Author’s response to reviews

Title: Getting messier with TIDieR: embracing context and complexity in intervention reporting.

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Author’s response to reviews:

Response to BMC MRM reviewer comments on the manuscript BMRM-D-17-00214

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We are pleased that you have invited us to submit a revised version of our paper for BMC Medical Research Methodology. We have re-drafted the paper as a Debate article, and amended it to address the helpful changes suggested by the editor and two reviewers.

We reprint each editor/reviewer comment and follow it with our response, indicating where we have revised the manuscript.

Editor Comments:

1. Please re-format your manuscript according to instructions for a Debate article that are available here - https://bmcmedresmethodol.biomedcentral.com/submission-guidelines/preparing-your-manuscript/debate.

Thank you for the suggestion that we re-format the manuscript as a Debate article. We have done so, following the layout suggested in the journal guidelines. Our changes are summarised below in the response to the review from Naiohm McMahon.
2. I would consider this as a series of six case studies on applicability of the TIDieR checklist, and suggest that you consider a title that reflects it.

We have changed the title to one that has the feel of a Debate article. The new title is:

‘Getting messier with TIDieR: embracing context and complexity in intervention reporting.’

We agree with the editor that this is a series of case studies, and we have added the term ‘case study’ throughout the paper [pages 2, 7, 9, 12, 13, 14, 18, 24]. On reflection, we have not included the term ‘case study’ in the title because we think that would give the impression to readers that this is a research article rather than a debate article.

Reviewer reports:

Naiomh McMahon (Reviewer 1):

1. Thank you for the opportunity to review this manuscript that reflects on the utility of the TIDieR checklist and makes recommendations for minor revisions to the checklist. This is a very clear and well written paper. My sense is that the content of the paper is a bit stretched presented as a research article and perhaps would make a better contribution framed as a debate - TIDieR or Messier?

We have now re-structured the paper as a debate paper, following the journal’s author guidelines – see details on this in our response to the first comment from the editor.

2. There is quite a bit of description of the checklist within the main text of the paper and repetition of ideas between the results and a very short discussion.

We feel it is necessary to describe the TIDieR checklist and how it is used in some detail at the start of the paper in order to provide adequate context for the reader: TIDieR is only a few years old and may not be known by all readers. We feel that the Discussion was mis-titled (because we were trying to force our debate paper into a traditional research article format) and we have now re-titled it as ‘Proposed changed to TIDieR’.

3. However, I think a rich and insightful debate on the utility of reporting checklists centred on the main ideas in this paper (capturing change over time, whose voice the checklist represents and what purpose it serves, capturing contextual influences and using checklists as a research tool) would make a timely contribution to thinking and practice in this field.

The authors have considerable experience using the TIDieR checklist across a range of studies and settings, and perhaps a more reflective format would allow for more indepth and thoughtful critique of the role of reporting checklists and discussion of their experiences.
We agree that this paper is better framed as a debate article, and we thank the reviewer for making the suggestion. This revised version of the paper is structured under the headings: Background,

Case studies-TIDieR templates,

Consensus workshops,

Different approaches to using TIDieR

The complexities of using TIDieR for applied health research

Proposed changes to TIDieR

Conclusions

We think this is an improvement on the previous version which followed a traditional paper format (introduction, aims, methods, results, conclusion, and discussion).

There have been many changes throughout, but I can highlight the following substantial changes to the text:

P6-7. The addition of a new paragraph in the introduction, which sets our paper in the context of wider discussions about the tension between fidelity of replication and the need to tailor interventions to specific contexts, using a very broad definition of context:

‘Complexity in health research is widely recognised,[22] not only in terms of the traditional understanding of the evaluation of multicomponent interventions but increasingly of the complexity of the context (or system) into which interventions are placed.[23] This itself highlights the apparent tensions between fidelity of replication and the need to tailor interventions to be sensitive to different contexts.[24] Furthermore, context needs to be recognised as a process involving persons, resources, perspectives and activities, and not just a place. However, the role of adaptations and evolving mechanisms of action are recognised less often than static reports of ‘barriers and facilitators’.[25]. The capacity for formal reporting tools such as TIDieR to accommodate such factors has not previously been discussed, but it is clear that a means of effectively capturing and reporting the interactions of context and intervention delivery is essential if we are to design and evaluate interventions that can be effectively delivered in practice.’

P25-26. The addition of text to the conclusion which emphasizes that our suggested amendments can contribute to improved reporting of the complexity of the context and the research process:

‘These amendments illuminate the need for the explicit and dynamic reporting of research contexts, agents and voices, and their combined role on knowledge production; aspects of the research process which have previously been overlooked.’
Garry Tew (Reviewer 2):

1. Title: "messier" instead of "Messier"

We have changed this to lower case.

