

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Fostering Humanism: A Mixed Method Evaluation of the Footprints Project in Critical Care
<b>AUTHORS</b>	Hoad, Neala; Swinton, Marilyn; Takaoka, Alyson; Tam, Benjamin; Shears, Melissa; Waugh, Lily; Toledo, Feli; Clarke, France J; Duan, Erick Huaileigh; Soth, Mark; Cook, Deborah J

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Tayana Soukup Centre for Implementation Science King's College London London, UK
<b>REVIEW RETURNED</b>	21-Mar-2019

<b>GENERAL COMMENTS</b>	<p>This is a very interesting and important piece of work, and I commend the authors for their efforts. There are however certain sections of the paper that could be improved; these are outlined below.</p> <ol style="list-style-type: none"><li>1. Methods section needs to be described in a bit more detail (to allow the study to be repeated in other sites.). You may want to use the standard subsections ie study design, participants, settings, materials, and statistical analysis and organise the existing information and add information if necessary within this framework.</li><li>2. Research ethics needs reference number please.</li><li>3. The outcomes are stated (uptake, sustainability and influence) but would benefit from being further defined within methods.</li><li>4. Statistics/quantitative data needs some descriptive statistics to enhance clarity. Also, can you please mark in the manuscript where you think your tables will go (e.g. Table 1 about here), this will help the reviewers understand the results a bit better and what is being reported.</li><li>5. Re qualitative results, I would like to encourage the authors to explore ways of presenting these data with a bit more clarity (if possible). Also, please address typos, for e.g. the second quote on page 10 does not have quotation marks.</li><li>6. Study limitations are missing from the discussion – please add a subsection titled 'Limitations' and discuss any limitations that exist and that you have encountered that can help readers interpret your results with more accuracy. I would also add a subsection 'further research' reflecting on the direction of your research.</li></ol>
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<b>REVIEWER</b>	Joanne Lewis University Technology Sydney, Australia
<b>REVIEW RETURNED</b>	01-Apr-2019

<b>GENERAL COMMENTS</b>	<p>This paper addresses an area of increasing importance and focus in healthcare-move towards compassion and personhood. My main concerns are about qualitative analysis and/or reporting. Firstly I am unsure due to the labelling which are the themes and subthemes from the analysis. I am assuming from the headings and subheadings that there are two main themes-Uptake and sustainability and Influence. The others (underlined) are subthemes?</p> <p>There is limited discussion to contextualise the verbatim quotes. They need further introduction to illustrate the findings and further discussion to outline the similarities and differences</p>
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<b>REVIEWER</b>	Souraya Sidani Research Chair and Professor, Ryerson University. Canada.
<b>REVIEW RETURNED</b>	01-May-2019

