



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 and Diabetes Care: A “New Normal” Emerges

As the dual pandemics of coronavirus disease 2019 (COVID-19) and diabetes grind on, we look at how care for individuals with diabetes has changed since COVID-19 emerged a year ago.

Experience in an Early Hotspot

One of the earliest outbreaks of COVID-19 occurred in the municipality of Vo’ in the Northern Italian province of Padua. Control measures (lockdown and case isolation) and mass testing effectively stopped that outbreak relatively early on, according to an investigation published in *Nature* (doi.org/gg3w87). Although the reported rate of asymptomatic cases (42.5%) is enlightening, the researchers found no links, at the time, with common comorbidities such as diabetes and cardiovascular disease (CVD).

Nevertheless, diabetes has emerged as a global risk factor for the worst outcomes of COVID-19, and we now learn that the impact of the virus on diabetes care levels in Padua Hospital (where most cases from Vo’ were admitted) was significant during the lockdown period of 15 March to 14 April 2020. In a letter published in *Diabetes Care* (doi.org/fhwr), Bonora et al. describe how the number of onsite and online visits for diabetes care was 47.7% lower during the lockdown period than during equivalent periods the previous 2 years.

The reductions in visits were reportedly higher for type 2 diabetes than for type 1 diabetes, with most visits that did occur carried out via email, telephone, and online methods. The authors note that patients with type 2 diabetes who were seen during lockdown were younger and had less severe disease compared to previous years, implying that older patients with a heavier disease burden struggled to connect to receive appropriate care. There

was also reportedly a halt in prescriptions for glucagon-like peptide 1 receptor agonists, as well as reduced use of antiplatelet and lipid-lowering therapies, suggesting a worsening of CVD risk. The authors noted, however, that there was a considerable reduction in the numbers of individuals seeking care for cardiovascular events.

On a brighter note, they found no equivalent drop in care levels for individuals with type 1 diabetes, likely because of the widespread use of Cloud-connected care technologies among these patients.

They concluded, “Preparing for the next pandemic phase, we should develop strategies that prevent the decrease in care for people with type 2 diabetes, giving priority to allowing access to those who most need assistance.”

Pandemic-Spurred Rapid Innovation in Diabetes Care

Diabetes UK has published a rapid review of health care professionals’ (HCPs’) views on inpatient care for individuals with diabetes during the first wave of COVID-19 (Burr et al., *Diabetic Medicine*, doi.org/fhws). Based on semi-structured interviews with 28 HCPs from around the United Kingdom, the authors present a mixed picture of experiences, including some cases in which disruption to care led to improved ways of working and a minority of other cases in which negative experiences affected the quality of care. They provide a series of recommendations for short-term preparedness and recovery and stress that the post-pandemic “new normal” should not involve a return to old ways.

An Endocrine Society task force has also been looking at new models of care that have rapidly emerged because of the COVID-19 pandemic (Agarwal et al., *Journal of Clinical Endocrinology & Metabolism*, doi.org/10.1210/clinem/dgaa704). The authors report on a rare pandemic upside: new opportunities to rapidly implement, test, and iterate different care models. The report focuses on models that task force members have had success with during the pandemic, all of which have sought to improve access to care through better coordination and new lines of communication.

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The authors state that the pandemic has provided the disruptive force needed to improve care, with challenges previously considered insurmountable being swept away almost overnight.

"We need to change the way we provide care, considering that outcomes of people with diabetes have not improved over the last decade," task force chair and ADA Chief Scientific & Medical Officer Robert A. Gabbay said in a statement (bit.ly/3pysaTZ). "Given the dual pandemics of COVID-19 and diabetes, adoption of these innovations has accelerated in the hopes of creating a 'new normal' and improvements in the care we provide people with diabetes."

Needed: A Post-COVID Marshall Plan for Diabetes Care

A "Marshall Plan" is needed for post-COVID-19 diabetes care in the United Kingdom, according to a hard-hitting commentary by Petrie et al. (*Diabetic Medicine*, doi.org/fhww). In the first 4 months of the pandemic, about one-third (14,000) of all deaths from COVID-19 in the United Kingdom occurred in people with diabetes.

The authors strongly suggest that it is now time to double down on efforts to prevent type 2 diabetes, induce remission where possible, and provide comprehensive (and safe) systems for treatment and monitoring. Citing a pandemic-caused "new normal," for health care systems, they make a case for fundamental change in the way type 2 diabetes is handled, citing new care models already being implemented.

