National Care Commission Inaugural Meeting

Wednesday, October 31, 2018

8:00 am — 5:00 pm EST

National Institutes of Health Building 35

John Edward Porter Neuroscience Research Center

35 Convent Drive, Bethesda, MD 20892

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Welcome

Clydette Powell, MD, MPH, FAAP, Designated Federal Officer (DFO) for the National Clinical Care Commission (NCCC); Director, Division of Health Care Quality, Office of Disease Prevention and Health Promotion (ODPHP), Office of the Assistant Secretary for Health (OASH), US Department of Health and Human Services (HHS), called the meeting to order at 8:00 am. She welcomed all meeting participants and the public and thanked the Commission members for their willingness to serve. She reviewed the agenda of the meeting and the guidelines that the Commission must follow, and she emphasized the importance of "making sure all voices are heard."

Dr. Powell noted that public comments are welcome and can be submitted through multiple channels, including health.gov. She stated that all materials related to the Commission including meeting materials can be found on the NCCC website (https://health.gov/hcq/national-clinical-care-commission.asp). Dr. Powell pointed out that while written comments from the public may be submitted at any time, oral comments need to be presented on site at the Commission's public meetings. Thirteen members from the public attended the meeting in person, and 61 registered to observe the meeting through a live webcast.

Introduction of the Assistant Secretary for Health

Carter Blakey, Deputy Director, Office of Disease Prevention and Health Promotion, OASH, HHS, introduced ADM Brett Giroir, MD, Assistant Secretary for Health, who leads the development of HHS-wide public health policy recommendations, and oversees the department's key public health initiatives and policies, including three Presidential and 11 Secretarial advisory committees. Ms. Blakey pointed out that as a clinician, Dr. Giroir cared for critically ill children for 14 years, and he continues to bring patient-centered health care to his role as the Assistant Secretary for Health at HHS.

Opening Remarks, Review of the Commission's Charge, and Swearing-in of the Commission

Opening Remarks

Dr. Giroir thanked the Commission members and welcomed all meeting participants. He noted that the Commission is governed by the provisions of the Federal Advisory Committee Act (FACA), and he emphasized that "we are here to work together" to achieve results.

Dr. Giroir stated that the purpose of the Commission is to evaluate and make recommendations to the Secretary and Congress regarding improvements to the coordination and leveraging of programs within HHS and other Federal agencies related to awareness and clinical care for at least one, but not more than two, complex metabolic or autoimmune diseases resulting from issues related to insulin that represent a significant disease burden in the United States, which

may include complications due to such diseases. He noted that the Commission will largely focus on diabetes and other complex metabolic issues related to insulin.

Diabetes affects more than 400 million people worldwide, and the cost is enormous. Reflecting upon his earlier experience of taking care of children with diabetes, Dr. Giroir said that he feels personally connected with patients.

Dr. Giroir explained that his office defines policies for the department, and they are trying to define policies that can transform care. In his view, "value is prevention at the first place." He encouraged the Commission to think of diabetes-related issues holistically and consider all affecting factors including social determinants while making recommendations. He stated that the Commission's report will not be filtered, and he hopes that the Commission's report will reflect public comments.

Review of the Charge of the Commission

Dr. Giroir reviewed the Commission's duties described in the Charter (https://health.gov/hcq/pdfs/2018_OASH_National_Clinical_Care_Commission_Charter.pdf). He stated that by no later than three years after the Commission's first meeting, the Commission shall submit to the Secretary and to Congress a final report containing all the findings and recommendations. He asked the Commission to inform his office if the Commission has important recommendations that need to be considered earlier.

Dr. Giroir then introduced the 23 members of the Commission, including 11 federal members and 12 non-federal public members (see Appendix for the full list of Commission members).

Swearing-in of Non-Federal Members

Following the introduction, Dr. Giroir sworn in the 12 non-federal members of the Commission.

Commission Chair Selection

Led by Dr. Powell, the Commission selected a Chairperson from three non-federal members who expressed interest to serve as the Chair prior to the meeting.

The Commission members selected the Chair through a four-step process.

- Step 1. Members of the Commission read the candidates' bios (available online at https://health.gov/hcq/nccc-members.asp).
- Step 2. The candidates explained their relevant experiences and their vision of leading the Commission.
- Step 3. The candidates answered questions from other Commission members.
- Step 4. The 23 Commission members voted for the Chair.

