



Meeting report

**Optimizing a client's first six months on ART:
Differentiated service delivery models to
promote early retention in care**

Boston, USA

8 March 2020



EXECUTIVE SUMMARY

In sub-Saharan Africa, national efforts to achieve the 95-95-95 targets of HIV diagnosis, treatment and viral suppression have led to substantial changes in the approaches to initiation of antiretroviral therapy (ART) (including rapid and same-day initiation) and retention of clinically stable clients, including differentiated service delivery (DSD) models for ART. Omitted from these innovations has been the period between ART initiation and eligibility for a DSD model, which is typically a client's first six to 12 months on ART. Recent and previous data consistently suggest high rates of attrition from care during this period, suggesting that new approaches to service delivery in the first six months are needed.

On 8 March 2020, prior to the Conference on Retroviruses and Opportunistic Infections (CROI 2020), the International AIDS Society (IAS) and the Boston University School of Public Health convened a half-day roundtable on optimizing a client's first six months on ART to improve retention in sub-Saharan Africa. Twenty-five stakeholders, including clinicians, researchers, implementers and policy makers, convened to discuss key priorities for clinical care and client engagement soon after treatment initiation. One-third of stakeholders attended the meeting in person and the others participated virtually. Although the roundtable was originally intended to be in person only, it was converted to a partially virtual meeting when CROI 2020 was made entirely virtual. All participants (Annex 1: Participant list) attended the first four sessions. Only in-person attendees participated in Session 5, developing an optimal DSD model (Annex 2: Agenda).

The discussion focused on early clinical and engagement needs of people living with HIV to maximize long-term retention and minimize time from ART initiation to viral suppression. Attendees also brainstormed potential DSD models to address these needs and research methods that could be applied to evaluate their impact. Existing data sources and research questions were proposed to inform innovative models of care delivery. Finally, a set of next steps was identified to support further analysis and advocacy for improving early retention and care. These include:

- **Developing specific service delivery recommendations** for the first six months on ART within World Health Organization (WHO) guidance
- **Promoting the use of existing routine data and research databases**, and implementing partner data to answer critical questions on early loss to follow up
- **Consolidating any existing published and unpublished evidence** on the impact of specific DSD models during the first six months on ART
- **Engaging with implementing partners** to understand models for the first six months that have been tried in the field to identify the successes, failures and lessons learned from implementation
- **Developing a research agenda** to prioritize evaluation of interventions to improve outcomes during the first six months on ART.



BACKGROUND AND RATIONALE

Throughout sub-Saharan Africa, most national HIV programmes are striving to achieve the 95-95-95 targets for HIV diagnosis, treatment and viral suppression. In response to the growing number of people living with HIV on ART, countries are scaling up differentiated service delivery (DSD) models. DSD models differ from conventional care in service delivery location, frequency of client interaction with the health system, intensity of services provided and cadre involved in care.

Most DSD models so far have focused on optimizing ART initiation and delivery of client-centred care to achieve long-term retention and viral suppression among clinically stable clients. Innovative models of HIV service delivery have provided client-centric methods of testing and initiation; models focusing on long-term retention of clients who have been on ART for at least six months have also been offered in high-burden settings.

However, the evidence demonstrates that the risk for attrition is the highest in the first six months of client enrolment. Optimization of the delivery of HIV services during these critical months is therefore the next challenge for researchers, implementers and policy makers alike.

MEETING OBJECTIVES

The meeting, titled “Optimizing a client’s first six months on ART: Differentiated service delivery models to promote early retention in care”, was organized by the International AIDS Society (IAS) with technical input from Boston University. It brought together 25 global thought leaders to brainstorm and propose DSD models to improve care in the first six months after ART initiation while considering potential infrastructural and research constraints. Attendees aimed to review research and generate programmatic ideas that could be implemented and evaluated within the existing financial and human resource limitations. This was a closed meeting limited to invited attendees; participants came from academic and research organizations, implementing partners and advocacy groups (Annex I).

