BMJ Open

COVID-19 hinterland: surveilling the self-reported impacts of the pandemic on diabetes management in the USA (cross-sectional results of the iNPHORM study)

Alexandria A Ratzki-Leewing,[1] Bridget L Ryan,[1,2] John D Buchenberger,[3] Joseph W Dickens,[4] Jason E Black,[2] Stewart B Harris [ID] [1,2]

[1]Department of Epidemiology and Biostatistics, Schulich School of Medicine and Dentistry, Western University, London, Ontario, Canada
[2]Department of Family Medicine, Western University Schulich School of Medicine and Dentistry, London, Ontario, Canada
[3]Ipsos Healthcare, Ipsos, New York, New York, USA
[4]SMX, Ipsos, Chicago, Illinois, USA

Correspondence to
Dr Stewart B Harris;
sharris1@uwo.ca

ABSTRACT

Main objective To determine how and to what extent COVID-19 has affected real-world, self-reported glycaemic management in Americans with type 1 or type 2 diabetes taking insulin and/or secretagogues, with or without infection.

Design A cross-sectional substudy using data from the Investigating Novel Predictions of Hypoglycemia Occurrence using Real-world Models panel survey.

Setting USA.

Participants Americans 18–90 years old with type 1 or 2 diabetes taking insulin and/or secretagogues were conveniently sampled from a probability-based internet panel.

Primary outcome measure A structured, COVID-19-specific questionnaire was administered to assess the impact of the pandemic (irrespective of infection) on socioeconomic, behavioural/clinical and psychosocial aspects of glycaemic management.

Results Data from 667 respondents (type 1 diabetes: 18%; type 2 diabetes: 82%) were analysed. Almost 25% reported A1c values ≥8.1%. Rates of severe and non-severe hypoglycaemia were 0.68 (95% CI 0.5 to 0.96) and 2.75 (95% CI 2.4 to 3.1) events per person-month, respectively. Ten respondents reported a confirmed or probable COVID-19 diagnosis. Because of the pandemic, 24% of respondents experienced difficulties affording housing; 28% struggled to maintain sufficient food to avoid hypoglycaemia; and 19% and 17% reported challenges accessing diabetes therapies and testing strips, respectively. Over one-quarter reported issues retrieving antihyperglycaemics from the pharmacy and over one-third reported challenges consulting with diabetes providers. The pandemic contributed to therapeutic non-adherence (14%), drug rationing (17%) and reduced monitoring (16%). Many struggled to keep track, and in control, of hypoglycaemia (12%–15%) and lacked social support to help manage their risk (19%). Nearly half reported decreased physical activity. Few statistically significant differences were observed by diabetes type.

Conclusions COVID-19 was found to cause substantial self-reported deficiencies in glycaemic management.

Strengths and limitations of this study

► This is the first US-based, primary research study to quantify the real-world, self-reported impact of the COVID-19 situation on the socioeconomic, behavioural/clinical and psychosocial aspects of glycaemic management.
► A novel COVID-19-specific questionnaire was developed and administered to a real-world cohort of Americans with type 1 and type 2 diabetes taking insulin and/or secretagogues; study participants were recruited from a large, probability-based internet panel.
► Estimates presented in this study may be conservative as they describe the early phase of the pandemic.

Study results signal the need for decisive action to restabilise routine diabetes care in the USA.

Trial registration number NCT04219514.

INTRODUCTION

COVID-19 is among the most devastating health crises in global history. In the USA, the first reported infection occurred on 19 January 2020.[1] Since then, the number of confirmed US cases has surpassed 33.5 million, including over 605 000 deaths (5 July 2021).[2]

People with diabetes (PWD) have been identified as clinically vulnerable to COVID-19. In the USA, diabetes ranks as the second most common underlying health condition among all cases and has been connected to more severe infection.[3 4] However, less appreciated in the literature are the disruptions caused by the pandemic on routine diabetes care. These disruptions expose those with COVID-19 and all 34+ million Americans with diabetes to poor outcomes. Understanding

how the pandemic affects diabetes services and management is crucial to informing short and long-term clinical decision-making and public health planning. Targeted measures to help protect these Americans from the direct and indirect effects of the COVID-19 pandemic should be a top priority for all healthcare and government officials.

The complex hinterland of COVID-19 and diabetes

The pathophysiological benefits of glycaemic control on diabetes outcomes have been well established. Numerous studies have linked chronic hyperglycaemia and glycaemic variability to increased risks of microvascular and macrovascular complications and mortality. In addition, dysglycaemia can potentiate immunosuppression,[5] increasing viral susceptibility and risk of poor clinical outcomes.[6] While the role of coexistent diabetes in the pathogenesis of COVID-19 is still being determined,[7] emerging signals suggest that euglycaemia protects against infection and severity of prognoses.[8 9] These data are consistent with evidence from other viral infections where glucose control showed to augment host immune response.[5 10]

To mitigate COVID-19 risks, several national and international organisations have published diabetes pandemic guides, urging PWD to maintain scrupulous adherence to all self-management and public health recommendations.[7 8] Notably, the Centers for Disease Control and Prevention (CDC)[11] has recommended maintaining at least a 30-day supply of medication and 2-week supply of food. The American Diabetes Association (ADA)[12] has advised storing blood glucose emergency supplies (ie, glucagon and ketone strips). The International Diabetes Federation[13] has encouraged healthy nutrition and regular monitoring to help avoid the complications of high and low blood glucose.

However, the COVID-19 situation has created a challenging terrain for effective glycaemic management.[14] Amid pressures to flatten the pandemic curve, PWD and their clinicians may divert focus and resources away from diabetes management, resulting in compromised care.[8] Moreover, home quarantine, physical distancing and community containment—while enacted to ensure the safety of Americans—can erode chronic disease services and make it increasingly difficult for PWD to access medical supplies and engage in optimal self-management behaviour (eg, healthy eating and physical activity).[15] Previous outbreaks have also been associated with inadequate diabetes monitoring and barriers to accessing healthcare, medications and testing supplies.[4 8] Such disruptions to routine care can lead to worse glycaemic outcomes during and after the event.[16 17]

Yet, to date, most diabetes-related COVID-19 studies in the USA have focused exclusively on the epidemiology of hospitalised cases[18 19] and failed to consider how community-based chronic diabetes management has suffered in the face of the pandemic. The lack of real-world evidence on the situational effects of COVID-19 bodes ill for the implementation of effective outbreak strategies that support Americans with diabetes. As the pandemic persists into the foreseeable future, the need to address this gap only intensifies.

