National Clinical Care Commission Webinar Meeting 10
Wednesday, February 17, 2021
1:00 pm — 5:30 pm EST

Meeting Summary

Table of Contents

National Clinical Care Commission Webinar Meeting 10 1

Welcome and Roll Call 2

Opening Remarks and Review of Agenda 2

Treatment and Complications Subcommittee Update 2
- Introduction and Overall Update 2
- Health Equity 3
- Virtual Care 3
- Digital Divide 6
- Team-based Care 7

Prevention—Targeted Population Subcommittee Update 9
- Introduction and Overall Update 9
- Focus Area 1: Screening/Diagnosis for Prediabetes/Diabetes 10
- Focus Area 2: Improve Access to and Utilization of Effective Type 2 Diabetes Prevention Interventions 13
- Focus Area 3: Sustainability of Type 2 Diabetes Prevention 15
- Focus Area 4: Develop New and More Effective Preventive Strategies for Type 1 and Type 2 Diabetes 17
- Update on Literature Search and Review 19

Prevention—General Population Subcommittee Update 20
- Introduction and Overall Update 20
- Update on Key Informant Calls and Literature Search and Review 21
- Presentation of Draft Recommendations 21

Public Comment 28

Health System-level Interventions Workgroup Update 28
- Access to Care 29
- Making Medications More Affordable 31

Discussion of Draft Recommendation Format 33

Next Steps 33

Adjournment 33

Appendix: Commission Members and HHS Support Staff 34
- Commission Members Present at NCCC Meeting 10 34
- HHS Staff in Attendance 36

Welcome and Roll Call

Dr. William (Bill) Herman, chair of the National Clinical Care Commission (NCCC), welcomed everyone to the meeting. He announced that Dr. Clydette Powell, Designated Federal Office (DFO) for NCCC, will not be able to attend today's meeting due to another urgent matter. He explained that DFO James (Jim) Berger, the Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services (HHS), will join the meeting.

Mr. Berger welcomed everyone to the meeting and conducted roll call (see Appendix for Attendance). The meeting started with a quorum.

Opening Remarks and Review of Agenda

Dr. Herman reviewed the Commission's charge and duties. He explained that the Commission has been conducting its work through three Subcommittees (the Prevention—General Population Subcommittee, the Prevention—Targeted Population Subcommittee, and the Treatment and Complications Subcommittee) and a small workgroup focusing on health system-level interventions. Dr. Herman noted that all of the Subcommittees and the workgroup address crosscutting issues related to health equity, social determinants of health, and research needs.

Dr. Herman explained that today the Commission will hear updates from the three Subcommittees; discuss the Subcommittees' new recommendations and the workgroup's preliminary draft recommendations at the health system level; and hear public comments.

Treatment and Complications Subcommittee Update

Introduction and Overall Update

Dr. Paul Conlin, co-chair of the Treatment and Complications Subcommittee, introduced Subcommittee members. He explained that in the past months, the Subcommittee conducted additional conference calls with stakeholders and Subcommittee members also attended webinars organized by other professional organizations.

Dr. Carol Greenlee, co-chair of the Treatment and Complications Subcommittee, reviewed the Subcommittee's priorities. She explained that the Subcommittee has been gathering information through literature review and conference calls with stakeholders, and 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 reviewed the Subcommittee's first draft recommendation on health equity, which had been presented at the previous Commission meeting.

Draft recommendation (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.

Dr. Greenlee reviewed Sections 3, 5, and 9 of President Biden's *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*, which are in line with the Subcommittee's draft recommendation on health equity. Dr. Greenlee shared that the Subcommittee has reviewed and discussed the executive order. Given that the executive order is not a law, the Subcommittee has decided to (1) keep the Subcommittee's draft recommendation on health equity, (2) acknowledge the executive order, and (3) specify federal policies and programs related to diabetes as well as relevant data that need to be evaluated in order to reduce disparities and improve health outcomes.

Discussion
In response to Dr. Dean Schillinger's and Dr. Bill Herman's questions, Dr. Greenlee confirmed her agreement that the Commission should recommend taking a global perspective when addressing health disparities (that is, beyond racial equity and minority groups).

Dr. Dean Schillinger suggested adding specificity around health disparities in the draft recommendation, and referencing Domestic Policy Council's scope but not being beholden to it.

Dr. Greenlee agreed. She explained that is why the Subcommittee decided to retain the recommendation.

Virtual Care

TOPIC: E-consultations
Dr. Greenlee explained that e-consultation is not telehealth; rather it is a clinician-to-clinician exchange that is initiated by the primary care physician to a medical specialist for a condition-specific question.

Dr. Greenlee explained the two codes that physicians can use to bill for e-consultations: 99451 for specialists and 99452 for primary care physicians. She pointed out that the code 99452 is rarely billed because of the following issues:

- Code 99452 recognizes the primary physician's effort in preparing and submitting the clinical question for the e-consultation (time must total 16-30 minutes).
- Most of the "work" of the primary care physician is done after the receipt of the recommendations from the specialist; the work currently is not counted in the time required for billing 99452.
- The benefit of the e-consultation to the patient can only occur when the treating physician receives a response from the specialist, reviews the response, and determines/takes a course of action accordingly.

Dr. Greenlee explained that the Subcommittee revised the following draft recommendation to improve clarity.

Revised draft recommendation: Expand 99452 to include not only the formulation and submission of a clinical question but also review of the specialty care response and incorporation of recommendations into the patient's care plan, as appropriate.

Discussion
Dr. John Boltri expressed appreciation for the clarification.

TOPIC: Telehealth Waivers
Dr. Greenlee highlighted the benefits of telehealth waivers granted during the COVID-19 Public Health Emergency and emphasized the need to expand the waivers. She noted that CMS, however, does not believe that it has the authority to extend those waivers beyond the COVID-19 Public Health Emergency. She shared that many stakeholders support permanent telehealth expansion, and the Subcommittee anticipates that certain elements of the waivers might be made permanent in the near future.

Dr. Greenlee reported that some policymakers have raised concern about potential overutilization and/or abuse of Medicare telehealth services. While multiple federal agencies and organizations are collecting data on telehealth usage and quality, evidence is still nascent. Dr. Greenlee noted that the Subcommittee supports population-based payment models to ensure appropriate utilization of telehealth.

Benefit of telehealth for patients with diabetes
Dr. Greenlee pointed out that during the COVID-19 pandemic, many individuals with diabetes have benefited from telehealth services, and continued televisits would further help those individuals. She noted that while evidence is limited, available data suggest that telehealth is safe and effective.

Considerations for potential draft recommendations

Dr. Greenlee reported that the Subcommittee is considering the following:

- Given that diabetes prevalence is higher in communities with low internet connectivity, lower income, and lower education, "audio-only" visits are needed, at least as a temporary fix to address the digital divide.
- Use of telehealth to benefit people with diabetes could be further optimized using a value-based care/payment model.
- Geographic and originating-site restrictions should be removed so that CMS can provide access to telehealth services as appropriate.
- Ability to provide telehealth services for the Federally Qualified Health Centers and Rural Health Centers as well as Diabetes Self-Management Training programs should be made permanent.
- Maintaining access to audio-only visits is necessary to comply with President Biden's *Executive Order on Advancing Racial Equity and Support for Underserved Communities*.
    - Access to audio-only services is critical for patients who do not have access to audio-video telehealth services. Discontinuing payment for these services would exacerbate inequities in health care, particularly for those who lack access to audio-video devices.

