The Case for Differentiation at Re-engagement

Anna Grimsrud, IAS
Biggest “gap” in the cascade is now between the first and second 95

91% of adults living with HIV in eastern and Southern Africa know their HIV status (93% and 88% in women and men, respectively)

But only 75% are on treatment.

HIV testing and treatment cascade, women (aged 15+ years) compared to men (aged 15+ years), eastern and southern Africa, 2021
UNAIDS, 2022.
More clients returning to treatment than initiating for the first time

New initiations compared to return to treatment 2020-2021, City of Johannesburg*

<table>
<thead>
<tr>
<th></th>
<th>Total 2020</th>
<th>Total 2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>New initiations</td>
<td>63,781</td>
<td>52,931</td>
</tr>
<tr>
<td>Return to ART</td>
<td>70,459</td>
<td>81,041</td>
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*Data source: NDOH report for the City of Johannesburg
Majority of those returning have had a short interruption in treatment

- Restarts are people who are more than 90 days late for their missed appointment while returns less than 90 days.
- Many more people less than 3 months late with short or no interruption (sourcing ART elsewhere).

*Restarts may be underestimated as requires assignment by data capturer rather than system automated.*
Reasons for silent transfer, disengagement or changes required to return

a. Reasons for silent transfer (N=289)

- Structural: 138 (48%)
  - Psychosocial: 36 (12%)
    - Clinic: 29 (10%)
- Clinic: 39 (14%)
- Psychosocial: 10 (4%)

b. Reasons for disengagement (N=255)

- Structural: 60 (24%)
  - Psychosocial: 22 (9%)
    - Clinic: 17 (7%)
- Clinic: 27 (11%)
- Psychosocial: 19 (7%)

- Structural: 67 (26%)
  - Psychosocial: 36 (14%)

- Clinic: 66 (26%)

Profiles among those disengaged

- More likely to remain disengaged
  - *including men mobile for work*

- More likely to transfer facilities
  - *except men mobile for work*

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Mody A, Sikombe K, Beres L.K et al. Profiles of HIV Care Disruptions Among Adult Patients Lost to Follow-up in Zambia: A Latent Class Analysis (2021), J Acquir Immune Defic Syndr;86:62–72
What will it take to return?

Public health: priority setting is necessary
Focus facility efforts on *prevailing* barriers

Prioritize psychosocial based barriers

Prioritize clinic-based barriers

Multiple reasons why people interrupt and return to ART

Among 562 people reinitiating in Joburg

Top reasons for interruption:
• Mobility/relocation (30%); distance from clinic (15%) & inability to get time off work (10%)

Reasons for returning:
• It becoming easier to attend the clinic (34%), worrying about not being on ART (19%)

“...I did not stop taking the treatment .. I was home and it was during COVID-19 and there was no transport coming to South ...they were able to do the refill for me, I went back again for the second time until I was able to come to South Africa”

“[...]with the kind of work that I do I travel a lot, I am a truck driver...I went to the nearest clinic to look for the treatment, but they refused to give me because they said that I did not have a transfer letter ”
Client preferences on re-engagement

“A recurring theme in respondents' descriptions of barriers to care was the inflexibility of HIV visit schedules and associated medication refills. Nearly half the patients mentioned these schedules, with experiences ranging from inconvenience to fundamental clashes with family or work commitments”

69 in-depth interviews, 8/31 randomly selected facilities including engaged, disengaged and family of deceased patients

Zanolini, Sikombe, Sikazwe et al, 2018, PLoS Medicine

Topp, Mwamba, Sharma et al, 2018, PLoS One
What does this tell us about service delivery needs after re-engagement?

- More welcoming, non-judgmental providers
  - Need to understand people's preferences, barriers
  - Accepting of transfers
  - Continue tracing
- Quality HIV initiation/re-initiation experience

- Tailor resources to heterogenous disengaged
- Increase visit schedule flexibility to support rather than punish high mobility
- Increase social support opportunities
  - Link to someone living with HIV

People re-engaging in care should be assessed for advanced HIV disease (AHD) and offered the AHD package.
Where does WHO 2021 guidance mention re-engagement?

“HIV programmes should implement interventions to trace people who have disengaged from care and provide support for re-engagement”

○ **New recommendation**

○ **Strong recommendation, low certainty evidence**
National guidelines already include SOPs for tracing
But what do we do once the recipient of care does return to clinic?

