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Strategies and ethical considerations for the recruitment of young men who have sex with men: challenges of a vaccination trial in Mexico

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Background The importance of recruiting and retaining study participants from minority groups is well recognized; however, there are no established rules for recruitment as its success depends on the setting and population.
Purpose To describe and analyze recruitment strategies, ethical considerations, and recruitment outcomes from a study to evaluate the efficacy the Human Papilloma Virus vaccine in young men who have sex with men (MSM).
Methods The recruitment settings were university and community sites in the state of Morelos, Mexico. Eligibility requirement were men between 18 and 23 years old, who were free of anal-genital lesions as confirmed by clinical exploration, HIV negative, with no history of sexual relations with female partners and with fewer than five male lifetime sexual partners. Recruitment goals were 25 study participants in a four and a half month period. In addition to traditional recruitment strategies (flyers and media advertising, specific training of the recruitment team and adequate choice of recruitment sites)–engagement of local leaders in the MSM community formed a crucial part of the strategy. Special consideration was given to confidentiality and respect for study participants and a Bill of Participant Rights was developed as an explicit commitment to respect and acceptance.
Results In total 723 MSM were initially contacted, 243 filled out the recruitment questionnaire, of which 151 met the criteria to be invited to the clinical examination. After clinical examination and interviews with the recruitment team, 131 fulfilled the inclusion criteria, of whom 73 were enrolled in the study – nearly triple the recruitment goal. Among the initial recruitment strategies (application of the screening questionnaire) attending meetings with MSM activist organizations was the most successful (326), followed by recruitment at bars and dance clubs (107).
Limitations The recruitment strategies should be formally evaluated for their effectiveness to identify those which are most successful. In addition, future studies should consider the evaluation of study participants' perceptions of the recruitment strategies.
Conclusions Recruiting MSM in a developing country such as Mexico presented multiple challenges. We recommend that future studies actively engage the local MSM community and pay special attention to designing recruitment strategies that guarantee the confidentiality of and respect for participants. *Clinical Trials* 2009; **6**: 365–372. http://ctj.sagepub.com

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Background

The success of clinical research trials depends on the recruitment of study participants [1]. Various methods, such as direct personal mailings, posters, brochures, and media campaigns have been used to promote participation and potentially increase recruitment rates. [2] Recent reviews that sought to identify best recruitment practices [3–5] concluded that uncertainty exists with regard to best practices and that the selection of strategies depends on the local context and the study population.

Determining adequate recruitment strategies is even more difficult when the study focuses on or includes minorities or vulnerable populations. The choice of strategies requires the consideration of factors such as culture, age, gender, and socioeconomic status. The inclusion of participants from underrepresented or vulnerable populations (i.e., low-income and/or minority groups) calls for special considerations because the interests of those populations may conflict with clinical trial objectives. Due to past abuses of vulnerable populations, they may also be more wary of participation in research. However, the assumption that minority groups are less willing to participate in health research may inadvertently increase stigmatization by implying that these groups are unwilling to bear their fair share of the burden required to improve medical care [6].

Choosing adequate recruitment strategies is of particular relevance when involving men who have sex with men (MSM) given the discrimination this group often suffers. For example, in Mexico, since very early in the epidemic health service providers dealing with HIV-positive MSM have often been biased against and discriminatory towards this group, resulting in deficient medical attention, among other consequences [7]. With regard to MSM as study participants, additional guidelines for behavior by participating researchers and the recruitment team may be necessary in order to guarantee respect for sexual diversity and participants' sexual rights, in addition to the more traditional ethical issues such as confidentiality, justice, and informed consent.

Since MSM may be involved in high-risk practices resulting in a higher probability for becoming infected by sexually transmitted infections (STIs) such as the Human Papilloma Virus (HPV), there is a greater need for preventative interventions such as education and vaccines; it is therefore important to include this population in clinical vaccine trials.

In the last decade, studies describing the experience of minority recruitment for research trials have focused on ethnic minorities or women [8–10]. For example, the WHO developed recommendations for conducting research on domestic violence among women [11]. However, there is less information on recruitment strategies for other minorities such as MSM. Although this study group has received a lot of attention since the appearance of the HIV infection in the 1980s, many publications from developing countries have focused on surveillance studies or sero-surveys, for which it is generally less difficult to recruit compared to clinical studies [12,13]. There is little information on recruitment of MSM for clinical trials in developing countries. Protection against discrimination and stigmatization is an important issue with regard to recruiting MSM. Additionally, this population tends to be hidden [14]; therefore, in order to reach potential study participants the use of unconventional recruitment strategies might be necessary.

