

## Use of a Rapid HIV Home Test to Screen Sexual Partners: An Evaluation of its Possible Use and Relative Risk

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**Abstract** We estimated the HIV risk reduction that could be attained by using a rapid HIV home test (HT) to screen sexual partners versus using condoms in different proportions of anal intercourse (AI) occasions among men who have sex with men (MSM). Special attention was paid to the role of the window period during which infected cases go undetected. Our results show that if MSM engage in AI without condoms following a non-reactive HT result, they have lower chances of becoming infected by someone still in the window period than by following heuristics and using condoms inconsistently. For MSM who do not use condoms, use of HT as a screening device may be a useful risk reduction strategy. This advantage increases with higher HIV population prevalence. With higher HIV incidence, this strategy will not provide any advantage if condoms are used in as little as one out of four occasions.

**Keywords** Serosorting · Rapid HIV test · Risk reduction for HIV · Gay men · Men who have sex with men

### Introduction

Evidence from recent studies on the sexual behavior of men who have sex with men (MSM) substantiates the assertion that some of the men who will not or cannot use condoms consistently are actively seeking and engaging in strategies to lower the risk of HIV transmission (Eaton et al. 2007; Elford et al. 2007; George et al. 2006; Golden et al. 2008; Halkitis et al. 2005; Mao et al. 2006; Parsons et al. 2005; Pinkerton 2008; Poppen et al. 2005; Truong et al. 2006; Xia et al. 2006). Serosorting, defined as “the practice of preferentially choosing sex partners, or deciding not to use condoms with selected partners, based on their disclosed, concordant HIV status” (Golden et al. 2008, p. 212), has increased in popularity among HIV-negative MSM. However, recent studies have demonstrated that this practice is not effective and may actually increase men’s risk of HIV transmission (Eaton et al. 2007; Golden et al. 2008; Pinkerton 2008). This may occur if, for example, assumptions about one’s own status are inaccurate (Eaton et al. 2007; Golden et al. 2008; Pinkerton 2008), as may be the case if one is tested for HIV infrequently. A recent study found that testing intervals were wide for the majority of MSM occurring 14 months, on average, after the last test (Eaton et al. 2007); knowledge of one’s own HIV status may be inaccurate if such a large interval is the norm and the individual engages in frequent HIV risk behavior.

Other studies have documented a widespread lack of accurate knowledge about one’s own HIV status.

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MacKellar et al. (2005), using data collected from MSM, ages 15–29, at 263 randomly sampled venues in six US cities between 1994 and 2000, found that the majority of MSM who tested positive were unaware of their infection. Estimates indicate that, compared to people who are aware of their infection, those who are unaware of their status engage in greater sexual risk behaviors (Marks et al. 2005), and contribute to new infections disproportionately (Marks et al. 2006).

Various efforts are underway to increase the number of individuals who are regularly tested for the virus in the US (Branson et al. 2006), including making a rapid HIV test available for over-the-counter (OTC) use (Huff 2005; Spielberg et al. 2004; Walensky and Paltiel 2006; Wright and Katz 2006). In November of 2005, the FDA started to consider licensing the OraQuick® ADVANCE™ Rapid HIV-1/2 Antibody Test, produced by OraSure Technologies Inc., for OTC sale (Richmond 2005; Wright and Katz 2006). This test is already approved by the FDA for use in testing facilities (Branson 2000) and, if approved for OTC sale, could be self-administered in the privacy of one's own home using an oral fluid sample.

Despite the potential of a rapid HIV home test (HT) to reach individuals who might be reluctant to test themselves in a clinical setting, there is concern that it could be used to screen partners prior to sexual intercourse (Walensky and Paltiel 2006; Goldstein 2005; Harris 2005). All antibody-based tests have a window period during which an infected individual tests negative (Fiebig et al. 2003); the home test is no exception. Most worrisome, this is a period of acute HIV infection during which a newly infected individual may be most contagious (Ahlgren et al. 1990; Jacquez et al. 1994; Pilcher et al. 2005; Rapatski et al. 2005; Wawer et al. 2005). If individuals decide to have sex without condoms after receiving a false non-reactive HT result, they might unknowingly put themselves at risk for infection.

Our study objective was to estimate the risk of HIV infection run by MSM if they use HT to screen potential sexual partners as compared to the risk run if they use condoms inconsistently. We used epidemiological and behavioral data from MSM to address the following research question: Given that antibodies are not likely to be detected during the 3-month window period of primary or acute HIV infection, a high-infectivity stage during which the rate of transmission is thought to be highest as compared to the subsequent asymptomatic stage of infection, and considering that partners are likely to get a false-negative result during this period, would lack of condom use following a non-reactive HT result increase an individual's risk of HIV infection when compared to inconsistent condom use without HT use?

