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

TITLE (PROVISIONAL)	Consequences of health condition labelling: protocol for a systematic scoping review
AUTHORS	Sims, Rebecca; Kazda, Luise; Michaleff, Zoe; Glasziou, Paul; Thomas, Rae

VERSION 1 – REVIEW

REVIEWER	David Armstrong King's College London, UK
REVIEW RETURNED	26-Feb-2020

GENERAL COMMENTS	I have no specific comments to make on this protocol. For a systematic scoping review it seems fine. However, I'm amazed that these investigators believe they can actually produce a worthwhile review from this project. I know a little about the sociological literature in this area and it is enormous. Labelling theory goes back to the 1950s and 1960s and has been extensively explored and developed and used as the basis for innumerable studies. Much of the anti-psychiatry movement, for example, was predicated on labelling as has been the field of disability and handicap as well as lots of other areas of clinical practice. And then there is Goffman's Stigma of 1963, the most highly cited qualitative study in the medical world, that has been the inspiration for lots of subsequent studies (I counted over 24,000 hits for stigma in PubMed). Perhaps by cutting out important books/monographs in this area – many of which have been very influential – this review can limit the material it investigates, but at the expense of the study's scope. I cannot imagine a three-year PhD could do anything but explore a small corner of this area; in other words, unless this project is very severely circumscribed, it looks like an impossible task. But maybe they can prove me wrong.

REVIEWER	Elizabeth McCrillis Trent University, Peterborough, Ontario, Canada
REVIEW RETURNED	16-Apr-2020

GENERAL COMMENTS	These are included as notes as well in the PDF attached. 1) there are many grammatical errors which I have highlighted. 2) do you have a set publication time frame you are seeking from the studies you locate? Since you are going beyond the typical available demographic info: How will you obtain these data sets, given that many are not published? Is this a part of your inclusion criterion, that data sets

	are available? If so, will this limit the studies you draw upon? Or, will you be contacting authors to obtain data? If so, how will this timeline affect your work? The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
1) For a systematic scoping review it seems fine. However, I'm amazed that these investigators believe they can actually produce a worthwhile review from this project. I know a little about the sociological literature in this area and it is enormous. Labelling theory goes back to the 1950s and 1960s and has been extensively explored and developed and used as the basis for innumerable studies. Much of the anti-psychiatry movement, for example, was predicated on labelling as has been the field of disability and handicap as well as lots of other areas of clinical practice. And then there is Goffman's Stigma of 1963, the most highly cited qualitative study in the medical world, that has been the inspiration for lots of subsequent studies (I counted over 24,000 hits for stigma in PubMed). Perhaps by cutting out important books/monographs in this area – many of which have been very influential – this review can limit the material it investigates, but at the expense of the study's scope. I cannot imagine a three-year PhD could do anything but explore a small corner of this area; in other words, unless this project is very severely circumscribed, it looks like an impossible task. But maybe they can prove me wrong.
Response: Thank you for this feedback and we acknowledge your concern regarding the potential volume of literature to be included in this scoping review. I am aware of the extensive amount of literature about labelling theories and have used this as a conceptual framework in my PhD. This scoping review will form a chapter in my PhD which aims to provide a broad overview of the consequences of health condition labelling as reported in the published literature. Therefore, this scoping review is limited to "Peer reviewed publications including systematic or literature reviews and original studies which describe the perceived consequences for individuals labelled with a non-cancer health condition will be included." (page 9, lines 2-4). As a result, the body of work you describe, books, monologues and theory-based literature, would not be considered eligible for inclusion. Additionally, we have specified the interrater reliability for study selection on page 11, line 15-17 of the manuscript, "When interrater reliability (Kappa) >0.8 is achieved for the screened studies, remaining studies will continue to be screened by one reviewer (RS)."

Since submission of this manuscript and following feedback from my PhD confirmation of candidature assessment and academic colleagues (who also raised concerns about the scope and size of this study), we have made several changes to the methods. Importantly, these changes will reduce the size of the scoping review without compromising the methodological rigor or generalisability of results. Specifically, the changes relate to the processes that will be used during the data extraction stage of the scoping review. To date the titles and abstracts have been screened (from initial search only) and we are commencing data extraction. Rather than extracting data from all eligible studies, a staged process will be used which has the potential to reduce the extraction process by up to a third. Qualitative data will initially be extracted from a random sample of one-third of included studies and mapped to the coding framework (provided on pages 7-8 of the manuscript). This framework will be expanded as additional themes emerge. A second third of included studies will be randomly selected, data extracted and mapped to the updated coding framework until data thematic saturation has been achieved. These changes are reported in the manuscript on page 12, lines 9-17. The revised text reads, "When interrater reliability (Kappa) >0.8 is achieved for extracted data, one reviewer (RS) will continue to extract data from a random sample of one-third of the remaining included studies, expanding and amending the coding framework as required. Queries will be resolved through discussion with a second reviewer (ZAM). A second third of the remaining included studies will be randomly selected and reviewed, and data extracted to the coding framework, which will be expanded and amended as necessary. Data saturation will be defined using indicative thematic saturation, which states data saturation as the non-emergence of new codes or themes33." Details regarding information to be extracted is provided on page 12, lines 20-21: "For qualitative studies, we will extract author reported themes and supporting quotes provided in the published manuscripts and apply these to the coding framework."

