Selection of populations represented in the NIMH Collaborative HIV/STD Prevention Trial

NIMH Collaborative HIV/STD Prevention Trial Group*

Objective: To identify venues with vulnerable populations suitable for testing the community popular opinion leader intervention in each of the five countries (China, India, Peru, Russia, and Zimbabwe) participating in the National Institute of Mental Health (NIMH) Collaborative HIV/STD Prevention Trial.

Design: HIV epidemiology and vulnerable populations differ considerably across the countries. Therefore, different community populations were targeted in the five countries.

Methods: Venues and populations were chosen on the basis of specific selection criteria (investigated during the Trial's ethnographic research phase): the willingness of stakeholders and gatekeepers of the venues to cooperate; geographical boundaries defining each venue; population stability within venues; the independence of venues and non-overlap of population members across multiple venues; population size within each venue; social interaction opportunities; and either a high level of sexual risk behavior or a high prevalence of sexually transmitted diseases (STDs) or HIV.

Results: Venues and populations selected were food market stall owners and workers in China, male patrons of wine shops and at-risk women congregating near the shops in India, young men and women in social gathering points in neighborhoods in Peru, trade and vocational school dormitory residents in Russia, and people congregating in growth points in Zimbabwe.

Conclusion: Although the target populations differed across countries, they shared in common high behavioral or biological risk at baseline and suitability for a randomized trial of a community-level HIV/STD prevention behavioral intervention.

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Introduction

Conduct of the National Institute of Mental Health (NIMH) Collaborative HIV/STD Prevention Trial (hereafter, the Trial) required the identification of vulnerable populations in each of the five countries (China, India, Peru, Russia, and Zimbabwe) represented in the Trial. HIV epidemiology differs considerably across the countries. Vulnerable populations also differ, and an objective of the trial was to determine the applicability of the community popular opinion leader (C-POL) intervention model across varied populations and cultures. For these reasons, different community populations were targeted in the five countries. The purpose of this article is to describe these populations, provide the rationale for the selection of each, and describe the community venues in which population members were assessed and intervention activities were conducted.

The target population selection process required each country site to identify at least 20 venues with similar populations, each of which would be randomly assigned to the experimental or comparison condition in the main outcome Trial. Venues were defined as geographically discrete places in which members of the site's target population live or extensively socialize. The nature of the C-POL intervention, the Trial's design, and the evaluation approach planned for the Trial required that venues be chosen with attention to a number of selection criteria. These criteria, which were the subject of investigation during the Trial's formative ethnographic research, included the following:

* See Appendix B for members of the NIMH Collaborative HIV/STD Prevention Trial Group.

Feasibility reflected the willingness of stakeholders and gatekeepers of the venues to cooperate with the research team in the conduct of assessment and intervention activities in the venue. These individuals included managers or owners of commercial venues, local officials, community leaders, and others whose cooperation was essential.

Boundaries were identified so that each venue became a geographically definable place. At some sites, a venue was a physical structure in which population members lived (Russia's dormitories), drank alcohol and socialized (India's wine shops), or worked (China's food markets). At other sites, a venue was defined as a discrete, compact neighborhood setting, such as Peru's barrios or Zimbabwe's growth points, rather than a single building.

Stability of population members present within a venue was sought. As a community-level intervention that rests on the premise that population members know one another and must be present regularly in a venue to be adequately exposed to the ongoing intervention, site researchers identified venues characterized by stable, non-transient populations. Under ideal circumstances, a high proportion of the same people would be seen regularly in the venue during multiple observation periods. Such stability would be critical for successful long-term study cohort maintenance and follow-up. At all sites and venues, inclusion criteria for participants in the Trial assessment cohort thus required that prospective participants report plans to remain present for at least the next year.

Independence of venues and non-overlap of population members across multiple venues was sought to minimize contamination across experimental conditions after randomization. To the greatest extent possible, site researchers selected venues that had populations that did not socialize or interact extensively with individuals from other venues so as to lessen the likelihood of 'cross contamination' among population members in intervention and comparison venues.

