

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)	Exploring the acceptability of a 'limited patient consent procedure' for a proposed blood-borne virus screening programme: a Delphi consensus building technique
AUTHORS	Crane, Denise; Henderson, Emily J.; Chadwick, David

VERSION 1 - REVIEW

REVIEWER	Rodney Hicks Western University of Health Sciences Pomona, Ca USA
REVIEW RETURNED	23-Dec-2016

GENERAL COMMENTS	<p>Title The title may be a bit confusing. The word "limited" is throwing off the wording. From reading the manuscript, the authors did not propose a limited consent form. Rather there was a brief exploration of ethical and societal pressures to change the process.</p> <p>Abstract The word "potentially" is soft. Take an approach, either it is or it is not.</p> <p>General comment (but first appears in conclusion) Some of the sentences are long and a reader stumbles. Please consider shorter sentences such that the intent is clear.</p> <p>Strengths This sentence will certainly raise controversy. Implementing the novel consent process must be considered from the lens of legal standards (privacy laws) in place.</p> <p>Page 4 Line 23. Instead of "and", perhaps the word "or" should be considered?</p> <p>General comment. Please check punctuation throughout. Missing commas, hypens, etc.</p> <p>Bottom of page 4. Despite 'this' (please substitute 'barrier' for the word this to add specificity.</p> <p>Editorial comment: reference on page 17 (17,11 should be 11,17)</p>
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	<p>Lines 29 = reads funny</p> <p>Page 5</p> <p>Second paragraph. I think the word “rates” is needed in the first sentence. The new approaches won’t reduce undiagnosed infections – the action affects rates.</p> <p>Page 6.</p> <p>There was no patient involvement in this study (change to was not is)</p> <p>Page 7</p> <p>Avoid starting a sentence with the word IT (check punctuation)</p> <p>Page 7. The sentence with vignettes were written ---- this reads funny, hard to follow</p> <p>Page 8. Line 30. Change “their” to “the”</p> <p>Page 9. Table 1. Consider adding the word “years” Age range (years) Mean Age (years)</p> <p>Page 15</p> <p>The paragraphs are excessively long; the content is most likely more than one paragraph.</p> <p>Page 17.</p> <p>I take exception to the conclusion about the special status. The example of the GP in Stigma (Case 1) demonstrated a short coming in the competence of the provider more so than the issue.</p> <p>Summary</p> <p>I wish to offer the following summary statements to assist the editor in reaching a decision.</p> <ol style="list-style-type: none"> 1. The scholarly writing of the manuscript meets scientific merit in most places. There are a few places where sentences can be restructured to emphasize content and help the reader. 2. Methodology. The method was appropriate for exploring this topic. The authors have followed generally approved methods. With the wording select and the negative words, a clear picture of findings was easy to follow. 3. Contribution to scientific merit. The manuscript offers very little to scientific knowledge. Rather the substance is more of public policy, ethics, and Health professional education. 4. The discussion on the computer screening was most intriguing. Computers do not replace the human context of the patient/provider
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	<p>interaction. The computer support logic can support the provider interaction with the patient; however, the provider must still have the knowledge, skills, and abilities to care for the patient.</p> <p>What is missing</p> <p>After reading, I am left with this set of questions.</p> <p>What would the results look with the stigma and patient consent section (omitting the technology section)? The reason I ask this is because of the statements in the technology section and the fact that no standard exists for electronic health records. This makes the material presented a mental exercise.</p> <p>How does this affect practice? This is a difficult question to answer given what may be differences in privacy laws of the various countries. The editors must determine the value. I admire the authors did include the limitation to U.K.</p> <p>The mass screening in the ED study was an interesting study referenced in the discussion. Similar studies have been conducted in the U.S. as a measure of population health (with de-identified specimens from inner-city hospitals). A true cost-benefit analysis must be performed with the assistance of economists and ethicists and probably others. I agree that earlier detection of a positive individual would likely be cheaper to treat and improve outcomes. The wide-scale screening is what I am considering for the issue.</p> <p>In summary, the paper is mechanically and methodologically sound. The rationale is sound. The application to public policy is a start.</p>
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REVIEWER	Oliver Mohr Germany Consultant (International Public Health; Infectious Disease Epidemiology, Primary Health Care)
REVIEW RETURNED	17-Jan-2017

