National Clinical Care Commission Webinar Meeting 8
Friday, September 11, 2020
1:00 pm — 5:30 pm EST

Meeting Summary

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Welcome and Review of Agenda

Dr. Jennifer Bishop, Designated Federal Office for the National Clinical Care Commission (NCCC), conducted 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 Charge and duties. Dr. Herman explained that the Commission's activities have been coordinated by three Subcommittees: the Prevention—General Population Subcommittee, the Prevention—Targeted Population Subcommittee, and the Treatment and Complications Subcommittee. He noted that all of the three Subcommittees 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' draft recommendations, and hear public comments.

Review of Timeline

Dr. Clydette Powell, Technical Advisor for the National Clinical Care Commission, reviewed the milestones and deliverables and explained the Commission's work process. She noted that today the Commission will discuss their first set of recommendations, which will be further refined between now and the Commission's November meeting. She explained that the Commission will use an iterative process to draft and revise their recommendations.

Dr. Powell explained that the Commission will begin drafting their full report early next year, present their next set of recommendations at a public meeting in February 2021, integrate recommendations into the report between February and June 2021, and review the full draft report at the June 2021 public meeting. She noted that the Commission will review and vote on the final report at the September 2021 public meeting, and the report will go through a final process (e.g., 508 compliance) before it is submitted to Congress and the Secretary of Health and Human Services in mid-October 2021.

Treatment and Complications Subcommittee Update

Introduction

Dr. Carol Greenlee, Co-Chair of the Treatment and Complications Subcommittee, briefly reviewed the Subcommittee's work process. She explained that the Subcommittee developed a framing statement, built a scaffold, created a grid, reviewed and analyzed the high-level data call, and developed their initial priority areas, including Diabetes Self-Management Education and Support (DSMES), virtual care, reduction of disparities in care and outcomes/optimized individualized care, and team-based care.

Dr. Greenlee further explained that the Subcommittee gathered information through literature review, input from external stakeholders, agencies' responses to the data call, additional information from some of the agencies through follow-up calls, and conference presentations

(e.g., CMS presentation at the Commission's February public meeting). She noted that the Subcommittee continued to refine their priority topic areas based on the information gathered, and they formed four small groups to focus on the following refined priority areas.

- DSMES
- Team-based Care
- Diabetes Technology
- Virtual Care

Dr. Greenlee explained that the small groups continued to gather additional information needed, generated and refined themes, and have begun generating draft recommendations. She noted that health equity and reduction of disparities are crosscutting themes and the Subcommittee has decided to address those topics across the four refined priority areas.

Update and Draft Recommendations on Health Equity

Dr. Greenlee explained that the information that the Subcommittee has gathered reveals fragmentation within federal agencies, and the fragmentation has created barriers to service delivery. She highlighted the specific impact of fragmentation within the Centers for Medicare and Medicaid Services (CMS) on DSMES and/or Diabetes Self-Management Training (DSMT) and diabetes technology (for example, disparities are exacerbated by many of the policies and regulations). Dr. Greenlee then presented the Subcommittee's first draft recommendation on health equity.

Draft Recommendation on Health Equity

Background

People with diabetes in vulnerable and disadvantaged populations currently have lower utilization of DSMES/DSMT, diabetes technologies, and other services (for example, recommended clinic visits, specialty care, and telemedicine).

Issue

Several CMS policies and regulations result in "collateral damage" by worsening disparities in optimal care (and thus outcomes) for people with diabetes. These policies and regulations also impact (serve as barriers to) care delivery for people with diabetes in Federally Qualified Health Centers and Indian Health Services (IHS).

Draft Recommendation (Applicable primarily to CMS and potentially to other agencies including the U.S. Department of Veterans Affairs [VA], the Health Resources and Services Administration [HRSA], IHS, the U.S. Department of Defense [DoD], and the Federal Bureau of Prisons): Federal agencies should review all new or revised policies or regulations involving the prevention, diagnosis and treatment of diabetes mellitus and/or related disorders for potential impacts on health equity and disparities. Steps should be taken before implementation to reduce or mitigate anticipated adverse effects, and appropriate data should be collected after implementation to direct corrective actions.

Team leads of the Subcommittee's small groups then presented draft recommendations proposed by their respective groups. For each draft recommendation, they provided brief background information and highlighted the key issues.

Draft Recommendations from the Diabetes Education and Support Group

Dr. Jasmine Gonzalvo noted that the group is focusing their recommendations on the following three areas.

- DSMES/DSMT policies that minimize barriers to access and utilization
- Supporting existing evidence-based models of care
- Aspects that have the potential to be addressed by federal agencies

Draft Recommendations Related to DSMT

Background

Modifications to the DSMT Medicare Benefit are needed to eliminate barriers to access and utilization.

Issue

Despite the efficacy of and recommendations for DSMES, studies show that fewer than 7% of individuals with private insurance and fewer than 5% of Medicare beneficiaries who were diagnosed with diabetes received DSMES during the first year after their diagnosis.

