EFFICACY OF TESTING SCENARIOS

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Cost Effectiveness Paradigm
NAT and Serology for HBV, HCV and HIV
Cost Effectiveness Paradigm
NAT and Serology for HBV, HCV and HIV
Cost Effectiveness Paradigm
NAT and Serology for HBV, HCV and HIV

NAT yield

Serology yield

Serology receives credit for antigen or antibody positive donations interdicted
Cost Effectiveness Paradigm
NAT and Serology for HBV, HCV and HIV

NAT yield

Serology yield

NAT only receives credit for WP or OBI donations interdicted
Cost Effectiveness Paradigm
NAT and Serology for HBV, HCV and HIV

But why NAT does not receive credit for all infectious donations interdicted?
Cost Effectiveness Paradigm
NAT and Serology for HBV, HCV and HIV

NAT yield
Serology yield

High probability to be not infectious
Foundations for a robust cost effectiveness analysis of screening scenarios

1. **Cost effectiveness (QALY’s saved)**
2. **Screening efficacy (% risk avoided)**
3. **Transmission risk (infections/million)**
4. **Infectivity in each stage of infection (MID$_{50}$)**
5. **Analytical sensitivity of assay (50%, 95% LOD)**
6. **Standardization in virions (nucleic acid copies/mL)**
7. **Prevalence of infectious disease markers (donor epidemiology)**
8. **Confirmatory testing to exclude false positive results (NAT & serology)**
International ID-NAT Survey

Switzerland 20 national blood services
Slovenia 15 countries
Poland 6 geographic regions
Finland
Denmark
Ireland
Italy
Spain
Egypt
South Africa
Malaysia
Singapore
Hong Kong
Australia
New Zealand

11,787,610 Donations
7,100 HIV Infections
5,070 HCV Infections
9,458 HBV Infections

Bruhn et al. Transfusion 2013:53:2399-2412
Bruhn et al Transfusion 2015 Epub ehead of print
Comparison of human immunodeficiency virus assays in window phase and elite controller samples: viral load distribution and implications for transmission risk

Marion Vermeulen, Charl Coleman, Josephine Mitchell, Ravi Reddy, Harry van Drimmelen, Tracy Fickett, Michael Busch, and Nico Lelie

Prevalence of human immunodeficiency virus RNA and antibody in first-time, lapsed, and repeat blood donations across five international regions and relative efficacy of alternative screening scenarios

Roberta Bruhn, Nico Lelie, Brian Custer, Michael Busch, Steven Kleinman, and the International NAT Study Group*
Viremia levels in hepatitis C infection among Egyptian blood donors and implications for transmission risk with different screening scenarios

Magdy El Ekiaby,¹ Faten Mostah,² Heidi Goubran,² Harry van Drimmelen,³ Syria LaPerche,⁴ Steve Kleinman,⁵ Michael Busch,⁶ and Nico Lelie⁷

Relative efficacy of nucleic acid amplification testing and serologic screening in preventing hepatitis C virus transmission risk in seven international regions

Roberta Bruhn,¹ Nico Lelie,² Michael Busch,¹ Steven Kleinman,³ and the International NAT Study Group
Course of HBV markers and residual transmission risk in ID-NAT


How safe is NAT screened OBI blood
Efficacy of HBV screening assays

MP-NAT

MP-NAT efficacy

HBsAg efficacy

Anti-HBc efficacy

ID-NAT

WP NAT yield
Concordant HBsAg and NAT yield
2nd WP/OBI NAT yield

Anti-HBc yield

More sensitive ID-NAT

WP NAT yield
Concordant HBsAg and NAT yield
2nd WP/OBI NAT yield

Pre-NAT WP risk

pre-HBsAg NAT yield WP
Transient (or undetectable) HBsAg
Post-NAT WP/OBI risk

post HBsAg NAT yield WP

occurrence of infectious donations over time
Viral load distribution in different stages of HBV infection

- Window period
- Early recovery
- OBI anti-HBs+
- OBI anti-HBs-
- Anti-HBs breakthrough
- HBsAg+/DNA-

83% of ID-NAT yields (Ultrio) had VL<LLQ TaqMan

Vermeulen M. et al, Transfusion 2014;54:2496-2504
Viral load distribution in OBI

Vermeulien M. et al, Transfusion 2014;54:2496-2504
WP and OBI transmission risk by ID-NAT (Ultero Plus) screened donations (RBCs)