Population size within a venue was an additional consideration. If venues were too large, it would be difficult to ensure adequate and sustained population member exposure to the intervention. Because the C-POL intervention model requires that at least 15% of population members be trained to deliver prevention messages, it was necessary to estimate the size of the population present in each venue to determine how many C-POLs would need to be trained. In general, sites attempted to select venues with estimated population sizes of between 150 and 500 individuals.

Social interaction opportunities within or near the venue were needed so that C-POLs could communicate HIV prevention messages to others in the venue during the course of everyday conversations. Most sites' venues were social and had naturally occurring opportunities for conversation between C-POLs and others. In cases in which social interaction opportunities were limited, research staff stimulated opportunities by staging events that created social interactions between C-POLs and other population members in or near the venues.

A high level of sexual risk behavior or a high prevalence of sexually transmitted disease (STD)/HIV among individuals present in study venues was essential both to justify the need for intervention and to ensure that baseline risk indicators would be great enough for the Trial to detect changes in behavior or STD incidence after the intervention. Although potential venues were initially selected because of expected behavioral or disease risk, each site performed initial epidemiological studies in the planned venues to verify the presence of high levels of sexual risk behavior, high STD prevalence, or both. As we will discuss shortly in more detail, these epidemiological studies confirmed sufficient risk in the planned venues chosen by some country sites but not in others. In the latter situations, new, higher-risk population segments and venues were identified for the main Trial.

The process of target population identification and venue selection required extensive fieldwork, ethnography, and preliminary epidemiological research to identify relevant vulnerable populations in each country and select venues appropriate for the design and methods followed in the Trial. Individuals within a venue were excluded from participation if they could not give informed consent (e.g. were intoxicated) or if they had a permanent disability (e.g. deafness, serious mental illness, mental retardation). Site-specific inclusion and exclusion criteria are given within the description of each site's target population.

In world regions with high HIV prevalence, high disease incidence and a high threat of HIV/AIDS, multiple community populations are vulnerable and could have been appropriately selected as Trial populations. At each country site, consideration was given early in the Trial to varied target populations, and epidemiological/formative studies were undertaken with multiple population segments at most sites. The final selection of a site's target population was determined by evidence of its behavioral or biological risk and also by study design, venue characteristics, feasibility, population access, and other considerations. The population selected in a country was not the only one vulnerable to HIV/AIDS, and others might also have been chosen. The selection of five varied target populations in five different countries is a strength of the Trial design.

The following sections separately describe venue selection in each of the participating countries. The section for each country first describes the country's ultimate target population, then describes the HIV epidemiology and

rationale for the target population selected as well as alternative populations considered but eliminated. Each section describes the rationale for the study venues and the initial epidemiological explorations that supported venue selection in that country.

China site study population

Description of the China site target population

In China, food market workers in Fuzhou were identified as an appropriate target population because they had the following characteristics: (i) a sufficient base rate of STD on the basis of the results of anonymous risk assessments; (ii) a relatively stable population that allowed for follow-up over an extended period of time; (iii) a sufficient number of venues of manageable size; (iv) stable social groups; (v) support of local gatekeepers and stakeholders for the intervention; (vi) organizational capacity in the local health department to mount the intervention; (vii) similar demographic profiles across potential venues; and (viii) sufficient distance separation between the venues to minimize contamination. Individuals 18–49 years of age who worked in a selected market were eligible for participation in the assessment cohort. Individuals were excluded if they reported having no sexual activity in the previous 6 months and if biological test results were also negative for STD and HIV at the baseline assessment.

HIV epidemiology in China and rationale for target population selection

Over the past 10 years, the incidence of STD and HIV infections in China has increased dramatically. The number of new STD reported in China increased from 13 in 1977 to over 460 000 in 1997 [1]. In 1997, the rate of reported STD increased 16% over the previous year, with further increases of 37% in 1998 and 42% in 1999 [2]. Simultaneously, HIV was identified in each of China's 31 provinces [3], with estimates of at least one million individuals infected [4] when target population selection began.

The HIV epidemic in China affects different populations in different regions and through different modes of transmission. In central China, HIV outbreaks have primarily been among former plasma donors. In southwest China, the epidemic is mainly driven by injection drug use. On the eastern coast of China (including Fujian Province), the major mode of transmission is heterosexual intercourse, which accounts for more than 80% of total reported HIV infections. Therefore, Fuzhou, the capital city of Fujian Province, was selected as the China study site.