Discussion

Dr. Bill Herman shared that the Health System-level Interventions Workgroup has been discussing moving away from the fee-for-service model to bundled payment or to care management fees provided to provider groups, which would let providers (1) use telehealth as they see appropriate for patient management, (2) get away from individual charges, and (3) prevent potential abuse. He suggested focusing some discussions on bundled payment or incorporating care management fees.

Dr. Greenlee agreed with population-based payments. She shared that the Subcommittee, however, has heard pushbacks about bundled payment, which is considered not appropriate for people with diabetes. She explained that the Subcommittee has learned that patients with diabetes would benefit more from patient-centered, comprehensive approaches.

Dr. Herman responded that the definition of bundled payment perhaps was not clear. He clarified that he was thinking holistically for patient populations.

Dr. John Boltri commented that access to and affordability of the internet is an issue for people in rural areas. He suggested adding internet access in the last bullet of the Subcommittee's considerations.

Dr. Greenlee responded that the Subcommittee will clarify the topic in the draft recommendation. She explained that Ms. Ellen Leake will address internet-related issues next.

Digital Divide

Ms. Ellen Leake highlighted the impact of digital connectivity on the health of people with diabetes or at risk for diabetes, referencing studies conducted by the Federal Communications Commission (FCC). Ms. Leake pointed out the importance of internet adoption (subscription and utilization of internet), highlighted the key findings of the study on the intersection of internet connectivity and health conducted by the FCC Connect2Health Task Force, and explained the strong inverse correlation between diabetes prevalence and broadband connectivity. She noted that data from FCC studies show that adoption of digital services makes a more powerful impact on health than access to digital connectivity, which is necessary but not sufficient.

Key findings of the study on the intersection of internet connectivity and health

- Most of the counties with a shortage of primary care physicians are also the least connected (40% to 60% of residents do not have basic internet at home).
- Preventable hospitalizations are almost three times higher in counties with the lowest internet adoption compared to those with the highest internet adoption.
- The least connected counties generally have the highest rates of chronic diseases: obesity prevalence is 25% higher and diabetes prevalence is 35% higher in counties where 60% of households lack broadband access.
- There is a distinct correlation between increasing broadband connectivity (both access and adoption) and improved health outcomes. Increasing broadband access by any quintile correlated with about 10% reduction of diabetes prevalence.
- Broadband adoption appears to have an even bigger impact on health outcomes. Increasing broadband access by a quintile correlated to about 16.5% reduction of diabetes prevalence after adjusting other factors.
- Almost half of U.S. counties have high burdens of chronic disease (for example, diabetes) and a need for improved broadband connectivity.
- Almost 60% of rural Americans live in these “double burden” counties, while less than 5% of urban Americans fall into the same category.
- Rural counties are 10 times as likely as urban areas to be in low broadband access (below 50%), high diabetes (above 10%) areas.

Dr. Greenlee further explained what the Subcommittee has learned from the Connect2Health Task Force and shared the Subcommittee’s thinking of potential recommendations.

Considerations for potential draft recommendations

- There is a critical need to accelerate broadband access and understand the barriers to adoption in order to improve health outcomes of and reduce disparities for those living with or at risk for diabetes.
- To improve connectivity for and the health outcome of people with diabetes, efforts to improve broadband connectivity is needed.
    - FCC needs to focus more broadly on connectivity (both access and adoption).

    - More research is needed to better understand the relations between connectivity and improved health.
- Propose a potential Center for Medicare and Medicaid Innovation (CMMI) initiative to pilot a virtual care ecosystem for people with diabetes, which would incorporate a whole-person approach provided by team-based care.

Discussion
Dr. Dean Schillinger asked what the FCC's role is in supporting broadband access.

Dr. Greenlee responded that she was not able to answer that question.

Ms. Leake added that Congress set aside $3.2 billion in the Stimulus Package for FCC to administer the Emergency Broadband Benefit Program through private-public relationships to help low-income consumers access the internet.

Dr. Naomi Fukagawa commented on the importance of gathering data to support the recommendations. She pointed out that multiple agencies are collecting data with cross purposes, and she wanted to know if the Subcommittee has thought about how to gather the needed data from the research perspective.

Dr. Greenlee responded that multiple organizations (for example, American Medical Association, Centers for Disease Control and Prevention [CDC], and diabetes organizations) are collecting data. She noted that the Subcommittee could potentially suggest that the federal agencies enhance coordination to prevent duplication. The Subcommittee's conference call with the CDC suggested that there is inter-agency coordinated efforts, she said.

Dr. Fukagawa encouraged the Subcommittee to leverage the efforts of the U.S. Department of Agriculture (USDA), given that part of USDA's mission is to improve rural communities' connectivity.

Team-based Care

Dr. Shari Bolen, team lead of the Subcommittee's priority area group focusing on team-based care, first provided overall background information and explained why team-based care is needed. She then presented draft recommendations intended to address various issues related to team-based care.

TOPIC: Workforce Training and Workforce Needs
Dr. Bolen pointed out that team-based care needs adequate workforce. She highlighted issues related to workforce training and explained that the focus group revised their draft recommendations based on additional information gathered since the last Commission meeting.

Revised draft recommendations: To improve diabetes care and outcomes, the NCCC recommends

- HHS establish a mechanism to routinely assess and identify all health care workforce needs and ensure that training program funding is directed to meet those needs.
- Evaluation of HRSA training programs to identify where regulatory or statutory limitations should be modified to allow flexibility to meet the needs of team-based care and new care models.
- Continue (or increase) exemplary programs that support training health care professionals in medical shortage areas such as the HRSA National Health Services Corp to provide available health care workforce and team-based care for underserved populations.

Dr. Bolen explained that the Subcommittee will refine the last bullet once they have learned more about the demands and needs.

Discussion
Dr. Dean Schillinger commented that the last bullet of the draft recommendation should be increasing HRSA training programs to fill the population-level needs.

Dr. Bolen agreed, and she noted that the group will need data to support that.

TOPIC: Reimbursement Mechanisms for Team-based Care
Dr. Bolen provided brief background information and presented the following revised draft recommendations on value-based payment and reimbursement for Medicaid community health workers (CHWs).

Revised draft recommendation on value-based payment model:

- CMS/CMMI should identify and implement mechanisms for use of CHWs, clinical pharmacists, and integrated (or collaborative) behavioral health services in existing and future value-based models of care (alternative payment models).

Revised draft recommendations on Medicaid reimbursement for CHWs:

- CMS should build on the 2013 Final Rule to expand the scope of Medicaid reimbursable services provided by CHWs by including them as a qualified provider type to address social, behavioral, and economic support services as part of allowable preventive services.
    - CMS should clarify that CHW qualifications should focus on life experience, interpersonal skills, and community membership as opposed to formal education or clinical training.
    - CMS should require CHW services be delivered in accordance with evidence-informed standards for CHW programs such as those being developed by the National Committee for Quality Assurance (NCQA).

