Presenter Abstracts:

Diabetes Mellitus Interagency Coordinating Committee Meeting on Implementing the Department of Health and Human Services National Action Plan for Hypoglycemic Safety

September 29, 2014

Donald Wright, MD, MPH, Deputy Assistant Secretary for Health, and Director, Office of Disease Prevention and Health Promotion—Creation of the National Action Plan

A 2011 NEJM article from Budnitz, et al., on emergency hospitalizations of older Americans due to adverse drug events (ADEs), highlighted the scope of the problem, and how these events contribute to morbidity, mortality, and high hospital readmission rates. Soon thereafter, Secretary Sebelius received a letter from Senators Olympia Snowe and Michael Bennet expressing concerns about this topic and encouraging her to utilize HHS resources to address problem. The HHS Office of Disease Prevention and Health Promotion was given the task of leading development of an action plan on ADEs. Importantly, other federal agencies have been involved throughout development of the Plan, including the Departments of Veterans Affairs, Defense, and Justice. A Steering Committee was established with the following objectives:

1. To identify ADEs that are common, preventable, clinically significant, and measurable;
2. To identify federal assets available to mitigate these problems; and
3. To coordinate the effort to utilize these assets for this purpose.

Classes of drugs identified (point 1) included: anticoagulants; insulin and oral hypoglycemic agents; and opioids. For each class, the Committee asked:

- Is there a way to measure these events? How can success be benchmarked, moving forward?
- What prevention strategies are available? If there are proven strategies, how can we disseminate them broadly?
- What kind of incentives and oversight can we bring to the table to try to ensure that hospitals and other caregivers take these problems seriously?
- What do we know/don't we know, and what should the research agenda be going forward?

The answers to these questions informed development of the new plan. The greater challenge will be to see that the Plan is implemented. There will be an event at the U.S. Peace Institute on October 30 to review the content of the Plan, and to set ambitious but achievable targets that can be followed longitudinally to benchmark success. DMICC attendees are encouraged to attend.

Leonard Pogach MD, MBA, FACP, National Director Medicine, Office of Specialty Care Services, Patient Care Services, Veterans Health Administration—Health and Human Services National Action Plan for Adverse Drug Events: Prevention of Serious Hypoglycemic Events in Outpatient Settings

Adverse drug events (ADE) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year. As a result, the U.S. Department of Health & Human Services (HHS), in partnership with the U.S. Department of Defense, U.S. Department of Veterans Affairs, and the U.S. Department of Justice developed the National Action Plan (NAP) for

Adverse Drug Event Prevention (http://www.health.gov/hai/ade.asp). This plan contains information, resources, and recommendations to reduce adverse drug events and enhance patient safety across all health care settings. Among ambulatory patients insulin is the first most common drug implicated in emergency department visits for ADEs overall; and insulin and oral diabetes drug are the third most common drug implicated in about 25 percent of emergent hospitalizations for ADEs in older adults. Broad recommendations in four key topic areas included:

Surveillance: Assess the adequacy of diagnostic and procedural coding for capturing hypoglycemic events, improve access to more integrated electronic health record (EHR) data linking pharmacy, laboratory, and outcomes data, improve efforts to collect additional information on risk factors and occurrence hypoglycemic events in the ambulatory setting.

Evidence-Based Prevention Tools: Improved uptake of individualized glycemic goals; development of tools to guide providers in engaging in shared decision-making with patients/caregivers; improve incorporation of hypoglycemia prevention in patient education/health literacy/health numeracy tools; integration of medication reconciliation and other care transition models

Incentives and Oversight: Include an overtreatment treatment measure to balance under-treatment measure would identify persons with diabetes on sulfonylurea or insulin therapy who were older and/or significant co-morbid conditions whose A1c was < 7 percent**.**

Research opportunities (in healthcare systems): Prevention tools in transitions of care; EHRs to facilitate monitoring over time; medication management interventions recorded in EHRs and impact on patient outcomes; Telephonic diabetes management for specific patient populations.

