



DIABETES IS PRIMARY

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

By Max Bingham, PhD

FROM THE JOURNALS.....

COVID-19 Linked to Type 2 Diabetes Risk Up to 1 year After Infection—But, the Jury Is Still Out

People who have had coronavirus disease 2019 (COVID-19) appear to have increased risks for incident diabetes 1 year after severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, according to a very large cohort study drawing on U.S. Department of Veterans Affairs data.

Although proving definitive causation is not yet possible, this study (Lancet Diabetes & Endocrinology, doi.org/hqb9) provides the latest and clearest indication of a link between COVID-19 and incident diabetes. It follows a series of other recently published studies that largely point in the same direction (e.g., doi.org/gpdf2b, doi.org/hsf7, doi.org/hsf8, and doi.org/hsf9), although other studies have cast some doubt (e.g., doi.org/hsgb and bit.ly/38LOAgx).

According to the latest study, veterans who were diagnosed with COVID-19 had a 40% higher risk of developing diabetes at 1 year than contemporary control subjects (hazard ratio 1.40, 95% CI 1.36–1.44). There was also a significantly higher level of excess burden of new diabetes among people who had had COVID-19 (13.46 excess cases of diabetes per 1,000 individuals). In parallel, authors Yan Xie and Ziyad Al-Aly also report increased risks for use of antihyperglycemic drugs at 1 year in people who had had COVID-19, and increased risk of a composite outcome including incident diabetes and antihyperglycemic drug use.

The study included 181,280 individuals in the COVID-19 group, with just over 4 million individuals without COVID-19 in a contemporary control group

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<https://doi.org/10.2337/cd22-dp03>

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and another 4 million in an historic control group. In addition to accounting for a series of confounders, the authors found that the results were consistent when using the historic control subjects as the comparator. They also used a full range of sensitivity analyses.

Based on these findings, the authors warn that these increased risks may translate into a substantial burden of diabetes, given that many people have been infected with SARS-CoV-2 globally. They also suggest that their evidence implies that post-acute COVID-19 care should probably include attention to and care for diabetes.

In a linked editorial (doi.org/hsgg), K.M. Venkat Narayan and Lisa R. Staimez said that, although the study has some significant limitations, its findings deserve further investigation. They call for multiethnic, prospective epidemiological studies to be conducted to confirm or refute the findings and also suggest a series of mechanistic studies to explore the relationship between COVID-19 and diabetes. Most strikingly, they suggest that the findings of Xie and Al-Aly will likely have major implications for clinical and public health policy.

“With large and growing numbers of people worldwide infected with SARS-CoV-2, any COVID-19–related increases in diabetes incidence could lead to unprecedented cases of diabetes worldwide, wreaking havoc on already over-stretched and under-resourced clinical and public health systems globally,” they wrote.

Writing in a Twitter thread (<https://bit.ly/3OTpFb8>), Al-Aly echoed the concern that the absolute numbers involved might translate to a substantial population-level diabetes burden that will further strain health care systems.

“Governments and health systems around the world should be prepared to screen and manage diabetes in people who had COVID-19,” he wrote. “And diabetes should be considered as a facet of the multifaceted long COVID syndrome.”

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TREATMENTS + THERAPIES

Generic Manufacturer Civica Rx to Launch Low-Cost Insulins in the United States in 2024

The nonprofit Civica Rx (civicarx.org) has announced plans for three biosimilar insulins that, once approved, will sell at dramatically discounted prices compared to currently available branded versions. The company will target biosimilar versions of Sanofi's Lantus, Lilly's Humalog, and Novo Nordisk's Novolog, with promises of prices no higher than \$30 per vial and \$55 per box of five pen cartridges. Pending U.S. Food and Drug Administration approval, the company expects its biosimilar glargine to be available for purchase early 2024, with manufacturing in its own facilities.

Calls to lower the cost of insulins have grown after years of extraordinary price increases from the three incumbent manufacturers and middlemen involved in the insulin market. The existing complex system of insulin sales has made breaking into the market difficult and expensive. Civica Rx's solution is to bypass outside manufacturers and the pharmacy benefits managers and instead supply hospitals and pharmacies directly. Money to pay for the operation comes from member hospitals, health systems, and philanthropic organizations. Since 2018, Civica Rx has supplied 50 generic drugs to hospital systems that together represent about one-third of U.S. hospital capacity.

"More than 8 million Americans rely on insulin to live, but many can't afford to take the amount they need because of the historically high and prohibitive cost of insulin," Civica Rx Chief Executive Officer Martin VanTrieste said in a statement (bit.ly/3w4YKAW). "We know that to really solve the insulin cost and access challenges so many Americans face, we need a process—from manufacturing to setting a transparent price—that ultimately lowers the cost of the drug for those living with diabetes."

