

Early risk assessment in paediatric and adult household contacts of infectious tuberculosis index cases by novel diagnostics

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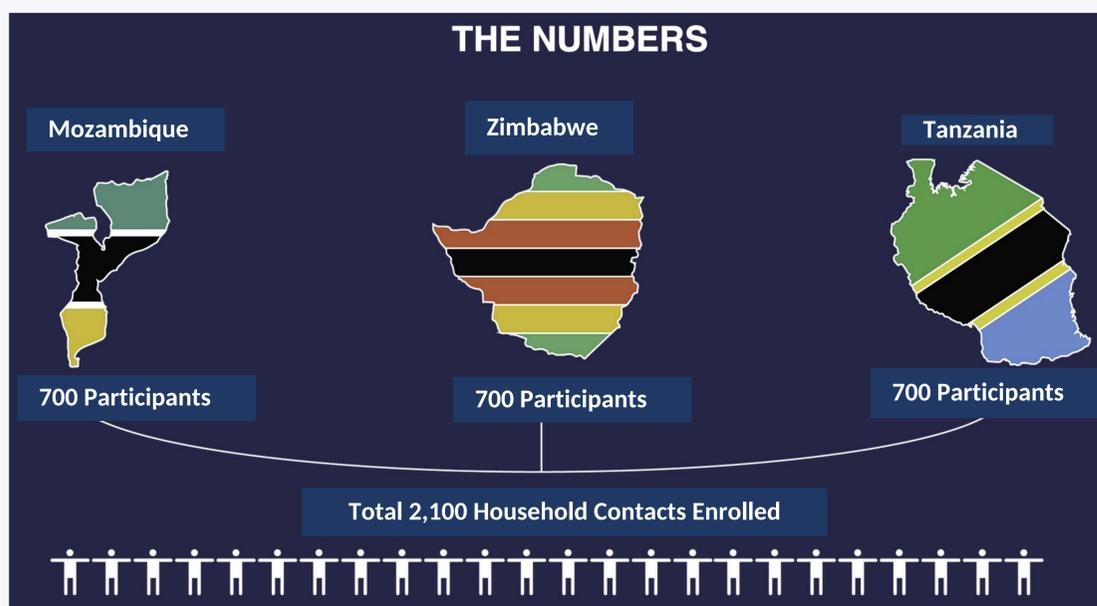
BACKGROUND

METHOD

- The “End TB Strategy” of WHO emphasises the urgency of developing novel improved diagnostics for accurately and rapidly detecting tuberculosis (TB) early combating further bacterial transmission
- The ERASE-TB study is being conducted at selected sites in Mozambique, Tanzania, and Zimbabwe aiming at evaluating conventional versus novel diagnostics for detecting incipient and subclinical TB among household contacts (HHCs) of confirmed, i.e. microscopy, WHO scale or GeneXpert, infectious index cases (ICs)

- Design:** non-interventional prospective multi-centre multi-country cohort study
- Target population:** HHCs aged ≥ 10 years of infectious tuberculosis ICs aged ≥ 18 years
- Sample size:** 2,100 HHCs in total or 700 HHCs by participating country
- Blood tests:** IGRA SD Biosensor, TAM-TB, Cepheid host response
- Sputum tests:** culture, Xpert Ultra MTB/RIF
- Other investigations** e.g. vital signs, chest X-ray, spirometry, HIV/CD4, urine
- Study endpoints:** detecting prevalent or incipient TB among HHCs
 - co-prevalent symptomatic TB
 - co-prevalent subclinical TB
 - minimal TB with incident TB during follow-up
 - remaining healthy
- Duration:** 36 months; 12 months recruitment; 24 months follow-up with 6- months re-visits and additional unscheduled unwell visits
- Future tests** e.g. Qure.ai, FLOW-TB, 4RISK&COR, multiplex PCR, biosignature, SeroSelect

THE NUMBERS



LATEST STUDY STATUS (September, 2021)

CHALLENGES

- Recruitment initiation:** Zimbabwe/March, Mozambique/August, Tanzania/September
- Total ICs enrolled:** 141 (34 years median age, 1:0.7 male/female ratio)
- Total HHCs enrolled:** 315 (27 years median age, 1:1.4 male/female ratio)

Multiple study components were impacted by the global COVID pandemic:

- Overall study initiation and obtainment of ethical and operational approvals
- Provision of on-site face-to-face training including study monitoring
- Impact on the recruitment of ICs due to repeated temporary closure of recruitment healthcare facilities augmented by anxiety and movement restrictions affecting care seeking and provision patterns of suspected TB cases and healthcare personnel
- Impact on the enrolment of HHCs due to movement restrictions and anxiety of high infection risk
- Procurement and provision of necessary study equipment and consumables