Vermeulen M. et al, Transfusion 2014;54:2496-2504
Estimated percentage of donations that are predicted to cause infection but not detected by ID and MP-NAT options

Vermeulen M. et al, Transfusion 2014;54:2496-2504
OBI transmission risk by ID-NAT screened blood

Data adapted from Vermeulen M. et al, Transfusion 2014;54:2496-2504
# Seed et al. Vox Sanguinis 2015;108:113-22
&Vermeulen M. et al, Vox Sang 105 Suppl. 1;56 (Abstract 4A-S32-02)
HBV ID-NAT survey

Europe (0.02%)

Mediterranean (0.04%)

Egypt (1.06%)

South Africa (0.10%)

Southeast Asia (0.36%)

Oceania (0.01%)

(Prevalence in all donors)

10 981 776 Donations
9458 Infections

Lelie et al, manuscript in preparation
### Types of confirmed HBV infections (n=9458) in international survey among ID-NAT (Ultrio) users

<table>
<thead>
<tr>
<th>Infection stage</th>
<th>HBV-DNA</th>
<th>HBsAg</th>
<th>anti-HBc</th>
<th>IgM-anti-HBc</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early WP</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>168</td>
<td>1.8%</td>
</tr>
<tr>
<td>HBsAg+/DNA+</td>
<td>+</td>
<td>+</td>
<td></td>
<td></td>
<td>8016</td>
<td>84.8%</td>
</tr>
<tr>
<td>Late WP</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>54</td>
<td>0.6%</td>
</tr>
<tr>
<td>HBsAg+/DNA-</td>
<td>-</td>
<td>+</td>
<td></td>
<td>+</td>
<td>610</td>
<td>6.4%</td>
</tr>
<tr>
<td>OBI</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>587</td>
<td>6.2%</td>
</tr>
<tr>
<td>Unclassified</td>
<td>+</td>
<td>-</td>
<td></td>
<td></td>
<td>23</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

Types of acute HBV NAT yields identified in international survey

<table>
<thead>
<tr>
<th>Acute HBV NAT yields</th>
<th>HBV-DNA</th>
<th>HBsAg</th>
<th>anti-HBc</th>
<th>IgM-anti-HBc</th>
<th>anti-HBs</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-HBsAg WP</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>137</td>
<td>61.7%</td>
</tr>
<tr>
<td>Acute occult*</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>9</td>
<td>4.1%</td>
</tr>
<tr>
<td>Anti-HBs breakthrough#</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>22</td>
<td>9.9%</td>
</tr>
<tr>
<td>Post-HBsAg WP</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+/-</td>
<td>54</td>
<td>24.3%</td>
</tr>
</tbody>
</table>

*Acute occult = acute viremia in multiple follow up samples without HBsAg ever detectable

#Anti-HBs breakthrough = viremia followed by rise in anti-HBs and later conversion to anti-HBc in vaccinated or unvaccinated individual

### Types of chronic HBV NAT yields identified in international survey

<table>
<thead>
<tr>
<th>Chronic HBV NAT yields</th>
<th>HBV-DNA</th>
<th>HBsAg</th>
<th>anti-HBc</th>
<th>IgM-anti-HBc</th>
<th>anti-HBs</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>OBI anti-HBs-</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>278</td>
<td>47.4%</td>
</tr>
<tr>
<td>OBI anti-HBs+</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>281</td>
<td>47.9%</td>
</tr>
<tr>
<td>OBI anti-HBs only</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>26</td>
<td>4.4%</td>
</tr>
<tr>
<td>OBI no marker</td>
<td>+</td>
<td>-</td>
<td>±</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

