

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Management of diabetes and associated costs in a complex humanitarian setting in the Democratic Republic of Congo: a retrospective cohort study
<b>AUTHORS</b>	Ansbro, Éimhín; Biringanine, Michel; Caleo, Grazia; Prieto-Merino, David; Sadique, Zia; Perel, Pablo; Jobanputra, Kiran; Roberts, Bayard

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Professor Gerardine Doyle Associate Dean, College of Business University College Dublin Ireland
<b>REVIEW RETURNED</b>	15-Apr-2019

<b>GENERAL COMMENTS</b>	<p>Thank you for a very interesting paper. It was enjoyable to read. While the research questions are clearly stated, the question surrounding cost, 'to analyse IDC-OPD programme costs' is not answered sufficiently.</p> <p>The Outcome measures listed in the abstract are not the same as those set out in Table 2. The authors should correct this.</p> <p>The main concern with the paper is the study design and the method concerning the cost analysis, which leads to a concern surrounding the contribution of the cost data to the existing body of knowledge. A very simple approach has been taken to the cost analysis performed and there is little information on how and from which information systems the cost data were collected. The following questions arise:</p> <ul style="list-style-type: none"><li>• Has the cost data of the clinic been audited? This would provide some assurance that all costs incurred have indeed been captured in the information system.</li><li>• Are all patients homogeneous? Could there be a variation in the cost per visit per patient? What would drive this cost variation? For example severity of disease, complications associated with diabetes? No attempt has been made to address such possible variations.</li><li>• What has been the impact of the periods of Suspension (S1 and S2 referred to in Table 1)?</li></ul> <p>The study finds that cost per visit has halved across 2014 and 2015 and that the cost per patient has halved. Aside from the concerns above surrounding the assumption of homogeneity of patients, study design and method, there is insufficient analysis to answer WHY this is the case. More analysis of the 'better' health outcomes reported re blood pressure control and glycaemic control in spite of the suspension periods is needed.</p> <p>Indeed the clinical outcome measures have been very narrowly defined within these two measures. Consideration of patient</p>
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	<p>reported outcome measures and diabetes related complications would have strengthened the paper.</p> <p>The discussion could further develop the potential for technology assisted patient support in this particular context of insecurity.</p> <p>In summary what is the contribution of the cost data and analysis to the existing body of knowledge on the health service cost of diabetes? How does this paper go beyond the state of the art in this context?</p> <p>The conclusion refers to cost being 'lower than chronic HIV care'. However the paper does not offer sufficient analysis of prior studies of HIV care to convince the reader of this conclusion.</p> <p>The authors should consider the above concerns surrounding the cost analysis element of the paper. As this is the weak component of the paper, the authors could consider excluding this research question on cost.</p> <p>Thank you for submitting this paper and I wish you every success improving the paper.</p>
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<b>REVIEWER</b>	Thomas Poder University of Sherbrooke
<b>REVIEW RETURNED</b>	28-Apr-2019

<b>GENERAL COMMENTS</b>	<p>This study adds very little to the existing literature and the design is not appropriate.</p> <p>Lack cost data for 2015/ 2016 and 2016/2017.</p> <p>Comparison with HIV care is inappropriate.</p> <p>No sample size calculation, no hypothesis, statistical plan is weak, do not use the cheers checklist or Drummond...</p>
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<b>REVIEWER</b>	Emily Mendenhall Georgetown University, USA
<b>REVIEW RETURNED</b>	10-Jun-2019

