PROJECT EVEREST RESEARCH PROTOCOL APPLICATION

Measuring the viability of a mHealth pre-diagnostic tool in a clinic in Blantyre, Malawi.

December 18, 2017
Andrew Vild,
Director XYZ For Good Pty Ltd (T/A Project Everest)
P.O Box 674, Blantyre

Dear COMREC,

Please find enclosed the protocol and necessary appendices for the study, “Measuring the viability of a mHealth pre-diagnostic tool in a clinic in Blantyre, Malawi.” We propose to conduct survey-research, looking at the viability of a pre-diagnostic tool in Pensulo clinic of individuals seeking medical treatment above the ages of 16. Patients participating in the project will not forego medical treatment, rather they will be taken through a precise sequence of events so the team may gain critical data while ensuring patients obtain the care they originally desired. We have met with clinicians from Pensulo clinic who have given informal approval, and we have received a letter of recommendation from the DHO. This research will give invaluable data to inform the future of using pre-diagnostic tools in a Malawi demographic.

The funding institution of this research is Project Everest, an international organisation working in the area of creating sustainable solutions using a business model. This protocol was created as a pathway to assessing whether using pre-diagnostic mHealth technology could provide a sustainable solution to healthcare barriers. Project Everest operates by using teams across various months of the year and as such is limited by a short-time frame to finish data collection, which will hopefully occur in February, 2018. We would appreciate consideration of this and look forward to your informed review and approval of the enclosed material.

Sincerely,

Andrew Vild
Director of XYZ For Good Pty Ltd (T/A Project Everest)

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Investigators

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Institutions Under Whose Umbrella the Research Protocol is Conducted.

The Institutions of Affiliation is a company called XYZ For Good PTY LTD (T/A Project Everest) and the College of Medicine. The work being done is through a SME (small to medium enterprise) that is privately funding the work, however, the results and outcome will be published publicly for anyone to read and use.

XYZ For Good Pty Ltd is an international company, based in Australia and registered in Malawi as an international corporation. The company is a “social business” that is oriented around “for purpose” rather than “for profit”.

As a result of approval and supporting letters, this research will also be affiliated with the College of Medicine.

Executive Summary

Research Design

The project follows a survey research design, allowing for the collection of quantitative data. This approach is often used in behavioural science studies, and requires participants to complete series of surveys and questionnaires. By adopting this research design we can understand the immediate response of participants and usability of the pre-diagnostic application.

Problem

The Malawian health care system is overwhelmed by various barriers including but not limited to extensive patient travel time and distance, overcrowding and associated inefficiency of health clinics, and the degree of health literacy within communities in Blantyre. By expanding within the space of mHealth technologies and developing pre-diagnostic applications, there is the opportunity to overcome these barriers and enable the healthcare system to operate to its full potential.

Goals and Objectives

A series of measurable goals are in place to guarantee the contextual relevance of such technologies. The main objective of the study is as follows:

- To test the viability and receptiveness of a mobile-based, pre-diagnostic application in the current context of the healthcare system within Blantyre District, Malawi

Specific goals for the study include:

- To review the accuracy of a pre-diagnostic application and its ability to provide a diagnosis based on a symptom assessment, comparative to a healthcare professionals diagnosis.
- To determine the efficiency of a pre-diagnostic application in the time it takes to achieve a clinical diagnosis.
- To identify the usability of a pre-diagnostic application from a user's perspective.

Methodology

The testing of the mHealth technology is projected to occur over a 450 day period within the Zingwangwa region, namely the Pensulo Clinic. It aims to reach the population seeking out medical treatment within Blantyre District, with a requirement of 384 responses to ensure results are statistically relevant.

The application testing follows a succinct structure to ensure the most effective and efficient process possible. Patients entering the clinic will be prompted to participate in the experiment. They will be required to fill out a written consent form according to their age (see Appendix 1-6) to ensure they are informed of certain requirements and the experimental process.

An ID form (Appendix 13 and 14) will be given to participants, with corresponding ID number to ensure patient confidentiality is maintained. An entry time and exit time of the clinic will be recorded on the form to monitor time spent in the clinic. Participants will be taken to a private area where a translator will guide them through the application, ensuring they understand the questions asked. Another set of timings; start and end time of application use, will be recorded on the ID form to measure efficiency. The results from the symptom assessment will not be given to the patient prior to consultation to minimise the risk of bias, however, they have the opportunity to receive this after consultation occurs. Patients will wait for their consultation, where they will give the ID Form for the health professional to record their diagnosis. At the end of the day, these slips will be collected for data analysis. Participants will also be asked to complete a usability survey (Appendix 11 and 12) post-consultation to assess ease and helpfulness of the application.

The results of the research process will reflect:

- *Accuracy* - which will be measured through the comparison of application diagnosis and medical practitioner diagnosis using a proportion test.
- *Efficiency* - by comparing the time taken to complete the application, to the time taken waiting for consultation by using a two- sample t-test.
- *Usability* - through conducting a usability survey to assess the user's perspective using a proportion test.

Dissemination of results

Following the completion of the research study, collection and collation of all relevant data, results will be published as a research article. This is to be funded by Project Everest and will be shared through various channels of public communication. The research will be available to the College of Medicine for further advice regarding publication of the article.

Background Information and Introduction

There are a multitude of barriers within the Malawian healthcare system preventing it from operating at its full potential. By conducting a review of the current literature surrounding the healthcare system, barriers towards health and the use of technology were outlined. From this research, several key barriers have been defined. These include long distances travelled to access health services, lack of health literacy leading to many seeking professional advice on basic illnesses that they themselves could treat, overcrowding in health facilities due to patient flow congestion and poor availability of services, influencing the lack of consultation time available to patients in order to receive the care they require. Due to an increased prevalence and growth of technology, there is a push for the use of technology-based interventions to overcome these barriers. Large advances in computing and smartphone technology within the developing world have resulted in evolving technologies, including cognitive learning machines, that are capable of making accurate diagnoses about individual symptoms after input from users.

In Sub-Saharan countries like Malawi, there is research depicting the successful implementation of various forms of technology to strengthen healthcare systems, predominantly using mobile phones (known as mHealth). The promise of these technologies to drastically reduce barriers to healthcare, especially in developing countries, is large and desirable. However, tailoring these solutions to local factors and ensuring the validity of this technology is needed and warrants investigation, which is the main aim of this project.

Significant problems regarding patients accessibility to healthcare resources have been identified, including the long travel times and distances required of patients to gain access to medical services. Barriers towards service provision in Malawi are highlighted by Geoffrey et al., (2014), in which the use of mobile health clinics is discussed as a potential solution. The article highlights the minimal evidence surrounding mobile health services and their ability to continuously provide basic primary health care, emphasising the absence of such facilities in rural areas. This space has been identified as one that can be further developed. In an attempt to address similar issues, a mobile clinic in Zambia was implemented, where a truck with medical equipment travelled to various rural communities to provide healthcare services, allowing medical doctors to provide diagnoses via telecommunication (Mupela, Mustarde & Jones, 2011). This concept, however successful, is not an easily scalable solution due to the large capital needed and hence has a weak ability to reduce barriers to healthcare across a broad area. It again stresses the lack of services available to those living in rural areas, and the need to develop new and innovative ideas to enable ease and efficiency of health communication. An article by Jafry et al., (2016) highlights the travel time experienced by Malawians wishing to access health services. On average, around two or more hours is spent travelling just to access healthcare services, singular to time spent waiting in these centres. The associated costs with travel expenditure significantly reduces the efficiency of healthcare services as well as its effect on patients accessing these facilities.

Major issues regarding patient care at health facilities have been identified including perceived poor service quality. Patients accessing health services on average spend one hundred and twenty-three minutes waiting to see a healthcare professional Jafry et.al., (2016). Furthermore, ninety-eight percent of the time at clinics is spent waiting for services; a total average of sixty-nine minutes to see registry clerks and sixty minutes for medical assistants. This indicates bottlenecks within the current system due to overcrowding and poor efficiency, and therefore an absence of quality care. The fundamental issue of patient congestion and minimal consultation time stems from the availability of healthcare professionals per population ratio. According to Redican et al., (2015) Malawi currently stands at a ratio of seven healthcare professionals per ten thousand people, in comparison to the minimum recommendation from the World Health Organisation of twenty-three healthcare professionals per ten thousand patients. This shortage of trained healthcare professionals as well as high population rates accessing these services, create significant pressure on patient flow within clinics, thus reducing the ability of the healthcare providers to expand into rural areas. These barriers are indicative of a pervasive problem within the healthcare system of Malawi, highlighting a need to explore innovative technologies and interventions to address these concerns.

The increasing use of technology within the healthcare systems of Malawi and similar systems within Africa has been investigated in great depth. A 2013 systematic review by Aranda-Jan, Mohutsiwa-Dibe and Loukanova reviewed forty-four pieces of peer-reviewed literature on mHealth projects within Africa during 2003 - 2013. The review found that a platform for mHealth was becoming more accessible in Africa as countries benefit from increasing mobile coverage and decreasing mobile costs. These telecommunication technologies have the potential to reduce cost expenditure associated with time and distance when accessing healthcare services amongst rural communities. Simultaneously, by facilities utilising mHealth interventions, issues such as inadequate finance, poor health information systems, limited resources and staff training problems can be overcome. Whilst there is a variety of existing mHealth technologies that address data collection, disease surveillance and patient education, there is no research pertaining to pre-diagnostic testing in Africa, which the project will operate within. These existing technologies have found benefit from working with mHealth interventions, highlighting increases in support for patients, reduction in communication delays, improvement in transportation time and costs and increased patient outreach. Another article by O'Byrne et al., (2013) examined the implementation of mHealth within the Blantyre region of Malawi. This article looked at the introduction of a triage system for delegating priority care, particularly in hospitals. It found that this system was effective in reducing patient loads and waiting times, lending support to the implementation of mHealth technologies as an effective tool to reduce barriers to health services. There is research to support the use of mHealth technologies as strengthening tools within healthcare systems (Labrique et al., 2013). By incorporating proven tools with the current healthcare system, particularly those with the capacity to reach patients in rural communities, barriers to accessing adequate care can be reduced.