## Methods

We computed probabilities of becoming HIV infected based on various assumptions about model parameters to identify the point at which HT use to screen partners presents an increase in risk, particularly since antibodies are not likely to be detected by HT during the first 3 months of infection, relative to the protection provided by different levels of condom use (proportion of anal intercourse [AI] occasions that are protected with a condom). Similar models have been used to estimate infection risks based on different patterns of sexual behavior (Pinkerton and Abramson 1993) and combinations of condom and microbicide use (Foss et al. 2003), as well as to model the effect of HAART on infectiousness (Blower et al. 2000; Law et al. 2001). The model is static, in that it provides probabilities over a fixed period of time and assumes fixed infectivity, prevalence and incidence rates. Although we recognize the importance of calculating the risk of ever being infected over a lifespan, as suggested by Pinkerton and Abramson (1993), in this model we consider a 1 year span for the sake of clarity. We assume statistical independence among the parameters (i.e., risk of HIV transmission is the same irrespective of the sexual occasion, whether it is the first or hundredth with an infected person; becoming infected from one partner is independent from becoming infected from other partners; Pinkerton and Abramson 1993; Foss et al. 2003). Parameter estimates were identified through data resulting from *Frontiers in Prevention* (FIP), a study conducted in New York City with MSM who reported using condoms inconsistently or not at all (see Carballo-Diéguez et al. 2006; and Ventuneac et al. 2009 for a description of the study and sample), and a literature search using MEDLINE with the search terms “HIV incidence” and “HIV prevalence,” and narrowing results to “MSM” and “NYC epidemiology” (national studies were reviewed for NYC data) from 1998 to July of 2008. We also contacted the New York City Department of Health and Mental Hygiene for data on inconsistent condom users.

We defined the parameters used in the equations and how we obtained their estimates as follows. Let  $\pi$  be the probability that a sexual partner is HIV infected. We varied  $\pi$  to be 8.4, 12.1, 14, 18, and 20%, based on HIV prevalence estimates among MSM in NYC ranging from 8.4 to 18% (Catania et al. 2001; Centers for Disease Control and Prevention 2001, 2005; Koblin et al. 2000; Manning et al. 2000; McQuillan et al. 2006; Torian et al. 2002; Valleroy et al. 2000). Let  $\delta$  be the probability that a sexual partner is in the acute infection stage. We used estimates of HIV incidence in NYC of 2.5% (2,500 per 100,000 person-years of follow up [p-y]; Nash et al. 2005), 5.5% (5,500/100,000

p-y; preliminarily estimated among MSM who used condoms inconsistently from the National HIV Behavioral Surveillance data; personal communication with Christopher S. Murrill at New York City Department of Health, December 15, 2005), and 7.6% (7,600/100,000 p-y; Centers for Disease Control and Prevention 2001) and divided these by  $4\pi$  (which we varied as stated above) to reflect that the acute stage lasts typically 3 months (Ahlgren et al. 1990; Jacquez et al. 1994; Pilcher et al. 2005; Rapatski et al. 2005; Wawer et al. 2005). Let  $\alpha$  be the probability of infection per contact (sex occasion) during the primary/acute infection, and let  $\beta$  be the probability of infection during the chronic asymptomatic stage. In our model, we estimated  $\alpha$  and  $\beta$  to be .024 and .002 respectively, based on estimates of infectivity per contact in gay men previously used by Rapatski et al. (2005). Their stage ratios are similar to stage ratios of estimates found by Wawer et al. (2005; actual stage infectivities for vaginal intercourse were lower).

