PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	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)
AUTHORS	Ratzki-Leewing, Alexandria A.; Ryan, BL; Buchenberger, John D.; Dickens, Joseph W.; Black, Jason; Harris, Stewart

VERSION 1 – REVIEW

REVIEWER	Barone, Mark TU Intersectoral Forum to Fight NCDs in Brazil , ForumDCNTs
REVIEW RETURNED	22-Mar-2021

GENERAL COMMENTS	The article is professionally written, describing a meaningful study about the impact of the COVID-19 pandemic on diabetes management, in the USA. Authors analyzed different important aspects from access to social support. It is clearly a useful contribution that will assist policy makers and health system managers to propose changes that will improve care for people with diabetes during the pandemic and, this way, reduce its short- and long-term burden. Few changes would be recommended for improvements: - It was shown in different studies with T1D during the pandemic improvements in glycemic management when associated with access to telemedicine and glucose sensors/pumps. You have in your sample glucose sensors users, which would allow you to analyze if these individuals responded differently to most of the questions, especially regarding glucose management. I would be curious to know if the 5% that responded “somewhat easier” or “much easier” are the ones wearing pumps/sensors. - I believe that you are right that your study was the first of its kind in the USA, but not globally. Several real-life studies with people with diabetes were performed in different countries including in India, Brazil, African and European countries, as cited in this article: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7724978/ Thus, I missed a discussion of similarities and differences with other countries. On page 9, lines 17-24 should be revised, since this may be true for the USA, but not globally. - Page 9, line 41, I suggest using “with other global deadly pandemic: Diabetes” or “with America’s other deadly epidemic: Diabetes”. - Between pages 15-16, you describe the percentage of individuals with complications and comorbidities. Since both would

	bring PWD to an even higher risky position, in terms of poor COVID-19 prognosis, I would suggest that you highlight the number/percentage of individuals without any of them (no complication and no comorbidity). This would be a powerful and informative result. - I miss references in different parts of your text. Such as: “In general, the pandemic was found to cause substantial deficiencies in routine diabetes care.” WHO has published a lot on this aspect. - As internationally recommended, substitute “diabetic” by “person/people with diabetes”, page 26/line 19, and “patients” by “people” or “people with diabetes”, page 28/line 10, and in other parts where these words may appear. - I would appreciate reading in your text a comment about limitations regarding your sample: majority white, highly schooled, most insured. Thus, I believe that communities/groups with different characteristics would present different results. - Since table 3 shows that COVID-19 infection was present only in T2D, I suggest eliminating this table and keep this information in the text.

REVIEWER	Schmitt, Andreas Research Institute of the Diabetes Academy Mergentheim (FIDAM), Bad Mergentheim, Germany
REVIEW RETURNED	16-Apr-2021

GENERAL COMMENTS	The authors present a study of COVID 19 impact on managing and living with type 2 and type 1 diabetes in the US based on self-reports of 667 adults participating in a population-based survey regarding hypoglycaemia problems. The manuscript is clearly structured and well organised and written which I appreciate! I think the study is of interest for the readership of BMJO and fits the journal scope and I suggest acceptance after thorough revisions. I have concerns regarding risks of bias due to subjective reporting, possibly influenced by negative feelings and attitudes towards the pandemic and its impact in general, as well as the assessment method using the questionnaire which needs to be explained in more detail. Further, any approaches are findings supporting psychometric adequacy of the tool well be of interest. I woudl request a rationale for abstracting the 5-point scale responses to only three categories reflecting negative neutral or positive impact (rather than differnetiating moderate versus severe negative impact). A finding of curiosity is the higher prevalence rate of severe hypoglycaemia in people with T2DM than T1DM - this must be explained and discussed as it might suggest caution against the validity of reported data. I am providing detailed comments and suggestions as well as minor hints within the commented manuscript file attached. I hope these comments are helpful. Best wishes for your work! The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1: Dr. Mark TU Barone, University of Sao Paulo

1. The article is professionally written, describing a meaningful study about the impact of the COVID-19 pandemic on diabetes management, in the USA. Authors analyzed different important aspects from access to social support. It is clearly a useful contribution that will assist policy makers and health system managers to propose changes that will improve care for people with diabetes during the pandemic and, this way, reduce its short- and long-term burden.

