PROMISE Participant Information Sheet 1 – Healthcare Surveillance Assistants (In depth Interviews, Focus Group Discussions, Workshops and Surveys)

Title: Psychosis Recovery Orientation in Malawi through Improved Services and Engagement (PROMISE) - a longitudinal study of mental health focussed on psychosis in people with lived experience and other key informants in Chiradzulu, Salima and Ntcheu districts, incorporating: participatory and qualitative investigation of community perspectives on psychosis, and how it should be managed. This will then lead on to the development and evaluation of detection and management systems strengthening in the study areas, and their impact on well-being and functioning.

Please read this leaflet carefully. It explains the research study we are currently conducting and ask for your help in participation. Please ask the researcher who explained the study if you require any further information or if you would like the researcher to read the information sheet for you. You will be given at least 24 hours to consider all this information and have the opportunity to ask questions. Taking part is purely voluntary and whether or not you agree to join the study will not change your employment, medical care or legal rights in any way.

1. Why is the study being done?

Researchers at the Kamazu University of Health Sciences (KUHeS), Blantyre, Malawi, and the University of Edinburgh, UK are going to conduct a large study of mental health in people families in Chiradzulu, Salima and Ntcheu districts called PROMISE.

In the first part of this study, the study team are assessing beliefs about psychosis ('madness') and how it is currently detected and treated; before the second part of the study to develop and evaluate a psychosis detection and management system combined with a strengthening of mental health services for psychosis in the study areas.

2. How long is the study, who is running the study, who is funding the study and has the study been approved ethically?

The whole "PROMISE" study will last for 5 years. This first stage will last for two years. Funding is provided by the Wellcome, major UK based research charity. The study proposal has been approved by both the College of Medicine Research Ethics Committee at the University of Edinburgh and by COMREC in Malawi.

The study is being conducted by a group of Researchers at the Kamazu University of Health Sciences (KUHeS), Blantyre, Malawi, and the University of Edinburgh, UK. The study is sponsored by the University of Edinburgh in the UK.

KAMUZU UNIVERSITY OF HEALTH SCIENCES
THE UNIVERSITY of EDINBURGH
accord
Academic and Clinical Central Office for Research and Development

3. Why have I been asked to take part?

We are inviting Health Surveillance Assistants (HSAs) living in Chiradzulu, Salima and Ntcheu to take part as these are the 3 sites in which the PROMISE Study will take place. We are also inviting other key informants and professionals who are involved in the delivery of health services for the study sites to take part. We are inviting you, as a Health Surveillance Assistant, to participate in order to obtain your views of psychosis and your views on psychosis detection and management, to assist in the development of psychosis screening tools and interventions, and to receive further training in psychosis screening and management.

4. Is taking part in the study voluntary?

It is entirely your decision to take part in the study. We will explain all that relates to this study and we will answer all your questions. You may decline to participate in the research at any time. This will not affect your employment, your legal rights or any healthcare for you or your family.

5. What does it mean to participate?

1. Qualitative interviews/focus group discussions:

After obtaining your informed consent, you will be invited to take part in the following face-to-face discussion activities in the study:

- An individual in depth discussion (Key Informant Interview)
- A Focus Group Discussion
- A group Workshop with about 6-14 other people.

On the consent form, you can choose whether to take part in all of the above activities, or just selected parts of the study. These activities will take up to 3 hours of your time. 1-2 researchers will be present. They will ask you or the group questions about one or more of: health issues affecting people in Malawi, particularly in relationship to psychosis; about the words used to describe psychosis in Malawi; and about the health services provided for psychosis in Malawi. There may be some general questions about topics that might be distressing (abuse in childhood and intimate partner violence). You will not be asked to discuss these topics if you do not wish to. In the course of the discussions, refreshments and snacks will be provided.

No one else will overhear the individual or group discussions and the information will be kept confidential from everyone except members of the research team. The answers will only be used for the purpose of research.

The individual and group discussions will be audio-recorded using a digital recorder. This will be listened to only by members of the research team and the recordings and transcriptions will be kept secure and separate from identifiable personal information that you provide. If you agree, we may also use them – anonymously - to illustrate the experience of psychosis.

Quantitative Surveys:

You will also be asked to complete 4 questionnaires about attitudes and knowledge about mental illness and psychosis. These questionnaires will include the Community Attitudes toward Mental Illness scale, the WHO mhGAP pre-and post-knowledge test, and confidence questionnaires. This will take up to one hour. These will only be seen by members of the research team and will be kept secure and separate from identifiable personal information that you provide.

