

ABSTRACT

Background

Despite significant increases in global health investment and the availability of low-cost, efficacious interventions to prevent mother-to-child HIV transmission (pMTCT) in low- and middle-income countries with high HIV burden, the translation of scientific advances into effective delivery strategies has been slow, uneven and incomplete. As a result, pediatric HIV infection remains largely uncontrolled. A five-step, facility-level systems analysis and improvement intervention (SAIA) was designed to maximize effectiveness of pMTCT service provision by improving understanding of inefficiencies (step one: cascade analysis), guiding identification and prioritization of low-cost workflow modifications (step two: value stream mapping), and iteratively testing and redesigning these modifications (steps three through five). This protocol describes the SAIA intervention and methods to evaluate the intervention's impact on reducing drop-offs along the pMTCT cascade.

Methods

This study employs a two-arm, longitudinal cluster randomized trial design. The unit of randomization is the health facility. A total of 90 facilities were identified in Côte d'Ivoire, Kenya and Mozambique (30 per country). A subset was randomly selected and assigned to intervention and comparison arms, stratified by country and service volume, resulting in 18 intervention and 18 comparison facilities across all three countries, with six intervention and six comparison facilities per country. The SAIA intervention will be implemented for six months in the 18 intervention facilities. Primary trial outcomes are designed to assess improvements in the pMTCT service cascade, and include the percentage of pregnant women being tested for HIV at the first antenatal care visit, the percentage of HIV-infected pregnant women receiving adequate prophylaxis or combination antiretroviral therapy in pregnancy, and the percentage of newborns exposed to HIV in pregnancy receiving an HIV diagnosis eight weeks postpartum. The Consolidated Framework for Implementation Research (CFIR) will guide collection and analysis of qualitative data on implementation process.

Discussion

This study is a pragmatic trial that has the potential benefit of improving maternal and infant outcomes by reducing drop-offs along the pMTCT cascade. The SAIA intervention is designed to provide simple tools to guide decision-making for pMTCT program staff at the facility level, and to identify low cost, contextually appropriate pMTCT improvement strategies.