Dan Budnitz, MD, MPH, Director, Medication Safety Program, Division of Healthcare Quality Promotion—Perspectives on Hypoglycemia Surveillance from the National Action Plan for Adverse Drug Event Prevention

Hypoglycemia induced by diabetes medications is one of the most common, most serious, and most preventable adverse drug events (ADEs) in both inpatient and outpatient settings. The National Action Plan for ADE Prevention seeks to identify existing data sources and metrics for monitoring progress in reducing ADEs from diabetes medications across the nation and within local facilities.

Because public health surveillance data are collected from a variety of systems for a variety of purposes, it is important to highlight key issues for determining what data sources and metrics are most useful for monitoring progress in ADE prevention. In general, active surveillance for injuries requiring healthcare intervention is most useful for monitoring progress in ADE prevention. Passive reporting systems that focus on errors in process rather than harms may be quite useful for signal detection but less useful for monitoring for improvements. Specific considerations in monitoring ADEs include the requirement to both identify and injury and attribute that injury to a drug; measure use of a drug in the population; and characterize ADE severity and setting of occurrence (e.g., cause of hospitalization vs. occurring during hospitalization). Finally, for data to be most useful it must by timely, so sometimes monitoring implementation of prevention practices can supplement monitoring outcomes.

While there are a number of potentially useful federal data sources for monitor progress in preventing hypoglycemia induced by diabetes medications, there are just a handful of metrics currently used. Healthy People 2020 Medical Product Safety Objective 5.2 monitors hypoglycemia in ambulatory patients and a new National Quality Forum (NQF) Endocrine measure was just adopted to calculate rates of inpatient hypoglycemia.

Silje Lier, MPH, Communication Advisor, ODPHP—Health Literacy and Diabetes Management

The degree to which individuals have the capacity to obtain, communicate, process, and understand basic health information and services needed to make appropriate health decisions. Nearly 9 out of 10 adults have difficulty using the everyday health information that is routinely available in health care facilities, retail outlets, media, and their communities. Limited health literacy is associated with poorer health outcomes and higher health care costs.

In the last few years, health literacy has been recognized through various policy initiatives, from the Affordable Care Act to the Plain Writing Act of 2010. Also, a proposed Health Literate Care Model, based on the Chronic Care Model, advocates for health literacy improvement efforts within all aspects of planning and operations in the health care system.

The ADE Action Plan advocates for the use of various health literacy strategies that improve patient satisfaction and outcomes. The Office of Disease Prevention and Health Promotion (ODPHP) recently launched an eLearning lesson to promote the recommendations outlined in the ADE Action Plan related to preventing hypoglycemia from diabetes agents. The lesson includes a comprehensive curriculum including evidence-based resources, interactive knowledge checks, and video scenarios of prevention strategies in action, to communicate the following learning objectives:

1. Understand the national burden of ADEs.
2. Define hypoglycemia and understand its potential for harm.
3. Recognize the factors that place individuals with diabetes at higher risk for hypoglycemic ADEs.
4. Understand the latest evidence-based guidelines for individualized target glycemic goals.
5. Apply evidence-based guidelines for diabetes management, focusing on setting individualized glycemic targets with patients to reduce the risk of hypoglycemia episodes.
6. Apply health literacy strategies to help patients understand and act on information to prevent ADEs

Mary Andrawis, PharmD, MPH, Senior Advisor, Center for Medicare and Medicaid Innovation—Inpatient: Scope of Problem and Challenges

According to 2010 Data from MPSMS on ADEs, 57 percent nationally are due to hypoglycemic agents. Hypoglycemic agents cause complications in both inpatient and outpatient settings. There are several challenges in the inpatient related to addressing hypoglycemia. First, there is no Standard Definition of Serious/Severe/Clinically Significant Hypoglycemia. In the National Action Plan, serious hypoglycemia is defined as having blood glucose <40 mg/dL and requiring third-party assistance (e.g., from a family member and/or medical personnel, or leading to an emergency department visit or hospital admissions).