- CMS should develop specific guidance to affirm that Medicaid funding is available for CHW services that address social determinants of health, building from the January 7, 2021 Roadmap.

Dr. Bolen explained that NCQA is expected to release the standards this month, and the Subcommittee may tweak the language accordingly.

TOPIC: Team-based Care Implementation and Research
Dr. Bolen explained that team-based care needs to be optimally implemented to help improve diabetes care and outcomes, and she presented the following draft recommendations on implementation and research.

Draft recommendations on implementation of team-based care:

- Expand the ability of 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, including the use of CHWs, clinical pharmacists, and integration of Behavioral Health services.
- The Centers for Disease Control and Prevention (CDC) should continue/expand work to help states integrate utilization of CHW services in a comprehensive, whole-person approach that includes economic, social and behavioral supports, as well as clinical and preventive services.

Draft recommendation on implementation research:

- Enhance funding for implementation research within and to specific federal agencies (for example, AHRQ, the Patient-Centered Outcomes Research Institute [PCORI], the National Institutes of Health [NIH], CMS, HRSA, IHS, CDC, and VA/DoD) for team-based care, in particular as relates to reducing barriers to and improving care for people with diabetes.

Discussion
Dr. Bolen noted that if other Subcommittees are making similar recommendations around research, the recommendations could potentially be combined.

Prevention—Targeted Population Subcommittee Update

Introduction and Overall Update

Dr. John Boltri, co-chair of the Prevention—Targeted Population Subcommittee, introduced members of the Subcommittee.

Subcommittee Co-Chair Dr. Howard Tracer explained the Subcommittee's four Focus Areas:

- Screening/Diagnosis for Prediabetes/Diabetes
- Improve Access to and Utilization of Effective Type 2 Diabetes Prevention Interventions
- Sustainability of Type 2 Diabetes Prevention Over the Longer Term

- Develop New and More Effective, Targeted Preventive Strategies for Type 1 and Type 2 Diabetes

Dr. Tracer noted that a large part of the Subcommittee's work is related to lifestyle interventions such as the National Diabetes Prevention Program (DPP). He explained why lifestyle interventions (behavioral counseling to promote healthy diet and physical activity) should be made available to all persons with prediabetes.

Rationale

- The risk of progression from prediabetes to diabetes is significant.
- Lifestyle interventions to prevent diabetes is effective in a broad range of adults with prediabetes.
- Lifestyle interventions to prevent diabetes such as DPP is cost-effective from health system and societal perspectives.
- Prediabetes has adverse health impacts beyond diabetes.
- Lifestyle interventions have health benefits beyond diabetes prevention.
- Prediabetes and diabetes disproportionately affect socioeconomically disadvantaged populations and certain racial/ethnic groups.

Discussion

Dr. Dean Schillinger expressed concern about the approach. He agreed that DPP is cost-effective; however, he pointed out that the cost of scaling it up for everyone would be substantial, given that about 30% to 35% of the population fit in the criteria. He commented that it would be more feasible to develop a tailored approach through additional research.

Dr. Tracer agreed with Dr. Schillinger that further research to understand the heterogeneity of the population is need. He pointed out that prediabetes has health and economic impacts beyond diabetes. Regarding scaling up, he explained that the intervention could be scaled up incrementally. He reiterated that DPP is cost-effective, and it will help reduce the overall cost if people don't progress to diabetes.

In response to Dr. Schillinger's follow-up question, Dr. Tracer explained that the Subcommittee has a recommendation for research to (1) understand the heterogeneity and (2) identify people for whom this approach may not be as critical as others.

Dr. Schillinger commented that what Dr. Tracer just described would be a great way to reframe the topic and recommendation.

Focus Area 1: Screening/Diagnosis for Prediabetes/Diabetes

Dr. David Strogatz, team lead of the Focus Area 1 Group, presented four draft recommendations and explained the changes made since the last full Commission meeting.

TOPIC: Raising Public Awareness About Prediabetes and the National DPP
Dr. Strogatz explained that since 2016, CDC has collaborated with the Ad Council on a national public service campaign to raise awareness about prediabetes; however, despite the success of the campaign, gaps in awareness and familiarity with the National DPP remain significant. He noted that the 2020 National Diabetes Statistics Report showed that only 15.3% of adults with prediabetes (based on fasting glucose 100-125 mg/dL or hemoglobin A1c 5.7% to 6.4%) reported having been told that they have prediabetes by a health professional.

Dr. Strogatz explained that the Subcommittee revised the draft recommendation about awareness based on additional input received.

Revised draft recommendation 1:

- Increase support to CDC to improve awareness of prediabetes and promote enrollment in the National DPP lifestyle change program, especially among populations disproportionately impacted by type 2 diabetes risk.
- Specifically, support CDC efforts to identify and engage popular social media influencers with numerous followers in key target audience populations to develop and post custom content on their channels focusing on prediabetes awareness and the urgency to prevent or delay type 2 diabetes.
- Continue tracking visits to the *Do I Have Prediabetes* campaign page and completions of the prediabetes risk test.

TOPIC: Expanded Coverage for Screening/Diagnostic Tests Used to Confirm Prediabetes
Dr. Strogatz explained that the 2015 United States Preventive Services Task Force (USPSTF) recommendations and the 2018 American Diabetes Association (ADA) guidelines for standards of medical care consider fasting blood glucose, oral glucose tolerance test, and hemoglobin A1c as equally appropriate tests for screening and testing for prediabetes and diabetes. However, Medicare does not cover hemoglobin A1c for prediabetes screening.

Dr. Strogatz noted that the Subcommittee presented the following draft recommendation at the last Commission meeting, and the draft recommendation remains unchanged.

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
Dr. Strogatz explained that in 2019, AMA proposed three new clinical quality measures for review by the National Quality Forum to monitor and improve quality of care for patients with prediabetes. The measure specific to screening and diagnosis states: “the percentage of patients aged 40 years and older with a body mass index (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.”

Dr. Strogatz noted that analyses of data from the National Health and Nutrition Examination Survey, however, 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.

Dr. Strogatz explained that the Subcommittee presented the following draft recommendation at the last Commission meeting, and the draft recommendation remains unchanged.

Draft recommendation 3: Endorsement and promotion of the 2019 AMA proposed quality measure related to screening for abnormal blood glucose 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

Dr. Strogatz explained that analyses of electronic medical records and laboratory claims data have shown that testing for abnormal blood glucose or hemoglobin A1c levels has become increasingly common in middle-aged and older adults. However, the opportunity to identify a patient at increased risk or meeting the criteria for prediabetes may be missed during an acute or a routine visit. Administrative data, he noted, could be utilized to identify and to reach out to patients at increased risk or already meeting the criteria for prediabetes. Additionally, the patients' medical record could also be flagged at future visits.

Dr. Strogatz explained that the Subcommittee revised the following draft recommendation (added "at increased risk") to improve clarity.

Revised draft recommendation 4: Federal agencies that deliver care (for example, VA, DoD, IHS) should implement a process for systematically using administrative data to identify patients at increased risk or already meeting criteria for prediabetes and to confirm appropriate follow-up.

Discussion

Dr. Shari Bolen asked about the purpose of the 3rd bullet of draft recommendation 1.

