PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Unmet Needs in Occupational Health Prevention and Management for Viral Hepatitis in Health Care Workers in Ho Chi Minh City, Vietnam: A Mixed-Methods Study
AUTHORS	Nguyen, Tran; Pham, Trang; Tang, Hong Kim; Phan, Loc; Mize, Gary; Lee, William; Gish, Robert; Trang, Amy; Le, Anh; Phan, Hai; Nguyen, Binh; Dao, Doan

VERSION 1 – REVIEW

REVIEWER	Wallace, Jack Burnet Institute
REVIEW RETURNED	19-May-2021

GENERAL COMMENTS	Nicely described study with a well thought-out presentation. It could do with an edit for grammatical consistency and accuracy. Much of the description about viral hepatitis and the government response is in the past tense, which would be better expressed in the present tense Overall, the paper appears to be seeking to provide evidence to change policy, but the depth of information provided, and particularly in the discussion section, this could be more clearly articulated. Abstract, Page 2 • Line 16 – the term “devices” is really unclear in this context – is it more about being at risk of possible exposure? • Line 22 – that the interviews for the “need or formal health policy” appears to be a finding, rather than a point of investigation • Line 43 – I’m concerned that the conclusions only talk of protecting health care workers from HBV: what happens to the 10% of HCW who are already infected with hepatitis B? Page 3 – nicely described limitations. Page 4: • Line 12 – the term “carriers” has not been used in care models for hepatitis B for several years. Rephrase. • Line 15 – “high” could be better expressed as “greater” • Line 18 – “increased risk” implies a comparison. • Line 21 – the sentence commencing “The incidence rates…” needs to be rewritten and requires a clearer point. • Line 51 – not sure that “occupational” is required Page 5 • Line 37 – The last sentence commencing “As a result….” would be better included in the discussion Page 6 • Line 25 – I’m not sure how the reported prevalence is relevant to the selection of the sample.

	• Line 52 – The rationale of recruitment being associated with "required frequent contact with patients with viral hepatitis" is obscure, and requires further explanation or deleted. Most health care workers dealing with patients with viral hepatitis are at no risk of infection. Page 7 • The description of the provision of the incentive could be better described – it sounds like more of a payment, rather than incentive, and with ethical issues related to payments. • Were surveys and interviews done in Vietnamese? How were these translated, and what processes were taken to assure the accuracy of the translations? • Issues of confidentiality need to be noted. • There are some ethical issues that have not been addressed, and given the implications of the project's activities, should be addressed. Given that the researchers could have anticipated that a proportion of the participants would be infected with either hepatitis B or hepatitis C – how were people who were diagnosed through the testing conducted by the provided with the diagnosis? Given the health and particularly in relation to hepatitis B familial implications of the infection, was there followup, and was their employment affected? Page 9 • Line 37 – whether a drug or person is "addictive" is irrelevant to exposure to a BBV • Line 46- "good" is a moral term rather than a description of correct information Page 10 • Line 5 – what assumption has been made about the description of "healthy people"? Most people with viral hepatitis do no have symptoms, and will consider themselves to be healthy. Again, the term "carriers" is rarely used in current viral hepatitis models of care – please rephrase • Line 30 – results from qualitative interviews should be providing perspectives from the interviewees, rather than being reported as a percentage or proportion. The changing denominator is puzzling without further explanation. • The "in-depth" interview protocol should be provided – the reporting in table 4 looks like that options were provided to participants, and which were deemed by the researchers to be correct or not. There is little of an "in-depth" provision of information, or the issues that were raised by the participants. Discussion • Much of this section is a reiteration of the findings, and requires an edit. • The finding of a high occupational risk would be as a result of the people being recruited • The proposition of pre-employment screening has significant implications, and in other countries has resulted in (unnecessary) discrimination against people with hepatitis B and hepatitis C. The lack of discussion about the human rights aspects of the proposal is concerning.

