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Health economic implications of testing blood donors in South Africa for HTLV 1 & 2 infection

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Abstract

Background and objectives: Currently HTLV screening is not performed in South Africa (SA). This report describes an economic assessment (budget impact and cost-effectiveness) of implementing different HTLV screening strategies

Methods: A modified version of the Alliance of Blood Operators risk-based decision-making framework was used to assess the risk and consequences of HTLV in the blood supply in SA. We developed a deterministic model of the cost and consequences of four screening strategies: none, universal, all donors once, and first time donors only assuming a transfusion-transmission (TT) efficiency of 10% and a manifestation of clinical disease of 6%

Results: Unscreened blood results in 3.55 symptomatic TT-HTLV cases and a total health care cost of Rand (R)3,446,950 (US Dollars (USD)229,800) annually. Universal screening would cost R24,000,000 (USD1,600,000) per annum and prevent 3.54 (99.8%) symptomatic TT-HTLV cases in the first year and 0.55 (98.4%) symptomatic TT-HTLV cases in the second year at a cost per TT-HTLV prevented of R6,780,000 (USD450,000) in year one and R43,254,000 (USD2,890,000) in year two. Screening all donors once would cost R16,200,000 (USD1,080,000) or R4,600,000 (USD306,000) per symptomatic TT-HTLV infection prevented in year one. Total costs decrease to R5,100,000 (USD340,000) in year 2 but the cost per TT-HTLV prevented increases to R10,700,000 (USD713,333).

Conclusion: This analysis contributed to the decision not to implement HTLV screening as the health care budget and particularly the budget for blood transfusion in SA is insufficient to provide appropriate treatment. Arguably, available resources can be more efficiently utilized in other health care programs.

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Contributions

Marion Vermeulen, Charlotte Ingram, Colwyn Poole and Ravi Reddy designed the research

Marion Vermeulen, Karin Van den Berg and Brian Custer designed the cost model, analysed and interpreted the data and wrote the draft manuscript. All other authors reviewed and approved the submitted manuscript.

INTRODUCTION

Human T-cell lymphotropic virus (HTLV) is transmitted by sexual intercourse, blood transfusion, injection drug use and vertical transmission via breastfeeding. As the virus is transmitted sexually and through breast milk, positive individuals are advised to disclose their status to their sexual partners and for women not to breast-feed. HTLV-1 infections may progress to two serious diseases, adult T-cell leukaemia (ATL) or HTLV-1 associated myelopathy (HAM). Globally, approximately 20 million people are estimated to be infected with the HTLV-1 virus of whom 95% remain asymptomatic for life.[1, 2]

In South Africa private and public healthcare systems exist in parallel with more than 80% of the population served by the public system which faces extreme resource constraints[3], such as significant unemployment, and a small tax base from which to fund healthcare. In 2015, the national treasury allocated R36 billion (**US** Dollars (USD) 2.4 billion) for the 46 million people who access public health services [R782.00 (USD52.00) per person per annum]. The South African National Blood Service (SANBS) supplies blood products to all hospitals in South Africa, except for those in the Western Cape Province. The majority of blood that SANBS provides goes to the public health care sector. The WHO guidelines for preventing transfusion-transmitted infection (TTI) through blood screening are:

> "Each country should have a national policy on blood screening, incorporated into the national blood policy that defines national requirements for the screening of all whole blood and apheresis donations for TTIs. The policy should define mandatory screening for specific infections and their markers and screening for other TTIs, based on national epidemiological data on blood borne pathogens. It should also outline the measures that will be taken to ensure that all screening is performed in the context of effective, quality-managed blood transfusion services and the consistent provision and most efficient use of available resources".[4]

HTLV-1/2 screening is not mandated in South Africa. Recently, SANBS had one highly suggestive case of transfusion-transmitted (TT) HTLV.[5]

A number of countries have questioned the cost-effectiveness of screening donations for HTLV considering the amount of resources required to prevent a small number of infections over a long time horizon especially when health care budgets are constrained.[6] In Norway, the cost of testing all new donors was estimated at US$ 9.2 million per life saved or US$ 420,000 per quality adjusted life year (QALY) gained.[7] More recently, Australia, UK and Canada have sought to implement a test first-time donors only strategy.[8–10]