The main objective of this investigation was to measure how, and the extent to which, the COVID-19 situation has affected self-reported glycaemic management in the general community population of Americans with type 1 and 2 diabetes. In so doing, we aimed to chart the complex hinterland of COVID-19 as it intersects with America's other deadly epidemic: diabetes. The results of this study will be instructive for handling chronic disease management both during the current public health emergency and in future.

RESEARCH DESIGN AND METHODS
Study design

This cross-sectional study describes the results of a COVID-19-specific subquestionnaire that was administered as part of the larger Investigating Novel Predictions of Hypoglycemia Occurrence using Real-world Models (iNPHORM) panel survey: a 1-year prospective analysis of real-world hypoglycaemia risk stratification in the USA.[20]

Participants and data collection

iNPHORM participants were conveniently sampled from randomly selected subsets of a probability-based internet panel comprising >10 000 Americans with type 1 diabetes and >58 000 with type 2 diabetes (≥18 years old). These subsets were defined based on study requirements, mainly diabetes status. Individuals in each subset were contacted via email about the study; those interested in participating were directed to complete a screening questionnaire.

Panel members 18–90 years old, living in the USA for the past year and with type 1 or 2 diabetes taking insulin and/or secretagogues were eligible to enrol. Individuals were ineligible if they were or had been pregnant within the past year, were involved in an interventional study or were unable to read/understand English. To finalise the enrolment, eligible respondents needed to provide consent and complete a baseline questionnaire. Once enrolled, participants were managed and hosted by Ipsos Interactive Services (IIS, www.ipsos.com), a leading global firm in diabetes insights and real-world survey conduct.

Respondent data were collected via the online IIS platform. In addition to the screener and baseline surveys, iNPHORM participants were asked to complete 12 prescheduled, monthly follow-up questionnaires. Follow-ups were required to be submitted within 7 days of the distribution date. Automatic reminders and notifications containing survey links were emailed throughout the prospective phase. As well, honoraria were issued in the form of e-gift cards; the incentivisation scheme (based on the quantity and timing of completed surveys) complied with social standards of reciprocity and Western University's Research Ethics Board.

Owing to the escalating severity of COVID-19 in the USA, iNPHORM follow-up questionnaires were emended after

study commencement (at follow-up month 2) to include a COVID-19-specific subquestionnaire. The subquestionnaire assessed the community infection and the impact of the pandemic on diabetes management. Data pertaining to the first administered COVID-19 subquestionnaire (21–28 April 2020) are summarised herein.

Survey instruments and variables

iNPHORM questionnaires (screening, baseline and follow-ups (including the COVID-19 subquestionnaire)) were developed by our team of epidemiologists and clinicians in consultation with the literature. All surveys were designed to be completed in English on diverse internet-equipped devices (eg, computers, smartphones, tablets). Efforts were taken to avoid double-barrelled questions, clinical jargon and value-laden or complex/ambiguous language. Additionally, each item was specified to ensure its mutual exclusivity, exhaustiveness and appropriateness of detail. When necessary, concise, clearly worded preambles, instructions and definitions (including expounding mouseover texts) were provided. Participants could take as much time as needed to reflect on items and/or review clinical documentation prior to completing the question/ survey; at any point, they could opt out of responding. Questionnaires were piloted via semistructured interviews prior to fielding.

COVID-19 status

To ascertain self-reported 1-month infection status (March to April 2020), we adapted the CDC COVID-19 case definitions (April 2020).[21] Two structured items were developed to capture clinical criteria (symptoms), laboratory criteria (confirmed diagnoses) and epidemiological exposure (eg, close contact with a confirmed or suspected case; international travel). Aligning with CDC recommendations, we classified respondents as confirmed, probable or possible cases. Confirmed cases were those who reported having been formally diagnosed with COVID-19. Probable cases were those who did not have a formal diagnosis but who reported (1) symptoms typical of COVID-19 and (2) ≥1 form of epidemiological exposure. If only one of the two latter conditions was met, we classified individuals as possible cases.

Impact of the COVID-19 situation on aspects of diabetes management

We developed 12 structured, 5-point Likert items to assess how, on a scale from 'much harder' to 'much easier', '… the Coronavirus (COVID-19) situation has impacted…' various socioeconomic, behavioural/clinical and psychosocial aspects of participants' diabetes management (past month). A neutral option (the pandemic has had no impact) was ordered in the middle between negative and positive response categories. Topics included drug affordability/accessibility, medication-taking behaviour, healthcare consultations, glucose monitoring and social support. Additionally, we incorporated two structured, binary items to assess drug rationing. See online supplemental appendix A for a complete list of these questions.

Sociodemographic and clinical characteristics of study sample

So as to align with the first administered COVID-19 subquestionnaire (analysed herein), sociodemographic and clinical characteristics were collated between the screening, baseline and follow-up questionnaires at months 1 and 2. Past-month frequencies of self-reported severe hypoglycaemia (SH) and non-severe hypoglycaemia (NSH), defined in accordance with the ADA,[22] were assessed at follow-up month 2. NSH was defined as any event that could be self-treated; SH was defined as a medical emergency that could not be self-treated (eg, required third-party assistance).

Statistical analysis

Categorical variables were summarised as frequencies and percentages, while continuous variables as means and SDs or medians and IQRs. Crude hypoglycaemia frequencies were calculated as incidence rates and proportions. Confirmed, probable and possible COVID-19 cases were calculated as 1-month period prevalences.

The impact of the COVID-19 situation on glycaemic management was descriptively analysed. Glycaemic management was operationalised according to different important aspects from drug affordability/accessibility to social support. Variability by diabetes type was assessed using the Wilcoxon-Mann-Whitney test for Likert responses and the two-sample test of proportions for binary responses. Tests were two sided at $\alpha=0.05$. All estimates were based on complete case analyses and were computed using STATA V.16.0.

