Quarterly Newsletter

112th Congress – July 2012

MESSAGE FROM THE CAUCUS LEADERSHIP

As the chairs and vice-chairs of the Congressional Diabetes Caucus, we would like to present the July 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

Weight Loss and Increased Fitness Slow Decline of Mobility in Adults

Recent findings from the NIDDK-supported Look AHEAD (Action for Health in Diabetes) trial, published March 29 in the *New England Journal of Medicine*, showed that weight loss and increased physical fitness nearly halved the risk of losing mobility in overweight or obese adults with type 2 diabetes. Look AHEAD is a multicenter, randomized clinical trial, with more than 5,000 participants, determining whether a lifestyle intervention designed to promote weight loss can improve health outcomes in overweight or obese people with type 2 diabetes. Participants were randomly assigned to either an intensive lifestyle intervention group (ILI) or a diabetes support and education group (DSE). Among the tests done in the trial, the researchers measured participants' weight, and they assessed the participants' fitness with a treadmill test. When the Look AHEAD trial began, nearly two-thirds of participants reported mild, moderate, or severe restrictions in mobility. After 4 years of the study, participants in the ILI group experienced a 48 percent reduction in mobility-related disability compared with the DSE group. Furthermore, 20.6 percent of ILI participants reported severe disability compared to 26.2 percent of participants in the DSE group. Likewise, 38.5 percent of those in the ILI group reported good mobility, whereas the rate was 31.9 percent in the DSE group. Weight loss was a slightly stronger predictor of better mobility than was improved fitness, but both contributed significantly to the observed reduction in risk. These benefits of the ILI are in addition to those previously demonstrated, which showed it led to significantly greater weight loss than did the DSE, as well as to improved fitness, glucose control, blood pressure, and HDL cholesterol, despite a reduced need for medication.

Ominous Findings for Youth with Type 2 Diabetes

Recent findings from the NIDDK-supported TODAY (Treatment Options for Type 2 Diabetes in Adolescents and Youth) trial, published April 29 in the *New England Journal of Medicine*, reveal that type 2 diabetes (T2D) is more difficult to treat in young people with the disease than in adults. Although T2D is most commonly diagnosed in people over the age of 40, an increase in childhood obesity and other factors has led to a significant increase in T2D cases in people under 20. (*Data from the SEARCH for Diabetes in Youth study show T2D prevalence increased 21 percent among American youth from 2001-2009.*) It was unknown whether treatments developed for adults would work well for younger patients. Metformin, the first-line drug of choice among adults with T2D, is currently the only oral medication with FDA approval for treatment of T2D in young people. TODAY tested how well three treatment approaches controlled blood glucose levels in youth recently diagnosed with T2D and enrolled between the ages 10 and 17. Participants were randomly assigned to receive either metformin alone, metformin and rosiglitazone together, or metformin plus intensive lifestyle changes aimed at helping participants lose weight and increase physical activity. Unfortunately, metformin alone failed to maintain acceptable, long-term, blood glucose control in 51.7 percent of youth over an average follow-up of 46 months—a much higher failure rate than expected. Metformin plus lifestyle failed 46.6 percent of the time, an improvement over metformin alone that is not statistically significant. The combination of metformin plus rosiglitazone was significantly better, but still failed 38.6 percent of the time over the follow-up

period. Importantly, after the study began, the FDA restricted use of rosiglitazone because of studies linking the medicine to a higher risk of heart attacks and stroke in adults. Thus, there is a pressing need for better ways to treat youth with T2D.