Research evaluating the usability of mHealth technologies and interventions, specifically pertaining to a user's perspective, is widely focused within the developed world. Shieshia et al., (2014) discusses the use of application technology within pharmaceutical supply chain management. Concluding this research, it is evident that innovation of telecommunication has a positive effect on supply chain management and is well received by healthcare professionals. This is significant for the viability of the mHealth technology, as it demonstrates openness of users to similar technologies within the health space. Furthermore, Banda and Gombachika (2012) highlight an overall positive attitude from users towards mHealth services. Additionally, this study found that mHealth technologies are non-discriminant to people from various demographics, namely within the demographic of age. However, many mHealth technologies within this space are not successful as they fail to consider users perspectives and community involvement (Dietrich, 2016). It is essential when operating in the developing world that we consider the usability of the application from a user's perspective, to ensure the most successful intervention can be created for a maximum therapeutic benefit.

Health literacy levels within rural Blantyre Malawi are not well researched and therefore information surrounding health education levels are significantly limited. The following is inferred through evaluating education levels and their correlation with knowledge surrounding health education. An article by Redican et al. (2015) shows that within healthcare facilities, health educational workshops are implemented to inform patients about hygiene, family planning, sexual health and nutrition. Additionally, in schools and communities, health programs aim to promote healthy behaviours and attitudes. Despite these efforts, poor attendance and lack of educational importance within Malawi minimise the impact of such programs. Furthermore, an article by Smith-Greenaway (2014) investigates the educational levels of young adults and their opinions on their health. There is a prominent delay in literacy skills amongst children in Malawi due to common problems associated with the provision of education. This includes overcrowding of classrooms, limited supplies and underpaid teachers leading to reduced levels of educational skills. As education is a key determinant of health, it is inferred that health literacy levels would be poor as many do not complete secondary school and receive a quality education. Whilst this trend is improving, approximately only 30% of children reach secondary school level within Malawi, highlighting the apparent lack of education received. Despite the insufficient amount of literature specifically discussing health literacy in Malawi, there are strong links between a lack of education and poor health literacy. From this, health illiteracy amongst the general Malawi population can be safely inferred.

Through conducting research into the health system in Malawi, various barriers to healthcare have been identified and considered. These barriers include but are not limited to long distances and travel times to access healthcare services, overcrowding in healthcare centres and waiting times, short patient consultation times and health illiteracy. The use of technology within the health system of Malawi, particularly surrounding mHealth, has been identified as a potential solution to reducing barriers to receiving adequate healthcare. Much research has already been done in this area, however, it is important to continue to build upon existing research, particularly as the existing information has specifically focused on the responses of healthcare

professionals. The concept of using mHealth in a way to alleviate healthcare system pressure deserves further exploration as it is proving to be a promising avenue. This research project will move toward validating the use of new mHealth tools to strengthen the provision of healthcare in Malawi, and overcome the barriers that exist in the current system.

Rationale/Justification for the Research Project

The current Malawi health system has many issues that need to be investigated in order for a relevant and beneficial intervention to be implemented. The main areas of investigation for this research study are aimed towards the length of patient travel time and distance, the overcrowded and inefficient health clinics (regarding the large patient waiting times and the inadequate patient assessment times) and the degree of health literacy within the communities. These areas of the Malawian health care system can be improved through the expansion of previously published research as well as the exploration of new beneficial structures.

Expansion of research is also needed regarding the use of technology and medical applications to understand if they are able to provide a beneficial impact on the health system, particularly improving patient flow within clinics, accessibility to clinics and health literacy. As technology continues to progress medical advancements, it is vital to investigate its benefits and how it can be implemented. The study will focus on these aspects to provide a cost-effective, accurate and viable solution for the issues presented within the current Malawian healthcare system.

Objectives of the Study

i) Broad Objective

To test the viability and receptiveness of a mobile-based, pre-diagnostic application in the current context of the healthcare system within Blantyre District, Malawi

ii) Specific Objectives

1. To review the accuracy of a pre-diagnostic application and its ability to provide a diagnosis based on a symptom assessment, comparative to a healthcare professionals diagnosis.
2. To determine the efficiency of a pre-diagnostic application in the time it takes to achieve a clinical diagnosis.
3. To identify the usability of a pre-diagnostic application from a user's perspective.

Methodology

i) *Type of research study*

The type of study design being used is a survey research design. By adopting this design it enables the interaction between participants and researcher through the use of questionnaires and surveys. The collection of data from the population mass will be undertaken through convenience sampling; patients are selected due to convenience and proximity to researchers. It is important to consider the incidence of nonsampling errors to ensure the most accurate data is collected. These errors are products of systematic biases, for example, participants responding to statements without a full understanding of what is being asked. In order to minimise the prevalence of nonsampling errors, we will consult with translators whom will be trained in the process of the application testing. These translators will be required to speak both Chichewa and English and ensure the questions being asked are completely understood by participants.

ii) *Study place*

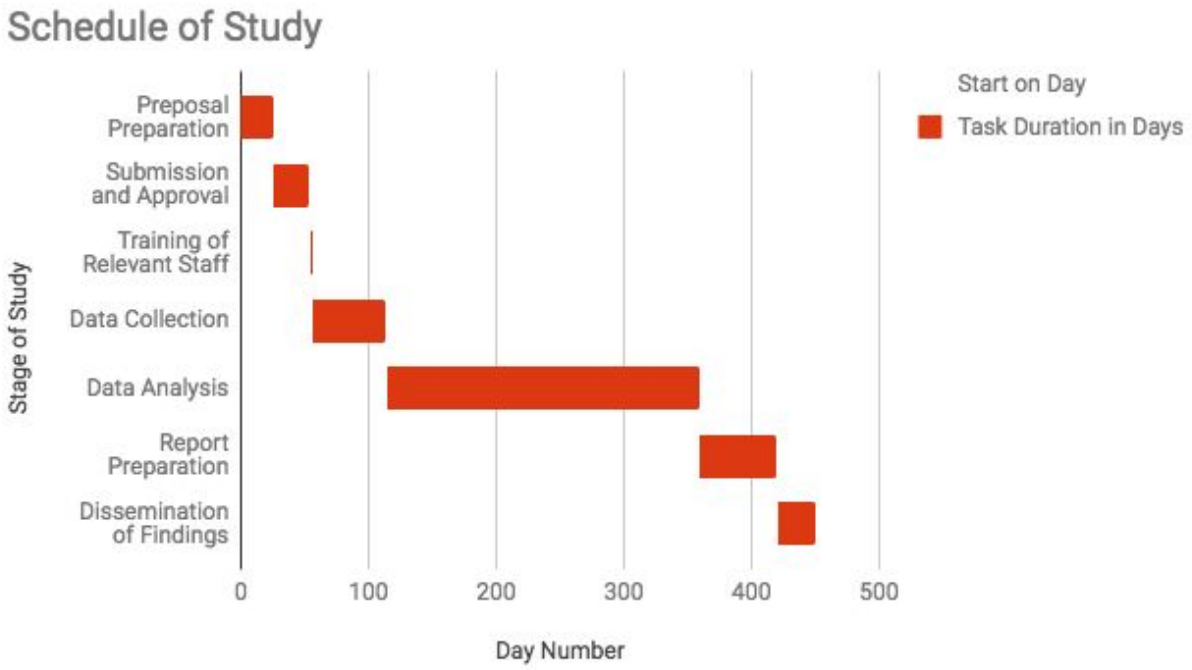
The testing of the pre-diagnostic applications will occur in the Zingwangwa area of Blantyre, specifically in the Pensulo clinic.

iii) *Study population*

This study will focus on the population within the Blantyre District that are above the age of 16, including its rural areas, that are seeking medical treatment at registered health clinics; there will be no exclusion of people based on race, gender, religion or physical illness. Those that are between the age of 16 to 18 years will be viewed as a child and will therefore need a parent to approve their voluntary consent.

iv) *Study period*

The entire research study is estimated to be conducted for approximately 450 days. This includes the preparation of the proposal, submission and approval, training of the relevant staff, pretesting of the application, data collection, data analysis, report preparation, and dissemination of the findings.



v) *Sample size*

The estimated population of the Zingwangwa region, for which Nancholi is located in, is approximately 147 000 (Maoulidi, 2013). By using sample size software technology, the experiment requires 384 participants for the results to be statistically relevant.

Participants that request to withdraw from the study will be granted dismissal through research assistants available at the time of requested withdrawal.

vi) *Survey Process*

Prior to the patient's involvement, the practitioner will be required to give their consent to participate in the study by signing the consent document (Appendix 7 - 8). Upon their agreement they will be shown how to complete the patient's identification form (Appendix 13 - 14), as well as a survey to assess the viability of the application (Appendix 9-10)

The patient would enter the health clinic (Pensulo) and proceed towards registration. Patients who most recently arrived at the clinic and who have not yet registered would be asked if they would be willing to participate in the experiment. By asking the patients who are yet to register

(i.e. last in the queue), no confusion or logistical concerns are created, as patients would not miss their appointment with the clinician or nurse.