We used a modified Alliance of Blood Operators (ABO) risk-based decision-making framework (RBDM) [11] to assess the risk and estimated consequences of HTLV in the blood supply in South Africa. The assessment took a limited scope and did not use all recommended parts of the RBDM. Specifically, a formal stakeholder engagement assessment was not conducted. Three decision drivers were identified; 1) Patient safety: a sustainable blood supply that protects recipients, 2) Economic factors: The appropriate allocation of finite resources within the health care system and 3) Social context: The psychological impact on an HTLV positive donor. These decision drivers lead to the

development of a risk assessment question “What HTLV screening strategy should be adopted by SANBS to mitigate the risk of TT-HTLV to patients, achieve the best use of finite health funds in the country and limit psychological impact to blood donors?” The Blood safety, Health economics, Budget impact and simplified cost-effectiveness, Operational risk and Ethical and Social concern/trust assessments were applied. The latter two are presented in the supplement and the HTLV seroprevalence study results are reported separately.[12] Briefly, in the seroprevalence study an overall South African donor HTLV-1/2 prevalence of 0.062% was found.

The objectives of this assessment were a budget impact and a short-term time horizon cost-effectiveness analysis to understand health benefits that could accrue. Four different risk management options were evaluated: universal HTLV screening of all donations, one-time screening of each donor **(i.e. all donors once and then only first time donors thereafter),** screening of first time donors only, or no screening for HTLV.

MATERIAL AND METHODS

Overview

The results of the HTLV seroprevalence study[12], intervention and treatment costs and TT efficiency data were used to estimate the economic implications of the four different strategies. We conducted a budget impact and cost-consequence analysis in terms of infections and disease prevented in recipients, but did not conduct a cost-utility analysis because health state preference weights (utilities) for HTLV infection are not available for South Africa or similar countries. The baseline analysis year was 2015. We used a healthcare payer/funder perspective rather than societal perspective because of the unavailability of data to fully account for all costs incurred in the public and private healthcare sectors in South Africa.

Health Economic Model Structure

A Microsoft Excel spreadsheet model was developed in which the number of donors, whole blood and apheresis donations, number of red blood cell (RBC), and 5-donation pooled buffy coat platelets issued annually were enumerated.

Donation Screening

In a seroprevalence study[12], we evaluated interventions where donation screening is conducted using a chemiluminescent immunoassay (ChLIA) (Abbott, Pleasanton, CA, USA), with confirmation testing performed using InnoLIA (Innogenetics, Ghent, Belgium). Confirmed positive donors are assumed to be notified, counselled and referred for clinical management. For HTLV disease progression in blood recipients only the two most severe diseases, ATL and HAM, were considered.

Probability Variables

The prevalence of HTLV in blood donations made to SANBS during 2013 was 0.062% which is equal to the probability of a donor being infected of 0.00062 which we used for the first time a donor is tested in the model. Incidence in an Australian study was reported to be

186 fold lower than the prevalence.[13] In Canada incidence in 2010 was reported to be 110 fold lower than prevalence [14]. No incident infections were detected over 20 years of testing in the UK[8] and in the USA, incidence was 25 fold lower than the prevalence.[15] Although Australia, UK and Canada report such low incidence we assumed with a higher prevalence in our donors the probability of a previously screened HTLV-negative donor becoming infected (incident infection) to be closer to the USA and chose a 40-fold lower or 0.000016. **From the reported 51 day HTLV window period[9] and published information[16] we assumed that universal screening would not detect 100% of infected donations, and that the residual risk was 10-fold lower than the incidence** i.e. 0.00000155. (Table 1) The equations used to determine the number of infected donations and products, the number of detected donations and remaining infected products for each screening strategy are documented in the supplement.

