OraQuick Implementation Program Plan

For Wake Teen Medical Services

By

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[Signatures and dates]
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includes two outreach activities. First, the services provided by Wake Teen,
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universities as well as other selected websites targeting young gay and bisexual
men of color. Second, posters and flyers about the services provided by Wake
Teen will be made available to local youth organizations. To assess the
program’s successful implementation, pre-intervention and post-intervention
surveys will be one strategy that will be used to evaluate the program objectives.
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INTRODUCTION

1. Overview

HIV is an infectious disease that is transmitted by: heterosexual intercourse, men having sex with men (MSM), sharing of needles for injection drug use (IDU) and, less frequently, by vertical transmission from mother to child. Although therapeutic advances have changed the character of HIV from a fatal disease to one that can be managed chronically, there is still no cure. Thus, prevention remains the principal means for deterring the epidemic. Countries such as Uganda and Thailand have shown strong commitments to reducing rates of HIV infections and of other STDs among adolescents. Through culturally appropriate messages, these countries have successfully reduced the spread of infection.\(^1\) Such successes as well as success of smaller U.S. programs suggest that culturally appropriate prevention efforts may reduce transmission in other ethnic and behavior subgroups of the United States population.

Reviews of HIV prevention for adults and youth by panels of experts in the Institute of Medicine, the National Institutes of Health, and the CDC Prevention Research Synthesis Project have all concluded that many HIV prevention programs in the U.S. are effective. Although effective programs to prevent HIV among youth exist, the rate of HIV among youth still continues to rise. Since the early 1990’s, an estimated 40,000 new HIV infections have occurred each year in the United States. At least half of all new HIV infections in the U.S. are among people under 25, and the majority of young people are infected sexually.\(^2\) Additionally, a surveillance report from the CDC in 1993
noted the high likelihood that many persons who are diagnosed between the ages of 20-29 years were infected during adolescence. And as we enter the third decade of the HIV pandemic, the infection rate among North American gay men has declined as rates among adolescents and people of color are rising. However, in the past two years, outbreaks of HIV infection have been documented among young gay men of color and increased risk behaviors have been reported among gay and bisexual men of all races. These findings stress the importance of interventions for young people of all races but more effort should target subgroups of adolescents at highest risk.

Several possible explanations exist for the continued increase in HIV incidence among adolescents. A few will be discussed in this paragraph. One possible explanation is that few effective prevention programs exist for all at-risk youth. Another explanation is that to gain access to outpatient medical care at-risk youth must overcome a variety of potential hurdles, including family issues, logistical issues, financial issues, service issues and having awareness. We can infer that those who are at highest risk may face more of these barriers to accessing medical care. A focus group on barriers for STD services among a diverse group of Wake county adolescents and young adults revealed some of the barriers to care. These barriers included limited knowledge of STDs, cost of services, lack of privacy and lengthy waits while seeking care. A third factor that contributes to increased HIV incidence among youth is the lack of understanding of sexual behavior and its complexities. This lack of understanding creates a major barrier to HIV prevention and limits the effectiveness of prevention
interventions. Finally, and perhaps most importantly, factors influenced by the wider context in which adolescents live, including social values and norms, policies and legislation, and their economic situation play very important roles in risk of HIV transmission. In other words, risky sexual behavior depends not only on individual risk factors but also on other less well understood societal and economic risk factors. An understanding of these societal and economic risk factors may be used to inform the development of counseling programs and community level programs and render them more effective.

Other explanations for the continuing infection rates among youth similar to adults include increased opportunities for HIV transmission by three sources: 1) HIV-infected people who are living longer 2) high number of HIV-positive individuals who do not know that they are infected 3) HIV-positive individuals who are aware of their infection but may not be receiving the treatment and prevention services that they need. Evidence reported by the CDC suggests that approximately two-thirds of the estimated 40,000 new HIV infections a year occur through transmission from persons who are unaware of their HIV-positive status. Thus, to reduce HIV incidence among adolescents and young adults one important step will be to identify those already infected but not yet diagnosed.

In summary, it is important to understand the multifactorial aspect of the disease and address many of these factors in a holistic approach in developing HIV prevention programs.

Understanding the need for a new approach to reduce HIV transmissions, the CDC recently introduced a new initiative, "Advancing HIV Prevention
(AHP): New Strategies for a Changing Epidemic.” One of the recommended strategies in this initiative is to make HIV testing a routine part of medical care. The recommendations include simplifying the protocol for testing and counseling and increasing outreach testing for adolescents who are unlikely to get tested. Many youth face barriers to accessing a confidential and affordable site to get sexual health information and testing for HIV.

This paper will report on the development of a new pilot program at Wake Teen Medical Services, a comprehensive adolescent clinic, to increase early diagnosis and treatment of HIV among high-risk youth. The proposed program is comprised of a number of objectives: 1) to implement the FDA-approved Rapid Antibody HIV-1 test known as OraQuick as an option for HIV testing at Wake Teen Medical Services; 2) to make HIV testing using OraQuick and effective counseling a routine part of examination for all at-risk adolescents, in accordance with the new CDC initiative; 3) to improve the effectiveness of STD education and behavioral modification by basing the counseling portion of the HIV testing and counseling on “client-centered” behavioral theory. Resident physicians in training who rotate through the clinic will be trained with this approach. Lastly, to improve awareness of the program to college students who need confidential testing at an off-campus site, the program includes two outreach activities. First, the services provided by Wake Teen, including OraQuick, will be listed on websites of all Wake County colleges and universities as well as other selected websites targeting young gay and bisexual men of color. Second, posters and flyers about the services provided by Wake Teen will be made available to local
youth organizations. To assess the program’s successful implementation, pre-intervention and post-intervention surveys and other data collection tools will be used to evaluate whether the program objectives were implemented as intended.
2. HIV in adolescents in North Carolina

The North Carolina epidemiologic profile on HIV is generated from surveillance systems data maintained by the HIV/STD Prevention and Care Branch of the North Carolina Department of Health and Human Services. According to the Report, North Carolina is one of five states in non-metropolitan areas with the highest number of reported HIV infections, excluding AIDS cases. Although the yearly reported number of new HIV infections has been relatively stable since 1996, totals have increased in the last three years. In 2002, there were 1,692 reports of newly diagnosed HIV infections; 50 cases were among the 13-19 age group and 211 cases were among the 19-24 age group or 3% and 12%, respectively. Because there is significant delay between infection and subsequent testing and reporting, the incidence among 19-24 year age group may reflect infections that occurred during adolescence.

To develop an appropriate prevention program for adolescents, it is important to understand their risk factors for acquiring HIV and how these may differ for subgroups. Exposure data in North Carolina for 2002 among those between the ages of 13-24 indicate that different risk factors exist for males and females. Among males, men who have sex with men (MSM) and MSM/IDU together account for about 84% of HIV disease reports, while heterosexual contact cases account for 16%. Among females, heterosexual contacts account for 97% and about 3% result from IDU. Although exposure data specific to those in the 13-24 age group is not available for different races due to low numbers,
Exposure data from blacks in all age groups indicate a higher percentage of heterosexual transmission among blacks 56% compared to 23% among whites.

Furthermore, there is great disparity in HIV infection among different ethnic groups. The highest rate of HIV infection in North Carolina is among black males (87.8 per 100,000); this rate is almost eight times that for white males (11.4 per 100,000). Black females (42.9 per 100,000) have a rate of HIV infection almost 18 times that of white women (2.4 per 100,000). The infection rate in Hispanic men (24.7 per 100,000) is twice that of white men, and the rate in Hispanic women is eight times that of white women. It is not well understood why such disparities in HIV infection exist. One hypothesis, epidemiologic synergy, provides one explanation. According to this explanation limited health care access that has existed among minorities historically particularly to STD treatment could result in higher community prevalence of STDs including HIV. Therefore, an adolescent involved in high risk behavior in a high-prevalence community would more likely lead to a new STD including HIV compared to an adolescent that engaged in a similar high risk behavior in a low-prevalence community. A biological explanation for epidemiologic synergy is that having an STD can increase the likelihood of getting and transmitting HIV due to higher burden of the HIV virus in lesions on mucous membranes. Additionally, the reduced physical and mechanical barrier as a result of having lesions also increases likelihood of body fluid exchange.