<b>GENERAL COMMENTS</b>	<p>This is a really meaningful paper -- data collected in and communicated from a difficult clinical context with urgent needs for diabetes care. This paper needs some revising in part because it doesn't spell out the need for this paper - why diabetes in crisis situations matter or how stress, underweight, and diabetes are interlinked. Also, some of the clinically-linked conclusions or assumptions overlook the potentially powerful social and personal factors that affect diabetes/insulin fluctuations. The paper would benefit from a bit better framing, justifying context and interventions, and providing the reader with a more powerful narrative about why these projects are so important, why diabetes care is so limited in this context, and why diabetes may be relevant (or becoming more visible in post-conflict contexts that grapple with enormous food and personal insecurities). A few key comments are laid out below.</p> <p>Notes:</p> <ol style="list-style-type: none"> <li>1) You need to provide more information about what the ICD-OPD is/does. What does integrated mean in this context?</li> <li>2) What does a context-baed intervention mean? Please provide more information.</li> <li>3) What type of nutrition and psychosocial support was provided? What were these educational tools?</li> <li>4) More context about DRC, MSF, the clinic, and population are need in the introduction -- it's not clear for readers less familiar with DRC context why such a project/intervention might be different than elsewhere. Please provide a few paragraphs describing context,</li> </ol>
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	<p>including political and social challenges and what is known about the disease profile to date (e.g., little is known about NCDs--making this project even more significant). Given the context, it would be important to provide a mental health / culturally resonant framing of psychological distress (chronic and cute).</p> <p>5) Was any distress / mental health data collected?</p> <p>6) There is an assumption that the 'education' program in the intervention was the most effective and potentially successful; but we don't know anything about the patients' social or personal lives, or the political-social context at the time. It's difficult to actually say the intervention worked without taking these factors into account.</p> <p>7) Can you describe what is secure vs insecure in this setting? We might assume that such patients' experiences with food and basic needs is always 'insecure' -- talking about violence itself is a major factor that should be described in more detail.</p> <p>8) Can you describe more on p11 what patient cost reductions mean? It's very unclear right now - "patient throughput"? Or drug costs? Or cost of other supplies (e.g., latex gloves)? More details would be helpful.</p> <p>9) As I read this paper, it feels as though there is a powerful narrative in and around the intervention and evaluation that is completely missing. Can the authors add more on the political and social challenges surrounding the evaluation? Health programs are never successful or fail in a vacuum.</p> <p>10) What are patient and provider difficulties with insulin management? For instance, many people have no trouble taking pills if they are affordable; people without reliable electricity/fridge/ice box have a very difficult time managing insulin.</p> <p>11) What's the nurse-patient, doctor-patient ratio?</p> <p>12) How does emergency preparedness or emergency response planning relate to diabetes care? More details on this recommendation would be relevant.</p> <p>13) What does patient triage by vulnerability mean? Age? gender? glucose?</p> <p>14) How do emergency kits work for diabetes care? This addition might be helpful as an additional panel for practitioners to apply to their work.</p> <p>15) There is such a strong link between stress/crisis and diabetes -- this should at least be mentioned in this paper. Look at the 2019 Carruth &amp; Mendenhall paper called "Wasting Away" in Social Science and Medicine--it's an in depth look at diabetes and wasting in Somali Region of Ethiopia. There is an important question of what diabetes types mean in this context -- and how people might be underweight with diabetes. Please connect your paper with this paper because there is a ton of overlap and other key points that can be connected but are not drawn out enough in this paper.</p> <p>* Note I am not an expert in evaluations so defer to comment on the statistics.</p>
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<b>REVIEWER</b>	Lauren Carruth American University USA
<b>REVIEW RETURNED</b>	21-Jun-2019

<b>GENERAL COMMENTS</b>	Thank you for this important study. I am sure that collecting data during this time period was challenging, and your efforts are appreciated. Studies of diabetes management and care, over time, during humanitarian emergencies are desperately needed, and this
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helps fill an important gap. This study suggests that patients and clinicians together can manage their diabetes during humanitarian emergencies, even when supply chains are interrupted and patients cannot always access the clinic. Furthermore, this study demonstrates that diabetes care is not exorbitantly expensive, even in austere settings.

One larger comment: This study in the final sections suggests there is a fourth “other” “type” of diabetes, “malnutrition-related” diabetes, and I wanted to know more about this from your data. (Sounds like “tropical diabetes” and other studies of wasting among diabetes patients.) This discussion topic as written is under-explored, given the potential contribution of your study. For example, I was surprised that Table S2 indicated low rates of malnutrition, but then the BMI figures were quite high (a greater number <18.5), which may indicate the malnutrition number is underreported. How was the “malnutrition” figure calculated? Specify the anthropometrics and cut-offs use to classify patients with “malnutrition” – and add, if you meant by this acute malnutrition, SAM, etc.? Also, since you raise this a finding, please address if BMIs improved for people <18.5 with “control” of blood glucose. What if weight/BMI was another way of measuring or classifying “control” for diabetes patients struggling to gain weight, with BMIs <18.5 upon presentation?

What you are suggesting, I think, is there is distinct “type” of diabetes that is common in humanitarian emergencies. This matches what I have seen, and so I want you to take this idea up more clearly, with more specific use of data, in the findings and discussion section of the paper.

A few minor suggestions for revisions:

The statement/finding that “Visit numbers and visit intervals increased on introduction of IDC-OPD” (Lines 44) is counterintuitive. I would have expected these numbers to move together in opposite directions, i.e. as numbers of visits decreased, visit intervals increased. Please explain more clearly what you mean, and state clearly this is counterintuitive or surprising early on. It is confusing as stated in the abstract, and even when first mentioned in the main body of the article (Lines 153-155, 189-194). This latter paragraph needs clarification, more careful use of language to explain what is going on to the best of your knowledge. This is important, too: I think most people thinking about how to best design diabetes care programs in emergencies need to know how patients’ behaviors (visiting) and outcomes respond to increases in insecurity.

Given recent attacks in North Kivu on clinical facilities, could you address if this kind of insecurity as an issue during your study?

The wording of the abstract could be improved to provide greater clarity in Line 47. The phrase “achieve control” is not obviously about blood glucose. Please clarify and specify what this means

The word Line 50 “throughput” is not appropriate in my experience. Perhaps this is jargon you use, but it could use clarification.

Line 110 main body text: it would help to state the major finding(s) of the qualitative portion of the study, especially if this helps elucidate points made in the discussion.

