National Clinical Care Commission Webinar Meeting 7
Friday, June 26, 2020
1:00 pm — 5:00 pm EST

Meeting Summary

Table of Contents

Welcome, Roll Call, and Review of Agenda

Jennifer Bishop, Designated Federal Officer for the National Clinical Care Commission, welcomed all meeting attendees and introduced the following two individuals who are new to working with the Commission.

- Dr. Richard (Rick) Olson, Technical Lead for the National Clinical Care Commission; Director of the Division of Prevention Science, Office of Disease Prevention and Health Promotion (ODPHP), Office of the Assistant Secretary for Health, the U.S. Department of Health and Human Services (HHS)
- Captain Paul Reed, Deputy Assistant Secretary for Health (Medicine and Science); Acting Director of ODPHP, Office of the Assistant Secretary for Health, HHS

Dr. Bishop conducted the roll call (see Appendix for attendance). The meeting started with a quorum.

Dr. William (Bill) Herman, Chair of the National Clinical Care Commission, welcomed everyone and briefly reviewed the Commission's work progress since the last public meeting (Meeting 6, February 19, 2020). Dr. Herman explained that the Commission's activities have been coordinated by three subcommittees: the Prevention—General Population Subcommittee, the Prevention—Target Population Subcommittee, and the Treatment and Complications Subcommittee. He noted that the Commission is focusing on crosscutting issues related to health equity, social determinants of health (SDOH), and research need. Since the last public meeting, the Commission has reviewed information provided by federal agencies through data call responses, information shared by key informant organizations, and information obtained from literature searches.

Dr. Herman explained that today the Commission will hear updates from the three subcommittees, discuss the subcommittees' work, and hear public comments.

Stakeholder Organization/Public Comments Update

Dr. Clydette Powell, Technical Advisor for the National Clinical Care Commission, explained that the Commission sought public comments on five key questions through a Federal Register Notice of Request for Information (https://www.federalregister.gov/documents/2020/01/15/2020-00505/solicitation-for-public-comments-on-questions-from-the-national-clinical-care-commission).

Dr. Powell reported that between January 2020 and the end of March 2020, the public provided 84 responses, and the respondents represented professional organizations based in the U.S., primary and specialty healthcare practices and systems, and individuals impacted by diabetes. She highlighted the following themes of the comments.

- Regulatory reform
- Federal reimbursement and payment reform
- School food programs

- Diabetes education
- Health care providers
- Nutrition
- Social determinants of health

Dr. Powell noted that the public comments are posted on regulations.gov (https://www.regulations.gov/document?D=HHS-OS-2019-0015-0001) and are available for the public to review.

Federal Data Call Update

Dr. Powell used a graph to demonstrate the step-by-step process of the data call that was sent to the 11 agencies represented on the Commission. She explained that the agencies' responses were sent to the ODPHP and organized by a contractor for the Commission to review.

Dr. Powell noted that a request was also sent to the Bureau of Prisons (BoP), which has programs for the population the Bureau serves who have diabetes. The Commission also solicited additional information about federal programs, policies, and research. For example, the Commission's public meeting in November 2019 was focused on social determinants of health; and half of the Commission's public meeting in February 2020 was dedicated to presentations and discussion regarding the Centers for Medicare and Medicaid Services (CMS).

Dr. Powell explained that the subcommittees began reviewing the data call responses in March 2020, and that they are still in the process of synthesizing the information. The data call responses, Dr. Powell noted, will inform the subcommittees' work and ultimately their recommendations, and will be incorporated in some fashion into the Commission's final report to Congress and the HHS Secretary.

Prevention—General Population Subcommittee Update

Following Dr. Powell's updates, Dr. Ann Bullock and Dr. Dean Schillinger, Co-Chairs of the Prevention—General Population Subcommittee, reported the subcommittee's progress and explained their next steps.

Dr. Bullock briefly introduced the subcommittee membership. She then explained that screening for diabetes and individual-level prevention programs are being addressed by the Prevention—Target Population Subcommittee; whereas the Prevention—General Population Subcommittee is focusing on prevention for type 2 diabetes because the majority of opportunity for prevention currently is associated with type 2 diabetes. Dr. Bullock pointed out that population-level interventions to prevent type 2 diabetes, however, may also benefit those living with prediabetes, type 1 or type 2 diabetes, as well as diabetes-related complications.

Framing Statement of the Prevention—General Population Subcommittee

Dr. Bullock then reviewed the subcommittee's framing statement, presented as follows.

The type 2 diabetes epidemic in the U.S. has emerged largely as a result of rapidly changing social and environmental factors (also known as "structural factors") that affect individual behaviors and exposures, such as physical activity, dietary choice, economic opportunity and stress. The Subcommittee recognizes that these factors and exposures are differentially and unequally distributed across the general population based on socioeconomic, racial/ethnic, and geographic characteristics, and that such exposures have differential impacts at different points both within and across the life course. Finally, the Subcommittee recognizes that diabetogenic exposures and associated interventions to reduce diabetes risk are determined by multilevel processes. This requires that we approach type 2 diabetes prevention from the socioecological perspective, with effective and scalable interventions and solutions that play out (a) at individual, family, workplace, institutional, neighborhood and policy levels; and (b) within settings associated with each level; and (c) in a fashion that at times is broad-based and other times is tailored to social and demographic (language/culture/age-specific) subgroups.

Care Model

Dr. Bullock presented the Commission's socioecological model for diabetes prevention and care, which the Commission uses to frame discussion of the Commission's work. Dr. Bullock highlighted areas/issues that the Prevention—General Population Subcommittee will discuss at today's meeting, including public policy, food systems, government, industry, communication, and marketing. She noted that the Subcommittee will address other sections of influence (e.g., diet, physical activity, psychological factors, stress, and trauma) in the future.

