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Assessing Association between IWantTheKit (IWTK) Risk Quiz Tool and Sexually Transmitted Infection (STI) Positivity in Male Users for STI Screening

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Abstract

Our previous pilot study during 2010–2013, based on the IWantTheKit (IWTK) home selfcollection program for sexually transmitted infections (STIs), showed that voluntary risk score tool predicted STIs well in female volunteers compared to the male counterparts. Risk score became a required part of the IWantTheKit program in August 2013. We investigated association of IWTK risk score and presence of STI in 592 male participants living in Maryland and Washington DC from August 2013 to April 2015. The risk score quiz includes questions on demographic and sexual risk behavior. Data were analyzed using Cochran-Armitage to determine if prevalence of STIs (chlamydia, gonorrhea, or trichomonas) increased with the higher risk score category. Overall, fifty-seven percent of participants were < 30 years (mean: 30.1 ± 9.3 years); 42% white, 42% black, and 16% other races. The majority (67%) of participants had medium risk scores of 3– 6, followed by high scores of 7–10 (22%), and 0–2 (11%). The overall prevalence of STIs was 10.5% (62/592). The prevalence of STIs was 3.1% for users with risk scores of 0–2, 10.4% for those with scores 3–6, and 14.3% for those with scores 7–10 (trend test: p=0.019). Medium and high IWTK risk scores successfully predicted the probability of STIs in male participants after elimination of potential selection biases.

Keywords

Sexually Transmitted Infection Screening; Risk Score; Internet-Based Recruitment; Chlamydia; Gonorrhea; Trichomonas

Please address correspondence to: Dr. Yu-Hsiang Hsieh, Johns Hopkins University Department of Emergency Medicine, 5801 Smith Avenue, Suite 3220 Davis Building, Baltimore, MD 21209, Phone: 410-735-6413, Fax: 410-735-6425, yhsieh1@jhmi.edu. Part of this work was presented at the World STI & HIV Congress 2015, Brisbane, Australia, September 13–16, 2015 **Conflicts of Interest:** For all authors, none were declared.

Introduction

Researchers worldwide focusing on sexually transmitted infections (STI) have proposed various STI prediction rules and risk score tools to aid public health policy decision makers in selective screening for an STI and in better allocation of resources, particularly focusing on STI prevention and diagnosis.^{1–5} These prediction rules over time have also been utilized and validated to stratify individuals at risk for having an STI in various clinical settings including emergency departments, population-based setting and STI clinics.²

Several efforts have been made previously to engage more high risk individuals into STI testing over the last decade, especially in hard-to-reach populations. One of the successful approaches has been to facilitate STI screening via internet based STI testing.^{6–9} These internet screening programs have proven to be successful in getting thousands of individuals getting tested for chlamydia, gonorrhea and trichomonas infections. This novel approach has supplemented the existing healthcare clinic based STI testing. The IWantTheKit (IWTK) program is one such internet-based STI testing program that has facilitated thousands of individuals get tested for chlamydia, gonorrhea and trichomonas infections by recruiting participants online and testing the mailed self-collected specimens at Johns Hopkins University International STI Research Laboratory.^{8–12}

The IWTK program implemented a voluntary risk quiz taken by participants, resulting in an individual risk score which assists them to estimate their own risk of having an STI based on their self-report.¹³ During 2010–2013, the IWTK risk-score quiz tool was voluntary for male and female IWTK users and demonstrated that the higher risk score groups were more likely to have an STI in females.¹³ However, the risk score tool did not demonstrate a similar statistically significant level in male participants. These results may have been possibly due to selection bias, as the risk quiz was voluntary. However, it remained unknown if male IWTK users could assess their own risk of having an STI and determine independently their risk for a urogenital/rectal STI infection caused by chlamydia, gonorrhea or trichomonas.

In August 2013, the risk score quiz tool was a requirement for all participants accessing the IWTK program for STI testing. Hence, the main goal of this study was to investigate the association of presence of STIs in male users with higher IWTK risk scores, after IWTK internet recruitment program required the risk quiz to be completed before ordering a kit.

