

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

The COVID-19 Hinterland: How the pandemic has affected chronic diabetes management in the United States

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-049782
Article Type:	Original research
Date Submitted by the Author:	04-Feb-2021
Complete List of Authors:	Ratzki-Leewing, Alexandria A.; Western University, Department of Epidemiology and Biostatistics Ryan, BL; University of Western Ontario Department of Epidemiology and Biostatistics; Western University Schulich School of Medicine & Dentistry Buchenberger, John D.; Ipsos Dickens, Joseph W.; ISPOS, SMX Harris, Stewart; Western University Department of Epidemiology and Biostatistics; Western University Schulich School of Medicine & Dentistry, Department of Family Medicine
Keywords:	DIABETES & ENDOCRINOLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, General endocrinology < DIABETES & ENDOCRINOLOGY, General diabetes < DIABETES & ENDOCRINOLOGY

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3 Full title: The COVID-19 Hinterland: How the pandemic has affected chronic diabetes
4
5
6 management in the United States
7

8
9
10 Short running title: Managing diabetes during the COVID-19 pandemic
11

12
13 Authors:
14

15
16 Alexandria A. Ratzki-Leewing MSc¹
17

18
19
20 Bridget L. Ryan PhD^{1,2}
21

22
23
24 John D. Buchenberger MS³
25

26
27 Joseph W. Dickens BA⁴
28

29
30
31 Stewart B. Harris MD^{1,2}
32

33 Author affiliations:
34

35
36 ¹Department of Epidemiology and Biostatistics, Schulich School of Medicine and
37
38
39 Dentistry, Western University, London, Ontario, Canada.
40

41
42
43 ²Department of Family Medicine, Schulich School of Medicine and Dentistry, Western
44
45
46 University, London, Ontario, Canada.
47

48
49
50 ³Ipsos Healthcare, New York, New York, United States of America.
51

52
53
54 ⁴Ipsos SMX, Chicago, Illinois, United States of America.
55

1
2
3 Corresponding author:
4

5
6 Stewart B. Harris MD
7

8
9 Department of Family Medicine, Western University,
10

11
12
13 1151 Richmond St, London, Ontario, N6A 3K7, Canada.
14

15
16
17 +1 519 661 2111 x.22050
18

19
20 Sharris1@uwo.ca
21

22
23 Abstract: 249

24
25 Word count: 3845

26
27 Number of tables: 4

28
29 Keywords: Diabetes Management, COVID, Hypoglycemia, Real-World
30

ABSTRACT

Objective: This is first study of its kind to measure how, and to what extent, the pandemic has affected diabetes management in Americans with or without COVID-19.

Research Design and Methods: We conducted a cross-sectional investigation using data from the real-world, population-based iNPHORM study. Participants 18-90 years old, living in the US, diagnosed with type 1 or 2 diabetes, taking insulin and/or secretagogues were recruited from online panels of the general public. We examined the impact of the COVID-19 situation on socio-economic, behavioural/clinical, and psychosocial aspects of glycemic management.

Results: Data from 667 respondents (type 1 diabetes: 18%; type 2 diabetes: 82%) were analyzed. Almost 25% reported A1C values $\geq 8.1\%$. Rates of severe and non-severe hypoglycemia were 0.68 (95%CI: 0.5-0.96) and 2.75 (95%CI: 2.4-3.1) events per-person month, respectively. Ten respondents reported a confirmed or probable COVID-19 diagnosis. Because of the pandemic, 20-28% of respondents experienced difficulties affording housing, sufficient food to avoid hypoglycemia, and diabetes therapies/testing strips. Over one-quarter reported issues retrieving antihyperglycemics from the

1
2
3 pharmacy and over one-third reported challenges consulting with diabetes providers.
4
5

6 The pandemic contributed to therapeutic non-adherence (14%), drug rationing (17%),
7
8
9 and reduced monitoring (16%). Many struggled to keep track, and in control, of
10
11
12
13 hypoglycemia (12-15%) and lacked social support to help manage their risk (19%).
14
15

16
17 Nearly half reported decreased physical activity. Few differences emerged by diabetes
18
19
20 type.
21
22

23
24 Conclusions: The results of this study can inform decisive action to re-stabilize routine
25
26
27 diabetes management amidst the pandemic, helping to protect the health of America's
28
29
30 vulnerable populations.
31
32

33
34
35
36
37
38
39
40
41 Strengths and limitations of this study
42
43

- 44 • This is the first and most comprehensive investigation to quantify the impact of
45
46
47 the COVID-19 situation on the socio-economic, behavioural/clinical, and
48
49
50
51 psychosocial aspects of glycemetic management in US outpatient communities.
52
53
54
55
56
57
58
59
60

- 1
2
3 • We developed a novel pandemic-specific questionnaire that was administered
4
5
6 online to a large, real-world cohort of Americans with type 1 and type 2 diabetes
7
8
9 taking insulin and/or secretagogues.
10
11
12
- 13 • Estimates presented in our study may be conservative as they describe the early
14
15
16 phase of the pandemic.
17
18
19
20
21
22
23

24 COVID-19 is among the most devastating health crises in American history. The first
25
26
27 reported infection in the United States (US) occurred on January 19th, 2020 (1). Since
28
29
30 then, the number of confirmed US-cases has surpassed 22.4 million, including over
31
32
33
34 374,000 deaths (2).
35
36

37 People with diabetes (PWD) have been identified as clinically vulnerable to COVID-19.
38
39
40
41 In the US, diabetes ranks as the second most common underlying health condition
42
43
44 among all cases and has been connected to more severe infection (3,4). However, less
45
46
47 appreciated in the literature are the disruptions caused by the pandemic on routine
48
49
50 diabetes care. These disruptions expose not only those with COVID-19, but all 34+
51
52
53
54 million Americans with diabetes to poor outcomes. Understanding how the pandemic
55
56
57
58
59
60

1
2
3 affects diabetes services and management is crucial to informing short- and long-term
4
5
6 clinical decision-making and public health planning. Targeted measures to help protect
7
8
9 these Americans from the direct and indirect effects of the COVID-19 pandemic should
10
11
12
13 be a top priority for all healthcare and government officials.
14
15
16
17
18
19

20 The complex hinterland of COVID-19 and diabetes

21
22
23 The pathophysiological benefits of glycemic control on diabetes outcomes have been
24
25
26
27 well-established. Numerous studies have linked chronic hyperglycemia and glycemic
28
29
30
31 variability to increased risks of micro- and macro-vascular complications and mortality.
32
33

34 In addition, dysglycemia can potentiate immunosuppression (5), increasing viral
35
36
37
38 susceptibility and risk of poor clinical outcomes (6). While the role of coexistent diabetes
39
40
41 in the pathogenesis of COVID-19 is still being determined (7), emerging signals suggest
42
43
44 that euglycemia protects against infection and severity of prognoses (8,9). These data
45
46
47
48 are consistent with evidence from other viral infections where glucose control showed to
49
50
51
52 augment host immune response (5,10).
53
54
55
56
57
58
59
60

1
2
3 To mitigate COVID-19 risks, several national and international organizations have
4
5
6 published diabetes pandemic guides, urging PWD to maintain scrupulous adherence to
7
8
9 all self-management and public health recommendations (7,8). Notably, the Centers for
10
11
12
13 Disease Control and Prevention (CDC) (11) has recommended maintaining at least a
14
15
16
17 30-day supply of medication and 2-week supply of food. The American Diabetes
18
19
20 Association (ADA) (12) has advised storing blood glucose (BG) emergency supplies
21
22
23 (i.e., glucagon and ketone strips). And the International Diabetes Federation (13) has
24
25
26
27 encouraged healthy nutrition and regular monitoring to help avoid the complications of
28
29
30
31 high and low BG.

32
33
34 However, the COVID-19 situation has created a challenging terrain for effective
35
36
37
38 glycemic management (14). Amid pressures to flatten the pandemic curve, patients and
39
40
41 clinicians may divert focus and resources away from diabetes management, resulting in
42
43
44
45 compromised care (8). Moreover, home quarantine, physical distancing, and community
46
47
48
49 containment—while enacted to ensure the safety of Americans—can erode chronic
50
51
52
53
54
55
56
57
58
59
60 disease services and make it increasingly difficult for PWD to access medical supplies
and engage in optimal self-management behaviour (e.g., healthy eating and physical

1
2
3 activity) (15). Previous outbreaks have also been associated with inadequate diabetes
4
5
6 monitoring and barriers to accessing healthcare, medications, and testing supplies (4,8).
7
8
9
10 Such disruptions to routine care can lead to worse glycemic outcomes during and after
11
12
13 the event (16,17).
14
15

16
17 Yet, to date, most diabetes-related COVID-19 studies have focused exclusively on the
18
19
20 epidemiology of hospitalized cases (18,19) and failed to consider how outpatient chronic
21
22
23 diabetes management has suffered in the face of the pandemic. The lack of real-world
24
25
26
27 evidence on the situational effects of COVID-19 bodes ill for the implementation of
28
29
30 effective outbreak strategies that support Americans with diabetes. As the pandemic
31
32
33
34 persists into the foreseeable future, the need to address this gap only intensifies.
35
36

37
38 The present investigation aims to chart the complex hinterland of COVID-19 as it
39
40
41 intersects with America's other deadly pandemic: Diabetes. We measured how, and the
42
43
44
45 extent to which, the COVID-19 situation has affected glycemic management in the
46
47
48
49 general US population with type 1 and 2 diabetes. The results of this study will be
50
51
52
53 instructive for handling chronic disease management both during the current public
54
55
56
57 health emergency and in future.
58
59
60

RESEARCH DESIGN AND METHODS

Study design, participants, and data collection

We conducted a cross-sectional investigation of data collected from the real-world, population-based iNPHORM Study (Investigating Novel Predictions of Hypoglycemia Occurrence Using Real-world Models): an ambidirectional (one-year retrospective/one-year prospective) survey of outpatient Americans with diabetes.

iNPHORM participants were recruited from five pre-existing online panels of the general US public. Collectively, these panels comprised >10,000 Americans (≥ 18 years old) with type 1 diabetes and >58,000 with type 2 diabetes. Panel members 18-90 years old, living in the US for the past year, and with type 1 or 2 diabetes taking insulin and/or secretagogues were eligible to enroll in our study. 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.

Convenience sampling was used to enroll two waves of participants: Wave 1 and Wave 2. First, a randomly selected subset of the panels was targeted based on study requirements, mainly diabetes status. These individuals were contacted via email about

1
2
3 the study; those interested in participating were directed to complete a screening
4
5
6 questionnaire. Recruitment of Wave 1 ended when we achieved our target sample size
7
8
9 of 1250 eligible enrollees. Those in Wave 1 who failed to submit the Month 1 follow-up
10
11
12 questionnaire were withdrawn from the study and replaced by new eligible recruits
13
14
15 (Wave 2) sampled from a different, randomly selected subset of the panels. To finalize
16
17 enrollment, Wave 1 and 2 eligible respondents needed to provide consent and complete
18
19 the baseline questionnaire. Once enrolled, participants were managed and hosted by
20
21
22
23
24
25
26
27 Ipsos Interactive Services (IIS).

28
29
30 Each recruitment wave, offset by two months, will complete up to 12 follow-up
31
32
33 questionnaires disseminated on a prescheduled, monthly basis. Questionnaires must be
34
35
36
37 submitted within seven-days of the distribution date. Reminders and honorariums are
38
39
40
41 being administered to optimize participant retention.

42
43
44 Data collection will occur February-2020 to April-2021. Further details regarding the
45
46
47
48 iNPHORM study, including sample size considerations, are available at clinicaltrials.gov
49
50
51 (NCT04219514) (20).

Survey instruments and variables

All questionnaires (screening, baseline, and follow-ups) were developed by our team of epidemiologists and clinicians in consultation with the literature. Prior to dissemination, questionnaires were pretested via semi-structured interviews for content, comprehensibility, skip patterns, and length

In this study, we summarize data from 16 items contained in our COVID-19 sub-questionnaire (described below). This sub-questionnaire was added *post hoc* in response to the escalating severity of the US COVID-19 situation. Beginning with the 'Wave 1 second follow-up questionnaire (FQ2)' (administered April 21st-28th, 2020), each monthly follow-up will contain the COVID-19 sub-questionnaire. We herein analyze 'Wave 1-FQ2' data.

COVID-19 status: To ascertain self-reported infection status (past month), 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 epidemiologic linkage (potential exposure). Aligning with CDC recommendations, we classified respondents as confirmed, probable, or possible cases.

1
2
3 Confirmed cases were those who reported having been formally diagnosed with
4
5
6 COVID-19. Probable cases were those who did not have a formal diagnosis but who
7
8
9 reported 1) symptoms typical of COVID-19 *and* 2) ≥ 1 form of epidemiologic linkage. If
10
11
12 only one of the two latter conditions was met, we classified individuals as possible
13
14
15
16 cases.
17

18
19
20 *Impact of the COVID-19 situation on aspects of diabetes management.* We developed
21
22
23 12 structured, 5-point Likert items to assess how, and to what extent, the COVID-19
24
25
26 situation has disrupted socio-economic, behavioural/clinical, and psychosocial aspects
27
28
29 of participants' diabetes management (past month). Respondents were asked to
30
31
32 evaluate whether these aspects were made much harder, somewhat harder, somewhat
33
34
35 easier, or much easier by the COVID-19 situation—a neutral option was provided.
36
37
38

39
40
41 Topics included drug affordability/accessibility, medication-taking behaviour, healthcare
42
43
44 consultations, glucose monitoring, and social support. Additionally, we incorporated two
45
46
47 structured, binary items to assess drug rationing.
48
49

50
51 *Socio-demographic and clinical characteristics of study sample:* Self-reported socio-
52
53
54 demographic and clinical characteristics were collected between the screening,
55
56
57
58
59
60

1
2
3 baseline, FQ1, and FQ2 questionnaires. Past-month frequencies of self-reported severe
4
5
6 hypoglycemia (SH) and non-severe hypoglycemia (NSH), defined in accordance with
7
8
9 the ADA (22), were assessed at FQ2. Non-severe hypoglycemia was defined as any
10
11
12 event that could be self-treated; SH was defined as a medical emergency that could not
13
14
15 be self-treated (e.g., required third-party assistance).
16
17
18

19 20 Statistical analysis

21
22
23 Categorical variables were summarized as frequencies and percentages, while
24
25
26 continuous variables as means and standard deviations (SD) or medians and
27
28
29 interquartile ranges (IQR). Crude hypoglycemia frequencies were calculated as
30
31
32 incidence rates (IR) and incidence proportions (IP). Confirmed, probable, and possible
33
34
35 COVID-19 cases were calculated as period prevalences.
36
37
38

39
40
41 The impact of the COVID-19 situation on glycemic management was descriptively
42
43
44 analyzed (Likert responses were trichotomized). Differences by diabetes type were
45
46
47 assessed using the Wilcoxin-Mann-Whitney test for Likert responses and the two-
48
49
50 sample test of proportions for binary responses. Tests were two-sided at $\alpha=0.05$.
51
52
53

54
55 Analyses were performed using STATA V.16.0.
56
57
58
59
60

Patient and public involvement

No patients were directly involved in designing or conducting this study.

Ethical considerations

Western investigators and IIS obtained approval from the Western University's Research Ethics Board and the Pearl Institutional Review Board (US), respectively.

RESULTS

The current evaluation is based on a sub-sample of 667 (type 1 diabetes: 18.0%; type 2 diabetes: 82%) out of 704 Wave 1-FQ2 respondents who reported taking insulin and/or secretagogues (i.e., were at-risk of hypoglycemia). Socio-demographic and clinical characteristics are summarized in Table 1. Half of participants were female. The mean age was 51.9 (SD: 14.6; Min, Max: 20, 87) years; 23.2% were ≥ 65 years old. Diabetes duration was 26.0 (IQR: 23.0) years in people with type 1 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

1
2
3 of insulin and secretagogues. Twenty-three percent (type 1 diabetes: 23.3%; type 2
4
5
6 diabetes: 23.0%) of the total sample reported A1C values $\geq 8.1\%$. Sixty-one percent
7
8
9 reported ≥ 1 diabetes-related complication, while 83.2% reported ≥ 1 comorbidity.