2. Abstract, line 1: "guide" not "quide"

We have corrected the mis-spelling of ‘guide’

3. Abstract: it would be useful for the four amendments to be briefly described in the abstract.

We agree and we have amended the conclusion of the Abstract to add a description of the four amendments (new text in italics):

‘We found the TIDieR tool to be a useful tool for applied research outside the context of clinical trials and we have identified four amendments to enhance its utility. An additional item, ‘voice’ can convey who was involved in preparing the TIDieR template, such as researchers, service users or service deliverers. An additional item, ‘stage of implementation’ can convey whether the TIDieR reflects first implementation or later roll-out. A new column, ‘modification’ would remind authors to describe modifications to any item in the checklist. Expand the ‘how well’ item to describe how contextual factors affected intervention delivery.’

4. Keyword: please consider replacing "TIDieR" with a different keyword.

We have deleted ‘TIDieR’ from the list of keywords. We have changed the keywords so they are all now MESH terms:

Checklist, Reproducibility of results, Intervention fidelity, Research reporting standards

5. Background, page 5, para 2: The following reference is pertinent to the discussion of the use of TIDieR in systematic reviews:

Hoffmann, T.C., Oxman, A.D., Ioannidis, J.P., Moher, D., Lasserson, T.J., Tovey, D.I., Stein, K., Sutcliffe, K., Ravaud, P., Altman, D.G. and Perera, R., 2017. Enhancing the usability of systematic reviews by improving the consideration and description of interventions. bmj, 358, p.j2998.

This is a useful reference in this context and we have added it to the paper

6. Page 6, para 1: shorten "British Medical Journal" to "BMJ"

We have shorted this to BMJ
7. **Background:** A general background to TIDieR is offered before the aim of the paper is stated. The section would be strengthened if the rationale for the focus of the paper was made clearer. For example, why do we need to know your experience? How would this be useful to readers? Also, you state that the aim is to describe "the experience…" - I think it should be clearer from the start whose experience will be described.

We have added a new paragraph to the Background section which sets our paper in the context of wider discussions about the tension between fidelity of replication and the need to tailor interventions to specific contexts, which we hope strengthens the rationale for the paper.

We have left the Aim at the end of the background section, because conventionally this is where the aim sits. However, we have expanded the aim to make it clearer (new text in italics):

‘The aim of the paper is to reflect on the experience of applying TIDieR in six case studies, covering a variety of applied health research contexts, and debate its usefulness as a research tool outside the context of clinical trials.’

8. **Methods, page 6:** define NDH at first use

We have used the term Impaired Glucose Tolerance (IGR) instead, because it is more accurate, and we have used that elsewhere in the paper and we want to be consistent throughout. We have defined it at first use (new text in italics):

A Diabetes Prevention Programme (DPP) to reduce the risk of diabetes in patients with a diagnosis of impaired glucose regulation (IGR) - blood glucose levels that are above the normal range but are not high enough for a diagnosis of type 2 diabetes - by use of regular telephone calls from a health advisor (Telephone DPP)

9. **Methods, page 6/Table 2:** please clarify in the text and table what the intervention is for (ii) and (iii). Is it the same intervention as (i)? In general the description of the clinical problems and interventions in table 2 could be clearer.

We have expanded both the text on page 6-7 and table 2 to include clear descriptions of all 5 interventions. The revised text is shown below in answer to point 11

10. **Table 2:** "TIDieR" instead of "TIDIER" in the column header

We have altered the spelling in the column header

11. **Methods, lines 18-20:** This text refers to results, not methods. Please edit accordingly. When editing this section, please can you clarify what the purpose of the consensus workshops was, the number and brief description of the researchers involved, and the process for identifying issues, themes and potential amendments to TIDieR. In relation to the second point, the authors currently use the term "we" several times, and it isn't clear whether this is just referring to the authors or a/the broader group of researchers involved
in the workshops. Overall, as currently written, the article seems like an opinion piece rather than original research.

