

**U.S. Department of Health and Human Services  
Office of Disease Prevention and Health Promotion**

**Partnering To Prevent Hypoglycemia:  
A Listening Session**

**Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC  
November 1, 2017**

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On November 1, 2017, the Office of Disease Prevention and Health Promotion (ODPHP) convened, in Washington, D.C., a meeting focused on the public health importance of reducing the incidence of hypoglycemia. The meeting served to describe Federal and organizational efforts to reduce hypoglycemia resulting from agents used in diabetes treatment and to present experiences of patients and patient advocates. It featured presentations by Federal partners, non-Federal partners, patients/families affected by diabetes and hypoglycemia, and patient advocates. Clydette Powell, M.D., M.P.H., FAAP, served as the meeting host.

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## ABBREVIATIONS

A1c – hemoglobin A1c  
ADA – American Diabetes Association  
ADE – adverse drug event  
AHRQ – Agency for Healthcare Research and Quality  
CGM – continuous glucose monitoring  
FDA – U.S. Food and Drug Administration  
HHS – U.S. Department of Health and Human Services  
ODPHP - Office of Disease Prevention and Health Promotion  
VHA – Veterans Health Administration

## **Welcome and Introduction**

**Clydette Powell, M.D., M.P.H., FAAP, Director, Division of Health Care Quality, ODPHP**

Dr. Powell welcomed the attendees. She presented the meeting's agenda, noting that the presentations would begin at a high level, with discussion of Federal policies and concerns about hypoglycemia, followed by discussion of efforts in the interface between Federal and non-Federal partners at the community level. This meeting would represent the first in a number of ODPHP listening sessions. Dr. Powell introduced the first two speakers.

## **Hypoglycemia as a Public Health Concern**

**Don Wright, M.D., M.P.H., Acting Assistant Secretary for Health and Director, ODPHP**

Dr. Wright stated that the ODPHP is one of 11 core public offices within the Office of Assistant Secretary for Health in the U.S. Department of Health and Human Services (HHS). The ODPHP features a significant focus on the problem of adverse drug events (ADEs), through the National Action Plan for ADE Prevention. Other ODPHP efforts include the National Action Plan To Prevent Healthcare-Associated Infections, dietary guidelines, physical activity guidelines, the Healthy People initiative, and Health Finder. The Office collaborates with partners nationally to develop intervention strategies.

ADEs are a significant health problem, and they occur in many health care settings, especially during transitions of care. The annual numbers of occurrence reach into the millions, and the cost is high. ADEs lead to emergency department visits and hospital visits. Many go unreported. The problem requires us to seek coordination regarding medication safety and to advance data collection and surveillance. The National Action Plan has addressed causes and has developed a plan to reduce harms. It seeks to disseminate tools that address the different levels of the problem. The regulatory agencies are exploring ways to incorporate ADE effects in payment models and quality measures. The Diabetes Federal Interagency Workgroup has been targeting hypoglycemia, partnering across HHS in promotional efforts and creating measures to track progress. The HHS goal of reducing ADEs by 10 percent by 2020 will require coordination among Federal agencies and private stakeholders.

**LaShawn McIver, M.D., M.P.H., Senior Vice President, Government Affairs and Advocacy, American Diabetes Association (ADA)**

Dr. McIver expressed the ADA's recognition of the importance of the issue of hypoglycemia. The ADA is the largest voluntary health association targeting all people with diabetes and seeking to improve their lives. It funds research and leverages digital platforms to drive discovery. It mobilizes action and engagement and seeks ways to increase urgency. It supports people with diabetes, for example, by seeking to increase the use of tools and resources. Dr. McIver stated that nearly 50 percent of Americans have diabetes or pre-diabetes. This includes 30 million children. Diabetes is the 7th leading cause of death in the Nation. It is associated with

blindness, heart disease, kidney disease, and stroke. The use of diabetic agents, such as insulin, can lead to hypoglycemia.

The ADA brings a voice to persons with diabetes. It publishes a consumer magazine, *Diabetes Forecast*, in which people share their experiences, including life-threatening events. Dr. McIver offered some examples related to hypoglycemia. The ADA addresses issues such as health insurance access, mental health issues, legal advocacy (as in supporting job participation), and tools/resources.