10
11
12
13 Table 2 summarizes self-reported hypoglycemia incidences (combined daytime and
14
15
16 nocturnal). The IR and IP of NSH were higher in people with type 1 diabetes (IR: 5.7
17
18
19 [95%CI: 4.6-7.1] events per person-month (PPM) and IP: 83.3% [95%CI: 75.7-88.9])
20
21
22
23 versus type 2 diabetes (IR: 2.1 [95%CI: 1.8-2.4] events PPM and IP: 55.0% [95%CI:
24
25
26 50.8-59.1]). However, SH, occurring at an overall rate of 0.7 (95%CI: 0.5-0.96) events
27
28
29 PPM, was almost twice as common in people with type 2 versus type 1 diabetes (0.8
30
31
32 [95%CI: 0.5-1.1] versus 0.4 [95%CI: 0.2-0.9] events PPM). Similarly, the monthly IP of
33
34
35
36
37 SH, affecting nearly 13% (95%CI: 10.6-15.7) of respondents, was higher in people with
38
39
40
41 type 2 diabetes compared to type 1 diabetes (13.2% [95%CI: 10.6-16.3] versus 11.7%
42
43
44 [95%CI: 7.08-18.6]).

45
46
47
48 The one-month period prevalences of confirmed, probable, and possible COVID-19
49
50
51 were 0.75%, 0.75%, and 8.9%, respectively (Table 3).
52
53
54
55
56
57
58
59
60

1
2
3 The impact of the COVID-19 situation on aspects of glycemetic management
4
5

6 A summary of results are provided in Table 4. Almost a quarter of respondents (type 1
7
8 diabetes: 30.0%; type 2 diabetes: 23.0%, P -value =0.07) reported that the COVID-19
9
10 situation had made affording rent and other living expenses somewhat or much harder.
11
12
13

14
15 Similarly, 27.6% (type 1 diabetes: 23.3%; type 2 diabetes: 28.5%, P -value =0.29) of
16
17 participants expressed difficulties ensuring adequate food supply to avoid
18
19 hypoglycemia. Close to one in five experienced challenges paying for their diabetes
20
21 medications (type 1 diabetes: 16.7%; type 2 diabetes: 19.0%, P -value =0.66) or test
22
23 strips/sensors (type 1 diabetes: 13.3%; type 2 diabetes: 18.3%, P -value =0.31). Amid
24
25 affordability concerns, access-related issues in retrieving diabetes medications from the
26
27 pharmacy were noted by 27.4% (type 1 diabetes: 30.8%; type 2 diabetes: 26.7%, P -
28
29 value =0.26) of our study sample. As well, because of the COVID-19 situation, ~17% of
30
31 participants reported rationing their diabetes medications either to make supplies last
32
33 longer (type 1 diabetes: 13.3%; type 2 diabetes: 17.4%, P -value =0.28) or avoid
34
35 hypoglycemia (overall: 16.8%; type 1 diabetes: 15.8%; type 2 diabetes: 17.0%, P -value
36
37 =0.76).
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 The COVID-19 situation also influenced participants' abilities to self-manage. Many
4
5
6 respondents struggled to remember to take their diabetes medication(s) as prescribed
7
8
9 (overall: 13.6%; type 1 diabetes: 6.7%; type 2 diabetes: 15.2%, P -value =0.052) as well
10
11
12 as test and monitor their BG (overall: 15.9%; type 1 diabetes: 5.0%; type 2 diabetes:
13
14
15
16 18.3%, P -value <0.001) and risk of hypoglycemia regularly (overall: 12.0%; type 1
17
18
19 diabetes: 7.5%; type 2 diabetes: 13.0%, P -value =0.02). Over a third of respondents
20
21
22 (type 1 diabetes: 35.0%; type 2 diabetes: 36.8%, P -value =0.78) found it somewhat or
23
24
25
26 much harder to consult with their diabetes care providers. In terms of exercise
27
28
29 maintenance, almost one in two respondents (type 1 diabetes: 47.5%; type 2 diabetes:
30
31
32 46.1, P -value =0.98) reported that it had been somewhat or much harder to stay as
33
34
35
36
37 physically active as usual.

38
39
40
41 Lastly, psychosocial effects were observed. Many participants (14.5%) felt less in
42
43
44 control of their hypoglycemia (type 1 diabetes: 11.7%; type 2 diabetes: 15.2%, P -value
45
46
47 =0.5); 19% also reported having insufficient social support to help manage their risk
48
49
50
51 (type 1 diabetes: 10.8%; type 2 diabetes: 20.3%, P -value =0.06).
52
53
54
55
56
57
58
59
60

1
2
3 The COVID-19 situation rarely had a beneficial impact on participants' lives. For almost
4
5
6 all aspects of diabetes management that were measured, <5% of the sample selected
7
8
9
10 "somewhat easier" or "much easier".
11
12

13 14 DISCUSSION 15

16
17
18
19 Experts have long been aware of the impacts a protracted emergency would have on
20
21
22 healthcare and outcomes. Now, as two widespread pandemics collide, many Americans
23
24
25 are finding themselves at the nidus of extreme clinical vulnerability, and with little
26
27
28 support. Despite advice furnished by several national and international organizations,
29
30
31
32
33 PWD are clearly struggling to maintain glycemic management standards during the
34
35
36 pandemic. This gap forebodes important, population-based consequences to diabetes-
37
38
39 related morbidities, both now and well-after vaccinations are distributed.
40
41
42

43
44 Our study is the first and most comprehensive investigation to quantify the impact of the
45
46
47 COVID-19 situation on the socio-economic, behavioural/clinical, and psychosocial
48
49
50 aspects of glycemic management in US outpatient communities. In general, the
51
52
53
54 pandemic was found to cause substantial deficiencies in routine diabetes care. Of note,
55
56
57
58
59
60

1
2
3 only few appreciable differences were observed by diabetes type; of those identified,
4
5
6 most related to the behavioural aspects of glycemic management.
7

8
9 COVID-19 and the socio-economic aspects of glycemic management
10

11
12 People with diabetes have been severely and disproportionately affected by the
13
14
15 pandemic. Based on recent data published by the ADA, 24% of PWD have been forced
16
17
18 to use savings, loans, or money from their stimulus checks (23). This percentage
19
20
21 increases to half among the 33% of PWD (compared to 29% of people without diabetes)
22
23
24 who have lost income since the pandemic began (23). It is thus not surprising that
25
26
27 almost a quarter of iNPHORM respondents revealed that the COVID-19 situation
28
29
30 impeded their abilities to afford rent and other living expenses. As the outbreak
31
32
33 continues to escalate across the country, it is expected that the financial situation of
34
35
36 many Americans will become increasingly precarious (18).
37
38
39
40
41
42

43 In this study, economic uncertainty also affected participants' access to healthy food (9).
44
45

46
47 COVID-19-related financial or environmental factors can invoke a state of food
48
49
50 insecurity, a major predictor of clinically significant hypoglycemia (24). One US study
51
52
53 found that exhaustion of food budgets was associated with a 27% increase in
54
55
56
57
58
59
60

1
2
3 hypoglycemia-related hospital admissions (25). Other research has associated food
4
5
6 insecurity among PWD with poorer glucose monitoring and higher A1C values (26).
7
8
9
10 Furthermore, decreases in financial resources, especially in the absence of health
11
12
13 coverage, can inhibit access to diabetes medical supplies. An American study found
14
15
16 that prescription refills for diabetes medications fell by 10% between January and
17
18
19 August 2020 (27); however, whether or not this was due to financial or environmental
20
21
22 factors was unclarified. Our data reveal that while roughly 20% of respondents
23
24
25
26
27 experienced difficulties affording medications or strips/sensors, over a quarter reported
28
29
30 issues physically retrieving medical supplies from pharmacies (perhaps due to
31
32
33 prevention orders or anxieties over potential exposure).
34
35
36
37 Interruptions in healthcare access may explain the significant percentages of
38
39
40 respondents who reported rationing their diabetes supplies. Our study investigated
41
42
43
44 whether or not PWD ration their medications not just to extend their lifespan, but to
45
46
47 prevent hypoglycemia. Despite evidence that lockdown exacerbates hypoglycemia risk
48
49
50
51 (28), no research yet existed measuring the potential risk of hypoglycemia-specific
52
53
54
55 medication rationing during COVID-19. Treatment rationing contradicts the CDC's
56
57
58
59
60

1
2
3 recommendations for managing diabetes during the pandemic (11). Not only can
4
5
6 antihyperglycemic underuse increase the likelihood of deleterious short-term outcomes,
7
8
9 but it can also drive up the cost of long-term diabetes-related complications (29).

10
11
12
13 The impact of the COVID-19 situation on socio-economic indicators predictably did not
14
15
16 vary by diabetes type with nearly equivalent percentages of each reporting financial and
17
18
19 environmental instabilities because of the pandemic.
20
21

22 23 24 COVID-19 and the behavioural/clinical aspects of glycaemic management

25
26
27 Evidence from past national emergencies underscores their profound and lasting
28
29
30 implications on self-management behaviours in people with coexistent illnesses (16,17).
31
32

33
34 Our study is the most comprehensive diabetes investigation to measure these
35
36
37 implications in the COVID-19 era. Because of the pandemic, several iNPHORM
38
39
40 participants reported forgetting to take their prescribed medications. This was especially
41
42
43 true of type 2 diabetes respondents, perhaps due to variability in medication regimens
44
45
46 compared to those with type 1 diabetes. Lapses in medication use can compromise
47
48
49 therapeutic adherence and efficacies, leading to elevated A1C values as far-out as 16
50
51
52 months post-emergency (17). This risk is compounded by sub-optimal BG tracking.
53
54
55
56
57
58
59
60

1
2
3 Many respondents, especially those with type 2 diabetes, reported difficulties
4
5
6 testing/monitoring their glucose and, specifically, hypoglycemia risk.
7

8
9
10 In addition, the pandemic has imposed dramatic changes on routine healthcare access
11
12
13 and delivery, particularly among individuals with underlying health conditions (30). To
14
15
16 prioritize access to hospital beds, equipment, and staff, as well as to minimize viral
17
18
19 transmission, much of routine healthcare has been postponed or cancelled. As well,
20
21
22 patients themselves may decline attendance at hospitals, clinics, and screening exams
23
24
25
26
27 over concerns of infection. More than a third of respondents indicated that the COVID-
28
29
30 19 situation made it harder to consult with their diabetes providers. Interestingly, this
31
32
33 finding did not significantly differ by diabetes type.
34
35
36

37
38 Research has shown that deferred or avoided healthcare due to the pandemic can
39
40
41 contribute to excess morbidity and mortality (31). Based on an article by Woolf SH et al.
42
43
44 (32), US states with large numbers of COVID-19-related deaths experience large
45
46
47
48 proportional increases in deaths from other underlying causes, including diabetes.
49

50
51 Impacts on health may worsen the longer community containment measures last. A
52
53
54
55 simulation study of data from previous global disasters found the duration of lockdown
56
57
58

1
2
3 to be directly proportional to A1C and number of diabetes-related complications
4
5

6 (33). Unfortunately, these effects may endure even after the viral outbreak has been
7
8
9
10 quelled. Evidence from past disasters, has shown that reduced access to healthcare
11
12
13 during the acute phase of an emergency can lead to an aftermath of increased deaths
14
15
16 and morbidities including stroke, myocardial infarctions, and diabetes-related
17
18
19
20 complications (34).
21
22

23
24 Finally, COVID-19 mitigation measures can restrict access to indoor and outdoor
25
26
27 physical activities, contributing to increased sedentary behaviours that adversely affect
28
29
30 immune defence, glycemic control, and metabolic health in general (9). Based on data
31
32
33
34 from other viral infections, sub-optimal physical activity can accentuate symptom
35
36
37 severity, recovery times, and transmissibility; it can also compromise post-vaccination
38
39
40 immunity and increase secondary infection risk (35). Regardless of diabetes type,
41
42
43
44 staggering percentages of participants reported reduced physical activity because of the
45
46
47
48 pandemic, a sure warning sign of the extensive health consequences to come.
49
50

51 COVID-19 and the psychosocial aspects of glycemic management
52
53
54
55
56
57
58
59
60

1
2
3 The psychosocial ramifications of COVID-19 in PWD has been minimally investigated in
4
5
6 the literature. Our study specifically assessed how the pandemic has impacted
7
8
9 respondents' senses of personal control over their hypoglycemia risk. Significant
10
11
12 decrements in self-perceived control were observed across all participants. Sense of
13
14
15 control—the learned belief that one does master, control, and shape one's life—has
16
17
18 been linked to several positive health effects including proactive behavior and emotional
19
20
21 well-being (36). However, inadequate supplies, financial loss, fear psychosis of being
22
23
24 infected, and media/disinformation can all contribute to increased feelings of
25
26
27 powerlessness (37). Reductions in sense of personal control have been associated with
28
29
30 heightened stress, anxiety, and depressive symptoms (38)—outcomes that have been
31
32
33 linked to poor medication adherence and diminished self-management (39).
34
35
36
37
38
39
40
41 While support from family and friends can mediate the contextual impacts of COVID-19,
42
43
44 several respondents in our study, particularly those with type 2 diabetes, reported
45
46
47
48 insufficient social support to help manage their hypoglycemia. Assistance from informal
49
50
51 relationships has been identified as a major component to hypoglycemia self-
52
53
54
55 management with demonstrable impacts on diabetes-related morbidity and mortality
56
57
58
59
60

1
2
3 reduction (14,38,40). The gap in social support observed in our study portend troubling
4
5
6 implications for hypoglycemia incidence as well as other clinical and psychosocial
7
8
9 sequelae. No study had yet quantified the effect the COVID-19 situation on social
10
11
12
13 support access in PWD.
14
15

16 Study strengths and limitations

17
18 This study evaluates a large, generalized outpatient cohort of diabetic Americans—with
19
20
21 and without infection—to derive insight into the real-world, real-time consequences of
22
23
24 the COVID-19 situation in diabetes. The sample cohort focused on insulin and/or
25
26
27 secretagogues users so variations in hypoglycemia management could be ascertained;
28
29
30 such data had yet to be garnered in the US. By developing a novel pandemic-specific
31
32
33 questionnaire, our research team was able to estimate the direct repercussions of the
34
35
36
37
38
39
40 COVID-19 situation in Americans with diabetes.
41
42

43 However, certain limitations should be noted. First, though counteracted by the high
44
45
46 national prevalence of internet users and rigorous sampling strategies, non-response
47
48
49 and coverage bias may have influenced study results. Second, self-reported data may
50
51
52
53
54 have been subject to information bias. To reduce this risk, measures were taken to
55
56
57
58
59
60

1
2
3 optimize recall intervals. Participants could also take time to reflect on items and/or
4
5
6 review clinical documentation prior to completing the question/survey. Finally, estimates
7
8
9 derived in our study may be conservative, as they stem from a one-month data capture
10
11
12
13 in the early phase of the pandemic trajectory.
14
15

16 17 CONCLUSIONS

18
19
20
21
22 A 'hinterland' is defined as an area lying beyond what is visible or known. As a society
23
24
25 we have exhibited unparalleled bravery in the face of one of the most terrifying crises
26
27
28 known to humankind. However, our mission to abate the pandemic is only just
29
30
31 beginning. Indeed, the COVID-19 calamity has had untold reverberations in the lives of
32
33
34 Americans, extending well-beyond the visible devastations caused by infection alone.
35
36
37 Not least are the impacts COVID-19 has had on PWD—cases and non-cases alike—
38
39
40
41
42
43 who have struggled to maintain control of their disease amidst the pandemic.
44
45

46
47 Yet, until now, the nature and scale of these impacts were largely unknown or
48
49
50 uncharacterized. Thus, the results of our study draw not only awareness to the far-
51
52
53 reaching and potential lasting consequences of the pandemic, but offer an evidence
54
55
56
57
58
59
60

1
2
3 base for decisive action. In identifying the unique needs of Americans with diabetes
4
5
6 during the COVID-19 era, we can begin to develop, implement, and assess clinical and
7
8
9 public health strategies that ensure safe, uninterrupted care within the context of patients'
10
11
12 communities. As we combat the acute phase of COVID-19, we must not lose sight of
13
14
15 the pernicious health challenges that coexist and await us in the aftermath.
16
17
18
19
20

21 ACKNOWLEDGMENTS

22
23
24
25
26 Author Contributions: A.A.R.-L. contributed to the discussion, researched data, and
27
28
29 wrote the manuscript. B.L.R. contributed to the discussion and reviewed/edited the
30
31
32 manuscript. J.D.B. contributed to the discussion and reviewed/edited the manuscript.
33
34
35
36 J.W.D. contributed to the discussion and reviewed/edited the manuscript. S.B.H.
37
38
39 contributed to the discussion, researched data, and reviewed/edited the manuscript.
40
41
42

