

Proposed Project Title: Qualitative Exploration of Enrolling Household contacts of Individuals Diagnosed with Tuberculosis for TB Vaccine Research

Project type: short-term project 10 weeks on site

Preferred Scholar On-Site Project Dates: 10 weeks on site, 5/1/2024-11/30/2024 (the start date is flexible)

Project Site: Lima, Peru (Peru CTU)

Project Overview:

Tuberculosis remains a highly prevalent and deadly disease affecting low- and middle-income countries, including Peru. A more effective vaccine for TB is desperately needed and understanding how best to deploy vaccines for clinical trials will help as more become available for field trials. The implementation of TB vaccine trials would help to curb morbidity and mortality from TB. Thus far TB vaccine studies have shown moderate success with a recent meta-analysis describing primarily phase II studies. While most were safe, information on efficacy remains in process. While the WHO recommends preventative TB treatment for household contacts of TB index cases the actual use of prevention medication is very low. This results in continued transmission of TB and is a multifaceted problem, including the stigmatization of TB, the difficulties associated with adherence to preventative medication, and issues around implementation.

Household contacts may represent a target for transmission-interrupting interventions, including preventative treatment as currently being tested in a large field trial. Household contacts may also be a key population to target for future preventative TB vaccination trials.

Project Summary:

To set the stage for future TB vaccine studies, we propose to assess the willingness and perceived barriers of enrolling household contacts of TB index cases and to determine if recruitment in health centers is sufficient or household visits would facilitate participation. This project will employ qualitative methods to conduct interviews with TB index cases and household contacts.

Study hypotheses and objectives

- 1) Household contacts of TB index patients will be willing to participate in TB vaccine research.
- 2) Conduct qualitative interviews with TB index cases and household contacts of TB index cases to explore willingness and facilitators/barriers to participation in TB vaccine research. To understand factors associated with willingness to participate in TB vaccine research among household contacts of TB index cases.

We plan to conduct 30 interviews, 10 with TB cases and 20 with TB household contacts. This information would be analyzed to assess willingness to participate in TB vaccine research, to understand barriers and facilitators of this participation and also toward the design of a quantitative survey that would be planned as a subsequent study. Written informed consent would be obtained from eligible individuals prior to their enrollment. The scholar would help with study recruitment, conduct or help to conduct interviews, analyze the interview data, and develop a manuscript based on the results.

The RAMP scholar would have to be fluent in Spanish for this project. They would also be asked to conduct CITI training for work with human subjects prior to arriving in Peru. In addition to the work described above, the scholar would be able to take part in ongoing Peru CTU training activities. While in Peru, training and mentoring for the qualitative data collection and analysis would be done with Dr.

Konda while Dr. Valencia would provide background on TB in Peru and past TB studies conducted by the CTU. Weekly meetings with the scholar, research assistant and Drs. Konda and Valencia would also take place to monitor progress and resolve any issues. The Peru CTU also has ongoing trainings for staff career development and mentoring, these occur twice a month and the scholar would be invited to take part in these activities as well.

Regulatory requirements for the project and plans for completing them:

We will need to apply for IRB approval to conduct a survey with TB patients and their household contacts. We will also need to apply for IRB approval to conduct interviews with both groups. The IRB application would be submitted to Via Libre for review, FWA00003081. This process generally takes 2-4 weeks for observational studies such as this proposal. We would plan to apply for IRB approval at least two months prior to the scholar's arrival in Peru to assure approval by the time they are in country. The scholar would be required to complete GCP training; online courses are available.

Expected Deliverables:

1. Interviews with TB household contacts and index TB patients
2. Oral and Poster Presentations
3. A manuscript based on the collected information.

Project Contact Person(s) (Name, Email):

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Dr. Javier Valencia, jvalencia@impactaperu.org – Primary Mentor