Given that all policies affect health, Dr. Bullock noted that many federal agencies' policies and programs are relevant to the Prevention—General Population Subcommittee's work. In addition to agencies traditionally considered "health agencies" (i.e., agencies under the HHS), the Subcommittee also needs to consider the work of the following "non-health agencies."

- The U.S. Department of Agriculture (USDA)
- The Department of Transportation (DoT)
- The Department of Education (ED)
- The Federal Trade Commission (FTC)
- The U.S. Department of Labor (DoL)
- The U.S Environmental Protection Agency (EPA)
- The Federal Communication Commission (FCC)
- The U.S. Department of Defense (DoD)
- The U.S. Department of the Treasury (USDT)
- The Federal Bureau of Prisons and the U.S. Department of Justice (DoJ)
- The U.S. Department of Housing and Urban Development (HUD)

Review of Data Call

Dr. Bullock pointed out that the questions contained in the data call were very specific to diabetes. As a result, many agencies did not report all the information that are relevant to the Subcommittee's work. Dr. Bullock expressed appreciation for the agencies' responses and

acknowledged the need to follow up with some of the agencies to seek clarification and additional information. She noted that the Subcommittee will follow up with the following nine agencies.

- The Centers for Disease Control and Prevention (CDC) regarding the agency's many initiatives affecting people at the population level (e.g., natural experiments, and Health in All Policies)
- The National Institutes of Health (NIH) regarding population-level research and nutritional research
- The Healthcare Resources and Services Administration (HRSA) regarding its many promising programs addressing risk factors along the life course
- The Food and Drug Administration (FDA) regarding nutrition and labeling
- The Indian Health Service (IHS), whose response is pending
- The Office of Minority Health (OMH), which did not provide information related to the Commission's care model
- The U.S. Department of Veterans Affairs (VA) for its programs and activities related to food security and housing security for veterans
- CMS, to learn more about its collaborations with other agencies on population-level issues
- USDA, to further discuss its many programs for helping improve nutrition and reduce food insecurity

Stakeholder Informant Presentations

Dr. Bullock noted that the Subcommittee has heard presentations from the following six organizations on various topics, and they will hear presentations from more organizations.

- University of Washington: Health Impact Assessments
- Public Health Institute: Health Impact Assessments
- New York University: Food Labeling
- Collective Health: Health Impact Assessments and Simulation Modeling
- Tufts School of Public Health: Nutrition
- Maternal and Child Health Bureau, HRSA: Maternal Child Health Interventions

Focus Areas

Following Dr. Bullock's presentation, Dr. Dean Schillinger explained two focus areas that the Subcommittee has been working on: Health in All Policies, and diet and nutrition.

Focus Area 1: Health in All Policies

Dr. Schillinger noted that one of the priority focus areas of the Subcommittee's work is advancing the Health in All Policies approach across federal agencies and areas that are relevant to diabetes. He explained that Health in All Policies is a collaborative approach that integrates health considerations into policymaking across sectors to improve the health of all communities and people. It recognizes that health is created by a multitude of factors beyond

healthcare and, in many cases, beyond the scope of traditional public health activities. The National Prevention Strategy, he noted, provides a Health in All Policies framework to guide our nation in the most effective and achievable means for improving health and wellbeing.

Dr. Schillinger noted that the CDC is taking the lead to disseminate the framework; however, the government in large (particularly "non-health agencies") are not yet embracing the approach.

Dr. Schillinger explained how health impact assessments can be used to evaluate and promote Health in All Polices, and he highlighted some of the main findings of recent reviews of health impact assessments. One of the reviews reported that health impact assessments facilitated novel inter-department, inter-sectoral, and inter-agency collaborations, which, Dr. Schillinger pointed out, is relevant to the Commission's work.

Dr. Schillinger highlighted some factors associated with health impact assessment success, and he asked the Commission to consider the following statements.

- Health impact assessments should be part of the active toolbox of federal agencies' decision-making processes, especially as they relate to the social-sector drivers of type 2 diabetes.
- Doing so in a consistent and streamlined manner has tremendous potential to better prevent and control type 2 diabetes at scale
- NCCC should consider:
    - Establishing requirements to perform health impact assessments
    - Establishing conditions under which health impact assessments are performed
    - Establishing or selecting entity/entities to conduct health impact assessments
    - Providing resources to generate health impact assessments
    - Establishing mechanisms to adjudicate and implement health impact assessment recommendations
    - Supporting training of highly skilled interdisciplinary workforce to build capacity to carry out health impact assessments
    - Funding rigorous evaluations of natural experiments that can inform future health impact assessments (health impact assessments are prospective)
    - Supporting research to maximize precision and robustness of health impact assessments, including health impacts and cost-effectiveness within health impact assessments and simulation research

Focus Area 2: Diet and Nutrition

Dr. Schillinger noted that 85% of total U.S. healthcare expenditures are related to management of diet-related chronic diseases such as type 2 diabetes, and that the estimated total annual direct and indirect cost for all obesity-related conditions is more than $1.72 trillion with $327 billion for diabetes alone.

Dr. Schillinger noted that the Subcommittee's key informants and literature review pointed out a number of key issues associated with diet and nutrition, including the following.

- High levels of consumption of foods and beverages with excess added sugars, simple carbs, refined grains, calorically dense/high glycemic load foods, and sugar-sweetened beverages are prevalent.
- Consumption of less healthy foods is promoted by unfettered marketing and advertising, inaccurate or false health and nutrition claims, low costs relative to healthier foods, easier access in numerous settings (especially lower income neighborhoods), social norms, attributes of and regional/local differences in the retail food environment, and an absence of clear and persuasive communications regarding what to avoid.
- The modern U.S. food system is largely designed to mass-produce highly-processed, shelf-stable food, including products that are especially diabetogenic.
- Most behavioral settings (e.g., workplaces, recreational [sports events, movie theaters]) serve highly-processed foods, often exclusively.
- Income inequality and food insecurity lead to disproportionate levels of consumption of diabetogenic foods among vulnerable populations and very low levels of consumption of nuts, fresh fruits, vegetables, and other healthy patterns of eating.
- Nutrition research has been disjointed, has not had a clear agenda or public health voice, has suffered from significant conflicts of interest and industry manipulation, and has focused on specific nutrients, rather than food-based dietary patterns.

