

## 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

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| <b>TITLE (PROVISIONAL)</b> | A Modified Delphi study towards developing a guideline to inform policy on Foetal Alcohol Spectrum Disorders in South Africa: A study protocol |
| <b>AUTHORS</b>             | ADEBIYI, BABATOPE; Mukumbang, Ferdinand; Okop, Kufre; Beytell, Anna-Marie  |

### VERSION 1 – REVIEW

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| <b>REVIEWER</b>        | Dorothy Badry<br>University of Calgary, Canada |
| <b>REVIEW RETURNED</b> | 05-Nov-2017                                    |

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| <b>GENERAL COMMENTS</b> | <p>This article describes research that is not yet undertaken and a methodological approach to undertaking various phases of a study and developing a prototype using a Delphi approach. There are claims about the potential value of this research in informing work on FASD in South Africa but there is no research to report on. There are multiple problems with the use of the literature. For example - line 92 refers to studies conducted in USA, South Africa, Canada and Australia and does not cite any studies. On line 113 - "Evidence shows..." - what evidence would be the question when one claims there is evidence. Line 135 - FASD is not yet formalized as a medical diagnosis - a lot of work needs to be done in articulating this and one should look at the Canadian Diagnostic Guidelines on FASD as well as the DSM VI appendix in relation to ND-PAE. The objectives and proposed methodological approach are problematic. The major question I would raise is why write this now? Why not write this once your research is complete so you can report it. I do not see how the proposed approach to research will contribute to the literature on FASD at this time. The proposed limitations of the study on p. 13 are problematic and it is too early to make this decision in the research process. There are a number of grammatical errors throughout the text. See Phase 3 - lines 328-338. See line 380 - "it was gathered" - what was gathered? Terms such as WHO need to be fully spelled out at first usage. It is important to recognize that some key guidelines on FASD research and practice do exist in the literature. L. 416 - this type of research is not generalizable. References are often incomplete and clearly cut and paste - see line 473 for example. Lind 480 - date missing on reference. Full names of journals need to be written out.</p> |
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| <b>REVIEWER</b>        | Dr. Carolyn Blackburn<br>Birmingham City University, England |
| <b>REVIEW RETURNED</b> | 04-Dec-2017  |

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| <b>GENERAL COMMENTS</b> | <p>This is a very important area of study and I enjoyed reading the protocol. The paper represents some interesting discussions, however, some aspects of the paper could be clearer as mentioned below.</p> <p>The methods are not mentioned in the abstract which is an omission and similarly neither are the findings and mention of contribution to new knowledge.</p> <p>The section on methods does not explain the method of data analysis in sufficient detail.</p> <p>The section on ethics does not mention which institution or government departments ethical clearance was obtained from. Nor does it discuss power relationships between researchers and participants, the process of obtaining informed consent or participants right to anonymity, right to withdraw and informed consent.</p> <p>The authors mention strengths and limitations but do not specify which of these two dimensions relates to the non-inclusion of people with FASD.</p> <p>Some of the initial explanations of FASD are quite superficial, for example the suggestion that FASD leads to primary and secondary disabilities is grammatically incorrect (FASD does not lead to this but suggestive of it) -</p> <p>The authors say that there is no national FASD prevalence stats anywhere in the world, yet they do not reference any of the authors from the UK for example, so there may be other omissions and I would recommend that an uptodate search for prevalence studies be conducted since there has been recent work on this in Europe I think.</p> <p>The discussion and conclusion are quite brief and again superficial. I would like to see the findings reported thematically - how many people contributed to each of the claims made by the authors - what was the strength of the claims (how strong was each theme) and a more critical discussion about how this work contributes to the international discussion about guidelines and protocols for FASD and how the work could be generalised / any future work identified and what next.</p> |
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| <b>REVIEWER</b>        | Hayley Passmore<br>Telethon Kids Institute, The University of Western Australia,<br>Australia |
| <b>REVIEW RETURNED</b> | 26-Dec-2017   |