The transmission of HTLV by blood transfusion in non-leukoreduced blood components is reported to be between 35% and 65%.[2] However, several factors may reduce the risk of transmission, including: age of the blood product at time of transfusion, cold storage, buffy coat reduction of red cells and leukodepletion.[16] A retrospective study in the UK estimated an HTLV transmission rate through either leukoreduced or buffy coat reduced red cells at 1%.[17] For this model a transmission rate of 10% was assumed. SANBS buffy-coat reduces all donations and further leukoreduces 16% of donations and has had one highly suggestive case of TT-HTLV in the last 12 years. Due to consistent shortages of blood in South Africa, the majority of red blood cells are transfused within 7 days. We therefore modelled a worst case scenario assuming all red cell and platelet products were transfused during the infectious period.

Recipients of blood products are by definition a group with significant morbidity and the PROTON study confirms a five-year post-transfusion survival rate of ~50%[18]. Post-transfusion survival data are not available for South Africa. In South Africa, 95% of patients receive red blood cells with or without other components and 5% receive platelets only. Therefore, we estimated the weighted annual probability of dying after transfusion during the five-year period to be 0.10753. We therefore reduced the cost of patient care by 10%. In this model we estimated TT by unit transfused rather than by patient.

HTLV Outcomes

Outside of TT infection, ATL develops in 2-4% of patients with HTLV over 20 years with a 26% survival rate after three years.[19] The lifetime probability for individuals of developing HAM is 0.25-4% after 20 years.[16] There is evidence to suggest this period may be as short as 3 months following TT infection.[20, 21] There is no specific evidence to support a higher mortality rate for patients with HAM. Although we could only find 2 cases of TT-HTLV that resulted in ATL in the literature [22] and neither HAM or ATL are likely to occur in year one, we chose to use a 6% probability of clinical manifestation to ensure potential clinical outcomes were included in the analysis.

Costs

Analyses are reported in South African Rands (R) in the text and both R and US dollars [US $] in the tables. An exchange rate of R15.00 = $US 1 was used. The following costs were included in the model: 1) cost of screening donations for HTLV, 2) cost of counselling HTLV-confirmed positive blood donors, 3) cost of treatment for ATL, and 4) cost of treatment for HAM. (Table 1 and for a detailed breakdown please see tables 1 and 2 in the supplement)

A cost of R25.00 per donation was used for HTLV screening by ChLIA with an incremental increase when screening only first time donors to R40.00 and a cost of R527.00 per confirmatory test. Donation screening costs include the cost of false positives but exclude the minimal labor costs as HTLV testing would be performed in parallel with serology testing for HIV, HBV and HCV.

We estimated the total blood service cost to counsel a HTLV positive donor to be R2,625.00 (Table 1 supplement). This estimate includes staff time and resources for contacting and recalling donors.

Costs of ATL treatment were separated into first year, initial treatment for symptomatic illness and the following years (Table 2 supplement). The preferred initial treatment is bone marrow transplant, followed by conventional chemotherapy if the patient relapses. Bone marrow transplant and follow-up chemotherapy costs for one year were approximated at R1,500,000.00 and R300,000.00 respectively.(personal communication Olivier, D Health economist)

There are little published data on the cost of care for HAM. Patients differ in severity. We estimated an average single cost for HAM of R236,733.00 per annum. (personal communication Olivier, D Health economist). We portioned the costs as per the rate of ATL/HAM manifestation.

The model estimated the number of HTLV infected donations in the blood supply, the probability of TT and the number of clinically apparent infections for a two-year period for each of the four strategies. The total cost of each strategy was estimated using intervention and treatment costs. The costs per HAM/ATL clinical infection prevented were calculated.

Sensitivity Analysis

For each parameter in the model a one way sensitivity analysis was performed The two parameters which had a large influence on the model; prevalence of HTLV infection and transmission efficiency were tested in a two way sensitivity analysis using a range of 0.55% - 1% prevalence and 1% - 25% transmission efficiency.

