



DIABETES IS PRIMARY

TIMELY NEWS FOR THE MULTIDISCIPLINARY CARE TEAM
from the American Diabetes Association

FROM THE JOURNALS.....

By Max Bingham, PhD

Welcome to *Diabetes Spectrum's* first installment of *Diabetes is Primary*, a round-up of the latest diabetes developments for health care providers. In this issue, we take a look at radical weight loss for diabetes remission, Hong Kong's diabetes risk assessment and management program, personalized A1C targets, and diabetes diagnoses. The American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) panel gives its verdict on continuous glucose monitoring (CGM) devices, and we learn how Medicare will soon pay for a diabetes prevention program.

Remission of Type 2 Diabetes With Radical Weight Loss

A low-calorie diet approach that induces substantial weight loss in patients with type 2 diabetes can also result in remission of the disease, according to Lean et al. (<http://doi.org/chn5>). In addition to eliminating the need for antidiabetes drugs to control glycemia, the authors point out that the result was achieved in a nonspecialist community primary care setting.

Writing in *The Lancet*, the authors report the outcomes of the Diabetes Remission Clinical Trial (DiRECT) that focused on primary care practices across Scotland and the Tyneside region of England. The practices were assigned either to provide a weight management program called Counterweight-Plus or standard care according to guidelines. Practice staff were provided structured training in delivery of the weight management program, which aimed to achieve a weight loss of 15 kg (33 lb). Primary outcomes were changes in patient weight and A1C between baseline and 12 months.

The authors report that one-fourth of the patients who received the weight management treatment lost at least 15 kg within 12 months, whereas none of the equivalent patients in the control group hit the target. Meanwhile, mean weight reduction in the intervention group was

10 kg, compared to 1 kg in the control group at 12 months. In the intervention group, 46% of participants experienced diabetes remission (broadly defined as an A1C <6.5%), compared to 4% in the control group. The authors describe an apparent inverse relationship between weight change and diabetes remission.

In a news release (<http://bit.ly/2zg0Wpu>), Michael Lean, co-lead author of the study, said, "Our findings suggest that even if you have had type 2 diabetes for 6 years, putting the disease into remission is feasible. In contrast to other approaches, we focus on the need for long-term maintenance of weight loss through diet and exercise and encourage flexibility to optimize individual results."

Hong Kong Type 2 Diabetes Management Program Is Effective

The Risk Assessment and Management Program for primary care patients with type 2 Diabetes Mellitus (RAMP-DM) has been running in Hong Kong since 2009 and was recently the subject of two studies investigating its effectiveness at reducing diabetes complications and its cost-effectiveness. In short, the program works and can save considerable sums compared to usual primary care for people with type 2 diabetes.

Published in the January 2018 issue of *Diabetes Care* (<http://doi.org/chn8>), the first study, by Wan et al., evaluated the effectiveness of RAMP-DM in delaying disease progression, preventing complications, and reducing hospitalizations compared to usual diabetes care.

The authors report that, after a median follow-up of 4.5 years, the cumulative incidence of any event was 23.2% in the RAMP-DM group, compared to 43.6% in the usual-care group. Specifically, RAMP-DM led to greater relative risk reductions for cardiovascular disease (56.6%), mortality (66.1%), and microvascular complications (11.9%). There was also substantially lower risk for overnight hospitalizations, emergency room visits, or specialist outpatient attendance.

Author Esther Yee Tak Yu said, "A systematic, structured risk assessment coupled with multidisciplinary care management could enhance routine doctor follow-up

Max Bingham, PhD, is a science writer and editor in Rotterdam, Netherlands. He can be reached on Twitter at @maxbingham.

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TREATMENTS + THERAPIES

Type 1 or Type 2 Diabetes in Adults?

Research suggesting that as much as 40% of type 1 diabetes cases likely occur after the age of 30 is probably worth some attention.

Thomas et al. in *Lancet Diabetes and Endocrinology* (<http://doi.org/chpg>) focus on the 500,000-strong U.K. Biobank cohort and use a novel genetic approach to identify type 1 diabetes in adults that crucially includes cases that might not have been picked up by family doctors.