The authors thank Dr. Barone for his very positive comments on this work. The authors are pleased Dr. Barone believes the article will be a useful contribution to policy makers and health system managers tasked with managing diabetes care during the pandemic.

2. It was shown in different studies with T1D during the pandemic improvements in glycemic management when associated with access to telemedicine and glucose sensors/pumps. You have in your sample glucose sensors users, which would allow you to analyze if these individuals responded differently to most of the questions, especially regarding glucose management. I would be curious to know if the 5% that responded “somewhat easier” or “much easier” are the ones wearing pumps/sensors.

Post hoc analyses reveal that the majority of participants that responded “somewhat easier” or “much easier” were not using a CGM device in this study. While such adjusted frequency estimates may help explain variability in risk among people with diabetes, they are beyond the scope of this manuscript. The authors intend to produce future studies assessing the effect of different risk factors on COVID-19 outcomes.

3. I believe that you are right that your study was the first of its kind in the USA, but not globally. Several real-life studies with people with diabetes were performed in different countries including in India, Brazil, African and European countries, as cited in this article: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7724978/ Thus, I missed a discussion of similarities and differences with other countries. On page 9, lines 17-24 should be revised, since this may be true for the USA, but not globally.

The authors changed line 19, page 7 (formerly lines 17-24 on page 9) to, “Yet, to date, most diabetes-related COVID-19 studies in the US...”

4. Page 9, line 41, I suggest using “with other global deadly pandemic: Diabetes” or “with America’s other deadly epidemic: Diabetes”.

We changed line 6 on page 8 (formerly line 41, page 9) to, “...America’s other deadly epidemic: Diabetes.”

5. Between pages 15-16, you describe the percentage of individuals with complications and comorbidities. Since both would bring PWD to an even higher risky position, in terms of poor COVID-19 prognosis, I would suggest that you highlight the number/percentage of individuals without any of them (no complication and no comorbidity). This would be a powerful and informative result.

Thank you for highlighting the importance of complications and comorbidities among people with diabetes. Almost 90% of respondents had some complication or comorbidity, which amplifies the significant impact of COVID-19 on healthcare access. The authors have included a sentence underscoring the importance of this among our cohort (Lines 21-23, Page 19). The specific complications/co-morbidities are detailed in Table 1. Additionally, the number/percentage of individuals with no complication/comorbidity was added to Table 1.

6. I miss references in different parts of your text. Such as: “In general, the pandemic was found to cause substantial deficiencies in routine diabetes care.” WHO has published a lot on this aspect.

The statement, “the pandemic was found to cause substantial deficiencies in routine diabetes care” was in reference to the results of our study, specifically. We have clarified this by modifying the statement to read, “Based on the results of our study, the pandemic was found to cause substantial deficiencies in routine diabetes care”, rather than “In general...” (Line 17, Page 16). Nevertheless, per Dr. Barone’s point, the authors agreed it worthwhile to draw parallels between study results and those published by the World Health Organization (Lines 18-19, Page 16).

7. As internationally recommended, substitute “diabetic” by “person/people with diabetes”, page 26/line 19, and “patients” by “people” or “people with diabetes”, page 28/line 10, and in other parts where these words may appear.

To correspond with international recommendations, “diabetic Americans” was changed to “Americans with diabetes” on line 1, page 22 (formerly line 19, page 26). “…patients’ communities” was changed to “communities of people with diabetes” on line 6, page 24 (formerly line 10, page 28). “patient(s)” was replaced with “person/people with diabetes”. On lines 10-11, page 7 (formerly line 38-41, page 8), “patients and clinicians” was changed to “people with diabetes and their clinicians”. As well, “…patients themselves may decline attendance...” on line 24, page 23, was changed to “people with diabetes may decline attendance at hospitals...” (Lines 7- 8, page 19.)

8. I would appreciate reading in your text a comment about limitations regarding your sample: majority white, highly schooled, most insured. Thus, I believe that communities/groups with different characteristics would present different results.

We have specified this limitation in the “Discussion” section. (Lines 18-20, page 22.)

9. Since table 3 shows that COVID-19 infection was present only in T2D, I suggest eliminating this table and keep this information in the text.