Dr. Schilinger noted that based on the information gathered and evaluated, the subcommittee is considering making specific recommendations around the following topics.

- Advance health communications around food or beverages
- Promote economic or setting-based incentive or disincentive interventions or policies
- Engage the private sector and agricultural policies to change the food systems through investments and innovation
- Encourage policy and implementation research, including coordination between the NIH, FDA, USDA, FTC, and CDC that is free from industry influence and financial conflicts of interest.

Next Steps

Dr. Schillinger noted that moving forward, the subcommittee plans to

- Complete literature review (questions have been submitted to the NIH librarian) within 4-6 weeks;
- Hear presentations from additional key informants;
- Conduct follow-up calls with federal agencies;
- Expand literature search and synthesize literature search findings;
- Draft specific recommendations related to HIAs and nutrition;
- Determine focus areas related to other drivers of type 2 diabetes and diabetes-related disparities; and

- Collaborate with other two subcommittees to address overlaps and generate synergy

COVID-19, Diabetes, and Health Equity
Following Dr. Schillinger's presentation, Dr. Bullock used a quote about COVID-19 from Williams and Cooper (JAMA 2020) to emphasize that similar to COVID-19 disparity, type 2 diabetes disparity is the outcome of disparities in social determinants. To reduce type 2 diabetes disparity and to improve health outcomes, the underlining issues need to be addressed, she said.

Discussion

Dr. Herman commented that the Prevention—General Population Subcommittee has begun addressing many issues highlighted in the public comments, and has demonstrated the rationale for the Commission's care model. He noted that the Subcommittee's next steps are reasonable.

Health Impact Assessments
Dr. Shari Bolen expressed support for advancing Health in All Policies across all agencies. She however, was not sure if health impact assessments would be restrictive to specific agencies.

Dr. Schillinger acknowledged that health impact assessments are complex. He noted that the PEW Charitable Trusts website provides answers to many questions including the one Dr. Bolen raised. In addition, CDC's website and a report from the National Academy of Medicine provide answers to many questions related to health impact assessments. He pointed out that how quickly and efficiently HIAs can be performed will depend on the agency's priorities, resources, and expertise. Dr. Schillinger noted that the CDC, the Institute of Medicine, and a number of other entities have recommended that HIAs be implemented across local and state health departments.

Dr. Ann Albright agreed with Dr. Schillinger. She noted that parts of the CDC have recommended health impact assessments as an important tool.

Dr. Bolen wanted to know if there are multiple ways to implement health impact assessments.

Dr. Schillinger responded that in countries where Health in All Policies have been adopted in decision-making at the federal level, it has been observed that the health impact assessment process itself begins to change the mindset of those in non-health sectors.

Dr. Herman commented that formal health impact assessments would have time and resource implications, and he suggested exploring other potentially less resource-intensive options in terms of getting all of the relevant parties to the table to include health in new policy initiatives.

Dr. Schillinger agreed and he suggested defining a framework for health impact assessments.

Collective Impact Model

Dr. Bolen asked again if there are other models (e.g., collective impact model) that can be used to bring diverse stakeholders together to address social problems. She noted that even though the collective impact model is not a formal assessment, it is another way to bring diverse stakeholders together. Dr. Bolen explained how the collective impact model works and offered to share a link with other Commission members.

Dr. Albright shared that at the CDC, they used a collective impact model to develop the National Diabetes Prevention Program (known as National DPP). She commented that the model is effective and can be very helpful in addressing the issues included in the Commission's socioecological model. She pointed out that the model, however, requires people to 1) understand and embrace the concept, and 2) use common measures with shared agendas and aligned efforts.

Dr. Schillinger noted that with the collective impact model, people generally come together with a shared vision on an outcome related to health. He pointed out that in order to use a collective health model or collective impact process to address diabetes, the non-health sector first needs to recognize health as an important part of its mission.

Diet and Food Policy
Dr. Albright noted that she is looking forward to discussing with the Subcommittee regarding CDC's initiatives and efforts.

Prevention—Target Population Subcommittee Update

Dr. John Boltri, co-chair of the Prevention—Target Population Subcommittee started his presentation by reviewing the Subcommittee's framing statement.

Framing Statement of the Prevention—Target Population Subcommittee

In the United States more than one out of three adults have prediabetes according to the current diagnostic criteria in the American Diabetes Association Standards of Care. Data from the CDC show that, among those 84 million Americans with prediabetes, 90% are unaware they have this serious precursor for type 2 diabetes and elevated risk of heart attack and stroke. Individuals at high risk for the transition to prediabetes and type 2 diabetes include those with obesity, low physical activity levels, a family history of diabetes; come from high-risk racial/ethnic populations; and women with a history of gestational diabetes. Effective prevention interventions, such as certain structured lifestyle change programs and medications, will markedly reduce the progression of prediabetes and have been shown to be cost effective and cost saving. To promote better uptake of effective interventions, the at-risk population needs to be identified, provided with increased understanding of risk factors, improved access to proven prevention strategies, and tools for positive behavior change. Health care providers also need strategies to increase their uptake of prediabetes screening and tools to increase awareness and implementation of proven prevention strategies. Both those at risk and clinicians need support for increasing awareness, accessibility and affordability of screening and prevention programs for type 2 diabetes. Additional research is needed to develop improved

strategies for promotion of and adherence to positive behavior change to prevent type 2 diabetes, especially over the long-term. Research is also needed to develop interventions to prevent development or slow progression of type 1 diabetes.

Focus Areas

Dr. Boltri noted that the Subcommittee will focus on the following four focus area.