Ethnographic data were collected to identify the specific population at risk of STD that could be targeted with the intervention, and to determine how the intervention should be tailored for the target population and venues. Ethnographic methods used included participant observation, focus groups, interviews, and social mapping. Interviews with Chinese food market managers and a few market employees suggested that market workers might have high-risk sexual behaviors. Additional ethnographic data supported the applicability of the C-POL model in this population [5]. Moreover, a self-administrated anonymous risk assessment questionnaire was implemented with 180 market employees during initial ethnographic studies. Sexual risk behaviors were high among market workers when sexual risk was defined as having multiple sexual partners in the past year.

Description of and rationale for study venues

The existing research literature in China identified five high-risk groups for HIV/STD: (i) sex workers and their clients [6,7]; (ii) injection drug users (IDU) and their sexual partners [8,9]; (iii) men who have sex with men (MSM) [10]; (iv) STD patients and their spouses [11]; and (v) migrants [12]. Each of these populations was investigated but eventually eliminated for a variety of reasons. Sex workers are very mobile, and it would not have been feasible to track a cohort over time. IDU engage in an illegal activity; identifying them as a high-risk population and tracking them over time in a highly visible study would be difficult and might result in incarceration and further stigmatization. MSM are not socially accepted in China; potential stigmatization would reduce the willingness to be identified and included in studies, particularly a longitudinal study. Individuals seeking treatment at STD clinics are also highly stigmatized; fewer than half of STD patients in China go to STD clinics [13,14]. Previous research suggests that no more than 50% of this population could be assessed and engaged to participate in the intervention, limiting the external validity of the sample. Migrants are at very high risk but are also highly mobile, preventing long-term tracking.

After examining and eliminating these five potential risk groups, the collaborative investigators conducted a series of interviews and focus groups with key informants that included public health officials, health education specialists, and HIV prevention researchers. These interviews suggested that food markets would satisfy the selection criteria for study venues. Food market workers in China are often stable migrants who live in the city on and off throughout their lives. Markets typically have 50–150 stalls, with a total of 100–300 stall owners and employees. Social activities for market workers usually center within a few blocks of the market because market workers usually live close by and socialize within the area. Maps have shown that karaoke bars and beauty parlors are often located near the markets. Fuzhou has approximately 150 food markets.

Initial epidemiological study findings that supported venue selection

The impression that food markets would be appropriate venues was confirmed during the epidemiological study

when 81 out of 739 male (11.0%) and 194 out of 789 female (24.6%) market stall owners or employees had at least one of the following STDs on biological testing: chlamydia, gonorrhea, HIV, herpes simplex virus type 2 (HSV-2), syphilis, or trichomonas. The higher STD prevalence among women than men was because of greater chlamydia rates and because only women's vaginal swabs were cultured for trichomonas. Although other groups from various geographical areas were considered, the risk characteristics of food market workers and the feasibility of food markets as study venues thus led to their selection as the China site population.

India site study population

Description of the India site target population

The India site target population was patrons of wine shops in Chennai, India, and the high-risk women who frequent the area near them. Wine shops serve mostly beer and distilled spirits of both local and international origin. A wine shop is usually a closed space approximately 28–56 square meters in size. In addition to selling liquor on a take-out basis, the shops cater to clients who want to sit down, order food, and drink. Seating areas are usually inside the wine shop or adjacent to it, and serve as a place of conversation and gathering. Wine shops are staffed by wine shop sellers (who sell liquor and receive cash) and by bar boys and bar help (who help serve food and snacks).

Wine shops are patronized primarily by men who may or may not be from nearby slum communities. Men commonly go with friends to a familiar wine shop where they drink and socialize in the attached bar. Women seldom drink in wine shops; they usually send a male friend to purchase liquor that they drink in private places such as homes. High-risk women, however, frequently meet men outside the wine shops. Typically, a small group of women will be found near a small cluster of wine shops. It is thus possible to link a group of women to a cluster of wine shops. As these women tend to frequent an area where they are known and know others, the likelihood of one of them meeting men from wine shops outside of a specific cluster is very low. A cluster of wine shops defined a venue for the Trial. Patrons aged 18–40 years who frequented the selected wine shops at least four times per week and the high-risk women associated with the cluster of wine shops were recruited to participate in the assessment cohort for the Trial.