Training in psychosis screening and management:

You will also be asked to take part in a training exercise using a detection and management manual in two people with possible psychosis during months 18-24 of the project. These training sessions are expected to last up to 4 hours. After that, in the second phase of the study, we will separately ask for your consent to continue to be involved in the study for an annual interview for a further 3 years. This annual interview will help researchers to understand the ongoing experiences of Health Surveillance Assistants, changes in their perceptions and views on the intervention tools.

You are free to do as many or as few parts of the research as you wish, and can change your mind or withdraw from the study entirely at any time.

6. What are the benefits from being in the study?

If you are identified as having a significant health problem, we will offer you referral to the appropriate facility for care.

Additionally, for the community and population of Malawi, your participation in this study offers researchers an opportunity to better understand psychosis and how this affects people.

You will not incur any financial costs in taking part in this study. It will take place within homes and the local community, and you will be reimbursed for travel expenses and assessment time at the standard KUHeS rate per diem.

At the end of the project you will be invited to a Research Meeting to discuss the results of the study with everyone who has taken part; and you will also be offered a summary of the research if you request it.

7. What are the risks of being in the study?

We do not expect that you will incur any risks by participating in this study.

You will not incur any costs as a result of your participation in this study.

If you are distressed by talking about any of the topics then please let the interviewer know. They will be able to direct you to where you can get support.

If you report that you have been harmed by others (or are at risk of this) we will not share any information with others that might put you at further risk. We will direct you to where you can access appropriate support.

8. How will information I give in the study be kept private?

All information which is collected about you in this study will be kept strictly confidential.

We will need to collect the following personal identifiable information from you for this research study:

- Name (for consent purposes)
- Age
- Gender
- Date of birth
- Address
- Telephone number
- The district you work in

To protect your privacy, any information that contains your name and personal identifiers will be removed using a unique code number to de-identify you and all information about you, including audio-recordings. Under no circumstances will your name, address or telephone number be shared with anyone outside the research team. We will keep your records securely stored in a locked cabinet in a locked room at KUHeS in Blantyre for the duration of the research project (5 years). Only the research team will have access to these records.

The interview audio recordings will be transcribed by experienced staff/students at KUHeS and employed by Lucinda Manda-Taylor's research team and given a unique number to de-identify them. If any unwanted personal information is revealed accidentally during the interviews, it will be removed from the transcripts to maintain your confidentiality. Once transcribed, the audio recordings will be deleted.

Only research team members from this study will be able to look at the data. Your name or any other facts that might point to you will not appear when we present this study or publish

its results. Data collected in Malawi for this research study will be de-identified and shared with researchers at the University of Edinburgh. Your data will be transferred to these institutions via a secure, password-protected online platform and then stored on a secure, password-protected data storage facility at the University of Edinburgh for a minimum of 5 years following the end of the study.

Your records will then be securely archived on the University of Edinburgh's Data Share platform for future research studies. Future research may be done by the current research team or by other research teams working in other countries. Only your records, which do not have your name or other identifiable information, will be stored and shared with other research teams.

If you have any concerns about how we will use your information, please contact:

- The University of Edinburgh Data Protection Officer: dpo@ed.ac.uk
- Contact the Principal Investigator (s.lawrie@ed.ac.uk)

9. What will happen if I don't want to carry on with the study?

You are free to withdraw your participation at any point during the course of this study without providing any reason.

If you decide to withdraw from the study, you will have the option of withdrawal from:

1. All aspects of the study but continued use of your data collected up to that point.

Or

2. All aspects of the study with the removal of all previously collected data.

Leaving the study will not affect your employment, legal rights or access to routine medical care.

10. Who can I contact if I have questions or complaints about the study?

We would like to answer all your questions. If you have any questions now, or have a problem and would like to discuss the study further, please contact the Principal Investigator Stephen Lawrie on s.lawrie@ed.ac.uk.

If you have any questions in the future, you can contact the local Principal Investigator of the research team Lucinda Manda-Taylor on mandal@kuhes.ac.mw

If you have any further concerns, or feel that your rights have been violated during the conduct of this study, you can contact the College of Medicine Research Ethics Committee on 0888118993.

If you would like to discuss this study with someone independent of the study please contact The Director of Research, P/Bag 360, Blantyre 3.

Thank you for taking the time to read this information sheet and considering if you will take part in this study.