Data on the recent HIV infections among college students in North Carolina indicate that of the 13% of newly infected college students, 88% are
African American and 91% are among MSM, some of whom have sex with women also. Those infected are more likely to be bisexual, to meet sex partners at gay clubs or over the internet and to use club drugs such as ecstasy. Overall, adolescents and young adult MSM account for a substantial proportion of all HIV disease reports in North Carolina. This illustrates the urgent need for comprehensive HIV prevention programs that provide culturally appropriate interventions for MSM adolescents and young adults. To reiterate an earlier point, to make a profound impact on the incidence of HIV among this population, it is important to have a comprehensive strategy that utilizes social policies and community interventions in addition to efforts at the individual level. HIV testing and counseling is one strategy targeting the individual that will be discussed further in the next section.
3. HIV prevention-Testing and Counseling

Since early in the epidemic, HIV testing has been a major foundation of the HIV prevention effort in the United States. Initially, HIV testing was used to screen infected blood from the blood bank. As improved AIDS treatment drugs became available, testing became not only a means to prevent transmission but also a tool to prolong life. As much research in many fields provide new information about HIV disease, new technology for testing and counseling have lead to improvements in voluntary counseling and testing programs. In 1993, counseling experts at the CDC developed a new client-centered approach to HIV prevention counseling after several studies showed weaknesses in the information-based counseling employed in the studies. This interactive approach recognizes the importance of tailoring counseling sessions to the individual’s particular circumstance. Further this approach takes into consideration the person’s culture, sexual identity, and primary language. This type of session aims to encourage the client to play an active role in developing a series of concrete, achievable and personalized HIV risk-reduction goals.

A revised guideline in a 2001 CDC Morbidity and Mortality Weekly Report lists several HIV counseling and testing goals that seek to ensure that HIV-infected persons and persons at increased risk for HIV receive proper medical services. These services include: 1) have access to HIV testing to promote early knowledge of their HIV status; 2) receive high-quality HIV prevention counseling to reduce their risk for transmitting or acquiring HIV; 3) have access to appropriate medical, preventive, and psychosocial support.
services. Besides the CDC, other organizations have developed and put forth guidelines specific for adolescents in the clinic setting. In particular, the American Academy of Pediatrics specifies a need for pediatricians to institute HIV prevention, sexual education and condom use among all adolescents. Also, the U.S. Preventive Services Task Force (USPSTF) recommends that practitioners advise adolescents about risk factors for HIV infection and other sexually transmitted diseases (STDs), and counsel them appropriately about effective measures to reduce their risk of infection. At the same time, however, the USPSTF reports that the effectiveness of clinician counseling is unknown. In the next section of this paper, I will discuss available studies that have evaluated the effectiveness of HIV prevention interventions and of clinic-based counseling and testing programs that target adolescents.
II Review of studies to inform development of prevention programs

1. Overview of effective behavioral intervention programs for youth

Because societal and economic risk factors impact individual risk factors, it is important to implement interventions and prevention programs that address the many levels of HIV risk. The CDC’s HIV/AIDS Prevention Research Synthesis Project defines three broad categories of interventions that impact health behaviour at multi-levels of the socio-ecological framework. These include programs at three levels: 1) social and community level interventions; 2) population/policy-level interventions; 3) individual level behavioral interventions. First, social interventions aspire to change environmental factors or structures that relate to HIV risk such as peer or community norms related to HIV risk. The CDC AIDS community demonstration project is an example of a community-level intervention that achieved greater consistent condom use and maintenance of consistent condom use with non-main partners compared to individuals in the comparison community.\textsuperscript{18} This intervention used the Transtheoretical Model of Behavior Change to modify attitudes and beliefs about prevention methods by drawing upon real-life experiences of local community members and helping them move from earlier to later stages of change.

Second, policy studies propose legal decisions or administrative changes to reduce HIV risk behaviors. These interventions work at the population level of the socio-ecological framework. Kirby et al’s high school curriculum on sexual risk-taking is one example of a policy intervention that has shown to be effective. The intervention was based on three theories; social learning, social inoculation
and cognitive behavioral theory. This high school based intervention was designed to be integrated into the 10th grade comprehensive health curriculum in 13 high schools in California. The aim was to allow adolescents to develop social skills to reduce sexual risk taking behavior and practice those skills by role-playing. The findings of this intervention showed statistically significant lower likelihood of initiating sexual intercourse in students receiving the intervention compared to the comparison group. Among the sexually experienced adolescents in the intervention, there were lower incidences of unprotected intercourse than sexually active students in the comparison group.

Third, the behavioral interventions aim to decrease incidence rates of STDs including HIV by changing risk behaviors at the individual level. This approach uses methods like counselling, small group discussions, and skills demonstration. Most HIV/STD interventions focus on the individual. A large number of studies exist that assess the effectiveness of this type of intervention. The proposed program at Wake Teen hopes to utilize counselling and testing as a behavioral intervention to reduce STDs, including HIV, in adolescents one individual at a time. The following section will review published counselling and testing studies that have been shown to be effective in a busy clinic.
Systematic Review of the efficacy of clinic-based HIV counseling and testing

a. Search Methodology

Electronic searches of PubMed (MEDLINE) using MESH terms “HIV” AND “post-test” AND “VCT” AND “counseling” AND “clinic” AND “United States” was used to identify papers for review and consideration. The search was limited to adolescents and English language journals only. Studies that dealt with prenatal testing, international setting or adults only were excluded. Separate searches were done to identify any meta-analyses, systematic reviews or randomized controlled trials having to do with HIV testing and counseling. A manual search of studies using references was done to identify relevant articles. Despite the large number of studies in HIV prevention, very few assessed the efficacy of clinic-based STD/HIV counseling in United States among adolescents or young adults. Even fewer studies evaluated the efficacy of clinic-based HIV testing and counseling. Only two articles were identified and will be summarized.

b. Results of Systematic Review of the efficacy of clinic-based HIV counseling and testing.

The first study, a cohort study by Clark et al., assessed the efficacy of HIV testing and counseling on reduction of subsequent risk behaviors in an urban adolescent medicine clinic. From a cohort of 500 high risk adolescents between ages 12 to 21 years, 149 were randomly selected to receive pre-test counseling and testing. The patients were divided into three groups based on their self-reported frequency of condom use. To assess changes in risk behavior, the authors used medical record documentation of STDs before and after HIV testing and
self-reported condom use frequency. Of the original 149 patients, 126 (85%) completed the pretest and posttest counseling and returned for a follow up risk-assessment. The assessment did not find a significant difference in STD diagnosis pre-testing and counseling compared to post-test in all three groups. Additionally, on a survey question regarding condom use, only 24% of those in the initial group who reported using condoms either frequently or always continued to use condoms. Moreover, the group who initially reported condom use as rarely/never increased from 32% to 53%. The authors concluded that HIV testing and counseling have no statistically significant effect on reducing HIV risk behaviors or associated decrease in the incident of STDs.

The design of the Clark et al. study had several weaknesses. First, it was unclear how the 149 participants were chosen for inclusion from 301 of the 500 high risk adolescents who met specific eligibility criteria. Additionally, the study did not provide information of the characteristics of the 149 pool of subjects and compare them to the rest of the 301 who ideally should have the same likelihood of enrolling in the study. Without additional data, it is unclear whether a difference that may impact the result of the study exists between those who participated compared to those who did not participate in the study. Suppose the 149 pool of subjects selected to participate had more frequent visit because of frequent exposure to high risk sexual activity. If these same participants are more resistant to change, then we would suspect that selection bias is partly responsible for the lack of efficacy seen in the study. Moreover, in the follow-up assessment 126 of the 149 responded were included in the final analysis but no effort was
made to identify those who were lost to follow up in one year. Despite being a small number, potential differences between full participants and those lost to follow up can alter the result. For instance, the participants that were lost to follow up may have reduced their high risk sexual behavior and didn’t see the need to return to the clinic. If this was the case, then the authors would have made a non differential misclassification that would lead to a type II error.

Another very important weakness of this study is the small sample size. The authors report that they did could not predict the effect size for the intervention and the study did not have the power due to insufficient sample size to detect a very small effect. Therefore, the small size increases the risk of a type II error, where the study does not see an effect when there is one.

Even though this study had several limitations, the findings of this small cohort study are similar to several adults studies including a meta-analysis who found lack of effectiveness of counseling and testing in modifying sexual behavior among HIV negative patients. Weinhardt et al. reviewed published research on HIV counseling and testing from 1985-1997 evaluating behavior outcomes from 27 different studies. The review reflects studies that assessed HIV testing and counseling prior to CDC’s client-centered counseling. These studies utilized the information-based counseling which emphasized providing scientific fact and advice on risk behavior without involving the client as the center of discussion. The client-centered counseling, included in the 1993 revised CDC guidelines for HIV testing and counseling is based on a tested theory by Carl Rogers, which emphasizes providing an environment that allows client’s
self-exploration with a counselor that actively listens, in a non-judgmental manner. Therefore, one important aspect of the Clark et al. study and the meta-analysis by Weinhardt et al. as well as results from other adult studies is the type of counseling provided; neither one assessed client-centered counseling. Additionally, the Clark et al. study did not provide any additional information on the time taken to counsel patients or the type of training providers received in counseling patients.