In discussion, a meeting attendee raised the idea of a strong consideration of diabetes treatment and understanding as an important investment for the Nation. Another attendee stated that we need health insurance policies that support the application of new tools. Dr. Wright stressed that all citizens can be advocates.

## **Patient Perspective Panel: Hearing the Patient**

### **Lorraine Stiehl, Business and Nonprofit Management Consultant, StiehlWorks**

Ms. Stiehl, a long-time patient advocate, presented a “big picture” of the issue of hypoglycemia, including its effects on patients and families. She focused on her husband’s journey with diabetes and its complications from a young age and on treatment advances that have occurred more recently. Hypoglycemia remains the main worry, and avoiding it is a constant battle. Ms. Stiehl wrote a book for people who care for partners with diabetes.

Most hypoglycemia episodes occur at night. New drugs and technology have been helping to battle it. The glucagon kit is important; yet people have difficulty with its method of mixing the insoluble glucagon and injecting it. An easier method is needed. In addition, most nocturnal hypoglycemic events are nonsymptomatic. There was a time years ago, when older and intensive Type 1 diabetes patients might suffer 10 episodes in a week. That number has been lowered a great deal. Yet we need better drugs and technology to reduce the risk further.

Ms. Stiehl suggested that use of the measurement of A1c in the blood is problematic. Time and range measures are more helpful. New technologies for continuous glucose monitoring (CGM) have been of great benefit. Medicare now covers CGM but does not support the use of a shared device for CGM.

### **Chris Stiehl, Business and Nonprofit Management Consultant, StiehlWorks**

Mr. Stiehl, who has had Type 1 diabetes since age 10 and now is 67, offered some of his experiences. He marveled at the ability of new technology to allow him to share his monitored blood sugar levels with his wife around the world. The average age of mortality for Type 1 diabetics has increased substantially. Years ago, Mr. Stiehl noted, many people with diabetes did not have a deep understanding of the disease. He has since tried to address that lack by engaging in educational, supportive, and promotional activities.

Mr. Stiehl has experienced many episodes of hypoglycemia. He stressed that a person with Type 1 diabetes must think constantly about how much insulin is in the body and how long it will last there. The patient must consider physical activity, ingested food, stress, anxiety, insulin, and illness. Hypoglycemia is characterized by an intense desire for food, even a desperation. Mr. Stiehl provided examples from his past in which health care workers attempted to take unwise actions in response to his blood sugar condition. He suggested that we need better training of health care professionals who treat diabetes. He encouraged diabetes patients to learn how to predict events by performing their own experiments—eating, walking, and measuring blood sugar before and after. Patient education and CGM are keys to better health. A genetic solution to Type 1 diabetes seems to be distant, as some 50 genes have been found to be associated with the disease.

**Paul Madden, M.Ed., Director, Diabetes and Behavioral Health, American Diabetes Association**

Mr. Madden, who also has Type 1 diabetes, described some of his experiences, such as attending and working in diabetes camps years ago. That experience taught him the power of peer support at all ages. The prevalence of diabetes in the world has been growing in recent years. Diabetes is now the leading noncommunicable disease in many countries. Unbalanced diabetes (extreme sugar highs and lows) diminishes a person’s productivity, quality of life, and quantity of life. Investing in optimal interventions and good life-style choices can lead to reduced expenses for health care, increased productivity, and more. Health care advances have included better training for psychologists and new technological approaches, such as the placement of a timing device on the top of an insulin pen, which indicates when the pen was used previously.

Mr. Madden agreed with others that the measure of hemoglobin A1c should be considered only as a guideline. He noted that, as he ages, he feels the effects of low blood sugar less readily. One important issue that needs addressing is ensuring that people with diabetes have proper access to health care providers. That can help reduce hypoglycemic events. We have new, long-lasting insulins and other new technologies, such as hybrid pumps and the ability to share sugar levels with other people. Mr. Madden called for new approaches that target specifically unbalanced diabetes. The patient is the expert. Partnering is key.

In discussion, Dr. Powell stated that we need a better understanding of time and range in management of diabetes. She agreed that the patient is the foremost expert. A meeting attendee asked how to obtain current statistics on national diabetes expenses. It was noted that the results of a new economic cost study will be released in 2018.