43 Guarantors' names: Stewart B. Harris and Alexandria A. Ratzki-Leewing
44
45

46
47 Funding/financial support: Funding for the iNPHORM study was provided through an
48
49
50 investigator-initiated grant from Sanofi Global.
51
52
53
54
55
56
57
58
59
60

1
2
3 Conflict of interest statement: A.A.R.-L.: Sanofi: grant; Eli Lilly: consultant; fees paid for
4
5
6 presentations; Novo Nordisk: consultant. B.L.R.: Nothing to disclose. J.D.B.: Nothing to
7
8
9 disclose. J.W.D.: Nothing to disclose. S.B.H: Sanofi: grant, member advisory board,
10
11
12 consultant; Eli Lilly: grant, member advisory board, consultant, clinical studies; Novo
13
14
15 Nordisk: grant, member advisory board, consultant, clinical studies; Janssen: grant,
16
17
18 member advisory board, consultant; AstraZeneca: grant, member advisory board,
19
20
21
22 consultant, clinical studies; Abbott: grant, member advisory board, consultant;
23
24
25
26
27 Boehringer Ingelheim: grant, member advisory board, consultant, clinical studies; JDRF:
28
29
30 grant; Lawson: grant; Canadian Institutes of Health and Research: grants.
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

REFERENCES

1. Holshue ML, DeBolt C, Lindquist S, et al. First case of 2019 novel coronavirus in the United States. *N Engl J Med* 2020;382(10):929-936. doi:10.1056/NEJMoa2001191
2. Johns Hopkins; Coronavirus resource center [article online] 2020. Available from <https://coronavirus.jhu.edu/>. Accessed 11 January 2020
3. Roncon L, Zuin M, Rigatelli G, Zuliani G. Diabetic patients with COVID-19 infection are at higher risk of ICU admission and poor short-term outcome. *J Clin Virol* 2020;127:104354. doi:10.1016/j.jcv.2020.104354
4. Hill MA, Mantzoros C, Sowers JR. Commentary: COVID-19 in patients with diabetes. *Metabolism* 2020;107:154217. doi:10.1016/j.metabol.2020.154217
5. Gupta R, Ghosh A, Singh AK, Misra A. Clinical considerations for patients with diabetes in times of COVID-19 epidemic. *Diabetes Metab Syndr* 2020;14(3):211-212. doi:10.1016/j.dsx.2020.03.002
6. Brownlee M. Biochemistry and molecular cell biology of diabetic complications. *Nature* 2001;414(6865):813-820. doi:10.1038/414813a
7. Morra ME, Van Thanh L, Kamel MG, et al. Clinical outcomes of current medical approaches for Middle East respiratory syndrome: A systematic review and meta-analysis. *Rev Med Virol* 2018;28(3):e1977. doi:10.1002/rmv.1977
8. Ma RCW, Holt RIG. COVID-19 and diabetes. *Diabet Med* 2020;37(5):723-725. doi:10.1111/dme.14300
9. Singh AK, Gupta R, Ghosh A, Misra A. Diabetes in COVID-19: Prevalence, pathophysiology, prognosis and practical considerations. *Diabetes Metab Syndr* 2020;14(4):303-310. doi:10.1016/j.dsx.2020.04.004
10. Geerlings SE, Hoepelman AI. Immune dysfunction in patients with diabetes mellitus (DM). *FEMS Immunol Med Microbiol* 1999;26(3-4):259-265. doi:10.1111/j.1574-695X.1999.tb01397.x
11. COVID-19 and your health; People with certain medical conditions [article online], 2020. Available from <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>. Accessed 26 December 2020
12. Diabetes and Coronavirus (COVID-19) [article online], 2021. Available from <https://www.diabetes.org/coronavirus-covid-19>. Accessed 26 December 2020
13. Coronavirus COVID-19 [article online], 2020. Available from <https://www.idf.org/aboutdiabetes/what-is-diabetes/covid-19-and-diabetes/1-covid-19-and-diabetes.html>. Accessed 26 December 2020
14. McEwen MM, Pasvogel A, Gallegos G, Barrera L. Type 2 diabetes self-management social support intervention at the U.S.-Mexico border. *Public Health Nurs* 2010;27(4):310-319. doi:10.1111/j.1525-1446.2010.00860.x
15. Yang Y, Shang W, Rao X. Facing the COVID-19 outbreak: What should we know and what could we do?. *J Med Virol* 2020;92(6):536-537. doi:10.1002/jmv.25720
16. Fonseca VA, Smith H, Kuhadiya N, et al. Impact of a natural disaster on diabetes: exacerbation of disparities and long-term consequences. *Diabetes Care* 2009;32(9):1632-1638. doi:10.2337/dc09-0670
17. Ng J, Atkin SL, Rigby AS, et al. The effect of extensive flooding in Hull on the glycaemic control of patients with diabetes. *Diabet Med* 2011;28(5):519-524. doi:10.1111/j.1464-5491.2011.03228.x
18. Impact of COVID-19 on the diabetes community in the United States [article online], 2020. Available from <https://d-qa.com/impact-of-covid-19-on-theusa-diabetes->

- community/?utm_source=Closer1Look1_Subscribers12018&utm_campaign=54285f7ac19-2020-04-19_WIR_4%2F13-4%2F1704_18_2020&utm_medium=email&utm_term=50_c55d924bf1-4285f7ac19-409220105. Accessed 26 December 2020
19. Qiu J, Shen B, Zhao M, et al. A nationwide survey of psychological distress among Chinese people in the COVID-19 epidemic: implications and policy recommendations. *Gen Psychiatry* 2020;33(2):e100213. Published 2020 Mar 6. doi:10.1136/gpsych-2020-100213
 20. Investigating novel predictions of hypoglycemia occurrence in real-world models. ClinicalTrials.gov identifier: NCT04219514. Updated May 20, 2020. Available from <https://clinicaltrials.gov/ct2/show/NCT04219514> (2020). Accessed 26 December 2020
 21. Coronavirus disease 2019 (COVID-19), 2020 interim case definition, Approved April 5, 2020 [article online], 2020. Available from <https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/>. Accessed 26 December 2020
 22. American Diabetes Association. 6. Glycemic Targets: *Standards of Medical Care in Diabetes-2019*. *Diabetes Care* 2019;42(Suppl 1):S61-S70. doi:10.2337/dc19-S006
 23. Diabetes and COVID 19: New Data Quantifies Extraordinary Challenges Faced by Americans with Diabetes During Pandemic [article online], 2020. Available from https://www.diabetes.org/sites/default/files/2020-07/7.29.2020_dQA-ADA%20Data%20Release.pdf. Accessed 26 December 2020
 24. Seligman HK, Jacobs EA, Lopez A, et al. Food insecurity and hypoglycemia among safety net patients with diabetes. *Arch Intern Med* 2011;171(13):1204-1206. doi:10.1001/archinternmed.2011.287
 25. Seligman HK, Bolger AF, Guzman D, et al. Exhaustion of food budgets at month's end and hospital admissions for hypoglycemia. *Health Aff (Millwood)* 2014;33(1):116-123. doi:10.1377/hlthaff.2013.0096
 26. Seligman HK, Davis TC, Schillinger D, Wolf MS. Food insecurity is associated with hypoglycemia and poor diabetes self-management in a low-income sample with diabetes. *J Health Care Poor Underserved* 2010;21(4):1227-1233. doi:10.1353/hpu.2010.0921
 27. Hartmann-Boyce J, Morris E, Goyder C, et al. Diabetes and COVID-19: Risks, Management, and Learnings From Other National Disasters. *Diabetes Care* 2020;43(8):1695-1703. doi:10.2337/dc20-1192
 28. Shah K, Tiwaskar M, Chawla P, et al. Hypoglycemia at the time of Covid-19 pandemic. *Diabetes Metab Syndr* 2020;14(5):1143-1146. doi:10.1016/j.dsx.2020.07.003
 29. Cutler RL, Fernandez-Llimos F, Frommer M, et al. Economic impact of medication non-adherence by disease groups: a systematic review. *BMJ Open* 2018;8(1):e016982. Published 2018 Jan 21. doi:10.1136/bmjopen-2017-016982
 30. Propper C, Stockton I, Stoye G. COVID-19 and disruptions to the health and social care of older people in England. Institute for Fiscal Studies, Briefing Note BN309, 2020. Available from <https://ifs.org.uk/uploads/BN309-COVID-19-and-disruptions-to-the-health-and-social-care-of-older-people-in-England-1.pdf>.
 31. National center for health statistics; Excess deaths associated with COVID-19 [article online], 2020. Available from https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm. Accessed 26 December 2020
 32. Woolf SH, Chapman DA, Sabo RT, et al. Excess Deaths From COVID-19 and Other Causes, March-April 2020. *JAMA* 2020;324(5):510-513. doi:10.1001/jama.2020.11787

- 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10
 - 11
 - 12
 - 13
 - 14
 - 15
 - 16
 - 17
 - 18
 - 19
 - 20
 - 21
 - 22
 - 23
 - 24
 - 25
 - 26
 - 27
 - 28
 - 29
 - 30
 - 31
 - 32
 - 33
 - 34
 - 35
 - 36
 - 37
 - 38
 - 39
 - 40
 - 41
 - 42
 - 43
 - 44
 - 45
 - 46
 - 47
 - 48
 - 49
 - 50
 - 51
 - 52
 - 53
 - 54
 - 55
 - 56
 - 57
 - 58
 - 59
 - 60
33. Ghosal S, Sinha B, Majumder M, Misra A. Estimation of effects of nationwide lockdown for containing coronavirus infection on worsening of glycosylated haemoglobin and increase in diabetes-related complications: A simulation model using multivariate regression analysis. *Diabetes Metab Syndr* 2020;14(4):319-323. doi:10.1016/j.dsx.2020.03.014.
34. Mokdad AH, Mensah GA, Posner SF, et al. When chronic conditions become acute: prevention and control of chronic diseases and adverse health outcomes during natural disasters. *Prev Chronic Dis* 2005;2 Spec no(Spec No):A04.
35. Pascoe AR, Singh MA, Edwards KM. The effects of exercise on vaccination responses: a review of chronic and acute exercise interventions in humans. *Brain Behav Immun* 2014;39:33-41. doi:10.1016/j.bbi.2013.10.003
36. Mirowsky J, Ross CE. Eliminating defense and agreement bias from measures of the sense of control: A 2 x 2 index. *Social Psychology Quarterly* 1991;54(2):127-45. <https://doi.org/10.2307/2786931>
37. Brooks SK, Webster RK, Smith LE, et al. The psychological impact of quarantine and how to reduce it: rapid review of the evidence. *Lancet* 2020;395(10227):912-920. doi:10.1016/S0140-6736(20)30460-8
38. Keeton CP, Perry-Jenkins M, Sayer AG. Sense of control predicts depressive and anxious symptoms across the transition to parenthood. *J Fam Psychol.* 2008;22(2):212-221. doi:10.1037/0893-3200.22.2.212
39. Sturt J, Dennick K, Due-Christensen M, McCarthy K. The detection and management of diabetes distress in people with type 1 diabetes. *Curr Diab Rep* 2015;15(11):101. doi:10.1007/s11892-015-0660-z
40. Nicklett EJ, Liang J. Diabetes-related support, regimen adherence, and health decline among older adults. *J Gerontol B Psychol Sci Soc Sci* 2010;65B(3):390-399. doi:10.1093/geronb/gbp050

Table 1. Socio-demographic and clinical characteristics of study sample

SOCIO-DEMOGRAPHIC CHARACTERISTICS		Total N=667	Type 1 Diabetes 120 (17.99%)	Type 2 Diabetes 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 (%)				
	Female	341 (51.12)	80 (66.67)	261 (47.71)
	Male	326 (48.88)	40 (33.33)	286 (52.29)
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/a, 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/a, 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/a, or Spanish origin	3 (0.45)	1 (0.83)	2 (0.37)
Not of Hispanic, Latino/a, or Spanish origin	629 (94.30)	116 (96.67)	513 (93.78)
Highest level of education at time of study enrolment, n (%)			
Elementary or high school (No diploma)	10 (1.50)	3 (2.50)	7 (1.28)
High school diploma or 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)
Employment status at time of study enrolment, 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)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

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) at time of study enrolment, n (%)*

<\$24,999	107 (16.21)	13 (11.21)	94 (17.28)
\$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)

Healthcare insurance at time of study enrolment, 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 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)
<hr/>				
CLINICAL CHARACTERISTICS		Total N=667	Type 1 Diabetes 120 (17.99%)	Type 2 Diabetes 547 (82.01%)
<hr/>				
Duration of diabetes, median (IQR)				
	Years	13 (15)	26 (23)	11 (14)
<hr/>				
Most recent hemoglobin A1C, n (%)*				
	≤ 7% (53 mmol/mol)	252 (37.78)	45 (37.50)	207 (37.84)
	7.1% (54 mmol/mol) to 8% (64 mmol/mol)	239 (35.83)	45 (37.50)	194 (35.47)
	8.1% (65 mmol/mol) to 9% (75 mmol/mol)	99 (14.84)	14 (11.67)	85 (15.54)
	≥ 9.1% (76 mmol/mol)	55 (8.25)	14 (11.67)	41 (7.50)
	Unsure	12 (1.80)	0	12 (2.19)
<hr/>				
Body mass index (BMI) at time of study enrolment, median (IQR)				
	BMI (kg/m ²)	30.38 (11.87)	26.43 (6.18)	32.19 (11.99)
<hr/>				
Current insulin and/or secretagogue use, n (%)				
<hr/>				

	Insulin <i>without</i> Secretagogues	330 (49.48)	120 (100.00)	210 (38.39)
	Secretagogues <i>without</i> Insulin	202 (30.28)	0	202 (36.93)
	Insulin <i>in combination with</i> 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)
	<i>Amputation</i>	91 (13.64)	12 (10.00)	79 (14.44)
	<i>Diabetes Ketoacidosis</i>	110 (16.49)	42 (35.00)	68 (12.43)
	<i>Foot damage</i>	123 (18.44)	18 (15.00)	105 (19.20)
	<i>Gastroparesis</i>	95 (14.24)	20 (16.67)	75 (13.71)
	<i>Hyperosmolar hyperglycemic nonketotic coma</i>	60 (9.00)	5 (4.17)	55 (10.05)
	<i>Nephropathy</i>	114 (17.09)	18 (15.00)	96 (17.55)
	<i>Neuropathy</i>	298 (44.68)	46 (38.33)	252 (46.07)
	<i>Retinopathy</i>	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)
	<i>Bone, joint, or muscle problem</i>	310 (46.48)	39 (32.50)	271 (49.54)
	<i>Cancer</i>	52 (7.80)	3 (2.50)	49 (8.96)

<i>Cardiovascular condition</i>	128 (19.19)	17 (14.17)	111 (20.29)
<i>Chronic kidney disease</i>	73 (10.94)	8 (6.67)	65 (11.88)
<i>Chronic liver failure or liver disease</i>	39 (5.85)	2 (1.67)	37 (6.76)
<i>Eating disorder</i>	35 (5.25)	7 (5.83)	28 (5.12)
<i>Gastrointestinal disease</i>	86 (12.89)	17 (14.17)	69 (12.61)
<i>HIV/AIDS</i>	11 (1.65)	2 (1.67)	9 (1.65)
<i>Hypertension</i>	363 (54.42)	50 (41.67)	313 (57.22)
<i>Mental health condition</i>	223 (33.43)	36 (30.00)	187 (34.19)
<i>Neurological disorder</i>	39 (5.85)	8 (6.67)	31 (5.67)
<i>Physical impairment</i>	168 (25.19)	29 (24.17)	139 (25.41)
<i>Respiratory condition</i>	125 (18.74)	24 (20.00)	101 (18.46)
<i>Stroke or transient ischemic attack</i>	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)
-----	-------------	------------	-------------

SD, standard deviation; IQR, interquartile range

* Cumulative percentage <100% due to missing data

† High Deductible Plan: Deductible >\$1,350 for an individual or >\$2,700 for a family

‡ Cumulative percentage >100% as participants could select more than one response

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

For peer review only

Table 2. Incidence rates and proportions of severe and non-severe hypoglycemia (daytime + nocturnal), overall and by diabetes type

INCIDENCE RATES	Total N=667	Type 1 Diabetes 120 (17.99%)	Type 2 Diabetes 547 (82.01%)
Severe Hypoglycemia			
Events per person-month (95% CI)	0.68 (0.48-0.96)	0.39 (0.18-0.85)	0.75 (0.51-1.09)
Non-Severe Hypoglycemia			
Events per person-month (95% CI)	2.75 (2.43-3.11)	5.73 (4.60-7.13)	2.10 (1.82-2.41)
INCIDENCE PROPORTIONS	Total N=667	Type 1 Diabetes 120 (17.99%)	Type 2 Diabetes 547 (82.01%)
Severe Hypoglycemia (past month)			
% with ≥ 1 event (95% CI)	12.91 (10.58-15.67)	11.67 (7.08-18.63)	13.19 (10.60-16.28)
Non-Severe Hypoglycemia (past month)			
% with ≥ 1 event (95% CI)	60.06 (56.29-63.71)	83.33 (75.66-88.94)	54.95 (50.75-59.07)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

CI, confidence interval.

