**ANSWERS TO QUESTIONS RAISED BY ETHICS COMMITTEE**

**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.

**Answer:**

The project requires approval from Ministry of Health to contact the patients diagnosed with ambulatory care sensitive conditions. All island hospitals are under Ministry of Health. Therefore, no separate approval is required from island hospitals.

Approval from Ministry of Health is contingent upon receiving University of Canterbury Ethics Committee approval. 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.

**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.

**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 in the world, regardless of countries with developed or developing health care systems. To illustrate, 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?

**Answer:**

In the context of this research, this is not relevant. My aim is to understand the under-utilisation of primary healthcare services in the Maldives and not over utilisation.

**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?

**Answer:**

*Typo –removed –*Hospitalisation due to these diseases is a growing problem in the world, regardless of countries with developed or developing health care systems. To illustrate, 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?

**Answer:**

In the context of this research, differentiation is irrelevant. My aim is to understand the under-utilisation of out-patient services given these disease, not about patients who over-utilise or regularly utilise in-patient services. That particular percentage is unknown and is accepted.

**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.

**Answer:** The cases for case-control study will only be patients with ambulatory care sensitive conditions hospitalised for consequences of these conditions. These patients include those who has been hospitalised due to deteriorated health conditions related to given diseases.

* 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?

**Answer:** The severity of the disease condition that mandated their hospitalisation will be coded, and adjusted for multivariable model to explain the variation in the admission patterns.

* Why are acute episodes included? ACSH relates to treating people with chronic conditions in primary care.

**Answer:** All acute episodes will be excluded from the 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.

**Answer:** The data collectors will have data backup using other means (offline and online collection of data), so intermittence of the availability of internet services will not invalidate data collection in anyway. Also, good internet connection is available in all islands.

* 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.

**Answer:** For the sake of anonymity and beneficence, interested participants will share the contact details with the researcher

**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:**

The project requires approval from Ministry of Health to contact the patients diagnosed with ambulatory care sensitive conditions. All island hospitals are under Ministry of Health. Therefore, no separate approval is required from island hospitals.

Approval from Ministry of Health is contingent upon receiving University of Canterbury Ethics Committee approval. 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 identify the pool of patients diagnosed with these conditions and to obtain permission to contact these patients. 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. Any potential respondent willing to participate will share the contact details with the researcher.

**COMMENT 9:**

Questions 12 and 20 - could participants provide times that would be suitable for them to be contacted when indicating interest in the study?

**Answer:** Respondents willing to participate in the research will share their contact details with the researcher. Researcher will contact them over phone to arrange a suitable date and time for interview.

* How will participants be selected?

**Answer:** 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 not selected through the lottery will receive a letter of appreciation by the research team.

* It appears that the “*calls*” will be undertaken by field workers visiting the homes of potential participants - is this correct?

**Answer:** No, the researcher will call.

* Please could you comment on the potential logistical and cost-related issues here?

**Answer:** Field workers will be from same atoll but different island to lessen the issues around anonymity, beneficence, and comfort of the participants. These field workers will travel between islands by atoll ferry. The ferry services are available during the day and vary between 5 to 7 days a week depending on the island. This will be considered in deciding a suitable time and date. It is to control the costs of the research. In case of extreme weather condition and rough sea, interview may have to be postponed to a different date and time. This is for safe travel between islands.

**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).

**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.

The field worker will go through the answers with the respondent on interview spot. Participant will be given 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?

**Answer:** In case denied, I will discuss with the supervisor and come up with a different plan.

**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?

**Answer:** Yes

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?

**Answer:** 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. The delivery of questionnaire will only be by face-to-face.

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

**Answer:**  All answers will be entered directly to computer or tablet during face-to-face interview. If a respondent chooses to be interviewed in English language, the answers will be entered directly to Qualtrics. 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.

**COMMENT 13:**

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

**Answer:** The identity of the participant will be kept confidential. Participant’s identity will not be shared even with the supervisors. 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 or Excel sheet. 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?

Terminology changed 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:** No third party involved. This is inapplicable.

**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.

**Answer:** Modified. Respondents willing to participate in the research will share their contact details with the researcher.

**COMMENT 16:**

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

**Answer:** No third party involved. This is inapplicable.

**COMMENT 17:**

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.

**Answer:** This survey is only going to be conducted in a public place in respondent’s island. No survey will be conducted in a private home. 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?

**Answer:** In case, a participant do not have a contact number, he/she will be excluded from the study

**Questionnaire overview:**

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

**Answer:** By signing the consent form, you willingly agree to participate in this study. You can withdraw your participation at interview process. Once your information is entered in the system, it will remain anonymous. We will be unable to delete it after this point. 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*”.

**Answer:** Maldives is a 100% Muslim country. Sex is more applicable in the context of the Maldives than gender.

Others cannot be added. This may become a legal issue in the Maldives.