Candidate Statements

William H. Herman, MD, MPH

Stefan S. Fajans/GlaxoSmithKline Professor of Diabetes, Division of Metabolism, Endocrinology, and Diabetes, University of Michigan

Dr. Herman explained that his interest in serving came from the recognition of an opportunity to make an impact in diabetes prevention and care in the US. He stated that he can bring his wide-range of experiences as a clinician, an epidemiologist, a researcher, and an administrator to the role of the Commission Chair. As an active clinician, he sees patients of all ages from different sectors at different settings; and he understands the barriers to care that patients face. As an epidemiologist, he has worked in public health and focused on health improvement and evidence-based medicine. As an administrator, he has served on numerous committees, including the National Committee for Quality Assurance. As a researcher, he has led and participated in multiple landmark clinical trials, including the Translating Research into Action for Diabetes, the Diabetes Control and Complications Trial (DCCT), and the Diabetes Prevention Program.. In addition, he has experience with the commercial side of the health care. In the past 15 years, he has directed two NIH-funded centers, supporting many researchers in basic biomedical, clinical, and health outcome research.

Q&A

In response to a question regarding the Commission's priorities, Dr. Herman explained that he would like to focus on both prevention and control, and he would also like to see the Commission tackle all the problems and strive to achieve as much as they possibly can.

In response to a question from Dr. Hawkins regarding translating recommendations into actions, Dr. Herman pointed out the following strategies.

- Understand the barriers to translation
- Increase awareness (e.g., more screening) to help with prevention
- Promote lifestyle intervention
- Provide more pharmacological therapies
- Talk to subject matter experts to lay out a comprehensive plan

In response to a question regarding the roles of other groups of health care providers, Dr. Herman replied that diabetes has been the "poster child" for team-based care. In his view, other groups of health care providers, including nurses, educators, dietitians, pharmacists, and others all play a role. Moving forward, it would be helpful to be inclusive, he said.

M. Carol Greenlee, MD, FACP, FACE

Faculty Co-Chair, Center for Medicare and Medicaid Innovation Transforming Clinical Practice for Initiative

Dr. Greenlee explained that as an endocrinologist, her main goal is to help her patients. Her experiences include taking care of patients of all ages in a variety of settings across the country, and having chaired a wide range of national committees. She noted that she wants to make sure everyone's voice is heard. In her view, the biggest gap in diabetes care is care delivery.

Q&A

In response to a question from Dr. Hawkins, Dr. Greenlee further shared her experience with chairing committees. She said that she is on her second term of chairing the American College of Physicians (ACP) Medical Neighbor workgroup, and she is a lead author of the ACP position paper titled "The Patient-centered Medical Home Neighbor." She also has developed and implemented many patient-engagement tools in her own practice, which has made a huge impact to patients. Her experience has helped her to become a faculty member of the Center for Medicare and Medicaid Innovation (CMMI) Transforming Clinical Practice Initiative, through which she teaches clinicians how to better deliver care. Overall, her care for her patients has led her to the improvement of care delivery.

In response to Dr. David Strogatz's question regarding similarities between different settings (e.g., rural vs urban areas), Dr. Greenlee noted that there are similarities between different health care settings, but the differences are mainly in resources. She hopes that the Medical Neighbor Model could help address the issue in various ways.

Dr. Aaron Lopata wanted to know if the Medical Neighbor Model that Dr. Greenlee mentioned addresses social and economic factors.

Dr. Greenlee clarified that the model is mainly about improving communication and collaboration between different teams. It does not directly address factors such as social-economic status, but it does bring all teams together to help patients in different ways. "We need tools, but we also need communication and collaboration," she said.

In response to Dr. Ann Albright's question regarding the role of public health and her experience with diabetes prevention, Dr. Greenlee noted that she believes in prevention; however, to be effective in prevention, we need to help all the stakeholders to recognize their unique roles. She pointed out that care providers, public health, and patients themselves all play a role. In her view, helping patients understand their unique role and giving them the tools they need will help with prevention. In her view, messaging is critical. She noted that she would love to diminish the stigma around diabetes.

J. William (Bill) Cook, MD

Chair, Board of Directors, Ascension Medical Group, Baltimore, MD

Dr. Cook said that as a primary care physician, he spends about 80 percent of his time taking care of patients with diabetes, and he sees more than 100 patients per week. He pointed out the rising risk of pre-diabetes, and said that we need to do something about that. In his view, we now know enough to intervene. He acknowledged that he does not have as much Federal or

national experiences as other two candidates; however, he has significant experience with problem solving, meeting management, and getting consensus.

Q&A

Dr. Gonzalvo asked Dr. Cook his perspective on the role of collaboration with other groups such as nurse practitioners and social workers. Dr. Cook acknowledged that it is a big issue. Collaborating with other groups is embedded in his practice, he said, however, limited resources pose challenges. He said that we need to do better with translating knowledge into implementation.

The committee members then asked all three candidates the following questions.

