National Clinical Care Commission 2nd Webinar Meeting
Wednesday, February 20, 2019
1:00 pm — 5:00 pm EST
Meeting Summary

Table of Contents

Welcome and Roll Call

Clydette Powell, MD, MPH, FAAP, Designated Federal Officer for the National Clinical Care Commission (NCCC); Director, Division of Health Care Quality, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services (HHS), called the meeting to order at 1:00 pm. She welcomed NCCC members and the public and then conducted a roll call (see Appendix for Commission member attendance).

Dr. Powell stated that today's meeting is a listen-only meeting. Public members who wish to provide input can do so through NCCC's website. The main purpose of the meeting was for the Commission to learn more about existing federal programs and activities in diabetes. She thanked the 10 invited speakers from 8 government agencies and introduced the first speaker, Dr. Susan Alu.

Invited Presentations on Current Activities in Diabetes by Federal Partners

Diabetes Management in the Federal Bureau of Prisons (BOP): Opportunities and Challenges

CDR Susan Alu, PharmD, U.S. Public Health Service, Deputy Chief Pharmacist, FMC Fort Worth, BOP

Dr. Alu stated that BOP's mission is to protect society by confining offenders in the controlled environments of prisons and community-based facilities that are safe, humane, cost-efficient, and appropriately secure; and that provide work and other self-improvement opportunities to assist offenders in becoming law-abiding citizens. She explained that the Health Services Division's mission is to deliver medically necessary health care to inmates effectively in accordance with proven standards of care without compromising public safety concerns inherent to the Bureau's overall mission.

After explaining the burden of diabetes at BOP—12,000 inmates with diabetes and 3800 of them are prescribed insulin, Dr. Alu introduced BOP's diabetes management programs customized for correctional settings.

Inmate Glucose Meter Program

Initiated in December 2009, the program permits insulin-dependent inmates to carry glucose meters for self-monitoring. Inmates with glucose meters are given additional tools to help them appropriately manage their blood sugar levels. The goal of the program is to reduce the frequency and severity of hypoglycemic episodes.

Clinical Guidance on Management of Diabetes
Dr. Alu noted that BOP follows evidence-based clinical guidelines. In consideration of its correctional settings, BOP makes necessary modifications when following the guidelines. For example, at BOP they use regular short-acting insulins instead of rapid-acting insulins. The administration of insulin at BOP is strictly observed to ensure needle and syringe accountability, and the timing for insulin administration and food intake are also controlled. They also educate the inmates on insulin dose management and the effect of carbohydrate intake on blood sugar levels.

Collaborative Practice Agreement for Clinical Pharmacists.
BOP in 2014 initiated a pharmacist residential training program to help pharmacists develop diabetes management skills suitable for correctional settings. In 2017 the Bureau developed a comprehensive, standardized pharmacy temple that includes cardiovascular risk reduction and screening for preventive health interventions.

Data Informatics
Dr. Alu noted that they can collect data using the Bureau's Electronic Medical Records and other electronic sources. She added that the new tool allows them to quickly review information at the institutional as well individual levels.

Questions and Answers

Dr. Herman wanted to know how many inmates are in the BOP. He also asked Dr. Alu to clarify "insulin-dependent diabetes," which Dr. Alu mentioned in her presentation. Dr. Alu replied that currently there are roughly 151,000 inmates in BOP custody. Regarding insulin-dependent diabetes, she said that as long as the inmates are on insulin therapy, they meet the criteria for using glucose meters.

Ms. Ellen Leake asked if the insulin line at BOP provides only bolus insulin to cover meals. She also wanted to know if there are enough data from the electronic health records (EHRs) to assess whether or not having access to self-monitoring meters is associated with better health outcomes. Dr. Alu clarified that at the insulin line, inmates receive any insulin they prescribed, including both basal and correctional insulins. Currently they are not able to separate results of inmates who carry monitors from those who do not. She added that they anticipate additional capabilities towards the end of the year.

Dr. Shari Bolen asked if weight loss programs and other programs similar to the Diabetes Prevention Programs (DPP) are offered to the inmates. Dr. Alu responded that in addition to the heart-healthy menu and recreation programs, there are many individual efforts at the institutional level.

Dr. Jasmine Gonzalvo asked if Dr. Alu has data on high glucose related incidents. Dr. Alu responded that they do have some data. For example, there were 16 incidents at her institution and 24 (from 215 inmates) at another institution. She said it is challenging to get all the data into the system and make them useful.

Dr. Bolen asked Dr. Alu to share her thoughts on opportunities for improvement in diabetes prevention and management. Dr. Alu responded that perhaps they need slightly more standardization in prevention education. She also acknowledged the need to individualize, given that each institution's situation is different.