	Line 166 needs re-wording to clarify.
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## VERSION 1 – AUTHOR RESPONSE

Reviewer One (Professor Geraldine Doyle):

We thank reviewer one for her helpful comments. Please note that we have had to keep some of the additions quite brief to remain within the 4000 word limit.

The Outcome measures listed in the abstract are not the same as those set out in Table 2. The authors should correct this.

o We have reorganised Table 2 and aligned it with the objectives in the abstract, background, methods and results text.

The main concern with the paper is the study design and the method concerning the cost analysis, which leads to a concern surrounding the contribution of the cost data to the existing body of knowledge. A very simple approach has been taken to the cost analysis performed and there is little information on how and from which information systems the cost data were collected. The following questions arise:

o We acknowledge that we have taken a simple, descriptive approach to the costing study. This was essentially operational research, undertaken in a chronic conflict setting that was designed to use routine, aggregate data and to cause minimal disruption to the programme and burden to the staff. We address the reviewers' specific concerns on costing below.

Has the cost data of the clinic been audited? This would provide some assurance that all costs incurred have indeed been captured in the information system.

o We could not confirm whether an external audit had taken place, but we are confident in the quality of these data. MSF utilise robust budgeting, human resources, supply and logistics tools and these are overseen by strong in-country and international management teams. We have noted this in the manuscript (lines 391- 393).

Are all patients homogeneous? Could there be a variation in the cost per visit per patient? What would drive this cost variation? For example severity of disease, complications associated with diabetes? No attempt has been made to address such possible variations

o We acknowledge heterogeneity among patients in the study cohort and that there may be variation in the cost per visit per person, depending on factors such as testing undertaken, severity of complications and/or on specific medications prescribed (insulin and syringes generally costing more than oral hypoglycaemic drugs). However, our cost data were available in aggregate form only and, therefore, we do not have patient-level cost data to explore inter-patient variations. For example, drug consumption is monitored at clinic- rather than at patient-level. To tease out the heterogeneity between patients would require a prospective study, collecting non-routine data. We have added this point to the Limitations section of our paper and to the suggestions for future research as follows: "We also suggest that the cost-effectiveness of different models of diabetes care, including use of technology-facilitated remote support, and patient level costing studies from both provider and patient perspectives should be undertaken, exploring patient heterogeneity and direct and indirect patient costs." (Lines 386 - 389).

What has been the impact of the periods of Suspension (S1 and S2 referred to in Table 1)? The study finds that cost per visit has halved across 2014 and 2015 and that the cost per patient has halved. Aside from the concerns above surrounding the assumption of homogeneity of patients, study design and method, there is insufficient analysis to answer WHY this is the case. More analysis of the 'better' health outcomes reported re blood pressure control and glycaemic control in spite of the suspension periods is needed. Indeed the clinical outcome measures have been very narrowly defined within these two measures. Consideration of patient reported outcome measures and diabetes related

complications would have strengthened the paper.

o We had not intended to examine the costs impact of the periods of suspension when designing the study. The study sought to describe programme costs for 2014 and 2015 reflecting the costs pre- and post-introduction of the formal IDC-OPD service. Cost data were collected in December 2015 and, thus, did not capture the periods of suspension, which took place in early 2016. We have clarified this in the costing methods section as follows: "...total cost, cost per visit and cost per patient were reported in Euro (€) for 2014 before formal implementation of the IDC-OPD programme and 2015 during its full implementation" (lines 229-231).

o In response to the point that there is insufficient analysis to answer why the cost per visit and cost per patient were halved between 2014 and 2015, we have now added additional results and explanation in the costing results section (line 277- 283) as follows: "While medication costs increased in 2015 relative to 2014, staff costs remained the same, and total costs decreased, largely driven by reduced excess consumption of latex gloves after it was identified during the IDP-OPD training sessions. The total number of patients and number of visits increased significantly from 2014 to 2015, rising from 77 and 626 to 144 and 1033, respectively. Thus, the cost per-patient per-year dropped from €417 to €183 and the cost per-visit was halved from €51 to €24. This was due to the combined effect of higher patient numbers, greater total number of visits and lower supply costs in 2015 compared to 2014 (Supplement SM3)." The significant overuse of latex gloves and large drop in usage following the IDC-OPD training sessions was double checked and verified to be a valid finding.

o In response to the request for more analysis of the 'better' health outcomes reported and the narrowness of the clinical outcome measures, we used intermediate clinical outcomes (control of blood pressure and blood glucose) as our outcome measures since these were collected routinely at each patient visit. Diabetes complications were recorded on enrolment and at six-monthly medical reviews. The short follow-up period and small cohort number make interpretation of any change in rate or severity of complications difficult. A longer follow up period, and ideally comparison with a control group who received similar treatment but in an area that was not subject to outbreaks of violence may have captured the impact of related treatment interruptions on rates or severity of diabetes complications. We agree that the inclusion of patient-reported outcome measures would have strengthened our study and this is something we could include in prospective research studies, which include the capacity to collect non-routine study data. We have now added these points in our strengths and limitations and further research sections.

o In response to the reviewer's suggestion, we have added additional information on how and from which information systems the cost data were collected as follows (lines 217- 233): "Information related to the nature, location and mode of delivery of the NCD services was collected during a field visit in late 2015 by the study team and was supplemented by informal interviews with clinical and administrative staff. A data analysis tool was designed to collate and calculate the relevant financial costs for the study period 2014 -2015, by cost category from routine programme documents including budget, drug consumption monitoring, logistics/supply tools, clinic records and programme reports."

o We have also adjusted our third objective to better reflect the analysis undertaken: "to describe incremental programme costs".