- Screening and diagnosis of prediabetes and diabetes
    - Best methods to identify people with prediabetes and increasing screening to reduce the number of undiagnosed persons with prediabetes
    - How to achieve universal screening of everyone at risk for prediabetes and diabetes
- Improve access to and utilization of effective methods to prevent or delay progression to type 2 diabetes in persons with prediabetes
    - Increase the availability, access, and utilization of proven effective interventions for preventing or delaying the onset of type 2 diabetes in people with prediabetes
    - Increase the proportion of people with prediabetes who complete formal training for preventing or delaying the onset of type 2 diabetes
    - Increase the proportion of people with prediabetes using proven medications to prevent or delay the onset of type 2 diabetes
- Sustainability of type 2 diabetes prevention – healthy lifestyle interventions
    - Reduce the transition of prediabetes to type 2 diabetes in people who have completed a diabetes prevention program
    - Develop and implement models and programs to maintain and build on improvements achieved from diabetes prevention programs
- Develop new and more effective preventive strategies for type 1 and type 2 diabetes
    - Identify and promote research to develop more effective individual and population strategies to prevent type 1 and type 2 diabetes
    - What research is needed to build on the current programs for diabetes prevention

Groups and Deliverables

Dr. Albright, Co-Chair of the Subcommittee, reviewed the Subcommittee's structure and explained how the Subcommittee conducted its work.

Dr. Albright explained that the Subcommittee divided its members into small groups to tackle different tasks.

- Group 1: Summarize federal agency data call reviews
- Group 2: Summarize stakeholder calls and comments
- Group 3: Identify gaps where more information is needed and obtain information needed to complete the Subcommittee's work
- Group 4: Develop search terms for literature search and summarize results

Dr. Albright explained that the Subcommittee together will develop recommendations.

After Dr. Albright's presentation, the small groups provided updates regarding their work.

Group 1 Update: Review of Federal Agency Data Call

Members of group 1 (Dr. Naomi Fukagawa, Dr. Barry Marx, and Dr. Don Shell) together reviewed responses from the 11 agencies, and they highlighted programs relevant to the Prevention—Target Population Subcommittee's work.

- CDC reported many relevant programs (including the National DPP), cooperative agreements with state and local health departments, and other projects.
- CMS highlighted the Medicare Diabetes Prevention Program (MDPP), Expanded Model Demonstration, Diabetes Self-Management Training (DSMT) benefit, coverage of technology and therapeutics, and Medical Nutrition Therapy (MNT) benefit.
- VA highlighted four programs, including MOVE! Weight Management Program for Veterans; Telephone Lifestyle Coaching; Lifestyle Training to Promote Healthy Eating, "Pre-Diabetes" Group Classes; and Glycemic Safety in the Inpatient Hospital Setting.
- DoD has many different initiatives for services members and their beneficiaries (e.g., DoD's group lifestyle program).
- OMH reported partnerships for 15 policies and supported programs through grants.
- HRSA highlighted two programs with a small focus on the targeted population.
- IHS shared three opportunities: Special Diabetes Program from Indians, Community Health Representatives, and Community Health Aid Program.
- BoP reported using CDC's National DDP in their initiatives.
- NIH reported many research programs. The agency funds observational and interventional research related to targeted prevention of all types of diabetes and in all populations across the lifespan.
- USDA reported no specific program for prevention of diabetes in targeted populations. However, research projects supported by the National Institute of Food and Agriculture may be applicable to diabetes prevention.
- AHRQ did not report specific programs relevant to prevention in the target population; however, its extramural U.S. Preventive Services Task Force (USPSTF) and intramural Annual National Healthcare Quality and Disparities Report could be relevant to targeted populations.

Group 2 Update: Summary of External Stakeholder Calls

Drs. David Strogatz and Shannon Idzik reviewed the major conclusions of the Subcommittee's conference calls with the following four organizations, and they highlighted common themes.

The National Association of Chronic Disease Directors pointed out the need to

- Improve public health surveillance (e.g., increase resources for screening);
- Increase access to curricula of the National DPP; and
- Allocate funds to improve social determinants of health (e.g., food and activity environments, transportation, and high-speed internet access).

The American Academy of Family Physicians encouraged the Commission to

- Address social determinants of health,
- Address Medicare and Medicaid coverage for screening and prevention programs in all states, and
- Support behavioral health coaches in primary care practices.

The American Association of Nurse Practitioners suggested the following.

- Increase access to virtual delivery of the National DPP
- Address reimbursement barriers (e.g., Medicare coverage of nurse practitioners who order medical nutrition therapy, and limits on services of certified nurse diabetes educators)
- Address social determinants of health such as transportation

The American Medical Association encouraged the Commission to

- Increase access to and participation in the National DPP,
- Improve coverage for A1c testing for screening patients for prediabetes under Medicare Part B,
- Adopt quality measures related to prediabetes, and
- Increase coverage for medical nutrition therapy and metformin in patients with prediabetes.

All of the four stakeholder organizations pointed out the need for the government to consider the following.

- Address social determinants of health
- Increase screening for prediabetes
- Address access and reimbursement barriers for prevention programs

Group 3 Update: Gaps in the Subcommittee Knowledge

Dr. Howard Tracer explained that the group plans to determine the following in the next few weeks.

- Additional data or knowledge the Subcommittee needs from specific agencies

- Important knowledge gaps at broader levels, including
    - Overarching or cross-agency gaps in diabetes activities (e.g., coordination of diabetes prevention activities across agencies)
    - Gaps in the Subcommittee's knowledge about diabetes prevention (e.g., role of medication or bariatric surgery in preventing diabetes, and strategies to prevent type 1 diabetes)

Group 4 Update: Literature Search

Dr. Boltri explained that the Subcommittee will conduct literature searches based on a series of questions. The goal, he noted, is to identify literature that is relevant to the Subcommittee's focus areas.

Next Steps and Future Directions

Dr. Albright noted that the Subcommittee's next steps include the following.