RESULTS

HTLV infected units in blood supply

During 2015, SANBS collected 816,066 blood donations from 388,648 blood donors of which 109,571 were donated by first time donors. Table 2 shows the breakdown RBC,

apheresis and 5-pool buffy coat platelets issued. We estimate that without implementing HTLV screening 504.5 undetected HTLV seropositive donations from 241 blood donors would enter the blood supply leading to 592 infected blood components annually. Implementing universal screening, screening all donors once, or screening first time donors only will interdict 503 (99.7%), 499 (98.8%) and 68 (13.5%) of the 504 infected donations, respectively, leaving a possible 1.5 (0.25%), 7 (1.2%) and 514 (86.5%) unidentified infected blood products in the blood supply. **In the second year of screening all donors once the unidentified infected blood products would increase to 14** (14.9%) and when implementing a universal screening strategy, the number of infected donors will decrease to 79 due to permanent deferral of the blood donors who previously tested positive.

TT-HTLV and health care costs

Assuming a TT efficiency of 10% and a clinical manifestation of 6% of all TT-HTLV, we estimate that unscreened blood would result in 3.55 clinical cases of TT-HTLV disease annually with a total health care cost estimated to be R3,400,000 consisting primarily of treatment costs (Table 2). A universal donation screening strategy would prevent 3.54 (99.8%) and 0.55 (98.4%) clinical cases in year one and two respectively leaving 0.009 clinical disease events annually. The one-year cost of screening is estimated to be R24,000,000, however the cost per clinical TT-HTLV infection avoided increases 6-fold from R6,800,000 in year one to R43,000,000 in year two. Screening all donors once would prevent 3.51 (98.8%) clinical cases in year one and 0.48 (84.8%) clinical cases in year two, leaving 0.04 clinical TT-HTLV cases in year one at a total cost of R16,200,000 or R4,600,000 per clinical TT-HTLV infection prevented (Table 2). In year two the clinical TT-HTLV cases increase to 0.09. The total costs decrease to R5,100,000 but the cost per clinical TT-HTLV prevented increases to R10,700,000. Screening first time donors only will prevent 0.48 (13.5%) clinical TT- HTLV annually leaving 3.07 clinical TT-HTLV cases at a total cost of R7,900,000 or R16,440,000 per preventable clinical TT-HTLV infection.

Sensitivity Analysis

First we conducted a one way sensitivity analysis on each parameter, the result of which are in Table 3. Secondly, we conducted a two way sensitivity analyses on the most uncertain parameters in the model, the prevalence and transmission efficiency. If the transmission efficiency is increased to 25% and the prevalence increases to 1%, the total costs increase 40-fold to R139,000,000 if no screening is implemented, primarily to treat clinical TT-HTLV cases which increase to 143 cases per annum. Increased transmission efficiency and prevalence improves the cost-effectiveness for all the screening strategies (Table 4). When we reduce the transmission efficiency to 1% as described in the UK study and the prevalence to 0.055%, the cost of not screening is 78 fold cheaper than universal screening which will prevent 0.31 clinically apparent TT-HTLV cases from entering the blood supply at a cost of R75,760,000 per preventable case.

Assuming a similar 50% survival over five years for HAM as for blood transfusion recipients, treatment may last for many years with the accumulated treatment costs become increasingly influential.

DISCUSSION

We estimate that implementing universal screening for HTLV in the first year would prevent 3.54 clinical TT-HTLV cases at a total cost of R24,000,000 compared to a total estimated TT infection treatment cost of R3,450,000 if screening is not implemented. Screening all donors once reduces the annual cost by a third in year one and 5-fold in the second and subsequent years, but increases the remaining clinical infections 10 fold from 0.009 for universal screening in year 1 to 0.09 in year two with progressively more TT-HTLV events in subsequent years.