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| <b>GENERAL COMMENTS</b> | <p>Thank you for the opportunity to review your article!<br/>The proposed study will be an important addition to the literature regarding FASD policy, which is currently scarce. Determining a consistent and adequate approach to FASD policy is essential, and this study will assist by adding to the knowledge about FASD policy in South Africa and also globally.<br/>I recommend that this article is published, however do make the following suggestions for your consideration.</p> <p>General comments:</p> <ul style="list-style-type: none"> <li>• Overall structure of the article could be improved, as there is</li> </ul> |
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|  | <p>some unnecessary repetition throughout</p> <ul style="list-style-type: none"> <li>• Sentences and paragraphs could be more concise, and some information (particularly in the introduction and discussion sections) deleted if not essential for the purpose of the proposed study</li> <li>• Some sentences have unnecessary words, so sentences could be made shorter and more to the point. I have not included too many suggestions for individual sentences in this review but instead suggest this could be done throughout to ensure the most relevant and important information is communicated</li> <li>• The ‘feasibility study’ mentioned twice in the article was never actually described – what and who did this involve? What methodological changes were made after the feasibility study?</li> <li>• There are some important references missing, particularly in relation to previous systematic reviews on FASD interventions. Suggestion to review and include the following references: <ul style="list-style-type: none"> <li>o Reid N, Dawe S, Shelton D, Harnett P, Warner J, Armstrong E, et al. Systematic Review of Fetal Alcohol Spectrum Disorder Interventions Across the Life Span. <i>Alcoholism: Clinical and Experimental Research</i>. 2015;39(12):2283-95.</li> <li>o Peadon E, Rhys-Jones B, Bower C, Elliott EJ. Systematic review of interventions for children with Fetal Alcohol Spectrum Disorders. <i>BMC Pediatrics</i>. 2009;9:35-43.</li> </ul> </li> <li>• It would also be helpful to describe how the proposed systematic review (Phase 1, Step 2 of proposed study) will add to the knowledge from the above articles, particularly the most recent being Reid et al. (2015) which was a comprehensive review of current FASD interventions worldwide</li> <li>• Suggestion to make it more clear that Phase 1 has 3 stages or steps, as this can get a bit confusing earlier in the article, particularly in the abstract</li> <li>• There is good detail about the methodology of the proposed study, particularly about phase 1 and its 3 stages/steps. It may be helpful to include more information in the section about Phase 3 by providing examples of what the experts will be asked to comment on and rank, for those who may not be familiar with the Delphi process.</li> <li>• There was some new information in the Discussion (particularly about the development of guidelines for policy, paragraph 3 of Discussion) that was lengthy but unclear, and how and why it was adapted for the proposed study was also unclear. Suggestion to revise this section and either bring it forward into the Introduction or relate it back to the proposed study more</li> <li>• Suggestion to revise Figure 1, possibly by adding in more labels to distinguish the 3 phases</li> </ul> <p>Suggested revisions:</p> <p><b>ABSTRACT</b></p> <ul style="list-style-type: none"> <li>• Introduction 1st sentence – currently says ‘Maternal alcohol consumption during pregnancy results in...defects’ suggestion to change to ‘can result in’, as it is not always the case</li> <li>• Methods and analysis – 2nd sentence – suggestion to add that the review will include global interventions</li> </ul> <p><b>INTRODUCTION</b></p> <ul style="list-style-type: none"> <li>• First paragraph – suggestion to move last sentence ‘FASDs include...’ to be the second sentence of this paragraph, to introduce the different diagnostic terms prior to introducing when the terms were first used</li> <li>• First paragraph 2nd sentence - suggestion to change to ‘The phrase ‘foetal alcohol syndrome’ was first used in 1973.’</li> <li>• First paragraph, 4th sentence – change order of ‘not was’ to ‘was</li> </ul> |
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|  | <p>not'</p> <ul style="list-style-type: none"> <li>• Second paragraph, 2nd sentence – suggestion to change 'attention deficit/hyperactivity' to just 'attention' given that all the other brains domains mentioned are neutral terms whereas this one is describing a deficit/negative term</li> <li>• Fourth paragraph - this reference may be useful here: <ul style="list-style-type: none"> <li>o Elliott EJ, Payne J, Morris A, Haan E, Bower C. Fetal alcohol syndrome: a prospective national surveillance study. Archives of disease in childhood. 2008;93(9):732-7.</li> </ul> </li> <li>• Fifth paragraph – suggestion to revise this paragraph as it's point is unclear. Prenatal alcohol exposure, alcohol disorders and/or dependency, FASD, alcohol advertising and labelling are all issues which of course are related but they require different prevention, intervention and policy approaches which is unclear here.</li> </ul> <p><b>BACKGROUND</b></p> <ul style="list-style-type: none"> <li>• Suggestion to consider merging the introduction and background sections for flow and to avoid repetition or the introduction of new terms which are later described in more detail</li> <li>• First paragraph, last sentence – suggestion to change 'has made FASD a huge problem...' to 'has led to FASD becoming an increasing concern...'</li> <li>• Last paragraph – 'The FASD task team has been successful in the development of FAS training manual for professionals...' what kind of professionals? Health, education or other professionals?</li> <li>• Last paragraph – sentence starting with 'However, a multi-sectorial national FASD task team is needed...' suggestion to revise this sentence</li> </ul> <p><b>RESEARCH AIM</b></p> <ul style="list-style-type: none"> <li>• Suggestion to remove this section entirely as it was already described at the end of the Background and is unnecessary, and the next section about Research Objectives is more detailed</li> </ul> <p><b>DISCUSSION</b></p> <ul style="list-style-type: none"> <li>• More general suggestions for the discussion have been included above in the general comments</li> </ul> <p><b>CONCLUSION</b></p> <ul style="list-style-type: none"> <li>• It may be helpful to comment on how the guidelines, once developed and finalised, will be disseminated and translated into practice for those working for government and other agencies where FASD related policies are necessary. If the researchers already have existing relationships with relevant agencies that will enable the uptake of the guidelines in at least some areas of South Africa, it would be great to bring attention to them here.</li> </ul> <p>An additional reference which may be of use:</p> <ul style="list-style-type: none"> <li>o Watkins RE, Elliott EJ, Halliday J, O'Leary CM, D'Antoine H, Russell E, et al. A modified Delphi study of screening for fetal alcohol spectrum disorders in Australia. BMC Pediatrics. 2013;13(1):13-24.</li> </ul> |
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| <b>REVIEWER</b>        | Roozen<br>Governor Kremers Centre-Maastricht University Medical Centre |
| <b>REVIEW RETURNED</b> | 31-Dec-2017  |

