



Sharing Experiences and Optimizing South-to-South Collaboration in Preparing Resource-Limited Sites for Vaccine Trials: The TB Vaccine Sites

Anne Wajja¹, Patrick Nabongo², Sabrina Bakeera-Kitaka^{1,3}, Philippa Musoke^{1,3} and Harriet Mayanja-Kizza^{1,4}

1. Makerere University Infectious Diseases Institute; 2. Iganga/Mayuge Demographic Surveillance Site, Uganda; 3. Makerere University Department of Paediatrics and Makerere University Department of Medicine

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Collaborators:

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Partner sites:

South Africa TB Vaccine Initiative (SATVI), Cape Town, South Africa; KEMRI/CDC field station, Kisumu, Kenya; Centro de Investigação em Saúde da Manhica (CISM), Mozambique; St. John Research Institute, Bangalore, India and other TBVACSIN members

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Background



- The **TB Vaccine Trial Sites Network** (TBVACSIN) is consortium of sites at different stages of conducting or preparing for TB vaccines trials
- The sites vary in development ranging from well-established to limited experience in clinical research.
- TBVACSIN members in Africa include
 - South Africa TB Vaccine Initiative (SATVI), Cape Town, South Africa
 - KEMRI/CDC field station, Kisumu, Kenya
 - Centro de Investigação em Saúde da Manhiça (CISM), Mozambique
 - TB Vaccine preparation project, Iganga/Mayuge, Uganda
- Sites in similar settings face common challenges that may be addressed through sharing experiences, knowledge and optimizing south-to-south collaboration
- TBVACSIN provides a forum for this opportunity



TBVACSIN Objectives



- To share between sites experiences related to TB vaccine trial site development
- To assist each other in building capacity to conduct TB vaccine clinical trials
- To work towards developing feasible diagnostic and quality standards for TB vaccine trials in developing countries
- To strengthen TB vaccine trial capacity in African countries
- Harmonize protocols



Methods



- Optimizing has been done through:
 - Targeted exchange visits
 - Training
 - Networking events
 - Harmonizing and sharing documents such as protocols, Standard Operating Procedures (SOPs) etc
 - Consultation and transfer of expertise in specialized fields
- The Uganda site shares some of the benefits afforded from the south-to south collaboration



Results (1)



- Exchange visits
 - Ugandans visited the South Africa site to learn its set up and operations
 - Ugandan researchers and personnel including clinicians, study coordinators, data managers, laboratory personnel have had short, focused visits to SATVI and KEMRI to gain specific experience
- In 2008, Uganda participated in a consensus-building workshop for all sites on interpretation of infant chest x-rays in Capetown. The Uganda attendees now form the panel of experts that reviews and interpretes the study radiographs
- Uganda lab staff spent a month in the India site lab to learn how to run BSL3 labs and returned to run the new lab in Uganda
- All sites have learned practical lessons through these visits



Results (2)



- Training
 - Staff from SATVI were part of the team that trained Uganda staff in conducting Tuberculin Skin Testing, sputum induction and gastric lavage in infants
 - The Uganda staff in turn trained Kenya staff on the latter procedures
 - Joint training sessions in clinical research methods, ethics, GCP, data quality management and professional development have been organized in Kenya and attended by Uganda staff
 - The Aeras Professional Development Programme (PDP) developed at the SATVI site is now implemented at all sites



- Networking
 - The network organizes 2 annual meetings at one of the sites and alongside the TB Union meeting
 - Meetings grown over the years both in numbers, scientific rigor and output

Founding meeting, Capetown 2007



TBVACSIN Meeting at IUATLD, Paris 2008

TBVACSIN Meeting in Jinja, Uganda 2009





Results (4)



- Harmonisation of site protocols
 - Diagnostic methods
 - Main outcomes: endpoints
 - Differences remain in e.g. logistics of enrolment
- Sharing of SOP documents and data collection tools. This helps to speed up the processes and reduces costs
- Strengthening of expertise in specialty fields such as clinical procedures, microbiology and immunology
- Joint funding applications with a successful EDCTP grant awarded to the consortium for a phase IIB multicentre clinical trial



Discussion & Conclusions



- This is a cost-effective way of building capacity in resource-limited settings offering practical lessons
- Sharing of experiences is vital as sites encounter similar issues and can therefore mutually benefit from the lessons learned
- The collaboration appears feasible and fruitful and increases potential for cross-site and multi-site grant applications
- Already established sites still benefit from strengthening of such collaboration as sites complement each other in their area of strength
- Collaboration enhances development of highly specialized expertise like immunology research in Africa



Future perspectives T B V A C S I N

Tuberculosis Vaccine Trial Sites Network

- Important to document and analyze what does or doesn't work
- Disseminate success stories & lessons
- Strengthening such networks maximizes the limited resources and expertise
- Support and apply similar strategies to other types of trials and high-burden diseases