**COMMENT 1:**

Please could you confirm if any additional approvals are required from the Maldives in order to carry out this research, and if so, please could copies of these be forwarded to the Committee.

**Question:**

Does the project require permission of an organisation, other people, to access participants or information? **YES** e.g., parents, guardians, school principals, teachers, boards, responsible authorities including employers, etc. If yes, please explain how this approval has been or will be obtained, enclosing copies of relevant correspondence. *Please ensure forms make the employers/organisations aware that even once they have given permission in principle to give you access to participant information, they will not be able to provide this until you have obtained agreement from the participants themselves.*

**Answer:**

The project requires permission from Ministry of Health to contact the patients diagnosed with ambulatory care sensitive conditions. All island hospitals come under Ministry of Health. Therefore, a separate approval is not required from island hospitals. Permission from Ministry of Health can only be requested after ethics approval from University of Canterbury. A separate ethics application is not required from the Maldives. This is because University of Canterbury falls under the Association of Commonwealth Universities. Following ethics approval a formal online request will be mailed to policy planning and international health division of the Ministry of Health. This is to obtain permission to contact the patients.

In any case approval is denied by Ministry of Health, the total population 20 years and above of the selected islands will be chosen. Every participant will be asked two screening questions in the questionnaire – B114 and B115. If the participant is not diagnosed with either one or more conditions of interest, their participation will be appreciated and will discontinue the survey.

The following are the screening questions:

Question ID: B114 Variable name: Screening-question Core: B

Question text: Has it ever been explained to you by a doctor or other health professional that you have had any one or more of the following conditions?

Response code:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Condition | 1. Yes | 2. No | D. Don’t know / Not sure | R. Refused |
| Hypertension (high blood pressure) |  |  |  |  |
| Hypertension (high blood pressure) ONLY during pregnancy  *Note 1: This is also called gestational hypertension and referred to as Pregnancy-Induced Hypertension. This is hypertension that develops after week 20 in pregnancy and goes away after delivery.*  *Note 2: This applies ONLY if you are currently pregnant and or was pregnant and have or had hypertension during pregnancy.* |  |  |  |  |
| Diabetes |  |  |  |  |
| Diabetes ONLY during pregnancy  *Note: This is also called gestational diabetes. This is diabetes that happens in pregnancy and goes away soon after delivery.*  *Note 2: This applies ONLY if you are currently pregnant and or was pregnant and have or had diabetes during pregnancy.* |  |  |  |  |
| Chronic heart failure |  |  |  |  |
| Chronic obstructive pulmonary disease |  |  |  |  |
| Asthma |  |  |  |  |
| Asthma ONLY during childhood  *Note: This is asthma that starts in childhood and goes away later in life.* |  |  |  |  |

*Note to Interviewer:*

If YES to 1) hypertension only during pregnancy; 2) diabetes only during pregnancy; and 3) asthma only during childhood - Appreciate the participation and discontinue the survey.

If NO / DON’T KNOW / REFUSED to all conditions – Appreciate the participation and discontinue the survey.

Question ID: B115 Variable name: Final-screening-question Core: B

Question text: Has it ever been explained to you by a doctor or other health professional that you currently have any one or more of the following conditions?

Response code:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Condition | 1. Yes | 2. No | D. Don’t know / Not sure | R. Refused |
| Hypertension (high blood pressure)  *Note 1: This excludes hypertension only during pregnancy* |  |  |  |  |
| Diabetes  *Note 1: This excludes diabetes only during pregnancy* |  |  |  |  |
| Chronic heart failure |  |  |  |  |
| Chronic obstructive pulmonary disease |  |  |  |  |
| Asthma  *Note 1: This excludes asthma only during childhood* |  |  |  |  |

*Note to Interviewer:*

*If “Yes” to one or more conditions, go to B116*

*If “No / Don’t Know / Refused” to all conditions – Appreciate the participation and discontinue the survey*

**COMMENT 2:**

A Committee member commented that the concept of “*Ambulatory care sensitive hospitalisations*” is used in countries with highly developed health services, as opposed to countries with less developed health services. For example, in question 3, it is stated “*Hospitalisations due to diseases that can otherwise be managed in the outpatients and community setting is a growing problem*”. Please could you provide more detail here about where this is a growing problem, and for whom, as currently this statement seemed to be more of a generalisation based on research related to developed health care systems.

**Question:**

Describe how this project arose i.e., please explain the academic area or issue etc. which generated the question(s) to be examined – this is to allow lay members of the committee some context for the research.

