EVALUATION OF A COMMUNITY DEVELOPED INTERVENTION TO REDUCE HIV RISK AMONG AFRICAN AMERICAN WOMEN

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In the United States, African American women are twenty times as likely as their Caucasian counterparts to become infected with HIV. At some point in her life, one in thirty-two African American women will be diagnosed with HIV. Developing and rigorously evaluating interventions to reduce the impact of this disease for African American women is thus a matter of great public health significance. The Girlfriends Project (TGP) is a community developed intervention designed to reduce HIV infection rates among African American women. TGP builds on social networks by recruiting women to host house parties for their friends and family members, during which trained facilitators provide HIV risk reduction information and on-site HIV testing and counseling.

This document describes the process of scientifically evaluating TGP using a study design that was developed with community partners and took place in community settings. This pilot study used a mixed methods approach, pairing a quantitative analysis using a wait-list design with a qualitative study in which semi-structured interviews were conducted with study participants.

A number of statistically significant findings were noted. As compared to the control group, women in the intervention group were four times as likely to decrease their frequency of anal sex without condoms, six times as likely to increase their frequency of anal sex with condoms, and two to three times more likely to talk with their male sex partners about preventing

HIV, preventing other sexually transmitted infections, or their partners' sex histories. Intervention group women were significantly more likely to have vaginal sex with a condom after participating in TGP and also experienced a statistically significant improvement in HIV knowledge after the intervention.

Preliminary qualitative data suggests that TGP participants increase the degree to which they talk with members of their social networks about HIV risk after participating in the intervention. Participants also report that TGP has helped them to prioritize their own health and to develop connections to support other women in doing the same.

Given these early indicators of success, further research is warranted to understand TGP's mechanisms for change and demonstrate program effectiveness.

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PREFACE

In 2004, I was working at the Pittsburgh AIDS Task Force and had written a proposal for CDC funding of several evidence-based HIV risk reduction interventions. The proposal was successful but given that its target population was African American women, I was uncomfortable with the fact that the concept was created by me and one other Caucasian individual. Although we were certainly committed to the risk reduction objectives we drafted and probably more tuned in to community needs than the general population, we certainly were not representative of the target population. I knew we could do better. It was this belief that drove me to speak with then-Executive Director Kathi Boyle about developing an in-house program to reduce HIV risk for African American women, and about the fact that to be effective, the intervention should not be created in a “white silo” but by those who knew best about how this work could be accomplished.

This values orientation toward community participation in program development and research has been important to every aspect of TGP, from development to implementation to evaluation and back again. When TGP was created, I certainly had no idea of the success that the program and its facilitators would experience, or of the way this process would become so intertwined with my professional (and personal) life. I am grateful to Kathi and to the women who are the heart of TGP: Lisa Dukes-Garner, Pamela Smith, Daphne, Sheila, Clarisse, Diana, Duprene, Janice, Michelle, Patty, and many, many more.

This has not always been an easy process for any of us. For me, one of the greatest challenges has been being able to be clear about my own role, which at different times included that of writer, implementer, evaluator, and champion. I had a loyalty not only to the program and its intended outcomes, but also to the data and research findings. I had to remind myself that the success of the intervention was not tied to the success of my dissertation, and that in my role as evaluator I had a very clear set of ethical responsibilities.

I feel incredibly lucky to have served in these roles, and even luckier to have an amazing support system of people who believed in me even when I was crazy. I dedicate this dissertation in memory of Kara, and in thanks to all of those who got me through it. These include Dr. Richard Day and the Biostatistics Consulting Lab, and the members of my incredible Dissertation Committee who were so generous with their time and wisdom: the indefatigable Beth Nolan; my Dissertation Chair, Edmund Ricci; my Academic Advisor and Research Mentor, Ron Stall; and of course, John Marx, who has made an indescribable impact. Nor can words describe the love and thanks for those who inspire me the most and have made all the difference in the world: Delaney, Reese, Carson, and of course, Bill. It’s always you!

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1.0 INTRODUCTION

In 1981, the first hint of the epidemic now known as AIDS was noted in the Morbidity and Mortality Weekly Report, with details about five unusual cases of Pneumocystis carinii pneumonia in previously health gay men (CDC, 1981). Now as we have marked thirty years of AIDS, more than one million people are living with HIV in our country alone, and at least 617,000 of our citizens have died of the disease (Hall, Song, & Rhodes, 2008). Tragically, this disease is largely preventable, and its history in our country is filled with examples of missed opportunities to slow or even stop the spread of this epidemic.

While the scientific community knows much more about HIV disease mechanisms and treatment than we did thirty years ago, we collectively persist in blocking opportunities to prevent new infections. HIV continues to hit hardest those populations that are marginalized and are living with multiple challenges such as poverty, addiction, and lack of access to educational and other resources. One population that has been severely overrepresented in this epidemic is African American women. Although many behavioral interventions have been developed to reduce infection rates, they clearly have not been successful in stopping the alarming HIV health disparities for this population. It is apparent that we must intensify and shift the focus of our efforts if we are to change the trajectory of HIV for African American women in our country. In doing so, we must also have an in-depth understanding of the underlying factors that have led to the current state of HIV in this population and then identify characteristics of the community and of risk reduction interventions that can be emphasized and built upon.

This dissertation documents one such attempt to reduce HIV infection rates among African American women in our country. It includes six main sections: (1) current statistics and underlying issues; (2) recommendations for intervention; (3) a description of The Girlfriends Project (TGP), a community-developed model for reducing HIV risk in the target population; (4) a description of the process of designing a community-informed evaluation to assess for the "real world" effects of TGP; (5) quantitative results of the evaluation; (6) preliminary qualitative results; and (6) a future research agenda to continue this important work.

2.0 HIV HEALTH DISPARITIES AND AFRICAN AMERICAN WOMEN

2.1 HIV STATISTICS

In the United States, HIV was initially identified in the population of sexually active men who have sex with men. As the disease progressed, it increasingly affected other populations, especially those with limited access to resources and health care. Today, African American women experience significant HIV health disparities. In 2006, AIDS was the third leading cause of death for African American women of all ages in the United States. African American women in our country are twenty times as likely as their Caucasian counterparts to become infected with HIV (CDC, 2010). At some point in her life, one in thirty-two African American women will be diagnosed with HIV (CDC, 2008).

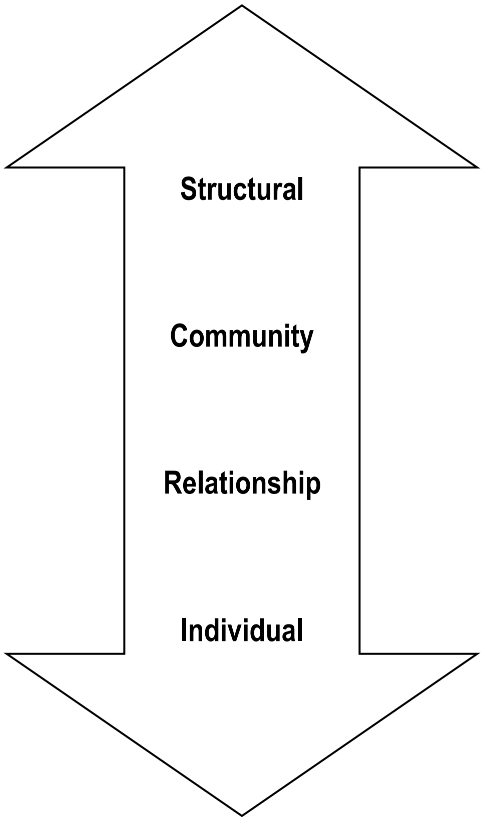
Similar HIV health disparities persist in Allegheny County, PA, which can therefore considered as a microcosm of this epidemic. Here the HIV prevalence rate is 45 per 100,000 for Caucasians but 503 per 100,000 for African Americans. African American women comprise 70% of cumulative AIDS cases among women despite the fact that they represent just 7.3% of women in our region (U.S. Census Bureau, 2008). In addition to being overrepresented in the number of AIDS diagnoses, African American women enter care much later than Caucasian women, resulting in poor clinical outcomes and higher death rates (Pennsylvania Department of Health, 2010). African Americans in our region represent 48% of cumulative AIDS cases

(Pennsylvania Department of Health, 2010) but only 39.5% of living HIV or AIDS cases (ACSWP, 2011/2013).

The terrible impact of AIDS goes far beyond the morbidity and mortality of HIV-infected women. As the primary caretakers of the young and old, when women become ill then whole families suffer. Living with HIV creates many additional challenges in the lives of women with already stretched resources. A recent qualitative study of women living with the disease documented that 60% of those interviewed reported that HIV had taken significant amounts of time away from their lives with their children, and that many of them felt forced to choose between mothering activities and their own health, including medication adherence (Murphy, Roberts, & Herbeck, 2011). Ask any working mother if she regularly experiences feelings of stress, guilt, and being overwhelmed while trying to manage multiple responsibilities, and she is likely to respond with a resounding “yes,” (or possibly a small whimper.) Add stigma, poverty, and physical ailments to the mix and she might not even have the energy to contemplate the question.

2.2 UNDERLYING ISSUES: A SOCIO-ECOLOGICAL MODEL OF HIV RISK MODIFIERS

Although HIV infection is of course caused by a viral agent and is therefore a biological event, its impact is significantly moderated by multiple other issues. As noted in a 2008 article that tracks the path of HIV in our country, “…the reasons that epidemics occur are largely a function of human behaviors and responses to environmental changes.” (Mayera, Pizerd, & Venkateshe, 2008, p. 1363). An understanding of the underlying issues relating to the HIV epidemic as it impacts African American women is therefore best grounded in a socio-ecological model. This model underscores the fact that there are many levels of factors that impact HIV infection rates and that there is significant interplay between these levels. Any single factor that one might describe as existing within a given level is affected by -- and affects – factors on other levels. For example, the presence of an “individual” factor such as a sexually transmitted infection (STI) increases a woman’s risk of HIV infection, but her likelihood of having that STI is impacted by factors on other levels such as poverty and access to care. While other diagrams of the socio-ecological model use borders between each of the levels to depict a specific order of influence, the model below is an attempt to demonstrate that the levels are continuous and interactive. The main issues surrounding risk for HIV that are discussed in this document include the following.



- Lack of Funding
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Figure 1. Socio-Ecological Model of HIV Risk Modifiers

2.2.1 Lack of Funding & "Top Down" Interventions

Although billions of dollars have been spent in attempts to control HIV in the United States, these efforts are not sufficient to reduce HIV risk for African American women as evidenced by population infection rates. In the President's Fiscal Year 2012 Federal Budget Request, the proposed prevention spending of $997 million represented just 4% of the total HIV/AIDS budget (Henry J. Kaiser Family Foundation, 2010). The majority of these funds is provided to the Centers for Disease Control and Prevention's (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP).

Limited funding for community based prevention is not a new problem. A 2002 statement by the Infectious Diseases Society of America suggested that in that year, the Bush Administration was limiting the prevention reach of the CDC noting, “President Bush and his administration need to work *with* community-based AIDS groups, instead of stonewalling those whose HIV prevention philosophies do not match their political ideologies. AIDS is a public health crisis, not a political campaign.” (IDSA, 2002, p.1) The CDC responded to this political environment of scrutiny by strengthening its promotion of science based interventions. Many prevention interventions have been tested in randomized controlled trials and found to be efficacious. However, we must question why these interventions aren’t effective in stopping the spread of this disease among African American women. It is likely that interventions that have been developed from the “top down” (that is, developed in research versus community based settings) have small effect sizes in the real world. Furthermore, there have been few intervention effectiveness studies in real world settings.

The CDC has identified forty-one best-evidence interventions, which means that “…they have been rigorously evaluated and shown to have significant effects in eliminating or reducing sex- or drug-related risk behaviors, reducing the rate of new HIV/STD infections, or increasing HIV-protective behaviors.” It has also identified twenty-eight promising-evidence interventions, which have been evaluated and have significant and positive evidence of efficacy, but do not meet the same level of rigor as the first group (CDC Prevention Resarch Synthesis, 2010). Several of the combined sixty-nine interventions are *inclusive* of African American women targets, such as those developed for the broader categories of heterosexual adults, people living with HIV, or intravenous drug users. And six of the interventions were either designed for African American women or tested with them as a majority of the sample. However, these interventions are targeted to specific segments of women, such as those seen in STI clinics or who are IV drug users. While it’s true that high risk women can be found in these settings it is also true that women not connected to services may remain unreached.

Only one intervention (SISTA) was developed specifically for the general population of African American women to be delivered in community settings. This intervention has been found to be effective in reducing risk behaviors (CDC, 2009). However, it requires a six week commitment that can be difficult for women to manage. As a result, SISTA is frequently implemented in other provider settings or in jails. This is problematic, since women who are not connected with other services or who are unable to commit to multiple sessions do not have other options for evidence-based, gender- and culturally-appropriate HIV prevention. Although SISTA continues to be disseminated it has been removed from the CDC’s *Compendium of Effective Interventions* as the SISTA research study no longer meets the CDC’s efficacy requirements for evidence based interventions. It is clear that there is a gap in the availability of prevention interventions that are appropriate for African American women, and in the research that tells us what works.

2.2.2 HIV Testing and Counseling Guidelines

Twenty-one percent of those living with HIV do not know their HIV status, which not only makes it impossible for them to access appropriate clinical care but also increases their likelihood of infecting others (CDC, 2008). *The National HIV/AIDS Strategy for the United States* emphasizes the need for HIV Testing and Counseling services and has set the goal of increasing the percentage of people living with HIV from 79% to 90% by 2015 ("White House Office of National AIDS Policy. National HIV/AIDS Strategy for the United States," 2010).

In September 2006, the CDC released its *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings*. These recommendations advise routine screening of adults, adolescents, and pregnant women in health care settings in the United States, and also advocate reducing barriers to HIV testing (CDC, 2006). Unfortunately, African American women demonstrate low rates for HIV testing. A recent article that utilized data from the 2002 National Survey of Family Growth found that less than 29% of African American women in the study had been tested for HIV. Not surprisingly, the study also found that low access to testing was correlated with low access to health care overall (Nearns, Baldwin, & Clayton, 2009). This means that efforts to reduce infection rates in African American women should increase community based HIV testing and also improve access to general health care.

2.2.3 Health Care & Community Viral Load

Health care is a critical factor in stopping the HIV epidemic. We must find more successful methods of diagnosing new cases of HIV and engaging and retaining those who are HIV positive into clinical care. Engagement into care soon after infection improves individuals' clinical prognoses, and also serves an important prevention function. When people enter care late in the disease process they typically have high HIV viral loads, meaning that there is a high presence of HIV in the body. Viral load is a marker of virologic suppression in response to clinical treatment, and total community viral load reflects the sum of the viral loads of all people in a given community. Reductions in community viral load have recently been shown to result in fewer new HIV infections in a community (Das et al., 2010). Linking people to clinical care soon after HIV infection results in reduced community viral load and fewer new infections.

Our region has leading edge HIV clinical care services available through the Pittsburgh AIDS Center for Treatment (part of the University of Pittsburgh Medical Center) and the West Penn Allegheny Health System's Positive Health Clinic. One might think that the availability of these resources would translate to increased survival for those living with HIV/AIDS in our region, but this is not necessarily the case. Allegheny County demonstrates one of the highest cumulative HIV mortality rates in our state (9.01 – 12/100,000) for the years 2005-2007 (Pennsylvania Department of Health, 2010). This is probably due to having a higher percentage of African Americans in our county as compared to the majority of our state; we know that African Americans are not engaged into care at the same rate as Caucasians. While the advent of Highly Active Antiretroviral Therapy has resulted in sharp declines in mortality rates that is similar across all populations, in Pennsylvania, African Americans account for more than 60% of all AIDS deaths each year though they represent less than 10% of the general population (Pennsylvania Department of Health, 2010).

Higher mortality rates and poor linkage to care is a persistent problem for our local African American population. Southwestern Pennsylvania is home to at least forty-five provider agencies that receive Ryan White Part B Funds (federal supportive services funds) and/or are members of the AIDS Coalition of Southwestern Pennsylvania, the local planning body for AIDS services. These forty-five agencies serve an estimated 7,300 individuals, although there is likely some redundancy in this number. Only 39% of those served are African American, even though this population demonstrates higher rates of both HIV infection and poverty (ACSWP, 2011/2013).

The alarming HIV health disparities that have already been documented in our region may only be the tip of the iceberg. Anecdotally, regional providers report recent surges in the number of young African Americans who have tested positive for HIV. Of particular concern is the fact that many of these young people of color are diagnosed late in the spectrum of their disease when antiretroviral therapies are less effective. Many first find out their HIV status at the same time as they receive an AIDS diagnosis (ACSWP, 2011/2013). Provider reports indicate that African Americans are not being tested early enough after infection and as a result are not receiving adequate clinical care. When this is the case, individuals typically demonstrate high viral loads, which we know increase infection rates in a vicious cycle.

2.2.4 Syndemics Theory

Syndemics theory has been developed to describe the determinant importance of social conditions and co-occurring, intersecting epidemics on the health of populations. Syndemics have been defined as “a set of mutually reinforcing epidemics that together lower the overall health profile of a population more than each epidemic by itself might be expected to do” (Wolitski, Stall, & Valdiserri, 2007, p.251). Groundbreaking work has been conducted to explore the intersecting relationships between HIV infection, substance abuse, childhood sexual abuse, and partner violence in urban gay men (Stall & Mills, 2003), and many of the same interaction effects apply to the vulnerable population of African American women. “SAVA syndemic” is a term used to define the “…concurrent, intertwined, and mutually reinforcing health and social problems of Substance Abuse, Violence, and HIV/AIDS that plague the urban poor” (Singer, 1994, p. 942). Multiple studies have determined that SAVA is positively associated with risk-taking behaviors, negatively associated with health care utilization, and that there is a bi-directional relationship between SAVA and HIV status. The association between substance abuse, violence, and HIV may be the result of poor sexual negotiation skills and/or of the pattern of high sexual risk and transactional sex that has been established for women who experience child sexual abuse. It may also be the result of forced sex with high risk or infected partners (Singer, 1994).

In addition to increasing risk for HIV infection, co-occurring conditions also escalate the progression of the disease once an individual is infected. Many studies have documented the biological interactions between two or more diseases or between social conditions and diseases, which can escalate the disease process. Psychoneuroimmunology is the study of psychological states and their interaction with the nervous or immune systems. Research shows that persistent stressors alter adaptive immune response (G. Miller, Chen, & Cole, 2009). This means that beyond social conditions that collectively increase risk for HIV, once infected, poor immune responses are associated with depression, with perceived negative early life experiences, and with the greater number of stressful events that are experienced by those with low socioeconomic status. In other words, the same social and health challenges that increase one's risk for HIV may also reduce the efficiency of the individual's immune system response. We see again a vicious cycle at play.

2.2.5 Poverty & Social Capital

We know that socio-economic status relates to all health disparities[1] and in fact, D.R. Williams has noted that "…socioeconomic status is part of the causal pathway by which race affects health" (Williams, 1999, p. 177). Poverty is correlated with HIV infection as well as with access

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[1] Given the ubiquitous effect of socioeconomic status among all levels of risk mediators, it is tempting to move this factor higher up on the model. It remains at the middle, however, since this discussion specifically relates to poverty and its correlation with infection rates and access to care in communities.

to HIV care. A recent study noted that in urban areas with high poverty rates, household income is inversely correlated with HIV prevalence (Denning & DiNenno, 2010). While there are many issues factoring into the poverty/infection correlation, a recent qualitative study examined contextual factors that were reported by African Americans in rural areas as being related to health disparities. Study participants noted that "…neighborhood poverty, lack of skilled jobs, segregation, political disenfranchisement, and institutional racism…" all were factors that limited a community's ability to successfully combat HIV infection (Cene et al., 2011, p.737).

On an individual level, people who lack resources are unlikely to prioritize their own health. A woman who doesn't have transportation or childcare will have a hard time transporting her children via public transportation to the HIV clinic. She may not want to deal with her own health, anyway, perhaps because she is more concerned with putting food on the table. Or perhaps she doesn't want to have to explain to her kids why she's getting an HIV test, picking up condoms, or going to the infectious disease clinic. It may also be the case that her experience of self simply does not include the abstract idea that her health matters, or that she can have control over her health status.

Besides the practical and logistical issues that disconnect women from accessing care or making optimal health decisions, living in grinding poverty brings about many negative feelings that can create health risks. In his 1966 seminal piece, The Culture of Poverty, Oscar Lewis wrote:

> *"The people in the culture of poverty have a strong feeling of marginality, of helplessness, of dependency, of not belonging. They are like aliens in their own country, convinced that the existing institutions do not serve their interests and*

> *needs. Along with this feeling of powerlessness is a widespread feeling of inferiority, of personal unworthiness."* (Lewis, 1966, p.21).

In consideration of these experiences, it is no wonder that those living in poverty are unable to prioritize their health, to trust the health care system, or to think about the impact of immediate decisions on long-term health.

HIV rates in combination with poverty rates for African Americans in our county create a formula for disaster. The Pittsburgh region has the highest rate of poverty among working-age African American populations of any of the forty largest metropolitan regions in the United States(U.S. Census Bureau, 2008). Our region is first in the country in the poverty rate of among African American children under age five, of whom 62% lived in poverty in 2008. One of the issues behind this high poverty rate for children is that more than 80% of African American women who have babies are unmarried, compared to 26% of the Caucasian women in our region (U.S. Census Bureau, 2008).

Social capital is also significantly correlated with HIV rates (Holtgrave & Crosby, 2003). Social capital refers to connections that people have with each other, and is most simply conceptualized by the idea that "…social networks have value…" (Putnam, 2000, p.19). The connections that people have with one another help them to access resources and also have a more generalized impact on public health. Social capital can influence norms for healthy behaviors and create policy change to improve community health outcomes.

Although community (contextual) social capital is linked to health disparities, social capital as demonstrated via individual cohesion presents a strength among African American women that may be built upon to reduce infection rates. Described as the strength of connections between individuals and groups, cohesion and social support may mitigate contextual factors for

HIV risk (Cene, et al., 2011; Wingood & DiClemente, 2006). This means that if women in a community can bond with and talk to each other about how to how to protect themselves against HIV, this may present opportunities to lower risk behaviors and infection rates for this population. The challenge, of course, is ensuring that groups of women have access to accurate HIV information and resources, which we already know is lacking in low-resource communities.

