Systems Analysis & Improvement: Simplifying Complexity to Optimize Performance

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Outline

- Systems and their application to HIV prevention & care
- Service gaps & need for systems interventions
- The SAIA & SAIA-SCALE trials for PMTCT
Taking a Systems Perspective

*Systems*: A regularly interacting or interdependent group of items forming a unified whole

*Systems engineering*: The disciplined process of involving determination of needs, exploration of concepts for systems to satisfy those needs, concept selection, design, and specification setting
Delivery systems to close the know-do gap

Discovery ($T_0$-$T_1$)  
Development ($T_2$)  
Delivery ($T_3$)  
Improved Health Outcomes ($T_4$)

“Every process is perfectly designed to give you exactly the outcome you get.” – Don Berwick, IHI
pMTCT Cascade

Antenatal care
- ANC attendance
- HIV counseling & testing
- CD4 testing
- Provision of ARV prophylaxis/cART to mother

Birth
- Safe delivery
- Provision of prophylaxis to infant
- Education on safe infant feeding and care

Postpartum care
- Safe infant feeding
- Infant follow up care and HIV testing
- Family planning
- Linkages to long-term HIV care and treatment
pMTCT Cascade (data from Mozambique)

**Antenatal care**
- ANC attendance
- HIV counseling & testing
- CD4 testing
- Provision of ARV prophylaxis/cART to mother

| ANC: 96% |
| CT: 87% |
| Women receiving ARVs: 51% |

**Birth**
- Safe delivery
- Provision of prophylaxis to infant
- Education on safe infant feeding and care

| Infants receiving ARVs: 42% |

**Postpartum care**
- Safe infant feeding
- Infant follow up care and HIV testing
- Family planning
- Linkages to long-term HIV care and treatment

| MTCT: 28% |

CD4 assessed ≤30 days of enrolment for adults diagnosed in:

- VCT (77.4%)
- pMTCT (75.2%)
- Youth VCT (73.3%)

Initiated ART ≤90 days of eligibility for adults diagnosed in:

- VCT (32.0%) vs. pMTCT (19.8%); p=0.01


RR=0.84 (0.7-1.0); p=0.08

RR=0.84 (0.7-1.0); p<0.001
Evolution of WHO PMTCT ARV Recommendations

<table>
<thead>
<tr>
<th>Year</th>
<th>PMTCT</th>
<th>ART</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>4 weeks AZT; AZT+3TC, or SD NVP</td>
<td>No recommendation</td>
</tr>
<tr>
<td>2004</td>
<td>AZT from 28 wks + SD NVP</td>
<td>CD4 &lt;200</td>
</tr>
<tr>
<td>2006</td>
<td>AZT from 28wks + sdNVP +AZT/3TC 7days</td>
<td>CD4 &lt;200</td>
</tr>
<tr>
<td>2010</td>
<td>Option A (AZT +infant NVP) Option B (triple ARVs)</td>
<td>CD4 &lt;350</td>
</tr>
<tr>
<td></td>
<td>Option B or B+ Moving to ART for all PW/BF</td>
<td>CD4 &lt;500</td>
</tr>
</tbody>
</table>

Move towards: more effective ARV drugs, extending coverage throughout MTCT risk period, and ART for the mother’s health
PMTCT Guideline Policy (2015)

% of eligible pregnant women, adults and children (0-14 years) receiving ART in 21 Global Plan priority countries, 2009-2014

Source: Courtesy of Karusa Kiragu, UNAIDS
Concerns about Option B+ Implementation

• Ongoing cohort of 1,536 women enrolled from Option B+ services at ANC in Sofala, Mozambique (R01HD075057 and the Doris Duke Charitable Foundation)

• 44% of women who initiated Option B+ lost to follow-up by 10 weeks postpartum

• 65% of those with viral load measured (n=317) failed to suppress viral load by delivery