Patient and public involvement

Neither the patients nor the public were directly involved in designing or conducting this study.

RESULTS

A total of 704 iNPHORM participants completed the first COVID-19 subquestionnaire (April 2020). Of these respondents, 667 (type 1 diabetes: 18.0%; type 2 diabetes: 82%) reported taking insulin and/or secretagogues (ie, met our study's eligibility criteria); their sociodemographic and clinical characteristics are summarised in tables 1 and 2, respectively.

Of the 667 eligible respondents, half were female. The mean age was 51.9 (SD: 14.6; min, max: 20, 87) years with 23.2% ≥65 years old. Diabetes duration was 26.0 (IQR: 23.0) years in people with type 1 diabetes and 11.0 (IQR: 14.0) years in people with type 2 diabetes. All respondents with type 1 diabetes and 38.4% with type 2 diabetes reported taking insulin without secretagogues; among the remaining participants with type 2 diabetes, 36.9% were taking secretagogues without insulin and 24.7% were taking a combination of insulin and secretagogues. Twenty-three per cent (type 1 diabetes: 23.3%; type 2

Table 1 Sociodemographic characteristics of study sample, overall and by diabetes type

Sociodemographic characteristics	Total n=667	T1DM 120 (17.99%)	T2DM 547 (82.01%)
Age, mean (SD)			
Years	51.85 (14.57)	45.96 (14.43)	53.14 (14.29)
Age (categorical), n (%)			
≥18 and ≤40 years	180 (26.99)	51 (42.50)	129 (23.58)
≥41 and ≤64 years	332 (49.78)	53 (44.17)	279 (51.01)
≥65 and ≤74 years	123 (18.44)	11 (9.17)	112 (20.48)
≥75 years	32 (4.80)	5 (4.17)	27 (4.94)
Sex assigned at birth, n (%)			
Male	326 (48.88)	40 (33.33)	286 (52.29)
Female	341 (51.12)	80 (66.67)	261 (47.71)
Race, n (%)			
White	555 (83.21)	111 (92.50)	444 (81.17)
Black or African American	52 (7.80)	3 (2.50)	49 (8.96)
Asian	17 (2.55)	3 (2.50)	14 (2.56)
Hispanic, Latino/Latina or Spanish origin	13 (1.95)	1 (0.83)	12 (2.19)
American Indian, Alaska Native, Native Hawaiian or Pacific Islander	4 (0.60)	0	4 (0.73)
Multiracial	23 (3.45)	2 (1.67)	21 (3.84)
Other	3 (0.45)	0	3 (0.55)
Hispanic, Latino/Latina or Spanish origin, n (%)			
Mexican, Mexican American, Chicano	27 (4.05)	2 (1.67)	25 (4.57)
Puerto Rican	6 (0.90)	1 (0.83)	5 (0.91)
Cuban	2 (0.30)	0	2 (0.37)
Other Hispanic, Latino/Latina or Spanish origin	3 (0.45)	1 (0.83)	2 (0.37)
Not of Hispanic, Latino/Latina or Spanish origin	629 (94.30)	116 (96.67)	513 (93.78)
Highest level of education, n (%)			
Elementary or high school (no diploma)	10 (1.50)	3 (2.50)	7 (1.28)
High school diploma or General Educational Development (GED)/ alternative credential	101 (15.14)	19 (15.83)	82 (14.99)
College degree or some college	425 (63.72)	75 (62.50)	350 (63.99)
Degree beyond completing first college bachelor's degree	131 (19.64)	23 (19.17)	108 (19.74)
Current employment status, n (%)			
Employed full time or part-time (including self-employment)	346 (51.87)	73 (60.83)	273 (49.91)
Temporarily laid off/temporarily unemployed due to a health issue	4 (0.60)	1 (0.83)	3 (0.55)
Unable to work due to disability	84 (12.59)	11 (9.17)	73 (13.35)
Unemployed	55 (8.25)	15 (12.50)	40 (7.31)
Student	4 (0.60)	1 (0.83)	3 (0.55)
Retired	174 (26.09)	19 (15.83)	155 (28.34)
Total annual household income (before taxes and deductions), n (%)			
<$24 999	107 (16.21)	13 (11.21)	94 (17.28)

Continued

Table 1 Continued			
Sociodemographic characteristics	**Total** **n=667**	**T1DM** **120 (17.99%)**	**T2DM** **547 (82.01%)**
$25 000 to $54 999	173 (26.21)	25 (21.55)	148 (27.21)
$55 000 to $84 999	142 (21.52)	39 (33.62)	103 (18.93)
$85 000 to $114 999	109 (16.52)	22 (18.97)	87 (15.99)
≥$115 000	129 (19.55)	17 (14.66)	112 (20.59)
Current healthcare insurance, n (%)			
Insurance through a current or former employer or union that is not a high-deductible plan*	153 (22.94)	36 (30.00)	117 (21.39)
Insurance purchased directly from an insurance company that is not a high-deductible plan*	49 (7.35)	11 (9.17)	38 (6.95)
High-deductible plan*	34 (5.10)	11 (9.17)	23 (4.20)
Medicare	77 (11.54)	7 (5.83)	70 (12.80)
Medicaid, Medical Assistance or other government assistance plan	74 (11.09)	17 (14.17)	57 (10.42)
TRICARE and Veterans Affairs	9 (1.35)	2 (1.67)	7 (1.28)
Other	5 (0.75)	2 (1.67)	3 (0.55)
Two or more insurance plans	257 (38.53)	32 (26.67)	225 (41.13)
No insurance coverage at all	9 (1.35)	2 (1.67)	7 (1.28)

Responses may not sum to total (n=667) due to missing data.
*High-deductible plan: deductible >$1350 for an individual or >$2700 for a family.
T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.

diabetes: 23.0%) of the total sample reported A1c values ≥8.1%. Sixty-one per cent reported ≥1 diabetes-related complication(s) while 83.2% reported ≥1 comorbidity.