REVIEWER	Auta, Asa University of Central Lancashire, Pharmacy and biomedical sciences
REVIEW RETURNED	22-May-2021

GENERAL COMMENTS	This is an important study that presents evidence for policy change to facilitate HBV vaccination and post-exposure management in Ho Chi Minh City, Vietnam. The manuscript has been written to demonstrate the key elements of a mixed methods research. The introduction sets the scene for the research and the methods used were appropriate. Furthermore, the strengths and limitations of the study were acknowledged. Please find below some suggested revisions for your consideration. Introduction It would be good to cite the literature to support the claim in lines 55-56 of page 4. Methods Study setting – It would be good to give readers an idea of the number of hospitals in HCMC. Page 6, lines 18 -21- Authors would need to include details on how the simple random sampling was conducted. Was there a sampling frame? How did you proceed with the sampling that gave all eligible healthcare workers an equal opportunity to participate in your study? Page 6, lines 28-34 – It would be good for the authors to include information on the validation of the questionnaire used for this study. Also, authors can include the questionnaire as part of the supplementary documents provided. Page 6, lines 36-43 – Again, more detail is needed on how participants for the qualitative interviews were selected. Were they selected purposefully or by convenience within each stratum? Page 6, lines 48-51 – It will be good to clarify how the invitation was sent and whether a probability method was used in the recruitment process. Page 7, lines 14-22 – How were the interview data recorded? Can authors include the interview guide/questionnaire in the supplementary information supplied? Thematic analysis – more information on how the thematic analysis was conducted is needed. Results Please clarify the number of people invited to participate in your study. The methods section states 360 while 210 was stated in the results. Page 8 line 25 – Were the 7 non-clinical staff among the 210 staff initially invited? Page 9 line 22 – Can you clarify if the data reported (34-38 years) was the mean age or the range of mean age values obtained from your study? Page 12 Lines 8 -16- Authors identified three themes from the interviews conducted but these were not supported with evidence from participants quotes. It will be good for authors to present quotes from participants to support their analysis. Furthermore, most of the qualitative data reported were quantified. This needs to be acknowledged in the data analysis section that reports how qualitative data were handled.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Dr. Jack Wallace, Burnet Institute
Comments to the Author:
Nicely described study with a well thought-out presentation. It could do with an edit for grammatical consistency and accuracy. Much of the description about viral hepatitis and the government response is in the past tense, which would be better expressed in the present tense

Overall, the paper appears to be seeking to provide evidence to change policy, but the depth of information provided, and particularly in the discussion section, this could be more clearly articulated.

Abstract, Page 2 (The abstract was rewritten to follow BMJ format)

- Line 16 – the term "devices" is really unclear in this context – is it more about being at risk of possible exposure? We rephrased to "at risk of viral hepatitis exposure"
- Line 22 – that the interviews for the "need or formal health policy" appears to be a finding, rather than a point of investigation. This section was rewritten.

- Line 43 – I'm concerned that the conclusions only talk of protecting health care workers from HBV: what happens to the 10% of HCW who are already infected with hepatitis B? Healthcare workers infected with HBV are covered by the national public health insurance for further HBV and liver assessment work up and anti-HBV therapy as indicated. This information was added to the Methods section for clarification.

Page 3 – nicely described limitations.

Page 4:

- Line 12 – the term "carriers" has not been used in care models for hepatitis B for several years. Rephrase. We rephrased to "living with chronic HBV".
- Line 15 – "high" could be better expressed as "greater". We changed to "greater".
- Line 18 – "increased risk" implies a comparison. We deleted the word. We meant to inform that HCWs are at higher risk of percutaneous needle sticks injuries than normal population.
- Line 21 – the sentence commencing "The incidence rates…" needs to be rewritten and requires a clearer point. We rephrased to "The incidence rate of acquiring HBV infection after exposure was 25 times higher than that of acquiring HIV after exposure."
- Line 51 – not sure that "occupational" is required. We deleted the word.

Page 5

- Line 37 – The last sentence commencing "As a result…." would be better included in the discussion. We moved it the the last paragraph of Discussion section.