The discussion could further develop the potential for technology assisted patient support in this particular context of insecurity.

o We have developed the discussion in relation to the potential for technology-assisted patient support in this insecure context as follows (lines 313 - 316): "Technology could facilitate continued patient treatment support when access to facilities is impossible e.g. via mobile phone SMS messaging or decentralisation of care to community-based health workers furnished with clinical decision support tools or support via telemedicine."

In summary what is the contribution of the cost data and analysis to the existing body of knowledge on the health service cost of diabetes? How does this paper go beyond the state of the art in this context?

o We argue that, since there are very few studies examining the costs of providing non communicable disease care in low-and middle-income settings and fewer still from complex conflict settings, the

study makes a valuable addition to the literature. It provides new costing information for humanitarian actors to support the initiation or adaptation of specific NCD programmes and may potentially support scale up of similar services in DRC (and other conflict-affected settings) (lines 357 - 359).

The conclusion refers to cost being 'lower than chronic HIV care'. However the paper does not offer sufficient analysis of prior studies of HIV care to convince the reader of this conclusion.

o We have added additional detail to the discussion and explained our reasoning in making this comparison. In brief, that there are no other costing studies to compare the costs of delivering diabetes care in a humanitarian setting and we have chosen to focus on HIV as the main lifelong condition that humanitarian actors have treated and that has adequate published cost data available for comparison. (Lines 345 -348).

Reviewer Two (Thomas Poder):

We thank reviewer two for his review.

This study adds very little to the existing literature and the design is not appropriate.

o As discussed in the paper, we argue that since there is a dearth of published data on the costs of delivering noncommunicable disease care in low-and middle-income countries, and still less from humanitarian settings, this study makes a valuable contribution to the existing literature (lines 342 - 343). Other reviewers have also recognised the dearth of literature on this topic.

o We suggest that the design allowed us to provide a retrospective, descriptive costing analysis based on existing data while imposing minimal burden on the programme staff.

Lack cost data for 2015/ 2016 and 2016/2017

o We had not intended to collect cost data for 2015/2016 or for 2016/2017 and have clarified this in the text (lines 229 - 231). We have also noted that a prospective study examining the impact of periods of insecurity on cost would be valuable and have suggested this in our "further research" section.

Comparison with HIV care is inappropriate

o We have included additional detail to the discussion to explain our rationale for comparing costs with those of HIV care (lines 345 - 346). We believe this is an appropriate comparison since there are few other cost data available in the literature to appropriately compare the costs of delivery of NCD care in humanitarian settings, and we have chosen to focus on HIV as the main lifelong condition that humanitarian actors have treated and that has adequate published cost data available for comparison. This comparison will also have meaning for decision makers within humanitarian organisations (as confirmed to us by MSF staff – one of the largest global humanitarian organisations).

No sample size calculation, no hypothesis, statistical plan is weak, do not use the cheers checklist or Drummond...

o We sought to retrospectively describe the incremental costs of initiating this programme within a pre-existing service from a provider perspective, using routine programmatic data, rather than to measure cost effectiveness. Therefore, a sample size calculation or hypothesis was not required.

o With regards to the use of Cheers or Drummond checklists, we have added additional detail to the costing methods, results and discussion.

o We consider the statistical plan appropriate given that we were using routine clinical data from a highly volatile, chronic conflict setting. We have now added to the text as follows (lines 156 - 158): "It has been acknowledged that traditional experimental and evaluation methods are unfeasible, inappropriate or even unethical to apply in humanitarian settings. Therefore, we have used a pragmatic approach to utilising programmatic data, with an open cohort design." Thus, any patient who attended in a given month contributed data, irrespective of whether their attendance/ treatment was ever interrupted. We also took a programmatic approach as this is useful for programme managers and planners. For future studies, we would suggest that patient-level data and follow up are undertaken and we have added these points to the study 'strengths/limitation's' and 'future studies' sections, as follows: "Each patient who attended in a given month contributed data, irrespective of whether they ever experienced a treatment interruption." (Lines 355 - 357)

“We recommend that future prospective studies should explore per-patient outcomes (as well as exploring programme-level outcomes as done in this study)”. (Lines 381 - 383)

Reviewer Three (Emily Mendenhall):

We thank reviewer one for her kind comments.