"The experience of working together within rapidly created services evolving on a daily basis during the COVID-19 pandemic has created a shared professional will and a collective hope and realization that changes to services made in the wake of the virus could go further than mere adaptation," they write. "By this way of thinking, the crisis presents an opportunity to drive the reform necessary to ensure that future diabetes services are shaped to deliver what is really required: a generational opportunity to 'reboot' services in a more radical way than would have been possible in normal times."



TREATMENTS + THERAPIES

Diabetes Drug Combination Effective at 2 Years

A combination of once-weekly exenatide (a glucagon-like peptide 1 receptor agonist) and daily dapagliflozin (a sodium-glucose cotransporter 2 inhibitor) remained more effective at reducing A1C over 2 years than either of its individual components in adults with type 2 diabetes. Further clinically relevant changes were also observed by Jabbour et al. (*Diabetes Care*, doi.org/fhwx). Although the combination has previously been shown to have benefits in type 2 diabetes, this is the first time the benefits have been reported over such a long period of intervention.

The phase 3 DURATION-8 randomized controlled trial included 695 adults with type 2 diabetes and inadequate glycemic control (A1C >8.0%) despite receiving metformin. The participants were randomized (1:1:1) to receive either exenatide and dapagliflozin or only one of the drugs plus a placebo. The trial was planned to run for 28 weeks but was extended to 52 weeks with the results published previously. A second extension, reported in this article, took the study to 104 weeks' duration, with the results considered exploratory.

Investigators found that the combination resulted in change in A1C from baseline to 104 weeks of -1.70%, whereas exenatide alone resulted in a change of -1.29%, and dapagliflozin alone yielded a change of -1.06%. The authors also report clinically relevant changes in weight, blood pressure, and various measures of glucose with the combination. Safety and tolerability were also found to be acceptable, according to the authors.

"Many therapies in diabetes management are short-lived, which is why it's useful to test for long-term effects," lead author Serge Jabbour said in a statement (bit.ly/2lz4D42). "Our study showed that a combo regimen of dapagliflozin and exenatide continued to control patients' glucose over 2 years. This is very encouraging. These two classes work synergistically to help control a type 2 diabetes patient's glucose levels, and other measures associated with diabetes. We can now feel more confident about prescribing these medicines long term."

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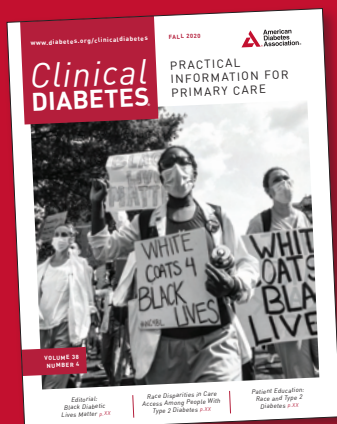
ADA NEWS

Simple Strategies to Reduce Therapeutic Inertia

The American Diabetes Association's (ADA's) Overcoming Therapeutic Inertia (OTI) initiative has brought together leading diabetes researchers and clinicians to understand contributors to therapeutic inertia (TI) and identify practical solutions that can be easily implemented in primary care. Defined as the failure to initiate, intensify, or deintensify the therapy regimen as needed when a patient's treatment goals are not met, TI increases risks for all severe diabetes-related complications.

Two factors appear to be absolutely crucial to any effective approach to reducing TI: timely therapy optimization and improved care plan adherence. The OTI Best Practices Framework (<https://professional.diabetes.org/meetings/best-practices-framework>) identifies 15 actions that can help address TI. Learn more and register for upcoming OTI webinars at http://bit.ly/OTI_webinars.

For an in-depth look at ADA's plan to overcome TI, we recommend "Addressing Therapeutic Inertia in 2020 and Beyond: A 3-Year Initiative of the American Diabetes Association" (doi.org/fhw6), published in the Fall 2020 issue of *Clinical Diabetes*.



Addressing Health Disparities Through Advocacy

The coronavirus disease 2019 (COVID-19) pandemic has shed a light on and widened the inequity and disparities that exist within the U.S. health care system. Health inequities contribute to worse outcomes and higher risk for people with inadequately managed diabetes and many other chronic diseases. These disparities undermine the well-being of our most underserved communities.

In response, the ADA has launched a new #HealthEquityNow platform, available from <https://www.diabetes.org/healthequitynow>, and is supporting legislation to address disparities, including Illinois Congresswoman Robin Kelly's Ending Health Disparities During COVID-19 Act.

American Diabetes Association
Connected for Life

Health Equity Bill of Rights Fact Sheet

Diabetes is pervasive.

- Over 34 million Americans, or 10.5 percent of the U.S. population, have diabetes. 1 in 5 don't know they have it.
- 122 million Americans, or 37 percent of the U.S. population, live with diabetes or prediabetes.
- 1.5 million Americans are diagnosed with diabetes every year.
- Diabetes, including prediabetes, is the most common underlying chronic condition in the U.S.
- Diabetes and other related chronic conditions are nearly twice as common among communities of color than among white Americans.