Dr. Donald Shell asked the candidates to share their relevant experiences at the Federal level.

Dr. Cook answered that studies have suggested that about 20% of persons' health is related to their experience with heath care providers in the medical field. He pointed out the importance of teaching, informing, and giving patients the resources they need.

Dr. Greenlee shared a similar view. She noted that what clinicians can do to is limited. Helping people recognize their role, educating them, helping them have their voices heard, and providing resources to the community are all important. She said that she could envision the Federal agencies work together and come up with a more consolidated approach.

Dr. Herman said that he has some experience at the Federal level as a commissioned officer at CDC's diabetes division. He too has noticed the five tasks the Commission is given are related to Federal agencies. He pointed out that the Federal government is the final decision maker regarding payment, which affects diabetes care. He pointed out that if we can impact Federal agencies' polices, we can impact the care in the whole country.

Dr. Dean Schillinger pointed out that the Commission's tasks will reach across various agencies, and the Commission needs to think of diabetes as a social/societal issue, not just a medical issue. He wanted to know the candidates' comfort levels with and interest in engaging government agencies.

Dr. Herman agreed that obesity and type 2 diabetes are societal, not just medical issues. As a Commission, he said, we can appoint committees to seek information from all agencies. And it is critical for the Commission to do so, he added.

Dr. Greenlee agreed it is important. She said she would embrace the idea.

Dr. Cook said it should be at the center of what the Commission is to do, and the Commission needs to spread the concept to the whole country.

Dr. Ann Bullock wanted to know how the Commission would address the cause(s) of type 2 diabetes. She commented that for type 2 diabetes, there are many affecting factors such as environment and poverty.

Dr. Greenlee said that she does not have an answer. She agreed that it is critical, and she emphasized that that's why she thinks the Commission needs remain open minded and hear all voices.

Dr. Herman agreed with Dr. Bullock and said that we need to take a broad approach to address all the critical issues.

Dr. Cook said that at the end of three years, we may not be able to solve poverty; but the Commission could present the concept that if we don't solve issues related to poverty, we won't be as successful.

Voting Result

All 23 Commission members casted a vote following the discussion. Based on the voting result, Dr. Powell announced that Dr. Herman has been elected as the Chair of the Commission, who will serve as the Chair for three years.

Current Activities in Diabetes by Federal Partners

The National Action Plan for Adverse Drug Event Prevention: Federal Activities in Diabetes

Dr. Powell provided a brief overview of the *National Action Plan for Adverse Drug Event (ADE) Prevention*. Based on the national ADE data from both inpatient and outpatient settings, three types of ADEs (anticoagulants, diabetes agents, and opioids) were considered common, clinically significant, preventable, and measurable; and therefore selected as the high-priority targets of the ADE Action Plan. For diabetes agents, the primary ADE of concern is hypoglycemia.

She noted that older adults are particularly vulnerable to hypoglycemia, and overtreatment is a significant contributing factor in this patient population. Despite the availability of newer diabetes medications such as DPP-4 inhibitors and GLP-1 agonists, hypoglycemia remains a significant concern.

She described how the national action plan was developed and the four-pronged approach it takes to reduce harms caused by the adverse events:

- Surveillance and data collection
- Evidence-based prevention tools
- Incentives and oversight
- research and unanswered questions

She pointed out that tools are needed at each step. She said that the ADE Action Plan recognizes how Health IT can support progress in each of these areas, and that ODPHP partners with several agencies in order to tackle the four-pronged approach of the ADE Action Plan.

In June 2017, HHS approved six national measures to track the reduction of ADEs and set a reduction target for each measure (https://health.gov/hcq/ade-measures.asp). National targets and measures are in alignment with other departments' measures.

"The first step to address hypoglycemia is to raise awareness about the problem. Patients, families, and clinicians all need to be aware that hypoglycemia is a significant yet preventable harm that affects many patients with diabetes," she said.

She noted that online training is available. ODPHP provides tools to help facilitate shared decision making and offers online continuing medical education (CME) that teaches principles of health literacy and shared decision making. The Action Plan can be freely accessed through https://health.gov/hcq/ade-action-plan.asp

Dr. Powell pointed out that all the agency partners of the ODPHP, including the US Department of Veterans Affairs (VA), the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), the Indian Health Service (IHS), the Federal Bureau of Prisons (BoP), the Defense Health Agency (DHA), the Health Resources and Services Administration (HRSA), and the National Institutes of Health (NIH), have some types of evidence-based tools and programs to help reduce ADEs.

She noted that today we'll hear presentations from CDC, IHS, VA, and NIH, and that representatives from other agencies and departments will present at the next meeting.