## Comparison of WP and OBI NAT yield rates in first time versus lapsed + repeat donations

<table>
<thead>
<tr>
<th></th>
<th>SE Asia</th>
<th>South Africa</th>
<th>Mediterranean</th>
<th>ECN Europe</th>
<th>South Pacific</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FT donations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WP NAT yields (rate)</td>
<td>14 (1:23 190)</td>
<td>47 (1:7677)</td>
<td>10 (1:29 004)</td>
<td>1 (1:294 367)</td>
<td>1 (1:152 961)</td>
</tr>
<tr>
<td>OBI NAT yields (rate)</td>
<td>43 (1:7 750)</td>
<td>93 (1:3 880)</td>
<td>24 (1:12 085)</td>
<td>5 (1:58 873)</td>
<td>5 (1:30 592)</td>
</tr>
<tr>
<td><strong>LPD+RPT donations</strong></td>
<td>726 716</td>
<td>3 210 497</td>
<td>1 806 690</td>
<td>2 323 315</td>
<td>1 389 519</td>
</tr>
<tr>
<td>WP NAT yields (rate)</td>
<td>18 (1:40 373)</td>
<td>106 (1:30 288)</td>
<td>20 (1:90 335)</td>
<td>5 (1:464 663)</td>
<td>0 (1:?)</td>
</tr>
<tr>
<td>OBI NAT yields (rate)</td>
<td>118 (1:6159)</td>
<td>101 (1:31 787)</td>
<td>110 (1:16 424)</td>
<td>36 (1:64 537)</td>
<td>40 (1:34 738)</td>
</tr>
<tr>
<td><strong>WP yield ratio FT/LPD+RPT (p value)</strong></td>
<td>1.74 (0.11)</td>
<td>3.95 (&lt;0.00001)</td>
<td>3.11 (0.00194)</td>
<td>1.58 (0.67)</td>
<td>?</td>
</tr>
<tr>
<td><strong>OBI yield ratio FT/LPD+RPT (p value)</strong></td>
<td>0.82 (0.28)</td>
<td>8.19 (&lt;0.00001)</td>
<td>1.36 (0.33)</td>
<td>1.10 (0.84)</td>
<td>1.14 (0.79)</td>
</tr>
</tbody>
</table>
Proportion of HBV infection types and clinical sensitivity of HBsAg and HBV-DNA detection

<table>
<thead>
<tr>
<th>Classification</th>
<th>First Time</th>
<th>Lapsed</th>
<th>Repeat</th>
</tr>
</thead>
<tbody>
<tr>
<td>All HBV infections</td>
<td>8354</td>
<td>378</td>
<td>700</td>
</tr>
<tr>
<td>WP NAT yields</td>
<td>74 (0.9%)</td>
<td>34 (9.0%)</td>
<td>115 (16.4%)</td>
</tr>
<tr>
<td>OBI NAT yields</td>
<td>178 (2.1%)</td>
<td>107 (28.3%)</td>
<td>298 (42.6%)</td>
</tr>
<tr>
<td>HBsAg+/DNA+</td>
<td>7523 (90.1%)</td>
<td>218 (57.7%)</td>
<td>275 (39.3%)</td>
</tr>
<tr>
<td>HBsAg+/DNA-</td>
<td>579 (6.9%)</td>
<td>19 (5.0%)</td>
<td>12 (1.7%)</td>
</tr>
<tr>
<td>All HBsAg+</td>
<td>8102 (97.0%)*</td>
<td>237 (62.7%)</td>
<td>287 (41.0%)§</td>
</tr>
<tr>
<td>All HBV-DNA+</td>
<td>7775 (93.1%)*</td>
<td>359 (95.0%)</td>
<td>688 (98.3%)§</td>
</tr>
</tbody>
</table>

*p<0.0001

Parameters HBV risk day equivalent (RDE) model

- **50% minimum infectious dose (MID\(_{50}\))**
  - WP: MID\(_{50}\) 3.16 (1-10) virions or copies
  - Late WP and OBI: 316 (100-1000) virions or copies

- **Geomean\# 50% LODs\(^1,2\)** \(\rightarrow\) early and late WP days
  - Ultrio - 63 copies/mL \(\rightarrow\) 23.2 and 4.0 days
  - Ultrio Plus - 4.1 copies/mL \(\rightarrow\) 13.1 and 0.8 days
  - TaqScreen - 3.9 - copies/mL \(\rightarrow\) (MP6) 20.0 days

- **Incidence rate adjustment factor\(^1\)**
  - HBsAg – 2.0
  - Ultrio – 1.08
  - Ultrio Plus – 1.0

\#Geometric mean of a) Ultrio NAT yield dilutions and b) HBsAg+/DNA- samples

1. Vermeulen M. et al, Vox Sang 105 Suppl. 1;56 (Abstract 4A-S32-02)
2. Vermeulen et al Transfusion 2013; 53: 2459-06
Parameters HBV NAT yield ratio model

- **Ultrio Plus to Ultrio ID-NAT yield improvement factors**
  - Early WP – 1.70
  - Late WP – 1.67
  - OBI – 1.72
  - HBsAg+/DNA –(seroyield) – 0.42

