MBARARA UNIVERSITY OF SCIENCE AND TECHNOLOGY INSTITUTIONAL REVIEW COMMITTEE P.O. Box 1410, Mbarara, Uganda

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INFORMED CONSENT DOCUMENT



Study Title:

Management of microbial keratitis by private pharmacies in Mbarara City, South Western Uganda: a study of knowledge, attitude, and practice.

Principal Investigator(s):

Dr. Simon Arunga

INTRODUCTION

What you should know about this study:

- 1. You are being asked to join a research study.
- 2. This consent form explains the research study and your part in the study.
- 3. Please read it carefully and take as much time as you need.
- You are a volunteer. You can choose not to take part and if you join, you
 may quit at any time. There will be no penalty if you decide to quit the
 study.

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APPROVAL DATE: Metember 26, 2020

APPROVED CONSENT IRB NUMBER: September 2020

PI: DY Simon Armaga

IRB NO: 18 07-20

You are being asked to join this research study. This consent form explains the research study and your role in the study. Please read it carefully and take your time to decide. You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to quit the study.

Brief background to the study

Infection of the clear part of the front of the eye (the cornea) is called microbial keratitis and is an important cause of blindness worldwide. A scratch in the cornea allows infection to enter the surface of the eye, and a corneal ulcer begins. As the infection progresses, the cornea can become severely affected, and sometimes can even become thinned. Often after it has been treated and healed the cornea is left with a scar that stops the eye from seeing.

There is very little information about this eye problem from African countries. Currently, this disease process is only poorly understood and the existing treatments for it are only partially effective. One of the key challenges has been delayed presentation of patients and barriers along the referral system. Usually, when patients present late, the outcome is almost always poor.

Purpose of the research project: As part of this study we are trying to develop ways of strengthening the health system to be able to detect, treat and promptly refer patients with this condition in order to improve outcomes.

Why you are being asked to participate:

We are inviting different pharmacy attendants within the catchment area of Mbarara University and Ruharo Eye Hospitals to provide us information on their experiences in managing this condition.

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Procedures:

If you agree to participate, we will use a questionnaire to ask you a series of questions about your facility, staffing, workload, equipment, consumables and drug stocks.

In addition, we will invite a smaller number of the pharmacy workers to have a more in depth interview with one of our team to discuss in more detail about your experiences of treating patients with this condition and any challenges faced. Not all people who agree to join the study will be asked to do this.

Finally, you may be selected and invited for a group discussion with other pharmacy attendants to share your experiences and views on different aspects which could relate to this condition and suggestions on what we can all do to improve this situation. Not all people who agree to join the study will be asked to do this.

During the process of the interviews, we may request to take some photographs of the interview process or your facility for purposes of context. These photographs will not have any identifying features of participants and non-participants. However, feel free to deny permission if this makes you uncomfortable in any way and this will not have any impact on the interview.

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Risks / discomforts: There is no risks involved with you participating in the study. The questionnaire will only take a few minutes of your time.

Benefits: It is only poorly understood how this disease causes blindness and the role of the health system in improving outcomes. Although you will not receive any direct benefits, will be helping us by sharing your experiences and suggestions on how the pharmacists can work with the health system to improve access to timely care for people with this disease.

At the end of participating in this study, we will provide information on the management of this disease.

Incentives / rewards for participating: There is absolutely no incentives/rewards e.g. monetary or any sort that will be given to you and others to participate in this study. The study is completely on a voluntary basis. If you are invited to participate in the Focused Group Discussion, we shall provide you with a transport refund of 10,000 shall be provided as well as a soft drink and snack during the discussions.

Protecting data confidentiality: The information collected about you will be kept confidentially in a controlled place. Your information will be identified by a participant number and not your name.

Protecting subject privacy during data collection: The interview will be conducted in a quiet free room free from interference.

Right to refuse / withdraw: The study is completely voluntary and you are completely free to decline to participate or withdraw from the study at any time.

What happens if you leave the study? There is no penalty for you if and when you decide to leave the study.

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Who do I ask/call if I have questions or a problem?

Contact Principal investigator

Dr Simon Arunga

Department of Ophthalmology

Mbarara University of Science and Technology

+256706397738

Contact for IRC office

Dr. Francis Bajunirwe

Chairman MUST-IRC

P.O Box 1410

Mbarara

Tel: 048543379

What does your signature (or thumbprint/mark) on this consent form mean?

Your signature on this form means

- You have been informed about this study's purpose, procedures, possible benefits and risks
- You have been given the chance to ask questions before you sign
- You have voluntarily agreed to be in this study

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Print name of adult participant	Signature of adult participant/legally authorized representative	Date
Print name of person obtaining consent	Signature	Date
Thumbprint/mark	signature of witness	

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