Evaluating Strategies to Reduce Risk of HIV Infection in the U.S. Blood Supply

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BACKGROUND

- Men who have sex with men (MSM) have been prohibited from donating blood in the U.S. since 1985.
- Current FDA policy bans donations from any man who has had sex with a man in the prior year.[1]
- All donated units are HIV-tested with 4th generation Ab/Ag and viral load testing, resulting in an HIV transmission risk via the blood supply of 1 in 1.5 million.[2]
- Given improvements in HIV testing over the past 3 decades,[3] the current MSM ban may be unnecessary

METHODS

We developed a descriptive model to compare 4 strategies to screen the blood supply:

1) Current: a deferral for MSM (based on self-reporting) followed by testing of all donated units.
2) Test-only: no deferral, with testing of all donated units.
3) Risk-based: a deferral for all male donors who report condomless anal intercourse in the past 6 weeks, followed by testing of all donated units.
4) Ask-only: a deferral for MSM (based on self-reporting) with no testing

- The primary outcome was the expected number of accepted HIV-infected donations per million units of donated blood.
- Sensitivity analyses were used to examine parameter uncertainty for the 2 strategies found in the base case to result in lowest risk.

Table 1. Input parameters

INPUT PARAMETERS	VALUE	RANGE EXAMINED
Prevalence of MSM	3.7%[4]	3-20%
Prevalence of acute HIV in MSM (per 100,000)	58.5[5]	
Prevalence of chronic HIV in MSM (per 100,000)	1,758[5]	
Prevalence of acute HIV in MSW (per 100,000)	1.3[5]	
Prevalence of acute HIV in MSW (per 100,000)	21.6[5]	
Percent of MSM having CAI (per month)	4.2%[6]	
Percent of MSW having CAI (per month)	0.6%[7]	
Probability of disclosing CAI	97.4%	85-100%
Probability of disclosing MSM status	97.4%[8]	94-100%
4th Generation Ab/Ag HIV Test Sensitivity	99.4%[9]	99-100%
Sensitivity of detecting acute HIV (within 6 weeks from infection)	75%[10]	0-90%

MSM: men who have sex with men, MSW: men who have sex with women, CAI: condomless anal intercourse. HIV prevalence indicates those unaware of diagnosis.

Table 2. Base case results (rounded to the nearest whole unit of blood)

STRATEGY	NUMBER OF HIV-INFECTED UNITS OF BLOOD ACCEPTED (PER 1 MILLION DONATIONS)
1) ***Current***	5
2) ***Test-only***	6
3) ***Risk-based***	2
4) ***Ask-only***	685

- The risk-based strategy resulted in the lowest number of expected HIV-infected units of blood accepted.
- The current strategy was the second best, resulting in a more than two-fold increase in the number of accepted HIV-infected units.

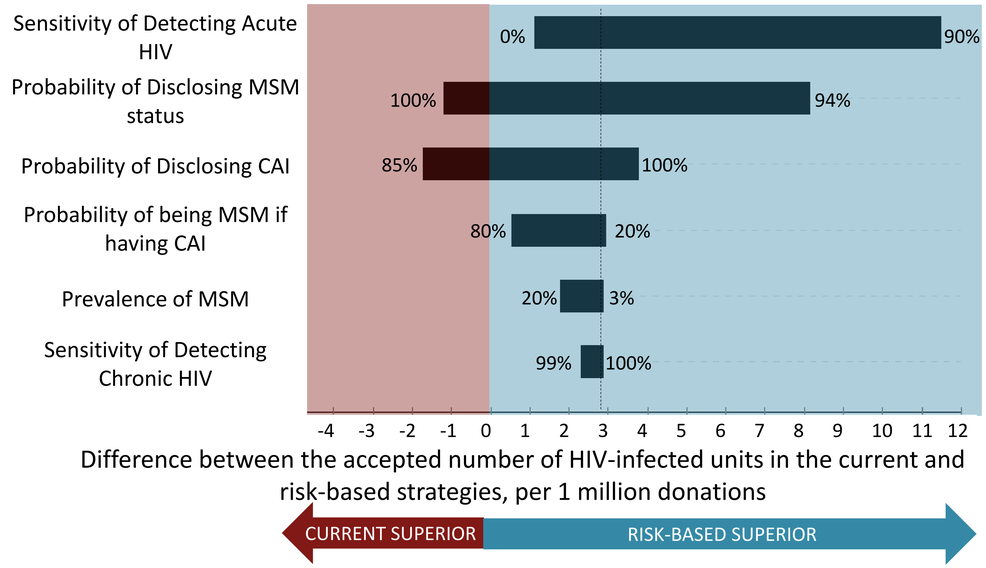

Figure 1. One-way sensitivity analyses where selected input parameters were varied over plausible ranges. Dashed line represents the base case.

- Across plausible ranges of test sensitivity (for acute and chronic infection) and MSM prevalence, a risk-based strategy remains superior to the current strategy.
- The current strategy becomes superior when there is either a low rate of accurate self-reported disclosure of CAI or a high rate of accurate self-reported MSM status.

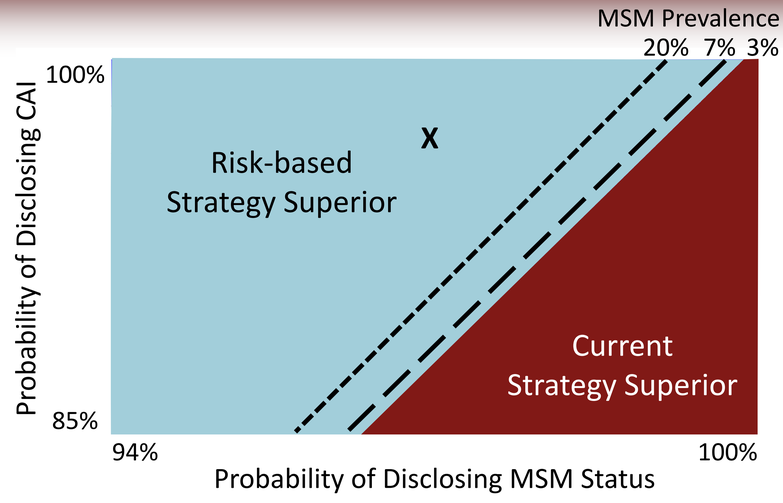

Figure 2. Three-way sensitivity analysis evaluating variations in probability of disclosing MSM status, CAI, and MSM prevalence. The base case is marked by an X.

- Over plausible ranges of variation, the risk-based strategy remains superior in the majority of cases, at all ranges of MSM prevalence evaluated.
- As both the current and risk-based screening strategies approach 100% probability of excluding the intended population, the current strategy becomes superior.

LIMITATIONS

- The analysis assumes no self-deferral, which would decrease the number of accepted HIV-infected units in all strategies.
- We defined acute HIV as infection less than 6 weeks; this model does not evaluate risk for a shorter deferral period.
- The probability of disclosing CAI is not defined for MSM and MSW and contributes uncertainty to the model.

CONCLUSION

- A risk-based screening strategy may improve the safety of the blood supply and decrease stigma associated with the current ban on MSM donors.
- Variations in effectiveness of the current and risk-based screening questions contribute the most uncertainty.

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