This is a really meaningful paper -- data collected in and communicated from a difficult clinical context with urgent needs for diabetes care. This paper needs some revising in part because it doesn't spell out the need for this paper - why diabetes in crisis situations matter or how stress, underweight, and diabetes are interlinked. Also, some of the clinically-linked conclusions or assumptions overlook the potentially powerful social and personal factors that affect diabetes/insulin fluctuations. The paper would benefit from a bit better framing, justifying context and interventions, and providing the reader with a more powerful narrative about why these projects are so important, why diabetes care is so limited in this context, and why diabetes may be relevant (or becoming more visible in post-conflict contexts that grapple with enormous food and personal insecurities). A few key comments are laid out below.

o We appreciate the comments above and have addressed them through the responses below.

Please note that we have had to keep some of the additions to the manuscript quite brief because of the 4000-word limit.

o With regards to the above point about social and personal factors that may affect diabetes/insulin fluctuations, the related qualitative paper by Murphy et al. discusses some of these, and is referenced several times in the text, (e.g. in the background lines 126 - 129: “The psychosocial aspects of patients and providers managing diabetes are discussed in a related paper, with major themes from the patient perspective including the difficulty adhering to the recommended diet and barriers to clinic access during outbreaks of violence....”). The qualitative interview data, however, were not linked to individual patient clinical outcomes and so we cannot draw an association between social and personal factors and the intermediate clinical outcomes we report on. We have recommended in our ‘further research’ section that future prospective studies include patient-derived outcome measures: “We suggest including a control group, collection of additional outcome variables, such as complication rates and patient-reported outcomes e.g. related to quality-of-life, including functionality and mental health, and exploration of the impact of psychosocial stressors and treatment interruption on clinical outcomes.” (Lines 383 - 386)

1) You need to provide more information about what the IDC-OPD is/does. What does integrated mean in this context?

o We have provided additional information on the IDC-OPD programme in the background section (lines 114 - 138) and spelled out what was meant by “integrated” in the text (line 114 - 115) as follows: “The IDC-OPD was integrated at the clinical level into usual outpatient activities, with pre-existing staff trained to provide this additional service.”

2) What does a context-based intervention mean? Please provide more information.

3) What type of nutrition and psychosocial support was provided? What were these educational tools?

o We have moved the term “context-adapted” and given further explanation on what was meant by this, including the nutrition and psychosocial support provided (lines 124 - 126): “The programme included context-adapted dietary advice (accounting for locally available and affordable foods and customs) and psychosocial support, including clinician-moderated peer support group and involvement of family or friends as treatment supporters.”

o We specified the education tools provided as follows (lines 132-133): “Patient educational tools (disease and diet education leaflets) ...”

4) More context about DRC, MSF, the clinic, and population are need in the introduction -- it's not clear for readers less familiar with DRC context why such a project/intervention might be different than



elsewhere. Please provide a few paragraphs describing context, including political and social challenges and what is known about the disease profile to date (e.g., little is known about NCDs--making this project even more significant). Given the context, it would be important to provide a mental health / culturally resonant framing of psychological distress (chronic and acute).

o We have provided more context about DRC, MSF, the clinic, and population, political and social challenges and what is known about the disease profile to date in the Background section. We have also included reference to the potential importance of psychological distress in the onset and management of diabetes in this setting in both the introduction and the discussion. However, we believe our data do not warrant us drawing associations between psychological distress and its impact on intermediate clinical outcomes, particularly as we do not have linked data on these phenomena and have not been able to perform a per-patient analysis of outcomes. We mention the need for further studies researching this potential link in the 'future research' section.

o In response to the reviewer's suggestion, we have added two paragraphs to the background section, spelling out the need for the paper more clearly by discussing the chronic conflict context in the DRC, the impact on the health system and the current knowledge base or lack thereof regarding diabetes burden and management in the DRC and in humanitarian settings more broadly. We have also referenced current evidence on the potential links between malnutrition and chronic stress to the onset of diabetes (lines 95 - 97).

5) Was any distress / mental health data collected?

o No data on distress or mental health were collected, other than those collected in the seven patient interviews performed by our colleague, Adrianna Murphy, in her related paper. These data, however, were not linked to clinical patient outcomes.

6) There is an assumption that the 'education' program in the intervention was the most effective and potentially successful; but we don't know anything about the patients' social or personal lives, or the political-social context at the time. It's difficult to actually say the intervention worked without taking these factors into account.

o We agree that we have assumed that the improvements that occurred between T1 and T2 were due to the systematisation and rationalisation of the diabetes service that occurred with introduction of locally-adapted clinical guidelines and training provided to the nurses and doctors involved in delivery of the programme. To be able to account for the effect of the prevailing socio-political circumstances, ideally, we would have had a control group of diabetic patients, who experienced the same socio-political circumstances but who weren't exposed to the IDC-OPD service. We have acknowledged this in our discussion. Additionally, our statistical analysis took a programmatic perspective, rather than a per-patient perspective.

7) Can you describe what is secure vs insecure in this setting? We might assume that such patients' experiences with food and basic needs is always 'insecure' -- talking about violence itself is a major factor that should be described in more detail.

o We have added more detail on the armed and structural violence, periods of insecurity etc. in the Background section.

