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#### Journal Article

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In July 2011, Malawi introduced an ambitious public health program known as “Option B+,” which provides all HIV- infected pregnant and breastfeeding women with lifelong combination antiretroviral therapy, regardless of clinical stage or CD4 count. Option B+ is expected to have benefits for HIV-infected women, their HIV-exposed infants, and their HIV-uninfected male sex partners. However, these benefits hinge on early uptake of prevention of mother-to-child transmission, good adherence, and long-term retention in care. The Prevention of mother-to-child transmission Uptake and REtention (PURE) study is a 3-arm cluster randomized controlled trial to evaluate whether clinic- or community-based peer support will improve care-seeking and retention in care by HIV- infected pregnant and breastfeeding women, their HIV-exposed infants, and their male sex partners, and ultimately improve health outcomes in all 3 populations. We describe the PURE Malawi Consortium, the initial work conducted to inform

the trial and interventions, the trial design, and the analysis plan. We then discuss concerns and expected contributions to Malawi and the region.

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