Conflict of Interest Disclosures: Mr Johnston reported receiving grants from the US Food and Drug Administration (FDA) through the Yale University–Mayo Clinic Center of Excellence in Regulatory Science and Innovation program. Dr Dhruva reported receiving research support from the National Heart, Lung, and Blood Institute of the National Institutes of Health (K12HL138046); the FDA; the Medical Device Innovation Consortium as part of National Evaluation System for Health Technology Coordinating Center; Arnold Ventures; and the Greenwall Foundation. Dr Ross reported receiving research support through Yale University from Johnson and Johnson to develop methods of clinical trial data sharing; the FDA to establish the Yale University–Mayo Clinic Center of Excellence in Regulatory Science and Innovation program (U01FD005938); the Medical Device Innovation Consortium as part of the National Evaluation System for Health Technology Coordinating Center; the Agency for Healthcare Research and Quality (R01HS022882); the National Heart, Lung, and Blood Institute of the National Institutes of Health (R01HS025164 and R01HL144644); and Arnold Ventures to establish the Good Pharma Scorecard at Bioethics International and the Collaboration for Research Integrity and Transparency at Yale. No other disclosures were reported.

Disclaimer: Dr Dhruva is a member of the Teachable Moments editorial team for *JAMA Internal Medicine* but was not involved in any of the decisions regarding review of the manuscript or its acceptance.

1. Design considerations for pivotal clinical investigations for medical devices: guidance for industry, clinical investigators, institutional review boards and Food and Drug Administration staff. US Food and Drug Administration. November 7, 2013. Accessed May 14, 2021. https://www.fda.gov/media/87363/download

2. Summary of safety and effectiveness data (SSED): Impella 2.5 system. US Food and Drug Administration. Updated May 10, 2021. Accessed May 15, 2021. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P140003

3. Premarket approval (PMA). US Food and Drug Administration. Updated May 10, 2021. Accessed May 15, 2021. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

4. Rathi VK, Krumholz HM, Masoudi FA, Ross JS. Characteristics of clinical studies conducted over the total product life cycle of high-risk therapeutic medical devices receiving FDA premarket approval in 2010 and 2011. *JAMA*. 2015;314(6):604-612. doi:10.1001/jama.2015.8761

5. Factors to consider when making benefit-risk determinations in medical device premarket approval and De Novo classifications: guidance for industry and Food and Drug Administration staff. US Food and Drug Administration. August 30, 2019. Accessed May 14, 2021. https://www.fda.gov/media/99769/download

6. Summary of safety and effectiveness data (SSED): XVIVO perfusion system (XPS) with STEEN solution perfusate. US Food and Drug Administration. April 26, 2019. Accessed May 14, 2021. https://www.accessdata.fda.gov/cdrh_docs/pdf18/P180014b.pdf

Diabetes Care and Glycemic Control During the COVID-19 Pandemic in the United States

Dramatic reductions in outpatient visits and laboratory testing early in the COVID-19 pandemic[1,2] raised concerns about gaps in diabetes management and glycemic control.[3] We therefore compared weekly rates of diabetes-related outpatient visits, screening tests, medication fills, and patients' hemoglobin A_{1c} (HbA_{1c})

Supplemental content

Table. Characteristics of Patients With Type 2 Diabetes in the Study Cohorts (2019, 2020)

Characteristic	No. (%)		Standardized difference[a]
	2019	2020	
Total cohort	1 357 029	1 364 522	
Age (mean)	67.0	67.2	0.02
Medication type			
Insulin users	213 369 (16)	217 978 (16)	0.01
Sulfonylurea users	272 038 (20)	269 058 (20)	0.01
Proportion of patients receiving service in prior year (2018 for 2019 cohort, 2019 for 2020 cohort)			
Outpatient visit	1 254 176 (92)	1 262 357 (93)	0
Hemoglobin A_{1c} test	1 209 563 (89)	1 227 942 (90)	0.03
Prescription fill	891 135 (66)	914 222 (67)	0.03
Retinal examination	111 960 (8)	111 297 (8)	0
Nephropathy examination	738 832 (54)	759 800 (56)	0.02
Insurance type			
Commercial	510 053 (38)	496 984 (36)	0.02
Medicare advantage	846 976 (62)	867 538 (64)	0.02
Gender			
Female	685 280 (51)	690323 (51)	0
Urban/rural designation[b]			
Urban	1 108 481 (82)	1 111 457 (82)	0
Large rural	133 905 (10)	136 810 (10)	0
Small rural	71 364 (5)	72 321 (5)	0
Rural isolated	40 750 (3)	41 196 (3)	0
County median household income, quartile[c]			
Low (<$41 042)	409 442 (30)	411 807 (30)	0
2 ($41 042-$52 197)	356 664 (26)	359 837 (26)	0
3 ($52 198-$69 240)	281 847 (21)	283 502 (21)	0
High (>$69 240)	305 351 (23)	305 442 (22)	0
County % White individuals, quartile[c]			
Low (<42.3%)	269 247 (20)	265 244 (19)	0.04
2 (42.3%-69.7%)	374 490 (28)	374 223 (28)	0.04
3 (69.8%-85.8%)	346 278 (26)	346 628 (25)	0.04
High (>85.8%)	363 289 (27)	374 493 (28)	0.04

[a] Standardized difference <0.05 for each patient characteristic, below the 0.10 threshold signifying minimal difference consistent with established methodology.

