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

<table>
<thead>
<tr>
<th>TITLE (PROVISIONAL)</th>
<th>What impact has the Centre of Research Excellence in Digestive Health made in the field of gastrointestinal health in Australia and internationally? Study protocol for impact evaluation using the FAIT framework.</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUTHORS</td>
<td>Koloski, Natasha; Duncanson, K; Ramanathan, Shanthi; Rao, M; Holtmann, Gerald; Talley, Nick</td>
</tr>
</tbody>
</table>

VERSION 1 – REVIEW

| REVIEWER            | McNamara, Kevin Deakin University |
| REVIEW RETURNED     | 17-Aug-2023 |

GENERAL COMMENTS

This is generally a well written manuscript and addresses an important issue – ensuring the impact of research programs being funded by public money. FAIT is a rationale choice to explore potential impact of a research program. While there is intrinsic benefit to this narrative description, there is possibly benefit from further discussion of methodological rigour - about the feasibility of data collection and the likely quality of data collection and analysis (presumably data collection is well underway at this point). I’d also like to see the authors identify the novelty of this work given that use of FAIT to measure impact of CREs has already been described by several research groups. The background and Discussion at the moment focus on how FAIT will be useful for achieving impact – it is not clear how the manuscript itself is adding to our understanding of the field of impact evaluation.

ABSTRACT

The abstract is well written and clear. In the introduction, the authors may wish to indicate where the science is at in terms of measuring or attempting to measure impact for a CRE or similar entity, not just stating that it is ‘challenging’.

FULL TEXT

Can the authors please describe in more detail how consumers and other end users were engaged to develop their impact framework? E.g. what consumers/end users, how extensive was consultation, how did you ensure a diversity of views, how were differences of opinion reconciled?

There is an inherent benefit from planning for impact, but there is also an incentive to select metrics and report/interpret data collection that (a) are easier to collect, and (b) reflect positively on success. Are there measures being taken to mitigate against this? i.e. as an effort to ensure accountability, does there need to be a greater emphasis on data and reporting transparency/validation?

Discussion
Table 1 metrics appropriately mirror the outputs and proposed outcomes from the logic model. However, they are somewhat vague in terms of defining how they would be measured. E.g. what sort of ‘Committee participation’ would count? Often we are recruited to committees dealing with a broader or indirectly related matter. Would any brief citation of research output in a government document relating to a policy change ‘National/State/Local policy changes’ count?

Reviewer: Flaviu, Moldovan
George Emil Palade University of Medicine Pharmacy Science and Technology of Targu Mures, Othopedics-Traumatology

Review returned: 29-Oct-2023

General Comments
The abstract structured but a final conclusion, timing and the future perspective of the protocol should be included. The ethics should be stated in the Methods section. The strengths and limitations of the study should be provided at the end of the discussion section. The introduction transposes the research into the topic and formulates the objective of the study at the end. In the methodology section, the stages of the protocol are clearly presented. In the discussion section there should be some references to other frameworks from various medical fields, for e.g. Moldovan, F.; Moldovan, L.; Bataga, T. The Environmental Sustainability Assessment of an Orthopedics Emergency Hospital Supported by a New Innovative Framework. Sustainability 2023, 15, 13402. doi: 10.3390/su151813402
A separate section with the final conclusion should be presented clearly and concise. The bibliography is adequate, but it needs proper editing and can be extended.

Version 1 – Author Response

Reviewer: 1

Query - This is generally a well written manuscript and addresses an important issue – ensuring the impact of research programs being funded by public money. FAIT is a rationale choice to explore potential impact of a research program. While there is intrinsic benefit to this narrative description, there is possibly benefit from further discussion of methodological rigour - about the feasibility of data collection and the likely quality of data collection and analysis (presumably data collection is well underway at this point). I’d also like to see the authors identify the novelty of this work given that use of FAIT to measure impact of CREs has already been described by several research groups. The background and Discussion at the moment focus on how FAIT will be useful for achieving impact – it is not clear how the manuscript itself is adding to our understanding of the field of impact evaluation.

Response: We have added a sentence to the discussion on this but the quality of the final data and how sub-standard data is managed as well as learnings from what strategies worked to ensure high quality data is better reflected on in the results manuscript.

On page 12

...Despite the benefits of comprehensively assessing the impact of the CRE-DH using three distinct methods namely quantified impact metrics, a cost-consequence analysis and a narrative of the impact, there are some potential risks and limitations. These include (1) Lag in translation could impact on the ability to capture and demonstrate longer term impacts. (2) Data collection for impact reporting whilst feasible, does require additional commitment by CRE partners to ensure it is
comprehensive and complete. Therefore this could be seen as an added administrative burden and may not be completed as required. However, the desire to continue the collaboration and the fact that CRE affiliates have been engaged with the impact assessment from the start should provide a counter-balance to the burden. The inclusion of the HMRI Research Impact Team as expert advisors will also ensure that multiple strategies previously used in other CRE impact assessments are employed to enhance data collection.

In terms of the novelty we have added the following statements to the manuscript

On page 7 of introduction
In addition, this paper will contribute to this growing area of research impact assessment.