HIV epidemiology in India and rationale for target population selection

The HIV epidemic is growing in India. Although HIV prevalence is less than 1% nationwide, India has a population of over one billion and the largest number of individuals living with HIV/AIDS outside of Africa. In India, HIV transmission is primarily through heterosexual intercourse. Studies suggest that intervening at the community level and targeting high-risk behaviors such as multiple sex partners and sex with sex workers is an important priority for HIV prevention [15].

An emerging factor of interest in HIV transmission is the role of alcohol use. Studies exploring the association between alcohol use and sexual risk, primarily conducted in the United States and other developed countries, have yielded mixed results. Some research on alcohol use and sexual risk behavior has been conducted in India. Early reports of the co-existence of alcohol use and risky sexual behaviors have, however, spurred calls for more research into the purported association. For example, 15.9% of truck drivers surveyed in northern India were HIV positive, whereas 60% reported alcohol consumption [16]. Evidence of alcohol dependency also exists among female sex workers; 81% of sex workers surveyed in Kolkata city in eastern India reported being dependent on alcohol [17]. Data from an alcohol rehabilitation center in south India suggest that over 70% of HIV-positive patients reportedly acquired HIV while under the influence of alcohol [18].

Description of and rationale for study venues

Four potential types of venues were initially explored for the Trial in India, industrial units, lodging houses called 'mansions', construction workers, and low-income public housing units called 'slums'. Of these, only the slums appeared to meet all of the venue selection criteria. Site researchers were able to secure the permission of key community gatekeepers, which made the slums feasible venues. Preliminary ethnographic studies suggested high levels of sexual risk and other behaviors such as alcohol use and intimate partner violence that might increase an individual's vulnerability to contracting HIV. Slum communities were also relatively stable. Most residents had lived there for a long time and anticipated living there through the time of the Trial. Finally, participation rates in the slums would be high because community stakeholders were keen to participate in the study. Upward of 700 slums existed in Chennai; therefore, it was possible to select the required number of slums in the size range specified by the Trial. As explained below, however, epidemiological study findings led the research team later to narrow the target population only to members of the slum population who frequented wine shops and the high-risk women near those shops.

Initial epidemiological study findings that supported venue selection

India site researchers first considered defining venues as entire slums, and conducted an epidemiological study of 1540 randomly selected slum residents to assess behavioral risk and the prevalence of HIV and other selected STDs. Only 0.7% of participants were HIV positive, and the frequency of multiple sex partnerships and other risk

behaviors was low. The prevalence of STD, including HIV, was under 10% in eight of 28 slum communities surveyed. On the other hand, over 20% of participants tested positive for an STD in seven communities. In the light of this evidence, the research team examined more closely the 10 slums with the highest STD rates. Ethnographic studies revealed that alcohol use was high in those venues, and that these slums were proximate to wine shops or alcohol outlets, places where sexual groups and alcohol users seemed to converge geographically. To test the effects of the intervention, the researchers selected 24 clusters of wine shops that conformed to the venue identification criteria. Each had four to five wine shops. A second epidemiological study of 1358 wine shop patrons was conducted. The findings revealed a high HIV prevalence (3.0%). Seventy-six per cent of wine shop patrons reported unprotected sex, and 43% of men reported that their most recent sexual partner was a female sex worker. These data, supported by in-depth ethnography findings, suggested that clusters of wine shops were appropriate venues for the Trial.

Peru site study population

Description of the Peru site target population

A barrio in Peru is a neighborhood with boundaries known to all inhabitants. The Trial venues in Peru were defined as sites composed of people within a lower socioeconomic barrio belonging to the following three subpopulations:

Esquineros: young men who are permanently or primarily unemployed, who generally are not in school, who usually drink large amounts of alcohol at least once a week, who often use drugs (mainly cocaine paste and marijuana), and who have sex with girlfriends, with loose girls (*movidas*), and often (in exchange for compensation) with men seen as gay or transvestites. They represent 70% of Peru site participants.