Secondly is the challenge of unclear Ideal Glycemic Targets. It is known that uncontrolled hyperglycemia is associated with poor outcomes and that the use of intensive insulin therapy is associated with reductions in mortality in ventilated ICU patients. However, these results were not replicated in the NICE-SUGAR study, in which intensive insulin therapy associated with serious hypoglycemia/increased mortality. Professional society-recommended upper-level glycemic targets in the ICU setting range from 150 mg/dL (Society of Critical Care Medicine) to 200 mg/dL (American College of Physicians). There is a need for careful balance in managing risks associated with hyperglycemia and hypoglycemia and a lack of clear guidance on how to accomplish this. Target values for glycemic control recommended by the Federal sector and multiple private and public stakeholder agencies should be individualized. Thirdly is the challenge of the lack of Systematic Identification of Patients at Risk. This includes patients who have had a decrease in oral intake (intake (*e.g.*, unexpected interruption of tube feedings or other sources of nutrition) or who have already had an initial hypoglycemic event ((>40 percent of patients who experience one episode go on to suffer at least one additional hypoglycemic episode). Federal partners should facilitate the use of systems that enhance recognition and documentation of risk factors, including prior hypoglycemic events, that contribute to inpatient hypoglycemic events. Fourthly are the barriers to Multidisciplinary Coordination. Information should be shared across all health care providers and shifts; includes documentation of nutritional intake, coordination of meal time/blood glucose testing, and changes in normal routine (*e.g.*, reduced dietary intake or use of parenteral nutrition). The use of EHR, order sets, and hypoglycemic management protocols can support tracking this information.

Anita Thomas, PharmD Center for Clinical Standards and Quality—Transitions of Care

Post discharge complications including adverse drug reactions occur during the care transition process. Hypoglycemia particularly can occur during care transition due to several factors from communication to medication changes, to nutritional considerations. Quality improvement can target prevention and reduction of hypoglycemia during the care transition process. Some areas of quality improvement that can be targeted during the care transition process include: increasing communication, engaging patients and families, including medication reconciliation at points of transition, nutritional considerations, and using evidenced-based and community specific best practices. To help identify these best practices in reducing hypoglycemia, improve the quality of care and reduce adverse drug events related to diabetic agents, CMS has one of the largest federal programs dedicated to improving health quality for Medicare beneficiaries, the Quality Improvement Organization (QIO) program. The QIO program is an integral part of the U.S. Department of Health and Human (HHS) Services' National Quality Strategy for providing better care and better health at lower cost. Recent success of the QIO program includes a nearly 1 billion dollar savings in improving transitions of care. Current work of this program aligns with the HHS National Action Plan for Adverse Drug Event Prevention, the CMS Quality Strategy and the HHS National Quality Strategy. Particularly related to diabetes care, the current QIO program work focuses on engaging patients and families, providing diabetes self-management education, reducing adverse drug events related to diabetic agents and reducing readmissions with a community of care and data-driven approach.

Karen Nakano, MD, MS, Quality Measurement and Health Assessment Group Center for Clinical Standards and Quality—Incentives/Oversight

The evidence for hypoglycemia related to ADEs resulting from hypoglycemic agents is well known and quantitated. During the creation of the ADE NAP the Diabetes Mellitus Federal Interagency Workgroup reviewed the current literature as well as performed an extensive environmental scan of processes, data sources and quality measures currently available to help reduce the incidence of hypoglycemic events related to the use of hypoglycemic agents. As part of their work, they also looked at the incentives and oversight responsibility that CMS has regarding this specific ADE for their beneficiaries. The ADE NAP dedicates a chapter on CMS's levers to encourage behavioral changes in everyday health care processes to decrease the frequency of ADEs associated with the use of oral hypoglycemic agents.

CMS programs for Medicare, Medicaid and Children Health Insurance Program beneficiaries are highly regulated and our work follows rigorous processes that are transparent and require review by the stakeholders through the statutorily mandated rule writing cycles associated with each CMS program. In addition to our rule writing cycles, CMS keeps the public abreast of our programs by collaborating with stakeholders through many different avenues of communication; some of these avenues include attendance at annual specialty society meetings, individual meetings at CMS, participation in consensus building processes sponsored by the National Quality Forum and interagency workgroups, and through meetings with Technical Expert Panels. CMS's main tool of communicating with the public about how our programs are operationalized, maintained and changed to address the fluid needs of health care is through rule writing. Through all of these activities CMS programs and goals are transparently made known to the stakeholders and our beneficiaries.