<b>GENERAL COMMENTS</b>	<p>The authors report on a mixed method study aimed to examine the uptake, sustainability and influence of the Footprints project, which appears to consist of a written tool (form) and a communication board (whiteboard).</p> <p>The argument for the study could be strengthened by 1) defining humanism upfront and explaining how this principle or approach to care is different or comparable to patient-centered or person-centered care (which is known to consist of holistic, individualistic and responsive care); and 2) explaining the importance or potential benefits to ICU patients and clinicians of the humanistic approach to care and synthesizing relevant evidence.</p> <p>The intervention is briefly introduced, making it difficult for readers (unfamiliar with this term or approach to care) to appreciate the potential value of the intervention. It would be helpful to describe the two components of the intervention and to delineate their mechanism of action or theory of change, as is recommended for the description of complex interventions.</p> <p>The objectives may be appropriate but it would be useful to define uptake, sustainability and influence – in particular, please specify the indicators and time frame that distinguish uptake from sustainability and clarify what ‘influences’ are of interest, early in the manuscript.</p> <p>What were the challenges encountered during the pilot test? Were any of these related to the feasibility and acceptability of the intervention?</p> <p>What is the rationale or reason for introducing 10 implementation strategies? What were these strategies?</p> <p>Overall, the context of the intervention and its implementation is not clearly described; points presented about prior work are not clear, making it hard to understand the situation in which the intervention is implemented and evaluated.</p> <p>The overall design of the study is not explicitly described. It seems the study was done in one ICU and data were collected at 3 points in time, using mixed methods to examine uptake and sustainability, and qualitative methods to examine ‘influences’ – this appears to be a case-study design with repeated measure and mixed methods – such a design is appropriate for implementation research.</p>
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	<p>Please, provide the time frame surrounding the implementation of the intervention, for conducting the audit – that is, was audit B done within 1 month following full implementation, and audit C within 9 months of audit B or of implementation of the intervention? Also, please justify the time frame- that is, are these time points appropriate / adequate to determine uptake and sustainability? Based on what theoretical expectation or empirical evidence?</p> <p>For the quantitative component:</p> <ul style="list-style-type: none"> <li>- Please provide more details about the specific variables for which data were collected with the audit.</li> <li>- Justify the decision for considering a form as completed if &gt; 1 question (out of 16!!) was answered; this reflects a wide range (1 to 16) in fidelity of implementing the intervention, potentially leading to type III error. It would have been more meaningful to extract data on the number of questions completed and compare that over time.</li> <li>- What was the sample size or the number of charts audited at each point? Please comment on the adequacy of the sample size and on the eligibility criteria / selection procedure.</li> </ul> <p>For the qualitative component:</p> <ul style="list-style-type: none"> <li>- What was the reason for holding individual and group interviews with clinicians? These two formats for data collection could potentially contribute to differences in responses – were such differences examined before collating the results?</li> <li>- Please, comment on the adequacy of the clinician and patient sample size.</li> </ul> <p>The information on public and patient involvement, role of sponsor, data sharing, transparency, dissemination, is important but could be presented at the end of the manuscript – to avoid disruption of the flow of information on the actual study.</p> <p>What statistical test was used to compare proportions of completed forms?</p> <p>What was the number of charts reviewed in audit C? to what extent could the difference in the time allotted to the chart audits and the number of charts reviewed in the three audits have influenced the findings? What specific statistical test was used in these comparisons, specifically, what ‘mean’ values were analyzed?</p> <p>The presentation of the qualitative findings involves direct quotes but does not clarify the main themes / categories derived from the analysis.</p> <p>Overall: The overall topic is of relevant to international readers. The intervention and its components are not explicitly and clearly described. The role of the 10 implementation strategies relative to the current study is not clarified. The study design may be appropriate but several aspects of the methods are not explicitly justified. The findings are not presented in a conceptually meaningful way.</p>
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### VERSION 1 – AUTHOR RESPONSE

**Reviewer: 1**

Please leave your comments for the authors below

This is a very interesting and important piece of work, and I commend the authors for their efforts.

\*\* We are glad that you find value in this project.

There are however certain sections of the paper that could be improved; these are outlined below.

1. Methods section needs to be described in a bit more detail (to allow the study to be repeated in other sites.). You may want to use the standard subsections ie study design, participants, settings, materials, and statistical analysis and organise the existing information and add information if necessary within this framework.

\*\* We appreciate this feedback and have re-arranged this section to incorporate subsections to frame our Methods, with details outlined below.

2. Research ethics needs reference number please.

\*\* Our Hamilton Integrated Research Ethics Number is Project #3214 which is now inserted in the manuscript.

3. The outcomes are stated (uptake, sustainability and influence) but would benefit from being further defined within methods.

\*\* We have briefly defined these outcomes in the text.

\*\* The uptake and sustainability outcomes are defined at the beginning of the Analysis section:

“We assessed uptake by calculating the proportion of completed Footprints activities in Audit B (e.g., completion of the form, information transposed onto the whiteboard, form on patients' chart) to Audit A. Whiteboard data was analyzed in two categories: dynamic (information that changed daily e.g., date, staff names or static (information that remained constant over the ICU stay, e.g., patient name, family members). We evaluated sustainability by comparing the proportion of completed Footprints activities between Audits B and C using a Chi square test with a significance level of  $p < 0.05$ .”