GENERAL COMMENTS	<p>many thanks for your text. I think the issue you cover and the way you handle it is definitely worth a publication. I like that your survey also targets the public - public opinion is unfortunately often neglected. Your approach strengthens the evidence of your results. However I do suggest minor changes.</p> <p>Abstract In the paragraph "results" you mention the number of rounds & participants etc. I suggest to put it under "methods".</p> <p>Article Summary The sentence that the special protected status of HIV is no longer necessary and hinders appropriate health care is one of the main results, it is not a strength. Also the proposal of a novel consent procedure is a result. Please change accordingly.</p> <p>Methods It would be helpful to explain why you have chosen the Delphi-Method, since it is not the only consensus technique. In the paragraph "Participants and recruitment" I miss a proper</p>
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	<p>description of the selection process of the participants; what kind of commercial database? Randomly selected - how? How many members of the public did you contact and how did you choose the 75 members of the public (if you contacted a large number of potential participants I suppose you had to do some sort of final selection? If yes, how did you do that?). Please describe further how you selected the experts.</p> <p>What did you do to avoid a biased selection of participants? I suggest to describe further why you have defined "consensus" as more than 70% of participants. References? Literature? (it might be useful to describe this important issue also in the limitations part. If you had defined another percentage of "consensus", you would have had other results...)</p> <p>Discussion Please discuss the limitations of your study. In the article summary you mention a small sample size and the limitation of the results to England. I suggest to elaborate in detail on the mentioned limitations in your discussion section, please cover also the issue of potential bias...</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Rodney Hicks

Institution and Country: Western University of Health Sciences, Pomona, USA

Competing Interests: None declared

Title

The title may be a bit confusing. The word "limited" is throwing off the wording. From reading the manuscript, the authors did not propose a limited consent form. Rather there was a brief exploration of ethical and societal pressures to change the process.

We have put quotes around the term 'limited consent procedure' and used a colon to indicate the method used to help clarify.

Abstract

The word "potentially" is soft. Take an approach, either it is or it is not.

We have deleted the word 'potentially' from the objective.

Some of the sentences are long and a reader stumbles. Please consider shorter sentences such that the intent is clear.

We have fully proofread and amended accordingly.

Strengths

This sentence will certainly raise controversy. Implementing the novel consent process must be considered from the lens of legal standards (privacy laws) in place.

This section has been rewritten.

Page 4/Line 23.

Instead of "and", perhaps the word "or" should be considered?

Changed as suggested.

General comment.

Please check punctuation throughout. Missing commas, hypens, etc.

We have fully proofread and amended accordingly.

Bottom of page 4.

Despite 'this' (please substitute 'barrier' for the word this to add specificity).

Changed as suggested.

Editorial comment:

reference on page 17 (17,11 should be 11,17)

Changed as suggested.

Lines 29 = reads funny

Added a comma.

Page 5/Second paragraph.

I think the word “rates” is needed in the first sentence. The new approaches won’t reduce undiagnosed infections – the action affects rates.

Added the word ‘rates’ as suggested.

Page 6.

There was no patient involvement in this study (change to was not is)

Changed as suggested.

Page 7

Avoid starting a sentence with the word IT (check punctuation)

Changed as suggested.

Page 7.

The sentence with vignettes were written ---- this reads funny, hard to follow

We have rewritten this sentence.

Page 8. Line 30.

Change “their” to “the”

Changed as suggested.

Page 9.

Table 1. Consider adding the word “years” Age range (years) Mean Age (years)

Added (years) as suggested.

