Seroprevalence of HTLV-I/II among first-time blood donors in the Western Cape, South Africa

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Background

Human T-cell Lymphotropic Virus type-1 (HTLV-1) is considered a major health challenge in endemic areas. The virus is associated with severe diseases, such as adult T-cell leukaemia/lymphoma (ATLL), HTLV-1-associated myelopathy/tropical spastic paraparesis (HAM/TSP), and Infective Dermatitis associated with HTLV-1(IDH). For reasons not yet fully understood, ~95% of infected individuals remain asymptomatic with only 2 – 5% developing disease states.

Known routes of transmission include:

1. Vertical (mother-to-child)
2. Parenteral
3. Sexual

In South Africa, HTLV screening is not mandatory for blood services.

Background

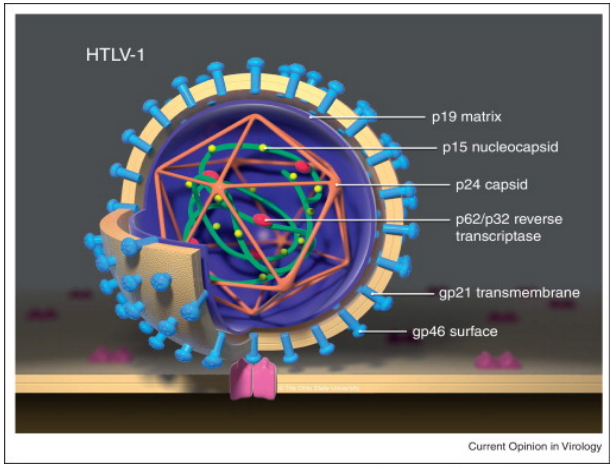
- Retrovirus
  - Orthoretrovirus
    - Alpharetrovirus
    - Betaretrovirus
    - Gammaretrovirus
    - Deltaretrovirus → e.g. STLV, HTLV (PTLV)
    - Epsilonretrovirus
    - Lentivirus → e.g. SIV, HIV
  - Spumaretrovirus
    - e.g. Human Foamy Virus

Genotypes

HTLV-1, HTLV-2, HTLV-3, HTLV-4

Subtypes

HTLV-1: 7 Subtypes
HTLV-2: 4 Subtypes



Research Objectives

1. To determine the seroprevalence of HTLV in the new/first-time donor population of the Western Cape, South Africa.

2. To utilise the bi-directional LIS and automate many of the processes:
   - Donor selection for the study.
   - Flagging repeat reactive donors.
   - Suitability as a template for future EID studies.

3. To determine the performance of the Roche Elecsys HTLV-I/II assay.

Method: Donor selection

1. During sample reception, the donor code and serial number were linked, initiating the interrogation of the Donor Master, a database containing all donor information.

   Software running in the background provided information on each donor's:
   a) Number of donations
   b) Race
   c) Gender
   d) Age

2. Donor selection for the study was based on the following criteria:
   a) Black donors: first-time and repeat donors.
   b) White, Coloured, Indian/Asian donors: only first-time donors.
   c) Eligibility to donate (excluded NST, TTD, D/lab, etc.).

Method: Blood Screening (Algorithm)

First-line screen

e801 analyser
Elecsys HTLV-I/II
(Roche Diagnostics)

Repeat Reactive

Donor's record blocked on system.
Products flagged for discard.

2nd-line screen

Architect i1000
Architect *r*HTLV-I/II assay
(Abbott Diagnostics)

Negative

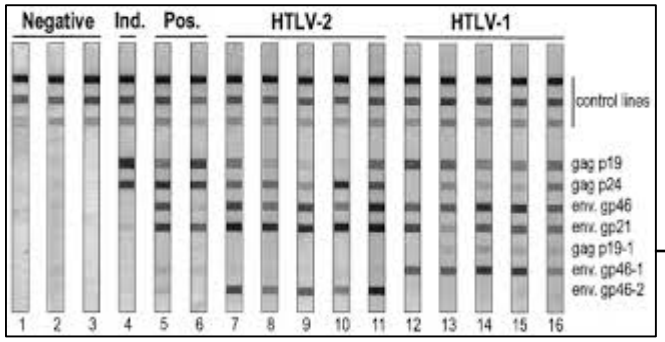
No further testing required

Repeat Reactive

PCR (HTLV-1)
NHLS/UCT

Positive

Counsel.
Request fresh samples.