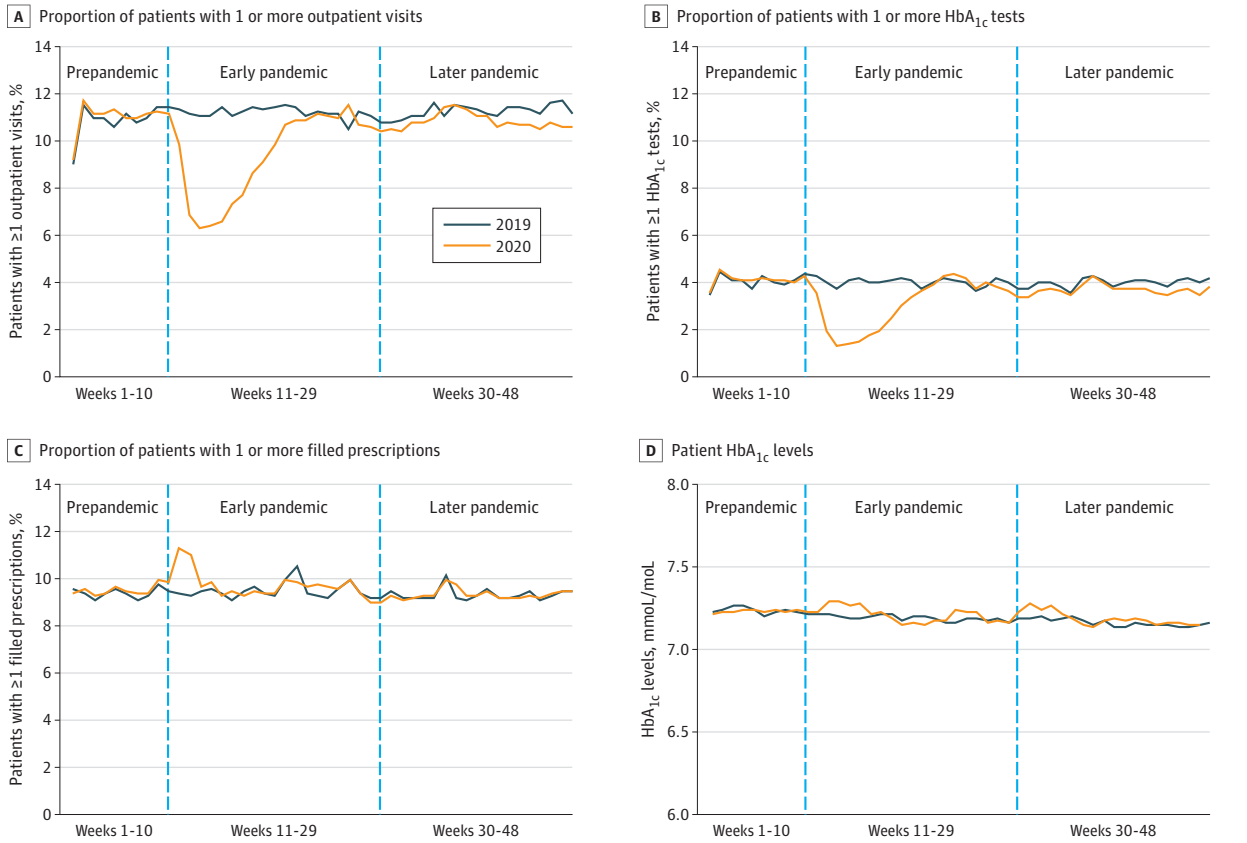
[b] Rural-urban communing area per the 4-category US Census designation.

[c] Enrollee county-level race and income indicators from the 2010 US Census. For meaningful interpretation, we divided county-level measures into quartiles (ie, percentage with White and median household income).

© 2021 American Medical Association. All rights reserved.