No single cost-effectiveness threshold is applicable to all countries, and determining a local cost-effectiveness threshold is complex. The WHO suggests using 3-times the Gross Domestic Product (GDP) per person of a country to define a 'cost-effective' threshold.[23] The WHO 3-times the GDP threshold is not necessarily used to make adoption decisions, and in many countries some medical treatments and also blood safety interventions are adopted which exceed the 3-times the GDP value, while other interventions which are less than this value may not be implemented. During 2015, 3-times the GDP per capita in South Africa was R260,000 ($17,300) which would define all of the results described for testing blood donations in South Africa for HTLV as not cost-effective. In contrast, Viscusi and Masterman[24] recommend using the value of a statistical life (VSL) for cost-effectiveness analysis. Income levels, life expectancies, and social norms regarding risk and death determine a nation's VSL. The reported VSL for South Africa is R15,840,000 ($1,056,000).[24] In this analysis, we estimated that implementing universal donation screening for HTLV in the first year would cost R6,800,000 per clinical disease avoided, i.e. cost-effective using a VSL threshold. However in the subsequent years it increases 6 fold to R43,253,700 and would no longer be classified as cost-effective using the VSL threshold. A strategy of screening all donors once would be classified as cost-effective using the VSL threshold but would not using the 3X GDP threshold. Moreover South Africa has the largest HIV positive population globally with 7 million people currently living with HIV and to achieve the 90-90-90 plan of test, treat and suppress, funding for HIV is expected to be more than R25 billion this year. Concurrently the Government is in the process of planning the implementation of the national health insurance to alleviate the poor conditions of the public sector, which will also require serious funding.

Stigum et al compared cost effectiveness for different pathogens, at a prevalence of 10 per 100,000 for HTLV or HIV, they determined that HTLV screening would result in a net cost increase while HIV screening would result in a net cost saving.[7] In our seroprevalence study we found a prevalence of 62 per 100,000 suggesting that the cost-effectiveness in year 1 would be 6-fold better than in Norway, however in subsequent years when the prevalence is assumed to decrease after screening out HTLV positive repeat donors, the cost effectiveness will become similar to the results reported in Norway.

In comparison in South Africa, the HIV prevalence is 210 per 100,000. A cost-effectiveness analysis of testing for HIV, HBV, and HCV in South Africa with no testing in place estimated that 6830, 790, and 109 HIV, HBV, and HCV infections would enter a 1-million unit blood supply. The use of serology and individual donation nucleic acid testing reduced

the number of predicted infections to 26, 18, and 0.3, respectively.[25] The model assumptions were a worst-case and TT HIV and HBV are much lower than estimated in this analysis.[26, 27] Using health state preference weights not measured in South Africa, ID-NAT had an incremental cost-effectiveness of R418,995 (US$27,933) per QALY gained for HIV, HBV, and HCV compared to serology alone.[25] This result for HIV, HBV, and HCV ID-NAT exceeds the 3-times the GDP threshold for South Africa, but is well below the VSL threshold.

A strategy of screening all blood donors once and then testing first time donors has the benefit of being 1.5-fold more cost-effective, but repeat donors with incident HTLV infections will not be detected. From our analysis, we estimated 14 incident cases per annum. This may be overestimated as we assumed an incidence ratio of 1:40 of the prevalence far higher than that reported in Australia [10], Canada [14] and in the UK[8] . Eleven percent of SANBS donors are under the age of 18 and 80% are under the age of 50, we showed in our seroprevalence study that HTLV prevalence increases with age with 50+ donors being 6.4 times more likely to be HTLV positive than their younger counterparts most probably due to an increased number of exposures through life. In addition, in future years, as prevalent infections are screened out by any of the three screening strategies the cost-effectiveness will become increasingly less favorable unless there is a significant new burden of incident HTLV infection in the donor base.

The NHS in the UK published a HTLV lookback study in 2013. Implementation of HTLV screening in 2002 led to the identification of 437 HTLV-positive historic donations.[17] These donations were either leukoreduced (284), buffy-coat reduced (60) or non-leukoreduced (93). Six potential TT infections were identified of which five were from non-leukoreduced red cell products and one was from a leukoreduced product (OR 0.027; $P<0.001$). The potential TT-HTLV involving the leukoreduced product was not confirmed with phylogenetic sequencing and the recipient was noted to be at high risk for acquiring HTLV infection through other routes. SANBS uses a buffy-coat reduced method to prepare all red blood cells products. This may explain the lower than expected number of reported cases of TT-HTLV in South Africa considering the observed HTLV seroprevalence. Another reason could be under-reporting of HTLV infection due to either poor reporting structures or inability to link infection to a transfusion received many years earlier.

