



An alternative consenting process: Is it appropriate for developing countries?

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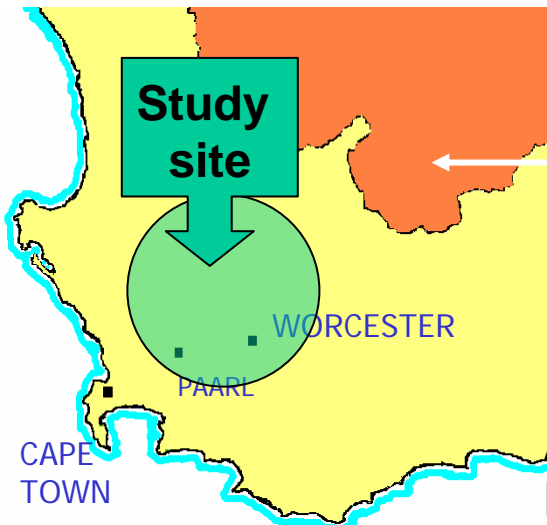
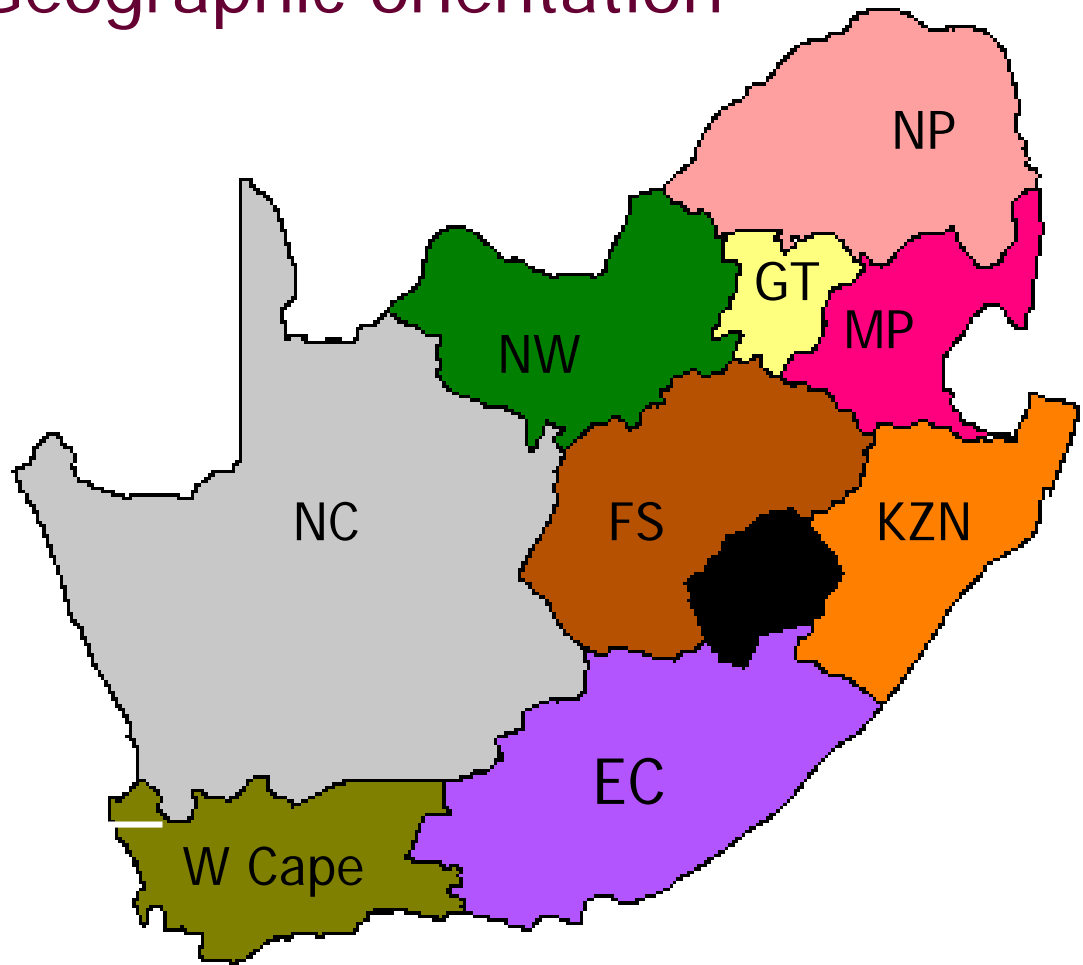
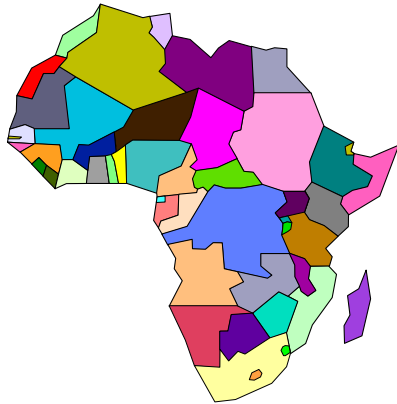


Background

- 2000 – Launch of The South African TB Vaccine Initiative (SATVI) at the University of Cape Town
- Mission - to develop new and effective TB vaccines
- Sponsor – Aeras Global TB Vaccine Foundation (USA)
- Clinical field site based in Worcester (100km outside of Cape Town)



Geographic orientation



Area ~ 200 x 200km, mountainous, farming.

Population ~ 350 000

Smear + TB rates 0.5-1.0% per annum, HIV rates ~10%



Current Phase 1 TB vaccine study





E D C T P





Background



Poor rural community predominantly Afrikaans and Xhosa speaking.

In 2006 Aeras approached SATVI to implement an alternative consenting process using:
DVD technology and;
Audio-taping



Description of Informed Consent(IC) Process



- DVD
 - Describes the study and elements of IC in 3 languages (English, Afrikaans and Xhosa)
 - All potential participants given IC documents 24 hours prior to consent discussion
 - In addition a DVD given to those with access to DVD technology
 - On the day of consent –DVD screened in waiting room, followed by question and answer session



Description cont.



- Participants consented individually in private setting (standard oral written approach used)
- The process is audio-taped.
- Copy of IC form and audio-tape given to participant



Potential Benefits: DVD and audio-taping



- Consenter
 - Random sample review of audio-tapes to:
 - Identify possible shortcomings in IC process
 - Identify FAQs
 - Self-development
- Participant
 - Information re-enforced through continuous viewing of DVD/listening to audio-tape
- Sponsor
 - Information to participant is consistent and more comprehensive
 - Tangible proof of IC process



Potential Disadvantages



- **Technology**
 - **Access to power supply**
 - **Access to equipment (such as TV, DVD player)**
 - **Cost**
 - **Appropriate for rural and urban settings?**
 - **Participants lack of technology creates unequal access to information**
- **Participants**
 - **Culture: Is the community comfortable with this approach?**
 - **Copy of audio-tape in home environment could result in potential loss of confidentiality**
 - **Is audio-taping appropriate when gathering sensitive information?**



Unanswered questions: Points to consider



- Is there added value?
 - Is there improved understanding?
- Is it cost-effective?
- Is it feasible?
- Is it acceptable?
- Is there another way?



Future perspectives



- Should other sites in Africa explore the use of this technology?
- Local site in Worcester should evaluate the usefulness of this alternative approach
 - Anecdotal evidence is that the DVD is effective. Potential participants are asking more questions than before.



Acknowledgements



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Thank-you