2.2.6 Religion & Religiosity

Besides the limitations of poverty and other resources that are experienced by many African Americans in urban and rural settings, the role of the Black Church may also restrict African Americans from addressing this problem head on. The church is incredibly important for this population, playing a significant role in values development and positive role modeling (Britt, 2004). However, like many churches, the Black Church often sends the message that abstinence is the only way to stop HIV. Churches that seek to support its infected congregants frequently purport that they "love the sinner but hate the sin," which still condemns those who are infected and effectively stops conversation around the disease (Muturi & An, 2010). Although there are notable exceptions of black leaders calling out for change, as a whole, Black Churches in our region still treat AIDS as a gay disease. Homophobia rages on in the African American community, and as a result, many churches have not been able to embrace the epidemic or push helpful public policy in response to it (R. Miller, 2007).

Given the role of the Black Church, it is easy to seek how it can serve as community strength and help individuals develop coping skills, but too often becomes a driving force behind stigma. A recent study demonstrated that after controlling for key factors, high religiosity was a significant factor in the prediction of the level of AIDS-related stigma (Muturi & An, 2010). As noted above, many people continue to believe that AIDS is a gay disease and since African Americans more than Caucasians report that homosexuality is wrong, the stigma associated with HIV is further strengthened in this population (Glick & Golden, 2010).

2.2.7 Stigma & Racism

Stigma presents a significant barrier to HIV infection and treatment. HIV is too often seen as a reflection of “moral impropriety” rather than a health concern. In these cases, stigma results in the removal of HIV risk reduction options from community discourse (Newman, 2008). It has also been documented that African Americans are more concerned than Caucasians with hiding their HIV status and report this as a reason for not wanting to enter clinical care services (M. O. Johnson et al., 2009).

Living in a world where one is marginalized by the larger community many times each day with numerous subtle and blatant insults means that survival can be a daily battle. It may well be the case that public acknowledgement of the high impact of this disease would further marginalize the African American community and increase internal and external racism. Marginalized communities are often characterized by prioritizing group needs over individual needs, which helps to ensure community success in the larger world. This strength can have the unfortunate consequence of community members denying their individual needs. This is particularly true for African American women whose self-sacrificial role is overtly linked to the “Strong Black Woman” script that is perhaps necessary for success, but results in the low prioritization of self-care (Black & Peacock, 2011).

Racism underlies all of the above community level factors and impacts all aspects of health disparities for African Americans. Racism may be defined as “…an organized system, rooted in an ideology of inferiority, that categorizes, ranks and differentially allocates societal resources to human population groups" (Williams and Rucker, 2000, p.76). Decades of racism in our country have created a complex mix of health related attitudes and behaviors (Thorburn-Bird & Bogart, 2005). Racism directly impacts all of the factors that have been discussed so far in this document as contributing to HIV health disparities among African American women, including access to care, poverty and resource disadvantages, and cultural constructs that inhibit individuals and groups from talking about or implementing HIV risk reduction behaviors.[2] Blatant examples of racism, such as the Tuskegee Syphilis study, have resulted in distrust of medical providers among some African Americans, creating a significant barrier to care (Thorburn-Bird & Bogart, 2005). Some African Americans believe that HIV was created by our government to extinguish their population, while others are reluctant to use condoms, which they perceive to be a societal attempt to limit African American population growth (Friedman, Cooper, & Osborne, 2009).

Interestingly, a recent study of African Americans visiting an STI clinic found that those individuals who perceived high frequencies of everyday racism demonstrated higher odds (odds ratio of 1.64) for accessing HIV testing (Ford et al., 2009). This study suggested that the association between perceived racism and HIV testing may have been the result of resilience or social support, although neither of these constructs was tested. The resiliency theory hypothesizes that African Americans who recognize racism but find ways to function in spite of it have higher resiliency levels and stronger coping skills, and may therefore have increased desire to protect themselves through HIV testing. Social support may have confounded the study

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[2] Given that racism impacts all other factors on the socio-ecological model diagram found on page 4, it would be reasonable to move the topic of "racism" to the highest possible level on the diagram, along with socioeconomic status. However, this document addresses racism as it relates to HIV infection specifically at the community level, which is why it is found in the middle of this model.

in that those individuals with high levels of support may be more comfortable not only reporting perceived racism but also accessing HIV testing. While further research must be done in these areas (perceived racism, resiliency, social support, and their impact on HIV testing behaviors), this study provides clues as to possible methods of increasing HIV testing rates and reducing HIV infection rates for African American women.

2.2.8 Sexual & Gender Power

In our culture and specifically in our region of Southwestern Pennsylvania, African American women may be among the least empowered, especially in terms of sexual relationships. Cultural and sexual dynamics coupled with high poverty rates significantly increase HIV risk for the target population, and also underscore the importance of empowerment in reducing risk for this target population. Our region demonstrates severe racial biases that further disempower African American women. As stated in the Benchmark Reports compiled by the University Center for Social and Urban Research, "Allegheny County continues to be the least racially and ethnically diverse large county in America. This suggests that racial and ethnic understanding and tolerance are likely to be low in the county." (Bangs, Anthou, Hughes, & Shorter, March 2004, p.2). The combination of poverty with racial and gender bias results in the fact that as a whole, the population of African American women may have the lowest relative power in our region in personal and economic relationships. They likely experience great difficulty in accessing care and in negotiating safer sex and safer drug use.

The lack of power that is experienced by some African American women relates directly to HIV risk. During a recent qualitative interview with a local African American woman, this researcher was informed that, "If a man doesn't want to use a condom and I want him to there's another woman next door who will let him go bare.” This example is consistent with the Theory of Gender and Power, which describes the social structures that influence relationships between men and women. These structures include the sexual division of labor, sexual division of power, and structure of cathexis or emotional investment (Wingood & DiClemente, 2000). An extreme example of the imbalance of sexual power is that of intimate partner violence. Research shows that women who experience violence victimization in intimate relationships are much more likely to experience an STI (Hogben et al., 2001; Laughon et al., 2007). Cumulative violence increases a women’s odds of sexually transmitted infection by 4.21 (Laughon, et al., 2007). It would be difficult for a woman who experiences violence at the hands of her sexual partners to propose using condoms. This information has important implications for HIV risk reduction interventions. Beyond stressing skills-building and the importance of condom use we must also find ways to empower women to make decisions about their own health and sexuality.

2.2.9 High Risk Sexual Networks, Assortative Mixing, Sexual Partner Concurrency, & Condom Use

Although HIV risk reduction interventions have typically focused on behavior change and specifically on increasing condom use, the socio-ecological model demonstrates that behavior is only one factor that impacts HIV risk. Differences in sexual behaviors including condoms use and the number of sex partners do not fully account for HIV health disparities in our country. Individual sexual behaviors do not occur in a vacuum but in the greater contexts of relationships and community characteristics. We know that African Americans are more likely than Caucasians to become infected with HIV through low risk behaviors as a result of living in environments where there is high HIV prevalence (Aral, Adimora, & Fenton, 2008). Having larger social networks and more members of a social network who used heroin or cocaine have been associated with having high risk sex partners (Neblett, 2011). African Americans are also more likely than Caucasians to have sex or share needles within their own groups, known as "assortative mixing" in social network lingo (Friedman, et al., 2009). This fact in combination with high prevalence rates and high community load greatly increases HIV risk for African Americans.

Sexual partner concurrency, defined as sexual relationships that overlap in time, is a key factor driving the transmission of HIV within sexual networks. Factors that increase the likelihood of sexual partner concurrency include relationship status, debut of sexual activity, incarceration of self or partner, self or partner drug use, and known or suspected partner nonmonogamy (Grieb, 2011). The scarcity of African American men, largely a function of disparities in incarceration rates in our country, also increases sexual partner concurrency by encouraging men to have sex with multiple women and women to have sex with men who are already in relationships (Grieb, 2011).

In this context of sexual partner concurrency, condom use is critical. Unfortunately, condom use among women in concurrent sexual partnerships remains low. A recent study of women in concurrent sexual relationships documented condom use prevalence at last sexual encounter of 26% (Richards et al., 2008). Although this rate is dismal given what we know about the risk of sexual networks, it is slightly encouraging to note that the study also found that condom use was more likely for women in casual partnerships, when drugs and alcohol were not used during sex, or when the woman perceived that her partner was not monogamous (Richards, et al., 2008).

2.2.10 Sexually Transmitted Infections and Biological Differences

It should be apparent at this point that there are no HIV risk factors that exist solely at the individual level, and that proximal factors are clearly impacted by those more distal. As noted earlier in this document, the presence of a sexually transmitted infection (STI) increases a woman’s risk for HIV infection, and this might be considered to be an “individual” factor. However, STI rates are impacted by many other factors on the socio-ecological model, such as intimate partner violence and access to health care. Health disparities for African Americans in our region persist in relation to all STIs. This population demonstrates significantly higher rates of syphilis, gonorrhea, and Chlamydia (ACSWP, 2011/2013). STI infection rates are important because other sexually transmitted infections (1) serve as proxy markers for HIV infection, since they are transmitted by the same behaviors including sexual activity without a condom; (2) indicate low access to clinical care and low use of barrier methods of safer sex; (3) increase the likelihood of an individual becoming infected with HIV, since STI lesions facilitate transmission; and (4) increase the likelihood of secondary HIV transmission to others, since HIV positive individuals shed more of the virus in genital secretions when co-infected with another STI. Observational studies suggest that an individual with an STI is between two to five times more likely to become infected with HIV if exposed to the virus (ACSWP, 2011/2013), although the application of this finding must be further researched: trials that have controlled bacterial STIs in an attempt to reduce HIV infection have failed to produce the desired results (Gray & Wawer, 2008).

Besides gender disparities and cultural conditions that increase HIV and STI infection rates, women are also more susceptible to HIV infection due to biological differences including (a) vaginal microbial biology; (b) hormonal changes that may increase the number of HIV target cells or immune suppression; and (c) the physical mechanisms of intercourse that can cause micro-tears in the vaginal mucosa, creating opportunities for HIV infection (Quinn & Overbaugh, 2005).

2.2.11 Risk Behaviors

There are numerous distal factors increasing HIV risk for African American women, but of course HIV infection is a conditional probability (Friedman, et al., 2009). One can only be infected if exposed to the virus. The primary risk factor for HIV infection for women in our county is heterosexual contact, documented in 54% of cumulative AIDS cases and in 75% of cumulative HIV cases through 2007 (Allegheny County Health Department, 2008). The difference between these two percentages is reflected in the fact that the second leading risk factor for women is intravenous drug use, which is noted in 35% of AIDS cases and 16% of HIV cases. IV drug users have poorer health outcomes, and comprise a greater proportion of AIDS cases than of HIV cases (Allegheny County Health Department, 2008).

It is important to note that in the broad category of heterosexual sex, there are many factors that impact the degree of risk a woman experiences. This document has already noted relationship factors that impact sexual activity, which in turn increase HIV risk. Sexual violence, substance abuse, transactional sex, and gender power inequities all increase HIV risk by reducing a woman’s ability to choose when and how to have sex, whether or not condoms will be used, and the type of sex (i.e., oral versus anal) that is experienced.

There are also many individual factors that lead to higher risk situations. A recent study of African American urban women found that while older age was associated with a reduced likelihood of having multiple (two or more) sexual partners, increased age was also significantly associated with having a risky sexual partner. Homelessness (Adaila, Cross, Stall, Harre, & Sumartojo, 2005) and depressive symptoms were both associated with having multiple sex partners and riskier sex partners (Friedman, et al., 2009). Women reporting recent heroin or cocaine use were more likely to have multiple sex partners and almost three times as likely to have risk sexual partners (Friedman, et al., 2009). We must note once again that these "individual" factors are rooted in more distal factors such as poverty, racism, and homelessness.

It should be clear that if we are to reduce HIV rates among African American women, we must aim to do more than increase partner condom use. We must also find ways to address the many underlying issues and health inequalities that are experienced by this population. The next section of this document considers these underlying issues and summarizes recommendations for effective interventions.

3.0 RECOMMENDATIONS FOR INTERVENTION

In 2010, The White House unveiled the first formal domestic HIV/AIDS strategy, which aims to reduce the number of new cases by 25 percent in the next five years. (See Figure 2.) The strategy is accompanied by a federal implementation plan that describes the role of federal agencies as well as state and local governments. It also outlines initiatives for prevention interventions, to increase access to care, and to address community level issues such as stigma and discrimination. This approach is appropriate. Just as HIV infection is impacted by both proximal and distal factors, there are many levels at which interventions can be implemented to reduce HIV infection in African American women. The next section of this document references the above-identified underlying issues to draw conclusions about structural, community, relationship, and individual opportunities for HIV risk reduction.

Reducing New HIV Infections

- Intensify HIV prevention efforts in the communities where HIV is most heavily concentrated
- Expand targeted efforts to prevent HIV infection using a combination of effective, evidence-based approaches
- Educate all Americans about the threat of HIV and how to prevent it

Increasing Access to Care and Improving Health Outcomes for People Living with HIV

- Establish a seamless system to immediately link people to continuous and coordinated quality care when they learn they are infected with HIV
- Take deliberate steps to increase the number and diversity of available providers of clinical care and related services
- Support people living with HIV with co-occurring health conditions and those who have challenges meeting their basic needs, such as housing

Reducing HIV-Related Disparities and Health Inequities

- Reduce HIV-related mortality in communities at high risk for HIV infection
- Adopt community-level approaches to reduce HIV infection in high-risk communities
- Reduce stigma and discrimination against people living with HIV

Figure 2. National HIV/AIDS Strategy for the United States

3.1 FUNDING AND STRUCTURAL INTERVENTIONS

Policies addressing testing recommendations and to increase funding for community based interventions are necessary to reduce infection rates for the target population. Such policies should include funding for prevention interventions, HIV testing and counseling, access to care, housing, and needle exchange.

It is clear that although there are a number of evidence based prevention interventions that have been shown to be efficacious in producing desired outcomes such as condom use, they have not been developed by the target community and rarely have been tested in community settings. While research to determine both efficacy and effectiveness is necessary, the degree to which we can demonstrate effects in “real world” settings will determine the true utility of the intervention. This type of research is often difficult to carry out, given that community based organizations may have the capacity to develop and implement interventions but not to scientifically evaluate them. Increasing capacity building opportunities for community based interventions is important, as is funding to encourage collaborations between community based organizations and university/research institutions for this purpose.

3.1.1 HIV Testing & Health Care

Improved health surveillance systems would also reduce infection rates. While HIV and AIDS are both reportable diseases at the federal level (McNabb et al., 2008), patient level data regarding medical referrals, engagement, and follow up are not (Mugavero, Norton, & Saag, 2011). Although collecting this type of patient level data is complicated and has many privacy implications, knowing if people are maintaining in appropriate clinical care would not only increase HIV-related health but also reduce HIV infections.

Linking those who are infected with clinical care services is obviously contingent upon adequate HIV testing. While the CDC's 2006 *Revised Recommendations for HIV Testing* advise routine screening on an "opt-out" basis, these recommendations are only specific to health care settings. Increased emphasis on and funding for community based testing would certainly improve HIV testing rates, particularly for those individuals who are not linked to other health care services. Locating testing services with trusted providers and making it available in many community venues would likely increase the number of people who get tested. HIV testing shouldn't be something one has to seek out; it should be readily available and even commonplace. Treating HIV testing as routine care in doctors' offices would also help to reduce stigma.

Because we know that testing rates are lower for those with poor access to health care, we must also find ways to improve health care for all individuals. This means ensuring health care coverage for all, and adequately funding providers that are accessible to and culturally relevant for those living in poverty. This could include increasing support for Federally Qualified Health Centers (FQHC) and FQHC Look-Alikes.

Besides access to health care overall, increased funding for HIV clinical care would also reduce individual and community viral loads, again improving HIV health and reducing opportunities for infection. As of June 2011, thirteen states (not including Pennsylvania) had waiting lists for the federal AIDS Drug Assistance Program, with more than 8,500 individuals on these lists (Kaiser Family Foundation, 2011). These barriers are unacceptable and contribute to poor health outcomes and high infection rates. They may also negatively influence community-level attitudes regarding HIV care if there is a perception that treatment is not accessible and affordable.

There are also ways to improve community attitudes to health care. Increasing cultural relevance of health care is crucial to ensuring that marginalized populations are able to engage and maintain in care. Cultural relevance might include offering non-traditional office hours or holding open scheduling, locating services in accessible locations, having on-site child watch services, providing transportation assistance, and increasing the number of clinicians who are representative of the populations they serve. Providers should also remain opens to their patients' "non-traditional" health practices, which might include alternative therapies, spiritual influences, or group/family decision-making.

3.1.2 Condom Distribution

Last year, the CDC circulated a fact sheet regarding the efficacy of condom distribution as a structural intervention. The fact sheet referenced a recent meta-analysis of structural interventions, which determined that condom distribution programs were efficacious in increasing condom use and reducing sexually transmitted infections. Further, these interventions demonstrated efficacy within diverse populations, including youth, adult males, sex workers, and high risk geographic populations. Interventions with the greatest levels of efficacy were those that combined condom distribution with individual, group, or community-level behavioral risk reduction activities (Charania et al., 2010). In addition to making sure that every individual who wants a condom has access to them, wide-scale condom distribution also sends the message that condom use is acceptable.

3.1.3 Needle Exchange

As much as 75% of HIV cases among women and children results from direct or indirect injection drug use (Loyce, 2008), so wide-scale needle exchange programs (NEP) offer an important structural intervention. Preventing HIV transmission via injection drug use may be more straightforward than other prevention efforts, such as encouraging abstinence or condom use, since providing IDUs with clean syringes is not only highly effective, it is highly desired by the population at risk. Using fresh, sharp needles is less painful than used, dull needles.

Numerous studies have demonstrated positive outcomes relating to needle exchange programs, the major points being that IV drug users who utilize syringe access programs are significantly less likely to share needles and other drug paraphernalia, and that not sharing needles dramatically reduces both HIV and Hepatitis C transmission. Hepatitis C is viewed as a surrogate marker for HIV infection since both diseases can be transmitted via similar activities (Holtzman, 2009).

A 2006 publication reviewed forty-five international studies that examined the impact of NEP. The manuscript included for review only those studies that met stringent analysis criteria such as strength and specificity of association, replication of findings, temporal sequence, and biological plausibility, in order to determine the strength of the research to date. The positive outcomes documented in these studies were significant and included reductions in needle-sharing incidents, in the number of needle-sharing partners, and in HIV risk behaviors. Most important of all, many studies documented reduced HIV seroconversion (Wodak & Cooney, 2006). The authors concluded this review by stating:

> *"Measured against any objective standards, the evidence to support the effectiveness of NSPs [needle syringe programs] in substantially reducing HIV*

> *must be regarded as overwhelming….There is no convincing evidence of any major unintended negative consequences* (Wodak & Cooney, 2006, p. 802).

Despite the overwhelming body of evidence underscoring the effectiveness of this approach, needle exchange remains controversial in this country, largely due to moral debates, misperceptions that syringe exchange increase drug use, and "NIMBYism" (Not in My Backyard). There is progress: A 1988 on federal funding for syringe access programs was lifted when President Obama signed the Omnibus Departments of Labor, Health and Human Services and Related Agency Appropriations Bill, 2010 without the former funding restrictions (NASTAD 2010). Nonetheless, needle exchange remains poorly funded and limited in its reach.

3.1.4 Housing

As noted above, homelessness is associated with having multiple sex and needle-using partners and with high risk sexual partners for African American women. Furthermore, homeless individuals have less access to care, meaning that they typically have higher viral loads. The need to address housing for this population has been well documented, and the feasibility of doing so was demonstrated in the USA-based Housing and Health Study, a multi-site, longitudinal randomized controlled trial that examined housing as a structural intervention for the target population (Kidder et al., 2007). In a recent meta-analysis of studies that examined housing status that utilized medication adherence as an intervention outcome, significant positive associations were found between increased housing stability and improved health outcomes in all of the studies cited (Leaver, Bargh, Dunn, & Hwang, 2007).

A recently published study describes the potential impact of providing housing for individuals who are chronically homeless and living with HIV. This study is unique in that it utilized HIV viral load as a marker of program effectiveness, and because it evaluated a true harm reduction housing program that was established specifically to improve treatment adherence for homeless individuals living with HIV/AIDS, most of whom were also addicted. The study found that 69% of study participants achieved undetectable viral loads within three months of access to supportive housing. This result far exceeds adherence rates ranging from 13-32% that were found in other studies of similar vulnerable populations. While the study employed a small sample size (n = 26, 85% African American), its findings are significant because they indicate success in helping residents access the services necessary to achieve undetectable viral loads, at rates much greater than previously noted in samples of other homeless populations. In addition to improved clinical prognoses for these individuals, the reductions in viral load approach will likely result in fewer new infections in the larger community (Hawk & Davis, 2011).

3.1.5 Stigma, Social Norms and Religion

The most influential community-level interventions would include reducing HIV-related stigma and improving social norms for condom use (Wingood & DiClemente, 2006). Interventions that increase the number of conversations about HIV risk that occur within a community would address both of these issues. Engaging community and religious institutions in these conversations might be most useful of all, providing that those discussions include accurate facts with a positive approach.

3.1.6 Poverty

While poverty is associated with all health disparities, it is too large an issue to address in this document (or likely in a lifetime). However, barriers that are associated with poverty should be addressed. These include removing transportation challenges, such as providing bus tickets to those who are accessing health care or HIV testing. Incentives for testing may be useful if they are culturally appropriate and desired by the target population. Case management services help patients to link to remove other barriers and access entitlements, and can sometimes provide people with the financial and emotional space to address their own health needs.

3.2 RELATIONSHIP AND BEHAVIORAL APPROACHES

3.2.1 High Risk Sexual Networks

Increased HIV risk for African American women is not a result of the type or frequency of sex that they have, but rather their sexual or drug using networks. African American women tend to engage in assortative mixing, have more high risk partners, and operate in networks where there is high community viral load. This means that testing more members of social and sexual networks and engaging those who are HIV positive into care early in the spectrum of the disease are important opportunities for impacting relationship issues. Reducing stigma and increasing social norms for risk reduction barriers are community-interventions that will have relationship impacts.