The objectives of the meeting were to:

- Summarize and share existing evidence on clients’ early retention in care
- Discuss clients’ clinical and engagement needs in the first six months of treatment initiation
- Propose DSD models to:
 - Maximize retention in care and/or viral suppression during the first six months on ART
 - Create conditions that will maximize long-term retention in care or viral suppression
 - Minimize time from ART initiation to viral suppression or meeting the definition of stability
 - Reduce burden on clients and providers
 - Improve the experience of the first six months on treatment for clients and providers.



MEETING OUTCOMES

The presentations and discussions are summarized in this section. The slide decks used for sessions 1 and 2 are hyperlinked in the session titles.

SESSION 1: [Framing and objectives](#); Sydney Rosen (Boston University, United States)

Professor Rosen provided a rationale for optimizing the delivery of care in the first six months after treatment initiation. Despite high rates of loss from care in the early period, most DSD models systematically exclude clients who have been on ART for less than six months. Progress has been made towards achieving long-term retention in care and optimizing HIV testing and ART initiation. Little change has been made in the past decade, however, to alleviate the logistic and clinical burden on clients during the first six months when they need treatment the most. Data are also sparse on the importance of clinical and social interactions during this time and their impact on outcomes. Optimizing the delivery of care during the first six months is the next challenge for researchers and implementers alike.

The objectives of this meeting, as framed by Professor Rosen, were to:

- Share existing evidence on clients' early retention in care
- Discuss clients' clinical and engagement needs in the first six months after treatment initiation
- Propose DSD models for the first six months after initiation.

Achieving these goals depends on the following baseline assumptions:

- Clients initiating care will continue to have high baseline CD4 counts; a minority will continue to present with advanced disease
- A declining proportion of clients will initiate ART for the first time and more clients will be re-initiators
- DSD models for stable clients will continue to be scaled up.

Future DSD models for early initiation should account for the existing constraints, including:

- Existing infrastructure and staff
- Existing management and implementation capacity
- Flat-lined or declining resource availability per client.

**SESSION 2: [Review of data on early retention in HIV care in Africa, country guidelines and interventions](#);
Anna Grimsrud (IAS, South Africa)**

In her talk, Dr Grimsrud presented the recent evidence on: a) early disengagement from HIV care; b) current standard of care for the first 12 months on ART in sub-Saharan Africa; and c) existing interventions to improve early retention in care.

a) *Early disengagement from HIV care*

Evidence from Eswatini, Malawi, South Africa, Uganda and Zambia demonstrates a high burden of disengagement from care and early loss in the first six months of treatment initiation. In Eswatini, men and younger women are more susceptible to attrition [1]. In Zambia, over a third (36%) of those lost to follow up were initiated in the past year (Figure 1), and in Malawi, the majority of missed appointments also took place early in treatment [2].

Figure 1: Proportion of lost to follow up (LTFU) patients in Zambia in FY2019 initiated in the past 12-months versus earlier