Page 6

- Line 25 – I'm not sure how the reported prevalence is relevant to the selection of the sample. We changed to "rate".
- Line 52 – The rationale of recruitment being associated with "required frequent contact with patients with viral hepatitis" is obscure, and requires further explanation or deleted. Most health care workers dealing with patients with viral hepatitis are at no risk of infection. In Vietnam, some positions are not required to contact frequently (i.e. daily) with blood or bodily fluids. Healthcare providers at the

outpatient department do not have bodily fluid/blood contact as frequent as providers in the inpatient clinical service. We rephrased to “required frequent contact with blood or bodily fluid”.

Page 7

- The description of the provision of the incentive could be better described – it sounds like more of a payment, rather than incentive, and with ethical issues related to payments. The incentive was to compensate for the time spent in the study (complete the survey questionnaire and get phlebotomy, which might take around 30-45 mintues) that the care providers had to leave their work during their work shift. We clarified the incentive as thank you gift card having value of $5 USD, which was allowed in Vietnam and had the IRB approval for.
- Were surveys and interviews done in Vietnamese? How were these translated, and what processes were taken to assure the accuracy of the translations? Yes, all survey interviews were conducted and analyzed in Vietnamese. The original KAP survey (Maxwell) that used in the Vietnamese American population were already in Vietnamese, and we validated this questionnaire prior to use in this study.

Most of the co-authors were bilingual and able to use English or Vietnamese in running this study. All interviews’ transcription and coding were done in Vietnamese. All data analysts were comprehended both Vietnamese and English. Therefore, no translation was needed for data analysis. The manuscript was written in English, and the study materials provided in the Supplement material were translated into English for publication purposes and got revised by professional editing and proofing service, Freelance Technical Writer and Medical Editor , Bookworm Editing Services LLC (https://headbookworm.com/) .

- Issues of confidentiality need to be noted. All participants were assigned a study ID. In-depth interview was conducted by trained interviewers, recording was recorded with study ID without mentioning participants’ identification info during the interview. This information was added to the Methods section for clarification.
- There are some ethical issues that have not been addressed, and given the implications of the project’s activities, should be addressed. Given that the researchers could have anticipated that a proportion of the participants would be infected with either hepatitis B or hepatitis C – how were people who were diagnosed through the testing conducted by the provided with the diagnosis? Given the health and particularly in relation to hepatitis B familial implications of the infection, was there followup, and was their employment affected? All participants received letters with results with interpretation and recommendation for vaccination or follow-up examination. Free vaccination and free follow-up testing for viral load were covered by the study. If the participant need to be treated, it was convered by the national public health insurance.

Page 9

- Line 37 – whether a drug or person is “addictive” is irrelevant to exposure to a BBV We changed to “ilicit”.
- Line 46- “good” is a moral term rather than a description of correct information. We changed to “provided correct answers”

Page 10

- Line 5 – what assumption has been made about the description of “healthy people”? Most people with viral hepatitis do no have symptoms, and will consider themselves to be healthy. Again, the term “carriers” is rarely used in current viral hepatitis models of care – please rephrase. We changed to “asymptomatic”and “have chronic HBV and HCV infection”.
- Line 30 – results from qualitative interviews should be providing perspectives from the interviewees, rather than being reported as a percentage or proportion. The changing denominator is

puzzling without further explanation. We added the quotes from interviewees. The interview transcript was decoded to identify themes and transformed to quantitative data. The changing denominator was due to missing data, which was not included.

- The "in-depth" interview protocol should be provided – the reporting in table 4 looks like that options were provided to participants, and which were deemed by the researchers to be correct or not. There is little of an “in-depth” provision of information, or the issues that were raised by the participants. The proposed in-depth interview questions will be added as Supplemental material. We decoded transcripts to identify themes and transformed pieces of information into quantitatively items while keeping the emergent theme as findings of the qualitative part. Table 4 was deducted from the quantitative data from decoding interview transcripts.

Discussion

- Much of this section is a reiteration of the findings, and requires an edit. The Discussion was rewritten.
- The finding of a high occupational risk would be as a result of the people being recruited. We agree with your statement.
- The proposition of pre-employment screening has significant implications, and in other countries has resulted in (unnecessary) discrimination against people with hepatitis B and hepatitis C. The lack of discussion about the human rights aspects of the proposal is concerning. The pre-employment screening was proposed for individuals who are new employees. These individuals were already hired to their positions. Therefore, their hepatitis status would not lead to discrimination. This point was clarified in the Discussion section.