Let  $\lambda$  be the probability of condom breakage and slippage, estimated to be 5.4% in our calculations (2.7% for each; Grady and Tanfer 1994), and let  $\varepsilon$  be the probability of HT correctly identifying HIV-positive partners, which we derived from sensitivity estimates provided by OraSure (sensitivity = 99.3%; 95% CI = 98.4–99.7%). Let  $\gamma_{HT}$  be the probability of having sex with a condom if HT indicates a reactive result. Based on findings from FIP data, 12% of HIV-negative men by self-report, will engage in unprotected AI with HIV infected partners. In our model, we conservatively anticipated an 88% condom usage rate for HT screeners with a reactive result for HIV, i.e.,  $\gamma_{HT} = .88$ . Let  $\mu_{HT}$  represent Foss et al. (2003) concept of a method's use-effectiveness against HIV; it combines the probabilities of a true positive test result (sensitivity  $\varepsilon$ ), having sex with a condom if HT indicates a positive result (with probability  $\gamma_{HT}$ ), and condom non-breakage and non-slippage (with probability  $1 - \lambda$ ). Thus,  $\mu_{HT}$  is the probability that an individual is protected by condom use with a positive partner in the non-acute stage, per contact after HT use, assuming that HT-use is consistent with all partners. From the above definitions,  $\mu_{HT} = \varepsilon\gamma_{HT}(1 - \lambda)$ , because the test must first show a reactive result (with probability  $\varepsilon$ ), a condom must be used (with probability  $\gamma_{HT}$ ), and properly so (with probability  $1 - \lambda$ ). Without use of HT, the condom use-effectiveness  $\mu_C$  then equals  $\gamma_C(1 - \lambda)$  where  $\gamma_C$  is the condom use consistency. This is because the condom is used with probability  $\gamma_C$  and is used properly with probability  $(1 - \lambda)$ . We varied  $\gamma_C$  from 0 to 75% in our calculation.

Let  $m$  be the number of partners per year. We used FIP data to estimate the number of male sexual partners in the previous 2 months of HIV-negative men in our sample (Mdn = 7,  $M = 11.83$ ,  $SD = 11.27$ ). In our model, we used the median (3.5 partners per month, therefore 42 per

year) rather than the mean because the distribution was skewed. Finally, let  $n$  be the number of occasions per partner per year. Although reasonable assumptions could be made about the number of occasions per partner type (e.g., greater occasions with familiar partners versus a few one-night stands, as Pinkerton and Abramson (1993) considered in their model), we used FIP data to estimate the average number of anal intercourse occasions in the previous 2 months (Mdn = 10,  $M = 17.03$ ,  $SD = 26.51$ ) and estimated 1.43 occasions per partner per month in our calculations (therefore 17 per year).

The equations used to calculate the probability of HIV infection are presented below. If HT is used to screen partners (i.e., under the *HT condition*), the probability of HIV infection is:

$$p_{HT} = 1 - ((1 - \pi) + [\pi\delta\{1 - \alpha\}^n + \pi(1 - \delta)\{1 - \beta(1 - \mu_{HT})\}^n])^m$$

If HT is not used to screen partners, the probability of HIV infection is:

$$p_C = 1 - ((1 - \pi) + [\pi\delta\{1 - \alpha(1 - \mu_C)\}^n + \pi(1 - \delta)\{1 - \beta(1 - \mu_C)\}^n])^m$$

Notice that the probability of no HIV infection under the HT condition ( $1 - p_{HT}$ ) is calculated as the disjoint union of three events: (1) partner not infected ( $1 - \pi$ ); (2) partner infected and in the acute stage ( $\pi \cdot \delta$ ); and (3) partner infected and in the chronic stage with probability  $\pi(1 - \delta)$ . The probability of no infection given an infected partner in the chronic stage in the HT condition is the term  $1 - \beta(1 - \mu_{HT})$ . This is in fact the complement of the probability of an infection given the conditions, which occurs if and only if there is a transmission (with probability  $\beta$ ) in the event of an unprotected occasion (with probability  $1 - \mu_{HT}$ ). It is important to note that we assume conservatively that if HT returns a non-reactive result, condoms will definitely not be used. Therefore, only one term is required to specify the probability of a successfully protected occasion ( $\mu_{HT}$ ). While HT is not used to screen partners, we vary levels of condom use consistency ( $\gamma_C$ ) to calculate the condom use-effectiveness ( $\mu_C$ ).

## Results

Table 1 lists the probabilities of HIV infection for HT-use to screen sexual partners versus varying levels of condom use by various HIV prevalence and incidence estimates, while factoring in infectiousness. The results of our calculations show that the effectiveness of HT-use as a strategy in reducing one's risk of becoming HIV infected largely depends on prevalence and incidence of HIV in the

