Task-shifted Adaptation of the WHO-PEN Intervention to Address Cardio-metabolic Complications in People Living With HIV in Zambia (TASKPEN)

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INFORMED CONSENT FORM FOR ADULT PARTICIPANTS

Title of study: Z 32008 - Mixed methods formative research and pilot testing of a task-shifted adaptation of the WHO-PEN intervention to address cardio-metabolic complications in people living with HIV in Zambia

Consent form version date: Version 1.3, dated 13 December 2021

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Funding Source and/or Sponsor: U.S. National Institutes of Health, through the National Heart, Lung, and Blood Institute (NHLBI) & the Fogarty International Center

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Concise Summary
This is a research study to learn about more effective ways the health care system in Zambia can care for people with non-communicable diseases (NCDs) who are also living with HIV. Participation lasts for about 9 months and involves questionnaires about your health and lifestyle, and having blood and urine samples collected. Your medical records may also be reviewed to collect some information about you. There are about three to four study visits which can be done during your routine care visits. Benefits to participation could include improved health care, as the study team will work to ensure you are receiving all Ministry of Health-recommended tests. Risks include possible breach of confidentiality and the risks associated with blood collection. If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?

You are being asked to take part in a research study. Joining the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason. Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researchers or your health care provider. It will also not have any effect on the quality of care you receive at this health facility. If you have an illness, you do not have to be in the research study to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be offered a copy of this consent form. You should ask the researchers named above, or staff members assisting them, any questions you have about this study at any time.

What is the purpose of this study?

This study seeks to add new information on how best to take care of NCDs like "BP," diabetes ("high sugar"), and high cholesterol, while also treating HIV for people living with HIV in Zambia. For this study, we are working with the Ministry of Health to improve the quality of NCD care and treatment for people living with HIV in a few clinics in Lusaka by: 1) training health workers on proven ways to treat common NCDs recommended by the World Health Organization; 2) improving the labs in the clinics to be able to identify NCDs and check how well patients are doing with their NCDs; 3) adapting the national electronic medical record (i.e., SmartCare) to address common NCDs; 4) taking advantage of the resources available for HIV treatment and care to improve NCD treatment and care; and 5) training nurses and community health workers to work alongside doctors and clinicians to make NCD treatment and care more accessible and efficient. While the study focuses on how to introduce this care package into Zambian clinics to manage NCDs affecting the heart and blood vessels in people living with HIV (called "cardio-metabolic" conditions), lessons learned from this study could apply to other NCDs like mental health problems and cancer.

For this part of the study, we would like to learn how well your HIV condition and NCDs like "BP", high cholesterol, and diabetes ("high sugar") are being controlled with time. We also want to learn more about your quality of life and treatment preferences with regards to living with HIV and NCDs, and how well your HIV and NCDs are being treated.

Where is this study being conducted?

This part of the study is being conducted in Lusaka at two (2) health facilities with ART clinics that have been selected as pilot sites.

Are there any reasons you should not be in this study?

You should not be in this study if you do not have HIV infection, you did not recently participate in a patient survey with our study team, or you are unlikely to continue coming to this site to get your healthcare. You can participate in this study if you are 18 years of age or older, voluntarily consent to join the study, and are affected by one or more of the following conditions: smoking tobacco; high blood pressure or "BP"; diabetes or pre-diabetes; or high or abnormal cholesterol.

How many people will take part in this study?
For this part of the study, we will select about 200 people living with HIV and one or more cardio-metabolic conditions from 2 health facilities. For all parts of the study, there will be about 1,250 people in total taking part in various study activities. An additional 1,000 people or so will have their medical records reviewed to understand how the clinics are doing managing HIV and NCDs.

How long will your part of this study last?
If you agree to take part in the study, we will follow you for about 9 months. During this time, we will collect health information about you by talking to you, taking blood samples from you, and reviewing your medical record. We will do this about 4 times, once today and then about 3 other times over the next 9 months or so. To complete all study procedures today will take about 1 and 1/2 to 2 hours. Later visits with the study team will coincide with your regular clinics visits and will take about 1 hour to 1 and 1/2 hours.