**Federal Partners’ Presentation: Amplifying the Message**

**Alaina Fournier, Ph.D., Health Communications Specialist, Agency for Healthcare Research and Quality**

Dr. Fournier described the SHARE approach to decision-making, an initiative of the Agency for Healthcare Research and Quality (AHRQ), which can be applied in the prevention of

hypoglycemia. Shared decision-making occurs when a health care provider and patient work together to make a health care decision that is best for the patient. It includes the patient's expertise, the clinician's expertise, and a shared understanding of a problem. The AHRQ SHARE program features the use of evidence and training workshops for clinicians. The workshops cover topics including engagement with patients, handling limited time, cultural competency, how to communicate harms and benefits, and how to find evidence-based decision aids. Studies have shown that shared decision-making improves patient satisfaction. It can lead to greater adherence to treatment.

The SHARE program emphasizes the idea that the whole medical team should be involved in decision-making. It should be a collaborative effort. Yet factors prevent shared decision-making, for example, the clinician's feeling that one is already doing so, the lack of time, the lack of skills, the lack of resources, and concern about the patient's ability to make choices. Dr. Fournier stated that we need leadership, training, and measures of success. We need to build a culture, to support development of infrastructure, to advance patient decision aids, to conduct new research, and to develop new measures.

**John J. Whyte, M.D., M.P.H., Director, Professional Affairs and Stakeholder Engagement, Center for Drug Evaluation and Research, U.S. Food and Drug Administration**

Dr. Whyte focused on communication and engagement. He noted that we do not always develop the needed tools and strategies. Supporting messaging efforts with science is important. Communicating effectively with stakeholders, including physicians, pharmacists, and patients, requires understanding the audience. The Food and Drug Administration (FDA) conducted a focus-group study of the use (or non-use) by stakeholders of FDA information on drug safety. The study participants indicated that they used a variety of other information sources, including Google, Micromedex, UpToDate, Epocrates, and WebMD. Dr. Whyte stated that there is a general lack of awareness of FDA resources. The agency is addressing the fact that many people have expressed dissatisfaction with FDA materials, including its website.

Dr. Whyte stated that the FDA agrees that A1c measurements need to be stratified by age and other factors. It recognizes a need to determine the hypoglycemic risk information that should be included in an electronic health record. We need research to that end. The agency has supported the development of a hypoglycemia risk prediction/stratification tool. Risk also varies across clinics and care teams.

**Sandra Hedin, Pharm.D., CACP, Veterans Health Administration**

Dr. Hedin spoke about the Veterans Health Administration's (VHA) Choosing Wisely Task Force and its Hypoglycemia Safety Initiative. The project has fostered shared decision-making, the use of best available evidence, reduction in unnecessary care, and improved glycemic safety. It seeks to put into clinical practice evidence that is available. The VHA addresses high-risk populations with many personal characteristics and comorbidities. The Safety Initiative has identified a cohort of high-risk patients who might be at risk of over-treatment when relying on electronic medical records.

The Safety Initiative provides the patients and providers with resources, tools, and education. In particular, it created a tool to help fill out electronic medical record forms, leading to the identification of people with hypoglycemic risk. It has used the tool with 9,300 patients, and about one-quarter of them reported episodes of hypoglycemia. Dr. Hedin provided examples of application of the tool, with its high-risk alert, and use of individual patient records. A result of the application and conversations revealed that it takes more than one discussion with a patient to cause the patient to change behaviors relating to hypoglycemic risk.

### ***Discussion***

A meeting attendee proposed that, relating to shared decision-making, every patient should have access to the physician's clinical notes. She suggested that patients be encouraged to act as faculty, or educators. Dr. Fournier responded that the SHARE program focuses on the patient side and not the clinician side (as with notes). Another attendee stated that there is evidence many patients do not use the notes when available. Patients have various interests and priorities. Dr. Whyte asked how we can encourage patients to read notes and laboratory data.

Another attendee cited a need for educational and promotional efforts regarding new clinical data and new products. Dr. Fournier responded that AHRQ made some attempts in that area, creating summaries of research for consumers and physicians. That project has been discontinued.