More recently it has been reported that $9x10^4$ infected leukocytes are required to cause TT-HTLV and that in an asymptomatic blood donor approximately 2% of the donors leukocytes would be infected [28]. Therefore an HTLV infected blood product would require $4.5x10^6$ leukocytes to transmit HTLV. Historically, non-leukoreduced RBC which have approximately $6x10^9$ leukocytes, were reported to have a transmission efficiency of 35-65%[2]. Quality control testing of 1% of the SANBS buffy-coat reduced RBC's reported a mean of $9.6x10^8$ leucocytes per RBC, 6-fold lower than non-reduced products. We therefore estimated that the transmission efficiency is closer to 6%-11%. For the model we assumed 10%, and used a range of 1%-25% in sensitivity analyses.

A major challenge with screening blood donors is the long latent, asymptomatic phase of the infection which can last a lifetime for 94% of individuals and up to 20 years for the 6% of

individuals who develop clinical disease. Blood transfusion services are obliged to inform blood donors if they test positive for any pathogens. For HTLV, this process is complicated by the significant psycho-social issues raised by an infection which has no curative treatment, is sexually and vertically transmitted, may require life-long annual screening tests and procedures for early identification of disease progression and disclosure of a sexually transmitted disease to past, current and future sexual partners as well as to children who may be at risk of the infection.[29]

There are a number of limitations in this study. Firstly, we assumed a patient survival rate of 50% after five years using the PROTON study data[18] however this information is not known in the South African context (survival may be worse given South Africa's disease burden and poorly resourced healthcare services.) However, 69% of the blood at SANBS is issued to the public sector where the majority of transfusion recipients are between 21 and 40 years old. In contrast, the majority of transfusion recipients in the private sector are older, between 51 and 80 years of age; similar to patients in high human development index countries.[30] Therefore it is possible that the survival rate, especially among the younger recipients in the public sector, could be higher than 50%, which would result in a more cost-effective intervention than modelled here although it showed very little difference in the sensitivity analysis. Secondly, the model is structured so that each blood recipient receives a single blood product, and does not account for the transfusion of multiple components. On average 2.39 and 2.16 red blood cells are transfused per transfusion event in the private and public sectors, respectively. This assumption simplifies the model and also leads to the highest count for the total number of TT-HTLV infections in recipients, but the probability of a recipient receiving two products that are HTLV positive would be negligible.

A third limitation not accounted for is that, South Africa has the largest HIV population globally with in-hospital HIV prevalence reported as high as 50%,[3] and transfusing HTLV-1 to HIV-1 positive patients may worsen both HIV-1 and/or HTLV disease with increasing risk for development of neurological complications including HAM, leukemia and lymphoma.[31, 32] In contrast HTLV-2 co-infection may confer an immunological and survival benefit with little evidence of neurological disease and malignancy.[33] We found in our prevalence study that all of our HTLV cases were HTLV-1.

We show in our analysis the significant economic implications of implementing either a universal or a first time donor only strategy for HTLV screening. While there are several ethical considerations to consider and prevention of TT infections remains a critical aspect of blood safety, at an annual screening cost of R24,000,000, we believe resources could be better utilized in preventative and primary health care programs. Such programs have the potential of improving the health status of larger numbers of the South African population as compared to HTLV screening of blood donations. At this time, SANBS has not implemented HTLV screening of the blood supply. Surveillance of donors and patient outcomes studies for HTLV should continue to be conducted so that this decision can be re-evaluated on an ongoing basis with contemporary data.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Model parameters for health economic assessment, including base case values, range used for sensitivity analyses, and data source.

