

Engagement of Males with Pulmonary Drug-Resistant Tuberculosis for Participation in Pretomanid Regimen (BPamZ) Testicular Safety Study



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BACKGROUND

Community Engagement (CE) has long been established as best practice in TB treatment clinical trials, and is critical to informing the design, planning and conduct of a study evaluating testicular safety of 26-weeks of pretomanid in adult males with drug-resistant tuberculosis (DR-TB) as part of the BPamZ (bedaquiline, pretomanid, moxifloxacin, pyrazinamide) regimen.

This is the first DR-TB treatment trial to require semen sample collection. Due to significant barriers expected in recruitment and retention, a coordinated strategy for engaging key stakeholders across all research sites was required.

METHODS

A global BPamZ/Sem study CE Lead advised the clinical study team and coordinated a CE strategy across four research sites in South Africa and Georgia. Pre-study individual and focus group discussions with male DR-TB patients and Community Advisory Boards (CABs), assessing feasibility and acceptability of this semen study, identified barriers to recruitment and retention and helped to inform recruitment and retention strategies.

Engagement and sensitivity trainings were provided to research and CE staff at all sites. A coordinated approach to engagement was used to ensure participants understood the purpose of the study to move TB treatment availability forward for a broader pediatric population. Individual and group support systems were available for each trial participant to improve morale and retention throughout the study.

RESULTS AND LESSONS LEARNED

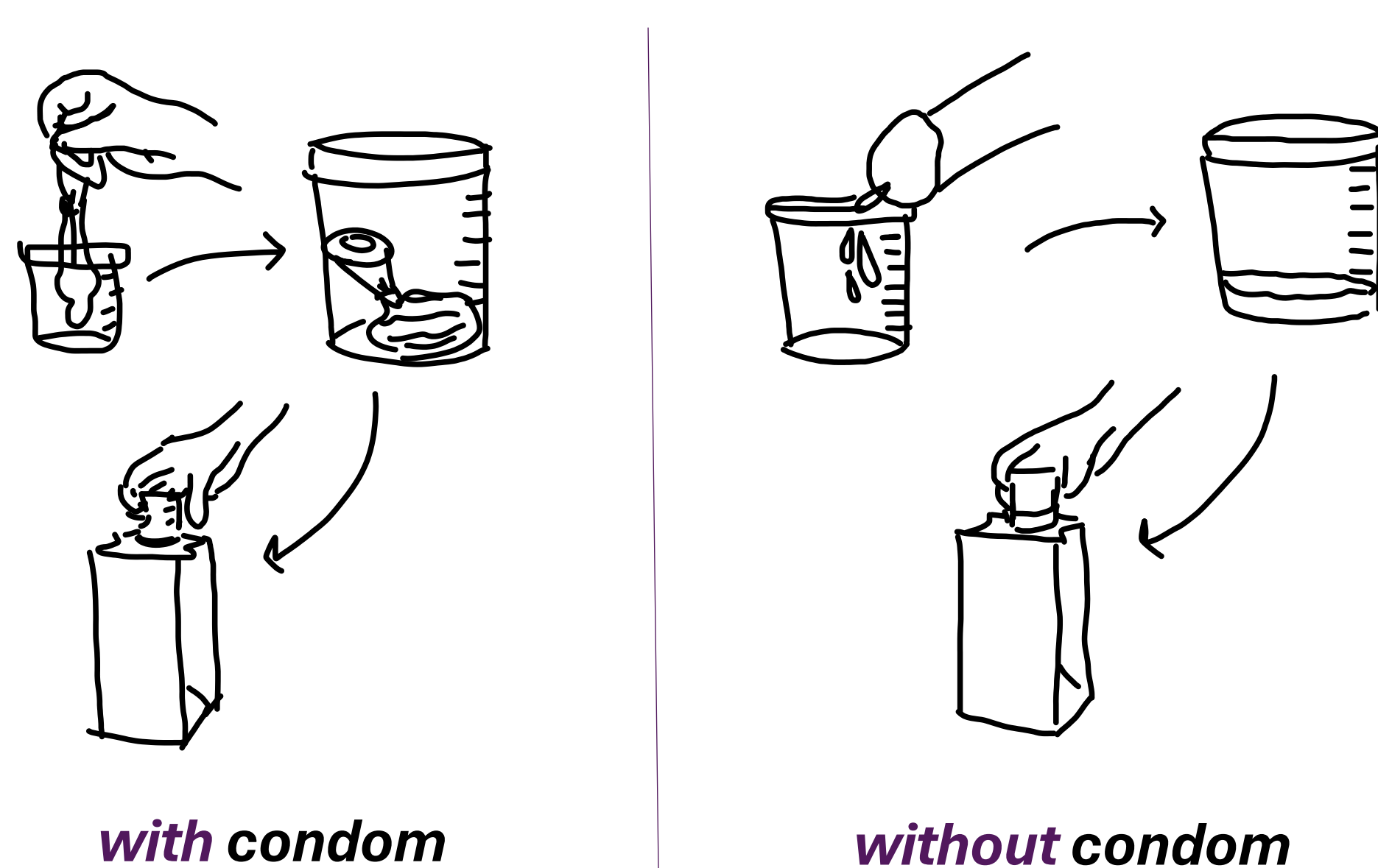
A coordinated CE strategy across all sites participating in the BPamZ/Sem study improved the recruitment and retention of participants by helping the study team anticipate unique issues, needs and concerns of the trial population.

Individual and group discussions with male DR-TB patients highlighted significant concerns about providing semen for a medical study. These were based on cultural and religious beliefs, fear and stigma associated with masturbation. Some participants expressed concerns about feeling too sick to produce samples. Some participants expressed concerns about how stress and depression would impact their ego and sense of manhood.

Education and counseling improved the trial participants' comfort with providing semen samples for clinical evaluation and study participation.

Feedback from participants and CABs informed the setting for participants to provide semen samples, and what materials were provided (books, television, headsets, internet, clips loaded to cell phones, privacy rooms) to assist with various methods of semen collection. Repeated education about the significance of taking part in the study and study requirements as well as text messages and calls to stay engaged helped with morale and retention of participants.

Semen Sample Collection Participant Instruction Leaflet



Privacy room at Sizwe for semen collection

RECOMMENDATIONS

A coordinated strategy for engagement of communities and participants in the BPamZ/Sem study helped clarify that sites experienced similar challenges, barriers, and concerns. Sharing site experiences helped in finding better solutions, and reduced repetition of challenges. Regular communication improved recruitment and retention of trial participants.

Communications, confidentiality, and transparency protected participant's rights and care in the study. Increased partnership and coordination between CE and clinical teams improved acceptability of the study, and ease of implementation. This kind of coordinated engagement approach is highly recommended for any clinical trial, and especially when barriers to participation are known or anticipated.



BPamZ/SEM

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