Downloaded From: https://jamanetwork.com/ on 08/04/2022

Figure. Proportion of Patients Receiving Diabetes-Related Care and HbA_{1c} Levels in a Given Week (January 1, 2020, through December 1, 2020) Compared With the Same Weeks in 2019



Among patients in the cohorts, 42% (n = 570 492) and 41% (n = 554 275) had at least 1 HbA_{1c} laboratory result in 2019 and 2020 cohorts, respectively.

levels in 2020 vs 2019 in a national cohort of adults with type 2 diabetes.

Methods | Using deidentified claims from OptumLabs Data Warehouse,[4] we created 2 cohorts of adults (age ≥18 years) with type 2 diabetes and continuous enrollment in commercial or Medicare Advantage health plans (criteria are listed in the Supplement).[5] The 2019 cohort was identified using 2018 data, and their outcomes were assessed during 2019. The 2020 cohort was identified using 2019 data and their outcomes were assessed during 2020.

We measured the proportion of patients in each cohort who received 1 or more of a given service in a week (services are defined in the Supplement). Outpatient visits included in-person or telemedicine visits. Glycemic control was assessed as the mean weekly HbA_{1c} level for the 41% of patients with available test results. Our study periods were the first 48 weeks of 2019 and 2020; we classified weeks 1 through 10 of 2020 as the prepandemic period and weeks 11 through 48 as the pandemic period.

To assess for differences in 2020 vs 2019, we calculated the average marginal effects from logistic and linear regression models adjusting for patient characteristics comparing weeks 1 through 10 and 11 through 48 of 2020 vs the same periods of 2019. Standard errors were clustered at the patient level. To address potential selection bias in which patients received a HbA_{1c} test result, we conducted sensitivity analyses testing HbA_{1c} levels within individual patients (detailed in the Supplement), with similar findings.

Statistical analyses were performed in SAS, version 9.4. The Harvard Medical School institutional review board exempted this study from review owing to the use of deidentified data.

Results | There were 1 357 029 and 1 364 522 adults with diabetes in the 2019 and 2020 cohorts, respectively, with similar baseline characteristics (**Table**). In 2019, 0.3% of cohort had 1 or more telemedicine visit, compared with 29.1% of the 2020 cohort during the pandemic period.

During the prepandemic period, there was no clinically meaningful difference between the cohorts across all 6 outcome measures (**Figure**). Early in the pandemic period, there were large reductions in visits and testing that rebounded to near-baseline levels by week 48. Across the entire pandemic period, adjusted use was lower in 2020 compared with 2019 for outpatient visits (85.0% vs 87.3% of patients in 2020 and 2019 cohorts with ≥1 outpatient visit during pandemic period; relative percent change −2.6%), HbA_{1c} testing (76.5% vs 81.8%; −6.5%), retinopathy testing (5.6% vs 6.9%; −18.8%), and nephropathy testing (40.1% vs 43.9%; −8.5%). In contrast,

© 2021 American Medical Association. All rights reserved.

Downloaded From: https://jamanetwork.com/ on 08/04/2022

medication fill rates were similar during the pandemic period of 2020 as compared with 2019 (64.2% vs 62.2%; 3.6%). Levels of HbA_{1c} were nearly identical during the pandemic period of 2020 compared with 2019 (7.16% vs 7.14%; 0.3%). Due to sample size, all comparisons between 2020 and 2019 were statistically significant at $P < .001$.

Discussion | While diabetes-related outpatient visits and testing fell during the pandemic, we observed no evidence of a negative association with medication fills or glycemic control. One explanation for these patterns could be the small increase in medication fill rates during the pandemic that may have protected against any disruptions in diabetes self-management during the pandemic and hence staved off detrimental effects on glycemic control. Mail-order pharmacies and pharmacy delivery services may have been key during the pandemic in ensuring patients receive their medications. Together, these would be consistent with diabetes disaster preparedness guidelines, which emphasize prioritizing access to medications over access to health care professionals during an emergency.[6]

The unprecedented increase in telemedicine visits we observe during the pandemic, although unable to overcome the overall decrease in visits, may have prevented substantive disruptions in medication prescribing. Our findings also emphasize that there is not a direct relationship between visit frequency and glycemic control. Limitations of our findings include that the results may not generalize to other populations such as those with Medicaid insurance or the uninsured.

Sadiq Y. Patel, PhD, MS, MSW
Rozalina G. McCoy, MD, MS
Michael L. Barnett, MD, MS
Nilay D. Shah, PhD
Ateev Mehrotra, MD, MPH

Author Affiliations: Department of Health Care Policy, Harvard Medical School, Boston, Massachusetts (Patel, Mehrotra); Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery, Mayo Clinic, Rochester, Minnesota (McCoy, Shah); Division of Community Internal Medicine, Department of Medicine, Mayo Clinic, Rochester, Minnesota (McCoy); Department of Health Policy and Management, Harvard T. H. Chan School of Public Health, Boston, Massachusetts (Barnett); Division of General Internal Medicine and Primary Care, Department of Medicine, Brigham and Women's Hospital, Boston, Massachusetts (Barnett); Division of General Medicine, Beth Israel Deaconess Medical Center, Boston, Massachusetts (Mehrotra); OptumLabs, Eden Prairie, Minnesota (Mehrotra).