Page 15

The paragraphs are excessively long; the content is most likely more than one paragraph.

Have changed accordingly.

Page 17.

I take exception to the conclusion about the special status. The example of the GP in Stigma (Case 1) demonstrated a short coming in the competence of the provider more so than the issue.

We have rewritten this sentence.

Summary

I wish to offer the following summary statements to assist the editor in reaching a decision.

1. The scholarly writing of the manuscript meets scientific merit in most places. There are a few places where sentences can be restructured to emphasize content and help the reader.
2. Methodology. The method was appropriate for exploring this topic. The authors have followed generally approved methods. With the wording select and the negative words, a clear picture of findings was easy to follow.
3. Contribution to scientific merit. The manuscript offers very little to scientific knowledge. Rather the substance is more of public policy, ethics, and Health professional education.
4. The discussion on the computer screening was most intriguing. Computers do not replace the human context of the patient/provider interaction. The computer support logic can support the provider interaction with the patient; however, the provider must still have the knowledge, skills, and abilities to care for the patient.

What is missing

After reading, I am left with this set of questions.

What would the results look with the stigma and patient consent section (omitting the technology section)? The reason I ask this is because of the statements in the technology section and the fact that no standard exists for electronic health records. This makes the material presented a mental exercise.

How does this affect practice? This is a difficult question to answer given what may be differences in privacy laws of the various countries. The editors must determine the value. I admire the authors did include the limitation to U.K.

The mass screening in the ED study was an interesting study referenced in the discussion. Similar

studies have been conducted in the U.S. as a measure of population health (with de-identified specimens from inner-city hospitals). A true cost-benefit analysis must be performed with the assistance of economists and ethicists and probably others. I agree that earlier detection of a positive individual would likely be cheaper to treat and improve outcomes. The wide-scale screening is what I am considering for the issue.

In summary, the paper is mechanically and methodologically sound. The rationale is sound. The application to public policy is a start.

Reviewer: 2

Reviewer Name: Oliver Mohr

Institution and Country: Germany Consultant (International Public Health; Infectious Disease Epidemiology, Primary Health Care)

Competing Interests: None declared

Dear authors,

many thanks for your text. I think the issue you cover and the way you handle it is definitely worth a publication. I like that your survey also targets the public - public opinion is unfortunately often neglected. Your approach strengthens the evidence of your results. However I do suggest minor changes.

Abstract

In the paragraph "results" you mention the number of rounds & participants etc. I suggest to put it under "methods".

Changed as suggested.

Article Summary

The sentence that the special protected status of HIV is no longer necessary and hinders appropriate health care is one of the main results, it is not a strength. Also the proposal of a novel consent procedure is a result. Please change accordingly.

We have rewritten this sentence.

Methods

It would be helpful to explain why you have chosen the Delphi-Method, since it is not the only consensus technique.

We chose Delphi as it allows for building consensus between participants virtually. Other building consensus techniques require participants to be in the same room, and this was not practical as we wished for a nationally representative sample and were dealing with busy professionals.

In the paragraph "Participants and recruitment" I miss a proper description of the selection process of the participants; what kind of commercial database? Randomly selected - how? How many members of the public did you contact and how did you choose the 75 members of the public (if you contacted a large number of potential participants I suppose you had to do some sort of final selection? If yes, how did you do that?). Please describe further how you selected the experts.

We have addressed this request.

What did you do to avoid a biased selection of participants?

We couldn't really avoid self-selection bias for the public but we did try to avoid some bias amongst HPs by targeting the invitations to a broad group of professionals and specialities.

I suggest to describe further why you have defined "consensus" as more than 70% of participants.

References? Literature? (it might be useful to describe this important issue also in the limitations part.

If you had defined another percentage of "consensus", you would have had other results...)

We have addressed this request and referenced accordingly.