Dr. Strogatz responded that it was about evaluation and awareness.

Ms. Pat Schumacher, Subcommittee member representing CDC, confirmed that the page is about education and awareness. She explained that CDC is updating the page to further find out where people go after visiting the page.

Dr. Dean Schillinger suggested reaching out to non-English-speaking and underserved populations through additional media outlets as well.

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

Dr. Shannon Idzik, team lead of the Focus Area 2 Group, presented the refined draft recommendations and explained the changes made since the last Commission meeting.

TOPIC: Metformin for Prediabetes

Dr. Idzik explained that the group revised the background information to improve clarity and further refined the draft recommendation based on additional information gathered.

Background: Metformin has been approved by the U.S. Food and Drug Administration (FDA) to improve glycemic control in patients with type 2 diabetes mellitus since 1995, and there is a body of clinical evidence supporting the use of metformin in delaying the onset of diabetes; however, metformin does not have an FDA approved indication for prediabetes.

Issue: Lack of an FDA approval affects coverage and payment for metformin. Prescribing metformin for prediabetes is currently considered "off-label" use.

Revised draft recommendation: Provide funding to collect, analyze, and organize the available data on the effectiveness and safety of using metformin in patients with prediabetes, with the purpose of submitting a request to FDA to review and consider an indication for the use of metformin in patients with prediabetes.

TOPIC: Interagency Coordinating Entity

Dr. Idzik explained the history and role of the Diabetes Mellitus Interagency Coordinating Committee (DMICC), highlighted associated issues, and noted that the following draft recommendation addressing the need for an interagency coordinating entity remains unchanged.

Background: Originally mandated by Public Law 93-354 and established in 1974, DMICC is chaired by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and includes other members of 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, and it also 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 for a federal interagency coordinating body within HHS to review, support, promote, and implement proven evidence-based programs.

Draft recommendation: 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: Modes of Delivery of Evidence-based Interventions
Dr. Idzik explained that the Subcommittee revised the draft recommendation to focus on evidence-based interventions, and that the background information and issue remain the same.

Background and Issue: 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.

Revised draft recommendation 3: Promote 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
Dr. Idzik provided brief background information, highlighted the issues, and explained that the group revised the draft recommendation to reflect that CDC is working on the issue

Background: 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 2017 Medicare Physician Fee Schedule final rule established a framework for the Medicare Diabetes Prevention Program (MDPP) expanded model, enabling National DPP program delivery organizations with full or preliminary CDC recognition to enroll as MDPP suppliers.

Issue: Some organizations in rural and underserved areas experience challenges in (1) achieving preliminary or full CDC recognition and (2) applying to become Medicare DPP suppliers.

Revised draft recommendation: Continue efforts to streamline the CDC recognition process and CMS payment process for the National DPP/MDPP while maintaining quality.

TOPIC: MDPP Restriction
Dr. Idzik provided brief background information and explained that the Subcommittee revised the draft recommendations to improve clarity and specificity.

Background: Section 1115A of the Social Security Act established the CMMI to test innovative payment techniques and service delivery models. As one of the models being tested, MDPP is considered a covered service under the model demonstration.

Issue: The future of MDPP as a covered service will be determined by the outcome of the CMMI model demonstration evaluation. However, full virtual delivery of MDPP is not currently included under the expanded model, which may limit CMS's ability to enroll a sufficient number of Medicare beneficiaries required to evaluate the expanded model. Additionally, there is a "once-in-a-lifetime limit" in the current MDPP.

Dr. Idzik explained that given that DPP has been extensively studied and there is substantial evidence supporting its effectiveness across settings and populations, the Subcommittee proposes the following draft recommendations to address the issues.

Revised draft recommendations:

- Approve MDPP as a permanent covered benefit (not just a model expansion service).
- Lift the "once-in-a-lifetime" limit on participation in the MDPP and expand coverage to include virtual delivery.

TOPIC: MDPP Reimbursement Rates

Dr. Idzik presented the group's last draft recommendation, which remains unchanged.

Background: The 2017 and 2018 Physician Fee Schedule final rules established the benefit structure and payment rates for MDPP based on a Diabetes Prevention Progress model test conducted from 2013 to 2015. The payments are adjusted annually.

Issues: Under current MDPP payment model, program delivery organizations assume a level of risk and bear upfront costs. However, the reimbursement rates may not be sufficient to cover the expenses. Currently, only a limited number of eligible organizations with preliminary or full CDC recognition have applied to become MDPP suppliers. Additionally, reimbursement rates may disproportionately affect smaller and rural programs.

Draft recommendation (CMS): Provide funding to support the testing of new models that allow for greater upfront payments and more equitable risk-sharing between payers and MDPP program delivery organizations.

Focus Area 3: Sustainability of Type 2 Diabetes Prevention

Dr. Howard Tracer, team lead of the Focus Area 3 Group, reviewed the draft recommendations and provided brief background information.

TOPIC: Identify "Booster" Doses Through Research

Dr. Tracer noted that the draft recommendation on this topic remains the same.

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: The optimal strategy to prevent the progression from prediabetes to type 2 diabetes in the longer term is uncertain, and the effects of lifestyle interventions and metformin on the risk of cardiovascular disease and other diabetes-related health outcomes in persons with prediabetes have not been well studied.

Draft recommendation (NIH, CDC): The NCCC recommends more research on the number, frequency, and content of "booster" doses (that is, 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: Insurance Coverage and Reimbursement
Dr. Tracer explained that the background information and main issue remain the same, and the draft recommendation has been refined to improve clarity.

Background: Insurance coverage of benefits is a major determinant of the implementation and availability.

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

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

TOPIC: Continued Commitment to Prediabetes and Diabetes Prevention
Dr. Tracer explained that the Subcommittee revised the draft recommendation on this topic to improve clarity and to expand the focus to cover disease prevention and health promotion.

Background: The overall incidence of type 2 diabetes is increasing in the United States, and it disparately affects certain racial and ethnic minorities. Reducing the incidence of type 2 diabetes will require a sustained focus on diabetes prevention.

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

Revised draft recommendation (NIH, CDC, HRSA, VA, DoD): Federal agencies focused on disease prevention and health promotion should continue or increase their current level of commitment to prediabetes detection and evidence-based type 2 diabetes prevention programs.

Discussion
Dr. Schillinger asked for clarification about the draft recommendation for CMS on reimbursement and coverage.

Dr. Tracer explained that the recommendation is not about sustaining what we have now; rather, it is about being proactive when we understand what works.

Dr. Schillinger expressed understanding of the intent. He, however, asked the following question: if the Commission does not know what works to sustain prevention after 1-year DPP, how could it recommend public insurance to cover it in the future?

Dr. Tracer acknowledged it is a good point. One way to handle it, he noted, is perhaps incorporating the idea in the recommendation on current insurance coverage.

Dr. Schillinger suggested seeking input from Dr. Herman.

Dr. Schillinger further commented that the dietary guidance part of the current DPP curriculum is fat based, and sugar-sweetened beverages are not addressed in DPP-approved curriculum. He commented DPP would likely be more effective than it is now if the dietary guideline addresses sugar-added beverages, which is believed to be driving type 2 diabetes.

Ms. Pat Schumacher responded that CDC is updating the curriculum with a panel of experts, and the updated version should be released by the end of this year.