The second study by Kamb et al. was a much larger multi-center study that was a randomized controlled trial involving five STD clinics in major cities including: Baltimore, Md; Denver, CO; Long Beach, CA; Newark, NJ and San Francisco, CA done in collaboration with the CDC. It is the first and only randomized controlled trial evaluating the efficacy of HIV/STD prevention counseling models in reducing high-risk sexual behaviors and consequently the incidence of STDs. It compared two interactive counseling models to each other to assess for feasibility in application in a busy clinic compared with the practice of didactic prevention counseling. There were four arms: 1) enhanced counseling, with four interactive theory based sessions using the theory of reasoned action and social cognitive theory; 2) brief counseling modeled after CDC’s client centered HIV prevention counseling, with two interactive risk reduction sessions; 3) brief didactic messages and 4) the fourth Arm was similar to third Arm except patients were not actively followed to test the effect of repeated contact. All three Arms were actively followed with questionnaires at 3, 6, 9, and 12 months as well as STD tests at 6 and 12 months. A fourth Arm was similar to third Arm except
patients were not actively followed to test the effect of repeated contact. Each arm had a sizable number of patients with 1438 in Arm 1, 1447 in Arm 2, 1443 in Arm 3 and 1430 in Arm 4. The participant were HIV-negative men and women aged 14 years or older who come to one of the five inner-city clinics for STD testing and agreed to have an HIV test. The exclusion criteria include men who reported having a male sex partner in the past 12 months, who identified as bisexual or homosexual. The results of this study demonstrated that interactive counseling increased disease reduction compared to didactic messages and there were equivalent STD reduction among those in the two interactive counseling models, the brief CDC modeled counseling as there were in the enhanced theory based counseling. There was an overall reduction in STD incidence in all 5 study sites of about 30% after 6 months and 20% after 12 months of follow up.

This study was overall a well designed study complying with published guidelines for conducting randomized controlled trials with good internal validity. The study subjects were well randomized with proper concealment protocols using services from a data management company. The control group and the treatment group were similar at baseline with respect to demographic characteristics, risk behaviors, condom use, and STD diagnoses at enrollment. The outcome analyses were based on all participants, thus an intention-to-treat analysis was performed. Overall, the study design was well done with great care to minimize bias that might affect the study. The sample size in each arm was large enough to detect even a small effect, minimizing type II error. Three weaknesses of the study were: 1) the high proportion of eligible patients who
refused to enroll; 2) of those enrolled the high proportion who were lost for follow up; 3) the rigid exclusion criteria that will impact the generalizability of the study findings. A comparison of those enrolled with those who refused revealed that participants were more likely to be women, to have had an STD at enrollment, and to have been previously tested for HIV. The high refusal rate may have lead to a selection bias in which potentially, those who remained in the study may have been more motivated and likely to change their behaviors. Another possibility is that some of those who refused may have had enough self motivation to change their behaviors themselves without the help of the study intervention. These biases may counteract one another but because it is difficult to quantify the effect of each bias, the net bias would be unknown. In this case, it is impossible to see which way the result of the study will be skewed. Another weakness of the study, is the large proportion of drop outs in all the intervention arms which signifies a drop out rate that is greater than the acceptable 20% rate. The follow up visit rates were 71% at 3-months, 70% at 6-months, 64% at 9-months, and 66% for the 12-months visits. The drop out rates did not differ significantly between intervention arms. The loss of follow up may partly explain a small amount of the difference found between interventions but it can’t account for all the difference. Therefore, the higher rate of STD reduction among those in arms 1 and 2 compared to arms 3 and 4 are likely due to a true difference in the intervention. Another important weakness in this study was the exclusion of MSM and individuals whose English speaking ability is limited. Therefore, the results of the study cannot be generalized to MSM, a subgroup of the population who have been highly affected
by the HIV epidemic according to epidemiology data both in North Carolina and nationally. Similarly, the study results are not generalizable to ethnic minorities i.e. Hispanic patients who also have higher burden of HIV infection.

Although the results of this large trial suggest efficacy in client-centered counseling, the generalizability of this finding to subgroups such as adolescents is not clear. A subset analysis using the same data from this large trial evaluated the efficacy of testing and counseling specifically among adolescents. This subset analysis also found fewer incidents of STDs among adolescents in the brief or enhanced groups than those in the educational messages group. In adolescents between ages 14-20 years there was a statistically significant difference between the different arms, 26.6% in the educational intervention had new STDs compared to 17.2% and 17.5% in the enhanced group and brief counseling group respectively. This translates to 9.4 of new STDs prevented per 100 adolescents counseled. However, since the setting of the study was among adolescents who attended STD clinics at various inner-city sites, the finding of this study may not be generalizable to adolescents attending a comprehensive adolescent clinic in a different state such as Wake Teen in North Carolina.

In summary, in all three studies, the two primary studies and the one meta-analysis that address clinic-based counseling, there is a significant difference in study design, type of intervention used and in the power of study. In both the adult literature and this literature review on adolescents, there is mixed results in regards to the effectiveness of clinic-based counseling and testing. One major reason for the conflicting result between these studies is the
different types of counseling used. Both the Clark et al study and the meta-
analysis by Weinhardt et al utilized the knowledge-based counseling and did not
include any theory based counseling recommended by the CDC. Another
difference was that the Clark et al. study did not provide specific training or
assess the competency of providers who provided the counseling which may have
weakened the effect of the intervention if improperly administered. The
differences in counseling approach may partly explain differences in effect on
outcomes. Another explanation for the varying result seen in the Clark et al,
study and the Kamb et al study may be the difference between the sample sizes of
the two studies. The RESPECT trial by Kamb et al. had the ability to detect even
a modest effect of the intervention which was not the case for the Clark et al.
study. A third reason for the conflicting result is the study design employed in
each study. The RESPECT trial was a randomized multi-center clinical trial in
public STD clinics. On the other hand, the Clark et al study was a cohort study in
an urban adolescent medicine clinic. Yet another major difference were the
primary outcomes used in the two studies, the Clark et al study used self reported
sexual behavior change or medical chart review of STD incidences both of which
are susceptible to major recall bias and measurement bias respectively as
compared to scheduled STD check up with a defined criteria of a positive result
used in the RESPECT trial.

In conclusion, there is a paucity of trials that specifically assessed the
efficacy of HIV testing and counseling in a busy clinical setting among
adolescents. Still, the findings of the RESPECT trial and the subset analysis of its
data showing efficacy in adolescents is valid. It is the only well designed randomized controlled trial that specifically evaluated the efficacy of the CDC recommended client-centered counseling model. Further research is required to confirm the findings of this trial and to characterize the effectiveness of HIV testing and counseling programs in comprehensive adolescent clinics. Moreover, effort should be put forth to test the efficacy of brief counseling models for providers in busy adolescent clinics or other private offices.
Table 1. Review of studies on HIV testing & counseling including adolescents

<table>
<thead>
<tr>
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<th>Multicenter* RCT (Project Respect)</th>
<th>Urban Adolescent clinic Cohort</th>
<th>Clark et al</th>
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<tbody>
<tr>
<td><strong>Sample size</strong></td>
<td>5748</td>
<td>149</td>
<td></td>
</tr>
<tr>
<td><strong>Population</strong></td>
<td>Inner-city STD clinics &gt;14 years (median age 25 years) 59% black 19% Hispanic 16% white 6% other races</td>
<td>Urban Adolescent-medicine clinic 35,59,50% black** 1,0,3% Hispanic 0,1,0% Other</td>
<td></td>
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<tr>
<td><strong>Intervention type</strong></td>
<td>Theory-based Enhanced counseling, (4 sessions); Brief counseling, (2 sessions)</td>
<td>HIV counseling and testing</td>
<td></td>
</tr>
<tr>
<td><strong>Cited behavioral theory</strong></td>
<td>Social Cognitive theory</td>
<td>Theory of Reasoned Action</td>
<td>Not theory based</td>
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<tr>
<td><strong>Control group</strong></td>
<td>Brief didactic messages (2 sessions)</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td><strong>Primary outcomes</strong></td>
<td>Self-reported condom use STD incidence</td>
<td>Self-reported condom use Medical documentation of STD incidence pre and post-testing</td>
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<tr>
<td><strong>Follow up time</strong></td>
<td>3,6,9, and 12 months and STD tests at 6 and 12 months</td>
<td>2 year</td>
<td></td>
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<tr>
<td><strong>Study findings</strong></td>
<td>--higher self reported condom use in enhanced (Arm 1) and brief counseling (Arm 2) group at 3 and 6 months --30% fewer new STDs in Arm 1&amp;2 at 6 months --20% fewer new STDs in Arm 1,2 &amp;3 at 12 months</td>
<td>--No change in frequency of STD visits per month.</td>
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* See Text for subset analysis
** Racial composition of frequently/always, sometimes, rarely/never group
V Program Plan

1. Program setting: Wake County

    Wake Teen is located in Wake County which is in the east central section of North Carolina. According to the 2002 projected population, Wake County is the second largest county in the State with a total population of 678,651 of which 21.2% are between ages 10-24. Approximately 72% of Wake County residents are Caucasian, 20% are African American, and 5% are Latino. Based on data from 2000, there are 127,114 married couples of which 63,825 families have children. There are a growing number of single family headed households nationally and in Wake County, according to the data from 2000, there are 14,880 female headed families and 3,677 male headed families with children. The annual mean wage in Wake County is $35,366, however as much as 18% of households have incomes below $25,000. According to set guidelines to assess poverty level, 26% of children between ages 17 years and below met the poverty level threshold in Wake County. Moreover, according to the Annie E. Casey Foundation, 12% of children in North Carolina are uninsured.