For peer review only

Table 3. Period prevalence of COVID-19 infection*

PERIOD PREVALENCE OF COVID-19	Total N=667	Type 1 Diabetes 120 (17.99%)	Type 2 Diabetes 547 (82.01%)
Confirmed (past month), n (%) [†]	5 (0.75)	0	5 (0.91)
Probable (past month), n (%) [‡]	5 (0.75)	0	5 (0.91)
Possible (past month), n (%) [§]	59 (8.86)	16 (13.33)	43 (7.86)

* Data collected April 21st-28th, 2020

[†] Had a formal diagnosis of COVID-19

[‡] No formal diagnosis of COVID-19; reported 1) symptoms typical of COVID-19 *and* 2) at least one form of epidemiologic linkage

[§] No formal diagnosis of COVID-19; reported 1) symptoms typical of COVID-19 *or* 2) at least one form of epidemiologic linkage

Table 4. Impact of the COVID-19 situation on aspects of participants' glycemic management (past month)*

ASPECT OF GLYCEMIC MANAGEMENT	...has been much/ somewhat harder...	...has <u>not</u> been impacted	... has been much/somewhat easier...	(\mathbb{R}) <i>P</i> -value [†]
<i>...Affording rent and other living expenses</i>				
Overall (N=667)	162 (24.29)	491 (73.61)	14 (2.10)	0.07
Type 1 Diabetes (n=120)	36 (30.00)	83 (69.17)	1 (0.83)	
Type 2 Diabetes (n=547)	126 (23.03)	408 (74.59)	13 (2.38)	
<i>...Ensuring enough food to avoid hypoglycemia</i>				
Overall (N=667)	184 (27.59)	475 (71.21)	8 (1.20)	

Type 1 Diabetes (n=120)	28 (23.33)	91 (75.83)	1 (0.83)	0.29
Type 2 Diabetes (n=547)	156 (28.52)	384 (70.20)	7 (1.28)	
<i>...Affording diabetes medication(s)</i>				
Overall (N=667)	124 (18.59)	534 (80.06)	9 (1.35)	0.66
Type 1 Diabetes (n=120)	20 (16.67)	99 (82.50)	1 (0.83)	
Type 2 Diabetes (n=547)	104 (19.01)	435 (79.52)	8 (1.46)	
<i>...Affording test strips and/or sensors</i>				
Overall (N=667)	116 (17.39)	540 (80.96)	11 (1.65)	0.31
Type 1 Diabetes (n=120)	16 (13.33)	103 (85.83)	1 (0.83)	
Type 2 Diabetes (n=547)	100 (18.28)	437 (79.89)	10 (1.83)	
<i>...Retrieving diabetes medication(s) from the pharmacy</i>				
Overall (N=667)	183 (27.44)	470 (70.46)	14 (2.10)	0.26
Type 1 Diabetes (n=120)	37 (30.83)	82 (68.33)	1 (0.83)	
Type 2 Diabetes (n=547)	146 (26.69)	388 (70.93)	13 (2.38)	
<i>...Consulting with healthcare provider(s) about diabetes</i>				
Overall (N=667)	243 (36.43)	410 (61.47)	14 (2.10)	0.78
Type 1 Diabetes (n=120)	42 (35.00)	76 (63.33)	2 (1.67)	
Type 2 Diabetes (n=547)	201 (36.75)	334 (61.06)	12 (2.19)	
<i>...Testing/monitoring blood glucose</i>				
Overall (N=667)	106 (15.89)	551 (82.61)	10 (1.50)	<0.001‡
Type 1 Diabetes (n=120)	6 (5.00)	110 (91.67)	4 (3.33)	
Type 2 Diabetes (n=547)	100 (18.28)	441 (80.62)	6 (1.10)	

1
2
3
4 *...Remembering to take diabetes medication(s) as prescribed*

5 Overall (N=667)	91 (13.64)	554 (83.06)	22 (3.30)	
6 Type 1 Diabetes (n=120)	8 (6.67)	109 (90.83)	3 (2.50)	
7 Type 2 Diabetes (n=547)	83 (15.17)	445 (81.35)	19 (3.47)	0.052

10
11 *...Monitoring risk of hypoglycemia regularly*

12 Overall (N=667)	80 (11.99)	561 (84.11)	26 (3.90)	
13 Type 1 Diabetes (n=120)	9 (7.50)	103 (85.83)	8 (6.67)	
14 Type 2 Diabetes (n=547)	71 (12.98)	458 (83.73)	18 (3.29)	0.02‡

17
18 *...Staying as physically active as usual*

19 Overall (N=667)	309 (46.33)	329 (49.33)	29 (4.35)	
20 Type 1 Diabetes (n=120)	57 (47.50)	55 (45.83)	8 (6.67)	
21 Type 2 Diabetes (n=547)	252 (46.07)	274 (50.09)	21 (3.84)	0.98

24
25 *...Feeling in control of hypoglycemia*

26 Overall (N=667)	97 (14.54)	528 (79.16)	42 (6.30)	
27 Type 1 Diabetes (n=120)	14 (11.67)	99 (82.50)	7 (5.83)	
28 Type 2 Diabetes (n=547)	83 (15.17)	429 (78.43)	35 (6.40)	0.50

31
32 *...Having enough social support to help manage hypoglycemia*

33 Overall (N=667)	124 (18.59)	518 (77.66)	25 (3.75)	
34 Type 1 Diabetes (n=120)	13 (10.83)	104 (86.67)	3 (2.50)	
35 Type 2 Diabetes (n=547)	111 (20.29)	414 (75.69)	22 (4.02)	0.06

ASPECT OF GLYCEMIC MANAGEMENT	Yes	No	<i>P</i> -value [§]
<i>...Rationing diabetes medication(s) to make supplies last longer</i>			
Overall (N=667)	111 (16.64)	556 (83.36)	
Type 1 Diabetes (n=120)	16 (13.33)	104 (86.67)	0.28
Type 2 Diabetes (n=547)	95 (17.37)	452 (82.63)	
<i>...Rationing diabetes medication(s) to avoid hypoglycemia</i>			
Overall (N=667)	112 (16.79)	555 (83.21)	
Type 1 Diabetes (n=120)	19 (15.83)	101 (84.17)	0.76
Type 2 Diabetes (n=547)	93 (17.00)	454 (83.00)	

n (%) are presented.

* Data collected April 21st-28th, 2020

† Item responses were compared between individuals with type 1 diabetes and type 2 diabetes. *P*-values were computed using two-sample Wilcoxin-Mann-Whitney tests.

‡ Statistically significant at an alpha value of 0.05 (i.e., the underlying distributions of item responses statistically significantly differed by diabetes type).

§ Item responses were compared between individuals with type 1 diabetes and type 2 diabetes. *P*-values were computed using two-sample Z tests for proportions.

For peer review only

BMJ Open

The COVID-19 Hinterland: Surveilling the self-reported impacts of the pandemic on diabetes management in the United States (Cross-sectional results of the iNPHORM Study)

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2021-049782.R1
Article Type:	Original research
Date Submitted by the Author:	06-Jul-2021
Complete List of Authors:	Ratzki-Leewing, Alexandria A.; Western University, Department of Epidemiology and Biostatistics Ryan, BL; University of Western Ontario Department of Epidemiology and Biostatistics; Western University Schulich School of Medicine & Dentistry Buchenberger, John D.; Ipsos Dickens, Joseph W.; ISPOS, SMX Black, Jason; Western University Schulich School of Medicine & Dentistry, Family Medicine Harris, Stewart; Western University Department of Epidemiology and Biostatistics; Western University Schulich School of Medicine & Dentistry, Department of Family Medicine
Primary Subject Heading:	Diabetes and endocrinology
Secondary Subject Heading:	Epidemiology, Public health
Keywords:	DIABETES & ENDOCRINOLOGY, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, General endocrinology < DIABETES & ENDOCRINOLOGY, General diabetes < DIABETES & ENDOCRINOLOGY, COVID-19, EPIDEMIOLOGY

SCHOLARONE™
Manuscripts



I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our [licence](#).

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which [Creative Commons](#) licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

1
2
3
4 1
5
6
7 2
8
9
10 3 Full title: The COVID-19 Hinterland: Surveilling the self-reported impacts of the pandemic on
11
12
13 4 diabetes management in the United States (Cross-sectional results of the iNPHORM Study)
14
15

16 5
17
18
19 6 Short running title: Impact of the COVID-19 situation on diabetes management
20
21

22 7
23
24
25
26 8 Authors:
27

28
29 9 Alexandria A. Ratzki-Leewing MSc¹
30

31
32 10 Bridget L. Ryan PhD^{1,2}
33

34
35
36 11 John D. Buchenberger MS³
37

38
39 12 Joseph W. Dickens BA⁴
40

41
42 13 Jason E. Black MSc²
43

44
45
46 14 Stewart B. Harris MD^{1,2}
47

48
49 15
50

51
52
53 16 Author affiliations:
54

1
2
3
4 1 ¹Department of Epidemiology and Biostatistics, Schulich School of Medicine and Dentistry,
5
6
7 2 Western University, London, Ontario, Canada.

8
9
10 3 ²Department of Family Medicine/Medicine, Schulich School of Medicine and Dentistry, Western
11
12
13 4 University, London, Ontario, Canada.

14
15
16
17 5 ³Ipsos Healthcare, New York, New York, United States of America.

18
19
20 6 ⁴Ipsos SMX, Chicago, Illinois, United States of America.

21
22
23
24
25
26
27 8 Corresponding author:

28
29
30 9 Stewart B. Harris MD

31
32
33
34 10 Centre for Studies in Family Medicine, Western University, WCPHFM

35
36
37 11 1465 Richmond St, London, Ontario, N6G 2M1, Canada.

38
39
40 12 +1 519 661 2111 x.22050

41
42
43
44 13 sharris1@uwo.ca

45
46
47 14

48
49
50 15 Word count:

51
52
53
54 16 Abstract: 289

1
2
3
4 1 Manuscript: 4,579
5
6

7 2
8
9

10 3 Number of tables: 5
11
12

13 4
14
15

16 5
17
18

19 6
20
21

22 7
23
24

25 8
26
27

28 9
29
30

31 10
32
33

34 11
35
36

37 12
38
39

40 13
41
42

43 14
44
45

46 15 ABSTRACT
47
48

1
2
3
4 1 Main Objective: To determine how and to what extent, COVID-19 has affected real-world, self-
5
6
7 2 reported glyceimic management in Americans with type 1 or type 2 diabetes taking insulin and/or
8
9
10 3 secretagogues, with or without infection.

11
12
13
14 4 Design: A cross-sectional sub-study using data from the iNPHORM panel survey.

15
16
17 5 Settings: United States (US).

18
19
20 6 Participants: Americans 18 to 90 years old with type 1 or 2 diabetes taking insulin and/or
21
22
23
24 7 secretagogues were conveniently sampled from a probability-based internet panel.

25
26
27 8 Primary Outcome Measure: A structured, COVID-19-specific questionnaire was administered to
28
29
30 9 assess the impact of the pandemic (irrespective of infection) on socio-economic,
31
32
33
34 10 behavioural/clinical, and psychosocial aspects of glyceimic management.

35
36
37 11 Results: Data from 667 respondents (type 1 diabetes: 18%; type 2 diabetes: 82%) were analyzed.
38
39
40 12 Almost 25% reported A1C values $\geq 8.1\%$. Rates of severe and non-severe hypoglycemia were
41
42
43
44 13 0.68 (95%CI: 0.5 to 0.96) and 2.75 (95%CI: 2.4 to 3.1) events per-person month, respectively.

45
46
47 14 Ten respondents reported a confirmed or probable COVID-19 diagnosis. Because of the
48
49
50
51 15 pandemic, 24% of respondents experienced difficulties affording housing; 28% struggled to
52
53
54 16 maintain sufficient food to avoid hypoglycemia; and 19% and 17% reported challenges accessing

1 diabetes therapies and testing strips, respectively. Over one-quarter reported issues retrieving
2 antihyperglycemics from the pharmacy and over one-third reported challenges consulting with
3 diabetes providers. The pandemic contributed to therapeutic non-adherence (14%), drug
4 rationing (17%), and reduced monitoring (16%). Many struggled to keep track, and in control, of
5 hypoglycemia (12 to 15%) and lacked social support to help manage their risk (19%). Nearly
6 half reported decreased physical activity. Few statistically significant differences were observed
7 by diabetes type.

8 Conclusions: COVID-19 was found to cause substantial self-reported deficiencies in glyceimic
9 management. Study results signal the need for decisive action to re-stabilize routine diabetes care
10 in the US.

11 Trial registration: ClinicalTrials.gov Identifier: NCT04219514.

13 STRENGTHS AND LIMITATIONS OF THIS STUDY:

- 14 • This is the first US-based, primary research study to quantify the real-world, self-
15 reported impact of the COVID-19 situation on the socio-economic,
16 behavioural/clinical, and psychosocial aspects of glyceimic management.

- 1
- 2
- 3
- 4 1 • A novel COVID-19-specific questionnaire was developed and administered to a real-
- 5
- 6
- 7 2 world cohort of Americans with type 1 and type 2 diabetes taking insulin and/or
- 8
- 9
- 10 3 secretagogues; study participants were recruited from a large, probability-based
- 11
- 12
- 13 4 internet panel.
- 14
- 15
- 16
- 17 5 • Estimates presented in this study may be conservative as they describe the early
- 18
- 19
- 20 6 phase of the pandemic.
- 21
- 22
- 23
- 24 7
- 25
- 26

27 8 SIGNIFICANCE OF THIS STUDY:

28

29

30 9 *1. What is already known about this subject?*

31

32

- 33
- 34 10 • The majority of COVID-19-related studies in the US have focused on hospitalized
- 35
- 36
- 37 11 case epidemiology.
- 38
- 39
- 40 12 • Little is known about the peripheral impacts of the COVID-19 situation on glyceimic
- 41
- 42
- 43 13 management in Americans with diabetes taking insulin and/or secretagogues.
- 44
- 45
- 46
- 47 14 • Disruptions to services, resources, and self-management forebode important
- 48
- 49
- 50 15 population-based consequences to diabetes-related morbidities, especially in the US
- 51
- 52
- 53
- 54 16 where COVID-19 and diabetes eminently collide.
- 55
- 56
- 57
- 58
- 59
- 60

1
2
3
4 1 2. *What this study adds*
5
6

- 7 2 • The pandemic situation was found to cause substantial and diverse repercussions on
8
9
10 3 participants' glycemic management, irrespective of diabetes type.
11
12
13 4 • The results of this study provide an instructive evidence base for improved diabetes
14
15
16 care in the US, both during the current public health emergency and in future.
17 5
18
19
20 6
21
22
23
24 7
25
26
27 8
28
29
30 9
31
32
33
34 10
35
36
37 11
38
39
40 12
41
42
43
44 13
45
46
47 14
48
49
50 15
51
52
53
54 16
55
56
57
58
59
60

1
2
3
4 1
5
6
7 2
8
9
10 3 COVID-19 is among the most devastating health crises in global history. In the United States
11
12
13 4 (US), the first reported infection occurred on January 19th, 2020.(1) Since then, the number of
14
15
16
17 5 confirmed US-cases has surpassed 33.5 million, including over 605,000 deaths (July 5, 2021).(2)
18
19

