention—General Population Subcommittee's approach to summarizing their first set/round of draft recommendations and focusing on new draft recommendations was effective, and he encouraged each of the Subcommittees to do the same for the next meeting. He added that the February and June meetings next year will be the only opportunities to bring forward new recommendations for full Commission discussion.

Dr. Powell announced that the Commission's meeting on February 17, 2021 will be virtual, and the format for the June 2021 meeting has not been determined yet.

Adjournment

Dr. Clydette Powell adjourned the meeting at 5:19 pm EST.

Appendix: Commission Members and HHS Support Staff

Commission Members Present at NCCC Meeting 9

Commission Chair
William Herman, MD, MPH, Director, Michigan Center for Diabetes Translational Research, University of Michigan, Ann Arbor, MI

Public Members (Special Government Employees)
Shari Bolen, MD, MPH, Associate Division Director of Internal Medicine, the MetroHealth System, Cleveland, OH

John Boltri, MD, FAAFP, Chair and Professor, Department of Family and Community Medicine, Northeast Ohio Medical University College of Medicine, Rootstown, OH

J. William (Bill) Cook, MD, Chair, Board of Directors, Ascension Medical Group, Baltimore, MD

Ayotunde Dokun, MD, PhD, FACE, Associate Professor of Medicine and Endocrinology; Director, Division of Endocrinology and Metabolism, Carver School of Medicine, University of Iowa, IA

Jasmine Gonzalvo, PharmD, BCPS, BC-ADM, CDE, LDE, Clinical Associate Professor, Purdue University College of Pharmacy, Indianapolis, IN

Carol Greenlee, MD, FACP, FACE, Faculty Co-Chair, Center for Medicare and Medicaid Innovation Transforming Clinical Practice Initiative, Grand Junction, CO

Meredith Hawkins, MD, MS, Director, Global Diabetes Institute, Albert Einstein College of Medicine, Bronx, NY

Shannon Idzik, DNP, ANP-BC, FAAN, FAANP, Associate Dean and Professor, Doctor of Nursing Practice Program, University of Maryland Baltimore School of Nursing, Baltimore, MD

Ellen Leake, Chair, Juvenile Diabetes Research Foundation, International Board of Directors, Jackson, MS

Dean Schillinger, MD, Chief, UCSF Division of General Internal Medicine, San Francisco General Hospital, San Francisco, CA

David Strogatz, PhD, MSPH, Director, Center for Rural Community Health, Bassett Research Institute, Bassett Health Care Network, Cooperstown, NY

Federal Members (Regular Government Employees)
Ann Albright, PhD, RDN, Division Director, Division of Diabetes Translation, Centers for Disease Control and Prevention, Department of Health and Human Services; *Pat Schumacher (alternate for Ann Albright, in presence)*

William Chong, MD, Acting Deputy Director, Division of Metabolism and Endocrinology Products, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, Department of Health and Human Services

Paul Conlin, MD, Chief, Medical Service, Veterans Affairs Boston Healthcare System, Department of Veterans Affairs

Naomi Fukagawa, MD, PhD, Director, Beltsville Human Nutrition Research Center, United States Department of Agriculture

Barbara Linder, MD, PhD, Senior Advisor, Childhood Diabetes Research, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Department of Health and Human Services

Aaron Lopata, MD, Chief Medical Officer, Maternal and Child Health Bureau, Office of the Associate Administrator, Health Resources and Services Administration, Department of Health and Human Services

Barry Marx, MD, Director, Office of Clinician Engagement, Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services, Department of Health and Human Services; *Jean Stiller (alternate for Barry Marx; in presence)*

Donald Shell, MD, MA, Director, Disease Prevention, Disease Management and Population Health Policy and Oversight, Office of the Assistant Secretary of Defense for Health Affairs Health Services Policy and Oversight, Department of Defense

Howard Tracer, MD, Medical Officer, U.S. Preventive Services Task Force Program, Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, Department of Health and Human Services

Commission members absent from the meeting

Ann Bullock, MD, Director, Division of Diabetes Treatment and Prevention, Office of Clinical and Preventive Services, Indian Health Service, Department of Health and Human Services

CAPT Samuel Wu, PharmD, Public Health Advisor, Office of Minority Health, Department of Health and Human Services

HHS Staff in Attendance

Office on Women's Health
Kara Elam, PhD, MPH, MS, ORISE Fellow, Office on Women's Health, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Dorothy Fink, MD, Deputy Assistant Secretary for Women's Health, Director of the Office on Women's Health, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Erika Kim, ORISE Fellow, Office on Women's Health, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Clydette Powell, MD, MPH, FAAP, Designated Federal Officer for the National Clinical Care Commission, Medical Officer, Office on Women's Health, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services