Reviewer: 2
Dr. Asa Auta, University of Central Lancashire
Comments to the Author:
This is an important study that presents evidence for policy change to facilitate HBV vaccination and post-exposure management in Ho Chi Minh City, Vietnam. The manuscript has been written to demonstrate the key elements of a mixed methods research. The introduction sets the scene for the research and the methods used were appropriate. Furthermore, the strengths and limitations of the study were acknowledged.
Please find below some suggested revisions for your consideration.

Introduction
It would be good to cite the literature to support the claim in lines 55-56 of page 4. We added the citation.

Methods
Study setting – It would be good to give readers an idea of the number of hospitals in HCMC. We added the information of 91 public hospitals as of 2016.
Page 6, lines 18 -21- Authors would need to include details on how the simple random sampling was conducted. Was there a sampling frame? How did you proceed with the sampling that gave all eligible healthcare workers an equal opportunity to participate in your study? This information was added to the Methods section for clarification.
Page 6, lines 28-34 – It would be good for the authors to include information on the validation of the questionnaire used for this study. Also, authors can include the questionnaire as part of the supplementary documents provided. We cited the study with the validated KAP questionnaires. We will include the questionnaires as Suplemental material.
Page 6, lines 36-43 – Again, more detail is needed on how participants for the qualitative interviews were selected. Were they selected purposefully or by convenience within each stratum? This information was added to the Methods section for clarification.

Page 6, lines 48-51 – It will be good to clarify how the invitation was sent and whether a probability method was used in the recruitment process. This information was added to the Methods section for clarification.
Page 7, lines 14-22 – How were the interview data recorded? Can authors include the interview guide/questionnaire in the supplementary information supplied? This information was added to the Methods section for clarification. Proposed in-depth interview questions were added as Supplemental material.
Thematic analysis – more information on how the thematic analysis was conducted is needed. This information was added to the Methods section for clarification.

Results
Please clarify the number of people invited to participate in your study. The methods section states 360 while 210 was stated in the results. 210 people were invited. The hospital provided a list of 120 participants, but we completed the recruitment within 3 days or reaching 70 participants at each hospital.
Page 8 line 25 – Were the 7 non-clinical staff among the 210 staff initially invited? These 7 individuals had both clinical and non-clinical responsibilities. After enrolling into the study, they reported that they only involved in clinical practice less than 50% effort and thus were excluded from the study.
Page 9 line 22 – Can you clarify if the data reported (34-38 years) was the mean age or the range of mean age values obtained from your study? We clarified it to be the age range.
Page 12 Lines 8 -16- Authors identified three themes from the interviews conducted but these were not supported with evidence from participants quotes. It will be good for authors to present quotes from participants to support their analysis. The themes of in-depth interview and quotes from of interviewees were added in Result section.

Furthermore, most of the qualitative data reported were quantified. This needs to be acknowledged in the data analysis section that reports how qualitative data were handled. This information was added to the Methods section for clarification.

Reviewer: 1
Competing interests of Reviewer: None

Reviewer: 2
Competing interests of Reviewer: None

VERSION 2 – REVIEW

REVIEWER	Wallace, Jack Burnet Institute
REVIEW RETURNED	20-Aug-2021

GENERAL COMMENTS	Thank you for your response to the review. Generally an edit is still required – there are many albeit minor grammatical and accuracy errors - issues such as “to provide information regarding” could be replaced with “investigating”; a missing “of” in line 30 on page 4 Page 10, Line 51 - A significant proportion of people completing the survey felt that hepatitis B vaccination had harmful side

