Use of point-of-care viral load among critical populations

IDC
September 2019
HIV and hepatitis laboratory structures have typically been very centralized: molecular and immunological assays requiring significant infrastructure.

High quality, robust new technologies are allowing for greater decentralization and testing closer to the patient.
Impact of POC testing – on identification and treatment initiation

POC CD4 for treatment initiation

HIV testing to CD4 testing
CD4 testing to receipt of result
CD4 testing to ART initiation, of eligible
HIV testing to ART initiation
Retained pre-CD4 testing
Retained pre-ART initiation, of eligible

Risk ratio (95% CI)

1.21 (1.15-1.27)
1.07 (1.04-1.09)
1.16 (1.03-1.31)
1.49 (1.12-1.98)
1.58 (1.35-1.85)
1.21 (1.04-1.40)

POC EID

<table>
<thead>
<tr>
<th>Country</th>
<th>Setting</th>
<th>Device/Sample</th>
<th># of sites</th>
<th>n</th>
<th>% result return to caregiver</th>
<th>TAT result return</th>
<th>% ART initiation</th>
<th>TAT ART Initiation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>≤ 30# days</td>
<td>Same day</td>
<td>≤ 60 days</td>
<td>Same day</td>
</tr>
<tr>
<td>Mozambique (Maputo, Sofala)</td>
<td>cRCT</td>
<td>AlereQ, WB</td>
<td>SOC - 8</td>
<td>1876</td>
<td>0.32%</td>
<td>0%</td>
<td>125</td>
<td>12.8%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>POC - 8</td>
<td>2034</td>
<td>98.7%</td>
<td>98.2%</td>
<td>0</td>
<td>89.7%</td>
</tr>
<tr>
<td>Malawi</td>
<td>Observational pre/post</td>
<td>AlereQ, WB</td>
<td>7 pre</td>
<td>963</td>
<td>18.1%</td>
<td>0%</td>
<td>56</td>
<td>41.9%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>7 post</td>
<td>789</td>
<td>100%</td>
<td>99.5%</td>
<td>0</td>
<td>91.1%</td>
</tr>
</tbody>
</table>
Near point-of-care viral load technologies

<table>
<thead>
<tr>
<th>Assay</th>
<th>Evaluator</th>
<th>Sample type</th>
<th>Sample size</th>
<th>Sensitivity (95% CI)(^a)</th>
<th>Specificity (95% CI)(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott™ m-PIMA HIV-1/2 VL(^b)</td>
<td>WHO prequalification/United States Centers for Disease Control and Prevention</td>
<td>Plasma</td>
<td>421</td>
<td>95.1% (91.7–97.5%) (23)</td>
<td>99.4% (96.8–99.9%) (23)</td>
</tr>
<tr>
<td>Cepheid Xpert® HIV-1 Viral Load</td>
<td>WHO prequalification/United States Centers for Disease Control and Prevention</td>
<td>Plasma</td>
<td>439</td>
<td>94.14% (90.37–96.76%) (29)</td>
<td>98.50% (95.68–99.69%) (29)</td>
</tr>
<tr>
<td></td>
<td>Meta-analysis</td>
<td>Plasma</td>
<td>3790</td>
<td>96.47% (95.10–97.47%) (72)</td>
<td>96.59% (92.90–98.39%) (72)</td>
</tr>
</tbody>
</table>

\(^a\) Sensitivity and specificity using a treatment failure threshold of 1000 copies/mL.

\(^b\) No meta-analysis has yet been prepared because of a lack of published independent technical evaluations.

For consideration in 2020 Consolidated Guidelines revision
### POC VL in general population

#### Results – Primary Study Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Intervention Arm</th>
<th>Standard-of-care Arm</th>
<th>Absolute Risk Difference</th>
<th>Non-inferiority (1-side 95% CI) P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral suppression (&lt;200 copies/mL) and Retention in care at study clinic</td>
<td>89.7% (175/195)</td>
<td>75.9% (148/195)</td>
<td>13.9%</td>
<td>(≥7.6) &lt;0.001</td>
</tr>
</tbody>
</table>

After 12 months of clinical follow-up, the intervention increased viral suppression and retention in care at the study clinic by 13.9% (95% CI 6.4 - 21.2)

#### Results – Follow-up HIV Care & Treatment

![Graph showing proportion related to community ART delivery program](image_url)
High viral suppression rates across countries

Key questions:

1) How might this change with DTG?

2) How do we best manage those unsuppressed to reduce transmission and improve patient health?
What is the impact of POC VL?

There is currently no WHO recommendation to use point-of-care or near point-of-care technologies for treatment monitoring; however, impact studies and implementation considerations are ongoing.
Advanced disease: a persistent problem

Figure 1. Number of patients receiving ART and number of deaths. Abbreviation: ART, antiretroviral therapy.

Figure 1. Mortality among patients diagnosed with tuberculosis, stratified by CD4 cell count at admission, Homa-Bay, Kenya (n = 60) and Kinshasa, Democratic Republic of Congo (n = 249).

Calmy CID 2018

Clinical Infectious Diseases
Advanced HIV Disease
Volume 66, Issue suppl_2
1 April 2018

Ousley CID 2018

IeDEA cohort 2018
Questions?