Development and Future of HIV-1 Incidence Assay in China

Yan Jiang MD, PhD.

National HIV Reference Laboratory, China CDC
中国HIV检测体系
HIV Testing in China

Screening ↓ EIA，RT
↓ Confirmatory ↓ WB，RIBA
↓ Recent Infection ↓ BED，Avidity
↓ Treatment ↓ CD4，Viral load
↓ Drug Resistance ↓ in house，kits
Development of HIV Incidence Assay with BED in China

- 2005: BED assay was introduced into China
- 2006: Used to monitoring the HIV incidence at 1 province
- 2007: Extended to 7 provinces
- 2009: Extended to 16 provinces
- 2011: Extended to 31 provinces
China (May, 2008)

Initial vs. Confirmatory Concordance

Predictive equation:
\[ y = 1.0235x + 0.0016 \]

Coefficient of determination:
\[ R^2 = 0.9913 \]

All International Labs (May, 2008)

Initial vs. Confirmatory Concordance

Predictive equation:
\[ y = 1.0179x + 0.0065 \]

Coefficient of determination:
\[ R^2 = 0.9846 \]

全国BED检测实验室PT考核结果
### The HIV-1 Incidence of IDUs in Xinjiang

<table>
<thead>
<tr>
<th>Assay</th>
<th>Total</th>
<th>HIV +</th>
<th>Recent</th>
<th>Incidence (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BED</td>
<td>1170</td>
<td>225</td>
<td>34</td>
<td>8.2 (5.5-11.0)</td>
</tr>
<tr>
<td>Cohort</td>
<td>475</td>
<td>42</td>
<td>---</td>
<td>8.8 (6.3-12.0)</td>
</tr>
</tbody>
</table>


### The HIV-1 Incidence of IDUs in Guangxi

<table>
<thead>
<tr>
<th>Assay</th>
<th>Total</th>
<th>HIV +</th>
<th>Recent</th>
<th>Incidence (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BED</td>
<td>399</td>
<td>92</td>
<td>10</td>
<td>4.30 (1.6-6.9)</td>
</tr>
<tr>
<td>Cohort</td>
<td>500</td>
<td>15</td>
<td>---</td>
<td>3.10 (1.6-5.2)</td>
</tr>
</tbody>
</table>

### 2006-2007云南省FSW人群CIPRA队列研究与BED方法新发感染率比较

The Comparison of Recent HIV Incidence from BED and Cohort Studies in Yunnan Province Supported by CIPRA, 2006-2007

<table>
<thead>
<tr>
<th>Methods</th>
<th>Survey at Baseline</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSWs</td>
<td>737</td>
<td>747</td>
<td>705</td>
</tr>
<tr>
<td>FSWs in follow-up</td>
<td>-</td>
<td>299</td>
<td>330</td>
</tr>
<tr>
<td>Seroconversion during follow-up</td>
<td>-</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Incidence from cohort studies/person-years (95% CI)</td>
<td>-</td>
<td>1.3 (0.2-4.7)</td>
<td>0.6 (0.1-2.0)</td>
</tr>
<tr>
<td>Long-term seroconversion(BED)</td>
<td>69</td>
<td>74</td>
<td>76</td>
</tr>
<tr>
<td>Recent seroconversion(BED)</td>
<td>7</td>
<td>15</td>
<td>16</td>
</tr>
<tr>
<td>Incidence from BED/person-years (95% CI)†</td>
<td>0.7 (0.1-1.2)</td>
<td>1.9 (0.7-3.1)</td>
<td>0.4 (0.1-0.7)</td>
</tr>
</tbody>
</table>

Recent HIV incidence and prevalence among MSM in Chongqing from 2006 to 2009

2011-2012年哨点监测重点人群新发感染检测结果

Incidence of high-risk populations

Percent(%)
HIV Ab Detection

RNA or p24

Ab Titer

Ab Avidity

Anti-HIV-IgG/Total IgG Proportion

HIV-IgG占总IgG的比例

IgM

感染后的时间
TIME since infection

水平
LEVEL

此文档由批量转 PDF 助手(试用版)生成, 注册后不会有此文字
BED False Recent Rate (FRR) for China IDU and Comparison to Other Countries

Vietnam - South: 1%
South Africa - KWN: 1.7%
Vietnam - Norte: 5%
Zimbabwe - post partum women: 5.2%
Rwanda - high risk women: 6.4%
China IDU: 6.6%
El Salvador BSS: 10.7%
Sur África - Tygerberg: 11.0%
Kenya AIS: 15.0%
Uganda Rakai: 15.3%
### Verification the Repeatability and Accuracy of LAg in China