Table 3 summarises self-reported hypoglycaemia incidences (combined daytime and nocturnal). The incidence rate and incidence proportion of NSH were higher in people with type 1 diabetes (incidence rate: 5.7 (95% CI 4.6 to 7.1) events per person-month (PPM) and incidence proportion: 83.3% (95% CI 75.7% to 88.9%)) versus type 2 diabetes (incidence rate: 2.1 (95% CI 1.8 to 2.4) events PPM and incidence proportion: 55.0% (95% CI 50.8% to 59.1%)). However, SH, occurring at an overall rate of 0.7 (95% CI 0.5 to 0.96) events PPM, was almost twice as common in people with type 2 versus type 1 diabetes (0.8 (95% CI 0.5 to 1.1) vs 0.4 (95% CI 0.2 to 0.9) events PPM). Similarly, the monthly incidence proportion of SH, affecting nearly 13% (95% CI 10.6% to 15.7%) of respondents, was higher in people with type 2 diabetes compared with type 1 diabetes (13.2% (95% CI 10.6% to 16.3%) vs 11.7% (95% CI 7.08% to 18.6%)).

The 1-month period prevalences of confirmed, probable and possible COVID-19 were 0.75% (type 1 diabetes mellitus (T1DM): n=0; type 2 diabetes mellitus (T2DM): n=5 (0.75%)), 0.75% (T1DM: n=0; T2DM: n=5 (0.75%)) and 8.9% (T1DM: n=16 (13.33%); T2DM: n=43 (7.86%)), respectively.

The impact of the COVID-19 situation on aspects of glycaemic management

A summary of results is provided in tables 4 and 5. Almost a quarter of respondents (type 1 diabetes: 30.0%; type 2 diabetes: 23.0%, p=0.08) reported that the COVID-19 situation made affording rent and other living expenses either 'somewhat harder' (type 1 diabetes: 19.2%; type 2 diabetes: 14.6%) or 'much harder' (type 1 diabetes: 10.8%; type 2 diabetes: 8.4%). Similarly, 27.6% (type 1 diabetes: 16.7%; type 2 diabetes: 28.5%, p=0.29) of participants expressed it was 'somewhat harder' (type 1 diabetes: 16.7%; type 2 diabetes: 20.1%) or 'much harder' (type 1 diabetes: 6.7%; type 2 diabetes: 8.4%) to ensure adequate food supply to avoid hypoglycaemia. Close to one in five experienced challenges paying for their diabetes medications (type 1 diabetes: 16.7%; type 2 diabetes: 19.0%, p=0.71) or test strips/sensors (type 1 diabetes: 13.3%; type 2 diabetes: 18.3%, p=0.38); of these individuals, approximately half reported that their ability to afford therapeutic supplies had been made 'much harder' by the pandemic. Access-related issues were also identified. Overall, 27.4% (type 1 diabetes: 30.8%; type 2 diabetes: 26.7%, p=0.24) found the pandemic made it 'somewhat harder' (overall: 18.7%; type 1 diabetes: 20.0%; type 2 diabetes: 18.5%) or 'much harder' (overall: 8.7%; type 1 diabetes: 10.8%; type 2 diabetes: 8.2%) to retrieve diabetes medications from the pharmacy. As well,

Table 2 Clinical characteristics of study sample, overall and by diabetes type

Clinical characteristics	Total n=667	T1DM 120 (17.99%)	T2DM 547 (82.01%)
Duration of diabetes, median (IQR)			
Years	13 (15)	26 (23)	11 (14)
Most recent haemoglobin A1c, n (%)			
≤7%	252 (37.78)	45 (37.50)	207 (37.84)
7.1%–8%	239 (35.83)	45 (37.50)	194 (35.47)
8.1%–9%	99 (14.84)	14 (11.67)	85 (15.54)
≥9.1%	55 (8.25)	14 (11.67)	41 (7.50)
Unsure	12 (1.80)	0	12 (2.19)
BMI at time of study enrolment, median (IQR)			
BMI (kg/m^2)	30.38 (11.87)	26.43 (6.18)	32.19 (11.99)
Current insulin and/or secretagogue use, n (%)			
Insulin *without* secretagogues	330 (49.48)	120 (100.00)	210 (38.39)
Secretagogues *without* insulin	202 (30.28)	0	202 (36.93)
Insulin *in combination with* secretagogues	135 (20.24)	0	135 (24.68)
Diagnosed diabetes-related complications since 1 year preceding study enrolment, n (%)*			
No complications	263 (39.43)	41 (34.17)	222 (40.59)
One or more complications	404 (60.57)	79 (65.83)	325 (59.41)
Amputation	91 (13.64)	12 (10.00)	79 (14.44)
Diabetes ketoacidosis	110 (16.49)	42 (35.00)	68 (12.43)
Foot damage	123 (18.44)	18 (15.00)	105 (19.20)
Gastroparesis	95 (14.24)	20 (16.67)	75 (13.71)
Hyperosmolar hyperglycaemic non-ketotic coma	60 (9.00)	5 (4.17)	55 (10.05)
Nephropathy	114 (17.09)	18 (15.00)	96 (17.55)
Neuropathy	298 (44.68)	46 (38.33)	252 (46.07)
Retinopathy	156 (23.39)	46 (38.33)	110 (20.11)
Comorbidity status at time of study enrolment, n (%)*			
No comorbidities	112 (16.79)	32 (26.67)	80 (14.63)
One or more comorbidities	555 (83.21)	88 (73.33)	467 (85.37)
Bone, joint or muscle problem	310 (46.48)	39 (32.50)	271 (49.54)
Cancer	52 (7.80)	3 (2.50)	49 (8.96)
Cardiovascular condition	128 (19.19)	17 (14.17)	111 (20.29)
Chronic kidney disease	73 (10.94)	8 (6.67)	65 (11.88)
Chronic liver failure or liver disease	39 (5.85)	2 (1.67)	37 (6.76)
Eating disorder	35 (5.25)	7 (5.83)	28 (5.12)
Gastrointestinal disease	86 (12.89)	17 (14.17)	69 (12.61)
HIV/AIDS	11 (1.65)	2 (1.67)	9 (1.65)
Hypertension	363 (54.42)	50 (41.67)	313 (57.22)
Mental health condition	223 (33.43)	36 (30.00)	187 (34.19)
Neurological disorder	39 (5.85)	8 (6.67)	31 (5.67)
Physical impairment	168 (25.19)	29 (24.17)	139 (25.41)
Respiratory condition	125 (18.74)	24 (20.00)	101 (18.46)
Stroke or transient ischaemic attack	44 (6.60)	5 (4.17)	39 (7.13)
Current continuous glucose monitoring device use, n (%)			
Yes	229 (34.33)	65 (54.17)	164 (29.98)

Responses may not sum to total (n=667) due to missing data.
*Cumulative percentage >100% as participants could select more than one response.
BMI, body mass index; T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.