Discussion

Please discuss the limitations of your study. In the article summary you mention a small sample size and the limitation of the results to England. I suggest to elaborate in detail on the mentioned limitations in your discussion section, please cover also the issue of potential bias...

We have addressed this request in a new penultimate paragraph in the discussion.

VERSION 2 – REVIEW

REVIEWER	Rodney W. Hicks Western University of Health Sciences College of Graduate Nursing Pomona, CA, USA
REVIEW RETURNED	17-Feb-2017

GENERAL COMMENTS	<p>Thank you for the opportunity to re-review the above captioned manuscript. My comments are listed below. The first comments are specific (indicating more consideration by the author/editor) and the second comments are general (indicating consideration by the author). Thank you for the providing the detailed responses.</p> <p>General. Much appreciation to the author(s) for the work invested in the revision. The result is a greatly enhanced document.</p> <p>Specific Comments</p> <p>Abstract, line 44-46. This line reads funny. Not only longer deemed necessary.... The "not only" is throwing my comprehension. Almost contradicts what is on the next page about the strengths.</p> <p>Page 5, line 8. Awkward sentence. I believe the intent is that were missed opportunities for earlier diagnosis.</p> <p>Line 17, reference, 17,11 (My preference would be 11,17)</p> <p>Line 27. Thanks for sharing the amount of expected and the values obtained.</p> <p>Page 9. Table 1. I would encourage the use of the word (YEARS) in the table after AGE. I deal with a pediatric population and switch between days, weeks, months, and years. Having the suffix is implied, but adding just shows more attention to detail.</p> <p>Page 10. I see bold in some of the rows without a foot note.</p> <p>Page 13. Line 40. Perhaps insert (Question 3) so the reader can return exactly to the question?</p> <p>(your headings: Stigma doesn't have a colon at the end, The next one does, the next doesn't)</p> <p>Page 15. Line 23. I would not call this a large study (as one of your limitations on 3 says opposite)</p> <p>Page 14. Line 34. Soften the language about a broad medical and nursing HPs. You had some variety but not really broad.</p> <p>I think the discussion paragraphs are long. Can the paragraphs be split up? The content is good (great). Long sentences and long paragraphs glaze over the reader's attention and this is your most important section.</p> <p>Page 17. The same line (lines 5-7) reads funny like the abstract.</p> <p>Finally, I don't know the laws of the U.K. The public approach to</p>
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	<p>acceptance of wide spread testing and the HCP acceptance in the U.S.; however, some privacy laws would prohibit such usefulness. Therefore, the author owes the reader a least a paragraph recognizing that this is a possible step in the direction of affecting public law/policy.</p> <p>Again, well done on the revision.</p> <p>General Comments. I believe that as scholars, each opening line of a paragraph should be direct. Avoid lead in phrases. Get the subject (topic) out clear and early. Example. Line 30, In a highly economically developed country.... (nice words, but the intent is really that reliable methods exist. I stress that this is a personal style but the approach reduces words and helps readers comprehend the subject earlier.</p> <p>Page 7 example. Avoid starting a sentence with the word IT. Tell us what IT means</p> <p>Generally, I teach my students to use less than 20 words per sentence; after that, the grammar, punctuation, and emphasis is lost. The discussion section has too long of paragraphs and sentences.</p>
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REVIEWER	Oliver Mohr Consultant
REVIEW RETURNED	04-Mar-2017

GENERAL COMMENTS	You have changed the text accordingly. I do not have any further comments. From my side the manuscript is ready for publication. Thank you
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VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
 Reviewer Name: Rodney W. Hicks
 Institution and Country: Western University of Health Sciences, College of Graduate Nursing, Pomona, CA, USA
 Competing Interests: There are none to declare

Thank you for the opportunity to re-review the above captioned manuscript. My comments are listed below. The first comments are specific (indicating more consideration by the author/editor) and the second comments are general (indicating consideration by the author). Thank you for the providing the detailed responses.