8) Can you describe more on p11 what patient cost reductions mean? It's very unclear right now - "patient throughput"? Or drug costs? Or cost of other supplies (e.g., latex gloves)? More details would be helpful.

o We believe the reviewer was referring to the "cost per-patient per-year" reported in the costing results section: "Costs of providing diabetes care" on page 11 of the original manuscript. The cost per patient per year is used to convey total programme costs from the provider perspective in a unit that may be comparable between different programmes. In this case, the cost per patient per year is calculated by summing the total annual costs from the provider perspective (supplies, salaries, drugs etc.) and dividing this total by the total number of patients treated that year. We have added more detail to the costing methods, results and discussion to clarify.

9) As I read this paper, it feels as though there is a powerful narrative in and around the intervention and evaluation that is completely missing. Can the authors add more on the political and social challenges surrounding the evaluation? Health programs are never successful or fail in a vacuum.  
o We have now added text on the difficulties of implementing an intervention and evaluation in an unstable conflict setting in the Background section (lines 139 – 144).

10) What are patient and provider difficulties with insulin management? For instance, many people have no trouble taking pills if they are affordable; people without reliable electricity/fridge/ice box have a very difficult time managing insulin.

o We have elaborated on the potential patient and provider difficulties with insulin management in the Background section, lines 134 - 138, (“Insulin doses were adjusted using single fasting capillary blood glucose readings and patients’ reported symptoms of hypo- or hyperglycaemia in the absence of home glucose monitoring. Insulin-dependent patients were prescribed human insulin, delivered via needle and syringe, and advised to store this at home in a clay pot (since refrigeration was unavailable), as has previously been recommended as a safe alternative in similar contexts.”).

o In lines 318 - 324 of the Discussion section, we expanded on this point as follows: “Adherence to daily insulin injections is difficult anywhere; in Mweso...barriers to accessing insulin and the fact that the recommended diabetes diet is often unavailable, unaffordable and burdensome for families, may additionally contribute to poor adherence.[26] In this programme, clinicians adjusted insulin doses, based on a single fasting glucose reading taken in clinic and on patients’ reported symptoms in the absence of home glucose monitoring and, therefore, dose adjustment was cautious and treatment targets were conservative.”

o We have, though, removed the sentence around insulin challenges from the opening paragraph of the discussion since it is not based directly on the data analysed for this paper.

11) What's the nurse-patient, doctor-patient ratio?

o The nurse to patient ratio was 1:122 and doctor to patient ratio was 1:243. This can now be inferred from the information added to the costing methods (line 223 - 226): “For salary costs, we included the incremental costs of an MSF-employed medical doctor and nurse and an MOH-employed nurse (with salary supplement paid by MSF) dedicating one day per month...”

12) How does emergency preparedness or emergency response planning relate to diabetes care? More details on this recommendation would be relevant.

o We have now elaborated on the recommendation that diabetes programmes in conflict settings engage in emergency preparedness or emergency response planning and specifically how it relates to diabetes care in the second paragraph of the Discussion.

13) What does patient triage by vulnerability mean? Age? gender? glucose?

o The phrase “patient triage by vulnerability” has been elaborated as follows: “(e.g. prioritising insulin-dependent diabetic patients, those with established complications and/or living far from the facility)” (line 308 - 309)

14) How do emergency kits work for diabetes care? This addition might be helpful as an additional panel for practitioners to apply to their work.

o We have elaborated what might be contained in a diabetes emergency kit in the Discussion section (line 310 - 311): “(including several months’ supply of regular medications, such as insulin, delivery devices and guidance as appropriate.)”

15) There is such a strong link between stress/crisis and diabetes -- this should at least be mentioned in this paper. Look at the 2019 Carruth & Mendenhall paper called "Wasting Away" in Social Science and Medicine--it's an in depth look at diabetes and wasting in Somali Region of Ethiopia. There is an important question of what diabetes types mean in this context -- and how people might be underweight with diabetes. Please connect your paper with this paper because there is a ton of overlap and other key points that can be connected but are not drawn out enough in this paper.

o We appreciate being referred to this very relevant paper and have now referenced it and strengthened the point about the potential link between psychosocial stress and /or underweight and diabetes. However, we do not feel our data warrant a more explicit association being made. Rather, we suggest that future studies should address this issue, e.g. the effect of individual stress and/or treatment interruption on glucose control and on complications (line 383 - 386): “We suggest including a control group, collection of additional outcome variables, such as complication rates and patient-reported outcomes e.g. related to quality-of-life, including functionality and mental health, and exploration of the impact of psychosocial stressors and treatment interruption on clinical outcomes”.