Dr. Whyte asked, in light of the many drugs available today, what the research agenda should look like going forward. How can we ensure that hypoglycemia is not ignored? Dr. Hedin responded that the VHA is attempting, in the Safety Initiative, to incorporate such issues and to develop tools that support shared decision-making.

Another attendee encouraged the Federal departments to work with patient advocates to address the issues raised here. Dr. Hedin stated that the VHA has all the medications, yet needs to identify the right targets or goals for each patient.

## **Non-Federal Partners' Presentation: Working Together**

### **Wendy Frisby, Novo Nordisk and Diabetes Advocacy Alliance**

Ms. Frisby, a Type 2 diabetes patient and advocate, described her journey with diabetes, which began with a diagnosis of gestational diabetes during her first pregnancy. She was given insulin during the pregnancy, and her newborn was found to have anencephaly. During a second pregnancy, Ms. Frisby again was given insulin and had healthy twins. Her condition evolved eventually to Type 2 diabetes.

Ms. Frisby recounted personal hypoglycemic episodes, including a dangerous experience of being caught in stopped traffic for hours and requiring aid. She expressed a current preference for allowing her blood sugar concentration to drift to higher numbers rather than lower numbers.

## **Beverley H. Johnson, President and CEO, Institute for Patient- and Family-Centered Care**

Ms. Johnson, President of the Institute for Patient- and Family-Centered Care, presented aspects of her organization's program to advance care that focuses on patient and family. The organization urges patients and family members to serve as teachers for the next generation of diabetes caregivers. As an example, they could be greeters in clinics. The organization seeks the following results:

- Patients and others across the interdisciplinary care team are treated with respect and dignity.
- Health care providers communicate and share useful information in practical ways and affirm the patient's ability to manage care.
- Patients and families participate in the care.
- There is collaboration in changing and improving care.

In encouraging collaboration, the organization insists that care workers engage "with" patients and families and not "for" them. The patient should be an integral part of the health care team. Ms. Johnson noted that the National Academy of Medicine encouraged the idea of patients and families being owners of their health information. She described personal challenges in finding a care team for a Type 1 diabetic patient and recalled difficulties she witnessed in the form of lack of respect, lack of information-sharing, and lack of support. Obtaining supplies for diabetes management is another challenge.

Ms. Johnson related her experience with hypoglycemia and stressed the importance of using CGM technology. She echoed others in lamenting the decision of the Medicare program not to cover the use of mobile devices/monitors. She encouraged all to think in terms of an information model in addition to a medical model. We need more information in the exam room, in the waiting room, from physician notes, and in reminders between doctor visits.

## **Kelly L. Close, Founder, diaTribe.org and diaTribe Foundation, and President, Close Concerns, Inc.**

Ms. Close, of diaTribe Foundation, which engages in advocacy for patients with diabetes, provided additional perspective as a patient with diabetes. She was diagnosed with diabetes in the mid-1980s, and, during the first 12 years following diagnosis, she visited the emergency department 24 times because of hypoglycemia. As the years progressed, she became aware of new tools, such as analog insulin, and developed a good support network. Ms. Close stated that the use of CGM eventually ought to prevent hypoglycemia. Its technology and use are advancing.

Ms. Close noted that research has suggested that A1c does not drive hypoglycemia risk, although when the former measure rises, the latter measure rises. The use of CGM can indicate the quality of one's A1c control. However, A1c does not necessarily indicate risk of hypoglycemia. We should create hypoglycemia profiles for particular diabetes treatments. Hypoglycemia drives costs, including costs that are not measured. One important question is whether time or

frequency of hypoglycemia correlates with long-term complications. Ms. Close proposed investing in long-term trials studying CGM and long-term complications.

### ***Discussion***

Mr. Madden emphasized the need to increase access—to diabetes educators, to relevant and understandable printed information, and to treatment technologies such as CGM. Ms. Close added the idea of increasing awareness. Ms. Frisby added the benefit of recognizing value.

Ms. Johnson stressed the importance of recognizing the capacity of people to learn and manage their condition. Peer support can be a large component of that. Automatic insulin dosing machines will be a big step forward.