On page 14 in discussion
... The novelty of this work is that the application of FAIT is still very much in its infancy with only two protocol papers (both using very different framings for the application) 24,28 and only one results paper published.29 There is still much to learn and reflect on in the application of such a comprehensive framework, and this protocol paper will provide a useful roadmap for other gastrointestinal research collaborations planning formal impact evaluations. A deepened understanding about what enhances the impact of a CRE will only be possible when we have benchmarked protocols and outcomes. We will then have the ability to undertake meta-analyses to ascertain what works under what circumstances in order to further enhance the impact in a large and complex research collaborative such as a CRE. Contribution to a larger bank of metrics will give visibility to the potential capacity and capability impacts from CREs.

Query: The abstract is well written and clear. In the introduction, the authors may wish to indicate where the science is at in terms of measuring or attempting to measure impact for a CRE or similar entity, not just stating that it is ‘challenging’.
Response: We have added the following highlight section to the abstract
This is particularly challenging and the science behind this form of research is in its infancy when applied to collaborative research funding such as provided by the Australian National Health and Medical Research Council to the Centre for Research Excellence in Digestive Health (CRE-DH).

Query: Can the authors please describe in more detail how consumers and other end users were engaged to develop their impact framework? E.g. what consumers/end users, how extensive was consultation, how did you ensure a diversity of views, how were differences of opinion reconciled? There is an inherent benefit from planning for impact, but there is also an incentive to select metrics and report/interpret data collection that (a) are easier to collect, and (b) reflect positively on success. Are there measures being taken to mitigate against this? i.e. as an effort to ensure accountability, does there need to be a greater emphasis on data and reporting transparency/validation?
Response: Thank you for this suggestion. This has been previously described above regarding patient and public involvement and added to the manuscript on page 8

Patient and Public Involvement
Development of the FAIT model involved extensive and broad end user engagement including interviews with the following key stakeholder groups – researchers from across the research spectrum, multiple Australian medical research institutes, health and medical research funders including the National Health and Medical Research Council, Australian Research Council, The Medical Research Futures Fund, NSW Office for Health and Medical Research, Brunel University, UK and Karolinska Institute, Sweden who were leaders in the field at the time and policymakers. All interviews were conducted by staff from the Health Economics and Impact team at HMRI and covered attitudes to impact measurements, barriers and enablers, what was being done at the time and
opinions about what should be done. There was a diversity of views and any differences were reconciled by designing a comprehensive framework (FAIT) that addressed all their different needs and perspectives. In an impact assessment, there is an absolute bias towards selecting and reporting metrics and impact for which there is data. This is addressed by planning for impact from the outset to ensure that as much data as possible is collected from the start to allow the most extensive assessment possible. However, there is the issue of lag so most impact assessment conducted at the conclusion of the project, program or CRE are bound to miss out on the downstream longer term impacts. Other ways this bias is addressed is by acknowledging the limitations and bias inherent in an impact assessment framework like FAIT so the reader is clear from the outset. The engagement involved in the development of FAIT was supplemented by broad consumer representation on the CRE-DH advisory board that provided feedback at all stages of the development of the CRE-DH impact assessment. The use of the existing Payback domains and input from consumers with a range of conditions and experiences will ensure that the metrics selected reflect a broad range of potential impacts beyond academic impacts.

Query: Table 1 metrics appropriately mirror the outputs and proposed outcomes from the logic model. However, they are somewhat vague in terms of defining how they would be measured. E.g. what sort of ‘Committee participation’ would count? Often we are recruited to committees dealing with a broader or indirectly related matter. Would any brief citation of research output in a government document relating to a policy change ‘National/State/Local policy changes’ count?

Response: Thank you for this suggestion. The more specific metrics for each of these outputs and outcome measures have been developed but were not included in this summary table for the protocol. However, we have updated some metrics to be more specific on page 20. For example:
- ‘Committee Participation’ expanded to ‘Participation in committees to develop national or international policy or guidelines’
- ‘Legislation introduced’ changed to ‘Legislation with substantial CRE-DH affiliate involvement introduced’
- ‘National/State/Local policy changes’ expanded to ‘National/State/Local policy changes where CRE-DH work has informed the policy e.g. via citation or representation on the policy development team’

Reviewer: 2

Query - The abstract structured but a final conclusion, timing and the future perspective of the protocol should be included. The ethics should be stated in the Methods section. The strengths and limitations of the study should be provided at the end of the discussion section.

Response: We have added a conclusion section to the abstract

Conclusion: We expect this impact evaluation to comprehensively describe the contribution of the CRE-DH for intentional activity over the CRE-DH lifespan and beyond to improve outcomes for people suffering with chronic and debilitating digestive disorders.