**Answer:**

Ambulatory care sensitive hospitalisations are diseases that can be managed in the outpatients and community setting. These diseases include asthma, chronic obstructive pulmonary disease, diabetes, chronic heart failure, and hypertension.

Hospitalisation due to these diseases is a growing problem. It is not different in middle income countries such as the Maldives in comparison to high income island nations New Zealand (NZ), United Kingdom (UK), and Singapore. Ambulatory care sensitive hospitalisations accounts for higher levels of hospitalisations in the Maldives compared with other island nations (36% of total hospitalisations in 2016 in the Maldives compared with about 24-25% in NZ, the UK, and Singapore).

These hospitalisations are preventable or avoidable where the setting of avoidance is in the primary healthcare. Theoretically, in a healthcare system that has high rates of ambulatory care sensitive hospitalisations indicate that people in that system have low levels of primary healthcare access and usage, or that the system fails to meet the needs of people to provide these services or both. In any case, patients have low levels of access to primary healthcare in the community.

Primary healthcare based interventions are effective in reducing ambulatory care sensitive hospitalisations; while primary healthcare in the Maldives continue to provide these interventions, it remains to be explained relatively higher rates of ambulatory care sensitive hospitalisations in the Maldives.

Island nations such as the Maldives have physical access barriers to healthcare services. Besides, in the Maldives, people also do not trust healthcare providers. As a result in the Maldives and likely in similar island countries, transportation, travel time, and trust are factors that possibly explain the variation in primary health care access.

**COMMENT 3:**

It is noted that “*High ambulatory care sensitive hospitalisations rates indicate lack of primary healthcare access*”. Could it also be the case that there are providers and people choose not to go to them for a variety of reasons, or that there is no confidence in the primary care providers?

**Paragraph 3 / question 3**

These hospitalisations are preventable or avoidable where the setting of avoidance is in the primary healthcare. Theoretically, in a healthcare system that has high rates of ambulatory care sensitive hospitalisations indicate that people in that system have low levels of primary healthcare access and usage, or that the system fails to meet the needs of people to provide these services or both. In any case, patients have low levels of access to primary healthcare in the community.

**COMMENT 4:**

Please clarify the term “*non-communicable hospitalisations”.* Is this suggesting that people who don't have a communicable disease are seen as not requiring admission?

**Paragraph 2 – Question 3**

*Typo –removed -*Hospitalisation due to these diseases is a growing problem. It is not different in middle income countries such as the Maldives in comparison to high income island nations New Zealand (NZ), United Kingdom (UK), and Singapore. Ambulatory care sensitive hospitalisations accounts for higher levels of hospitalisations in the Maldives compared with other island nations (36% of total hospitalisations in 2016 in the Maldives compared with about 24-25% in NZ, the UK, and Singapore).

**COMMENT 5:**

Please clarify how differentiation will be made between: those that were admitted even though the level of care required meant that a primary care practitioner could care for them, those that needed admission and would benefit from care in the community after discharge, and those who could only be cared for in the hospital setting. As a general comment, please could the cohesion of information in this section as a whole be increased.

?

**COMMENT 6:**

Question 6 - the cases for case-control study will be patients with ambulatory care sensitive conditions hospitalised due to the consequences of these conditions (such as cerebrovascular accident, intracerebral haemorrhage, ischemic stroke, respiratory failure, chronic heart failure, retinopathy, renal failure, and gangrene). The controls for case-control study will be patients with ambulatory care sensitive conditions not hospitalised for consequences of these conditions. Please increase the clarity of information here. For example, is this related to the severity of the “*cerebral accident*” (a brain bleed caused by head injury, stroke etc.) for example? If yes, then it seem self-evident - the more severe the injury, the more likely the hospitalisation.

* How is the sample differentiated into those who were not hospitalised and therefore deteriorated and then had to be admitted, and those that had a severe first episode? Why are acute episodes included? ACSH relates to treating people with chronic conditions in primary care.

**Question:**

How many participants will be involved (of each category where relevant)? Please include statistical justification where necessary.

**Answer:**

The cases for case-control study will be patients with ambulatory care sensitive conditions hospitalised for consequences of these conditions. The controls for case-control study will be patients with ambulatory care sensitive conditions not hospitalised for consequences of these conditions. These two categories of patients will be identified from the cross-sectional survey.