From there, the patient would proceed to confirm their willingness to participate by signing a consent document (Appendix 1-6) after having the research and their role-requirements within the experiment explained to them in their native language. The participant would then be assigned an identification number, to ensure the confidentiality of the patient. Identification numbers are located on an identification form (Appendix 13 and 14), where multiple timings and clinician diagnosis may be recorded. Their entrance time into the clinic would be recorded on as they agree to participate in the project.

A translator, who has been shown how to use the application, would question and guide the patient through the symptom assessment on the application. To further ensure the participant's privacy, every time an entry begins, a new profile with the patient's corresponding identification number would be created.

This process would occur in a separate and private area to ensure the protection of the participant's privacy. The beginning and finishing times of using the pre-diagnostic application would be recorded. These recordings would be made to quantify the efficiency of the application in a time measurement. During data analysis the length of time it takes for the application to make a diagnosis would be compared to the time it takes for a patient to receive a diagnosis from a healthcare practitioner (time of entry measured to the time of receiving a diagnosis from clinician).

The participant would not be shown the pre-diagnostic result from the application to avoid bias. Bias may arise as this may influence a skewed opinion regarding their diagnosis. This may incline them to not fully disclose their symptoms with the clinician or nurse, perhaps leading to an incorrect diagnosis, thus creating a misrepresentation of the application's accuracy, rendering the experiment and its results inaccurate and not valuable.

The patient would then be sent to the clinician or nurse for their appointment with their identification form. The patient is required to pass on their ID form the nurse or clinician, which would be complete as they write down their diagnosis (nurse or clinician) The completed identification forms would then be collected at the end of surveying.

Whilst the patient is with the clinician or nurse, the translator or field operator would view the pre-diagnostic result of the application. The diagnosis would be recorded by the translator screenshotting the outcome and sending it to a cloud database where all the results will be stored. Later, the diagnoses of the clinician or nurse will be compared to the ones completed by the application. This will test the accuracy of the application, assuming all of the diagnoses made by the clinician/nurse are correct.

Following the completion of the consultation, the patient will be asked to participate in a survey regarding the usability of the application (Appendix 11 and 12). A translator will ask the participants questions regarding the application's helpfulness, ease of use and whether the participant would still visit the clinic after using the application. The final question would investigate the accessibility of the application through mobile phone availability.

vii) *Data collection*

Data will be collected and collated by Project Everest research assistants and conducted through screenshots of the pre-diagnostic application with the patient's name replaced with an identification number, therefore protecting their anonymity. The only relevant data that will be collected is their gender, age and diagnosis. Field operators will work with the research assistants to provide translation from English to Chichewa and vice versa and to assist in the documentation of relevant data.

An identification form (Appendix 13 and 14) will be used to record the patient's entry time and exit time in the clinic, the start and finish time of the application and their diagnosis. A usability survey (Appendix 11 and 12) will be conducted by a research assistant with the study participant to identify the complexity of the application's functionality. It will be documented using a separate sheet of tallied scores to record the answers from each individual question. This data will be uploaded and stored in a cloud-based storage facility for convenience and security of sensitive information.

The software "Microsoft Excel" will be used for further statistical analysis.

viii) *Data Management and Analysis*

The results of the experiment would help indicate the application's efficiency, accuracy and usability. The efficiency of the application would be measured by comparing the time the application required to diagnose the patient, with the time the patient spent at the clinic, i.e when the patient arrived at the clinic and when the clinician or nurse gave their diagnosis.

The accuracy would be measured by comparing the diagnoses completed by the application compared to the diagnoses made by the clinician or nurse, assuming their diagnoses are correct. This will be quantified by a one or a zero, one being a correct diagnosis by the application and zero being an incorrect diagnosis. The number of correct diagnoses will then be totalled to enable the analysis of the application's efficiency.

The accuracy and efficiency idata will be inputted into an excel spreadsheet. Once this is completed, the data will be transferred into R-studio where a proportion test will be conducted since the result from the experiment can either be a success (correct diagnosis) or failure (incorrect diagnosis). For the application to be used with confidence, a 90% accuracy test result is desirable. To measure whether this is correct, the null hypothesis will be, $P < 0.90$. If the results display a p-value less than 0.05 then there will be evidence to reject the null hypothesis

in favour of the alternative hypothesis (P≥0.90). This would indicate that there is evidence suggesting the application is 90% accurate.

The efficiency will be analysed by completing a two-sample t-test. This is because the sample means and common variance are unknown. The times recorded for patients at the clinic will be compared to the time taken for the application to finish its diagnosis. The null hypothesis will be that the average time taken for clinical diagnosis will be equal to the average time taken for application diagnosis. The test will be-one sided as there is a reason to believe that the mean time for time spent at the clinic will be greater than the mean time recorded using the application. Therefore, if the p-value is less than 0.05 then there will be evidence to reject the null hypothesis in favour of the alternative hypothesis, suggesting that the application is more efficient and less time consuming than visiting a clinic for a diagnosis.

The results of the usability survey (Appendix 11 and 12) will be analysed by conducting a proportion test for each question. The usability results that will be considered a success is 70% for each question investigating the application's helpfulness, straightforwardness and its inclination to change people's behaviour. The null hypothesis will be that P < 0.70, and any p-value less than 0.05 will lead to the null hypothesis being rejected in favour of the alternative hypothesis that, P≥0.70.

ix) *Results Presentation*

A table will be used to present the results. It will outline what the parameter is, its target, question whether it was reached and a qualitative reason discussing why the result occurred.

Example of Results Table

Parameter	Target	Result	Why this occurred
Accuracy	90% Accuracy		
Efficiency	Faster than clinical diagnosis		
Usability 1. Usefulnes 2. Helpfulness 3. Changes participant's future behaviour	70%		

x) *Dissemination of the Results*

Upon completion of the research study, once all data has been collected, collated and analysed and disseminated to COMREC, a research article will be created. This will detail the entirety of the project as well as discussion of the results and future implications. The research article will be funded and published by Project Everest. Project Everest is not an officially recognised peer-reviewed journal, however, the results of this research will be openly shared through their various channels of public communication. The research article will be made available to the College of Medicine and all results will be shared with COMREC, so that they may provide assistance on the journals they see as the most suitable for the research.

Ethical Consideration

In formulating this research protocol, the team has accounted for ethical considerations throughout the entire process. Although the research falls under the category of human experimentation, it does not require any physical or mental application on the patient as the patient is answering questions on their current illness, rather than having a foreign substance administered to them. Although this does reduce a large number of ethical concerns inherent in human experimentation, the team is still implementing numerous safeguards to adhere to the highest possible ethical standards. To do this, the team is adhering to the four ethical principles of beneficence, non-maleficence, respect and distributive justice, all of which are outlined in the World Medical Association Declaration of Helsinki (2013).

In ensuring beneficence, the team believes they have developed a scientifically and technically sound study design that will answer the research question. This has been achieved through discussion both internally and externally with key stakeholders to continually iterate on the study design. Through this process, the team has developed a design that will provide necessary data while minimising disruption to both patients and practitioners at clinics.

In ensuring non-maleficence, the team has taken into account the fact that this study does not require physical or mental applications upon the participant. This greatly reduces the risks generally inherent in human experimentation, leaving the main risk from this research as creating confusion amongst participants, who may already be disorientated from their illness. This confusion is based on the assumption that they may become disorientated to the normal process of receiving care from a health practitioner as the team are asking them to undertake different actions. The team has considered this and will ensure the research is carefully explained to participants and that they understand what is asked of them before gaining consent and beginning the study process, which will reduce any potential confusion that may be created.

In ensuring respect, the team has implemented several safeguards to achieve this. In order to ensure patients are fully informed of what the research is about, as well as their rights within the study, the team has developed consent forms (Appendix 1 - 6), tailored to the age of participants, that will be provided in both English and the local language Chichewa. This will be

explained in the language that the participant most readily understands, and the team will ensure participants have a complete understanding of the research before their written consent is gained for participation in the research. The consent form will include such things as research purpose and procedures, risks and benefits of the study, the fact they are volunteering to participate but can discontinue participation at any point in time and also contacts to gain further information about the study. When providing this information, the team will ensure that potential participants are not pressured into participating and do so of their own free will. If the team suspects that participants are not participating of their own free will, these participants will be prevented from participating. For participants who are under 18 years of age, consent will be gained from both them and their parent or guardian. Any participants who are under 16 years of age have been excluded from the study and will not be allowed to participate.

An important aspect of ensuring respect is creating confidentiality within the study. This has been achieved by removing names from the research and using ID numbers instead, which means that even if the information is handled by various people, there will be no links between names and diagnoses. ID numbers will be assigned when patients arrive at the clinic and register for an appointment, so normal confidentiality will be maintained in that researchers will not be part of this part of the process. Although the health professionals at the clinic may be aware of which participant has which number, there is no loss of confidentiality created as a result of participation in the research as these people already have access to patients' illnesses.

In terms of ensuring distributive justice, it is understood that physical and mental health benefits of the study will not impact directly on participants as nothing is being administered to them. However, participants will benefit from gaining a secondary opinion on what illness may afflict them. Although they may still prefer the opinion of their medical practitioner, this information will be beneficial for them. They can gain this information following the completion of the consultation with their practitioner, as per the study design process.

Possible Constraints

Although the team has ensured that most issues regarding this study have been addressed and accounted for, there are some problems inherent in the study that will be difficult to overcome and may impact upon the results of the study. Understanding these potential issues have been a significant process for the team, and has allowed them to develop further safeguards for them to minimise their impact on the results of the study.

A prominent issue in the study design is the reliance upon a medical practitioners diagnosis in identifying the accuracy of the pre-diagnostic application. The presumption in this scenario is that the practitioners diagnosis is one hundred percent accurate, however this is unlikely to be correct due to human error in diagnosis. To reduce this issue, the practitioners used will have a high level of training, and will be highly qualified and experienced practitioners. This will reduce

this issue significantly, however the team acknowledges that this does not completely remove this problem.