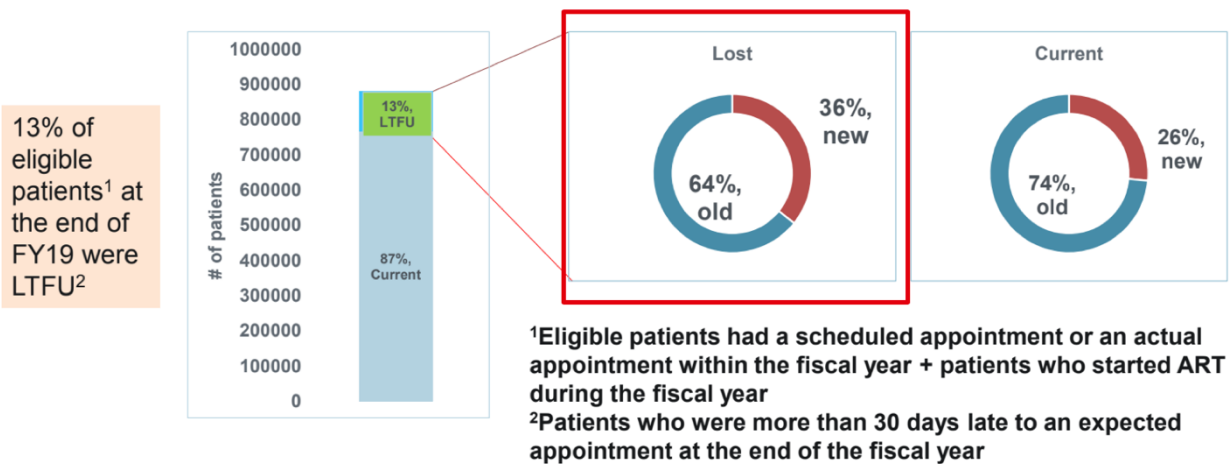
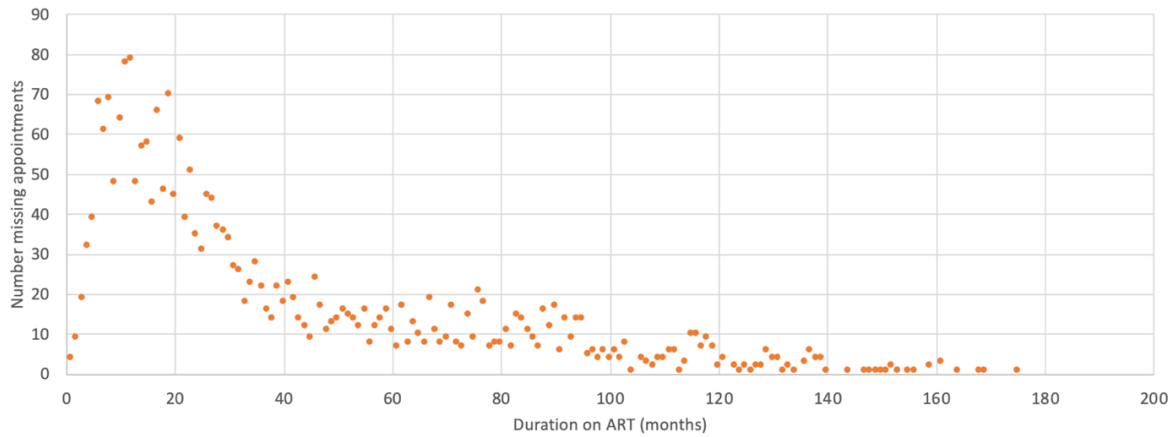


Figure 2: Frequency of missed appointments by duration on ART in Malawi



**Majority of patients missed appointments early in treatment (within 12 months).
Patients on ART for >5 years(60 Months) less likely to miss appointments**



In a South African study, even with the same-day initiation policy, almost half of all initiated clients (47.7%) experienced 12-month attrition [3]. Data from a Ugandan study demonstrated a similar trend in high loss-to-follow-up rates within the first three months of initiation [4].

b) Current standard of care for the first 12 months on ART in sub-Saharan Africa

Despite these high rates of early attrition, national guidelines on HIV treatment mandate frequent client interaction with the health system, with most countries requiring monthly clinical visits in the six-month period after initiation and two- to three-monthly (or more frequent) visits in the following six months (Figure 3).

Figure 3: National policy on the frequency clinical visits and timing of viral load monitoring in the first year on ART

| Country | D0 | Week 2 | Month 1 | Month 2 | Month 3 | Month 4 | Month 5 | Month 6 | Month 7 | Month 8 | Month 9 | Month 10 | Month 11 | Month 12 |
|--------------|----|--------|---------|---------|---------|---------|---------|---------|---|---------|---------|----------|----------|---------------------|
| Eswatini | X | | X | X | X | X | X | X VL | X | X | X | X | X | X VL |
| Ghana | X | X | X | X | X | X | X | X VL | | X | | X | | X VL |
| Kenya | X | X | X | X | X | X | X | X VL | Every 1-2 months depending on stability | | | | | X VL |
| South Africa | X | X | X | X | X | X | X | X VL | | | | | | X VL |
| Tanzania | X | X | X | X | X | X | X | X VL | Every 2-3 months depending on stability | | | | | X VL |
| Uganda | X | | X | X | X | | | X VL | Every 3 months | | | | | X VL (for children) |
| Zimbabwe | X | X | X | | X | | | X VL | X | | | | | X VL |