Draft Recommendation (CMS): Expand access and reduce current barriers to delivery of DSMT

- Allow the initial 10 hours of DSMT to remain available until fully used. Cover an additional 6 hours of DSMT services during the first year and in subsequent years, if medically necessary
- Permit DSMT and Medical Nutrition Therapy services to be covered when provided on the same day
- Exclude DSMT services from Part B cost-sharing and deductible requirements
- Permit physicians and qualified nonphysician practitioners working in coordination with a treating physician or qualified nonphysician to refer for DSMT services
- Revise the Medicare Benefit Policy Manual to ensure that hospital outpatient departments can provide DSMT services in community-based locations

Draft Recommendations Related to DSMES

Background

The complexity of the DSMES accreditation requirements are a consistent source of frustration for accredited programs, programs seeking accreditation, and individual providers. The documentation, compliance, and reporting requirements to meet the National Standards for DSMES, with additional requirements to meet CMS accreditation standards are rigorous, requiring considerable staff resources and leading to difficulties with sustainability given low reimbursement rates. Medicare Administrative Contractors (MACs) appear to interpret DSMES claim criteria and requirements differently, leading to denials with inconsistent rationales.

Additionally, data standards for electronic medical records vary greatly, presenting an additional burden to programs.

Issue
High administrative burden and high rates of claim denials prevent the growth and sustainability of DSMES programs.

Draft Recommendation (CMS): Reduce administrative burden regarding standards and documentation requirements for DSMES programs

- Ease documentation requirements for accredited/recognized DSMES programs and improve consistency of claims review process across MACs
- Set data standards for electronic medical records for DSMES to ensure uniformity in referrals and data collection

Draft Recommendations Related to the National Standards for DSMES
Background
National Standards for DSMES govern accredited and recognized DSMES programs

- Created by a workgroup from the Association of Diabetes Care and Education Specialists (ADCES) and American Diabetes Association (ADA)
- Must meet or exceed the Medicare Quality Standards (originally developed around 1997)
- Standards are approved by CMS Quality, Safety, and Oversight Group (formerly Survey and Certification Group). However, the current team sits in the Acute Care Division (formerly Clinical Standards Group Office of Clinical Standards and Quality prior to 2018). ADA and ADCES also both have written policies around accreditation that are approved by CMS.

Issue
The Medicare Quality Standards do not allow for much needed modifications to the delivery of DSMT, resulting in access barriers and restrictive models of care.

Draft Recommendation (CMS): Create a task force (members TBD) with the authority to update the Medicare Quality Standards (1997) that govern DSMT

- Establish a process for ongoing timely review, updating and revision with input from external stakeholders

Draft Recommendation Related to Quality Innovation Networks-Quality Improvement Organizations (QIN-QIO)
Background

- Existing Quality Innovation Networks-Quality Improvement Organizations (QIN-QIO) data support community-based diabetes education programs that are currently unaccredited and/or not recognized.
    - Significant improvements in clinical and behavioral outcomes

    - Strong evidence in minority communities
- Proposed framework for recognition and reimbursement
    - Standardize expectations for community-based diabetes education and support
    - Reinforce the role of peer educators and their scope of work
    - Contract with community-based diabetes education programs, with an agreement to pay per successful graduate (defined by specific outcomes)

Issue
Lack of a mechanism for QIN-QIO data to inform subsequent policy to support community-based diabetes education programs

Draft Recommendation (CMS): Develop processes to utilize QIN-QIO data to generate CMS policies that support community-based diabetes education programs

Draft Recommendation on Research
Background
Additional research related to practical implementation of DSMES would inform best practices moving forward.

Issue
Despite the efficacy of and recommendations for DSMES, studies show that fewer than 7% of individuals with private insurance and fewer than 5% of Medicare beneficiaries who were diagnosed with diabetes received DSMES during the first year after their diagnosis.

Draft Recommendation (NIH, CDC, AHRQ, VA): Prioritize funding for innovative research to explore factors that affect referrals to and patient uptake of DSMES, including

- Patient, clinician, and system-level barriers
- Quality measures and incentives
- Patient-reported outcomes and perspectives

Draft Recommendations from the Diabetes Technology Group

Dr. Bill Chong briefly reviewed the benefits associated with using diabetes technology; highlighted factors affecting utilization, most of which are related to insurance coverage; and presented draft recommendations.

Draft Recommendations on CMS Eligibility Requirements
Background
Improving access to innovative diabetes technologies (e.g., insulin pumps, continuous glucose monitors, closed-loop insulin delivery devices) can improve the quality of life and clinical care of patients with diabetes. Alignment between eligibility requirements and coverage of pre-requisites, and alignment between CMS coverage requirements and requirements of Medicare Administrative Contractors (MACs) and auditors need to be improved.

Draft Recommendation (CMS): Develop a process that regularly evaluates the eligibility requirements for different diabetes technologies to ensure that they align with coverage of pre-requisites and with current evidence of clinical benefits. Include factors beyond glycemic control, such as patient-reported outcomes, as part of eligibility determination

Draft Recommendation (CMS): Establish a process for alignment of coverage determination (eligibility) and reimbursement requirements to ensure that coverage requirements are interpreted and applied similarly by all parties

Draft Recommendation on Access to Diabetes Technologies
Background
Reduce burden on patients and providers in order to improve obtaining and maintaining access to diabetes technologies

Draft Recommendation: Continue the temporary waivers on coverage requirements, such as those requiring in-person visits, to minimize disruption of care and reduce unnecessary patient burden

Draft Recommendations from the Team-based Care Group

Dr. Shari Bolen explained that for this report, the group is focusing its recommendations on aspects of team-based care that can have the greatest impact on the quadruple aim (improved diabetes outcomes, improved patient and provider experience, and reduced health care costs); and has the potential to be addressed by federal agencies.

Community Health Workers
Rationale for focusing on community health workers
Dr. Bolen explained that the information they have gathered clearly shows that community health workers (CHW) help address social determinants of health and many diabetes management issues, and are cost-effective. However, the implementation of community health workers is hindered by many barriers, including unsustainable payment models; limited protocols for hiring, training, oversight, and implementation of community health workers in different contexts; and lack of national standards for documentation of community health workers' work and reimbursement.