Overview: CDC's Division of Diabetes Translation

Ann Albright, PhD, RDN, Director, Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention

Dr. Albright briefly reviewed the Division of Diabetes Translation (DDT) organizational chart and what they are responsible for. She noted that they collaborate internally and externally, and their goal is to make science real to people.

She then introduced DDT's 2017-2021 strategic plan and its goals.

Goal 1: Prevent or delay type 2 diabetes

She noted that we need to understand the causes and affecting factors (e.g., social, economic, and environmental), and she briefly reviewed a few programs and studies funded by CDC and what they have achieve so far.

Dr. Albright highlighted the National Diabetes Prevention Program (DPP), which is the largest national effort to mobilize and bring an effective lifestyle change program to communities across the country. It is moving to reality.

She explained how the program works and CDC's strategies for meeting their goals, including

- Raising awareness
- Increasing engagement
- Increasing referrals
- Getting payer coverage

She said that the goal is to achieve all-payer coverage for the DPP.

Goal 2: Prevent complications and disability

Dr. Albright reviewed the following studies and services.

- SEARCH for Diabetes in Youth Study,
- Diabetes Self-Management Education and Support Services
- Chronic Kidney Disease (CKD) initiative
- Vision Health Initiative

The goal is to intervene early, she said.

Goal 3: Reduce differences in health that impact people affected by diabetes

Dr. Albright introduced multiple studies and projects, including the LEAD Study, which is to better understand the pathways through which environmental or socioeconomic circumstance have their greatest influence on a community's exposure to type 2 diabetes.

She noted that we need to understand not only the characters but also mechanisms and pathways.

Other studies and programs supported by CDC in this effort include

- Appalachian Diabetes Control and Translation Project;
- Good Health and Wellness in Indian Country;
- Public Health Actions in the US Affiliated Pacific Islands, Virgin Islands, and Puerto Rio;
- Scaling the National DPP in Under-served Areas and Populations.

Goal 4: Maximize organizational capability to achieve DDT goals

More information about DDT's activities is available at http://cdc.gov/diabetes, and https://nationaldppcsc.cdc.gov.

Diabetes and the Indian Health Service

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

Dr. Bullock provided a brief overview of the history and activities of the Indian Health Service (IHS), a HHS agency serving members of 573 federally-recognized Tribes in 36 states, including 2.3 million American Indians and Alaska Natives (AI/AN). She then highlighted the improvements they have made.

The 2017 CDC National Diabetes Statistics Report shows that the prevalence of diabetes in the AI/AN population is decreasing in recent years compared with other groups. She noted that the prevalence of type 2 diabetes was increasing in AI/ANs a few decades ago. In response, the IHS established a National Diabetes Program in 1979. This later became the Division of Diabetes Treatment and Prevention (DDTP). The IHS developed IHS Diabetes Standards of Care and started the Diabetes Care and Outcomes Audit in 1986, and began promoting comprehensive approaches to diabetes care.

The DDTP provides tools, training, and culturally-appropriate patient educational materials and online resources. They also collect and provide diabetes-related data, including diabetes care and outcomes audit and prevalence estimates.

For them, adapting national tools is important. For example, they modified the USDA's MyPlate into "My Native Plate" and provided more ideas that are appropriate to the people. They also use a screening tool to help address issues associated with food insecurity.

Message is common, Dr. Bullock said, but images and educational materials need to be modified to encourage behavior change.

Special Diabetes Program for Indians (SDPI)

Established by Congress in 1997 in response to the diabetes epidemic among American Indians and Alaska Natives, SDPI provides funding for diabetes treatment and prevention to IHS, Tribal, and Urban Indian health programs across the US. Dr. Bullock said that local communities determine their priorities based on their own situations, and she thinks it is critical to their success. "Without resources to implement, knowledge alone is not enough," Dr. Bullock said.

In summary, Dr. Bullock noted that the prevalence of diabetes in AI/AN adults remains the highest among all US racial and ethnic groups; however, significant progress has been achieved in reducing diabetes complications and managing diabetes prevalence and childhood obesity.

She attributed the success to honoring the culture, keeping the people engaged, and working with the community. Compared with other populations, the AI/ANs have made the most progress, she said.

Discussion

Dr. Marx thanked the agencies for their work. He commented that great progress can be achieved by engaging with community and public health. He said that studies have shown that hypoglycemia is an important problem, and there are also a lot of other important factors such as food insecurity.

In response to a question from Dr. Gonzalvo, Dr. Bullock clarified that they used two types of models to deliver the care: The Community Health Aids Program, which brings primary care to local communities; and the Community Representative Program, through which the community health representatives serve as a link between the clinical setting and the community. She clarified that the curriculum for Community Health Aids Program is standardized and will be expanded. She pointed out that reimbursement is critical.