- The small groups complete their respective tasks.
- The Subcommittee members together develop initial recommendations for the final report.

Dr. Albright explained that additionally, the Subcommittee will begin working on the following focus areas.

- Medications for prevention of type 2 diabetes
- Surgical invention for type 2 diabetes
- Areas of research for prevention of type 1 and for improving type 2 diabetes prevention

Discussion

Case Finding and Referral

Dr. Herman commented on the importance of prediabetes case finding and referral. He noted there are people who are undiagnosed and there are people who are diagnosed but are not aware of it. He pointed out the issue of a lack of provider referral. He asked the Subcommittee to drill down more on the issue of case finding and referral. Dr. Herman also asked Dr. Albright's and Dr. Boltri's thoughts on hybrid approaches (e.g., a combination of lifestyle interventions and pharmacotherapies) for weight loss and maintenance.

Dr. Albright agreed these are critical questions. She noted that the Subcommittee would perhaps use searches to find out what is available in the literature. Dr. Albright also shared that the CDC has been working on these areas, particularly around referrals.

Limitations of Testing, Research Need, and Targeted Intervention

Dr. Schillinger commented that the diagnosis testing criteria for determining if an individual has prediabetes are a subject of debate. He noted that current tests have varied sensitivities and specificities, and there are no great tests that are feasible, easy to administer, and able to distinguish people with elevated glucose who are likely to progress to type 2 diabetes from those who are unlikely to progress to type 2 diabetes. He wanted to know if the Subcommittee's future work could include advancing research agenda to better understand markers of prediabetes, and to identify the subgroups for whom the National DPP would be most effective.

Dr. Albright noted that the Subcommittee would add the topic to their potential areas of future research and also examine it through literature review. Dr. Albright also commented on the cutoff for the fasting glucose, and she noted that it is time to re-exam the issue. Dr. Albright agreed that the prediabetes population is heterogeneous, and the more targeted interventions could be used, the better the outcomes would be. Meanwhile, she suggested continuing to improve the infrastructure.

Dr. Bolen pointed out that people with obesity would still benefit from weight reduction for other health conditions, even if they do not progress to type 2 diabetes.

Dr. Schillinger commented on the cost-effectiveness of the programs and acknowledged the benefits to weight loss. He suggested applying the right type of intervention to the right person to achieve "precision public health."

Dr. Herman responded that applying a costly program such as the National DPP to people who have low risk and may never develop diabetes is probably not a good use of resources; additionally pharmacotherapies with side effects probably should not be applied to those individuals. He noted there might be a less expensive yet effective intervention for those individual.

Barriers to Setting up and Running National DPP Programs
Dr. Greenlee asked if the Subcommittee would reach out to entities (e.g., the YMCA) that strive to qualify for running a National DPP program to find out their barriers.

Dr. Strogatz responded that the National Association of Chronic Disease Directors is actively working with community-based partners, including the YMCA and other community organizations that provide National DPP. He shared that the Association mentioned about organizations providing certain administrative support.

Dr. Albright added that the CDC has a lot of data from various organizations because the CDC runs the entire recognition program. She explained that there are additional barriers to becoming an MDPP supplier, and the CDC has related information and is developing new models (e.g., a new network model) so that a network can take care of the administrative responsibilities. She noted that CDC staff spend a lot of time communicating with its partners, stakeholders, and the delivery organizations about their barriers; and this is a big area that the CDC is working on.

Alignment between Medicare DPP and National DPP
Dr. Herman commented that an improved alignment between Medicare DPP and National DPP might help facilitate program expansion and reduce cost.

Dr. Albright agreed and noted that the Subcommittee perhaps would make some recommendations for the Commission to consider.

Program Uptake
In response to Dr. Fukagawa's question regarding the usage of these federal support programs, Dr. Albright pointed out that multiple factors contribute to their low utilization rates, which involve long-term lifestyle interventions. She shared that the CDC is making significant efforts to improve engagement and retention, and she pointed out that this is an area needs further research (e.g., behavioral economics).

Dr. Herman asked if the Subcommittee has thought about 1) identifying the most effective interventions, and 2) finding out if those intervention could be implemented more consistently across agencies.

Dr. Albright responded that the Subcommittee will look into it and will consider making a recommendation.

After a 10-minute break, Dr. Jennifer Bishop conducted roll call and the meeting resumed with a quorum.

Treatment and Complications Subcommittee Update

Dr. Carol Greenlee, Co-Chair of the Treatment and Complications Subcommittee, acknowledged Subcommittee members and reviewed the Subcommittee's framing statement.

Framing Statement of the Treatment and Complications Subcommittee

Diabetes is a complex metabolic condition that significantly impacts personal choices, affects both quality of life and life expectancy, and requires substantial healthcare system resources. Achieving and maintaining one's maximal potential health status and wellbeing while living with diabetes requires the availability of appropriate and comprehensive treatment options and the ability of the patient/caregiver to attend to self-care/self-management aspects of the condition. This requires that the patient/caregiver

(1) have access to and understand information about diabetes, its management, and potential complications,
(2) participate with health care providers in selecting appropriate treatment options,
(3) have the skills, confidence and psychosocial support to perform the necessary and beneficial self-management tasks, and
(4) collaborate with health care providers to achieve treatment targets that are consistent with their unique characteristics and goals of care.

It also requires that healthcare systems proactively deliver high quality individualized diabetes care and support population health improvement activities for the communities they serve.

Thus, the work of this Subcommittee will identify factors at the person, practice, healthcare system, environmental and policy levels that facilitate or hinder the delivery and receipt of high-quality care by all persons with diabetes and its complications.
Dr. Greenlee emphasized that the framing statement is intentionally patient-centered. She noted that the Subcommittee focuses on priority topics that could make the biggest impact in closing/reducing the gap between available resources and patients.