Dr. John Boltri asked if every inmate is screened for diabetes and prediabetes, and if BOP shares same EHRs between different prisons. Dr. Alu responded that at BOP they follow American Diabetes Association's (ADA) guideline for screening. She added that young people who do not have a record of diabetes or prediabetes may not get screened. She emphasized that BOP is good at following guidelines on screening, and they do share EHRs between prisons.

Dr. Powell asked a question about care after an inmate is released. Dr. Alu explained that they make sure the to-be-released inmates have at least a 30-day supply including insulin and syringes, and they have teams of social and case workers who assist the inmates with plans and arrangements to ensure smooth transition to the community.

Overview of the Food and Drug Administration (FDA) and Diabetes-related Activities

William Chong, MD, Acting Deputy Director, Division of Metabolism and Endocrinology Products, Center for Drug Evaluation and Research, FDA

Christine Lee, PharmD, PhD, Health Scientist, Center for Drug Evaluation and Research, FDA

Dr. Chong first stated FDA's mission and reviewed FDA's organization chart. He then introduced the two centers that are responsible for most of the FDA's efforts in diabetes: the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH).

Dr. Chong noted that CDER protects public health by regulating drug products, including drugs improving glycemic control, drugs treating complications of diabetes, and drugs reducing the risk of cardiovascular events in patients with diabetes. He said that CDRH regulates drug delivery devices for diabetes (e.g., insulin pumps and syringes), diabetes monitoring devices (e.g., blood glucose meters), devices for treatment of diabetes complications (e.g., YAG laser), and devices and laboratory tests for detection and diagnosis of diabetes and complications (e.g., IDX-DR). Both CDER and CDRH conduct post-marketing monitoring to ensure safety.

Dr. Chong explained that FDA communicates with the public through multiple media channels, including press releases, safety communications, Twitter (e.g., @US_FDA), as well as consumer and patient resources.

Following Dr. Chong's presentation, Dr. Lee provided an overview of the National Action Plan, particularly the action on patient safety and hypoglycemia. Given that diabetes agents (insulin and 4 oral agents) are among the 3 drug classes accounting for the majority of emergency visits for older adults, Dr. Lee noted that it is critical to amplify the message and effectively

disseminate and implement research findings through education, partnership with professional and private organizations, collaboration with other agencies, and utilization of social media listening strategies.

She then introduced her team's research on the science of engagement, a pilot study to understand what can be learned from unstructured data gathered from available FDA resources and the social media regarding people's experience with and treatment of diabetes.

Preliminary results of Dr. Lee's study showed that the most frequently talked about topics related to diabetes include personal experiences, the effect of diet and exercise, and the importance of comorbidity awareness. In addition, indirect links to diabetes can put individuals at increased risk. Patient support, community engagement, and individualized care also play important roles in diabetes prevention and management.

The main challenge with social media data mining, Dr. Lee pointed out, is that the data are fragmented and unstructured. As a result, it is challenging to use social media to identify common themes.

Dr. Lee noted that when mining social media data, the following questions need to be considered.

- How will the data be utilized?
- What can the agency do to enhance social media engagement?
- What social media platform would be the most informative to explore?
- Are there certain segments of the population that use certain social media platforms more than others?
- Are there novel ways that can be tested to further engage with the public in order to better capture the patient's voice?

Dr. Lee summarized her research finding with the following takeaways.

- Implementing hypoglycemia risk prediction tools is feasible.
- Variations exist in risk across clinics and care teams.
- Pilot low-cost approaches could help reduce risk and improve health outcomes.
- Collecting self-reported risks associated with hypoglycemia has potential benefits.

Questions and Answers

Dr. Dean Schillinger shared what he and his team have learned about communicating diabetes-related topics and the strategies they use. For example, they first learn patient-preferred language and then use the same language to frame their message. He wondered if the FDA has done similar work. Dr. Lee agreed that social media listening is great for hypothesis generation. She added that they use both social media data and FDA data to enhance findings.

Dr. Schillinger asked if FDA has a social media panel to provide feedback on different messages, and if FDA uses focus group testing or social media companies to gather representative information. Dr. Lee replied that she personally hasn't done so. She said that their first project was to understand how to improve the scientific vigor of social media data, and they haven't focused on communication yet.

Dr. Fukagawa asked if any information on diet or specific food emerged from the social media data mining. Dr. Lee replied that there are conversions about food. However, social media conversions tend to be the richest in stigmatized topics (e.g., opioids) and rare diseases. People affected by these diseases do talk about food on social media, but people with diabetes do not share as much. She added that she wants to expand her work but does not have enough staff members to work on obesity-related research.

Dr. Herman asked Dr. Chong to comment on challenges around biosimilars and drug costs. Dr. Chong responded that FDA is working on bring more biosimilars to the market with the hope to encourage competition and eventually bring down costs, but there are regulatory and scientific challenges. He added that FDA has nothing to do with drug pricing.