Dr. Conlin shared that VA is also heavily investing in virtual health care. He wanted to know possible ways of breaking down barriers so that care can be provided across state lines.

Dr. Albright agreed that this needs to happen. She said that they have some successful examples, and they need to show policy makers that it can be safely and effectively done with proper standards.

In response to Dr. Greenlee's question regarding childhood diabetes and causes, Dr. Bullock acknowledged that it is a complex issue. She said that the history of cultural and other types of trauma has caused issues for the children. They are trying to find a way to appropriately screen for factors affecting the children without re-traumatizing them.

Ms. Leake asked Dr. Bullock to share experience with successfully getting patients use technology for self-management.

Dr. Bullock noted that their populations seem less prone to type 1 diabetes. For type 2 diabetes, they do not charge patients for their care. For them it is about prioritizing. Many decisions are made at the local level. In her view, it is all about resources.

Public Comments

Five public members provided oral comments at the meeting.

Cynthia Rice

Ms. Rice, senior vice president for Advocacy and Policy at the Juvenile Diabetes Research Foundation (JDRF), provided public comment on behalf of JDRF. Type 1 diabetes, an autoimmune disease, can be diagnosed at any age, and it lasts a lifetime, she said. She highlighted three areas that JDRF considers important.

- Innovation: Maintaining a strong federal commitment to research in insulin-related diseases should be a priority.

- Access: Clear pathways for FDA approval and coverage at CMS are needed to improve patient access to treatment and care.
- Outcomes: Utilizing a range of meaningful outcomes, not just average glucose, when making healthcare decisions.

Joan Bardsley

Ms. Bardsley spoke on behalf the American Association of Diabetes Educators (AADE), a multi-disciplinary association of healthcare professionals representing 14,000 professional members including nurses, dietitians, pharmacists, exercise specialists, and others. She encouraged the Commission to support innovation to improve the current care delivery models, and put people with diabetes at the center of decision-making.

Ms. Bardsley pointed out the need for an integrated approach to diabetes prevention, treatment, and management, including self-management; and she encouraged the Commission to leverage technology and all available tools to improve care for people with diabetes.

She thanked the Commission members for their time and willingness to serve, and she noted that AADE is ready to support the Commission in their efforts over the course of the next three years.

Leyla Mansour-Cole

Ms. Mansour-Cole spoke on behalf of the Diabetes Advocacy Alliance (DAA), a coalition of 24 member organizations dedicated to changing how diabetes is viewed and treated in the US. She expressed DAA's readiness to support the Commission, and she urged the Commission to review the written comments submitted by DAA.

She recommended the Commission focus on the following areas.

- Increase access, coverage, and participation in the CDC's National Diabetes Prevention Program and Medicare Diabetes Prevention Program
- Support a consistent interpretation of the US Preventive Services Task Force's recommendation on screening for abnormal blood glucose and type 2 diabetes mellitus
- Increase participation in diabetes self-management education and support (DSMES, also known as DSMT in Medicare) programs

Given that the benefit is severely underutilized by Medicare beneficiaries, she said that the DAA recommends the Commission address barriers to accessing DSMT.

Emily Fitts

Ms. Fitts, senior manager, Advocacy and Policy at the diaTribe Foundation, provided an added-on comment. She urged the Commission to seek input, facilitate engagement, and interact with people with diabetes each step of the way. She recommended the Commission critically exam the role of outcomes beyond A1c that better capture the experience of people living with

diabetes. She asked the Commission to address issues associated with access to care, social determinants of diabetes, and prevention. She welcomed the Commission to reach out to the diaTribe Foundation at any point.

Krista Maier

Ms. Maier of the American Diabetes Association emphasized the immense burden of diabetes. She urged the Commission to bring all stakeholders together to address the disparities and stigma, and to remove the barriers. She is looking forward to working together with the Commission.

Dr. Powell asked Ms. Fitts and Ms. Maier to submit their comments electronically through the NCCC website.

In response to a question from a Commission member, Dr. Powell clarified that written comments can be submitted at any time via email (OHQ@hhs.gov), but oral comments need to be presented on site.

Current Activities in Diabetes by Federal Partners

Overview of NIH Diabetes Research

Barbara Linder, MD, PhD, Senior Advisor, Childhood Diabetes Research, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH

Dr. Linder started her presentation by stating that the NIH's mission is "to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability." She noted that diabetes research at NIH is collaborative.

Dr. Linder pointed out that a large portion of NIDDK's funding supports investigator-initiated research, and another large part is devoted to initiatives addressing gaps or understudied areas.