20 6 People with diabetes (PWD) have been identified as clinically vulnerable to COVID-19. In
21
22
23 7 the US, diabetes ranks as the second most common underlying health condition among all cases
24
25
26
27 8 and has been connected to more severe infection.(3,4) However, less appreciated in the literature
28
29
30 9 are the disruptions caused by the pandemic on routine diabetes care. These disruptions expose
31
32
33
34 10 not only those with COVID-19, but all 34+ million Americans with diabetes to poor outcomes.
35
36
37 11 Understanding how the pandemic affects diabetes services and management is crucial to
38
39
40 12 informing short- and long-term clinical decision-making and public health planning. Targeted
41
42
43
44 13 measures to help protect these Americans from the direct and indirect effects of the COVID-19
45
46
47 14 pandemic should be a top priority for all healthcare and government officials.
48
49

50
51 15
52
53
54
55
56
57
58

1
2
3
4 1 The complex hinterland of COVID-19 and diabetes
5
6

7 2
8
9
10 3 The pathophysiological benefits of glycemic control on diabetes outcomes have been well-
11
12
13 4 established. Numerous studies have linked chronic hyperglycemia and glycemic variability to
14
15
16
17 5 increased risks of micro- and macro-vascular complications and mortality. In addition,
18
19
20 6 dysglycemia can potentiate immunosuppression,(5) increasing viral susceptibility and risk of
21
22
23
24 7 poor clinical outcomes.(6) While the role of coexistent diabetes in the pathogenesis of COVID-
25
26
27 8 19 is still being determined,(7) emerging signals suggest that euglycemia protects against
28
29
30 9 infection and severity of prognoses.(8,9) These data are consistent with evidence from other viral
31
32
33
34 10 infections where glucose control showed to augment host immune response.(5,10)
35
36

37 11 To mitigate COVID-19 risks, several national and international organizations have published
38
39
40 12 diabetes pandemic guides, urging PWD to maintain scrupulous adherence to all self-management
41
42
43
44 13 and public health recommendations.(7,8) Notably, the Centers for Disease Control and
45
46
47 14 Prevention (CDC)(11) has recommended maintaining at least a 30-day supply of medication and
48
49
50
51 15 2-week supply of food. The American Diabetes Association (ADA)(12) has advised storing
52
53
54 16 blood glucose emergency supplies (i.e., glucagon and ketone strips). And the International
55
56
57
58
59
60

1
2
3
4 1 Diabetes Federation(13) has encouraged healthy nutrition and regular monitoring to help avoid
5
6
7 2 the complications of high and low blood glucose.
8
9

10 3 However, the COVID-19 situation has created a challenging terrain for effective glyceimic
11
12
13 4 management.(14) Amid pressures to flatten the pandemic curve, people with diabetes and their
14
15
16
17 5 clinicians may divert focus and resources away from diabetes management, resulting in
18
19
20 6 compromised care.(8) Moreover, home quarantine, physical distancing, and community
21
22
23
24 7 containment—while enacted to ensure the safety of Americans—can erode chronic disease
25
26
27 8 services and make it increasingly difficult for PWD to access medical supplies and engage in
28
29
30 9 optimal self-management behaviour (e.g., healthy eating and physical activity).(15) Previous
31
32
33
34 10 outbreaks have also been associated with inadequate diabetes monitoring and barriers to
35
36
37 11 accessing healthcare, medications, and testing supplies.(4,8) Such disruptions to routine care can
38
39
40
41 12 lead to worse glyceimic outcomes during and after the event.(16,17)
42
43

44 13 Yet, to date, most diabetes-related COVID-19 studies in the US have focused exclusively on
45
46
47 14 the epidemiology of hospitalized cases(18,19) and failed to consider how community-based
48
49
50
51 15 chronic diabetes management has suffered in the face of the pandemic. The lack of real-world
52
53
54 16 evidence on the situational effects of COVID-19 bodes ill for the implementation of effective
55
56
57
58
59
60

1
2
3 1 outbreak strategies that support Americans with diabetes. As the pandemic persists into the
4
5
6
7 2 foreseeable future, the need to address this gap only intensifies.
8
9

10 3 The main objective of this investigation was to measure how, and the extent to which, the
11
12
13 4 COVID-19 situation has affected self-reported glycemetic management in the general community
14
15
16
17 5 population of Americans with type 1 and 2 diabetes. In so doing, we aimed to chart the complex
18
19
20 6 hinterland of COVID-19 as it intersects with America's other deadly epidemic: Diabetes. The
21
22
23
24 7 results of this study will be instructive for handling chronic disease management both during the
25
26
27 8 current public health emergency and in future.
28
29
30
31
32

33 34 RESEARCH DESIGN AND METHODS 35 36

37 38 39 12 Study design 40 41 42 43 44 45

46 14 This cross-sectional study describes the results of a COVID-19-specific sub-questionnaire that
47
48
49 15 was administered as part of the larger iNPHORM (Investigating Novel Predictions of
50
51
52
53
54
55
56
57
58

1
2
3
4 1 Hypoglycemia Occurrence Using Real-world Models) panel survey: a one-year prospective
5
6
7 2 analysis of real-world hypoglycemia risk stratification in the US (NCT04219514).(20)
8
9

10 3

11
12
13 4 Participants and data collection
14
15 5

16
17
18 6 iNPHORM participants were conveniently sampled from randomly selected subsets of a
19
20
21 7 probability-based internet panel comprising >10,000 Americans with type 1 diabetes and
22
23
24 8 >58,000 with type 2 diabetes (≥ 18 years old). These subsets were defined based on study
25
26
27 9 requirements, mainly diabetes status. Individuals in each subset were contacted via email about
28
29
30 10 the study; those interested in participating were directed to complete a screening
31
32
33 11 questionnaire.
34
35

36 12 Panel members 18-90 years old, living in the US for the past year, and with type 1 or 2
37
38
39 13 diabetes taking insulin and/or secretagogues were eligible to enroll. Individuals were ineligible if
40
41
42 14 they were or had been pregnant within the past year, were involved in an interventional study, or
43
44
45 15 were unable to read/understand English. To finalize enrollment, eligible respondents needed to
46
47
48
49 16 provide consent and complete a baseline questionnaire. Once enrolled, participants were
50
51
52
53
54
55
56
57
58
59
60

1 managed and hosted by Ipsos Interactive Services (IIS, www.ipsos.com), a leading global firm in
2 diabetes insights and real-world survey conduct.

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

10 Owing to the escalating severity of COVID-19 in the US, iNPHORM follow-up
11 questionnaires were emended post study commencement (at follow-up Month 2) to include a
12 COVID-19-specific sub-questionnaire. The sub-questionnaire assessed community infection, and
13 the impact of the pandemic on diabetes management. Data pertaining to the first administered
14 COVID-19 sub-questionnaire (April 21st to 28th, 2020) are summarized herein.

Survey instruments and variables

iNPHORM questionnaires (screening, baseline, and follow-ups [including the COVID-19 sub-questionnaire]) 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 (e.g., computers, smart phones, tablets). Efforts were taken to avoid double-barreled 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 semi-structured interviews prior to fielding.

COVID-19 status: To ascertain self-reported one-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

1
2
3
4 1 epidemiologic exposure (e.g., close contact with a confirmed or suspected case; international
5
6
7 2 travel). Aligning with CDC recommendations, we classified respondents as confirmed, probable,
8
9
10 3 or possible cases. Confirmed cases were those who reported having been formally diagnosed
11
12
13 4 with COVID-19. Probable cases were those who did not have a formal diagnosis but who
14
15
16
17 5 reported 1) symptoms typical of COVID-19 and 2) ≥ 1 form of epidemiologic exposure. If only
18
19
20 6 one of the two latter conditions was met, we classified individuals as possible cases.

21
22
23 7 *Impact of the COVID-19 situation on aspects of diabetes management:* We developed 12
24
25
26
27 8 structured, 5-point Likert items to assess how, on a scale from “much harder” to “much easier”,
28
29
30 9 “...the Coronavirus (COVID-19) situation has impacted...” various socio-economic,
31
32
33
34 10 behavioural/clinical, and psychosocial aspects of participants’ diabetes management (past
35
36
37 11 month). A neutral option (the pandemic has had no impact) was ordered in the middle between
38
39
40
41 12 negative and positive response categories. Topics included drug affordability/accessibility,
42
43
44 13 medication-taking behaviour, healthcare consultations, glucose monitoring, and social support.
45
46
47 14 Additionally, we incorporated two structured, binary items to assess drug rationing. See
48
49
50
51 15 Appendix A for a complete list of these questions.
52
53
54
55
56
57
58
59
60

1
2
3
4 1 *Socio-demographic and clinical characteristics of study sample*: So as to align with the first
5
6
7 2 administered COVID-19 sub-questionnaire (analyzed herein), socio-demographic and clinical
8
9
10 3 characteristics were collated between the screening, baseline, and follow-up questionnaires
11
12
13 4 Months 1 and 2. Past-month frequencies of self-reported severe hypoglycemia (SH) and non-
14
15
16
17 5 severe hypoglycemia (NSH), defined in accordance with the ADA,(22) were assessed at follow-
18
19
20 6 up Month 2. Non-severe hypoglycemia was defined as any event that could be self-treated; SH
21
22
23 7 was defined as a medical emergency that could not be self-treated (e.g., required third-party
24
25
26
27 8 assistance).

10 Statistical analysis

11
12 12 Categorical variables were summarized as frequencies and percentages, while continuous
13
14
15 13 variables as means and standard deviations (SD) or medians and interquartile ranges (IQR).
16
17
18 14 Crude hypoglycemia frequencies were calculated as incidence rates and proportions. Confirmed,
19
20
21 15 probable, and possible COVID-19 cases were calculated as one-month period prevalences.

1 The impact of the COVID-19 situation on glycemetic management was descriptively analyzed.
2 Glycemetic management was operationalized according to different important aspects from drug
3 affordability/accessibility to social support. Variability by diabetes type was assessed using the
4 Wilcoxin-Mann-Whitney test for Likert responses and the two-sample test of proportions for
5 binary responses. Tests were two-sided at $\alpha=0.05$. All estimates were based on complete case
6 analyses and were computed using STATA V.16.0.

8 Patient and public involvement

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

12 Ethical considerations

14 Western investigators and IIS obtained ethics approval from the Western University's Research
15 Ethics Board and the Pearl Institutional Review Board (US), respectively (ID: 112986).
16 Participants gave informed consent before taking part in the study.

1
2
3
4 1
5
67 2 RESULTS
8
910 3
11
12

13 4 A total of 704 iNPHORM participants completed the first COVID-19 sub-questionnaire (April,
14
15
16
17 5 2020). Of these respondents, 667 (type 1 diabetes: 18.0%; type 2 diabetes: 82%) reported taking
18
19
20 6 insulin and/or secretagogues (i.e., met our study's eligibility criteria); their socio-demographic
21
22
23
24 7 and clinical characteristics are summarized in Tables 1 and 2, respectively.
25
26

27 8 Of the 667 eligible respondents, half were female. The mean age was 51.9 (SD: 14.6; Min,
28
29
30 9 Max: 20, 87) years with 23.2% \geq 65 years old. Diabetes duration was 26.0 (IQR: 23.0) years in
31
32
33
34 10 people with type 1 and 11.0 (IQR: 14.0) years in people with type 2 diabetes. All respondents
35
36
37 11 with type 1 diabetes, and 38.4% with type 2 diabetes, reported taking insulin without
38
39
40 12 secretagogues; among the remaining participants with type 2 diabetes, 36.9% were taking
41
42
43
44 13 secretagogues without insulin, and 24.7% were taking a combination of insulin and
45
46
47 14 secretagogues. Twenty-three percent (type 1 diabetes: 23.3%; type 2 diabetes: 23.0%) of the total
48
49
50 15 sample reported A1C values \geq 8.1%. Sixty-one percent reported \geq 1 diabetes-related
51
52
53
54 16 complication(s), while 83.2% reported \geq 1 comorbidity.
55
56
57
58
59
60

1
2
3
4 1 Table 3 summarizes self-reported hypoglycemia incidences (combined daytime and
5
6
7 2 nocturnal). The incidence rate and incidence proportion of NSH were higher in people with type
8
9
10 3 1 diabetes (incidence rate: 5.7 [95%CI: 4.6 to 7.1] events per person-month (PPM) and incidence
11
12
13 4 proportion: 83.3% [95%CI: 75.7 to 88.9]) versus type 2 diabetes (incidence rate: 2.1 [95%CI: 1.8
14
15
16
17 5 to 2.4] events PPM and incidence proportion: 55.0% [95%CI: 50.8 to 59.1]). However, SH,
18
19
20 6 occurring at an overall rate of 0.7 (95%CI: 0.5 to 0.96) events PPM, was almost twice as
21
22
23
24 7 common in people with type 2 versus type 1 diabetes (0.8 [95%CI: 0.5 to 1.1] versus 0.4
25
26
27 8 [95%CI: 0.2 to 0.9] events PPM). Similarly, the monthly incidence proportion of SH, affecting
28
29
30 9 nearly 13% (95%CI: 10.6 to 15.7) of respondents, was higher in people with type 2 diabetes
31
32
33
34 10 compared to type 1 diabetes (13.2% [95%CI: 10.6 to 16.3] versus 11.7% [95%CI: 7.08 to 18.6]).
35
36

37 11 The one-month period prevalences of confirmed, probable, and possible COVID-19 were
38
39
40 12 0.75% (T1DM: n=0; T2DM: n=5 [0.75%]), 0.75% (T1DM: n=0; T2DM: n=5 [0.75%]), and
41
42
43
44 13 8.9% (T1DM: n=16 [13.33%]; T2DM: n=43 [7.86%]), respectively.
45
46
47
48
49
50
51
52
53
54 14
55
56
57
58
59
60

15 The impact of the COVID-19 situation on aspects of glycemic management
16

1
2
3
4 1 A summary of results is provided in Tables 4 and 5. Almost a quarter of respondents (type 1
5
6
7 2 diabetes: 30.0%; type 2 diabetes: 23.0%, P -value =0.08) reported that the COVID-19 situation
8
9
10 3 made affording rent and other living expenses either “somewhat harder” (type 1 diabetes: 19.2%;
11
12
13 4 type 2 diabetes: 14.6%) or “much harder” (type 1 diabetes: 10.8%; type 2 diabetes: 8.4%).
14
15
16
17 5 Similarly, 27.6% (type 1 diabetes: 16.7%; type 2 diabetes: 28.5%, P -value =0.29) of participants
18
19
20 6 expressed it was “somewhat harder” (type 1 diabetes: 16.7%; type 2 diabetes: 20.1%) or “much
21
22
23 7 harder” (type 1 diabetes: 6.7%; type 2 diabetes: 8.4%) to ensure adequate food supply to avoid
24
25
26
27 8 hypoglycemia. Close to one in five experienced challenges paying for their diabetes medications
28
29
30 9 (type 1 diabetes: 16.7%; type 2 diabetes: 19.0%, P -value =0.71) or test strips/sensors (type 1
31
32
33 10 diabetes: 13.3%; type 2 diabetes: 18.3%, P -value =0.38); of these individuals, approximately half
34
35
36
37 11 reported that their ability to afford therapeutic supplies had been made “much harder” by the
38
39
40 12 pandemic. Access-related issues were also identified. Overall, 27.4% (type 1 diabetes: 30.8%;
41
42
43 13 type 2 diabetes: 26.7%, P -value =0.24) found the pandemic made it “somewhat harder” (overall:
44
45
46
47 14 18.7%; type 1 diabetes: 20.0%; type 2 diabetes: 18.5%) or “much harder” (overall: 8.7%; type 1
48
49
50 15 diabetes: 10.8%; type 2 diabetes: 8.2%) to retrieve diabetes medications from the pharmacy. As
51
52
53
54 16 well, because of the COVID-19 situation, ~17% of participants reported rationing their diabetes
55
56
57
58
59
60

1
2
3
4 1 medications either to make supplies last longer (type 1 diabetes: 13.3%; type 2 diabetes: 17.4%,
5
6
7 2 P -value =0.28) or avoid hypoglycemia (overall: 16.8%; type 1 diabetes: 15.8%; type 2 diabetes:
8
9
10 3 17.0%, P -value =0.76).