Dr. Schillinger asked what would happen to the dietary portion of the curriculum.

Ms. Schumacher responded that she will take the question back to the agency and will share more information when it becomes available.

After a short break, Mr. James Berger conducted roll call, and the meeting resumed with a quorum.

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, presented revised draft recommendations in this focus area and explained the changes.

Type 2 Diabetes Research
Background and Issues

- The DPP developed proven effective methods for preventing type 2 diabetes; yet a majority of patients with prediabetes have not participated in a diabetes prevention program. Disparities in implementation and uptake of diabetes prevention programs exist and may be exacerbated by social determinants of health.
- Few medications have been proven effective in preventing or delaying the onset of type 2 diabetes.

- Most people who have achieved weight loss from diabetes prevention programs regain the weight.
- People with prediabetes are a heterogeneous group. Individuals have different underlying physiologic abnormalities that contribute to dysglycemia, and some people with prediabetes may develop diabetes and other complications (such as kidney failure) more quickly than other people in this group. More research is needed to better identify those people with prediabetes who are at high risk for developing diabetes and complications so that screening and interventions can be tailored to maximize effectiveness.

Dr. Boltri explained that the group added the 4th bullet point under Background and Issues.

Draft recommendation 1: The NCCC recommends funding to

a. Promote widespread implementation of the most effective in-person and virtual diabetes prevention programs.
b. Study impediments to participation in effective diabetes prevention programs for the communities of greatest need.
c. Disseminate new knowledge about effective diabetes prevention programs both in-person and virtually.

Revised draft recommendation 2: The NCCC recommends funding to support research to better define the heterogeneity of prediabetes and type 2 diabetes to better understand intervention response and develop tailored interventions.

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 weight loss in the long term.

Discussion

Dr. Boltri asked Dr. Schillinger if the revised recommendation 2 has addressed Dr. Schillinger's concern and incorporated the suggestion that Dr. Schillinger made at the last Commission meeting.

Dr. Schillinger said yes, and he suggested adding what Dr. Tracer explained (that is, identifying people at low risk) as well.

Type 1 Diabetes Research

Background:

1. It is not well understood why people develop type 1 diabetes. Current research indicates that some interventions (for example, 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 Special Diabetes Program funds research including TrialNet and the Environmental Determinants of Diabetes in the Young (TEDDY) study. TrialNet performs studies (1) to prevent development of type 1 diabetes in individuals at high risk for developing the disease, and (2) of early treatment of type 1 diabetes to preserve insulin production. TrialNet also conducts risk screening for relatives of people with type 1 diabetes to examine the natural history of this disease and determine eligibility for participating in prevention studies. TEDDY performs studies to determine the causes of type 1 diabetes mellitus by following newborns with increased genetic risk for type 1 diabetes through adolescence.

Issues and Needs:

1. Research is needed to figure out how 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. In the United States, hospital admissions for diabetic ketoacidosis are on the rise.
3. The Special Diabetes Program was originally funded for five years but the program has frequently been funded only on an annual basis. Annual funding inhibits the opportunity for significant research programs because research projects require multiyear funding to be successful.

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

Dr. Boltri explained that the group revised the fourth bullet under Background and the second and the third bullets under Issues to improve clarity and accuracy. The draft recommendation, he noted, remains the same.

Update on Literature Search and Review

Dr. John Boltri reported that literature search on the safety and effectiveness of surgical interventions did not reveal many relevant studies involving people with prediabetes. He asked if the Commission should address the need for research on bariatric surgery for type 2 diabetes prevention or treatment in their report to Congress and HHS Secretary.

Dr. Bill Herman commented that bariatric surgery is not affordable for diabetes prevention as a population-level approach.

Dr. Idzik commented that it might be appropriate for certain group of people and suggested addressing it as a research need.

Dr. Meredith Hawkins shared her view that if it is mentioned in the report, the Commission would have to hope that in the future there might be less expensive, more feasible, less invasive means that might still have metabolic benefits. She expressed preference for mentioning the topic in the report.

Commission members discussed if the Treatment and Complications Subcommittee should discuss the topic as a treatment option for people with type 2 diabetes. Dr. Paul Conlin explained that the Treatment and Complications Subcommittee will discuss it at its next Subcommittee meeting. He explained that the Treatment and Complications Subcommittee is trying to stay away from specific treatment options as the amount of work required to evaluate all effective treatment options would be substantial.

Dr. Bill Herman commented that the topic might belong to the Focus Area on research needs, and he suggested expanding the topic beyond bariatric surgery to other approaches to diabetes prevention.

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.

Dr. Schillinger first reviewed the charge to the Commission and explained that the Subcommittee has sought input from the HHS Office of General Counsel to ensure that the Subcommittee's work is within the charge. Dr. Schillinger explained that the feedback the Subcommittee received around Health Impact Assessment was that it is within the scope, and the Office of General Counsel suggested limiting it to just a few agencies. The Office of General Counsel also offered to review the Subcommittee's draft recommendations, he said.

To affirm that the Subcommittee's work, including learning about non-health agencies' work through key informant presentations and developing corresponding recommendations, is relevant and within the charge, Dr. Schillinger pointed out the following:

- To improve diabetes prevention and care in the United States, and to reduce extant diabetes-related disparities, it is widely recognized that supportive changes to the social and environmental conditions are essential to improve both individual and population-level outcomes.
- Clinicians are routinely encouraged to refer for social services (food, housing, etc.) but resources are inadequate.
- Clinicians who care for people with diabetes have been found to have high rates of burnout as a result of feeling unable to address their patients' social needs.
- Increasingly, both private and public health plans have been making investments in addressing such factors, and CMS is involved.

- Non-health agencies must become more aware of how their policies and practices either advance or undermine efforts to prevent and control diabetes.
- In some instances, the work of relevant non-health agencies must be *leveraged and coordinated* to prevent and control diabetes.

Update on Key Informant Calls and Literature Search and Review

Dr. Schillinger reported that the Subcommittee has conducted six key informant calls and received written comments since the Commission's last public meeting. He noted that the Subcommittee will share what they have learned and present additional draft recommendations at the next Commission meeting.

Dr. Schillinger explained that the Subcommittee has also completed comprehensive literature search on diet and nutrition, and have reviewed extensive search results (more than 1,500 articles).

Presentation of Draft Recommendations

Dr. Schillinger first presented the Subcommittee's draft recommendations on trans-agency collaborations.

TOPIC: Trans-agency Collaborations
Revised draft recommendations:

- The NCCC recommends the creation of the Office of National Diabetes Policy (ONDP) in the Domestic Policy Council (DPC) of the Executive Branch (akin to the Office of National AIDS Policy) to develop and facilitate a national diabetes strategy that leverages and coordinates the work of relevant federal departments and agencies as outlined in the NCCC report.
- The NCCC recommends that a new federal program be created within the Office of the Secretary of HHS to work with the ONDP and CDC 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 agencies within HHS, this entity should include, but not be limited to, the Departments of Agriculture, Transportation, Education, Justice, Defense, Labor, Federal Trade Commission, 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;
        2) make recommendations to the executive and legislative branches regarding actions they can take to prevent and control type 2 diabetes;
        3) pursue a health-in-all-policies agenda with respect to diabetes; and

4) promote the use of health impact assessments for relevant policies across non-health departments and agencies.

Dr. Schillinger explained that the Subcommittee revised the draft recommendation to bolster the national efforts of the HHS by creating an Office of National Diabetes Policy to promote and facilitate the work of non-HHS agencies in collaboration with HHS and CDC.

Discussion
Dr. Meredith Hawkins commented that it is a great recommendation.

Dr. Bill Chong asked for clarification about the relationship between the HHS program and the DPC office.

Dr. Dean Schillinger responded that the Subcommittee has been modeling the work on the National HIV/AIDS policy.

Dr. Aaron Lopata explained that the idea of creating an office under DPC is to elevate it to the White House level to pull in other departments outside HHS. Regarding HIV/AIDS, he explained that the HHS Office on HIV/AIDS and the DPC Office for HIV/AIDS Policy work closely together. Regarding the Subcommittee's draft recommendation, he clarified that (1) there would be two different offices (an office within HHS and an office under DPC); (2) the DPC office will help drive policy; and (3) the two offices will work closely together.

Multiple members of the Commission commented that the concept makes sense. A couple Commission members asked if all HHS agencies, instead of a single agency such as CDC, should work together to develop the policy.

Dr. Schillinger explained that the intent was to empower CDC to do the trans-agency work that the agency has been striving to do.

Dr. Lopata explained that the idea is for the office at the HHS Secretary level to work with the DPC office. He agreed that the Commission does not have to call out CDC specifically.

Ms. Pat Schumacher noted that she would get feedback from CDC's Division of Diabetes. She pointed out that the Prevention—Targeted Population Subcommittee also has a recommendation on creating an interagency coordinating body, and that the Subcommittees perhaps need to consolidate the overlapping draft recommendations.

Dr. Dean Schillinger responded that this draft recommendation is applicable to the entire Commission.

Another Commission member cautioned about relying heavily on DPC or political appointees, and suggested that the strategy needs to be sustainable across administrations.

Dr. Aaron Lopata shared that the HIV/AIDS office has survived multiple administrations. He shared his view that having a DPC office would not undermine the HHS office's effort.

Dr. Dean Schillinger pointed out that the country needs, but does not have, a national strategy on diabetes.

Dr. Lopata added that support is needed from the administration to develop such a national strategy.

Based on the discussion, Dr. Bill Herman concluded that there was a consensus among Commission members to pursue this recommendation.

TOPIC: Supplemental Nutrition Assistance Program (SNAP)
Dr. Carol Greenlee presented the draft recommendations related to SNAP. She explained that the Subcommittee consolidated related draft recommendations into one single draft recommendation.

Revised draft recommendation: The NCCC recommends that the USDA modernize the SNAP program to further reduce food insecurity and improve dietary quality to help prevent the development of diabetes and diabetes complications by implementing the following changes:

1. Expand SNAP eligibility by updating income criteria.
2. Update the formula for calculating SNAP benefits to allow for both improved food security and dietary quality.
3. Change the basis for calculating SNAP allotments by replacing the Thrifty Food Plan with the Low-Cost Food Plan.
4. Scale up/implement fruits and vegetables incentive program for all SNAP beneficiaries to prevent and control diabetes.
5. Eliminate sugar-sweetened beverages from allowable SNAP purchases.
6. Improve and expand diabetes education and awareness programs for SNAP beneficiaries to better prevent and control diabetes, including critical media and marketing literacy.

Discussion
Dr. Schillinger explained that bullets 2, 4, 5, and 6 were presented at the last Commission meeting, and bullets 1 and 3 have been revised.

Commission members expressed support for the combined draft recommendation.

TOPIC: Non-SNAP Programs for Children
Dr. Aaron Lopata presented the updated draft recommendation related to non-SNAP programs for children and briefly reviewed the background information.

Revised draft recommendations:

- Maintain the nutrition standards found to be salutary (the Healthy, Hunger-Free Kids Act).
- Provide 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.
- Prohibit the sale of "junk food" on public school campuses and develop an incentive program to enable schools to cover essential costs previously underwritten by the sale of such unhealthy food and beverages.
- Strengthen and increase funding for, and improve 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. Funding for the program should be increased to enable scaling to meet population needs.
- Strengthen and expand 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. Funding for the program should be increased to enable scaling to meet population needs.
- Further strengthen the Women, Infants, and Children (WIC) program by sustaining the evidence-based, prescriptive WIC food package; expanding funding for breast-feeding peer counseling services; improving information systems and technology to better access/enroll in and better serve WIC participants and prevent diabetes.

Discussion

Dr. Schillinger explained that while CDC has long recommended eliminating junk food and sugar-sweetened beverages from public schools to prevent diabetes, many schools do not prohibit the sale of junk food from their campuses. He shared that studies have shown that states that have more rigorous regulations on selling junk food on school campuses have lower rates of obesity than states that lack regulations.

Dr. Lopata explained that studies have also shown that schools have higher standards for food quality tend to have lower rates of diabetes among children who attend those schools.

TOPIC: USDA Programs in Food Supply

Dr. Lopata reviewed the following recommendation, which has been revised to improve clarity.

Revised draft recommendation: The NCCC recommends that the USDA support more robust efforts to change the food supply and healthy food access in the United States to promote the prevention and control of diabetes by:

- Significantly 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).
- Significantly expanding and increasing funding for the Specialty Crop Block Grants to 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*.
- Significantly expanding and increasing funding for the evidence-based Healthy Food Financing Initiative (HFFI), a federal effort to improve food access and health in low-income, underserved communities and communities of color in urban and rural areas that supports farmers and healthy food retailers to improve access to nutritious, affordable, fresh food.
- Expansion and funding should be implemented to achieve population-wide benefits by 2030.

Discussion
Commission members expressed support for the recommendation.

TOPIC: Sugar-sweetened Beverage Sales Ban
Dr. Schillinger explained that the following draft recommendation has been revised since the last Commission meeting.

Revised draft recommendation: Policies should be adopted across federal agencies to prohibit the sale of sugar-sweetened beverages in federal government-owned or -leased offices, workplaces, health care facilities, and public spaces. Federal agencies should ensure onsite access to safe, clean water.

Discussion
Commission members discussed the feasibility of the draft recommendation, and they generally agreed that the concept of the draft recommendation is reasonable. However, multiple Commission members pointed out that implementing the recommendation would be challenging, especially in military bases where a large portion of the service members live on military installations. Commission members commented that disincentivizing the sales/purchases of sugar-sweetened beverages might be easier to implement than banning them. Concerns over taking away people's right to choose was also raised.

Commission members further discussed if the draft recommendation should be limited to HHS agencies to send a message. A couple Commission members noted that they were more comfortable with such an approach, and they also supported prohibiting/eliminating sugar-sweetened beverages from public schools.

TOPIC: Housing
Dr. Bill Cook presented the following revised recommendations related to housing.

Revised draft recommendations: The NCCC recommends that, in order to reduce type 2 diabetes incidence and diabetes complications and reduce costs to the government and to society,

- The United States Department of Housing and Urban Development (HUD) expand its federal housing assistance programs to allow access for more qualifying families, such that over a 20-year period, all that qualify can access subsidized or public housing.
- The Internal Revenue Service (IRS) further incentivize developers to place new housing units in areas of low poverty, as data show that moving people from areas of high poverty to low poverty favorably affects the prevalence of obesity and diabetes.
- IRS integrate neighborhood health parameters into the qualified allocation plan process in their scoring systems in all states using the Low-Income Housing Tax Credit 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 health care service, transportation, employment opportunities, education opportunities, food availability, and recreation/physical activity availability.
- HUD establish a means to fund or subsidize 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.

Discussion
In response to Commission members' questions, Dr. Bill Cook clarified that the MOVE UP study has shown that people moved from high-poverty neighborhoods to lower-poverty communities did better.

Commission members suggested revising the second bullet point to improve clarity; for example, replacing "...to place new housing units in areas of low poverty" with "…to place public or subsidized housing in areas of low poverty."

TOPIC: Smoke-Free Policies in Subsidized Housing
Dr. Dean Schillinger explained that the following draft recommendation has been revised based on input from subject matter experts.

Revised draft recommendation: 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 implementation of indoor smoke-free policies to include subsidized multi-unit housing, beyond public housing authority housing.
- HUD require subsidized multi-unit housing to have designated outdoor locations for smokers' use.

- HUD require multi-unit housing adopting smoke-free policies to also provide access to cessation resources (that is, referrals to cessation resources).
- HUD align these policies with its related policies in public housing so as to ensure that loss of housing is not an unintended consequence, and work with the CDC Office on Smoking and Health so that an appropriate public health approach is taken.

Discussion
In response to Commission members' questions, Dr. Schillinger explained that HUD's smoke-free policies are apparently very effective in reducing exposure to secondhand smoke, and there have also been demonstrations of reduction of smoking among smokers. He clarified that the main health benefit is related to drastic reduction in exposure to secondhand smoke.

Dr. Ayotunde asked if the policies referenced in the draft recommendation are existing policies.

Dr. Schillinger replied yes. He explained that these are existing policies in public housing owned by the federal government.

Dr. Ayotunde expressed support for the draft recommendation based on the data Dr. Schillinger presented and the proven benefits (for example, people are not evicted and reduction in exposure to secondhand smoke).

TOPIC: Research Needs
Dr. Schillinger presented the following new draft recommendations developed to address research needs.

New draft recommendations:
a. NIH (especially NIDDK) and CDC should support large-scale natural experiments research--including cost effectiveness analysis--to inform the evidence base related to social and environmental policies that prevent and control type 2 diabetes. Particular focus should be paid to "health in all policies" types of interventions relevant to non-health agencies' activities and to other public health (non-clinical) interventions.
b. NIH should expand its initiative on Precision Nutrition to (a) include trials that can inform critical population health questions related to which foods, beverages, ingredients and additives promote or prevent the development of type 2 diabetes; (b) include studies of communication interventions and (counter) marketing practices to inform which practices work best for which sub-populations with respect to changing dietary patterns to prevent type 2 diabetes and which practices elevate diabetes risk; and (c) expand the definition of "precision" to go beyond targeting the individual to include targeting geographic entities (neighborhoods).
c. NIH should also support research (in collaboration with other agencies) to better understand the role of (1) exposures related to environmental toxins/contaminants/unclean water/synthetic products and on metabolic function and

diabetes risk and (2) life course trauma on metabolic function and diabetes risk, and associated interventions

d. CMMI should support demonstration projects in collaboration with non-health agencies related to influencing social determinants of health and reducing diabetes risk and diabetes control and complications (for example, USDA/SNAP interventions, HUD/housing interventions, EPA/fresh water, DoT, etc).
e. USDA, EPA, DoT, Federal Trade Commission (FTC), FDA etc. should also fund research into how their policies and practices affect diabetes risk and could be changed or (if/when beneficial) amplified to better prevent and control diabetes.
f. Research training investments need to be made by NIH and CDC to enhance the workforce skilled in the competencies needed to carry out robust simulation work to inform health impact assessments.

Discussion

Dr. Bill Chong asked for clarification about the first recommendation. He wanted to know whether the intent is to ask Congress to provide more funds to NIH or NIH to relocate current funds to support the research.

Dr. Schillinger replied that his understanding was that the Commission is not supposed to make such distinction. The wording, he explained, is intented to suggest that more funding is needed for NIH to support large-scale natural experiment research.

Public Comment

Professor Joe Thomas, head of the School of Public health at the MIT World Peace University in India, provided verbal comments over the phone. He thanked the Commission for highlighting the issues of health equity and diabetes, and encouraged the Commission to pay more attention to the global dimension of health inequity caused by diabetes. He commented that global prevention efforts and data on social determinants of diabetes could contribute to the domestic policy and programs in the United States, and that the Commission's recommendations will have a global dimension as well. Professor Thomas provided the following recommendations to the Commission:

- Pay attention to the intersectionality of the Covid19 Pandemic and diabetes.
- Develop a mechanism to integrate the global dimension of diabetes into the Commission's recommendations.
- Develop a mechanism to address the global health burden of diabetes, particularly gestational diabetes in developing countries.
- Develop a mechanism to work with the U.S. Secretary of State, the U.S. Agency for International Development, and the Office of Global Health Diplomacy.

Health System-level Interventions Workgroup Update

Dr. Bill Herman reported that the workgroup conducted multiple key informant calls in the past few months and has developed three documents focusing on the following topics:

- Health insurance and access to care for people with diabetes

- Making medications affordable for people with diabetes
- Service delivery and payment models to improve care for people with diabetes

Dr. Herman emphasized the importance of health insurance coverage and highlighted gaps affecting the access to care for people with diabetes.

- The health insurance system in the United States is pluralistic, and the system has left substantial numbers of Americans uninsured.
- The Affordable Care Act addressed some gaps in insurance coverage, but many gaps remain.
- Major barriers include eligibility; affordability; difficulty to access; lack of continuity of care; lack of providers and facilities; and inability to make appropriate use of resources (health literacy).

Dr. Herman presented the following draft recommendations related to access to care and affordability of medications.

Access to Care

Draft recommendation 1: Address disparities in employer-sponsored health insurance coverage (Cadillac plans vs high-deductible health plans).

- Limit the tax exclusion for employer-sponsored health insurance to a dollar amount equivalent to a silver Marketplace health insurance policy.
- Remove the tax penalty for employers that do not provide employees with qualified health insurance coverage.
- Require employers that do not provide employees with health insurance coverage to provide sufficient funds to employees' health reimbursement accounts to cover the cost of silver Marketplace health insurance policies for those employees, their dependents, and their children up to 26 years of age.

Discussion

Dr. Schillinger asked for clarification about the sliver-level Marketplace plan. Dr. Herman responded that there are different levels of Marketplace plans and a silver-level Marketplace plan is considered a good insurance plan.

Draft recommendation 2: Expand Marketplace health insurance coverage, make premiums more affordable, and stabilize premiums.

- Restore funding for advertising and consumer assistance for Marketplace plans and increase the enrollment period from 30 to 90 days.
- Establish special enrollment periods for individuals who lose employer-sponsored health insurance or whose incomes change dramatically during the year because of changes in employment.
- Restore cost-sharing reduction payments for individuals with incomes below 250% of the federal poverty level who are not eligible for Medicaid.

- Provide premium tax credits to individuals with incomes between 250% and 500% of the federal poverty level who do not have employer-sponsored health insurance so that they can purchase health insurance through the Marketplace.
- Give states the authority to auto-enroll subsidy-eligible individuals into Marketplace plans, provided that the premium is less than or equal to the amount of the individuals premium tax credit.
- Establish a federally funded and state-administered reinsurance program to cover high-cost individuals enrolled in Marketplace plans.

Draft recommendation 3: Improve access to Medicaid

- Provide financial incentives by offering a 100% federal match rate to encourage states to expand Medicaid to all Americans with incomes ≤138% of the federal poverty level.
- Subsidize Marketplace private insurance for all low-income individuals who currently fall into the coverage gap.
- Explicitly guarantee the long-term federal match rate to reduce states' concerns about their financial liability.
- Offer continuous 12-month eligibility to adults enrolled in Medicaid even if a family experiences a change in income during the year.

Discussion

Dr. Carol Greenlee commented on the 4th bullet point under draft recommendation 3. She pointed out that the impact of income changes may vary from patient to patient; for example, while some patients may lose coverage because of a small increase in income, others may become employed and have good health insurance coverage. She commented that there needs to be a way to protect the patient and the state as well.

Dr. Herman welcomed Dr. Greenlee to help address the issue in the recommendation.

Dr. Dean Schillinger commented that the recommendation on Medicaid is strong.

Dr. Shari Bolen asked if the Commission should recommend a national health insurance plan.

Dr. Herman responded that he was trying to work with existing health delivery systems to fill gaps.

Dr. Dean Schillinger expressed his view that the Commission is tasked to present evidence-based recommendations, and that they do not have the evidence to recommend a national plan. He suggested recommending that every American should have affordable, adequate insurance instead.

Dr. Meredith Hawkins raised concern of making a broad recommendation for all Americans. She wondered if the Commission should focus the recommendation on insurance coverage for people with or at risk for diabetes.

Dr. Herman responded that he was not sure if the Commission could recommend a national health insurance program for people with diabetes. Regarding health insurance coverage, he noted that the Commission should take a broad perspective. He explained that some of the recommendations on making medications more affordable apply to the general population and some apply to just people with diabetes.

Making Medications More Affordable

Dr. Herman noted that prescription medications are essential for preventing and managing diabetes, complications of diabetes, and comorbidities. He pointed out that policies designed to contain medication costs, however, have adversely affected appropriate utilization of medications especially among low-income individuals with diabetes.

Dr. Herman presented the following four draft recommendations.

Draft recommendation 1: To keep prices in check and medications affordable for people with diabetes, encourage robust competition by generic medications.

- FTC and FDA should ensure that generic drugs are available and inexpensive by
    - Limiting pay-for-delay arrangements to curtail anticompetitive behaviors; and
    - Closing loopholes in the 180-day exclusivity period given to first-to-file generic manufacturers by requiring a reasonable justification for any delay in bringing a medication to market.

Draft recommendation 2: Balance the rewards for innovation provided to brand-name drug manufacturers against unnecessary barriers to competition.

- The FDA should ensure that drug discovery incentives are adequate but not excessive.
- Patent laws should be modified to discourage manufacturers from applying for multiple patents on a single drug and from making slight modifications to old drugs to obtain new patents to extend a drug's exclusivity period.
- Shadow pricing for drugs with few manufacturers should be curtailed.
- The market exclusivity for biologic drugs should be reduced from 12 years to seven years and unnecessary barriers to biosimilar market entry including patent extensions should be curtailed.
- Incentives offered by the Orphan Drug Act should be removed from mass-produced drugs initially developed for common conditions that are subsequently repurposed as orphan drugs.

Draft recommendation 3: Introduce greater transparency in the pharmaceutical distribution system to ensure that returns are justified across all parties.

Dr. Herman explained that the growing difference between the list price and the net price of a drug reflects rebates and discounts negotiated between wholesalers, pharmacies, pharmacy benefit managers, and insurers to influence formulary placement. However, high list prices

disadvantage patients who pay the list price or pay coinsurance based on the list price of a medication. Dr. Herman noted that the Commission recommends greater transparency and simplicity in pricing to eliminate distortions related to rebates and discounts that are beyond the reach of individual payers to address.

Draft recommendation 4: Reduce regulatory barriers to value-based pricing to better align the price of drugs to their benefits.

- Remove regulatory barriers to value-based pricing to better align the price of drugs to their benefits. Such value-based pricing may take many forms including:
    - Value-based pricing (where the formulary placement of a drug and/or its cost to patients is inversely related to its health benefit).
    - Indication-based pricing (where the price of a drug depends upon which disease it is being used to treat).
    - Drug licensing schemes (where a drug manufacturer sells a license for a lump sum payment that entitles licensees to an unlimited supply of the drug for a fixed time period at zero or very low cost).
    - Money-back guarantees (where drug companies provide refunds for patients who try a drug but see no clinical benefits).

Discussion

Dr. Greenlee commented on recommendation on the orphan drugs. She pointed out that some drugs that were initially mass-produced for common conditions may later be found useful for rare conditions. She wanted to know if the drug price would increase only if the drug is used for the rare condition or for all conditions.

Dr. Herman responded that he thought about the topic as well, and he welcomed Commission members to share examples relevant to diabetes. He noted that the Commission would probably drop the draft recommendation if it does not apply to diabetes.

Dr. Dean Schillinger wanted to know if value-based pricing would include the ability of Medicare to negotiate medication prices.

Dr. Herman agreed that it should be part of the recommendation. He added that the draft recommendation perhaps needs to be more specific.

Dr. Bill Chong pointed out that draft recommendation 2 needs to be revised because FDA does not play any role in patent law. Dr. Chong also commented on the draft recommendation on generic drugs. He pointed out that there is already a mechanism in place to prevent misusing the exclusivity for generics. He offered to find out and share more information.

Dr. Herman thanked Dr. Chong for his input and invited Dr. Chong and everyone else interested in the topic to join future discussions.

Discussion of Draft Recommendation Format

Dr. Herman asked Commission members to think about the topic and discuss it at the next Commission meeting.

Next Steps

Dr. Herman asked the Subcommittees and the workgroup to

- Continue refine the existing draft recommendations,
- Develop new draft recommendations, and
- Solicit public comment on the relatively final ones.

Dr. Herman encouraged Commission members to keep the momentum going and begin writing their report to Congress and HHS Secretary soon. He noted that the date for the next Commission meeting has not been determined.

Adjournment

DFO Jim Berger adjourned the meeting at 5:42 pm EST.

Appendix: Commission Members and HHS Support Staff

Commission Members Present at NCCC Meeting 10

Commission Chair
William Herman, MD, MPH, Professor of Medicine and Epidemiology, Co-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 (*joined after roll call*)

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

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;

Pat Schumacher, MS, RD, Chief, Program Implementation Branch, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention

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 (*joined after roll call*)

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

Office of Infectious Disease and HIV/AIDS Policy
James J. Berger, MS, MT(ASCP), SBB, Designated Federal Officer, Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services