General.
 Much appreciation to the author(s) for the work invested in the revision. The result is a greatly enhanced document.

Specific Comments
 Abstract, line 44-46. This line reads funny. Not only longer deemed necessary.... The “not only” is

throwing my comprehension. Almost contradicts what is on the next page about the strengths.
We have removed the term “not only” and reworded this sentence
Page 5, line 8. Awkward sentence. I believe the intent is that were missed opportunities for earlier diagnosis.
We have reworded this sentence with your suggestion
Line 17, reference, 17,11 (My preference would be 11,17)
Amended
Line 27. Thanks for sharing the amount of expected and the values obtained.
Page 9. Table 1. I would encourage the use of the word (YEARS) in the table after AGE. I deal with a pediatric population and switch between days, weeks, months, and years. Having the suffix is implied, but adding just shows more attention to detail.
Added the word “years” in Table 1 as suggested
Page 10. I see bold in some of the rows without a foot note.
Inserted a footnote at the bottom of the table
Page 13. Line 40. Perhaps insert (Question 3) so the reader can return exactly to the question?
Inserted “Question 3” as suggested
(your headings: Stigma doesn’t have a colon at the end, The next one does, the next doesn’t)
Checked and amended accordingly
Page 15. Line 23. I would not call this a large study (as one of your limitations on 3 says opposite)
We have removed the word “large”
Page 14. Line 34. Soften the language about a broad medical and nursing HPs. You had some variety but not really broad.
We have removed the word “broad” and replaced with “varied”
I think the discussion paragraphs are long. Can the paragraphs be split up? The content is good (great). Long sentences and long paragraphs glaze over the reader’s attention and this is your most important section.
We have split up some paragraphs sentences in the discussion as suggested
Page 17. The same line (lines 5-7) reads funny like the abstract.
We have reworded this sentence
Finally, I don’t know the laws of the U.K. The public approach to acceptance of wide spread testing and the HCP acceptance in the U.S.; however, some privacy laws would prohibit such usefulness. Therefore, the author owes the reader a least a paragraph recognizing that this is a possible step in the direction of affecting public law/policy.
We have added a section at the end of the final paragraph of the discussion which hopefully addresses and satisfies your suggestion.
Again, well done on the revision.
General Comments.
I believe that as scholars, each opening line of a paragraph should be direct. Avoid lead in phrases. Get the subject (topic) out clear and early. Example. Line 30, In a highly economically developed country.... (nice words, but the intent is really that reliable methods exist. I stress that this is a personal style but the approach reduces words and helps readers comprehend the subject earlier.
Page 7 example. Avoid starting a sentence with the word IT. Tell us what IT means
Generally, I teach my students to use less than 20 words per sentence; after that, the grammar, punctuation, and emphasis is lost. The discussion section has too long of paragraphs and sentences.
Thank you for your suggestions and we hope we have reworded and reformatted to your satisfaction.

Reviewer: 2

Reviewer Name: Oliver Mohr

Institution and Country: Germany Consultant (International Public Health; Infectious Disease Epidemiology, Primary Health Care)

Competing Interests: None declared

You have changed the text accordingly. I do not have any further comments. From my side the manuscript is ready for publication. Thank you

VERSION 3 – REVIEW

REVIEWER	Rodney W. Hicks, PhD RN, FAANP, FAANP, Professor Western University of Health Sciences College of Graduate Nursing Pomona, California, USA
REVIEW RETURNED	17-Mar-2017

GENERAL COMMENTS	The authors have addressed prior concerns. Each version was an improvement. Thank you for the "little details" that you addressed.
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REVIEWER	Oliver Mohr Independent International Public Health Consultant Primary Health Care / Infectious Disease Epidemiology / Nutrition
REVIEW RETURNED	28-Mar-2017

GENERAL COMMENTS	As mentioned before, I do not have any further comments. Many thanks for the revised manuscript.
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