\*\* We conceptualized influence as an outcome without a one-phrase definition, given the scope of the word and the context of this project. Accordingly, concepts associated with our broad definition of influence as it relates to the Footprints Project included the effect of the Footprints form and/or Whiteboard on the patient, the family and clinicians. For patients and family members, the scope of influence included their initial reactions to the project, their feelings about completing the Footprints Form and having information displayed on the Whiteboard, and whether sharing that information had an effect on their perception of or relationship with the medical team. For clinicians, the scope of influence included the Footprints Project's effect on their interactions with patients and family members, their clinical practice, their relationships with their colleagues and, the potential effect of the project on the unit. This passage seems too long a passage to be incorporated into our revised text but we would be happy to reconsider.

4. Statistics/quantitative data needs some descriptive statistics to enhance clarity. Also, can you please mark in the manuscript where you think your tables will go (e.g. Table 1 about here), this will help the reviewers understand the results a bit better and what is being reported.

\*\* In this revision we have added greater statistical detail. We have also indicated where we think the tables will be inserted.

5. Re qualitative results, I would like to encourage the authors to explore ways of presenting these data with a bit more clarity (if possible). Also, please address typos, for e.g. the second quote on page 10 does not have quotation marks.

\*\* Thank you for this encouragement. Rather than numbering our themes, we kept the main themes bolded and the subthemes bolded and italicized (we deleted the underlining). Our themes are prefaced by A, B and C. The subthemes are prefaced by i, ii, and iii. We have included an additional Supplementary File 3 depicting the organization of our themes and subthemes from the qualitative work on the Influence of Footprints, and added a sentence introducing the themes at the beginning of the Qualitative Results section:

“The themes and subthemes from the analysis of the qualitative data on influence are illustrated in Supplementary File 3.”

To recap in this letter, our qualitative results about the influence of Footprints are:

#### **A. Facilitating holistic, patient-centered care**

The Footprints Project **sets the stage for the patient and family, motivates the patient, and humanizes the patient for clinicians.**

*i) Setting the stage*

*ii) Motivating the patient*

*iii) Humanizing the patient*

#### **B. Informing clinical encounters**

The Footprints Project was perceived as influencing clinical encounters by helping to **start conversations, foster deeper relationships and guide treatment.**

*i) A conversation-starter*

*ii) Fostering deeper relationships*

*iii) Guiding treatment*

### **C. Influencing professional practice**

Footprints was perceived as influencing practice by **refocusing clinician attention on personhood, enhancing interdisciplinary communication, and changing community culture.**

*i) Refocusing attention on personhood*

*ii) Enhancing interdisciplinary communication*

*iii) Changing community culture*

\*\* We hope these various improvements help to express and clarify our findings. Also, we have corrected this typographical error – thank you.

6. Study limitations are missing from the discussion – please add a subsection titled ‘Limitations’ and discuss any limitations that exist and that you have encountered that can help readers interpret your results with more accuracy. I would also add a subsection ‘further research’ reflecting on the direction of your research.

\*\* In response to these suggestions, we have consolidated our study strengths and limitations each in their own paragraph of the Discussion (the information was present but not grouped and labelled per se). We have also included a subsection entitled Future Research wherein we describe worthy further investigative steps. Thank you.

#### **Reviewer: 2**

This paper addresses an area of increasing importance and focus in healthcare-move towards compassion and personhood. My main concerns are about qualitative analysis and/or reporting.

Firstly I am unsure due to the labelling which are the themes and subthemes from the analysis. I am assuming from the headings and subheadings that there are two main themes-Uptake and sustainability and Influence. The others (underlined) are subthemes?

\*\* Yes we apologize and Reviewer 1 had a similar comment. Thank you for the chance to highlight and share the organization of our qualitative results. As per our responses to Reviewers 1 and 2, for the qualitative results, we kept the main themes bolded and the subthemes bolded and italicized. Our themes are prefaced by A, B and C. The subthemes are prefaced by i, ii, and iii. We have included an additional Supplementary File 3 depicting the organization of our themes and subthemes, and added a sentence introducing the themes at the beginning of the Qualitative Results section:

“The themes and subthemes from the analysis of the qualitative data on influence are illustrated in Supplementary File 3.”