Movidas: young women who are open to, and usually compensated for, having sex with men in their barrio and sometimes with men from outside the barrio. Most *movidas* are single mothers and most drink alcohol. They represent 10% of the site's participants.

Homosexuals: men who are self-identified and locally regarded as gay or homosexual, including transvestites. These men often work as hairdressers or commercial sex workers in the barrio. They frequently offer young, unemployed men compensation, including free hair cuts, drinks, money, or presents, for having sex with them. They represent 20% of participants.

Within each venue, a cluster of two to four microvenues were identified. Microvenues are well-defined spaces, such as outdoor sports fields, hair salons, and cantinas, bars and *chicherías*, where liquor is sold and people drink large amounts of alcohol. These are settings in which there are multiple opportunities for conversations and where people in the three subpopulations initiate risky behavior.

Eligible members of the assessment cohort in each venue included approximately 200 individuals 18–40 years of age who attended at least one microvenue in a venue at least twice a week and who lived within 30 min walking distance of the barrio. Individuals who reported that they had not engaged in sexual activity within the 6 months before the baseline were excluded.

HIV epidemiology in Peru and rationale for target population selection

The HIV/AIDS epidemic in Peru probably began in the early 1980s and evolved through the early 1990s, reaching a relatively stable level in the mid 1990s. The first cases of HIV infection occurred in MSM, and the epidemic became concentrated in that group early, reaching a prevalence of over 10%. The expansion of the epidemic to women resulted in a shift in the male : female ratio among reported AIDS cases from 18 : 1 in the mid-1980s to 3 : 1 in the mid-1990s. The overall HIV prevalence in male and female adults in urban centers has remained below 0.5%.

In a country with a high prevalence of bisexual behavior among men, HIV prevalence of over 5% in MSM and under 1% in all other groups can be explained by the rapid expansion of HIV within urban MSM sexual groups, which include female partners of MSM and their children. Because these women were for the most part monogamous and remained so, the epidemic did not generalize and remains largely driven by sex between men.

Description of and rationale for study venues

The Peru site first planned to work with young people from the general population in selected barrios. Barrios are home to local and community organizations and to an intense street life. People know each other and are related through diverse social groups. As a result of limited behavioral and biological risk found in an initial epidemiological study of a household probability sample of that population, site researchers used the ethnographic findings to identify three interrelated subpopulations in the same venues, and conducted a new epidemiological study that showed much higher behavioral and biological risks among these subpopulations.

Within barrios, researchers identified places where young people congregate, including hair salons, bars, street corners, pool halls, sports fields, and parks. Transvestites and self-identified gay men congregate around the volleyball courts and hair salons, whereas young

unemployed men and women congregate around the street corners, football fields, and at pool halls. All of these population segments interact in cantinas and hair salons. Young unemployed men go to street corners in the barrio to talk or play with their friends or be with their girlfriends, and go to cantinas or pool halls to see other friends and drink. They also go to hair salons for haircuts, and sometimes have sex with the male owner to pay for the haircut or to obtain money. Risky sexual interactions are common in these barrio subpopulations.

Initial epidemiological study findings that supported venue selection

The population targeted in the first epidemiological study of the general barrio population and the later epidemiological study of subpopulations in the high-risk venues (*esquineros*, *movidas*, homosexuals) subsequently chosen for the Trial differed in their sociodemographic profiles, the frequency of unprotected, non-spousal sex, and the prevalence of STD. Compared with the general population survey, participants from the high-risk subpopulations were predominantly male (90.9 versus 41.2%), were less likely to have finished high school (51.5 versus 76.6%), and were less likely to be in stable relationships (25.2 versus 35.5%; all $P < 0.001$). Their rate of unprotected sex outside of primary relationships in the previous 3 months was disproportionately higher than in the general barrio population (57.8 versus 2.4%; prevalence ratio 24.14; $P < 0.001$). They also had higher rates of HIV (1.5 versus 0.1%), HSV-2 (29.9 versus 14.8%) and syphilis (5.5 versus 0.8%; all $P < 0.001$). Members of the three high-risk subpopulations in the barrios were thus selected as the target population for the intervention.