Research highlights

Dr. Linder provided a list of research on type 1 and type 2 diabetes. She highlighted the Glycemia Reduction Approaches in Diabetes (GRADE) study as a great example of comparative effectiveness research in type 2 diabetes. It is a randomized study and the goal is to understand the optimal 2nd-line therapy after metformin. The study also investigates patient-reported outcomes, which will help with personalized treatment and care. It also pays attention to recruitment of minorities so the study can reflect real world. She noted that two studies funded by NIDDK showed that type 2 diabetes can cause more harm to young adults.

For research on type 1 diabetes, Dr. Linder highlighted the Human Islet Research Network (HiRN), which was established in 2014 to help organize and support collaborative research

related to the loss of functional beta cell mass in type 1 diabetes. HiRN focuses on molecular biology, and consists of five independent research initiatives.

Dr. Linder also gave two examples to illustrate how the agency strives to translate research results into the real world.

The Diabetes Prevention Program (DPP) has shown that people who are at high risk for type 2 diabetes can prevent or delay the disease through lifestyle changes (e.g., maintaining a healthy weight and increasing physical activities) or metformin. Based on the success of the program, NIDDK has supported proposals on how to implement the program (or revised version of the program) to larger populations. Other organizations have adopted this model as well.

The Diabetes Control and Complications Trial (DCCT) has shown that keeping blood glucose levels close to normal could greatly reduce the risks of heart, kidney, eye, and nerve diseases. The Epidemiology of Diabetes Interventions and Complications (EDIC) study, a follow-up to the DCCT, has shown benefits of early and intensive blood glucose control. Results of the DCCT/EDIC study have changed the way that type 1 diabetes is treated. As a result of the DCCT/EDIC study, early and intensive blood glucose control is now a standard treatment for type 1 and type 2 diabetes.

New technologies for treating type 1 diabetes.

In addition to the studies funded by NIDDK, Dr. Linder said that the agency has also funded the early development of new technologies.

She noted that there are many opportunities in diabetes a such as gestational diabetes. The incidence of gestational diabetes is increasing and it has metabolic imprint. However, we do not know what is the best way to diagnose, and when is a good time to treat. “We need to understand the mechanisms so we can develop better prevention and treatment programs,” she said.

Other gaps and research opportunities include type 2 diabetes in children and young adults, health disparities, and evidence-based therapy for the elderly.

VA-DoD Clinical Practice Guidelines and Hypoglycemia Safety Initiative

Paul R. Conlin, MD, Chief, Medical Service, Veterans Affairs Boston Healthcare System; Professor of Medicine, Harvard Medical School

2017 VA-DoD Clinical Practice Guidelines (CPG)

Dr. Conlin highlighted the following key recommendations from the 2017 VA and DoD Clinical Practice Guidelines (CPG) for Diabetes. He noted that the full 25 recommendations are available online (https://www.healthquality.va.gov/guidelines/CD/diabetes/).

- Using shared decision making to enhance patient knowledge and engagement

- Interpreting A1c result in the context of the patient's characteristics and lab variability
- Developing an individualized treatment plan using target A1c ranges
- Choosing medications based on evidence-based efficacy, adverse events, and comorbidities
- Patients should be engaged in the decision making

Dr. Conlin summarized that the VA-DoD CPG offers evidence-based recommendations while considering the patient's individual needs and unique goals of care. He pointed out some of the main differences between VA-DoD CPGs and other CPGs. He noted that the VA-DoD CPG balances benefits and risks, and believe that the patient's preferences are important.

Hypoglycemia Safety Initiative

Dr. Conlin noted that the VA-DoD recommendations limit the use of treatments of low value. Regarding hypoglycemia safety, he pointed out that a wide range of factors can put patients at a higher risk, including A1c, insulin, age, cognitive impairment, decreased renal function, low health literacy, and food insecurity.

Dr. Conlin pointed out that overtreatment remains a concern and many clinicians need tools to help with decision making. According to Dr. Conlin, VA has developed a tool box to help clinicians make decisions, which include multi-disciplinary education, EHR tools, and online panel reports. Preliminary results of the Hypoglycemia Safety Initiative showed that significant progress has been made with significantly decreased hypoglycemia in a high-risk cohort and de-intensified therapies.

He noted that patient-directed videos can be used effectively to provide patient education. He then pointed out, through a short video, that low blood sugar can be dangerous but can be managed, and many options exist. Given that everyone is different, the best options may differ from person to person. It is a shared decision making process between the patient and the healthcare team.

In closing, Dr. Conlin noted that their mission is to help clinicians create individualized treatment plans that are

- Safe and effective;
- Accommodate patients' goals, priorities, and lifestyles; and
- Make it easier for patients to successfully manage diabetes and achieve optimal health.