HIV risk is clearly associated with intimate partner violence and substance abuse, so these issues must be addressed as well. Too often, women who are in abusive relationships don’t recognize these relationships as such, and when they do, they don’t know to get help. It is important to increase support for victims of intimate partner violence. Interventions that focus on condom use should help women to consider the safest way to introduce condoms in their relationships. An abused woman who suddenly asks her partner to wear a condom will risk being beaten, so she needs to consider the safest way to broach the topic, and using a female condom might be a much safer option. We must also improve methods to support women in reducing the harm associated with substance abuse, which includes reducing drug use before sex so that risk reduction decisions are not impaired.

3.2.2 Harm Reduction

The overarching approach that should be utilized when implementing any HIV risk reduction intervention is that of harm reduction, particularly when targeting vulnerable and marginalized populations such as African American women. Harm reduction is a philosophy that encourages any positive change even if the individual continues to engage in high risk behaviors, such as illicit drug use. Using harm reduction has been shown to facilitate adherence in marginalized populations (Bamberger et al., 2000; Hawk & Davis, 2011). Although harm reduction is most frequently associated with needle exchange, its principles should guide all efforts with regards to HIV prevention and engagement in care. The approach advises approaching individuals with compassion, seeks to reduce negative consequences of behaviors, and prioritizes meeting clients “where they’re at.” This means that the emphasis is on moving individuals to the next lowest acceptable level of risk, rather than necessarily removing risk completely. Examples of harm reduction mechanisms in the context of behavioral HIV prevention interventions would be helping a woman to negotiate less risky sex with her partner even if he won't use condoms (i.e., oral sex as opposed to anal sex) or encouraging her to "shoot first" when sharing drug needles so that there is no chance of infection. Harm is not completely eliminated in either example, but the risk of HIV infection is reduced or eliminated.

3.2.3 Culture and Gender Relevance

While there are have been many studies documenting the efficacy of HIV behavioral interventions, this document has already noted that only one intervention has been developed specifically for the general population of African American women in community settings. There is an additional challenge in the fact that interventions developed via randomized controlled trials many not yield the same outcomes in practice settings. The challenge of creating targeted interventions is not solely a problem when serving African American women. Within the field of public health there is a growing understanding of the challenge in translating efficacious interventions to effective, community-based interventions (Glasgow & Emmons, 2007; Hohman & Shear, 2002). This tension between efficacy and effectiveness research is widely debated in the field of HIV behavioral interventions, especially since last year the federal government spent more than $727 million on funding these interventions, although infection rates are holding steady (Henry J. Kaiser Family Foundation, 2010). There is great concern that interventions tested in randomized controlled trials may present implementation challenges for community based organizations that have to deal with real world "noise" (Kelly, Spielberg, & McAuliffe, 2008; Rebchook, Kegeles, & Huebner, 2006). There is a wealth of literature regarding the efficacy of HIV risk reduction interventions, and much less regarding the effectiveness of interventions.

We do know, however, that the most efficacious interventions for our target population, at least in terms of producing short term behavioral outcomes, (changes in HIV risk knowledge or intentions for change), are those interventions that are developed specifically for African American women and include approaches that are culturally relevant and build on women's strengths (Crepaz et al., 2009; Mallory, Harris, & Stampley, 2009). The need for cultural relevance in the design of risk reduction interventions is well documented. The CDC recognizes that effective HIV risk reduction interventions must incorporate culture- and gender-relevant material to increase their effectiveness for this target population (Friedman, et al., 2009; Prather et al., 2006). This approach is also validated by a recent meta-analysis of HIV/STI risk behavioral interventions, which determined that interventions that were highly efficacious included those specifically targeted to African American women and also facilitated by women (B. T. Johnson et al., 2009). Effective, community based HIV risk reduction interventions must not only consider behavioral factors that place women at risk for HIV, but also ensure that they are culturally relevant, placing the interventions in the context of the target population (Bogart & Bird, 2003; Gilbert & Goddard, 2007; Moreno, El-Bassel, & Morrill, 2007; Prather, et al., 2006). This means that an intervention developed for the target population of African American women will not be appropriate for *all* African American women.

In addition to the inclusion of cultural references, gender-specific information also increases the efficacy of interventions (Mize, Robinson, Bockting, & Scheltema, 2002). In an early analysis of women-focused HIV interventions, it was found that in terms of gender specificity, eight out of twelve studies targeted specifically to women had significant impacts, as compared to one out of four studies involving adults generally (Exner, 1997). These findings were duplicated in a meta-analysis of behavioral interventions targeting African American women. This study coded interventions as to whether or not they included gender-specific and/or culture-specific elements, and found that the interventions that included both of these elements were more effective in producing behavior change related to HIV risk (Crepaz, et al., 2009). This underscores the fact that interventions should be targeted specifically for African American women.

It is also important to note that it is not enough to choose an intervention that has been found to be effective and/or efficacious, even if it was researched with a broad similar target population, such as African American women in general. We must also consider the context in which the intervention research was conducted and whether or not there is enough information available to ensure implementation fidelity (Rychetnick, Frommer, Hawe, & Shiell, 2002). In other words, just because an intervention was successful in one setting does not mean it will be successful in all settings, and it's necessary to review the research that was conducted to make sure the program is relevant to the target population. As noted by the Infectious Diseases Society of American in 2002 "Locally developed and implemented HIV prevention programs offer the best hope for controlling the epidemic. Local communities know what's best in their areas." (IDSA, 2002, p.1).

4.0 THE GIRLFRIENDS PROJECT: A COMMUNITY-DEVELOPED MODEL FOR REDUCING HIV RISK AMONG AFRICAN AMERICAN WOMEN

4.1 BACKGROUND

The Girlfriends Project (TGP) is an HIV risk reduction intervention that was developed in Allegheny County *by* African American women *for* African American women. TGP was created by staff and clients of the Pittsburgh AIDS Task Force (PATF), out of concern that their CDC-funded behavioral interventions did not fully meet the needs of the local target population. While the staff members found that the SISTA curriculum for which they received funding had strong programmatic content, the fact that the intervention required women to attend SISTA groups for six weeks in a row largely limited implementation to provider settings such as inpatient recovery programs or the Allegheny County Jail, since otherwise it was difficult to get women to commit to this six-session intervention. TGP was developed as a single session intervention that builds on the social network strengths of women, to be delivered in the homes of African American women.

The goal of TGP is to reduce HIV infection rates among African American women by increasing HIV risk knowledge, improving HIV risk behaviors related to sex and drug use, and increasing the rate of HIV testing in the target population. TGP has been funded by local foundations since 2008 and in that time has served more than 600 women. PATF is committed to scientifically evaluating the intervention, not only to understand the program effects but also in hopes of replicating the intervention in other communities.

Through the TGP intervention, women receive incentives to host parties for other members of their social networks, much like direct sales parties. TGP facilitators provide HIV risk reduction information, informal assessments and referrals related to addiction and domestic violence, empowerment around sexual decision making, and on-site HIV oral swab testing. HIV test results are given approximately two weeks after the party in the homes of the women who have been tested or in other safe and confidential community settings as selected by the individual. The procedural guidance for TGP is included in Appendix A. House parties as an intervention venue have been used in other evidence based interventions (Diallo, 2010; Lauby, Smith, Stark, Person, & Adams, 2000) but they do not typically include on-site HIV testing.

According to verbal and written feedback from TGP participants, the program appears to create real understanding of the rationale for condom use and commitment to attempt to use condoms. One of the program's greatest assets is that it also seems to increase motivation among women to share HIV risk reduction with friends, family members, and other members of the natural social networks. This motivation has been dubbed by one participant as "The Girlfriends Effect."

Women are incentivized to increase participation. They receive $50 Giant Eagle gift cards to host parties for their friends and family, and each program participant receives a $10 Giant Eagle gift card at the conclusion of the party. Food and beverages are also provided at the parties. Women who choose to participate in HIV testing also receive a second $10 gift card when they receive test results. Follow up assessments are conducted with women at three months post intervention.

4.2 THEORETICAL FOUNDATIONS

TGP builds on several theoretical frameworks that can explain the program effects and guide evaluation of the intervention. One such theory is the Health Belief Model, which describes how participants change their perceptions about (a) their susceptibility for HIV; (b) how serious it is to live with the disease; (c) the positive results of protecting themselves against infection; (d) barriers to safer sex/safer drug use, and how these can be overcome; (e) “cues to action” that help prepare women for change; and (f) self-beliefs in their own abilities to make protective behavioral changes ("Theory at a Glance: A Guide for Health Promotion Practice," 2005).

TGP is loosely based on the central assumption of Social Norms Theory, which holds that peer norms are influential in health behavior decision making (Perkins & Berkowitz, 1986). By helping participants to see that women in their social networks accept condoms as an appropriate risk reduction behavior, TGP may be able to help them increase their use of condoms.

TGP also relates to the Theory of Gender and Power in its intention to address the social structures that influence relationships between men and women (i.e., the sexual division of labor, the sexual division of power, and the structure of cathexis or emotional investment) (Wingood & DiClemente, 2000). By briefly exploring these characteristics in group settings, TGP facilitators help women plan for the negotiation of condom use and the integration of risk reduction behaviors with their sexual partners. However, it is critical that we don’t fall into the middle class assumption that when discussing sexual relationships, we are talking only about sex experienced in the context of domestic or romantic relationships, or even about casual sex for the sole purpose of pleasure. TGP participants have sex in exchange for drugs or money, because their partners force them to, or because it’s how they experience feeling powerful, beautiful, or validated. As noted in the first part of this document, there are multiple factors influencing a woman's sexual or drug using behaviors, and therefore also impact her risk reduction behaviors and decision-making.

4.3 TGP STRENGTHS: BUILDING ON THE RECOMMENDATIONS

Once again using the socio-ecological model as a point of reference, one can see that TGP relates to several of the previously identified levels of influence in its efforts to reduce HIV risk for women. Although TGP was not designed to be a structural intervention[3], it does relate to risk modifiers that appear at various levels of the model. While structural interventions will be necessary to remediate high-level, structural risk modifiers, TGP does help women respond to some of these issues, as will be discussed below. The following diagram displays an additional column in the socio-ecological model, which reflects aspects of TGP that relate to HIV risk factors discussed in more detail below.

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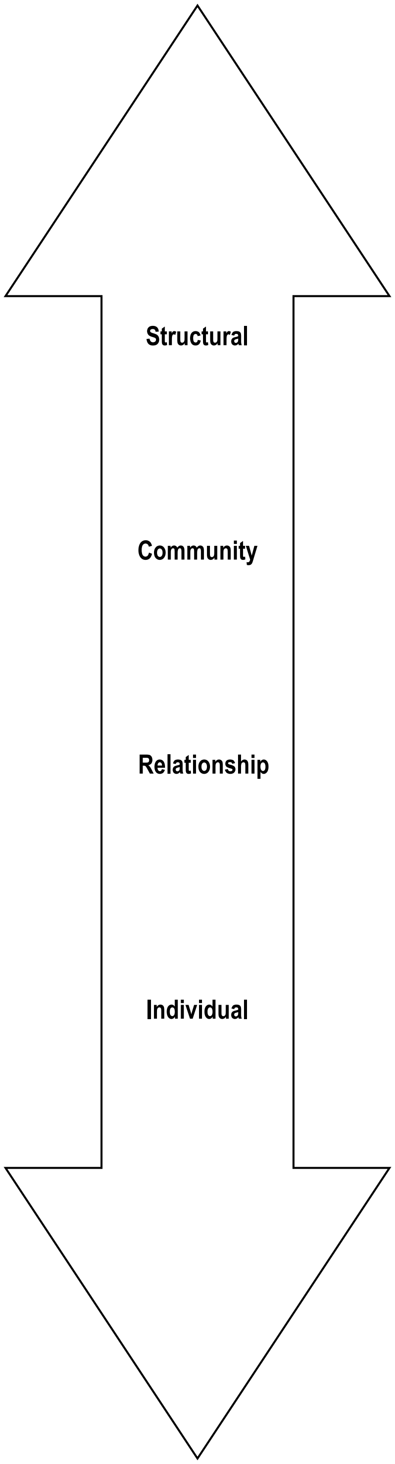
[3] Structural interventions can be defined as those that address factors associated with HIV risk and risk reduction efforts such as "…physical, social, cultural, organizational, community, economic, legal or policy aspects of the environment that impede or facilitate HIV transmission" (Dean & Fenton, 2010).



Risk Moderators	Correlating TGP Strengths
Lack of funding	
"Top down" interventions	"Home grown" intervention Community involvement in development, implementation, evaluation Evaluated in real world settings
HIV testing guidelines	On-site testing & counseling Excellent rate of return for results
Health care	Linkage to health care STI screening referrals
Community viral load	Case finding → reductions in community viral load
Syndemics theory	IPV & D&A brief assessments and referrals
Poverty	Removes practical barriers (transportation) Utilizes meaningful incentives
Social capital	Builds social cohesion among women
Religion	
Stigma	Addresses HIV stigma & social norms for risk reduction
Racism	Specific to African American women Embraces ethnic pride Highly relevant – uses peer facilitators
Sexual & gender power	Explores sexual & gender power Female condoms
High risk sexual networks	Targeted outreach and recruitment
Assortative mixing	
Sexual partner concurrency	
Condom negotiation	Condom negotiation skills building Condom distribution
STIs & biological differences	STI screening referrals
Risk behaviors	Skills building for risk reduction behaviors Harm reduction model

Figure 3. Socio-Ecological Model of HIV Risk Modifiers and Correlating TGP Strengths

The CDC refers to locally developed interventions as “home grown interventions,” and recently released a Request for Proposal to fund interventions in this category that are not necessarily evidence based. This change in funding criteria likely reflects a growing awareness that home grown interventions may deliver strengths that cannot be captured by interventions that are primarily theory based and that have only been evaluated in controlled settings.

Evaluating TGP in its natural setting is crucial to understanding its true program effects. As stated by Hubbard-McCree, Jones, and O’Leary, “Working in partnership with members of the affected population throughout the research process is particularly important, not only for gaining access to African American communities, but for ensuring that the methodological approaches taken are appropriate, relevant, and will result in the collection of valid and credible data” (Hubbard McCree, O'Leary, & Jones, 2010, p.44).

That fact that TGP was developed and is implemented by African American women familiar with the prevention needs of the target population greatly increases its relevance to participants. The program not only takes place in community settings – primarily the homes of women who host parties for their friends – it also builds on the strengths of naturally occurring groups of friends. Unlike “top down” interventions that may fail to account for real world effects during implementation and evaluation, TGP was developed specifically for community implementation. It is also important that TGP is evaluated in its natural community setting, which gives us more information about the effectiveness and generalizability of the results.

TGP also greatly increases the number of African American women who access HIV testing and counseling services. In the three years since its inception, TGP has served more than 646 women, of whom 540 (84%) accessed HIV testing and counseling. Of those tested, 524 of them (97%) received their HIV test results. This return rate is very high and far exceeds return for result rates found in clinic-based settings. The CDC reports that approximately one-third of those who get tested in our country do not return for test results, and an estimated one quarter of positive test results are never delivered (CDC, 2000). HIV case finding and linkage to care are necessary to reducing community viral load. A further TGP study of interest would be to perform modeling analyses to predict the impact that the intervention could have on our local population of African American women, given the increases in the number of women who get tested and are linked to clinical care.

TGP also supports access to care, since the rapport that facilitators build with participants not only helps them to place appropriate referrals, but also enables them to bridge participants to health care services, STI screening referrals, the local needle exchange program, and domestic violence support services. When a TGP facilitator delivers a positive test result to a TGP participant the facilitator actually accompanies the woman to her first appointment for HIV clinical care. This responsiveness is a significant asset, and greatly improves the likelihood that women will receive appropriate care as soon after receiving a positive test result as possible. HIV case finding followed by linkage to care is necessary to decreasing community viral load.

Of course, TGP is not a program that is sufficient to address the large underlying issues of poverty or syndemics. However, it does meet women where they are within the context of poverty and syndemics. TGP is sensitive to the fact that many participants are resource-challenged, so it is free for participants and utilizes incentives that are meaningful to them. Because it takes place in the homes of friends and family members, it is highly accessible. Women do not need to access transportation or child care to participate, as children tend to play in another room together during the intervention. Condom distribution is also considered to be an intervention that addresses barriers related to poverty, since it removes the financial burden of purchasing condoms (Cohen & Scribner, 2000). TGP also incorporates brief assessments and information relating to domestic violence and substance abuse. While these are by no means clinical assessments, the TGP facilitators are trained and experienced in exploring these issues and providing referrals when appropriate.

One of the most important aspects of TGP is likely that it builds on naturally occurring social networks of women. This may strengthen social cohesion, which we know can help buffer the effects of other HIV risk factors. In addition, discussing prevention strategies and perceptions of risk for HIV in open settings with friends and family members will likely strengthen social norms for condom use and address issues related to HIV stigma. Using peers as facilitators is key factor in building rapport and reducing stigma. If the TGP facilitator who is providing the intervention is herself living with HIV, she may share her HIV status with the TGP groups, which goes a long way to removing the feeling that many women have that HIV happens to "Others." Given the importance of the Black Church in the African American community, it would be ideal if an effort could be made to increase the number of TGP parties that take place in women's faith groups.

While TGP cannot address the broad social issue of racism, it does send a strong message of ethnic pride that can help buffer some of the effects of racism. TGP was developed specifically for African American women and is delivered by African American facilitators who clearly value participants as strong, beautiful, African American women. The most successful prevention interventions for African American women to date have incorporated positive messages of gender and ethnic pride (Wingood & DiClemente, 2000). Assessment tools and program literature have also been created with this message in mind. For example, rather than referring to Group A or Group B, they have been renamed the Amazing Group and the Beautiful

Group. Surveys also incorporate culturally appropriate and beautiful images of African American women.

A significant amount of time during the TGP party is spent discussing condom negotiation, other risk reduction behaviors such as shooting first and using clean needles, and the role of women in initiation risk reduction communication with sexual partners. By exploring sexual and gender power, rather than just talking about the need for condom use, the intervention becomes much more relevant for participants. Many women who have attended TGP parties have expressed surprise about the existence of female condoms. They have indicated that they feel empowered that there is a method of barrier protection that they can initiate with their partners. Anecdotally, participants who have been interviewed have also indicated that their male partners react much more favorably to female condoms than male condoms.

TGP also utilizes a harm reduction model in its prevention messages. This model is operationalized by helping women to develop their own plans to reduce their individual risk even if they don't feel they can remove risk completely. For example, women are encouraged to shoot first, use bleach kits, and to access the local needle exchange program if they continue to share IV drug equipment. Women are also encouraged to think about ways to make sexual activity less risky, perhaps by participating in oral sex rather than anal sex, or by reducing drug use prior to sexual activity since it is associated with increased risk for HIV infection. Above all, women are never judged for their risk taking behaviors and are supported in developing personal risk reduction plans.

5.0 DESIGNING A COMMUNITY-INFORMED EVALUATION

While much work has been attempted in our country to implement effective risk reduction interventions for this target population, challenges persist related to program specificity, translation, and evaluation. There is a dearth of behavioral interventions designed specifically for African American women in community environments. In its current *Compendium of Effective Interventions*, the CDC documents the efficacy of seven evidence-based interventions aimed at reducing HIV incidence among African American women; however, all but one of these interventions are targeted to specific segments of women, such as patients in STI clinics or known IV drug users (CDC, 2011). If women must already be connected to care in order to be engaged in one of these targeted intervention, then women who are not in services are likely to miss out on these evidence based interventions. Outreach must expand beyond service settings and include women in community settings.

There is only one evidence-based intervention documented by the CDC that has been developed for the general population of African American women (Diallo, 2010). Healthy Love has been implemented and evaluated in community settings, but has not yet been replicated by the CDC's Replicating Effective Programs Plus (REP+) initiative for dissemination through the Diffusion of Effective Interventions (DEBI) project. Perhaps the most widely disseminated risk reduction intervention for this target population is SISTA, a five session intervention that is culturally specific and is disseminated through the DEBI project. However, SISTA does not meet the CDC's current efficacy criteria for evidence based behavioral interventions and has been removed from the CDC's Compendium and REP+ rosters. There is clearly a need for new and replicable evidence-based interventions that are targeted to this population and specifically designed for community-based implementation.

A second challenge lies in the fact that interventions developed in controlled settings may not translate into "real world" effectiveness. Within the field of public health there is a growing understanding of the complexities of translating efficacious interventions to effective, community-based interventions (Glasgow & Emmons, 2007; Hohman & Shear, 2002). Interventions developed via randomized controlled trials often do not yield the same outcomes in practice settings where "real world" issues, such as participant variability and reduced financial and research resources, often diminish effect sizes. Replicating interventions that have been community-developed and community-evaluated is likely to reduce implementation costs, since there will be reduced need for translation. Further, adherence to program fidelity may be more achievable for community organizations, given that the core values of the program were developed in real-world settings that may share similar characteristics.

Evaluating interventions in community settings is critical to understanding program effectiveness. There is great concern that interventions tested in randomized controlled trials may present implementation challenges for community based organizations that have to deal with real world "noise." Effect sizes demonstrated through RCTs may not persist for interventions once they are implemented in the community (Kelly, et al., 2008; Rebchook, et al., 2006). Implementing interventions evaluated in uncontrolled environments may present a clearer picture of what community based organizations can expect during the implementation process, in contrast to programs evaluated in traditional research environments, which may have different sets of resources and skills.

The challenges of target specificity, translation, and evaluation may be greatly reduced for interventions developed by community members and evaluated in community settings. It has been well documented that when community members are involved in program development and implementation, cultural relevance and program sustainability are improved (Castro, 2004). Community-developed interventions present more direct paths to program effectiveness since community input and decision making increase cultural relevance and community acceptance. Interventions embraced by the target community are much more likely to be implemented and disseminated and have increased potential for sustainability as they have greater opportunities for institutionalization through existing community supports. Such interventions may also stand a greater chance of being successfully replicated in other communities or community based organizations since implementation challenges would be more readily identified, and implementation costs may be more realistic than interventions developed in controlled settings.

This community-rooted evaluation approach is both needed and timely: as noted previously, the 2010 National HIV/AIDS Strategy Federal Implementation Plan is overtly states the federal commitment to evaluating community-generated interventions in an effort to identify innovative prevention approaches ("White House Office of National AIDS Policy. National HIV/AIDS Strategy for the United States," 2010). The next portion of this document describes the process of developing, implementing, and evaluating one such community-developed intervention and discusses challenges, success, and benefits of evaluating the intervention in natural community settings.