Priorities

Dr. Greenlee explained that the Subcommittee built a scaffold for their priorities and has been using the scaffold to guide the Subcommittee's discussion with stakeholders and also as a filter for federal data call review.

Dr. Greenlee noted that the Subcommittee identified and is focusing on the following intertwined priorities.

- **Increasing access to, and receipt and utilization of DSMES**
    - Policies/payment/available programs/regulations and certification requirements
    - Patient barriers (intimidation, time, transportation, literacy, numeracy, patient activation, etc.)
- **Enhancing coverage and utilization of virtual care**
    - Issues related to telehealth (visits and education) such as regulations, reimbursement, and barriers
    - Virtual consults to increase access to needed care and enhance capacity of primary care teams
    - Remote monitoring (e.g., technology and digital access)
    - Improved access to virtual care for vulnerable populations (broad band issues, etc.). For example, how increased use of virtual care can reduce disparities for vulnerable populations.
- **Reduction of disparities in care and outcomes/optimized individualized care**
    - Data on disparities within the clinical care agencies for their population and national data
    - Pilots or programs for vulnerable populations – especially if evaluated – evidence on outcomes
    - Access to needed individualized care, including devices/technology, critical mediations, availability of expertise and services, as well as adequate work force
    - Diabetes distress
    - Shared decision-making opportunities and tools
    - Social determinants of health
- **Team-based care**
    - Team members, including community health workers, pharmacists on care teams, and primary care and endocrinology specialists
    - Operations (including tools and technologies) for team-based care and population health management
    - Financial model to support team-based care

External Stakeholder Calls and Public Comments

Dr. Greenlee explained that the Subcommittee began conducting conference calls with and requesting written comments from external stakeholder in late 2019 to obtain information related to the Subcommittee's priority areas. She noted that the Subcommittee also reviewed public responses to the Federal Register Notice of Request for Information. She explained that many of the public comments provided guidance and references.

Federal Agency Data Call Review and Follow-up Calls

Dr. Greenlee explained that the Subcommittee reviewed the agencies' responses to the data call and have sought clarifications and additional information from some of the agencies via conference call (e.g., CMS, VA, FDA, AHRQ) and written comments (e.g., the U.S. Preventive Services Task Force). For example, the Subcommittee submitted questions to the CMS in preparation for the agency's presentation at the Commission's virtual meeting in February 2020, and the Subcommittee subsequently conducted a follow-up call with Dr. Jenny Lloyd to learn more about her research on diabetes education and training. Dr. Greenlee highlighted some information the Subcommittee has learned, including

- VA's virtual medical center
- OMH-funded pilot projects focused on diabetes, which has shown great results in helping qualified centers improve their programs
- CDC's work in the realm of community health workers and other programs around DSMES

Dr. Greenlee noted that responses from some agencies have been delayed due to the COVID-19 pandemic, and that the Subcommittee will continue to seek more information from the agencies.

Following Dr. Greenlee's presentation, team leads of the Subcommittee's small groups working on various focus areas provided updates regarding their work.

Update on Diabetes Education and Support

Dr. Jasmine Gonzalvo first explained the information the Subcommittee has gathered and will continue to gather around diabetes education and support. She then reviewed the main findings of the Subcommittee's analysis of the information gathered, including benefits of the programs (including DSMES and DSMT), gaps, barriers, and federal agencies involved or impacted.

Benefits

Dr. Gonzalvo highlighted the following benefits of DSMES and DSMT.

- Shown to be cost effective
- Associated with reduction in A1c levels and serious complications (e.g., heart disease, lower extremities amputations, chronic kidney disease, and blindness); increased patient empowerment and improved lifestyle behaviors and psychological outcomes
- Reduction in preventable events and reduction in hospitalizations and emergency visits

Gaps

Dr. Gonzalvo pointed out that DSMES is vastly underutilized despite of its significant impact for people with diabetes.

- 51% of people with diabetes in the U.S. receive DSMES (with marked variability across states). The Indian Health Service achieves ~80% receipt of DMSES but faces cost and reimbursement challenges.

- Less than 5% of newly diagnosed Medicare beneficiaries receive DMST in the first year (6-7% for commercially insured, newly diagnosed patients with diabetes) (average time to receipt of DSMT is 13 years). The percentages are even lower for minority, rural, and low income populations.

Barriers
Dr. Gonzalvo pointed out the following barriers.

- There are inadequate number of DSMES programs to meet the needs of people with diabetes.
- Existing programs are struggling to stay afloat due to a variety of challenges associated with program reimbursement and maintenance.
- Requirements set forth for the provision and reimbursement of DSMES present additional challenges that affect Medicare beneficiaries.

Dr. Gonzalvo pointed out that rural (nonmetropolitan) residents have a 17% higher rate of type 2 diabetes than urban residents; and in 2016, 62% of nonmetropolitan counties did not have a DSME program.

Agencies Involved or Impacted
Dr. Gonzalvo noted that available information suggests that many agencies are involved with diabetes education and support in varied ways, including CMS, HRSA, IHS, VA, DoD, CDC, AHRQ, NIH, and OMH.

Update on CGM/Other Diabetes Technology

After explaining how the Subcommittee gathered and will continue to gather information around continuous glucose monitoring (CGM) and other devices, Dr. Bill Chong reviewed the results of the Subcommittee's analysis of the information.

Benefits
Dr. Chong noted that based on the information gathered, the Subcommittee found that CGM is associated with the following benefits.

- Glycemic-related benefits: improved A1c, reduced hypoglycemia, improved time and range, less glucose variability, and improvement in hypoglycemia unawareness
- Non-glycemic-related benefits: improved fetal outcomes and less diabetes distress for pregnant women with diabetes, as well as reduced patient and caregiver burden
- Proven effectiveness in helping a broad range of patients including children, adults, patients who are on insulin therapy, and patients with cognitive impairment

Gaps
Dr. Chong noted that the Subcommittee still needs more information regarding the following.

