



# DIABETES IS PRIMARY

TIMELY NEWS AND NOTES FOR PRIMARY CARE PROVIDERS  
from the American Diabetes Association

By Max Bingham, PhD

## FROM THE JOURNALS.....

### **Poor Diet Linked to Type 2 Diabetes in Global Study**

Seventy percent of new type 2 diabetes cases in 2018 can be linked to poor diet, according to a study by O’Hearn et al. (*Nature Medicine*, doi.org/j8gj). Specifically, they found that, of 20 million new cases of type 2 diabetes in 2018, just over 14 million could be attributed to specific dietary factors for which there is probable or convincing evidence of influence on type 2 diabetes incidence.

Inadequate intake of whole grains and excessive intake of refined rice and wheat and processed meat had the greatest impacts. Other factors such as increased consumption of fruit juice and low consumption of vegetables, nuts, and seeds also contributed, but to a lesser extent. Excesses of six harmful factors (i.e., refined rice and wheat, processed meats, unprocessed red meat, sugar-sweetened beverages, potatoes, and fruit juice) in the diet contributed ~60% of the diet-attributable burden, while insufficient intake of five protective factors (whole grains, yogurt, fruit, nonstarchy vegetables, and nuts and seeds) contributed ~40%.

“Our study suggests poor carbohydrate quality is a leading driver of diet-attributable type 2 diabetes globally, and with important variation by nation and over time,” senior author Dariush Mozaffarian said. “These new findings reveal critical areas for national and global focus to improve nutrition and reduce devastating burdens of diabetes.”

The findings come from modeling of dietary data from 1990 and 2018 from 184 countries. The authors also included population demographics, estimates of type 2 diabetes incidence, and the impact of food choices on obesity and diabetes from prior published sources.

In addition to the overall contribution of poor diet to diabetes incidence, they found wide regional differences

in terms of both incidence rates and food choices that likely explain the patterns. Incidence was also higher for males, younger adults, and urban residents compared to females, older adults, and rural residents, respectively.

“These findings can help inform nutritional priorities for clinicians, policymakers, and private sector actors as they encourage healthier dietary choices that address this global epidemic,” lead author Meghan O’Hearn said.

### **One in 20 New Diabetes Cases Linked to COVID-19**

Individuals, and especially men, who tested positive for coronavirus disease 2019 (COVID-19) had increased risk for incident diabetes compared to individuals who tested negative, according to Naveed et al. (*JAMA Network Open*, doi.org/gr5jvt). Indeed, up to one in 20 new diabetes cases might be related to COVID-19 infection, according to the analysis.

A growing number of studies have now looked at the relationship between COVID-19 and diabetes, with the majority suggesting there might be some cause for concern. However, most of these studies have been small or in very defined populations, making generalizability tricky. Also, questions remain around whether the pandemic has simply uncovered more cases than usual because of the intensity of care given to COVID-19 patients (i.e., surveillance bias).

The authors examined the records of just under 630,000 individuals in the British Columbia COVID-19 cohort who were tested with RT-PCR (reverse transcription–polymerase chain reaction) for severe acute respiratory syndrome coronavirus 2 infection in 2020 and 2021. Individuals who were positive (i.e., exposed) were then matched 1:4 with control subjects matched for sex, age, and RT-PCR collection date who tested negative (i.e., unexposed).

They found the risk of incident diabetes 30 days after a test result increased in the exposed group (hazard ratio 1.17, 95% CI 1.06–1.28), with slightly higher risks evident in males. The risk was also particularly severe in individuals

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## TREATMENTS + THERAPIES

### Pilot Study Suggests Potential Longer Shelf Life for Insulin

A pilot study by Pendsey et al. (*The Lancet Diabetes & Endocrinology*, doi.org/gr4pf2) suggests that insulin likely can be stored at room temperature and potentially for much longer than insulin manufacturers and authorities currently recommend. The finding could have major implications in resource-poor settings such as developing countries, where insulin is often in short supply and very expensive.

One of the concerns with insulin (apart from its U.S. pricing; more on that below) surrounds its perceived temperature sensitivity and thus its shelf life and potency, with concerns raised for situations in which refrigeration is not available. At room temperatures that can exceed 86° F, insulin is thought to keep for about 4 weeks, after which recommendations indicate that it should be discarded.

To investigate the actual stability of insulin in such conditions, the authors asked six families from Nagpur, India, to store insulin samples unopened for 1–4 months in nonrefrigerated, real-world conditions during the summer. Control samples were kept refrigerated. They also compared the effects of storing the samples on a shelf or in clay pots that are traditionally used to keep contents cooler than surroundings.

The authors found that, with temperatures hovering around 86° F, the unrefrigerated insulin generally maintained 95% of the potency of refrigerated control products after as long as 4 months of storage.