Ásbjörnsdóttir K, et al. Low retention in Option B+ care among women in Mozambique. CFAR 2016 Symposium on Women and HIV. Birmingham, AL.
Systems Analysis & Improvement to Optimize pMTCT: The SAIA Trial (R01HD075057)

- Facility-level RCT in 18 intervention/18 control facilities (6/6 in Kenya, Mozambique and Côte d’Ivoire)
- 9 months of intervention implementation (9 analysis & improvement cycles)
- Outcome measures chosen to be sensitive to pMTCT cascade improvements
SAIA Intervention

Step 1: Describe pMTCT performance and identify priority areas for improvement

- pMTCT Cascade Analysis Tool (PCAT) to provide a ‘systems view’ of the sequential, linked pMTCT cascade steps

Step 2: Process mapping to identify modifiable facility-level bottlenecks

Tica Rural Health Center pMTCT Flow

1. **Day 1**
   - Preg ♀ arrives for 1st ANC visit with MCH nurse
   - HIV Rapid Test
   - Reception CHW opens chart
   - MCH community health worker (CHW) accompanies HIV+ ♀ to reception

2. **Day 1**
   - HIV+ ♀ to reception
   - CD4 Nurse
     - Blood draw for CD4 count (if initial visit is on Monday, Tuesday or Wednesday)
     - Triage for immediate care
     - Determines WHO clinical stage
   - Returns to nurse for CD4 results
   - CD4 nurse prescribes CTZ and orders blood tests (biochemistry, haematology)

3. **Following week**
   - CD4 blood draw (if initial visit was Thursday or Friday)
   - ART Committee (at Nhamatanda Rural Hospital) to determine eligibility
     - ART eligible?
       - yes
         - ART starts 3 phases of ART adherence counseling with a social worker (total 1-3 weeks).
       - no
         - ≥ 250
           - ≥ Day 28
             - Evaluation with physician’s asst (Tuesdays)
             - Phase 1
           - ≤ 250
             - ≤ Day 28
               - Evaluation with physician’s asst (Tuesdays)
               - Phase 2
             - no
               - ≥ Day 28
                 - Evaluation with physician’s asst (Tuesdays)
                 - Phase 3
             - ≤ Day 28
               - Evaluation with physician’s asst (Tuesdays)
               - Phase 2

4. **Stage**
   - CD4 nurse prescribes CTZ and orders blood tests (biochemistry, haematology)

5. **Postpartum**
   - Preg ♀ takes NVP
   - Newborn gets: sdNVP & AZT
   - Contraction start
   - Labor starts at home
     - Contractions start
     - Female takes NVP
     - Duovir (AZT+3TC)
   - At Hospital Maternity
     - During labor
     - Duovir (AZT+3TC)
   - In The Home
     - For one week postpartum
     - AZT

6. **Newborn**
   - Postpartum
     - Drops off ART card at pharmacy
     - Newborn gets: sdNVP & AZT
     - Postpartum
     - Picks up ART at pharmacy
     - 2-3 days later

7. **Evaluation with physician’s asst**
   - Phase 1
     - Phase 2
     - Phase 3
   - Evaluation with physician’s asst (Tuesdays)
   - DOT for the first 14 days of ART
   - 2-3 days later
   - Drops off ART card at pharmacy
   - Newborn gets: sdNVP & AZT
   - Postpartum
   - Picks up ART at pharmacy
   - 2-3 days later

8. **Social worker gives ♀ the ART (triple therapy) prescription**
   - ~1-4 weeks after dx
   - Social worker gives ♀ the ART (triple therapy) prescription
   - ~1-4 weeks after dx
   - Evaluation with physician’s asst (Tuesdays)
   - Phase 1
   - Phase 2
   - Phase 3
Potential Areas For Improvement

Tica Rural Health Center pMTCT Flow

Day 1
- Preg ♀ arrives for 1st ANC visit with MCH nurse
- HIV Rapid Test
- MCH community health worker (CHW) accompanies HIV+ ♀ to reception
- Reception CHW opens chart
  - HIV+ ♀ to reception
  - Day 1 MCH community health worker (CHW) accompanies HIV+ ♀ to reception