Discussion

Following Drs. Linder's and Conlin's presentations, the Commission members asked the speakers numerous questions related to the presentations.

Dr. Marx thanked Dr. Conlin for reviewing the guidelines. He pointed out that A1c levels in certain ethnic groups may be falsely elevated. He asked Dr. Conlin to elaborate how the

Commission should approach the measurement-related issue, and how clinicians can diagnose and treat patients properly without labeling them.

Dr. Conlin noted that the topic is worth the Commission's discussion. It's important for clinicians to know there are racial differences. Meanwhile, A1c variations also exist between different measurements, and we can't make decisions based on a single value.

Dr. Albright acknowledged that it is a real yet complex issue, and it will affect how we conduct surveillance. She said that at CDC they are trying to figure out how to improve the use of health system-related data (e.g., EHR) in surveillance.

Dr. Herman commented on the VA diagnostic ranges. In his view, A1c in conjunction with glucose monitoring and patient self-monitoring can help with diabetes management. He pointed out the importance of recognizing the fact that A1c alone is not a perfect measure.

Dr. Linder shared that there should be data coming out soon from the GRADE study comparing A1c and CMG data, which could help the Commissiondo more sophisticated work.

Dr. Dokun cautioned that we need to be careful so clinicians do not miss at-risk patients based on race.

Dr. Cook noted that payers need to understand that the target measurement needs to make sense so that they do not ask health care providers to do something that may not be good for everybody.

Regarding target A1c level, Dr. Hawkins commented that many providers seem to operate under fear.

Dr. Conlin agreed. He noted that it is a mixture of external pressure, and the issue needs to be dealt with in a delicate way that factors in racial and individual differences.

Dr. Idzik liked the idea of target ranges and acknowledged that challenges exist.

In response to Dr. Dokun's question on gestational diabetes, Dr. Linder noted that we need further study to figure out when to intervene. She shared with the Commission that a NIDDK study tries to benchmark to get a better sense of glucose during pregnancy.

Regarding hypoglycemia, Dr. Albright noted that we need more data.

NCCC Discussion on Focus Topics, Subcommittee Formation

Led by Dr. Herman, newly elected NCCC Chair, the Commission members discussed potential areas that the Commission should focus on.

Focus Topics

Dr. Herman reminded the Commission members to keep the Charter in mind while thinking of focus topics. Dr. Powell suggested that the topics should not be too broad nor too deep, and clarified that there will be supporting teams to assist the Commission with their activities. The Commission members discussed a range of important topics.

Goals and actionable areas

Dr. Shell ask the Commission members to think about the end goal. For example, what do we want to achieve at the end of the term, and what do we want the reader to achieve by reading our final report?

Dr. Shari Bolen noted that it would be helpful to take a broad-brush stroke and look at each agency's activities. However, the Commission also needs to prioritize and "move the needle."

Dr. Albright suggested identifying drivers and gaps. In the final report, the Commission should recommend how things can be better outside the agencies. To achieve the goal, the Commission needs to identify actionable areas.

Potential topics of focus

Dr. Fukagawa noted that we don't want people to be afraid of food, and that we should work together to change the message. Dr. Greenlee pointed out the patient's role in diabetes management. She said that the care team needs tools to help patients better understand their roles.

Dr. Conlin proposed a list of random topics based on what he has heard from the presentations and discussion.

- Quality of care
- Adverse drug events
- How to identify patients at risk
- Evaluating social determinants of health
- Food insecurity
- Ensuring care is delivered the best way regardless of the setting
- Improving messaging
- Ensuring clinical delivery and measure based on performance
- Aligning financial incentives with patients

Other Commission members added additional topics.

- Education
- Accessibility to available programs
- Accessibility to care
- Prevention

- Gaps

Dr. Gonzalvo mentioned the Congressional Diabetes Caucus. She said that knowing what is coming out of there would be helpful.

Dr. Powell agreed that it is worth knowing. She clarified that it should be fine if the Commission just wants to be informed.

Action items:

- Dr. Powell will find out more about the activities of the Congressional Diabetes Caucus.

Mechanisms of information gathering

Dr. Herman commented that the Commission needs to know what the agencies are doing first before they can highlight actionable areas and make recommendations.

Dr. Hawkins suggested the Commission put together a list of important questions, and then ask for information from the agencies.

Dr. Powell clarified that the ex officio members of the Commission can speak for their agencies.

Template

Dr. Albright noted that a standard template would be helpful for gathering meaningful information from the agencies, and they need a framework to operate from.

Dr. Powell reminded the committee to think about how much detail they want to get. She suggested the Commission consider "the order of magnitude of funding, and trends of funding" in the template.