Table 3 Incidence rates and proportions of severe and non-severe hypoglycaemia, overall and by diabetes type

Incidence rates*	Total n=667	T1DM 120 (17.99%)	T2DM 547 (82.01%)
Severe hypoglycaemia (1 month retrospective)			
Daytime+nocturnal			
Events per person-month (95% CI†)	0.68 (0.48 to 0.96)	0.39 (0.18 to 0.85)	0.75 (0.51 to 1.09)
Non-severe hypoglycaemia (1 month retrospective)			
Daytime+nocturnal			
Events per person-month (95% CI†)	2.75 (2.43 to 3.11)	5.73 (4.60 to 7.13)	2.10 (1.82 to 2.41)
Incidence proportions*			
Severe hypoglycaemia (1 month retrospective)			
Daytime or nocturnal			
% with ≥1 event (95% CI‡)	12.91 (10.58 to 15.67)	11.67 (7.078 to 18.63)	13.19 (10.6 to 16.28)
Non-severe hypoglycaemia (1 month retrospective)			
Daytime or nocturnal			
% with ≥1 event (95% CI‡)	60.06 (56.29 to 63.71)	83.33 (75.66 to 88.94)	54.95 (50.75 to 59.07)

*Incidence rates and proportions are based on data from participants who reported taking insulin and/or secretagogues at month 2 follow-up.
†Based on negative binomial distribution.
‡Based on Wilson score interval.
T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.

because of the COVID-19 situation, ~17% of participants reported rationing their diabetes medications either to make supplies last longer (type 1 diabetes: 13.3%; type 2 diabetes: 17.4%, p=0.28) or avoid hypoglycaemia (overall: 16.8%; type 1 diabetes: 15.8%; type 2 diabetes: 17.0%, p=0.76).

The COVID-19 situation also influenced participants' abilities to self-manage. Many respondents struggled to remember to take their diabetes medication(s) as prescribed (overall: 13.7%; type 1 diabetes: 6.7%; type 2 diabetes: 15.2%, p=0.047) as well as test and monitor their blood glucose (overall: 15.9%; type 1 diabetes: 5.0%; type 2 diabetes: 18.3%, p<0.001) and risk of hypoglycaemia regularly (overall: 12.0%; type 1 diabetes: 7.5%; type 2 diabetes: 13.0%, p=0.026). Over a third of respondents (type 1 diabetes: 35.0%; type 2 diabetes: 36.8%, p=0.75) found it 'somewhat harder' (overall: 23.7%; type 1 diabetes: 23.3%; type 2 diabetes: 23.8%) or 'much harder' (overall: 12.7%; type 1 diabetes: 11.7%; type 2 diabetes: 13.0%) to consult with their diabetes care providers. In terms of exercise maintenance, almost one in two respondents (type 1 diabetes: 47.5%; type 2 diabetes: 46.1%, p=0.84) reported that it had been 'somewhat harder' (overall: 31.3%; type 1 diabetes: 30.0%; type 2 diabetes: 31.6%) or 'much harder' (overall: 15.0%; type 1 diabetes: 17.5%; type 2 diabetes: 14.4%) to stay as physically active as usual.

Lastly, psychosocial effects were observed. Many participants (overall: 14.6%; type 1 diabetes: 11.7%; type 2 diabetes: 15.2%, p=0.5) felt the pandemic situation had made it 'somewhat harder' (overall: 9.3%; type 1 diabetes: 7.5%; type 2 diabetes: 9.7%) or 'much harder' (overall:

5.3%; type 1 diabetes: 4.2%; type 2 diabetes: 5.5%) to remain in control of their hypoglycaemia. Nineteen per cent also reported having insufficient social support to help manage their risk (type 1 diabetes: 10.8%; type 2 diabetes: 20.3%, p=0.056); for 12.4% (type 1 diabetes: 8.3%; type 2 diabetes: 13.4%) accessing social support was 'somewhat harder', while for 6.2% (type 1 diabetes: 2.5%; type 2 diabetes: 7.0%) it was 'much harder'.

Although approximately 50% of respondents believed the pandemic situation had no impact on their glycaemic management, rarely was a beneficial impact on participants' lives observed. In general, less than 5% of the sample reported that the pandemic made aspects of their diabetes management either 'somewhat easier' or 'much easier'.

DISCUSSION

Experts have long been aware of the impacts a protracted emergency would have on healthcare and outcomes. Now, as two life-altering diseases collide, many Americans are finding themselves at the nidus of extreme clinical vulnerability, and with little support. Despite advice furnished by several national and international organisations, PWD are clearly struggling to maintain glycaemic management standards during the pandemic. This gap forebodes important, population-based consequences to diabetes-related morbidities, both now and well after vaccinations are distributed.

iNPHORM is the first investigation to quantify the impact of the COVID-19 situation on the socioeconomic,

Table 4 Impact of the COVID-19 situation on aspects of participants' glycaemic management (past month)*, overall and by diabetes type

