

National Clinical Care Commission Webinar Meeting 11

Tuesday, June 1, 2021

1:00 pm — 6:00 pm EDT

Meeting Summary

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Welcome and Roll Call

Dr. Kara Elam, Designated Federal Officer (DFO) for the National Clinical Care Commission (NCCC), welcomed everyone to the first day the NCCC public meeting 11 and conducted roll call. The meeting started with a quorum (see Appendix for Commission member attendance).

New Commission member CAPT Jana Towne introduced herself. CAPT Towne takes Dr. Ann Bullock's place to represent the Indian Health Service (IHS). Dr. Bullock retired earlier this year,

Opening Remarks and Review of Agenda

Dr. William (Bill) Herman, chair of the NCCC, welcomed everyone to the meeting.

NCCC's Charge

Dr. Herman reviewed the Commission's charge and duties, as follows:

The Commission shall evaluate and make recommendations, as appropriate, to the Secretary and Congress regarding:

1. Federal programs of the Department of Health and Human Services (HHS) that focus on preventing and reducing the incidence of diabetes
2. Current activities and gaps in Federal efforts to support clinicians in providing integrated, high-quality care to individuals with the diseases and complications
3. The improvement in, and improved coordination of, Federal education and awareness activities related to the prevention and treatment of the diseases and complications, which may include the utilization of new and existing technologies
4. Methods for outreach and dissemination of education and awareness materials that
 - a) Address the diseases and complications
 - b) Are funded by the Federal Government
 - c) Are intended for health care professionals and the public
5. Whether there are opportunities for consolidation of inappropriately overlapping or duplicative Federal programs related to the diseases and complications

NCCC's Approach

Dr. Herman explained that the Commission has been conducting its work through three Subcommittees (the Prevention—General Population Subcommittee, the Prevention—Targeted Population Subcommittee, and the Treatment and Complications Subcommittee) and a small workgroup focusing on health system-level interventions. Dr. Herman noted that the Subcommittees and the workgroup have addressed a broad range of issues to improve diabetes prevention and care. Additionally, the Subcommittees and the workgroup also address crosscutting issues related to health equity, social determinants of health, and research needs.

Dr. Herman further explained the Commission's work since the last Commission meeting:

- Completed key informant interviews and sought additional stakeholder input
- Reviewed and discussed public comments
- Refined draft recommendations based on stakeholder input and public comments

Goal of NCCC Meeting 11

Dr. Herman explained that today (day 1 of NCCC meeting 11), the Commission will review and revise the draft recommendations, with a focus on the new and revised ones; and on June 22, 2021 (day 2 of NCCC meeting 11), the Commission will 1) vote on the final recommendations to be included in the final report to Congress and the HHS Secretary, 2) finalize the report outline, and 3) assign writing groups. Dr. Herman said that the Commission will meet on September 8, 2021 to vote and approve the final report, which will be submitted by September 30, 2021.

Prevention—General Population Subcommittee Presentation

Introduction and Overall Update

Dr. Dean Schillinger, co-chair of the Prevention—General Population Subcommittee, explained that today the Subcommittee will present its final set of draft recommendations, which have incorporated relevant public comments.

Dr. Schillinger reviewed the overall rationale for the Subcommittee’s draft recommendations and explained why the Subcommittee is taking a broad approach to assess federal programs relevant to diabetes. He highlighted that diabetes-related clinical care has evolved over time, and that contemporary diabetes care involves a comprehensive approach that combines the “traditional model of care” (i.e., medication and lifestyle counseling) with an “integrated, patient-centered model,” which includes clinic-community linkages and extends beyond the clinical setting. He noted that it is critical for the Commission to assess how a range of federal programs can be leveraged and coordinated to enable the integrated model of care.

Dr. Schillinger explained that the Subcommittee’s draft recommendations are related to the Commission’s second duty (ensuring high-quality, integrated clinical care) and third duty (federal education and awareness activities).

Presentation of Draft Recommendations

Dr. Schillinger presented the Subcommittee’s first draft recommendation on inter-agency collaboration, which, he noted, is related to the Commission’s third duty. Given that the draft recommendation, along with the background information, has been presented at previous NCCC public meetings, Dr. Schillinger did not provide detailed background at this time.

Topic. Ensure Trans-Agency Collaboration

Draft recommendation 1: The NCCC recommends the creation of the Office of National Diabetes Policy (ONDP) in the Domestic Policy Council of the Executive Branch (akin to the Office of National AIDS Policy) to develop and implement a national diabetes strategy that leverages and coordinates the work of relevant federal departments and agencies as outlined in the NCCC report.

- The ONDP would have as its primary responsibilities to
 - 1) facilitate coordination among federal agencies with respect to trans-agency approaches to preventing and controlling type 2 diabetes;

- 2) make recommendations to the executive and legislative branches regarding actions they can take to prevent and control type 2 diabetes;
 - 3) advance a health-in-all-policies agenda with respect to diabetes;
 - 4) promote use of health impact assessments (HIAs) for relevant policies across non-health departments and agencies; and
 - 5) establish the conditions and methodologies for HIAs and entities to conduct HIAs, identify resources and mechanisms to generate HIAs, adjudicate and implement HIA recommendations, and train a skilled workforce to carry out HIAs.
- The NCCC also recommends that the Office of the Secretary of HHS establish a process to work with the ONDP to foster broad, trans-agency collaborative work between HHS and non-HHS federal agencies aimed at positively changing the social and environmental contexts that accelerate the type 2 diabetes epidemic.

Topic. Modernize the United States Department of Agriculture (USDA) Supplemental Nutrition Assistance Program (SNAP)

Dr. Carol Greenlee presented the Subcommittee’s second recommendation. She explained that draft recommendations 2a, 2b, and 2h are new; and 2g has been enhanced.

Draft recommendation 2: The NCCC recommends the following changes to the SNAP program to further reduce food insecurity and improve dietary quality to help prevent type 2 diabetes and its complications:

- 2a. The adjustments to SNAP made for the COVID-19 Public Health Emergency should be extended until more permanent adjustments can be legislated through the 2023 Farm Bill.
- 2b. The USDA should assess the adequacy of the current SNAP benefit allotments to meet food and nutrition security so as to ensure the benefit is adequate, and establish a process to reassess the adequacy on a regular basis (every 10 years).
- 2c. The formula to calculate SNAP benefit allotments should be adjusted, as detailed in the full report, so that SNAP participants are able to adequately meet both food and nutrition security.
- 2d. Fully implement a fruits and vegetables incentive program, demonstrated to be effective by Food Insecurity Nutrition Incentive/Gus Schumacher Nutrition Incentive Program, by providing at least a 30% incentive on the purchase of fruits and vegetables for all SNAP beneficiaries to improve dietary quality.
- 2e. Eliminate sugar-sweetened beverages from allowable SNAP purchases.
- 2f. Make enhancements to SNAP to enable its access and use, including working with states to streamline the application process, increasing public awareness of the benefit and how to access it, increasing the number of sites that accept SNAP, and helping stores in rural areas and “food deserts” meet minimum stocking requirements.
- 2g. Improve and expand diabetes and nutrition education and awareness programs for beneficiaries to increase fruit and vegetable consumption, reduce added sugars consumption (especially sugar-sweetened beverages), and increase media/marketing

literacy. Additional SNAP-Education allocations should be made to support policy, systems, and environmental approaches rather than only focus on one-one-one counseling.

- 2h. The USDA should incentivize the testing and implementation of innovative state-level policies, practices, and programs designed to reduce geographic, racial, ethnic, and linguistic disparities in SNAP enrollment and retention.

Discussion

Dr. John Boltri wanted to know how USDA could incentivize what was suggested in draft recommendation 2h.

Dr. Greenlee responded that the intent of the recommendation is to ensure that people who are currently eligible could get the food they need. She said that the Subcommittee has another recommendation about expanding the eligibility, and that the Subcommittee perhaps could add examples to improve clarity.

Dr. Schillinger pointed out that eligibility varies from state to state, and that incentivizing states to improve outreach materials (e.g., materials in different languages) would be helpful. He noted that the Subcommittee could provide the context in the report and could consider combining 2f and 2h to tighten up the overall recommendation.

Dr. Shari Bolen wanted to know whether SNAP-Education is allowed to conduct the type of work described in Recommendation 2g (i.e., “Additional SNAP-Ed allocations should be made to support policy, systems, and environmental approaches rather than only focus on one-on-one counseling”), or the work has to be done someplace else.

Dr. Schillinger responded that USDA is funding a number of state health departments to do the work. The issue is that the funding is small despite the successful outcomes, he said.

Dr. Bolen asked if the efforts would be duplicative of what the Centers for Disease Control and Prevention (CDC) does.

Dr. Schillinger responded that based on his knowledge, they are not; for example, the USDA SNAP-Education program could support activities striving to change practices in schools; however, CDC does not have that level of reach.

Topic. Improve Nutrition for Children Through USDA non-SNAP Nutrition Assistance Programs and Related Agency Efforts

Dr. Aaron Lopata, co-chair of the Prevention—General Population Subcommittee, presented the Subcommittee’s third draft recommendation. He explained that draft recommendation 3g is new and others remain the same.

Draft recommendation 3:

- 3a. Further strengthen the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) by sustaining the evidence-based, prescriptive WIC food package; expand funding for breastfeeding peer counseling services; invest in improvements to information systems and technology to enable greater access and service for WIC participants.
- 3b. Maintain the nutrition standards found to be salutary in the Healthy Hunger-Free Kids Act (HHFKA).
- 3c. Provide adequate funding for schools to (a) purchase, prepare, and serve healthy, quality foods and beverages for school meals and snacks to meet HHFKA nutrition standards; and (b) deliver training and technical assistance to support maintenance and attainment of HHFKA nutrition standards and skills to run such a program.
- 3d. In collaboration with the Department of Education and the Environment Protection Agency (EPA), USDA should ensure that all students in public schools have access to safe, appealing, and free drinking water. This includes (i) providing water and drinking vessel access located in strategic locations across campuses; (ii) developing an incentive program to enable schools to cover implementation costs; (iii) tying receipt of federal funds for school-based food programs to water access; (iv) providing funding to upgrade plumbing and facilities in schools to ensure access to clean and safe tap water, including earmarking proportion of federal resources provided to local education authorities to improve health/safety conditions in K-12 schools via the American Rescue Plan (>\$100B), the WATER Act of 2021 (HR 1352), and the Reopen and Rebuild America's Schools Act of 2021; and (v) creating and implementing uniform national lead testing policy and methods for schools and childcare settings. Temporary exemptions to the water accessibility requirements could be made for regions that do not have safe tap water, and/or incentives should be provided to such sites to encourage provision of clean, filtered water.
- 3e. Prohibit sale of unhealthy foods/beverages ("junk food" and sugar-sweetened beverages) at public schools and employ an incentive program to enable schools to cover essential costs such as those for physical activity/athletic programs previously underwritten by sales. Receipt of federal funds for school-based food programs should be tied to the implementation of such restrictions.
- 3f. Strengthen and improve access to and participation in summer feeding programs, including innovative partnerships between public and private sectors in rural areas and other high-risk areas where participation is low. Further increases in program participation should be achieved by offering a summer Electronic Benefits Transfer (EBT) benefit, whereby children and youth in the National School Lunch Program receive SNAP-like benefits for healthy foods over the summer, reducing the need to go to a specific participating location to get meals. The food and beverage package covered by this benefit must be aligned with the nutritional standards of the HHFKA and summer feeding programs. Funding for the program should be increased to enable scaling to meet population needs.