Based on genetic risk scores, the authors found that ~4% of the population had genetically defined type 1 diabetes and that 42% were individuals 31–60 years of age. The clinical characteristics of the group did not differ from those of patients with type 1 diabetes who were ≤30 years of age, but they did differ from those of individuals with type 2 diabetes. The middle-aged individuals with type 1 diabetes were thinner, more likely to use insulin, and experienced diabetic ketoacidosis slightly more often than their counterparts with type 2 diabetes.

Unlike diagnosing type 1 diabetes in younger populations, identifying it in adults >30 years of age is challenging simply because of the higher prevalence of type 2 diabetes in that age-group. Accurately distinguishing between the two types of diabetes is crucial because it affects treatment decisions; many adult patients with type 1 diabetes initially receive a diagnosis of type 2 diabetes and do not receive the insulin they actually need.

In a news release (<http://bit.ly/2CWRGZX>), author Richard Oram said, “Diabetes textbooks for doctors say that type 1 diabetes is a childhood illness. But our study shows that it is prevalent throughout life. The assumption among many doctors is that adults presenting with the symptoms of diabetes will have type 2, but this misconception can lead to misdiagnosis with potentially serious consequences. This study should raise awareness that type 1 diabetes occurs throughout adulthood and should be considered as a diagnosis.”

Type 2 or Type 3c Diabetes in Adults?

A relatively unknown form of diabetes, called type 3c or diabetes of the exocrine pancreas, may be more common than type 1 diabetes in adults, and more worrisome, it might be regularly misdiagnosed as type 2 diabetes, according to a study in *Diabetes Care* by Woodmansey et al. (<http://doi.org/gcg8bz>).

consultations in usual care in order to provide timely detection of risk factors and subsequent treatments to prevent further deterioration. A key next step is to investigate the optimal frequency of repeat RAMP-DM and the evaluation of cost-effectiveness and budget impact of RAMP-DM.”

Cost-Effectiveness of RAMP-DM

Rather helpfully, the question of RAMP-DM’s cost-effectiveness is addressed in a follow-up study published in the February 2018 issue of *Diabetes Care* (<http://doi.org/chn9>), in which we learn that implementation of the approach has likely saved many millions of dollars during its implementation period.

Jiao et al. describe a prospective cohort study involving just over 17,000 diabetes patients to determine the effectiveness of the program, as well as the costs involved, compared to usual care. In addition to again demonstrating the effectiveness of the program in terms of reduced diabetes complications and lower mortality, they identified substantial cost savings compared to usual care. They say that the overall average cost of the RAMP-DM program was \$157 per patient over 5 years, which resulted in savings of just under \$7,300 in overall health care costs. The average cost of usual care over 5 years was just under \$20,000, whereas the addition of RAMP-DM reduced the figure to just over \$12,000.

Study author Colman Siu Cheung Fung said, “RAMP-DM complemented to usual primary care was a cost-saving program in managing people with diabetes over 5 years. This evidence leads us to recommend the integration of RAMP-DM as part of routine primary care for all patients with diabetes.”

Personalized A1C Targets May Save Money and Improve Quality of Life

Personalized glycemic control targets for type 2 diabetes are more cost-effective than a uniform intensive target such as an A1C <7%, according to Laiteerapong et al. (*Annals of Internal Medicine*, <http://doi.org/chpb>). The costs of care were \$13,547 lower over patients’ lifetimes when they had personalized targets instead of a uniform

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MARKETPLACE

ADA/EASD Joint Statement on CGM Technologies: Progress Still Needed

ADA and EASD have published a joint scientific statement on CGM systems (<http://doi.org/chpd>), with a particular focus on their clinical value and the ways in which health care professionals, manufacturers, regulators, and consumers might get the most from the technology. The panel makes a series of recommendations for improving the technology, which currently has relatively poor uptake and fractured development, despite holding great promise for diabetes management.