An attendee suggested that pharmacists remain an untapped resource. They can offer important useful information. An attendee cited the current movement of pharmacies to become part of the integrated diabetes team. The VHA has been a leader in clinical pharmacy practice and can serve as a model. Today's developing technologies and new drugs are illuminating the challenges. The patient must have a voice, providing feedback and engagement to move forward.

## **Federal Partners' Presentation: Putting It Into Practice**

### **Christine Lee, Ph.D., Pharm.D., Professional Affairs and Stakeholder Engagement, Center for Drug Evaluation and Research, U.S. Food and Drug Administration**

Dr. Lee expressed appreciation for the many collaborations the FDA has experienced with non-Federal partners, and she stressed her devotion to patient-centeredness. She focused on FDA efforts to develop a national action plan for hypoglycemia, featuring implementation and amplification of messages. The FDA recently held a workshop on raising awareness of hypoglycemia as a serious problem that is preventable. The workshop featured organizational and public participants, presentations, and videos of patients from the VHA. The FDA has been involved in other activities, including making presentations at conferences and creating messages for audiences.

In the area of implementation, an FDA safety initiative collaborated with other groups to fund development of a risk stratification tool for hypoglycemia. The FDA has developed a hypoglycemia program in continuing medical education. Dr. Lee re-emphasized the importance of addressing comorbidities, targets/goals, shared decision-making, and peer-support groups. Her office is supporting a project to study the Web-based social media scene to learn what subjects and barriers relating to diabetes are being discussed.

### **Leonard Pogach, M.D., M.B.A., Office of Specialty Care/Office of Patient Care Services, Veterans Health Administration**

Dr. Pogach noted that the VHA/U.S. Department of Defense's *2017 Clinical Practice Guideline: Management of Type 2 Diabetes* is intended to inform shared decision-making. One in four

veterans receiving care in the VHA has diabetes, and about 30 percent of those veterans receive insulin. This is an older cohort of individuals, and the numbers resemble the numbers in the older general population. The guideline, which was published in the *Annals of Internal Medicine*, offers target goals and presents individual risks and benefits. It gives target ranges for A1c and presents individualized treatment plans. It makes many recommendations, including the following:

- Shared decision-making should be included, at a minimum, at the time of diagnosis, during difficulties with management, and at times of transition.
- The VHA proposes use of the SHARE model, with its five steps.
- A1c goals should target absolute risk reduction in microvascular complications over a patient's lifetime and consider preferences and social determinants of health.

The A1c test is considered one of the best standardized tests; yet it may not be perfect. It features statistical variation. Dr. Pogach referred to various studies and concluded that the test's application is not "one size fits all." We must be careful when interpreting results.

Dr. Pogach noted the Federal interagency workgroup that developed the tool to measure risk for hypoglycemia. He stressed that the VHA feels that patients cannot participate effectively in care and share in decision-making unless they understand diabetes and how they can be involved in planning and carrying out a jointly developed diabetes care plan.

### **Brian Burke, M.D., Co-Chair, Choosing Wisely: Hypoglycemia Safety Initiative, Veterans Health Administration**

Dr. Burke presented a focus on shared decision-making in the clinic, especially for elderly, high-risk, low-literacy patients who suffer from hypoglycemia. This is addressed by the VHA's Choosing Wisely: Hypoglycemia Safety Initiative, which targets older patients with low resources. Shared decision-making is a method for delivering informed consent and involves a moral imperative. It adds the dimension of evidence-based medicine. Such preference-sensitive discussions can compose 30 to 35 percent of care.

Dr. Burke presented a shared-decision-making model that respects the fact that health care is a service. In service industries, outcomes are co-produced. Shared decision-making is necessary when the clinician is essentially a service provider and the patient a service receiver. Shared decision-making will lead to value, as seen when it prevents over-treatment. Challenges to shared decision-making include cognitive inertia, lack of trainers, and patient expectations (often patients wish simply to hear the advice of the clinician). Shared decision-making is further complicated by essential complexities and unknowns of treatment options, for example, possible range/levels of A1c. Literacy and numeracy are large problems in the population of patients described in the VHA program.