Reviewer Four (Lauren Carruth):

Thank you for this important study. I am sure that collecting data during this time period was challenging, and your efforts are appreciated. Studies of diabetes management and care, over time, during humanitarian emergencies are desperately needed, and this helps fill an important gap. This study suggests that patients and clinicians together can manage their diabetes during humanitarian emergencies, even when supply chains are interrupted and patients cannot always access the clinic. Furthermore, this study demonstrates that diabetes care is not exorbitantly expensive, even in austere settings.

o We thank reviewer one for her review and kind comments. Please note that we have had to keep some of the additions quite brief to remain within the 4000 word limit.

One larger comment: This study in the final sections suggests there is a fourth “other” “type” of diabetes, “malnutrition-related” diabetes, and I wanted to know more about this from your data. (Sounds like “tropical diabetes” and other studies of wasting among diabetes patients.) This discussion topic as written is under-explored, given the potential contribution of your study. For example, I was surprised that Table S2 indicated low rates of malnutrition, but then the BMI figures were quite high (a greater number <18.5), which may indicate the malnutrition number is underreported. How was the “malnutrition” figure calculated? Specify the anthropometrics and cut-offs use to classify patients with “malnutrition” – and add, if you meant by this acute malnutrition, SAM, etc.? Also, since you raise this a finding, please address if BMIs improved for people <18.5 with “control” of blood glucose. What if weight/BMI was another way of measuring or classifying “control” for diabetes patients struggling to gain weight, with BMIs <18.5 upon presentation? What you are suggesting, I think, is there is distinct “type” of diabetes that is common in humanitarian emergencies. This matches what I have seen, and so I want you to take this idea up more clearly, with more specific use of data, in the findings and discussion section of the paper.

o With regards to atypical forms of diabetes discussed in the literature and WHO guidelines, we have added additional details. We noted from our results, that there was a relatively high proportion of “lean” diabetics i.e. those with normal or underweight BMI (Supplementary Table SM3). This is in keeping with what we have seen in the literature, although our own study was not designed to explore the differing aetiology and clinical course of diabetes in this setting. We have recommended further studies would do this (lines 332 - 334).

o Regarding the reviewer’s comments on Table S2, to clarify that “malnutrition” referred to self-reported childhood malnutrition we have now included this in the methods/data section, lines 180 - 181, as follows: “... and self-reported history of childhood malnutrition and/or tuberculosis were recorded.” In asking patients, we did not specify the category of malnutrition (severe/moderate acute, chronic).

o The BMI reflected the enrolment weight/height ratio. However, since our objectives were to explore the changes in intermediate clinical outcomes from a programmatic perspective and BMI was only recorded at baseline and on 6-monthly reviews, we do not feel that we can adequately comment on change in BMI. As we have now elaborated on in the Discussion section, based on current evidence, it is unclear whether past or current malnutrition is causative or related to hyperglycaemia or pancreatic insufficiency. We suggest that further studies to elucidate diabetes phenotypes is needed to shed further light on these ‘atypical’ forms of diabetes and the influence of current or past

malnutrition (lines 332 - 334).

The statement/finding that “Visit numbers and visit intervals increased on introduction of IDC-OPD” (Lines 44) is counterintuitive. I would have expected these numbers to move together in opposite directions, i.e. as numbers of visits decreased, visit intervals increased. Please explain more clearly what you mean, and state clearly this is counterintuitive or surprising early on. It is confusing as stated in the abstract, and even when first mentioned in the main body of the article (Lines 153-155, 189-194). This latter paragraph needs clarification, more careful use of language to explain what is going on to the best of your knowledge. This is important, too: I think most people thinking about how to best design diabetes care programs in emergencies need to know how patients’ behaviors (visiting) and outcomes respond to increases in insecurity.

o Following the reviewers’ suggestion, we have clarified the statement that “Visit numbers and visit intervals increased on introduction of IDC-OPD” (Lines 45), as follows: “On introduction of IDC-OPD, glucose control improved and patient volume and visit interval increased. During insecurity, clinical control rates were initially maintained by a nurse-provided, scaled-back service, while patient volume and visit interval decreased.”

Given recent attacks in North Kivu on clinical facilities, could you address if this kind of insecurity as an issue during your study?

o We have also expanded in the Background section on what we defined as insecurity in this setting and during our study period (lines 139 - 144). A An armed robbery took place at the MSF offices in Mweso in early 2015 and two staff were abducted in early 2016. Outbreaks of armed violence directed at the population/communications/roads in the community prevented patients from accessing the service and prevented supplies from being delivered from Goma to the facility. Furthermore, the international MSF staff were evacuated from the service, meaning there was reduced clinical supervision of the service for a period of several months in early 2016.

The wording of the abstract could be improved to provide greater clarity in Line 47. The phrase “achieve control” is not obviously about blood glucose. Please clarify and specify what this means

o We have significantly revised the abstract, including the phrase in Line 44 “achieve control”, as follows: “On introduction of IDC-OPD, glucose control improved and patient volume and visit interval increased. During insecurity, clinical control rates were initially maintained...”. Clinical outcomes were earlier defined as glycaemic and blood pressure control.