For Americans with diabetes, the cost of care is staggering and increasingly out of reach.

- Diabetes is the most expensive chronic condition in the U.S., costing \$327 billion annually.
- The cost of health care is nearly two and a half times higher for Americans with diabetes than those without.
- People with diabetes account for \$1 of every \$4 spent on health care in the United States.
- One in four insulin-dependent people with diabetes ration their insulin due to financial difficulty.
- In the past decade, the cost of insulin alone has tripled.
- Nearly one third of diabetes patients report not self-monitoring blood glucose levels because test strips are too expensive.

Loss of preventative care has grave consequences for people with diabetes.

- Diabetes is the primary cause of death for more than 80,000 Americans each year.
- Every four minutes in America, a limb is amputated due to diabetes.
- More than 60 percent of nontraumatic lower-limb amputations occur in people with diabetes.
- Minorities experience amputation at a rate twice as high as non-minorities.
- Nearly 80,000 Americans begin treatment for kidney failure due to diabetes every year.
- Diabetes is a major cause of blindness, kidney failure, heart attacks, stroke, and more.

People with diabetes face social, economic, and environmental barriers that leave them at a higher risk.

- Diabetes prevalence is inversely related to household income level.
- Living in poverty in the two years prior to diagnosis increases the risk of developing Type 2 diabetes by nearly 25 percent.
- Low-income communities in America have fewer grocery stores, more convenience stores, and less transportation access to reach supermarkets than higher income areas. Low-income census tracts have half as many supermarkets as wealthy tracts.
- In Chicago and Detroit alone, residents who live farther from grocery stores than from convenience stores and fast food restaurants have significantly higher rates of premature death from diabetes.
- Diabetes risk is inversely related to the amount of green space in a person's neighborhood.
- One in five chronic disease patients report having experienced discrimination in health care.
- Clinical trial participants are predominantly white – sometimes 80 to 90 percent – despite minority populations seeing higher rates of chronic diseases that many new drugs are used to treat.

Health Equity Bill of Rights

Disproportionate toll on minority, low-income, and a troubling light on historic, systemic inequities in equity now.

It is a future without unjust health disparities. It ensures lives and prediabetes, along with the millions more for their race, income, zip code, age, education or of human rights: their health. These rights include:

- Drugs affordably.
- \$4 spent on health care in our country, and growing need to survive. One in four insulin-dependent people with diabetes should be able to get the medication filling their prescription, paying rent, or putting food

you are to have a grocery store within walking distance tied to income level, and nutrition is critical to diabetes (with diabetes and prediabetes must have access to formation they require to eat healthily.

diabetes management and future cures.

tion in the U.S., and people with diabetes incur higher than others. Costs skyrocket for Americans (race – they are hospitalized nearly 170% as often; leaving them medically worse off than if they sought better care, it is essential that all people with or at risk

discrimination.

legally protected against discrimination at work and try barriers to equal treatment. Children with diabetes not, and frontline workers too often reduced the ability physician with diabetes should be able to live and work

Continued >>

1-800-DIABETES (300-340-2346)

Learn more at diabetes.org | 1-800-DIABETES (300-340-2346)

This legislation would:

- Enhance COVID-19 testing and contact tracing efforts among medically underserved populations
- Ensure that federal agencies and state governments are capturing data on health disparities



- Provide COVID-19 treatment at no cost
- Create a national COVID-19 Racial and Ethnic Disparities Task Force
- Provide additional health insurance enrollment opportunities for those who have lost coverage

"This important legislation would help level the playing field by implementing nationwide COVID testing, providing free treatment for the virus once it becomes available, and expanding access to insurance for those who lose health coverage when they lose their job," said Tracey D. Brown, ADA's Chief Executive Officer. "We urge all members of Congress to support this bill."

Diabetes and COVID-19

Diabetes Care has published its third collection of articles examining diabetes and COVID-19 in a special section of its October 2020 issue. In a commentary introducing the section, *Diabetes Care* Editor-in-Chief Matthew C. Riddle, MD, wrote that, while we learned a lot from early reports providing "helpful but necessarily tentative guidance," studies reported more recently in *Diabetes Care* "have tested specific questions about COVID-19 and diabetes, adding further insights."

These questions include:

- Are people with type 1 diabetes as vulnerable as those with type 2 diabetes?
- Can increases in risk of complications from diabetes, including amputation, be attributed to disruptions in care during lockdown?
- What are the physiologic links between diabetes and COVID-19, including body composition, as well as social and economic factors that play a role?
- Does hyperglycemia influence progression to severe COVID-19 illness? If so, can improving glycemic control reduce the likelihood of severe illness or improve outcomes?