“This study shows that insulin probably has a considerably longer shelf life at room temperature—up to four times as long as was previously believed,” author Gun Forsander said. “The study also showed that the simple solution, with cooling clay pots, can be helpful when the weather is at its hottest.”

### “What Just Happened” With the Price of Insulin in the United States?

As was widely reported in the media, all three manufacturers of insulin recently announced substantial price cuts for insulin in the United States. Sanofi was the latest to announce the changes, following similar moves by Eli Lilly and Novo Nordisk. Together, the three companies control ~90% of the U.S. insulin market, and all have now announced price cuts in the region of 70–75% that will take effect in early 2024.

“As of this afternoon, all three of the leading insulin producers in America have agreed to substantially

*continued on p. 334 →*

who were hospitalized or admitted to an intensive care unit with COVID-19.

According to the authors, this increased risk might have contributed a 3–5% excess burden of diabetes at a population level, which will likely be associated with a substantial number of extra diabetes cases. The authors point out that the size of the study helps address the issues with generalizability of previous studies but that they still cannot rule out residual confounding and surveillance bias as limitations.

“Our study highlights the importance of health agencies and clinicians being aware of the potential long-term consequences of COVID-19 and monitoring people after COVID-19 infection for new-onset diabetes for timely diagnosis and treatment,” they write.

## Automated Insulin Delivery Boosts Time in Range for Very Young Children

A hybrid closed-loop automated insulin delivery (AID) system improves blood glucose time in range (TIR) in very young children with type 1 diabetes, according to Wadwa et al. (*New England Journal of Medicine*, doi.org/j8gm). Specifically, children using the system had ~12% more time within the target glycemic range overall than those receiving standard care and ~18% more TIR during the night. This increase in TIR equated to an average of an extra 3 hours/day in range over the 13-week trial, compared to no change in TIR with standard care. The children involved in the trial were 2 to <6 years of age.

The study enrolled 102 children from across the United States and randomly assigned 68 to use the AID system and 34 to standard care with the use of a continuous glucose monitoring system. Of note, the study was carried out during the coronavirus disease 2019 pandemic; as a result, just over 80% of training sessions and 90% of overall visits were carried out virtually.

The mean TIR rose from 57% at baseline to nearly 70% after 13 weeks in the group using the AID system. Meanwhile, TIR in the group receiving standard care was 55% at baseline and 56% after 13 weeks. The authors also note similar treatment effects favoring the system in terms of time above range, mean glucose level, and A1C, and there were no between-group differences in time below range.

“At the end of the day, this technology significantly improved glycemia and ensured safety of our youngest patients, but perhaps just as importantly, it lessened these families’ constant anxiety about glucose levels, especially during the night,” senior author Marc Breton said. “It is incredibly rewarding for us to hear about these families’ experiences and how they manage to integrate these new tools in their life, offering some reprieve to the challenges they face.”

## ChatGPT Performs Well for Diabetes Education

ChatGPT, the new chatbot driven by artificial intelligence (AI) that has attracted equal amounts of interest, surprise, derision, and concern, can give largely accurate answers to routine patient questions about diabetes care.

According to Sng et al. (*Diabetes Care*, doi.org/grzwp5), ChatGTP performed well when posed a series of routine patient questions about diabetes, although they did have some reservations. For example, there were inaccuracies in certain responses, and the chatbot occasionally required a bit of encouragement to provide any answer at all. It was also prone to that most modern affliction of at times presenting “inaccurate and untruthful information in a persuasive and linguistically fluent manner.”

The authors note that their use of a version of the language model that was trained before 2021 using general rather than medical information might explain some of these limitations.

AI-driven chatbots, assuming they can overcome their current limitations, are widely seen to have potential for answering routine questions such as those often posed by patients. Despite its performance issues in this study, the authors note that ChatGTP was able to pass a U.S. medical licensing examination. They suggest that, should such obstacles be overcome, it might revolutionize how patients access medical advice.

In the meantime, they urge caution with using this approach, with lead author Gerald Gui Ren Sng telling Medscape (wb.md/3LNeD83), “In the same way . . . [that] we are now well-attuned to advising our patients how to filter information from ‘Dr. Google,’ perhaps a better understanding of ‘Dr. ChatGPT’ will also be useful moving forward.”

The authors also caution that, “Health care providers should be aware of such models’ strengths and limitations to accurately advise their patients and exercise due caution if AI chatbots are contemplated for augmentation of clinical care.”

## Treatments + Therapies, continued from p. 333

reduce their prices, following my calls to expand my \$35 cap for seniors to all Americans,” U.S. President Joe Biden said. “Sanofi is the latest company to recognize that charging hundreds of dollars for insulin that costs \$10 to produce is just wrong, especially when the lives of so many children, parents, and grandparents depend on it.”