Per Dr. Barone’s suggestion, Table 3 (formerly “Period prevalence of COVID-19 infection”) has been removed; these data are instead summarized exclusively in-text. (Lines 1-3, page 14.)

Reviewer 2: Dr. Andreas Schmitt, Bad Mergentheim, Germany

1. The authors present a study of COVID 19 impact on managing and living with type 2 and type 1 diabetes in the US based on self-reports of 667 adults participating in a population-based survey regarding hypoglycaemia problems. The manuscript is clearly structured and well organised and written which I appreciate! I think the study is of interest for the readership of BMJO and fits the journal scope and I suggest acceptance after thorough revisions.

We would like to thank Dr. Schmitt for his kind comments. We are pleased that he believes the paper is within scope of the BMJO and that it would be of interest to the journal's readership. The authors are grateful for Dr. Schmitt's extremely comprehensive and detailed feedback, which has helped improve the quality of this manuscript.

2. I have concerns regarding risks of bias due to subjective reporting, possibly influenced by negative feelings and attitudes towards the pandemic and its impact in general.

Re: "Second, self-reported data may have been subject to information bias." (Lines 50-54, Page 26)

This is a core problem of the study and should be discussed in more detail. I find the questions regarding possible negative impact are likely to create affirmative responding. I fear the responses may be influenced by personal feelings and heuristic thoughts rather than reflect objective conditions. It is unlikely that people who are feeling endangered and restricted in most areas of life by the COVID pandemic will report anything but negative impact on most fields of life including their diabetes. I think that the results regarding problems of retrieving medications from the pharmacy reflect this aspect. Reported problems may be exaggerated. The data abstraction in to three categories of negative, neutral or positive impact rather than five as requested originally even increases this problem. Please discuss possible methodological approaches to deal with this issue in the future.

This study aimed to assess the lived realities of the COVID-19 pandemic on aspects of glycemic management in the American general public with diabetes at-risk for hypoglycemia. Gaining such an understanding was the intent of this investigation. Respectfully, we see this differently than Dr. Schmitt when he states, "rather than reflect objective conditions". What the authors report on are the participants' conditions, which necessitates an investigation of individuals' self-reported experiences.
We attempted to mitigate the concern raised by Dr. Schmitt by designing a sub-questionnaire that, as unbiasedly as possible, assessed the direct perceived impact of the pandemic situation on aspects of glycemic management. The exact wording of questions/response options has been provided in Appendix A. Leading question stems suggesting either a negative or affirmative position were avoided and a neutral response option (the pandemic has had no impact) was provided. To further address Dr. Schmitt's concern that the overall effect of the pandemic could have influenced participants' assessments of specific items, we have added a statement in the "Study strengths and limitations" section that highlights the self-reported nature of our results (Lines 10-15, Page 22; Lines 2-8, Page 23). Future health services research could look at measuring the effects of the pandemic on the effectiveness/deficiencies of diabetes service delivery.

3. ...The assessment method using the questionnaire needs to be explained in more detail. Further, any approaches are findings supporting psychometric adequacy of the tool well be of interest.

To improve the clarity of the questionnaire assessment method, the authors have revised "Research Design and Methods"; the study's design is now described at the outset of this section (Lines 14-17, Page 8).
Given the descriptive, novel, and time-sensitive nature of this manuscript, psychometric tests were not performed. Instead, the authors have included additional information regarding the rigorous development and testing of all iNPHORM questionnaires ("Survey instruments and variables" section, Lines 3-13, Page 10).

4. I would request a rationale for abstracting the 5-point scale responses to only three categories reflecting negative neutral or positive impact (rather than differentiating moderate versus severe negative impact).

Dr. Schmitt's concern is well-taken. The authors have updated the results using the original 5-point Likert abstraction to provide more detailed descriptions of the impact of the COVID-19 situation on diabetes management.

5. A finding of curiosity is the higher prevalence rate of severe hypoglycaemia in people with T2DM than T1DM - this must be explained and discussed as it might suggest caution against the validity of reported data.

The authors have emended the "Discussion" section to address Dr. Schmitt's queries (Lines 7-19, Page 21).

6. I am providing detailed comments and suggestions as well as minor hints within the commented manuscript file attached.