To recap in this letter, our qualitative results about the influence of Footprints are:

### **A. Facilitating holistic, patient-centered care**

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Footprints was perceived as influencing practice by **refocusing clinician attention on personhood, enhancing interdisciplinary communication, and changing community culture.**

*i) Refocusing attention on personhood*

*ii) Enhancing interdisciplinary communication*

*iii) Changing community culture*

There is limited discussion to contextualise the verbatim quotes. They need further introduction to illustrate the findings and further discussion to outline the similarities and differences.

\*\* We have modified the text in several places to include more explanation of how our quotations support our findings in a few places in the Results section of our manuscript. We hope that these contextualizations are satisfactory; we were concerned about adding too many more words, since several additional phrases and sections were needed in response to other suggestions arising in the peer review process.

### **Reviewer: 3**

The authors report on a mixed method study aimed to examine the uptake, sustainability and influence of the Footprints project, which appears to consist of a written tool (form) and a communication board (whiteboard). The argument for the study could be strengthened by 1) defining humanism upfront and explaining how this principle or approach to care is different or comparable to

patient-centered or person-centered care (which is known to consist of holistic, individualistic and responsive care); and 2) explaining the importance or potential benefits to ICU patients and clinicians of the humanistic approach to care and synthesizing relevant evidence.

\*\* We appreciate these suggestions to clarify humanism. Our study is also about respect and acknowledging the inherent dignity of all patients. We also added a passage about dignity for persons and respect, as per our note below. In the Introduction, we had provided context with other form-based and board-based humanizing interventions.. We hope is it acceptable to retain this set-up for our own Footprint Form and Whiteboard rather than starting with definitions. However, since work on humanizing patients is a relatively nascent domain of critical care research, we have incorporated this feedback by adding a new paragraph in the Discussion describing a systematic review by Galvin and colleagues on humanizing interventions in the ICU which was just published. With the addition of new references, we have highlighted added the last names of the first authors of new citations throughout this letter (these are appropriately numbered in the revised manuscript).

“A recent systematic review (Galvin) focused on the effect of humanized care of critically ill patients on empathy among healthcare professionals, anxiety among relatives, and burnout and compassion fatigue in both groups, Galvin and colleagues identified 12 studies addressing 4 interventions (liberal visitation, diaries, family participation in basic care, and witnessed resuscitation) and 1 mixed intervention. Of 12 studies, 11 were at high risk of bias, 10 measured anxiety among 1,055 relatives, 2 measured burnout in 288 ICU professionals, and none addressed empathy or compassion fatigue. The effect of humanizing interventions on any of these psychologic outcomes was not quantifiable, but reviewers identified a trend towards reduced anxiety among families participating in basic patient care, liberal visitation, and diary keeping; the effects of liberal visitation on burnout among clinicians was conflicting.”

\*\*Also, in response, we have added text in the Discussion about respect for persons and dignity, and now cite a few other key references, including a new critical care perspective publication by Brown and colleagues:

“If dignity represents the inherent worth of all human beings, and respect represents the actions that appropriately honor and acknowledge such dignity (Gazarian, Sokol), this conceptualization can facilitate identification of concrete, observable behaviors of respectful and disrespectful care (Brown). As such, many participants in this study considered the Footprints Project as an intervention promoting respectful care, aligned with the definition that respect is recognition of the unconditional value of patients as persons (Beach). “

The intervention is briefly introduced, making it difficult for readers (unfamiliar with this term or approach to care) to appreciate the potential value of the intervention. It would be helpful to describe the two components of the intervention and to delineate their mechanism of action or theory of change, as is recommended for the description of complex interventions.