- 3g. Continue the use of USDA waivers and innovative strategies used by the Summer Food Service Program and Seamless Summer Option sites during the pandemic to strengthen the summer feeding programs.
- 3h Strengthen and expand the reach of the successful Fresh Fruit and Vegetable Program for elementary students from economically disadvantaged families to support a reduction in diabetes through improved dietary quality. Funding for the program should be increased to enable scaling to meet population needs.

Discussion

Dr. Paul Conlin suggested clarifying “junk food and sugar-sweetened beverages” in Recommendation 3e. The terms, he commented, could be interpreted differently.

Dr. Lopata explained that the Subcommittee has discussed the issue and will define the terms in the report.

Dr. Schillinger added that the Subcommittee has discussed the topic and generally agreed to define “junk food” as calorie-dense, nutrient-poor foods based on the Dietary Guidelines for Americans.

Dr. Conlin suggested linking the recommendation to the guidelines. Dr. Conlin went on to comment that Recommendation 3d (iv) and (v) about plumbing might be beyond the Commission’s scope.

Dr. Schillinger responded that the Subcommittee tries to suggest some strategic solutions, and that they will discuss and decide whether to include the details in the recommendation or address them in the report.

Topic. Modify USDA Programs That Support Farmers to Make the U.S. Food Supply Healthier

Dr. Lopata presented the following draft recommendation, which, he explained, remains the same.

Draft recommendation 4: USDA should increase its support for programs to change the food supply and healthy food access in the U.S. so as to promote the prevention and control of diabetes by:

- 4a. Significantly expanding and increasing funding for the Specialty Crop Block Grants to support food safety and drive demand through education for specialty crops (fresh fruits and vegetables, tree nuts) to increase dietary diversity to help people achieve the Dietary Guidelines for Americans.
- 4b. Significantly increasing funding for Specialty Crop Research Initiative grants for research on how to improve specialty crop production efficiency, handling and processing, productivity, and profitability over the long term (including specialty crop policy and marketing).

- 4c. Significantly expanding and increasing funding for the evidence-based Healthy Food Financing Initiative (HFFI), a federal effort to improve food access and health in low-income, underserved communities, and communities of color in urban and rural areas that supports farmers and healthy food retailers to improve access to nutritious, affordable, fresh food.
- 4d. Expansion and funding should be implemented to achieve population-wide benefits by 2030.

Discussion

Dr. John Boltri asked for clarification about specialty crops. Specifically, he wanted to know if all of the specialty crops are healthy or helpful for preventing diabetes.

Dr. Lopata responded that they are all healthy, and none of them would worsen public health.

Dr. Naomi Fukagawa explained that the specialty crops are intensively cultivated, and that the types of food/crops generally considered healthy (e.g., fruits and vegetables) fall under the category (more information is available at <https://www.ams.usda.gov/services/grants/scbgp/specialty-crop>).

Dr. Schillinger suggested Dr. Lopata review the list to ensure all of them are good for diabetes.

Dr. Greenlee added that the Farm Bill defines specialty crops as “fruits and vegetables, tree nuts, dried fruits and horticulture and nursery crops, including floriculture.”

Topic. Encourage the Consumption of Water over Sugar-Sweetened Beverages

Dr. Schillinger presented the following draft recommendation and explained that the Subcommittee combined their original draft recommendations 5 and 6. He clarified that recommendation 5c was developed based on public comment.

Draft recommendation 5:

- 5a. USDA should add a symbol for drinking water to the MyPlate graphic and increase water promotion messaging in all consumer-facing materials issued by its Center for Nutrition Policy Promotion (water is not currently depicted on MyPlate).
- 5b. Child nutrition programs should be a conduit for education to promote consumption of water and reduce consumption of sugar-sweetened beverages. USDA should encourage healthy hydration and provide safe water education in WIC nutrition education and in childcare settings. Congress should harness the Child Nutrition Reauthorization to strengthen existing water provisions for school nutrition programs.
- 5c. HHS should commission a scientific report of the evidence regarding the causal relationship between sugar-sweetened beverages consumption and diabetes, under the joint auspices of the U.S. Surgeon General, CDC, and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Contributions should be made by experts in diabetes and clinical medicine, nutrition and metabolism, epidemiology and public

health, and health disparities. Experts must be free of food and beverage industry conflicts.

- 5d. The CDC and NIDDK should develop and implement a national campaign and associated materials to both promote consumption of water and reduce consumption of sugar-sweetened beverages as a strategy to promote overall health, including the prevention of obesity, diabetes, and cardiovascular disease. The CDC should include such messages across all of its relevant programs, including the National Diabetes Prevention Program (DPP) and its associated DPP curriculum.
- 5e. All federal agencies should promote drinking water and reducing sugar-sweetened beverage consumption within their own organizations and through the grants and programs they fund or administer. All agencies should increase access to free, clean, and appealing sources of drinking water for their employees and visitors. Water sources should preferably be tap, but in sites where the tap water is known to be contaminated, filtered or bottled water is acceptable. Agencies should develop procurement and other policies that curb the availability and sale of sugar-sweetened beverages.
- 5f. HHS should serve as a federal model by (a) ensuring onsite access to safe, clean, and appealing drinking water; and (b) prohibiting the sale of sugar-sweetened beverages in HHS government-owned or -leased offices, workplaces, and healthcare facilities. HHS should collaborate with CDC or National Institutes of Health (NIH) to formally evaluate implementation, employee behavioral change, and diabetes-related outcomes.
- 5g. The U.S. Department of the Treasury should impose an *excise* tax (not sales tax) on sugar-sweetened beverages to cause at least a 10% increase in their shelf price. In addition to a base tax rate of 10%, to stimulate reformulation by industry, calculations regarding the amount of tax should consider a graded taxation model based on amount of added sugar in sugar-sweetened beverages. The revenues generated should be reinvested in a manner that promotes the health of those communities that bear a disproportionate burden of type 2 diabetes. This federal sugar-sweetened beverage tax should not serve as a means to pre-empt state or local authorities from levying their own additional excise tax on sugar-sweetened beverages.
- 5h. The Office of the U.S Trade Representative should ensure that all international trade agreements allow for the taxation of sugar-sweetened beverages and front-of-package health advisory labels and icons (see draft recommendation 6).

Topic. Enhance the U.S. Food and Drug Administration’s Role in Preventing and Controlling Diabetes Through New Labeling Requirements

Dr. Schillinger explained that the Subcommittee revised the following draft recommendation based on public input.

Draft recommendation 6: The U.S. Food and Drug Administration (FDA) should improve its food and beverage labeling regulations that influence food and beverage industry practices so as to better prevent and control diabetes. These include:

- 6a. Implementing a new national, compulsory, uniform, simple, easily recognizable and understandable front-of-package icon system that alerts consumers to the health

attributes (or health risks) of food and beverage products based on their ingredients. The front-of-package icon/warning system should be informed by evidence accrued from epidemiological, clinical, and nutritional sciences, and its design should be informed by health communication science.

- 6b. The use of teaspoon units in addition to grams for added sugar content contained in the product in the revised Nutrition Facts Label (and Recommended Dietary Allowance) should be implemented to enable consumers to accurately assess their added sugar intake relative to daily limits.
- 6c. A robust, multilingual communication campaign related to the new added sugar labeling and its rationale should be conducted (the hazards of consuming excess added sugars).
- 6d. Updating its policies and regulations so as to prevent industry claims on food and beverage products that mislead U.S. consumers to believe that unhealthy foods are healthy. For example,
 - (a) including “added sugars” to the existing regulation that disqualifies the use of health claims or qualified health claims if a product contains excess levels of total fat, saturated fat, cholesterol, or sodium, and apply the rule to nutrient content claims;
 - (b) setting new science-based standards regarding the use of the term “whole grain;” and
 - (c) regulating standards of identity, nutrition labeling, and claim allowances under “toddler drinks,” prohibiting use of misleading terms such as “milk” and “formula” and “recommended” or “necessary,” mandating scientific evidence for all health claims, and requiring disclaimers that such products are not intended for children younger than 12 months or as a substitute for breastmilk or infant formula.

Discussion

Dr. John Boltri asked if the Subcommittee would clarify “added sugar” highlighted in Recommendation 6d (a).

Dr. Schillinger agreed that the Subcommittee needs to add a qualifier to the draft recommendation. He explained that existing guidelines/regulations use the word “excess” as a qualifier.

Topic. Restrict Commercial Advertising and Marketing of Unhealthy Food and Beverages to Children <13 years

Dr. Schillinger presented the following new recommendation and briefly reviewed the background information.

Background: Rates of type 2 diabetes have been exploding among U.S. youth of color, with rates tripling among Native American youth, doubling among Black youth, and increasing up to 50% among Latinx and Asian/Pacific Islander youth. The expansion the type 2 diabetes

epidemic into children and adolescents in large part is a result of a food environment that increasingly promotes unhealthy dietary patterns. The unfettered advertising and marketing of so-called “junk food” to children through television, film, social media, and other internet platforms, including marketing campaigns targeting children of color, have been shown to be significant drivers of the consumption of “junk food” and beverages among children. Children younger than 13 years of age are especially vulnerable to industry messages; they also lack the critical media skills to detect when they are being deceived.

Over a decade ago, the Federal Trade Commission (FTC) examined and exposed those industry practices that were contributing to the obesity and diabetes epidemics in children and adolescents, but the FTC was not empowered to regulate the practices of advertisers or their communication platforms so as to protect children and it was instructed to cease such monitoring. The food and beverage industry’s commitment to self-regulate what and how it markets to children is widely acknowledged to have failed to reverse or change either these marketing practices or children’s diets. A number of countries have instituted regulations and/or bans related to the marketing of unhealthy food to children in their efforts to prevent diabetes in younger people. These strategies have been shown to significantly reduce children’s exposure to unhealthy food advertisements. For example, Chile’s 2016 food labeling and advertisement regulations contributed to a 23.7% reduction in household-level consumption of sugar-sweetened beverages.

Draft recommendation 7: FTC should be provided the authority, mandate, and requisite resources to

- create guidelines and promulgate regulations through notice-and-comment rulemaking, based on consultations with CDC, FDA, and USDA, regarding food and beverage advertising to children age <13;
- restrict commercial advertising and marketing to children <13 years old by advertisers, communication networks, and online platforms of specific types of foods and beverages that contribute to unhealthy dietary patterns (as defined by U.S. Dietary Guidelines);
- enforce these regulations by being able to send compulsory process orders to food and beverage manufacturers, sellers, and platforms who are in violation of regulations; and
- actively monitor the practices of all food and beverage advertisers, and any associated communication networks and online platforms, by routinely accessing marketing and advertising information about their work to enable FTC regulation and enforcement and report on industry progress over time.

Discussion

DFO Kara Elam voiced concern that the recommendation may be outside of the Commission’s scope because it does not appear to be directly related to the clinical aspect of diabetes care.

Dr. Schillinger responded that this recommendation aligns with the Commission’s second duty and third duty. He explained that the Commission’s third duty is about improvement of public awareness regarding diabetes risk, which involves marketing of unhealthy foods. Additionally,

he said, this recommendation is also in line with the Commission's second regarding clinicians providing consultation to patients who are at risk of diabetes. He shared that in his hospital, clinicians at the pediatric settings recommend children avoid certain kinds of food; however, advertisements targeting children (e.g., those on television) can influence children to eat the kinds of food their doctors advise them to avoid.

Dr. Elam commented that the recommendation and background information may give the impression that the Commission is making a generalized statement that children are getting their education on nutrition and health from television, rather than from home and classrooms.

Dr. Schillinger clarified that the Subcommittee is not making a generalized statement, and that FTC does have a responsibility to ensure there is no deception in advertising. He further explained that based on prior law, advertising and marketing to children under the age of 13 are eligible to be regulated, and that the Subcommittee's draft recommendation is not overreaching.