- **Probability RBC infectivity**
  - Pre ID-NAT (Ultrio Plus) WP residual risk – +45.5%
  - Early WP ID-NAT yield – 100%
  - HBsAg+/HBV-DNA+ concordant – 100%
  - Late WP and OBI ID-NAT yield – 12.8%
  - Late WP and OBI ID-NAT residual risk – +2.6%
  - Late WP and OBI MP6-NAT residual risk – +7.8%
  - HBsAg+/HBV-DNA –(seroyield) – 17.2%

1. Vermeulen M. et al, Vox Sang 105 Suppl. 1;56 (Abstract 4A-S32-02)
Estimated residual HBV WP and OBI transmission risk with ID-NAT* in South Africa as calculated by ratio modelling

<table>
<thead>
<tr>
<th>Donation category</th>
<th>pre-WP</th>
<th>post-WP</th>
<th>OBI</th>
<th>HBsAg+/DNA-</th>
</tr>
</thead>
<tbody>
<tr>
<td>First time</td>
<td>1:17941</td>
<td>1:395,712</td>
<td>1:86,757</td>
<td>1:47,006</td>
</tr>
<tr>
<td>Lapsed</td>
<td>1:29,206</td>
<td>1:2,774,520</td>
<td>1:269,387</td>
<td>~</td>
</tr>
<tr>
<td>Repeat</td>
<td>1:50,454</td>
<td>1:4,686,925</td>
<td>1:897,317</td>
<td>~</td>
</tr>
<tr>
<td>Lapsed + Repeat</td>
<td>1:46,642</td>
<td>1:4,349,442</td>
<td>1:710,803</td>
<td>~</td>
</tr>
<tr>
<td>All</td>
<td>1:40.149</td>
<td>1:2,164,486</td>
<td>1:411,647</td>
<td>1:465,295</td>
</tr>
</tbody>
</table>

~ no HBsAg+/DNA- in lapsed and repeat donors observed with Ultrio Plus in one year analysis of Vermeulen M. et al (Vox Sang 105 Suppl. 1;56 (Abstract 4A-S32-02))

*Residual risk estimated for Ultrio Plus on Ultrio prevalence data
Estimated residual HBV transmission risk per million RBC transfusions in South Africa with different screening scenarios

<table>
<thead>
<tr>
<th>Testing scenario</th>
<th>FT</th>
<th>LPD</th>
<th>RPT</th>
<th>LPD + RPT</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>219.8</td>
<td>133.6</td>
<td>71.2</td>
<td>78.3</td>
<td>96.8</td>
</tr>
<tr>
<td>HBsAg + anti-HBc</td>
<td>136.6</td>
<td>109.5</td>
<td>63.4</td>
<td>68.6</td>
<td>79.6</td>
</tr>
<tr>
<td>HBsAg + anti-HBc + MP16-NAT</td>
<td>100.9</td>
<td>62.0</td>
<td>35.9</td>
<td>38.8</td>
<td>45.1</td>
</tr>
<tr>
<td>HBsAg + MP6-NAT</td>
<td>127.5</td>
<td>64.6</td>
<td>34.3</td>
<td>37.7</td>
<td>46.8</td>
</tr>
<tr>
<td>HBsAg + anti-HBc + MP6-NAT</td>
<td>85.3</td>
<td>52.4</td>
<td>30.3</td>
<td>32.8</td>
<td>38.1</td>
</tr>
<tr>
<td>ID-NAT only</td>
<td>49.4</td>
<td>38.3</td>
<td>21.1</td>
<td>23.1</td>
<td>29.9</td>
</tr>
<tr>
<td>HBsAg + ID-NAT</td>
<td>28.1</td>
<td>38.3</td>
<td>21.1</td>
<td>23.1</td>
<td>27.8</td>
</tr>
<tr>
<td>HBsAg + anti-HBc + ID-NAT*</td>
<td>14.1</td>
<td>34.2</td>
<td>19.8</td>
<td>21.4</td>
<td>24.9</td>
</tr>
</tbody>
</table>

* Equivalent to anti-HBc + ID-NAT

FT= first time, LPD=lapsed RPT= repeat donations
Efficacy (%) in removing HBV transmission risk by RBC transfusions in South Africa with different screening scenarios