\*\* Thank you. In our Introduction, we have referred to Dr. Max Chochinov’s dignity therapy which conceptually inspired this work (2 of our original references). Context is key; our work differs by being situated in the ICU, focusing on critically ill patients. We did not draw on change theory specifically for



this project but have laid out our objectives faithfully and developed Footprints as per our Methods, which are better presented now; thank you for urging this clarity. To report a more detailed and organized description of our intervention, we added the challenges to the pre-existing Table 2 outlining the associated 10 implementation steps. We have added a subsection within the Methods section entitled Intervention. We now added to the Discussion a recent systematic review by Galvin and colleagues described above, about the sparse quantitative evidence about the effect of humanizing interventions on patients, families and clinicians. Our mixed-methods study will add to this emerging literature.

The objectives may be appropriate but it would be useful to define uptake, sustainability and influence – in particular, please specify the indicators and time frame that distinguish uptake from sustainability and clarify what ‘influences’ are of interest, early in the manuscript.

\*\*Reviewer 1 had similar suggestions, and we have now clarified this in the Analysis section:

“We assessed uptake by calculating the proportion of completed Footprints activities in Audit B (e.g., completion of the form, information transposed onto the whiteboard, form on patients' chart) to Audit A. Whiteboard data was analyzed in two categories: dynamic (information that changed daily e.g., date, staff names, patient milestones), or static (information that remained constant over the ICU stay, e.g., patient name, family members). We evaluated sustainability by comparing the proportion of completed Footprints activities between Audits B and C using a Chi square test with a significance level of  $p < 0.05$ .”

\*\* Also as mentioned for Reviewer 1, we conceptualized influence as an outcome without a one-phrase definition, given the scope of the word and the context of this project. Accordingly, concepts associated with our broad definition of influence as it relates to the Footprints Project included the effect of the Footprints form and/or Whiteboard on the patient, the family and clinicians. For patients and family members, the scope of influence included their initial reactions to the project, their feelings about completing the Footprints Form and having information displayed on the Whiteboard, and whether sharing that information had an effect on their perception of or relationship with the medical team. For clinicians, the scope of influence included the Footprints Project's effect on their interactions with patients and family members, their clinical practice, their relationships with their colleagues and, the potential effect of the project on the unit. This passage seems too long a passage to be incorporated into our revised text but we would be happy to reconsider.

\*\*We have added in some explanatory headings and phrases to the Methods section. Our investigative team considered that a conventional calendar year would be a reasonable time period to allow practice to unfold and to allow for possible seasonal variation across audits. Intercurrently, we also changed our electronic medical record system during this period. Concerned that this may have influenced the uptake of Footprints, we judged that 12 months would provide sufficient time for the clinical team to adapt to the new charting and order system, and re-align Footprints into the new charting workflow.

What were the challenges encountered during the pilot test? Were any of these related to the feasibility and acceptability of the intervention? What is the rationale or reason for introducing 10 implementation strategies? What were these strategies?

\*\* Thank you for this great question. We have added a column on the left of Table 2 to describe challenges encountered in the pilot phases of our project which provide direct explanation and rationale for the 10 implementation strategies originally noted in the right side of the table.

Overall, the context of the intervention and its implementation is not clearly described; points presented about prior work are not clear, making it hard to understand the situation in which the intervention is implemented and evaluated.

\*\* We understand how implementation projects are often developed after a sentinel event, which may ignite or motivate the creation and institution of an initiative such as Footprints. However, in our ICU, there was no singular event that prompted this project; the overarching goal of this initiative was to underscore our shared humanity with patients and families, in the hopes of continuing to recognize the innate dignity of everyone we care for. We did not alter our report, accordingly. However, we have revised our Methods section and refer to Supplementary File 3 to illustrate our Methods. We have bolstered Table 2 outlining the challenges that led to our 10 implementation steps. We added text to describe our qualitative findings, as well as a new Supplementary File 3 to illustrate the qualitative findings about the influence of Footprints on patients, families and clinicians. We regret that this was not as clear as it could have been and hope that these improvements are welcome.