Effectiveness	Base Case Value (Range used in Sensitivity Analyses)	Parameter Source or Citation
Incidence, Prevalence, and Residual risk		
Prevalence HTLV infection in donations	0.00062 (0.00055 to 0.01)	Vermeulen
Incidence of new infection in donors	0.000016 (6.2^{-5} to 6.2^{-6})	[8, 13–15]
Residual risk of HTLV with screening	0.00000155 (1.55^{-6} to 1.55^{-7})	[9, 16]
Event Probabilities		
Probability of transfusion transmitted HTLV	0.10 (0.1 to 0.25)	[17]
Annual probability of developing HAM or ATL	0.06 (0.0025 to 0.06)	[16, 19, 22]
Annual probability of mortality after transfusion	0.10753 (0.15 to 0.05)	[18]
Cost		
Donation Screening Costs	Rand [USD] (−50%-50%)	
ChLIA for universal screening per donation	25.00 [1.7] (12.50–37.50)	Abbott
ChLIA for screening all donors once per donation	35.00 [2.3] (17.50–52.50)	Abbott
ChLIA for screening first time donors per donation	40.00 [2.7] (20.00–60.00)	Abbott
InnoLIA confirmatory	527.00 [35] (263.50–790.50)	Innogenetics
Donor notification counselling	2,625.00 [175] (1312.50–3937.50)	Van Den Berg
Treatment Costs		
Cost to treat ATL	189 568.96 [12 637.93]	Olivier, D
Cost of Bone marrow transplant	1 500 000.00 [100 000.00]	
Follow up chemotherapy	300 000.00 [20 000.00]	
Cost to treat HAM	236 773.10 [15 784.87]	
Total treatment cost used in model	1 078 911.00 [71 900.40] (539 455.50-1 618 366.50)	
Blood Supply		
Annual Numbers for Donations, Donors, and Products		
Number of donations	816 066 (±20%)	SANBS 2015
Number of donors	388 648 (±20%)	BI reporting
Number of first-time donors	109 571 (±20%)	
Number of RBC blood products issued	777 368 (±20%)	
Number of first time donor RBC issued	95 683 (±20%)	
Number of 5-pool buffy coat platelets issued	29 396 (±20%)	
Number of apheresis platelets issued	27 524 (±20%)	

Table 2

Base case results for modelled impact in first and second year of screening donors for HTLV in South Africa.

Outcome	Implementation Year	No screening	New donors only	All donors once	Universal screening
Number of HTLV positive donors interdicted	1 2	0 0	68 68	499 68	503 79
Number of HTLV infections remaining in components	1 2	592 592	512 512	6.8 14.3	1.48 1.48
Number of TTI's prevented (% of TT cases)	1 2		7.96 (13.5) 7.96 (13.5)	58.51 (98.8) 7.96 (84.8)	59.02 (99.8) 9.24 (98.4)
Number of clinical infections prevented (% of clinical cases)	1 2		0.48 (13.5) 0.48 (13.5)	3.51 (98.8) 0.48 (84.8)	3.54 (99.8) 0.55 (98.4)
Remaining transmitted infections (% of TT cases)	1 2	59.16 (100) 59.16 (100)	51.20 (86.5) 51.20 (86.5)	0.68 (1.20) 1.43 (15.2)	0.15 (0.2) 0.15 (1.6)
Remaining clinically apparent infections (% of clinical cases)	1 2	3.55 (100) 3.55 (100)	3.07 (86.5) 3.07 (86.5)	0.04 (1.2) 0.09 (15.2)	0.01 (0.2) 0.01 (1.6)
Total cost annual cost in Rand [USD]	1 2	3 446 942 [229 796] 3 446 942 [229 796]	7 853 017 [523 534] 7 853 017 [523 534]	16 193 510 [1 079 567] 5 109 092 [340 606]	23 985 661 [1 599 044] 23 985 661 [1 599 044]
Cost per clinical infection prevented in Rand [USD]	1 2		16 437 719 [1 095 848] 16 437 719 [1 095 848]	4 614 867 [307 658] 10 694 457 [712 963]	6 773 766 [451 584] 43 253 683 [2 883 579]