Day 1
- CD4 Nurse
  - Blood draw for CD4 count (if initial visit is on Monday, Tuesday or Wednesday)
  - Triage for immediate care
  - Determines WHO clinical stage

≥ Day 28
CD4 Nurse prescribes CTZ and orders blood tests (biochemistry, haematology)

≤ 250
CD4 Nurse

I-II
Stage

III-IV
Stage

≥ Day 28
returns to nurse for CD4 results

Day 1

♀ receives AZT & sdNVP

At 28 weeks
♀ receives AZT & sdNVP

♀ takes NVP

Labor Starts At Home
- Contraction start
- At Hospital Maternity
- During labor
- Duovir (AZT+3TC)
- In The Home
  - For one week postpartum
  - AZT

Postpartum
Newborn gets: sdNVP & AZT

Postpartum
Newborn gets: sdNVP & AZT

♀ takes NVP

At Hospital Maternity
- Duovir (AZT+3TC)
- In The Home
  - For one week postpartum
  - AZT

Picks up ART at pharmacy

♀ starts 3 phases of ART adherence counseling with a social worker (total 1-3 weeks).

2-3 days later
♀ drops off ART card at pharmacy

< 14 weeks after dx
♀ picks up ART at pharmacy

< 14 weeks after dx
♀ drops off ART card at pharmacy

≤ 250
CD4 Nurse

♀ starts 3 phases of ART adherence counseling with a social worker (total 1-3 weeks).

Evaluation with physician’s asst (Tuesdays)

Phase 3 Phase 2 Phase 1

♀ picks up ART at pharmacy

♀ drops off ART card at pharmacy

< 14 weeks after dx
♀ picks up ART at pharmacy

< 14 weeks after dx
♀ drops off ART card at pharmacy

≤ 250
CD4 Nurse

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Phase 3 Phase 2 Phase 1

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♀ drops off ART card at pharmacy

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♀ picks up ART at pharmacy

< 14 weeks after dx
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Evaluation with physician’s asst (Tuesdays)

Phase 3 Phase 2 Phase 1

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♀ drops off ART card at pharmacy

< 14 weeks after dx
♀ picks up ART at pharmacy

< 14 weeks after dx
♀ drops off ART card at pharmacy
Step 3-5: Continuous Quality Improvement

– Define & implement facility-specific workflow adaptations
– Monitor changes in performance; initiate additional iterations
– Repeat analysis and improvement cycle
## Results: ARV coverage

Mean (95% CI) change in ARV coverage among HIV-positive women from baseline to endline periods, by study arm.

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Mean change</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>17*</td>
<td>4.1%</td>
<td>-12.6%</td>
</tr>
<tr>
<td>Intervention</td>
<td>17*</td>
<td>13.3%</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

Kenya: p <0.02


* 2 sites in Côte d’Ivoire (1 intervention, 1 control) drop out of the analysis as this outcome was 0/0 for all three endline months. Abbreviations: ARV=antiretroviral; CI=confidence interval.
Results: HIV-exposed Infant Screening

Mean (95% CI) change in HIV PCR screening coverage among HIV-exposed infants by 2 months of age from baseline to endline periods, by study arm.

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Mean change</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>17*</td>
<td>0.7%</td>
<td>-12.9%</td>
</tr>
<tr>
<td>Intervention</td>
<td>17**</td>
<td>11.6%</td>
<td>-2.6%</td>
</tr>
</tbody>
</table>

Mozambique: p < 0.04

* 1 site did not offer infant testing until July 2014, so baseline estimates cannot be calculated. ** 1 site had 0 infants who were eligible for HEI during both the baseline and endline periods, so outcome 3 could not be calculated. Abbreviations: CI=confidence interval; HEI = HIV-exposed infant.
SAIA-SCALE

- Goal: develop a dissemination and implementation model for the SAIA intervention (SAIA-SCALE) that is delivered by district maternal and child health (MCH) supervisors (rather than research nurses), to serve as a foundation for further scale-up
### SAIA-SCALE