    Wake County has twelve municipalities, two universities, four colleges and several public schools. Recently, health professionals and researchers have voiced alarm about the incidence of STIs and HIV infection among youth, especially college students. Many barriers exist that prevent many youth, including college students, from receiving the services needed. In particular, there is a lack of enough services that are both available and confidential. Wake County's colleges and universities are prime locations for some young people to
meet potential sexual partners and engage in high risk sexual behaviors. Yet, few prevention services are available. For example, some of the health clinics at some of these universities and colleges lack confidential settings for young people to receive information about STDs and treatment if infected. In others, the hours that services are available are limited. For example, at one college, the health department staffs the clinic one afternoon per week for the evaluation and treatment of STDs. Another college provides no HIV testing. Other options for STD services in Wake County include Wake County Human Services Public Health Center, community center, private or not-for-profit medical centers and many private physician practices. Although private clinics and not-for-profit medical centers are confidential and have better availability in terms of hours of operation, only adolescents that have health insurance and/or have financial resources can access these services.

A focus group involving fifty-seven diverse youth from Wake County, provides some insights into what constitutes an ideal STD services and the barriers of currently available clinics. Some of the common themes expressed include a welcoming, private, efficient clinic where STD services are offered with non-STD services during extended hours. The Wake Teen clinic, discussed further in the next section, may be one example of a clinic that approximates this description.
Program site: Wake Teen

Wake Teen was first established in 1983 due to a recognized need for an adolescent clinic in Wake County. Adolescents come to Wake Teen from the entire Wake County as well as surrounding counties. Wake Teen is a not-for-profit clinic that provides affordable and accessible medical and mental health care to adolescents and young adults ages 10 to 23. Since being incorporated in 1983, Wake Teen has provided services to thousands of youth. Clients are referred by school counselors, health care providers, patients, and other professionals who work with youth. In addition to the Wake County School District, Wake Teen also serves colleges and universities in the area. Fees for the services are charged on a sliding scale, based on the individual’s or family’s income; therefore Wake Teen sees adolescents who are financially needy and underserved. In 2002-2003, 20% of patients seen at Wake Teen had no health insurance and 66% had family incomes at or below poverty levels. (Personal communication with executive director)

Wake Teen’s mission is: “To improve the health and well being of adolescents and young adults (age 10-23) by providing affordable and accessible medical and mental health services; by educating the community about the health concern of adolescents and young adults; and by training professionals who provide care to this population.”

One quality highly valued by the staff at Wake Teen and that likely reduces barriers to care for adolescents is its regard for confidentiality. At Wake Teen, patients can address concerns and ask questions about sex, drugs and other
sensitive issues. Each staff member is trained to abide by the confidentiality law set forth for the clinic. Every new patient has an enhanced first visit with a staff member who will explain Wake Teen’s confidentiality rule including the exceptions. Wake Teen is a safe place to discuss any issue of concern with strict confidentiality except when a patient reports homicide or suicide ideation and rape or sexual abuse. Patients are taught that by law, the Wake Teen staff has to report the exceptions to the confidentiality rule. Additionally, the clinic has a comprehensive package of services without isolating STD services. This approach increases confidentiality because one cannot predict what treatment an adolescent will be receiving if seen in the waiting room. Therefore, within the context of a safe and supportive atmosphere, patients are able to explore their experiences honestly and openly allowing for clinicians to provide appropriate advice, answer questions and help each adolescent reach a solution to his or her problem.

The clinic provides a broad range of health services, from general medical care to gynecological care to individual and family counseling for family conflicts. It is estimated that 60% of the adolescents come for services related to their sexuality including STDs, contraception and pregnancy testing (personal communication with executive director).
Program implementation: OraQuick test

Wake Teen clinic has a holistic approach in treating adolescents providing medical, educational and counseling services as well as STD treatment in the same clinic. Again, the availability of non-STD services and STD services in the same clinic increases confidentiality in that, a patient in the waiting room can be waiting to receive a number of services. This setting is ideal for screening for STDs including HIV. Currently, Wake Teen performs HIV testing on all patients who report high risk sexual behavior namely unprotected sexual intercourse. Adolescents that consent to HIV testing have their blood drawn. Their blood sample is sent to the state laboratory or, when faster turnaround is required, a private laboratory. The laboratory uses a standard sequential two-test algorithm, the enzyme-linked immunoassay (ELISA) screening test and a Western blot or immunofluorescence assay to confirm HIV positive results and reduce false-positive results. The test requires the time necessary to transport laboratory specimens, perform the tests in batches at the laboratory, and report the result to Wake Teen. Thus, patients have to wait two weeks to receive their results.

On November 2002, the Food and Drug Administration (FDA) approved OraQuick, one of several Rapid HIV tests under development that does not require additional equipment or refrigeration. Additionally, this test can be performed in a laboratory that is not CLEA approved. This single step new technology uses lateral flow strips where the testing device is placed in a vial with diluted specimens, the specimen migrates through the strips and combines with a signal reagent- an HIV antigen visual line. This test uses whole blood from the
puncture of the finger, and the results are available within 20-60 minutes so that, in most cases, only one visit is required for testing and counseling. To assess the effectiveness of the tests, the CDC bought OraQuick testing kits to distribute to HIV testing sites. Wake Teen clinic is one of the sites that requested and received 200 kits to initiate Rapid HIV-testing and pilot test its use.

The OraQuick test is a screening test that detects antibodies to HIV-1 found in blood specimens of sero-positive individuals. The sensitivity and specificity of the OraQuick are comparable to those of enzyme immunoassay (EIA), the test that is currently used in screening. Clinical studies by the manufacturer, OraSure Technologies, Inc., have shown that the test correctly identified 99.6% of those who were sero-positive (sensitivity) and 100% of people who were sero-negative (specificity). More important in a screening test is the predictive value, the probability that the test result accurately predicts infection status of the person tested. Using the same test in a population with two different prevalences can produce very different results. The HIV prevalence observed in most U.S. testing settings is low and the negative predictive value is high. Therefore, since the likelihood of a false negative is very low, patients can be told they are not infected. However, if the person had a recent exposure he/she may not have developed HIV antibodies and retesting within three months is necessary.

On the other hand, the low prevalence setting in most U.S. testing sites including Wake Teen results in low positive predictive value. Therefore, unlike negative results, all reactive results are preliminary and confirmation with a second test is required. For example, if 1000 persons are tested in an adolescent
clinic with an HIV prevalence of 1%, then the positive predictive value is 83%, with 10 true positives and 2 false positives. But if the prevalence is estimated at 0.2%, the positive predictive value is now 50%, with 2 true positives and 2 false positives. Therefore to avoid the risk of giving false-positive results, every reactive rapid test must be confirmed by the current gold standard applied by the state laboratory, the EIA and Western blot confirmation test. If a test result is preliminary positive, then the turn around time is around a week or two, time required to perform confirmatory testing.
Program Behavioral Theory

An articulated theory is essential to successful implementation of any health program's effect on health. According to Issel's book on Health program and evaluation, a program theory serves several purposes including: 1) providing guidance for the intervention; 2) enabling expectations of the intervention's efficacy; 3) forming a basis for communication about the program's intervention. Several health behavior theories have been developed to explain health behavior determinants. These include the health belief model, social cognitive theory, theory of reasoned action, and stages of change theory. The AIDs Risk reduction model (AARM) is another model that was specifically tailored to HIV prevention counseling. These same theories have been applied in sexual risk reduction counseling of high-risk patients.