In the cross sectional survey, patients will be asked whether they have been hospitalised in a public hospital overnight for one or more of the conditions in the last 12 months. Those patients who say yes to this question, will be further questioned what was the reason / or were the reasons for the hospitalisation. *The reason for hospitalisation will be verified from patient discharge sheet or on spot call to hospital by the respondent prior to entry. Patients who have only been hospitalised for consequences of* ambulatory care sensitive conditions will be selected for cases. The controls will be patients who say they have not been hospitalised in a public hospital overnight for one or more of the conditions in the last 12 months.

The maximum number of cases identified by cross-sectional survey will be studied in a ratio of 1:1 with controls that will be identified from the cross-sectional study.

**COMMENT 7:**

Question 8 - please provide more detail on the recruitment process, as participants may cover a lot of islands/a large geographic area and may not have access to the Internet.

* The Committee recommend that it is advisable for the interested participants to contact you directly rather than for the MoH to collect names and pass them on, to lessen the sense of obligation.

**Question:**

Describe how potential participants will be identified and recruited?

**Answer:**

The island hospitals keep a record of patients diagnosed with ambulatory care sensitive conditions in every island. Following ethics approval from University of Canterbury, a formal online request will be mailed to policy planning and international health division of Ministry of Health. This is to identify the pool of patients diagnosed with these conditions. Once approved, Ministry of Health will inform the patients about the research through island hospitals. Island hospitals will provide information sheet to all potential participants. Since Maldives islands are very small, this will be carried out door-to-door by hospital support staff. Any potential respondent willing to participate will share the contact details with the researcher. From this pool of patients, respondents will be selected randomly through lottery. All patients selected via lottery will be contacted to participate voluntarily in a survey via face-to-face. Others will receive a letter of appreciation from the research team.

**COMMENT 8:**

Questions 8 and 15 - please outline the process of obtaining approval from the MoH and the public health units in all the hospitals (patient coding and selection). See first comment.

**Answer:**

Discussed under comment 1 – Question 15 and Question 8

**COMMENT 9:**

Patients will be given an identification code but at the interview process – **Question 20 –changed**

* Questions 12 and 20 - could participants provide times that would be suitable for them to be contacted when indicating interest in the study?
* How will participants be selected?
* It appears that the “*calls*” will be undertaken by field workers visiting the homes of potential participants - is this correct? Please could you comment on the potential logistical and cost-related issues here?

**Question:**

How will the participants be treated? Describe in practical terms how the participants will be treated, what tasks they will be asked to perform, etc. Indicate how much time is likely to be involved in carrying out the various tasks.

**Answer:**

Island hospitals will provide information sheet to all potential participants. The information sheet will let know the participants that

* They will be answering a set of questions.
* Their participation is voluntary and they have the right to withdraw before commencement of the interview and during the interview. If a participant withdraw during the interview, interviewer will remove the information relating to him/her. Once the interview is complete and entered to the system it will remain anonymous. Therefore, research team will be unable to locate his/her specific information and delete it. .
* Their information will be stored securely in an electronic format, and research team will make sure his/her identity is not revealed to anyone and all information he/she share with the research team will remain confidential. Any information they provide will be used for research only.
* If they become concerned about their condition, research team recommends to discuss this with their primary provider.
* The results will be published as a doctoral thesis. The electronic version of the thesis is a public document and will be available free of cost through University of Canterbury Library. As participant’s information is collected anonymous his/her contribution will not be identified. The information they provide will be stored for next 10 years.
* If they have any questions, they can contact me Fazeela Mohamed and my supervisory team Arindam Basu and Wendy Maddocks by the addresses and contact numbers provided on the information sheet. We will be pleased to discuss any concerns they may have about participation in the project.

Respondents willing to participate in the research will share their contact details with the researcher. From this pool of patients, participants will be selected randomly through lottery.

Those patients selected via lottery will be contacted to participate voluntarily in the survey. One of the interviewers will contact them over phone to arrange a time of interview. If a respondent is a ‘non-contact’, then the lottery process will be repeated till 540 samples are collected. Field workers will make up to four calls on different hours of the day and on different days of the week to decide a potential participant is a 'non-contact'. Field workers will first make two calls. If a potential respondent is not able to be contacted, they will make another call after two weeks gap. This will be followed until fourth call is over. The initial two calls would be recorded between at least four hours of gap, to be considered as a new event. This will help to contact the potential participants who might not be in the island or in contact at the initial call for data collection. Any potential participant not selected through the lottery will receive a letter of appreciation from the research team.