More information on the initiative is available on the Civica Rx website that focuses on the insulin initiative (bit.ly/3s3oNHu). Additionally, an in-depth interview with Civica Rx Board Chair Dan Lilienquist is available through the patient advocacy organization Beyond Type 1 (bit.ly/38ISiqV).

Glycemic Control in Youth With Diabetes Did Not Improve Between 2002 and 2019

Data from the SEARCH for Diabetes in Youth study suggest that a substantial percentage of U.S. youths and young adults are not achieving recommended A1C goals, according to a report by Malik et al. (*Diabetes Care*, doi.org/hsgh). This lack of improvement is despite the development of many new therapies for diabetes, as well as greater availability of and improvements in technologies such as continuous glucose monitoring (CGM) systems and insulin pumps over the ~20-year study period.

Most notably, many age-groups from more recent years had worse glycemic control than their counterparts from the earlier years of 2002–2007.

The study included just under 6,400 youths with type 1 or type 2 diabetes who were categorized into three time periods stretching from 2002 to 2019 in age-groups ranging from 1 to ≥25 years. Randomly selected A1C data points from the individuals were then used to test for differences in glycemic control in each time period according to age and duration of diabetes.

After adjusting for a range of factors, the authors found that individuals with type 1 diabetes (who made up most of the cohort) generally had worse glycemic control in the later periods compared to the 2002–2007 period. Meanwhile, individuals with type 2 diabetes had largely stable A1C levels with the exception of participants with ≥10 years, disease duration, who demonstrated a substantial increase in A1C in the 2014–2019 time period compared to the 2008–2013 period.

"These results suggest that not all youth and young adults with diabetes are directly benefiting from the increased availability of diabetes technology, newer therapies, and the use of more aggressive glycemic targets for youth with diabetes over time," lead author Faisal Malik said.

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MARKETPLACE.....

Dexcom Edges Forward With the G7 CGM, While Abbott Announces New Direct-to-Consumer Ketone, Glucose, and Lactate Biosensors

Dexcom seems to be making progress toward bringing its G7 continuous glucose monitoring (CGM) system to market. Trials are now complete, the system has received a European CE mark of approval, and the review process is underway with the U.S. Food and Drug Administration (FDA). At the time of writing, the company was poised to announce details on the system's usage and performance at the ATTD (Advanced Technologies & Treatments for Diabetes) 2022 conference in Barcelona, Spain (bit.ly/3y8ILEz). For now, we know that the G7 is 60% smaller than the G6, has an all-in-one sensor/transmitter instead of separate devices, and has a 30-minute warmup time (compared to 2 hours for the G6). It also includes a 12-hour grace period after sensor expiration and a mobile app reader with more options and alert configurations.

In a related announcement (bit.ly/3OQoBoG), Dexcom said the FDA has granted a "breakthrough device" designation for its CGM systems to be used in hospital settings.

"During the [coronavirus disease 2019] pandemic, the FDA allowed CGM to be used in hospitals to help health care

providers manage patient glucose levels," said Gil Rivas, a Dexcom vice president and general manager. "What started as a response during the pandemic has shown promise as a better alternative to fingerstick blood glucose tests, with greater quality of care and patient satisfaction."

The designation means that the full FDA approval process will be faster and more efficient—a bonus for Dexcom and hopefully a win for people using its CGM systems.

Meanwhile, Dexcom competitor Abbott has announced a move into direct-to-consumer biosensors (bit.ly/3OVAV7g), suggesting that the company wants to build on its success in the diabetes space and move into larger general health and wellness markets. First up is a ketone monitoring device, and in the wings are glucose and lactate sensors. So far, no launch dates, prices, or other details are available. However, the move suggests that Abbott (and maybe others in the diabetes technology space) are looking to expand from the highly specialized diabetes arena to broader commercial opportunities in general health and wellness.

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Based on their findings, the authors stress that lower A1C levels in childhood and young adulthood should translate into lower risks and rates of complications later on.

"Given the evidence highlighting the benefits of tight glycemic control, this study reinforces the need for interventions that combine the use of diabetes technology with effective behavioral and social approaches to improve A1C levels," Malik said.

Systematic Review: Adult Onset of Type 1 Diabetes Is Substantial

Although type 1 diabetes is traditionally viewed as a disease that starts in childhood, researchers have found that adult onset of the disease is substantial. A systematic review by Harding et al. (*Diabetes Care*, doi.org/hsgj) looked at population-based studies that focused on adult-onset type 1 diabetes from 1990 to 2021. Although rates varied

among countries and regions, the authors noted that rates may be as high as 92.9 per 100,000 in certain adult groups. The authors also found that overall patterns appear to be consistent with those found in children and adolescents.