INNO LIA HTLV-I/II Score (Fujirebio)

Method: Ethical considerations

Three options:

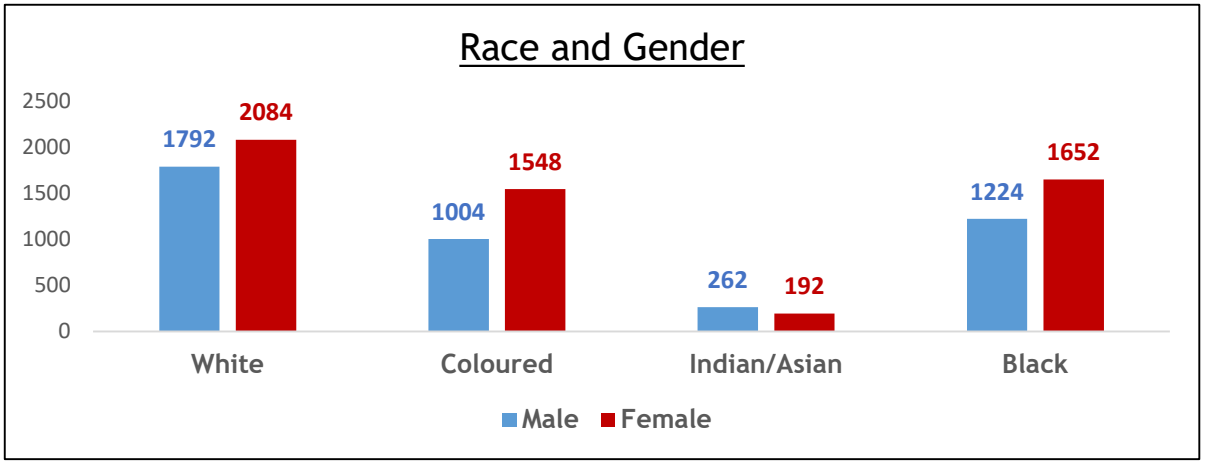
1. Obtain informed consent from each donor, counsel those we find positive for HTLV, block and prevent their products from being issued to recipients.

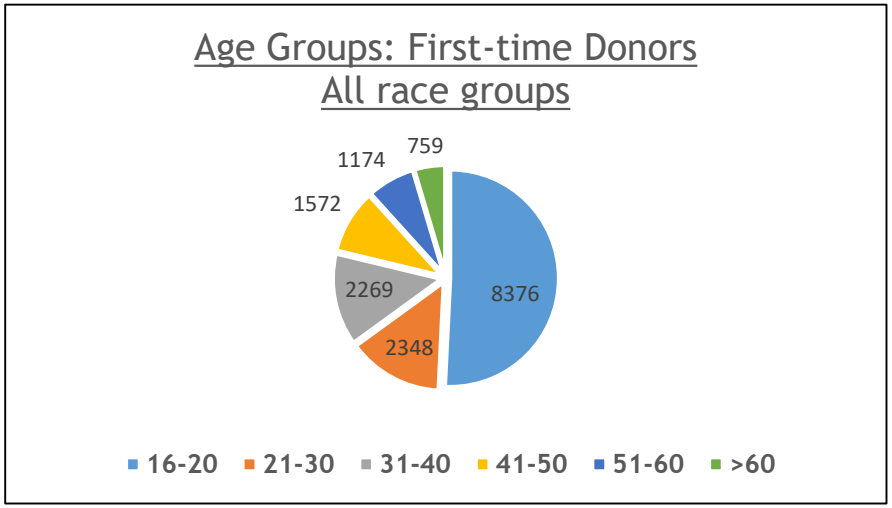
2. Do not obtain informed consent, **nor** counsel any donor found positive, **nor** block their donated blood.

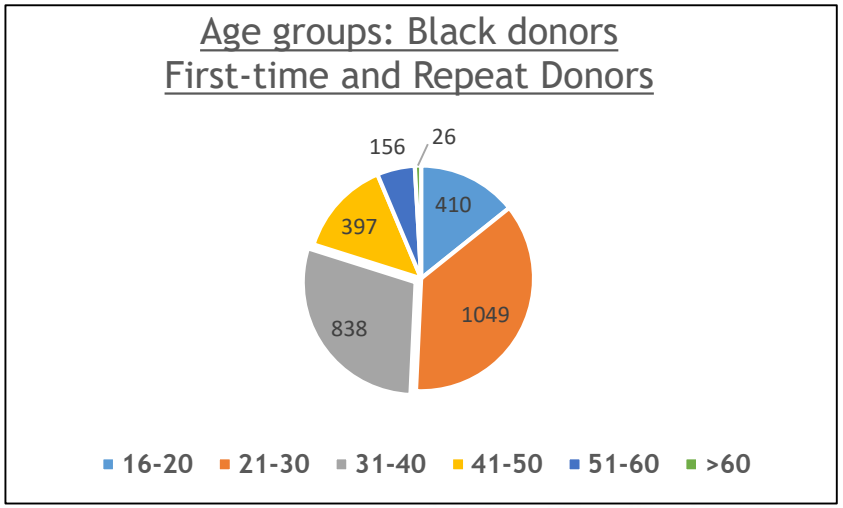
3. Do not obtain informed consent but counsel those found positive for HTLV, block and prevent their products from being issued to recipients.

Results: Donors screened (n = 9758)

Originally planned to screen about >14000 donors (software “glitch”).