Accepted for Publication: May 5, 2021.

Published Online: July 6, 2021. doi:10.1001/jamainternmed.2021.3047

Corresponding Author: Ateev Mehrotra, MD, MPH, Department of Health Care Policy, Harvard Medical School, 180A Longwood Ave, Boston, MA 02115 (mehrotra@hcp.med.harvard.edu).

Author Contributions: Dr Patel had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Patel, Barnett, Mehrotra.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Patel.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Patel, Barnett.
Obtained funding: Mehrotra.
Administrative, technical, or material support: McCoy, Mehrotra.
Supervision: Mehrotra.

Conflict of Interest Disclosures: Dr McCoy reported grants from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) during the conduct of the study; grants from AARP and grants from NIDDK outside the submitted work. Dr Shah reported research support through Mayo Clinic from the US Food and Drug Administration to establish the Yale-Mayo Clinic Center for Excellence in Regulatory Science and Innovation (CERSI) program (U01FD005938); the Centers of Medicare and Medicaid Innovation under the Transforming Clinical Practice Initiative (TCPI); the Agency for Healthcare Research and Quality (R01HS025164; R01HS025402; R03HS025517; K12HS026379); the National Heart, Lung and Blood Institute of the National Institutes of Health (NIH) (R56HL130496; R01HL131535; R01HL151662); the National Science Foundation; from the Medical Device Innovation Consortium as part of the National Evaluation System for Health Technology (NEST) and the Patient Centered Outcomes Research Institute (PCORI) to develop a Clinical Data Research Network (LHSNet). Dr Mehrotra reported grants from Commonwealth Fund during the conduct of the study. No other disclosures were reported.

Funding/Support: This project was supported by the Commonwealth Fund. There was also support from the National Institute of Diabetes and Digestive and Kidney Diseases (K23DK114497; RGM), National Institute on Aging of the National Institutes of Health (K23 AG058806-01; MLB), and National Institute of Mental Health (T32MH019733; SYP).

Role of the Funder/Sponsor: The Commonwealth Fund and the National Institutes of Health had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Additional Contributions: We thank Rebecca Shyu, University of Missouri, for contributing to manuscript preparation efforts. She was not compensated.

1. Patel SY, Mehrotra A, Huskamp HA, Uscher-Pines L, Ganguli I, Barnett ML. Variation in telemedicine use and outpatient care during the COVID-19 pandemic in the United States. *Health Aff (Millwood)*. 2021;40(2):349-358. doi:10.1377/hlthaff.2020.01786

2. Patel SY, Mehrotra A, Huskamp HA, Uscher-Pines L, Ganguli I, Barnett ML. Trends in outpatient care delivery and telemedicine during the COVID-19 pandemic in the US. *JAMA Intern Med*. 2021;181(3):388-391. doi:10.1001/jamainternmed.2020.5928

3. Lu D. 2020 was especially deadly. Covid wasn't the only culprit. *New York Times*. December 13, 2020. Accessed March 1, 2021. https://www.nytimes.com/interactive/2020/12/13/us/deaths-covid-other-causes.html

4. OptumLabs. OptumLabs and OptumLabs Data Warehouse Descriptions and Citation. July 2020. Reproduced with permission from OptumLabs.

5. National Committee for Quality Assurance (NCQA). HEDIS 2018 Volume 2 technical update. Accessed March 1, 2021. https://www.ncqa.org/wp-content/uploads/2018/10/20171002_HEDIS_2017_OctoberUpdate.pdf

6. Allweiss P. Diabetes and disasters: recent studies and resources for preparedness. *Curr Diab Rep*. 2019;19(11):131. doi:10.1007/s11892-019-1258-7

Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members

Efforts to control drug prices have highlighted the role of the pharmaceutical supply chain. Rather than driving efficiencies, this complex web of highly concentrated intermediaries with proprietary contracts may instead raise prices.[1]

Much attention has focused on brand name drugs, although recent reports show that intermediaries can capture significant profits in the generic market as well.[2] With 88% of Medicare Part D prescriptions dispensed for generic medications in 2018,[3] excess profits retained by intermediaries in the generic supply chain could be substantial. This analysis compared the amount Medicare pays for common generic prescriptions in Part D with prices available to patients without insurance at Costco.

© 2021 American Medical Association. All rights reserved.

Downloaded From: https://jamanetwork.com/ on 08/04/2022