The where, when, and how of community-based versus clinic-based ART delivery in South Africa and Uganda

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Antiretroviral therapy (ART) can suppress HIV plasma RNA concentrations and harmful effects of the virus. However, at present, only about 60% of people living with HIV are virally suppressed.[1] Therefore, global public health programmes urgently need innovative approaches to improve the rapidity and durability of engaging patients in treatment. In this issue of *The Lancet Global Health*, Ruanne Barnabas and colleagues report results of the Delivery Optimization of Antiretroviral Therapy (DO-ART) study, a multicentre, randomised trial comparing community-based ART initiation, monitoring, and resupply with use of a hybrid approach (ART initiation at the clinic with community monitoring and resupply), and with standard clinic-based ART delivery among individuals from South Africa and Uganda with detectable HIV viral load.[2] The investigators hypothesised that community-based ART could overcome logistical barriers, simplify monitoring and ART resupply, and increase viral suppression rates, especially among men, enough to make community-based interventions cost-effective. They found that community-based initiation and treatment significantly increased viral suppression compared with standard clinic-based care among all participants from 63·1% to 73·9%, and among men from 54·3% to 73·2%. The hybrid approach registered smaller but similar effects.

The report of the DO-ART study contributes to a growing body of literature showing that community-based interventions result in similar or improved patient outcomes compared with clinic-based ART delivery.[3,4] Home-based, same-day ART initiation integrated with community-based HIV testing improved viral suppression at 12 months in a trial in Lesotho.[5] Community-based HIV care using differentiated service delivery models, including community-based multi-month ART dispensing, have been shown to have favourable outcomes[6] and result in cost savings to both patients and providers.[7] However, most community-based differentiated service delivery models for ART delivery have been developed for patients who are already stable on ART, and the most important contribution of the study by Barnabas and colleagues is that community-based, same-day ART initiation in individuals with elevated viral load was safe and resulted in improved viral suppression after 12 months, particularly among men.

With these promising results, the next questions are whether, where, when, and how global public implementers should scale up the DO-ART approach, particularly among men. The answers, however, depend not only on the rigour or internal validity of the study (for which the investigators should be applauded) but also on the external validity, for which some additional information would be useful. Emerging perspectives in implementation research can help position researchers to offer findings that are maximally interpretable in other implementing contexts that differ by geographical (urban *vs* rural), economic (Kenya *vs* Mozambique), and social factors—what do these perspectives suggest for future research that aims to influence execution of the HIV response?

Mechanisms can inform decisions about scale up. First, an important insight is that the external validity of a finding depends on the mechanism of effect. In this study, more information about how community-based approaches improved viral suppression would be helpful. If the community-based approach worked through availing ART to patients unable or unwilling to get to a clinic, then this approach is most applicable to rural settings, where distance is important. Conversely, if patients in the standard of care arm of the trial reached the clinic but did not start ART due to lengthy preparation practices, the observed effects might be attenuated since immediate ART initiation in the clinic has become the norm over the past 2 years.

Second, so-called adjunctive practices that accompany study interventions but are not explicitly considered important complicate external validity. In the DO-ART study, patients starting ART in the community also received text message appointment reminders, facilitated rescheduling, follow-up monitoring calls, and potentially more intensive counselling. Unless community-based ART initiation is universally scaled up concomitantly with these adjunctive practices, the real-world effects might show a drop in ART compliance and viral suppression rates compared with trial findings.

Parsimonious intervention design could improve generalisability.

Third, measuring and reporting patient preferences is also important. Someone living with stigma and near a clinic, for example, might have different preferences for home-based ART initiation than someone living far from a clinic. In preference-sensitive interventions such as these, the comparison of interest might not be between community-based and clinic-based ART initiation, but rather between a health system that offers both (from which patients could choose) versus a system that only offers one—a concept termed mosaic effectiveness.[8] If preferences are measured, effects stratified by such preferences can inform tailoring of services to the individual.

Overall, the results from the DO-ART study extend our public health tool kit and has implications for management of adults with virological failure who are not eligible for differentiated service delivery. Further research with longer-term follow-up is required to measure sustained success over time and cost-effectiveness to inform policy makers. Furthermore, home-based case management could be effective for adolescents in particular,[9] but these patients were not included in the study and whether community-based ART initiation and resupply is safe and effective for this population is unknown. The DO-ART study adds further to the ongoing debate and dialogue on the optimal package of care needed to achieve the third 90 (virological suppression) of the UNAIDS 90-90-90 targets for AIDS elimination by 2030.[10]

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