<table>
<thead>
<tr>
<th>Testing scenario</th>
<th>FT</th>
<th>LPD</th>
<th>RPT</th>
<th>LPD + RPT</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>97.1</td>
<td>71.1</td>
<td>50.5</td>
<td>56.5</td>
<td>89.7</td>
</tr>
<tr>
<td>HBsAg + anti-HBc</td>
<td>98.2</td>
<td>76.3</td>
<td>56.0</td>
<td>61.9</td>
<td>91.6</td>
</tr>
<tr>
<td>HBsAg + anti-HBc + MP16-NAT</td>
<td>99.2</td>
<td>86.6</td>
<td>75.1</td>
<td>78.4</td>
<td>95.2</td>
</tr>
<tr>
<td>HBsAg + MP6-NAT</td>
<td>98.9</td>
<td>86.0</td>
<td>76.1</td>
<td>79.0</td>
<td>95.0</td>
</tr>
<tr>
<td>HBsAg + anti-HBc + MP6-NAT</td>
<td>99.4</td>
<td>88.7</td>
<td>78.9</td>
<td>81.7</td>
<td>96.0</td>
</tr>
<tr>
<td>ID-NAT only</td>
<td>99.4</td>
<td>91.7</td>
<td>85.3</td>
<td>87.2</td>
<td>96.8</td>
</tr>
<tr>
<td>HBsAg + ID-NAT</td>
<td>99.6</td>
<td>91.7</td>
<td>85.3</td>
<td>87.2</td>
<td>97.1</td>
</tr>
<tr>
<td>HBsAg + anti-HBc + ID-NAT*</td>
<td>99.8</td>
<td>92.6</td>
<td>86.2</td>
<td>88.1</td>
<td>97.4</td>
</tr>
</tbody>
</table>

* Equivalent to anti-HBc + ID-NAT

FT= first time, LPD=lapsed RPT= repeat donations
Incremental efficacy (%) in reducing HBV transmission risk by RBC transfusions in South Africa achieved by addition of ID-NAT to serology and vice versa

<table>
<thead>
<tr>
<th>Addition of:</th>
<th>FT</th>
<th>LPD</th>
<th>RPT</th>
<th>LPD + RPT</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID-NAT to HBsAg</td>
<td>2.49</td>
<td>20.6</td>
<td>34.8</td>
<td>30.7</td>
<td>7.31</td>
</tr>
<tr>
<td>ID-NAT to HBsAg &amp; anti-HBc</td>
<td>1.59</td>
<td>16.3</td>
<td>30.3</td>
<td>26.2</td>
<td>5.81</td>
</tr>
<tr>
<td>HBsAg to ID-NAT</td>
<td>0.28</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.23</td>
</tr>
<tr>
<td>anti-HBc to ID-NAT</td>
<td>0.46</td>
<td>0.88</td>
<td>0.92</td>
<td>0.91</td>
<td>0.53</td>
</tr>
</tbody>
</table>

FT= first time, LPD=lapsed RPT= repeat donations
Efficacy of NAT and Serology for HBV, HCV and HIV

Conclusions and discussion

- An ID-NAT alone screening scenario is more efficacious than MP-NAT and serology together
  - and could be a cost effective strategy, particularly for lapsed and repeat donors
  (e.g. in a setting where platelets and FFP are subjected to pathogen inactivation technology)

- An Ag/Ab (combo) assay testing* strategy is far less efficacious than ID-NAT alone

- The international data base of the ID-NAT user group is instrumental to calculate cost effectiveness of different screening (or blood safety) scenarios

*also HBsAg combined with anti-HBc
On-site co-investigators I

- Marion Vermeulen, Ravi Reddy, South African National Blood Service, Johannesburg, South Africa
- Arthur Bird, Russell Cable, Western Province Blood Transfusion Service, Cape Town, South Africa
- Heidi Goubran, Faten Moftah, National Blood Transfusion Service, Cairo, Egypt
- Magdy El Ekiaby, Shabrawishi Hospital, Dokki, Egypt
- Silvia Sauleda, Banc de Sang I Teixits, Barcelona, Spain
- Roberto Roig, Manolo Alvarez, Valencia Regional Blood Tx Center, Valencia, Spain
- Paola Ghiazza, St Anna Hospital, Turin, Italy
- Paola Manzini, University of Turin, Turin, Italy
- Cecilia Peduzzi, S.O.D University of Careggi, Florence, Italy
- Flavia Favilli, S. Chiara Hospital, Italy
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