We have added this section to the conclusion of the manuscript on page 15

Conclusion
This study will capture outputs and impacts that have been initiated or enhanced as a result of the CRE-DH’s collaborative efforts of basic scientists, allied health and medical clinician researchers, translational scientists, consumers and advisors across the spectrum from animal, preclinical laboratory research to health service delivery from acute to integrated and primary care settings. All costs for CRE-DH activity will be valued and where possible, the economic analysis will monetise reportable CRE-DH outcomes and impacts. If this is not possible, these impacts will be reported in their natural units. We expect this impact evaluation to comprehensively describe the contribution of the CRE-DH to a range of impacts including any improved outcomes for people suffering with chronic
and debilitating digestive disorders. The impact evaluation will inform future directions for digestive health research and assessment of its impact.

Query: In the discussion section there should be some references to other frameworks from various medical fields, for e.g. Moldovan, F.; Moldovan, L.; Bataga, T. The Environmental Sustainability Assessment of an Orthopedics Emergency Hospital Supported by a New Innovative Framework. Sustainability 2023, 15, 13402. doi: 10.3390/su151813402
Response: We have added on page 13.
..Although, there are other frameworks from various medical fields 27 to assess evaluation of research outcomes, this evaluation applied the Framework to Assess the Impact of Translational health research (FAIT) to the CRE-DH with the explicit aim of optimising research impact and providing direction for future digestive health planning and prioritisation.

Query: The bibliography is adequate, but it needs proper editing and can be extended.
Response: We have added the references below and edited the list

Moldovan, F.; Moldovan, L.; Bataga, T. The Environmental Sustainability Assessment of an Orthopedics Emergency Hospital Supported by a New Innovative Framework. Sustainability 2023, 15, 13402.

VERSION 2 – REVIEW

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>McNamara, Kevin</th>
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<tbody>
<tr>
<td>Deakin University</td>
<td></td>
</tr>
<tr>
<td>REVIEW RETURNED</td>
<td>23-Jan-2024</td>
</tr>
</tbody>
</table>

GENERAL COMMENTS

I am happy that this article meets the necessary requirements for publication. I have just couple of points that may warrant further consideration:
1. The authors state that the third objective of the mixed methods study is to “assess the suitability of FAIT”. While I can see how some insights might emerge as by-products of its application, it remains unstated in the protocol how ‘suitability’ will be defined and directly assessed; i.e. is this really a core objective, or do they just want to apply it? Such an evaluation could easily be incorporated into the section describing Phase 4 interviews, for example.
2. Given the welcome translational nature of many desired outcomes - ranging from policy change and partnerships, to community behaviour change and licences etc - the authors might want to consider describing additional approaches to dissemination, not just publications, that are likely to be required to influence such a wide range of stakeholders.
3. While it is usual for journals to seek ethics approvals to be in place prior to publishing protocols, it is understandable and reasonable for this large program of work that it is not in place. The risk of having to significantly change the approach of relevant
phases following ethics review seems low, but nonetheless it might be worth noting those phases that require future ethics review.

**VERSION 2 – AUTHOR RESPONSE**

Reviewer: 1

Comments to the Author:

I am happy that this article meets the necessary requirements for publication. I have just couple of points that may warrant further consideration:

1. The authors state that the third objective of the mixed methods study is to “assess the suitability of FAIT”. While I can see how some insights might emerge as by-products of its application, it remains unstated in the protocol how ‘suitability’ will be defined and directly assessed; i.e. is this really a core objective, or do they just want to apply it? Such an evaluation could easily be incorporated into the section describing Phase 4 interviews, for example.

Response: Given that impact evaluation is, relatively speaking, still in its infancy, with little, if any, clear direction for researchers on which frameworks are most suitable for what purposes and in what contexts; the authors decided that it would be remiss not to reflect on the suitability of FAIT for application to the CRE in Digestive Health. This assessment will take the form of a facilitated discussion amongst authors, at the conclusion of the impact evaluation, to identify the strengths and limitations of FAIT in the context of its application to the CRE and to make suggestions, if appropriate, for its future application. This would be done for the sole purpose of informing readers who may be considering the application of FAIT.

This has been added to the methods section on page 8 of the manuscript.

….The assessment of the suitability of FAIT will take the form of a facilitated discussion amongst authors, at the conclusion of the impact evaluation, to identify the strengths and limitations of FAIT in the context of its application to the CRE and to make suggestions, if appropriate, for its future application.

2. Given the welcome translational nature of many desired outcomes - ranging from policy change and partnerships, to community behaviour change and licences etc - the authors might want to consider describing additional approaches to dissemination, not just publications, that are likely to be required to influence such a wide range of stakeholders.

Response: We have added more details to the abstract statement for ethics and dissemination and on page 14.

Ethics and dissemination. …Results of this study will be disseminated via medical conferences, peer reviewed publications, policy submissions, direct communication with relevant stakeholders, media and social media channels such as X.
3. While it is usual for journals to seek ethics approvals to be in place prior to publishing protocols, it is understandable and reasonable for this large program of work that it is not in place. The risk of having to significantly change the approach of relevant phases following ethics review seems low, but nonetheless it might be worth noting those phases that require future ethics review.

Response: We have added to the abstract and page 14

Ethics and dissemination. This impact evaluation study has been registered with Hunter New England Human Research Ethics Committee as project 2024/PID00336 and ethics application 2024/ETH00290.