Thank you. The authors have transcribed Dr. Schmitt's annotations and all associated text within this document. All comments, suggestions, and edits are addressed in detail below.

a. Re: "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."

What is the meaning/information value of these results for the study objective?

Measures of glycemic control (i.e., A1C and hypoglycemia incidence) were included to help describe the participant population.

b. Only 10 cases with COVID = does this limit power regarding specific analyses and research questions possibly?
A sufficient number of COVID-19 cases would be important for measuring the impact of infection on respondents' attitudes/behaviors/circumstances; however, this was not the objective of the current manuscript. Rather, this study aimed to descriptively analyze the crude impact of the COVID-19 situation (e.g., public health restriction, pandemic-induced fears, etc.) on people with diabetes and their diabetes management.

c. Re: A1C values ≥8.1%" (Line 38, Page 4)

What is the rationale for this exact cut-off criterion? Usually expected would be 7.5% according to international guidelines.

This cut-off was selected to align with the Healthcare Effectiveness Data and Information Set (HEDIS), which is a standard recommended target range for evaluation of diabetes control in US-based clinical practice settings/health organizations.

d. Re: "Because of the pandemic, 20-28% of respondents experienced difficulties affording housing, sufficient food to avoid hypoglycemia, and diabetes therapies/testing strips." (Line 48-55, Page 4).

I would suggest reporting the percentages by each variable or aspect rather than across the three aspects. Supports readability and comprehensibility.

The abstract has been emended per Dr. Schmitt's suggestion (Line 15-18, Page 3).

e. How was this causal attribution from the patient perspective operationalised in the questions?

The authors have addressed this question in the "Study strengths and limitations" section (Line 12-15, Page 22).

f. Re: "reported issues retrieving antihyperglycemics from the pharmacy" (Line 55, Page 4)

Of what exact kind were these issues? Were there people who felt unable to retrieve their medications? The result sound a bit exaggerated to me, as if people who were asked whether they possibly experienced any difficulties tended to affirm this (suggestive questioning)? I mean everything in a social world becomes a little bit more complicated with COVID but how serious were these issues really?

The authors did not ask participants to detail the exact nature of the issues they faced regarding their ability/inability to retrieve their medications. A comment to this effect has been added in the "Study strengths and limitations" section (from Lines 3-8, Page 23).
The authors have added Appendix A, which provides the exact wording of our COVID-19 sub-questionnaire, including question stems and response categories. To optimize the granularity of our results, Tables 3 and 4 were also modified to summarize frequencies/percentages for all 5-point (rather than 3-point) abstractions.

g. Re: "...contributed to therapeutic non-adherence (14%), drug rationing (17%), and reduced monitoring (16%)." (Line 6-10, Page 5)

Can the authors provide any insights into the mechanisms of this contribution? If not, based on the data, I would request some thoughts on possible mechanisms by the authors.

The authors have provided comment to Dr. Schmitt's request in the "Discussion" section (Line 23, Page 18 to Lines 1-2, Page 19).

h. Re: lacked social support to help manage their risk (19%) (Line 13, Page 5)

Did this question/item assess "lacking social support" OR "lacking support for managing risks"? In a time of social distancing and lacking generally social support which is badly felt by the people, persons may tend to affirm items requesting lacking support in specific regards, i.e., over-reporting and over-affirmation. How was the exact item wording and would it be possible to support that really negative impact on patients' managment was reflected rather than a general feeling of social support limitations?

Items were meticulously crafted to avoid leading or ambiguous language. The exact wording of questions/response options has been provided in Appendix A. The authors specifically asked participants to report on a 5-point Likert scale the extent to which the COVID-19 situation has made "...Having enough social support to help manage hypoglycemia" "much harder", "somewhat harder", "somewhat easier", or "much easier" (neutral option [no impact] was also included). In this way, the direct effect of the pandemic on participants' hypoglycemia-relevant social support could be assessed, rather than general feelings of

social support limitations. Notwithstanding, volunteer or self-report bias may have influenced the validity of responses; this has been discussed in the “Study strengths and limitations” section of our manuscript (Lines 16-23, Page 22 to Lines 1-6, Page 23).

i. Re: “This is the...most comprehensive investigation” (Line 45, Page 5)

According to which criteria? Who evaluates this?