Dr. Bolen presented the following two recommendations on community health workers. She noted there are ongoing efforts to address some of these issues, and if the issues are addressed before the Commission submits its report, the group will revise these recommendations accordingly.

Issues

- No standard reimbursement models exist for CHWs within Medicaid and Medicare
- Current CMS legislation (2014 rule) allows CHW reimbursement for clinical preventive services only

- Mandated CHW training and certification has the potential unintentional consequence of leaving out excellent and/or experienced CHWs from the work force
- Lack of Medicare codes for the full range of CHW services may make future reimbursement challenging

Draft Recommendation (for CMS): Develop standard reimbursement mechanisms within Medicaid and Medicare for Community Health Workers

- Do not mandate specific certification or training requirements for CHWs.
- Broaden the 2014 rule so Medicaid can reimburse a broad range of preventive care provided by CHWs, including those addressing the social determinants of health, health promotion, and advocacy.
- Add CHWs as an optional benefit within Medicaid.
- Expand the Medicare codes (i.e. z codes) to allow for full documentation of CHW activities.

Issues

Limited protocols and familiarity with hiring, training, oversight and implementation of CHWs in different contexts

Draft Recommendation (for all federal agencies involved in research, for example the NIH, CDC, AHRQ, OMH): Prioritize funding for implementation research focused on use of CHWs in diabetes management among disadvantaged populations

Dr. Bolen noted that this recommendation is underdeveloped at this moment, and the group may address the role of other members of the care team (e.g., pharmacists) later.

Next Steps

Dr. Paul Conlin, Co-Chair of the Treatment and Complications Subcommittee, explained that the Subcommittee will further refine the draft recommendations presented today and continue to explore other priority topics, including the following.

- Virtual care: The Subcommittee plans to address telemedicine, the digital divide, and specialty care access
- Team-based care: The Subcommittee will explore issues related to nonphysician members (e.g., pharmacists) as evidence-based team members, and the implementation of team-based care

Discussion

Primary physician workforce

Dr. Dean Schillinger suggested the Subcommittee expand the recommendation on community health workers and think about the primary care team more broadly. He commented on the shortage of primary care physicians, especially in underserved areas, and he asked if the Subcommittee will address this issue (primary physician workforce).

Dr. Bolen responded the issue does fit in the recommendation and the group will discuss the topic at their next meeting.

Dr. Schillinger commented that the topic (primary physician workforce) also fit in DSMES-related issues.

Dr. Greenlee explained that the topic was on their initial list; however, when the Subcommittee reached out to the relevant organizations regarding the topic, they did not receive much response.

Action item: Dr. Schillinger offered to help make connections.

Other interlinked issues

Dr. Ann Albright pointed out three interlinked issues: workforce shortage, sustainability of the programs, and engagement of the end users. She commented that all these issues need to be addressed.

Dr. Herman commented that it makes sense for the Treatment and Complications Subcommittee to think about crosscutting issues and the linkage of the three issues Dr. Ann Albright mentioned. He suggested the Subcommittee take a broader view within team-based care.

Technology

In response to Dr. Schillinger's comment on the first draft recommendation on technology, Dr. Bill Chong explained that early data were from people with type 1 diabetes; however, recent data suggest that diabetes technology benefit individuals with type 2 diabetes as well. He clarified that the intent of the recommendation is to think more broadly, continue to review data, and update coverage-related requirements accordingly to benefit a wide population.

Community health workers, national standards, and flexibility

Dr. John Boltri commented on the recommendation on community health workers. He expressed his support for community health workers, and he pointed out challenges associated with variations from state to state due to a lack of a national standard.

Dr. Bolen noted that the Subcommittee members do want national standards that improve the utilization of community health workers; however, they do not think mandates for training and certificates are the way to go. She clarified that the goal of the recommendation is to make it easier for states to implement community health workers.

Dr. Schillinger wanted to know if Medicaid programs could develop standards for states.

Dr. Greenlee clarified that CMS gives waivers to Medicaid to pay for clinical support provided by community health workers. She noted that the limit (clinical support only, not other types of

support) can be redefined without big rule changes, and when it is redefined, it would help improve uptake from states.

Dr. Ann Bullock shared that IHS has been using community health workers successfully. She expressed her support for moving away from mandates for training and certificates. She pointed out the importance of cultural context and the need for flexibility.

Research
Regarding the recommendation around supporting research focused on community health workers, Dr. John Boltri suggested revising the language to improve clarity. For example, replacing "Prioritize funding" with "Provide new funding."

Outcome versus credential
Dr. Ann Albright shared that the National Diabetes Prevention Programs (DPP) focuses on accrediting and certifying facilities that show/achieve improved outcomes, which moves away from requiring credentials for individuals. She noted that focusing more on achieving desired outcomes, less about credentials of individuals, would be worthy of pursuing.

Dr. Bill Herman asked if the approach Dr. Albright described could be a model for community health workers.

Dr. Bolen replied that it is a question for the group to think about. She pointed out there are different models.

Medicine pricing
Dr. Dean Schillinger wanted to know if the pricing of pharmacological products such as insulin will be addressed by the Treatment and Complications Subcommittee or a new group/Subcommittee proposed by Dr. Herman.

Dr. Greenlee clarified that the topic is not on the Treatment and Complications Subcommittee's agenda.

Dr. Herman confirmed that the new group will address the topic.