Bariatric Surgery Can Restore Blood Glucose Control in Type 2 Diabetes

Two studies published March 26 in the *New England Journal of Medicine* showed that bariatric surgery (in adults) can help control T2D more effectively than medical therapy alone, and can help reduce the need for medications to lower glucose, lipids, and blood pressure. Although there were technical differences between the procedures tested in the two studies, both found that many patients receiving surgery achieved target HbA1c levels without further use of antidiabetic medication—in contrast, none in the control groups were able to control blood glucose without medicaton. The participant follow-up times in the studies were 12 months and 2 years for the U.S. and Italian studies respectively. Further research with larger cohorts from multiple sites will be necessary to determine whether this result is broadly generalizable, and longer follow-up times will be necessary to assess the capacity of these surgeries to produce long-term relief from T2D. Other, ongoing NIDDK-supported research seeks to determine the biological reasons why bariatric surgery can markedly improve blood glucose control independent of significant weight loss. Understanding the physiological response to bariatric surgery may make it possible to design therapeutic approaches with similar efficacy that do not require expensive, potentially risky surgical procedures. Other NIH-funded studies, such as the Longitudinal Assessment of Bariatric Surgery (LABS) and Teen LABS studies, are looking at long-term safety and efficacy of bariatric surgery for both weight loss and obesity-related medical conditions, including type 2 diabetes.

Diabetes News

- http://www.businessweek.com/news/2012-05-09/immune-cell-therapy-cures-diabetic-mice-researchers-find (Business Week)
- http://www.washingtontimes.com/news/2012/jul/5/a-public-private-cure-for-diabetes/ (Washington Times)

GUEST OPINION: LOCAL HEALTH DEPARTMENTS - ON THE FRONT LINES OF PREVENTING DIABETES IN AMERICA'S COMMUNITIES

By Robert M. Pestronk, Executive Director, National Association of County and City Health Officials

The number of people with diabetes in the United States is roughly equal to the combined population of Los Angeles, New York City, Chicago, Seattle, and St. Louis. Diabetes is the seventh leading cause of death in the United States. From 1980 through 2010, the number of American adults with diabetes more than tripled. Your local health department plays an important

role in mitigating this unprecedented epidemic and emergency. Its toll on quality of life and surging health care costs is profound. While the work of your local health department may not always be visible, we are safer and healthier because of it.

Every day, local health departments mobilize with community partners like schools, businesses, restaurants, and city planners. Together, these partnerships inform community members about diabetes prevention and control and awareness is heightened about risk factors such as obesity, lack of physical activity, and poor nutrition. Many local health departments work to make fresh, nutritious produce more accessible. They help to create safe places to exercise and conduct media campaigns to educate the public.

Through their state governments, some local health departments receive funding for diabetes prevention from the Centers for Disease Control and Prevention's Division of Diabetes Translation. Congress also provides funding for the National Diabetes Prevention Program, supporting intensive community-based work designed to help people who are pre-diabetic and at risk of developing the disease. These investments pay back in diabetes prevention, reduced emergency room visits and less frequent hospitalizations. Federal support for these activities is all the more important given the budget challenges at the state and local level.

The National Association of County and City Health Officials (NACCHO) is the voice of the approximately 2,800 local health departments across the country.
www.naccho.org

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.

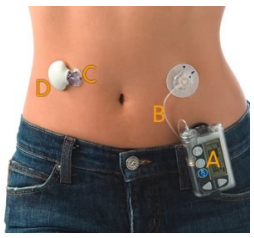
RECENT EVENTS

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.

On July 24, the Diabetes Caucus co-hosted a briefing entitled, "Diabetes: Innovative Approaches to Care, Treatment and Education" along with the California Healthcare Institute. The briefing included a distinguished panel of doctors and researchers who are working on innovative tools and programs to better understand, prevent, and treat diabetes and its related conditions.



REGULATORY PRIORITIES

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

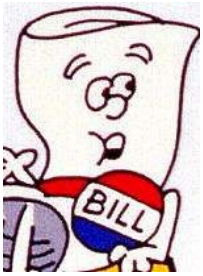
Thank you to the 252 of our House colleagues and members of the Diabetes Caucus who signed the letter to FDA Commissioner Margaret Hamburg , 134 Democrats and 118 Republicans, in bipartisan support of advancing artificial pancreas technology guidance. The artificial pancreas is a potentially life-saving 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.

FDA is working on finalizing the draft guidance for low glucose suspend (LGS) systems and artificial pancreas (AP) systems as a high priority and has based this on feedback from patients and clinicians. Research on artificial pancreas systems is continuing including for the first time a study being performed in a more real-world setting outside of the hospital.

LEGISLATIVE PRIORITIES



The **Special Diabetes Program** (SDP) is set to expire in September 2013 and needs to be reauthorized this Congress. Earlier this year, the Diabetes Caucus circulated 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.