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| <b>GENERAL COMMENTS</b> | <p>I compliment the researchers for addressing the need of FASD policy. FASD is indeed an important health topic. The authors propose a study which could potentially contribute to better development of guidelines on FASD policy.</p> <p>To my opinion this manuscript is not suitable for this journal as a Review article (i.e. not the aim of this manuscript). Given the important and complexity of this health topic, the researcher could improve their manuscript by i) reporting overview articles describing</p> |
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|  | the situation in SA (e.g., meta-analysis of global prevalence rates),<br>ii) using an evidence-based framework to address the study objectives in a systematic way. |
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### VERSION 1 – AUTHOR RESPONSE

Reviewer 1:

There are multiple problems with the use of the literature.

Query: For example - line 92 refers to studies conducted in USA, South Africa, Canada and Australia and does not cite any studies.

Response: This has been address accordingly. It was a systematic review and the findings were drawn from studies conducted from the mentioned countries. We, therefore, have indicated that it was a systematic review.

Action: "A systematic review conducted to identify maternal risk factor for FASD that showed the demographic..."

Query: On line 113 - "Evidence shows..." – what evidence would be the question when one claims there is evidence.

Response: We agree with the reviewer that this is a nonspecific statement. The phrase "Evidence shows..." have been removed and the sentence has been referenced.

Action: Nevertheless, some developed countries like Sweden and Canada provide universal health care (health care for all), making effort to recognise and accommodate the needs of women with an alcohol problem and their children [15].

Query: Line 135 - FASD is not yet formalized as a medical diagnosis – a lot of work needs to be done in articulating this and one should look at the Canadian Diagnostic Guidelines on FASD as well as the DSM-VI appendix in relation to ND-PAE.

Response: We agree with the reviewer that this is a nonspecific statement. The phrase "Evidence shows..." have been removed and the sentence has been referenced.

