APPENDIX A.

INFORMED CONSENT FORM FOR ETHNOGRAPHIC OBSERVATIONS AND INTERVIEWS

Informing the design of interventions to reduce reliance on antibiotics while minimizing unintended consequences

Protocol Title: Antimicrobials in Society (AMIS) Project Uganda: Understanding the role of antimicrobials in daily life in Tororo, Wakiso and Kampala districts of Uganda through three entry points: Health Care, Farming and Urban Work.
Site of Research: Tororo, Wakiso and Kampala, Uganda
Principal Investigator: Ms Susan Nayiga (IDRC) and Dr. Clare Chandler (LSHTM)
Investigators and Institutions: Ms Nabirye Christine (IDRC), Ms Miriam Kayendeke (IDRC), Dr Laurie Denyer Willis (LSHTM), Prof. Sarah Staedke (LSHTM/IDRC)
Version Date: V1.0, 23 February 2018

Introduction

Susan Nayiga and colleagues from the Infectious Diseases Research Collaboration (IDRC) and the London School of Hygiene & Tropical Medicine (LSHTM) are carrying out a research study to understand how medicines used to treat different types of infections have become a part of health care and daily life in Uganda. This study will be conducted in three places: 1) public and private sources of health care and surrounding communities in Nagongera sub-county, Tororo district; 2) farms of different scales and technologies of production in Wakiso district and; 3) Soweto and Banda informal settlements in Kampala district.

How will this study be done?

We want to understand how certain types of medicines are part of daily life for people living and working in three different places in Uganda. The medicines we are interested in are those that may be used to treat or prevent infections caused by bacteria, parasites, viruses and fungi. If you agree to participate, we will try first to understand what life and work is like for you, and second try to understand how these medicines play a role in your life, if at all. We can never truly know life from someone else's perspective but in anthropology we try to achieve some insights by experiencing some of that person's life together with them. For this study, this means we want to spend time with you in your area of residence, the places where you seek care when ill, and farm or place of work, to experience and observe what life is like for you. We are interested in perspectives from health care providers, farmers, urban workers and residents within communities. We will also talk to you about our observations and may ask you questions about what we see during the time we are with you.

If you agree to take part in the medicines survey, we will ask you questions about yourself, your household and the people that live there, the illnesses that people in your household experience frequently, the medicines that you use in your household and your experience using antibiotics. For the livestock survey, we will ask you questions about yourself, the farm, animal health and diseases, medicines that you use on your farm, animal

health services and your experience treating your livestock with antibiotics. We will ask you to show us the medicines that you keep at home or at your farm, and to tell us what illnesses you treat with these medicines. We will also show you a bag of medicines we have acquired locally that may be used to treat bacterial infections, and we will ask you to share your experiences using these medicines.

In each place where this study will be done, we plan to observe 15-30 people, carry out the medicine sorting exercise with 50-100 people, and discuss our findings with approximately 30-40 people. In our 3 study sites, we shall spend time with and observe approximately 45-90 people, carry out the medicine sorting exercise with 150-300 people and discuss our observations with 90-120 people, in total.

In each site, 1-2 members of the study team will spend 2-4 days a week with you (either at the health facility where you work, or your farm, or place of residence), typically for a period of two to three months. In some cases, we may return for subsequent visits over a period of 15 months by arrangement and agreement with you.

What will happen if I take part in this study?

If you agree, you will take part in the study activities outlined above. We are interested to observe and hear about your experiences and opinions. There are no right or wrong answers. We simply want to understand your experiences with medicines and how these are used in your everyday life. We will take notes during observations and may ask you questions informally. Sometimes, we may ask to interview you formally, and a recording will be made of the discussions using a digital voice recorder. Afterwards, we will type up our notes and transcribe audio recordings into a computer for analysis.

We will take photographs of medicines that people keep in their homes. We will also take photographs of houses, farms, livestock, features of the urban and natural landscape, social and cultural events. We will not take photographs of individuals participating in the research themselves. The photographs will help us remember key issues and to convey the context of the research more visually. We will ensure that the identities of all participants are protected using identification numbers or fake names (pseudonyms) and not including any participants' faces or identifiable features in any reports or publications arising from this study.

How will the information collected in this study be used?

The information we collect will be used by project investigators and may be shared with other researchers to answer questions about how medicines are important to people in different settings. The findings will be important to provide locally relevant advice for governmental and non-governmental programmes that want to ensure that medicines continue to work effectively for everyone.

