

***Expected Questions and Proposed Answers  
Regarding  
Explore Results***

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1. *What community and CAB involvement was there in the development of the intervention, protocol and during the study?*

- CABs were involved in the pilot study and the national CAB coined the name “EXPLORE”.
- During the recruitment and retention phases of the study, CAB members were involved initially and throughout study (participation varying by site).
- Ethnic minority retention strategies were coordinated with CABs and CBOs at some sites – ethnic staffing at sites helped in recruitment efforts.
- We note there were challenges in involving CABs, their comments, and contributions varied by site.

2. *What is the scientific foundation of the intervention?*

Overall, multiple theoretical frameworks influenced the development of the intervention including:

- The information-motivation-behavioral skills model (Fisher & Fisher, 1992)
- Problem-posing education (Freire, 1973; Sanchez-Merki & Wallerstein, 1989)
- Self-management and social learning theory (Bandura, 1986)
- Cognitive-behavioral therapy (Beck, 1976; Persons, 1989)
- Motivational enhancement (Miller 1985, Carey, 1996)

The intervention strategies based upon these frameworks include identifying the needs and risks of individuals being counseled, training in skills for negotiating and implementing risk reduction in the context of various partner relationships. The intervention strategies also include counseling in self-management specific to the relationship between substance use and sex, management emotions leading to high-risk sex, and maintaining risk reduction goals over time. These principles and strategies, common to previously demonstrated successful behavior intervention studies (e.g. Peterson, et al. 1996), provide the content for the behavioral intervention.

3. *How does Explore differ from available, tested interventions?*

Explore is based on multiple theoretical frameworks and strategies which have been previously demonstrated to change reported sexual risk behaviors. The goal was to see if this type of individualized counseling would reduce acquisition of HIV infection, as well as reduce reported sexual risk behaviors.

A recent meta-analysis of behavioral interventions for MSM showed that interventions focused on interpersonal skills related to risk reduction could reduce self-reported episodes of unprotected anal intercourse (Johnson *et al.*, 2002, JAIDS). The literature also indicates that interventions should target use of alcohol and recreational drugs, social

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norms encouraging risk taking, enjoyment of risk-related sexual behavior, and life events and environments that trigger risk taking (Stall *et al.*, 2000, AIDS; Strathdee *et al.*, 1998 JAIDS). These components built into individually-tailored interventions assisting individuals in moving toward risk reduction based on his own and his partners' serostatus, may have the greatest success in reducing risk of infection among MSM (Chesney *et al.*, 2003 AJPH).

There is one other trial of an HIV risk reduction intervention for MSM that involved a biological endpoint, "A cognitive behavioural intervention to reduce sexually transmitted infections among gay men: randomised trial", *BMJ* 2001; 322:1451-56. This study introduced the MI intervention in a one-day workshop and participants were followed for one year. Final results showed intervention participants with more STDs than the standard arm, and no decrease in overall behavioral outcomes.

Two large-scale trials of behavioral interventions with biologic outcomes were conducted among heterosexuals in the US (Project Respect and The NIMH Multisite HIV Prevention Trial). The Project RESPECT trial tested individually-delivered interactive risk reduction interventions delivered in either two or four sessions and found, over 12 months, a 20% reduction in new STDs compared to those receiving didactic messages. The effect of the intervention was strongest early in follow-up. The NIMH Multisite HIV Prevention Trial of a seven-session small group intervention found no difference in overall STD re-infection rate over 12 months by arm of the study.

4. *How might the intervention or elements of the interventions be adapted by agencies?*  
We do not recommend that the Explore intervention be implemented, as is, by agencies. We have a rich data source to conduct further analyses to generate hypotheses for ways to develop more highly efficacious behavioral interventions.
5. *What are some of the options for such technology transfer?*  
(see answer 4 above for this answer)
6. *What steps will the Explore Team or HPTN take to identify and assign human financial resources for technology transfer?*  
(see answer 4 above for this answer)
7. *What should clinicians/providers do differently as a result of the Explore findings?*  
(see answer 4 above for this answer)
8. *Why was Explore a Phase IIb clinical trial?*  
A Phase IIb trial design is a useful approach to identify highly efficacious intervention or ones that have no benefit.
9. *Are these findings consistent with other studies? If it is, then why is Explore different?*

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The reduction in HIV acquisition in the first 18 months of follow-up in EXPLORE was similar to that found with STDs in Project RESPECT. Furthermore, the EXPLORE study found similar reductions in risk behaviors over 12 to 18 months of follow-up as compared to Project RESPECT and the meta-analysis of HIV intervention studies among MSM.