Action: This is probably because FASD is not yet formalised as a medical diagnosis, even though it is now over 40 years that it was first diagnosed [25]. In spite of this, efforts toward developing guidelines for the diagnoses (Cook et al.; ND-PAE) and management (Australian Action Plan) of FASD have been made to taken steps toward formalising FASD as a public health problem.

Query: The objectives and proposed methodological approach are problematic. The major question I would raise is why write this now? Why not write this once your research is complete so you can report it. I do not see how the proposed approach to research will contribute to the literature on FASD at this time.

Response: This query does align with the journal policy

Query: The proposed limitations of the study on p. 13 are problematic and it is too early to make this decision in the research process.

Response: This query does align with the journal policy

Query: There are a number of grammatical errors throughout the text. See Phase 3 - lines 328-338. See line 380 - "it was gathered" - what was gathered? Terms such as WHO need to be fully spelled out at first usage.

Response: We have addressed the grammatical errors identified by the reviewer

Action: We have gone through the document and addressed the grammatical errors.

Query: It is important to recognize that some key guidelines on FASD research and practice do exist in the literature. L. 416 - this type of research is not generalizable. References are often incomplete

and clearly cut and paste - see line 473 for example. Line 480 - date missing on reference. Full names of journals need to be written out.

Response: We have addressed the grammatical errors identified by the reviewer

Action: We have gone through the document and addressed the issues related to the references.

#### Reviewer 2

Query: The methods are not mentioned in the abstract, which is an omission, and similarly neither are the findings and mention of contribution to new knowledge.

Response: The article outlines a proposed study for developing a guideline for FASD. Therefore, this query does align with the journal policy

Query: The section on methods does not explain the method of data analysis in sufficient detail

Response: We have added more information to this section

Action: The following statements have been added: Both inductive – making interpretations from the raw data – and deductive – using a framework – analytic approaches will be used to analyse the data [Burnard et al 2008]. The framework will be developed from the prevention and management aspects of FASD.

Query: The section on ethics does not mention which institution or government department's ethical clearance was obtained from. Nor does it discuss power relationships between researchers and participants, the process of obtaining informed consent or participants' right to anonymity, right to withdraw and informed consent.

Response: We have added more information to this section

Action: The following statement has been added.

The approval for the study was obtained from the research ethics committee of the University of the Western Cape (BM/16/4/4) and further approvals were obtained from the Western Cape Department of Education (20161212-6937), Department of Health (WC\_2016RP29\_862), and Social Development (12/1/2/4). Before the interviews and the FGDs, the study aims and objectives will be explained to the potential participants and they will be provided with an information sheet written in English explaining their roles. The potential participants will be requested to sign a consent form if they agreed to participate in the study. All participants for the interviews and FGDs will be asked to sign a consent form. All information obtained during the study will be kept strictly confidential in a computer with password known only to the researchers in this study.

Query: The authors mention strengths and limitations but do not specify which of these two dimensions relates to the non-inclusion of people with FASD.

Response: We have clarified this point

Action: A potential limitation to the study is that the study will not include people with FASD

Query: Some of the initial explanations of FASD are quite superficial, for example, the suggestion that FASD leads to primary and secondary disabilities is grammatically incorrect (FASD does not lead to this but suggestive of it)

Response: We have clarified this point

Action: FASD may lead to primary and secondary disabilities.

Query: The authors say that there is no national FASD prevalence stats anywhere in the world, yet they do not reference any of the authors from the UK for example, so there may be other omissions and I would recommend that an up-to-date search for prevalence studies be conducted since there has been recent work on this in Europe I think.

Response: We have found literature on the South African national prevalence of FASD. Following paragraphs have been added.

Action: In South Africa (SA), the national prevalence of FASD ranges from 29 to 290 per 1 000 live births (Olivier, Curfs, Viljoen, 2016). The prevalence of FASD has also been reported in various regions such as in the Northern and Western Cape Provinces. The focus on these two regions is related to the high prevalence of FASD.