Barbara Bartman, M.D., M.P.H. Medical Officer, Center for Outcomes and Evidence—AHRQ Perspective

Dr. Bartman reviewed the contributions that AHRQ will be making to the ADE Action Plan to reduce hypoglycemic events. To assess the national incidence and rate of hypoglycemia, data from the Healthcare Cost and Utilization Project (HCUP) and the Medicare Patient Safety Monitoring System (MPSMS) is analyzed. To improve safety, AHRQ produces several evidence-based prevention tools related to the management of diabetes including a systematic review entitled, "Oral Diabetes Medications for Adults with Type 2 Diabetes," and a resource for communication and coordination of care entitled, "Project Red – Re-engineered Discharge Toolkit." There are also resources for patients and family engagement that deal with medications for Type 2 Diabetes Mellitus and methods for delivering insulin and monitoring blood sugar. To improve care transitions for patients with diabetes AHRQ has a toolkit, "Medications at Transitions and Clinical Handoffs [MATCH] to assist with medication reconciliation during transfer from inpatient to outpatient settings. An overview of a grant funded by AHRQ, "Innovations Reducing Hyper- and Hypo-glycemic Events in Inpatients," was provided (PI Greg Maynard, MD, MSc of UCSD Center for Innovation and Improvement Science in partnership with the Society of Hospital Medicine). Dr. Bartman also emphasized that AHRQ's Patient Safety (PS) Portfolio is addressing patient safety and medication research by focusing on the safe usage of medications. This perspective centers on how medications move through the health care system and how this systemic process can be improved so that patients are not harmed, while health care delivery is improved. The PS Portfolio encourages the involvement of all members of the health care team,

especially patients, and families; nurses, pharmacists, technicians (pharmacy and medication administration technicians), health care administrators, risk managers, and physicians) across all settings of care (including in the home) as well as the home). AHRQ has an FOA that funds in investigative research demonstration projects that examine the effective implementation of processes, Advancing Patient Safety Implementation through Safe Medication Use Research (R18) which can be found at http://ahrq.hhs.gov.

Sharon Saydah, Ph.D., Division of Diabetes Translation—Surveillance

Dr. Saydah, from the Centers for Disease Control and Prevention, Division of Diabetes Translation (DDT) presented an update on diabetes and hypoglycemia and efforts to both track and prevent hypoglycemia. Tracking the burden of hypoglycemia is through surveillance efforts at CDC which include the National Adverse Drug Reporting system and national surveys. There is also potential to explore Emergency Medical Systems and electronic health records as sources for surveillance. Using National Emergency Department Survey and the National Health Interview Survey, it is estimated that there were 282,254 visits for hypoglycemia in 2011 (crude rate of 1.4 percent (95 percent CI: 1.3,1.5)). Hypoglycemia accounts for 2.2 percent of all ED diabetes related visits. DDT agrees that individualized targets for diabetes treatment are an important component in preventing hypoglycemic events. Percent of adults with diabetes meeting glucose goals based on individualized targets were presented. To prevent hypoglycemia, the CDC has worked with an interagency group to develop an eLearning tool aimed at health care professionals addressing hypoglycemia. Additionally, CDC funds states to increase access to, participation in and reimbursement for Diabetes Self-Management Education (DSME) programs to provide people with diabetes the skills to successfully manage diabetes. There are currently 51 funded grantees to address this and 45 who are doing additional in depth work to address issues of access and reimbursement for DSME programs recognized/accredited by the American Diabetes Association or the American Association of Diabetes Educators. DDT is actively looking for ways to increase both surveillance and prevention of hypoglycemia that are within our strategic priorities and resources.

Daralyn Hassan, Division of Laboratory Services, Clinical Laboratory Improvement Amendments program, Survey & Certification CMS/CCSQ/SCG/DLS—CLIA Requirements for Blood Glucose Meters (BGM) in the Professional Setting

- CMS regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA).
- A laboratory is any facility that examines human specimens for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of health of human beings.
- All clinical laboratories must obtain the appropriate CLIA certificate and follow the applicable requirements.
- There are two types of BGMs: self-monitoring devices for home use and professional use which can be used on multiple patients, taking care to clean between patients.
- When using the professional use BGM, follow the manufacturer's instructions completely; any modification to the manufacturer's instructions is off-label use.

Joel Kaiser CM-DEMEPOS (Director)—Glucose Monitoring Strips

Dr. Elizabeth Koller, CMS, spoke on behalf of Dr. Kaiser, who was unable to attend.