	…has been much harder	…has been somewhat harder	…has not been impacted	…has been somewhat easier	…has been much easier	P value†
Affording my rent and other living expenses…						
Overall (n=667)	59 (8.85)	103 (15.44)	491 (73.61)	12 (1.80)	2 (0.30)	0.08
T1DM (n=120)	13 (10.83)	23 (19.17)	83 (69.17)	1 (0.83)	0	
T2DM (n=547)	46 (8.41)	80 (14.63)	408 (74.59)	11 (2.01)	2 (0.37)	
Making sure I have enough food to avoid hypoglycaemia…						
Overall (n=667)	54 (8.10)	130 (19.49)	475 (71.21)	7 (1.05)	1 (0.15)	0.29
T1DM (n=120)	8 (6.67)	20 (16.67)	91 (75.83)	1 (0.83)	0	
T2DM (n=547)	46 (8.41)	110 (20.11)	384 (70.20)	6 (1.10)	1 (0.18)	
Affording my diabetes medication(s)…						
Overall (n=667)	53 (7.95)	71 (10.64)	534 (80.06)	5 (0.75)	4 (0.60)	0.71
T1DM (n=120)	10 (8.33)	10 (8.33)	99 (82.50)	1 (0.83)	0	
T2DM (n=547)	43 (7.86)	61 (11.15)	435 (79.52)	4 (0.73)	4 (0.73)	
Affording my test strips and/or sensors…						
Overall (n=667)	42 (6.30)	74 (11.09)	540 (80.96)	5 (0.75)	6 (0.90)	0.38
T1DM (n=120)	9 (7.50)	7 (5.83)	103 (85.83)	1 (0.83)	0	
T2DM (n=547)	33 (6.03)	67 (12.25)	437 (79.89)	4 (0.73)	6 (1.10)	
Getting my diabetes medication(s) from the pharmacy…						
Overall (n=667)	58 (8.70)	125 (18.74)	470 (70.46)	8 (1.20)	6 (0.90)	0.24
T1DM (n=120)	13 (10.83)	24 (20.00)	82 (68.33)	1 (0.83)	0	
T2DM (n=547)	45 (8.23)	101 (18.46)	388 (70.93)	7 (1.28)	6 (1.10)	
Consulting with my healthcare provider(s) about my diabetes…						
Overall (n=667)	85 (12.74)	158 (23.69)	410 (61.47)	13 (1.95)	1 (0.15)	0.75
T1DM (n=120)	14 (11.67)	28 (23.33)	76 (63.33)	2 (1.67)	0	
T2DM (n=547)	71 (12.98)	130 (23.77)	334 (61.06)	11 (2.01)	1 (0.18)	
Testing/monitoring my blood glucose…						
Overall (n=667)	34 (5.10)	72 (10.79)	551 (82.61)	7 (1.05)	3 (0.45)	<0.001‡
T1DM (n=120)	4 (3.33)	2 (1.67)	110 (91.67)	4 (3.33)	0	
T2DM (n=547)	30 (5.48)	70 (12.80)	441 (80.62)	3 (0.55)	3 (0.55)	
Remembering to take my diabetes medication(s) as prescribed…						
Overall (n=667)	26 (3.90)	65 (9.75)	554 (83.06)	18 (2.70)	4 (0.60)	0.047‡
T1DM (n=120)	1 (0.83)	7 (5.83)	109 (90.83)	3 (2.50)	0	
T2DM (n=547)	25 (4.57)	58 (10.60)	445 (81.35)	15 (2.74)	4 (0.73)	
Monitoring my risk of hypoglycaemia regularly…						
Overall (n=667)	29 (4.35)	51 (7.65)	561 (84.11)	23 (3.45)	3 (0.45)	0.026‡
T1DM (n=120)	3 (2.50)	6 (5.00)	103 (85.83)	8 (6.67)	0	
T2DM (n=547)	26 (4.75)	45 (8.23)	458 (83.73)	15 (2.74)	3 (0.55)	
Staying as physically active as I usually am…						
Overall (n=667)	100 (14.99)	209 (31.33)	329 (49.33)	23 (3.45)	6 (0.90)	0.84
T1DM (n=120)	21 (17.50)	36 (30.00)	55 (45.83)	7 (5.83)	1 (0.83)	
T2DM (n=547)	79 (14.44)	173 (31.63)	274 (50.09)	16 (2.93)	5 (0.91)	
Feeling in control of my hypoglycaemia…						
Overall (n=667)	35 (5.25)	62 (9.30)	528 (79.16)	35 (5.25)	7 (1.05)	0.50
T1DM (n=120)	5 (4.17)	9 (7.50)	99 (82.50)	6 (5.00)	1 (0.83)	
T2DM (n=547)	30 (5.48)	53 (9.69)	429 (78.43)	29 (5.30)	6 (1.10)	
Having enough social support to help me manage my hypoglycaemia…						

Continued

Table 4 Continued

	...has been much harder	...has been somewhat harder	...has not been impacted	...has been somewhat easier	...has been much easier	P value†
Overall (n=667)	41 (6.15)	83 (12.44)	518 (77.66)	21 (3.15)	4 (0.60)	0.056
T1DM (n=120)	3 (2.50)	10 (8.33)	104 (86.67)	3 (2.50)	0	
T2DM (n=547)	38 (6.95)	73 (13.35)	414 (75.69)	18 (3.29)	4 (0.73)	

n (%) are presented.
*Data collected from 21 to 28 April 2020.
†Item responses were compared between individuals with T1DM and T2DM. P values were computed using two-sample Wilcoxon-Mann-Whitney tests.
‡Statistically significant at α=0.05 (ie, the underlying distributions of item responses statistically significantly differed by diabetes type).
T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.

behavioural/clinical and psychosocial aspects of glycaemic management among community-dwelling Americans. Based on the results of our study, the pandemic was found to cause substantial deficiencies in routine diabetes care in the USA, a finding consistent with international data published by the WHO.[23] Of note, only few appreciable differences were observed by diabetes type; of those identified, most related to the behavioural aspects of glycaemic management.

COVID-19 and the socioeconomic aspects of glycaemic management

PWD have been severely and disproportionately affected by the pandemic. Based on recent data published by the ADA, 24% of PWD have been forced to use savings, loans or money from their stimulus checks.[24] This percentage increases to half among the 33% of PWD (compared with 29% of people without diabetes) who have lost income since the pandemic began.[24] It is thus not surprising that almost a quarter of iNPHORM respondents revealed that the COVID-19 situation impeded their abilities to afford rent and other living expenses. As the outbreak continues to escalate across the country, it is expected that the

financial situation of many Americans will become increasingly precarious.[18]

In this study, economic incertitude also affected participants' access to healthy food.[9] COVID-19-related financial or environmental factors can invoke a state of food insecurity, a major predictor of clinically significant hypoglycaemia.[25] One US study found that exhaustion of food budgets was associated with a 27% increase in hypoglycaemia-related hospital admissions.[26] Food insecurity among PWD has also been associated with poorer glucose monitoring and higher A1c values.[26]

Furthermore, decreases in financial resources, especially in the absence of health coverage, can inhibit access to diabetes medical supplies. An American study found that prescription refills for diabetes medications fell by 10% between January and August 2020[27]; however, whether or not this was due to financial or environmental factors was unclarified. Our data reveal that while roughly 20% of respondents experienced difficulties affording medications or strips/sensors, over a quarter reported issues physically retrieving medical supplies from pharmacies (perhaps due to prevention orders or anxieties over potential exposure).