The authors summarize a series of studies relating to CGM, including growing evidence supporting the benefits of CGM in adults with type 1 diabetes and mixed results in children and adolescents. The authors noted that evidence in support of CGM for type 2 diabetes is limited, saying that, although clinical studies have moved the field forward somewhat, common design limitations are hindering progress. Even meta-analyses have reportedly come to mixed conclusions, likely because of nonstandardized reporting of clinical trial outcomes.

The authors go on to say that, despite clear progress in the design of CGM systems, numerous issues remain. Finding solutions will require a high level of cooperation among stakeholders and that better CGM education and training will be needed for both patients and health care providers. They also touch on the potential of remote data from CGM devices but caution on issues such as data privacy and cybersecurity.

“We envision an ongoing role of the ADA, EASD, and other professional medical associations in supporting the virtuous circle of CGM innovation, confirmation of value to users, increased utilization, and greater resources reinvested to support innovation,” the panel members write. “For this vision to be realized without further delay, we call upon

regulators and manufacturing companies to work urgently with health professionals and people with diabetes to create an environment with much greater standardization of outcome measures, a high level of attention to safety, and full transparency of adverse event reporting.”



CONFERENCE SPOTLIGHT

BENEFITS OF BARIATRIC SURGERY IN PATIENTS WITH TYPE 2 DIABETES

Bariatric surgery can lead to significant long-term metabolic benefits in patients with type 2 diabetes treated with insulin, according to a study presented at the 2017 ObesityWeek conference (<http://bit.ly/2xSbHi4>). Benefits included diabetes remission without the need for insulin for up to 7 years after gastric bypass surgery or sleeve gastrectomy.

Using a retrospective analysis of data from a cohort of 252 patients who underwent surgery, the researchers reported that 51% of insulin-treated patients with type 2 diabetes reached an A1C of <7% without insulin use 1–2 years after surgery. Forty-four percent of the patients met the primary target ≥ 5 years after their procedure. Moreover, bariatric surgery also led to significant rates of diabetes remission, weight loss, reductions in LDL cholesterol and increases in HDL cholesterol, and reductions in diastolic and systolic blood pressure and triglycerides.

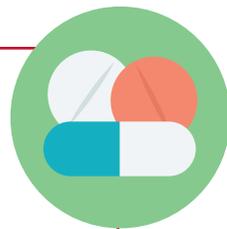
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As a result, the authors say, patients often receive suboptimal care because type 3c diabetes often causes very poor glycemic control with much greater insulin requirements.

Type 3c diabetes occurs after damage to the pancreas through inflammation, abnormal tissue growth, or surgery and results in the loss of ability to produce insulin.

The authors' report involved searches of more than 2.3 million primary care records in England and the extraction of cases of adult-onset diabetes with and without pancreatic disease before the diagnosis of diabetes. The authors found just under 32,000 cases of new, adult-onset diabetes. Of the 559 cases that occurred after some sort of pancreatic disease, ~8% actually had type 1 diabetes, ~3% were classified correctly as having type 3c diabetes, and ~88% were incorrectly classified as having type 2 diabetes. In addition, the individuals in these cases had much poorer glycemic control and much greater insulin use than individuals with type 2 diabetes.

In a statement (<http://bit.ly/2kXMttb>), author Simon de Lusignan said, “Greater awareness of type 3c diabetes within the medical profession is required immediately to improve management of this disease, which now has a higher incidence than type 1 diabetes in adults. Our research shows that the majority of people with type 3c diabetes are being misdiagnosed with type 2 diabetes, putting both their short- and long-term health at risk.”



ADA NEWS

INSULIN AFFORDABILITY

The average price of insulin has skyrocketed in recent years—nearly tripling between 2002 and 2013. Insulin isn't optional. For millions of people living with diabetes, including all individuals living with type 1 diabetes, access to insulin is a matter of life and death. There is no medicine that can be substituted for insulin.

For more than a year, the ADA's Make Insulin Affordable campaign has been bringing attention to this crucial issue. In 2016, the ADA board of directors issued a resolution calling on all entities in the insulin supply chain, including manufacturers, wholesalers, pharmacy benefit managers, insurers, and pharmacies, to substantially increase transparency in pricing associated with the delivery of insulin to individuals with diabetes. Transparency in this process is the first step to identifying viable long-term solutions for individuals with diabetes who are unable to afford the insulin they need. The resolution also calls on all entities in the insulin supply chain to ensure that no person with diabetes is denied affordable access to insulin.