5.1 INTERVENTION DEVELOPMENT

As noted previously, in 2004 a group of African American women familiar with the HIV risk reduction needs of their community developed The Girlfriends Project (TGP), an HIV risk reduction intervention targeted specifically to African American women. TGP was created by four African American women who were staff members and/or clients of the Pittsburgh AIDS Task Force (PATF). It was developed as a single session intervention that builds on the social network strengths of women, specifically to be delivered in community settings. (A description of the TGP intervention was detailed earlier in this document, and the TGP implementation guide can be found in Appendix A.) The TGP founders were committed to providing an intervention that was highly accessible and entertaining, which they felt would help to attract a broad range of women who might not otherwise be engaged in services. It is important to understand all of the means by which community input was utilized to develop not only the intervention but also its evaluation design.

Within the original group of TGP founders, several women have been involved since its inception. Beyond serving as driving forces to ensure program continuation, the consistency of their participation has likely impacted program success. Two of the community members who were TGP founders are the Girlfriends Project Coordinator and the Girlfriends Outreach Liaison, both paid staff positions at the Pittsburgh AIDS Task Force. One of the other program founders continues to serve on the project's community stakeholders group. A grant proposal writer was also part of the first TGP meeting because of her commitment to securing funding for a consumer-developed intervention. This individual has been involved in TGP throughout its course, now serves as the Principal Investigator for the TGP evaluation study, and is the author of this paper. Beyond the commitment of these individuals, the leadership of the Pittsburgh

AIDS Task Force has been highly supportive of TGP. The agency's Executive Director participated in the first TGP meeting and consistently supported the intervention, as have her successor and the agency's Board of Directors.

TGP's development and evaluation history is consistent with the values of Community Based Participatory Research. There is not only a shared commitment to program success by the researchers and community members, but also shared decision-making and shared ownership. There is also mutual respect: while the community members in this case do not claim research expertise, the Principal Investigator is well aware that she does not have community expertise. The ability of the collaborators to know and respect their respective roles has been critical to moving the program forward and addressing challenges as they arise.

5.1.1 Organic Theory

It has been widely documented that interventions that are theory-based are more likely to achieve their desired outcomes ("Theory at a Glance: A Guide for Health Promotion Practice," 2005). Program theory is also integral to understanding what aspects of change can be assessed when evaluating program efficacy or effectiveness. When the TGP founders were developing the intervention, no formal thought was given to theory derived from literature. However, several main determinants of change were identified by the founders that are consistent with health behavior change theories. First, the TGP creators believed that for the intervention to be effective, participants would need to (1) have an increased awareness of their susceptibility for HIV, (2) believe that the identified behavior changes would produce desirable results, (3) have help overcoming barriers to risk reduction behaviors, (4) have the skills necessary to enact behavior change, and (5) believe that they would be successful in implementing risk reduction behaviors. These program tenants are nearly identical to the structure of the Health Belief Model ("Theory at a Glance: A Guide for Health Promotion Practice," 2005) .

Again, without consulting the literature but based solely on real world experience, the TGP founders also borrowed from Social Norms Theory, in its intention to help women understand that members of their social networks approve of condom use, as well as from the Theory of Gender and Power, since the program acknowledges disparities in sexual power that women experience. The theory used to develop TGP was not literature-driven but was based specifically on community members' experiences. This use of "organic theory" not only improves the likelihood of program effectiveness, but also gives further credence to the tenets of the Health Belief Model, Social Norms Theory, and the Theory of Gender and Power as being highly relevant to this type of intervention.

5.1.2 Community Collaboration and Its Effect on Study Design

In addition to creating TGP, community members have been integral to the successful study design process. Community input regarding the research design has been solicited and integrated in three main ways (See Figure 2.) First, as previously noted, two of the program's founders now serve as paid TGP facilitators. Their continued presence since TGP's inception has been important to maintaining the vision of the intervention as well as to ensuring its cultural relevance. Second, a community stakeholders group includes one of the program's founders as well as women who have been TGP hostesses or participants. This group of women is brought together every few months to celebrate successes, provide feedback regarding program processes, and problem-solve implementation and evaluation challenges. In addition to spreading the word about the availability of the intervention, this group has been integral in developing recruitment strategies, piloting assessment tools, and selecting community-relevant incentives. Third, the TGP facilitators/founders participated in weekly research team meetings to ensure that the evaluation research process is responsive to participants' needs and settings and that evaluation process objectives were being met. Input from these community members has influenced the research design methodology in several specific ways.

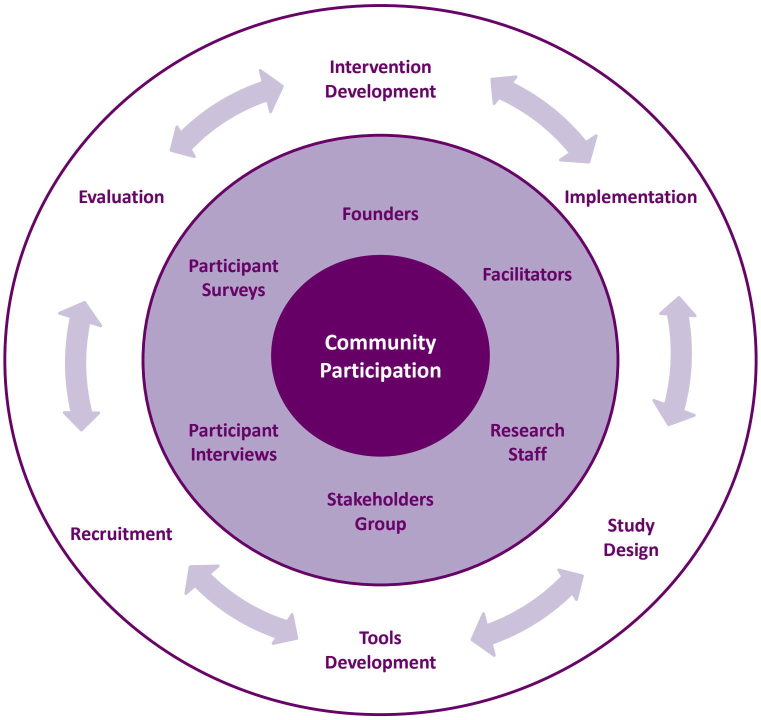


Figure 4. Community Input Model

5.1.2.1 Use of Gender Positive Tools and Language

While the study assessment tools were largely adapted from previous research studies (M. P. Carey et al., 2000), the tools' aesthetics and some of the language were influenced by community members' input. The program facilitators/founders and the community stakeholders reviewed all of the pen-and-paper assessment tools for their appearance and language, in order to assess if women would complete the surveys and to improve the likelihood that they would be accepted and understood by program participants. Positive images of African American women were added to the surveys to make them more pleasing to the eye, and all of the tools were color-coded to make the process of using them easier for the facilitators.

The language used to describe the intervention and control groups was gender positive. The terms “intervention arm” and “control arm” were not naturally meaningful to the community participants, and rather than referring to them as Group A and Group B, it was intentionally decided to refer to them as “Amazing Groups” (intervention groups) and “Beautiful Groups” (control groups.) Although this use of language may seem trivial, it is a simple example of the respect and positive approach that the program collaborators had for the study and its participants.

5.1.2.2 Shared Decision Making

A TGP Research Group was formed to ensure that the study process kept moving forward. This group met semi-weekly during the study phase-in process and weekly once the study was initiated. This Research Group was comprised of the Principal Investigator; the Girlfriends Project Coordinator; the Girlfriends Outreach Liaison; the Director of Prevention at the Pittsburgh AIDS Task Force, who is their immediate supervisor; and the agency’s Executive Director. Weekly meetings were integral to ensuring that all involved were operating from the same viewpoint. Even though notes from these meetings were taken and distributed, on several occasions the team would leave a meeting in agreement on a specific action plan, only to find out at the next meeting that members of the group were not actually in accordance. Meetings consistently gave the team the opportunity to clear up confusion before going too far off track.

The main method of decision making in the evaluation study was that the Principal Investigator would make recommendations regarding the research design or processes and the TGP Research Group would discuss and make decisions, with the facilitators/founders' input having significant weight. This was the case even for research-specific activities. For example, the Principal Investigator was interested in an intern to assist with data collection, but the intern was not secured until she was approved by the TGP Coordinator/Outreach Liaison. Funding decisions were ultimately those of the Executive Director, although when these decisions were directly related to the experience of study participants, such as those involving incentives or food at parties, the Executive Director tried to follow the recommendations of the community representatives.

5.1.2.3 Community Members Served as Research Staff

Given the commitment to keeping the program evaluation as similar to real world implementation as possible, the evaluation study did not use outside recruiters but relied on the TGP facilitators to recruit women to the study. In addition to their roles as facilitators, The Girlfriends Project Coordinator and Liaison took on the additional responsibilities of recruiting women to the study, obtaining participant informed consent, and retaining women for the three month follow up period. In order to serve in these capacities, both of these women participated in the University of Pittsburgh's Institutional Review Board's training modules on Integrity in Human Research, a clear demonstration of their flexibility in this process as well as their commitment to its success.

Having the facilitators take on responsibilities that are traditionally performed by "outsiders" not only increased the cultural relevance of the study but also reduced research costs. Their participation in recruitment also gave them the opportunity to build rapport with study participants, which was a key factor in retaining women for the three-month follow up period. Finally, their participation in these research efforts also improves the likelihood that effects demonstrated through this research study are likely to be achieved if the program is replicated by other community based organizations sharing similar characteristics.

5.1.2.4 Recruitment of Participants to the Intervention First Followed by Recruitment to the Study

The CDC's Compendium of Effective Interventions includes seven interventions targeted to African American women. Their efficacy has been tested with members of the target community; however, all but one of them recruited women to the study first and then randomized them to the intervention or a control. One exception to this method was the Healthy Love project, which is one of the CDC's "Promising Practices" (Diallo, 2010) and which utilized naturally-existing groups of women for implementation and evaluation.

The TGP evaluation study utilized the same recruitment methods as the intervention itself. Recruitment was conducted by the TGP facilitators, not by researchers. Women were recruited to host TGP parties through community settings including street outreach, social environments, civic or provider groups, and subsidized housing communities. TGP facilitators shared information about the research study when they recruited women to the intervention. TGP facilitators report that only one woman who was recruited to host a TGP refused to have her part as part of the research study. TGP facilitators then conducted a second level of study recruitment targeted to participants of TGP parties. At the start of each of the study parties, TGP facilitators explained the study purpose and design and obtained signed consent for all women who elected to be part of the study. It was made clear that women who did not want to be part of the study were still able to participate in the intervention and in fact completed the same assessment tools. The only difference was that demographic and assessment information collected on these women was not shared with researchers or included in evaluation study results.

Recruiting women or groups of women to an intervention and subsequently engaging them in the research process is likely to reveal more accurate data regarding intervention effectiveness than traditional research recruitment mechanisms. The study's processes demonstrate the feasibility of recruitment in "real world" settings and describe outcomes that can be expected from implementation in other uncontrolled settings. It is more likely that community based organizations will experience similar program effects as found in research studies if recruitment strategies rely on natural community processes rather than controlled recruitment.

5.1.2.5 Randomization by Group Rather than Individual

Participants were randomized by groups rather than by individual to build on natural social network strengths. Although Randomized Controlled Trials (RCTs) are the gold standard in research, the traditional RCT in which participants are randomized to treatment groups is not the best design for TGP evaluation purposes. TGP builds on existing social networks to recruit and intervene with women. Providing a setting for women to join together to learn about and discuss HIV risk and condom use is not just an effective recruitment mechanism, it also strengthens the social normalization process experienced by participants. Starting conversations about HIV risk and reinforcing risk reduction behaviors within groups of women who see each other and could support each other every day is a program benefit that would be lost if individuals were randomly assigned to TGP study arms. The connectedness and solidarity that women bring to the intervention may be integral to the relaxed nature of the parties, which provides further incentive for women to participate and host parties. Substituting random selection for peer recruitment would likely reduce the program effect.

Instead, the TGP study design utilized peer recruitment as described above and then randomized assignment by group. The initial evaluation plan was to randomize to the intervention arm or the study arm after a hostess committed to a party; however, this process resulted in scheduling delays and in some hostesses being lost to the study. A randomization process was instead instituted in which during the first few months of the study, all hostesses were assigned to the control arm. During the subsequent months, all hostesses were assigned to the intervention arm. This process was much more straightforward, resulting in quicker scheduling of baseline parties and more women retained in the study. The idea of "front-loading" the control arm was specifically conceived by the Girlfriends Outreach Liaison.

5.1.2.6 Utilization of a Wait-List Design versus Routine Standard of Care as Control

A number of evidence based interventions have utilized either didactic "AIDS 101" training sessions or health promotion activities that are not HIV specific as study control arms (Carey et al., 2000; Diallo 2010). While this approach would likely improve the intervention effect size, in the case of TGP, community representatives believed that providing a less-engaging intervention might result in women dropping out of the study or not returning for the full TGP intervention. Because TGP facilitators were committed to ensuring that every woman they reached received TGP services, a wait-list design was decided upon.

In the TGP study, groups assigned to the intervention arm participated in TGP parties immediately. Typically parties were able to be booked within two weeks of a woman expressing interest in hosting a party. Intervention group participants completed pre- and post-intervention assessment tools immediately before and after the intervention, and again at three month follow up. Once participants passed the three month data collection point, a number of them were engaged in qualitative interviews with the Principal Investigator to better understand facilitators and barriers to risk reduction intervention.

Women who were referred to the control arm (wait-list) received a baseline group, the purposes of which were to build rapport, to explain the study process, to obtain signed consent to participate, and for participants to complete baseline assessment tools. No HIV or domestic violence information was shared during the baseline groups and no HIV testing was provided. Three months after the baseline group, each of the control groups received the TGP intervention. Control group participants completed pen-and-paper assessment tools immediately pre- and post-intervention, and at three month follow up.

It is important to note that the decision to use Baseline groups was specifically the idea of the TGP facilitators. They didn’t just reject the idea of using a didactic AIDS 101 as a control group, they also created the idea of using Baseline parties. In addition to committing to a quasi-experimental design to increase the richness of our findings, they correctly believed that they would be able to recruit and engage women in the control groups, as well as to obtain informed signed consent and retain women in intervention parties three months later. This example indicates a more sophisticated level of community input towards research than might be expected. It also demonstrates the community members’ commitment to the research process.

5.1.2.7 Creating an Additional Assessment Domain

The assessment domains evaluated in the TGP study included behavior change to reduce risk for HIV as well as HIV risk knowledge, perception of risk, intentions for change, perception of social norms for condom use, sexual communication with partners. The degree to which each of the secondary assessment domains predicted behavior changes was also assessed.

However, an eighth assessment domain was added to the study as a direct result of comments made by community stakeholders. During a stakeholders' group, the Principal Investigator was exploring the possibility that women were more likely to talk to each other about HIV after attending a TGP party. One of the women spontaneously referred to this phenomenon as "The Girlfriends Effect," referring to the increased motivation to talk to people they know about HIV risk that is experienced by many women who participate in TGP. The Girlfriends Effect may be one of the most important program components, as it has the potential to produce a community-level effect by improving social norms for condom use, HIV testing, and other risk reduction opportunities. The Girlfriends Effect may well be a key factor in ensuring true sustainability by empowering women to adopt risk reduction messages and continue sharing information within the community.

5.1.3 Useful Tools and Processes

Although community-based evaluation is an important process, the fact that this study did not take place in controlled settings means that it was also rather messy at times. The TGP Research Group utilized a number of specific processes during the evaluation study to increase study precision and clean data collection. Some of these processes were more successful than others, and a discussion of these is included in hopes of informing future community-based evaluation studies.

The importance of weekly Research Group meetings cannot be overstated. While some meetings were simply thirty-minute check-ins to exchange completed consent forms and surveys, in most cases, meetings were good opportunities to problem solve challenges and clear up confusion on the part of the Principal Investigator or the facilitators. Brief minutes were taken at every research meeting, with action items highlighted. The minutes were distributed to each member of the research group prior to the subsequent meeting.

A number of data tracking mechanisms were utilized to ensure that the appropriate consent forms and data were collected. A Microsoft Access database was created for tracking study participants. This database was developed at the request of the Principal Investigator, in hopes that the TGP Coordinator and Liaison could use it as a tool to enter information regarding scheduled parties and study participants. However, this was not culturally responsive and was therefore ineffective. Although the TGP facilitators were fully able to use the technology, it was not their usual method of keeping track of women and was never utilized. Instead, both facilitators kept hard copies of party sign-in sheets, which was their process prior to the study. The Principal Investigator developed an Excel-based spreadsheet for participant tracking, which noted participants' unique identifiers and tracked the collection of consent forms and data on each participant. Women were only entered into the participant tracking form if informed consent had been obtained; otherwise, their information was never shared with the Principal Investigator.

Several other methods were utilized to keep track of parties, participants, and follow up due dates. These included a white board that indicated hostess names and due dates for follow up, as well as a poster board that showed the number of women that had been engaged in each of the study arms, meant to be used as a recruitment motivator. Neither of these methods was useful. The only tool that was used consistently was the Excel-based participant tracking form. This form was reviewed in detail at each weekly Research Group meeting. While this process was at times tedious, it was the only effective method to ensure that study participants were not lost to follow up due to oversight.

5.1.4 Challenges to and Limitations of Community Evaluation

The TGP evaluation study includes a number of limitations in terms of implementation and results. While utilizing a wait-list as a control group was the most ethical approach for the facilitators, it was at times very difficult for the facilitators to have women come together for baseline groups, but then to be unable to share HIV information or testing with them. A more controlled sample with true randomization would yield more rigorous evaluation results, although such results might not be replicable if the intervention were to be implemented by other community based organization that may have fewer research resources and less controlled research environments.

Many HIV evidence-based interventions rely on implementation in provider settings, such as STI clinics or primary care settings. The fact that TGP relies on social networks for recruitment and intervention means that women who are not otherwise connected to services are more likely to be reached through TGP. However, women who are the most marginalized and do not belong to social networks would not be reached through TGP. This may limit the generalizability of the study results. It may also be the case that women who agree to host TGP house parties may be different than other women in the community. Perhaps they have greater perception of HIV risk, which might influence their decision to become involved in the intervention. Additional research is needed to compare HIV awareness of community members to that of TGP hostesses at baseline. Additional discussion regarding community-informed evaluation is included on page 99 of this document.

6.0 QUANTITATIVE ANALYSIS AND EVALUATION RESULTS

6.1 STUDY DESIGN

The purpose of the TGP quantitative study is to evaluate program efficacy. The study aims were:

1. Using process measures, document the number of women who participate in the TGP evaluation study and describe their characteristics including age, education, and HIV risk histories.
2. Compare outcomes for participants of the TGP intervention versus a control group across seven assessment domains: (a) HIV risk reduction behaviors, (b) HIV risk knowledge, (c) perception of HIV risk, (d) intentions for implementing HIV risk reduction behaviors, (e) perceptions of social norms for condom use, (f) communication with sexual partners, and (g) sharing HIV risk reduction information within social networks.
3. Examine correlations among the assessment domains that significantly predict changes in HIV risk reduction behaviors in order to inform intervention refinement as well as the development of future HIV risk reduction interventions for the target population.

Although Randomized Controlled Trials are the gold standard in research, the traditional RCT in which participants are randomized to treatment groups is not the best approach to evaluate TGP. Building on social networks to recruit women to TGP is not just an effective recruitment mechanism; it also strengthens the social normalization process experienced by participants. Starting conversations about HIV risk and reinforcing risk reduction behaviors within groups of women who see each other (and could support each other) every day is a program benefit that would be lost by randomly selecting women for TGP. In addition, the connectedness and solidarity that women bring to the intervention may be integral to the relaxed nature of the parties. Thus, substituting random selection for peer recruitment may reduce the program effect.

However, it was possible to utilize the existing peer recruitment mechanism and then randomize assignment by group. This is a non-equivalent control group design -- assignment to groups was not random (since these women presented in pre-existing or naturally occurring groups), but group assignment to the intervention was random. Groups were randomized to either TGP (the intervention group) or a wait-list for TGP, (the control group.) As described previously in this document, ensuring that every participant received the TGP intervention was a core value for the research team. Each participant of the intervention group completed a pre-intervention and post-intervention HIV Assessment Tool immediately before and after the intervention, and was assessed on same domains at three month follow up. Groups referred to the wait-list received a non-HIV intervention where no HIV risk reduction or other information was shared. Three months after its baseline group, each of control groups received the TGP intervention. Members of the control groups completed the HIV Assessment Tool at the start of the TGP intervention, immediately pre- and post-TGP, and at three months post-TGP intervention. Figure 5 demonstrates this research design.