The fact that the pre-diagnostic tool being used has a limited age range will also create a constraint in the research. The age limit being used is that participants must be sixteen years or older. This is significant as it means that the results of this study should not be considered valid for people younger than sixteen. This is a limitation that is understood and accepted by the team, as there is not a lot that can be done to address this. The team has also implemented safeguards to ensure that this limitation is maintained.

In regards to data collection, there is somewhat of a reliance on the use of people within the collection. This will inherently produce a risk for human error in collecting the data. This error will mainly occur from people incorrectly transferring data into the excel spreadsheet. To minimise this issue, the team will ensure that those inputting the data are alert, take regular breaks in order to remain focused as well as make sure they double check what they have just inputted. Secondary to this, there is a possible issue in transferring a practitioner's diagnosis to the excel spreadsheet, as a form of shorthand may be used by the practitioner that is not understood by the data collector. This is an issue easily fixed by good communication, ensuring that shorthand is not used and that any issues with understanding diagnoses are discussed between the practitioner and data collector. Although these errors are acknowledged, they are not expected to be major issues, as the data being entered is relatively simple, and any risks should be greatly reduced through the above statements regarding how to address the issues.

A possible issue that research assistants, COM students and field operators may face is fatigue from traveling by foot to Pensulo clinic. To reach the Pensulo clinic the research assistants, COM students and field operators must travel up and down hilly terrain in challenging and at times adverse weather conditions. Therefore, the research assistants, COM students and field operators may fatigue at a more rapid pace than if they could have accessed the clinic by a four-wheel drive vehicle. This fatigue may lead to the research assistants, COM students and field operators to not maintain the level of attention to detail required to conduct the experiment, meaning they could possibly overlook symptoms or forget to ask necessary questions for a correct pre-diagnosis by the application. This will be overcome by providing research assistants, COM students and field operators with sustenance and fluids to ensure they recover and will be able to maintain the required level of performance to perform the experiment.

Inaccurate diagnoses may arise due to the participants providing the research assistants with self-reported data. This data may not provide the full scope of the participant’s issue due to selective memory, telescoping, and exaggeration problems. Selective memory issues may arise when the participant doesn’t remember all their most recent experiences or events. This may lead to possible symptoms being forgotten and therefore overlooked, which may not provide the application with the full scope of information needed to complete a correct pre-diagnosis.

Telescoping, when events are recalled at one time as if they occurred at another, may also lead to the incorrect input of symptoms, also leading to an incorrect diagnosis. Exaggeration of symptoms or events regarding the participant's illness or injury may also lead to an incorrect symptom input, and therefore a possible incorrect pre-diagnosis.
To minimise this, research assistants will provide the participants with an adequate amount of time to fully understand the participant's symptoms and to communicate all past events with clarity and full comprehension.

Cultural issues within Malawi may also create a constraint in the accuracy of the data presented. These issues could create a bias or inaccuracy during the symptom diagnosis using the pre-diagnostic application. This could occur from several reasons, firstly that the participant may have a low level of health literacy, meaning they may not understand their own symptoms enough to be able to provide them for use in the application. Although this issue exists anyway in a normal medical practitioners diagnosis, this problem is reduced because of their understanding of their field. In regards to the applications collection of the symptoms, this issue will be reduced by using translators who have a medical background. Although the knowledge of the translators may be less than that of a traditional practitioner, they will still be knowledgeable enough to help patients understand their symptoms.

A secondary cultural issue relates to how participants discuss their symptoms, as some may be reluctant to discuss health issues with the translators. This will lead to a distortion of their symptoms, as what they are saying may not necessarily be correct, which will impact upon the accuracy of the application. In order to alleviate this issue, it will be ensured that the study has the full support of the participant's medical practitioner, who will communicate this to the participant so that they trust the translator. The translator will also ensure they conduct themselves in a friendly and trustworthy manner to evoke trust from the participant. Lastly, it will be ensured that the patient fully understands what is required of them, why the study is occurring and that their confidentiality is being respected throughout the entire process. This will be conveyed through the relevant consent forms (Appendix 1 - 4) explained to the patient.

A tertiary cultural issue that may impact upon the accuracy of the study is that the language of the local people and that of the pre-diagnostic application is different. This could create an issue of questions and answers being lost in translation. This will be reduced by ensuring that translators are highly trained in both languages.

Requirements

Personnel

The overall team involved in the execution of the research study will consist of Project Everest representatives and staff, Malawi College of Medicine (COM) students, Field Operators and the District Medical Officer of Blantyre as the co-investigator.

The principal investigator, Andrew Vild of Project Everest, and co-investigator Ella Grier of Project Everest, will oversee the productivity of the research study and ensure that data points are collected and collated as per the schedule outlined in the methodology. Their tasks will also be extended to budget control and community and clinic relations management.
Research Assistants within the Project Everest team will execute on the delivery and implementation of the protocol and collaborate with operators from the COM. Their primary responsibilities will be to collect, collate and analyse the acquired data and to provide pertinent information for the progression of the research.

The role of the COM students is to facilitate the use of the application by participants and the process of patient tracking to verify accurate collection of data points. They will also be utilised due to their medical knowledge to assist with any minor complications with the application regarding incorrect health data input.

Field Operators will be required to assist the Research Assistants when working within the health clinics. Their primary duties will be to translate from English to Chichewa, and vice versa, to ensure accurate input of health data as well as helping to build rapport with the clinic works and Project Everest staff.

Paper

The experiment will require the use of paper for consent forms, usability surveys and identification documents. The majority of the paper requirements will be attributed to the consent forms and identification documents as each individual participant will be required to complete a consent form and be assigned an identification form.

Transport

The personnel of the research project will be utilising a 12-seater Toyota van for transportation around the communities and to passage various personnel to their respective work sites. The van is spacious enough to carry all personnel if needed and the vehicle build allows it to travel on rugged terrain, to a certain extent, for rural areas. The personnel will also be utilising public transportation for ease of convenience around the Blantyre district, if the van is unable to be used due to other staff priorities within the research project.

Space

The space required at the Pensulo clinic will be a private room, meaning that the information exchanged between the research assistants and the participants will remain confidential. This

will be the only required experiment space as the sampling will only occur at the Pensulo clinic. Another required space is the team's office where collating and analysis of data will occur.

Electronics

The Project Everest staff will be incorporating an array of electronic devices to assist in data collection and collation, data analysis, communication, GPS location and application testing within the research study. Devices such as computers and smartphones will provide the primary basis for communication, accurate location, data collection and analysis, as well as providing a platform for the pre-diagnostic application to be utilised and tested. The bulk of the data and research material will be stored in an online cloud-based storage facility, "Google Drive", for ease of access as well as a secure site to store information. In order to communicate efficiently, access the Internet for further research and to upload documents and data to Google Drive, the team will consume a large amount of data, approximately 20 gigabytes per month, in order to fully operate the chosen equipment.

Budgetary Estimates

	Institutional Contribution	**Amount being asked for**
Protocol Submission Fee	**150 USD (107,021.12 mwk)**	**Nil**
10% Overhead Fee to the COMREC Board	**150,000 mwk**	**Nil**
Logistical Resources		
Office Costs	**600,000mwk**	**Nil**
Materials associated with patient tracking	**20,000mwk**	**Nil**
Reimbursement to medical facility for any resources used	**10,000mwk**	**Nil**
Transport costs in assisting necessary personal to study site	**18,000mwk**	**Nil**
Technology costs for application use	**70,000mwk**	**Nil**
Mobile data costs for application use	**10,000mwk**	**Nil**
Misc. Logistical Costs	**50,000mwk**	**Nil**
Subtotal	**1, 369, 000mwk**	**0**
Human Resources		
Co-investigator wage	**2000 p.h.**	**Nil**
Operator wage	**72,000**	**Nil**
Subtotal	**72,000mwk**	**0**
Data Collection		
Disturbance Reimbursement	**384,000mwk**	**Nil**
Subtotal	**384,000mwk**	**0**
TOTAL	**1,825,000**	**0**

Justification of Budget

The ultimate goal of our research into the accuracy, efficiency and usability of this cognitive technology within the Malawian healthcare system is to establish how effectively it can be incorporated into a lean social enterprise that addresses access barriers to basic healthcare needs. As such, the design and model of this protocol is catered to a restricted budget such that viability of a cost-driven business model can be accurately assessed. The human resources required, as well as capacity for data analysis and electronic requirements are all inherent in the Project Everest teams that work with on the ground in Malawi. These three components account for a large portion of our key activities throughout the research process and thus we have concluded that our requisite budget components culminate in a modest financial estimate.

Office Costs

Project Everest currently uses an office space for all of their project operations across health, energy, agriculture and sustainable fuels. The cost of this space is 300,000mwk per month, and is weighted to represent the amount of space and use the health project consumes. This is inclusive of operating costs throughout the property (ie. electricity and water bills). The estimated costs of the health team is 50,000mwk per month x 12 months of the project run-time = 600,000mwk.

Materials associated with patient tracking

This cost is to cover any printouts of consent forms, patient tracking cards (for privacy and accuracy of collecting results) and any other miscellaneous stationary required for patient tracking.

Reimbursement to medical facility for any resources used

In the event that our study impedes on the medical facility's resources or operations, this allowance will act as a reimbursement. This may occur in the event to charge mobile resources at the study location, or when the execution of the study requires the use of a private medical room that may need to be vacated.

Transport costs in assisting necessary personnel to study site

This cost is a transport allowance for our operators, translators to make it out to our clinics. Given we expect to make 18 specific trips to clinics, with 2 assisting personnel at 500mwk/person/day = 18,000mwk

Technology costs for application use

Our research is reliant on the use of smartphones or tablets with an internet connection. We will be purchasing 2x 35,000mwk smart phones or tablets that will have the computing power to run the internet-powered app.