c) *Existing interventions to improve early retention in care*

Effective interventions that have been used to improve early retention include using “case managers” in South Africa, where linkage officers or “buddies” are provided to clients initiating ART [5]. A “one-stop-shop” approach for youth and adolescents is implemented in Mozambique. As part of this model, integrated services are offered at sites, which include HIV counselling and testing, contraceptive method mix, post-violence care and prenatal care, as well as ART initiation, psychosocial support and drug distribution. A “walk methodology” is implemented in Zambia where clients are supported through each step of the treatment initiation process and strengthened through treatment literacy, positive messaging and flexibility on where to receive ART services [2,6–8]. While these approaches are being tested, innovative methods to address gaps in early retention are urgently needed.

SESSION 3: Open discussion: What are the clinical needs of people living with HIV in the first six (12) months of treatment and given the resource constraints? Is it possible (and appropriate) to deliver less intensive care without jeopardizing health outcomes? (facilitated discussion; discussion chair – Dr Ingrid Katz)

This discussion session focused on a few primary considerations that help us understand the early clinical needs of people living with HIV and the appropriate intensity of care at initiation. Attendees identified effective client triage prompting disease packages of clinically justified intensity as one of the primary goals of the first few hospital visits after initiation. Dr Katz provided the framing for the key considerations for these clinical packages, including: a) the types of tests conducted; b) the location and cadre involved in care; and c) the frequency and mode of in-person clinical visits.

a) *What tests would be needed for early clinical visits and why?*

The declining rate of CD4 count testing has been a combined effect of its cost, donor policies and usefulness in predicting early outcomes as compared with viral load testing. Attendees discussed the potential role of CD4 count testing for client triage to identify those at risk of advanced HIV disease. Gaps in evidence on its costs and benefits, as well as the challenges of using CD4 count data at the clinic level, were identified as potential avenues of inquiry.

The higher resistance threshold of dolutegravir (DTG) prompted discussion about the earliest time to conduct viral load monitoring, as well as the frequency of viral load monitoring in the first year after initiation. Most clinician attendees would be comfortable with the first repeat viral load being conducted three months after initiation and once annually thereafter.

b) *What is the recommended mode and location of clinical visits?*

While discussing the value of frequent in-person clinical interactions at initiation, the attendees generally agreed that monthly hospital visits are not indispensable. Innovative approaches of communication, such as



text messages, bots or WhatsApp, can be used to reliably transfer health information between the provider and the client. However, strong health systems, reliable data flow and data security are essential to ensure that providers have timely access to information on any adverse health outcomes at initiation. Client health education on potential side-effects and other notable clinical signs and symptoms are also important for remote communication methods to be effective. The relationship between the provider and client was also discussed, acknowledging that there may be a positive association between relationship with a provider and client outcomes. It should be noted that the provider could be a clinician or a peer provider, but that these relationships may be crucial to client outcomes.

In addition to these considerations for clinical care delivery, the attendees discussed the importance of client choice and shared decision making in ensuring successful early retention. While frequent face-to-face clinical visits may not be essential for high-quality clinical care, some clients may still prefer to see a clinician in person rather than virtually. These concerns should be openly communicated between the client and the provider. Shared decision making facilitates client buy in and is likely to improve long-term retention in care. The complexity of client preference (which depends on available options, client-provider communication and the client's familiarity with the options available) was noted as an additional important consideration. These issues should all be accounted for while thinking about the extent to which client preference for in-person clinical care can (and should) be the driving force of care, especially in low-resource settings.