We have edited this section quite heavily in response to the comments. Instead of a Methods section there are now two sections, the first describing the six case studies and the second describing the consensus workshops. In both sections we now focus only on the methods and have taken out any results. These two sections now read as follows:

CASE STUDIES – TIDIER TEMPLATES

The TIDieR template was used as a tool for intervention description in six projects, summarised in table 2. ‘The interventions were (i) A Diabetes Prevention Programme (DPP) to reduce the risk of diabetes in patients with a diagnosis of impaired glucose regulation (IGR) - blood glucose levels that are above the normal range but are not high enough for a diagnosis of type 2 diabetes - by use of regular telephone calls from a health advisor (Telephone DPP) [26]: IGR; (ii) Primary care referral into diabetes prevention programmes: a nurse facilitator attended selected GP practices, searched the electronic records for patients at risk of diabetes, made appointment with patients to discuss their condition, and referred appropriate patients to a local diabetes prevention programme (GP referral DPP) [27]; (iii) Community referral into diabetes prevention programmes: a community organisation and the local authority health improvement team approached members of the public in community settings, completing diabetes risk scores. offering blood tests to those at risk of diabetes and referring eligible people to local diabetes prevention programmes (Community referral DPP) [27]; (iv) A commitment based intervention to promote behaviour change for weight loss among overweight adults attending weight loss groups in low socioeconomic areas (SMART-C booklet); (v) A primary care intervention, based on ‘targeted audit and feedback’, using audit, health professional education and processes of care, such as medication reviews, to improve management for people who have had an episode of acute kidney injury (AKI) (Primary Care Management of AKI Intervention) [28]; (vi) A primary care intervention to reduce the risk of harm from acute kidney injury (AKI) in people taking certain groups of medicines, by providing information on which types of medications to stop taking temporarily whilst ill (AKI sick day guidance) [29]. TIDieR descriptions of the six interventions are included in Appendix 1. All the projects were undertaken by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care Greater Manchester (NIHR CLAHRC GM) which is a partnership between providers and commissioners from the NHS, industry, the third sector and The University of Manchester to help facilitate research getting into practice [30].

CONSENSUS WORKSHOPS

Eight researchers involved in the six applied health research projects that had used the TIDieR templates met in two consensus workshops. The purpose of the workshop was to share information, identify any common themes arising from their experience of using TIDieR and to consider whether any changes were warranted for using TIDieR in such settings. During the first workshop the six cases were classified by clinical problem, population, setting, stage of intervention, leadership of the intervention and the time point that TIDieR was employed (Table 2). The studies covered various clinical problems in population health and primary care, and
settings across the community, local health authorities, and primary and secondary care services. The stage of intervention was based on a NIHR CLAHRC GM typology of studies [2631], which specifies five stages of research: Exploration (finding out what is going on), Explanation (explaining something new), Development (developing and implementing interventions), Feasibility in Context (implementation of an intervention previously developed somewhere else) and Exploitation (spread of an intervention into routine practice). Leadership, referring to whether the intervention originated with NIHR CLAHRC GM or was initiated by the services or stakeholders involved in delivery, was included to enable us to consider how the TIDieR was used across the different cases. The classification of the case studies was followed by an unstructured discussion on the experience of using TIDieR in the six applied health research projects. The findings of the first workshop were written up, and discussed again at a second workshop, at which the initial ideas were clarified and developed further.

We identified four themes which capture the difficulties or complexities of using TIDieR in applied health research: fidelity and adaptation, voice, communication beyond the immediate context, and use of TIDieR as a research tool, which are described in the results section. We also identified potential revisions or additions to the original TIDieR which would enable it to better capture and reflect key issues in applied health research, described in the discussion section.

12. Results: I think it would help if this section opened with a summary of the results, for example, that four key themes and four potential amendments were identified, before going on to explain these in further detail.

13. We have re-titled the ‘results’ section as ‘The complexities of using TIDieR for applied health research’ to reflect that this is now a debate piece, rather than a research article. We have added a new introduction which identifies the four key themes and four potential amendments early on, before going into further detail:

‘The complexities of using TIDieR for applied health research

We identified four themes which capture the difficulties or complexities of using TIDieR in applied health research: fidelity and adaptation, voice, communication beyond the immediate context, and use of TIDieR as a research tool, which are described in the results section. These are each discussed below. We also identified potential revisions or additions to the original TIDieR which would enable it to better capture and reflect key issues in applied health research, described in the discussion section.’

14. It is stated that the data generated during the studies are available from the corresponding author on reasonable request. Please clarify what data you are referring to here. Transcripts from the consensus workshops?

By ‘data generated during the studies’ we meant ‘data generated during the case studies’. On reflection we don’t think it is necessary in this debate paper to offer to share any data from the original six case studies, so we have deleted that remark, and replaced it with:

‘No new data was generated for this paper.’
15. Appendix 1 - Please amend the intervention descriptions so that they are presented in a consistent format.

We have re-formatted the intervention descriptions to be consistent with one another.