Mobile data costs for application use

As the application is mainly text-based, the data requirements for a patient diagnosis is very small. The allocation of 1GB is considered to be much more than necessary and will cost 2500mwk per month x 4 months of active interaction with the relevant clinics.

Miscellaneous Logistical Costs

The miscellaneous logistical costs are incorporated to cover any oversights made in the budget forecasts. The costs that may go under this category are repair costs to technology, additional staff or resources required for the logistics.

Co-investigator wage

A co-investigator will be required to have input on the research, project etc. The price quoted is based on 1 day per fortnight.

Operator wage

An allowance for our field operators who will assist in using the medical application. This is based off 2x translators for 18 direct clinic contact days.

Disturbance Reimbursement

The disturbance reimbursement is based off our requirement for 384 data points to have an accurate ‘p’ value, with the assumption that 1000mwk is enough for the 15-minute disturbance in the patients day. This value is actually deemed too high, given the low socio-economic status of the communities we will be interacting with. From a development and impact assessment perspective, such a relatively large sum of money for such a simple task will result in unemployed or low-income community members to attend the clinic in the hope they will be reimbursed in exchange for participating. This is not in the true nature of the research.

References

Aranda-Jan, C. B., Mohutsiwa-Dibe, N., & Loukanova, S. (2014). Systematic review on what works, what does not work and why of implementation of mobile health (mHealth) projects in Africa. *BioMed Central Public Health, 14,* 188. doi: 10.1186/1471-2458-14-188

Banda, C. K., & Gombachika, H. (2012). Mobile phone technology acceptance and usability in the delivery of health services among health surveillance assistants in rural areas of Malawi. *International Conference on e-Infrastructure and e-Services for Developing Countries,* 119. doi: https://doi.org/10.1007/978-3-642-41178-6_26

Dietrich, L. (2016). *The utility of mobile phones for health among women living with HIV in urban Malawi. (PhD thesis). Retrieved from: https://search-proquest-com.ezproxy.lib.uts.edu.au/docview/1855589314*

Geoffroy, E., Harries, A. D., Bissell, K., Schell, E., Bvumbwe, A., Tayler-Smith, K., & Kizito, W. (2014) Bringing care to the community: expanding access to health care in rural Malawi through mobile health clinics. *Public Health Action, 4*(4), 252-258. doi: 10.5588/pha.14.0064

Jafry, M. A., Jenny, A. M., Lubinga, S. J., Larsen-Cooper, E., Crawford, J., & Matemba, C. (2016). Examination of patient flow in a rural health center in Malawi. *BMC Research Notes 9(*1). doi: 10.1186/s13104-016-2144-x

Labrique, A. B., Vasudevan, L., Kochi, E., Fabricant, R., & Mehl, G. (2013). mHealth innovations as health system strengthening tools: 12 common applications and a visual framework. *Global Health: Science and Practice, 1(*2), 160-171. doi: 10.9745/GHSP-D-13-00031

Maoulidi, M. (2013). Health Needs Assessment for Blantyre, Malawi. *Columbia University Academic Commons*. Doi: 10.7916/D8NS0SPB

Mupela, E. N., Mustarde, P., & Jones, H. L. C. (2011). Telemedicine in primary health: The virtual doctor project Zambia. *Philosophy, Ethics and Humanities in Medicine, 6,* 9. doi: 10.1186/1747-5341-6-9

O'Byrne, T., Nyirenda, D., Perrin, R., Marshall, S., Geldof, M., Bar-Zeev, S., Lufesi, N., Nyirenda, E., Dube, Q., Bar-Zeev, N., Glennie, L., Molyneux, E., Heyderman, R., Desmond, N. (2013). Improving recognition of severe illness and patient pathways in primary health services using mHealth technology in urban Blantyre Malawi. *Journal of Manufacturing Technology Management, 2*(4), 2-3. doi: 10.7309/jmtm.2.4S.2

Redican, K. J., Abbas, K., Elvinger, F., Hosig, K., Marmagas, S. W., Chitsulo, P., Kelly, P., Burton, J., Tlou, J., & Carter-Tod, S. (2015). Making a difference in Malawi and Zambia through health education and public health best practices. *Global Journal of Health Education Promotion, 16*(2), 18-32. doi: 10.18666/GJHEP-2015-V16-I2-5964

Shieshia, M., Noel, M., Andersson, S., Felling, B., Alva, S., Agarwal, S., Lefevre, A., Misomali, A., Chimphanga, B., Nsona, H., & Chandani, T. (2014). *Journal of Global Health, 4*(2). doi: 10.7189/jogh.04.020406

Smith-Greenaway, E. (2014). Are literacy skills associated with young adults' health in Africa? Evidence from Malawi. *Social Science and Medicine, 127*, 124-133. doi: 10.1016/j.socscimed.2014.07.036

World Medical Association. (1964). WMA Declaration of Helsinki: Ethical principles for medical research involving human subjects. Retrieved from: https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/

APPENDIX 1 *Adolescent/Guardian Consent Form - English version*

PROJECT EVEREST
PARENTAL CONSENT FORM FOR ADOLESCENT PARTICIPATION IN RESEARCH

Research Title: Measuring a mHealth pre-diagnostic tool in a clinic in Blantyre, Malawi.

Protocol Number:

Your child has been invited to participate in a research study conducted by Project Everest. This form contains information regarding what is currently being tested and how the information gathered will be used in the study if you choose to allow your child to participate. Since your child is in the age range of 16 to 18 years of age, you will be required to give consent for your child to voluntarily participate in this study.

This study uses a pre-diagnostic application which allows you to enter symptoms into a database and receive a diagnosis. The overall aim is to test the viability of this application within communities around Blantyre, Malawi, and ensure that the following technology is relevant to the area. Your child is being asked to participate in this study in order to gain information on the efficiency and accuracy of the application.

Your child will be asked to answer questions regarding their symptoms and current health status. Depending on the symptoms there may be personal or sensitive questions involved in the application testing. Participation should take approximately 10-15 minutes.

As a parent, Project Everest appreciates that you may have a better understanding of your child's symptoms and therefore, you may be required to answer certain questions within the application testing. The questions and activities surrounding this application pose no harm or risk to you or your child. If your child does become tired, upset or restless during the testing of the application, they may take a break or stop the testing altogether. In the event your child may become uncomfortable with questions or topics being discussed, they are free to not answer or skip to the next question.

As with all research studies, there is a risk of breaching confidentiality. There are various strategies in place to reduce this risk and provide complete anonymity to you

and your child. Your child's name will not be recorded or discussed, and instead will be replaced with an identification number.

This questionnaire will provide your child with a diagnosis, as well as recommended treatment options pertaining to this diagnosis. This may not be an immediate benefit, however, the information gathered in this study will generate a better understanding of the application's viability in the future.

Results of this study may be used in publications and presentations. By securing your child's anonymity, confidentiality will be retained with little risk of breaching your child's privacy. In the event that these results are shared with researchers, identification numbers will not be released and there will be no correlation between your child and the collected data.

Participation in this research study is voluntary. You may refuse to allow your child to participate or withdraw your child from the study at any time. Your child will not be penalised in any way should you decide not to allow your child to participate or to withdraw your child from this study.

Contact information

If you have any questions or concerns about this study or if any problems arise, please contact Andrew Vild or Ella Grier at Project Everest at 0992 59 38 45 (Andrew Vild) or 0992 50 26 64 (Ella Grier) or at malawi@projecteverest.ventures. If you have any questions or concerns about your child's rights as a research participant, please contact the Office of Ombudsman Malawi at the Kanabar House, Blantyre at (+265) 1833317.

Consent

I have read this parental permission form and have been given the opportunity to ask questions. I voluntarily agree to give my permission for my child to participate in this study.

Parent/Guardian's signature:_____Date:_____

Child's Name:_____

APPENDIX 2 *Adolescent/Guardian Consent Form - Chichewa version*

PROJECT EVEREST
CHIVOMEREZO CHA KHOLO CHA KUTENGA NAWO GAWO KWA MWANA MU KAFUKUFUKU

Mutu wa kafukufuku: kuyesa chida cha zaumoyo cha m'manja choyezera matenda mzipatala zazin'gonozin'gono ku Blantyre, Malawi.

Nambala ya ndondomeko:

Mwana wanu waitanidwa kuti atenge nawo gawo mu kafukufuku yemwe akupangidwa ndi a Project Everest. Fomu iyi ili ndi uthenga okhudzana ndi zomwe zikuyesedwa pakadali pano komanso fomuyi yafotokoza momwe uthenga womwe utatoleledwe utagwilire ntchito mu kafukufuku ngati mutasankhe kulora mwana wanu kuti atenge nawo gawo. Popeza mwana wanu ali ndi zaka zapakati pa 16 ndi 18, mudzafunikila kuvomereza mwana wanu kuti achite nawo phunziroli mwadzidzidzi.

Kafukufukuyu amagwiritsa ntchito makina a compyuta omwe amantchula nthenda yomwe munthu wadwala ngati zizindikiro za matenda zalowetsedwa mu makinawo. Cholinga chenicheni cha kafuufukuyu ndi kufuna kuyesa ngati njira imeneyi ili yodalirika mmadera ozungulira Blantyre kuno ku Malawi komanso kuonetsetsa kuti njirayi ndi yofunikira ku delali. Mwana wanu akufunsidwa kuti atenge nawo gawo mu kafuufukuyi ndi cholinga choti tidziwe ngati njira imeneyi ikugwira ntchito bwino komanso molondola.