Methods

Study Design

A retrospective analysis of reported risk scores among male IWTK users was performed, as part of an analysis of the IWTK program for home self-collection for STI screening, to determine the predictability of the risk quiz score for having an STI infection.

IWTK Internet Program

The IWTK program invited males and females 14 years and older residing in Maryland and Washington, DC to request a free STI testing kit at the IWTK website (http://www.iwantthekit.org) which would be mailed to the participants reported address online.^{8,9}

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The kit provided at home consisted of (1) self-collection penile-meatal, vaginal and/or rectal swabs for detection of chlamydia, gonorrhea and trichomonas, (2) enclosed collection instructions, and (3) a pre-addressed return mailer for mailing swabs to the laboratory. The use of penile-meatal samples is off label, but was compared to urine samples as a validation method in an earlier report.^{10,11} Testing was free and was done using the U.S. Food and Drug Administration-cleared nucleic acid amplification tests, Aptima Combo2 (AC2) for chlamydia and gonorrhea and Aptima TV for trichomonas (Gen-Probe/Hologic, San Diego, California, USA).

Risk quiz, Risk score and Risk Category

A quiz determining participants risk score (Table 1) has been a requirement of the IWTK program since August 2013. The quiz consists a total of six questions, including one question inquiring of age of being 25 years old or younger, three questions on the number of prior and current sexual partners, one about prior STI diagnosis history, and one on condom use. Questions regarding sexual orientation or sexual practice with a man were not part of IWTK quiz. After a participant took the required quiz online, a risk score was provided and recorded by the website at the end of the quiz. Answers to each individual question has never been reported or recorded.

Setting and Population

From August 2013 to April 2015, all male IWTK participants (ages 14 years and older and residing in Maryland and Washington DC, USA), who filled out the risk quiz, requested, and returned an STI home self-collection kit were included. Participants who requested an STI self-collection kit for rescreening purpose were excluded. This study was a part of the IWTK public health screening program evaluation, all collected data were completely de-identified. This program evaluation has been approved by the Johns Hopkins School of Medicine Institution of Review Board.

Statistical Analysis

Descriptive data analyses were first performed to determine the characteristics of study population by age, race and ethnicity, place of residence and risk score. Based on STI prevalence among IWTK male participants, risk scores were categorized as following: Risk scores 0–2 were designated as 'Low Risk', 3–6 as 'Medium Risk' and 7–10 as 'High Risk'. Multivariate logistic regression analysis was performed to determine the association between risk score category and an STI infection, after adjusting for covariates (age, race and ethnicity). A Cochran-Armitage trend test was performed to determine if the prevalence of STIs (chlamydia, gonorrhea, or trichomonas infection) increased with the higher score of risk score category. A subgroup data analysis was performed limited on those participants who submitted rectal specimens. Collinearity diagnostics analysis by using variance inflation factor and tolerance index was performed for the final multivariate regression model. Collinearity was considered as present if a variance inflation factor was 5 above and/or the tolerance index was less than 0.20. The area of under receiver operating characteristic (ROC) curve of the final multivariate logistic regression model as well as the sensitivity and specificity of the final model by the prevalence of STI to detect the infection

was estimated. All data analyses were performed by using SAS V.9.4 (SAS Institute, Cary, North Carolina, USA). P-values of <0.05 were considered significant.