The theories mentioned above have been tested and have shown efficacy in clinic-based settings to alter behavior towards a variety of risk factors such as smoking and alcohol abuse. And many studies have conclusively demonstrated the lack of effectiveness of solely knowledge-based counseling in reducing STD high risk behavior. The RESPECT trial has found efficacy of client-oriented counseling. The RESPECT trial showed equivalent efficacy in STD reduction among the brief counseling arm and the enhanced counseling arm. The similar result found in the two arms demonstrates that spending more time on the theoretical aspects such as self-efficacy and attitudes towards behavior did not improve risk reduction. Therefore, the brief client-centered HIV counseling that is recommended by the CDC is effective and feasible in a busy clinic. The
scientific evidence for an effective strategy in same-day HIV testing and counseling is still in clinical trials. The RESPECT-2 trial is another CDC collaborative multi-center RCT comparing single session counseling with two session theory based client interactive counseling that was shown to be effective as part of the RESPECT trial. Even though the results of this trial are not available, brief interactive counseling has shown to be effective in STD clinics, this same theory can be applied to adolescents at Wake Teen who are coming in for HIV/STD screening.
Program Planning: Goals and Objectives

Goals:

- To reduce incidence of STDs including HIV among adolescents and young adults at risk in Wake County
- To increase early detection of HIV infection and encourage early identification of sero-positive adolescents
- To reduce the ethnic disparity in HIV infection

Objectives:

- After six months, at least 100% of adolescents at Wake Teen requesting HIV testing will be given the option for rapid HIV testing.
- After one year, 100% of residents rotating through Wake Teen will receive training on how to provide effective behavioral HIV counseling for adolescents and young adults
- After six months, all universities and colleges in Wake County will have information on Wake Teen’s services including its HIV testing options in their clinics and/or the school’s website.
- After six months, the Alliance of AIDS Services will be supplied with brochures on Wake Teen’s services to include it as part of the package of information given to high risk adolescents by outreach workers.
- After one year, there will be a 30% increase in the number of Hispanic adolescents at Wake Teen who access services. A resident will coordinate this as part of an outreach project.
Activities:

- Objective 1. After six months, at least 100% of adolescents requesting HIV testing will be given the option for rapid HIV testing by the physician and nurse.
  
  ⇒ Revise the current HIV consent form to include Rapid-testing or OraQuick as one of the HIV testing options

- Objective 2. After one year, 100% of residents rotating through Wake Teen will receive training on how to provide effective behavioral HIV counseling for adolescents and young adults. The health educator at Wake Teen will provide monthly seminars for residents.
  
  ⇒ Research effective model counseling manuals effectively used in STD clinics for pre and post-test provider counseling
  
  ⇒ After six months, develop a training manual tailored for an adolescent comprehensive clinic to teach residents and develop procedures for routinely training residents upon arrival to clinic rotation.

- Objective 3. After six months, all university and colleges in Wake County will have information on Wake Teen’s services including its HIV testing options in their clinics and/or the school’s website. A resident will coordinate this as part of an outreach project.
  
  ⇒ Contact appropriate staff in each university or college to provide advertisement on Wake Teen’s services to student via website information and posters at the school clinic.
Objective 4. After six months, Alliance of AIDS services will have brochures on Wake Teen on 100% of the package information given to high risk adolescents. The nurse at Wake Teen will maintain constant distribution of brochures.

⇒ Contact outreach workers who work with adolescents and provide them with brochures on Wake Teen’s services.

⇒ Set up a tour for outreach workers to visit Wake Teen and discuss Wake Teen’s services and barriers to access among high risk adolescents.

Objective 5. After one year, there will be a 30% increase in the number of Hispanic adolescents at Wake Teen who access services. A resident will coordinate this as part of an outreach project

⇒ Contact area community centers and places of worship that cater to Hispanics on available services at Wake Teen including HIV testing options.
Program Planning: Quality Assurance Program

To comply with the FDA requirement for centers receiving free OraQuick kits, the quality assurance plan provided from the CDC website has been modified to address the specific needs for providing testing services for Wake Teen. Prior to offering the OraQuick to patients, the following must be completed: 1) identify a manager for the QA program 2) ensure that the staff are competent to perform the test 3) perform quality control and pilot test runs on test kits 4) work out the logistics for providing confirmatory testing. A quality assurance program will be established to ensure that high quality testing and counseling is implemented and the tasks listed above are accomplished. A manual will be written to describe the job characteristics of each staff and how each can participate in creating a quality testing program. The following section discusses the major necessities in organizing this high quality testing program:

➢ Selection of manager for the Quality Assurance program

Currently Wake Teen has a lab manager who does all the testing, handles quality control and keeps up with orders. This lab manager is also responsible for documenting and reporting tests and communicating with other contracted laboratories such as State lab and Lab Corp. Because this person is responsible for all the testing and documentation of tests, this lab manager will also manage the quality assurance program.

➢ Step-by-Step instructions for testing:

A copy of the manufacturer’s step-by-step instructions has been posted in the lab. Five employees including the medical director, executive director
lab manager and front desk personnel have undergone training for OraQuick. As the program planner, I read the training documents from the CDC website and watched the training video. Additionally, I went to the training session provided by the OraSure company, where I practiced performing the test with positive and negative control materials. The lab manager viewed the training video and observed testing process twice prior to testing under observation for competence. All personnel involved in the testing process completed the training checklist. A training manual has been created with copies of protocol, pretest consent forms and other additional forms. The training manual is organized in a folder to document the competence of newly trained employees. Every six months, the lab manager would watch the video to ensure that the testing protocol is being followed as was initially implemented. In addition, test records and quality control results will be reviewed monthly.

Testing process:

There are several issues to consider when providing testing and counseling on the same day or point-of-care testing. The following conditions need to be met to ensure the proper implementation of a high quality testing and counseling program.

1) The clinic visit has to be efficient so that it is not an impediment to clinic flow.

2) The pre-test and post-test counseling should be client-centered providing information to patients about their risks, why and how
they can reduce their risk, and making sure that the meaning of HIV test results is understood.

3) Because negative HIV results can reinforce high risk sexual behavior, a great effort has to be made to ensure that patients understand a negative result does not mean that one is immune to HIV. Those with recent exposure are encouraged to get a repeat test in three months.

4) Similarly, the meaning of a preliminary positive result and the need for confirmatory testing must be well communicated.

5) All patients should be provided a resource package with contact information for other services in the area.

6) The clinic should have an action plan for adolescents who might be HIV positive. There need to be a resources package and information on available HIV treatment clinics such as Duke and UNC.

➢ Ensure staff know the testing process:

To ensure that the staff know the testing process, there will be an in-service on the testing process including locations of the protocol and pre/post test counseling forms. The State laboratory has been contacted to work out the logistics of providing confirmatory testing. The state lab provided the necessary forms for sending preliminary positive. The process of documentation of the test results was also discussed.
IV. Evaluation Plan

The general purposes of program evaluations are to assess the program’s effectiveness, to determine whether the program is implemented as intended, to improve future interventions and to provide useful information to stakeholders. Researchers have established the importance of linking evaluations of pilot program planning on prevention and program outcomes. In 1999, the CDC began asking city health departments and community prevention projects to develop evaluation plans to assess the effectiveness of their programs. The CDC established guidelines for effective evaluations of HIV prevention programs for health departments. The Houston Department of Health and Human Services (HDHHS), in collaboration with the University of Texas-Houston School of Public Health (SPH) and in support by the CDC, developed a workbook called “Practical Evaluation of Public Health Programs” following the guidelines prescribed by the CDC. This workbook was designed to facilitate program evaluators at health departments on monitoring outcomes on their prevention programs. In particular, the workbook discusses the framework for planning and implementing practical program evaluations. In this section, I will utilize the section in the workbook that discusses the framework for planning and implementing program evaluations as well as a report published by the HDHHS called “Evaluating Outcomes of HIV Prevention Programs: Lessons Learned From Houston, Texas” to design an evaluation plan for this program.

The evaluation framework involves two steps. The first step involves engaging stakeholders or people who have interests in what will be learned from
evaluating the OraQuick intervention plan. These stakeholders include the following: insiders—people who manage or work in the program; outsiders—those who are served or affected by the program; and primary intended users of the evaluation—people who are in position to provide funding for the program. The evaluation team should include a variety of program staff and other external stakeholders. An example of potential team members include management, program staff, clerical staff, people from the community, people receiving services of the program, and those with relevant technical expertise. The goal of this collaboration will be to review the epidemiologic assessment need described earlier in the program plan and decide which target populations to focus on for the prevention intervention. Once there is an agreement on the target populations, then the evaluation team can evaluate the effectiveness and the acceptability of OraQuick by the selected target populations. More importantly, the evaluation team will need to be clear of their roles and responsibilities in the evaluation process. Each member will have a role based on their expertise. For example, the management team may be responsible to come up with source of funding to carry out the evaluation.

The second step of the evaluation framework involves agreement on the program description and the scope. Different stakeholders may have different ideas about the scope and goals of the program. Therefore, it is important that there is consensus concerning the key features of the program so that evaluation decisions will be made more efficiently. An important practical way to describe a program is to have well written, measurable objectives. In the OraQuick
Implementation Plan, the objectives of the program have been already written.