Mwana wanu adzafunsidwa kuti ayankhe mafunso okhudzana ndi zizindikiro zake za matenda komanso za nthanzi lake. Kutengera ndi zizindikiro za matenda a mwana wanu, pakhonza kukhala mafunso okhudza komanso a iye yekha omwe adzafunsidwa poyesa njirayi. Kutenga gawo kudzatha pafupifupi mphindi khumi keleza mphindi khumi ndi zisanu.

Ngati kholo, Project Everest ikadakonda mukadadziwa bwino zizindikiro za matenda a amwana wanu chifukwa mukhonza kufunsidwa mafunso mukuyesa kwa njirayi. Mafunso komanso zochitika zilizonse zokhuzana ndi njirayi sizidzapereka chiopsyezo chilichonse kwa inu ndi mwana wanu. Ngati mwana wanu atadzatope, kukhumudwa kapena kusowa mtendere nthawi yoyesa njirayi, adzapatsidwa mpata opumula kapena kusiya kuyesako nthawi yomweyo. Ngati mwana wanu adzakhale osasangalatsidwa ndi mafunso komanso zokambirana, ali ndu ufulu osadzayakha mafunsowo kapena kupitiliza ndi mafunso otsatira.

Monga mwa kafukufuku wina aliyense, pali chiophyezo choti zinsinsi zikhonza kuululika kotero takhazikitsa njira zochepetsera chiophyezochi komanso kuonetsetsa kuti inu ndi mwana wanu musadziwike. Dzina la mwana wanu silidzalembedwa kapena kukambidwa, mmalo mwake, nambala ndi yomwe idzagwiritsidwe ntchito.

Mafunsowa adzadziwitsa chomwe mwana wanu akudwala komanso chithandizo choyenera malingana ndi nthenda ya mwana wanu. Ichi chikhonza osakhala cholowa cha pompopompo komabe uthenga womwe tidatolera mu kafukufukuyi adzathandiza kumvetsetsa kukhazikika kwa njirayi mtsogolo.

Zotsatira za kafukufukuyi zitha kugwiritsidwa ncthito mu kufutukuza komanso kuphunzitsa. Poteteza kusadziwika kwa mwana wanu, chinsinsi chidzasungidwa ndi chiopsyezo chochepa choululira chinsinsichi. Pa nthawi yomwe zotsatira zizagawidwa ndi akafukufuku, nambala yoimira mwana wanu siidzaperekedwa komanso padzakhala kusalumikizana pakati pa mwana wanu ndi uthenga otengedwawo.

Kutenga nawo gawo mu kafukufukuyi ndi kosakakamiza. Mukhonza kukana kuloleza mwana wanu kutenga nawo gawo, muthanso kumuchotsa mwana wanu mu kafukufukuyi nthawi iliyonse. Mwana wanu sadzapatsidwa chilango mu njira ina iliyonse ngati inu mutasakha kusamulola kuti atenge nawo gawo kapena kumuchotsa mu kafukufukuyi.

Uthenga wa kalumikizidwe

Ngati muli ndi mafunso kapena chilichonse chokhudza kafukufukuyi kapena padza vuto lililonse, chonde lumikizanani ndi Andrew Vild/Ella Grier ku Project Everest pa 0992 59 38 45 (Andrew Vild) or 0992 50 26 64 (Ella Grier) at malawi@projecteverest.ventures. Ngati muli ndi mafunso kapena chilichonse chokhuza ufulu wa mwana wanu ngati otenga nawo gawo mu kafukufuku, chonde lumikizanani ndi ofesi ya **ombudsman Malawi ku kanabar house, Blantyre pa (+265) 1833317.**

Chilolezo

Ndawerenga fomu ya chivomerezo cha makoloyi ndipo ndapatsidwa mwayi wofunsa mafunso. Mosakakamizidwa, ndavomera kupereka chivomerezokuti mwana wanga atenge nawo gawo mu kafukufukuyi

Siginechala ya kholo/womuyang'anira _____ tsiku _____

Dzina la mwana_____

APPENDIX 3 *Adult Consent Form - English version*

PROJECT EVEREST
CONSENT FORM FOR
PARTICIPATION IN RESEARCH

Research Title: Measuring a mHealth pre-diagnostic tool in a clinic in Blantyre, Malawi.

Protocol Number:

You have been invited to participate in a research study conducted by Project Everest. This form contains information regarding what is currently being tested and how the information gathered will be used within the study, if you choose to participate.

This study uses a pre-diagnostic application which allows you to enter symptoms into a database and receive a diagnosis. The overall aim is to test the viability of this application within communities around Blantyre, Malawi, and ensure that the following technology is relevant to the area. You are being asked to participate in this study in order to gain information on the efficiency and accuracy of the application.

You will be asked to answer a series of questions regarding your symptoms and current health status. Depending on the symptoms, there may be personal or sensitive questions involved within the application testing. Participation should take approximately 10-15 minutes.

Project Everest appreciates that the questions and activities surrounding this application may be sensitive in nature although they are not intended to pose any harm or insult to you. If you become tired, upset or irritated during the testing of the application, you are more than welcome to take a break or stop the testing altogether. In the event that you become uncomfortable with questions or topics being discussed, you are free to not answer or skip to the next question.

As with all research studies, there is a risk of breaching confidentiality. There are various strategies in place to reduce this risk and provide complete anonymity to you. Your name will not be recorded or discussed, and instead will be replaced with an identification number.

This questionnaire will provide you with a diagnosis, as well as recommended treatment options pertaining to this diagnosis. It is important to understand that this is simply a recommendation of diagnosis and treatment and that you should consult a medical physician before acting on these results. This may not be an immediate benefit, however, the information gathered in this study will generate a better understanding of the application's viability in the future.

Results of this study may be used in publications and presentations. By securing your anonymity, confidentiality will be retained with little risk of breaching your privacy. In the event that these results are shared with researchers, identification numbers will not be released and there will be no correlation between you and the collected data.

Participation in this research study is voluntary. You may refuse to participate or withdraw from the study at any time. You will not be penalised in any way should you decide not to participate or to withdraw from this study.

Contact information

If you have any questions or concerns about this study or if any problems arise, please contact Andrew Vild or Ella Grier at Project Everest at 0992 59 38 45 (Andrew Vild) or 0992 50 26 64 (Ella Grier) or at malawi@projecteverest.ventures. If you have any questions or concerns about your rights as a research participant, please contact the **Office of The Malawi Human Rights, Lilongwe at (+265) 1750946/1750900.**

Consent

I have read this parental permission form and have been given the opportunity to ask questions. I voluntarily agree to give my permission to participate in this study.

Participant's signature:_____Date:_____

APPENDIX 4 *Adult Consent Form - Chichewa version*

PROJECT EVEREST
FOMU YA CHIVOMEREZO CHA OTENGA NAWO GAWO MU KAFUKUFUKU

Mutu wa kafukufuku: kuyesa chida cha zaumoyo cha m'manja choyezera matenda mzipatala zazin'gonozin'gono ku Blantyre, Malawi.

Nambala ya ndondomeko:

Ndinu woitanidwa kuti mutenge nawo gawo mu kafukufuku yemwe akupangidwa ndi a Project Everest. Fomu iyi ili ndi uthenga okhudzana ndi zomwe zikuyesedwa pakadali pano komanso fomuyi yafotokoza momwe uthenga womwe utatoleledwe utagwilire ntchito mu kafukufuku ngati mutasankhe kutenga nawo gawo.

Kafukufukuyu amagwiritsa ntchito makina a compyuta omwe amantchula nthenda yomwe munthu wadwala ngati zizindikiro za matenda zalowetsedwa mu makinawo. Cholinga chenicheni cha kafuufukuyu ndi kufuna kuyesa ngati njira imeneyi ili yodalirika mmadera ozungulira Blantyre kuno ku Malawi komanso kuonetsetsa kuti njirayi ndi yofunikira ku delali. Mukufunsidwa kutenga nawo gawo mu kafukufukuyi ndi cholinga choti tidziwe ngati njira imeneyi ikugwira ntchito bwino komanso molondola.

Mudzafunsidwa kuyankha mafunso okhudzana ndi zizindikiro zanu za matenda komanso thanzi lanu. Kutengera ndi zizindikiro zanu za matenda. Pakhonza kukhala mafunso okhudza komanso a inu nokha omwe adzafunsidwa poyesa njirayi. Kutenga gawo kudzatha pafupifupi mphindi khumi kuleleza mphindi khumi ndi zisanu.

Project Everest ikudziwa kuti mafunso ndi zochitika zina zokhuzana ndi njirayi zikhonza kukhala zokhudza ngakhale kuti sicholinga chake kuti zipereke chiopsyezo kapena kunyozetsa inu ayi. Ngati mudzatopa, kukhumudwa kapena kunyansidwa panthawi yoyesa njirayi, ndinu ololedwa kudzapatsidwa mpata opumula kapena kusiya kuyesa njirayi. Ngati mudzakhala osasangalatsidwa ndi mafunso komanso zokambirana, muli ndi ufulu osadzayakha mafunsowo kapena kupitiliza ndi mafunso otsatira.

Monga mwa kafukufuku wina aliyense, pali chiophyezo choti zinsinsi zikhonza kuululika kotero takhazikitsa njira zochepetsera chiopsyezochi komanso kuonetsetsa kuti inu musadziwike. Dzina lanu silidzalembedwa kapena kukambidwa, mmalo mwake, nambala ndi yomwe idzagwiritsidwe ntchito.