The Commission members then discussed the types of questions they need to ask, and how to ask them. The general consensus was that the template should be simple yet consist of well-phrased questions with a balanced granularity (enough but not too much) so the Commission can obtain meaningful information.

Questions to ask

Dr. Lopata commented that the first three duties described in the Charter seem to ask the Commission to evaluate agency programs. Having a list of the programs would be critical for the Commission to identify gaps and overlaps, and start to evaluate. He added that the Commission also needs to know what the USDA is doing.

Dr. Dokun noted that it is important for the Commission to know what programs are important or effective. When gathering information from the agencies, the Commission needs to ask what programs are effective or working, not just what programs they have. Other Commission members agreed.

Commission members noted that they would need the following information.

- Programs and policies
- What are working and what are not working
- Priority areas
- Limitations
- Underutilized resources

Dr. Powell commented on the idea of understanding what's working what's not working. She pointed out the charter does mention dissemination, and it can be connected to health promotion.

Dr. Marx asked how to a consensus on the list of what's working or not working?

Dr. Herman suggested asking the agencies what they think is working first, and the Commission can then drill down afterward.

How to ask the questions

Dr. Shell pointed out that how the questions are asked will affect the responses. Dr. Albright suggested they need to clarify the term "program" because it may be interpreted differently by different agencies.

Dr. Powell added that certain information could be obtained through conference calls, and that her office can help facilitate the calls.

The Commission further discussed the logistics of gathering information. The general consensus was to talk to agencies to set a framework first, conduct high-level data calls next, and obtain more information through conversations/conference calls last.

Timeline

Ms. Leake suggested the Commission perhaps should develop a timeline.

Subcommittee Formation

Referring to Dr. Conlin's primary list of items, Dr. Gonzalvo suggested the Commission should set up parallel tracks to address the topics.

Dr. Herman proposed a preliminary list of six topics for the Commission to pick to form subcommittees. Based on the Commission members' choices, the topic on complications was combined with treatment.

- Social determinants of health
- Education
- Prevention

- Treatment
- Complications
- Health policy

In response to a question regarding overlaps among the topics, Dr. Powell clarified that this is just the first step to get the work started, and that the Commission can define and refine the topics along the way.

Action Items:

- Drs. Herman and Powell will share the list of topics with all Commission members and find out if the members want to switch subcommittees.

Dr. Powell suggested that subcommittee members think and pick a lead, and the Commission chair and subcommittee leads can decide together how to move forward.

Next Steps

90-day Operating Plan

To meet the 90-operating plan described in the Charter, Dr. Powell suggested within the first month the Commission should form the subcommittees, select subcommittee chairs, decide how often they want to meet, identify goals, figure out a budget, and perhaps clarify their deliverables.

In response to questions from the Commission members regarding budget, Dr. Powell clarified that the Commission is not asked to do original research, but they do need to work out a plan on how they are going to carry out their activities. Resources outside of the Commission (e.g., resources from Commission members' own agencies or institutions) should be used with caution and will be evaluated case by case. She asked the members to check with the DFO first.

Dr. Gonzalvo suggested each subcommittee share its summary of activities with all members of the Commission.

SharePoint Introduction

Dr. Powell explained that they have asked a contractor to provide information about SharePoint, which the Commission will use to communicate and collaborate. She then showed what the Commission can do through SharePoint.

Dr. Herman suggested using both SharePoint and email for communication.

NCCC Meeting #2:

Dr. Herman expressed his concern about the 90-day operating plan requirement. He wanted to know if they could schedule something soon so that they can begin working.

Action Items

- Dr. Powell asked the Commission members to
  - Recommend subject matter experts to help provide guidance, and her office will arrange time for them to present.
  - Send her any suggestions on improving the work.
- Dr. Powell will
  - Gather all Commission members' email addresses and share with every member within a week.
  - Check with the Commission members via email to determine a best time for the Commission members to meet.

Closing Remarks

Dr. Herman thanked all the Commission members and encouraged them to keep the momentum to move forward.

Adjournment

The meeting was adjourned at 5:00 pm.

Appendix: Committee Members and HHS Support Staff

Committee Members Present for the Inaugural Meeting

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

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

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

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

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

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, US 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

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

Carter Blakey, Deputy Director, Office of Disease Prevention and Health Promotion; Director, Division of Community Strategies, Department of Health and Human Services

Joyce Yu, Pharm D, ORISE fellow, 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

Holly H. McPeak, MS, Nutrition Advisor, Division of Prevention Sciences, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Department of Health and Human Services

Pamela Kurland, JD, Senior Attorney, Public Health Division, Public Health and Science Branch, Office of the General Counsel, United States Department of Health and Human Service