Russia site study population

Description of the Russia site target population

The Trial's Russia site is St Petersburg, the country's second largest city, with approximately 5 million residents. The target population in St Petersburg consists of young adult men and women between 18 and 30 years of age, most unmarried, who attend vocational and technical training schools and institutes located throughout the city. Young people enter these 5-year training programmes after high school.

Each vocational or technical school operates a dormitory for the young people who attend its training programme. Dormitories provide housing for 140–800 young adults, many coming from outside the St Petersburg area. Most dormitories house both men and women. The Russia site study population consisted of residents of 24 vocational and trade school dormitories widely dispersed throughout the city. The Trial enrolled between 52 and 120 residents from each dormitory venue ($n = 2212$ participants) as the study cohort, with nearly equal numbers of men and women. Study participants were randomly selected from among the entire population of young people living in each dormitory, but excluded individuals in their final school year who would soon leave the dormitories and be unavailable for follow-up.

HIV epidemiology in Russia and rationale for target population selection

The HIV epidemic appeared later in Russia than in many other world areas, but has emerged quickly and grown explosively. During Soviet-era Russia, very few HIV infections were diagnosed; even as late as 1995, a cumulative total of fewer than 1100 cases had been detected in the country [19]. Beginning in 1996, the number of new infections recorded in Russia began doubling each year, and the epidemic accelerated in its pace. By 2004, approximately 300 000 infections were officially recorded [20], but the number of officially recorded cases is believed to underestimate the true number substantially. Most Russian and international public health authorities estimate the actual number of HIV infections to be between one and two million [21,22], most contracted during the past decade, making Russia's HIV incidence rate one of the highest in the world.

Injection drug use, almost unknown during the Soviet era, became extremely common among young people after the breakup of socialist controls, and the large majority of HIV infections in Russia and other post-Soviet countries have been diagnosed among young IDU. Russia's difficult cultural transitions have, however, resulted in the liberalization of sexual behavior values among young people, declining age at first sex, acceptance of multiple sexual partners, growing levels of prostitution, and the emergence of a wide-scale STD epidemic that has produced sharp increases in the rates of syphilis, gonorrhea, and other STDs among young people [23,24]. These enabling factors together have set the stage for efficient sexual HIV transmission, and the shift from a drug-related HIV epidemic to a sexual transmission epidemic has begun. Recent surveillance data indicate a decline in the percentage of new HIV infections attributable to injection drug use and an increase in cases attributable to sexual transmission. Some data suggest that half of all new HIV infections now occurring in Russia are the result of sexual exposure [25].

Several studies have examined patterns of sexual HIV risk behaviors in community samples of adolescents and young adults in Russia, especially in the major population centers of St Petersburg and Moscow. These studies have established that a high proportion of young people are sexually active, that multiple concurrent sexual partners or brief serial relationships are common, and that rates of consistent condom use are low [26,27]. These studies indicate that HIV/AIDS is widely perceived by the public to be a threat primarily to drug users and gay men,

knowledge about correct condom use is still limited, and condoms are seen as protection primarily against pregnancy rather than HIV/STD. Earlier research carried out specifically with vocational and trade school students established a high prevalence of sexual risk behavior [28]. Stopping the emerging sexual HIV epidemic in Russia requires that interventions to reduce high-risk behavior practices be directed towards sexually active young adults.

Description of and rationale for study venues

Vocational and trade school dormitories constitute urban environments appropriate for reaching a community population of young, at-risk adults. The dormitories are drab, overcrowded, and in disrepair, usually with large numbers of young people crowded together in small sleeping rooms. Most dormitories are surrounded by storefront cafes, drinking clubs, and socializing areas. Heavy alcohol use, marijuana use, and opiate smoking are widespread in the dormitories, although injection drug use is less common.

