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Rheumatologists' perceptions of the co-incidence of tuberculosis associated with TNF-a inhibitors used for the treatment of rheumatoid arthritis in South Africa.

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2014-03-28
http://hdl.handle.net10539/14383

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APPENDIX II

QUALITATIVE SURVEY INFORMATION SHEET FOR RHEUMATOLOGISTS,TO BE INTERVEIWED; AND INFORMED CONSENT

Good Day, my name is Trudy Leong, a master's student, and I am doing a qualitative survey on rheumatologists' perceptions, on the co-incidence of TB infections in RA patients on Tumour Necrosis Factor (TNF) inhibitors*, in South Africa.

*Tumour Necrosis Factor – inhibitors is a group of medication that is used to treat Rheumatoid Arthritis, and includes the following products: Enbrel© (Etanercept),Humira©(Adalimumab) and Revellex© (Infliximab). These products are currently registered to treat Rheumatoid Arthritis in the South African market.

Background: Most studies on Rheumatoid Arthritis (RA) patients exposed to Tumour Necrosis Factor (TNF) inhibitors have been conducted in countries with a low to intermediate burden of TB (USA, Sweden, United Kingdom, Korea, Portugal, and Spain). However, in South Africa, there is currently a lack of local robust data to analyse the incidence of TB co-incident with TNF-inhibitors. This limits the utilization of a quantitative approach to analyse the occurrence of TB infection in RA patients treated with infliximab, etanercept and adalimumab in South Africa, a TB endemic country. A qualitative survey researching rheumatologists' perception, attitude and concerns regarding the risk of TB associated with TNF-inhibitors would be more meaningful.

Ethics approval: This study is under reviewwiththe University of the Witwatersrand and the Human Research Ethics Committee, which is a committee whose task it is to make sure that research participants are protected from harm.

Your participation is voluntary and you may refuse to participate or discontinue participation at any time.If you choose to participate in this study, no personal gain or disadvantages will be conferred.

Procedure: The study methodology involves face-to-face interviewing of rheumatologists, using a schedule of questions. These interviews will be recorded and the transcripts will be

analysed.The amount of time required for your participation in this study will be approximately 45 minutes. Tapes will be kept in a locked cupboard for two years after publication or for 6 years if the data remains unpublished, thereafter they will be destroyed.

Confidentiality: Confidentiality will be maintained, and names of interviewees will not be used in the transcripts and subsequent reports. The identity of each interviewee will be anonymised by allocation of a participant number for the purposes of the transcripts. The identifiable data will be coded and the links will be kept separatelyon an excel spread sheet that is password protected. It will not be shared with or given to anyone except if compelled by law to do so. There will be limited access to this data, which will be kept at a locked location at the University of the Witwatersrand, Department of Pharmacy and Pharmacology.

If you so wish, you, the participant, will be given any pertinent information on the study when the results are available. Furthermore, this study may be published in a journal.

There will be no cost to you to participate in this study. However, your participation is likely to help us find the answer to the research question. This study may benefit society, the medical fraternity and future generations. If any further information is required, please contact me on e-mail address trudyl88@gmail.com or trudyl@ymail.comor Mrs. Shirra Moch, my supervisor may be contacted on shirra.moch@wits.ac.za or 011 7172372 or 0832291851.

Thank you for your participation.

INFORMED CONSENT FOR PARTICIPATING DOCTORS:

- I have read and understood the foregoing information, and have been informed by the researcher about the conduct, method, benefits and risks of the study entitled: RHEUMATOLOGISTS' PERCEPTIONS ON THE CO-INCIDENCE OF TUBERCULOSIS ASSOCIATED WITH TNF-INHIBITORS USED FOR THE TREATMENT OF RHEUMATOID ARTHRITIS IN SOUTH AFRICA.

- I have had sufficient opportunity to ask questions about the study and any questions that I have asked have been answered to my satisfaction. I may, at any stage, without penalty, withdraw my consent and discontinue my participation in the study.

Iconsent voluntarily to participate in this study.

PARTICIPANT:

Print Name of Participant_____

Signature of Participant _____

Date _____

Statement by the researcher, Trudy Leong:

I confirm that the above-mentioned participant has been fully informed about the conduct, method, benefits and risks of the above-mentioned study; including the confidentiality and voluntary participation in this study.

Furthermore, I confirmthat the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

RESEARCHER:

Print Name of Researcher _____

Signature of Researcher_____

Date _____

Day/month/year