Results

Between August 2013 and April 2015, 592 male participants requested an STI testing kit for home sampling and submitted specimens for STI testing, including 171 submitting a rectal swab specimen. Data from risk quiz taken by the male participants showed that 57% were <30 years with mean age of 30.1 ± 9.3 years) with a median age of 28 years (interquartile range 24–34 years) and with an equally distributed Black and White male participant populations (42 % each). (Table 2). Ninety-five percent of the participants were from Maryland, of which 34.3% participants resided in the zip codes of Baltimore City. Distribution based on risk score category showed more than two third (67%) of the participants had a "Medium Risk" (score of 3–6), followed by 22% "High Risk" (score of 7– 10) and 11% "Low Risk" (score of 0–2). The overall prevalence of STIs was 10.5% amongst all participants with chlamydial infection as most common (8%), followed by genital gonococcal infection (2%) and trichomonas infections (1%) (Table 2). The rectal prevalence of STIs among 171 participants was 13.5% with a prevalence of chlamydial infection 9.4%, 0.6% for gonococcal and 0.6% for trichomonas infection.

STI prevalence differed by some of participants' demographic characteristics. Participants aged 25–29 years had the highest prevalence, 16%, followed by those aged < 25 years (11%), 30–34 years (10%), and 35 years (4%) (p=0.014). Participants living in Baltimore City had the highest STI prevalence (16%), significantly higher than those living in the rest of Maryland (9%) or Washington DC (7%) (p=0.026). However, STI prevalence did not differ by race and ethnicity. STI prevalence by risk score category is presented in Table 3. STI prevalence increased with higher risk score category: 3.1% among participants with "Low Risk", 10.4% with "Medium Risk" and 14.3 % with "High Risk" (trend test: p=0.019). Multivariate logistic analysis (Table 4), controlled for age group, demonstrated that "High Risk" (OR= 5.93, 95% CI: 1.32, 26.62) and "Medium Risk" (OR= 4.37, 95% CI: 1.02, 18.72) risk score category both were independently associated with having an STI as compared to those with "Low Risk" risk score category (collinearity diagnostics of the regression model: variance inflation factor=1.01, tolerance index=0.99). In addition, Age group 25–29 years was also associated with having an STI as compared to those aged 35 years (OR= 4.22, 95% CI: 1.68, 10.55). The area of under ROC curve of the multivariate logistic regression model was 0.659. The sensitivity and specificity of the model were 87.1% and 34.5%, respectively, if the STI prevalence was 0.08; the sensitivity dropped to 58.1% and specificity remained the same, if the prevalence was 0.10.

Rectal STI prevalence only differed by age group but did not differ by other demographic characteristics or risk score category. Participants aged 25–29 years had the highest prevalence of STI (25.0%), followed by those aged 24 years or younger (10.9%), 30–34 years (9.7%), and 35 years and older (5.4%) (p=0.041). Participants with "High Risk" risk score category had higher prevalence of STI (17.3%) then the other two groups (both 11.8%) but not statistically significant (p=0.328).

Discussion

Similar to our finding for female IWTK users,¹³ we found that male users with higher risk score on IWTK risk quiz tool appeared to have a greater possibility of having an STI as compared to participants with low risk score, after we made response to the risk quiz questions reported as a required element of the program. The probable reason that we did not find there was a positive association between high risk score category and presence of an STI infection in male users in the previous study¹³ may have been due to selection bias resulting from non-requirement of risk quiz score. Thus, for IWTK users of both sexes, this risk quiz tool has successfully demonstrated that it could be used to assist individuals to determine their own risk or probability of having an STI. The tool might be useful for repeat IWTK users to monitor their own risk for STIs over time.

Several STI risk score estimation tools have been previously investigated elaborately and quite a few have also been validated in clinical settings.² These risk assessing tools had been developed with an idea to decrease unnecessary screening and reduce the associated cost by stratifying individuals based on increased risk of STI.¹ The use of these available STI risk score estimating tools tend to help clinicians in screening or selecting patients for STI testing.² In addition to the usefulness for clinicians, these risk score tools such as the simple IWTK risk tool, can be used independently by individuals in assessing the necessity to seek testing for STIs based on their own risk, eventually leading to self-managing of one's reproductive health.