The authors have removed “most comprehensive” in light of its ambiguity (Line 9, Page 4).

j. Re: “COVID-19 is among the most devastating health crises in American history.” (Line 24, Page 6)

AND worldwide! This reads a bit as if the authors' perspective was restricted to the US only.

The authors have edited this sentence. It now reads, “COVID-19 is among the most devastating health crises in global history.” (Line 1, Page 6)

k. Re: “...the number of confirmed US-cases has surpassed 22.4 million, including over 374,000 deaths.” (Line 31-34, Page 6)

Giving an assessment date for these numbers would be useful as they are continuously changing/increasing.

The authors have updated the number of cases and deaths and included an assessment date.

l. Re: “...poor outcomes. Understanding...”

Double Space

The double space was removed between lines 8 and 9 (Page 6).

m. “...The Centers for Disease Control and Prevention (CDC) has...” (Lines 10-13, Page 8)

Plural vs. ...singular?

The authors have kept “has” as the CDC is a single entity.

n. Re: “BG” (Line 20, Page 8)

Necessary abbrev.? Consider writing out.

The authors have changed “BG” to “blood glucose” throughout the manuscript.

o. Re: “Complex hinterland” (Line 38, Page 9)

Possibly over-general, non-specific expression for explaining study objectives? What are the exact research questions and/or hypotheses?

The authors have modified the “Background” section to state more explicitly the study’s main objective (Lines 3-5, Page 8).

p. Re: “Convenience sampling was used to enroll two waves of participants: Wave 1 and Wave” (Line 49, Page 10)

I suppose explaining that there were two waves would suffice. Readers will then understand the later used terms wave 1 and wave 2.

The authors have edited the “Participants and data collection” section to improve its directness/simplicity, clarity, and concision (Lines 21-23, Page 8 to Lines 1-22, Page 9).

q. Re: “Those in Wave 1 who failed to submit the Month 1 follow-up questionnaire were withdrawn from the study and replaced by new eligible recruits (Wave 2) sampled from a different, randomly selected subset of the panels.” (Line 10, Page 11)

How many participants were withdrawn? How may this affect generalisability?

The authors have edited the “Participants and data collection” section to improve its directness/simplicity, clarity, and concision (Lines 21-23, Page 8 to Lines 1-22, Page 9).

r. Re: “Ipsos Interactive Services (IIS).” (Line 27, Page 8)

Should possibly be explained?

The authors have included a brief description of Ipsos Interactive Services (Lines 9-10, Page 9).

s. Re: “...will complete up to 12 follow-up questionnaires disseminated on a prescheduled, monthly basis.” (Lines 30-35, Page 11)

This reads odd to me. Is it a cross-sectional study as written above or a twelve-month prospective study? What is the idea of the twelve monthly assessments, what is the content?

The current evaluation is a cross-sectional sub-study of the larger iNPHORM panel survey. To improve the clarity of the manuscript, the authors have revised the “Research Design and Methods” section. A designated sub-section on “Study design” is now included at the outset (Lines 14-17, Page 8).

What do the authors mean writing in future tense? Is this a perspective to the next step within this study to be reported later on? Or may this be a sentence taken from a study protocol which was not updated properly (re tenses)?

The authors have revised the “Research Design and Methods” section to ensure it is written in past tense.

t. Re: “Reminders and honorariums are being administered...” (Lines 38-41, Page 11)

Automatic reminders? What did they tell?

The authors have provided further detail regarding the logistics and content of study reminders. (Lines 14-15, Page 9)

What kind of honorariums were offered? Might this affect risks of bias?

Financial incentives were offered in the form of e-gift cards. To mitigate the potential risk of bias, the incentivization scheme was determined in accordance with social standards of reciprocity and Western University's Research Ethics Board; it was outlined in the letter of information. (Lines 15-17, Page 9)

u. Re: "Data collection will occur February-2020 to April-2021." (Line 44, Page 11)

If this is the perspective regarding the ongoing study, how does it relate to the present cross-sectional study (baseline data?)? Will the additional assessments cover themes of COVID too? Is the study purpose hypoglycaemia or other aspects too?