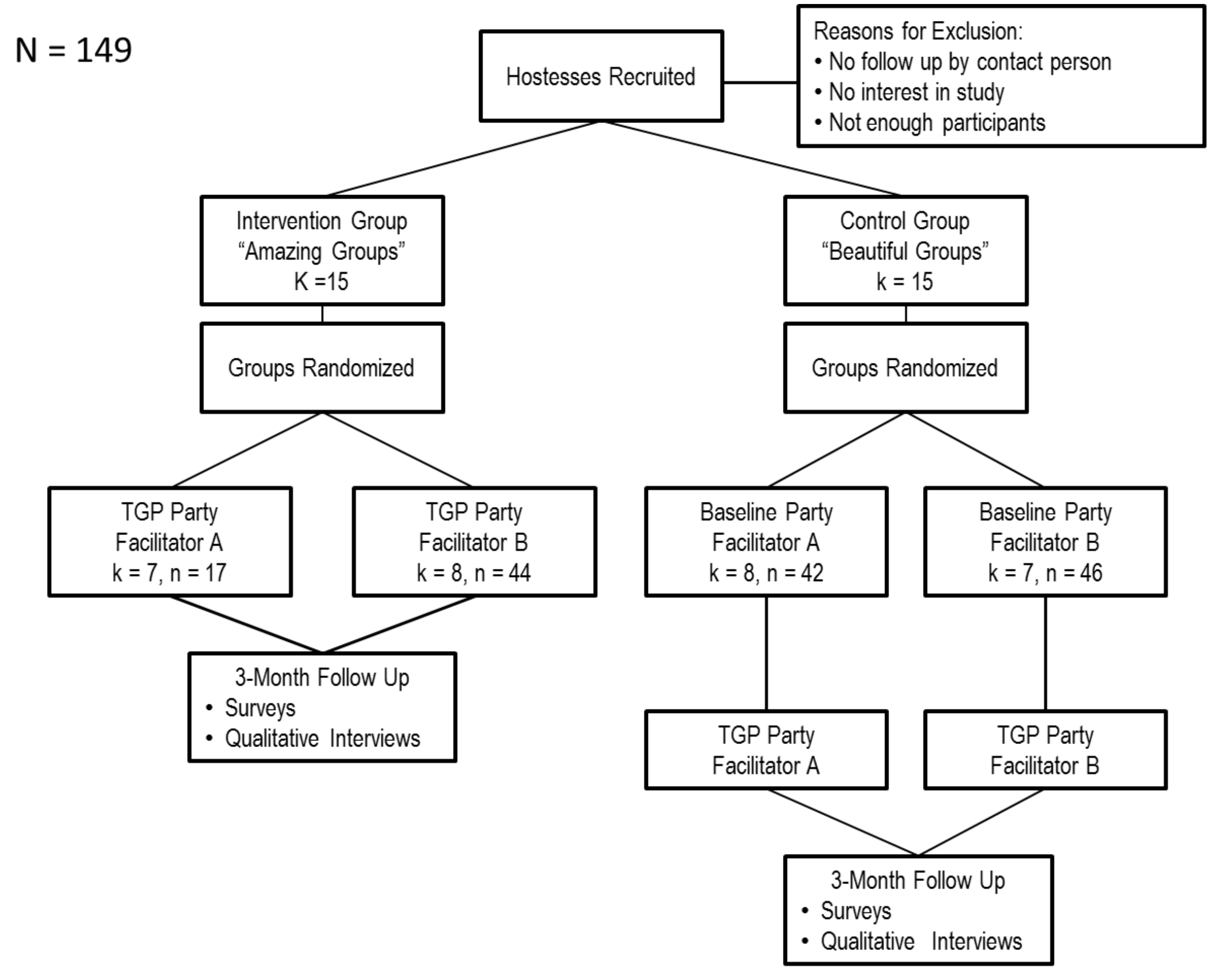


Figure 5. TGP Study Design

As noted previously, the study employs a wait-list design with the following observation and intervention points.

	Month 1			Month 3			Month 6
TGP	O_1	X_{TGP}	O_2	O_3			
Control	O_4	$X_{Control}$		O_5	X_{TGP}	O_6	0_7

Figure 6. TGP Study Observation Points

O_1, O_2, O_3 respectively represent completion by the Intervention groups of the pre-intervention, post-intervention, and three-month assessment tool. O_4 represents the observation point for the baseline assessment tool for women in the control group wait-listed for TGP. O_5 represents completion of the pre-intervention assessment tool for the control group participants, and will be completed three months after the alternative intervention, and immediately before the TGP intervention. O_6 represents completion of the assessment tool immediately after the TGP intervention for the Control groups. O_7 represents completion of the assessment tool three months after the TGP intervention for the Control groups.

6.1.1 Hypotheses

The primary hypothesis of the study was that participants' sexual risk behaviors (RB) would be reduced after participating in TGP.

$RB\ O_1 > RB\ O_2$

$RB\ O_1 > RB\ O_3$

$RB\ O_1 = RB\ O_4$

$RB\ O_3 < RB\ O_5$

$RB\ O_5 > RB\ O_6$

$RB\ O_5 > RB\ O_7$

$RB\ O_2 = RB\ O_6$

$RB\ O_3 = RB\ O_7$

Conversely, post-intervention increases in were hypothesized for the following assessment domains: HIV knowledge (HK), perception of risk (PR), intentions for implementing changes in risk reduction behaviors (IC), perceptions of social norms for condom use (C), and increased frequency of discussions about HIV risk reduction with members of social networks (TGE.) Thus, hypotheses for these domains were as follows:

$O_1 < O_2$

$O_1 < O_3$

$O_1 = O_4$

$O_3 > O_5$

$O_5 < O_6$

$O_5 < O_7$

$O_2 = O_6$

$O_3 = O_7$

In order to assess for desired program effects, both process and outcomes measures were utilized. Process measures were not only integral to the evaluation of TGP, but also are a necessary part of intervention replication. Process evaluation detailed the scope of the intervention, including the number of recipients reached and their characteristics, as well as the extent of the evaluation, including the number and quality of components delivered.

Participant characteristics were gathered via pre-intervention participant surveys, and tracked the number of participants, the number of women who accessed testing and received their results, and participant information such as race, age, income, zip code, and education completed. These data were examined to ensure that there were no significant differences between participants in the two interventions.

Program characteristics were collected to describe where interventions took place and what occurred during the TGP parties. An Intervention Scope Assessment tool was to be completed after each intervention to assess the degree to which each part of the intervention was delivered as planned, unique characteristics of the program or the group, and the number and types of referrals that were placed. Beyond describing how many interventions where delivered, to whom, by whom, and when, dosage information was collected to describe the proportion of the intervention that was actually delivered and the extent to which individuals participated. The point of the Scope Assessment tool was to ensure that information and program components were shared consistently all among interventions. Further, intervention fidelity was to be assessed, that is, describing the content that was delivered and the degree to which the intervention plan was met. To make sure that programs were carried out as intended, a TGP Procedural Guidance was developed. This document describes what are believed to be the core elements of TGP, as well as the order, manner, and spirit in which the program components are to be delivered.

Outcome measures focused on several assessment domains: (1) HIV risk knowledge, (2) perception of risk, (3) intentions for risk reduction behavior changes, (4) HIV risk behavior, (5) changes in perceived norms for condom use, and (6) motivation to increase discussions about HIV risk reduction with members of social networks. The study specifically addresses the following research questions.

RQ 1: Is there a significant difference in TGP participants' risk behavior scores post-intervention as compared to pre-intervention?

RQ 2: Is there a significant difference in TGP participants' AIDS risk knowledge scores post-intervention as compared to pre-intervention?

RQ 3: Is there a significant difference in TGP participants' perception of risk behavior scores post-intervention as compared to pre-intervention?

RQ 4: Is there a significant difference in TGP participants' intentions for risk behavior change scores post-intervention as compared to pre-intervention?

RQ 5: Is there a significant difference in TGP participants' perception of social norms for condom use post-intervention as compared to control groups?

RQ 6: Is there a significant difference in TGP participants' communication with sexual partners post-intervention as compared to control groups?

RQ7: Is there a significant difference in the frequency of TGP participants' discussions about HIV risk with members of their social networks, as compared to control groups?

RQ8: What are the significant correlations between scores on assessment domains?

6.1.2 Recruitment

The study took place between August 20011 and May 2012 in Allegheny County, Pennsylvania, which includes the metropolitan area of Pittsburgh. Women eligible for the study included those who self-identified as being African American and between the ages of 18-65, with no other screen out criteria. Recruitment was conducted by the TGP facilitators, not by researchers, and the TGP evaluation study utilized the same recruitment methods as the intervention itself. Specifically, women were recruited to host TGP parties through community settings including outreach on the street, in social environments, to civic or provider groups, and to leaders of subsidized housing communities. Women who expressed interest in hosting a party were also informed of the research study. TGP facilitators report that of the twenty-nine women who were recruited to host parties, only one elected to host a party without also participating in the study. One TGP group was eliminated from the study because it was determined by the research team that, as a professional group of retired nurses, they did not fit the study purpose of engaging women from the community based on social networks.

The TGP facilitators then conducted a second level of study recruitment targeted to participants of TGP parties. At the start of each of the study parties, TGP facilitators explained the study purpose and design and obtained signed consent for all women who elected to be part of the study. It was made clear that women who did *not* want to be part of the study were still able to participate in the intervention and would complete the same assessment tools. Demographic and assessment information collected on women who did not elect to be part of the study was not shared with researchers or included in evaluation study results. Of 219 women who participated in TGP parties during the study period 149(68%) of them elected to participate in the study.

6.1.3 Assessment Tools

A sample assessment tool is included in Appendix C of this document. As noted above, outcome measures focused on the following assessment domains: (1) HIV risk knowledge, (2) perception of risk, (3) intentions for risk reduction behavior changes, (4) HIV risk behavior, (5) changes in perceived norms for condom use, and (6) motivation to increase discussions about HIV risk reduction with members of social networks.

Changes in HIV risk knowledge were assessed via the HIV Risk Knowledge Questionnaire (HIV –KQ), 18-item version. This tool was modified from an original 45-item questionnaire, and has been shown to have high levels of validity and reliability for use with this target population. While the 18-item version is equally as sensitive and useful as the 45-item version, the brief version is much less cumbersome to complete and is suitable for low-literacy populations (M. P. Carey, et al., 2000). However, the 18-item scale does not assess for knowledge for risk related to drug use and other needle sharing, which was of interest in the TGP evaluation. For this reason, three of the questions from the original 45-item survey that address facts around safer drug use were added to the measurement tool. An additional question was added to include risk knowledge for needle sharing beyond drug use; i.e. sharing insulin needles. The HIV-KQ was completed by participants immediately pre- and post-intervention, and again during a three-month post-intervention follow up to allow for detection of changes in knowledge resulting from the intervention, as well as persistency of effects. Participants were scored on a scale of 0 (no questions correct) to 23 (all questions correct.)

Risk perception was measured to assess for participants' differences between pre-, and post-, and three-month post-intervention scores. The five-item scale tool that was utilized was adapted from the Women's Health Project (M.P. Carey et al., 2000), and assessed the degree to which participants perceived (a) she could someday get HIV, (b) the average man or woman is at risk for HIV, and (c) HIV is a serious problem in her community. This index has been found to be reliable with similar populations in previous studies (Carey et al., 1997). The risk perception tool uses a five-item Likert scale, with responses ranging from 1 (No Risk At All) to 5 (Extremely At Risk). Two questions assessed for personal risk, so a Perception of Personal Risk score was tabulated ranging from 2, (where both questions were scored as 1, No Risk At All), to 10, (where both questions were scored Extremely At Risk.) The remaining three questions were tabulated to assign a Perception of Community Risk Score ranging from 3 (No Risk At All on all three questions) to 15 (Extremely At Risk on all three questions.)

Intentions for risk reduction behaviors were also assessed, given the theoretical link between intentions and behavior change, and in order to detect for pre- and post- intervention differences immediately after the party. The tool that was utilized has been demonstrated as being reliable for use in similar study populations to that of TGP (Kalichman, Rompa, & Coley, 1996). For this assessment, participants read a vignette that described a high risk situation (a man and women are drinking at a party and both want to have sex) and then indicated the degree to which they felt were likely to utilize risk reduction strategies. This seven-item Likert scale assessed for intentions regarding condom use, reducing substance use in order to make safer decisions, and initiating discussions with the sexual partner regarding safer sex. Responses ranged from 1 (Definitely Will Not Do) to 5 (Definitely Will Do). A total Intentions for Change score was tabulated by adding all of the participant's responses. Thus, possible scores range from 7 (Definitely Will Not Do on all five questions) to 35 (Definitely Will Do on all five questions.)

HIV Risk Behaviors were assessed immediately pre-intervention and at the three-month follow up, utilizing tools previously developed and evaluated. These tools were previously found to be reliable risk perception indices for the target population (Carey, et al., 1997). Several sub-domains relating to risk behavior were evaluated. Sexual decision making and empowerment, (conceptualized as sexual communication, talking with a partner about HIV testing, and refusal to have sex without a condom), was measured since there is a link between these characteristics and HIV risk (Kalichman, et al., 1996). These were assessed via a series of questions dealing with the number of times participants talked with sexual partners about condom use, getting tested for HIV, and other issues relating to sexual risk histories. Women were also asked specifically if they believed they had the power to reduce their risk for HIV.

HIV risk behaviors were directly assessed by asking women to use a three-month recall period to report their number of male and female sexual partners, including number and frequency of sex acts with and without condoms, etc. Substance and needle use was also assessed, although most women indicated they did not use intravenous needles. These measures have been used in multiple studies with the research population. In addition, two questions were included to serve as proxy measures for HIV risk over the past year. These questions were, "In the past year, how many times have you had a sexual disease (STI or VD) such as Syphilis, Gonorrhea, Herpes, and/or Chlamydia?" and "In the past year, how many times has a man given you money or drugs to have sex with him?" In a recent national study of trends of sexually transmitted diseases, 7% of African American women reported having been treated for and STI in the past year, although 16.6% of women in our study reported an STI in the past year (Chandra, 2012). Another study noted that 13.1% of African American women in the United States reported having engaged in transactional sex; however, 21.2% of our study population reported engaging in transactional sex in the past year (Dunkle, Wingood, Camp, & DiClemente, 2010).

Changes in perceived norms for HIV risk reduction were assessed via a series of questions regarding frequency of condom use, how many friends were perceived to use condoms, how many friends talked about using condoms, and how many friends talked about HIV risk reduction. Additional items for assessment included how many members of participants' social networks have attended TGP parties and whether or not they felt motivated to host parties themselves.

6.2 STUDY SAMPLE

Twenty-eight parties were delivered during the study period, through which 149 women were engaged in the study including 61 in the intervention arm and 88 in the control arm. Women ranged in age from 18-65 with a mean age of 34.0 years. Of these women, 47.7% reported income less than $10,000, 24.8% between $10,000 and $24,999, and 14.8% greater than $25,000. (12.8% of the women did not respond to the income question; this was the variable most frequently not reported.) A total of 73 women (49%) reported working outside the home ranging in hours from 5 to 65 with a mean of 10 hours, (although in keeping with income data, 12.8% of women also did not report hours worked data.) Seven women (4.7%) reported elementary school as the highest grade completed, 90 (60.4%) high school or GED, with the remaining women reporting a professional certification or higher degree. Study participants reported a low number of male sexual partners in the three month prior to completion of the assessment tool, ranging from 0 (36 women) to 15 (1 woman), with the mean number of male sexual partners being 1. Of the participants, 11 (7.3%) reported have sex with one or more women during the three month recall period, and seven of these participants also reported having male partners. No women reported being HIV positive upon entering the study; however, eighty-seven women (58.4%) reported knowing someone with HIV or AIDS. A Chi-square test was conducted to examine for significant differences in perception of risk for women who knew someone with HIV versus those who did not; no significant differences were found, (χ^2 = 17.42, df = 18, p=.494).

A series of analyses was conducted to examine for baseline differences between groups. Two sets of chi-square tests were conducted to detect differences in frequencies comparing (a) the intervention and control groups; and (b) the intervention versus control groups by facilitator, (i.e., Intervention Groups conducted by Facilitator 1, Intervention Groups conducted by Facilitator 2, Control Groups conducted by Facilitator 1, and Control Groups conducted by Facilitator 2). Chi-square tests were conducted on the following baseline variables:

- Having income less than $10,000
- One or more STIs in the past year
- Transactional sex (having sex with a man in exchange for drugs or money) in the past year
- Belief that no or few friends use condoms
- Inability to talk to sexual partners about condoms
- Inability to talk to friends or family members about condoms
- Not feeling empowered to reduce risk for HIV

No significant differences were detected on these variables when comparing the intervention versus control groups, as demonstrated in Table 1.

Table 1. Sample Characteristics: Intervention versus Control groups

	TOTAL N = 149	**INTERVENTION** n = 61 (40.9)	**CONTROL** n = 88 (59.1)	
	No. (%)	*No. (%)*	*No. (%)*	χ^2
Income Less than $10,000	71 (47.7)	33 (54.1)	38 (43.2)	χ^2 =2.75, df=2, p=.253
One or more STIs in Last Year	25 (16.6)	10 (16.9)	15 (17.0)	χ^2 =5.150, df=2, p=.076
Transactional Sex One or More Times in Last Year	32 (21.2)	11(18.0)	21 (23.9)	χ^2 =1.51, df=4, p=.825
Believe No or Few Friends Use Condoms	91 (61.1)	32 (52.5)	59 (68.6)	χ^2 =4.79, df=3, p=.188
Cannot talk to sexual partners about condoms	**22 (14.8)**	**6 (9.8)**	**16 (18.4)**	**χ^2 =9.45, df=4, p=.051**
Talk to no or few friends/ family members about HIV/condoms	97 (65.1)	36 (59.0)	61 (70.1)	χ^2 = 13.3, df=16, p=.651
Do not feel empowered to reduce HIV risk	40 (26.8)	15 (25.0)	25 (28.4)	χ^2 =8.85, df=7, p=.264

No significant differences were detected on the same baseline variables when comparing the intervention versus control groups by facilitators, as demonstrated in Table 2.

Table 2. Sample Characteristics: Intervention versus Control Groups by Facilitators

	TOTAL N = 149	**Intervention/ Facilitator 1** n = 17	**Intervention/ Facilitator 2** n =44	**Control/ Facilitator 1** n = 42	**Control/ Facilitator 2** n = 46	
	No. (%)	*No. (%)*	*No. (%)*	*No. (%)*	*No. (%)*	χ^2
Income Less than $10,000	71 (47.7)	11 (64.7)	22 (50.0)	16 (38.1)	22 (47.8)	χ^2 =10.63, df=6, p=.101
One or more STIs in Last Year	25 (16.8)	1 (5.9)	9 (20.4)	10 (23.8)	5 (10.9)	χ^2 =11.78, df=6, p=.065
Transactional Sex One or More Times in Last Year	32 (21.4)	2 (11.8)	9 (20.4)	11 (26.2)	10 (21.7)	χ^2 =5.12, df=12, p=.954
Believe No or Few Friends Use Condoms	91 (65.1)	8 (47.0)	24 (54.5)	28 (66.7)	31 (67.4)	χ^2 =9.43, df=9, p=.398
Cannot talk to sexual partners about condoms	22 (14.8)	2 (11.8)	4 (9.0)	7 (16.7)	9 (19.6)	χ^2 =12.13, df=12, p=.435
Talk to no or few friends/ family members about HIV/condoms	97 (65.1)	11 (64.7)	25 (56.8)	29 (69.0)	32 (69.6)	χ^2 =2.97, df=6, p=.813
Do not feel empowered to reduce HIV risk	40 (26.8)	5 (29.4)	10(22.7)	12 (28.6)	13 (28.3)	χ^2 =.445, df=3, p=.931

Similarly, two sets of ANOVA tests were conducted to tests differences in means comparing the intervention and control groups and the intervention versus control groups by facilitator. ANOVAs were conducted on the following variables:

- Age
- Number of male sexual partners
- Number of times having vaginal sex without condoms in the three month study recall period.
- Number of times having anal sex without condoms in the three month study recall period.
- HIV knowledge, with possible scores ranging from 0-23, where 23 represents the highest possible score.
- Perception of personal HIV risk, with scores ranging from 2-10 where 10 represents the highest perception of risk.
- Perception of community HIV risk, with scores ranging from 3-15 where 15 represents the highest perception of risk.
- Intentions for implementing risk reduction behaviors, with scores ranging from 7-35 with the highest score representing the greatest intention to implement behavior change.

Table 3 demonstrates that no significant differences were found in the means of these variables when comparing Intervention versus Control groups.

Table 3. Differences in Means of Baseline Variables: Intervention versus Control Groups

	TOTAL N = 149	**INTERVENTION** n = 61 (40.9)	**CONTROL** n = 88 (59.1)	
	Mean (SD)	*Mean (SD)*	*Mean (SD)*	*F-statistic (P-value)*
Age	34.0 (12.6)	35.2 (13.3)	34.3 (12.3)	F(1,146)=.155, p=.695
Number of Male Sex Partners	1.2 (1.6)	1.16 (1.1)	1.22 (1.8)	F(1,141)=.046, p=.830
Number of Times having Vaginal Sex without Condoms	7.04 (11.5)	7.74 (11.8)	6.6 (11.4)	F(1,135) =.317, p=.574
Number of Times having Anal Sex without Condoms	.48 (1.9)	.66 (2.0)	.36 (1.8)	F (1,141) = .887, p=.351
HIV Knowledge (Possible score = 0-23)	17.7 (3.7)	17.6 (3.9)	17.8 (3.6)	F(1,147)=.083, p=.774
Perception of Personal Risk (Possible score = 2 – 10)	4.2 (1.7)	4.3 (1.9)	4.1 (1.6)	F(1,144)=.302, p=.583
Perception of Community Risk (Possible score = 3 – 15)	11.8 (2)	11.7 (1.9)	11.9 (2.0)	F(1,146)=1.03, p=.311
Intentions for Change (Possible Score = 7 – 35)	29.0 (8.4)	28.7 (7.3)	29.2 (9.1)	F(1,143)=.184, p=.668

One significant difference was found when comparing the means of the same baseline variables for the intervention versus control groups by facilitators. As demonstrated in Table 5, there was a statistically significant difference in the Perception of Personal Risk.

Table 4. Difference in Means of Baseline Variables: Intervention versus Control Groups by Facilitators

	TOTAL N = 149	**Intervention/ Facilitator 1** n = 17	**Intervention/ Facilitator 2** n =44	**Control/ Facilitator 1** n = 42	**Control/ Facilitator 2** n = 46	
	Mean (SD)	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*	*F-statistic (P-value)*
Age	34.0 (12.6)	33.9 (13.5)	35.7 (13.4)	32.5 (11.6)	36.0 (12.8)	F(3,144)=.673, p=.570
Number of Male Sex Partners	1.2 (1.6)	.87 (.64)	1.27 (1.2)	1.1 (1.2)	1.3 (2.2)	F(3,139)=.353, p=.787
Number of Times having Vaginal Sex without Condoms	7.04 (11.5)	5.57 (9.4)	8.51 (12.5)	5.12 (10.1)	7.82 (12.4)	F(3,133)=.692, p=.559
Number of Times having Anal Sex without Condoms	.48 (1.9)	.87 (.3.1)	.58 (1.5)	.12 (.51)	.57 (2.4)	F(3,141)=.775, p=.510
HIV Knowledge (0 – 23)	17.7 (3.7)	16.2 (5.4)	18.2 (3.0)	18.1 (4.1)	17.5 (3.1)	F(3,145) = 1.39, p = .248
Perception of Personal Risk (2 – 10)	4.2 (1.7)	3.8 (1.8)	4.5 (1.9)	4.6 (1.5)	3.7 (1.6)	**F(3,142)=2.93, p =.036**
Perception of Community Risk (3 – 15)	11.8 (2)	11.9 (1.6)	11.6 (2.0)	12.5 (1.6)	11.5 (2.3)	F(3,144)=2.59, p=.055
Intentions for Change (7 – 35)	29.0 (8.4)	29.1 (8.9)	28.4 (6.9)	31.5 (9.8)	27.0 (7.8)	F(3,144)=2.22, p=.088

6.3 METHODS

The number of women who reported sexual risk behavior change after three months was calculated, comparing the intervention group pre-assessment data versus three month follow up data, as well as control group baseline data versus pre-intervention data. Both of these comparisons represent three month time intervals. At the time of the analysis, paired data was available for 37 women in the intervention group (61% retention) and 48 women in the control group (55% retention). This retention rate is expected to increase as more women reach their three month follow up or intervention dates.