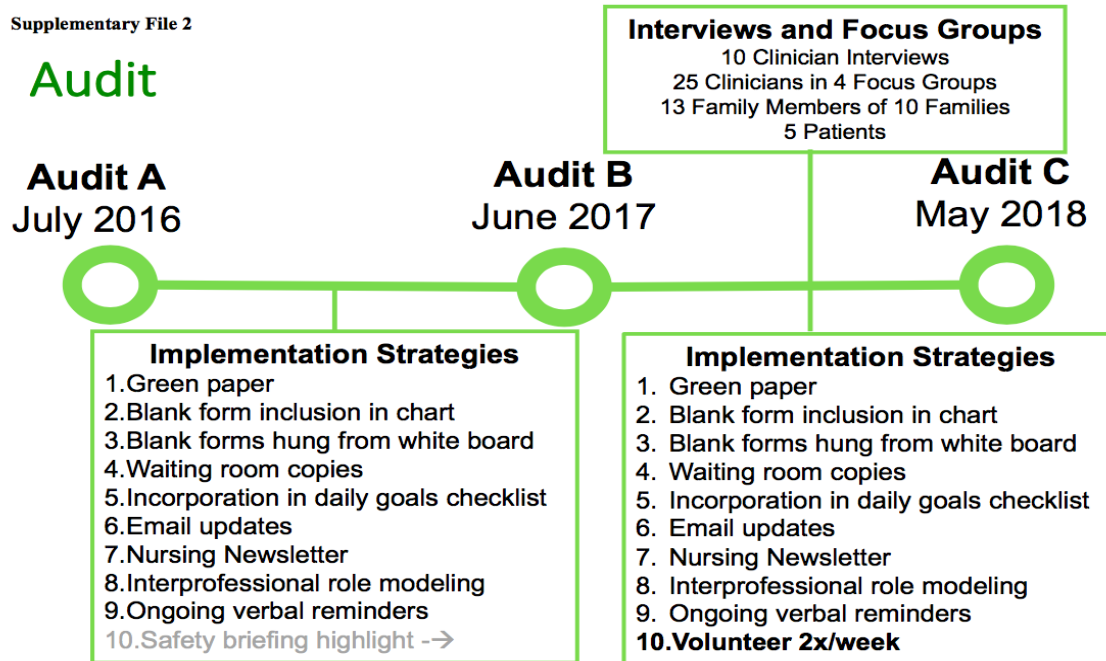
The overall design of the study is not explicitly described. It seems the study was done in one ICU and data were collected at 3 points in time, using mixed methods to examine uptake and sustainability, and qualitative methods to examine 'influences' – this appears to be a case-study design with repeated measure and mixed methods – such a design is appropriate for implementation research.

\*\* Thank you for your feedback. This suggested design label is certainly a way in which this study may be labelled, but we hope you don't mind if we retain our original methodologic descriptor, as per our research ethics board approval documents, and as aligned with our prior presentations and abstracts. To recap, our quantitative methods support our objectives of uptake and sustainability. Our qualitative methods support our objectives addressing uptake and sustainability, and explore the project's influence on clinicians, families and patients.

Please, provide the time frame surrounding the implementation of the intervention, for conducting the audit – that is, was audit B done within 1 month following full implementation, and audit C within 9 months of audit B or of implementation of the intervention? Also, please justify the time frame- that is, are these time points appropriate / adequate to determine uptake and sustainability? Based on what theoretical expectation or empirical evidence?

\*\* Thank you for this question. We refer you to Supplementary File 2 which does clearly indicate the 9 implementation strategies introduced between Audits A and B, and continued between Audits B and C with the addition of a tenth strategy (introduction of a volunteer). In Table 2, we have serially listed

the implementation strategies and have added the precursor challenges which prompted these proposed solutions. Our word limit precludes us writing more about this, but the Supplementary File 2 outlines our approach. The following represents our original Supplementary File 2 which is the same and which we refer to, to aid readers in understanding the work flow:



\*\* Further, the implementation of the intervention steps occurred between January and July 2017. It was during this period that we received REB approval for the study and during the following few months, we carried out the clinician interviews and Audit B. Audit C was conducted 1 year later. This timeline was necessary to accommodate the implementation of training and uptake of a new hospital wide electronic medical record. Below, for your interest, we add a Footprints Timeline Table but we did not add this to the revised resubmitted files.

