

Progress Report: Case study on the acceptance of a new tuberculosis vaccine in the general public of three TB-affected districts of Nepal.

Full title of study: Case study on the acceptance of a new tuberculosis vaccine in the general public of three TB-affected districts of Nepal.	
OXTREC Approval Reference: 571-23	
NHRC Approval Reference: 1008	NHRC Protocol no. 656/2023
Principal Investigator: Ms. Ashata Dahal	
Sponsor: Oxford University Clinical Research Unit-Vietnam	

Listed Investigators	Ms. Ashata Dahal Dr. Abhilasha Karkey Ms. Kritika Dixit
Study Start and End date (As per protocol)	Approval date: 22 Jan 2024 Study ends: 21 Jan 2025
Study Design	Qualitative study
Sample size (As per protocol)	Total 6 FGDs. A minimum of 7 and a maximum of 12 participants will be considered per FGD, which would result in a total of 42-72 participants for the study.
Actual number of participants enrolled	As per the protocol, the FGDs were conducted in 3 districts. 2 FGDs per districts with male and female participants were conducted that totals to 6 FGDs. There were 10 participants in each FGD, hence the total number of participants is 60 as per the protocol. From three sites of Nepal: - 1. Bankey – 2 FGDs (10 Male +10 Female) 2. Mahottari- 2 FGDs (10 Male +10 Female) 3. Morang - 2 FGDs (10 Male +10 Female)

Inclusion Criteria	The study population are adults from high TB burden communities in the target districts. Inclusion criteria are 18 to 65 years old and above and ability to consent.
Exclusion criteria	People under 18 years and above 65 years of age were excluded and people who did not provide consent were excluded from the study.
Investigational Medicinal Product(s) & Mode of administration	Not applicable
Duration of Treatment	Not applicable
Primary Objective and secondary objective(s)	<p><u>Primary objective</u></p> <ul style="list-style-type: none"> To explore the acceptance of a new, hypothetical TB vaccine in the general population of communities with high TB burden in Nepal. <p><u>Secondary objective</u></p> <ul style="list-style-type: none"> To identify the self-perceived barriers and drivers of acceptance of a new, hypothetical TB vaccine in three selected study areas of Nepal: To predict which sub-populations have additional barriers to vaccination with a new TB vaccine To assist in developing strategies to address barriers, especially for the TB-vulnerable populations at risk of not getting vaccinated
Collaboration	OUCRU Nepal collaborated with Birat Nepal Medical Trust (BNMT), Lazimpat, Kathmandu. BNMT were responsible to conduct all fieldwork activities that included approaching participants, conducting FGDs for data collection, taking informed consent and transcribing the FGDs.
Study progress	Data collection, transcription and translation has been completed. The translated data has been imported into NVivo. Data analysis is in progress.
Statistical Methods	Not applicable
Conclusions	This qualitative study utilized FGD to explore the acceptance and perceived barriers of a new hypothetical TB vaccine among the general public within the affected community of Nepal. We conducted 6 FGDs with male and female participants from 3 districts with high prevalence of TB cases engaging 60 individuals in total.

	With our study, we are focused on exploring the acceptance and perceived barriers of a new hypothetical TB vaccine among the public within the affected community using the COM-B model. We expect the model to predict sub-populations with added challenges, and inform strategies to support TB-vulnerable groups.
List of Publications (or plans for publications) including those for patients (if applicable)	We plan to publish a scientific article in an international journal after the completion of data analysis.

Signature:



Principal Investigator: Ashata Dahal

Date: 10th Jan 2025