6.3.1 Comparing Improvements in Risk and Risk Reduction Behaviors: Intervention versus Control Groups

Analyses were conducted to examine for improvements in risk reduction behaviors comparing the intervention group to the control group. The ability to directly compare outcomes of the study arms is the main point of the quasi-experimental design and allows for an examination of the primary study hypotheses (reduction in HIV risk behaviors.)

Differences in risk and risk reduction behaviors over the three-month study period were calculated and recoded to reflect binary values for both of the study arms. Increases in risk reduction behavior or decreases in high-risk behavior were recoded with the value of 1. Decreases in high-risk reduction behavior, increases in high-risk behavior, or no change at all were recoded with the value of 0. Decreases in the following high risk behaviors were recoded as positive change:

- Vaginal sex without condoms
- Anal sex without condoms
- Number of male sexual partners

Increases in the following risk reduction behaviors were recoded as positive change:

- Vaginal sex with condoms
- Anal sex with condoms
- Talking with sex partners about preventing pregnancy
- Talking with sex partners about using condoms
- Talking with sex partners about how to prevent HIV
- Talking with sex partners about how to prevent STIs

- Talking with sex partners about the partners' sexual histories
- Talking with family about HIV risk
- Talking with friends about HIV risk
- Feeling empowered to reduce risk for HIV

Table 5 documents the number of women in each group that reported positive change compared to no change or negative change after three months. This two-by-two table demonstrates increases and decreases in positive behavior for the intervention group versus the control group. Odds ratios were calculated to show the comparative likelihood of risk and risk reduction behaviors between the two study arms. The level of significance for p=values was set *a priori* at α=.05; however it is reasonable for pilot studies with small sample size to set the significance level at .10. For this reason, both significant findings (p<.05) and marginally significant findings (p<.10) will be highlighted for the remainder of this quantitative analysis. Odds ratios greater than 2.0 are also considered to be significant and are highlighted.

Women in the intervention group were more than four times as likely as those in the control group to report decreasing the frequency of anal sex without condoms, and nearly six times as likely to report increasing the frequency of anal sex with condoms. Intervention group women were two to three times more likely to report talking with their partners about preventing HIV, talking with their partners about preventing STIs, and talking with their partners about the partners' sexual histories. Increases were also noted in the likelihood of intervention group women to report decreases in vaginal sex without condoms, decreasing the number of male sex partners, and talking with their partners about preventing pregnancy.

Chi-squared tests were conducted to examine for statistical significance. A significant difference was found in the number of women who reported talking with their partners about

STIs in the intervention group as compared to the control group, $\chi^2 = (1,78)=4.468, p=.035$. While no other statistical significance was found, the analysis is likely constrained by small sample size. Statistical significance was approached on several variables including decreases in anal sex without condoms, $\chi^2 =(1,82)=3.481,p=.062$, increases in anal sex with condoms $\chi^2 =(1,83)=2.906, p=.088$, and talking with partners about how to prevent HIV, $\chi^2 =(1,77)=3.126, p=.077$.

Table 5. Improvements in Risk and Risk Reduction Behaviors: Intervention versus Control Groups

	INTERVENTION GROUP		**CONTROL GROUP**			
	n	Number (%) of Women	n	Number (%) of Women	OR	χ^2
Vaginal Sex Without Condoms	31		45		1.70	(1,76)=1.088, p=.297
Decreased Frequency		11 (35.5)		11 (35.5)		
No Change or Increased Frequency		20 (64.5)		34 (75.6)		
Vaginal Sex With Condoms	34		45		0.99	(1,79)=.001, p=.981
Increased Frequency		12 (35.3)		16 (35.6)		
No Change or Decreased Frequency		22 (64.7)		29 (64.4)		
Anal Sex Without Condoms	36		46		**4.40**	**(1,82)=3.481,p=.062**
Decreased Frequency		6 (16.7)		2 (4.3)		
No Change or Increased Frequency		30 (83.30)		44 (95.7)		
Anal Sex With Condoms	36		47		**5.75**	**(1,83)=2.906, p=.088**
Increased Frequency		4 (11.1)		1 (2.1)		
No Change or Decreased Frequency		32 (88.9)		46 (97.9)		
Number of Male Sex Partners	33		46		1.52	(1,79)=.558, p=.455
Decreased Frequency		8 (24.2)		8 (17.4)		
No Change or Increased Frequency		25 (75.8)		38 (82.6)		
Talk to Partner(s) About Preventing Pregnancy	33		44		1.69	(1,77)=.984, p=.321
Increased Frequency		10 (30.3)		9 (20.5)		
Stable or Decreased Frequency		23 (69.7)		35 (79.5)		
Talk to Partner(s) About Using Condoms	33		46		0.68	(1,79)=.505, p=.477
Increased Frequency		7 (21.2)		13 (28.3)		
Stable or Decreased Frequency		26 (78.8)		33 (71.7)		
Talk to Partner(s) About Preventing HIV	31		46		**2.65**	**(1,77)=3.126, p=.077**
Increased Frequency		10 (32.3)		7 (15.2)		
Stable or Decreased Frequency		21 (67.7)		39 (84.8)		
Talk to Partner(s) About Preventing STIs	33		45		**3.25**	**(1,78)=4.468, p=.035**
Increased Frequency		11 (33.3)		6 (13.3)		
Stable or Decreased Frequency		22 (66.7)		39 (86.7)		
Talk to Partner(s) About Sexual History	32		46		**2.16**	(1,78)=2.042, p=.153
Increased Frequency		10 (31.3)		8 (17.4)		
Stable or Decreased Frequency		22 (68.8)		38 (82.6)		
Talk to Family about HIV Risk	37		47		1.78	(1,84)=1.546, p=.214
Increased Frequency		15 (40.5)		13 (27.7)		
Stable or Decreased Frequency		22 (59.5)		34 (72.3)		
Talk to Friends about HIV Risk	37		47		1.40	(1,84)=.483, p=.487
Increased Frequency		12 (32.4)		12 (25.5)		
Stable or Decreased Frequency		25 (67.6)		35 (74.5)		
Empowered to Reduce HIV Risk	37		47		1.16	(1,84)=.078, p=.779
Increased Frequency		8 (21.6)		9 (19.1)		
Stable or Decreased Frequency		29 (78.4)		38 (80.9)		

6.3.2 Comparing Means of Risk and Risk Reduction Behavior: Repeated Measures of Intervention and Control Groups

Wilcoxon Signed Rank Tests were conducted to compare the mean number of times women reported engaging in risk behaviors at initial observation points and three month follow up. Results are provided in Table 6. There was a statistically significant difference in the reported mean number of times women had vaginal sex with a condom pre-intervention as compared to three-month follow up data *(z=-2.236, p=.025.)* While this was the only significant finding for the intervention group, p-values are again likely limited by small sample size. Overall, data trends suggest improvements in HIV risk related to vaginal sex for the intervention group versus the control group. For the intervention group, there was a decrease in the mean number of times women reported having vaginal sex without a condom while the mean number of reported incidents of vaginal sex with a condom doubled. These data are in contrast to the control group, where the number of incidents of vaginal sex without a condom nearly doubled while the reports of vaginal sex with a condom decreased. The mean number of reports of anal sex with and without condoms was small for both groups at both observation points.

For women in the intervention group, there was no change in the mean number of male sex partners, although in the control group there was a statistically significant increase in the mean number of male partners *(z=-2.374, p=0.018).* The study time frame included the winter holiday season; it is possible that the control group's increase in male partners is related to seasonal effects. If this is true, then it is a positive indicator that the intervention group did not report increases in the number of male sex partners.

Table 6. Comparing Means of Risk and Risk Reduction Behavior: Repeated Measures of Intervention and Control Groups

	Intervention Group				Control Group			
	n	Mean (SD) Pre-IV	Mean (SD) 3-Month	Sig.†	n	Mean (SD) Baseline	Mean (SD) Pre-IV	Sig.
Vaginal Sex Without Condom	31	8.84	6.87	z=-.027, p=.978	45	3.71	6.11	z=-1.395, p=.163
Vaginal Sex With Condom	34	1.47	3.06	**z=-2.236, p=.025**	45	4.56	3.49	z=-.443, p=.657
Anal Sex Without Condom	36	.56	.83	z=-.535, p=.593	46	.09	.17	z=-.954, p=.340
Anal Sex With Condom	36	.17	.69	z=-1.018, p=.309	47	.38	.11	z=-.535, p=.593
Number of Male Partners	33	1.15	1.15	z=.000, p=1.00	46	1.52	2.02	**z=-2.374, p=.018**

6.3.3 Comparing Means of HIV Knowledge, Perception of Risk, and Intentions for Change Scores: Repeated Measures of Intervention and Control Groups

While the primary hypothesis for this study was that participation in the intervention would reduce HIV risk behaviors, secondary hypothesis projected increases in HIV knowledge, perception of personal risk, perception of community risk, and intentions for risk reduction change for study participants. Raw scores for each of these variables were calculated as described on page 68. Paired t-tests were used to examine for statistical significance in the means of scores for both the intervention and control groups. Results of these tests are reported in Table 7. Two statistically significant differences were found. In the intervention group there was a significant improvement in the mean of HIV knowledge comparing the pre-intervention group data to 3-month follow up surveys, *t(36)=-2.09, p=.043*. In the control group, there was a significant decrease in the mean of intentions for change comparing the baseline data to pre-intervention data, *t(44)=2.96, p=.005.*

Table 7. Comparing Means of HIV Knowledge, Perception of Risk, and Intentions for Change: Intervention and Control Groups

	INTERVENTION GROUP Mean (SD)				CONTROL GROUP Mean (SD)			
	n	**Pre-IV**	**3Mo**	**Sig.**	**n**	**Baseline**	**Pre-IV**	**Sig.**
HIV Knowledge	37	17.6 (3.5)	18.8 (3.0)	**t(36)= -2.09,p=.043**	47	17.6 (3.9)	16.7 (4.3)	t(46)=1.23, p=.225
Perception of Risk - Personal	33	4.2 (1.8)	4.2 (1.7)	t(32)=.149, p=.883	47	4.7 (1.8)	4.7 (1.7)	t(46)=.000, p=1.00
Perception of Risk - Community	37	11.6 (1.8)	12.0 (1.5)	t(36)=-1.04, p=.306	46	12.3 (2.0)	11.9 (2.0)	t(45)=1.45, p=.153
Intentions for Change	35	27.3 (7.4)	27.8 (5.2)	t(34)=-.430, p=.670	45	29.8 (5.0)	26.9 (6.3)	**t(44)=2.96, p=.005**

6.3.4 Comparing Dichotomous Variables: Repeated Measures of Intervention and Control Groups

Data from focus groups during the study design phase suggested that TGP increased participants' motivation to share HIV risk reduction information with members of their social networks. A series of questions assessing frequency of HIV information sharing with friends, family members, and sexual partners was included on the assessment tools. Study participants were not asked to state the specific number of times they had conversations about HIV as it is unlikely that the recall effect would allow for reliable data at this level. Instead, women were asked to report on communication and empowerment variables using a four-point Likert scale (1=None/Never, 2=A Few/Sometimes, 3=Most/Often, 4=All/A Lot). To examine for statistical significance using a McNemar test, these variables were recoded to binary values where 1 (None/Never) was recoded to 0 and all other values were recoded to 1. The purpose of this recode was to examine for changes in the number of women who reported never talking about HIV at pre-intervention versus three-month follow up for the intervention group and baseline versus pre-intervention for the control group. This approach also allowed for increased test sensitivity in consideration of the small sample size. Table 8 shows the result of this analysis displayed in a two-by-two table, where 0 = None or Never and 1=All Other Values. Odds ratios were also calculated for each of the groups.

Though no significance was found for the control group, marginal statistical significance was for two of the variables in the intervention group. On the variable "Talked with partners about how to prevent HIV," 48% of intervention group participants at baseline but only 32% at follow up indicated they never talk to their sex partners about HIV *(p=.070),* with an odds ratio of 7.0. For the variable "Talked with sex partners about how to prevent STIs, 45% of intervention group women at baseline but only 33% at follow up indicated they never talked with sex partners about how to prevent STIs *(p=.109, OR=4.0.)*

Table 8. Comparing Dichotomous Variables: Repeated Measures of Intervention and Control Groups

		INTERVENTION GROUP						CONTROL GROUP			
Talked with sex partner(s) about how to prevent pregnancy.											
		3 Mo. Follow Up		p=1.000	OR= 1.2			3 Mo. Follow Up		p=1.000	OR=1.0
		0	1					0	1		
Pre IV	0	9	7	16		Pre IV	0	18	5	23	
	1	6	11	17			1	5	16	21	
		15	18	33				23	21	44	
Talked with sex partner (s) about how to use condoms.											
		3 Mo. Follow Up		p=1.000	OR=.83			3 Mo. Follow Up		p=1.000	OR=1.1
		0	1					0	1		
Pre IV	0	12	5	17		Pre IV	0	14	11	25	
	1	6	10	16			1	10	11	21	
		18	15	33				24	22	46	
Talked with sex partner (s) about how to prevent HIV.											
		3 Mo. Follow Up		**p=0.070**	**OR=7.0**			3 Mo. Follow Up		p=1.000	OR=1.2
		0	1					0	1		
Pre IV	0	8	7	15		Pre IV	0	22	7	29	
	1	1	15	16			1	6	11	17	
		9	22	31				28	18	46	
Talked with sex partner(s) about how to prevent STIs.											
		3 Mo. Follow Up		**p=0.109**	**OR=4.0**			3 Mo. Follow Up		p=0.549	OR=.57
		0	1					0	1		
Pre IV	0	7	8	15		Pre IV	0	21	4	25	
	1	2	16	18			1	7	14	21	
		9	24	33				28	18	46	
Talked with sex partner(s) about the partners' sex history.											
		3 Mo. Follow Up		p=1.000	OR=.80			3 Mo. Follow Up		p=0.424	OR=.56
		0	1					0	1		
Pre IV	0	4	4	8		Pre IV	0	16	5	21	
	1	5	19	24			1	9	16	25	
		9	23	32				25	21	46	
Talked with family about HIV.											
		3 Mo. Follow Up		**p=0.108**	**OR=3.5**			3 Mo. Follow Up		p=0.629	OR=1.4
		0	1					0	1		
Pre IV	0	3	7	10		Pre IV	0	8	10	18	
	1	2	25	27			1	7	21	28	
		5	32	37				15	31	46	
Talked with friends about HIV risk.											
		3 Mo. Follow Up		p=0.687	**OR=2.0**			3 Mo. Follow Up		p=0.359	OR=.58

Table 8. Continued

		INTERVENTION GROUP						**CONTROL GROUP**			
		0	1					0	1		
Pre IV	0	2	4	6		Pre IV	0	7	7	14	
	1	2	29	31			1	12	21	33	
		4	33	37				19	28	47	
Feel empowered to reduce HIV risk.											
		3 Mo. Follow Up		p=0.500	n/a			3 Mo. Follow Up		p=1.000	**OR=2.0**
		0	1					0	1		
Pre IV	0	0	2	2		Pre IV	0	2	2	4	
	1	0	35	35			1	1	42	43	
		0	37	37				3	44	47	

6.3.5 Predicting HIV Risk Behavior Change by Increases in HIV Knowledge, Perception of Risk, and Intentions for Change

In order to better understand TGP's mechanisms for success and inform intervention refinement, it is necessary to understand what changes were experienced by study participants that may correlate with behavior change. A stepwise binary logistic regression analysis was conducted to examine the degree to which increases in HIV knowledge, perception of personal risk, perception of community risk, and intentions for change predicted behavior change. The differences between pre-intervention and three month follow up scores were calculated for these four variables. Differences in risk and risk reduction behaviors over the three-month study period were calculated and recoded to reflect binary values, this time only reflecting increased or decreased frequency. The predicted behaviors of interest were vaginal sex without a condom, vaginal sex with a condom, anal sex without a condom, anal sex with a condom, and number of male sex partners. Table 9 demonstrates the results of these analyses.

No concerns regarding multicollinearity were noted. Two marginally significant statistics were found. With a one-unit increase in intentions for change, the logit of vaginal sex without a condom was reduced by .149 *(p=.091)* when controlling for all other variables. With a one-unit increase in Perception of Personal Risk, the log odds of Anal Sex With a Condom increased by .793, increasing the odds of this risk reduction behavior by 2.210 *(CI .974, 5.013)* when controlling for HIV Knowledge, Perception of Community Risk, and Intentions for Change. It is interesting to note that changes in HIV Knowledge seem to be the least significant predictor of change on risk and risk reduction behavior variables.

Table 9. Predicting HIV Risk Behavior Change by Increases in HIV Knowledge, Perception of Risk, and Intentions for Change

	B	SE	Wald	df	Sig	Exp(B)	CI Lower	CI Upper
Vaginal Sex Without a Condom								
HIV Knowledge	0.178	0.160	1.239	1	0.266	1.194	0.874	1.633
Perception of Risk - Personal	-0.283	0.207	1.869	1	0.172	0.754	0.503	1.103
Perception of Risk - Community	0.361	0.240	2.267	1	0.132	1.434	0.897	2.294
Intentions for Change	-0.149	0.088	2.856	1	**0.091**	0.862	0.725	1.024
Vaginal Sex With a Condom								
HIV Knowledge	-0.028	0.128	0.048	1	0.826	0.972	0.757	1.249
Perception of Risk - Personal	0.170	0.212	0.643	1	0.423	1.185	0.785	1.797
Perception of Risk - Community	0.031	0.189	0.027	1	0.870	1.031	0.712	1.494
Intentions for Change	-0.011	0.065	0.028	1	0.866	0.989	0.871	1.124
Anal Sex Without a Condom								
HIV Knowledge	0.031	0.250	0.015	1	0.902	1.031	0.631	1.685
Perception of Risk - Personal	0.387	0.408	0.900	1	0.343	1.472	0.662	3.273
Perception of Risk - Community	-0.603	0.606	0.989	1	0.320	0.547	0.167	1.796
Intentions for Change	-0.214	0.159	1.809	1	0.179	0.807	0.591	1.103
Anal Sex With a Condom								
HIV Knowledge	0.056	0.232	0.058	1	0.810	1.058	0.671	1.667
Perception of Risk - Personal	0.793	0.418	3.600	1	**0.058**	2.210	0.974	5.013
Perception of Risk - Community	0.078	0.261	0.089	1	0.765	1.081	0.649	1.803
Intentions for Change	-0.119	0.123	0.926	1	0.336	0.888	0.697	1.131
Number of Male Sex Partners								
HIV Knowledge	0.034	0.157	0.047	1	0.828	1.035	0.760	1.408
Perception of Risk - Personal	0.261	0.264	0.982	1	0.322	1.299	0.774	2.078
Perception of Risk - Community	-0.374	0.265	1.988	1	0.159	0.688	0.409	1.157
Intentions for Change	-0.047	0.081	0.338	1	0.561	0.954	0.814	1.118

6.4 DISCUSSION OF QUANTITATIVE ANALYSIS

6.4.1 Limitations

The major limitation of this study is that the small sample size restricts the interpretation and generalizability of results. The positive data trends suggest the likelihood that when data is available for a larger group of TGP participants, additional findings of significance will be noted. A cluster analysis is also necessary to understand how group variables impact the intervention effect. This is especially important given that TGP relies on existing social networks of women who are likely to share characteristics that may affect their knowledge of or beliefs about HIV. Education, income, and knowing people with HIV all may be similar within a social group, and all of these characteristics would likely affect the impact of the intervention for these women.

Sample size also constrains our understanding of the variables that predict the primary outcome of interest, which is behavior change to reduce risk for HIV. A larger sample would enable more sophisticated methods using a multi-level regression analysis for this purpose. Additional research is needed to understand the interplay between HIV knowledge, risk perception, and intentions for change.

The fact that TGP relies on social networks for recruitment and intervention is both an asset and a limitation. Natural recruitment processes that build on existing social networks mean that women do not need to be connected to services as in the case of many of the CDC's evidence based interventions that are located in STI clinics or other provider settings. Women who are not connected to services are more likely to be reached through TGP. However, women who are the most marginalized and do not belong to social networks would not be reached through TGP. This may limit the generalizability of the study results. It may also be the case that women who agree to host TGP house parties are different than other women in the community. Perhaps they have greater perception of HIV risk, which might influence their decision to become involved in the intervention. These factors would bias the study results.

6.4.2 Conclusions

It is apparent that there is something interesting going on with The Girlfriends Project, and that further research is warranted to understand intervention mechanisms and demonstrate program efficacy. A number of important findings were noted suggesting that TGP is effective in helping women reduce their risk for HIV and other sexually transmitted infections. When comparing women in the intervention group to those in the control group, women who received the intervention were much more likely to decrease the frequency of anal sex without condoms and increase the frequency of anal sex with condoms. Women in the intervention arm were also more likely to talk about their sexual partners about preventing HIV, preventing other sexually transmitted infections, and their partners' sexual histories.

Women in the intervention group were significantly more likely to have vaginal sex with a condom after participating in TGP and also experienced a statistically significant improvement in HIV knowledge after the intervention. Intervention group women were seven times as likely to talk to their sexual partners about HIV after participating in TGP and four times as likely to talk to their partners about preventing other STIs. They were also three-and-a-half times as likely to talk with members of their family about reducing risk for HIV, and twice as likely to talk with their friends about HIV. Though not statistically significant, changes in the means of reported risk/risk reduction behaviors were noted for intervention group women, including decreases in vaginal sex without a condom, increases in perception of personal and community risk, and intentions for risk reduction change. In the control group, the changes in the means of these reported behaviors moved in the opposite direction. Control group women reported increases in the frequency of vaginal sex without condoms, decreases in vaginal sex with condoms, and a statistically significant increase in the number of male sex partners. Baseline versus pre-intervention scores for the control group also decreased on the variables of HIV knowledge, perception of community risk, and intentions for change.

