

Publication

Feasibility of implementing the advanced HIV disease care package as part of community-based HIV/TB activities: a mixed-methods study protocol

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INTRODUCTION: Although the advanced HIV disease (AHD) care package reduces morbidity and mortality in people with AHD (defined in people living with HIV as WHO stage 3 or 4, CD4 count <200 cells/microL or age <5 years), it is barely implemented in many countries. A novel point-of-care CD4 test rapidly identifies AHD. We evaluate the feasibility of implementing the AHD care package as part of community-based HIV/tuberculosis services. **METHODS AND ANALYSIS:** This two-phased study is guided by the Medical Research Council framework for evaluation of complex interventions. Stage 1 is a stakeholder consultation to define tools and indicators to assess feasibility of the AHD care package. Stage 2 is the implementation of the AHD care package during a facility-based tuberculosis diagnostic accuracy study in high-burden HIV/tuberculosis settings. Consenting adults with tuberculosis symptoms in two sites in Lesotho and South Africa are eligible for inclusion. HIV-positive participants are included in the feasibility study and are offered a CD4 test, a tuberculosis-lipoarabinomannan assay and those with CD4 count of ≤ 200 cells/microL a cryptococcal antigen lateral flow assay. Participants are referred for clinical management following national guidelines. The evaluation includes group discussions, participant observation (qualitative strand) and a semistructured questionnaire to assess acceptability among implementers. The quantitative strand also evaluates process compliance (process rating and process cascade) and early outcomes (vital and treatment status after twelve weeks). Thematic content analysis, descriptive statistics and data triangulation will be performed. **ETHICS AND DISSEMINATION:** The National Health Research and Ethics Committee, Lesotho, the Human Sciences Research Council Research Ethics Committee and Provincial Department of Health, South Africa and the Ethikkommission Nordwest- und Zentralschweiz, Switzerland, approved the protocol. Dissemination will happen locally and internationally at scientific conferences and in peer-reviewed journals. **TRIAL REGISTRATION NUMBER:** NCT04666311.

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