Interruptions in healthcare access may explain the significant percentages of respondents who reported rationing their diabetes supplies. Our study investigated whether or not PWD ration their medications not just to extend their lifespan, but to prevent hypoglycaemia. Despite evidence that lockdown exacerbates hypoglycaemia risk,[28] no research yet existed measuring the potential risk of hypoglycaemia-specific medication rationing during COVID-19. Treatment rationing contradicts the CDC's recommendations for managing diabetes during the pandemic.[11] Antihyperglycaemic underuse can increase the likelihood of deleterious short-term outcomes, and it can drive up the cost of long-term diabetes-related complications.[29]

The impact of the COVID-19 situation on socioeconomic indicators predictably did not vary by diabetes type with nearly equivalent percentages of each reporting financial and environmental instabilities because of the pandemic.

Table 5 Impact of the COVID-19 situation on diabetes medication rationing (past month)*, overall and by diabetes type

	Total n=667	T1DM 120 (17.99%)	T2DM 547 (82.01%)	P value†
Rationed to make diabetes medication(s) supply last longer				
Yes	111 (16.64)	16 (13.33)	95 (17.37)	0.28
Rationed to avoid hypoglycaemia				
Yes	112 (16.79)	19 (15.83)	93 (17.00)	0.76

n (%) are presented.
*Data collected from 21 to 28 April 2020.
†Item responses were compared between individuals with T1DM and T2DM. P values were computed using two-sample Z tests for proportions.
T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.

COVID-19 and the behavioural/clinical aspects of glycaemic management

Evidence from past national emergencies underscores their profound and lasting implications on self-management behaviours in people with coexistent illnesses.[16 17] Our study is the first American diabetes investigation to measure these implications in the COVID-19 era. Because of the pandemic, several iNPHORM participants reported forgetting to take their prescribed medications. This was especially true of type 2 diabetes respondents, perhaps due to variability in medication regimens compared with those with type 1 diabetes. Lapses in medication use can compromise therapeutic adherence and efficacies, leading to elevated A1c values as far-out as 16 months postemergency.[17] This risk is likely compounded by financial and access-related issues resulting from the pandemic (described in previous section) as well as suboptimal blood glucose tracking. Many respondents, especially those with type 2 diabetes, reported difficulties testing/monitoring their glucose and, specifically, hypoglycaemia risk.

In addition, the pandemic has imposed dramatic changes on routine healthcare access and delivery, particularly among individuals with underlying health conditions.[30] To prioritise access to hospital beds, equipment and staff, as well as to minimise viral transmission, much of routine healthcare has been postponed or cancelled. As well, PWD may decline attendance at hospitals, clinics and screening examinations over concerns of infection. More than a third of respondents indicated that the COVID-19 situation made it harder to consult with their diabetes providers. Interestingly, this finding did not significantly differ by diabetes type.

Research has shown that deferred or avoided healthcare due to the pandemic can contribute to excess morbidity and mortality.[31] Based on an article by Woolf et al,[32] US states with large numbers of COVID-19-related deaths experience large proportional increases in deaths from other underlying causes, including diabetes. Impacts on health may worsen the longer community containment measures last. A simulation study of data from previous global disasters found the duration of lockdown to be directly proportional to A1c and number of diabetes-related complications.[33] Unfortunately, these effects may endure even after the viral outbreak has been quelled. Evidence from past disasters has shown that reduced access to healthcare during the acute phase of an emergency can lead to an aftermath of increased deaths and morbidities including stroke, myocardial infarctions and diabetes-related complications.[34] Such increases in morbidity and mortality resulting from delayed and reduced healthcare access are especially concerning among iNPHORM participants, of whom almost 90% reported some comorbidity or diabetes-related complication.

Finally, COVID-19 mitigation measures can restrict access to indoor and outdoor physical activities, contributing to increased sedentary behaviours that adversely affect immune defence, glycaemic control and metabolic health in general.[9] Based on data from other viral infections, suboptimal physical activity can accentuate symptom severity, recovery times and transmissibility; it can also compromise postvaccination immunity and increase secondary infection risk.[35] Regardless of diabetes type, staggering percentages of participants reported reduced physical activity because of the pandemic, a sure warning sign of the extensive health consequences to come.

COVID-19 and the psychosocial aspects of glycaemic management

The psychosocial ramifications of COVID-19 in PWD have been minimally investigated in the literature. Our study specifically assessed how the pandemic has impacted respondents' senses of personal control over their hypoglycaemia risk. Significant decrements in self-perceived control were observed across all participants. Sense of control—the learnt belief that one does master, control and shape one's life—has been linked to several positive health effects including proactive behaviour and emotional well-being.[36] However, inadequate supplies, financial loss, fear psychosis of being infected and media/disinformation can all contribute to increased feelings of powerlessness.[37] Reductions in sense of personal control have been associated with heightened stress, anxiety and depressive symptoms[38]—outcomes that have been linked to poor medication adherence and diminished self-management.[39]

No study had yet quantified the effect of the COVID-19 situation on social support access in PWD. While support from family and friends can mediate the contextual impacts of COVID-19, several respondents in our study, particularly those with type 2 diabetes, reported insufficient social support to help manage their hypoglycaemia. Assistance from informal relationships has been identified as a major component to hypoglycaemia self-management with demonstrable impacts on diabetes-related morbidity and mortality reduction.[14 38 40] The gap in social support observed in our study portends troubling implications for hypoglycaemia incidence as well as other clinical and psychosocial sequelae.