Mafunsowa , adzadziwitsa chomwe inu mukudwala komanso chithandizo choyenera malingana ndi nthenda yanu. Kuli kofunika kumvetsetsa kuti iyi ndi njira yosakhazikitsidwa younikira matenda komanso kuperekera chithandizo kotero muyenera kufunsa a dotolo musanagwiritse ntchito zotsatirazi. Ichi chikhonza osakhala cholowa cha pompopompo komabe uthenga womwe titatolera mu kafukufukuyi udzathandiza kumvetsetsa kukhazikika kwa njirayi mtsogolo.

Zotsatira za kafukufukuyi zitha kugwiritsidwa ncthito mu kufutukuza komanso kuphunzitsa. Poteteza kusadziwika kwanu, chinsinsi chidzasungidwa ndi chiopsyezo chochepa choululira chinsinsichi. Pa nthawi yomwe zotsatira zizagawidwa ndi akafukufuku, nambala yoimira inu siidzaperekedwa komanso padzakhala kusalumikizana pakati pa inu ndi uthenga otengedwawo

Kutenga nawo gawo mu kafukufukuyi ndi kosakakamiza. Mukhonza kukana kutenga nawo gawo kapena kuchoka mu kafukufukuyu nthawi ina iliyonse

Uthenga wa kalumikizidwe

Ngati muli ndi mafunso kapena chilichonse chokhudza kafukufukuyi kapena padza vuto lililonse, chonde lumikizanani ndi Andrew Vild/Ella Grier ku Project Everest pa 0992 59 38 45 (Andrew Vild) or 0992 50 26 64 (Ella Grier) at malawi@projecteverest.ventures. Ngati muli ndi mafunso kapena chilichonse chokhuza ufulu wanu ngati otenga nawo gawo mu kafukufuku, chonde lumikizanani ndi ofesi ya **ombudsman Malawi ku kanabar house, Blantyre pa (+265) 1833317.**

Chivomerezo

Ndawerenga fomu ya chivomerezo cha makoloyi ndipo ndapatsidwa mwayi wofunsa mafunso. Mosakakamizidwa, ndavomera kupereka chivomerezo kuti ine nditenge nawo gawo mu kafukufukuyi.

Siginechala ya otenga gawo _____ Tsiku_____

APPENDIX 5 *Adolescent Assent Form - English version*

PROJECT EVEREST
ADOLESCENT ASSENT FORM FOR PARTICIPATION IN RESEARCH

Research Title: Measuring a mHealth pre-diagnostic tool in a clinic in Blantyre, Malawi.

Protocol Number:

Your guardian has given permission for you to be involved with the research study, conducted by Project Everest. This form contains information regarding what is currently being tested and how the information gathered will be used in this study, if you choose to participate.

This study uses a pre-diagnostic application which allows you to enter symptoms into a database and receive a diagnosis. The overall aim is to test the viability of this application within communities around Blantyre, Malawi, and ensure that the following technology is relevant to the area. You are being asked to participate in this study to gain information on the efficiency and accuracy of the application
.
You will be asked to answer questions regarding your symptoms and current health status. You will not be required to provide us with names, as we value your privacy and confidentiality. Participation should take approximately 10-15 minutes.

In the event that you may become restless, you may take a break or stop the testing all together. Depending on the symptom assessment, there may be personal or sensitive questions involved in the application testing. If you feel uncomfortable with any questions or topics raised, you are free to not answer and skip to the next question. If at any time you wish to stop the application testing, you may do so. You may also ask any questions at the beginning, during and end of the application testing.

Adolescent Signature: _____ Date: _____

Name of Person Obtaining Assent: _____

Signature of Person Obtaining Assent: _____ Date: _____

APPENDIX 6 *Adolescent Assent Form - Chichewa version*

PROJECT EVEREST
CHIVOMEREZO CHA ACHINYAMATA KUTENGA NAWO GAWO MU KAFUKUFUKU

Mutu wa kafukufuku: kuyesa chida cha zaumoyo cha m'manja choyezera matenda mzipatala zazin'gonozin'gono ku Blantyre, Malawi.

Nambala ya ndondomeko:

Makolo anu apereka chilolezo kuti mutenge nawo mbali pa kafukufuku wochitidwa ndi Project Everest. Fomu iyi ili ndi zokhudzana ndi zomwe zikuyesedwa pakali pano komanso momwe zidziwitso zasonkhanitsira zidzagwiritsidwe ntchito mu phunziro ili, ngati mutasankha kutenga nawo mbali.
Phunziroli limagwiritsa ntchito pulogulamu yoti mumalowetsa zizindikiro zanu kuti ikuuzeni matenda omwe ali pathupi.Cholinga chachikulu ndi kuyesa momwe pulogulamuyi ikuyendera m'madera akumidzi ku Blantyre, Malawi ndikuonetsetsa kuti zipangizo zamakonozi zikuthandizira kudera lanu. Mukufunsidwa kutenga nawo mbali mu phunziro lino kuti mudziwe zambiri za momwe ntchitoyo ikuyendera komanso kuti ndi yolondola.
Mudzafunsidwa kuti muyankhe mafunso okhudzana ndi zizindikiro zanu komanso zaumoyo wamakono. Simudzafunikila kutipatsa mayina pamene tikuyang'ana chinsinsi chanu. Gawo liyenera kutenga pafupifupi mphindi 10 kapena 15.

Mukakhala kuti mwatopa mutha kupuma kapena kusiya kuyesedwa palimodzi. Malingana ndi kuyesedwa kwa zizindikiro pakhoza kukhala mafunso okhudzana ndi zaumwini kapena zapadera.Ngati simukumva bwino ndi mafunso aliwonse kapena nkhani zomwe zatulutsidwa, ndinu mfulu kuti musayankhe ndikudumpha ku funso lotsatira. Ngati nthawi iliyonse mukufuna kuimitsa kuyesa, mungachite zimenezo. Mukhozanso kufunsa mafunso aliwonse pamene mukutenga mbali mu kafukufukuwu. Tathokoza.

Siginechala ya wachinyamata: _____
Tsiku: _____
Dzina la muntha opeza chilolezo: _____

Signichela la munthu opeza chilolezo: _____
Tsiku: _____

APPENDIX 7 *Practitioner Consent Form - English version*

PROJECT EVEREST
CONSENT FORM FOR PRACTITIONER PARTICIPATION IN RESEARCH

Research Title: Measuring a mHealth pre-diagnostic tool in a clinic in Blantyre, Malawi.

Protocol Number:

You have been invited to participate in a research study conducted by Project Everest. This form contains information regarding what is currently being tested and how the information gathered will be used in the study if you choose to participate.

This study uses a pre-diagnostic application which allows patients to enter symptoms into a database and receive a diagnosis. The overall aim is to test the viability of this application within communities around Blantyre, Malawi, and ensure that the following technology is relevant to the area. You are being asked to participate in this study in order to gain information on the efficiency and accuracy of the application.

The patient will be asked to answer a series of questions regarding their symptoms and current health status. Depending on their symptoms, there may be personal or sensitive questions involved within the application testing. Participation should take approximately 10-15 minutes for the patients. Once they have completed their application assessment they will proceed to a medical consultation with you or one of your colleagues. Once you have given your diagnosis to the patient, the application diagnosis will be compared with your assessment to test the accuracy of the application.

Project Everest appreciates that the questions and activities surrounding this application may be sensitive in nature although they are not intended to pose any harm or insult to the patients. In the event that they become uncomfortable with questions or topics being discussed, they are welcome to not answer or skip to the next question. In the event that you become uncomfortable with the comparison of results the Project Everest staff will stop asking for comparative results.

As with all research studies, there is a risk of breaching confidentiality. There are various strategies in place to reduce this risk and provide complete anonymity to you and the patient. Your name will not be recorded or discussed, only the diagnosis. The patient's identity will also be secured by assigning a number to them instead of their given name.

This questionnaire will provide the patient with a diagnosis, as well as recommended treatment options pertaining to this diagnosis. It is important to understand that this is simply a recommendation of diagnosis and treatment and that they should always consult you before proceeding with any recommendations. This may not be an immediate benefit, however, the information gathered in this study will generate a better understanding of the application's viability in the future.

Results of this study may be used in publications and presentations. By securing your anonymity, confidentiality will be retained with little risk of breaching your privacy. In the event that these results are shared with researchers, your name will not be released and there will be no correlation between you and the collected data.

Participation in this research study is voluntary. You may refuse to participate or withdraw from the study at any time. You will not be penalised in any way should you decide not to participate or to withdraw from this study.

Contact information

If you have any questions or concerns about this study or if any problems arise, please contact Andrew Vild or Ella Grier at Project Everest at 0992 59 38 45 (Andrew Vild) or 0992 50 26 64 (Ella Grier) or at malawi@projecteverest.ventures. If you have any questions or concerns about your rights as a research participant, please contact the **Office of The Malawi Human Rights, Lilongwe at (+265) 1750946/1750900.**

Consent

I have read this practitioner permission form and have been given the opportunity to ask questions. I voluntarily agree to give my permission to participate in this study.

Practitioner's Full Name & Title:_____ Date:_____

Practitioner's Signature:_____

APPENDIX 8 *Practitioner Consent Form - Chichewa version*

PROJECT EVEREST
FOMU YA CHIVOMEREZO CHA WA ZAUMOYO OTENGA NAWO GAWO MU KAFUKUFUKU

Mutu wa kafukufuku: kuyesa chida cha zaumoyo cha m'manja choyezera matenda mzipatala zazin'gonozin'gono ku Blantyre, Malawi.