Dormitories constitute venues well-suited for a research trial of the C-POL intervention. The dormitories are residential and also social communities in which students know one another well. Young people who live in a given dormitory extensively socialize with others residing in the same building in common social areas at the dormitory and in adjacent 'hangout' areas. Because dormitory residents attend the same school and live and socialize together, popular opinion leaders influential with others could be readily identified. The dormitory populations are stable and non-transient. With the exception of the outmigration of young people finishing their final year and the in-immigration of new first-year students, population turnover in a given dormitory is minimal. Because of the compactness of the venues, the resident population size was known, the proportion of C-POLs to be trained could be accurately determined, and high intervention exposure could be ensured.

Initial epidemiological study findings that supported venue selection

Before finalizing the Russia site's selection of 24 vocational or trade school dormitories as venues for the Trial, initial ethnographic studies were conducted in two other similar dormitories that served as locations for formative phase studies. In more extensive epidemiological research, risk behavior interviews and STD specimen collection were carried out with a sample of 1000 dormitory residents in 20 dormitories, equally divided between men and women, 90% unmarried, and averaging 20.2 years of age. Overall, 91% of students (96% of men and 87% of women) were sexually experienced, with a median of three lifetime sexual partners reported. At interview, 88% reported being sexually active during the past year, and 75% were sexually active during the past 3 months. The median number of sexual partners in the past year and in the past 3 months was one, although 47% reported two or more partners in the past year and 21% reported two or more partners in the past 3 months. Among the young people who had at least one sexual partner in the past 3 months, a median of 12 unprotected intercourse acts was reported, and 37% of students reported never using a condom during this period. On most indices related to sex with casual or non-spousal partners, Russia site men reported risk behaviors nearly twice as high as women. Biospecimen testing revealed that approximately 15% of students had an STD, predominantly chlamydia (8%) and HSV-2 (6.2%), with 1% or fewer diagnosed with syphilis, gonorrhea, HIV, or trichomonas. These data verified that the Russia dormitory resident sample is high in behavioral risk, and that vocational and trade school dormitories were appropriate venues for the Trial.

Zimbabwe site study population

Description of the Zimbabwe site target population

The site researchers chose to implement the C-POL intervention in 'growth points' in Zimbabwe. Growth points are designated sites in rural areas selected for economic and infrastructure development by the government. These areas are surrounded by villages and act as social and economic magnets for the surrounding community.

Individuals 18–30 years of age who patronized a growth point microvenues (e.g. a selected bottle store or market) at least twice a week were eligible to participate in the assessment cohort. Prospective participants were excluded if they had lived in the selected growth point for less than 2 years or if they lived in the area fewer than 9 out of 12 months of a year.

HIV epidemiology in Zimbabwe and rationale for target population selection

Zimbabwe is a landlocked country in southern Africa, bordered by Botswana on the west, South Africa on the south, Mozambique on the east, and Zambia on the north. With a population of approximately 11.6 million individuals [29], an estimated 1.4 million individuals in Zimbabwe are currently living with HIV/AIDS [30]. Approximately 58% of the population resides in rural areas, 32% in urban areas, and 10% in areas that are not classified as strictly urban or rural. Women constitute 51% of the population [29]. The first AIDS case was identified in Zimbabwe in 1985. AIDS case surveillance began in 1987, and sentinel surveillance of pregnant women receiving antenatal care services at public clinics has been ongoing since 1990. In 2005, the Zimbabwean Ministry of Health and Child Welfare (MOHCW) reported that the estimated HIV prevalence among adults 15–49 years of age in Zimbabwe was 20.1%, down from the 24.6% estimate in 2003 [30].

Zimbabwe has one of the highest adult HIV prevalence rates in the world, approximately 33.7% in 2001 [31,32]. Antenatal clinic sentinel survey results showed that HIV prevalence among pregnant women in Zimbabwe increased from approximately 25% in 1997 to 35% in 1999. Overall prevalence rates were 33% in 2000 and 27% in 2001 [33]. Modeling based on antenatal clinic surveillance data, reported by the MOHCW in 2003, estimated prevalence rates of approximately 25% in the population of 15–49 year olds [34]. Although these HIV estimates are based on antenatal clinic surveillance data, one nationally representative survey, the Young Adult Survey (which included HIV testing) was conducted in 2001–2002 with a randomly selected sample of 15–29 year olds by the MOHCW and the US Centers for Disease Control and Prevention Global AIDS Programme Zimbabwe office. That survey showed prevalence rates of 22% among 15–29-year old women and 10% among 15–29-year old men [35]. The country is experiencing a generalized HIV epidemic, with women having approximately twice the risk of men [35]. Mortality is high [36]. An estimated 3252 men, women, and children die each week from AIDS in Zimbabwe [30].