In addition to the clinical considerations for loss to follow up, attendees discussed the importance of socio-economic determinants of high rates of early loss. Stigma, difficulty in taking time off work and direct costs associated with accessing HIV treatment can all lead to high attrition rates. Currently, most DSD models focus on easing the treatment burden on stable, "successful" clients. Meanwhile, clients who need extra support remain on more intensive models that require frequent clinic visits; a client may not be able to adhere to this due to socio-economic barriers, thus exacerbating the vicious cycle of higher demand/intensity models and lower retention. Therefore, the new DSD models for early retention must ensure that clients who most need care receive it in a way that addresses these barriers.

One caveat with the latter approach is the multitude of DSD models that would inundate the health system if different models were to accommodate the various client cohorts and their diverse health needs and vulnerabilities. Given the budget, human resource training and logistic barriers to developing, successfully implementing and evaluating these models, feasibility and fidelity of implementing a large number of models may not be possible. The importance of a dichotomy between the actual quality of services and the guidelines "on paper" was also pointed out. As previous studies have shown [9], assuming the fidelity and quality of implementation may lead us to overestimate their projected impact on client outcomes. The attendees emphasized the importance of striking the balance between "how fast", "how much" and "how good".



SESSION 4: Engagement: What do people living with HIV need and want in terms of engagement? Can we triage to more or less engagement? (facilitated discussion; discussion chair – Dr Kim Green)

In Session 4, the discussion moved away from clients' clinical needs in the first few months of initiation and towards engagement needs to improve retention. Dr Kim Green provided the framing discussion, which focused on a few key questions: a) how should clinicians approach engagement in care among people without the advanced disease and how would this approach differ by country context? b) could electronic and/or remote communication tools be leveraged to monitor clients? and c) how can we enable habit formation and self-efficacy while putting client preference at the forefront of programming for improved early retention?

Attendees emphasized the importance of the quality of the ART initiation process as a significant determinant of long-term retention in care. It was also emphasized that there is a need to improve understanding of what clients prefer and how to offer services that reflect the largest number of clients so as not to be too complex or expensive. In-person counselling could be used to deliver motivational interviewing, strengthen self-efficacy and elicit clients' own rationale for adhering to treatment, rather than accept that of the provider.

Treatment literacy for self-triage and informed health-seeking behaviour is an important component of high-quality initiation counselling. Health literacy and shared decision making empowers clients and could improve early engagement. Decision-making support tools and checklists can also allow for client triage and help providers identify clients who might be at a higher risk for attrition. Attendees discussed the feasibility of electronic methods of counselling, self-triage and tracking lost clients who are currently being tested in various low-resource settings; however, these innovative methods should undergo further testing to generate a stronger evidence base.

The mode of testing and initiation was also identified as an important determinant of retention and for developing potential avenues of intervention. As reasons and modalities for testing differ among clients, so do their treatment pathways. This could inform programmes that are based on the different barriers clients may face at the testing point.

SESSION 5: Developing an optimal DSD model (facilitated discussion)

The final discussion session focused on developing an optimal DSD model and its evaluation strategy. While cluster randomized controlled trials offer a robust study design, clients are likely to vote with their feet and seek care from a model that is most convenient for them, irrespective of their assigned arm. Quasi-experimental studies using the regression discontinuity design can further generate strong evidence on the impact of implementing novel guidelines for early HIV care.

a) Clinical care needs

Brainstorming of potential DSD models focused on variations in the frequency and type of clinical engagement and different modalities of client-driven engagement in care.



b) *Engagement strategies*

As for engagement strategies, some currently implemented and novel models were discussed. These included peer pairing for newly tested positive clients and how bots and other virtual and digital platforms can facilitate early retention. Randomized controlled trials assessing the impact of giving clients a choice of a return date or the location of their three-month viral load testing (clinic or home visit) were also proposed.