Dr. Herman asked if Drs. Chong and Lee could talk about tobacco. Dr. Chong explained that tobacco is a relatively new addition to FDA's authority. He was not sure about the details, but he offered to help get answers if Dr. Herman and NCCC have specific questions.

Diabetes in the Department of Defense (DoD)

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, DoD

Dr. Shell stated that diabetes is a disqualifying condition for entering the U.S. military service. However, hundreds of active duty service members (ADSMs) are diagnosed with diabetes each year. Data from 2008 to 2015 showed that the prevalence of diabetes in male ADSMs was twice as high as in female ADSMs, and the incidence rate increased with age in both gender groups. Compared with Caucasians, African Americans, Hispanics and Latinos, American Indians, Pacific Islanders, and some Asian Americans are at high risk. However, the incidence rates of diabetes in ADSMs markedly reduced from 2010 to 2015 (MSMR. 2017 Jan;24(1):8-11).

Dr. Shell then introduced DoD's policies on and approaches to diabetes management.

Diabetes Quality of Care

Dr. Shell said that screening through the TRICARE program has improved in recent years and is approaching the National Committee for Quality Assurance benchmark.

DoD Policies

Dr. Shell noted that the DoD directives and DoD insurances provide guidance on readiness, health services, and support to members of the Armed Forces. All Service members have access

to education and training on diabetes through the Air Force Diabetes Center of Excellence. Service members diagnosed with diabetes are referred to the Medical Examination Review Board and Physical Examination Board to determine if they can be retained in service.

Veterans Affairs (VA)/DoD Clinical Practice Guideline for the Management of Type 2 Diabetes
Diabetes management in the Military Health System follows the VA/DoD Clinical Practice Guideline for the Management of Type 2 Diabetes Mellitus in Primary Care (Version 5.0—2017). Developed by the VA and DoD Evidence-based Practice Work Group, the guideline provides evidence-based practice guidance to help healthcare providers diagnose and treat diabetes. In addition, it clearly explains the relationships between different care options and health outcomes, rates both the quality of the evidence and the strength of the recommendations, and emphasizes shared decision-making and individualized care.

Questions and Answers

Dr. Boltri asked what diabetes prevention programs are available to active Service members and how the programs may vary by location. Dr. Shell replied that all ADSMs are eligible to receive care, and DoD has different programs including DPP programs. The programs, however, might be delivered in different formats depending on the location. He pointed out that chronic diseases such as diabetes may affect the Service member's deployment.

In response to Dr. Boltri's question about the relationship between VA and DoD, Dr. Shell explained that the VA is not under DoD; however, VA and DoD do work together and share resources. For example, the two agencies have developed the clinical guideline together and are working towards using the same EHR system. The goal is to ensure seamless transition of care for those who are moving from the DoD health system to the VA health system.

In response to Drs. Herman's and Schillinger's questions about DoD's policies and programs on tobacco, Dr. Shell explained that DoD does have tobacco policies. He clarified that tobacco is a legal substance and Service members are free to purchase tobacco for personal use but with some environmental limitations. He mentioned there are some changes in pricing to discourage tobacco use.

The United States Department of Agriculture (USDA): Considerations for Food Supply, Food Choice, Food Policy

Naomi Fukagawa, MD, PhD, Director, Beltsville Human Nutrition Research Center, USDA

Dr. Fukagawa provided an overview of the USDA's organization chart and introduced the agencies and branches within the USDA whose responsibilities and programs are associated with food safety and food policies.

Dr. Fukagawa first introduced the following two centers within the Office of the Under Secretary for Food, Nutrition, and Consumer Services.

Food and Nutrition Service (FNS)
FNS is responsible for the administration of 15 federal nutrition assistance programs. It partners with organizations across the country to provide food for children and low-income families, and their focus is on food security and hunger reduction.

Center for Nutrition Policy and Promotion (CNPP)
The CNPP is responsible for developing and promoting dietary guidance that links research to nutritional needs of consumers.

Dr. Fukagawa then explained the responsibilities and activities of the following branches and agencies under the Office of the Under Secretary for Research, Education, and Economics.

National Agricultural Library (NAL)
NAL is one of the four national libraries, and it houses one of the world's largest collections devoted to agriculture and related sciences.

Economic Research Services (ERS)
The mission of ERS is to anticipate trends and emerging issues in agriculture, food, the environment, and rural America. It conducts economic research and is responsible for ensuring the quality, objectivity, and transparency of the statistical information it provides.

National Agricultural Statistics Service (NASS)
Dr. Fukagawa said that NASS conducts annual surveys and develops reports covering essentially all aspects of U.S. agriculture.

National Institute of Food and Agriculture (NIFA)
Dr. Fukagawa explained that the creation of NIFA was mandated in the Food, Conservation, and Energy Action of 2008 (known as the 2008 U.S. Farm Bill). NIFA is responsible for consolidating all federally funded agricultural research. She pointed out even though NIFA's research is not directly focused on diabetes, all their research could shed light on diabetes prevention and management.