We are conducting this study in collaboration with colleagues from Mahidol University and the Ministry of Public Health in Thailand and colleagues from LSHTM. Information collected in this study will be shared with our research partners so that we can compare findings from Uganda and Thailand. The information collected

may also be shared with other researchers outside of the study (not part of the AMIS group) who request permission to access the data. However, no personal information about you will be included in the information shared. Data collected in the study will be stored for a minimum of 10 years and a maximum of 15 years following project completion on the main IDRC server in Kampala and the LSHTM server in London.

Where will the study take place?

The study will take place in Tororo, Wakiso, and Kampala districts. We will focus on health facilities, places of informal work, places where people seek care or where medicines are sold, households, farms, and surrounding neighborhoods.

How long will the study last?

The study will last for about 15 months. The study team will stay in your area for about 6-10 weeks at a time. During this time, the study team will spend between 2-4 days every week in your area. The amount of time the study team spends with you will depend on your willingness, availability and interest in the study.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study, or to stop taking part at any point. If you decide not to take part in this study, you can tell one of the study team your wishes and there will be no penalty to you.

What risks can I expect from being in the study?

Participation in any research study may involve a loss of privacy or confidentiality. Information you provide will be recorded, but your name will not be used in any reports.No one else will have access to the recordings of your voice and this will be destroyed after transcription is complete. We will remove any personal information to ensure that you are not identifiable in any interview records or reports of the information provided. The information obtained from these study activities will be locked up at our project offices. All personal information will be stored electronically in a secure, password protected database to ensure privacy.

Are there benefits to taking part in the study?

We will not provide any direct benefit to you for participating in this study. The information that you provide will help researchers and policy-makers to understand how people use medicines that can treat infections, and the importance of these medicines for people's everyday lives and livelihoods.

Who can answer my questions about the study?

If you have any questions, comments or concerns, or feel that you have been harmed from taking part in these activities, please talk to the researchers first. Contact Ms Susan Nayiga, the principal Investigator of the AMIS Uganda Project on +256 (0) 752900565 or the Infectious Diseases Research Collaboration on telephone number +256 (0) 414 540 624.If for any reason you do not wish to do this, or you have questions or concerns about your rights, you may contact Dr Erisa Mwaka, the Chair of the School of Biomedical Sciences Research and Ethics Committee (SBS REC) at telephone number +256 (0) 752 575050.

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25 APR 2019
RESEARCH & ETHICS COMMETTEE
P. O. BOX 7072, KAMPALA

AMIS FRESH APPROACHES to the STUDY of ANTIMICROBIALS IN SOCIETY

IDRC INFECTIOUS DISEASES RESEARCH COLLABORATION

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

WHAT YOUR SIGNATURE MEANS

Your signature below means that you understand the information given to you in this consent form about your participation in the study and agree with the following statements:

1 "I have read the consent form concerning this study (or have understood the verbal explanation of the consent form) and I understand what will be required of me and what will happen to me if I take part in it."

2 "My questions concerning this study have been answered by the person who signed below."

3 "I understand that at any time, I may withdraw from this study without giving a reason."

4 "I agree to take part in this study."

If you wish to participate in this study, you should sign on the following page. If you do not agree to quotes or other results arising from your participation in the study being included, even anonymously, in any reports about the study, please tell the researcher now.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

	Yes	No
I agree to participate in this research. Participating in this research means that I agree for study personnel to observe my activities and actions that relate to my daily life and use of medicines. *(Note to study staff: if a person answered "No" to this question, it means that s/he has refused to participate in the study and should not be enrolled)*	[___]	[___]
I agree to be interviewed about my opinions, thoughts and perceptions of use of medicines in my daily life.	[___]	[___]
I agree to my interviews being recorded when this is appropriate and I give my permission.	[___]	[___]
I agree that short anonymized direct quotes from my responses may be used in reports and publications emerging from this research.	[___]	[___]
I agree to photographs of medicines, houses, farms, livestock, features of the urban and natural landscape, social and cultural events being taken when this is appropriate.	[___]	[___]

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Name of Participant (printed)

Signature of Participant Date/Time

Name of Researcher administering consent (printed)

Signature of Researcher Date/Time

If the participant is unable to read and/or write, an impartial witness should be present during the entire informed consent discussion. After the written informed consent form is read and explained to the participant, and after they have orally consented to participate in the study, the witness should print the name of the participant above, and then the participant should provide their fingerprint. Then the witness should print their name, provide their signature, and date the consent form below. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by the participant, and that informed consent was freely given by the participant.

Name of Person Witnessing Consent (printed)

Signature of Person Witnessing Consent Date/Time

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