In the Northern Cape Province, an estimated 88 per 1,000 of first grade pupils were reported to have FASD in 2008 (Urban et al., 2008). In 2015, although the prevalence had dropped at 63.9 per 1,000 in grade one pupils, the prevalence was still relatively high (Urban et al., 2015). In the Western Cape Province, the prevalence of FASD among primary school pupils was estimated at 89.2/1,000 in 2007 (May et al., 2007). By 2013, the prevalence of FASD among first grade pupils had doubled (135.1 to 207.5 per 1,000) (May et al., 2013). In 2015, the prevalence of FASD among first grade pupils recorded another increase (170 to 233 per 1,000) in the Western Cape (May et al., 2016).

Query: The discussion and conclusion are quite brief and again superficial. I would like to see the findings reported thematically - how many people contributed to each of the claims made by the authors - what was the strength of the claims (how strong was each theme) and a more critical discussion about how this work contributes to the international discussion about guidelines and protocols for FASD and how the work could be generalised / any future work identified and what next.

Response: The article outlines a proposed study for developing a guideline for FASD. It therefore does not have any results yet.

Reviewer 3:

ABSTRACT

Query: Introduction 1st sentence – currently says ‘Maternal alcohol consumption during pregnancy results in...defects’ suggestion to change to ‘can result in’, as it is not always the case.

Response: We agree with the reviewer

Action: We have changed the phrase to ‘can result in’...

Query: Methods and analysis – 2nd sentence – suggestion to add that the review will include global interventions

Response: We agree with the reviewer

Action: We have changed the phrase to ‘global’...

INTRODUCTION

Query: First paragraph – suggestion to move last sentence ‘FASDs include...’ to be the second sentence of this paragraph, to introduce the different diagnostic terms prior to introducing when the terms were first used

Response: We agree with the reviewer

Action: We have moved it to the second sentence

Query: First paragraph 2nd sentence - suggestion to change to ‘The phrase ‘foetal alcohol syndrome’ was first used in 1973.’

Response: We agree with the reviewer

Action: We have moved it

Query: First paragraph, 4th sentence – change order of ‘not was’ to ‘was not’

Response: We agree with the reviewer

Action: We have changed it

Query: Second paragraph, 2nd sentence – suggestion to change ‘attention deficit/hyperactivity’ to just ‘attention’ given that all the other brains domains mentioned are neutral terms whereas this one is describing a deficit/negative term

Response: We agree with the reviewer

Action: We have changed it

Query: Fourth paragraph – this reference may be useful here: Elliott EJ, Payne J, Morris A, Haan E, Bower C. Fetal alcohol syndrome: a prospective national surveillance study. Archives of disease in childhood. 2008;93(9):732-7.

Response: We have found literature on the South African national prevalence of FASD. Following paragraphs have been added.

Query: Fifth paragraph – suggestion to revise this paragraph as it's point is unclear. Prenatal alcohol exposure, alcohol disorders and/or dependency, FASD, alcohol advertising and labelling are all issues which of course are related but they require different prevention, intervention and policy approaches which is unclear here.

Response: We agree with the reviewer

Action: We have changed it to read:

Prevention, care and support for persons affected by FAS and other alcohol-related disorders are not being implemented, particular in developing countries [15]. Peadon et al. and Reid et al. [26, 27] reported the lack of good quality study studies and limited strong evidence for specific interventions in managing FASD [26]. The authors, therefore, advocated for interventions targeting the specific clinical and neuropsychological deficits usually seen in individuals with FASD.

## BACKGROUND

Query: First paragraph, last sentence – suggestion to change ‘has made FASD a huge problem...’ to ‘has led to FASD becoming an increasing concern...’

Response: We agree with the reviewer

Action: We have changed it as suggested

Query: Last paragraph – ‘The FASD task team has been successful in the development of FAS training manual for professionals...’ what kind of professionals? Health, education or other professionals?

Response: We agree with the reviewer

Action: We have included the types of professions involved

The FASD task team has been successful in the development of FAS training manual for health care workers, educators, school psychologists, social workers and other professionals working with individuals with FASD, their families and caregivers. In addition, the FASD task team has designed posters for creating awareness on FASD, organising special events to improve public awareness on International FASD Days, organising FASD training workshop and, the development of a website and Facebook page on FASD [32, 33].