The word Line 50 “throughput” is not appropriate in my experience. Perhaps this is jargon you use, but it could use clarification.

o The word in former Line 50 “throughput” is used in economic analyses but we have changed it to “patient numbers” for greater clarity in response to the reviewer’s comment.

Line 110 main body text: it would help to state the major finding(s) of the qualitative portion of the study, especially if this helps elucidate points made in the discussion.

o We have added the major finding(s) of the qualitative portion of the study in the background section, as follows, lines 127 - 129: “...with major themes from the patient perspective including the difficulty adhering to the recommended diet and barriers to clinic access during outbreaks of violence.”

Line 166 needs re-wording to clarify.

o We have clarified Line 166 (now Line 211), as follows: “Our main analysis used only complete data; records with missing data were excluded.”

## VERSION 2 – REVIEW

<b>REVIEWER</b>	Professor Gerardine Doyle University College Dublin Ireland
<b>REVIEW RETURNED</b>	25-Sep-2019
<b>GENERAL COMMENTS</b>	Thank you for a very interesting and much improved paper. This is an important paper in highlighting the vulnerability of patients with NCD in conflicted affected areas with some clear recommendations

	<p>to improve the quality of life and patient outcomes of patients with diabetes during periods of conflict.</p> <p>The main concerns surrounding the study design and cost analysis have now been addressed in this version of the paper. The contribution of the study to the existing body of knowledge is now more clearly articulated.</p> <p>While a simple approach has been taken to the cost data collection and analysis, the limitations of the setting are recognized and the overall impact of cost within a changing complex humanitarian setting are revealed by the study (the main cost drivers being supply and medication costs).</p> <p>The discussion has now been developed with clear recommendations for practice where the supply chain is vulnerable to disruption. The potential role of technology assisted patient support has now been addressed.</p> <p>One further recommendation that the authors should include in the discussion section is the role and potential power of enhancing the health literacy of this particular patient population and the role of diabetes self management education which can improve health outcomes during periods of conflict.</p> <p>Thank you for resubmitting this paper which is now much improved and suitable for publication with one minor change (reference to the power of enhancing health literacy in this particular patient population).</p> <p>Note: There is a typing error in Table 1, first variable – ‘were’ should read ‘where’.</p>
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<b>REVIEWER</b>	Lauren Carruth American University USA
<b>REVIEW RETURNED</b>	03-Sep-2019

<b>GENERAL COMMENTS</b>	<p>This is an important and timely study. Studies of NCD and diabetes management and care, over time, during humanitarian emergencies are desperately needed, and this helps fill an important gap in the global medical practice literature. This study suggests that patients and clinicians together can manage their diabetes during humanitarian emergencies, even when supply chains are interrupted and patients cannot always access the clinic. Furthermore, this study demonstrates that diabetes care is not exorbitantly expensive, even in austere settings. It is my hope that this study proves the need for more and better NCD care initiatives as part of humanitarian interventions.</p> <p>In this revised paper, the authors adequately addressed my critiques and questions, as much as their data allows.</p> <p>The additional details and discussion about the methods and research design help me understand the data and limitations, and are appreciated.</p> <p>The details about the security setting in DRC during the study period</p>
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	<p>are important, and appreciated.</p> <p>The recommendations for other clinical operations and medical providers working in insecure settings are also well-written and appreciated. The details about what worked, and what did not contribute to improvements, are well taken.</p> <p>I look forward to teaching with this article.</p>
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**VERSION 2 – AUTHOR RESPONSE**

Reviewer One (Professor Geraldine Doyle):

We thank reviewer one for her further review and helpful comments and her additional suggestion below.

"One further recommendation that the authors should include in the discussion section is the role and potential power of enhancing the health literacy of this particular patient population and the role of diabetes self management education which can improve health outcomes during periods of conflict."

In response, we have expanded on the issues of enhancing health literacy and on the role of self-management education in the discussion. We have had to keep this brief in order to stay within the 4000-word limit. The addition is as follows (lines 335-340):

“Preparation could include: triaging patients by vulnerability (e.g. prioritising insulin-dependent diabetic patients, those with established complications and/or living far from the facility); enhancing patients’ health literacy and self-management education and provision of patient-held personal treatment plans and emergency kits (including several months’ supply of medications, such as insulin, delivery devices and guidance as appropriate) to facilitate self-care during insecure periods...”

There is a typing error in Table 1, first variable – ‘were’ should read ‘where’.

Thank you also for pointing out this error, which we noted in Table 2, and have revised accordingly.

Reviewer Four (Lauren Carruth):

We thank reviewer four for her further review of the paper and her positive comments.

We would like to mention to the editors that it has come to our attention during the final review of the paper that there was a minor error in the cost calculations, which we have now remediated. This resulted from initially costing the diabetes clinics as a monthly event, when they actually took place weekly. Most costs remained the same but staff costs increased by a factor of four. This resulted in minor overall changes to our costing figures (see page 13 and Table 3) but did not in any way alter our main message, which still stands.

Additionally, we have made minor changes throughout to bring the total word count below the 4000 limit after incorporating the reviewers’ comments and to improve the flow.