#### Precision of 70 runs

<table>
<thead>
<tr>
<th></th>
<th>OD values</th>
<th></th>
<th></th>
<th>ODn values</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean</td>
<td>SD</td>
<td>CV%</td>
<td>mean</td>
<td>SD</td>
<td>CV%</td>
</tr>
<tr>
<td>NC</td>
<td>0.076</td>
<td>0.029</td>
<td>37.6 M</td>
<td>0.111</td>
<td>0.040</td>
<td>36.5 M</td>
</tr>
<tr>
<td>CAL</td>
<td>0.690</td>
<td>0.061</td>
<td>8.8 M</td>
<td>1.000</td>
<td>0.000</td>
<td>0.0 M</td>
</tr>
<tr>
<td>LPC</td>
<td>0.335</td>
<td>0.041</td>
<td>12.3 M</td>
<td>0.486</td>
<td>0.036</td>
<td>7.5 M</td>
</tr>
<tr>
<td>HPC</td>
<td>1.400</td>
<td>0.109</td>
<td>7.8 M</td>
<td>2.033</td>
<td>0.105</td>
<td>5.1 M</td>
</tr>
</tbody>
</table>
不同检测人员检测结果的一致性

**Correlation of Different Technicians**

- **Average ODn value of 4 person**
- **China CDC Average ODn value of 4 person**
- **US CDC ODn value**

\[ y = 0.8877x + 0.1392 \]

\[ R^2 = 0.9849 \]
Characterization of LAg in China

• Mean Duration of Recency
  – China seroconversion specimens

• False Recent Ratio
  – China specimens from individuals with true long-term infections (>1 year), ART-naïve

• Misclassification of specimens from ART patients
Mean Duration of Recency

Originally Tested Specimens:
• 94 Panels from Yunnan (n=304 samples)
• 91 Panels from Dehong (n=386 samples)

*Not all panels were useful for MDRI calculation due to missing information, ART use, poor Ab kinetics, single specimen per panel, etc.*

Specimens Used for MDRI Calculation:
• 25 Panels from Yunnan (n=119 samples)
• 11 Panels from Dehong (n=70 samples)
Using SACEMA’s binomial regression method:

$$MDRI = 121 \text{ days}$$

(95% CI 99-145 days)
China False Recent Rate (FRR)

China Specimens for Analysis*:
- Yunnan: 257 Individuals
- Guizhou: 222 Individuals

*Some specimens were excluded due to HIV neg, collection interval < 1 year, etc.

- Each individual had 2 serial specimens collected.
- For Guizhou, the average time between specimens is 3.2 years. Data not available for Yunnan.
- FRR calculated using the ODn results from the follow-up specimen to ensure infection is >1 year.
## Overall FRR

<table>
<thead>
<tr>
<th>Origin</th>
<th>Type</th>
<th># Specimens</th>
<th>Subtype</th>
<th>FRR 1.5 ODn</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAg</td>
<td>Long-term &gt;1 year</td>
<td>479</td>
<td>C</td>
<td>2.30%*</td>
</tr>
</tbody>
</table>

**BED** 6.6%

*10/11 False Recents came from Guizhou while only 1/11 came from Yunnan.*
Misclassification of ART patients

• Specimens from Individuals on ART

• No other clinical information (duration of infection, duration of ART, etc.) is available

• Tested both on BED and LAg

• N=726 Specimens
抗病毒治疗病人样本的误判率

Misclassification of ART Patients

Sedia&BED

ART 726 specimens

Sedia Avidity ODn vs. Sedia&BED (ART 726 specimens)
### The Testing Results of AIDS Samples with Different CD4 Count Using LAg-Avidity EIA and BED-CEIA

<table>
<thead>
<tr>
<th>CD4 cell count (cell/ul)</th>
<th>N</th>
<th>BED-CEIA</th>
<th>LAg-Avidity EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>RECENT</td>
<td>FRR(%)</td>
</tr>
<tr>
<td>&lt;200</td>
<td>503</td>
<td>29</td>
<td>5.77</td>
</tr>
<tr>
<td>200~</td>
<td>34</td>
<td>2</td>
<td>5.88</td>
</tr>
<tr>
<td>300~</td>
<td>20</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>400~</td>
<td>12</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>≥400</td>
<td>9</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Unclear</td>
<td>13</td>
<td>1</td>
<td>7.69</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>591</td>
<td>32</td>
<td><strong>5.41</strong></td>
</tr>
</tbody>
</table>
下一步工作
BED与亲和力应用的比较研究
培训
质控
技术推广与应用

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Next step
Comparing BED and LAg Training
QA/QC
Using for incidence assay

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Province central laboratory teams