What will happen if you take part in the study?
If you agree to take part in the study, we will collect information about your health. This will include information about your HIV condition and any cardio-metabolic conditions (like "BP" or "diabetes") you may have, any treatments or medications you take, any habits you may have that could affect your health like smoking or drinking alcohol, and the results of all blood tests.

We will make sure that you have blood samples taken about once quarterly to monitor your HIV and any cardiometabolic condition you might have. We will make sure that you have blood and urine samples taken to check to see how your HIV and your cardio-metabolic conditions are being controlled. If these are not taken by the health workers at your regular clinic visit, we will have these tests performed through the study. This usually involves collecting 1 or 2 tubes of blood (about 5 to 10 ml, or 2 to 3 tablespoons) and a little bit of urine (about 2 to 3 ml) at each study visit. If possible, we will use a machine in the clinic to do this testing known as "point-of-care" testing. In the case of a point-of-care test, the amount of blood collected will be less and will be around 2-3 drops of whole blood (less than 10 microL). For urine, a few drops (less than 10 microL) are required for testing. You will be given the results of any tests that are performed. The samples collected from you will only be used for the testing described in this form. The samples will not be used for other research now or in the future. The samples will not be sold or used for commercial profit.

We will use the routine data collection practices at your facility to get information about your health, this will involve reviewing your medical records from the facility registers and electronic platform (SmartCare). We will also ask you questions about your health directly during study visits. This will include questions about how you take your medications, what you think about your quality of life, how you prefer to receive services for HIV and NCDs, what foods you eat, whether you smoke tobacco or use alcohol, and other questions related to your HIV and cardio-metabolic condition(s) and your preferences for the different features of integrated HIV and NCD services.

What are the possible benefits of being in this study?
There are a few ways you may benefit from being in this study. You may benefit by being asked

questions that may reveal possible health problems, for which you will be referred for further assistance at this clinic or another referral hospital. You may also benefit from receiving basic education and counseling on HIV and cardio-metabolic conditions at your follow-up visit or in the community. You may benefit from having study staff available to you for counseling or answering your questions about HIV and cardio-metabolic conditions, which might otherwise be harder to access. Lastly, we will make sure you get tests recommended by the Ministry of Health to keep your HIV and cardio-metabolic condition under control, even if these are unavailable at the clinic.

There may also be some indirect benefits if you take part in this study. You will help us learn about the current challenges that people with HIV and cardio-metabolic conditions are facing in Zambia. This will help us and the Ministry of Health to design and provide the right services to improve the care and treatment of cardio-metabolic conditions and other non-communicable diseases for people living with HIV and potentially the general public.

What are the possible risks or discomforts involved with being in this study?

Although the risk is low, it is possible that your personal information could become known to someone who should not have it. If that happened, you could face discrimination, stress, and embarrassment. However, the risk of this happening is very low since we will take several steps to prevent that from happening.

Some of the questions we ask about your health or habits could be sensitive, including questions about your HIV or use of substances. If you agree to participate, you can decide to skip questions or refuse to answer any questions that you do not want to answer. If you feel you need it, study staff can provide you with basic counseling and information on where and how to access mental and emotional support.

Taking a blood sample for testing has a small risk of pain, bleeding, bruising, and infection. To keep this risk low, all study staff have been trained on how to safely take a blood sample and we will take the smallest of amount of blood necessary to make sure your HIV infection and cardio-metabolic condition(s) are being managed properly, and will only take blood if you have not had the test done recently at the clinic. The risks involved with giving a blood sample are the same as those you would find when going to the clinic for a regular check-up or to get care for a health problem.

If you choose not to be in the study, what other treatment options do you have?

You do not have to be in this study to receive treatment. If you do not want to participate, you will receive the standard care and treatment for your HIV and NCDs from the clinic or hospital.

What if we learn about new findings or information during the study?

You will be given any new information learned during the study that might affect your willingness to continue your participation.

How will your privacy be protected?