Although data gaps prevented the authors from making a truly global assessment, their review provides a clear picture of the burden of new-onset type 1 diabetes in adulthood. Importantly, rates did not appear to wane with age or over time, as would be expected. The authors stress that further research is needed to validate their findings.

The key takeaway from this study is that there was no clear relationship between age and adult onset of type 1 diabetes. In a statement (bit.ly/37WF1ex), lead author Jessica Harding suggested that the findings might dispel conventional thinking that the disease rarely starts in adulthood.



ADA NEWS

CDC: More Than 1 in 10 people in the United States Have Diabetes

More than 1 in 10 Americans have diabetes according to the Centers for Disease Control and Prevention's (CDC's) latest National Diabetes Statistics Report (bit.ly/3y8P4b5). According to the report, which now includes data from 2017–2020, 37.3 million Americans (~10% of the population) have diabetes. Of those, about three-fourths have diagnosed diabetes, and one-fourth (8.5 million individuals) are not diagnosed. Another 96 million individuals (~38% of the population) have prediabetes, and only one-fifth of those individuals know they have it.

In a statement (bit.ly/3MBMz58), the American Diabetes Association (ADA) called these increases alarming and had particular concern for the large number of individuals who do not know they have prediabetes.

"The new CDC data show an alarming increase of diabetes in our nation among adults," said Robert Gabbay, the ADA's chief scientific and medical officer. "Overall, the National Diabetes Statistics Report reaffirms why the ADA is dedicated to innovative research to find a cure for diabetes once and for all."

ADA Develops New Resources on Key Nutrition Topics

The ADA has developed a six-part series of nutrition videos and handouts addressing popular nutrition topics. These materials are designed for use with low-literacy populations, and the nutrition recommendations they offer are relevant to people with prediabetes or diabetes. All of the videos and handouts are available in English and Spanish.

Video titles include:

- Food Groups and Portion Sizes
- Healthy Ways to Cook
- Navigating the Grocery Store
- Food Label Know-How
- Plan Your Plate
- Sugar Substitutes

The materials address topics relevant to a broad range of audiences and are available free of charge on the ADA's YouTube channel (bit.ly/3s5o2gS). Accompanying handouts are available in the ADA's patient education library (bit.ly/3ncfKRv).

Eye Health Risk Calculator Now Available

RetinaRisk, a diabetic retinopathy risk calculator, is now available. People with diabetes can use this clinically validated calculator to assess their risk of developing diabetic retinopathy, better understand the factors affecting their risk, and learn ways to prevent vision complications. The RetinaRisk calculator furthers the goals of the ADA's Focus on Diabetes eye health initiative by increasing awareness and understanding of the importance of annual comprehensive eye exams for people with diabetes. Patients and health care professionals can access the calculator on the ADA's website (bit.ly/3vWV9og).



CONFERENCE SPOTLIGHT

Diabetes UK Professional Conference: 57 Varieties . . . of Complications

Diabetes UK held its annual conference for professionals live in London at the end of March 2022. Day 1 highlights (bit.ly/38FQU8D) included health inequities in gestational diabetes and the potential effects of the coronavirus disease 2019 pandemic on rates of diabetes complications. Nutrition was the focus on Day 2 (bit.ly/3kyE6ng), with reports on the role of dietary fiber, diabetes remission through dietary and weight loss intervention, and eating disorders in type 1 diabetes. Day 3 (bit.ly/3kzMFhM) brought discussion of the costs and potential quality of life improvements associated with intermittently scanned continue glucose monitoring systems, as well as the need for increased awareness of nonalcoholic fatty liver disease. Day 4 (bit.ly/3F7hELj) brought an update on the use of artificial intelligence for earlier identification of type 1 diabetes, and Day 5 (bit.ly/3s5RH9A) featured new findings from the ReTUNE study of type 2 diabetes remission through reduction of fat in the liver and pancreas.

However, the stand-out report of the conference focused on a stark and alarming enumeration of type 2 diabetes complications. Researchers at the University of Cambridge reported on their identification of a whopping 57 type 2 diabetes–related complications, including various cancers, kidney diseases, neurological diseases, eye issues, and circulatory problems. The researchers warned that their findings underscore the urgent need for diabetes prevention and reduction of related risks.

“This study illustrates in alarming detail the unacceptable prevalence of poor health in middle-aged people with type 2 diabetes and is a stark reminder of the extensive and serious long-term effects of diabetes on the body,” said Elizabeth Robertson, Diabetes UK’s Director of Research. Although a peer-reviewed report of the findings has not yet been published, the study was summarized in an article in *The Guardian* (bit.ly/3OUiCis).

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