11
12
13 4 The COVID-19 situation also influenced participants' abilities to self-manage. Many
14
15
16
17 5 respondents struggled to remember to take their diabetes medication(s) as prescribed (overall:
18
19
20 6 13.7%; type 1 diabetes: 6.7%; type 2 diabetes: 15.2%, P -value =0.047) as well as test and
21
22
23 7 monitor their blood glucose (overall: 15.9%; type 1 diabetes: 5.0%; type 2 diabetes: 18.3%, P -
24
25
26 8 value <0.001) and risk of hypoglycemia regularly (overall: 12.0%; type 1 diabetes: 7.5%; type 2
27
28
29 9 diabetes: 13.0%, P -value =0.026). Over a third of respondents (type 1 diabetes: 35.0%; type 2
30
31
32
33 10 diabetes: 36.8%, P -value =0.75) found it "somewhat harder" (overall: 23.7%; type 1 diabetes:
34
35
36 11 23.3%; type 2 diabetes: 23.8%) or "much harder" (overall: 12.7%; type 1 diabetes: 11.7%; type 2
37
38
39 12 diabetes: 13.0%) to consult with their diabetes care providers. In terms of exercise maintenance,
40
41
42
43 13 almost one in two respondents (type 1 diabetes: 47.5%; type 2 diabetes: 46.1, P -value =0.84)
44
45
46 14 reported that it had been "somewhat harder" (overall: 31.3%; type 1 diabetes: 30.0%; type 2
47
48
49 15 diabetes: 31.6%) or "much harder" (overall: 15.0%; type 1 diabetes: 17.5%; type 2 diabetes:
50
51
52
53 16 14.4%) to stay as physically active as usual.
54
55
56
57
58
59
60

1
2
3
4 1 Lastly, psychosocial effects were observed. Many participants (overall: 14.6%; type 1
5
6
7 2 diabetes: 11.7%; type 2 diabetes: 15.2%, P -value =0.5) felt the pandemic situation had made it
8
9
10 3 “somewhat harder” (overall: 9.3%; type 1 diabetes: 7.5%; type 2 diabetes: 9.7%) or “much
11
12
13 4 harder” (overall: 5.3%; type 1 diabetes: 4.2%; type 2 diabetes: 5.5%) to remain in control of their
14
15
16
17 5 hypoglycemia. Nineteen percent also reported having insufficient social support to help manage
18
19
20 6 their risk (type 1 diabetes: 10.8%; type 2 diabetes: 20.3%, P -value =0.056); for 12.4% (type 1
21
22
23 7 diabetes: 8.3%; type 2 diabetes: 13.4%) accessing social support was “somewhat harder”, while
24
25
26
27 8 for 6.2% (type 1 diabetes: 2.5%; type 2 diabetes: 7.0%) it was “much harder”.

28
29
30 9 Although approximately 50% of respondents believed the pandemic situation had no impact
31
32
33
34 10 on their glycaemic management, rarely was a beneficial impact on participants’ lives observed. In
35
36
37 11 general, less than 5% of the sample reported that the pandemic made aspects of their diabetes
38
39
40
41 12 management either “somewhat easier” or “much easier”.

42
43
44 13

47 14 DISCUSSION

48
49
50 15

1
2
3
4 1 Experts have long been aware of the impacts a protracted emergency would have on healthcare
5
6
7 2 and outcomes. Now, as two life-altering diseases collide, many Americans are finding
8
9
10 3 themselves at the nidus of extreme clinical vulnerability, and with little support. Despite advice
11
12
13 4 furnished by several national and international organizations, PWD are clearly struggling to
14
15
16
17 5 maintain glycemic management standards during the pandemic. This gap forebodes important,
18
19
20 6 population-based consequences to diabetes-related morbidities, both now and well-after
21
22
23
24 7 vaccinations are distributed.

25
26
27 8 iNPHORM is the first investigation to quantify the impact of the COVID-19 situation on the
28
29
30 9 socio-economic, behavioural/clinical, and psychosocial aspects of glycemic management among
31
32
33
34 10 community-dwelling Americans. Based on the results of our study, the pandemic was found to
35
36
37 11 cause substantial deficiencies in routine diabetes care in the US, a finding consistent with
38
39
40 12 international data published by the World Health Organization.(23) Of note, only few
41
42
43
44 13 appreciable differences were observed by diabetes type; of those identified, most related to the
45
46
47 14 behavioural aspects of glycemic management.

48
49
50 15

COVID-19 and the socio-economic aspects of glycemic management

People with diabetes 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 to 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 uncertainty 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 hypoglycemia.(25) One US study found that exhaustion of food budgets was associated with a 27% increase in hypoglycemia-related hospital admissions.(26) Food insecurity among PWD has also been associated with poorer glucose monitoring and higher A1C values.(26)

1
2
3
4 1 Furthermore, decreases in financial resources, especially in the absence of health coverage,
5
6
7 2 can inhibit access to diabetes medical supplies. An American study found that prescription refills
8
9
10 3 for diabetes medications fell by 10% between January and August 2020(27); however, whether
11
12
13 4 or not this was due to financial or environmental factors was unclarified. Our data reveal that
14
15
16
17 5 while roughly 20% of respondents experienced difficulties affording medications or
18
19
20 6 strips/sensors, over a quarter reported issues physically retrieving medical supplies from
21
22
23
24 7 pharmacies (perhaps due to prevention orders or anxieties over potential exposure).
25
26

27 8 Interruptions in healthcare access may explain the significant percentages of respondents who
28
29
30 9 reported rationing their diabetes supplies. Our study investigated whether or not PWD ration
31
32
33
34 10 their medications not just to extend their lifespan, but to prevent hypoglycemia. Despite evidence
35
36
37 11 that lockdown exacerbates hypoglycemia risk,(28) no research yet existed measuring the
38
39
40 12 potential risk of hypoglycemia-specific medication rationing during COVID-19. Treatment
41
42
43
44 13 rationing contradicts the CDC's recommendations for managing diabetes during the
45
46
47 14 pandemic.(11) Not only can antihyperglycemic underuse increase the likelihood of deleterious
48
49
50
51 15 short-term outcomes, but it can also drive up the cost of long-term diabetes-related
52
53
54 16 complications.(29)
55
56
57
58
59
60

1
2
3
4 1 The impact of the COVID-19 situation on socio-economic indicators predictably did not vary
5
6
7 2 by diabetes type with nearly equivalent percentages of each reporting financial and
8
9
10 3 environmental instabilities because of the pandemic.
11
12
13
14 4

5 COVID-19 and the behavioural/clinical aspects of glycemc management

6
7 Evidence from past national emergencies underscores their profound and lasting implications on
8 self-management behaviours in people with coexistent illnesses.(16,17) Our study is the first
9 American diabetes investigation to measure these implications in the COVID-19 era. Because of
10 the pandemic, several iNPHORM participants reported forgetting to take their prescribed
11 medications. This was especially true of type 2 diabetes respondents, perhaps due to variability
12 in medication regimens compared to those with type 1 diabetes. Lapses in medication use can
13 compromise therapeutic adherence and efficacies, leading to elevated A1C values as far-out as
14 16 months post-emergency.(17) This risk is likely compounded by financial- and access-related
15 issues resulting from the pandemic (described in previous section) as well as sub-optimal blood

1
2
3
4 1 glucose tracking. Many respondents, especially those with type 2 diabetes, reported difficulties
5
6
7 2 testing/monitoring their glucose and, specifically, hypoglycemia risk.
8
9

10 3 In addition, the pandemic has imposed dramatic changes on routine healthcare access and
11
12
13 4 delivery, particularly among individuals with underlying health conditions.(30) To prioritize
14
15
16
17 5 access to hospital beds, equipment, and staff, as well as to minimize viral transmission, much of
18
19
20
21 6 routine healthcare has been postponed or cancelled. As well, people with diabetes may decline
22
23
24 7 attendance at hospitals, clinics, and screening exams over concerns of infection. More than a
25
26
27 8 third of respondents indicated that the COVID-19 situation made it harder to consult with their
28
29
30
31 9 diabetes providers. Interestingly, this finding did not significantly differ by diabetes type.
32
33

34 10 Research has shown that deferred or avoided healthcare due to the pandemic can contribute to
35
36
37 11 excess morbidity and mortality.(31) Based on an article by Woolf SH et al.,(32) US states with
38
39
40
41 12 large numbers of COVID-19-related deaths experience large proportional increases in deaths
42
43
44 13 from other underlying causes, including diabetes. Impacts on health may worsen the longer
45
46
47 14 community containment measures last. A simulation study of data from previous global disasters
48
49
50
51 15 found the duration of lockdown to be directly proportional to A1C and number of diabetes-
52
53
54 16 related complications.(33) Unfortunately, these effects may endure even after the viral outbreak
55
56
57
58
59
60

1
2
3
4 1 has been quelled. Evidence from past disasters, has shown that reduced access to healthcare
5
6
7 2 during the acute phase of an emergency can lead to an aftermath of increased deaths and
8
9
10 3 morbidities including stroke, myocardial infarctions, and diabetes-related complications.(34)
11
12
13 4 Such increases in morbidity and mortality resulting from delayed and reduced healthcare access
14
15
16
17 5 are especially concerning among iNPHORM participants, of whom almost 90% reported some
18
19
20 6 comorbidity or diabetes-related complication.
21
22

23
24 7 Finally, COVID-19 mitigation measures can restrict access to indoor and outdoor physical
25
26
27 8 activities, contributing to increased sedentary behaviours that adversely affect immune defence,
28
29
30 9 glycemic control, and metabolic health in general.(9) Based on data from other viral infections,
31
32
33
34 10 sub-optimal physical activity can accentuate symptom severity, recovery times, and
35
36
37 11 transmissibility; it can also compromise post-vaccination immunity and increase secondary
38
39
40 12 infection risk.(35) Regardless of diabetes type, staggering percentages of participants reported
41
42
43
44 13 reduced physical activity because of the pandemic, a sure warning sign of the extensive health
45
46
47 14 consequences to come.
48
49
50
51 15

1
2
3
4 1 COVID-19 and the psychosocial aspects of glycemic management
5
6
7 2
8
9

10 3 The psychosocial ramifications of COVID-19 in PWD have been minimally investigated in the
11
12
13 4 literature. Our study specifically assessed how the pandemic has impacted respondents' senses of
14
15
16
17 5 personal control over their hypoglycemia risk. Significant decrements in self-perceived control
18
19
20 6 were observed across all participants. Sense of control—the learned belief that one does master,
21
22
23
24 7 control, and shape one's life—has been linked to several positive health effects including
25
26
27 8 proactive behavior and emotional well-being.(36) However, inadequate supplies, financial loss,
28
29
30 9 fear psychosis of being infected, and media/disinformation can all contribute to increased
31
32
33
34 10 feelings of powerlessness.(37) Reductions in sense of personal control have been associated with
35
36
37 11 heightened stress, anxiety, and depressive symptoms(38)—outcomes that have been linked to
38
39
40
41 12 poor medication adherence and diminished self-management.(39)
42
43

44 13 No study had yet quantified the effect the COVID-19 situation on social support access in
45
46
47 14 PWD. While support from family and friends can mediate the contextual impacts of COVID-19,
48
49
50
51 15 several respondents in our study, particularly those with type 2 diabetes, reported insufficient
52
53
54 16 social support to help manage their hypoglycemia. Assistance from informal relationships has
55
56
57
58
59
60

1
2
3
4 1 been identified as a major component to hypoglycemia self-management with demonstrable
5
6
7 2 impacts on diabetes-related morbidity and mortality reduction.(14,38,40) The gap in social
8
9
10 3 support observed in our study portend troubling implications for hypoglycemia incidence as well
11
12
13 4 as other clinical and psychosocial sequelae.

14
15
16
17 5 Indeed, sub-optimal social support among people with type 2 diabetes, compounded by
18
19
20 6 inadequate hypoglycemia risk monitoring, could explain why SH was found to be more common
21
22
23 7 in our respondents with type 2 versus type 1 diabetes. Though comparable overall hypoglycemia
24
25
26 8 incidences have been observed in other real-world studies,(41) the 2018 InHypo-DM study(42)
27
28
29 9 reported similarly higher SH events rates in people with type 2 versus type 1 diabetes. This
30
31
32
33 10 finding suggests that important deficiencies—irrespective of the pandemic situation—may exist
34
35
36 11 with regard to hypoglycemia education, management behaviors, and/or primary care in people
37
38
39 12 with type 2 diabetes when compared to their type 1 diabetes counterpart. Parenthetically, unlike
40
41
42
43 13 many other real-world hypoglycemia investigations that focus exclusively on insulin-treated
44
45
46 14 diabetes,(43–45) it should be noted that 25% and 18% of participants in iNPHORM and InHypo-
47
48
49 15 DM, respectively, reported taking insulin in combination with secretagogues. Research has
50
51
52
53 16 shown that insulin-secretagogue therapy substantially increases the rate of SH compared to
54
55
56
57
58
59
60

1
2
3
4 1 insulin without secretagogues and secretagogues without insulin.(46)
5
6

7 2
8
9

10 3
11
12

13 4
14

15
16 5 Study strengths and limitations
17

18
19 6
20
21

22
23 7 This study evaluates a general, community-based cohort of Americans with diabetes—
24

25
26 8 irrespective of infection status—to derive insight into the real-world, real-time consequences of
27

28
29 9 the COVID-19 situation in diabetes. To mitigate selection bias, a broad sample of participants
30

31
32
33 10 was recruited from a large, probability-based internet panel. Online data collection enabled us to
34

35
36 11 capitalize on the high prevalence of internet use in the US,(47) while optimizing survey reach
37

38
39 12 and accessibility, respondent honesty, and representativeness, as well as reducing item
40

41
42
43 13 nonresponse.(48,49) Participant anonymity and confidentiality were assured to decrease the risk
44

45
46 14 of social desirability bias.(50)
47
48

49 15 By developing a pandemic-specific questionnaire, our research team was able to elucidate the
50

51
52
53 16 once unknown repercussions of the COVID-19 situation in Americans with diabetes; indeed,
54

55
56 17 self-report data can offer unique and robust insight routinely uncaptured by other methods.
57

1
2
3
4 1 Though the study is cross-sectional in design, self-reported causal attributions of the pandemic
5
6
7 2 were operationalized for each questionnaire item: respondents were asked to indicate to what
8
9
10 3 extent “...the Coronavirus (COVID-19) situation [had] impacted” given aspects of glycemic
11
12
13 4 management. Such information had yet to be garnered in the US.

15
16 5 Nevertheless, certain study limitations should be noted. Selection biases may have arisen to
17
18
19 6 the extent that respondents differed non-randomly from the general US population with diabetes
20
21
22 7 taking insulin and/or secretagogues. Specifically, survivorship and coverage bias (e.g., due to
23
24
25
26 8 high observed percentages of Caucasian, educated, and insured participants) could have curtailed
27
28
29 9 the external validity of results. Volunteer bias may have also led participants to over- or under-
30
31
32
33 10 estimate their responses. For example, those who chose to complete the first COVID-19 sub-
34
35
36 11 questionnaire may have possessed systemically different (positive or negative) pandemic-related
37
38
39
40 12 perspectives and/or experiences than those who did not.

41
42
43 13 Estimates derived in our study may be conservative, as they stem from a one-month data
44
45
46 14 capture in the early phase of the pandemic trajectory. In addition, self-reported responses could
47
48
49 15 have been influenced by social desirability bias and/or recall error. Even so, self-report data—
50
51
52 16 typically the Hobson’s choice for information on perspectives, views, and opinions—enabled us
53
54
55 17 to capture, for the first time, the impacts of COVID-19 on various socio-economic,

1 behavioural/clinical, and psychosocial aspects of diabetes management in the US. The results of
2 our study (though not exhaustive, per se), provide important, unprecedented insight into the real-
3 world fallouts of the pandemic situation on diabetes-related health.

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

8 9 CONCLUSIONS

10
11 A ‘hinterland’ is defined as an area lying beyond what is visible or known. As a society we have
12 exhibited unparalleled bravery in the face of one of the most terrifying crises known to
13 humankind. However, our mission to abate the pandemic is only just beginning. Indeed, the
14 COVID-19 calamity has had untold reverberations in the lives of Americans, extending well-
15 beyond the visible devastations caused by infection alone. Not least are the impacts COVID-19
16 has had on PWD—cases and non-cases alike—who have struggled to maintain control of their
17 disease amidst the pandemic.