- Data on utilization by different patient populations and by payers
- Data on long-term and ongoing benefits

- Adequate patient and caregiver training to optimize benefit
- Clinician and care team capacity

Barriers
Dr. Chong pointed out that the Subcommittee identified the following barriers based on their current information.

- Eligibility and coverage challenges. For example, there is a disconnect between the requirement for self-monitored blood glucose checks and the coverage for test strips. And in some states, Medicaid recipients with diabetes do not have any form of CGM coverage.
- Costs to patients with diabetes and to the system. Dr. Chong pointed out that cost-effectiveness analyses and research are needed to support potential changes in coverage.

Dr. Chong noted that agencies that are involved with CGM and other diabetes technologies and might potentially be impacted by potential recommendation the Subcommittee might make include CMS, HRSA, IHS, VA, NIH, AHRQ, and FDA.

Update on Team-based Care and Community Health Workers

Dr. Bolen first explained how the Subcommittee gathered information around team-based care. She then used a graph to demonstrate disparities in developing diabetes.

Benefits
Dr. Bolen explained that based on the available information, the Subcommittee identified the following benefits associated with community health workers.

- Address social determinants of health, which affect the management of chronic conditions, preventive care, and overall health
- Address diabetes management issues. Dr. Bolen noted that many programs have shown improved diabetes knowledge, self-care, and lifestyle; some studies also have shown cost-effectiveness.

Dr. Bolen noted that the gaps they have noticed in this area include a lack of wide-spread or sustained utilization of community health workers within the care team, as well as a social service team.

Barriers
Dr. Bolen noted that the Subcommittee identified the following barriers.

- Reimbursement (e.g., funding mostly via grants, State Innovation Model awards, or Medicaid waiver)
- Challenges associated with ensuring qualifications of community health workers without imposing restrictions that could eliminate those who could serve as a good resource and with good community connections
- Wide variabilities in how community health workers are used

- No standard training requirements

Dr. Bolen noted that agencies that are involved or might be impacted by the Subcommittee's recommendations include CMS, HRSA, IHS, VA, NIH, CDC, and OMH. The Subcommittee will continue to seek further information from these agencies, she said.

Future Directions

Dr. Paul Conlin, Co-Chair of the Treatment and Complications Subcommittee, updated the Commission on the Subcommittee's next steps. He noted that the small groups will complete their own next steps, and the Subcommittee will continue to work on other priority areas, including virtual care, pharmacists as members of team-based care, and health equity.

Virtual Care and Telehealth

Dr. Conlin explained that the Subcommittee recognizes that virtual care is a crosscutting topic, but it also can be addressed as a freestanding topic. He noted that federal agencies have relaxed restrictions on the use of telehealth during the COVID-19 pandemic; however, improvement is needed. To address the topic, the Subcommittee will need to collect data, including data on the impact of virtual care on people with diabetes. Dr. Conlin pointed out that virtual care unfortunately also exacerbate disparities (e.g., access to broadband). He noted that the Subcommittee will form a sub-group to review the impacts of virtual care and the digital divide. Additionally, the Subcommittee will also look into some specific programs using virtual care.

Team-based Care and Pharmacists

Dr. Conlin explained that the Subcommittee will expand the priority topic of team-based care to include not only community health workers (as Dr. Bolen explained earlier in her presentation) but also other members of care teams (e.g., pharmacists who provide care for people with diabetes) as well as other workforce-related issues.

Health Equity, Reduction of Disparity, and Data

Dr. Conlin noted that the Subcommittee is also interested in the topic of reducing disparities in diabetes. Specifically, the Subcommittee wants to find out 1) if they could identify key areas or interventions that can effectively reduce disparities in diabetes, and 2) if the inventions can be more broadly implemented. Dr. Conlin used DSMES as an example to highlight the impacts of disparities in health policies (e.g., DSMES may not be accessible to people with limited access to broadband). He noted that the Subcommittee also would like to know what the agencies are doing in terms of data collection, and how the data collected can be better used to reduce disparities in people with diabetes.

Discussion

Linkage Between Patients and Services

Given that the Subcommittee intentionally developed a patient-centered framework and highlighted the underutilization of DSMES, CGM, and community health workers, Dr. Herman

wanted to know how the subcommittee plans to address issues related to providers and systems in order to 1) link patients to the resources, and 2) achieve optimized outcomes.

Dr. Greenlee responded that the Subcommittee will discuss the topic next week. Dr. Conlin responded that the Subcommittee will explore how to address the topic, which might fit in the team-based care section.

Dr. Albright praised the Subcommittee's topic-focused approach. She agreed that DSMES needs to be better utilized, and she expressed her eagerness to speak with the Treatment and Complications Subcommittee in its follow-up call with the CDC.

Price Control
Dr. Schillinger asked if the Subcommittee discussed price control.

Dr. Bolen responded that the subcommittee did discuss the topic, but they do not have an answer yet.

Dr. Greenlee commented that pricing is a complex and often politicized issue, and she was not sure how the Commission could address the problem.

Regarding recent policy changes at CMS (e.g., reducing the price of insulin for Medicare beneficiaries). Dr. Greenlee explained that the Subcommittee members have read a few review articles, and they were concerned that the lowered cost might be offset by other costs such as copays. She noted that recent publications indicate that for people with diabetes, the main issue is not just the cost of insulin but the cost of everything.

Dr. Albright noted that her team has conducted economic studies around insulin, and she offered to share the article.

Action item: Dr. Albright will share publications of economic studies on insulin with the Treatment and Complications Subcommittee by email.

Indian Health Service's Experiences
Dr. Bullock noted that the IHS is looking forward to 1) sharing their experiences, approaches, and lessons learned; 2) discussing the community health workers' roles; and sharing the IHS's unique ability to take care of patients with or without insurance throughout the lifespan, as well as IHS's ability to have some impact on drug pricing.

Oral Public Comments

Four members from the public provided oral comments.