• Do we treat all people re-engaging the same or is “differentiation” needed?

• Currently no WHO specific guidance on what to do after re-engagement

• A few countries (South Africa, Zimbabwe) have developed algorithms to try and address this differentiation
How could we adapt our services for recipients of care who have previously been on ART?

» What if health systems barriers contributed to disengagement?

» How can we support retention for these people?
Key considerations for differentiation at re-engagement

Duration not on ART + Clinical Factors
The duration not on ART determines:

- Who to return immediately to DSD model
- Who to return to facility-based follow-up and appropriate refill length (1-3 months) after re-initiation
Clinical considerations

1. Clinical assessment
   - Clinically assessed as unwell or stage 3 or 4
   - Psychosocial challenge
   - Uncontrolled mental health condition

2. When to perform a CD4
   - If clinically unwell
   - Previous documented VL not suppressed
   - If not on ART for 3 months or more

3. Viral load
   - Is there a VL documented within the last 6-12 months
   - Was the last VL suppressed
   - When to perform the first VL after re-initiation

4. Regimen
   - Is client eligible to transition to WHO preferred DTG based regimen
Two countries have used these considerations to develop an algorithm.
Example

Use of the considerations in Zimbabwe algorithm

Is the RoC re-engaging in care?
If the RoC has previously been on ART, explore reasons for stopping.

It is important that healthcare workers adopt a non-judgemental approach for the RoC who is re-engaging in care.

The RoC should be congratulated for re-engaging in care and the reasons for stopping and the barriers faced should be openly discussed.
1. Clinical Assessment

**Person living with HIV re-engaging in care**
**Perform clinical and psychological assessment**
**Establish when ART was last dispensed**

- Clinically well and/or last VL <50 copies/mL in the past 12 months
- People who have interrupted their treatment (non-naive)

**No ART for less than 3 months**
- Counselling to address factors that led to stopping
- Rapid initiation
- Offer entry/re-entry to DSD model
- 6MMD
- VL according to annual schedule

**No ART for more than 3 months**
- Perform CD4
- CD4 >200 copies/mm³ offer AHD package
- Rapid initiation
- Follow-up under standard follow-up schedule
- Enhanced counselling
- Follow-up for priority populations (see Page x)
- VL after 6 months

**Clinically unwell and/or last VL >50 copies/mL in the past 12 months**
**OR**
- Major psychosocial barrier identified

- Treat as clinically indicated
- If VL >1000 copies/mL, perform CD4
- If CD4 <200 copies/mm³ offer AHD package
- Rapid initiation
- Follow-up under standard follow-up schedule
- Enhanced counselling
- Follow-up for priority populations (see Page x)
- VL after 6 months
2. When to perform a CD4

- Clinically well and/or last VL <50 copies/mL in the past 12 months
  - No ART for less than 3 months
    - Counselling to address factors that led to stopping
      Rapid initiation
      - Offer entry/re-entry to DSD model
      - 6MMD
      - VL according to annual schedule
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        - Follow-up for priority populations (see Page x)
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      - If VL >1000 copies/mL, perform CD4
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      - Follow-up under standard follow-up schedule
      - Enhanced counselling
      - Follow-up for priority populations (see Page x)
      - VL after 6 months
- People who have interrupted their treatment (non-naïve)
Person living with HIV re-engaging in care

Perform clinical and psychological assessment
Establish when ART was last dispensed

3. VL

Clinically well and/or last VL <50 copies/mL in the past 12 months

People who have interrupted their treatment (non-naive)

No ART for less than 3 months

No ART for more than 3 months

Counselling to address factors that led to stopping
Rapid initiation

Perform CD4

Offer entry/re-entry to DSD model
6MMD
VL according to annual schedule

CD4 >200 copies/mm³ offer AHD package
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Follow-up under standard follow-up schedule
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Follow-up for priority populations (see Page x)
VL after 6 months

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Treat as clinically indicated
If VL >1000 copies/mL, perform CD4
If CD4 <200 copies/mm³ offer AHD package

Rapid initiation
Follow-up under standard follow-up schedule
Enhanced counselling
Follow-up for priority populations
VL after 6 months
WHO VL algorithm

Fig. 4.2 Treatment monitoring algorithm updated in 2021

Routine viral load monitoring for early detection of treatment failure: obtain and review result by 6 months after ART initiation, 12 months after ART initiation and yearly thereafter.