NEXT STEPS

Based on the above discussions, attendees explored a few proposed research questions. While some of these can be answered using existing or currently collected data, some require additional primary data collection:

- What is the minimum amount of treatment literacy that is effective in improving outcomes? How can we deliver it effectively?
- How are clients initiated in care and what impact does this have on their retention?
- What specific clinical services are provided at clinic visits during the first six months and which of these services are essential to outcomes, if any?
- What is the impact of baseline CD4 counts on client outcomes? How can it be used to triage clients?
- How can we explore preferences of people not (yet) in care to inform future models?

To answer these research questions and move the DSD agenda forward for clients recently initiated in care, the following next steps were proposed:

i. *Fill the research gaps using the existing data*

Attendees discussed using existing research databases to understand current gaps in evidence, specifically on the role of the CD4 count testing on client outcomes, the impact of testing and initiation modality on early retention, and different methods of client triage. These sources may include the International epidemiology Database to Evaluate AIDS (IeDEA), Alternative Models of ART Delivery—Optimizing the Benefits (AMBIT) and President’s Emergency Plan for AIDS Relief (PEPFAR) implementing partners and other collaborators. Utilizing existing information is important to understand what data exist and whether they are sufficient to answer the burning research questions. Attendees also proposed developing a research agenda, where the research questions above would be more clearly defined, along with the potential data sources to answer them.

ii. *Summarize the existing data*

A review of published and/or unpublished literature on the impact of interventions aimed at optimizing care in the first six (12) months of treatment initiation would summarize existing evidence and help bridge a



communication gap between researchers, programme implementers and policy makers. Understanding the existing literature could inform future study designs and evaluate the progress to date.

iii. Engage with implementing partners

To understand the current scope, coverage and uptake of service delivery efforts to improve early retention, it is essential to partner with organizations currently implementing DSD models. Understanding the failures and lessons learned from the interventions that have been tried in the field could help predict the logistic, human resource and infrastructural barriers and ensure successful DSD model implementation.

iv. Partner with WHO and policy makers

Generating evidence on improved methods of client triage, including appropriate laboratory testing (CD4 count and/or viral load), as well as more client-centric ways of early treatment delivery, could inform the updated WHO guidance and, subsequently, national policies. Developing an advocacy agenda was further discussed, thus promising pathways for further collaboration with WHO and PEPFAR, as well as other major players, in shaping DSD implementation agenda in high-burden countries.



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Annex I: Attendee list

| Name | Affiliation | Country | Email |
|---------------------|---------------------------------|--------------|--------------------------------------|
| In-person attendees | | | |
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Annex II: Agenda

| Time | Description | Facilitator |
|-------------|---|---|
| 10:00-10:30 | Arrival | |
| 10:30-10:40 | SESSION 1: Welcome and framing | |
| 10:30-10:45 | 1.1 Welcome, framing and objectives | Sydney Rosen (BU, USA) |
| 10:45-11:10 | SESSION 2: Review of data and existing information | |
| 10:45-11:10 | 2.1 Review of data on early retention in HIV care in Africa, country guidelines and interventions | Anna Grimsrud (IAS, South Africa) |
| 11:10-12:30 | SESSION 3: Facilitated discussions | |
| 11:10-11:40 | 3.1 Discussion: Clinical optimization – what is the easiest way to provide high-quality but low-impact clinical care during months 0-6? | Facilitators: James Ayieko (KEMRI, Kenya), Ingrid Katz (Harvard Global Health Institute, USA) |
| 11:40-12:10 | 3.2 Discussion: Engagement optimization – what interactions are needed to ensure that clients have adequate social support during months 0-6? | Solange Baptise (ITPC, South Africa), Izukanji Sikazwe (CIDRZ, Zambia) |
| 12:10-12:30 | SESSION 4: Where to from here? | |
| 12:10-12:30 | 4.1 Discussion: What would a new model of service delivery for months 0-6 look like? | Anna Grimsrud (IAS, South Africa), Sydney Rosen (BU, USA) |
| 12:30-14:00 | Brunch with continued discussion | |