Prevention—Targeted Population Subcommittee Update

Introduction and Work Status

Dr. Ann Albright, Co-Chair of the Prevention—Targeted Population Subcommittee briefly reviewed the Subcommittee's accomplishments and work status, explained the process used to develop draft recommendations, and highlighted the Subcommittee's focus areas.

Accomplishments

- Completed the summary of stakeholder calls
- Completed summaries of data call responses

Activities underway

- Seeking further information from agencies (e.g., regarding effectiveness and coordination of the programs)
- Reviewing literature search results with the help of the HHS support team
- Developing first round of draft recommendations

Strategies for developing draft recommendations

- Using the Subcommittee's four focus areas and the Charge to the Commission as a guide to remain focused and to address fragmentation/overlap
- Using a strategic planning process to brainstorming draft recommendations. Dr. Albright explained that the Subcommittee clarified the intent and addressed duplicate recommendations during the Subcommittee's meeting yesterday.

Team leads of the Subcommittee's small groups then presented draft recommendations developed by their respective groups.

Focus Area 1: 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)

Focus Areas 1 Draft Recommendations

- Continue support of the CDC/AMA/Ad Council public awareness (or other such campaigns) to raise awareness about prediabetes and to engage people in the National DPP.
- Endorse and promote the new clinical quality measures that have been proposed by the AMA for screening of abnormal blood glucose and care of people with prediabetes
- Increase coordination among federal agencies for consistent communication and recommendations regarding screening and referral for prediabetes
- Use existing claims and medical record data to more efficiently 1) identify people who may already meet criteria for the National DPP, and 2) identify people at increased risk for prediabetes for targeted screening
- Increase resources for screening in medically underserved areas and populations
- Provide coverage for all screening/diagnostic tests used for prediabetes

Focus Area 2: Improve access to and utilization of affective methods to prevent or delay progress to type 2 diabetes in persons with prediabetes

- Increasing the availability, access, and utilization of proven effective interventions for preventing or delaying the onset of type 2 diabetes in people with prediabetes

- Increasing the proportion of people with prediabetes who complete formal training for preventing or delaying the onset of type 2 diabetes
- Increasing the proportion of people with prediabetes using proven safe and effective medications to prevent or delay the onset of type 2 diabetes

Focus Area 2 Draft Recommendations

- FDA approve metformin for delay of type 2 diabetes
- Create an inter-agency coordinating taskforce within HHS to review, support, promote, and implement proven evidence-based programs shown to be effective in preventing or delaying type 2 diabetes
- Coverage for all proven modes of delivery for evidence-based type 2 diabetes prevention interventions. (virtual DPP, access to internet)
- Approve Medicare DPP as a covered benefit (not only a model expansion)
- Streamline the CDC certification, recording keeping, and CMS payment process for the National DPP/Medicare DPP while maintaining quality. (also discussion of administrative support)
- Lift the once-in-a-lifetime requirement for the Medicare DPP
- Increase reimbursement rate for the Medicare DPP
- Increase Medicaid coverage for the National DPP and other evidence-based interventions
- Promote Medicaid delivery models for diabetes prevention

Focus Area 3: Sustainability of type 2 diabetes prevention –healthy lifestyle interventions (programmatic and individual)

- Reducing the transition of prediabetes to type 2 diabetes in people who have completed a diabetes prevention program (sustaining the gains achieved in DPPs)
- Developing and implementing models and programs to maintain and build on improvements achieved from diabetes prevention programs long term (individual and programmatic)

Focus Area 3 Draft Recommendations

- More research on the number, frequency, and content of “booster” doses (i.e., lifestyle intervention sessions) needed, to effectively sustain type 2 diabetes prevention in the longer-term, after successful completion of a diabetes prevention intervention
    - The results of the DPP Outcomes Study suggest that group lifestyle intervention is effective in sustaining diabetes prevention
- Ensure that coverage and reimbursement are included in the payment system (Medicare/ Medicaid/ other insurers) for strategies that sustain lifestyle change.
- Fund research to study the effectiveness of combined approaches (e.g. lifestyle interventions and medication) for type 2 diabetes prevention
    - No great use of medication yet
- Research to identify persons who will better respond to lifestyle and who will better respond to metformin or other type 2 diabetes prevention interventions

Briefly explained available data. Different age groups respond to metformin differently (for example, younger people seem to respond better than older people; among women with histories of gestational diabetes, both effective; women without gestational diabetes respond better to lifestyle)

- Federal agency initiatives and programs targeting type 2 diabetes prevention should maintain a continued commitment to prediabetes and preventing type 2 diabetes

Focus Area 4: Develop new and more effective preventive strategies for type 1 and type 2 diabetes

- Identifying and promoting 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

Focus Area 4 Draft Recommendations

- Increased research funding to better identify methods to reduce the prevalence of obesity and prediabetes, to better prevent the progression from prediabetes to type 2 diabetes, and to improve the availability and uptake of proven prevention methods (i.e., DPP), especially in communities/ populations that are disproportionately affected by type 2 diabetes
- Funding for research that focuses on how participants with prediabetes can sustain lifestyle changes over the long term (after completing a diabetes prevention program)
- Funding to investigate other methods for type 2 diabetes prevention
- Funding to investigate less intensive methods for type 2 diabetes prevention
- Increased research funding for type 1 diabetes prevention. For example, immunomodulators
- Increased research funding for early identification of people who are at high risk for type 1 diabetes to prevent early complications associated with rapid new onset

Discussion

Booster

Dr. Ann Albright shared that stakeholders are continuing their efforts to get metformin approved. She pointed out the need to revise the application language based on FDA's response and try again.