Jean Drummond

Ms. Drummond, President and Chief Executive Officer of HealthCare Dynamics (HCD) International, shared her organization's experience with the National DPP and DSMES, and she provided the following suggestions

- Streamline the current delivery process (e.g., not requiring additional applications for each model)
- Align Medicare and Medicaid payments
- Shorten the time before the DPP provider is considered fully recognized to permit Medicare billing
- Include community health workers into the DPP workforce
- Increase reimbursement (e.g., considering all aspects of setting up and operating the program)

In summary, Ms. Drummond noted that HCD International requests the National Clinical Care Commission to put forth recommendations that risk-adjusts for multiple populations so that those patients can have improved health outcomes and a better quality of life.

Kate Thomas

Ms. Thomas provided comment on behalf of the Diabetes Advocacy Alliance (DAA). She shared that the DAA has raised concerns over the health complications of COVID-19 in people with underlying conditions such as diabetes. She noted that the pandemic has underscored the stark disparities existing in the current healthcare system, and she stressed that now is the time to reduce the disparities by addressing social determinants of health to help achieve health equity.

Ms. Thomas urged the Commission to continue focusing on the role of social determinants of health and improving health outcomes; develop final recommendations that support interagency collaboration to achieve health equity; and consider the role of existing Medicare benefits and address barriers to these benefits.

In summary, Ms. Thomas noted that the DAA urges the Commission to recommend that Congress address the following.

- Increase utilization of the Medicare DPP by aligning with the National DPP
- Explore options to expand Medicare coverage for medical nutrition therapy to include individuals with prediabetes
- Remove barriers to accessing DSMES
- Recommend regulatory reforms that would give CMS flexibility to cover innovative diabetes technologies and services
- Remove existing coverage barriers to diabetes technology, such as eliminating the four times per day testing requirement for continuous glucose monitors

Kate Kirley

Dr. Kirley, Director of Chronic Disease Prevention at the American Medical Association (AMA), provided comment on behalf of AMA. She noted that AMA addresses prediabetes screening

and management, and has developed three prediabetes quality measures for which they are seeking inclusion into Medicare and other payment programs.

Dr. Kirley noted that preventing type 2 diabetes requires a multilayered approach that addresses social, economic, and environmental factors; as well as individuals' health behavior.

Dr. Kirley also commented on the impact of COVID-19 and other issues that need to be addressed (e.g., infrastructure to connect patients with inventions, insurance coverage, workforce, and delivery of diabetes preventive services). She noted that the AMA suggests considering specific policy changes that could improve the delivery of diabetes preventive services, including the following.

- Modify the Medicare DPP by eliminating the one-time benefit provision
- Cover all program delivery modalities, including virtual and online
- Align program length and lab values with the CDC National DPP standards
- Under Medicare part B, expand coverage of hemoglobin A1c testing to include screening for abnormal glucose metabolism
- Under Medicare part B, expand Medicare coverage of medical nutrition therapy to cover people with prediabetes

In summary, Dr. Kirley noted that AMA urges the Commission to align the federal agencies to create a mechanism that supports ongoing research and promotion of interventions that demonstrate improved outcomes. The pandemic clearly demonstrates the need to accelerate working together across many sectors like never before to improve the health of the nation, she said.

David Moskowitz

Dr. Moskowitz, founder of GenoMed, shared his experience of interacting with federal agencies regarding his research, including his earlier experience of sharing data on reversing diabetic nephropathy and a more recent experience regarding quercetin as a potentially universal viral antidote. He commented that it is challenging to come up with solutions when the healthcare system is not open to accepting research findings.

Dr. Herman thanked all commenters for their input, and he welcomed the public to continue provide comments and share thoughts.

Closing Remarks

Dr. Herman thanked all Commission members for their hard work. He noted that the subcommittees have made great progresses and laid out future directions, and he is looking forward to continued engagement of all members. Dr. Herman also thanked the public for their engagement and for providing comments.

Jennifer Bishop also thanked all Commission members for their hard work and the public for their engagement.

Adjournment

Dr. Jennifer Bishop adjourned the meeting at 4:44 pm EST.

Appendix: Commission Members and HHS Support Staff

Commission Members Present for NCCC Meeting 7

Commission Chair
William Herman, MD, MPH, Stefan S. Fajans/GlaxoSmithKline Professor of Diabetes, Division of Metabolism, Endocrinology, and Diabetes, University of Michigan, Ann Arbor, MI

Public Members (Special Government Employees)
Shari Bolen, MD, MPH, Associate Division Director of Internal Medicine, Center for Health Care Research and Policy, Case Western Reserve University, Cleveland, OH

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

Ayotunde Dokun, MD, PhD, FACE, Chief of Endocrine Service, Division of Endocrinology, Diabetes and Metabolism Regional One Health System, Memphis, TN

Jasmine Gonzalvo, PharmD, BCPS, BC-ADM, CDE, LDE, Clinical Pharmacy Specialist, Primary Care, Midtown Medical, Eskenazi Health, 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 (joined after the roll call)

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)*

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 (joined after the roll call)

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, Department of Agriculture

Barbara Linder, MD, PhD, Program Director, Division of Diabetes, Endocrinology, and Metabolic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Department of Health and Human Services

Aaron Lopata, MD, Senior Medical Advisor, 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 and Medicaid Services, Department of Health and Human Services; *Jean Stiller (alternate for Barry Marx; in presence)*

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

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 NCCC Meeting 7

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

HHS Staff in Attendance

Jennifer Bishop, ScD., MPH, Designated Federal Officer for the National Clinical Care Commission, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Richard D. Olson, MD, MPH, Technical Lead for the National Clinical Care Commission, Director, Division of Prevention Science, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Clydette Powell, MD, MPH, FAAP, Technical Advisor for the National Clinical Care Commission, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services

Captain Paul Reed, MD, Deputy Assistant Secretary for Health (Medicine and Science); Acting Director of ODPHP, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services