- Medicare definition and scope of the DME benefit
- Why monitors are considered DME
- Why the test strips and other supplies are covered under the DME benefit
  - General policy related to supplies necessary for the effective use of DME
  - 1997 change to the statutory definition of DME
- How the Medicare payment rates were established
- Implementation of the statutory mandate for competitive bidding programs for DME including glucose monitors and supplies
  - What the statute requires
  - Special rules developed to address access

Madlyn Kruh, CMS—Medicaid Drug Utilization Review (DUR) Fact Sheet

- Section 4401 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) and section 1927(g) of the Social Security Act require States to provide for a Medicaid drug utilization review (DUR) program for covered outpatient drugs.
- OBRA '90 incentivized the development of online claims management systems to facilitate an automated means of reviewing prescriptions prospectively, prior to being filled and to enable retrospective post-payment review of prescribing patterns and information retrieval for ongoing examination of claims data.
- The DUR program consists of prospective drug utilization review (ProDUR), which involves electronic review of each prescription prior to dispensing, with intervention by the pharmacist if necessary, according to predetermined standards. This electronic screening process checks for potential drug therapy problems related to therapeutic duplication (two drugs from the same drug classification) drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy alerts and clinical misuse or abuse.
- The DUR program's other component is retrospective drug utilization review (RetroDUR) which is the evaluation of therapy and interventions after therapy has been initiated. Through ongoing periodic examination of claims data to identify patterns or trends in drug therapy which may need intervention activity with physicians, pharmacists and/or patients, and to identify patterns of fraud or abuse, gross overuse.
- The end results are the development of strategies to improve quality of care and conserve Medicaid funds.
- Annually, States submit a report to CMS detailing their activities during the previous year.
- The FFY 2013 DUR survey contains questions on Lock-In programs, PDMPs, sections addressing Pain Management, Opioids, Morphine Equivalent Daily Dose, Buprenorphine, Psychotropic Drugs/Stimulants (use in children in foster care as well as children, and in adults) and Managed Care. (This information will not be posted until late Fall 2014.)
- Please visit our DUR landing page for more information including individual state DUR reports, innovative practices and reports summarizing the states' reporting found at

http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Drug-Utilization-Review.html

Darshak Sanghavi, MD, Director, Preventive and Population Healthcare Models Group, Center for Medicare & Medicare Innovation, Centers for Medicare& Medicare Services—Center for Medicare and Medicaid Innovation Overview

The Centers for Medicare & Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) was established by section 1115A of the Social Security Act (as added by section 3021 of the Affordable Care Act). Congress created the Innovation Center for the purpose of testing "innovative payment and service delivery models to reduce program expenditures …while preserving or enhancing the quality of care" for those individuals who receive Medicare, Medicaid, or Children's Health Insurance Program (CHIP) benefits. The Innovation Center is currently focused on the following priorities: testing new payment and service delivery models, evaluating results and advancing best practices, and engaging a broad range of stakeholders to develop additional models for testing. The Innovation Center portfolio includes three main areas of investment: strengthen incentives for providers, payers, and consumers; support providers and states in their capacity to change new models of care; and increase the information available for effective, informed decision-making by consumers and providers. During the development of models, the Innovation Center builds on the ideas received from stakeholders and consults with clinical and analytical experts, as well as with representatives of relevant Federal agencies. The Innovation Center solicits and selects organizations to participate in model tests through open, competitive processes. The Innovation Center conducts an evaluation of each new payment and service delivery model tested. Statute specifies that measures in each evaluation must include an analysis of the quality of care furnished under the model (including the measurement of patient-level outcomes and patient-centeredness criteria) as well as changes in spending. Evaluation results are shared with participating providers on an ongoing basis in order to promote more rapid learning. The Innovation Center has also created learning collaboratives for providers in its models to promote broad and rapid dissemination of evidence and best practices that have the potential to deliver higher quality and lower cost care for Medicare, Medicaid and CHIP beneficiaries.

Jennifer Rodriguez Pippins, MD, MPH, Deputy Division Director for Safety, DMEP/OND/CDER/FDA—DHHS National Action Plan for Hypoglycemic Safety: FDA's Activities to Support Implementation

There are multiple FDA activities that align with the DHHS National Action Plan (NAP) for Hypoglycemic Safety, particularly in three of the NAP's four areas of focus: prevention, surveillance, and research. FDA's prevention activities include careful attention to the prescriber and patient labeling describing the risk of hypoglycemia. In situations where risk management efforts beyond routine professional labeling are needed, FDA can require a Risk Evaluation and Mitigation Strategy (REMS). SymlinPen is an injectable amylin analog approved by FDA in 2005. Postmarketing reports of adverse events of hypoglycemia in patients who were poor candidates led to approval of a REMS communication plan approved in 2014. With regard to surveillance, FDA conducts ongoing surveillance using the FDA Adverse Event Reporting System (FAERS). FAERS is a database that includes over 9 million adverse event reports associated with approved products. FDA has become

aware of FAERS reports of adverse events and medication errors involving U-500 insulin; incorrect dosing of this product can lead to hypoglycemia. FDA continues to monitor this safety issue. In addition to FAERS, the Food and Drug Administration Amendments Act (FDAAA) of 2007 established the 915 Postmarketing Safety Evaluation. This is a comprehensive review of the postmarketing safety experience for recently approved products, and is performed either 18 months after approval or after use of the product by at least 10,000 individuals. This safety activity provides a mechanism for ongoing surveillance of hypoglycemia for recently approved antidiabetic agents. In terms of research, under FDAAA the FDA has the authority to require postmarketing studies or trials to investigate safety issues. A postmarketing requirement (PMR) may be required at initial approval, or anytime thereafter if new safety information becomes available. A PMR pertaining to hypoglycemia was required Afrezza, an inhaled insulin product approved in June 2014. A pharmacokinetic-pharmacodynamic euglycemic glucose-clamp trial to characterize within-subject variability is being required; these data may impact labeling recommendations for glucose monitoring and thereby mitigate the risk of hypoglycemia.

Ann Bullock, MD, Clinical Consultant, Indian Health Service Division of Diabetes Treatment and Prevention—IHS Perspective

There are 2.9 million American Indian/Alaska Native (AI/AN) people and 566 federally-recognized Tribes in the U.S. The Indian Health Service (IHS) is the federal agency responsible for the provision of health care to AI/AN people, which it does either directly or through agreements with Tribes and Urban Indian organizations. The prevalence of type 2 diabetes in AI/AN people is among the highest in the country with 15.9 percent of Native adults having diagnosed diabetes as compared with 7.6 percent of non-Hispanic whites in 2012.

IHS has been working on issues related to hypoglycemia for several years and has taken steps to reduce the risk of this in AI/AN diabetic patients. As performance measures can be interpreted as requiring tight glucose control even in patients for whom there is increased risk related to hypoglycemia, in 2013 IHS adjusted its national performance measure to be more inclusive of the ranges necessary for individualized glucose targets: A1C <8 percent.

Through its Division of Diabetes Treatment and Prevention (DDTP), IHS provides training and clinical tools for Indian health clinicians through a monthly CME/CE webinar series as well as on its website: www.diabetes.ihs.gov. A number of these trainings and tools have discussed the need to individualize glucose treatment targets and to avoid hypoglycemia. DDTP also coordinates the annual IHS Diabetes Care and Outcomes Audit, which collects data on a number of key diabetes treatment elements, including A1Cs. Audit results provide feedback to local facilities on important aspects of their diabetes care as well as inform IHS' national efforts. In 2014, nearly 116,000 charts of AI/AN patients with diabetes across the country were included in the Audit.

IHS has a long history of successfully addressing diabetes in AI/AN people. The strategy includes disseminating evidence-based diabetes practices throughout the national, regional, and local levels of the Indian health system. IHS provides resources, tools, and training to help local sites implement those practices and then provides feedback on their progress. In this same way, IHS is working across the Indian health system to reduce hypoglycemia risk and ensure appropriate and safe diabetes care.