Table 3

One-way sensitivity analyses of the key model parameters

Model Parameter	Range for 1-way sensitivity (low and high values			Impact on cost per clinically apparent infection prevented		
				New donors only Rand [USD]	All donors once Rand [USD]	Universal screening Rand [USD]
Prevalence	0.055% 1%			17 678 091 [1 178 539] 7 296 183 [486 412]	5 143 766 [342 918] 716 877 [47 792]	7 578 588 [505 239] 842 227 [56 148]
Incidence	6.2^{-5} 6.2^{-6}			15 572 085 [1 038 139] 16 622 525 [1 108 168]	4 763 347 [317 556] 4 586 140 [305 743]	6 777 109 [451 807] 6 773 098 [451 540]
Residual Risk	1.55^{-6} 1.55^{-7}			16 437 719 [1 095 848] 16 744 893 [1 116 326]	4 614 867 [307 658] 4 611 345 [307 423]	6 773 766 [451 584] 6 772 663 [451 511]
Cost of screening	R20.00[a] R60.00	17.50[b] 52.50	12.50[c] 37.50	11 853 630 [790 242] 21 021 809 [1 401 454]	R2 676 602 [178 440] R6 553 131 [436 875]	R3 901 490 [260 099] R9 646 042 [643 069]
Cost of confirmation	R263.50 R790.50			16 400 274 [1 093 352] 16 475 165 [1 098 344]	4 577 421 [305 161] 4 652 313 [310 154]	6 736 336 [449 089] 6 811 196 [454 080]
Cost of counselling	R1312.50 R3937.50			16 251 204 [1 083 414] 16 624 235 [1 108 282]	4 428 348 [295 223] 4 801 386 [320 092]	6 587 328 [439 155] 6 960 204 [464 014]
Cost of treatment	R539 455.50 R1 618 366.50			13 315 707 [887 714] 19 559 732 [1 303 982]	4 609 218 [307 281] 4 620 516 [308 034]	6 772 552 [451 503] 6 774 980 [451 665]
Annual survival	85% 95%			16 090 829 [1 072 722] 16 784 610 [1 118 974]	4 614 239 [307 616] 4 615 495 [307 700]	6 773 631 [451 575] 6 773 901 [451 593]
Transmission Efficiency	1% 25%			108 180 973 [7 212 065] 10 321 502 [688 100]	46 046 984 [3 069 799] 1 852 726 [123 515]	67 715 813 [4 514 388] 2 710 963 [180 731]
Number of collections	−20% +20%			12 661 557 [844 104] 20 536 778 [1 369 119]	5 419 740 [361 316] 4 038 486 [269 232]	6 511 214 [434 081] 6 962 593 [464 173]

Note:

[a] cost of screening when only screening first time donors

[b] cost of screening when screening donors once

[c] cost of screening when performing universal screening

Table 4

Two-way sensitivity analysis using a low value prevalence of 0.055% and high value prevalence of 1% and a transfusion transmission efficiency range low value of 1% and high value of 25%.

Outcome	Sensitivity Scenario	No screening	New donors only	All donors once	Universal screening
Number of TTI's prevented	Low prevalence & Low transmission High prevalence & High transmission	- -	0.71 321.06	5.19 2358.19	5.24 2379.68
Number of clinical infections prevented (6%)	Low prevalence & Low transmission High prevalence & High transmission	- -	0.04 19.26	0.31 141.49	0.31 142.78
Remaining transmitted infections	Low prevalence & Low transmission High prevalence & High transmission	5.25 2385.63	4.54 2064.56	0.06 27.44	0.01 5.95
Remaining clinically apparent infections (6%)	Low prevalence & Low transmission High prevalence & High transmission	0.31 143.14	0.27 123.87	0.00 1.65	0.00 0.36
Total cost in Rand [USD]	Low prevalence & Low transmission High prevalence & High transmission	305 777 [20 385] 138 989 606 [9 265 974]	5 110 438 [340 696] 128 391 468 [8 559 431]	15 979 922 [1 065 328] 41 531 971 [2 768 798]	23 798 829 [1 586 589] 48 309 496 [3 220 633]
Cost per clinical infection prevented in Rand [USD]	Low prevalence & Low transmission High prevalence & High transmission	- -	120 584 686 [8 038 979] 6 664 888 [442 993]	51 335 980 [3 422 399] 293 530 [19 569]	75 764 034 [5 050 936] 338 347 [22 556]