- Undetectable (≤50 copies/ml)
  - Maintain ARV drug regimen

- Viral load >50 to ≤1000 copies/ml
  - Provide enhanced adherence counselling: repeat viral load testing after 3 months

- Viral load >1000 copies/ml
  - If on NNRTI-based regimen, switch to appropriate regimen

- Undetectable (≤50 copies/ml)
  - Maintain ARV drug regimen

- Viral load >50 to ≤1000 copies/ml
  - Maintain ARV drug regimen, but continue enhanced adherence counselling and repeat viral load testing after 3 months

- Viral load >1000 copies/ml
  - Switch to appropriate regimen

Obtain and review result by 6 months

Often VL taken at 6 months
Rates of suppression with DTG

High suppression rates with DTG at 12 weeks

Can VL be taken earlier e.g. 3 months especially in context of re-initiation

If suppressed enabling earlier entry / re-entry to DSD for clients established on ART

Lockman S et al ; Lancet. 2021 Apr;397
Who eligible for immediate return to DSD

- Person living with HIV re-engaging in care
  - Perform clinical and psychological assessment
  - Establish when ART was last dispensed

  - Clinically well and/or last VL <50 copies/mL in the past 12 months
  - People who have interrupted their treatment (non-naive)

  - No ART for less than 3 months
    - Counselling to address factors that led to stopping
      - Rapid initiation
      - Offer entry/re-entry to DSD model
        - 6MMD
        - VL according to annual schedule

  - No ART for more than 3 months
    - Perform CD4
      - CD4 >200 copies/mm³
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          - follow-up schedule
          - Enhanced counselling
          - Follow-up for priority populations (see Page x)
          - VL after 6 months

  - Clinically unwell and/or last VL >50 copies/mL in the past 12 months
    - OR
    - Major psychosocial barrier identified
      - Treat as clinically indicated
        - If VL >1000 copies/mL, perform CD4
        - If CD4 <200 copies/mm³ offer AHD package
        - Rapid initiation
        - Follow-up under standard
          - follow-up schedule
          - Enhanced counselling
          - Follow-up for priority populations (see Page x)
          - VL after 6 months
Who to return to facility based follow up and appropriate refill length (1-3 months) after re-initiation

Person living with HIV re-engaging in care
Perform clinical and psychological assessment
Establish when ART was last dispensed

Clinically well and/or last VL <50 copies/mL in the past 12 months

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Treat as clinically indicated
If VL >1000 copies/mL, perform CD4
If CD4 <200 copies/mm³ offer AHD package

People who have interrupted their treatment (non-naïve)
Example

Use of the considerations in South Africa algorithm
South Africa: Creating an enabling environment for re-engagement
SOP 9 – Differentiate between those unwell and who DID and DID NOT interrupt treatment

Time not on ART (true interruption or not)

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No interruption

- Suppressed VL controlled HbA1c in last 6 months or BP <140/90
  1. Offer enrolment/re-enrolment in RPCs available at your facility
  2. Immediately rescript according to patient choice

- No recent VL or HbA1c
  1. Immediately rescript
  2. Take VL or HbA1c if due/available

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Interruption

- Previous suppressed VL or controlled HbA1c or BP <140/90 and no side effects
  1. Immediately restart treatment on same regimen
  2. Offer adherence counselling if wanted by patient (FPC session 3+4 combined)
  3. Explain next assessment in 3 months + offer multi-month treatment supply until next assessment + rescript accordingly
  4. Explain if next assessment is normal, will be able to offer RPCs options for easier treatment collection

- VL >50 copies/ml, HbA1c >7% or BP >140/90 or side effects or ill
  1. Follow clinical guidelines management
  2. Refer for EAC session 1 (unless clinic not concerned about adherence)
  3. Explain next assessment in 3 months
  4. Explain after next assessment: IF NORMAL can offer RPCs enrolment
     IF ABNORMAL: will consider treatment regimen switch and refer for EAC session 2

RPCs = Repeat prescription collection strategies (EMOC)
SOP 9 – Differentiate between those unwell and who DID and DID NOT interrupt treatment

Clinical factors

No interruption

- Suppressed VL, controlled HbA1c in last 6 months or BP <140/90
  1. Offer enrolment/re-enrolment in RPCs available at your facility
  2. Immediately rescript according to patient choice