For most of the behavioral outcomes, changes in HIV Knowledge were the least significant predictor. This is consistent with preliminary data from qualitative interviews, in which TGP participants have shared that the components of TGP that affected them the most were the belief that “HIV could happen to me” (Perception of Personal Risk), and that after TGP they felt motivated to put themselves first and take charge of their risk for HIV (Intentions for Change.)

The quantitative findings of this research are especially important given that the study took place in community contexts, using natural recruitment mechanisms and members of the community as research staff. The study demonstrates that with support, community members play an important role in conducting efficacy research. The research team model, which bridges a community organization with researchers from an academic setting, is one that will hopefully be used with increased frequency given the emphasis of the National HIV/AIDS Strategy for the United Status on evaluating innovative, “home grown” interventions. This model present opportunities for decreased research costs and increased community relevance. This values orientation toward engaging community participation across all levels of evaluation also improves the odds that other agencies would experience similar outcomes, since the research findings do not rely on controlled settings. While randomized controlled trials may be the gold standard of research, it is important to remember that contextual and community factors are not problems to overcome, but are instead strengths to help improve intervention relevance and interpretation of results.

7.0 QUALITATIVE ANALYSIS: PRELIMINARY FINDINGS

The qualitative study of TGP is only in its initial stages, so any reported results are strictly preliminary and must be considered with caution. However, pairing qualitative findings along with the quantitative data greatly increases the understanding of TGP's effects. Preliminary qualitative feedback has been rich and largely consistent among the first six interviews, and these data are too compelling to ignore, even in the early stages of the qualitative study.

The primary purpose of the qualitative interviews was to explore barriers and facilitators to HIV risk reduction behaviors for study participants. Qualitative interviews were chosen over focus groups or participant observation to allow maximum confidentiality for participants, who are asked to share highly sensitive information, as well as to improve opportunities to explore and probe participant feedback. During TGP parties, the facilitators informed participants that some of them would be selected to be interviewed about their TGP experience after they complete the three-month follow up survey, and that if they were selected for and participate in the interview they would receive an additional incentive (a $25.00 gift card.) Intervention group participants who completed three month follow up surveys and control group women who have completed the TGP intervention were considered for interviews. The blinded surveys or post-intervention assessments were reviewed for content so that a variety of women were included in interviews. Women who reported changes as well as those who noted no change after participating in TGP were engaged in interviews in order to get a broad range of feedback. Once surveys were selected, they were matched by unique identifier to the participant. The TGP facilitator made the initial contact with the identified participant to see if she was willing to be interviewed. The Principal Investigator then followed up with the woman to schedule the interview. Interviews were primarily conducted in the homes of the participants.

The target number of interviews to be completed is between fifteen and twenty; six have been conducted to date. A copy of the interview protocol for the semi-structured interviews is included in Appendix D. Questions move from individual to broad, community-level factors. Information was solicited on items such as what women learn from the intervention, what changes they have experienced since participating, and what else can be done to reduce HIV risk for African Americans. Though no coding has been completed as of this writing, all of the interviews will be analyzed by two coders using ATLAS.ti version 6.2. A preliminary list of codes and their definitions have been developed, driven by program themes and theory as well as by data from the first three interviews. While these codes are likely to evolve over time, they are included in Table 10 as they provide some insight as to the themes of the interviews so far.

One of the most interesting themes that seems to be emerging is that each of the six women interviewed indicated that after participating in TGP she has continued sharing information about HIV with members of her social networks. Frequently this has occurred with family members, especially children, nieces and nephews. Intergenerational sharing may be an important way of changing how communities think about reducing the impact of HIV. Several of the women have asked PATF to consider having parties specifically for women and their daughters and other younger family members.

For some women, continuing the work of TGP has occurred in structured ways. One woman talked about initiating a “Wellbeing Group,” where women gather to take walks or to talk about a specific health topic. Several of the interviewees have talked about distributing condoms to friends during other activities, such as through game nights, “Girls Nights Out,” or meetings of other social or civic groups.

Three of the women explicitly noted changes in behaviors or communication with sexual partners after participating in TGP. In some cases this has occurred in the form of initiating conversations about condoms or risk prevention with sex partners. One married woman said that she and her husband had a conversation for the first time about their past sexual partners. Another woman who has been dating three men said that after TGP, she now only has sex with one of them because TGP helped her think about all of the ways she had not been putting her own health first. This concept of “doing me first” is important. Several of the TGP participants have noted that African American women often do not self-prioritize. TGP helps them see that they are worth caring for themselves and that they must do so before they can care for anyone else.

A number of ideas are emerging regarding TGP change mechanisms. All of the women interviewed talked about the importance of the fun, comfortable atmosphere, which made it easy for them to participate and to ask questions. Two participants said that a positive aspect of TGP is seeing that other women have the same questions as they did. All of the women felt that accessing HIV testing in their own or their friends’ homes was a huge benefit of the program, and that this characteristic made it much more likely for women to get tested. Some of the women said that they also brought their partners to be tested at the end of the TGP party. Women also commented on the graphic STI pictures that are show at parties, which seemed to open their eyes to the possibility of an STI – what that might look like, and that anyone could be infected.

When asked what could be done to improve TGP, a few themes may be emerging. Several of the women thought that having a personal perspective from someone living with HIV would help participants understand that HIV is real. One woman strongly emphasized this idea, saying that in her party participants talked a lot about their own experiences with STIs. This type of personal sharing made the importance of risk prevention much more real for her. A couple of the interviewees noted that they really liked the safer sex kits and brochures that are distributed through parties and would like to see more of these available. Most of the women said that they would like to see more TGP parties in their communities, and also said that they would like to see TGP follow-up parties or planned check-ins with participants to reinforce risk prevention and woman-to-woman support.

As TGP qualitative interviews continue, it will be interesting to see how these themes develop and how other ideas emerge. One additional item of note is that of the six women interviewed so far, two of them had demonstrated leadership in their social groups around sharing HIV information prior to TGP. This may mean that they are not representative of the target population and have different responses to the intervention than other participants have had. Their feedback is important, especially if it is found that one of the core mechanisms of TGP is that natural community leaders can be engaged through TGP to spread risk reduction messages through their communities. Nonetheless, an effort will be made going forward to coordinate with the TGP facilitators to ensure that women who are interviewed include those who have not served in these kinds of informal leadership positions with regards to HIV risk prevention.

Table 10. Preliminary Codes for Qualitative Analysis

CODE NAME	DEFINITION
TGP	Catchall; project related comments
TGP-OpportunityForImprovement	Specific mentions of ways in which project can be improved (e.g. newer pictures, personal perspectives, make them ongoing)
TGP-Confidentiality	Either way mention of confidentiality as important in the project
TGP-Stuff	Materials, pictures, pamphlets, safer sex kits, perks, free stuff, etc.
TGP-Atmosphere	Perception of the atmosphere created in the parties (e.g. easy, relaxed, fun, interesting, etc.)
TGP-Questions	Specific references to how questions are asked, answered, perceived in the context of the party.
TGP-Personalized	Connection with facilitator, follow-up, accessibility of the information
TGP-InterestHosting	Mention of interest, or no interest, of hosting a future party.
Relationships	Catchall; relationships category focuses on the quality of the relationships, more than in behavior or action
Relationships-ConnectingWithOthers	References to feeling connected, or not, to others, as well as what brings them together (e.g. sharing experiences, understanding)
Relationships-BetweenWomen	Descriptives regarding quality of relationships, how women relate with each other (generally), including getting along or not getting along
Relationships-MaleFemale	Descriptives regarding the quality of intimate male /female relationships.
Relationships-ReachingOut	Selflessness, advocacy, networking and other references of interest/value of helping others.
Behavior	Catchall; specific mentions of what behaviors are like in testing, sex, condoms, partners, drug use
Behavior-Change	Specific mentions of behavior that has changed.
Behavior-RiskAssessment	Thoughts about risk in the context of behavior, includes taking chances, acting in the heat of the moment (or the contrary)
Barriers/Facilitators	Catchall; barriers or facilitators (non-specific to TGP) of accessing services, getting information, communication, safer sex
Barriers/Facilitators-Fear	All mention of fear on asking, disease, testing, knowing, etc.
Barriers/Facilitators-Comfort	Comfort (positive or negative) in talking sex, testing, or others (non TGP)
Barriers/Facilitators-Access	Access as a barrier or facilitator to action (getting services, tested)
Knowledge	Catchall; knowledge about anything not in the two categories below (e.g. domestic violence)
Knowledge-Risk	Knowledge about risks and also how to prevent
Knowledge-Services	Knowledge of available services, where to go.

Table 10. Continued

ScialNetworks	Catchall; networks in which information is passed, but also references to these references of definition of networks
SocialNetworks-Friends	Friends
SocialNetworks-Family	Family as understood by women, or specific references to sons, daughters
SocialNetworks-Church	Church
SocialNetworks-Intergenerational	When intergenerational issues or dynamics make a difference
Self	Catchall; mentions of self, includes self-knowledge
Self-ResponsibleForSelf	Cannot blame someone else, it's up to you, do me first.
Self-ConfidenceInWhatYouKnow	Knowing what to do, being able to have a plan of action
Self-Esteem	Self-esteem
Miscellaneous	Catchall; all without a place
Miscellaneous-Stigma	Stigma
Miscellaneous-AfricanAmerican	Explicit references to being / experiencing / etc. for or as African-American
Miscellaneous-Men	Not in the context of intimate relationships with women (other code). Can include men's needs or characteristics
Miscellaneous-PastExperiences	Past experience
Miscellaneous-DiseaseDeath	Disease / death

8.0 THE GIRLFRIENDS PROJECT: SETTING A FUTURE RESEARCH AGENDA

It is apparent from the results of the quantitative analysis and preliminary qualitative findings that TGP has the potential to be an effective intervention. It certainly merits further research. The program has significant strengths that should be considered, which suggest a future research agenda. The remainder of this document is a discussion of this research agenda, including (1) the importance of this community-based evaluation model; (2) opportunities for program refinement and targeted recruitment; and (3) and additional options for program evaluation.

8.1 BENEFITS OF COMMUNITY-INFORMED EVALUATION

The section of this document that describes the development of a community- informed evaluation details a unique method of assessing process and outcome objectives. This research study was not just a research approach, but actually reflects a values orientation toward shared participation, decision-making, and ownership with community members. This approach is highly consistent with the principles of Community Based Participatory Research. These principles are increasingly used in evaluation research and include fostering community collaboratives throughout the research process, building on community strengths, promoting co-learning and capacity building, and emphasizing long term commitment and iterative systems development, among others (Israel, 2003). The TGP study supports the case that it is possible to conduct sound evaluation research with high levels of community input and decision-making, while maintaining compliance with the American Evaluation Associations Guiding Principles of systematic inquiry, competence, integrity, respect for people, and responsibilities for general and public welfare (AEA). It is hoped that this model of evaluation will be used more frequently in public health, particularly in the area of HIV risk reduction interventions.

Evaluating interventions in community settings will likely yield valuable information regarding "real world" effect size and may also increase the ease in which community based interventions are able to replicate and adopt evidence-based interventions. These are important steps in building true program sustainability. If efficacy research answers the question "Can it work?" and effectiveness research seeks to answer "Does it work?" hybrid models such as this one may bridge the efficacy vs. effectiveness gap by conducing rigorous evaluation in natural community settings (Atkins, Frazier, & Cappella, 2006; Luce et al., 2010). It is important that researchers consider contextual and community factors not as problems to overcome, but rather as strengths to help improve intervention relevance and interpretation of results.

There are a number of program assets underlying the success of this evaluation approach, which suggest best practices for future evaluation studies. Chief among these factors are the commitment and readiness to evaluate of the TGP founders, of the research collaborators, and of the Pittsburgh AIDS Task Force as the sponsor agency. The fact that the evaluation study was the Principal Investigator's dissertation research resulted in the evaluation being inexpensive while still being university-sponsored and mentored by experienced evaluation and HIV researchers. Building research collaboratives between academic settings and community based efforts is an important method of conducting effectiveness research, and this project is one model for success in this arena.

Besides the quantitative study results, the evaluation model itself is an indicator of success with its heavy reliance on community action and expertise. It is significant to note that approximately 150 African American women were engaged in a research study using natural recruitment methods, and that the vast majority of them were also engaged in HIV testing and counseling with a reported return rate for results that of 95%. It is hoped that more partnerships will be developed between academic research institutions, community based organizations, and funders to evaluate community developed interventions in real world settings.

8.2 INTERVENTION AND RECRUITMENT RECOMMENDATIONS

The preliminary results from the TGP evaluation provide some recommendations that may be useful for PATF to consider when refining and replicating the intervention. These recommendations focus on the areas of implementation processes, recruitment, and strengthening components of the intervention that may be integral to supporting risk reduction change. A summary of future opportunities for research is also included.

8.2.1 Process Measures and Implementation

Greater attention needs to be paid to TGP processes and consistency of implementation. Prior to the initiation of the study, both TGP facilitators did practice runs of the intervention for the research team and other members of the PATF prevention staff. The information that was delivered by each of the facilitators was fairly consistent. However, at the study mid-point, another practice run was conducted to check that the intervention elements and messages were stable. This time there was greater variability in the intervention delivery and some risk reduction messages were lost. It is difficult to know if this "slippage" was due to real differences in how the intervention was delivered or if it was a byproduct of delivering the intervention in an artificial environment. The facilitators contend it was the latter, and their perspectives and input are highly respected.

The Intervention Scope Assessment tool (See Appendix B) was understood and used by the facilitators, but had limited utility since all of the tools came back with the same results. According to the surveys, each of the TGP elements was delivered consistently for every party. This is unlikely, simply due to human nature and contextual issues. The tool should be re-evaluated for sensitivity. While the idea behind the tool was to give the facilitators an aid to improve consistency in implementation, it would be a more effective evaluation tool if a research assistant could accompany the facilitators to the parties and complete the scope assessment with a more impartial eye. This could be accomplished with additional funding.

Another concern lies in the apparent difference between the rate at which each of the facilitators recruited women for parties and engaged participants for follow up and qualitative interviews. This difference could be a reflection of diversity in work styles – one facilitator might simply be more steadfast about calling women, following up with them, etc. However, it could also be the case that there was a difference in how each of the facilitators was able to develop rapport or engage with the target population, or in the type of women to whom they were reaching out. These differences may or may not matter given that there was no apparent change in outcomes for TGP participants based on facilitator. Chi-square analyses were conducted to examine for differences in risk reduction outcomes based on which facilitator provided the intervention, and no significant differences were found. However, with additional funding support it would be useful to have a research assistant keep a closer eye on recruitment, paperwork, implementation, and follow up processes.

8.2.2 Recruitment Considerations

It will be important to evaluate the degree to which the intervention is able to reach the most high-risk members of the target population. The mean age of TGP participants was higher than expected, approximately 34 years of age. Feedback from community stakeholders and TGP participants has suggested that the program should reach younger women, who purportedly engage in greater frequencies of sexual and drug using behaviors that increase their risk for HIV. As noted previously, the only requirements for this study were that women self-identified as being African American and were between the ages of 18-65. It might be useful to focus recruitment specifically on young women, which could be achieved by increasing the emphasis on street outreach, African American sororities, and bars or clubs. However, it might also be the case that these women might not be interested in participation or might not experience the same program effects. One of unknowns regarding TGP is whether or not it will reach women who are the most marginalized and may be at highest risk for HIV, especially since the intervention is built on recruitment through existing social networks. It is quite possible that women who have limited social connections would never be recruited to TGP, and these are the women might be at highest risk for HIV.

It may also be the case that the program is reaching exactly who it needs to reach: African American women who are informal leaders in their communities and who could drive social change. Each one of the women who has participated in qualitative interviews to date has stressed that after participating in TGP, she has had more conversations about HIV risk with young family members, including children, cousins, nieces, and nephews. In some African American cultures, referring to others as all aunts, nieces, nephews and cousins does not actually infer a biological connection but might include close family friends as well. Thus, the reach of these conversations might be quite broad. An increase in intergenerational conversations could have a significant impact on how the community deals with HIV in the future. All of the participants of qualitative interviews have also indicated that since participating in TGP they have changed the way they relate to other women on issues related to self-care. If these outcomes are sustainable, they are huge.

8.2.3 "Tweaking" the Intervention

Preliminary research findings may be considered by PATF in order to refine and strengthen the intervention elements. It appears that, although there was a significant difference in changes in HIV Knowledge scores for the intervention group, increasing HIV knowledge change may not actually predict risk behavior change. Intentions for change and perception of risk may be better predictors. If this is true, the intervention could be altered to emphasize these ideas, perhaps by including personal perspectives from women who are HIV positive or who have had STIs, as has been suggested in several of the qualitative interviews. Being able to prioritize self-care has been mentioned repeatedly in the follow up surveys and also in the interviews. TGP could build this effect by making the "do me first" message more explicit. This could perhaps be accomplished by asking each woman to make a pledge to the group to carry out one activity or goal in which she commits to improving her own health.

The woman-to-woman connection that has been reported in qualitative interviews might also be strengthened. Women could be encouraged to create a buddy system or informal support network in which they check on each other's goals or otherwise provide support to one another around health goals. Given that some of the women who have hosted TGP parties have gone on to continue the process of sharing health messages, it might also be feasible to "deputize" women to serve as community contacts for HIV risk prevention or other health messages. Such TGP Deputies could serve as bridges to PATF and other providers, and could provide rich opportunities to link people at risk to HIV testing, clinical care, and other services.

Although TGP was developed as a single-session intervention, it is interesting that most of the qualitative interviewees have suggested that follow up or refresher sessions would be helpful. Discussions about the future of TGP should evaluate the possibility of adding a session to the intervention. These discussions should be heavily informed by the TGP facilitators, community stakeholders group, and qualitative interviews.

8.2.4 Future Research

While this evaluation study has required an incredible amount of time and commitment from the TGP research team and especially the facilitators, there is much more research to be done. First and foremost, a larger sample size is required to improve interpretation of results and assess the generalizability of the findings. It is hoped that research funding can be secured to conduct a stronger research design with a greater reach. Ideally, this would include a multi-site study, using one city as an intervention site with another matched city as a control site. This would provide a cleaner view of the intervention effects. It would also help determine if the intervention would work in other locations besides Allegheny County, where the population tends to be not very transient. Social network effects could be diluted in locations where people are more likely to move around.

Facilitator characteristics and strengths should also be evaluated, along with a better understanding of the core components of the intervention. In an ideal world we could systematically remove each of the elements of TGP (on site testing, STI pictures, social recruitment, etc.) to better assess the degree to which each element correlated with the target outcomes. A more realistic method might be to survey and interview participants more explicitly about why they did or did not change communication patterns or risk behaviors as a result of the TGP intervention, or to develop assessment tools with stronger psychometric properties to better assess the predictors of these changes.

An evaluation of the social network effects of TGP is particularly intriguing. Tracking the reach of TGP in an intervention naïve community would reveal important information about how risk reduction information could be disseminated and even saturated within the community. Community-wide intervention effects could then be modeled to understand its potential impact.

8.3 FINAL THOUGHTS

The results of the TGP evaluation study indicate that this community developed intervention may be a viable option for reducing HIV risk in the target population of African American women. The study also demonstrates the feasibility of conducting a community-rooted evaluation in real world settings, as well as the value of engaging community input through all phases of the development, implementation, and evaluation.

TGP may achieve its intended outcomes on several levels. Although it was designed as a behavioral intervention to reduce HIV rates among African American women, preliminary findings suggest that its greatest impact may occur on a structural level. "The Girlfriends Effect" describes women's increased propensity to share HIV risk reduction information within their social networks after participating in TGP. This effect suggests that the intervention may be useful in producing a community-level effect by improving social norms for condom use, HIV testing, and other risk reduction opportunities. Improving social communication specific to HIV could have a much bigger impact on the trajectory of the disease than encouraging condom use alone.

Improving accessibility of HIV testing to this population may be one of the most important components of TGP. Knowing one's status and accessing treatment early in the spectrum of the disease not only improves clinical prognoses but also decreases the likelihood of secondary transmission. Changing the way women and families access HIV testing and are linked to clinical care are aspects of TGP that are also structural in nature. While sustainability is challenged frequently faced by behavioral interventions, TGP may be a program that is sustainable in the truest sense. By empowering women to adopt risk reduction messages and to continue sharing information within the community, and by changing the way people access HIV testing, the HIV risk reduction processes could continue long after the program is gone.

The house party recruitment and intervention approach may be a strong vehicle for getting a variety of health resources to high risk and hard-to-reach individuals. This model could be used to share information with members of the target population on issues such as diabetes, heart disease, HPV vaccines for young women, and biological HIV prevention opportunities such as Pre-Exposure Prophylaxis or HIV vaccine research. The intervention could also be tailored to reach other populations. Through post-intervention surveys and qualitative interviews, women have asked that TGP be adapted to provide mother-daughter parties, couples parties, MSM parties, and parties for straight men. Additional research is needed to fully understand the impact that risk reduction interventions based on social network approaches may have toward improving population health.

In summary, this pilot study has cast a wide net to evaluate TGP's program effects and has demonstrated some exciting results. Statistically significant differences were noted for women who participated in the study in relation to increased condom use, improved sexual communication, decreases in high risk behaviors, and increases in risk reduction behaviors. Many of the women who have participated in TGP are excited about the intervention, value its intended goals, and wish to remain involved. TGP has also been well received by community leaders, the foundation community, and other AIDS service organizations. Clearly the program and this research study have been successful on a number of levels. It is hoped that the results contained in this document create a strong foundation for the next phase of TGP research.

APPENDIX A

THE GIRLFRIENDS PROJECT PROCEDURAL GUIDANCE

THE GIRLFRIENDS PROJECT
Policies and Procedures

1.0 OVERVIEW

1.1 The Girlfriends Project

The Girlfriends Project (TGP) is an HIV risk reduction intervention that was developed *by* African American women *for* African American women in order to reduce HIV incidence within their own communities. TGP builds on population strengths and is delivered in community settings. African American women are recruited to host TGP parties for their social networks. During the parties, trained facilitators present information specific to Human Immunodeficiency Virus (HIV), other sexually transmitted infections (STDs), Intimate Partner Violence, and proper condom use. Free HIV antibody testing is offered on-site.

1.2 Purpose

1.2.a. To empower women to improve or maintain sexual health by reducing the incidence of STDs, primarily HIV, by providing accurate information and demonstration.