In this study, we found that STI prevalence increased from "Low Risk" to "Medium Risk" and from "Medium Risk" to "High Risk" risk score category. This pattern suggested a positive linear trend in STI prevalence to risk score category identified by the IWTK risk score tool, pointing towards a stronger association between higher risk scores and STI prevalence. Based on the above finding, we could potentially utilize IWTK risk score tool for STI surveillance in larger populations, in an attempt to characterize the distribution of risk scores of individuals residing in various communities. Then, the estimated aggregate risk behavior of a specific community estimated from IWTK risk score tool could be tracked longitudinally in order to assist public health professionals in conducting STI surveillance at the individual zip code or census tract community level. Data gathered from such efforts could potentially facilitate STI prevention and awareness programs identify communities with higher prevalence (hotspots), especially where the resources for STI control and prevention are limited.

In comparison to our previous study conducted during 2010 to 2013,¹³ we noticed a 2.5% increase in STI prevalence to a prevalence of 10% during 2013 to 2015 amongst male IWTK users. The main reason likely comes from the significant change in STI prevalence in the "Medium Risk" risk score category. We observed that the STI prevalence was double in the "Medium Risk" risk score category in the current study as compared to our previous study¹³ (10.4% vs. 5.7%) while the prevalence rates for the "Low Risk" (3.1% vs. 2.9%) and High Risk" (14.3% vs. 13.2%) risk score category were similar between two studies, despite very similar proportion of participants by risk score category ("Low Risk": 11% vs. 13%; "Medium Risk": 67% vs 66%; "High Risk": 22% vs. 22%) in both studies. A possible

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explanation could be that, in the previous study, many of infected male participants with "Medium Risk" opted not to answer the IWTK risk quiz resulting in under-estimation of STI prevalence in this risk score category in our previous study. This could be one of main reasons that we could not find a significant association between STI positivity and higher risk score category previously.¹³

While comparing other studies, we noticed that the STI prevalence (overall of 10%, chlamydia of 8%) in our study was on the higher side in comparison to prevalence rate of chlamydia infection of 4 to 8% in other STI risk estimation studies.^{14–16} The high STI prevalence in our study could possibly reflect the fact of high STI prevalence in Maryland in general¹⁷ or hypothetically due to individuals who are certain of recent STI exposure or individuals perceiving themselves at higher risk for STIs after accessing the IWTK website.

Further reviewing the STI prevalences among our male participants, we found that those aged 25–29 years had the highest prevalence of STI. This observation is relatively unique since CDC and most of literature have shown men younger than 25 years have the highest prevalence, followed by those aged 25–29 years.¹⁸ One of the main explanations regarding this finding is that the relatively high prevalence of STI in those aged 25–29 years might result from a high positivity rate of rectal specimens (25%) from this group of participants as compared to those younger (11%). The overall prevalence (13.5%) of STIs among rectal specimens submitted by our participants was similar to the prevalence of chlamydia and gonorrhea 10–14% from a study of men who have sex with men (MSM) in an STD Surveillance Network which had patients from 42 STD clinics in the U.S.¹⁹ Only few studies have presented mean or median age information but not age-specific prevalence information among extragenital STIs in men.^{19–21} Further investigations should be carried out regarding epidemiology of the extragenital STI prevalence in men (with a focus on age group-specific prevalence) since these data are limited.

Our study has several limitations. First, we are not able to ascertain entirely if the risk quiz questions were answered truthfully. Second, it is possible that our study was susceptible to social desirability bias due to over-reporting or under-reporting of sexual health behavior by participants while taking the risk quiz online. Third, the study population might not represent the male population who is at risk for STIs in Maryland, possibly due to socio-economic factors limiting certain individuals to be aware of IWTK program or to access the Internet. These limitations may prohibit our finding from being generalized. Finally, less than 30% of participants provided rectal swab specimens for STI testing. Thus, this study did not allow us to have enough power to detect the association of IWTK risk score and presence of rectal STIs in MSM in the subgroup data analysis.