During follow-up, the HIV incidence rate was high (2.1% of men became infected with HIV each year). As well, other rates of risk factors, such as unprotected receptive anal sex were elevated; Explore recruited a higher risk-taking cohort).

*10. Were racial and ethnic minorities adequately represented? What was done to make the study as representative as possible?*

There were site variations in methods to recruit and retain ethnic and racial groups in Explore. Some sites were more successful. Special planning sessions were held to assist sites in considering alternative/more effective recruitment and retention approaches. For example, study materials were translated (and back-translated) to assure that language was a minimum barrier to participation.

*11. Have we learned anything that would help the highest risk men if they were the most likely to dropout?*

Retention was one the most important priorities of the study. One of the most important aspects of Explore retention is that those in the experimental group who did not complete the intervention had a lower overall retention rate than those who completed at least 9 of the initial ten session-modules.

First work is needed to improve the retention of, for example, younger men of color and highest risk men in interventions such as this. NOTE: The intervention may have been "acceptable" in the way this term is used by the PUBLIC (not in science) but the younger men of color, for example, who were also at high risk may have lifestyles or values that compete with the intervention commitment.

Second, for future intervention trials, approaches are needed to improve the capture of longer-term outcome results particularly among those participants who have lower levels of adherence to behavioral interventions.

*12. What is the take home message for:*

*me as an MSM/gay man?*

- intensive, individualized counseling can reduce reported high risk taking behaviors
- the data suggest that intensive, individualize counseling may reduce HIV seroincidence somewhat
- join a study

*scientific/clinical community?*

- warrants further research, particularly focused on maintaining and enhancing change over time, after the intensive intervention is over

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- lots of data from baseline papers – high prevalence of depression, childhood abuse, and substance abuse.

*government representatives?*

- EXPLORE has many lessons learned about behavioral trial methods, including how to recruit and retain high risk participants, administering multi-site intervention trials, strategies for quality assurance and monitoring.
- lends support to the idea of practitioners spending time with patients.
- need more research to show the long-term effect of tailored individualized counseling on reducing HIV incidence.
- Reinforces the idea that research on behavioral interventions with both behavioral and biological endpoints are a good idea.
- retention statistics were very good – these types of trials can retain participants.

*public health professionals?*

- PH professionals need further studies to translate results.
- increase awareness of MSM health issues.
- shows HIV still a big problem in the community.
- PH professionals need to stay tuned for additional results - ie, different behaviors, ancillary studies.

*NGOs/CBOs/ASOs?*

- NGOs/CBOs/ASOs should help in result dissemination and messaging.

*13. How much did the study cost and who paid for it?*

The costs of the study cannot be thoroughly assessed due to the various types of costs experienced or absorbed by sites. However, the NIH Division of AIDS spent over \$30 million dollars to complete the trial.

*14. What does the study tell us is/are the most active ingredient(s) for behavior change?*

It is premature to answer this question. Further analyses are underway to generate hypotheses about effectiveness of components of the intervention.

*15. Who changed and who didn't? Who was the intervention good for?*

Study researchers are currently involved in analyses to provide answers to this question.

*16. What new have we learned about the gay community that we didn't know?*

The study gave us a stronger understanding of:

- the high substance abuse rates
- levels of depression (an important cofactor for men with high risk behaviors)
- other biological endpoints such as HPV and HHV-8 (ancillary studies) found and risk factors (see forthcoming papers)

*17. Why only MSM?*

In 2002, men who have sex with men (MSM) accounted for 44% of all new HIV and AIDS diagnoses in the United States (CDC 2002 HIV/AIDS Surveillance Report). The

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need for HIV preventive interventions with proved efficacy in MSM is reinforced by data demonstrating an increase in HIV infection among MSM over the past seven years, in contrast to declining rates of risk behaviors and seroincidence among MSM observed in the 1980's and early 1990's (various authors).

*18. What populations will benefit from the results?*

Study researchers are investigating subset analyses by age, ethnicity, and risk behaviors to answer this question.

*19. What recruitment bias existed in MSM recruited and how does this affect generalizability?*

The population recruited for this study represents high risk urban MSM in the six US study cities that were willing to discuss their risk taking behaviors over an on average 3.25 year period. The results are not generalizable to the larger MSM population with varying risk-taking behaviors, nor are the results generalizable to rural or general national MSM populations.

*20. What does site specific data mean?*

Due to a required sample size, only the aggregate data can provide meaningful information on the effectiveness of the intervention to reduce the acquisition of HIV. However, site-specific data can inform meaningful and important information on risk taking behaviors and demographics, as well as retention and behavior change.