Dr. Burke stated that, when he presents the VHA clinical guidelines and use of the SHARE model to his patients, they express a readiness to hear and accept options. The VHA is engaged in multiple activities with a goal of closing the gaps in shared decision-making. It has developed

and is now piloting a virtual medical center, which will be used to simulate decision-making and train providers. The VHA's National Center for Health Promotion and Disease Prevention created an initiative aimed at asking about episodes of low blood sugar. The VHA recently produced a video to encourage patients to become advocates for their care and to prevent hypoglycemia. As always, the VHA mission is to create an individualized diabetes plan that is safe, effective, and evidence-based. We must make it easier for the patient to manage diabetes successfully. Shared decision-making is a collaborative process about treatment options based on many factors, including adverse drug reactions, A1c targets, and more.

### ***Discussion***

An attendee who is a resident at Johns Hopkins Hospital stated that he has found shared decision-making concerning diabetes to be difficult, in part, because much of the data from landmark trials are old. We could use better evidence, especially about A1c. Dr. Pogach agreed and added that we have to deal with the evidence we have. A clinician can present what is known and what is not known.

Dr. Burke suggested that a clinician often will know a patient for only 1 or 2 years, when the patient is in a particular phase of life. Diabetes is a long-term chronic disease, and the patient at some point, in spite of the level of A1c, may be turned off by the health care system or empowered by it. The clinician must encourage empowerment. Dr. Lee stressed that the patient must be the center of the conversation, and she welcomed the use, by the clinician, of the teach-back method.

An attendee asked whether medical schools are teaching the processes for individualizing plans and ensuring shared decision-making. Dr. Lee noted that time is a valuable resource in the clinic. How can we maximize resources? Another attendee noted that systems often do not allow enough time for individualizing therapies. Dr. Lee called for more time to present patient-reported data while seeking efficiency.

Another attendee added to the discussion of training, asking how, in the context of evolving studies, we should train residents and other professionals to navigate the issues and have conversations with patients.

Another attendee noted that shared decision-making is a process without an explicit order. We should seek to change the dynamic of the clinician-patient discussion, realizing that many aspects of the discussion are outside debate. A shared-decision discussion can be considered necessary because of the fact that some of the data are old.

Dr. Whyte noted that many clinicians feel that they already are engaging in shared decision-making. Perhaps there should be studies of what shared decision-making means to clinicians. Change for them can be difficult. Dr. Pogach spoke of eliminating barriers to shared decision-making (barriers such as insufficient guidelines). We should teach communication skills and consider this a movement involving the whole health care team. Dr. Lee called for recognizing a basis on empathy.

Another attendee stated that we place much of the communication burden on the physicians. It is also important for the other health care team members to be trained in communication skills, helping to advance effective shared decision-making. A respondent noted that one small study found that nurses and nurse practitioners were champions in boosting shared decision-making. Dr. Pogach suggested creating promotional campaigns that encourage patients to ask questions. Medical schools should be encouraged to teach clinicians how to present new data. Dr. Powell noted that the ODPHP has an office of health communication that is engaging in projects focused on shared decision-making.

An attendee who characterized himself as a layperson raised the issue of compliance and stated that patients who have engaged in shared decision-making will show greater compliance.

## **Patient Perspective: Bringing It Back to the Patient**

**Barbarajean Shaneman-Robinson, R.N., M.S., Senior Program Specialist, University of Maryland School of Pharmacy**

Ms. Shaneman-Robinson shared some of her experiences with diabetes and health care. She is 73 and has experienced triple bypass surgery. Her goal today is to be able to take care of herself. She also would like to inform the new generations.

Ms. Shaneman-Robinson was treated for diabetes as a caution during heart surgery and eventually developed some neuropathy. Her two brothers also developed diabetes.

In her work today, Ms. Shaneman-Robinson shares her experiences with her clients. The clients listen to her stories and hear her messages.

## **Final Thoughts**

Dr. Powell thanked the speakers, other participants, and staff. She restated the important message that conversations have consequences. She listed other lessons: We must make connections. We must have action. Willingness to do is not enough. We must partner.

Dr. Powell concluded by stating that the ODPHP will proceed to define what shared decision-making means to physicians, to identify ways to move the issue and process upstream, and to encourage teaching—about communication, empathy, peer support, and patient care.