The respondent will select a suitable date and time. Note that the availability of ferry services will be considered in deciding a suitable time and date. The ferry services are available during the day. The availability of ferry services vary between 5 to 7 days a week depending on the island. The cost of ferry tickets will be covered by the researcher. In case of extreme weather condition and rough sea, interviewer may have to postpone the interview to a different date. This is for safe travel between islands.

The interview will be in-person in a suitable public place at his or her island. The participant will decide the interview spot that he/she feels safe and comfortable. The interview will take about 30 minutes of his/her time. In appreciation of his/her time, research team will provide him/her with light refreshments.

During the interview process field workers will strictly treat the participants ethically and equally. The field workers will keep appropriate pace, and the respondent focused to complete the questionnaire within the timeframe. Field workers will apply same standardised technique in asking the questions. Field workers will instruct the participants what type of questions will be asked in each section prior to answering every section of the questionnaire. Field workers will instruct the participants to take time before answering questions and to provide accurate response to the best of his/her of knowledge.

**COMMENT 10:**

Questions 13 and 25 - please confirm if a structured or semi-structured interview is to be used in this study (you have currently indicated “*yes*”, but this has not been specified).

**Question 13 –** Will forms for participants need to be translated? **YES**  If yes, what language?

**Answer:** A semi-structured questionnaire will be delivered in English and Dhivehi languages. The questionnaire translation will be carried out by 2 lecturers of Faculty of Arts of the Maldives National University. The researcher will compare the original English version and the translated version and the process will be repeated till maximum match is achieved.

**Question 25 –** Will participants will be given the opportunity to check the transcript and/or notes of their interview/focus group? **YES** It is normal practice to give participants the opportunity to review their transcription. If this is not to be the case, please explain why you believe it is not necessary. Participants must be informed of interview recording both in the information sheet and at the time of the recording, and the process by which they can review the related transcription. *Please note that transcripts of focus groups may raise privacy issues (particularly if the participants are children, since other parents will see comments by children who are not their own).*

**Answer:** It is a semi-structured interview. The field worker will go through the answers with the respondent on interview spot. Participant has the opportunity to change any answer or delete any entry before interviewer completes the interview.

**COMMENT 11:**

Question 15 - what would be the plans for the research should this request be denied?

**Discussed under comment 1 – Question 15**

**COMMENT 12:**

Question 20 - please clarify if the Qualtrics form will be filled out by the researchers whilst they are doing face to face interviews? In question 12 it appeared to be the case that phone calls, an online survey and face to face interviews are all to be used?

* Will the interviewer manually fill out verbal answers on a questionnaire that will then be entered into Qualtrics?

**Question 20 –** Does the project involve a questionnaire? **YES**. If yes, please include a copy. The HEC does not normally approve a project which involves a questionnaire without seeing the questionnaire, although it may preview applications in some cases where the production of the questionnaire is delayed for good reason. If there is a questionnaire please answer the following questions:

**Answer:** The project involves a semi-structured questionnaire. A copy of this questionnaire is provided with this form. The questionnaire will be entered to Qualtrics following the comments and suggestions provided by ethics committee.

The delivery of questionnaire will only be by face-to-face. All answers will be entered directly to computer or tablet during face-to-face interview. It is important to note that if a respondent chooses to be interviewed in Dhivehi language, the questionnaire will be in Excel format. Therefore, answers will be entered to spreadsheet by the interviewer. This information will be later transferred to Qualtrics by the researcher. If a respondent chooses to be interviewed in English language, the answers will be entered directly to Qualtrics.

Note: The participants will be contacted by telephone to arrange a suitable date and time for the interview. No interview will be carried out by telephone.

**COMMENT 13:**

Question 20a - the response here is another reason for the responses to the invitation to participate to not come via the MoH.

**Question**

Explain how and why the questionnaire(s) will be anonymous or confidential (Anonymous: you could ***not*** conceivably know who completed it; Confidential: not anonymous, but you will not reveal the identity of the participants to anybody outside the research team)

**Answer:**

Each participant will be given a study code at the interview process. Patient’s identification, this includes name and contact details will not be entered to Qualtrics. Therefore, this study code will have no link to patient’s name or contact details. Any information given by the participant will be entered under this particular study code. Therefore, the information given by the participants will remain anonymous, once the data is entered in the system. This data will only be accessible to researcher and supervisors.

**COMMENT 14:**

Question 28 - as stated on the MoH Maldives website, the focus of the public health sections of the hospitals is on communicable diseases. Please could you comment on how they may be able to assist with identifying people with non-communicable diseases?