The announcements have been widely, but not universally, applauded. American economist Leemore S. Dafny (*New England Journal of Medicine*, doi.org/j8gq) explains that, initially, she could not join the applause but that, on reflection, her initial reaction might have been wrong.

In an article entitled “Falling Insulin Prices—What Just Happened?” Dafny argues that, while moral

suasion (or public shaming) might have had a hand in the companies’ decision-making process, it was unlikely the only factor. Rather, it was likely a series of events that forced the hand of manufacturers. These events included the introduction of interchangeable biosimilar insulins, legislation, lawsuits, investigations, and impending caps on rebates via new regulations.

“A possible silver lining of this lengthy and painful episode in U.S. drug history is that high, oligopolistic pricing will most likely be harder to sustain for mass-market products that have therapeutic substitutes and for which copycats can be made relatively easily,” Dafny concludes. “If that sounds like qualified, muted applause, it is. But it is applause nonetheless.”



## ADA NEWS

### Medicare Expands Coverage for Continuous Glucose Monitoring

Effective on 16 April 2023, all Medicare beneficiaries who are insulin users, as well as others who have a history of problematic hypoglycemia, are now eligible to get a continuous glucose monitoring (CGM) system. The American Diabetes Association (ADA), working individually and with its Technology Access Project coalition, submitted comments and oral testimony on the proposed rule.

The new Centers for Medicare & Medicaid Services (CMS) rule allows people to receive a CGM system if they are treated with any type or amount of insulin. Previously, CMS coverage for CGM required people with diabetes to take a certain amount of insulin per day. The new rule also allows individuals with diabetes who do not take insulin to receive a CGM system if they have a history of problematic hypoglycemia.

Under CMS rules, individuals must have an appointment with their health care provider within 6 months of ordering a CGM system. That appointment may now either be in person or via telehealth.

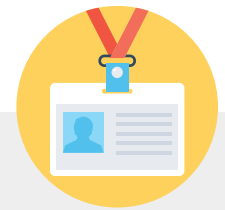
Additional information, including detailed eligibility requirements, is available on the ADA website ([bit.ly/411DAkD](https://bit.ly/411DAkD)).

### ADA Offers a Free Lifestyle Change Program for the Whole Family

The ADA's Project Power is a no-cost lifestyle change and diabetes awareness program designed to empower adults and youth aged 5–12 years to reduce their risk of diabetes or manage and thrive with type 2 diabetes.

Created in partnership with CVS Health, the program encourages behavior changes, improved knowledge, and confidence in participants, so they can take steps to lower their risk for type 2 diabetes or better manage their diabetes. For adults, the program combines interactive lessons with a health coach, small support groups, and other tools and resources. For children, the program promotes healthy food choices, increased physical activity, and peer and family support.

Details about Project Power are available on the ADA website ([bit.ly/420W4TI](https://bit.ly/420W4TI)).



## CONFERENCE SPOTLIGHT

### ***Blood Pressure Drug May Preserve $\beta$ -Cell Function***

The blood pressure medication verapamil appears to preserve some  $\beta$ -cell function in early type 1 diabetes, according to Forlenza et al. Specifically, the drug appears to partially preserve C-peptide levels (a measure of  $\beta$ -cell function). C-peptide levels were significantly higher after 52 weeks of treatment with verapamil compared to placebo.

These findings were from the CLVer (Hybrid Closed Loop Therapy and Verapamil for Beta Cell Preservation in New Onset Type 1 Diabetes) trial, which investigated the effects of verapamil and, separately, automated insulin delivery (AID) on C-peptide levels in new cases of pediatric type 1 diabetes. The findings were presented at the 16th International Conference on Advanced Technologies & Treatments for Diabetes on 24 February in Berlin, Germany, and published in *JAMA* (doi.org/grtvc6).

The trial included 88 children and adolescents with newly diagnosed type 1

diabetes, with 47 randomized to verapamil and 41 to placebo. Participants were also assigned to receive intensive diabetes management using an AID system or standard care that included continuous glucose monitoring. The primary outcome was area under the curve for C-peptide, as measured in a mixed-meal tolerance test after 52 weeks.

In the verapamil group, mean C-peptide was 0.66 pmol/mL at baseline and 0.65 pmol/mL after 52 weeks. In the placebo group, the values were 0.60 and 0.44 pmol/mL, respectively. Thus, at 52 weeks, C-peptide levels were 30% higher with verapamil than with placebo.

“The beneficial effect of verapamil observed in the trial is extremely exciting,” senior author Antoinette Moran said. “Although we don’t know whether the beneficial effect of verapamil on insulin secretion by the pancreas will be sustained once treatment was stopped at 12 months, we do know that better pancreas function in the first year is associated with better long-term outcomes in type 1 diabetes.”

To learn more about ADA’s continuing education opportunities, including Diabetes Is Primary events in your community, please visit [professional.diabetes.org/ce](http://professional.diabetes.org/ce).