Query: Last paragraph – sentence starting with ‘However, a multi-sectorial national FASD task team is needed...’ suggestion to revise this sentence

Response: We agree with the reviewer

Action: We have changed it as suggested. The sentence now reads:

The above development is an important and commendable step in developing the capacity to support the prevention and management of FASD at the provincial level. Nevertheless, a coordinated effort toward the prevention and management of FASD at the national level is required. To this end, we are proposing a national FASD guideline that will inform policy on coordinated and multi-sectoral response to FASD in South Africa. In this protocol, we propose systematic steps toward developing a guideline to inform policy for FASD prevention and management.

## RESEARCH AIM

Query: Suggestion to remove this section entirely as it was already described at the end of the Background and is unnecessary, and the next section about Research Objectives is more detailed

Response: We agree with the reviewer



Action: We have removed it as suggested.

## CONCLUSION

Query: It may be helpful to comment on how the guidelines, once developed and finalised, will be disseminated and translated into practice for those working for government and other agencies where FASD related policies are necessary. If the researchers already have existing relationships with relevant agencies that will enable the uptake of the guidelines in at least some areas of South Africa, it would be great to bring attention to them here.

An additional reference, which may be of use:

Response: We agree with the reviewer

Action: We have included this in last paragraph of the discussion

Reviewer 4:

Query: To my opinion this manuscript is not suitable for this journal as a Review article (i.e. not the aim of this manuscript). Given the important and complexity of this health topic, the researcher could improve their manuscript by i) reporting overview articles describing the situation in SA (e.g., meta-analysis of global prevalence rates), ii) using an evidence-based framework to address the study objectives in a systematic way.

Response: The article outlines a proposed study for developing a guideline for FASD. Therefore, this query does align with the journal policy

## VERSION 2 – REVIEW

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| <b>REVIEWER</b>        | Hayley Passmore<br>Telethon Kids Institute, The University of Western Australia,<br>Australia |
| <b>REVIEW RETURNED</b> | 01-Feb-2018   |

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| <b>GENERAL COMMENTS</b> | <p>Thank you for the opportunity to review this article again.</p> <p>I appreciate the authors have agreed with and revised the article based on some of the reviewers' comments, and made several positive changes to the manuscript. I do make the following suggestions for consideration:</p> <ul style="list-style-type: none"><li>• Unfortunately, many sentences that have been edited or added in the revised version are now grammatically incorrect, and the tense used is not consistent throughout the article. I suggest that the entire article is checked for grammatical errors, as some sections do not use a level of English acceptable for publication and there are too many minor grammatical errors to go through individually</li><li>• Sentences and paragraphs throughout could be more concise, and some information deleted if not essential (e.g. definitions of common terms, examples are useful but definitions may be unnecessary)</li><li>• While the abstract has been revised to make clear that there are 3 steps to Phase 1, this clarity should also be present in the first paragraph after the heading 'Phase 1: Information gleaning' (end of page 10). Suggestion to edit sentence starting with "In the first phase..." to mention that in Phase 1, 3 steps will be undertaken with the purpose of obtaining diverse information to develop a prototype guideline.</li></ul> |
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|  | <ul style="list-style-type: none"> <li>• As the previous reviews stated, there are several issues with the literature and references that are still yet to be corrected. The reference list should be checked to ensure all references conform to the referencing style. For example, the full reference for reference #5 (Streissguth et al., 1996) currently does not conform. For reference #17, page numbers '35-43' should be added. There are a couple of references with 'Epub ahead of print' where the articles are a few years old, so full references may now be available to include. Reference #50 may have an error in the title name (and should it be italicised?). Reference #52 appears to have an error with two links included.</li> <li>• Suggestion to expand 'FGDs' and 'PICO'.</li> <li>• The list included in the second paragraph of the Discussion is still unclear, and not introduced clearly as steps the authors will undertake to develop the guidelines. Suggestion to revise this paragraph</li> <li>• Suggestion to change the phrase 'huge problem' to 'major concern' or similar</li> </ul> <p>Thank you again, I look forward to reading your published article.</p> |
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## VERSION 2 – AUTHOR RESPONSE

### RESPONSE TO REVIEWER

#### REVIEW

Query: Unfortunately, many sentences that have been edited or added in the revised version are now grammatically incorrect, and the tense used is not consistent throughout the article. I suggest that the entire article is checked for grammatical errors, as some sections do not use a level of English acceptable for publication and there are too many minor grammatical errors to go through individually

Response: We agreed with the reviewer

Action: The entire article has been checked for grammatical errors.

Query: Sentences and paragraphs throughout could be more concise, and some information deleted if not essential (e.g. definitions of common terms, examples are useful but definitions may be unnecessary)

Response: We agreed with the reviewer

Action: The sentences and paragraphs have been made concise and some information that are not essential deleted.

Query: While the abstract has been revised to make clear that there are 3 steps to Phase 1, this clarity should also be present in the first paragraph after the heading 'Phase 1: Information gleaning' (end of page 10). Suggestion to edit sentence starting with "In the first phase..." to mention that in Phase 1, 3 steps will be undertaken with the purpose of obtaining diverse information to develop a prototype guideline.

Response: We agreed with the reviewer. We have added the reviewer's suggestion

Action: The following statements have been added: "In Phase 1, three steps will be undertaken with the purpose of obtaining diverse information to develop a prototype guideline.

Query: As the previous reviews stated, there are several issues with the literature and references that are still yet to be corrected. The reference list should be checked to ensure all references conform to the referencing style. For example, the full reference for reference #5 (Streissguth et al., 1996) currently does not conform. For reference #17, page numbers '35-43' should be added. There are a couple of references with 'Epub ahead of print' where the articles are a few years old, so full

references may now be available to include. Reference #50 may have an error in the title name (and should it be italicised?). Reference #52 appears to have an error with two links included

Response: We agreed with the reviewer

Action: The references have been corrected.

Query: Suggestion to expand 'FGDs' and 'PICO'.

Response: We agreed with the reviewer

Action: We added, "Focus groups use unstructured discussion subjects involving small ranges of subjects (6-10). It is cost-effective and time-efficient and participants are allowed to express their viewpoints in detail. Discussants are often motivated to contribute more in the presence of their co-participants [42]. In addition, focus group discussions can give rich information as discussants contribute in moderated discussions".

"The team formulated key PICO questions [39]

Population – individuals with FASDs,

Intervention – a guideline to inform policy,

Comparison – (Not applicable) and

Outcomes – a guideline for the prevention and management of FASDs".

Query: The list included in the second paragraph of the Discussion is still unclear, and not introduced clearly as steps the authors will undertake to develop the guidelines. Suggestion to revise this paragraph

Response: We agreed with the reviewer

Action: The paragraph has been revised. "In developing the guideline for FASDs, we adopted the WHO's approach (steps) as stipulated in the WHO's Handbook for guideline development [35, 36].

- We agreed to design a guideline for the prevention and management of FASDs based-on informal discussions with relevant stakeholders on the need for a policy governing the prevention and management efforts of FASDs;

- We planned on scoping of the literature and conducting a needs assessment;

- After gathering preliminary information, the team formulated key PICO questions [39]

Population – individuals with FASDs,

Intervention – a guideline to inform policy,

Comparison – (Not applicable) and

Outcomes – a guideline for the prevention and management of FASDs;

- After agreeing on the need to design the guideline to inform policy on the prevention and management of FASDs, the next step involved designing the project protocol (which is reported in this paper).

- The team applied for Ethics clearance for the project from the University of the Western Cape – this has been obtained.

- The next step will entail conducting the various studies and exercises outlined in this protocol;

- The team will develop and prepare the guideline to inform policy on FASDs based on the findings of the various studies and the outcomes of the various exercises.

- The team will disseminate the developed guideline through various channels including having feedback meetings with the various stakeholders and sharing our findings, publish the guideline in a peer-reviewed journal, present the findings in journal club meeting organised at the provincial department of Health and at other national and international conferences [35, 36].

Some of the steps outlined in the WHO's handbook were adapted to our context. The reason for the adaptation is that some parts of the process are not applicable to this study and other parts are beyond the scope of this project.

Query: Suggestion to change the phrase 'huge problem' to 'major concern' or similar

Response: We agreed with the reviewer.

Action: 'huge problem' has been changed to 'major concern'