<table>
<thead>
<tr>
<th>District</th>
<th>Pop (2015)&lt;sup&gt;1&lt;/sup&gt;</th>
<th>MOH Clinics</th>
<th>Clinics with Option B+</th>
<th>1st ANC visits&lt;sup&gt;2&lt;/sup&gt;</th>
<th>HIV+ in ANC&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Clinics</td>
<td>Clinics with B+</td>
<td>N</td>
<td>N (%)</td>
</tr>
<tr>
<td>Barue</td>
<td>224,884</td>
<td>14</td>
<td>7 (50)</td>
<td>10,707</td>
<td>6.5%</td>
</tr>
<tr>
<td>Chimoio City</td>
<td>314,751</td>
<td>7</td>
<td>7 (100)</td>
<td>23,543</td>
<td>13.8%</td>
</tr>
<tr>
<td>Gondola</td>
<td>255,431</td>
<td>8</td>
<td>5 (63)</td>
<td>16,842</td>
<td>9.3%</td>
</tr>
<tr>
<td>Guro</td>
<td>93,184</td>
<td>9</td>
<td>7 (78)</td>
<td>5,599</td>
<td>6.0%</td>
</tr>
<tr>
<td>Macate</td>
<td>85,144</td>
<td>4</td>
<td>3 (75)</td>
<td>5,625</td>
<td>8.6%</td>
</tr>
<tr>
<td>Manica</td>
<td>197,315</td>
<td>16</td>
<td>11 (69)</td>
<td>13,583</td>
<td>11.8%</td>
</tr>
<tr>
<td>Machaze</td>
<td>134,515</td>
<td>10</td>
<td>7 (70)</td>
<td>6,813</td>
<td>11.9%</td>
</tr>
<tr>
<td>Macossa</td>
<td>45,570</td>
<td>5</td>
<td>3 (60)</td>
<td>2,159</td>
<td>5.1%</td>
</tr>
<tr>
<td>Mossurize</td>
<td>278,133</td>
<td>11</td>
<td>9 (82)</td>
<td>13,716</td>
<td>7.5%</td>
</tr>
<tr>
<td>Sussundenga</td>
<td>165,616</td>
<td>13</td>
<td>7 (54)</td>
<td>11,448</td>
<td>7.8%</td>
</tr>
<tr>
<td>Tambara</td>
<td>54,416</td>
<td>7</td>
<td>4 (57)</td>
<td>4,399</td>
<td>5.4%</td>
</tr>
<tr>
<td>Vanduzi</td>
<td>84,563</td>
<td>7</td>
<td>3 (43)</td>
<td>5,821</td>
<td>10.9%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,933,522</strong></td>
<td><strong>111</strong></td>
<td><strong>73 (66)</strong></td>
<td><strong>120,255</strong></td>
<td><strong>9.2%</strong></td>
</tr>
</tbody>
</table>

<sup>1</sup>projections from 2007 census; <sup>2</sup>2015 annual estimates from routine health management information system
## RE-AIM Model

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Definition (Proportions)</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reach</td>
<td>Target population participating</td>
<td>Individual</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>Positive minus negative outcomes</td>
<td>Individual</td>
</tr>
<tr>
<td>Adoption</td>
<td>Settings planning to implement</td>
<td>Organization</td>
</tr>
<tr>
<td>Implementation</td>
<td>In place as intended in “real world”</td>
<td>Organization</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Program sustained over time</td>
<td>Individual &amp; Organization</td>
</tr>
</tbody>
</table>

Impact = $R \times E \times A \times I \times M$

Summary

• To close performance gaps in reaching vulnerable populations:
  – Systems-oriented interventions are needed to capture complexity
  – Interventions should be flexible to context and scalable as program implementation is scaled across broad facility networks
Acknowledgements (SAIA Trial):

• Network of AIDS Researchers of East and Southern Africa
  – Ruth Nduati
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  – Amelia Cruz

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