In regards to the program objectives, these could be categorized as either process objectives or outcome objectives. Process objectives measure whether the program was implemented using the interventions described in the program planning stage. An improper administration of the performance or utilization of the interventions can impact the outcome or result in a type III error, which is an incorrect conclusion about the program's effectiveness. The other type of objective is outcome objectives which measure whether there was a quantifiable change in health condition, level of mortality/morbidity or change in behavioral measure such as increased use of condoms. Considering that the OraQuick program is a pilot program that is limited by time and funding resources, it will not be feasible at this time to evaluate any outcome objective for this new program. Although the literature review has indicated efficacy in testing and counseling in outcome objectives such as decreasing new STD rates and higher rates of condom use when proper counseling is in place. It is important to assess the long-term effectiveness of such intervention among patients who reside in Wake County. Again, it is important for the evaluation team to discuss what would be feasible and important to evaluate to determine whether this program should be sustained. Once the program has been running for four or five years, then evaluating outcome objectives will be more appropriate.

To develop an effective process evaluation, it is important to gather data using various methods to collect detailed information on the characteristics of the interventions including the following: the population targeted; the qualifications
of prevention counselors, i.e. resident physicians and attending physicians who do the pre-post counseling. In addition to collecting baseline information on the intervention, it is important to collect information to determine if the project objectives are being implemented effectively. For example, to assess whether objectives 1 was implemented as planned, an exit survey may be administered randomly to adolescents that come to Wake Teen requesting an HIV test. Similarly for objective 2, an end of rotation survey can be used to evaluate that residents that rotate through Wake Teen are receiving training using a manual on how to provide client-centered HIV risk reduction counseling. Each objective can be evaluated separately using an appropriate data collection method. The last steps of the evaluation process involve administering the actual pre-post surveys to clients, collecting and analyzing the data, and providing feedback to the program staff and funding agency.
VI. Discussion and Conclusion

VCT has been the cornerstone of HIV prevention efforts in the U.S and recent scientific evidence suggests its efficacy both among adults and adolescents.\textsuperscript{24} Even though the evidence for secondary prevention of HIV through testing and counseling has been uncontested, \textsuperscript{23,43,44} there are conflicting results for the efficacy of HIV testing and counseling in primary prevention among adolescents. The primary evidence for efficacy of primary prevention of STDs among adolescents comes from a subset analysis of a well-designed RCT that evaluated HIV testing and client-centered counseling among attendants of an STD clinic.\textsuperscript{25} However, evidence for rapid HIV testing and same-day counseling is underway.

There are several limitations in the results of this finding. The literature review only focused on studies done in the U.S to ensure generalizability to the population at Wake Teen. However, there is great advantage in learning about the success of VCT from the tremendous amount of studies internationally. Adolescents have some basic similar developmental stages and efficacy in adolescents in any other setting may have been useful. Another limitation was that this paper was restricted to studies that assessed both HIV counseling and testing among adolescents. Studies that reviewed HIV counseling only as well as studies that evaluated motivational counseling were not considered. Lastly, another limitation of the literature review is that only one RCT was found and this study was done in collaboration with the CDC, who may have a vested interest in the positive outcome of the results.
Overall, the finding of this review highlights the paucity of evaluations on HIV testing and counseling programs among adolescents. Despite the development of CDC guidelines on HIV testing and counseling reporting efficacy, only one RCT has shown efficacy among adolescents in contrast to a cohort study which did not find any effectiveness. However, the differences between these studies may be explained by the different degree of emphasis given to the counseling provided before and after HIV testing. The RESPECT trial employed an optimum guideline in counseling portion which most likely is not replicated in most setting where HIV testing and counseling takes place. In the RESPECT trial efforts to ensure quality and effectiveness, counselor training, ongoing supervision and feedback was an integral part of the prevention counseling. On the other hand, the cohort study by Clark et al. did not employ additional training for the providers who gave the counseling and there were no additional reports on the specific type of counseling model used. This difference potentially can be an issue with lack of effective implementation of the counseling portion in the clinic setting. Other reasons may be related to the differences in study design as well as the sample size. Therefore, of the only two studies evaluating the efficacy of VCT among adolescents, the results of the well designed RCT are more likely closer to the true findings.

Therefore, the finding of efficacy among adolescents at STD clinics does provide some evidence that with proper implementation it is possible to see similar results at Wake Teen. Still, it is important to acknowledge that the efficacy of same day testing and counseling is under investigation. Although
there are a number of existing VCT programs that are using OraQuick in their clinics, there are no published reports on the feasibility and cost-effectiveness of VCT among adolescents. Thus, there is a strong need to encourage clinics to publish their experiences with using OraQuick in their VCT programs. Hence, the results of the evaluation of this proposed pilot program will be very useful in learning if similar effectiveness in risk reduction as the seen by Kamb et al. can be achieved. In addition, the evaluation of the ability to explain preliminary positive results and its impact on sexual health behavior will bring more insights into the improvements that need to be made. It is especially important to study whether giving negative test results to adolescents promotes high risk sexual behavior due to the wrong assumption that negative result mean immunity from getting HIV.

Several issues of feasibility exist in instituting the same standards as the one’s used by the RESPECT trial to the proposed program at Wake Teen. One issue is that the findings in the respect trial were done in inner-cities that are composed of different risk factors and problems. Second, the trials were done at STD clinics and not private adolescent clinics such as Wake Teen. At Wake Teen, the majority of the counseling will be done by pediatrician attendings or resident physicians who rotate through the clinic only for a period of one month. The lack of continuity of counselors will affect the rapport that adolescents may build over time and, therefore, may impact the quality of counseling.

Additionally, it is important to understand the properties of the OraQuick test and the fact that the test is more effective in higher prevalence settings because of the low positive predictive value. The use of OraQuick in a low
prevalence setting can be potentially harmful if false positive results are given to adolescents. It is therefore important to first identify the characteristics of the adolescents that utilize health services at Wake Teen as well as those who are not seeking care. If the adolescents that are being seen at Wake Teen are not from the high risk group of adolescents, it is important to identify what barriers exist to accessing care in this group of adolescents. Identifying barriers to accessing Wake Teen's services among the high risk groups, i.e. MSM, will be informative. Providing testing to adolescents who have a higher likelihood of being seropositive will increase the acceptability of OraQuick at Wake Teen. Addressing some of the barriers in accessing Wake Teen's services among high risk populations and an increased utilization of Wake Teen's health services by this group defines the optimal use of the OraQuick testing at Wake Teen.

Besides the optimal setting related to the test, the addition of a third HIV testing option for Wake Teen requires logistical and economic feasibility. The advantages and disadvantages of OraQuick testing can help speculate the demand and favorability of this new testing option at Wake Teen. One main advantage is the option for same day HIV testing and counseling without the need for a second visit. Adolescents can receive their test results, receive counseling on their HIV status and obtain appropriate care and prevention services. This reduces the rate of undelivered test results and may potentially reduce the inconvenience of time and effort spent to identify a potentially HIV positive adolescent. Another advantage is that rapid notification of results has higher favorability based on preliminary OraQuick testing client surveys. This favorable test may result in
more HIV testing. One main disadvantage of the OraQuick test compared to current state-processed testing is the cost. The OraQuick test is $12 per test plus additional cost to confirm results compared to cheaper cost when performed by the state laboratory for the ELISA/Western blot combination (See Appendix D). However, the cost of OraQuick will still be cheaper and provide results same-day compared to the current cost of the private laboratory, which takes two days and costs more. Another theoretical disadvantage is lowering the perceived risk of infection and having an unintentional increase in high risk sexual behavior after receiving a negative test result. This unintended consequence has been documented by some studies and requires more investigation.\textsuperscript{46,47}

In conclusion, there are several benefits of implementing the OraQuick test at Wake Teen. Ultimately, what will define whether OraQuick is continued will be based on the findings of the favorability of the same day testing option, the success of reducing barriers to allow high risk adolescents and area college students to get tested, and the economic feasibility of providing the test if the CDC no longer provides it for free.
Appendix A

Patient Name

Date

INFORMED PATIENT COUNSELING & CONSENT: HIV TESTING

The patient will initial all of the following ___ to indicate that s/he has read the information, understands the information, and consents to the HIV test. The provider will review the consent with the patient to ensure competency of understanding and consent.

- I chose the Wake County HIV PCR test ($20 for pre-test counseling and bloodwork then return to clinic in ~3 weeks for results and post-test counseling)
- I chose the Lab Corp HIV Antibody test ($40 for pre-test counseling and bloodwork then return to clinic in ~3-4 days for results and post-test counseling)
- I chose the Rapid or same-day test ($30 for pre and post test counseling and bloodwork and a 60 minute visit)

THE HIV VIRUS

The HIV virus causes a life-threatening disorder of the immune system called Acquired Immune Deficiency Syndrome (AIDS). Antibodies to the HIV virus are found in the blood of people with AIDS and can be found in people who do not have AIDS but have been exposed to the virus.

