Serology and Nucleic Acid Test Screening in Organ and Tissue Transplantation

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Structure of Talk

- Organ and tissue transplantation (OTT)
- Risk of blood borne virus (BBV) transmission in OTT
- Serology and nucleic acid test (NAT) screening at SEALS
- Outcome of serology and NAT screening
Organ and Tissue Transplantation

- Organ and tissue transplantation (OTT) is vital to provide quality health care
- Each organ donor can help transform the lives of 10 or more people
- Australia is a world leader in successful transplant outcomes
- About 76% of Australians are willing to become organ and tissue donors
- However the number of transplantations are still low compared to the waiting list of patients needing a transplant
- There are many factors that determine if a transplantation proceeds
- The government implemented a reform programme that focuses on ‘A World’s Best Practice Approach to Organ and Tissue Donation for Transplant’ to raise community awareness and to maximise donation rates
OTT in Australia and NSW

- National Reform Programme
- Organ and Tissue Authority (OTA)
- Donate Life Network
- NSW Organ and Tissue Donation Service (OTDS)
- Serology and NAT Screening at SEALS
Types of Organ and Tissue Donation

**Deceased Donation**

- Donation after Brain Death (DBD)
  - the Australian and New Zealand Intensive Care Society (ANZICs) statement (2013)
- Donation after Circulatory Death (DCD)
  - the National Protocol developed by the National Health & Medical Research Council (2010)

**Live Donation**

- Kidney and part liver donation
- Australian Paired Kidney Exchange (AKX) programme
Successful Transplantation

- Donor organ retrieval
- Proper time management to ensure organ viability and availability of recipient
- Risk management of acquisition of blood borne and other infections
Serology and NAT Infectious Window

- HIV
- HCV
- HBV
Serology and NAT Screening at SEALS

**Serology (Prospective)**
- HIV (Anti-HIV I/II Ag/Ab)
- HCV (Anti-HCV)
- HBV (HBsAg, Anti-HBc, Anti-HBs)
- HTLV (Anti-HTLV I/II)
- CMV (Anti-CMV IgG, Anti-CMV IgM)
- EBV (EBNA-1 IgG, EBV VCA IgG, EBV VCA IgM)
- Syphilis (TP)

**NAT (Retrospective/Prospective)**
- HIV-I RNA
- HCV RNA
- HBV DNA
Procedure for Serology Screening

Prospective serology screening (4 hrs TAT)

Negative

- Report to Donor Coordinator via email/phone

- Report to ARCBS via fax

Positive

- Spin & re-test in duplicate

2X Pos

- Inform microbiologist on-call

- Report as Positive

1Pos & 1Neg

- Order confirmatory tests

2X Neg

- Report as Negative
Procedure for NAT Screening

Average risk

Retrospective NAT (24hrs TAT)

1/2 assay

Increased risk

Prospective NAT (8hrs TAT)

3 assays

Second operator check

Report to Donor Coordinator via email/phone
Deceased Donor Screening

![Chart showing Deceased Donor Screening from July 09 to June 15 with categories for Retrospective, Prospective, and Cancelled.](chart.png)
Total Number of Retrieved Organs/Tissues

July 09 - June 10
July 10 - June 11
July 11 - June 12
July 12 - June 13
July 13 - June 14
July 14 - June 15

Retrospective
Prospective
Number of Organs/Tissues per Screened Donor

- July 09 - June 10
- July 10 - June 11
- July 11 - June 12
- July 12 - June 13
- July 13 - June 14
- July 14 - June 15

**Legend:**
- Blue: Retrospective
- Red: Prospective

**Graph Details:**
- Y-axis: Number of Organs/Tissues (0 to 4.5)
- X-axis: Periods (July 09 - June 10 to July 14 - June 15)
## Number of Specific Organs/Tissues

<table>
<thead>
<tr>
<th></th>
<th>Retrospective</th>
<th>Prospective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kidney</td>
<td>781</td>
<td>200</td>
</tr>
<tr>
<td>Liver</td>
<td>269</td>
<td>81</td>
</tr>
<tr>
<td>Heart/valves</td>
<td>155</td>
<td>47</td>
</tr>
<tr>
<td>Pancreas/islets</td>
<td>80</td>
<td>29</td>
</tr>
<tr>
<td>Lung</td>
<td>340</td>
<td>85</td>
</tr>
<tr>
<td>Cornea</td>
<td>199</td>
<td>48</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1824</strong></td>
<td><strong>490</strong></td>
</tr>
</tbody>
</table>
NAT Screening in Increased Risk Donors

• Increased risk donors:
  – known prior history
  – upgraded after serology screening

• Prospective NAT screening with short TAT is crucial to support decision making.
### Outcome of Increased Risk Donor Screening

<table>
<thead>
<tr>
<th>Virus</th>
<th>Test Results</th>
<th>Organ Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>1 seropositive donor was confirmed as NAT positive</td>
<td></td>
</tr>
<tr>
<td>HBV</td>
<td>2 HBsAg, HBcAb and NAT positive</td>
<td>0 organs</td>
</tr>
<tr>
<td></td>
<td>46 HBcAb positive/ NAT negative</td>
<td>31 transplanted, 99 organs</td>
</tr>
<tr>
<td>HCV</td>
<td>14 serology and NAT positive</td>
<td>4 organs</td>
</tr>
<tr>
<td></td>
<td>7 serology positive/NAT negative</td>
<td>2 organs</td>
</tr>
<tr>
<td></td>
<td>5 serology positive with no NAT</td>
<td>0 organs</td>
</tr>
</tbody>
</table>
HCV Positive Transplantation

- Organs from HCV positive donors are now made available to HCV viraemic recipients
- Different HCV genotypes have different severity of infection and different response to therapy
- Early knowledge of donor HCV genotypes will support decision making and early medication in recipients
- To facilitate the process we introduced rapid HCV genotyping of HCV donors
- Genotyping performed concurrent with screening and reported together
Live Donor Screening

- NAT screening for live kidney donors
- Work with the AKX programme since 2010
- Screen for HIV, HCV and HBV
- TAT = 1 week; Average TAT = 2.26 working days
NAT for Kidney Donation

- July 09 - June 10
- July 10 - June 11
- July 11 - June 12
- July 12 - June 13
- July 13 - June 14
- July 14 - June 15
Summary

- Serology screening served as the “gate-keeper” to provide the BBV status of organ/tissue donors
- NAT screening allowed the resolution of discrepant results and the use of organs from positive serology and negative NAT
- Prospective NAT screening also enabled the retrieval of organs from increased risk donors.
- Combination of serology and NAT screening is important for safer expansion of the donor pool
Future Aims

• Continue to review and develop our screening procedure to the requirement of organ and tissue transplantation

• Adopt new approved technology to reduce turn-around-time and provide ongoing high quality service

• Perform all NAT testing prospectively to achieve quick and safe result on donor BBV status
Our Team

SEALS Serology and Virology Division (SAViD)
Prof. William Rawlinson

Serology
- Ross Whybin
- Serology Staff

BBV Laboratory
- Vidiya Ramachandran
- Sanghamitra Ray
- Chee Choy Kok

On-call Scientists
- Zin Naing
- Stuart Hamilton
Acknowledgement

- Donate Life Network and NSW OTDS
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- SEALS scientists involved in the screening process
- Everyone involved in organ and tissue transplantation
- NRL