In summary, just like female IWTK users, we demonstrated that IWTK STI risk score tool could help predict STI positivity in male users, after we made the completion of IWTK risk quiz required, in order to eliminate potential selection bias. We can now attempt to validate the utility of the IWTK risk quiz tool in various clinical settings such as STI clinics, adolescent clinics, and emergency departments. Individual's risks for STIs could potentially be self-monitored longitudinally through provision of risk quiz to patients in outpatient settings, community health fairs and adolescent sexual health awareness programs. Future

research on implementing the risk quiz score in various clinical settings could also help to disclose additional benefits of STI risk awareness among patients.

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"IWantTheKit" (IWTK) Risk Quiz Questions and Scoring Scheme

Risk Quiz Questions	Response and Scoring [*]
1. Are you less than or equal to 25 years old?	No= 0 point; Yes= 1 point.
2. Have you had either (or both) a new sex partner or multiple partners in the last 90 days?	No= 0 point; Yes= 1 point.
3. Do you have more than one sex partner at the present time?	No= 0 point; Yes=1 point.
4. Have you ever been told you had or been treated for a sexually transmitted infection in the past?	No= 0 point; Yes=1 point.
5. How many sex partners have you had in the last 90 days?	0–1 partner= 0 points; 2–4 partners=1 point; 5–9 partners= 2 points; 10 or more partners= 3 points
6. When you have sex, do you use a condom?	Always= 0 points; Sometimes= 3 points; Never= 3 point

With a score range of 0–10.

Demographics and Sexually Transmitted Infection (STI) status of 592 "IWantTheKit" (IWTK) Male Participants during August 2013 to April 2015.

Characteristics	Category	Number (%) n = 592
Age (Years)	14 – 24	161 (27)
	25 - 29	180 (30)
	30 - 34	113 (19)
	35	138 (23)
Race	White	249 (42)
	Black	250 (42)
	Other	93 (16)
Ethnicity	Hispanic	74 (13)
Residence	Baltimore City	155 (26)
	Other in Maryland	407 (69)
	Washington DC	30 (5)
Chlamydial Infection	Yes	49 (8)
Gonococcal Infection	Yes	13 (2)
Trichomonas Infection	Yes	6(1)
Any of Three STIs Infection Above	Yes	62 (10)
Risk Score	0 – 2	65 (11)
	3 - 6	394 (67)
	7 – 10	133 (22)

Prevalence of Sexually Transmitted Infections (STIs) amongst "IWantTheKit" (IWTK) Male Participants by Demographic Characteristics and Risk Score Category.

Characteristics	Total	STI Infection (%)		
AGE*				
<25 years	161	17 (10.6)		
25-29 years	180	28 (15.6)		
30-34 years	113	11 (9.7)		
35 years	138	6 (4.4)		
RACE				
White	249	4 (8.4)		
Black	250	31 (12.4)		
Other Race	93	10 (10.8)		
Hispanic	74	7 (9.5)		
Geographic Location				
Baltimore City	155	25 (16.1)		
Washington DC	30	2 (6.7)		
Other in Maryland	407	35 (8.6)		
Risk Score Category **				
Low Risk (Score 0 – 2)	65	2 (3.1)		
Medium Risk (Score 3 – 6)	394	41 (10.4)		
High Risk (Score 7 – 10)	133	19 (14.3)		

* p=0.014

** p=0.019

Multivariate Regression Analysis: Association of IWantTheKit (IWTK) risk score and prevalence of sexually transmitted infections (STIs) (chlamydia, gonorrhea and trichomonas) in 592 IWTK male participants

Characteristics	Category	Odds Ratio (95% CI)
Age (years)	14 - 24	2.33 (0.89, 6.11)
	25 – 29	4.22 (1.68, 10.55)
	30 - 34	2.43 (0.87, 6.81)
	35	1.00
Risk Score	0 – 2 ("Low Risk")	1.00
	3 – 6 ("Medium Risk")	4.37 (1.02, 18.72)
	7 – 10 ("High Risk")	5.93 (1.32, 26.62)