1
2
3
4 1 Yet, until now, the nature and scale of these impacts in the US were largely unknown or
5
6
7 2 uncharacterized. Thus, the results of our study draw not only awareness to the far-reaching and
8
9
10 3 potential lasting consequences of the pandemic, but offer an evidence base for decisive action. In
11
12
13 4 identifying the unique needs of Americans with diabetes during the COVID-19 era, we can begin
14
15
16
17 5 to develop, implement, and assess clinical and public health strategies that ensure safe,
18
19
20 6 undisrupted care within communities of people with diabetes. As we combat the acute phase of
21
22
23
24 7 COVID-19, we must not lose sight of the pernicious health challenges that coexist and await us
25
26
27 8 in the aftermath.
28
29
30
31
32
33
34 10
35
36
37 11
38
39
40 12
41
42
43
44 13
45
46
47 14
48
49
50 15
51
52
53
54 16
55
56
57
58
59
60

1
2
3
4 1
5
6
7 2
8
9
10 3
11
12
13
14 4
15
16
17 5
18
19
20 6 CONTRIBUTORSHIP STATEMENT: A.A.R.-L. contributed to the discussion, researched data,
21
22
23
24 7 and wrote the manuscript. B.L.R. contributed to the discussion and reviewed/edited the
25
26
27 8 manuscript. J.D.B. contributed to the discussion and reviewed/edited the manuscript. J.W.D.
28
29
30 9 contributed to the discussion and reviewed/edited the manuscript. J.E.B. reviewed/edited the
31
32
33
34 10 manuscript. S.B.H. contributed to the discussion, researched data, and reviewed/edited the
35
36
37 11 manuscript.
38
39
40
41 12
42
43
44 13 GUARANTOR'S NAMES: Stewart B. Harris and Alexandria A. Ratzki-Leewing
45
46
47 14
48
49
50 15 TRANSPARENCY DELCARATION: S.B.H. affirms that the manuscript is an honest, accurate,
51
52
53 16 and transparent account of the study being reported; that no important aspects of the study have
54
55
56
57
58
59
60

1 been omitted; and that any discrepancies from the study as originally planned (and, if relevant,
2 registered) have been explained.

3
4
5
6
7
8
9
10
11 FUNDING/FINANCIAL SUPPORT: Funding for this study was provided through an
12
13
14
15 investigator-initiated grant from Sanofi Global.

16
17
18
19
20
21 ROLE OF FUNDING SOURCE: Sanofi Global was not involved in the study design; in the
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

7
8 collection, analysis, and interpretation of data; in the writing of the report; and in the decision to
9 submit the article for publication. All researchers confirm their independence from funders and
10 all authors had full access to all of the data (including statistical reports and tables) in the study
11 and can take responsibility for the integrity of the data and the accuracy of the data analysis.

12 CONFLICT OF INTEREST STATEMENT: A.A.R.-L.: Sanofi: grant; Eli Lilly: consultant; fees
13 paid for presentations; Novo Nordisk: consultant. B.L.R.: Nothing to disclose. J.D.B.: Nothing to
14 disclose. J.W.D.: Nothing to disclose. J.E.B.: Nothing to disclose. S.B.H: Sanofi: grant, member
15 advisory board, consultant; Eli Lilly: grant, member advisory board, consultant, clinical studies;
16 Novo Nordisk: grant, member advisory board, consultant, clinical studies; Janssen: grant,
17 member advisory board, consultant; AstraZeneca: grant, member advisory board, consultant,
18 clinical studies; Abbott: grant, member advisory board, consultant; Boehringer Ingelheim: grant,

1
2
3
4 1 member advisory board, consultant, clinical studies; JDRF: grant; Lawson: grant; Canadian
5
6
7 2 Institutes of Health and Research: grants.
8
9

10
11 3
12
13 4 COPYRIGHT/LICENCE STATEMENT: The Corresponding Author has the right to grant on
14
15
16 5 behalf of all authors and does grant on behalf of all authors, a worldwide licence to the
17
18
19 6 Publishers and its licences in perpetuity, in all forms, formats and media (whether known now or
20
21
22 7 created in the future), to i) publish, reproduce, distribute, display and store the Contribution, ii)
23
24
25 8 translate the Contribution into other languages, create adaptations, reprints, include within
26
27
28 9 collections and create summaries, extracts and/or, abstracts of the Contribution, iii) create any
29
30
31 10 other derivative work(s) based on the Contribution, iv) to exploit all subsidiary rights in the
32
33
34 11 Contribution, v) the inclusion of electronic links from the Contribution to third party material
35
36
37 12 where—ever it may be located; and, vi) licence any third party to do any or all of the above.
38
39
40
41
42
43
44 13

45
46 14 DATA AVAILABILITY STATEMENT: No additional data are available.
47
48
49
50 15

1
2
3 1 ETHICS STATEMENT: Western investigators and IIS obtained ethics approval from the
4
5 2 Western University's Research Ethics Board and the Pearl Institutional Review Board (US),
6
7 3 respectively (ID: 112986). Participants gave informed consent before taking part in the study.
8
9
10
11 4
12
13
14 5
15
16 6
17 ACKNOWLEDGMENTS
18
19 7 We thank Nadia Khan and Kristina Timcevska for their valuable feedback on this manuscript.
20
21
22 8
23
24
25
26 9
27
28
29 10
30
31
32 11
33
34
35
36 12
37
38
39 13
40
41
42 14
43
44
45
46 15
47
48
49 16
50
51
52 17
53
54
55
56
57
58
59
60

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

REFERENCES

1. Holshue ML, DeBolt C, Lindquist S, Lofy KH, Wiesman J, Bruce H, et al. First Case of 2019 Novel Coronavirus in the United States. *N Engl J Med*. 2020 Mar 5;382(10):929–36.
2. Johns Hopkins. Coronavirus Resource Center [Internet]. Johns Hopkins Coronavirus Resource Center. [cited 2020 Dec 26]. Available from: <https://coronavirus.jhu.edu/>
3. Roncon L, Zuin M, Rigatelli G, Zuliani G. Diabetic patients with COVID-19 infection are at higher risk of ICU admission and poor short-term outcome. *J Clin Virol*. 2020 Jun;127:104354.
4. Hill MA, Mantzoros C, Sowers JR. Commentary: COVID-19 in patients with diabetes. *Metabolism*. 2020 Jun;107:154217.
5. Gupta R, Ghosh A, Singh AK, Misra A. Clinical considerations for patients with diabetes in times of COVID-19 epidemic. *Diabetes Metab Syndr*. 2020 Jun;14(3):211–2.
6. Brownlee M. Biochemistry and molecular cell biology of diabetic complications. *Nature*. 2001 Dec 13;414(6865):813–20.

- 1 7. Morra ME, Van Thanh L, Kamel MG, Ghazy AA, Altibi AMA, Dat LM, et al. Clinical
2 outcomes of current medical approaches for Middle East respiratory syndrome: A
3 systematic review and meta-analysis. *Rev Med Virol*. 2018 May;28(3):e1977.
- 4 8. Ma RCW, Holt RIG. COVID-19 and diabetes. *Diabet Med*. 2020;37(5):723–5.
- 5 9. Singh AK, Gupta R, Ghosh A, Misra A. Diabetes in COVID-19: Prevalence,
6 pathophysiology, prognosis and practical considerations. *Diabetes Metab Syndr*. 2020
7 Aug;14(4):303–10.
- 8 10. Geerlings SE, Hoepelman AI. Immune dysfunction in patients with diabetes mellitus (DM).
9 *FEMS Immunol Med Microbiol*. 1999 Dec;26(3–4):259–65.
- 10 11. CDC. COVID-19 and Your Health [Internet]. Centers for Disease Control and Prevention.
11 2020 [cited 2020 Dec 26]. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>
- 12 12. Diabetes and Coronavirus (COVID-19) | ADA [Internet]. [cited 2020 Dec 26]. Available
13 from: <https://www.diabetes.org/coronavirus-covid-19>
- 14 13. International Diabetes Federation. Coronavirus COVID-19. 2020 [cited 2020 Dec 26]
15 Available from: <https://www.idf.org/aboutdiabetes/what-is-diabetes/covid-19-and-diabetes/1-covid-19-and-diabetes.html>.
- 16 14. McEwen MM, Pasvogel A, Gallegos G, Barrera L. Type 2 diabetes self-management social
17 support intervention at the U.S.-Mexico border. *Public Health Nurs Boston Mass*. 2010
18 Aug;27(4):310–9.
- 19 15. Yang Y, Shang W, Rao X. Facing the COVID-19 outbreak: What should we know and what
20 could we do? *J Med Virol*. 2020;92(6):536–7.

- 1
2
3 1 16. Fonseca VA, Smith H, Kuhadiya N, Leger SM, Yau CL, Reynolds K, et al. Impact of a
4
5 2 natural disaster on diabetes: exacerbation of disparities and long-term consequences.
6
7 3 Diabetes Care. 2009 Sep;32(9):1632–8.
8
9
10 4 17. Ng J, Atkin SL, Rigby AS, Walton C, Kilpatrick ES. The effect of extensive flooding in Hull
11
12 5 on the glycaemic control of patients with diabetes. Diabet Med J Br Diabet Assoc. 2011
13
14 6 May;28(5):519–24.
15
16
17 7 18. dQ&A. Impact of COVID-19 on the diabetes community in the United States, 2020
18
19 8 [Internet]. [cited 2020 Dec 24]. Available from: [https://d-qa.com/impact-of-covid-19-on-](https://d-qa.com/impact-of-covid-19-on-theusa-diabetes-community/?utm_source5Closer1Look1Subscribers12018&utm_campaign54285f7ac19-2020-04-19_WIR_4%2F13-4%2F1704_18_2020&utm_medium5email&utm_term50_c55d924bf1-4285f7ac19-409220105)
20
21 9 [theusa-diabetes-community/?utm_source5Closer1Look1](https://d-qa.com/impact-of-covid-19-on-theusa-diabetes-community/?utm_source5Closer1Look1Subscribers12018&utm_campaign54285f7ac19-2020-04-19_WIR_4%2F13-4%2F1704_18_2020&utm_medium5email&utm_term50_c55d924bf1-4285f7ac19-409220105)
22
23 10 [Subscribers12018&utm_campaign54285f7ac19-2020-04-19_WIR_4%2F13-](https://d-qa.com/impact-of-covid-19-on-theusa-diabetes-community/?utm_source5Closer1Look1Subscribers12018&utm_campaign54285f7ac19-2020-04-19_WIR_4%2F13-4%2F1704_18_2020&utm_medium5email&utm_term50_c55d924bf1-4285f7ac19-409220105)
24
25 11 [4%2F1704_18_2020&utm_medium5email&utm_term50_c55d924bf1-4285f7ac19-](https://d-qa.com/impact-of-covid-19-on-theusa-diabetes-community/?utm_source5Closer1Look1Subscribers12018&utm_campaign54285f7ac19-2020-04-19_WIR_4%2F13-4%2F1704_18_2020&utm_medium5email&utm_term50_c55d924bf1-4285f7ac19-409220105)
26
27 12 [409220105](https://d-qa.com/impact-of-covid-19-on-theusa-diabetes-community/?utm_source5Closer1Look1Subscribers12018&utm_campaign54285f7ac19-2020-04-19_WIR_4%2F13-4%2F1704_18_2020&utm_medium5email&utm_term50_c55d924bf1-4285f7ac19-409220105)
28
29
30
31 13 19. Qiu J, Shen B, Zhao M, Wang Z, Xie B, Xu Y. A nationwide survey of psychological
32
33 14 distress among Chinese people in the COVID-19 epidemic: implications and policy
34
35 15 recommendations. Gen Psychiatry. 2020;33(2):e100213.
36
37
38 16 20. Harris S. Investigating Novel Predictions of Hypoglycemia Occurrence in Real-world
39
40 17 Models [Internet]. clinicaltrials.gov; 2020 May [cited 2020 Dec 23]. Report No.:
41
42 18 NCT04219514. Available from: <https://clinicaltrials.gov/ct2/show/NCT04219514>
43
44
45 19 21. Coronavirus Disease 2019 (COVID-19) | 2020 Interim Case Definition, Approved April 5,
46
47 20 2020 [Internet]. [cited 2020 Dec 24]. Available from: [/nndss/conditions/coronavirus-](https://nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/)
48
49 21 [disease-2019-covid-19/case-definition/2020/](https://nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/)
50
51
52 22 22. Association AD. 6. Glycemic Targets: Standards of Medical Care in Diabetes—2019.
53
54 23 Diabetes Care. 2019 Jan 1;42(Supplement 1):S61–70.
55
56
57
58
59
60

- 1
2
3 1 23. COVID-19 significantly impacts health services for noncommunicable diseases [Internet].
4
5 2 [cited 2021 Jul 5]. Available from: [https://www.who.int/news/item/01-06-2020-covid-19-](https://www.who.int/news/item/01-06-2020-covid-19-significantly-impacts-health-services-for-noncommunicable-diseases)
6
7 3 significantly-impacts-health-services-for-noncommunicable-diseases
8
9
10 4 24. dQ&A - The Diabetes Research Company and the, American Diabetes Association. Diabetes
11
12 5 and COVID 19:New Data Quantifies Extraordinary Challenges Faced by Americans with
13
14 6 Diabetes During Pandemic. 2020.
15
16
17 7 25. Seligman HK, Jacobs EA, Lopez A, Sarkar U, Tschann J, Fernandez A. Food Insecurity and
18
19 8 Hypoglycemia Among Safety Net Patients with Diabetes. Arch Intern Med. 2011 Jul
20
21 9 11;171(13):1204–6.
22
23
24 10 26. Seligman HK, Bolger AF, Guzman D, López A, Bibbins-Domingo K. Exhaustion of food
25
26 11 budgets at month’s end and hospital admissions for hypoglycemia. Health Aff Proj Hope.
27
28 12 2014 Jan;33(1):116–23.
29
30
31 13 27. Hartmann-Boyce J, Morris E, Goyder C, Kinton J, Perring J, Nunan D, et al. Diabetes and
32
33 14 COVID-19: Risks, Management, and Learnings From Other National Disasters. Diabetes
34
35 15 Care. 2020 Aug;43(8):1695–703.
36
37
38 16 28. Shah K, Tiwaskar M, Chawla P, Kale M, Deshmane R, Sowani A. Hypoglycemia at the time
39
40 17 of Covid-19 pandemic. Diabetes Metab Syndr. 2020 Oct;14(5):1143–6.
41
42
43 18 29. Cutler RL, Fernandez-Llimos F, Frommer M, Benrimoj C, Garcia-Cardenas V. Economic
44
45 19 impact of medication non-adherence by disease groups: a systematic review. BMJ Open
46
47 20 [Internet]. 2018 Jan 21 [cited 2020 Dec 24];8(1). Available from:
48
49 21 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5780689/>
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 1 30. Propper C, Stockton I, Stoye G. COVID-19 and disruptions to the health and social care of
4
5 2 older people in England [Internet]. 2020 [cited 2020 Dec 24]. Available from:
6
7 3 <https://www.ifs.org.uk/publications/15160>
8
9
10 4 31. Center For Disease Control and Prevention. Excess Deaths Associated with COVID-19
11
12 5 [Internet]. 2020 [cited 2020 Dec 24]. Available from:
13
14 6 https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess_deaths.htm
15
16
17 7 32. Woolf SH, Chapman DA, Sabo RT, Weinberger DM, Hill L. Excess Deaths From COVID-
18
19 8 19 and Other Causes, March-April 2020. *JAMA*. 2020 Aug 4;324(5):510–3.
20
21
22 9 33. Ghosal S, Sinha B, Majumder M, Misra A. Estimation of effects of nationwide lockdown for
23
24 10 containing coronavirus infection on worsening of glycosylated haemoglobin and increase in
25
26 11 diabetes-related complications: A simulation model using multivariate regression analysis.
27
28 12 *Diabetes Metab Syndr*. 2020;14(4):319–23.
29
30
31 13 34. Mokdad AH, Mensah GA, Posner SF, Reed E, Simoes EJ, Engelgau MM, et al. When
32
33 14 chronic conditions become acute: prevention and control of chronic diseases and adverse
34
35 15 health outcomes during natural disasters. *Prev Chronic Dis*. 2005 Nov;2 Spec no:A04.
36
37
38 16 35. Pascoe AR, Fiatarone Singh MA, Edwards KM. The effects of exercise on vaccination
39
40 17 responses: A review of chronic and acute exercise interventions in humans. *Brain Behav*
41
42 18 *Immun*. 2014 Jul 1;39:33–41.
43
44
45 19 36. Mirowsky J, Ross CE. Eliminating Defense and Agreement Bias from Measures of the Sense
46
47 20 of Control: A 2 X 2 Index. *Soc Psychol Q*. 1991;54(2):127–45.
48
49
50 21 37. Brooks SK, Webster RK, Smith LE, Woodland L, Wessely S, Greenberg N, et al. The
51
52 22 psychological impact of quarantine and how to reduce it: rapid review of the evidence.
53
54 23 *Lancet Lond Engl*. 2020 Mar 14;395(10227):912–20.
55
56
57
58
59
60