**Table 1** Probability of becoming HIV infected using HT to screen versus inconsistent condom use

$\pi$ (%)	$\gamma_C$	$\delta_{(2.5\%/4\pi)}$		$\delta_{(5.5\%/4\pi)}$		$\delta_{(7.6\%/4\pi)}$	
		$p_{HT}$	$p_C$	$p_{HT}$	$p_C$	$p_{HT}$	$p_C$
8.4	0	.103	.180	.192	.256	.249	.304
	.25		.143		.207		.249
	.50		.103		.152		.185
	.75		.060		.090		.110
12.1	0	.111	.222	.199	.294	.256	.340
	.25		.177		.238		.278
	.50		.128		.175		.207
	.75		.074		.103		.123
14	0	.115	.242	.203	.312	.260	.357
	.25		.194		.254		.293
	.50		.140		.187		.218
	.75		.081		.110		.130
18	0	.124	.284	.211	.350	.267	.393
	.25		.228		.286		.323
	.50		.166		.211		.241
	.75		.096		.125		.145
20	0	.128	.304	.215	.368	.271	.410
	.25		.245		.301		.338
	.50		.178		.223		.253
	.75		.104		.132		.152

$\pi$  = HIV prevalence;  $\delta$  = HIV incidence/ $4\pi$  (e.g.,  $2.5\% \div (4 \times 8.4\%)$ );  $\gamma_C$  = condom-use consistency;  $p_{HT}$  = probability of infection under the HT condition;  $p_C$  = probability of infection under various condom-use consistency levels (HT is not used to screen partners)

population. The relative advantage of HT-use as a risk reduction strategy in comparison to no condom use is greater with higher prevalence. With lower prevalence (8.4%) and factoring in incidence of 2.5%, the probability of infection is ~8% lower under the HT condition versus no condom use (.103 vs. .180, respectively). The difference doubles (17.6%) with a prevalence of 20% (.128 for HT vs. .304 for no condom use, with 2.5% incidence factored in). This is mainly attributable to a device's ability to accurately detect antibodies to HIV after antibody seroconversion (Busch et al. 2003).

When condom use is inconsistent, HT-use provides some advantage (i.e., lower risk of HIV infection); however, underlying HIV prevalence and incidence rates determine the point at which such advantage is present. Under the 8.4% prevalence and 2.5% incidence condition, the point at which there is greater risk of becoming infected occurs for HT-use when condoms are used on half of occasions, meaning men would have lower chances of becoming HIV infected, if they used condoms on half or more of AI occasions than if they used HT to screen their

partners before AI. HT-use would be advantageous to men who use condoms on less than half of AI occasions they engage in. With prevalence of 20%, increased risk occurs for HT-use only when condoms are used on 68% or more of occasions. In other words, the advantage of HT-use increases with higher prevalence in the population.

However, the relative advantage of HT-use compared to inconsistent condom use as a risk reduction strategy decreases with higher incidence in the population. This is attributable to the "window period" with its high infectiousness (Ahlgren et al. 1990; Jacquez et al. 1994; Pilcher et al. 2005; Rapatski et al. 2005; Wawer et al. 2005). In our calculations, the relative advantage of HT is lowest with high incidence and low prevalence populations, but still present over no condom use. With 7.6% incidence and 8.4% prevalence, there is a 5.4% lower probability of HIV infection for the HT condition versus no condom use. With 20% prevalence, the difference is 14%. The point at which there is greater risk of becoming infected under the HT-use condition occurs when condoms are used on a quarter of occasions for populations with high HIV incidence, highlighting the effectiveness of condom use in preventing HIV.

Although our calculations illustrate that, depending on HIV prevalence and incidence, HT-use could be beneficial for MSM who engage in unprotected AI, it is important to point out that we assumed consistent use of HT. This point must be stressed because realistic estimates need to be made about possible factors that can impact consistent HT-use with partners, including cost, availability, convenience, and partner characteristics. Further insights could be gained by calculating probabilities for different levels of HT-use.

## Discussion

Our mathematical modeling involved calculating the relative risk of using HT to screen sexual partners versus inconsistent condom use. The probability of HIV infection was calculated based on the following factors: HIV prevalence and incidence estimates; infectiousness; HT and condom use-effectiveness (HT-use was constant in our equation); condom breakage and slippage; HT sensitivity estimates; condom use if HT result is reactive; and number of partners and AI occasions. A key strength of our analyses is that the number of partners and number of AI occasions used in our calculations were not set arbitrarily; rather, they were estimated based on data collected in a prior study of HIV-uninfected MSM who are at high risk of HIV infection due to inconsistent or no condom use. Our calculations indicate that, as HIV prevalence increases in the population, there is advantage in using HT to screen

partners versus low levels of condom use. However, the advantage dissipates with higher HIV incidence.