- No recent VL or HbA1c
  1. Immediately rescript
  2. Take VL or HbA1c if due/average

Interruption

- Previous suppressed VL or controlled HbA1c or BP <140/90 and no side effects
  1. Immediately restart treatment on same regimen
  2. Offer adherence counselling if needed by patient (FTC session 3+4 combined)
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  IF ABNORMAL: will consider treatment regimen switch and refer for EAC session 2

RPCs = Repeat prescription collection strategies (EMO)
SOP 9 – Differentiate between those unwell and who DID and DID NOT interrupt treatment

Accelerated access to RPCs (DSD) if no interruption

- Offer enrolment/re-enrolment in RPCs available at your facility
- Immediately rescript according to patient choice

Accelerated access to 3MMD until VL assessment

1. Immediately rescript
2. Take VL or HbA1c if due/amenable

Suppressed VL, controlled HbA1c in last 6 months or BP <140/90

No recent VL or HbA1c

Accelerated access to 3MMD until VL assessment

1. Immediately restart treatment on same regimen
2. Offer adherence counselling if wanted by patient (FTC session 3+4 combined)
3. Explain next assessment in 3 months + offer multi-month treatment supply until next assessment + rescript accordingly
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4. Explain after next assessment: IF NORMAL: can offer RPC enrolment
   IF ABNORMAL: will consider treatment regimen switch and refer for EAC session 2

Interruption

Clinical concerns

VL >50 copies/ml, HbA1c >7% or BP >140/90 or side effects or ill

Early VL assessment (following WHO elevated VL algorithm)
- If no interruption and overdue for VL same day as re-engagement
- If interrupted ART – 3 months after re-engagement

Updated in 2020
Limited uptake and implementation of this new SOP
From policy to implementation – City of Johannesburg SOP 9 project

1st objective
• Feasibility & acceptability of SOP in Johannesburg/ similar setting

2nd objectives
• Fidelity of SOP implementation
• Quantify re-engaging clients
• Describe clinical picture of re-engaging clients
• Measure retention & viral suppression in re-engaging clients
Job aides for each re-engagement stakeholder at the facility
SOP 9 RE-ENGAGEMENT THREE KEY PRINCIPLES

1. For returning patients, the first return visit experience is critical
   - Welcoming, supportive and empathetic
   - Clear facility visit flow focused on a positive patient experience

2. Not all patients late for scheduled appointments are re-engaging patients
   - Only if they are >14 days after scheduled appointment OR silent transfer from another facility

3. All re-engaging patients DO NOT have the same service delivery needs
   - Easier access to treatment
   - Psychosocial support
   - Clinical management

Always be kind
Who is a re-engaging patient?

Assess all patients returning after scheduled appointment date

- \( \leq 14 \text{ days} \)
  - 14 days or less after scheduled appointment
  - Routine care patient
  - Patient receives care according to scheduled appointment plan

- \( >14 \text{ days} \)
  - More than 14 days after scheduled appointment or silent transfer
  - RE-ENGAGING (RE) patient
  - AGL SOP 9: Re-engagement
    - Clinical assessment + differentiated follow-up plan
Details clinical assessment approach for a re-engaging patient

STEP 1: Conduct clinical assessment

Step 1: Create safe supportive space for positive patient interaction
“Good to see you today” “I hope you didn’t have to wait long. This is a supportive space for your return to care”

Step 2: Check for any clinical concerns
“How are you feeling today?” “Any worrying illness or symptoms recently?”
Identify patient clinically unwell or with any red flag symptoms requiring clinical action

Step 3: Check last scheduled visit and discuss reasons for missing visit
“When was your last scheduled visit?”
“Can you tell me what made it difficult for you to attend?”
Document last visit date on SOP RE-ENGAGE form
Document any critical reasons for missing scheduled visit relevant to assessment

Step 4: Discuss any concerns about returning to care
“Did you have any worries about coming back to us?”
“Do you have any concerns about being able to continue your care and treatment at this facility”
“Anything else you are worried about”

Step 5: Check previous history of disengagements using an open, non-judgemental approach
“Have you been off treatment before?”
“Tell me about these times and any worries you had at the time”
Check file for previous history of disengagement

Step 6: Check VL history
Review most recent VL result
Review previous VL result history
Review NCD history (if applicable)
Document on SOP RE-ENGAGE form