Indeed, suboptimal social support among people with type 2 diabetes, compounded by inadequate hypoglycaemia risk monitoring, could explain why SH was found to be more common in our respondents with type 2 versus type 1 diabetes. Though comparable overall hypoglycaemia incidences have been observed in other real-world studies,[41] the 2018 UnderstandINg the impact of HYPOglycemia on Diabetes Management (InHypo-DM) study[42] reported similarly higher SH event rates in people with type 2 versus type 1 diabetes. This finding suggests that important deficiencies—irrespective of the pandemic situation—may exist with regard to hypoglycaemia education, management behaviours and/or primary care in people with type 2 diabetes when compared with their type 1 diabetes counterpart. Parenthetically, unlike many other real-world hypoglycaemia investigations that focus exclusively on insulin-treated diabetes,[43–45] it should be

noted that 25% and 18% of participants in iNPHORM and InHypo-DM, respectively, reported taking insulin in combination with secretagogues. Research has shown that insulin-secretagogue therapy substantially increases the rate of SH compared with insulin without secretagogues and secretagogues without insulin.[46]

Study strengths and limitations

This study evaluates a general, community-based cohort of Americans with diabetes—irrespective of infection status—to derive insight into the real-world, real-time consequences of the COVID-19 situation in diabetes. To mitigate selection bias, a broad sample of participants was recruited from a large, probability-based internet panel. Online data collection enabled us to capitalise on the high prevalence of internet use in the USA,[47] while optimising survey reach and accessibility, respondent honesty and representativeness, as well as reducing item non-response.[48 49] Participant anonymity and confidentiality were assured to decrease the risk of social desirability bias.[50]

By developing a pandemic-specific questionnaire, our research team was able to elucidate the once unknown repercussions of the COVID-19 situation in Americans with diabetes; indeed, self-report data can offer unique and robust insight routinely uncaptured by other methods. Though the study is cross-sectional in design, self-reported causal attributions of the pandemic were operationalised for each questionnaire item: respondents were asked to indicate to what extent '…the Coronavirus (COVID-19) situation [had] impacted' given aspects of glycaemic management. Such information had yet to be garnered in the USA.

Nevertheless, certain study limitations should be noted. Selection biases may have arisen to the extent that respondents differed non-randomly from the general US population with diabetes taking insulin and/or secretagogues. Specifically, survivorship and coverage bias (eg, due to high observed percentages of Caucasian, educated and insured participants) could have curtailed the external validity of results. Volunteer bias may have also led participants to overestimate or underestimate their responses. For example, those who chose to complete the first COVID-19 subquestionnaire may have possessed systemically different (positive or negative) pandemic-related perspectives and/or experiences than those who did not.

Estimates derived in our study may be conservative, as they stem from a 1-month data capture in the early phase of the pandemic trajectory. In addition, self-reported responses could have been influenced by social desirability bias and/or recall error. Even so, self-report data—typically the Hobson's choice for information on perspectives, views and opinions—enabled us to capture, for the first time, the impacts of COVID-19 on various socioeconomic, behavioural/clinical and psychosocial aspects of diabetes management in the USA. The results of our study (though not exhaustive, per se) provide important, unprecedented insight into the real-world fallouts of the pandemic situation on diabetes-related health.

Analyses of psychometric properties and/or adjusted frequency estimates were beyond the scope of this manuscript. Rather this study supplies descriptive, novel and time-sensitive evidence at the convergence of COVID-19 and diabetes, contributing to both the national and international body of pandemic literature.

CONCLUSIONS

A 'hinterland' is defined as an area lying beyond what is visible or known. As a society, we have exhibited unparalleled bravery in the face of one of the most terrifying crises known to humankind. However, our mission to abate the pandemic is only just beginning. Indeed, the COVID-19 calamity has had untold reverberations in the lives of Americans, extending well beyond the visible devastations caused by infection alone. Not least are the impacts COVID-19 has had on PWD—cases and non-cases alike—who have struggled to maintain control of their disease amidst the pandemic.

Yet, until now, the nature and scale of these impacts in the USA were largely unknown or uncharacterised. Thus, the results of our study draw awareness to the far-reaching and potential lasting consequences of the pandemic, and offer an evidence base for decisive action. In identifying the unique needs of Americans with diabetes during the COVID-19 era, we can begin to develop, implement and assess clinical and public health strategies that ensure safe, undisrupted care within communities of PWD. As we combat the acute phase of COVID-19, we must not lose sight of the pernicious health challenges that coexist and await us in the aftermath.

(USA), respectively (ID: 112986). Participants gave informed consent before taking part in the study.

ORCID iD
Stewart B Harris http://orcid.org/0000-0002-1794-6551

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Appendix A. Items assessing the impact of the COVID-19 situation on aspects of diabetes management

On a scale from *much harder* to *much easier*, please tell us how the Coronavirus (COVID-19) situation has impacted the following aspects of your life.

In general, **since the last time I completed an iNPHORM survey**...

	...has been much harder	...has been somewhat harder	...has **not** been impacted	...has been somewhat easier	...has been much easier
1. ...Affording my rent and other living expenses	☐	☐	☐	☐	☐
2. ...Affording my diabetes medication(s)	☐	☐	☐	☐	☐
3. ...Affording my test strips and/or sensors	☐	☐	☐	☐	☐
4. ...Getting my diabetes medication(s) from the pharmacy	☐	☐	☐	☐	☐
5. ...Making sure I have enough food to avoid hypoglycemia	☐	☐	☐	☐	☐
6. ...Testing/monitoring my blood glucose	☐	☐	☐	☐	☐
7. ...Staying as physically active as I usually am	☐	☐	☐	☐	☐
8. ...Consulting with my healthcare provider(s) about my diabetes	☐	☐	☐	☐	☐
9. ...Remembering to take my diabetes medication(s) as prescribed	☐	☐	☐	☐	☐
10. ...Monitoring my risk of hypoglycemia regularly	☐	☐	☐	☐	☐
11. ...Having enough social support to help me manage my hypoglycemia	☐	☐	☐	☐	☐
12. ...Feeling in control of my hypoglycemia	☐	☐	☐	☐	☐

When answering this next question, please think about the time **since you last completed an iNPHORM survey**.

Because of the Coronavirus (*COVID-19)* situation, did you ever **cut back** on your diabetes medication(s) in order to...

	Yes	No
13. ...make your diabetes medication(s) supply last longer?	☐	☐
14. ...avoid hypoglycemia?	☐	☐