Every effort will be made to keep your personal information confidential. We will train and supervise all study staff on how to protect your study information. Your study information will only be identified by a secret code to protect your privacy. We will also protect the confidentiality

of your study information to the maximum extent possible by handling and storing it securely at all times. We will not share confidential study information, including health or locator information, with anyone outside the study team and your healthcare provider(s), and only with your permission and for the purposes of supporting your routine care and treatment. Study staff will take every precaution to make sure *no* confidential study information is shared with your friends, relatives, or community members. When the results of the study are shared or published, we will not use your name or identify you personally. We may use de-identified data from this study in future research without additional consent.

Your records may be reviewed by representatives of the University of Zambia Biomedical Research Ethics Committee, the University of North Carolina IRB, the study sponsor (NIH), or the Zambian Ministry of Health through the National Health Research Authority. However, this information will be kept confidential and will only be used to ensure that the study is being conducted properly and that your records are being stored appropriately.

What is a Certificate of Confidentiality?

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

What if you want to stop before your part in the study is complete?

Your participation in this study is completely voluntary. There is no penalty if you do not join the study or do not complete the study. Even if you agree to join the study, you may choose not to answer questions asked of you or to stop any study procedure at any time. You may withdraw from the study for any reason and at any time. If you choose to withdraw, you may notify the study team by contacting the study phone. If you withdraw from the study, we will not collect any further information from you for study purposes. Any information collected from you before your withdrawal may be discarded if you wish. Your decision to withdraw from the study will not affect your access to health services or your relationship with the people providing you health services.

Will you receive anything for being in this study?

You will be given 100 kwacha at the end of each study visit to pay for the costs of transport to the clinic.

Will it cost you anything to be in this study?

It will not cost you anything to participate in this study.

Who is sponsoring this study?

This research is funded by the Centre for Infectious Disease Research in Zambia (CIDRZ), and the National Institutes of Health (NIH) through the National Heart, Lung, and Blood Institute (NHLBI) and Fogarty International Center. This means that the research team is being paid by the sponsor for doing the study. Dr. Michael Herce, one of the principal investigators on this study,

participates in unpaid activities which are not part of this study for the Centre for Infectious Disease Research in Zambia (CIDRZ). These activities may include consulting, service on committees or boards, giving speeches, or writing reports.

If you would like more information, please ask the researchers listed in the first page of this form.

What if you have questions about this study?
You have the right to ask and have answered, any questions you may have about this study. If you have questions, complaints, concerns, or if a study-related injury occurs, please contact:

Dr. Wilbroad Mutale
Centre for Infectious Disease Research in Zambia
Plot # 34620, Corner of Lukasu and Danny Pule Roads,
Mass Media, PO Box 34681 Lusaka, ZAMBIA
Tel: +2600967780284
Email: Wilbroad.Mutale@cidrz.org

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions about your rights as a study participant, or problems or concerns about how you are being treated in this study, you may contact:

The Chairperson
University of Zambia Biomedical Research Ethics Committee
Ridgeway Campus, Nationalist Road, Lusaka
Landline Telephone: 0211-256-067

Informed consent form signature page

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Principal Investigators: Dr. Wilbroad Mutale, UNZA & CIDRZ, and Dr. Michael Herce, CIDRZ & UNC

Participant's Agreement

If you agree to join this study, you will need to sign or make your mark below. Before you sign or make your mark on this consent form, make sure of the following:

- I have read this consent form, or someone has read it to me.
- I understand what the study is about and what will happen to me if I join. I understand what the possible risks and benefits are.
- I have had my questions answered and know that I can ask more.
- I agree to join this study.

I will not be giving up any of my rights by signing this consent form.

_____ _____

Signature/thumbprint of research participant Date

_____

Printed name of the research participant

_____ _____

Signature of research team member obtaining consent Date

_____

Printed name of research team member obtaining consent

_____ _____

*Signature of witness Date

_____

*Printed Name of witness

***Note: Witness name, signature and date are required on this consent form only when the consenting volunteer is not able to read and/or is illiterate**