	effects. It should be noted that in Vietnam several years ago there was much media focus on deaths of infants supposedly related to hepatitis B vaccination, and that the impact of this may still be felt. Page 11, Line 11 – the title of the section could better be described as “awareness of …”, with the heading of the next section relating to management of occupational exposure Page 11, Lines 32 – 35 – the section mentions financial support in relation to HIV, and should also state that in relation to lack of support and self-pay, that this relates viral hepatitis exposure. Reducing the number of the sequentially used quotes in this section would make more sense to a reader. Page 12, From line 51, the issue of vaccination has been included in the previous section on vaccination policy, and should not be repeated. This section could better be described as Disclosure and Stigma Page 13, Lines 21 – 30: could the authors clearly state why a separate policy for viral hepatitis should be developed “independent” of the HIV policy. This is the opinion or a recommendation of the authors and goes further than the findings, and which could be more strongly articulated. Page 15, Line 43 – 47: the recommendation for screening prior to employment has been used in many countries to deny employment to people with hepatitis B, and raises issues related to stigma and discrimination experienced already by many people with hepatitis B. It could be more clearly that the screening will not be used to deny employment, and will only be used to benefit the employee as supported by the WHO Viral Hepatitis Testing policy.

VERSION 2 – AUTHOR RESPONSE

Dear Dr. Wallace,

We appreciate your time and constructive comments on our manuscript. Below is the response. Thank you so much!

Generally an edit is still required – there are many albeit minor grammatical and accuracy errors - issues such as “to provide information regarding” could be replaced with “investigating”; a missing “of” in line 30 on page 4

Thank you for these suggestions. We edited according to your suggestions. Additionally, we asked our technical editor, Kelly Schrank (Bookworm Editing Services LLC), to provide editorial services for this manuscript again.

Page 10, Line 51 - A significant proportion of people completing the survey felt that hepatitis B vaccination had harmful side effects. It should be noted that in Vietnam several years ago there was much media focus on deaths of infants supposedly related to hepatitis B vaccination, and that the impact of this may still be felt.

We appreciate your knowledge about possible reason that might have caused hesitancy about HBV vaccine in newborns in Vietnam. We have been aware of the news as well. However, for this manuscript, we elected not to discuss about it but to focus on HBV vaccine in healthcare workers.

Page 11, Line 11 – the title of the section could better be described as “awareness of …”, with the heading of the next section relating to management of occupational exposure

The heading has been revised.

Page 11, Lines 32 – 35 – the section mentions financial support in relation to HIV, and should also state that in relation to lack of support and self-pay, that this relates viral hepatitis exposure. Reducing the number of the sequentially used quotes in this section would make more sense to a reader.

This section has been revised.

Page 12, From line 51, the issue of vaccination has been included in the previous section on vaccination policy, and should not be repeated. This section could better be described as Disclosure and Stigma

The heading has been revised.

Page 13, Lines 21 – 30: could the authors clearly state why a separate policy for viral hepatitis should be developed “independent” of the HIV policy. This is the opinion or a recommendation of the authors and goes further than the findings, and which could be more strongly articulated.

This is our recommendations from lessons we learned from the study. Although there is similarity on preventing occupational exposure between HIV and HBV-HCV, post-exposure management is vastly different between HIV and viral hepatitis. While post exposure to HIV requires post-exposure prophylaxis (PEP) and serological testing at 3 months and 6 months per CDC guidelines, post-exposure to HBV and/or HCV requires information on serological status of healthcare workers and different timeline on follow up testings.

Page 15, Line 43 – 47: the recommendation for screening prior to employment has been used in many countries to deny employment to people with hepatitis B, and raises issues related to stigma and discrimination experienced already by many people with hepatitis B. It could be more clearly that the screening will not be used to deny employment, and will only be used to benefit the employee as supported by the WHO Viral Hepatitis Testing policy.

Thank you for raising this concern. We clarified in our manuscript that we suggest testing to be done before healthcare workers start working. Therefore, their viral hepatitis status should not influence the hiring process. Knowing HBV-HCV status would benefit healthcare workers, especially those who are exposed to blood and bodily fluid at work. Non-immune workers are aware of their status and can get vaccination. Workers with chronic HBV-HCV are aware of their status and seek medical care. Moreover, we also learned from the in-depth interviews that HBV vaccination is not routinely offered and that surveillance of HBV-HCV is not uniformly practiced at least in the three hospitals where we conducted the study. Having a formal pathway for screening before starting work and annual surveillance would greatly benefit healthcare workers in Vietnam as an endemic area for HBV-HCV.