Option B+ Beyond ART: Maternal Engagement in Care

Landon Myer

8th International Workshop on HIV Pediatrics

16 July 2016
Outline

1. Background: where are we with Option B+

2. Key concepts: thinking about maternal engagement in ART services during pregnancy & postpartum

3. How much disengagement? Who & where?

4. Drivers of disengagement & interventions to address

5. Charting a way forward: where are we headed?
1. Background
Nationally recommended PMTCT option as per MoH guidelines or directive in low- and middle-income countries (situation as of beginning 2016)

“Treat All” for pregnant and BF women adopted in 95% of 144 LMIC in 2016
Dramatic increases in ART coverage in pregnancy with Option B+

Total n=2315

<table>
<thead>
<tr>
<th></th>
<th>Option A</th>
<th>Option B+</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever starting ART</td>
<td>35% (440)</td>
<td>94% (979)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CD4 &lt;350 starting ART</td>
<td>66% (263)</td>
<td>94% (351)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Start ART 1st ANC visit</td>
<td>2% (18)</td>
<td>86% (896)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Gupta CROI 2016; Abrams CROI 2016

Malawi national programme evaluation, 2011-2015

Swaziland stepped-wedge evaluation, 2013-2015
ART initiation simplifies & delays to initiation decrease

**Graphs and Data:**

- **Malawi**
- **Zimbabwe**
- **South Africa**

- Proportion of patients starting ART over time from enrollment to ART initiation.
- Timing of ART initiation from HIV diagnosis.
- Probability of ART initiation before delivery.
- Proportion of patients starting ART over time from HIV testing to ART initiation.

**References:**

Kim *JAIDS* 2015
Tenthani *AIDS* 2015
Dzangare *TM&IH* 2016
Myer *JAIDS* 2015
Option B+
No turning back
Benefits of Option B+ require high levels of adherence & retention

Most models assume at least 80-90% of mothers initiating ART will be:

- retained in care
- adherent to ART
- virologically suppressed

Ishikawa *PLoS ONE* 2014
Khanna *PLoS ONE* 2015
Van Deusen *BMC ID* 2015
Gopalappa *AIDS* 2014
Binghwayo *PloS ONE* 2013
Ciaranello *CID* 2013
2. Key concepts
(i) Constructs

Spectrum of behaviours
Eg, Pill-taking
Visit attendance
Care interface

Separate but correlated manifestations of same underlying phenomena
Non-adherence to treatment predicts discontinuation
(ii) Major life events

**Physiologic**  **Psychological**  **Social**  **Economic**

- Pregnancy
- Delivery
- 6 weeks
- 12 months
- 18 months
- Years on ART
- Repeat pregnancies
- Breastfeeding
(iii) Health systems complexity

- Antenatal care service
- Obstetric / delivery service
- General adult ART service
- EID / EPI
- ‘Well baby’ care
- Differentiated models of care
3. Evidence
Lower retention with B+ compared with ART for eligible adults, Malawi

Women initiating ART in pregnancy ~5 times more likely to have **no follow-up** and 1.6 times more likely to be **lost to follow-up** during 1st year on ART vs non-pregnant adults

[Diagram showing cumulative incidence of ART retention]
Option B+ retention cascade
186 health facilities, Uganda, 2014

- 75% of baseline
- 68% of second visit
- 65% of third visit
- 64% of fourth visit
- 63% of fifth visit
- 62% of sixth visit
- 58% of seventh visit

25% of women never came back after 1st visit

Baseline (M0) | M1  | M2  | M3  | M4  | M5  | M6  | M7  |
---|---|---|---|---|---|---|---|
1,868 | 1,404 | 1,218 | 1,177 | 1,097 | 1,061 | 1,026 | 936 |
Antepartum and Postpartum Retention: Option A vs Option B+, Swaziland

<table>
<thead>
<tr>
<th></th>
<th>Option A N=1272</th>
<th>Option B+ N=1043</th>
<th>aRR* (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antenatal Retention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All HIV+ women</td>
<td>54% (692)</td>
<td>68% (713)</td>
<td>1.23 (1.09-1.37)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Women on ART</td>
<td>82% (313)</td>
<td>71% (693)</td>
<td>0.71 (0.58-0.89)</td>
<td>0.002</td>
</tr>
<tr>
<td><strong>Postnatal Retention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All HIV+ women</td>
<td>26% (326)</td>
<td>50% (522)</td>
<td>1.56 (1.15-1.32)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Women on ART</td>
<td>65% (284)</td>
<td>53% (521)</td>
<td>0.76 (0.64-0.91)</td>
<td>0.003</td>
</tr>
</tbody>
</table>

Little variation in associations by site or month of observation

*Adjusted risk ratios (aRR) adjusted for age, gestation at 1st ANC visit, known HIV status

Abrams CROI 2016
Postpartum viral rebound

• Routine care cohort (n=620) initiating ART in Cape Town (median gestation at initiation, 20w)
• 91% reach VL≤1000 copies/mL by delivery
• 30% rebound to VL >1000 by 12 months postpartum

CROI 2016
HIV Med, in press
A global phenomenon?

