Quarterly Newsletter

112th Congress – April 2012

MESSAGE FROM THE CAUCUS LEADERSHIP

As the chairs and vice-chairs of the Congressional Diabetes Caucus, we would like to present the April edition of the Caucus Quarterly Newsletter. Below you will find the latest news in diabetes, summaries of recent diabetes events, and updates on the legislative priorities of the Caucus. We hope that you and your staff find this newsletter helpful and informative.

Can't find last quarter's newsletter? Want to learn about Diabetes Caucus legislation? Head to the Diabetes Caucus website at http://www.house.gov/degette/diabetes/. If you introduce diabetes legislation, please let emily.katz@mail.house.gov know so it can be featured on the site!

Rep. Diana DeGette	Rep. Ed Whitfield	Rep. Xavier Becerra	Rep. Tom Reed
D-CO	R-KY	D-CA	R-NY
Co-Chair	Co-Chair	Vice-Chair	Vice-Chair

NEWS FROM NIH

Interventions to Prevent Type 2 Diabetes Provide Good Return on Investment: Programs to implement interventions used in the landmark NIDDK-led Diabetes Prevention Program (DPP) clinical trial among people with a similar risk for diabetes to those in the DPP would be a very cost-effective way to improve their health and quality of life. These conclusions emerge from a new report analyzing data from the DPP and its long-term follow up, the DPP Outcomes Study (DPPOS). The DPP tested whether modest weight loss through dietary changes and increased physical activity or treatment with the oral diabetes drug metformin could prevent or delay the onset of type 2 diabetes in people at high risk. The DPP's initial findings, published in 2002, demonstrated that diabetes risk was lowered by 58 percent through intensive lifestyle changes and by 31 percent with metformin treatment as compared to placebo. In 2009, researchers showed that the health benefits of DPP interventions persisted for 10 years. In the new report, DPP researchers performed an economic analysis of the trial costs and outcomes. They examined per capita cost of the interventions during the trial and follow up, cumulative direct medical costs outside the DPP/DPPOS, and quality-adjusted life years accrued over 10 years. This analysis showed that intensive lifestyle intervention was cost-effective—i.e., justified by the benefits of diabetes prevention and improved health—compared to placebo, while the metformin intervention was marginally cost-saving. Throughout the study, quality of life as measured by mobility, level of pain, emotional outlook, and other indicators was consistently better for the lifestyle intervention group. These findings are particularly encouraging in light of other NIH research demonstrating the feasibility of delivering an intensive lifestyle intervention at much lower cost in community-based settings such as YMCAs.

New Study Being Launched on Long Term Health Effects of High Blood Sugar Levels in Pregnancy: Gestational diabetes (GDM), a form of diabetes unique to pregnancy, raises the risk for complications during pregnancy and birth. GDM also raises future risk for diabetes in affected mothers and obesity and diabetes in the children. Recent research shows that the risk of large babies and pregnancy and birth complications increases at blood sugar levels not previously considered high enough for a diagnosis of GDM—are these women and their babies also at greater risk of developing metabolic problems later in life? Researchers will seek to answer this question in a new study founded on the landmark Hyperglycemia and Adverse Pregnancy (HAPO) study. Completed in 2006, the NICHD-led HAPO study found that there is a continuum of risk for immediate neonatal and maternal complications according to the mother's glycemia levels at levels less severe than GDM—findings that have led to new recommendations for GDM diagnosis. Now, NIDDK is launching the HAPO Follow Up study. This study will build on the information gathered in HAPO to determine whether high maternal blood sugar levels less severe than GDM are associated—8 to 12 years after delivery—with obesity or adverse metabolic or cardiovascular status in children, and diabetes or cardiovascular risk factors in the mothers. Several thousand mother-child pairs from 10 of the 15 original HAPO study sites will be recruited to participate in this follow up study. Through this study, researchers hope to gain insights that could inform or

modify strategies to improve the health of women and their babies during pregnancy and in the long-term.

Newly Identified Muscle Hormone May Have Anti-Diabetic Effects: Recent research shows that exercise induces muscle to release a newly discovered small hormone, irisin, in both mice and humans. In turn, this hormone may be an important effecter of the health benefits of exercise. Irisin appears to induce conversion of white adipose tissue, which stores fat for energy, to brown adipose tissue, which "burns" fat to help maintain body heat without shivering—thereby increasing the body's energy expenditure. When the scientists modestly increased the amounts of circulating irisin in a mouse model of type 2 diabetes, this treatment reduced obesity and improved blood glucose control without apparent side effects. These results suggest a potential new therapeutic approach to type 2 diabetes.

