**Multi-month dispensing of antiretroviral therapy for stable patients increases retention and reduces costs**

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Achieving HIV treatment targets such as 95-95-951 will help control the HIV epidemic. Key to this is implementation of efficient models that optimise patient engagement. WHO recommend multi-month dispensing of antiretroviral therapy (ART) for up to six months for stable patients because of positive effects in reducing the burden on health systems and time and opportunity costs for patients.2 Six-month dispensing intervals through differentiated community-based models demonstrate non-inferiority to 3-month facility-collection models.3,4 In this issue of the Lancet Global Health, Risa Hoffman and colleagues add to this evidence by reporting on a pragmatic non-inferiority cluster randomised trial of facility-based multi-month dispensing in Malawi and Zambia (INTERVAL).5

Authors randomised 30 health facilities to three ART refill intervals for stable patients: i) standard of care (SOC), guidelines of which specified facility ART refills at 3-month intervals but was invariably implemented at baseline, ii) facility-based three-month dispensing intervals (3MD), and iii) facility-based six-month dispensing intervals (6MD). Questionnaires completed at enrolment included sociodemographic information and visit costs. Follow-up was done by health facilities according to standard of care, with research teams providing support for implementation fidelity. After 14 months of follow-up study staff abstracted ART refill data from health facility records. Costs of providing ART services were collected from representative sites and national sources. The primary outcome of retention in care at 12 months was defined as not having >60 consecutive days without ART and the secondary outcomes included costs of service provision and clinic visits.

Authors found that 6MD increased retention by 9.1 (95%CI 0.9-17.2) and 5.0 (95%CI 1.0-9.1) percentage points when compared with SOC and 3MD respectively. Patients in 6MD arm had 17.6 days without ART (95%CI 16.1-19.2) versus 30.6 (95%CI 28.5-32.7) for 3MD and 36.1 (33.8-38.4) for SOC. Viral load data were not available and would be key to investigate given the lower suppression levels in another multi-month ART dispensing study.4 Although the non-inferiority margin was achieved in Malawi, the overall increase was driven by Zambia which showed increases in retention of 15.5 (95%CI 0.4-29.8) and 7.4 (1.7-13.1) percentage points when 6MD was compared with SOC and 3MD respectively. One reason for improved retention may be the observed reduction in out-of-pocket costs to patients. Costs to patients were lowest in the 6MD arm, with 45% and 33% reductions in annual costs for time losses in Malawi and Zambia, while lost potential income was reduced by 25% and 33% respectively, and transport costs by 25% overall. The trial also showed slight reductions in ART program costs; the average cost per patient retained was $89, $88, and $86 for SOC, 3MD and 6MD respectively in Malawi. The corresponding costs were $144, $142 and $132 in Zambia. The slight reductions can translate to large savings if implemented at scale. It should however be noted that program costs were likely underestimated by non-inclusion of costs for support offered by study staff.

Countries need to be supported to ensure successful implementation. In the INTERVAL trial SOC arm, where no support was given, the 3-month dispensing interval was only employed 59% of the time. Key to successful implementation of multi-month dispensing are robust supply chain systems, particularly in low and middle income countries where complex global supply chains and shortage of trained logistics staff are associated with ARV drug stockouts and shortages.6 It will be important for programs implementing multi-month dispensing intervals to share lessons learned so that barriers can be addressed.

Optimisation of dispensing programs also requires investigation to ensure practises that uphold the positive effects of the intervention for patients. Although qualitative studies among patients show strong acceptability of 6MD,7concerns raised by health workers about poor storage of long-term drug supplies and sharing of medicines7 need to be investigated and addressed. Given the difference between Malawi and Zambia in the primary outcome it would be important to conduct additional research to determine what components of programs and context optimised retention among patients.

In summary, the INTERVAL trial is timely in that it adds to the evidence on multi-month dispensing of ART in the midst of the COVID-19 pandemic when programs are looking to develop person-centred approaches for limiting exposure of people living with HIV to health facilities.8 Implementation is presently suboptimal - only 21 of 32 PEPFAR-supported countries have 6-month dispensing policies9, although interest in 6MD is accelerating. As ART programs worldwide shift stable patients to multi-month dispensing additional data on health outcomes, operational challenges and barriers to implementation will help refine and optimise service delivery models to the needs of individuals and their contexts.

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