Dr. Elam and Dr. Schillinger further discussed the power of media influence. Dr. Schillinger explained that media research shows that children's decision-making regarding food and beverage is predominantly driven by the commercial environment. He acknowledged there are other influences, which, he pointed out, are not regulated. Some of the Subcommittee's other draft recommendations (e.g., draft recommendation 3) hopefully would help influence what is being taught in schools, he said.

Dr. Herman added that childhood obesity is a huge problem and there is no single intervention to address the issue. There are a number of complementary recommendations/strategies across the agencies, he said, and the recommendation is one of the strategies.

Topic. Increase Breastfeeding Promotion and Support

Dr. Lopata provided background information and presented the following new draft recommendation.

Background: Breastfeeding is associated with lower odds of type 1 diabetes and of obesity in children. Women who breastfeed have about a 30% reduction in the risk of developing diabetes and a lower risk of cardiovascular disease. Benefits of breastfeeding are associated with greater breastfeeding intensity and duration, a threshold effect at a six-month duration. Breastfeeding promotion policies and programs have been guided by strategies in the *2011 Surgeon General's Call to Action*.

Four out of five U.S. mothers begin breastfeeding at birth, but the number quickly declines to less than half. The rates of breastfeeding have increased overall; however, racial/ethnic, socioeconomic, geographic and occupation-related disparities still remain.

Hospitals designated as Baby Friendly that have staff trained on maternal care practices based on the Ten Steps to Successful Breastfeeding framework have been shown to be positively

associated with increased duration of breastfeeding and have made a positive impact on minority populations by decreasing disparities.

A leading reason for mothers, especially low-income mothers, to stop breastfeeding is the need to return to work. Paid maternity leave for at least three months is positively associated with breastfeeding duration, with women who return to work at or after 13 weeks postpartum having 2-3 times higher odds of predominantly breastfeeding beyond three months and nearly two-fold greater odds of breastfeeding for at least six months.

Draft recommendation 8: The NCCC recommends that federal agencies promote and support breastfeeding as follows:

- 8a. Ensure adequate funding for federal programs that 1) promote and support breastfeeding, and 2) address persistent societal and employment-based obstacles that lead women to shorten duration of breastfeeding. Programs that promote and support breastfeeding include USDA Food Nutrition Service WIC Peer Counselor programs; Health Resources and Services Administration (HRSA) Maternal and Child Health Bureau's Healthy Start and Maternal, Infant, and Early Childhood Home Visiting program; and CDC's Maternity Practices in Infant Nutrition and Care and Breastfeeding Report Card.
- 8b. NIH, the Agency for Healthcare Research and Quality (AHRQ), IHS, Centers for Medicare & Medicaid Innovation (CMMI), USDA, and others should conduct community-based and community-informed demonstration projects to evaluate the impact of combinations of evidence-based breastfeeding support interventions among minority and lower income women.
- 8c. Update the 2011 *The Surgeon General's Call to Action* to reflect the current "landscape" of breastfeeding research and provide updated policy and program guidance for health care providers, public health officials, women, and families.
- 8d. Fund new federal grants to states for the purposes of increasing the number of hospitals/birthing centers designated as Baby Friendly Hospitals. Hospitals would use the "Baby Friendly Hospital" grants to train their staff in maternity best practices and provide technical assistance to effectively implement the Ten Steps to Successful Breastfeeding framework.
- 8e. Expand workplace protections so that all mothers have reasonable breaktime and access to a private space for pumping/expressing breastmilk. This includes mothers covered under Fair Labor Standards Act (non-salaried employees) and those who are not (salaried employees). The Department of Labor should employ a monitoring system to ensure employer compliance.
- 8f. Provide mothers with up to three months of paid maternity leave to care for and bond with a child following birth. This leave would be distinct from unpaid leave available to all employees as a result of the Family and Medical Leave Act.

Discussion

Dr. Boltri asked for clarification about draft recommendation 8f. He wanted to know whether the intent is asking for legislation or suggesting the federal agencies to provide paid maternity leave).

Dr. Lopata responded that the Subcommittee is looking for federal legislation.

Dr. Schillinger pointed out that the overarching draft recommendation 8 focuses on federal agencies whereas 8f reflects activities that include and beyond federal agencies. He suggested that the Subcommittee refine the language to avoid confusion.

In response to Dr. Herman's question about the intended scope, Dr. Lopata explained that the intent is beyond federal employees.

In response to Dr. Elam's question about implementation in the private sector, Dr. Lopata explained that the Subcommittee will provide more details in the report.

Topic. Improve the Ambient and Built Environments to Prevent Diabetes and Its Complications

Dr. Schillinger provided background information on this topic and presented a new recommendation.

Background: Attributes of both the ambient and built environments have significant population-level impacts on the risk of developing diabetes and its complications.

- Research links ambient environmental factors (e.g., air pollution, water contamination, and exposure to endocrine-disrupting chemicals) to metabolic dysfunction and diabetes.
- Disproportionate environmental exposure is an underappreciated contributor to racial, ethnic, and geographic disparities in diabetes (e.g., higher exposures to diabetogenic endocrine-disrupting chemicals, including multiple chemical constituents of air pollution, water contaminated with heavy metals, polychlorinated biphenyls, organochlorine pesticides, bisphenol A, and phthalates).
- Reducing the individual and societal burden of diabetes should include educating clinicians and the public on environmental exposures that may increase diabetes risk, strategies to reduce those exposures, and social policies to reduce exposure and address environmental inequality as a source of diabetes disparities.
- With respect to the built environment, walkability, green space, urban sprawl, physical activity resources, and active transport opportunities have been shown to be determinants of type 2 diabetes and its complications.
- Differences in these area-level attributes contribute to disparities in diabetes and its complications.
- Enhancing the built environment will also improve the ambient environment by reducing air pollution.

Draft recommendation 9:

- 9a. Federal agencies should limit the extent to which their work contributes to individual- and population-level exposure to environmental pollutants and contaminants that have been shown to be associated with the development of diabetes and/or its complications. In addition, EPA and the National Institute of Environmental Health Sciences should ensure that appropriate environmental protections--based on scientific evidence--are in place to limit individual- and population-level exposure and should implement appropriate abatement measures when necessary, prioritizing those exposures that contribute to diabetes disparities.
 - Relevant pollutants and contaminants are present in the air, land, water, and/or in manufactured and household products; and include (a) air pollution (particulate matters and nitrogen oxides), (b) water containing heavy metals (Arsenic, Lead, Uranium), and (c) endocrine-disrupting chemicals (including polychlorinated biphenyls, organochlorine pesticides, multiple chemical constituents of air pollution, bisphenol A, phthalates, and possibly per- and polyfluoroalkyl substances).
- 9b. All federal agencies (in particular, the Department of Transportation and the Department of Housing and Urban Development [HUD]) should assess how their policies, practices, regulations, and funding decisions related to the built environment can be modified to prevent diabetes and its complications by enhancing walkability, green space, physical activity resources, and active transport opportunities. Priority should be given to those areas where mitigation of unhealthy environments would reduce diabetes disparities.

Discussion

Dr. Herman commented that it makes sense to address green place and pollution together in one recommendation.

Dr. Conlin expressed support for draft recommendation 9b, which, he commented, fits naturally with housing (draft recommendation 11). He, however, voiced concern that 9a might be beyond diabetes.

Dr. Schillinger responded that 9a has a number of health benefits, and that the Subcommittee is focusing on diabetes incidence and metabolic control.

Dr. Herman added that studies have shown that a lot of contaminants and pollutants (e.g., heavy metals) are associated with increased risk of obesity and diabetes, and that the literature evolves rapidly on this topic.

Dr. Schillinger agreed. He noted there is a strong association between exposure to endocrine disrupters and the risk of obesity and diabetes. The causation, he acknowledged, is uncertain at this time.

Dr. Schillinger then presented the Subcommittee's last three draft recommendations (draft recommendations 10-12), which have been presented at previous NCCC public meetings.

Draft recommendation 10: Improve housing policy

In order to reduce type 2 diabetes incidence and diabetes complications, NCCC recommends:

- a. HUD should expand its federal housing assistance programs to allow access for more qualifying families, such that over a 20-year period, all that qualify can access subsidized or public housing.
- b. The Internal Revenue Service (IRS) should further incentivize developers to place new housing units in areas of low poverty, as data show that moving people from areas of high poverty to low poverty has a favorable impact on the prevalence of obesity and diabetes.
- c. HUD and the IRS should mandate that states include neighborhood health parameters (availability of health care services, transportation, employment opportunities, education opportunities, food availability, and physical activity resources) when making decisions regarding where and to whom to give tax credits when supporting low-income/subsidized or mixed housing developments.
- d. HUD should establish a means to fund or subsidize cost of embedding health services (if needed) in housing developments to incentivize committing space or employing unused space for such services in their plans.

Draft recommendation 11: Expand smoke-free policies to HUD's subsidized housing

In order to reduce type 2 diabetes incidence and macrovascular diabetes complications, NCCC recommends:

- HUD should broaden implementation of indoor smoke-free policies to include subsidized multi-unit housing, beyond public housing.
- HUD should require subsidized multi-unit housing to have designated outdoor locations for smokers' use.
- HUD should require multi-unit housing adopting smoke-free policies to also provide access to cessation resources (i.e., referrals to cessation resources).
- HUD align these policies with its related policies in public housing to ensure that loss of housing is not an unintended consequence and work with the CDC Office on Smoking and Health so that an appropriate public health approach is taken.

Draft recommendation 12: Align Federal Research Priorities

The NCCC recommends federal investments in research that will yield discoveries that generate population-level benefits in the prevention and control of type 2 diabetes. Focus areas are as follows:

- a. USDA, EPA, Department of Transportation (DoT), FTC, FDA, etc. should fund research into how their policies and practices affect diabetes risk and could be changed or (if/when beneficial) amplified to better prevent and control diabetes.
- b. NIH and CDC should support large scale natural experiments research (including cost-effectiveness analysis) to inform the evidence base related to social and environmental

policies that prevent and control type 2 diabetes. Particular focus should be paid to "health in all policies" types of interventions relevant to non-health agencies' activities and other public health (non-clinical) interventions. The CMMI should support demonstration projects in collaboration with non-health agencies related to influencing social determinants of health and reducing diabetes risk and diabetes control and complications (USDA/SNAP interventions, HUD/housing interventions, EPA/fresh water, DoT, etc).

- c. NIH should expand its initiative on Precision Nutrition to (a) include trials that can inform critical population health questions related to which foods, beverages, ingredients, and additives promote/prevent type 2 diabetes; (b) include studies of communication interventions and (counter) marketing practices to inform which practices work best for which sub-populations with respect to changing dietary patterns to prevent type 2 diabetes and which practices elevate diabetes risk; (c) expand the definition of "precision" to go beyond targeting the individual to include targeting geographic entities.
- d. NIH should encourage that nutrition and metabolic research accurately quantify water intake and use this information to better study the associations between water consumption and health during all stages of life. USDA and NIH should develop methods to incorporate water consumption into USDA Food Patterns (water is a beverage that currently is not a contributor to the USDA food groups or subgroups).
- e. NIH should support research (in collaboration with other agencies) to better understand the impact of exposures related to
 - environmental pollutants, toxins, contaminants, unclean water, and endocrine-disrupting chemicals on metabolic function and diabetes risk; and
 - early childhood and life course trauma on metabolic function and diabetes risk, and associated interventions.
- f. Investments in research training need to be made by NIH, CDC, and non-health agencies to enhance the workforce skilled in competencies needed to carry out health impact assessments and related simulation work.

Prevention—Targeted Population Subcommittee Presentation

Dr. Howard Tracer, co-chair of the Prevention—Targeted Population Subcommittee, expressed appreciation for public comments, which, he noted, have been reviewed and incorporated in the Subcommittee's recommendations. Team leads of the Subcommittee's four focus area groups then presented their draft recommendations.

Focus Area 1: Screening/Diagnosis for Prediabetes/Diabetes

Dr. David Strogatz, team lead of the Focus Area 1 group, reviewed the group's four recommendations, three of which, he noted, remain largely unchanged since the last NCCC public meeting. Commission members provided input after Dr. Strogatz's presentation.

Topic. Raise Public Awareness About Prediabetes and the National DPP

Draft recommendation 1:

- Increase support to CDC for its campaign to improve awareness of prediabetes and promote enrollment in the National DPP lifestyle change program.
- In order to more effectively reach populations disproportionately impacted by type 2 diabetes risk, identify and engage popular social media influencers with numerous followers in key target audience populations to develop and post custom content on their platforms focusing on prediabetes awareness and the urgency to prevent or delay type 2 diabetes.
- Continue tracking visits to the *Do I Have Prediabetes* campaign page and completions of the prediabetes risk test, with an expanded focus on the degree to which populations at increased risk are being reached in order to reduce disparities in both awareness and engagement in interventions.

Topic. Expand Coverage for Screening/Diagnostic Tests Used to Identify Individuals with Prediabetes

Draft recommendation 2:

- The Centers for Medicare & Medicaid Services (CMS) should provide coverage for hemoglobin A1c testing when used to screen for prediabetes.

Topic. Clinical Quality Measures for Screening and Followup of Abnormal Blood Glucose

Dr. Strogatz explained that the group revised the recommendation on this topic based on public input and described the three measures (currently on CMS's Measures under Consideration [MUC] list) in the background. He noted that the revised draft recommendation aligns with the Commission's second duty and fourth duty.

Background: In 2019, an American Medical Association (AMA) technical expert panel proposed three electronic clinical quality measures for review by the National Quality Forum to monitor and improve the quality of care for patients with prediabetes. The proposed measures are:

- Screening patients aged 40 and older with a BMI ≥ 25 kg/m² (≥ 23 kg/m² for Asians) for abnormal blood glucose at least once in the previous 3 years
- Providing an evidence-based intervention for patients with prediabetes during the 12 months following the determination of abnormal blood glucose
- Retesting patients for abnormal blood glucose in the year after they were identified with prediabetes

While rates of screening for diabetes have improved, data from the National Health and Nutrition Examination Survey suggest there may still be a substantial gap in awareness for adults with prediabetes based on levels of fasting glucose and hemoglobin A1c. Studies of patients, clinicians, and medical records also indicate low levels of referral for adults with prediabetes to receive individual counseling or participate in programs to reduce the risk of diabetes. These findings underscore the salience of the proposed measures for improving timely diagnosis of prediabetes and implementation of preventive measures.

Draft recommendation 3:

- All federal agencies that directly deliver or influence the delivery of medical care should implement the 2019 AMA-proposed prediabetes quality measures related to screening for abnormal blood glucose, intervention for prediabetes, and retesting of abnormal blood glucose in patients with prediabetes.
- To support the implementation of these measures, quality-improvement programs should be introduced to improve performance and reduce disparities.

Topic 4. Use Existing Administrative Data to Identify Patients Meeting Criteria for Prediabetes

Dr. Strogatz provided background information and presented the draft recommendation. He explained that the recommendation aligns with the Commission's second duty.

Background: Analyses of electronic medical records and laboratory data have shown that testing for abnormal blood glucose or hemoglobin A1c has become more common in middle-aged and older adults. The opportunity to identify patients at risk for or meeting the diagnostic criteria for prediabetes may be missed during an acute or routine visit because of competing priorities or incomplete information available at the time. Administrative and clinical data can be queried to create a registry of patients at higher risk or already meeting the criteria for prediabetes (e.g., on the basis of age, BMI and history of hypertension or abnormal blood glucose or hemoglobin A1c results). Patients in the registry could be contacted by clinic staff to discuss prediabetes, definitive diagnostic testing, and opportunities to enroll in the National DPP. The patient's medical record could be flagged for reinforcement of these messages at a future visit.

Draft recommendation 4: Federal agencies that deliver care (e.g., VA, Department of Defense [DoD], IHS, the Federal Bureau of Prison [BoP], and HRSA) should implement a process for systematically using administrative and clinical data to identify patients at risk for or already meeting criteria for prediabetes and to ensure appropriate followup.

Discussion

Dr. Schillinger thanked the group for including BoP in draft recommendation 4, and he asked for clarification about followups.

Dr. Strogatz explained that the recommendation is related to quality measures. He acknowledged that for individuals who are incarcerated, the logistics regarding followups might be impossible.

Dr. Bolen asked if draft recommendation 3 would apply to CMS as well.

Dr. Strogatz responded that it would. He explained that the group revised the draft recommendation based on public comment. He explained that the second measure is on CMS's MUC list.

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

Dr. Shannon Idzik, team lead of the Focus Area 2 group, presented the group's ten draft recommendations and provided brief background information for each draft recommendation. (The background information and key issues the draft recommendations intended to address have been presented at the previous NCCC public meeting and are not included in this summary.)

Topic. Metformin

Draft recommendation 1: Provide funding to NIH to collect, analyze, and organize the available data from the DPP describing the effectiveness and safety of metformin for diabetes prevention in patients with prediabetes, including subpopulations most likely to benefit. Such a summary could then inform an appropriate submitter's request to FDA to review and consider an indication for the use of metformin in high-risk patients with prediabetes.

Topic. Coverage for All Proven-effective Modes of Delivery

Draft recommendation 2: Promote coverage for all proven-effective modes of delivery (e.g., in-person, online, distance learning/telehealth) for evidence-based interventions that produce successful participant outcomes that meet or exceed those of the DPP research trial in preventing or delaying the onset of type 2 diabetes.

Discussion

Dr. Greenlee asked to which agency the draft recommendation is directed, CMS or all agencies that deliver care.

Dr. Idzik responded that it is directed to all agencies.

Commission members discussed what the criteria for successful outcomes should be and how to prove a program's value for reimbursement. Given that the DPP research trial was conducted in a controlled setting, not in the real-world clinic, a couple members suggested replacing "meet or exceed those of the DPP research trial" with "meet or exceed those of the National DPP." Regarding how to prove a program's effectiveness in producing successful outcomes with respect to seeking reimbursement, Dr. Herman explained that DPP providers do need to provide results of their programs but do not have to conduct clinical trials.

Dr. Pat Schumacher added that to achieve CDC's full recognition, the applicant needs to show that their program has achieved results higher or equivalent to the weight-loss standard. She explained that CDC does collect the data; however, CDC does not follow participants for the long term to look at diabetes incidence.

Dr. Greenlee wanted to know whether or not a program needs to show the efficacy of the modes they use, if they want to receive reimbursement for non-in-person services.

Dr. Idzik responded that the recommendation is to promote coverage for all proven-effective methods of delivery.

Dr. Conlin suggested clarifying the two components of the recommendation: reimbursement given to the modalities used and the benchmark. He agreed that the “the DPP research trial” sets a high bar given that trials are done in a controlled environment. He then asked how modalities of delivery could be determined as effective.

Dr. Herman explained that historically the requirement was for the program to be delivered in person, and that the intent here is to cover programs that are delivered virtually and are proven to be able to achieve the same outcomes.

Topic. Medicare Diabetes Prevention Program (MDPP)

Dr. Idzik presented the group’s draft recommendations 3, 4, and 5, which, she noted, have been reorganized since the last NCCC public meeting.

Draft recommendations 3, 4, and 5:

- Approve MDPP as a permanent covered benefit (not only a model expansion service).
- Expand coverage of MDPP to include virtual delivery.
- Lift the “once in a lifetime” limit on participation in the MDPP.

Topic. Alignment Between National DPP and MDPP

Draft recommendation 6: Continue efforts to streamline the CDC recognition process and CMS payment process for the National DPP/MDPP while maintaining quality. Standardize program eligibility and duration differences between National DPP (led by CDC) and the MDPP (led by CMS).

Topic. Sustainability of MDPP

Draft recommendation 7: Provide funding to support the testing of new financial models that allow for greater upfront payments and more equitable risk-sharing between payers and MDPP program delivery organizations and increase the level of funding to make MDPP programs sustainable.

Discussion

Dr. Greenlee asked to which agency draft recommendation 7 is directed.

Dr. Idzik said the draft recommendation is directed to CMS because it is about MDPP.

Topic. Support and Promote State Medicaid Coverage of Evidence-based Interventions

Draft recommendations 8 and 9:

- Provide financial incentives for states to cover the National DPP and other evidence-based interventions that produce successful participant outcomes that meet or exceed

those of the DPP research trial in preventing or delaying the onset of type 2 diabetes within their Medicaid programs.

- Promote state Medicaid coverage of all proven modes of delivery (e.g., in-person, online, distance learning/telehealth) for evidence-based interventions that produce successful participant outcomes that meet or exceed those of the DPP research trial in preventing or delaying the onset of type 2 diabetes.

Discussion

Dr. Herman suggested recommending the National DPP as a benchmark. Dr. Idzik responded that she will discuss with other members of the group after the meeting.

Topic. Inter-agency Coordination

Draft recommendation 10: Identify or establish a federal inter-agency coordinating body across HHS and relevant non-HHS federal agencies to review, support, promote, and implement proven evidence-based programs shown to be effective in preventing or delaying type 2 diabetes.

Dr. Idzik noted that this draft recommendation is similar to the first recommendation presented by the Prevention—General Population Subcommittee.

Discussion

Commission members briefly discussed the possibility of consolidating the Prevention—Targeted Population Subcommittee’s draft recommendation 10 and the Prevention—General Population Subcommittee’s draft recommendation 1, both focusing on inter-agency coordination. Both Dr. Idzik and Dr. Schillinger expressed support for consolidation. Dr. Schillinger also voiced concern based on previous discussion that the Diabetes Mellitus Interagency Coordinating Committee (DMICC) does not have the authority to carry out the responsibilities described in the draft recommendations. (DMICC has been serving as a venue for the agencies to exchange ideas and disseminate information).

Focus Area 3: Sustainability of Type 2 Diabetes Prevention

Dr. Howard Tracer, team lead of the Focus Area 3 group, explained that the group’s first draft recommendation on research needs has been revised and moved to the Focus Area 4.

Dr. Tracer then presented the following revised recommendation related to implementation.

Topic: Implementation

Draft recommendation (CMS): The NCCC recommends ensuring that prompt coverage and sufficient reimbursement to cover all program costs are included in the public payment system (Medicare and Medicaid) for evidence-based strategies that are shown to sustain long-term type 2 diabetes prevention.

Discussion

Commission members asked for clarification of the intent of the draft recommendation, and the differences between this one and the Subcommittee’s previous draft recommendation on coverage and reimbursement.

Dr. Tracer explained that compared with the Subcommittee’s other draft recommendations on coverage, this draft recommendation is more future looking, and that the intent of this draft recommendation is to ensure that all evidence-based strategies are covered/reimbursed as soon as they are shown to be effective. He shared that the Subcommittee discussed the possibility of combining this draft recommendation with others, but ultimately decided to keep this one as a stand-alone recommendation to avoid confusion.

In response Commission members’ questions, Dr. Tracer acknowledged that it would be great if private payers could cover all of the evidence-based strategies as well; however, making a recommendation directed to private payers might be beyond the Commission’s scope, he said.

Topic. Sustainability at the Pragmatic Level

Dr. Tracer presented the following revised draft recommendation regarding sustainability at the pragmatic level. The original draft recommendation and background information, he explained, has been presented at previous NCCC public meetings.

Draft recommendation (NIH, CDC, HRSA, the United States Department of Veterans Affairs [VA], DoD):

- Federal agencies focused on disease prevention should continue or increase their current level of funding to prediabetes detection and evidence-based type 2 diabetes prevention.
- Increase resources to HRSA’s Delta States Network Grant Program to allow the program to include diabetes prevention as a focus.

Dr. Tracer noted that the second bullet of the draft recommendation is new. He explained that HRSA’s Delta States Grant Program requires the grantees to focus on diabetes, cardiovascular diseases, and obesity; and that additional resources could allow the program to include diabetes prevention as an additional focus.

Discussion

Commission members discussed whether or not they should specify “continue or increase.” Dr. Idzik suggested improving clarity. She expressed concern that leaving it open may not lead to any change.

Dr. Tracer responded that the group has discussed the issue and decided not to specify a number. The Subcommittee could further discuss the topic after the meeting, he said.

Focus Area 4: Diabetes Mellitus Prevention Research

Dr. John Boltri presented the revised background information and draft recommendations. He explained that Focus Area 3 and Focus Area 4 have combined some of their background information.

Background: Despite the significant outcomes of the DPP, the majority of people with prediabetes have not participated in the program and are not taking metformin. Without intervention, the risk of individuals with prediabetes developing diabetes mellitus increases over time. As shown in the DPP study, 29% of those in the placebo group progressed to type 2 diabetes over 3 years, and 52% of those in the placebo group progressed to type 2 diabetes over 15 years. The best way to prevent the progression from prediabetes to type 2 diabetes over the long term is uncertain; however, weight loss in the DPP study was highly correlated with diabetes prevention. Unfortunately, many people in the lifestyle intervention group of the DPP study who lost weight ultimately regained the weight after completing the randomized intervention.

The majority of people with prediabetes who would benefit from metformin are not taking the medication because of multiple reasons, including concerns over the side effects of metformin. Alternative medications are needed for people with prediabetes. Disparities in implementation and uptake of diabetes prevention programs also exist, which may reflect social determinants of health.

Finally, people with prediabetes are a heterogeneous group. Individuals have different physiologic abnormalities that contribute to dysglycemia, which is why some people with prediabetes may develop diabetes mellitus and other complications (such as kidney failure) more quickly than others. More research is needed to better identify those people with prediabetes who are at high risk for developing diabetes mellitus and complications so that screening and interventions can be tailored to maximize effectiveness.

Draft recommendations. The NCCC recommends funding to:

1. promote widespread implementation of the most effective in-person and virtual diabetes prevention programs;
2. study impediments to participation in effective diabetes prevention programs for the communities at greatest need;
3. study programs that combine both lifestyle intervention and metformin to prevent diabetes mellitus;
4. study and develop new medications that safely and effectively delay or prevent the onset of type 2 diabetes mellitus and its complications;
5. understand the number, frequency, duration, and content of lifestyle intervention sessions needed to effectively prevent diabetes in the long term;
6. understand and mitigate barriers to long-term maintenance of weight loss achieved in diabetes prevention programs; and

7. disseminate new knowledge about effective in-person and virtual diabetes prevention programs and create education programs for the general public, health professionals/providers, and policy makers.

Dr. Boltri explained that draft recommendations 3, 4, 5, and 6 have been refined, and recommendation 7, which addresses the Commission's fourth duty, is new.

Discussion

Dr. Schillinger commented on the importance of developing new diagnostic tests that could identify subgroups of people who are at high risk to progress or who would mostly benefit from DPP. Given the cost of scaling up the DPP, the cost would be significant if only a small group would benefit, he said.

Dr. Boltri explained that the Subcommittee added the information in the background, and that the reason the Subcommittee did not revise the recommendation accordingly is to avoid limiting research.

Dr. Boltri and Dr. Schillinger further discussed research on developing predictive serologic tests to stratify risk. Dr. Boltri said that the Subcommittee could discuss and decide whether or not to address the topic in the draft recommendation.

Dr. Jasmine Gonzalvo asked if the Subcommittee has considered using existing state-level data to assess different Medicaid models. Dr. Herman commented that it would be interesting to conduct a natural experiment to see if different state Medicaid coverages for the DPP are associated with different outcomes in the state Medicaid populations.

Topic. Type 1 Diabetes Mellitus Prevention Research

Draft recommendation: The NCCC recommends funding the special diabetes mellitus program in five-year increments so that new, innovative research can effectively be developed.

Dr. Boltri explained that the group revised the wording around funding, and that they plan to add, before the Commission's meeting on June 22, 2021, one more recommendation to address the fact that funding has been flat.

Discussion

Ms. Ellen Leake confirmed that funding for the Special Diabetes Program for Indians (\$150 million annual grant) has also been flat since 2004.

Dr. Boltri explained that the Special Diabetes Program for Indians is not just for research, and that the group will add it and will present the added information at the next Commission meeting.

After a short break, DFO Kara Elam conducted roll call, and the Commission resumed the meeting with a quorum.

Treatment and Complications Subcommittee Presentation

Introduction and Overall Update

Dr. Carol Greenlee, co-chair of the Treatment and Complications Subcommittee, stated that the Subcommittee's main focus is to close the gap between existing resources and individuals with diabetes. She then presented the Subcommittee's first recommendation on health equity.

Presentation of Draft Recommendations

Topic. Health Equity

Draft recommendation: The NCCC recommends that health equity should be a component of all policies and programs that impact diabetes prevention, pre-diabetes, and diabetes. To all federal agencies involved in health care for people with diabetes or at risk for diabetes, the NCCC recommends:

- For all new, all revised, and select existing policies and programs that affect diabetes prevention, pre-diabetes and diabetes, the relevant federal agencies will prospectively consider and retrospectively evaluate the impact on health disparities.
- Federal agencies will ensure collection of appropriate and relevant data and will use such data to assess the impact and modify the policies and/or programs to reduce health disparities.

Dr. Greenlee explained that the draft recommendation is in line with President Biden's executive order on *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*, and that the Subcommittee revised the wording of the draft recommendation to make it inclusive of relevant policies and programs affecting diabetes prevention, prediabetes, and diabetes.

Topic: Diabetes Self-Management Education and Support/Training

Dr. Jasmine Gonzalo presented the following draft recommendation, which largely remains the same as what the Subcommittee presented at the last NCCC public meeting.

Draft recommendation: The NCCC recommends that HHS and CMS expand access and reduce barriers to delivery of Diabetes Self-Management Training (DSMT) by

- Reducing administrative burden regarding standard and documentation requirements for diabetes self-management education and support (DSMES) programs
- Creating a task force with the authority to update the Medicare Quality Standards (1997) that govern DSMT
 - Establishing a process for ongoing timely review, updating, and revision with input from external stakeholders
- Making the telehealth waiver for DSMES/DSMT permanent

Discussion

Dr. Schillinger asked if the term "task force" has any specific meaning within the agency.

Dr. Conlin responded that the term is not well defined, and that the sub-bullet of the draft recommendation explains the function of the task force. He noted that the Subcommittee will work with the DFO and other federal partners to ensure an appropriate term is used.

Dr. Herman wondered if the task force could be combined with some other oversights or advisory agencies that have been recommended by other Subcommittees.

Topic. Peer-led Diabetes Education and Support

Draft recommendation: The NCCC recommends that HHS/CMS develop reimbursement mechanisms for community-based diabetes education programs when evidence shows that they improve diabetes outcomes, as a complement to existing accredited/recognized DSMES/DSMT programs.

Dr. Gonzalvo clarified that this draft recommendation focuses on peer-led diabetes self-management education and support programs, not accredited DSMES programs.

Discussion

Dr. Shari Bolen suggested replacing “when” with “where” for clarity. Dr. Gonzalvo agreed.

Topic. Diabetes Education and Support

Draft recommendation: The NCCC recommends that NIH prioritize funding for research to explore factors that affect referrals to and patient uptake of DSMES, such as patient-, clinician-, and system-level barriers, quality measures and incentives, and patient-reported outcomes and perspectives.

Discussion

Dr. Schillinger suggested clarifying “patient uptake” because there are different levels of uptake (e.g., accepting DSMES as a service, uptake at home, etc.).

Dr. Gonzalvo noted that the draft recommendation could be potentially combined with the related draft recommendations developed by the Prevention—General Population Subcommittee.

Topic: Diabetes Technology

Dr. William (Bill) Chong explained that the draft recommendations in this section remain largely unchanged, and that the focus area group has reviewed public comments and will address certain specific issues in the report, not in the recommendations.

Draft recommendations: To improve access to proven-effective diabetes technologies and to keep pace with new and evolving evidence, and to reduce administrative burden on patients and providers, the NCCC recommends the following to CMS:

- Continue to allow for virtual visits to meet requirements for continued use of diabetes technologies (as has been done during the current COVID-19 pandemic) to minimize disruption of care and reduce unnecessary burden to patients and providers.
- Update current eligibility requirements for various diabetes technologies and establish a process for regular re-evaluation of the eligibility requirements (i.e., at least every three years) leading to a National Coverage Determination (NCD) for different diabetes technologies.
 - This should include review of coverage for testing supplies and other materials and tests needed to determine eligibility to ensure that patients are able to demonstrate that they meet eligibility requirements without unnecessary barriers or out-of-pocket costs.
 - In evaluating the data to revise eligibility requirements as part of an NCD, CMS should evaluate the current data and consider both glycemic benefits and non-glycemic benefits (including patient-reported outcomes such as quality-of-life and diabetes distress).
- Establish a process to ensure clarity and consistent application of eligibility and reimbursement requirements across all parties involved, including Medicare Administrative Contractors and auditors.

Discussion

Commission members briefly discussed reimbursement for virtual visits. Dr. Schillinger suggested revising the first bullet to clarify that the intent of the draft recommendation is to allow patients to have their supplies (e.g., pump and CGM supplies) refilled through virtual visits.

Topic. Team-based Care

Dr. Shari Bolen briefly explained the benefits of team-based care, highlighted key barriers to implementing team-based care, and presented the draft recommendations. Dr. Bolen explained that the group reorganized the draft recommendations to reduce the volume of the recommendations. The content, she clarified, remains unchanged.

Draft recommendations: The NCCC recommends that HHS

- Establish a mechanism to routinely assess and identify all health care workforce needs and ensure that funding for training programs across agencies is directed to meet those needs; and
- Ensure that HRSA’s training programs meet unmet team-based health care workforce needs. To do this, the NCCC recommends the following:
 - Evaluate and address regulatory or statutory limitations on HRSA’s training programs that affect the agency’s flexibility to meet the needs of team-based care and new care models; and
 - Increase funding for exemplary HRSA programs that support training health care professionals in team-based care within medical shortage areas (e.g., the HRSA National Health Services Corp) to meet unmet workforce needs.

Discussion

Dr. Bill Cook suggested calling out mental health because it is an important part of team-based care.

Dr. Bolen responded that the group will include mental health in the report.

Dr. Greenlee added that it was the Subcommittee's intent to include "behavioral and mental health" in the draft recommendation.