All three COVID-19 special collections are freely accessible at <https://care.diabetesjournals.org/collection/diabetes-and-COVID19>.



TREATMENTS + THERAPIES, *continued from p. 7*

Text Messaging Reduces A1C, But Not in the Long Term

Medication adherence in type 2 diabetes is a serious issue, but text messaging to nudge patients toward better adherence has had some positive results. The issue, however, is whether the approach works in the long term. According to Nelson et al. (*Diabetes Care*, doi.org/fhwz), the

approach works in the short term but loses its effect over about 1 year. Based on these results, they suggest that any gains from texting in terms of improved A1C will require further efforts to sustain.

"To sustain effects, it may be necessary for robust text messaging interventions . . . to be meaningfully integrated into clinical care or with other effective interventions," they write.

CODING, REGULATIONS, + REIMBURSEMENTS

CMS CHANGES COULD EXPAND ACCESS TO CGM AND INSULIN PUMPS



The Centers for Medicare & Medicaid Services (CMS) has announced proposed rule changes that would expand Medicare coverage to a number of devices commonly used in personal diabetes management, including all continuous glucose monitoring (CGM) devices. Announcing the move in a press statement ([go.cms.gov/3ppSRtE](https://www.cms.gov/3ppSRtE)), CMS explained that, if the proposed rule changes are finalized, it will continue to cover CGM devices that are considered “therapeutic” but will also cover those considered “adjunctive,” essentially expanding coverage to all CGM systems. CGM devices deemed “therapeutic” are those that do not require results to be verified with traditional blood glucose testing before treatment changes are made, whereas those considered “adjunctive” require blood glucose testing before changes in treatment are made.

Much of the thinking behind the changes is set out in the proposed rule (bit.ly/2IBGTwt), but it comes down to this: they propose to consider all CGM devices as durable medical equipment and therefore eligible for Medicare coverage. With one in three Medicare beneficiaries having diabetes, the rule change will significantly expand the technology choices available for beneficiaries and their physicians.

The rule change would also likely affect thinking and strategy for the developers of these technologies, providing clarity on the standards needed to secure approval. For example, the agency has dropped its opposition to CGM devices that are linked to smartphones to operate fully.

“With the policies outlined in this proposed rule, innovators have a much more predictable path to understanding the kinds of products that Medicare will pay for,” CMS administrator Seema Verma said in the press release. “For manufacturers, bringing a new product to market will mean they can get a Medicare payment amount and billing code right off the bat, resulting in quicker access for Medicare beneficiaries to the latest technological advances and the most cutting-edge devices available. It’s clearly a win-win for patients and innovators alike.”

The proposed changes have been broadly welcomed by the American Diabetes Association, the Endocrine Society, and industry figures, according to reports from MedpageToday (bit.ly/36BVyQx) and Endocrine Today (bit.ly/3f44G4c).



CONFERENCE SPOTLIGHT

Digital Diabetes Prevention Program Reduces A1C and Weight

A study presented at Obesity Week 2020 Interactive suggests that a 12-month digital diabetes prevention program (DPP) can significantly reduce A1C and body weight in people with prediabetes compared to standard care. The preliminary report by Katula et al. (Obesity Week 2020, oral presentation 041) described a randomized controlled trial (RCT) of the digital DPP approach and suggested that a greater proportion of individuals with prediabetes achieved clinically significant weight loss of $\geq 5\%$ and A1C reductions to below levels considered to be prediabetes.

According to the report, the PREDICTS trial (clinicaltrials.gov NCT03312764) randomized 599 individuals with documented prediabetes to either the digital DPP comprising weekly sessions plus coaching and various support approaches or a single-session diabetes prevention class (standard care). Both groups were then assessed

at baseline, 4 months, and 12 months for changes in A1C (the primary outcome) and weight (a secondary outcome).

The authors reported that 81% of randomized participants completed the trial, although there is no indication in the preliminary report of whether completion was balanced between the groups. Participants in the digital DPP arm had significantly greater reductions in A1C than those receiving standard care (-0.23 vs. -0.15% , $P < 0.01$). Weight reduction from baseline was also greater in the digital DPP arm (-5.4 vs 2.0% in the standard care arm, $P < 0.01$) at 12 months.

“This digital adaptation of the DPP has clinical effectiveness and great potential for widespread dissemination, particularly in light of the growing demand for remote delivery of health care services,” the authors concluded. The trial was funded by Omada Health, the vendor of the digital DPP.

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