A cluster-randomised controlled trial to determine the effect of peer delivery HIV Self-Screening to support linkage to HIV prevention in rural KwaZulu-Natal, South Africa: interim analysis

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### **ABSTRACT**

# Study Objective:

Uptake of HIV testing and linkage to care or prevention interventions remains sub-optimal in young South Africans, contributing to high levels of HIV transmission. We investigated whether HIV self-screening (HIV-SS) delivered by peers either directly or through incentivized peer-networks, could increase the uptake of antiretroviral therapy (ART) and Pre-Exposure Prophylaxis (PrEP) amongst young women (18-24 years) in a high HIV transmission setting in KwaZulu-Natal (KZN), South Africa.

### Methods:

In a cluster-randomised trial in rural KZN, 24 area-based pairs of peer-navigators, working with ~12000 young people aged 18-30 were randomised to: (1) *incentivized-peer-networks (IPN)*: peer-navigators recruited participants "seeds" to distribute up to 5 HIV-SS packs and HIV prevention information to peers within social networks. Seeds received an incentive (20 Rand = \$1.5) for each respondent who contacted peer-navigators for additional HIV-SS packs to distribute; (2) *peer-navigator-distribution (PND)*: peer-navigators distributed HIV-SS packs and information directly to young people; (3) *standard of care (SOC)*: peer-navigators distribute referral slips and information. All arms promoted sexual health and HIV care and prevention (including PrEP and ART), and provided barcoded clinic referral slips. The primary outcome compared the difference in linkage rate between arms, defined as the number of women (18-24 years) per peer-navigator month of outreach work (/pnm) who linked to clinic-based PrEP eligibility screening or started ART, based on HIV-status, within 90 days of referral. The secondary outcome was the same outcome in women and men aged 18-30 years. Process and cost-effectiveness analyses are ongoing. Ethical approval was provided by the World Health Organization, London School of Hygiene and Tropical Medicine, University of KwaZulu-Natal, and KwaZulu-Natal Department of Health. *Trial registration number*: NCT03751826.

## Results:

On interim analysis (15/3/2019-1/6/2019), n=2216 referral packs were distributed across the three arms over a period of 60 peer-navigator outreach months, with similar numbers per arm (632, 898, 686, in IPD, PND and SOC respectively). Overall 103 (1.7/pnm) men and women aged 18-30, of which 37 were women aged 18-24, were linked to HIV care or prevention. The linkage rate was significantly

lower for 18-24-year-old women in the IPN arm compared to SOC, but similar between PND and SOC: In SOC arm 16, (0.4/ pnm); in the IPN arm 4, (0.2/pnm; rate difference with SOC: -0.65: 95%CI; -1.26: -0.04), and in the PND arm n=18, (0.5/pnm; rate difference with SOC: 0.10: 95%CI; -1.04: 1.24). The linkage rate was significantly lower in the IPN arm compared to both PND and SOC in those aged 18-30 (-2.20:95%CI; -3.23: -1.17 and -2.20: 95%CI; -3.33: -1.07 respectively).

#### Discussion:

The interim results show both HIV-SS arms (IPN and PND) reached large numbers of young men and women, without significantly increasing demand for HIV prevention and care services. Contact with a peer-navigator, who promoted PrEP and ART, generated more linkage events than incentivized peer networks in both young men and women. While, these interim results must be interpreted with caution, findings suggest further research is needed to optimize HIV-SS implementation for PrEP and ART demand creation amongst young people in South Africa.