As the organization whose mission is to improve the lives of all people affected by diabetes, ADA believes that no individual in need of lifesaving insulin should ever go without it due to prohibitive costs. To address this issue, the association has convened an Insulin Access and Affordability Working Group, which is working with multiple stakeholders at all levels of the insulin supply chain, people affected by the rising cost of insulin, and the U.S. Congress in an active effort to understand the underlying causes of the dramatic increase in insulin prices. The major objective of the working group is to bring about long-term solutions to ensure that insulin is affordable for all who need it. More information on these efforts is available from www.makeinsulinaffordable.org.

THE USE OF LANGUAGE IN DIABETES CARE AND EDUCATION: A CONSENSUS REPORT

Language has a strong impact on perceptions and behavior, and this may be especially true with regard to medical care and health-related behaviors. An ADA/American Association of Diabetes Educators joint task force has examined this issue with regard to diabetes care and education and developed recommendations for language used by health care professionals and others when discussing diabetes with patients, colleagues, or the general public. These recommendations, in addition to research questions related to language and diabetes, are outlined in a consensus report released simultaneously in October 2017 by *Diabetes Care* and *The Diabetes Educator* (<http://doi.org/cfrz>).

CODING, REGULATIONS, + REIMBURSEMENTS



DIABETES PREVENTION PROGRAM ADDED AS A MEDICARE BENEFIT

The Centers for Medicare & Medicaid Services (CMS) recently released its final rule for the 2018 physician fee schedule, which contains detailed regulations for the expanded model of the Medicare Diabetes Prevention Program (MDPP) (<http://bit.ly/2p75AXj>, <http://bit.ly/2IK3lre>). In short, as of 1 April 2018, CMS will cover MDPP as a benefit for Medicare beneficiaries who meet certain criteria.

Designed specifically for individuals with prediabetes, the program provides coaching to encourage weight loss, dietary improvements, and increased physical activity in a bid to help at-risk individuals avoid developing type 2 diabetes. The program will be delivered by community health workers and health professionals in various settings.

According to the rule, the MDPP includes 6 months of core sessions, followed by maintenance sessions for 6 months and through a second year. Participants must complete 16 sessions in the first 6 months based on the notion that the greatest weight loss is most likely to occur in this period. Additionally, beneficiaries should achieve a minimum weight loss of 5% in the first year to remain eligible for the second year of maintenance sessions. Crucially, reimbursements are tied to some extent to the weight loss achieved by beneficiaries.

Eligibility criteria for the program include enrollment in Medicare Part B, a BMI >25 kg/m² (or >23 kg/m² if Asian) at first attendance, an A1C of 5.7–6.4%, a fasting blood glucose value of 110–125 mg/dL or a 2-hour plasma glucose value of 140–199 mg/dL, no previous diagnosis of type 1 or type 2 diabetes (other than gestational diabetes), and no end-stage renal disease. Individuals are only eligible for this benefit once in their lifetime.

A detailed overview of performance reimbursements payments is available at <http://bit.ly/2BtDOtM>. Details relating to supplier enrollment and compliance are available at <http://bit.ly/2DnYDUN>.

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target. Although the average life span of those with personalized targets was expected to be slightly shorter (by 1 month), their quality of life was expected to be higher. As a result, the authors say it may be possible to save as much as \$234 billion if all 17.3 million patients with type 2 diabetes in the United States were given individualized targets.

In a statement (<http://bit.ly/2BIY7Fg>), author Neda Laiteerapong said, "People don't want to be treated by a standard value or an algorithm, they want to be treated like individuals. I think this model will give evidence to physicians that individualized glycemic control is something to consider. It can help save our health system, and it's in line with what many patients want."

To learn more about ADA's continuing education opportunities, including Diabetes Is Primary events in your community, please visit <http://professional.diabetes.org/ce>.