Results: HTLV-positive donors

HTLV Positive donors

No. of donors screened	9758
No. of HTLV-positive donors	2
Prevalence	0.02% (20.50 in 100 000 donors)

No.	Donor status	Race	Gender	Age
1	Repeat donor	Black	Female	34
2	Repeat donor	Black	Female	16

TTI-positive donors during study period:

HIV-1/2	HBV	HCV	Syphilis	Co-infection with HTLV-I/II
28	67	3	55	0*

* Including the cross reactive/false positive HTLV results

Results: Assay performance

Elecsys HTLV assay performance

Elecsys	Architect	Immuno Blot	PCR
Repeat reactive	Repeat reactive	Positive (HTLV-1)	Positive (HTLV-1)
12	4	2	2

Parameter	Result	95% Confidence Interval
Sensitivity	100%	15.81% - 100.00%
Specificity	99.90%	99.81% - 99.95%
Accuracy	99.90%	99.81% - 99.95%

Discussion / Conclusion

1. Most HTLV seroprevalence studies are conducted on:
    - blood donors
    - ante-natal clinics
    - specific groups within communities

The results from these types of studies may therefore not be a true reflection of the seroprevalence in the general population.

Although our study population was smaller than originally planned, we know the virus is in our donor population. To what extent it is in the general population remains to be determined. Therefore, the potential risk to our blood recipients is a concern which requires further investigation.

Options available to reduce the risk of HTLV-transmission include:

- HTLV screening of donors (universal or first-time donors only)
- Leucocyte reduction through filtration
- Pathogen Reduction Technology.

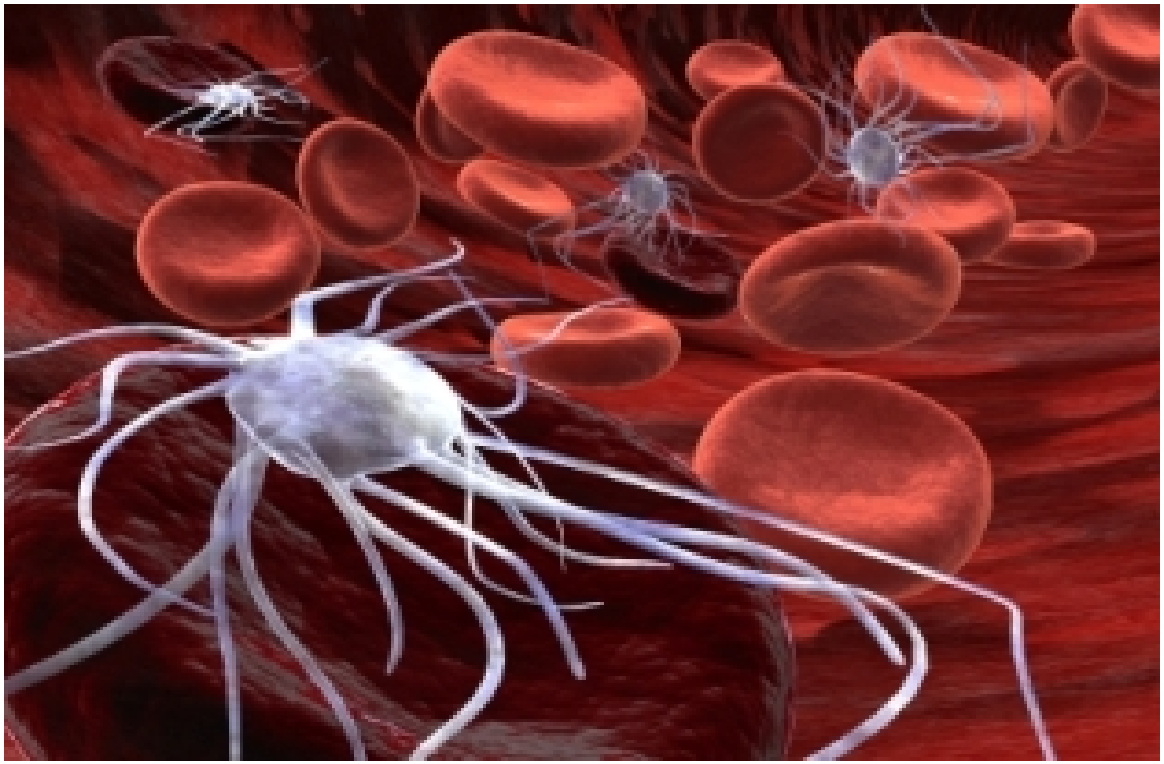
However, every option has significant cost implications.

Discussion / Conclusion

2. We've established that the bi-directional LIS is a useful tool for automating the donor selection process for future studies of a similar nature. This streamlines the testing procedure and reduces any extra work needed by the technologists, i.e. less disruption to their routine work.

3. Assay specificity was calculated at 99.90%. Results from other HTLV assay comparative studies performed in Europe ranged from 99.91% to 99.99%. At WCBS, an assay specificity of 99.80% is considered acceptable for routine use as a screening assay.

Thank you!



Questions?