## Footprints Timeline



Date	Action
January 2015 - December 2016	Pilot Work
July 2016	Form and Whiteboard Audit A
January - July 2017	Implementation steps identified and implemented
May 2017	Footprints Study Funding and REB approval
May - July 2017	Clinician Interviews
June 2017	Form and Whiteboard Audit B
February – May 2018	Patient and Family Interviews
May 2018	Form and Whiteboard Audit C

For the quantitative component:

Please provide more details about the specific variables for which data were collected with the audit.

\*\* We have explained these in the Methods and Results, and thank you for also referring to Tables 3 and 4 to identify the individual variables and groups of variable analyzed.

Justify the decision for considering a form as completed if > 1 question (out of 16!!) was answered; this reflects a wide range (1 to 16) in fidelity of implementing the intervention, potentially leading to type III error. It would have been more meaningful to extract data on the number of questions completed and compare that over time.

\*\* Most forms had the majority of items completed. However, we selected just one item as complete to honour the non-obligatory nature of the form. We made an offering to the family to get to know the patient better. We didn't want family members (or patients when they were competent to complete the form) to feel coerced into disclosing information on the Footprints forms if they were uncomfortable or uncertain about doing so. We clarified this in the Quantitative Methods:

"We defined a completed form as having  $\geq 1$  question completed. This low threshold was defined to respect the invitational, non-coercive nature of the form, but typically most questions were completed."

What was the sample size or the number of charts audited at each point? Please comment on the adequacy of the sample size and on the eligibility criteria / selection procedure.

\*\* The sample size of patients exposed was predicated on patients admitted to the ICU during the study timeframe including all 6 phases of the pilot work and from beginning to the end of the main study. Therefore, no sample size calculation was made. The Audit B denominator was 70 patients or 247 patient audit days and Audit C denominator was 64 patients or 242 patient audit days. Regarding the sample size for interview and focus group participants, we ceased the qualitative data at the point of saturation, which we have also indicated in the Methods section. We acknowledge that a longer period of observation would have generated larger sample sizes but this was not within the scope of our funding.

What statistical test was used to compare proportions of completed forms?

\*\* This was a Chi-square test now added to the Analysis section.

What was the number of charts reviewed in audit C? to what extent could the difference in the time allotted to the chart audits and the number of charts reviewed in the three audits have influenced the

findings? What specific statistical test was used in these comparisons, specifically, what 'mean' values were analyzed?

\*\* The Audit B denominator was 70 patients or 247 patient audit days and Audit C denominator was 64 patients or 242 patient audit days. For physiotherapist name completion rates, we calculated audit weekdays, which for Audit b was 166 and Audit C was 198, given that physiotherapists work only weekdays and we wanted to avoid falsely low completion rates under this category. The statistical tests used to compare audits were t tests and Chi square tests. We acknowledge that a longer period of observation would have generated larger sample sizes but this was not within the scope of our funding. We could not confidently state how results may have differed if we had used an alternate time frame or number.

For the qualitative component:

What was the reason for holding individual and group interviews with clinicians? These two formats for data collection could potentially contribute to differences in responses – were such differences examined before collating the results?

\*\*For the Footprints Project, considering the objective of understanding the influence of Footprints on patients, we used individual interviews to help understand the isolated individual experiences, thoughts and feelings of patients. Most family interviews were individual as well for this reason, but sometimes a family member wished to have another family member present, which we allowed. As focus groups are helpful when people feel comfortable sharing in a group, we used this strategy with clinicians to encourage conversation, which can in turn generate more ideas that may not have come up in an individual clinician interview. Also because the Footprints intervention is clinical, based in an ICU, the possible community influence was theoretically more likely to be elicited in a focus group of clinicians by harnessing the power of group dynamics to spur conversation about the Footprints Form and Whiteboard. We did not aim to compare or contrast interview data versus collective responses from focus groups. Since the foregoing statements reflect some conventional qualitative methodology we did not add these general points to our revised manuscript but can expand if preferred.