OK, got it. Maybe distinguish between the general study and COVID substudy more clearly above so to get the idea that one needs to understand the longitudinal study in order to explain your present cross-sectional sub-study. This might support readibility.

The authors have edited the "Participants and data collection" section to improve its directness/simplicity, clarity, and concision (Lines 21-23, Page 8 to Lines 1-22, Page 9).

v. Re: "1 form of epidemiologic linkage" (Line 10, Page 13)

What does this mean? example?

For clarity, the authors have changed "linkage" to "exposure". The authors have also provided examples of how epidemiologic exposure was measured (Line 18-19, Page 10).

w. Re: We developed 12 structured, 5-point Likert items to assess how, and to what extent, the COVID-19 situation has disrupted socio-economic, behavioural/clinical, and psychosocial aspects of participants' diabetes management." (Line 20-27, Page 13)

Example item / format?

The authors have provided the exact wording and formatting of the question stems/response options for all 12 structured, 5-point Likert items in Appendix A.

x. Re: "...evaluate whether these aspects were made much harder, somewhat harder, somewhat easier, or much easier by the COVID-19 situation—a neutral option was provided." (Line 34, Page 13)

What was the exact wording of the neutral option? Did this option reflect "no change" compared to before COVID or something different? The neutral option was ordered in the middle between negative and positive options, wasn't it?

Appendix A provides the exact wording and formatting of the question stems/response options. A neutral option (the pandemic situation has had no impact) was ordered in the middle between all negative and positive options. This point has been clarified in text (Line 5-6, Page 11).

I understand the order of response options started with "much harder" and went to "much easier"? This might increase affirmative responding, i.e. increase bias towards exaggerated negative impact. Please comment.

Appendix A provides the exact wording and formatting of the question stems/response options. Items were meticulously crafted to avoid leading question stems that suggested either a negative or affirmative position. A neutral response option (the pandemic has had no impact) was also provided between anchors.

y. Re: “Topics included drug affordability/accessibility, medication-taking behaviour, healthcare consultations, glucose monitoring, and social support”

Provide examples of wording.

The authors have provided the exact wording and formatting of question stems/response options in Appendix A.

z. Re: “COVID-19 cases were calculated as period prevalences”

Which period?

March to April, 2020. This is stated in text (Line 15, Page 10).

aa. Re: “...glycemic management...” (Line 41, Page 14)

How is glycaemic management operationalised based upon the above stated assessed topics (i.e. drug affordability/accessibility, medication-taking behaviour, healthcare
consultations, glucose monitoring, and social support)?

Yes. This has been clarified in the manuscript (Lines 4-5, Page 12).

bb. Re: “...(Likert responses were trichotomized)...” (Line 45, Page 14)

Please provide a rationale for trichotomisation. What were the three categories and what is the meaning? Positive, negative and neutral? What is the idea of this data abstraction, i.e. why not distinguish moderate vs. strong negative/positive impact of COVID on management behaviours and circumstances?

The revised manuscript provides data and interpretation for all 5, rather than 3, response categories.

cc. Re: “No patients were directly involved in designing or conducting this study.” (Line 6, Page 15)

Times New Roman.

Font has been revised (Line 12, Page 12).

dd. Re: “The current evaluation is based on a sub-sample of 667 (type 1 diabetes: 18.0%; type diabetes: 82%) out of 704 Wave 1-FQ2...” (Line 25, Page 15).

What about the non-included 37 persons? Is 704 the full number of wave1-FQ2 participants or were further cases excluded? If yes, why? If yes, how might this affect generalisabilty?

Yes, 704 is the total number of Wave 1 FQ2 responders. The authors have provided a clearer explanation in text (i.e., exclusion due to ineligible medication regimen) (Lines 22-23, Page 12 to line 1, Page 13).

ee. Re: “Sixty-one percent reported ≥ 1 diabetes-related complication...” (Lines 6-10, Page 16)

complication(s)?

This change has been made (Line 11, Page 13).

ff. Re: “The IR and IP...” (Line 17, Page 16)

If word count allows, I'd suggest writing these abbrev.s out for better readibility.