Dr. Herman asked if the National DPP is once in a lifetime benefit for participants and if there is any booster beyond one year.

Dr. Albright responded that a portion of National DPP is once in a lifetime. She explained that CDC is currently collecting data on the second year benefit. She clarified currently there is no standardization, and it is up to the payer to decide if they want to pay for it.

Dr. Bill Herman asked if CDC has a mechanism to look at those individuals who enrolled in the second year.

Dr. Albright responded that the delivery organizations know those individuals but CDC currently does not. She noted that funding for research in this area would be helpful.

Medicare DPP and reimbursement rate

Dr. Bolen asked if the Subcommittee will provide specification around reimbursement rates in the recommendation on Medicare DPP.

Dr. Albright explained that the Subcommittee has not gone to that level of detail yet but will discuss the topic further. She pointed out the need to help the organizations develop a good business model so that they can stay sustainable. She shared that National DPP is assessing various models and exploring different ways to help address the issue.

Dr. Bolen suggested the Subcommittee add specificity to the recommendation on reimbursement rate for Medicare DPP and the recommendation on Medicaid reimbursement for implementation.

Research

Dr. Schillinger suggested expanding research on biomarkers to better identify people for screening. He commented that the diabetes prevention program does not mention much about sugary beverages, and he wanted to know if a repeat study could/should be conducted to investigate the effect of added sugar.

Dr. Ann Albright responded that a CDC team is evaluating the components of the diet. She noted that randomized clinical trials might be done by the NIH or other organizations with funding. Regarding biomarkers, Dr. Albright explained it is the intent of one of their recommendations on targeted screening.

Dr. Bill Herman commented that there is no need to repeat such a large scale of lifestyle study. He pointed out that a number of smaller studies are addressing the topic (that is, the effect of added sugar).

The group further discussed diet quality. Dr. Herman pointed out that individuals have different preference for diet. Dr. Barbara Linder shared that in the obesity field, there is a debate over which type of diet is better and there is a lot of ongoing research in the field.

Organization/presentation of recommendations

Dr. Paul Conlin commented that the number of draft recommendations is large. While some of the draft recommendations are broad, some are narrow. He suggested the Subcommittee group the draft recommendations into overarching themes, begin with a broad statement, and then present the specific draft recommendations using sub-bullets.

Dr. Ann Albright responded that this is the Subcommittee's first round of recommendations. She acknowledged there are different ways to present recommendations. She pointed out that the Commission perhaps needs to revisit the outline of the report and decide how to present the recommendations consistently across the Subcommittees.

Dr. John Boltri explained the Subcommittee's process of generating, clarifying, and ranking the recommendations. He noted that the Subcommittee will assess the feasibility and rank the draft recommendations after the Commission meeting.

Basic and clinical research

Dr. Meredith Hawkins commented that she liked the research questions raised (e.g., prevention on type 1). She pointed out that both basic research and clinical research are needed, and she wondered how to address the balance.

Dr. Ann Albright responded that the federal agencies have different focuses and CDC's research is focusing on implementation of research. She noted that adequate funding is needed for the agencies to maintain the continuum (that is, from basic research to translational/clinical research, and to implementation research).

Dr. Herman agreed.

Prevention—General Population Subcommittee Update

Introduction

Dr. Dean Schillinger, Co-Chair of the Prevention—General Population Subcommittee, reviewed the Subcommittee's framing statement. He explained that the Subcommittee focuses its efforts on type 2 diabetes because 1) the majority of opportunity for prevention currently is associated with type 2 diabetes, and 2) type 2 diabetes represents ~95% of the diabetes burden.

Dr. Schillinger reviewed the Diabetes Prevention and Care Model and explained that the Subcommittee's first round of recommendations are related to diet and nutrition.

Dr. Schillinger explained that the Subcommittee is reviewing federal programs and policies affecting the general population, including those relevant to "non-health focused" federal agencies (e.g., the U.S. Department of Agriculture [USDA]) because non-health agencies' polices can affect population health. Dr. Schillinger then presented the Subcommittee's first draft recommendation on Health in All Policies.

Draft Recommendation on Health in All Policies

Background

Despite the impact of a wide range of federal (non-healthcare) agencies' programs on the health of the population, agencies' policies and rule-making decisions are not influenced by their associated health and economic consequences. Public health is "not at the table" when decisions are made related to food, transportation, housing, and education systems.

The rapid rise in diabetes in the U.S. has been driven by dramatic changes in the social and environmental milieu. The attributes of this environment are a function in part of federal policies that affect everything from transportation systems to housing to food systems to marketing/advertising to clean air and water. To date, federal policies and programs emanating from these "non-healthcare" sectors and agencies have been enacted without consideration of their impacts on diabetes prevention or control.

Health in All Policies (HiAP) are an evidence-based collaborative approach that integrates and articulates health considerations into policymaking across sectors to improve the health of all communities and people. HiAPs can promote diabetes prevention by engaging and influencing policies and practices of non-health agencies.

Despite the evidence, and despite CDC's recommendations to adopt health in all policies, to date there has been no targeted or sustained effort to advance a HiAP agenda at the federal level, either within or across federal agencies. There is no mandate that federal agencies adopt a Health in All Policies process to their programs and policies at the rule-making stage, or that the U.S. Congress consider it at the legislative stage. A significant and costly gap in federal effort to prevent and control diabetes could be filled by creating requirements and interagency coordination around Health in All Policies.