In addition, for quantitative studies, author summaries of primary and secondary outcomes will be extracted. This will reduce the volume of data extraction, while maintaining wealth of information. These changes have been reflected in the manuscript on page 12, lines 21-25: "For studies with quantitative measures, extracted data will include, but is not limited to, author interpretations of primary and secondary outcomes from validated and unvalidated measures (for example, Short Form Health Survey (SF-36)34, or General Health Questionnaire (GHQ)35), as identified in the results section of the published study."

Reviewer: 2
1) there are many grammatical errors which I have highlighted.
Response: Thank you for highlighting the typographic errors throughout the manuscript. I have amended these to reflect correct grammar, with all changes made as per suggestions.

2) do you have a set publication time frame you are seeking from the studies you locate? Since you are going beyond the typical available demographic info: How will you obtain these data sets, given that many are not published? Is this a part of your inclusion criterion, that data sets are available? If so, will this limit the studies you draw upon? Or, will you be contacting authors to obtain data? If so, how will this timeline affect your work?

Response: As per our response to Reviewer 1, our inclusion criteria is any "Peer reviewed publications including systematic or literature reviews and original studies which describe the perceived consequences for individuals labelled with a non-cancer health condition will be included." (page 9, lines 2-4). Our inclusion criteria will not be limited by the date of publication.

The findings of this scoping review will be based on data extracted from published peer-reviewed articles. Specifically, we will extract the themes as identified by the authors of the publication i.e. we will not access or reanalyse the study raw data. As such, we do not require access to original datasets.

We have revised the manuscript to make this point clearer. These changes are on page 12, line 20-21 and the revision now reads, "For qualitative studies, we will extract author reported themes and supporting quotes provided in the published manuscripts and apply these to the coding framework."

VERSION 2 – REVIEW

REVIEWER	Elizabeth McCrillis Trent University, Canada
REVIEW RETURNED	30-Jun-2020

GENERAL COMMENTS	I do not feel my comment below has been addressed at all. I do not see where you are obtaining the data set from, and how you will know once you select your articles if that data set is or is not available. It should be very clearly laid out - once you select X

	articles for inclusion, how, specifically, will you obtain the data set? Data sets are typically not associated with articles and so that process in and of itself has to be articulated. Will you simply be emailing first authors? How long will you wait to hear back? How will you compile all the data that will come in so many different formats? What is the minimum # of datasets you need to receive back in order to continue with the analysis? Overall I would simply like to hear how you plan to obtain the data set. My initial comment: Since you are going beyond the typical available demographic info: How will you obtain these data sets, given that many are not published? Is this a part of your inclusion criterion, that data sets are available? If so, will this limit the studies you draw upon? Or, will you be contacting authors to obtain data? If so, how will this timeline affect your work? I do think the process of qualitative analysis isn't that clearly articulated. Once this is clarified I am happy with the manuscript from my perspective.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 2
1) I do not feel my comment below has been addressed at all. I do not see where you are obtaining the data set from, and how you will know once you select your articles if that data set is or is not available. It should be very clearly laid out - once you select X articles for inclusion, how, specifically, will you obtain the data set? Data sets are typically not associated with articles and so that process in and of itself has to be articulated. Will you simply be emailing first authors? How long will you wait to hear back? How will you compile all the data that will come in so many different formats? What is the minimum # of datasets you need to receive back in order to continue with the analysis? Overall I would simply like to hear how you plan to obtain the data set.

My initial comment: Since you are going beyond the typical available demographic info: How will you obtain these data sets, given that many are not published? Is this a part of your inclusion criterion, that data sets are available? If so, will this limit the studies you draw upon? Or, will you be contacting authors to obtain data? If so, how will this timeline affect your work?

I do think the process of qualitative analysis isn't that clearly articulated.

Once this is clarified I am happy with the manuscript from my perspective.

Response: We appreciate your feedback and apologise for appearing to not adequately address your concerns previously. We meant no offence. To clarify, the data that will be extracted and synthesized in the qualitative component of this scoping review is the abstracted themes and relevant quotations obtained from published articles. When undertaking a qualitative meta-analysis, the original data sets are not the unit of analysis and therefore will not be obtained. This method of qualitative synthesis, or meta-analysis, aligns with the techniques described by Sandelowski, Barroso and Voils (2007), Thomas and Harden (2008), and Timulak (2009). These meta-analytic techniques suggest that data for qualitative analysis is extracted from the results (not discussion or abstract) section of included papers and includes both abstracted findings and contextual information (e.g. quotations from participants). This approach, i.e. extracting the findings as reported by the authors and any supporting quotations, will be used to ensure that the extracted data “retains its meaning” and is not interpreted out of context of the original publication. We have since revised the methods section to clarify this. This methodology has previously been published in BMJ Open, see Anderson et al 2014.

We have made many revisions throughout our methods section to clarify our data extraction and analysis and hope that these address your concerns. The changes that have been made to the manuscript can be found from page 12 line 1 to page 14 line 2.

On behalf of the authorship team, thank you for reviewing our manuscript.

Anderson, K, Stowasser, D, Freeman, C, Scott, I. Prescriber barriers and enablers to minimising potentially inappropriate medications in adults: a systematic review and thematic synthesis. BMJ Open 2014;4:e006544. doi: 10.1136/bmjopen-2014-006544.