This change has been made.

gg. Re: “However, SH, occurring at an overall rate of 0.7 (95%CI: 0.5-0.96) events PPM, was almost twice as common in people with type 2 versus type 1 diabetes (0.8 [95%CI: 0.5-1.1] versus 0.4 [95%CI: 0.2-0.9] events PPM]). Similarly, the monthly IP of SH, affecting nearly 13% (95%CI: 10.6-15.7) of respondents, was higher in people with type 2 diabetes compared to type 1 diabetes...” (Lines 27-45, Page 16)

This is surprising? T2DM glucose metabolism is more stable compared to T1 due to the remaining insulin secretion and reduced sensibility to insulin in certain doses. How can you explain that people with T2DM reported more severe hypo events? Severe hypoglycaemia tends to be a very rare occurrence even in insulin-treated T2DM usually? Any support for the validity of the data/results?

The authors have emended the “Discussion” section to address Dr. Schmitt’s queries (Lines 7-19, Page 21).

hh. Re: “0.75%, 0.75%, and 8.9%” (Line 52, Page 16)

Since these rates differ between diabetes types, consider referring to this finding too here?

Per Dr. Schmitt’s suggestion, we have included infection prevalences overall as well as by diabetes type (Lines 2-3, Page 14).

ii. Re: “A summary of results are provided in Table 4.” (Line 6, Page 17)

is?

This change has been made (Line 7, Page 14).

jj. Re: I would like to understand the exact wording of the question or statement to be answered here. Please provide the question set in a table or the appendix or provide example items. Does table 4 include the exact item wording as presented to the respondents?

How should adequate food supply for avoiding hypos be defined? Criterion?

The authors have provided the exact wording and formatting of question stems/response options in Appendix A. This measure is intended to capture individuals' self-perceptions to maintain adequate food supply to avoid hypoglycemia.

kk. Re: "Discussion"

I miss a section discussing the unexpected finding of higher rates of sever hypoglycaemic events in T2DM than T1DM! This result might conflict the assumption of validity of the reported data. Please discuss and consider inclusion into the list of study limitations.

The authors have emended the "Discussion" section to address Dr. Schmitt's queries (Lines 7-19, Page 21).

ll. Re: "most comprehensive investigation"

In which meaning was it most comprehensive? I mean it is only one questionnaire (14 items?) assessing possible impact in a very subjective, prone-to-bias way? Please explain.

The authors have removed "most comprehensive" in light of its ambiguity (Line 9, Page 4). See Response #2 to Dr. Schmitt for authors' comments regarding the potential subjectivity of the questionnaire.

mm. "Table 4"

I don't see why the data presented here should be abstracted to three rather than five response categories as reported by the respondents. Results would be more detailed, more specific and more meaningful if distinguishing between moderate ("somewhat") and severe ("much") negative impact of COVID on diabetes and glycaemia management.

The authors have updated the results using the original 5-point Likert abstraction to provide more detailed descriptions of the impact of the COVID-19 situation on diabetes management.

nn. This section should include any information supporting psychometric goodness / reliability / validity of the questionnaire or its items! Did the authors test the tool before applying to this study sample it and what did they find? What can be said in terms of psychometric properties, i.e. objectivity, reliability, validity, about this new tool?

This is the first time the COVID-19 sub-questionnaire has been deployed, capitalizing on the opportunity to collect real-time data and publish on them expediently. Thus, for the purposes of this manuscript, no psychometric testing was performed (this has been stated in the "Study strengths and limitations" section). Rather, the authors focused on descriptively summarizing the results of the iNPHORM COVID-19 sub-questionnaire. To this end, additional information regarding the rigorous development of all iNPHORM questionnaires was included in the "Survey instruments and variables" section (Lines 3-13, Page 10).

VERSION 2 – REVIEW

REVIEWER	Barone, Mark TU Intersectoral Forum to Fight NCDs in Brazil , ForumDCNTs
REVIEW RETURNED	12-Jul-2021

GENERAL COMMENTS	Authors have adequately reviewed all aspects raised by reviewers.

REVIEWER	Schmitt, Andreas Research Institute of the Diabetes Academy Mergentheim (FIDAM), Bad Mergentheim, Germany
REVIEW RETURNED	07-Jul-2021

GENERAL COMMENTS	I thank the authors for being responsive to my comments and for their thorough revisions. I support acceptance and publication. Tank you.