Agriculture Research Service (ARS) and Human Nutrition Research Centers (HNRCs)
Dr. Fukagawa pointed out that unlike NIFA, which supports extramural research through grants, the ARS conducts intramural research. Its mission is to find solutions to agricultural problems affecting Americans. ARS has 6 HNRCs and is responsible for monitoring nutritional health and food composition.

Dr. Fukagawa explained that the FoodData Central is a modern, integrated data system that provides expanded data on nutrient and links to related agricultural and experimental research. Dr. Fukagawa clarified that the USDA Branded Food Products Database is the result of a public-private partnership with the purpose of enhancing public health by sharing data. She noted that many food products are frequently being reformulated, and it is challenging for the USDA to

keep up with testing what all food products contain. Hopefully the databases could help, she said.

The Beltsville HNRC, the oldest of the six centers, has five research laboratories, two of which focus on dietary and nutrition and three of which are basic research oriented. Dr. Fukagawa noted that their Human Studies Facility can handle 60-80 people per day and is a perfect place to collaborate with other investigators on what constitutes a healthy plate.

In summary, Dr. Fukagawa noted that USDA is not directly involved with clinical care management; however, it is involved with ensuring the safety of the U.S. food supply and assists with developing food policies.

Questions and Answers

Dr. Bolen asked about USDA's efforts in addressing food and security and supporting local farmers. Dr. Fukagawa explained that the agencies within the USDA are relatively siloed. Efforts to harmonize the efforts have just began. With respect to food and nutrition, Dr. Fukagawa said there are not enough good data on efficacy, and a lot of reports on efficacy are not subject to accountability.

Dr. Schillinger suggested NCCC invite Dr. Fukagawa to come back and speak more about the Farm Bill, and how it interacts with diabetes. Dr. Fukagawa responded that she would be happy to do so. She added that one of the challenges USDA faces, especially with regard to the Farm Bill, is their programs end with production.

Dr. Schillinger commented that it is difficult to secure funding for feeding-related research. He asked Dr. Fukagawa if USDA collaborates with other agencies on feeding studies with respect to diabetes control. Dr. Fukagawa responded that currently there are no such collaborations. She pointed out that a better way, in her view, is to use USDA's infrastructure and work directly with scientists on such research. She noted that they have been working hard to collaborate with the National Institutes of Health (NIH), DoD, and the Army to increase compacity to conduct long-term metabolic research.

Centers for Medicare and Medicaid Services (CMS)—Focus Upon Diabetes

Barry Marx, MD, FAAP, Director, Office of Clinician Engagement, Center for Clinical Standards and Quality, CMS

Dr. Marx highlighted the following programs.

The Medicare Diabetes Prevention Program (MDPP)

Dr. Marx stated that diabetes affects more 25% of Americans 65 years and older, and the care for these individuals' costs Medicare about $104 billion each year. The MDPP is structured clinical intervention designed to help prevent type 2 diabetes in Medicare beneficiaries with an indication of prediabetes. Through MDPP, Medicare pays organizations, called MDPP suppliers, to provide group-based training to eligible Medical beneficiaries using a Centers for Disease

Control and Prevention (CDC) approved National Diabetes Prevention Program (NDPP) curriculum. The NDPP program was developed based on the results of the DPP study funded by the NIH, which suggest that modest weight loss resulted from lifestyle changes can drastically reduce the development of type 2 diabetes in people at high risk.

Dr. Marx said that the goal of the clinical intervention is to achieve at least 5 percent weight loss in the participants. To qualify as a MDPP supplier, an organization must maintain CDC recognition, follow CDC's quality standards, and remain compliant with specific requirements established by Medicare.

To be eligible for MDPP services, a Medicare beneficiary must meet the following criteria.

- Enrolled in the Original Medicare (Part B) or Medicaid Advantage (Part C).
- Body Mass Index (BMI) of 25 or higher (23 for self-identified Asians) on the day of the first core session.
- Meet 1 of the following 3 blood test requirements within the 12 months before attending the first core session:
    - A hemoglobin A1c test with a value of 5.7-6.4%,
    - Fasting plasma glucose test with a value of 110-125 mg/dl, or
    - Oral glucose tolerance test with a value of 140-199 mg/dl.
- No history of type 1 or type 2 diabetes, with the exception of gestational diabetes.
- No end-stage renal disease.
- Not received MDPP services previously.

To help make the MDPP a success, Dr. Marx encouraged the Commission members and other meeting attendees to take action and learn more about the program by visiting the MDPP website (https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/).

The Quality Payment Program (QPP)

Dr. Marx noted that the QPP is an incentive program implemented by CMS based on the Medicare Access and the Children's Health Insurance Program Reauthorization Act of 2015. The program offers participating clinicians the following two tracks: the Merit-based Incentive Payment System (MIPS) and the Advanced Alternative Payment Models.