Nambala ya ndondomeko:

Ndinu woitanidwa kuti mutenge nawo gawo mu kafukufuku yemwe akupangidwa ndi a project everest. Fomu iyi ili ndi uthenga okhudzana ndi zomwe zikuyesedwa pakadali pano komanso fomuyi yafotokoza momwe uthenga womwe utatoleledwe utagwilire ntchito mu kafukufuku ngati mutasankhe kutenga nawo gawo

Kafukufukuyu amagwiritsa ntchito makina a compyuta omwe amantchula nthenda yomwe munthu wadwala ngati zizindikiro za matenda zalowetsedwa mu makinawo. Cholinga chenicheni cha kafuufukuyu ndi kufuna kuyesa ngati njira imeneyi ili yodalirika mmadera ozungulira Blantyre kuno ku Malawi komanso kuonetsetsa kuti njirayi ndi yofunikira ku delali. Mukufunsidwa kutenga nawo gawo mu kafukufukuyi ndi cholinga choti tidziwe ngati njira imeneyi ikugwira ntchito bwino komanso molondola.

Odwala adzafunsidwa kuyankha mafunso okhudzana ndi zizindikiro zawo za matenda komanso thanzi lawo. Kutengera ndi zizindikiro zawo za matenda, pakhonza kukhala mafunso okhudza komanso a iwo okha omwe adzafunsidwa poyesa njirayi. Kutenga gawo kudzatha pafupifupi mphindi khumi kuleleza mphindi khumi ndi zisanu. Odwalawa akamaliza kutenga gawo kwawo mukuyesa njirayi adzapitilira kukalandira chithandizo cha mankhwala kuchokera kwa inu kapena anthu omwe inu mukugwira nawo ntchito. Nthenda yomwe njirayi idzapereka, idzafananizidwa ndi nthenda yomwe inu mudzapereka kwa odwala ndi cholinga choyesa kulondola kwa njirayi.

Project Everest ikudziwa kuti mafunso ndi zochitika zina zokhuzana ndi njirayi zikhonza kukhala zokhudza ngakhale kuti sicholinga chake kuti zipereke chiopsyezo kapena kunyozetsa odwala anu ayi. Ngati odwala adzakhala osasangalatsidwa ndi mafunso komanso zokambirana, ali ndi ufulu osadzayakha mafunsowo kapena kupitiliza ndi mafunso otsatira. Ngati inu mudzakhala osasangalatsidwa ndi kufananitsidwa kwa zotsatira, Project Everest idzasiya kufunsa zotsatira zofananitsidwazo.

Monga mwa kafukufuku wina aliyense, pali chiopsyezo choti zinsinsi zikhonza kuululika kotero takhazikitsa njira zochepetsera chiophyezochi komanso kuonetsetsa kuti inu

komanso odwala wanu musadziwike. Dzina lanu silidzalembedwa kapena kukambidwa koma nthenda yopezedwayo basi. Chinsinsi cha odwala chidzatetezedwanso pogwiritsa ncthito nambala mmalo mwa dzina lawo lopatsidwa.

Mafunsowa, adzadziwitsa chomwe nthenda yomwe odwala akudwala komanso chithandizo choyenera malingana ndi nthenda ya odwala. Kuli kofunika kumvetsetsa kuti iyi ndi njira yosakhazikitsidwa younikira matenda komanso kuperekera chithandizo kotero iwo akuyenera kufunsa inu kaye asanagwiritse ntchito zotsatira za njirayi. Ichi chikhonza osakhala cholowa cha pompopompo komabe uthenga womwe tidatolera mu kafukufukuyi adzathandiza kumvetsetsa ukhazikika kwa njirayi mtsogolo.

Zotsatira za kafukufukuyi zitha kugwiritsidwa ncthito mu kufutukuza komanso kuphunzitsa. Poteteza kusadziwika kwanu, chinsinsi chidzasungidwa ndi chiopsyezo chochepa choululira chinsinsichi. Pa nthawi yomwe zotsatira zizagawidwa ndi akafukufuku, nambala yoimira inu siidzaperekedwa komanso padzakhala kusalumikizana pakati pa inu ndi uthenga otengedwawo

Kutenga nawo gawo mu kafukufukuyi ndi kosakakamiza. Mukhonza kukana kutenga nawo gawo kapena kuchoka mu kafukufukuyu nthawi ina iliyonse

Uthenga wa kalumikizidwe

Ngati muli ndi mafunso kapena chilichonse chokhudza kafukufukuyi kapena padza vuto lililonse, chonde lumikizanani ndi Andrew Vild/Ella Grier ku Project Everest pa 0992 59 38 45 (Andrew Vild) or 0992 50 26 64 (Ella Grier) at malawi@projecteverest.ventures. Ngati muli ndi mafunso kapena chilichonse chokhuza ufulu wanu ngati otenga nawo gawo mu kafukufuku, chonde lumikizanani ndi ofesi ya **ombudsman Malawi ku kanabar house, Blantyre pa (+265) 1833317.**

Chivomerezo

Ndawerenga fomu ya chivomerezo cha a zaumoyochi ndipo ndapatsidwa mwayi wofunsa mafunso. Mosakakamizidwa, ndavomera kupereka chivomerezo kuti ine nditenge nawo gawo mu kafukufukuyi

Dzina ndi udindo wa wazaumoyo_____ tsiku_____

Siginechala ya wazaumoyo _____

APPENDIX 9 *Practitioner Survey - English version*

Clinician Survey

*Clinic*_____ *Role*_____

1. Do you find you have enough time for patients during consultations?

o **Yes**
o **No**

2. Do you often find your clinic overcrowded or congested?

o **Yes**
o **No**

3. Do you feel you are not able to perform the best of your ability due to these factors?

o **Yes**
o **Maybe**
o **No**

4. Do you believe an application like Your.MD would help assist in improving the efficiency of healthcare services?

o **Yes**
o **No**

5. Do you believe an application like Your.MD would be beneficial in rural areas within Malawi, to provide health services and care to those who cannot reach clinics easily?

o **Yes**
o **No**

APPENDIX 10 *Practitioner Survey - Chichewa version*

Kafukufuku wa adotolo

*Chipatala*_____ *Udindo*_____

1.Mukuona kuti mumakhala ndi nthawi yokwanira yofunsa mafunso odwala?

- o Eya
- o Ayi

2.Kodi mumapeza kuti chipatala chanu chadzadzitsa kapena kuthithikana kawirikawiri?

- o Eya
- o Ayi

3 Kodi mukuganiza kuti mumalephera kugwira ntchito yanu bwino kamba ka zimenezi?

- o Eya
- o Mwina
- o Ayi

4. Kodi mukukhulupilira kuti application like Your.MD ikhonza kuthandiza kulimbikitsa kupereka chithandizo chabwino cha za umoyo?

- o Eya
- o Ayi

5. Kodi mukukhulupilira kuti application like Your.MD ikhonza kuthandiza mmadera akumidzi muno mmalawi kupereka chithandizo cha za umoyo choposa kwa iwo amene sangafikire zipatala mosavuta?

- o Eya
- o Ayi

APPENDIX 11 *Usability Survey- English version*

User Survey

Age_____ Sex_____

1. *Did you find Your.MD easy to use?*
   - ❑ **Yes**
   - ❑ **No**

2. *Did you find Your.MD helpful?*
   - ❑ **Yes**
   - ❑ **No**

3. *Would you still go and visit a clinic after using Your.MD*
   - ❑ **Yes**
   - ❑ **Maybe**
   - ❑ **No**
   - ❑ **Unsure**

4. *If you used Your.MD to get an understanding of your symptoms, would you still go to the clinic?*

   ❑ **Yes**

   a) I would use the application without consulting a clinic.
   b) I would use the application and visit a pharmacy straight away.
   c) I would use the application and delay my visit.

   ❑ **No - I would not use the application at all.**

5. *How are you able to access mobile phones?*

a) **I own a mobile phone**
b) **I have friends/family with a mobile phone**
c) **It would be very difficult to access a mobile phone**
d) **I have no access to a mobile phone**

APPENDIX 12 *Usability Survey - Chichewa version*

Kafukufuku wa ogwiritsa ntchito

Zaka _____ *Wammuna/Wamkazi* _____

1 Kodi mwapeza kuti Your.MD ndiyosavuta kugwiritsa ntchito?

- o Eya
- o Ayi

2 Kodi mwapeza kuti Your.MD ndiyothandiza?

- o Eya
- o Ayi

3 Kodi mukhonza kupitabe kuchipatala mutagwiritsa ntchito Your.MD?

- o Eya
- o Mwina
- o Ayi
- o Sindikudziwa

4 Kodi mmutagwiritsa ncthito Your.MD kuti mumvetsetse zizindikiro zanu za matenda, mukhonza kupitabe kuchipatala?

- o Eya

a) Ndikhonza kugwiritsa ncthito njirayi osakafunsira ku chipatala

b) Ndikhonza kugwiritsa ncthito njirayi kenako ndikupita kukagula mankhwala nthawi yomweyo

c) Ndikhonza kugwiritsa ncthito njirayi ndi kuchedwerako kupita ku chipatala

- o Ayi

5. Mumapeza bwanji ma lamya a mmanja?

a) ndili ndi lamya yammanja

b) ndili ndi achibale/anzanga omwe ali ndi lamya ya mmanja

c) zikhonza kukhala zovuta kuti ndipeze lamya ya mmamja

d) sindingapeze lamya ya mmanja

APPENDIX 13 *Your.MD Identification Form - English version*

ID # 0001

Please Keep

PROJECT EVEREST

Please Hand to Practitioner

ID # 0001 **Date:**

Entry: **Exit:**

Your.MD Start:

Your.MD End:

Practitioner's Diagnosis:

APPENDIX 14 *Your.MD Identification Form - Chichewa version*

ID # 0001

Chonde Sungani

PROJECT EVEREST

Chonde Perekani Kwa Wa Za Uimoyo

ID # 0001 **Tsiku:**

Kulowa: **Kutuluka:**

Your.MD Yamba:

Your.MD Maliza:

Diagnosis: