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)	An investigation of alcohol's role in self-harm in rural Sri Lanka: a protocol for a multi-method, qualitative study
AUTHORS	Soerensen, Jane; Rheinländer, Thilde; Soerensen, Birgitte; Pearson, Melissa; Agampodi, Thilini; Siribaddana, Sisira; Konradsen, Flemming

VERSION 1 - REVIEW

REVIEWER	John Foster University of Greenwich United Kingdom
REVIEW RETURNED	06-Jul-2014

GENERAL COMMENTS	I think overall this paper is high and generalities and lacking in specific details that would make it hard if not impossible to replicate. I also have significant concerns about the ethical standards of the study as they are presented here. This is a paper which descibes the protocol for a qualitative study and is not testing any hypotheses. Throughout the paper is too long for the BMJ. I also feel it is high in generalities and lacking specific details that could justify publication. Abstract needs to be far more tighter and detailed. Page 5: Alcohol and self-harm etc: Needs to introduce pesticides at this point- especially bearing in mind where the study is being conducted. Page 6: The section on alcohol use leads me to question the expertise of the team. It is true alcohol consumption is on the rise but the legal purchase of alcohol is at a low level. By far most consumption is illicitly distilled such as kassipu- see Foster and Jayasinghe. There is no indication of this in this section. Again this is particulalrly pertinent considering where the study is conducted and the links of alcohol to DSH and suicide in Sri Lanka. Page 10: Selection. What you have described are inclusion criteria. There is minimal details about how the study participants are selected. Bearing in mind the sensitivity of the subject matter this needs to be spelled out so that the reviewers can assess the ethical standards of the study.- i.e consent, coercion etc. Currently I am not satisfied the study is ethically sound not withstanding ethical approval having been granted. Page 11- what is theoretical saturation- do you mean data

	saturation? If not state clearly what you mean and equally importantly how this is to be assessed/agreed upon. Page 12: Participant Observation. Far more detail is required here. How the sites selected- who selects the participants?- what is the protection against harm for the participants. What is the data?- notes, diaries, taped transcripts? How can participants opt out of being observed? What about people who happen to be in the setting but have not consented to be observed? Page 16: Is the analysis linked to a theory? I assume Kleinmann. Previously you have mentioned the term theoretical saturation!!! Page 17: Line 17. The sentence begining "The participants will serve etc...." is meaningless- it tells me nothing- how is this done? Also reflexivity- the same comments apply- how?

REVIEWER	Norman Giesbrecht Senior Scientist Emeritus Centre for Addiction & Mental Health, Canada
REVIEW RETURNED	10-Jul-2014

GENERAL COMMENTS	This paper provides useful background information, goals and methods for a study to be conducted. However no results are provided. Very interesting information is presented about the topic and context of alcohol and self-harm in Sri Lanka. The objectives, as stated, relate to a paper where results are presented, not to this manuscript, where a protocol is presented. I have reservations about a manuscript focusing on a protocol for a study to be conducted. The opening pages of the manuscript also need to refer to access to alcohol as contributing cause and references provided. Also, recent papers by Mark Kaplan and colleagues on acute alcohol and suicide in the US might be cited. I recommend that the paper have a new title and be restructured and revised. with four interrelated main parts: 1.Provide more information on drinking levels, patterns and contexts of alcohol use in Sri Lanka and in the region that will be the focus of the proposed study. 2. Expand on current text and provide literature review of self-harm and alcohol [both acute and chronic] focusing on literature most relevant to Sri Lanka - so not a comprehensive review. This review would inform part 3 - i.e., what conceptual framework, if any, have other authors used who have written on this topic; also point to specific questions to be addressed in future studies - part 4 3. Provide a conceptual framework for understanding the relationship between alcohol use and self-harm - possible with a diagram(s) illustrating a conceptual framework (s).

	This part should also seek to systematically discuss what role alcohol plays relative to other key factors. A very interesting point raised in the manuscript is self-harm linked to heavy drinking or abuse behavior related to alcohol intake by others, in this case they might seek to draw in some of the new evidence on 'harm to others' from alcohol. 4. This version of the manuscript might end with a short description of the protocol, using an abridged version of pages 8 to middle of 15. Specific comments. Does self-harm mean suicide attempts/suicide, or include other behavior? If the former, why not use suicide. pg 4, line 12. Suggest adding quantitative information pg 5, line 24 -expand on access to alcohol pg 5, line 44, How is"influence of alcohol' measured? pg 5, line 48: Does 'alcohol misuse' refer to chronic use or dependencre, or acute alcohol use, or a combination? pg 6, first paragraph, Suggest providing information/data on estimates of per capita consumption, % current drinkers by males and females, I have not provided specific comments on page 8 onward, other than to suggest that a revised version of the paper might conclude with abridged version of pages 10 to middle of page 15.

VERSION 1 – AUTHOR RESPONSE

Throughout the paper is too long for the BMJ. I also feel it is high in generalities and lacking specific details that could justify publication.

- The length of the paper is within the limits recommended by the journal.

Abstract needs to be far more tighter and detailed.

- The abstract has been revised and more detail provided.

Page 5: Alcohol and self-harm etc: Needs to introduce pesticides at this point- especially bearing in mind where the study is being conducted.

- This point has been included:
"A few researchers have touched on it(5,23–25) and a Sri Lankan study of 159 acute self-poisoning cases - the most common method of self-harm in Sri Lanka being pesticide poisoning(26)(…)"

Page 6: The section on alcohol use leads me to question the expertise of the team. It is true alcohol consumption is on the rise but the legal purchase of alcohol is at a low level. By far most consumption is illicitly distilled such as kassipu- see Foster and Jayasinghe. There is no indication of this in this

section. Again this is particulalrly pertinent considering where the study is conducted and the links of alcohol to DSH and suicide in Sri Lanka.

- This section has been revised with a special emphasis on the role of kassipu. The Foster and Jayasinghe paper has been cited.
"Officially, alcohol consumption is relatively low in Sri Lanka with an alcohol per capita intake of 3.7 litres in 2010 (2.2 in 2005) – numbers which include the WHO estimate of unrecorded liquor. (15) However, Sri Lankan alcohol data is believed to be inaccurate.(27) Most alcohol consumed is the easily accessible, cheap, unrecorded, and illicitly brewed 'kassipu', mainly consumed in poor, rural areas,(23,28,29) – and difficult to document. Some suggest that up to 50 – 90% of alcohol consumed is illicit (24,29,30) and the actual alcohol consumption level potentially much higher. Further, with a lifetime abstinence rate at a high 69%,(15) many drinkers consume alcohol above the average."

Page 10: Selection. What you have described are inclusion criteria. There is minimal details about how the study participants are selected. Bearing in mind the sensitivity of the subject matter this needs to be spelled out so that the reviewers can assess the ethical standards of the study.- i.e consent, coercion etc. Currently I am not satisfied the study is ethically sound not withstanding ethical approval having been granted.

- We have from the onset of the preparation of this study been concerned about the protection of individuals in relation to talking about these highly sensitive and potentially traumatizing issues. Taking the above comments into account, we have elaborated on and revised the sampling strategy to provide greater clarity – it has now been gathered in one chapter "Inclusion criteria and selection of participants ". Please also refer to the last chapters of the paper covering sensitive data collection, consent and other ethical issues.

Page 11- what is theoretical saturation- do you mean data saturation? If not state clearly what you mean and equally importantly how this is to be assessed/agreed upon.

- We mean data saturation, which has now been reflected.

Page 12: Participant Observation. Far more detail is required here. How the sites selected- who selects the participants?- what is the protection against harm for the participants. What is the data?- notes, diaries, taped transcripts? How can participants opt out of being observed? What about people who happen to be in the setting but have not consented to be observed?

- More details have been included about participant observation:

In terms of selection, this is covered in "Inclusion criteria and selection of participants".

In terms of the data obtained, this is covered in "data management"

In terms of opting out, this is covered in "informed consent". At any new encounter participants will be presented the opportunity of opting out of the study.

General ethical concerns are reflected in the chapter "Ethics and dissemination", which also includes the ethical clearance of the project by the relevant Sri Lankan authorities.

Page 16: Is the analysis linked to a theory? I assume Kleinmann. Previously you have mentioned the term theoretical saturation!!!

- The conceptual framework chapter covering the linkage between theory and analysis has been

revised; please refer to the chapter “Conceptual framework”. A reference to the conceptual framework is also made in the paragraph “analysis”. Kleinmann is one of the main theories we use.

Page 17: Line 17. The sentence begining "The participants will serve etc...." is meaningless- it tells me nothing- how is this done?

- This sentence has been taken out.

Also reflexivity- the same comments apply- how?

- The wording of this sentence has been changed and now reads:
“This will carefully be considered throughout the study by discussing such preconceptions within the research team, by maintaining diaries to systematically document them and thus enhance trustworthiness and transparency. (70)”

This paper provides useful background information, goals and methods for a study to be conducted. However no results are provided.
The paper is a protocol for a study and therefore no results have been provided.

Very interesting information is presented about the topic and context of alcohol and self-harm in Sri Lanka.

The objectives, as stated, relate to a paper where results are presented, not to this manuscript, where a protocol is presented. I have reservations about a manuscript focusing on a protocol for a study to be conducted.

- Only parts of this and following comments have been included as per the suggestions from the editor ("to an extent the reviews below clash. The first wants more detail on the methods of the study; the second wants a rewrite to downplay the protocol element. As this is a protocol paper please follow the prompts of the first reviewer, accommodating those elements of the second review which can cohere with the protocol structure").

The opening pages of the manuscript also need to refer to access to alcohol as contributing cause and references provided.

- This has been included (p. 5).
“International research shows that both acute and chronic alcohol use are associated with suicidal behaviour,(10–15) influenced by access to alcohol in a certain context(13) as well as the amounts consumed.(16)”

Also, recent papers by Mark Kaplan and colleagues on acute alcohol and suicide in the US might be cited.

- A paper by Mark Kaplan has been cited (p. 5).

I recommend that the paper have a new title and be restructured and revised. with four interrelated main parts:

- This comment was not considered relevant for this article format.

1. Provide more information on drinking levels, patterns and contexts of alcohol use in Sri Lanka and in the region that will be the focus of the proposed study.

- More information is now included in the section “Alcohol use in Sri Lanka” (p. 6):
“Officially, alcohol levels are relatively low in Sri Lanka with an alcohol per capita intake of 3.7 litres in 2010 (2.2 in 2005) – numbers which include the WHO estimate of unrecorded liquor. (15) However, Sri Lankan alcohol data is believed to be inaccurate.(27) Most alcohol consumed is the easily accessible, cheap, unrecorded, and illicitly brewed ‘kassipu’, mainly consumed in poor, rural areas,(23,28,29) – and difficult to document. Some suggest that up to 50 – 90% of alcohol consumed is illicit (24,29,30) and the actual alcohol consumption level potentially much higher. Further, with a lifetime abstinence rate at a high 69%,(15) many drinkers consume alcohol above the average.”

2. Expand on current text and provide literature review of self-harm and alcohol [both acute and chronic] focusing on literature most relevant to Sri Lanka - so not a comprehensive review.

- The text has been expanded and now contains more specific information on alcohol and self-harm in Sri Lanka, i.e. see previous comment.

This review would inform part 3 - i.e., what conceptual framework, if any, have other authors used who have written on this topic; also point to specific questions to be addressed in future studies - part 4

- This comment was not considered relevant for this article format however it will be taken into consideration in future papers.

3. Provide a conceptual framework for understanding the relationship between alcohol use and self-harm - possible with a diagram(s) illustrating a conceptual framework (s).

- The conceptual framework has been revised. Please refer to: “Conceptual framework”

This part should also seek to systematically discuss what role alcohol plays relative to other key factors.

- This is an important point, which will be considered and included in future publications.

A very interesting point raised in the manuscript is self-harm linked to heavy drinking or abuse behavior related to alcohol intake by others, in this case they might seek to draw in some of the new evidence on 'harm to others' from alcohol.

- The concept of alcohol’s harm to others is included in the “conceptual framework” and is a very important point for the study and future papers.

4. This version of the manuscript might end with a short description of the protocol, using an abridged version of pages 8 to middle of 15.

- This is not considered relevant for this article format.

Specific comments.

Does self-harm mean suicide attempts/suicide, or include other behavior? If the former, why not use suicide.

- A definition of self-harm has been included (p.5):
“It should be noted that the term ‘self-harm’ is used throughout this paper to describe deliberate injury

to one self. This definition captures two important points; that most cases of self-harm in the Sri Lankan context are non-fatal, and with little or no intent to die, and can thus not be classified as 'suicide attempts'.(22)"

pg 4, line 12. Suggest adding quantitative information

- This has been included.
"Though a decrease has been seen in recent years (from 47 to 23 per 100,000 population in 1995 and 2006, respectively), Sri Lanka still has one of the highest suicide and self-harm rates globally.(3)"

pg 5, line 24 -expand on access to alcohol

- This has been included – see previous comment.

pg 5, line 44, How is"influence of alcohol' measured?

- "Influence of alcohol" was measured as individuals visibly intoxicated by alcohol. Families and bystanders confirmed the alcohol intake. This has been included in the revised paper.
"A few researchers have touched on it(5,23–25) and a Sri Lankan study of 159 acute self-poisoning cases - the most common method of self-harm in Sri Lanka being pesticide poisoning(26) - found that 32% were visibly affected by alcohol when admitted to hospital, which was confirmed by family and bystanders.(5) "

pg 5, line 48: Does 'alcohol misuse' refer to chronic use or dependencre, or acute alcohol use, or a combination?

- It refers to problem drinking or alcohol dependence. This has been reflected.
"Another study conducted a psychological autopsy of 372 suicides in rural Sri Lanka to find that problem drinking or alcohol dependence was common among male suicides in 61% of cases while alcohol misuse in another family member was believed to contribute to 14% of female suicides.(7)"

pg 6, first paragraph, Suggest providing information/data on estimates of per capita consumption, % current drinkers by males and females,

- This has been included.
"Alcohol consumption in Sri Lanka is almost exclusively a male practise (25) (annual per capita consumption was 7.3 litres for males and 0.3 litres for females, according to 2010 estimates)(15) and the types of alcohol consumed are closely linked to class and status.(30)"

I have not provided specific comments on page 8 onward, other than to suggest that a revised version of the paper might conclude with abridged version

- This is not considered relevant for this article format.

VERSION 2 – REVIEW

REVIEWER	John Foster University of Greenwich UK
REVIEW RETURNED	23-Aug-2014

GENERAL COMMENTS	In the end this is your call as to whether to proceed. Whilst this is an improvement key issues of Sri Lankan alcohol culture are barely

	considered in my judgement the whole of the manuscript needs to be re-visited. This is an improvement on the first version and it is far clearer however in consequence a major limitation becomes apparent. Whilst you have mentioned responding to Sri Lankan culture on numerous occasions in my opinion you have only paid lip service to key aspects of the Sri Lankan alcohol culture which are fundamental to this study. I feel that this still is underpinned with assumptions about western alcohol culture. In particular the fact that most of the alcohol consumed will be illicitly distilled and very strong is barely addressed in the protocol. This will have issues in terms of availability of the alcohol, impulsive behaviours etc. In my opinion the whole of the manauscript needs to be re visited so that these facets of Sri Lankan alcohol culture are interwoven throughout. Currently they are barely addressed: Other issues:Page 11: What is the professional background of the "Safe Storage Colleagues" how are they qualified to identify self harm cases in the area. Page 12: What is the rationale for interviewing households where self-harm or alcohol use is not an issue- what can these participants add? - they might carry stigma.

VERSION 2 – AUTHOR RESPONSE

In the end this is your call as to whether to proceed. Whilst this is an improvement key issues of Sri Lankan alcohol culture are barely considered in my judgement the whole of the manuscript needs to be re-visited. See below

This is an improvement on the first version and it is far clearer however in consequence a major limitation becomes apparent. Whilst you have mentioned responding to Sri Lankan culture on numerous occasions in my opinion you have only paid lip service to key aspects of the Sri Lankan alcohol culture which are fundamental to this study. I feel that this still is underpinned with assumptions about western alcohol culture. In particular the fact that most of the alcohol consumed will be illicitly distilled and very strong is barely addressed in the protocol. This will have issues in terms of availability of the alcohol, impulsive behaviours etc. In my opinion the whole of the manauscript needs to be re visited so that these facets of Sri Lankan alcohol culture are interwoven throughout. Currently they are barely addressed:

- We fully acknowledge that alcohol culture is an important part of this study and following your input the team will place an even greater focus on these aspects of the study. This is also the reason why an exploration of perceptions of alcohol's role in self-harm at the community level is part of the study.

While illicit alcohol is an important component in Sri Lankan alcohol consumption, it is evident that an increase of licit brewed brands has been happening in recent years with alcohol being marketed and consumed in the open.The role and culture around both branded alcohol as well as the continued high consumption of illicitly brewed alcohol will be thoroughly investigated in the study. This has been more clearly reflected in the section where we describe the themes for the narrative, life-story interviews:

"Themes to be explored include: Perceptions and beliefs of alcohol use and misuse; alcohol

preferences; availability and access to alcohol; perceived impact of alcohol use; coping strategies used by alcohol consumers and significant others; and explanatory models of self-harm, including perceived causes." (p.13).

In terms of impulsive behavior, as you mention, this has been reflected several places – for example on p. 5 in the section on alcohol, self-harm and suicide. The patterns of alcohol drinking in the specific cases of self-harm will be vital for the study and future papers. We have further included a sentence in the section on Alcohol, self-harm and suicide in Sri Lanka:

"None of these studies thoroughly investigated the dynamics and complex interlinkages between alcohol and self-harm and researchers have called for further investigation of the links between alcohol, impulsive behavior and self-harm in Sri Lanka.(23)" (p.6)

It should further be noted that the first author will spend considerable time in Sri Lanka to fully grasp the situation on the ground (about 10 months), and work closely with two highly qualified research assistants trained in sociology and social work and who have previously carried out similar kinds of interviews.

While in Sri Lanka she is attached to The Department of Community Medicine, Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka. Two very experienced health professionals from said University, Prof. Siribaddana and Dr. Thilini Agampodi, are co-investigators of the study. Prof. Siribaddana has been involved in studies investigating illicit alcohol and is familiar with illicit (kassipu-susduwa) and semi-legal (ra) alcohol culture. Dr. Thilini Agampodi has carried out extensive qualitative work in villages in the Anuradhapura area and is thus also very familiar with the dynamics and workings of such communities. Throughout the data collection and analysis findings will be presented and discussed within the research group to ensure all relevant aspects of the connection between alcohol and self-harm are captured.

In that connection, it has been a great concern for the research group to ensure that all cultural, religious and context specific issues are captured in this research. As per the suggestion of the Sri Lankan co-investigators, we will in carrying out the in-depth interviews and FGDs keep transcripts in both English and Sinhala to ensure we capture all details important to understand Sri Lankan alcohol culture and the role it plays in self-harm cases. This is reflected in the chapters about Data Management and Analysis.

Other issues:Page 11: What is the professional background of the "Safe Storage Colleagues" how are they qualified to identify self harm cases in the area.

- For more than 13 years, SACTRC/the Safe Storage project has worked with a carefully trained team of data collectors. This team consists of highly professional and trained individuals with a background in clinical medicine, public health and data collection methods, who on a daily basis report on self-harm cases admitted to hospitals within the study area. Mechanisms for standard reporting and measures of quality insurance have been put into place. As part of SACTRC/Safe Storage - a national and international network of collaboration, backed at the province and district level - their data collection has laid the ground for a large number of high impact papers.

We acknowledge that this fact should be better presented in the paper and this has now been reflected in the chapter on Inclusion criteria and selection of participants:

"A) and B) will be identified by trained Safe Storage research officers, who are already on a daily basis identifying all self-harm cases within the study area. Mechanisms for standard reporting and

measures of quality insurance have been put into place and their presence are supported at the Province and District levels."(p.11)

Page 12: What is the rationale for interviewing households where self-harm or alcohol use is not an issue- what can these participants add? - they might carry stigma.

- The focus group discussions (FGDs) will be carried out to get the broader community perspectives of alcohol's role in self-harm, and they will be key in fully grasping the alcohol culture and perceptions of the same in the study area, in terms of how alcohol and self-harm are perceived, how communities react towards intoxicated individuals and their families as well as towards individuals who has previously self-harmed and their families. We believe an exploration of community dynamics is essential for fully understanding the alcohol culture and how it is linked to self-harm cases and that FGDs are a relevant method to achieving that. The topics will be raised as general, non-personal issues with respect for what the participants feel comfortable discussing. The FGDs will not be carried out in villages where the narrative, life-story interviews will take place in order to ensure and maintain the anonymity and trust of those participants.

- Finally, we have in the Introduction included a more recent reference on the statistics of suicide in Sri Lanka from the recently published report by WHO:

Though a decrease has been seen in recent years (from 47 per 100,000 population in 1995(3) to 28.8 per 100.000 in 2012, the latter estimate is based on expert modeling methods),(4) Sri Lanka still has one of the highest suicide and self-harm rates globally.(5)