Draft Recommendation: The NCCC recommends that Congress adopt a Health in All Policies approach and establish requirements that relevant federal agencies beyond those in healthcare delivery perform Health Impact Assessments (HIAs) to ensure that their programs and policies contribute to diabetes prevention and control efforts. *Health Impact Assessments (HIAs) are a widely-accepted and evidence-based systematic process to promote health in all policies.* HIAs use an array of data sources and analytic methods and consider input from stakeholders to determine the potential effects of a proposed policy, plan, program, or project on the health of a population and the distribution of those effects within the population. HIAs also provide recommendations on monitoring and managing/mitigating those effects. HIAs are useful to promote health and mitigate adverse impacts of decisions made outside of the health sector. Furthermore, we recommend that such programs and policies with significant potential to affect diabetes prevention and control be subject to prospective evaluations of their health impacts.

- Establish conditions/methodology/thresholds; entity/entities to conduct HIAs; resources to efficiently generate reliable HIAs; mechanisms to adjudicate and implement HIA recommendations; training of skilled workforce to carry out HIAs

Draft Recommendations in the Diet and Nutrition Domains

Dr. Schillinger briefly explained the Subcommittee's rationale for focusing on diet and nutrition, and noted that the Subcommittee will refine the recommendations based on literature review results.

Other members of the Subcommittee then presented their draft recommendations.

Supplemental Nutrition Assistance Program (SNAP) Policy: Incentive and Restriction

Dr. Carol Greenlee provided background, highlighted key issues related to SNAP, and proposed draft recommendations aimed at addressing those issues.

Background

The SNAP program is by far the largest federal nutrition assistance program ($80B per year), serving 38 million people (2019). SNAP beneficiaries are at high risk of cardiometabolic diseases, especially diabetes. The SNAP Fruit and Vegetable Incentive Programs have been found to successfully increase the intake of fruits and vegetables by SNAP participants. Sugar-sweetened beverage restrictions have been found to reduce the added sugar intake of SNAP participants.

Multiple stakeholders support changes to SNAP to "improve nutrition and overall health" and favor both a fruit and vegetable incentive and a sugar-sweetened beverage restriction to increase the percentage of SNAP participants meeting dietary guidelines.

Both randomized clinical trials and micro-simulation studies find that a combined fruit and vegetable incentive and sugar-sweetened beverage restriction would be cost effective with the potential for marked cost savings. Currently only a minority of SNAP participants meet the dietary guidelines. Not meeting the goals of a healthy diet contributes to poorer health outcomes (including diabetes) and greater healthcare costs.

Draft Recommendation: NCCC recommends that the U.S. Department of Agriculture implement changes to SNAP policy and the SNAP program to reduce the incidence of diabetes and other diet related conditions via a 30% fruit and vegetable incentive combined with restrictions (exclusion) of the purchase of sugar-sweetened beverages with SNAP benefits

SNAP Policy: Eligibility and Benefit

Dr. Ann Bullock presented the second draft recommendation related to SNAP.

Background and Issue

SNAP has been shown to reduce poverty and chronic disease impacts, including health care costs. However, there are underserved groups whose health could be improved by SNAP, but who are not currently eligible (e.g., certain categories of legal immigrants, low income college students, etc.). In addition, SNAP benefits are often insufficient to provide nutritious foods

throughout the month, resulting in less healthy foods being consumed and even reduction in food intake for many beneficiaries toward the end of the month.

Dr. Bullock explained that SNAP has lifted 3.4 million out of poverty, and half of them are children. She pointed out that receiving SNAP in early life not only helps the individual's life later but also benefit society and the health system.

Draft Recommendation: The NCCC recommends SNAP eligibility be expanded to more underserved groups and SNAP benefits be increased to better address the nutritional needs of SNAP beneficiaries. These benefit changes should be informed by existing data that shed light onto the optimum thresholds of eligibility and benefit amounts, taking into account the costs of inadequate nutrition on health (e.g. diabetes) over the life course as well as upfront program costs.

SNAP-Ed Policy: Improving Education

Background

SNAP-Ed is an evidence-based program that helps people lead healthier lives by teaching those who are using or eligible for SNAP about good nutrition and how to make their food dollars stretch further. SNAP-Ed participants also learn to be physically active. SNAP-Ed works by building partnerships with a wide range of community organizations. Communities have social marketing campaigns; hold nutrition education classes; and improve their policies, systems, and the environment of the community. Prior research suggests that incentives combined with education is more effective than either alone. In addition, any changes in SNAP eligibility or food benefits (recommendations 2, 3) would need to be communicated clearly via the SNAP-Ed program.

Draft Recommendation: NCCC recommends that the U.S. Department of Agriculture bolster the evidence-based SNAP-Ed program to further improve nutrition education provided to SNAP beneficiaries. Effective communication models should be employed which meet the health literacy needs of SNAP beneficiaries so as to prevent diabetes.

Food and Beverage Labeling

Background

Dr. Dean Schillinger explained that the general public, especially those of lower income and educational status, is frequently misinformed about the nutritional value and health risk of foods and beverages, especially processed foods and retail foods. Current labeling regulations have been inadequate with respect to reducing the consumption of foods and beverages that can lead to the high burden of diabetes and other cardiometabolic disease in the general population.