- http://www.sciencedaily.com/releases/2012/03/120319094405.htm (Science Daily)
- http://www.diabeteshealth.com/read/2012/03/28/7483/type-1-diabetes-researchers-reach-important-milestone--/ (Diabetes Health)
- http://espn.go.com/espnw/more-sports/7809528/flo-allen-hopson-runs-boston-marathon-grandson (ESPN)
- http://www.sciencedaily.com/releases/2012/03/120322151522.htm (Science Daily)

GUEST OPINION: GESTATIONAL DIABETES

As an OB-GYN, I see pregnant women every week that have gestational diabetes (GDM) – when the body is not able to make and use all the insulin it needs during pregnancy. When I first started practicing medicine, more than 20 years ago, that was not the case. Unfortunately, the rate of gestational diabetes is increasing in the U.S. – up to 18% of all pregnancies are affected.

GDM poses serious risks to both mother and baby including large babies (with increased risk of birth injury or cesarean delivery), neonatal hypoglycemia, and preeclampsia. There is also evidence that both mother and child are at a higher risk of developing type 2 diabetes later in life. Since GDM causes adverse health outcomes and has few symptoms, it is recommended that all pregnant women are screened for the disease during weeks 24-28 of pregnancy. Despite this recommendation, one out of three pregnant women never get tested during her pregnancy and of women diagnosed with GDM, only one in five receive the appropriate GDM follow-up test postpartum. Gestational diabetes can be treated through diet and exercise modification and sometimes through the use of medications – but only if it is diagnosed.

Some women are at greater risk for developing GDM because of their age, race or other characteristics; however, there is a lot we do not know about GDM. Legislation like the Gestational Diabetes Act (HR 2184/S. 1221) will provide important resources to establish a tracking and surveillance system for GDM and fund research to help us understand what women are at greatest risk and may even help us prevent GDM. Given the magnitude of the diabetes epidemic, this legislation is a wise investment to help reduce diabetes costs and the number of new diabetes cases.

- **L. Natalie Carroll, MD,** Member, American Diabetes Association African American Diabetes Action Council (AADAC)

FASCINATING FACT

Prediabetes

79 million Americans—more than three times the number who have diabetes—have prediabetes and are at elevated risk for developing type 2 diabetes. Sadly, only about 7 percent even know they have prediabetes. The good news is there is a proven, evidence-based program, showing that with modest weight loss through healthy eating and increased physical activity, individuals with prediabetes can prevent or delay the disease. The successful NIH clinical trial, the Diabetes Prevention Program, showed that people with prediabetes can reduce their risk of diabetes by 58 percent with this lifestyle intervention. The CDC further showed that this program can be effectively translated to community setting, providing the intervention to at-risk individuals for a much lower cost. This program is the basis for the national network of community-based programs called the National Diabetes Prevention Program, which was authorized by Congress in the 111th Congress. Once funded and implemented, the National Diabetes Prevention Program will provide access to this proven intervention to many of the 79 million Americans with prediabetes and bring us closer to stopping diabetes. It has been estimated that bringing these programs to scale nationally will save the nation $190 billion in heathcare costs over ten years.

RECENT EVENTS

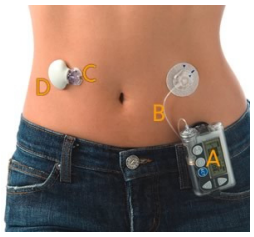
In November, the Diabetes Caucus offered the opportunity for members to record public service announcements. Members then used social media and local media to spread awareness about their state's statistics on diabetes and how to find resources to get tested.

This January, Health Affairs released an issue devoted to diabetes policy research entitled, "Confronting The Growing Diabetes Crisis." Included is a CDC study on the potential cost-savings for a national Diabetes Prevention Program, a life-style intervention program that caucus leadership and many members have urged the Secretary to fund. The CDC found that within 25 years, the program would prevent or delay about 885,000 cases of type 2 diabetes in the United

States and produce savings of $5.7 billion nationwide. If restricted to people ages 65-84, the program would save $2.4 billion.

On April 20, the Diabetes Caucus hosted a briefing on "Tackling Pre-Diabetes: Successful Strategies to Stem a Growing Epidemic." Speakers include Dr. Ann Albright, Director of CDC's Division of Diabetes Translation and Dr. Paul Bill, Chief Medical Officer of Life Technologies Corporation.

On April 26, the Diabetes Caucus leadership sent a letter to Speaker Boehner and Minority Leader Pelosi supporting the Special Diabetes Program and the need for timely reauthorization. 268 members of the House of Representatives, many of whom are members of the Diabetes Caucus, signed the letter.