- 1
2
3 1 38. Keeton CP, Perry-Jenkins M, Sayer AG. Sense of Control Predicts Depressive and Anxious
4
5 2 Symptoms Across the Transition to Parenthood. *J Fam Psychol JFP J Div Fam Psychol Am*
6
7 3 Psychol Assoc Div 43. 2008 Apr;22(2):212–21.
8
9
10 4 39. Sturt J, Dennick K, Due-Christensen M, McCarthy K. The detection and management of
11
12 5 diabetes distress in people with type 1 diabetes. *Curr Diab Rep*. 2015 Nov;15(11):101.
13
14 6 40. Nicklett EJ, Liang J. Diabetes-related support, regimen adherence, and health decline among
15
16 7 older adults. *J Gerontol B Psychol Sci Soc Sci*. 2010 May;65B(3):390–9.
17
18 8 41. Edridge CL, Dunkley AJ, Bodicoat DH, Rose TC, Gray LJ, Davies MJ, et al. Prevalence and
19
20 9 Incidence of Hypoglycaemia in 532,542 People with Type 2 Diabetes on Oral Therapies
21
22 10 and Insulin: A Systematic Review and Meta-Analysis of Population Based Studies. *PLoS*
23
24 11 *One*. 2015;10(6):e0126427.
25
26 12 42. Ratzki-Leewing A, Harris SB, Mequanint S, Reichert SM, Belle Brown J, Black JE, et al.
27
28 13 Real-world crude incidence of hypoglycemia in adults with diabetes: Results of the
29
30 14 InHypo-DM Study, Canada. *BMJ Open Diabetes Res Care*. 2018;6(1):e000503.
31
32 15 43. Leiter L, Yale J, Chiasson J, Harris S, Kleinstiver P, Sauriol L. Assessment of the impact of
33
34 16 fear of hypoglycemic episodes on glycemic and hypoglycemia management. *Can J*
35
36 17 *Diabetes*. 2005;29:186–92.
37
38 18 44. Leiter LA, Boras D, Woo VC. Dosing irregularities and self-treated hypoglycemia in type 2
39
40 19 diabetes: results from the Canadian cohort of an international survey of patients and
41
42 20 healthcare professionals. *Can J Diabetes*. 2014 Feb;38(1):38–44.
43
44 21 45. Aronson R, Goldenberg R, Boras D, Skovgaard R, Bajaj H. The Canadian Hypoglycemia
45
46 22 Assessment Tool Program: Insights Into Rates and Implications of Hypoglycemia From an
47
48 23 Observational Study. *Can J Diabetes*. 2017 May 17;

- 1
2
3 1 46. Mogensen UM, Andersson C, Fosbøl EL, Schramm TK, Vaag A, Scheller NM, et al.
4
5 2 Sulfonylurea in combination with insulin is associated with increased mortality compared
6
7 3 with a combination of insulin and metformin in a retrospective Danish nationwide study.
8
9 4 Diabetologia. 2015 Jan 1;58(1):50–8.
10
11
12 5 47. Pew Research Center. Demographics of Internet and Home Broadband Usage in the United
13
14 6 States [Internet]. Pew Research Center: Internet, Science & Tech. 2021 [cited 2021 May 4].
15
16 7 Available from: <https://www.pewresearch.org/internet/fact-sheet/internet-broadband/>
17
18
19 8 48. Warner CH, Appenzeller GN, Grieger T, Belenkiy S, Breitbach J, Parker J, et al. Importance
20
21 9 of anonymity to encourage honest reporting in mental health screening after combat
22
23 10 deployment. Arch Gen Psychiatry. 2011 Oct;68(10):1065–71.
24
25
26 11 49. Gnamb T, Kaspar K. Disclosure of sensitive behaviors across self-administered survey
27
28 12 modes: a meta-analysis. Behav Res Methods. 2015 Dec;47(4):1237–59.
29
30
31 13 50. Althubaiti A. Information bias in health research: definition, pitfalls, and adjustment
32
33 14 methods. J Multidiscip Healthc. 2016 May 4;9:211–7.
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Table 1. Socio-demographic characteristics of study sample, overall and by diabetes type

SOCIO-DEMOGRAPHIC 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/a, 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/a, 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/a, or Spanish origin	3 (0.45)	1 (0.83)	2 (0.37)
	Not of Hispanic, Latino/a, 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 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)
	\$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)

T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus; SD, standard deviation.

* Responses may not sum to total (N=667) due to missing data.

[†] High Deductible Plan: Deductible >\$1,350 for an individual or >\$2,700 for a family.

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 hemoglobin 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 <i>without</i> Secretagogues	330 (49.48)	120 (100.00)	210 (38.39)
Secretagogues <i>without</i> Insulin	202 (30.28)	0	202 (36.93)
Insulin <i>in combination with</i> 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)
	<i>Amputation</i>	91 (13.64)	12 (10.00)	79 (14.44)
	<i>Diabetes Ketoacidosis</i>	110 (16.49)	42 (35.00)	68 (12.43)
	<i>Foot damage</i>	123 (18.44)	18 (15.00)	105 (19.20)
	<i>Gastroparesis</i>	95 (14.24)	20 (16.67)	75 (13.71)
	<i>Hyperosmolar hyperglycemic nonketotic coma</i>	60 (9.00)	5 (4.17)	55 (10.05)
	<i>Nephropathy</i>	114 (17.09)	18 (15.00)	96 (17.55)
	<i>Neuropathy</i>	298 (44.68)	46 (38.33)	252 (46.07)
	<i>Retinopathy</i>	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)
	<i>Bone, joint, or muscle problem</i>	310 (46.48)	39 (32.50)	271 (49.54)
	<i>Cancer</i>	52 (7.80)	3 (2.50)	49 (8.96)
	<i>Cardiovascular condition</i>	128 (19.19)	17 (14.17)	111 (20.29)
	<i>Chronic kidney disease</i>	73 (10.94)	8 (6.67)	65 (11.88)
	<i>Chronic liver failure or liver disease</i>	39 (5.85)	2 (1.67)	37 (6.76)
	<i>Eating disorder</i>	35 (5.25)	7 (5.83)	28 (5.12)
	<i>Gastrointestinal disease</i>	86 (12.89)	17 (14.17)	69 (12.61)
	<i>HIV/AIDS</i>	11 (1.65)	2 (1.67)	9 (1.65)
	<i>Hypertension</i>	363 (54.42)	50 (41.67)	313 (57.22)
	<i>Mental health condition</i>	223 (33.43)	36 (30.00)	187 (34.19)
	<i>Neurological disorder</i>	39 (5.85)	8 (6.67)	31 (5.67)

<i>Physical impairment</i>	168 (25.19)	29 (24.17)	139 (25.41)
<i>Respiratory condition</i>	125 (18.74)	24 (20.00)	101 (18.46)
<i>Stroke or transient ischemic attack</i>	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)
-----	-------------	------------	-------------

T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus; IQR, interquartile range; BMI: body mass index.

* Responses may not sum to total (N=667) due to missing data.

‡ Cumulative percentage >100% as participants could select more than one response.

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

INCIDENCE RATES*	Total N=667	T1DM 120 (17.99%)	T2DM 547 (82.01%)
Severe Hypoglycemia (one-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 Hypoglycemia (one-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*	Total N=667	T1DM 120 (17.99%)	T2DM 547 (82.01%)
Severe Hypoglycemia (one-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 Hypoglycemia (one-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)

T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus; CI, confidence interval.

* 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.

Table 4. Impact of the COVID-19 situation on aspects of participants' glycemic 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	χ^2 / P value†
<i>Affording my rent and other living expenses...</i>						
Overall (N=667)	59 (8.85)	103 (15.44)	491 (73.61)	12 (1.80)	2 (0.30)	
T1DM (n=120)	13 (10.83)	23 (19.17)	83 (69.17)	1 (0.83)	0	0.08
T2DM (n=547)	46 (8.41)	80 (14.63)	408 (74.59)	11 (2.01)	2 (0.37)	
<i>Making sure I have enough food to avoid hypoglycemia...</i>						
Overall (N=667)	54 (8.10)	130 (19.49)	475 (71.21)	7 (1.05)	1 (0.15)	
T1DM (n=120)	8 (6.67)	20 (16.67)	91 (75.83)	1 (0.83)	0	0.29
T2DM (n=547)	46 (8.41)	110 (20.11)	384 (70.20)	6 (1.10)	1 (0.18)	
<i>Affording my diabetes medication(s)...</i>						
Overall (N=667)	53 (7.95)	71 (10.64)	534 (80.06)	5 (0.75)	4 (0.60)	
T1DM (n=120)	10 (8.33)	10 (8.33)	99 (82.50)	1 (0.83)	0	0.71

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

T2DM (n=547)	43 (7.86)	61 (11.15)	435 (79.52)	4 (0.73)	4 (0.73)	
<i>Affording my test strips and/or sensors...</i>						
Overall (N=667)	42 (6.30)	74 (11.09)	540 (80.96)	5 (0.75)	6 (0.90)	
T1DM (n=120)	9 (7.50)	7 (5.83)	103 (85.83)	1 (0.83)	0	0.38
T2DM (n=547)	33 (6.03)	67 (12.25)	437 (79.89)	4 (0.73)	6 (1.10)	
<i>Getting my diabetes medication(s) from the pharmacy...</i>						
Overall (N=667)	58 (8.70)	125 (18.74)	470 (70.46)	8 (1.20)	6 (0.90)	
T1DM (n=120)	13 (10.83)	24 (20.00)	82 (68.33)	1 (0.83)	0	0.24
T2DM (n=547)	45 (8.23)	101 (18.46)	388 (70.93)	7 (1.28)	6 (1.10)	
<i>Consulting with my healthcare provider(s) about my diabetes...</i>						
Overall (N=667)	85 (12.74)	158 (23.69)	410 (61.47)	13 (1.95)	1 (0.15)	
T1DM (n=120)	14 (11.67)	28 (23.33)	76 (63.33)	2 (1.67)	0	0.75
T2DM (n=547)	71 (12.98)	130 (23.77)	334 (61.06)	11 (2.01)	1 (0.18)	
<i>Testing/monitoring my blood glucose...</i>						
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)	
<i>Remembering to take my diabetes medication(s) as prescribed...</i>						
Overall (N=667)	26 (3.90)	65 (9.75)	554 (83.06)	18 (2.70)	4 (0.60)	
T1DM (n=120)	1 (0.83)	7 (5.83)	109 (90.83)	3 (2.50)	0	0.047‡
T2DM (n=547)	25 (4.57)	58 (10.60)	445 (81.35)	15 (2.74)	4 (0.73)	
<i>Monitoring my risk of hypoglycemia regularly...</i>						
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)	
<i>Staying as physically active as I usually am...</i>						
Overall (N=667)	100 (14.99)	209 (31.33)	329 (49.33)	23 (3.45)	6 (0.90)	
T1DM (n=120)	21 (17.50)	36 (30.00)	55 (45.83)	7 (5.83)	1 (0.83)	0.84
T2DM (n=547)	79 (14.44)	173 (31.63)	274 (50.09)	16 (2.93)	5 (0.91)	
<i>Feeling in control of my hypoglycemia...</i>						
Overall (N=667)	35 (5.25)	62 (9.30)	528 (79.16)	35 (5.25)	7 (1.05)	
T1DM (n=120)	5 (4.17)	9 (7.50)	99 (82.50)	6 (5.00)	1 (0.83)	0.50
T2DM (n=547)	30 (5.48)	53 (9.69)	429 (78.43)	29 (5.30)	6 (1.10)	
<i>Having enough social support to help me manage my hypoglycemia...</i>						
Overall (N=667)	41 (6.15)	83 (12.44)	518 (77.66)	21 (3.15)	4 (0.60)	
T1DM (n=120)	3 (2.50)	10 (8.33)	104 (86.67)	3 (2.50)	0	0.056
T2DM (n=547)	38 (6.95)	73 (13.35)	414 (75.69)	18 (3.29)	4 (0.73)	

T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus.

n (%) are presented.

* Data collected April 21st to 28th, 2020.

† Item responses were compared between individuals with T1DM and T2DM. *P*-values were computed using two-sample Wilcoxin-Mann-Whitney tests.

‡ Statistically significant at an alpha value of 0.05 (i.e., the underlying distributions of item responses statistically significantly differed by diabetes type).

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

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

T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus.

n (%) are presented.

* Data collected April 21st to 28th, 2020

† Item responses were compared between individuals with T1DM and T2DM. *P*-values were computed using two-sample Z tests for proportions.

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ...Affording my diabetes medication(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. ...Affording my test strips and/or sensors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. ...Getting my diabetes medication(s) from the pharmacy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. ...Making sure I have enough food to avoid hypoglycemia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. ...Testing/monitoring my blood glucose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. ...Staying as physically active as I usually am	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. ...Consulting with my healthcare provider(s) about my diabetes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. ...Remembering to take my diabetes medication(s) as prescribed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. ...Monitoring my risk of hypoglycemia regularly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. ...Having enough social support to help me manage my hypoglycemia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. ...Feeling in control of my hypoglycemia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1
2
3
4 When answering this next question, please think about the time **since you last completed an**
5 **iNPHORM survey**.
6

7
8 **Because of the Coronavirus (COVID-19) situation**, did you ever **cut back** on your diabetes
9 medication(s) in order to...

	Yes	No
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		
31		
32		
33		
34		
35		
36		
37		
38		
39		
40		
41		
42		
43		
44		
45		
46		
47		
48		
49		
50		
51		
52		
53		
54		
55		
56		
57		
58		
59		
60		

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page # (line #)
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Page 1 (lines 3-4)
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Pages 3 and 4 (lines 1-6)
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Pages 4 (lines 20-22), 5 (lines 1-10), 7 (lines 9-22), and 8 (lines 1-2)
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 8 (lines 3-8)
Methods			
Study design	4	Present key elements of study design early in the paper	Pages 8 (lines 14-23) and 9 (all)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 8 (line 17) and 9 (line 22)
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	Pages 8 (lines 21-23) 9 (lines 4-7)
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Pages 10 and 11 (lines 1-18)
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Pages 10 (lines 3-6 and 20-23), 11 (lines 1-6, 8, 11-14), 40, and 41
Bias	9	Describe any efforts to address potential sources of bias	Pages 22 and 23 (lines 1-12)
Study size	10	Explain how the study size was arrived at	Pages 8 (lines 21-23) and 9 (lines 1-22)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Pages 10 (lines 1-23) and 11 (lines 1-18)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Pages 11 (lines 20-23) and 12 (lines 1-8)

		(b) Describe any methods used to examine subgroups and interactions	n/a
		(c) Explain how missing data were addressed	Page 12 (lines 7-8)
		(d) If applicable, describe analytical methods taking account of sampling strategy	Page 8 (lines 21-23)
		(e) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Pages 8 (lines 21-23); 9 (lines 1-10); 12 (lines 22-23) and 10 (lines 1-11).
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Pages 12 (lines 22-23) and 12 (lines 1-11). Also Table 1 page 33-34
		(b) Indicate number of participants with missing data for each variable of interest	Tables 1, 2, 3, 4
Outcome data	15*	Report numbers of outcome events or summary measures	Pages 12 (lines 22-23); 13 (1-21); 14 (1-23); 15 (1-23); and 16 (1-4)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Pages 13 (lines 12-21); 14 (lines 1-23); 15 (lines 1-23); and 16 (lines 1-4)
		(b) Report category boundaries when continuous variables were categorized	n/a
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	Pages 16 (lines 8 -21); 17 (lines 1-23); 18 (lines 1-23);

			19 (lines 1-23); 20 (lines 1-23); 21 (lines 1-23); 22 (lines 1-23); and 23 (lines 1-12)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Pages 22 (lines 16-23) and 23 (lines 1-12)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Pages 16 (lines 8 -21); 17 (lines 1-23); 18 (lines 1-23); 19 (lines 1-23); 20 (lines 1-23); 21 (lines 1-23); 22 (lines 1-23); and 23 (lines 1-12)
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 22 (line 18-20)
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 24 (lines 16-17)

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.