Inaccurate marketing claims about the health benefits of certain products, combined with a federal nutrition label that requires very high levels of scientific numeracy and health literacy, leave many consumers unprepared and unprotected when it comes to promoting their own health and the health of their families. The lack of focused efforts on the part of the FDA to

enact programs and policies to prevent and control diabetes has made the work of many other federal health agencies that deal with diabetes (e.g., CDC, CMS, and HRSA) more challenging and more costly. There is strong evidence from around the globe that clear and compelling food and beverage labeling can improve dietary quality at individual and population levels.

Draft Recommendation: The NCCC recommends that the FDA revise and/or develop specific policies and actions to reduce the risk and the burden of diabetes among U.S. consumers by enabling comprehension and influencing healthy food and beverage choices. These include:

- mandating clear, simple, and evidence-based Front of Package alerts and/or icons to inform consumers of the presence of levels of added sugar, salt, and fat in excess of thresholds;
- enhancing the new "added sugar" requirement on nutrition labels through the addition of "units in teaspoons" (now conveyed in grams per serving); and
- developing a more robust communication campaign that is targeted to ethnically and linguistically diverse audiences disproportionately affected by type 2 diabetes, and that conveys how the new added sugar labeling requirement can be helpful in an individual and a family's efforts to prevent diabetes and its complications.

Healthy Food Access and Availability

Dr. Jasmine Gonzalvo reviewed the background and presented the draft recommendation on availability of and access to healthy food.

Background

Inadequate access to and availability of affordable healthy food outlets is a significant contributor to diabetes prevalence in the U.S. There are significant socioeconomic and racial disparities in healthy food access and availability because of structural and geographic barriers intrinsic to "underserved" areas. Land availability, construction and operation costs, market demand, and approval or zoning requirements in underserved areas all pose significant barriers to establishing and developing grocery retailers.

Inadequacies in transportation infrastructure and affordability exacerbate healthy food access and availability problems. Demonstration projects involving local health departments, planning, housing, economic development, and local legislative support have shown that innovative programs can provide zoning and financial incentives to promote grocery store development, upgrading, and expansion into underserved areas.

Draft Recommendation: NCCC recommends that robust interagency collaborative efforts be created and funded to create new programs (or scale up current programs) that support state and/or local entities to:

- Maximize transit access to grocery stores and farmers' markets by evaluating existing transportation routes and coordination of bus routes, bus stops, and schedules, and adding vanpools or shuttle services.

- Promote longer-term transportation and land use planning and infrastructure development that enables the co-location of food retail, transit access, and affordable housing.
- Incentivize and promote healthy food retail, including land use planning, zoning, economic development and redevelopment, and nutrition assistance.

Next Steps

Dr. Schillinger explained the Subcommittee's plan for the next steps.

- Conduct additional interviews with key informants and key agency contacts across health and non-health sectors and agencies
- Synthesize literature search results in nutrition and diet domains
- Complete current recommendations, and compose new draft recommendations in the nutrition domain (e.g., sugar-sweetened beverage reduction; GRAS [Generally Regarded as Safe] status of added sugar; incentivizing change/growth/shift in crops to fruits, vegetables, nuts, beans, whole grains; food system innovation; non-SNAP federal food nutrition assistance programs such as school lunch program, etc.)
- Expand literature search to include other domains (e.g., transportation, childcare, housing, media/communications, etc.)
- Compose new draft recommendations in these other domains

Discussion

Availability and access to healthy food

Dr. Meredith Hawkins asked if the Subcommittee is going to address locally owned neighborhood stores.

Dr. Gonzalvo explained that preliminary literature search and review suggests that retailors might help improve access to healthy food. She noted that the Subcommittee will review the literature to refine the recommendation.

Dr. Greenlee shared that stores accepting WIC (Women, Infants, and Children) fruit and vegetable vouchers tend to supply more fruit and vegetables and increase varieties and options, which seems to encourage nearby stores without WIC participants to increase healthier food options as well.

Dr. Schillinger pointed out that many local stores do not have refrigerators to keep flesh foods and veggies, and incentives are needed to help them. He explained that recent data show that the changes put in place in 2009 (that is, increased restrictions on purchases of refined grains, fruit juices, and sugar-sweetened beverages) have led to reductions of gestational diabetes and improved the health outcome of the children.

Recommendation on transit and zoning

Dr. Paul Conlin commented that transit and zoning are under local authority with limited federal involvement. He asked if the recommendation can be restructured to make a bigger impact.

Dr. Gonzalvo agreed that individuals with authority need to be identified to carry it through. She acknowledged that the recommendation needs further discussion.

Dr. Greenlee added that at the Commission's meeting in November 2019, a speaker from the Department of Transportation (DoT) shared during her presentation that DoT provided funding to the local community for planning. She pointed out that federal agencies can provide funding to support infrastructure and innovation.

Dr. Schillinger noted that the Department of Housing and Urban Development (HUD) can create standards around public housing. The great impact would be for DoT and HUD to provide funding to localities to redesign certain areas to meet the Health in All policies objectives.

Prioritization

Dr. Bill Herman asked if the Subcommittee has prioritized their topic areas and recommendations, and if it is feasible for the Subcommittee to address all of the topics within the timeframe.

Dr. Ann Bullock responded that the Subcommittee members are aware of the timeframe and they are going to tackle the issues in the next few months. She explained that the idea to bring all the important topics (all types of stressors) into discussion, even if the Subcommittee is not able to go as deep as they would like to in all topic areas. She noted that the Commission would miss the opportunity otherwise. She noted that the Subcommittee members also feel strongly about diet and nutrition, which have strong evidence and can make huge impact.

Dr. Bill Herman asked what would be the best way forward.