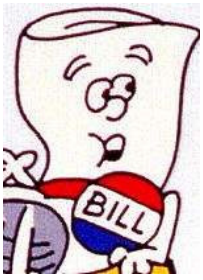


REGULATORY PRIORITIES

Artificial Pancreas Technology at the U.S. Food and Drug Administration (FDA)

Thank you to the 252 of our House colleagues and members of the Diabetes Caucus who signed the letter to FDA Commissioner Margaret Hamburg ,134 Democrats and 118 Republicans, in bipartisan support of advancing artificial pancreas technology guidance. The artificial pancreas is a potentially life-saving technology that would minimize dangerous high and low blood sugar levels, and would help prevent the devastating and costly long-term complications of type 1 diabetes such as: seizures, coma, kidney failure, heart disease, blindness, and amputations. The artificial pancreas draft guidance is under consideration at the agency and will allow outpatient trials to begin so that this technology can be made available to those with type 1 diabetes in the near future.

The artificial pancreas essentially combines a continuous glucose monitor (CGM) and insulin pump to act in place of a person's pancreas. When the CGM detects an abnormal blood sugar level, it speaks to the insulin pump ,which then automatically delivers a dose of insulin or sugar to bring blood sugar levels back to normal. This system is regarded by clinical experts as being the most groundbreaking development in type 1 diabetes care since the discovery of insulin. The Caucus' work to help it along has been noted by FDA and led to the publication of its draft guidance by its previously announced December deadline.



LEGISLATIVE PRIORITIES

The **Special Diabetes Program** (SDP) is set to expire in September 2013 and needs to be reauthorized this Congress. This month, the Diabetes Caucus is circulating a letter to House leadership on the importance of this program to advancing diabetes research. Thank you to all members who signed the letter. The Caucus leadership looks forward to working with all members on reauthorization by the end of the 112th Congress.

H.R. 2787, the ***Medicare Diabetes Self-Management Training Act of 2011.*** Introduced by Representative Whitfield. The bill would make a technical clarification to recognize certified diabetes educators (CDE) as providers for Medicare diabetes outpatient self-management training services (DSMT). CDEs are the only health professionals who are specially trained and uniquely qualified to teach patients with diabetes how to improve their health and avoid serious diabetes-related complications. The 1997 authorizing DSMT statute did not include CDEs as Medicare providers and it has become increasingly difficult to ensure that DSMT is available to patients who need these services, particularly those with unique cultural needs or who reside in rural areas.

H.R. 2741, the ***Preventing Diabetes in Medicare Act of 2011.*** Introduced by Representative DeGette. The bill would extend Medicare coverage to medical nutrition therapy (MNT) services for people with pre-diabetes and other risk factors for developing type 2 diabetes. Under current law, Medicare pays for MNT provided by a Registered Dietitian for beneficiaries with diabetes and renal diseases. Unfortunately, Medicare does not cover MNT for beneficiaries diagnosed with pre-diabetes. Nutrition therapy services have proven very effective in preventing diabetes by providing access to the best possible nutritional advice about how to handle their condition. By helping people with pre-diabetes manage their condition, Medicare will avoid having to pay for the much more expensive treatment of diabetes.

H.R. 3150, the ***Medicare Safe Needle Disposal Coverage Act of 2011***. Introduced by Representative Whitfield. The bill would provide Medicare Part D coverage of needle disposal supplies such as sharps containers or other destruction devices. The legislation would protect type 1 and type 2 insulin-dependent Medicare diabetes patients as well as caregivers and handlers of waste from accidental needle-stick injuries

CAUCUS MEMBERS WITH DIABETES LEGISLATION

Representatives Engel and Burgess have reintroduced the ***Gestational Diabetes (GEDI) Act***. H.R. 2194 directs the Director of the Centers for Disease Control and Prevention (CDC) to develop a multisite gestational diabetes research project within the diabetes program of the CDC to expand and enhance surveillance data and public health research on gestational diabetes.

Representative Waters reintroduced the ***Minority Diabetes Initiative Act***. H.R. 2799 allows the Secretary of Health and Human Services (HHS) to make grants to public and nonprofit private health care providers to provide treatment for diabetes in minority communities.

Representative Pete Olsen introduced the ***National Diabetes Clinical Care Commission Act***. H.R. 2960 establishes a National Diabetes Clinical Care Commission comprised of diabetes experts to provide a mechanism for federal engagement with professionals and advocates who will bring clinical expertise to implementing initiatives intended to improve diabetes care.

Representative Barbara Lee reintroduced the ***Health Equity and Accountability Act.*** H.R. 2954 improves and guides federal efforts in the following vital areas: data collection and reporting; culturally and linguistically appropriate health care; health workforce diversity, improvement of health outcomes for women, children and families; mental health; high impact minority diseases

(hepatitis B, HIV/AIDS, diabetes, cancer); health information technology; emboldened accountability and evaluation; and, addressing social determinants of health.

Representative Lee Terry reintroduced the ***Equity and Access for Podiatric Physicians Under Medicaid Act***. H.R. 3364 amends title XIX of the Social Security Act to cover physician services delivered by podiatric physicians, ensuring that Medicaid beneficiaries have access to appropriate quality foot and ankle care.