Clinic Support Staff and Village Health Team Participant Study Information and Informed Consent Form

Study Title: ImpleMEntation of a Digital-first care deLiverY model for heart failure in Uganda (MEDLY Uganda)

Substudy: *Medly Uganda Digital Bundle:* Exploring Opportunities for Early Heart Failure Screening and Diagnosis

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Participating Research Centres: UINCD, Kampala, Uganda; University of Toronto, Toronto, Canada; University Health Network, Toronto, Canada; Yale School of Medicine, New Haven, CT, USA

Funding: University of Toronto, Toronto, Ontario, Canada

Background and Rationale

The Medly Uganda program was created with patients and clinicians from hospitals in Kampala, Gulu, and Lira to help patients improve their ability to care for their heart failure through the use of its mobile phone application. We hope to expand the scope of Medly Uganda beyond self-care management and develop a new accompanying intervention to increase access and capacity for early heart failure screening and diagnosis, initiating the Digital Bundle.

The purpose of this study is to gain a better understanding of how you support the delivery of heart failure care, the challenges you encounter in this process, and the feedback you receive from patients. Your perspective will allow us to better understand the barriers and facilitators associated with early screening and/or diagnosis of heart failure from both the provider's and patient's perspectives. Together, we will co-design an intervention to improve clinic processes and healthcare provider decision-making as it pertains to heart failure screening and diagnosis.

Research Project Sponsors and Researcher Organizational Affiliations

The researchers for this study are staff of Makerere University, Kampala, Uganda; University Health Network, Canada; University of Toronto, Canada, and Yale University, USA. This study is part of our larger research efforts in the development of the Medly Uganda program. Medly Uganda is endorsed by the Uganda Ministry of Health, and its baseline innovation is integrated into another successful mobile

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phone application– FamilyConnect.

How Much Time is Required From Participants?
Your involvement will require approximately 45 minutes today, and no additional follow-up visits.

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also change your mind at any time. Whatever choice you make will not have any effect on your relationship with the health centre where this research is being conducted.

Please note that you may be observed by the research team at the health centre as part of our clinic observations. This will not require any additional effort or activities on your part.

Who Will Participate in the Study?
You are eligible to participate in this study if you are a clinic support staff or village health team member with the UHI, Ogur Health Centre IV, Amach Health Centre IV, Lira Regional Referral Hospital, Kiyumba Health Centre IV, Kalisizo General Hospital, and/or Masaka Regional Referral Hospital.

Study Procedures
If you agree to participate, you will be asked to complete two surveys (i.e. demographic survey and feedback form) and a focus group discussion. This will include discussing how you support heart failure care delivery, your experiences throughout this process, and the feedback you receive from patients.

Please note that during your scheduled shift at the health facility, you may be asked to be observed by the research team as part of our clinic observations. This will not require any additional effort or activities on your part.

Risks and Discomforts
There may be some risks from participating in this study, but these are minimal and limited to your time spent completing the study activities and any emotional discomfort you may experience while discussing your experiences during the focus group discussion. However, you are free to not answer any questions which are not comfortable for you and to stop participating in the focus group discussion at any time.

Benefits
There are no direct benefits to you as a participant. However, the information you provide will aid in developing an intervention to support clinic processes to address late heart failure diagnosis.

Confidentiality
If you choose to participate, the Research Assistant may obtain certain personal information from you, including your name, gender, age, level of education and clinic role. We will keep the information we collect about you confidential. When we publish the results of the research or talk about it at conferences, we will not use your name or any other details that could identify you publicly.

How will you Keep My Data Safe and Private?
The survey questions will be read to you from either a digital or paper-based form, and your responses will be recorded directly. In addition, your contributions during focus group discussions will be audio recorded and paraphrased in a digital format. All of your responses will remain confidential, and only the researchers involved in this study will have access to the information you provide.
These individuals include:

- Representatives from University Health Network, Yale School of Medicine, and Makerere University School of Medicine Research Ethics Boards (committee that reviews, approves, and

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monitors research on human participants), who are responsible for ensuring research compliance
- University Health Network, UINCD, Yale School of Medicine, and Ugandan Principal Investigators
- University Health Network, University of Toronto, UINCD, Yale School of Medicine, and Ugandan Co-Investigators and other members

Research records will be kept in a locked file. All electronic materials will be stored in password-protected databases. Information about you collected as part of this research will not be used or distributed for future research studies. We will only use your information to conduct the study described in this consent form.

Cost
You will not incur any study-related costs as a research participant.

Compensation for Participation Time and Reimbursement
After each session, a transport refund of UGX 15,000 (if applicable) and time compensation of UGX 40,000 will be given to you as a token of appreciation.

Questions about the Study
If you have any questions about the research, you can ask now or later. If you wish to ask questions later, you may contact the Local Principal Investigator, Dr. Ssinabulya Isaac, at
0782 083968, and he will, in turn, work with Miss Lombardi Selena (MASc candidate) and Dr. Tamale Elvis (medical officer) to resolve any questions during the study.

Questions about Participants' Rights
If you have any questions related to your rights as a study participant, please call Prof. Ponsiano Ocama, Chairman of the Makerere University School of Medicine Research and Ethics Committee, at 0772 421190, or the office of the Executive Secretary, Uganda National Council for Science and Technology, at 0414 705500

Statement of Voluntary Participation
Participation in this study is entirely voluntary. You are free to not participate, to withdraw from the study at any time, or not participate in any aspect of the study as you decide. Whatever choice you make will not affect your role or employment at health centres and/or hospitals. You may withdraw your permission by telling the study staff or by writing to the Study Coordinator and Investigators.

Dissemination of Results
Information on the progress and findings of this study will be shared with health facilities involved in the study, UHI, Uganda Ministry of Health, and in national and international meetings when the opportunity arises. No personal information that could identify you will be shared.

Ethical Approval
This study has been approved by the School of Medicine Research and Ethics Committee of Makerere University College of Health Sciences and Yale University, and the Ethics Committee at the University Health Network. It has also gotten approval from the Uganda National Council for Science and Technology and is cleared by the Ministry of Health of Uganda.

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Statement of Consent

I ....., have read/been read the foregoing information. I have had the opportunity to ask questions about this study (including its procedures, the risks, the benefits involved and my rights regarding this research), and all my questions have been answered to my satisfaction. I consent voluntarily to participate in this study and also understand that I can withdraw from this study for any reason and at any time. In the use of this information, my identity will be concealed.

I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name of participant _____

Signature_____ or thumbprint

Date _____

Name of witness (if thumbprint) _____

Signature_____

Date _____

Name of study staff obtaining consent _____

Signature_____ Date _____

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