The MIPS includes 4 performance categories including quality measures, costs, improvement activities, and promoting interoperability. The 2018 MIPS quality measures related to diabetes care include diabetic foot and ankle care, eye exam, foot exam, and diabetic retinopathy care. The 2018 MIPS improvement activities include engagement with a Quality Innovation Network-Quality Improvement Organization (QIN-QIO), glycemic management services, glycemic screening services, glycemic referring services, and use of certified EHR to capture patient reported outcomes.

Hospital Improvement Innovation Networks (HIINs): Glycemic Management
In 2016, CMS awarded 16 national, regional, and state hospital associations to serve as HIINs. As a key element of the Partnership for Patients (PfP) initiative, the HIINs support 4,000 acute care hospitals with the goals of reducing overall patient harm by 20% and reducing 30-day hospital readmissions by 12% by 2019. The PfP has 11 core areas of focus, and one of them is about adverse events caused by various agents, including hypoglycemics. Dr. Marx highlighted front-line staff engagement as one of the successful interventions regarding HIINs' glycemic management.

Person and Family Engagement (PFE) Strategy
Published in December 2016, the PFE Strategy provides specific, actionable goals and objectives to help more people understand and get involved with person and family engagement. The PFE improvement metrics include patient and family voices, shared decision-making, e-tools, patient activation, health literacy, and medication management.

To improve health equality, the QIN-QIOs provide education and training to educators in multiple languages and offers technical assistance to physician practices. Dr. Marx noted that recent patient activation survey showed significant improvement in diabetes control and management after education.

Questions and Answers
Dr. Ann Bullock expressed her concerns over the eligibility requirements for MDPP (e.g., requirements for the 2nd year reimbursement), which can be difficult for some rural patients affected by food and security issues to meet; as a result, the requirements could limit the number of patients who can access the program. Dr. Marx responded the criteria were developed on the basis of a previous success model, and the purpose is to ensure resources are being properly utilized.

In response to Dr. Bullock's follow-on question on unintended harms that could result from certain eligibility criteria (e.g., hospital readmission requirements), Dr. Marx said that the question is beyond his presentation, and he offered to help get clarifications.

In response to Dr. Bullock's another question about the quality measures for reimbursement, Dr. Marx explained that CMS's quality measures focus on service delivery and individualized care, and the agency emphasizes collaborations between patients, care givers, and clinicians.

Office of Minority Health (OMH) Activities Supporting the Reduction of Diabetes-related Disparities
CAPT David Wong, MD, FAAP, Medical Officer, OMS, Office of the Assistant Secretary for Health, HHS

Dr. Wong started his presentation with a brief overview of the OMH, which was established in 1986 as a direct outcome of the landmark HHS report on health disparities (known as the Heckler Report). Seven other HHS agencies have also established their own minority health-

focused offices or institutions based on the Heckler Report, including CDC, the Agency for Healthcare Research and Quality (AHRQ), the Health Resources and Services (HRSA), CMS, FDA, the Substance Abuse and Mental Health Services Administration, and NIH.

OMH's mission is to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities. Their activities cover a range of health topics, including chronic diseases, infectious diseases, injury, environmental health, and access to care. Given their small staff (31), OMH, however, must prioritize their activities. They currently focus on the following activities.

- Align with HHS strategic goals and initiatives (e.g., opioid epidemic, and sickle cell disease).
- Address underlying factors such as social determinants of health, workforce development, and language access.
- Leverage partnerships to highlight disparities and identify solutions that are effective, scalable, and replicable.

Dr. Wong noted that OMH strives to make a difference using a multipronged approach.

- Award grants and contracts to encourage development of novel paradigms and approaches, identify innovative partners, and transition successful programs to HHS agencies and other partners.
- Curate data for HHS; the federal, state and local governments; and the general public.
- Raise awareness for priority conditions and health disparities affecting minority populations and inform policies.
- Convene meetings involving federal, state, and local agencies; professional societies; non-profit organizations; academia; and patient advocates.
- Build teams and set a common agenda.

Dr. Wong then presented a few examples of OMH activities addressing diabetes.

Screen at 23 Campaign
Dr. Wong noted that studies have shown that Asian Americans are at risk for type 2 diabetes at a lower BMI, and more than 50% of Asian Americans with diabetes are unaware of their status for the disease. ADA, NIH, and CDC all agree that Asian Americans should be screened for diabetes at a BMI of 23. In response, OMH awarded a grant to the National Council of Asian Pacific Islander Physicians to support their Screen at 23 Campaign. To date, 4 states (Hawaii, California, Massachusetts, and Illinois) and the San Francisco County have signed the Screen at 23 resolutions.

State Partnership Initiative
OMH also provided grants to Texas and Nebraska to help address health disparities at their states. The states implemented different programs based on their unique situation. For

example, Nebraska engages community health representatives to develop individualized care plans for diabetic patients of the Omaha and Winnebago tribes using the Pathways Hub model, and creates task forces.

Youth Engagement in Sports
In collaboration with ODPHP, Office of Adolescent Health, and the President's Council on Sports, Fitness, and Nutrition, OMH plans to provide funding in 2019 to support youth engagement in sports. The goal is to improve physical activity and nutrition for 6^{th}-8^{th} graders in minority communities where no or few youth sports programs exist.

OMH Minority Population Profiles
Dr. Wong noted that these profiles provide detailed information (e.g., detailed demographics, health status, insurance coverage, and full census reports) about minority populations.

Healthy People 2020 Disparity Widget
The widget is an online tool that people can use to view up-to-date disparity data. The tool can also be used to stratify data by different disparity types, including race/ethnicity, age, sex, disability, location, income, and education.

At the end of his presentation, Dr. Wong noted that OMH's established partnerships can be leveraged to implement NCCC's recommendations and help eliminate diabetes-related health disparities.

Questions and Answers

In response to Dr. Fukagawa's question about OMH's interactions with other federal agencies such as USDA, Dr. Wong responded they have a group called the Federal Interagency Health Equity Team, which reaches out to different departments, including USDA and DoD.

Dr. Fukagawa asked if OMH offers extramural grants. Dr. Wong responded yes. He explained that the grants generally target specific organizations. He added that they also have grants for advocacy groups working with minority health organizations.

Dr. Herman asked why the 7 agencies Dr. Wong mentioned have minority-focused offices, but others do not. Dr. Wong responded that the creation of many of the minority offices at the 7 agencies was also the direct result of the Hackler Report. Some agencies such as the Indian Health Services do not have a minority office; however, working with minorities is what they do. He added that OMH is trying to collaborate more with the minority offices at other agencies to address various health issues including the opioid crisis.

In response to Dr. Shell's comment on potential interagency collaboration with DoD, Dr. Wong responded that he will reach out to Dr. Shell when opportunity arises.

About HRSA and the Diabetes Quality Improvement Initiative

Aaron Lopata, MD, MPP, Chief Medical Officer, Maternal and Child Health Bureau, Office of the Associate Administrator, HRSA

Tracy Branch, DHSc, CPH, MPAS, PA-C, DFAAPA, Commander, U.S. Public Health Service, Senior Advisor, Strategic Partnerships Division, Office of Quality Improvement, HRSA

Dr. Lopata first provided a brief overview of HRSA. He explained that HRSA supports more than 90 programs and provides services through grants and cooperative agreements to tens of millions of people who are geographically isolated, economically, or medical vulnerable, including people living with HIV/AIDS, pregnant women, mothers and their families, and those otherwise unable to access quality health care.

Dr. Tracy Branch then introduced HRSA-funded health centers that provide services to under-served populations. The Bureau of Primary Health Care (BPHC), one of the 6 HRSA bureaus, administers the Health Center program, and diabetes is a major health problem in the Health Center program. In 2017, there were 2.4 million diabetic patients in the Health Center program, and 33% of these patients experienced uncontrolled diabetes with HbA1c levels greater than 9%. Currently only 4% of HRSA-funded health centers meet the Healthy People 2020 diabetes objective.

Health Center Diabetes Quality Improvement (QI) Initiative

To improve diabetes care quality and reduce healthcare costs, HRSA in 2017 launched the Health Center Diabetes QI Initiative. Facilitated by BPHC, the initiative focuses on diabetes prevention and disease treatment and management, including childhood obesity prevention and treatment, and health disparities.

Dr. Branch noted that the health centers have proved to be cost-effective healthcare delivery facilities. If patients with uncontrolled diabetes could reduce their HbA1c by just 1.25%, there would be an associated cost savings of more than $3 billion over three years.

The QI initiative applies a two-pronged approach to diabetes prevention and management. The first prong focuses on prevention efforts, which require the health centers to increase weight screening and nutritional education for children and adults. The second prong strives to improve the health outcomes of the diabetic patients by improving disease control (HbA1c below 9%) and conducting secondary screening for diabetic complications such as renal and eye diseases and amputation risk.

To help the health centers address challenges associated with diabetes care delivery, HRSA also provides training and technical assistance to the health centers through Primary Care Associations, National Cooperative Agreement Organizations, and Health Center Controlled Networks.

Dr. Branch noted that HRSA-funded health centers have identified many needs to improve quality of care. Of the greatest need are models that can do the following.

- Demonstrate multidisciplinary care team approaches to diabetes management.
- Employ diabetes group visits.
- Integrate technology such as texts, patient portals, video chat, telehealth, and EHR with diabetes clinical decision tools into patient management.
- Provide resources that are scalable to rural/frontier settings, urban/inner-city settings, and other resource-limited clinical settings such as mobile units, public housing, and school-based clinics.

In addition, HRSA also recognizes the risks and costs associated with complicated obstetrics cases and provides health centers free access to the ECRI Institute Clinical Risk Management Program.

Questions and Answers

Dr. Herman asked a question about behavior modification for diabetes prevention, and he wanted to know if HRSA incorporates the NDPP. Dr. Branch responded that each center is different, and the centers determine what program they want to implement on the basis of their own capacity. She said that HRSA has been working with CDC to better understand the criteria for recognition, and they are working towards getting recognized. She acknowledged that the NDPP has not yet been adopted by all facilities at this time.

Dr. Bullock asked about vacancy rates for clinicians at the centers and the potential impact of payment on the care they provide. Dr. Branch responded that the vacancy rate is dependent upon the medical specialty. She noted that workforce development and retention is a huge issue for them, and small-sized centers tend to have trouble with workforce retention. She said that they are aware of and are actively working on addressing the issue.

Overview of AHRQ: Data and Analytics, Evidence Synthesis, and Implementation Science Activities

Howard Tracer, MD, Medical Officer, U.S. Preventive Services Task Force Program, Center for Evidence and Practice Improvement, AHRQ

Dr. Tracer provided an overview of AHRQ's activities and presented a few examples that could be applied to diabetes.

AHRQ's mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable; and to work with HHS and other partners to make sure that the evidence is understood and used.

Dr. Tracer noted that AHRQ strives to make a difference by doing the following.

- Collecting and generating measures and data that can be used to track and improve performance and evaluate progress of the U.S. health system (data and analytics).
- Investing in research and evidence to understand how to make health care safer and better (evidence synthesis).
- Creating materials to teach and train healthcare systems and professionals (implementation).

Dr. Tracer said that their ultimate goal is to help patients.

Data and Analytics
One example of AHRQ's activity in data and analytics is the Healthcare Cost and Utilization Project (HCUP). HCUP includes the largest collection of longitudinal hospital data in the U.S., and the data can be used to answer questions associated with a range of factors, including the following.

- Use of hospital, emergency department, and ambulatory surgery services.
- Expected payer.
- Patient demographics (e.g., age, race/ethnicity, and residence).
- Clinical conditions, comorbidities, and procedures.
- Trends over time in various topics such as hospitalization of diabetic patients in a specific state.

Another AHRQ initiative in data and analytics is the Medical Expenditure Panel Survey (MEPS). Considered the most complete source of data on medical care and costs, MEPS consists of 3 components, including a household component, a medical provider component, and an insurance component. Dr. Tracer pointed out that of the 3 components, the household component is of greatest importance. Because the project is designed to be a national representative, the data can be used to not only show the rise of diabetes and hypertension, but also identify the most prescribed medications.

Evidence Synthesis: The Evidence-based Practice Center Program
AHRQ synthesizes evidence through its Evidence-based Practice Center program. Through the program, AHRQ supports 12 academic/research organizations, provides independent and unbiased synthesis of evidence, and partners with external organizations to promote evidence-based decisions.

Dr. Tracer said one example is the systematic review on diabetic neuropathy. Designed to evaluate benefits and harms of interventions for preventing diabetic peripheral neuropathy (DPN) complications and treatment of DPN symptoms, the systematic review found out the following.

- Intensive glycemic control is not more effective than standard control for preventing foot ulcers, but it does prevent amputations.

- Intensive glycemic control is associated with higher rates of hypoglycemia than standard treatment.
- Home monitoring of foot skin temperature, therapeutic footwear, and integrated foot care are effective for prevention foot ulcers.
- Oral pain medication and spinal cord stimulation are effective for reducing pain but can cause substantial adverse events.

The U.S. Preventive Services Task Force (USPSTF) program is another example of AHRQ's effort in evidence synthesis. The USPSTF is an independent panel of non-federal experts in prevention and evidence-based medicine. Supported by AHRQ, USPSTF makes evidence-based recommendations about clinical preventive services, including screening, counseling, and preventive medications.

Regarding screening for diabetes, the USPSTF recommends the following.

- Screening for abnormal blood glucose as part of cardiovascular risk assessment in adults (40-70 years of age) who are overweight or obese.
- Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthy diet and physical activity.
- Clinicians should offer or refer adults with a BMI of 30 or higher to intensive, multicomponent behavioral interventions.

Implementation Science

Dr. Tracer noted that incorporating evidence-based practices into routine practice takes time and effort. The emerging field of implementation sciences strives to understand how to facilitate and promote the spread of evidence-based practices, which is in alignment with AHRQ's mission. One of AHRQ's efforts in implementation science is promoting shared decision-making, which could be a useful approach for diabetes treatment and management.