Our findings are in line with the work of Varghese et al. (2002) who estimated that, among MSM, engaging in sexual intercourse with a partner who tested negative reduced the relative risk of HIV infection as compared to sexual intercourse with untested partners. Based on their calculations for MSM, they noted that “[e]nsuring that a partner is HIV-negative can be one of the most effective strategies for prevention of HIV infection” (p. 42). However, the findings point to the importance of infectiousness during the acute stage (Eaton et al. 2007; Pinkerton 2008) in determining risk, particularly for populations with high HIV incidence. If MSM engage in AI without condoms following a non-reactive HT result, they would have lower chances of becoming infected by someone still in the window period of infection than by using condoms in as much as five out of ten sexual occasions. HT as a sexual partner screening device may be a useful risk reduction strategy for MSM who do not use condoms. This advantage increases with higher prevalence in the population. However, with higher incidence in the population, this strategy will not provide any advantage to men over and above condom use, if condoms are used in as little as one out of four occasions.

This study has some limitations. First, we did not include in our calculations other factors that could potentially impact the probability of HIV infection, such as the presence of sexually transmitted infections or circumcision status. Assumptions could be made for other parameters of interest (e.g., type of partner and thereby number of AI occasions). For example, reasonable assumptions could be made about the distribution of the number of AI occasions by partner-type, in that many more occasions may take place with a few “steady” partners and only a few occasions with “other” partners, such as one-night stands (Pinkerton and Abramson 1993). Thus realistic patterns of sexual behavior with long-term versus short-term partners could be factored in. For example, Pinkerton and Abramson (1993) found that a substantial risk reduction can be made if condom-use is consistent with all one-night stands in high prevalence populations.

In addition, our approach was intentionally chosen to be conservative in order to provide an upper bound for the risk. We assumed that acutely infected partners would not be detected by HT (i.e., HT would return a non-reactive result) and condoms will definitely not be used. In practice, other factors may decrease the risk of transmission: MSM may choose not to have sex after all, condoms may be used even with a non-reactive HT result, the kit may return a reactive result before the end of the 3-month acute stage, etc. Lastly, we assumed constant HT-use with all partners. More realistic estimates could be made by varying HT-use

consistency. Future research examining differing condom and HT use patterns would be useful.

Despite these limitations, our results provide important insights about the potential benefits of using HT to screen partners for low condom-users. Although consistent condom use can substantially reduce the probability of HIV infection, many individuals choose not to use condoms for various reasons (Carballo-Diéguez and Bauermeister 2004; Bauermeister et al. 2009), and consistent condom use seems to be an unattainable ideal for some MSM. As technological developments become available, the question of how people will use them becomes very important. In this study, we have provided evidence that there is likely to be some advantage to employing a soon-to-be made available technology for individuals who choose to forego condom use in risky circumstances. Without careful study, individuals at the forefront of the battle with HIV may promote various strategies that are not at all beneficial and may in fact be harmful, as studies on Nonoxynol-9 have shown (Carballo-Diéguez et al. 2007; Gayle 2000; Gross et al. 1998; Phillips and Zacharopoulos 1998; Stephenson 2000).

Alternative strategies to reduce the risk of HIV infection need to be studied to know how reasonable and effective a method may be for individuals who choose not to use condoms. Recent studies have begun to examine serosorting and its impact on HIV transmission more carefully (Eaton et al. 2007; Golden et al. 2008; Pinkerton 2008). In the case of HT-use to screen partners, a great deal of work and attention is necessary, particularly for projecting use-effectiveness of HT (varying levels of use) and with different combinations of both HT and condom use to mimic more realistic circumstances. Similarly, considering sexual behavior by partner type would allow better informed strategies about when and who to screen. Of particular concern would be individuals who “migrate” from using condoms consistently to relying on HT-use, as Foss et al. (2003) have explored in their work on shifts in condom use after the introduction of microbicides.

There are clearly a number of issues that affect potential users differently (How? Where? When? With whom?). As Varghese et al. (2002) have noted, all sex acts have some level of risk for HIV, and prevention efforts could benefit from estimates of the magnitude of risk reduction derived from various choices, in order to be able to provide more accurate information on sexual decisions that can effectively reduce individuals’ risk. Our inquiry maintained the exploration in the realm of the hypothetical rather than taking it a step further to conduct a systematic exploration on possible uses of HT with various types of partners and actual experimentation of HT-use with partners. This should be the next step in integrating biomedical and behavioral research to inform HIV prevention programs (Rosengarten et al. 2008).

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