Dr. Schillinger explained that they have scheduled additional key informant calls and developed additional literature questions.

HIA

Regarding HIA, Dr. Schillinger noted that the Subcommittee would need consultation with someone with legal knowledge to develop an applicable recommendation. He asked Dr. Ann Albright's view on the HIA recommendation.

Dr. Ann Albright explained that she has reached out to colleagues at CDC who have experience with HIA and they acknowledged that it is time consuming and difficult to implement; in addition, resources and authorities are needed. She further explained that CDC's HIA-related efforts are more at local levels, and she commented that implementing HIA at the national level

might be more challenging. She pointed out that the Subcommittee and Commission need to be clear about the outcome of the recommendation.

Dr. Schillinger and Dr. Albright further discussed HIA and if CDC is an appropriate entity to do it. Dr. Ann Albright noted that she will need to check with the agency. She pointed out that if an agency is responsible for doing it, the agency will need authority and resources to implement it. She agreed that HIA is a concept to explore, and she also note that she couldn't find anyone from CDC who continues to conduct HIA.

Dr. Don Shell agreed that is a great concept. He pointed out that to ensure success, partnerships at all levels are critical and a champion at the legislation side is also needed.

Discussion of Health Systems Organization

Introduction

Dr. Bill Herman noted that he would like to form a group to address the following crosscutting topics.

Crosscutting Topic 1: Access to Care

Dr. Herman explained that diabetes treatment and prevention of complications require access to care. In the U.S., access to care is not as streamlined and COIVD-19 has highlighted the fragility of the system. He noted that the Commission needs to address access to care for people with chronic conditions including diabetes.

Dr. Herman asked if it is within the Charge for the Commission to develop recommendations to address access to care.

Dr. Dean Schillinger and Dr. Ann Bullock both replied yes.

Crosscutting Topic 2: System-level Interventions to Improve the Delivery of Dare

Dr. Herman explained that studies, including the Translating Research Into Action for Diabetes (TRIAD) study, have found that

- Health care and provider group structure and organization are strongly associated with processes and outcomes of care.
- The processes and outcomes of diabetes care may be improved by increasing integration of health systems, more intensive disease management, reduced cost shifting to patients for preventive services and necessary medications, and financial incentives for quality.

Discussion

In response to Dr. Schillinger's comment on the TRIAD study, Dr. Herman explained that the TRIAD study was an observational study, and he noted that more recent prospective studies

have demonstrated efficacy of system-level interventions and other strategies to improve care. He noted that now is the time to promote those cost-effective interventions.

The Commission members generally agreed that these are important topics to address and the Commission needs to make a statement around access to care. However, Commission members also expressed concern that the Commission may not have the time and capacity to tackle these large issues and make recommendations around the broad range of topics Dr. Herman mentioned.

Dr. Paul Conlin suggested Dr. Herman narrow down the list of topics and focus on diabetes, which is within the Charge to the Commission.

Dr. Carol Greenlee suggested Dr. Herman focusing on access to are and access to critical medicine. She commented that the federal agencies such as HRSA already use many of the tools Dr. Herman mentioned particularly registries.

Dr. Herman agreed that narrowing down would be more practical.

At the end of the discussion, Dr. Herman stated that he will 1) focus more based on the Commission members' suggestion, and 2) solicit volunteers to work with him to address these topics.

Public Comment

Dr. Deneen Vojta, Vice President at the UnitedHealth Group, provided comment on metformin. She noted that metformin is well tolerated and is recommended as a safe therapy for the treatment and prevention of type 2 diabetes in many guidelines; however, despite of its well documented efficacy, metformin is not prescribed for prediabetes. Dr. Vojta highlighted the effectiveness of metformin in weight reduction in a study conducted by her group. She expressed willingness to work with the Commission to seek FDA approval of metformin.

Additional Discussion

Dr. Schillinger asked if there is a general consensus that the Subcommittees can move forward with their draft recommendations, or if the Subcommittees will need another process to vet on the draft recommendations discussed today.

Dr. Herman confirmed there is general consensus. He suggested the Subcommittees continue to revise their draft recommendations based on the discussion while pushing forward with additional recommendations.

Dr. Clydette Powell agreed. She pointed out that some of the recommendations perhaps can be consolidated, and she suggested the Subcommittees to determine the relevancy of the recommendations using the Charge to the Commission as a guide.

Announcement of transition

At the end of the meeting, Dr. Rick Olson announced that the HHS support for the Commission will be transitioned from the Office of Disease Prevention and Health Promotion to the Office on Women's Health (OWH). He explained the following.

- The transition began about a month ago and will continue in the next month.
- Dr. Powell and ORISE Fellow Erika Kim will continue to support the Commission from OWH.
- Dr. Powell may serve as the Designated Federal Officer in the interim; however, a staff member from OWH will probably serve as the new DFO eventually.

Adjournment

Dr. Jennifer Bishop adjourned the meeting at 5:34 pm EST.

Appendix: Commission Members and HHS Support Staff

Commission Members Present for NCCC Meeting 8

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

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

Ayotunde Dokun, MD, PhD, FACE, Director, Division of Endocrinology and Metabolism, Carver College of Medicine, University of Iowa Health Care, Iowa City, IA

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

HHS Staff in Attendance

Office of Disease Prevention and Health Promotion
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

Office on Women's Health
Olumayowa Azeez, Women's Health, Office of the Assistant Secretary for Health

Dorothy Fink, MD, Deputy Assistant Secretary for Women's Health, Director of the Office on Women's Health, Office of the Assistant Secretary for Health