*Though website says that their focus is on communicable diseases, administrative and record keeping is done by these departments. It might not be easy to explain how things work in Maldives, so I have changed this to island hospitals.*

**Question 28c –**

How will you obtain consent from the participant and the third party/parties) to gather that data. Please ensure the information sheet is very clear about any data gathered about participants from third party participants, and how you intend to gain permission to see the data.

**Answer:**

Following ethics approval from University of Canterbury, a formal online request will be mailed to policy planning and international health division of Ministry of Health. This is to identify the pool of patients diagnosed with ambulatory care sensitive conditions. Once approved, Ministry of Health will inform the patients about the research through island hospitals. Island hospitals will provide information sheet to all patients diagnosed with ambulatory care sensitive conditions. The respondents willing to participate in the research will share their contact details with the researcher. Therefore, Ministry of Health would not have a list of those who agreed to participate in the research.

**COMMENT 15:**

Question 28c - although the MoH will not be able to link any individual answer to a specific person, they will have a list of those who agreed to participate. Please ensure that this is either modified (MoH not having a list of people), or that participants are clearly informed about this.

**Question 28c – modified – last sentence above**

**COMMENT 16:**

Question 28d - please clarify the steps that can be taken to protect participants’ confidentiality – which is an important consideration for this research.

**Question 28d**

The processes you will use to obtain that data. If you are using recruitment strategies that access potential participants via a third party please discuss your specific methods here. In general, it is not legal for your participants to give private contact details of other people to you. Usually, should you wish to snowball recruit, you should give your participants an information sheet or advertisement that they can give to others, in the hope that those third parties will then contact you.

It may happen that by virtue of your job, you have right of access to information concerning the participants. Where information has been collected from individuals for a purpose other than your research, it is probable that potential participants will need to be informed that their agreement to participate may involve such use. Guidance on privacy can be found in the policies of the University, and on the website of the Privacy Commissioner.

**Answer:**

Island hospitals will provide information sheet to all patients diagnosed with ambulatory care sensitive conditions. All patients willing to participate in the research will share their contact details with the researcher. Therefore, Ministry of Health would not have a list of those who agreed to participate in the research.

Participant’s information is collected anonymous. Therefore, his/her contribution will not be identified. Each participant will be given a study code at the interview process. Patient’s identification, this includes name and contact details will not be entered to Qualtrics. Therefore, this study code will have no link to patient’s name or contact details. Any information given by the participant will be entered under this particular study code. Therefore, the information given by the participants will remain anonymous, once the data is entered in the system.

Their information will be stored securely in an electronic format, and research team will make sure his/her identity is not revealed to anyone and all information he/she share with the research team will remain confidential.

**COMMENT 16:**

Question 32 - please provide more detail here regarding specific locations. For example, is there a possibility that the survey will be administered in participants’ homes? Please consider any potential risks involved here.

**Question:**

Where will the project be conducted? It is recommended that interviews be conducted in public spaces, not in private homes. *The committee appreciates that in some cases there may be good academic reasons for conducting research in private homes. If you believe this applies to your project, we ask you to provide (a) a concise justification of why research in the home is necessary for your project, what alternative locations were considered, and why they were discounted, and (b) detail how you anticipate and will seek to mitigate potential risks to both participants and researchers when undertaking research in a private home(s).*

Please note: in the case of research involving children, young adults and participants who need particular care, an adult other than the researcher is required to be present.

**Answer:**

The interview will be in-person in a suitable public place in respondent’s island. The participant will decide the interview spot that he/she feels safe and comfortable. This can be a park, jetty area, or café.

**OTHER COMMENTS:**

**Information Sheet:**

* Please could you clarify how you will contact participants if they don’t have a telephone?

**Shall I put contact number / address in???**

**Questionnaire overview:**

* Please review paragraph 2, as this is somewhat difficult to follow currently.

**Can we discuss this statement since I couldn’t find why it is difficult to understand the following paragraph?**

**By signing the consent form you willingly agree to participate in this study. However, you can withdraw your participation at this stage. Please note that as your information will remain anonymous, once this data are entered in the system, we will be unable to locate your specific information and therefore cannot delete it. Please let me know if you do not wish to answer a particular question.**

**Demographics:**

* Please change “*sex*” to “*gender*”, and add an “*other*” category in addition to “*refused*”.

**This will become a legal issue in the Maldives. I can change to gender but I cannot add other.**