Step 7: Ask patient self-report on treatment interruption
“Did you have enough treatment?”
If no - “When did you run out”
Document on SOP 9 RE-ENGAGE form

Step 8: Decide re-engagement clinical assessment outcome
Make your assessment
1. Clinically unwell:
   - Yes or No
2. Likely interruption took place:
   - Yes or No
Determine SOP 9 follow-up plan
- Interruption unlikely + VL≤60
- Interruption unlikely + no VL<60
- Interruption + well (no clinical concerns): with VL<60 VL
- clinical concerns: uncontrolled NCD/VL>60

Document on SOP 9 RE-ENGAGE form
Follow SOP 9 colour coded follow-up plan

No judgement zone
Differentiates follow-up based on each patient’s needs and preferences

Step 5: Determine and provide SOP 9 colour-coded follow-up plan

- Interruption unlikely + VLS within 6m
  1. TLD offer
  2. Explain RPCs + offer
  3. Decanting/CCMDD 6m script (2x3 month refills)

- Interruption unlikely + no VL within 6m
  1. Take VL
  2. Explain visit schedule and RPCs assessment at next visit
  3. Script for 1 month

- Interrupted treatment + well (no clinical concerns)
  1. CD4 (AHI identification)
  2. Explain visit schedule + timing of RPCs assessment
  3. If VL within 6m, TLD offer
  4. Script for 3 month refill

- Clinical concerns or uncontrolled NCD or VL>50
  1. Manage clinically - follow ART clinical guidelines
  2. CD4 (AHI identification)
  3. Explain visit schedule + timing of RPCs assessment
  4. Script for 1 month

IAS

All re-engaging patients DO NOT have the same service delivery needs

Easier access to treatment
Psychosocial support
Clinical management
Sets out procedural steps at re-engagement visit for each of the four groups

**GOLD**: Interrupted treatment + well (no clinical concerns) with VL suppression result or no VL result within 6 months

**Re-engagement visit procedure**

**Step 1: Take CD4 count if interrupted ART>90 days**
- Take CD4 count to identify AHF for AHF package provision
- Unless CD4<200 in last 6 months, then switch to SOP 9 (new follow-up plan)
- IF CRAG result received by facility urgently recall

**Step 2: Assess for TPT**
- If patient has not completed TPT, assess for and initiate TPT
- Explain visit schedule (see below) - return in 3 months, then 1 month later for VL result and if VL, will offer IPCs options.

**Step 3: Restart ART immediately**
- If NO VL within 6 months: restart same ART regimen for THREE months ART and TPT refill
- If VL within 6 months: offer TLD and script for THREE months ART and TPT refill
- Record on SOP 9 form any reason 3-month ART refill could not be scripted

**Step 4: Explain important to see counsellor and what counsellor will provide**
- Where clinician is of the view that patient will benefit from counselling review and VL education: explain importance of seeing counsellor
- At facility with case management: explain counsellor will also offer care management support
- Refer to counsellor for Fast Track initiation and Counselling combined session 3 and 4 combined and low risk CM offer

**Be understanding**
And the follow-up visit schedule

**Visit schedule**

**Re-engagement visit**
See detailed steps above

**RE month 3 visit**
- If CD4<200 and not already recalled for action – provide ART package and switch to SOP 9 Brown follow-up plan including following ART guidelines
- Explain VL again and RPCs options
- Take VL
- 1 month script + refill

**RE month 4 visit**
- Check and communicate VL result

If VL<50 copies/ml:
- Switch to SOP 9 Brown follow-up plan including following ART guidelines

If VLS AND well:
- TLD and RPCs offer
- If RPCs offer accepted: 6-month script (Decanting) CCMDD with THREE months ART (and TPT) refills
- Stop low risk case management

**Facilities with case management (CM) only**
- Provide low risk CM support if patient accepted

Think POSITIVE

Talk POSITIVE

Feel POSITIVE
Key messages

- More of the people we are initiating on ART have been on ART before

- No current WHO guidance on the “how to” support people after they re-engage (including timing of VL)

- Re-engagement pathways should not be one-size-fits all

- Re-engagement pathways should not become a barrier to retention and should adapt to address client access challenges

- When designing a re-engagement pathway
  - Consider the duration the client has been off ART
  - Consider the clinical considerations