Topic. Reimbursement for Team-based Care

Draft recommendations:

- The NCCC recommends that HHS/CMS identify and implement mechanisms for involvement of Community Health Workers (CHWs), clinical pharmacists, and integrated (or collaborative) behavioral health in existing and future Value-Based Models of Care (Alternative Payment Models).
- The NCCC recommends that CMS optimize the ability of CHWs to assist in improving the care for people with diabetes by the following approaches:
 - Build on the 2013 final rule, expanding the scope of Medicaid reimbursable services by CHWs to include social, behavioral, and economic support as part of covered services.
 - To enhance use of CHW services across states, CMS should develop specific guidance clarifying that Medicaid funding is available for CHWs to address social determinants of health, building on the CMS Medicaid Social Determinants of Health Roadmap (issued on January 7, 2021).
 - Clarify that CHW qualifications should focus on life experiences, interpersonal skills as natural helpers, and community membership as opposed to formal education or clinical training.
 - Require CHW services be delivered in accordance with evidence-informed standards for CHW programs such as those being developed by the National Committee for Quality Assurance.
 - Allow expansion of Z codes to cover more social determinants of health categories so that CHWs and other health care professionals can better document their activities.
- The NCCC recommends that CMS add clinical pharmacists to the list of providers whose patient care services, when delivered to patients in medically underserved communities, are covered by Medicare Part B (i.e., grant them "provider status").

Discussion

Dr. Schillinger suggested revising the language to highlight the clinical-community linkage. He also suggested adding social workers in the first bullet.

Dr. Bolen agreed to incorporate the concept of clinical-community linkage in the recommendation and in the background. Regarding social workers, Drs. Bolen and Greenlee explained that a mechanism already exists for social workers to get reimbursed for their services.

Topic. Team-based Care--Implementation Research and Programs

Dr. Bolen provided brief background information and presented the draft recommendations focused on implementation research and implementation programs.

Background: Implementation programs and research can help promote the uptake of team-based care models and establish new care delivery models; however, 2020 data suggested that compared to funding for basic research, implementation research and programs were underfunded.

Draft recommendations:

- The NCCC recommends Congress increase funding for implementation programs and implementation research across federal agencies (e.g., AHRQ, NIH, CMS, HRSA, IHS, CDC, VA, and DoD) to better translate evidence-based team-based care into practice and test new team-based care models to improve diabetes care and outcomes on a broad scale.
- In addition to broad scale implementation of team-based care to drive improved outcomes, the NCCC recommends the following as specific focus areas for funding:
 - HHS/CDC should expand programs to help states integrate CHW services in a comprehensive, whole-person approach that includes economic, social, and behavioral support as well as clinical and preventive services.
 - HHS should enhance funding to AHRQ through Primary Care Extension Programs and other mechanisms to provide technical assistance to medical practices to implement team-based care, including support for the roles of CHWs, clinical pharmacists, and integration of behavioral health services.

Discussion

Dr. Bolen and Dr. Schillinger briefly discussed and agreed to explore the possibility of combining these draft recommendations with the research-related draft recommendations developed by the Prevention—General Population Subcommittee.

Topic. Virtual Care—Access to Best Practices and Specialty Care

Dr. Greenlee highlighted the rationale and presented the draft recommendations.

Background: Patients with diabetes need primary as well as multiple types of specialty care. Digital/virtual care options (e.g., technology-enabled collaborative-learning and capacity-building programs) can help care teams implement best practices and deliver care to patients efficiently and cost-effectively.

Draft recommendation: CMMI should fund a demonstration project with HRSA and IHS utilizing a technology-enabled collaborative-learning and capacity-building model (e.g., a Project ECHO type of model) to support the uptake and implementation of diabetes care best practices among primary care providers and care teams, ensuring that the project includes training of CHWs.

- In collaboration with HRSA, provide diabetes or endocrine outreach to small or rural health clinics (spokes) to include focus on social determinants of health and behavioral health issues that affect diabetes outcomes and leverage existing academic center hubs to support uptake and implementation of diabetes care best practices.
- In collaboration with IHS and Tribal and Urban Indian clinics to create supportive learning and mentorship relationships to assist in implementing diabetes care best practice and to leverage existing Tribal Epidemiology Center and academic center hubs.
- Include payment for both hub and spoke participants' time.
- Use a shared-services approach (e.g., collaborate with entities with appropriate expertise) for training on the telementoring model, infrastructure, and data collection.
- Collect and analyze interim data such as clinical quality metrics on diabetes care, utilization (emergency department visits, hospitalizations, etc.) to show cost-effectiveness.

Discussion

Dr. Greenlee explained that both IHS and HRSA are interested but neither of them has the capacity to do the administrative component of the work.

Dr. Boltri commented that the first bullet (endocrine and diabetes) is rather broad and might lead to confusion.

Dr. Greenlee responded that the Subcommittee could remove “or endocrine” to focus on diabetes.

Dr. Schillinger asked if the model could include other specialists. Dr. Greenlee said yes.

Dr. Conlin added that the concept of the draft recommendation is to improve the care for people with diabetes across all disciplines that are relevant to diabetes.

Topic. Telehealth

Dr. Greenlee highlighted the advantages of telehealth and explained that the reason the Subcommittee developed the following draft recommendation is that CMS does not have the authority to expand the waivers.

Draft recommendation: The NCCC recommends that Congress

- Remove geographic and originating site restrictions so that CMS can provide access to telehealth services as appropriate;

- Make permanent the ability for Federally Qualified Health Centers and Rural Health Centers to provide services by telehealth; and
- Maintain coverage for audio-only visits as necessary to comply with the Executive Order on *“Advancing Racial Equity and Support for Underserved Communities.”*

Topic. Digital Connectivity

Dr. Greenlee highlighted the inverse relationship between digital connectivity and the prevalence of diabetes and presented the following draft recommendations.

Draft recommendations: To improve digital connectivity and its impact for people with diabetes,

- FCC should
 - Focus more broadly on digital connectivity to include adoption as well as access; and
 - Conduct research to better understand the associations of digital connectivity, diabetes prevalence, and improved diabetes health outcomes.
- FCC, USDA, and HHS should
 - Expand the scope of an inter-agency memorandum of understanding (MOU) beyond the Rural Telehealth Initiative or establish another similar mechanism to bring together the appropriate federal agencies to share information on and investigate the relationship between connectivity and health, and the types and extent of digital services required to positively impact health.

Discussion

Ms. Ellen Leake added that the intent of the second bullet is to encourage federal collaboration through MOU or other mechanisms.

Workgroup on Health Systems-level Interventions Presentation

Dr. Herman, who led the workgroup on health systems-level interventions, explained that the workgroup addresses the following three topics:

1. Access to health insurance for people with diabetes
2. Making medications affordable for people with diabetes
3. Health care delivery and payment models to improve care for people with diabetes

Dr. Herman explained that the Commission has received many useful comments from the public, which helped revise the draft recommendations. Dr. Herman provided brief background information and presented the workgroup’s draft recommendations on the three topics.

Topic 1: Access to Health Insurance for People with Diabetes

Dr. Herman noted that access to affordable health care is critical for people at risk for diabetes and individuals with diabetes. To address the gaps in the current public-private system and as an alternative to either “repealing and replacing the Affordable Care Act [ACA]” or “Medicare for all,” the Commission needs to address gaps in various coverages and insurance plans,

including 1) employer-sponsored health insurance coverage, 2) individual marketplace health insurance plans, 3) Medicare coverage, and 4) Medicaid coverage.

Dr. Herman provided brief background and presented draft recommendations for addressing gaps in each of the coverages/plans.

Improving Access to Employer-sponsored Health Insurance Coverage

Background: The ACA requires that employers with more than 50 full-time employees offer health insurance that is affordable and provides certain mandated benefits. Employers who fail to comply pay a tax penalty. At the same time, employers can offer employees health reimbursement accounts that provide sufficient funds to cover 80% of the cost of silver marketplace plan with employer contributions made on a pre-tax basis and employee reimbursement being tax exempt.

Draft recommendation: To improve access to employer-sponsored health insurance coverage, the NCCC recommends

- The tax penalty be removed for employers that do not provide employees with qualified health insurance coverage, but those employers be required to provide funds to employees' health reimbursement accounts to cover the cost of silver marketplace health insurance policies for those employees and their dependents;
- Eligibility for dependent coverage be expanded from age 26 to age 30;
- High-value services including certain preventive services, assessments, and treatments, for diabetes (including DSMES, medical nutrition therapy [MNT], behavioral health care, monitoring and insulin delivery devices, diabetic retinal exams, and insulin) be provided free or at a very low cost; and
- Nonmedical switching be curtailed so that diabetic patients using previously approved products not be forced to switch to different medications or devices due to a change in formularies.

Expanding Coverage, Increasing the Affordability, and Stabilizing Premiums for Individual Marketplace Health Insurance Plans

Background: Individual health insurance marketplaces provide a source of insurance for workers without employer-sponsored health insurance and those with incomes below 400% of the federal poverty level but above the threshold for Medicaid eligibility. Under the ACA, premium subsidies are provided for individuals and families with incomes between 400% and 250% of the federal poverty level and waived for those with incomes below 250% of the federal poverty level.

Unfortunately, changes in federal policies resulted in reductions in spending on advertising for open enrollment and for in-person enrollment assistance, and shortened the open enrollment period. In addition, federal cost-sharing reduction payments were terminated, leaving many low-income individuals and families not otherwise eligible for Medicaid without health insurance. In addition, some individuals who qualified for subsidies chose not to enroll in

coverage even when the subsidies would cover the entire premium costs. Finally, high-cost individuals enrolled in marketplace plans can destabilize the cost of the plan.

Draft recommendations:

- Restore funding for advertising and consumer assistance for marketplace plans and increase the length of the enrollment period.
- Establish special enrollment periods for individuals who lose employer-sponsored health insurance or whose incomes change dramatically during the year due to changes in employment.
- Increase market risk pool support to ensure adequate offerings in all areas of the country.
- Restore cost-sharing reduction payments for individuals with incomes below 250% of the federal poverty level.
- Expand the availability of premium tax credits to individuals and families with incomes as high as 600% of the federal poverty level who do not have access to employer-sponsored health insurance coverage.
- Give states the authority to auto-enroll subsidy-eligible individuals into marketplace plans, provided the premium is less than or equal to the amount of the individual's premium tax credit; and
- Establish a federally-funded and state-administered reinsurance program for high-cost individuals enrolled in marketplace plans.

Expanding and Improving Access to Medicaid

Background: Access to Medicaid would be facilitated by expanding Medicaid eligibility in all states to individuals with incomes less than 139% of the federal poverty level. Permitting states to offer continuous 12-month eligibility for adults would also facilitate coverage.

Draft recommendations:

- Financial incentives be provided to encourage all states to expand Medicaid.
- Qualify diabetes as a disability eligible for Medicaid buy-in for low- and moderate-income individuals.
- Cover telehealth services, including video, phone, and audio-only delivery.
- Expand coverage for needed supplies and devices especially for people with type 2 diabetes and gestational diabetes.
- Cover all forms of insulin, including pens, vials, inhaled insulin and other insulin products that may be approved in the future.
- Adults enrolled in Medicaid be offered continuous 12-month eligibility.

Expanding Medicare Coverage

Dr. Herman noted that Medicare has been extremely successful in ensuring access to care for Americans 65 years of age and older and those with disabilities. Access to care could, however, be improved.

Draft recommendations: The NCCC recommends that CMS

- Facilitate comparisons among traditional Medicare fee-for-service, Medicare Advantage, and Alternative Payment Model Medicare plans and provide estimates of total cost-sharing for enrollees.
- Develop and implement a more streamlined enrollment process for dual Medicaid and Medicare beneficiaries.
- Make permanent waivers established during the COVID-19 public health emergency including
 - Coverage and reimbursement for telehealth services
 - Waived video requirement for DSMT and MNT, allowing delivery by phone or audio only
 - Expanded eligible practitioners that may furnish and bill for telehealth services
 - Waived prior authorization and medical necessity documentation requirements
 - Waived in-person visit requirement for CGM and insulin pumps, allowing Medicare beneficiaries with diabetes to get their supplies without an in-person visit
 - Waived in-person visit requirement for replacement of durable medical equipment that is lost, destroyed, irreparably damaged, or otherwise rendered unusable or unavailable
 - Cover 90-day supply of prescription medications
 - Cover 90-day supply of diabetes testing supplies
- Expand coverage for obesity treatments for the management of diabetes
 - Expand Medicare Part B coverage for outpatient MNT for obesity and prediabetes. Currently, Medicare Part B only covers MNT for people with diabetes.
 - Improve coverage for intensive behavioral therapy by expanding the range of providers that are reimbursed for these services. Currently, Medicare only covers these services when provided by a primary care provider in a primary care setting.
 - Revise Part D plan guidance to cover all FDA-approved anti-obesity medications in conjunction with intensive behavioral therapy.

Discussion

Following Dr. Herman’s presentation, Commission members discussed a range of topics.

Impact of insurance changes on medication

Dr. Bolen wanted to know how the draft recommendation on nonmedical switching would be implemented and whether or not it would be through CMS. She agreed that it is a big problem but she was not sure how to address the issue. She commented that it might be challenging to put it in practice.

Dr. Herman responded that the draft recommendation currently is included under employer-sponsored plans. He noted that it is a general problem and it is worth considering.

Dr. Greenlee agreed that switching plans causes challenges; however, the topic, she commented, might be out of the Commission’s scope.

Dr. Herman explained that the draft recommendation was developed based on public comments.

Telehealth services

Dr. Bolen commented that some of the draft recommendations on telehealth services overlap with some of the Treatment and Complications Subcommittee's draft recommendations.

Dr. Herman agreed that there are overlaps and that the duplicative ones could be deleted.

Part D

Dr. Schillinger commented on the draft recommendation suggesting "revise Part D plan guidance to cover all FDA-approved anti-obesity medications in conjunction with intensive behavioral therapy." He pointed out that the medications need to have efficacy data to show they could prevent diabetes.

Dr. Herman explained that the "Standards of Medical Care in Diabetes" of the American Diabetes Association (ADA) addresses weight loss and highlights that obesity management can delay the progress of prediabetes and is beneficial in type 2 diabetes treatment. The evidence, he said, is adequate for most FDA-approved anti-obesity medications.

In response to Dr. Schillinger's followup question, Dr. Herman clarified that the ADA recommends that if a patient's response to a weight-loss medication is not adequate (i.e., less than 5% weight loss) after three months, the medication should be discontinued.

Dr. Schillinger suggested to provide more specifics to improve clarity.

Connection with recommendations from the Subcommittee

Dr. Naomi Fukagawa expressed support for commenting on the importance of insurance coverage. She wanted to know if the draft recommendations from the workgroup would serve as the Commission's overarching recommendations; if so, the connection/flow between these draft recommendations and the Subcommittees' draft recommendations does not seem clear to her.

Dr. Herman responded that some of the draft recommendations were added based on public comments. He explained that the key point of the draft recommendations is that people with diabetes and individuals at risk of diabetes need access to health insurance. The main recommendations related to marketplace plans as an alternative for people without employer-sponsored insurance and Medicaid coverage perhaps should be the Commission's focus, he said.

Relevance, scope, and specificity of the recommendations

Commission members discussed the relevance of the draft recommendations and whether they are within the Commission's scope. Commission members generally agreed that access to care and affordability of diabetes medications are important topics. However, different views were

expressed regarding how to address these topics, how specific the draft recommendations should be, and whether or not some of the draft recommendations are within the Commission's scope.

Dr. Greenlee expressed her preference for making a strong statement in the report but not making specific recommendations on health care reform. She commented that some of the draft recommendations are broad and not diabetes-specific, and she voiced concern that these broad recommendations may dilute the diabetes-focused recommendations that the three Subcommittees have developed. She also commented that unlike the draft recommendations presented by the three Subcommittees, the draft recommendations from the workgroup have not been fully vetted.

Dr. Schillinger shared his view that health insurance and some of the details Dr. Herman provided could fall under the section on treatment and complications of the report. He agreed that the Commission has not extensively discussed these draft recommendations, and he suggested Commission members work with Dr. Herman to assess them. He suggested that as long as the evidence-based recommendations are within the Commission's duty, it is up to Congress to decide what to do with them. To not include something that is clearly important based on evidence, he continued, would be more problematic with respect of the Commission's duty.

Dr. Conlin shared Dr. Greenlee's concerns, and agreed with Dr. Greenlee that the Commission should make a strong statement in the report but not make specific recommendations regarding health care reform, which in his view might be out of the Commission's scope.

In response to Dr. Idzik's request for clarification about the concerns, Dr. Herman explained that he would like to focus on the gaps in insurance coverage among employer-sponsored plans, marketplace plans, Medicaid coverage, and Medicare coverage to make a point that access to health insurance is an enormous topic that it is critical to the recommendations of the Prevention—Targeted Population Subcommittee and the Treatment and Complications Subcommittee. He expressed his view that the Commission needs to call out that people with diabetes and prediabetes need to have health insurance coverage. To do less than that, he said, is ignoring the elephant in the room.

Dr. Bolen commented that some of the draft recommendations are very specific, and she acknowledged that she was not sure if there is adequate evidence and what the potential implications might be.

Multiple Commission members commented that the Commission should have a recommendation(s) regarding health insurance; however, Commission members did not reach a consensus over how detailed the recommendations should be and where in the report the recommendations should be presented.

Dr. Herman suggested convening a meeting for members to further discuss the draft recommendations.

Topic 2: Making Medications Affordable for People with Diabetes

Dr. Herman highlighted the importance of the affordability of insulin and other lifesaving prescription medications to people with diabetes or at risk of diabetes, proposed strategies to address the issues, and presented specific draft recommendations under each strategy.

Strategies

To improve access to insulin and other lifesaving prescription medications for patients with diabetes or at risk for diabetes, the NCCC recommends the following:

- Encourage competition in the market for generic drugs and biosimilars.
- Review the incentives provided to brand manufacturers to reward innovation without creating unnecessary barriers to competition.
- Increase the flexibility of the federal government to negotiate drug prices.
- Increase transparency in the pharmaceutical distribution system to ensure that financial returns are justified across all parties.
- Reduce regulatory barriers to value-based insurance design to better align the out-of-pocket cost of drugs to their benefits and promote the Medicare Part D Senior Savings Model.

Strategy 1. Encourage Competition in the Market for Generic Drugs and Biosimilars

Draft recommendation: To ensure that generic drugs are available and affordable, the NCCC recommends the following:

- Pay-for-delay arrangements that block access to lower-cost generic drugs be curtailed to address anticompetitive behaviors and gaming.
- The 180-day exclusivity period given to generic manufacturers to provide an incentive for taking the financial risk associated with being the first-to-file generic manufacturer be revised to close loopholes that limit competition beyond 180 days without a reasonable justification for the delay.

Strategy 2. Review the Incentives Provided to Brand Manufacturers

Draft recommendation: To ensure that drug discovery incentives are adequate but not excessive and to encourage competition, the NCCC recommends:

- Modify patent laws to discourage manufacturers from applying for multiple patents on a single drug and from making slight modifications to old drugs to obtain new patents to extend a drug's patent protection.
- Curtail shadow pricing for drugs with few manufacturers.
- Reduce the period of market exclusivity for biological products from 12 years to seven years.
- Remove barriers to biosimilar market entry.

Strategy 3. Increase the Flexibility of the Federal Government to Negotiate Drug Prices

Background: By statute, Medicaid is permitted to negotiate drug prices and by doing so is able to provide beneficiaries with an extensive choice of medications at low out-of-pocket cost. This is in sharp contrast to Medicare Part D, which is currently prohibited from negotiating drug prices.

Draft recommendation: The NCCC recommends that all federal drug benefit programs be given flexibility to negotiate medication prices with manufacturers and pharmacy benefit managers to capitalize on their market shares and volumes. Similar to Medicaid, these programs should elicit best price requirements and protections against medication net price increases greater than the rate of inflation.

Strategy 4. Increase Transparency in the Pharmaceutical Distribution System

Background: For every \$100 spent on retail drugs, \$41 goes to parties in the distribution chain: wholesalers, pharmacies, pharmacy benefit managers, and insurers. The growing difference between the list price and the net price of a drug reflects negotiated rebates and discounts put into place to influence formulary placement among competing brands within a drug class. High list prices disadvantage patients without insurance who pay the list price or pay coinsurance based on the list price of the medication, and affect both medication adherence and health outcomes. To address these issues, greater transparency and simplicity should be introduced into drug pricing to eliminate distortions that are currently beyond individual payers' ability to address.

Draft recommendations:

- Increase transparency throughout the pharmaceutical supply chain especially in the pharmacy benefit manager market.
- Pass on to patients all negotiated rebates and discounts for prescription drugs (including insulin) at the point of sale during the deductible phase. A person with diabetes should never pay more for a medication than a plan would pay if the plan were paying 100% of the cost.

Strategy 5. Reduce Regulatory Barriers to Value-based Insurance Design

Background: Value-based insurance design (V-BID) aligns patient out-of-pocket costs with the value of a health service regardless of its actual price. V-BID plans encourage patients to use high-value medications such as insulin by lowering its cost to patients. Tools employed by V-BID include covering high-value treatments without applying their costs to the patient's deductibles (predeductible coverage) and covering high-value treatments without any patient coinsurance or copayment.

Draft recommendations:

- Insulin and other high-value treatments be covered without applying their costs to the patient's deductibles (predeductible coverage).
- Insulin and other high-value treatments be covered without any patient coinsurance or copayment.

- Insurance practices that force patients to choose between affordability and quality be curtailed. This includes step therapy (“fail first policies”) that require patients to try the least expensive drugs in a therapeutic class before being eligible to receive the medication that the prescriber believes to be the best for the patient, and prior authorization requirements.
- Given that the Part D Senior Savings Model/Program has the potential to provide stable, predictable co-pays for the insulins that beneficiaries with diabetes need throughout the different phases of the Part D benefit, the NCCC recommends:
 - Ensuring that eligible beneficiaries are aware of the Part D Senior Savings Model and making enrollment easier to navigate for beneficiaries.
 - Encouraging widespread testing, rigorous evaluation, and if effective, broad implementation of the Part D Senior Savings Model.
 - Exploring and facilitating broader implementation of alternative models for medication benefit design including value-based pricing where the formulary placement of a drug and its cost to patients is inversely related to its health benefits.

Discussion

Following Dr. Herman’s presentation on the second topic, Commission members discussed and provided input on various topics.

Possibility of consolidation

Dr. Fukagawa commented that the recommendations contain valuable, broad ideas and are related to some of the Subcommittees’ recommendations. She suggested the Commission find a way to incorporate the ideas in the Subcommittees’ recommendations rather than having a separate set of recommendations.

Dr. Herman responded that many of the draft recommendations in this section are related to treatment and complications, and he expressed support for incorporating them in the Treatment and Complications Subcommittee’s recommendations.

Incentives for developing new drugs

Dr. Barbara Linder asked about the specifics of the recommendations. In terms of incentives for developing new drugs, she wanted to know if the recommendation from “12 years to 7 years” is based on any analysis.

Dr. Herman responded that it is more in line with patented life for chemical/new molecular entities, instead of biosimilars.

Dr. Bill Chong added that based on his understanding, biological products are more challenging to develop.

Affordability of insulin

Dr. Conlin commented that the recommendation on the affordability of insulin has great relevance. Given that other entities have investigated the issue but none of them have identified a specific cause, he wanted to know if Dr. Herman has identified any specific reason that can be addressed by the federal government.

Dr. Herman responded that many of the recommendations came from an analysis.

High-value treatments and step therapy

Dr. Bolen agreed that affordability is a huge barrier for patients to obtain medication. Regarding the draft recommendation on “Insulin and other high-value treatments be covered...,” she wanted to know how high-value treatment will be determined and who will determine it. Regarding “step therapy,” she wanted to know how to deal with potential pushbacks.

Dr. Herman explained that non-medical switching, step therapy, as well as issues related to prior authorization came from public comments, and that he presented them for the Commission to discuss. He acknowledged that the draft recommendations may not be consistent with other recommendations and could be pulled back.

Dr. Chong wanted to know the potential impact of the draft recommendation on “Increase transparency throughout the pharmaceutical supply chain especially in the pharmacy benefit manager market” and how it would work.

Dr. Herman explained that negotiations between insurers, pharmaceutical benefit managers, and pharmacies are confidential. Shedding light on those arrangements, he noted, would help improve transparency and allow people to understand where the money is going.

Dr. Greenlee suggested focusing on out-of-pocket costs. Regarding curtailing shadow pricing, she wanted to know to which agency the recommendation would be directed and how it is controlled.

Dr. Chong and Dr. Herman responded that it might be FTC.

Task force and Office of National Diabetes Policy

Dr. Greenlee shared that the Treatment and Complications Subcommittee plans to recommend a task force to determine which secondary and tertiary preventive services should be pre-deductible. That recommendation, she noted, could pull together some of the recommendations Dr. Herman proposed (e.g., diabetes education, eye and foot exam, and some medications). She commented that there needs to be an entity to determine valuable secondary and tertiary preventions, which may fall under the Office of National Diabetes Policy. She expressed support for the recommendation.

Topic 3: Health Care Delivery and Payment Models to Improve Diabetes Care for People with Diabetes

Dr. Herman presented the draft recommendations on various topics but did not have time to explain the rationales.

Quality Measurement

Draft recommendations:

- Quality measures for primary prevention of diabetes. The electronic clinical quality measures recommended by the AMA for primary prevention of diabetes should be implemented to assess
 - rates of utilization of diagnostic tests to identify individuals with prediabetes;
 - rates of referral to, enrollment in, retention, and outcomes of lifestyle programs and prescriptions for metformin to prevent type 2 diabetes; and
 - rates of retesting of abnormal blood glucose in patients with prediabetes.
- Measures of overtreatment. A measure should be constructed and tested to assess potential overtreatment of hyperglycemia and to counter pressure to intensify therapy inappropriately in the name of performance improvement. An example is overtreatment of hyperglycemia in elderly patients with multiple comorbidities in whom the benefits of adding another antihyperglycemic medication or further lowering the A1c are outweighed by the risks related to hypoglycemia, treatment burden, and cost.
- Uniform measures to assess the quality of diabetes care be developed and implemented across payers and federal agencies that deliver direct health care.

Health Care Delivery and Payment Models

Draft recommendations:

- The NCCC recommends that health care delivery and payment models be redesigned to provide improved organizational and financial support for
 - Connecting patients to diabetes self-management education and support at four critical time points including diagnosis of diabetes, annually when not meeting treatment targets, when complicating factors develop, and when transitions in care and life occur.
 - Use of multidisciplinary care teams and care managers to engage, support, educate, and manage patients with diabetes by actively reaching out to them and connecting them to community resources.
 - Integrating behavioral health providers into practices to proactively integrate physical and behavioral health care to address the behavioral health needs and social determinants of health of patients with diabetes.
- The NCCC recommends that health care delivery and payment models be redesigned to provide improved organizational and financial support for:
 - Providing monthly care management payments to support practice redesign and care delivery.
 - Providing payment models with longer time periods before implementation of downside risk.

- Providing additional support to practices treating marginalized patients to facilitate improvements in health equity.

Payment Models

Draft recommendations to CMS:

- Provide ongoing coverage of telehealth services including video, audio-only, and digital health tools for diabetes management.
- Provide care management fees (non-visit-based payments made to practices based on the size of the patient panel and the intensity of care management services required for the practice's specific population) to support practice redesign.
- Facilitate continuous measurement systems that provide timely feedback to clinicians on performance.
- Hold clinicians accountable for performance measures that are fewer in number but assess patient care, care quality, and clinical outcomes that are important to patients.
- Judge Accountable Care Organizations (ACOs) against their own historical performance rather than external benchmarks so that issues of inadequate risk adjustment become less problematic. Every program succeeds by improving, no matter where it starts.
- Ensure that performance-based payments (payments based on clinical quality measures, patient experience measures, and utilization measures) are sufficiently large to incentivize quality improvement.
- Implement payment models that provide assistance to low-resourced practices in poor and underserved areas to develop the infrastructure needed to succeed.
- Rigorously evaluate the impact of implementing longer contract periods and delaying implementation of downside financial risk to recognize the substantial practice redesign that may be required.
- Allow the development and implementation of patient incentive programs.
- Increases funding for social services and establish better linkages between clinical care and community resources to address social determinants of health and health equity.

Discussion

How to move forward

Dr. Schillinger commented that some of the draft recommendations to CMS (e.g., the last six bullets) would be challenging to implement.

Dr. Herman responded that he could tighten up the draft recommendations and let the Treatment and Complications Subcommittee to review.

Dr. Conlin and Dr. Greenlee acknowledged the merit of the overall recommendations. They, however, expressed concerns that the draft recommendations have not been extensively vetted like other draft recommendations, and therefore may not be ready to move forward. Given the time constraint, they noted, the Treatment and Complications Subcommittee may not be able to take on the task (i.e., vet and refine the draft recommendations and bring them forward to vote at the Commission's meeting on June 22, 2021).

Dr. Schillinger suggested distinguishing those draft recommendations that are straightforward to tackle from those that would need extensive work.

Dr. Conlin and Dr. Greenlee commented that draft recommendations related to the following three areas could potentially be harmonized and refined:

- Affordability of insulin (focusing on out-of-pocket cost)
- Coverage of preventive services (e.g., foot care, eye care, secondary and tertiary prevention services)
- Quality measures (e.g., overtreatment)

Commission members briefly discussed whether access to care and insurance coverage are within the Commission's scope. Different opinions were expressed. While some members were concerned that it is not what the Commission is charged to do, others pointed out that the topic is directly related to the Commission's duty 1, which calls out insulin, and the Commission's duty 2 regarding "gaps in federal efforts to support clinicians in providing integrated, high-quality care to individuals with these diseases and complications." Given the importance of the topic, Dr. Schillinger suggested the Commission as a whole decide how to address the issue (that is, make a recommendation or address the issue in the report without making a recommendation.)

Public Comment

Dr. Kate Kirley, a family physician and the director of Chronic Disease Prevention at the American Medical Association (AMA), provided comments on behalf of AMA. Dr. Kirley said that her following comments highlight AMA's written comments and also address some of the Commission's updates.

- Overall, the AMA supports the comprehensive approach in the Commission's draft report.
- The AMA recommends that the health equity lens be applied broadly to diabetes and diabetes prevention policies and programs to better serve marginalized communities.
- The AMA supports a team-based approach for both diabetes care and prevention but recommends that the Commission adds "physician-led" to the recommendation because it is important to have the team led by a physician to ensure appropriate diagnosis and treatment.
- The AMA supports Medicare coverage of screening for hemoglobin A1c tests. This coverage is needed to align with clinical guidelines. Hemoglobin A1c is generally preferred by physicians and is the most programmatic test for screening patients.
- The AMA appreciates the Commission's updated recommendation to include all three measures from AMA's prediabetes quality measure set. These measures are intended to be used together to incentivize comprehensive diabetes preventive care.
- The AMA believes that the Commission's recommendation to fund research on the benefits of metformin for treating prediabetes is unnecessary as sufficient evidence also

exists. The AMA recommends that the Commission present the current available data to the FDA.

- The AMA urges the Commission to recommend that the CDC's Division of Diabetes Translation establish a system to track the outcomes of all evidence-based interventions for preventing type 2 diabetes and not to limit to the lifestyle change program and its weight loss metrics. The Commission should also recommend that all commercial and public insurers cover all of these evidence-based preventions.
- The AMA appreciates the updated recommendation for improving the MDPP. However, the AMA does not think that new model tests are needed and believes that the CMS can fix several problems that threaten the existence of the MDPP through the Medicare Physician Fee Schedule process or via statute.

Dr. Kirley noted that the AMA welcomes an opportunity to discuss their comments with the Commission and identify other areas that would benefit from the inclusion of organized medicine.

Additional Discussion on Federal Education and Awareness Activities

Dr. Schillinger pointed out that all three Subcommittees have discussed the improvement in, and improved coordination of, federal education and activities related to the prevention and treatment of diabetes and complications (Commission's duty 3); however, none of the Subcommittees have addressed the National Diabetes Education Program. He suggested that the three Subcommittees address diabetes education together, and he asked if CDC and NIDDK representatives know what happened to the National Diabetes Education Program.

Dr. Barbara Linder, Commission member representing NIDDK, and Dr. Pat Schumacher, Commission member representing CDC, both acknowledged that they did not have personal knowledge about the program, and they offered to help seek more information (e.g., why it ended).

Closing Remarks

Dr. Herman remarked that the Subcommittees and the workgroup all presented good draft recommendations. He encouraged them to finalize and prioritize the draft recommendations and think about how to align the draft recommendations with the duties. After today's meeting, he said, the Commission will meet to consolidate crosscutting issues and discuss draft recommendations on making diabetes medications affordable.

DFO Kara Elam expressed concern that the Commission has not made recommendations addressing duty 5 (i.e., Opportunities for consolidating any inappropriately overlapping or duplicative federal programs related to these diseases [diabetes] and complications). She agreed with Dr. Herman that the Subcommittees need to prioritize their draft recommendations and align them with the duties.

Adjournment

The meeting was adjourned at 5:52 pm EDT.

Appendix: Commission Members and HHS Support Staff

Commission Members Present at NCCC Meeting 11

Commission Chair

William Herman, MD, MPH, Professor of Medicine and Epidemiology, Co-Director, Michigan Center for Diabetes Translational Research, University of Michigan, Ann Arbor, MI

Public Members (Special Government Employees)

Shari Bolen, MD, MPH, Associate Division Director of Internal Medicine, the MetroHealth System, Cleveland, OH

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

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

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

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

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

Shannon Idzik, DNP, ANP-BC, FAAN, FAANP, Associate Dean and Professor, Doctor of Nursing Practice Program, University of Maryland Baltimore School of Nursing, Baltimore, MD (*joined after roll call*)

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

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

David Strogatz, PhD, MSPH, Director, Center for Rural Community Health, Bassett Research Institute, Bassett Health Care Network, Cooperstown, NY (*joined after roll call*)

Federal Members (Regular Government Employees)

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

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

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

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

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

Barry Marx, MD, Director, Office of Clinician Engagement, Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services, Department of Health and Human Services

Pat Schumacher, MS, RD, Chief, Program Implementation Branch, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (*joined after roll call*)

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

CAPT Jana Towne, RN, BSN, MHA, U.S. Public Health Service, Division of Diabetes Treatment and Prevention, Office of Clinical and Preventive Services, Indian Health Service, Department of Health and Human Services

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

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

Commission Members Absent from NCCC Meeting 11

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

HHS Staff in Attendance

Office on Women's Health

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

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

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