Another example in implementation science is the EvidenceNOW initiative, which is designed to help small- and medium-sized primary care practices across the U.S. use the latest evidence to improve the heart health of millions of Americans. While EvidenceNOW focuses on heart health, Dr. Tracer pointed out that its findings are directly relevant to diabetes and other chronic diseases. The goals of the initiative are to help practices implement evidence, and build and disseminate a blueprint of what works. Strategies they use include health IT support, shared learning collaborations, expert consultation, data feedback and benchmarking, and onsite practice facilitation and coaching.

Dr. Tracer said that EvidenceNOW has a collection of more than 100 tools and resources, which are available on www.ahrq.gov/evidencenow/tools.

Commission Discussion

Following the last presentation, Dr. Powell commented that the presentations will help the Commission set a foundation for their work forward.

Dr. David Strogatz commented that it would be helpful if the Commission could obtain more information on the MDPP and the NDPP, especially data on implementation, valuation, and access to the programs.

Dr. Marx offered to help gather MDPP-related information for NCCC.

Dr. Ann Albright clarified that the MDPP is part of the National DPP. She noted that they have real-time data, including health outcome data, and they provide the data through publications. She said that they also work with states and agencies on engagement and retention, and they would be happy to provide more information. She pointed out that to make the program successful, all stakeholders need to be involved in order to improve engagement and retention. She commented that sometimes debate can be less productive, and it might be worthy to address communication challenges associated with implementing nation-wide programs.

Dr. Boltri commented that he is struck by the number of ongoing federal programs that they didn't even know before the meeting, which makes him think how NCCC can help raise awareness of all the available federal programs.

Dr. Shell agreed there are a lot of good information and programs. The question is how to maximize the potential of the existing programs and make the biggest impact.

Dr. Herman noted that the next task for the Commission is to review what the Commission has heard from the federal agencies and then decide what additional information they need to obtain from the agencies. He said that the information will help the Commission to identify common themes among different agency programs, highlight opportunities, and guide future directions. Dr. Boltri agreed.

Dr. Powell suggested the Commission revisit previous framing statements and the grid the subcommittees have been developing. Dr. Herman agreed.

Dr. Powell encouraged the Commission member to listen to the recordings of the meeting to digest all the information provided by the speakers. She added that if necessary, the Commission could invite the agencies to speak more on specific topics in subsequent meetings.

Dr. Bolen wanted to know if there is a way to compile a list of tools (such as the tools for decision-making) from different agencies.

Dr. Herman noted that the Commission discussed about gathering information through a government inventory at the 1st NCCC meeting. He said that after today's meeting, the Commission has a better idea regarding what to ask and what topics to expand.

Dr. Powell said that she will work with Dr. Herman to revise the matrix based on today's presentations and will share the matrix with NCCC members.

Closing Remarks

Designated Federal Officer

At the end of the discussion, Dr. Powell thanked all meeting participants, especially the invited speakers and the public. She said that the meeting materials will be posted on the Commission's website.

Chairperson

Dr. Herman also expressed his gratitude to all presenters and meeting attendees.

Next Meeting

Dr. Powell announced that the next NCCC public meeting will take place on June 27, 2019 in Bethesda, and the subcommittees will conduct a half-day business meeting on June 26 to prepare for the next day's full Commission meeting. Dr. Powell noted that the meetings will be open to the public, and she welcomed the public to register for the meeting.

Adjournment

The meeting was adjourned at 4:57 pm.

Appendix: Commission Members and HHS Support Staff

Commission Members Present for the 2nd NCCC Meeting

Commission Chair

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

Public Members

Shari Bolen, MD, MPH, Associate Division Director of Internal Medicine, Center for Health Care Research and Policy, Case Western Reserve University, Cleveland, OH

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

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

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

Jasmine Gonzalvo, PharmD, BCPS, BC-ADM, CDE, LDE, Clinical Pharmacy Specialist, Primary Care, Midtown Medical, Eskenazi Health, Indianapolis, IN

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

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

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

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

Federal Members

Ann Albright, PhD, RDN, Division Director, Division of Diabetes Translation, Centers for Disease Control and Prevention, Department of Health and Human Services

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

William Chong, MD, Acting Division 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

Leonard Pogach, MD, MBA, Alternate for Paul R. Conlin, MD, Chief, Medical Service, Veterans Affairs Boston Healthcare System, Department of Veterans Affairs

Naomi K. Fukagawa, MD, PhD, Director, Beltsville Human Nutrition Research Center, Department of Agriculture

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

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

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

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

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

CAPT David Wong, MD, FAAP, Medical Officer, Office of Minority Health, Office of Assistant Secretary for Health, Department of Health and Human Services

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

***** Dr. Greenlee was on for part of the meeting as she was on travel status and could only attend in part.

HHS Support Staff in Attendance

Clydette Powell, MD, MPH, FAAP, Designated Federal Officer for the NCCC, Director, Division of Health Care Quality, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Department of Health and Human Services

Commission Members Absent from the 2nd NCCC Meeting

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