Although Zimbabwe has a generalized AIDS epidemic, Zimbabwean MOHCW data show that rates vary in different locales. In 2001, antenatal clinic surveillance data found that urban areas had an approximate prevalence of 30% compared with 20% prevalence in rural areas. Areas considered neither urban nor rural, however, such as commercial farming areas and growth points, had the highest estimated HIV prevalence, approximately 35% [30]. The Zimbabwean MOHCW and the National AIDS Council thus recommended those areas for intensified HIV prevention interventions.

Description of and rationale for study venues

Growth points are rural centers designated by the government in 1985 to facilitate commercial and industrial development. With such a designation, these centers received public investments in electrification, telephone installation, construction of water supply dams and waste disposal systems, administrative facilities, feeder roads, and banking facilities. The growth points consist of small commercial areas of shops and markets, and entertainment and other businesses, such as bottle stores (places that sell alcohol and provide centers of leisure, especially for men), beer halls, and night clubs. Small residential areas may be present at the growth points, and secondary schools and health centers are sometimes associated with them. Growth points have populations ranging from 2500 to 5000 people.

The growth points represent hubs of economic and population exchange because they usually have good transport connections and provide trading opportunities. This confluence of population and disposable income, against a background of rural poverty and limited job opportunities, presents a situation of high sexual risk. The preparatory ethnographic studies confirmed that drinking alcohol was a popular pastime for men (and some women), and that drinking took place in small groups of friends and relatives in bottle stores and beer halls. A distinguishing feature of growth points was the existence of a large number of bottle stores, some of which serve as night clubs later in the evenings. Sexual relations, including the exchange of sex for goods and money, often took place in association with drinking and night clubbing. Although men tended to socialize around bottle stores, socialization for women was more diffuse, often taking place in churches. The clustering of social groups for women was also found in markets and general dealers stores [37–39]. In some cases, market women by day sold sex by night. We thus selected growth points because they represented a high-risk population with distinct segments (men, women, and sex workers) and identifiable social groups in a relatively small population.

Initial epidemiological study findings that supported venue selection

An initial epidemiological study randomly selected residents of rural households in villages around 32 growth points to determine HIV/STD prevalence. It showed that overall HIV prevalence among randomly selected 16–30 year olds was 26%, over twice as high in women (33.9%) as in men (14.8%). Despite the high HIV rates, the prevalence of some STDs was relatively low, probably because of an STD control programme launched in the 1990s and based on a syndromic management approach and the provision of prenatal care services. Gonorrhea and chlamydia, previously relatively common infections, had prevalence rates less than 5%, and syphilis less than 2% [40,41]. HSV-2 prevalence was, however, approximately 45% [42], much greater among women (58.6%) than men (26.6%). Household residents' reported number of sexual partners was relatively low (median one in the past year, with 22% reporting two or more partners), indicating a population whose recent behavior was not particularly risky against the background of a generalized HIV epidemic.

Because general residents of villages near growth points did not exhibit high current behavioral risk, and because the social groups and links to places of high risk were not clear, site researchers decided to focus on populations present in the specific microvenues of bottle stores, general dealers stores, and markets with growth points. These microvenues were selected through rapid ethnographic methods, which then confirmed their high risk. Another epidemiological study to assess HIV/STD prevalence was not performed with microvenues because sufficient biological risk existed in the village community and MOHCW data showed that growth points had among the highest HIV prevalence rates.

In conclusion, HIV epidemiology and the populations most imminently threatened vary throughout the world.

The objective of the Trial is to evaluate the C-POL intervention with different but high-risk populations at each country site. Although the target populations included in the Trial differed across countries, each was selected on the basis of a common set of criteria related to high behavioral or biological risk at baseline, venues for accessing high-risk community populations, and the suitability of these venues for a randomized trial of a community-level HIV/STD prevention intervention.

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