The virus is spread by behaviors that allow for contact with infected blood or other body fluids such as: sexual contact with an infected person; by exposure to infected blood (as in needle sharing during intravenous drug use, or rarely, as a result of a blood transfusion); or from an infected mother to her new-born infant. The virus is NOT spread by casual contact (living in same household, shaking hands, or a kiss on the cheek).

RISK ASSESSMENT

I have had ___ # new partner(s) in the past six months; OR # ___ in the past year; OR # ___ in lifetime.
I have previously tested for HIV: no yes date: _____ results: _______

Partners: male female both
Types of sex: anal oral vaginal other
Frequency of condom use: never always other
Has client ever been a victim of sexual assault: no yes
Type/Frequency of alcohol and/or drug use: ____________________________
Blood transfusion history: no yes
I have positive STI results and a particularly risky event in the last 6 months: no yes
Estimated date of last unsafe exposure: ____________

VULNERABILITY AND TRIGGERS TO RISK BEHAVIOR

Please check any/all of the following that are true:
- There is something going on in my life that increases my risk behavior.
- There are times or situations when I am more likely to take risks.
- Drinking alcohol or other drugs influences my decision to have unsafe sex

CONFIDENTIAL TESTING:

At this clinic we offer confidential testing, which means that your test result will be recorded in your medical record. Knowing your HIV status will enable your medical provider to give you better medical care. If you test positive for HIV, this information is not casually disclosed to other persons but does become a part of your medical record. North Carolina law requires that local and state health departments be notified regarding positive test results. While we encourage sharing test results with your health care providers, sexual partners, and close and supportive people in your life, sharing test results can result in discrimination issues in relationships, employment, housing, and
insurance. However, there is great benefit to being diagnosed early in the disease to help you get the best treatments available.

MEANING OF TEST RESULTS:
- If the test gives a **negative result**, there is still a small but real possibility you may be infected with HIV as sometimes the antibodies to the HIV virus are not detectable early in the infection. It takes at least 4 to 12 weeks for a positive test result to develop after a person is infected, and may take as long as 6 to 12 months.
- HIV test results are highly reliable but not 100% accurate. If the test gives a positive, we will retest your blood with an additional test in order to confirm the result. While a **positive test** result does not necessarily mean that you have HIV or AIDS, it does mean that you are at serious risk of development AIDS or AIDS-related conditions. You are infected with the HIV virus and infectious to others. The health department will talk with you about partner notification. It is important that you notify your current partner that you tested positive and do not have unprotected sex or share drugs/needles. You should seek medical follow-up care with your personal health care provider as this can affect whether or not you get AIDS or how severe it will become. If you test positive you will return to this clinic for further counseling and referral to an HIV/AIDS specialty clinic.

DISCLOSURE OF TEST RESULTS
- **No test results** (either positive or negative) will be revealed over the phone and it may take as long as 3-6 weeks to get your test results back. You will need to return to clinic to get your results!
- If you test positive, you will need to have a second confirmatory Western Blot blood test to determine whether or not your first test is correct and that you truly have HIV infection. If today’s PCR is positive, you should consider yourself as being HIV positive unless 3 subsequent antibody testings return negative (HIV antibody testing at 2, 4 and 12 weeks after the initial test).
- If you have ordered your HIV testing through the **Wake County**, you will be given a card with your confidential test code number on it; bring this back to your follow up appointment. If you have a positive PCR test for HIV, then you will be notified by the Wake County Health Department Disease Intervention Specialist (DIS).
- If you ordered your HIV test via **LabCorp** you will be notified at your follow up clinic appointment of your results, or may be contacted by a Wake County Health Department DIS.
- If your **Rapid or same-day** testing is positive, we will draw and send a confirmatory Western Blot and schedule a follow up visit to discuss the results.

IMPACT OF TEST RESULTS

What would a negative test mean for you and what changes would you make in your life?

What would a positive test mean for you and what changes would you make in your life?

Who is your support system and will help you if you receive positive test results?

******************************************************************************

CONSENT FOR HIV TESTING:
I have read and I understand this HIV Test Informed Consent Form. I voluntarily consent to the withdrawal of blood, and testing of my blood for HIV antibodies, and the disclosure of the test results as described above. This consent is valid for this ninety (90) day period. I understand that I have the right to request and receive a copy of this authorization. A photocopy of this form will be as valid as the original.

I, ________________________________, have read (or have had read to me) a copy of the pamphlet “Information about AIDS and HIV Antibody Testing”. If I choose not to be tested for HIV infection, I understand that services will still be provided. My questions about the test have been answered to my satisfaction.

☐ YES, I DO agree to be tested confidentially and understand that my test results will be recorded in my medical record.

☐ NO, I DO NOT agree to be tested confidentially at this time for HIV infection. But I do understand that I can return to clinic at any time to be counseled and re-consent for this test. I also understand that there are other resources for HIV testing in the community that are available to me.

Name __________________________________ __
Signature ________________________________ Date

*******************************************************************************

To be completed by the medical personnel consenting the patient:

I have assessed this patient for consent to HIV testing.

☐ I have done risk reduction education/counseling which includes a plan to: __________

Patient has scheduled a follow up visit for post test counseling in: ___ 1 week ___ 3-4 weeks

Name/Signature of medical personnel providing consent __________________________ Date
**Appendix B**

**HIV POSITIVE**

<table>
<thead>
<tr>
<th>POST TEST COUNSELING</th>
<th>Patient Name</th>
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</thead>
<tbody>
<tr>
<td>_____________________</td>
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The provider will review the consent with the patient to ensure competency of understanding. Providers will allow time for clients to absorb the implication of a positive test and ask if there is a support person to include in the counseling procedure. The provider will initial or complete the post test follow up form.

**RE-ASSESS PATIENT’S READINESS**

- Assess patient as ready to receive their HIV results and understanding of the nature and limitations of the test.

**EXPLAIN TEST RESULT**

- Explain what “antibodies detected” means (Client is infected with HIV; is presumed to be infectious and can transmit virus to others; does not necessarily have AIDS, but can develop AIDS in the future; can live with HIV, with currently available treatments, for an undetermined length of time)
- Explain that blood will be drawn for a confirmatory test

**RISK REDUCTION MEASURES**

- Review state law mandated control measures for people with HIV
  - Must receive TB skin test
  - Condoms must be used during all sexual intercourse
  - Must not share needles or syringes
  - Must not donate blood (products), semen, organs, plasma, platelets, tissue, breastmilk
  - Must notify future and past sexual and needle-sharing partners of infection
  - Perinatal transmission and breastfeeding risks
  - Explain North Carolina state reporting laws
  - Partner Notification- must tell all partners in last year or DIS officer will tell anonymously
  - Illegal to have sex without a condom if you know you are HIV positive

**RISK REDUCTION GUIDELINES (*denotes required by law)**

- Always use condoms during sex*  Limit number of sexual partners
- Breastfeeding*  Do not share drug equipment; clean with bleach
- Cleaning up blood & other body fluids*  Do not donate blood, semen
- Perinatal transmission*  Abstinence
- Do not share razors, toothbrushes, etc.  Do not get pregnant

**DISCLOSURE OF RESULTS (Encourage patient to tell parent, current partner/s)**

- Discuss disclosure issues; who to tell, when, how
- Review options for partner notification
- Address the possible need for partner to come in for testing and counseling
- Assess safety and identify/build client’s social support network

**MEDICAL FOLLOW-UP**

- Explain importance and benefits of medical follow-up
- Describe standard medical interventions for people with HIV
Immune system monitoring
Screening for TB and STDs
Preventive (prophylactic) treatment
ART - antiretroviral therapy

Discuss basic health promotion (regular exercise and good nutrition; stress reduction and adequate sleep; avoid smoking and limit drug and alcohol use which compromise immune system; avoid exposure to STDs which compromise immune system; emotional support)

REFERRALS
Offer information and discuss referral to UNC or Duke University HIV Infectious Disease clinic.
Discuss with clients resources listed on HIV Resources Card
Help client identify services he/she may wish to pursue (support groups; informational resources; counseling or mental health services; legal services;
other: ____________________________________________

SUMMARY
Any questions or concerns?
Describe:

Remind client about state reporting laws
Assess emotional state of client and assess safety
Describe:

Escort client to lab for confirmatory testing

DO NOT FORGET:
  • Give client condoms
  • Give Referral sheets/ brochures/ resource card
  • Complete Communicable disease Report Card (NC)

ADDITIONAL COMMENTS:

Name/Signature of medical personnel providing consent  Date
HIV NEGATIVE POST TEST COUNSELING

Patient Name __________________________
DOB: __________________________

Date: __________________________

The provider will review the consent with the patient to ensure competency of understanding. The provider will initial or complete the post test follow up form.