1.2.b. To increase the number women who are aware of their status and are knowledgeable regarding HIV testing.

1.2.c. To minimize stigma associated with HIV by increasing knowledge and awareness.

2.0 IMPLEMENTATION

2.1 Logistics

2.1.a. Party duration: 1.5 – 2 hours for presentation plus 1 hour for testing.

2.1.b Minimum number of guests: 4 (Maximum set at facilitator's discretion.)

2.2 Recruitment

2.2.a. Utilize existing social networks

2.2.b. Identify women who are active and respected within the community & have them advocate with their peers

2.2.c. Connect with relevant community organizations & businesses

2.2.d. Attend health fairs

2.2.e. Speak to women's and parent's groups

2.2.f. Contact housing communities including senior residence communities

2.2.g. Contact past party guests via phone or mail to recruit them as hostesses and inform past hostesses of the incentive for referring others

2.2.h Posters in common, relevant areas i.e. libraries, support centers, etc.

2.3. Scheduling a Party

2.3.a. Ensure Hostess understands what the party entails, including University of Pittsburgh Research design

- Discuss Group Randomization Process
- Explain Intervention Arm (Amazing Groups) versus Wait-List Arm (Beautiful Groups) and Baseline Parties

2.3.b. Cover the expectations of the hostess and what the facilitator will provide

2.3.c. Information to gather
- Name and contact information
- Date and time
- Location
- Number of guests
- Type of food and drinks to bring
- Confirm that there is a confidential space for informed consent & testing

2.4. Before the Party

2.4.a. One to two weeks before the scheduled party date, mail a letter of confirmation to the Party Hostess confirming the date and time of the party. Along with this letter, mail a hostess contract detailing the expectations of what PATF and the hostess will each provide. Lastly include Initial Assessments for the Party Participants to complete before the party begins.

2.4.b. Confirmation Letter Checklist
- Confirmation Letter – Specify Amazing or Beautiful Group
- Hostess Contract
- Envelope with Girlfriends Project written or stamped on it

2.4.c. At least one day before the party, call to confirm the time, answer last-minute questions, and to determine the number of participants that are expected to attend.

2.5. Party Supplies checklist

2.5.a. Data Collection
- Sign-in sheet

- Consent Forms – Amazing Group or Beautiful Group
- Baseline Survey *or*
- Pre-Intervention Survey – Amazing Groups *or*
- Pre-Intervention Survey – Beautiful Groups
- Post-Intervention Survey
- Gift card incentive log

2.5.b. Educational

- Demonstrations: Penis & Vagina plastic models
- Male & Female Condoms
- Slideshow – laptop or slide printouts
- Pens
- Folders
- TGP brochure
- Pamphlets
- HIV information packet
- Domestic violence packet
- "Where to Turn" card
- Resource list

2.5.c. Food Supplies

- Plates
- Cups
- Napkins
- Forks
- Mints/Candy

2.5.d. Incentives

- Safe sex goody bag
- Condoms: two male, two female, two flavored, one dental dam, two lube packets
- Condom cases
- Extra condoms, lube, dental dams
- Raffle prizes
- Raffle slips/tickets

2.5.e. Testing Supplies

- Consent forms
- Bubble sheets
- Lab sheets
- Test kits
- Testing number card and/or business cards
- Biohazard bags
- Bag to collect testing trash

3.0 The Party

3.1 Informed Consent – Amazing or Beautiful Groups

3.1.a. Read the University of Pittsburgh IRB script to the group and distribute an informed consent form to each participant

3.1.b. Participants are taken into testing area one at a time to determine if they have any questions or concerns. Signed consent is received at this time.

3.2 Introduction

3.2.a. Introduction & Explanation of the program

3.2.b. Who we are, why we're here, PATF

3.2.c. University of Pittsburgh - Information we collect and why

3.3. Pre-Intervention Survey

3.3.a. Distribute Pre-Test & Folder – explanation of both

3.3.b. Remind participants of right to refuse

3.3.c. Collect Pre-Tests

3.3 Discussion

3.3.a Icebreaker

- Introductions
- Ground Rules
- Emphasize that all questions and discussions are confidential and stay in the room

3.3.b Gauge audience knowledge (asking questions about HIV, transmission, etc.)

3.3.c. Presentation: HIV and other STIS

- HIV/ AIDS – What it is, How it is transmitted, fluids, prevention, etc.
- Address misconceptions, common myths, stigma
- HIV Prevention Methods
- Abstinence, Safer Sex, Safer Drug Use, Riskier vs. Safer Behaviors & Other related behaviors – drinking, etc.
- STDs
- Present slides and provide information on the different types of STDs, common symptoms, some specifics
- Condom demonstration

- Show guests how to use the male & female condoms and a dental dam
- Allow guests to try using the condoms with the demonstrators

3.3.d. Intimate Partner Violence

- Definition – domestic abuse is about control, etc.
- Facts & Statistics
- Types of Abuse & Cycle of Abuse
- Prevention & Escaping an abusive relationship

3.3.e. Wrap Up

- Review HIV prevention & transmission
- Remind participants of folder resources & contact information
- Talk about scheduling future parties

3.3.f. Distribute Post-Test & Collect upon completion

3.3.g. HIV Testing and Counseling

- Ensure that participants know that testing is optional, free, and painless
- Hand out consent forms
- Counsel & test in a confidential space
- Inform participants when to expect results and explain how they will be contacted for results

3.4 After the Party

3.4.a. Gather all informed consent forms and place in sealed 8.5 x 11" envelope. On the outside of the envelope, record the facilitator's name and the date of the party. Informed consent forms are placed in locked filing cabinets at PATF.

3.4.b. Gather all sign-in sheets and place in sealed 8.5 x 11" envelope. On the outside of the envelope, record the facilitator's name and the date of the party. Sign-in sheets with contact information will be placed in locked filing cabinets at PATF.

3.4.c. Gather all Baseline, Pre- and Post Assessment tools and place in sealed 8.5 x 11" envelope. On the outside of the envelope, record the facilitator's name and the date of the party. No participant identifying information is to be included in this envelope. These envelopes are handed to the Principal Investigator during weekly TGP Research Team meetings.

3.4.d. Complete **TGP Intervention Scope Assessment Tool**

4.0 HIV Testing and Counseling Results

4.1. When results are in, call the hostess to arrange a time to give her and her guests their results.

- Schedule time with individuals as needed.
- Facilitators strive to ensure that all results will be given within two weeks after results arrive at PATF.

4.2. Procedure for Positives

4.2.a. If someone tests positive, the facilitator will schedule a time to give the result in the most private setting. The facilitator will follow the same policies and procedures as when giving a positive result in the PATF office.

4.2.b. During the weekly TGP Research Team Meeting, the Principal Investigator is informed of any positive results. Demographic information is included (race, age, risk factors, date of party attended, etc.), however no identifying information will be shared with the PI.

5.0 Follow-up

5.1. Three months from the party date, follow-up assessments are conducted with party participants

5.1.a. Facilitators call hostesses and participants to advise them to watch for the survey, and to remind them of the incentive options

5.1.b. Post Assessment packets are mailed to participants

5.1.c. Post-Assessment Checklist

- Information regarding incentives for completing the Post-Assessment survey
- Post-Assessment
- Incentive Letter
- Return envelope
- Envelope with “Girlfriends Project” written or stamped on it.

6.0 Tips

- Refer to “The Girlfriends Project” instead of PATF when leaving a message or talking to a participant in front of others. They may be uncomfortable being associated with PATF.
- If electricity is needed, make sure the hostess can accommodate.
- During the active evaluation period, ensure that hostesses and participants understand the purpose of the data collection process, and how confidentiality of data is assured

Forms Checklist for TGP Parties

AMAZING GROUPS

☐ Sign-in sheet
☐ Participant Recruitment Scripts – Amazing Groups
☐ Consent Forms – Amazing Groups (Twice as many as needed)
☐ Pre-Intervention Survey – Amazing Groups (Green)
☐ Post-Intervention Survey (Purple)
☐ TGP Intervention Scope Assessment Tool
☐ Gift card incentive log

BEAUTIFUL BASELINE GROUPS

☐ Sign-in sheet
☐ Participant Recruitment Scripts – Beautiful Groups
☐ Consent Forms –Beautiful Group (Twice as many as needed)
☐ Pre-Party Survey – Beautiful Groups (Blue)
☐ Gift card incentive log

BEAUTIFUL PARTY GROUPS

☐ Sign-in sheet
☐ Pre-Intervention - Beautiful Groups (Yellow)
☐ Post-Intervention Survey (White)
☐ TGP Intervention Scope Assessment Tool
☐ Gift card incentive log

APPENDIX B

TGP INTERVENTION SCOPE ASSESSMENT TOOL

TGP INTERVENTION SCOPE ASSESSMENT TOOL

Facilitator ______________________________ Observer ___________________________________ Date of Party ___________________

Exercise	Purpose	Fidelity Ranking (1 – 3*)	Notes
3.1.Informed Consent	Ensures that all participants understand data collection processes, purpose of data collection, involvement of University of Pittsburgh researcher, and that no identifying information is shared with Principal Investigator		
3.2. Introduction	Explain background of TGP and PATF, begins data collection process, ensures that all participants understand data collection tool and their right to refuse		
3.3 Discussion	Information-sharing portion of the intervention		
3.3.a. Icebreaker	Sets informal and fun tone of intervention, ensures introduction of facilitators and participants, ensures that all participant understand their responsibilities to confidentiality, enables participants to warm up to each other and to facilitator. Begins rapport-building process.		
3.3.b.Gauge audience knowledge	Allows facilitator to informally asses group level of knowledge regarding HIV, identify participants that are outspoken versus in need of encouragement to participate		
3.3.c. HIV & STIs	Ensures that participants have information regarding HIV and STIs, methods of risk		

	reduction, and how to access and use male and female condoms.		
3.3.d. IPV	Ensures that participants are able to identify risk factors for IPV and how to know if they are in a violent relationship. Ensures participants know how to access support.		
3.3.e. Wrap Up	Ensures that main points are emphasized and that participants know how to access additional information including future TGP parties.		
3.3.f. Post-Test	Post intervention surveys are distributed and collected.		
3.3.g. HIV Testing and Counseling	Enables participants to access confidential HIV testing and ensures they understand how and when results will be shared.		

Fidelity Ranking Code
1 = Many elements of the exercise were *not* delivered as intended
2 = Most of the elements of the exercise were delivered as intended
3 = All of the elements of the exercise were delivered as intended

Observer Notes: (Include any anecdotal information such as the spirit of the party, general response to the intervention and facilitator, comments women made about the intervention, etc.)

____

____

____

____

____

____

____

Referrals Placed (if place, indicate number):
______ Domestic Violence
______ STD Screening
______ Medical Care
______ Medical Care for HIV
______ Addictions Support
______ Mental Health Support
______ Other: ____

APPENDIX C

TGP SAMPLE ASSESSMENT TOOL

The Girlfriends Project

Pittsburgh AIDS Task Force

Pre-Party Survey

Please write your initials: ____________

Please write the YEAR you were born: ____________

A. For each statement, please circle "True" (T), "False" (F), or "Don't Know" (DK). If you do not know, please do not guess, just circle "DK."

1.	Coughing and sneezing DO NOT spread HIV.	T	F	DK
2.	A person can get HIV by sharing a glass of water with someone who has HIV/AIDS.	T	F	DK
3.	Pulling out the penis before a man climaxes/cums keeps a woman from getting HIV during sex.	T	F	DK
4.	A woman can get HIV if she has anal sex with a man who has HIV/AIDS.	T	F	DK
5.	Showering or washing one's genitals/private parts after sex keeps a person from getting HIV.	T	F	DK
6.	All pregnant women infected with HIV will have babies born with AIDS.	T	F	DK
7.	People who have been infected with HIV quickly show serious signs of being infected.	T	F	DK
8.	There is a vaccine that can stop adults from getting HIV.	T	F	DK
9.	People are likely to get HIV by deep kissing, putting their tongue in their partner's mouth, if their partner has HIV/AIDS.	T	F	DK

Facilitator Initials & Date: ____________

10. A woman cannot get HIV if she has sex during her period. T F DK

11. Washing drug use equipment/ “works” with cold water kills HIV. T F DK

12. There is a female condom that can help decrease a woman’s chance of getting HIV. T F DK

13. A natural skin condom works better against HIV than does a latex condom. T F DK

14. A person will NOT get HIV if she or he is taking antibiotics. T F DK

15. Having sex with more than one partner can increase a person’s chance of being infected with HIV. T F DK

16. Taking a test for HIV one week after having sex will tell a person if she or he has HIV. T F DK

17. A person can get HIV by sitting in a hot tub or a swimming pool with a person who has HIV/AIDS. T F DK

18. A person can get HIV from oral sex with someone with HIV/AIDS. T F DK

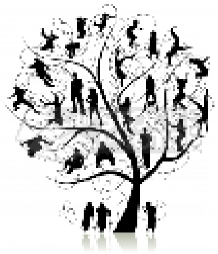
19. Using Vaseline or baby oil with condoms lowers the chance of getting HIV. T F DK

20. HIV is killed on needles or syringes by cleaning with bleach. T F DK

21. Diabetics who share needles to use insulin can get HIV from the needles. T F DK

22. Athletes who share needles when using steroids can get HIV from the needles. T F DK

23. You can tell if someone has HIV by the way they look. T F DK



B. The next questions ask what you think about people's chances of getting AIDS. Please circle the number that best describes what you think.

1. Based on your sexual behavior over the past year, how much do you think you are at risk for getting HIV?

(1)	(2)	(3)	(4)	(5)
No Risk	Not Much	No Feelings	A Good Deal	Extremely
At All	Risk	Either Way	at Risk	At Risk

2. What is the chance that you will someday get HIV?

(1)	(2)	(3)	(4)	(5)
No Risk	Not Much	No Feelings	A Good Deal	Extremely
At All	Risk	Either Way	at Risk	At Risk

3. If you were to make a guess, what is the chance that the average woman in your community will someday get HIV?

(1)	(2)	(3)	(4)	(5)
No Risk	Not Much	No Feelings	A Good Deal	Extremely
At All	Risk	Either Way	at Risk	At Risk

4. If you were to make a guess, what is the chance that the average man in your community will someday get HIV?

(1)	(2)	(3)	(4)	(5)
No Risk	Not Much	No Feelings	A Good Deal	Extremely
At All	Risk	Either Way	at Risk	At Risk

5. Do you think that HIV/AIDS is a serious problem in your community?

(1)	(2)	(3)	(4)	(5)
No Problem	Not Much	No Feelings	It is Somewhat	It is a Very
At All	of a Problem	Either Way	of a Problem	Serious Problem

C. Imagine this situation:

You are at a party. You are having a great time. A man you like wants to have sex with you. You are very attracted to this man and you really want to be with him. You are dancing together, and you are both very turned on. You talk about going back to your place, but you already know that he hates condoms. He is really fine, and you are turned on by him. He says, "Let's go back to your place, have a drink, and have sex."

With this scene in your mind, read the statements below. Think about each statement, and circle the number that describes what you would do. Please say **what you would really do**, not what you think you should do.

	Definitely Will Not Do	Unlikely To Do	May or May Not Do	Likely To Do	Definitely Will Do
1. I will use a condom.	1	2	3	4	5
2. I will tell the man that we need to practice safer sex.	1	2	3	4	5
3. I will only do safer-sex behaviors.	1	2	3	4	5
4. I will not drink or use drugs before sex so I can be clear-headed.	1	2	3	4	5
5. I will tell the man I don't want to have intercourse without a condom.	1	2	3	4	5
6. I will decide ahead of time what I will and will not be willing to do.	1	2	3	4	5
7. I will actively guide our actions to have safe sex.	1	2	3	4	5

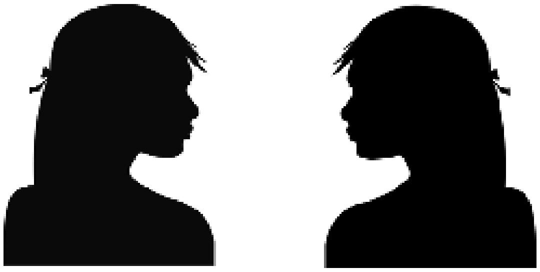
D. Please think about the PAST 3 MONTHS. ***Write in the number of times you have done each behavior during the past 3 months.*** **If you cannot remember the exact number of times, please try to guess this number as close as you can. If you did not do a behavior, write a zero (0) in the space. Please write a number in every space.**

1. In the past 3 months, how many times have you had **vaginal** sex (man's penis in your vagina) **without** condoms?	____ times in the past 3 months
2. In the past 3 months, how many times have you had **vaginal** sex (man's penis in your vagina) **with** condoms?	____ times in the past 3 months
3. In the past 3 months, how many times have you had **anal** sex (man's penis in your rectum) **without** condoms?	____ times in the past 3 months
4. In the past 3 months, how many times have you had **anal** sex (man's penis in your rectum) **with** condoms?	____ times in the past 3 months
5. In the past 3 months, how many times have you used a dirty needle (already used by someone else) to inject drugs **or** medicine?	____ times in the past 3 months
6. In the past 3 months, how many men have you had sex with?	____ men
7. In the past 3 months, how many women have you had sex with?	____ women
8. In the past 3 months, how many times have you talked with a sex partner about using condoms or having safer sex?	____ times in the past 3 months
9. In the past 3 months, how many times have you refused to have sex with a man because he would not use a condom?	____ times in the past 3 months
10. In the past 3 months, how many times have you tried to cut down on your drinking or drug use before having sex?	____ times in the past 3 months ____ I don't drink or use drugs
11. In the past 3 months, how many times have you talked with a sex partner about getting tested for the AIDS virus?	____ times in the past 3 months
12. In the past 3 months, how many times have you cleaned your needles/ "works" with bleach?	____ times in the past 3 months ____ I don't use needles

13. In the past 3 months, how many times have you and your sex partner(s) talked about:				
a. How to prevent pregnancy?	Never	Sometimes (1 – 3 times)	Often (4 – 6 times)	A Lot (7 or more times)
b. How to use condoms?	Never	Sometimes (1 – 3 times)	Often (4 – 6 times)	A Lot (7 or more times)
c. How to prevent HIV?	Never	Sometimes (1 – 3 times)	Often (4 – 6 times)	A Lot (7 or more times)
d. How to prevent Sexually Transmitted Diseases?	Never	Sometimes (1 – 3 times)	Often (4 – 6 times)	A Lot (7 or more times)
e. Your partner's sex history?	Never	Sometimes (1 – 3 times)	Often (4 – 6 times)	A Lot (7 or more times)

E. Please circle one answer to each question.

1. **In the past year**, how many times have you had a sexual disease (STI or VD) such as Syphilis, Gonorrhea, Herpes, and/or Chlamydia?	None	1 or 2 Times	3 – 10 Times	More than 10 Times
2. **In the past year**, how many times has a man given you money or drugs to have sex with him?	None	1 or 2 Times	3 – 10 Times	More than 10 Times



Keep going… you're almost done!

F. Tell us a little bit about your history with The Girlfriends Project.

1a. How many Girlfriends Parties have you been to before today? __________

1b. Other than the women at this party and the party hostess, how many women do you know that have attended Girlfriends Parties? __________

2. Do you talk to any family members about HIV risk?

None A Few Most All

3. Do you talk to any friends about HIV risk?

None A Few Most All

4. Do you think any of your friends use male or female condoms?

None A Few Most All

5. Do any of your friends talk to you about using male or female condoms?

None A Few Most All

6. Do you feel you are able to talk to your sexual partner(s) about using condoms?

No, Not at All Not Very Much Somewhat Yes, Very Much

7. Do you feel that you have the power to reduce your risk for HIV?

No, Not at All Not Very Much Somewhat Yes, Very Much

G. Please answer the last few questions.

1. Circle the highest grade you have completed.	☐ Elementary School ☐ High School or GED ☐ Professional Certification ☐ College ☐ Master's or Higher
2. What is your total yearly income?	☐ Less than $10,000 ☐ $10,000 to $14,999 ☐ $15,000 to $24,999 ☐ $25,000 to $34,999 ☐ $35,000 to $49,999 ☐ $50,000 or more

3. How many hours per week do you work outside of your home? _______ hours per week

4. What is your zip code? ____________________________

5. Which of the following best describes you?

(1) African American	(4) European American/White
(2) Hispanic American	(5) Asian American
(3) Native American	(6) Other, please list: ______________________

6. Have you known or do you know anyone who has HIV or AIDS?	(1) Yes	(2) No	(3) Don't Know
7. Have you been tested for HIV, the AIDS virus?	(1) Yes	(2) No	(3) Don't Know
8. If yes, please circle your HIV status:	(1) HIV Negative	(2) HIV Positive	(3) Don't Know

THANK YOU FOR YOUR HELP!

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APPENDIX D

SEMI-STRUCTURED INTERVIEW PROTOCOL

1. Overall, what did you think about The Girlfriends Project?
2. What was the most useful thing about TGP? Least useful?
3. Would you say TGP helped you to reduce your risk?
    a. If yes, what helped?
    b. If no, what kept you from changing?
4. What if anything did you learn about how to decrease HIV risk related to IV drug use? Is this something you've been able to do?
5. Did you get tested at the TGP party? Was that the first time you had tested? If so, why did you get a test this time?
6. How do you think your friends feel about using condoms? What do you think about condoms? Has this changed since the party?
7. Is there a situation when would you *always* use a condom? When would you *never* use a condom?
8. Are there certain groups of friends you talk to about using condoms? Are there friends you never talk to about using condoms?
9. The way TGP works is that women host house parties for their friends to learn about HIV and get tested. Do you think this house party idea works? Why or why not?
10. Have the conversations you've had with other people about HIV risk changed at all since TGP? How have they changed or not changed?
11. One of the ideas behind TGP is that women talking together about HIV will help to reduce HIV infection rates. Do you think this will make a difference?

12. Without naming names, what are some of the things that the people you know that increase their risks for HIV?
13. How big of a problem do you think HIV is for African Americans in our area? Why?
    a. Is this different for men and women?
14. If we want to stop HIV infections in our region, what are all of the things that get in the way of that?
15. When you think of your community, who do you include in that? What are things that people in your community can do to reduce HIV?
16. What are things that people outside your community can do to help reduce HIV among African Americans?
17. Is there anything else you want me to know about HIV or TGP?

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