Leonard Pogach MD, MBA, FACP National Director Medicine, Office of Specialty Care Services, Patient Care Services—Veterans Health Administration Choosing Wisely Hypoglycemia Safety Initiative (HSI)

The *Choosing Wisely*® initiative of the American Board of Internal Medicine is meant to promote conversations between providers and patients to ensure that the right care is delivered at the right time. Participating organizations created lists of "Things Providers and Patients Should Question." The HSI was developed by a VHA Choosing Wisely Taskforce chartered by the Deputy Undersecretary for Policy and Services in early 2013. The American Geriatric Society had recommended to "avoid using medications to achieve hemoglobin A1c <7.5 percent in most adults age 65 and older; moderate control is generally better." This Choosing Wisely recommendation is congruent with guidelines from the American Geriatrics Society and American Diabetes Association (2012), and Veterans Affairs/Department of Defense Guidelines (2010, www.healthquality.va.gov), all of which recommend individualized glycemic goals based upon age, co-morbid conditions, life expectancy, and patient preference. The taskforce recommended a specific focus upon hypoglycemic safety in highest risk patients the ambulatory care setting. A recent research study reported that 50 percent of all Veterans with diabetes in 2009 who were on hypoglycemic agents and were over 75, and/or had chronic renal insufficiency or cognitive had an A1c <7 percent, and thus were possibly over-treated.

A pilot program for HSI had been established in Veterans Integrated Network System (VISN) 12. The emphasis was upon shared decision making within the Patient Aligned Care Team (PACT). The VISN Data Warehouse was utilized to generate lists for each PACT panel of patients meeting the above criteria, and can generate a clinical reminder designed to prompt a discussion with patients about their goals (Clinical Decision Support), consistent with Meaningful Use Criteria for Electronic Medical Records. Each PACT team (Providers, Nurses, Diabetes Educators, and Clinical Pharmacy Specialists) was encouraged to review their lists of patients and decide on a strategy for contacting them. Process outcomes were recorded by using uniform health factors.

The National voluntary program, to be launched in fall, 2014, builds upon this pilot. The VHA National Center for Prevention Patient Education Program will provide health literate information and tools which will inform patients/family members about the risks of hypoglycemia, research on glycemic targets and appropriate therapies, and the importance of tailoring glycemic targets to patient preferences, clinical conditions, lifestyle and family support. The tools will help patient/family members discuss risks and their glycemic target preferences with their provider/health care team, actively share decision making for their preferred glycemic target, and review symptoms and treatment of hypoglycemia using the teach-back method. The VHA Primary Care Homeless PACT initiative is leading the development of a food insufficiency program to identify patients at risk, and coordinate social work resources. The VHA's Employee Education System has created a one hour interactive learning module with a target audience of all clinicians who care for patients. It follows a patient with T2DM at ages 48, 58, and 68 when his (and his family's) goals and comorbidities change. The emphasis is on showing how to do what we all talk about: individualizing care based on best evidence and honoring patient choice, and

how all clinicians can help mitigate the risk by being aware of causes/symptoms/management of hypoglycemia.

Meeting Participants

Speakers

Dr. Ann Bullock (IHS, via telephone)
Dr. Mary Andrawis (CMS)
Dr. Barbara Bartman (AHRQ)
Dr. Tracy Branch (OMH)
Dr. Dan Budnitz (CDC, via telephone)
Dr. Judith Fradkin (NIDDK, DMICC Chair)
Dr. Daralyn Hassan (CMS)
Dr. Dale Hu (ODPHP)
Dr. Madlyn Kruh (CMS, via telephone)
Dr. Silje Lier (ODPHP)
Dr. Karen Nakano (CMS, via telephone)
Dr. Jennifer Rodriguez Pippins (FDA)
Dr. Darshak Sanghavi (CMS, via telephone)
Dr. Sharon Saydah (CDC)
Dr. Anita Thomas (CMS)
Dr. Donald Wright (OASH)

DMICC Members (Participating but not Presenting)

Dr. Tibor Roberts (NIDDK, DMICC Executive Secretary)
Dr. Jane Atkinson (NIDCR)
Dr. Larissa Avilés-Santa (NHLBI)
Dr. Barbara Bartman (AHRQ)
Dr. Tracy Branch–Subbing for J. Nadine Gracia (OMH)
Dr. Ann Bullock (IHS, via telephone)
Dr. Gilman Grave (NICHD)
Dr. Reed Graves (CSR)
Dr. Elizabeth Koller (CMS)
Dr. Leonard Pogach (VHA)
Dr. Rex Robison (NLM)
Dr. Sharon Saydah (CDC)