RE-ASSESS PATIENT'S READINESS
____ Assess patient as ready to receive their HIV results and understanding of the nature and limitations of the test.

EXPLAIN TEST RESULT
____ Explain what “antibodies not detected” means (Patient is NOT infected with HIV OR is infected with HIV but antibodies have not yet developed in the body (window period)
____ Explain what negative test result does NOT mean (Patient is NOT immune to HIV now or in the future and that negative result is NOT an “OK” to engage in high risk behaviors)
____ Emphasize importance of re-testing 6 months after last exposure (if appropriate)

EDUCATION
____ Discuss risk reduction plan (condoms; other safer sex practices such as abstinence, one partner in a committed relationship, communication w/partners; seek emotional counseling if necessary)
____ Address the possible need for partner to come in for testing and counseling

SUMMARY
____ Any questions or concerns?
Describe: ______________________________________________________

____ Make referrals for additional support and/or counseling
Referrals: ______________________________________________________

DO NOT FORGET:
○ Give client condoms
○ Give Referral sheets/ brochures/ resource card

ADDITIONAL COMMENTS:
____________________________________________________________
____________________________________________________________
____________________________________________________________
____________________________________________________________

Name/Signature of medical personnel providing consent Date
Appendix C

HIV Testing / OraQuick

Testing process and one session pre/post test counseling

Screening

A. All patients who request STI testing or specifically HIV testing will receive information on the different types of HIV testing including costs and turn around time for each.

B. All patients who exhibit high risk sexual behavior during annual health check will be offered HIV testing.

C. Only patients who are over 13 year-old will be offered the Rapid HIV-1 Antibody test (OraQuick).

Before testing

Patient requesting HIV testing only:

A. Patients who request HIV testing only will go directly to an examining room for pre-test counseling.

B. Physician will go through patient’s risk for STI, completing pre-test counseling checklist to help cover all the issues including: enhancement of the Patient’s Self-Perception of Risk, exploring specifics of most recent risk incident and review previous risk reduction experiences.

C. After all questions have been answered, the patient will sign the informed consent form and go to the lab to give blood for testing. *(Verbalize need for confirmatory testing if OraQuick is preliminarily positive)*

D. Verify that two reliable phone numbers are available in an event that further testing is required.

E. After giving blood, the patient will watch a 30 min STI video in the patient education room while the test in brewing. *(if the room is occupied then send patient to the lobby)*

Patient requesting STI/HIV testing:

A. Patients who come for a sick visit will have their vital signs taken and will then be escorted to an examining room.

B. Physician will go through usual assessment of sick patient as well as obtaining information on risk for STI and pregnancy. Physician will use pre-test counseling checklist to aid in thoroughly covering all the issues including: enhancement of the Patient’s Self-Perception of Risk, exploring specifics of most recent risk incident and review previous risk reduction experiences.

C. After all questions have been answered in the history, the patient will sign the informed consent form and go the lab to give blood for testing prior to physical exam or gynecological examination. *(Verbalize need for confirmatory testing if OraQuick is preliminarily positive)*
D. Verify that two reliable phone numbers are available in an event that further testing is required.
E. After giving blood, the patient will either return to the examining room for further assessment or go to patient education room to watch STI video while the test is brewing.

During testing
A. The nurse will verify that the informed consent is signed, two reliable telephone numbers are available and all questions have been answered.
B. Patient will then complete testing forms found in red book in nurse’s office (copy of an example of completed form is taped inside cover).
C. The nurse will provide patient the pamphlet provided with the kit before collecting specimen.
D. Next, the nurse will collect specimen and allow patient to return to examining room if further assessment is necessary eg gynecological exam.
E. If no further testing is needed then provide STI prevention/education video in the patient education room or send patient to lobby to wait for result.

After testing
III Reporting results and documentation

Preliminary Negative Result
A. Call patient back in a room if in lobby to a room or the patient education room.
B. Give patient result, explain meaning of negative result taking recent exposure (window period) into consideration
C. Review original risk information, patient’s risk reduction plan and reinforce patient’s plan to remain HIV negative
D. Schedule retest date to cover window period, if necessary

Preliminary Positive Result
A. Discuss with clinician the result, gather resource package and establish a plan.
B. Call patient back in a room if in lobby or the patient education room.
C. Give patient result using post-test counseling form
D. Explain meaning of OraQuick vs confirmatory test result and emphasis importance of return visit to receive confirmatory result.
E. Review risk reduction plan, go over what to expect in F/U visit, and provide clinic contact number and other available local support services.
F. Underscore the importance of taking precautions to prevent transmitting infection to others while awaiting results of confirmatory testing.
G. Assist patient in developing a plan for the next 24 hours, and help in obtaining support persons.
H. Assess patient’s safety and answer any additional questions. Involuntary commitment forms are available if needed.
I. Schedule an appointment for confirmatory test result, verify patient’s contact number and give patient appointment card.
J. Escort patient to give blood and send confirmatory test specimen to State lab.
K. Receive referral laboratory results, record result and place copy in patient’s chart

**Confirmed Positive Result**

A. Discuss result with physician and establish a plan.
B. Provide result using explaining meaning of the confirmatory test.
C. Assist client in developing a plan for the next 24 hours, and assist in obtaining support persons.
D. Assess suicidal ideation and contract emergency mental health counselors.
E. Provide patient with local resources, primary HIV/AIDS providers and help make an appointment.
A PRELIMINARY POSITIVE result means:

- This test detected HIV antibodies (your body’s response to HIV infection) in your blood.
- It is an initial test and requires another more specific test to confirm that you are HIV positive.
- The confirmatory testing (the more specific test) is needed to rule out any chance that your initial test was falsely positive.
- It takes 2 weeks to get results back for a confirmatory test.
- Absolutely no confirmatory test will be revealed over the phone.

While you are waiting for the confirmatory testing:

- Understand that even if the confirmed test is positive, the result does not mean that you have AIDS or that it is “a death sentence”.
- If results are confirmed positive, medical care is available to monitor the health of your immune system and limit the harmful activity of HIV in the body.
- It is EXTREMELY IMPORTANT you practice safer sex and needle use behavior to avoid passing the virus to someone else.
- Call Wake Teen or the resources below if you have any concerns.
- If you feel that your life or someone else’s life is in danger, call 911 immediately.

Your appointment for getting your confirmatory test result is:

On _____________________ at __ __

Other resources:

National HIV/AIDS Hotline 1-800-342-AIDS (2437),
[Espanol: 1-800-344-7432]

National STD Hotline 1-800-227-8922

Gay/Lesbian Helpline: TREVOR hotline 1-866-488-7386
PFLAG (919)929-0192
Shelter and counseling: Wrenn House (919)832-7866
A NEGATIVE result means:

• That this test **did not detect** HIV antibodies.
• HIV antibodies are weapons your body uses to fight the HIV virus.
• It does not mean you are protected from getting HIV.
• If you recently (within 3 months) had any unsafe sexual or drug behavior, your body may not have had time to develop antibodies that are detected by the test. So, you may still be infected with HIV.

The only protection from HIV infection is to abstain from sex, practice safer sex using condoms every single time and not sharing dirty needles.

If you recently had unsafe sexual intercourse or shared needle for drug use then you should consider getting tested again in three to six months.

If your exposure is more than 3-6 months prior to testing then you are more likely to be HIV negative. The test is very accurate (at least 99.6%).

For additional information contact:

- National HIV/AIDS Hotline 1-800-342-AIDS (2437), [Espanol: 1-800-344-7432]
- National STD Hotline 1-800-227-8922
- Gay/Lesbian Helpline: TREVOR hotline 1-866-488-7386
- PFLAG (919)929-0192
- Shelter and counseling: Wrenn House (919)832-7866
- Centers for Disease Control www.cdc.gov
Patient Name __________________________
DOB _______________________________
Date ________________________________

Confirmed HIV Referral Form:
OraQuick □ Positive □ Negative Date: ____________
EIA □ Positive □ Negative Date: ____________
Western blot □ Positive □ Negative Date: ____________

Appointment:
UNC Pediatric (<18yr)
Infectious disease clinic
(919)966-2331
Date/Time __________________________
Physician __________________________

UNC Adult (>18yr)
Infectious disease clinic
(919)966-7198
Date/Time __________________________
Physician __________________________

DUKE Pediatric (<17yr)
Infectious disease clinic
(919)684-6335
Date/Time __________________________
Physician __________________________

DUKE Pediatric (>17yr)
Infectious disease clinic
(919)681-6261
Date/Time __________________________
Physician __________________________
## Appendix D

### Budget for OraQuick

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<th>EXPENSES</th>
<th>Cost for per person w/ CDC funding</th>
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<tr>
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<td>$0.75</td>
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</table>
Reference:

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