Please, comment on the adequacy of the clinician and patient sample size.

\*\* We have included a sentence in our Methods section related to saturation of our qualitative data. We excerpt this here from the Qualitative Methods section:

“We conducted interviews until data saturation was reached and no further themes emerged in our analysis.”

The information on public and patient involvement, role of sponsor, data sharing, transparency, dissemination, is important but could be presented at the end of the manuscript – to avoid disruption of the flow of information on the actual study.

\*\* Thank you – we have moved this to the end of the manuscript.

The presentation of the qualitative findings involves direct quotes but does not clarify the main themes / categories derived from the analysis.

\*\* Thank you for the chance to highlight and share the organization of our qualitative results. As per our responses to Reviewers 1 and 2, for the qualitative results, we kept the main themes bolded and the subthemes bolded and italicized. Our themes are prefaced by A, B and C. The subthemes are prefaced by i, ii, and iii. We have included an additional Supplementary File 3 depicting the organization of our themes and subthemes, and added a sentence introducing the themes at the beginning of the Qualitative Results section:

“The themes and subthemes from the analysis of the qualitative data on influence are illustrated in Supplementary File 3.”

To recap in this letter, our qualitative results about the influence of Footprints are:

#### **A. Facilitating holistic, patient-centered care**

The Footprints Project **sets the stage for the patient and family, motivates the patient, and humanizes the patient for clinicians.**

*i) Setting the stage*

*ii) Motivating the patient*

*iii) Humanizing the patient*

#### **B. Informing clinical encounters**

The Footprints Project was perceived as influencing clinical encounters by helping to **start conversations, foster deeper relationships and guide treatment.**

*i) A conversation-starter*

*ii) Fostering deeper relationships*

*iii) Guiding treatment*

#### **C. Influencing professional practice**

Footprints was perceived as influencing practice by **refocusing clinician attention on personhood, enhancing interdisciplinary communication, and changing community culture.**

*i) Refocusing attention on personhood*

**ii) Enhancing interdisciplinary communication**

**iii) Changing community culture**

Overall: The overall topic is of relevant to international readers. The intervention and its components are not explicitly and clearly described. The role of the 10 implementation strategies relative to the current study is not clarified. The study design may be appropriate but several aspects of the methods are not explicitly justified. The findings are not presented in a conceptually meaningful way.

\*\* We are delighted that the relevance of this study is clear to BMJ Open's international audience. We hope that we have addressed the suggestions outlined in the foregoing passages. As mentioned above, we have added the context of challenges in a column that precedes the description of the 10 implementation steps which was an excellent idea. We provide an new organizational figure for our qualitative results which is reflected in a new Supplementary file 3, and made corresponding changes to the text.

\*\* Also, we made a few other changes to rearrange references (due to paragraph modifications and new paragraphs in the Discussion there are new reference insertions; we also corrected one original reference error). We updated the cover page, in that one of our coauthors has since graduated from the Masters of Science Program at McMaster University. Most Reviewers' comments were requests to expand the text so this revised manuscript is longer than the original submission; however we have done some light editing to trim other text. We are grateful for your interest in this manuscript and appreciate the opportunity to improve the presentation of this study. We hope that you consider it worthy of publication in BMJ Open. Thank you kindly for your consideration.

**VERSION 2 – REVIEW**

<b>REVIEWER</b>	Tayana Soukup King's College London
<b>REVIEW RETURNED</b>	11-Sep-2019

<b>GENERAL COMMENTS</b>	No further comments. The paper has significantly improved following the revision.
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<b>REVIEWER</b>	Joanne Lewis University Technology Sydney
<b>REVIEW RETURNED</b>	20-Aug-2019

<b>GENERAL COMMENTS</b>	Requested revisions noted. Recommendation-accept for publication
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