Postnatal care ‘cascade’: Philadelphia, USA, 2005-2011

31% of women receiving HIV care in pregnancy virally suppressed @ 1 year postpartum

UK & Ireland cohort, 2006-2011

~42% of women suppressed at delivery experience viral rebound @ 1 year postpartum

Adams CID 2015; Huntington AIDS 2016
Nationally recommended PMTCT option as per MoH guidelines or directive in low- and middle-income countries (situation as of beginning 2016)

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines.
Countries with documented challenges in engagement of pregnant & postpartum women on ART, 2008-2016

Countries with at least one published/presented study
4. Drivers & interventions
4. Drivers & interventions

WARNING
4. Drivers & interventions

WARNING

The absence of data available on these topics may cause discomfort.
Understanding drivers of disengagement

Clinical & biological

Socio-demographic & psychological

Health services & systems
Clinical & biological factors

Do side effects (SE) contribute to disengagement?

Burden of symptoms/SE in HIV+ pregnant women on universal ART:
- >90% for most SE classes
- Difficult to distinguish aetiology
- Total SE burden associated with non-adherence

Qualitative evidence: SE cited as one reason for discontinuation (Malawi)
Sociodemographic & psychological factors

“Risk factor” data heterogeneous & contextual

Some consistency: Younger, recent HIV diagnosis, cost/transport, unintended pregnancy

Mixed evidence: ART “readiness”? Partner involvement? Disclosure? Depression/mental illness?
Health services & health factors

- Structure of health services shapes ability of patients to engage in care
- Women may be particularly vulnerable in navigating different health services during pregnancy & postpartum
Impact of model of care on retention

• District-level health facility survey & cohort analysis, Malawi

• 4 distinct models of care identified
  – Site of antenatal ART
  – Site of postnatal ART & timing of transfer

• 10-20% of women defaulted Option B+ by 6 months postpartum
  – Strong associations with model of care
  – Retention lowest in facilities with ART initiation in ANC, then referral for separate follow-up
What do we know about the drivers of disengagement?

Insights scattered
Gaps loom large
Factors diverse across contexts
  – *Policies are universal*
  – *People are not*

No single universal driver to target for intervention
Interventions to support adherence & retention

1. Clinical & biological
2. Socio-demographic & psychological
3. Health services & systems
Many ideas to promote engagement

- Enhanced patient education & counselling?
- Ongoing engagement of women in MCH setting?
- Enhanced peer support on ART?
- Lay health worker home support?
- Increased male partner involvement?
- Text message reminders / mHealth?
- Directly observed therapy (DOT)?
- Community-based ‘adherence clubs’?
- Conditional cash transfers?
- Case manager systems?

Exciting implementation science

Few data from “Option B+” era
Duration & effect sizes are modest
Most interventions target a single, specific issue

→ Little multicomponent thinking

References:
- Fatti *AIDS Care* 2016
- Foster *JAIDS* 2014
- Mwapasa *JAIDS* 2014
- Schwartz *MCHJ* 2015
- Yotebieng *Lancet HIV* 2015

- Zerbe *IAC* 2016
- Herlihy *JAIDS* 2015
- Rosenberg *Lancet HIV* 2015
- Aliyu *Lancet HIV* 2016
- Fayorsey *CROI* 2016
- Nachega *Pat Pref Adh* 2016
Health Services & Health Systems: *How* to provide universal ART

Understanding models of care for delivering universal ART during pregnancy & postpartum

– What features of services can **address women’s needs & promote adherence/retention**?

– How to deliver **ART at scale & with efficiency** in severely resource-limited health systems?

Tailoring services to women’s needs

Health systems constraints
5. Where are we headed?
5. Where are we headed?

Hear no Evil
See no Evil
Speak no Evil
Is this unique to HIV / ART?

A Pregnancy and Postpartum Lifestyle Intervention in Women With Gestational Diabetes Mellitus Reduces Diabetes Risk Factors

A feasibility randomized control trial

Reciprocal Peer Support for Post-partum Patients with Diabetes: A Needs Assessment for the Diabetes Buddy Program

Effects of telephone follow-up on blood glucose levels and post-partum screening in mothers with Gestational Diabetes Mellitus

The impact of switching to the one-step method for GDM diagnosis on the rates of postpartum screening attendance and glucose disorder in women with prior GDM. The San Carlos Gestational Study

Postpartum Glucose Testing in Women With Gestational Diabetes Mellitus and Factors Affecting Testing Non-compliance from Four Tertiary Centers in Korea
Retention research agenda

• **Individual-level questions**
  – Why do some patients disengage from care, and others are retained over the long-term?
  – What groups of factors can we promote through multicomponent intervention packages?

• **Health services & systems questions**
  – What approaches to delivering care optimise health outcomes with lowest cost and greatest coverage?
    • Linking maternal & child health over long-term?
  – Balance individual vs public health approaches
Are we missing advocacy?
Acknowledgements

Elaine Abrams,
Kirsty Brittain
Nei-Yuan Hsiao
Victoria Iyun
Nontokozo Langwenya
James McIntyre
Lynne Mofenson
Jasantha Odayar
Tamsin Phillips
Steve Reynolds
Agnes Ronan

MCH-ART study team

NICHID: R01HD074558
MRC: MR/M007464/1