Supplementary file 6: Patient information and consent form

Part 1: Study Information Sheet for patients

Patient guidance: ***Please read this document carefully and ask for clarity where it is required.***

Introduction

Previous studies conducted in other parts of the world have indicated that people with diabetes may have varying treatment outcomes when receiving treatment for tuberculosis and that treatment for tuberculosis may predispose them to develop diabetes. This study will verify the status of these claims in patients receiving TB treatment in Eswatini and also identify means of improving treatment outcomes for diabetic persons receiving treatment for tuberculosis. The title of this study is ***"Diabetes-Tuberculosis comorbidity: Epidemiology, Predictive factors, and Control in Eswatini"***. The principal investigator of this study, Dr Victor Williams will also utilise findings from this study to fulfil part of the requirement for the award of a Doctor of Philosophy degree (PhD) by the University Medical Centre, Utrecht University, Utrecht, Netherlands.

This research will be implemented at the different hospitals and health centres that provide TB services in Eswatini. These include Mbabane Government Hospital, The Luke Commission, Phocweni Clinic, TB Center, Siphofaneni clinic, Mankayane Hospital, AHF Lamvelase Clinic, Raleigh Fitkin Memorial Hospital, AHF Matsapha, Pigg's Peak Government Hospital, Nhlangano Health Center, Hlathikulu Hospital TB Clinic.

Aim of the research

The study aims to describe the epidemiology, predictive factors, and control measures of diabetes in patients who are being treated for tuberculosis in Eswatini. The study has four objectives and one of them is to identify factors that hinder effective Diabetes Mellitus care for diabetics receiving TB treatment in Eswatini and to propose a context-specific approach to address these factors. To achieve this objective, health care workers who directly provide care for these patients will be interviewed. As healthcare personnel who is experienced in the care of TB patients, you are invited to participate in this study.

If you agree to participate in the study, a convenient date and time will be arranged for you to be interviewed.

Potential benefits and risks

There will be no direct benefit for you from taking part in the interview. However, the information you provide will help the researcher understand the best practices and challenges in the care of TB clients with diabetes and provide recommendations that will help improve services delivery for these clients. Participating in the interview carry's a low risk for you as a participant if there is a breach of confidentiality but the researchers have been trained in research ethics to ensure your confidentiality. Comments you make will not be directly linked to your name in the final study report. Also, there is a possibility that the interview may evoke sad memories concerning your patients. Kindly let the interviewer know if you feel this way and would like to end the interview.

Voluntary participation

Your participation in this interview is voluntary. There are no right or wrong answers. You can at any time choose to withdraw from the study completely (including deletion of audio-recording and transcript of interview if you wish). You can decide not to take part or to stop taking part in this study at any time, without giving a reason, and without any impact on your work. We would like to record the interview, if you consent to this, solely for the study, to ensure we capture everything you say.

Confidentiality

The information you provide during the interview will be confidential and accessible only to the research team. The audio recording will only be heard by the research team. This will be transcribed onto paper and the original recording will be kept securely for the duration of the study. All written information collected (transcripts of interviews, notes, signed informed consent form) will be kept privately and anonymously (including password-protected storage) for about 10 years or as recommended by the Eswatini Health and Human Research Review Board (EHHRRB).

The researchers will make every effort to ensure that the information you provide as part of this study remains confidential. When using quotes from an interview, the researcher will make sure that the identity of the cited person cannot be revealed. Any information you share during the interview will be confidential and your privacy will be maintained. Also, the research assistants and interviewers conducting this research have been made to sign a confidentiality agreement to further ensure your confidentiality and privacy.

Contact for additional information

If you have any questions regarding this study, please contact the study's Principal Investigator Dr Victor Williams at +268 7618 4334; victormw55@gmail.com or P.O Box 9482, Mbabane, H100, Eswatini.

OR

The Secretariat of Eswatini Health and Human Research Review Board (EHHRRB) on (00268) 2404 0865 / (00268) 24044905.

Part 2: Patient Consent form

Thank you for considering taking part in this study. The person organising the interview must explain the study to you before you agree to take part. If you have any questions, from the information sheet above or the explanation given to you, please ask the researcher before you decide to take part. You wi/ll be given a copy of the information sheet to keep if you wish.

Informed consent

□□I have been informed by the undersigned person of the purpose of this study, and the possible benefits and risks of my participation.

□□Any questions, I had about my participation in this study have been answered to my satisfaction. I will receive a copy of the document I have signed if I wish.

□□I was given enough time to decide if I will participate in the study.

□□I am participating in this study voluntarily. I may withdraw at any time without giving a reason and my decision not to take part will not affect my access to health services.

□□I permit the researchers and the Ethics Committee to see my anonymised data, with the understanding that this data will remain confidential.

I, _____ consent voluntarily to being a participant of this study.

I consent to this interview being recorded
□Yes □No
I consent to be contacted for a follow-up interview
□Yes □No

_____
Signature of the study participant with Date (**or thumbprint if cannot sign**)

_____
Name and Signature of researcher with Date