In this article, we analyze recruitment strategies used in a multicentric clinical trial in Mexico of the efficacy of an HPV vaccine in young men who have sex with men. Of the 32 countries that participated in the trial, the Mexican site recruited the greatest number of participants. The objective of this article is to identify the reasons why recruitment in Mexico was so successful and which recruitment strategies can be recommended to future studies.

We will start by describing the tasks, responsibilities, and training involved in recruitment, as well as the recruitment strategies used. The focus of our discussion will be the ethical considerations found to be particularly relevant to this study population as well as community awareness as a mechanism to increase participation in the trial. Finally, we will discuss the strategies chosen and provide some recommendations with respect to ethical considerations for recruiting sexual minorities for clinical trials to be conducted in developing countries.

Participants

The present analysis refers to the recruitment phase of the international, multicentric clinical trial of the prophylactic vaccine against HPV types 6, 11, 16, and 18 conducted from February 2005 to March 2006 (NCT00090285, ClinicalTrials.gov). The study group was young men who have sex with men. Inclusion criteria were men 18–23 years old, who reported fewer than five male sexual partners during their lifetime, were free of anal-genital lesions as confirmed by clinical exploration, were HIV negative, and had no history of sexual relations with female partners. Since these inclusion criteria were strict, with the likelihood that that only a very small proportion of MSM would meet them, the recruitment goal was set at 25

individuals over a four and a half month period. The study site was Morelos State, Mexico, a small state on the southern border of Mexico City.

Although this was not the first time that the scientific community reached out to the MSM community in Morelos, to our knowledge a clinical trial exclusively focusing on MSM had not been undertaken. Previous studies recruited participants of groups with high risk of acquiring STIs due to behavioral characteristics [15]. Other studies, which focused on the MSM community, did so through a social perspective and qualitative data collection techniques such as interviews and surveys, but not clinical trials.

The recruitment team

The recruitment team consisted of a physician, a psychologist, and other nonhealth care professionals, all of whom had experience from previous research studies on the effectiveness of the HPV vaccine. In addition, some of the recruitment staff had similar sexual preferences as the potential participants without identifying themselves as being part of the MSM community in Morelos.

The team was responsible for coordinating trial recruitment activities; its primary activity was to visit the recruitment sites and provide information to potential participants. The psychologist's responsibility was to consult with study participants regarding STI screening and to evaluate potential participants in terms of their likelihood for remaining in the study throughout the study period and for adhering to study protocol (Table 1). The physician was in charge of the clinic exploration for anal-genital lesions of the potential participants, which was carried out in the study clinic. During this visit he also provided information about study procedures to each potential participant.

All of the recruitment staff was trained in the disease basics, protocol procedures, and Good Clinical Practice (ICH) [16]. The recruitment team coordinator assigned different roles to each team member according to their previous experience and professional skills. Each team member was required to describe the recruitment strategies they would use and to undergo several recruitment simulations before putting the strategies into practice. Team members were also asked to suggest potential recruitment sites. A recruitment assistance program was developed to improve the language used for communicating with potential participants and to identify possible barriers related to the acceptability of the study.

Awareness campaign

An HPV awareness campaign was implemented among the student population and the entire state population using posters, flyers, radio spots, and promotion on websites, inviting potential participants to educational meetings. The theme was 'Together for the health of young people' ('*Juntos por la salud de los jóvenes*'). The campaign provided general information about STI such as genital herpes, gonorrhea, chlamydia, and syphilis, with a special focus on HPV. The HPV information included the impact of the infection in men (anogential warts, cancer, and penis cancer), its diagnosis and treatment, and the importance of a vaccine against HPV. It also explained study objectives, procedures, selection criteria, and benefits and risks, as well as invited participation in the study. This allowed the entire population to familiarize themselves with the study and, hence, reduce the tension that the topic of STI could provoke. The main message of the campaign was kept very general to avoid controversy in the general population.

Recruitment sites

For the first one and a half months, recruitment was conducted at the university campus. However, potential participants felt that they were being observed by other students when entering the information and recruitment stand and therefore, at risk of being stigmatized as gay. As a result, the

Table 1 Evaluation of study participants' commitment to adhering to study protocol

(a) Willingness to participate;
(b) Seriousness: criteria included punctuality for appointments with research team members. In the event that potential participants missed the appointment and had no clear justification for not showing up, the recruitment team was cautious about inclusion, anticipating that this could result in non-adherence to study protocol later in the trial;
(c) Self-care criteria included personal hygiene and medical visits for check-ups;
(d) Truthfulness of the information provided: whether the potential participants answered with honesty was a consideration. Nevertheless, since in the case of MSM pseudonyms are commonly used to avoid identification in the greater population as being MSM, this information was permitted;
(e) Willingness to communicate with the recruitment team, the researchers and health care professionals involved in the study.

recruitment site was changed in favor of more anonymous locations such as common meeting places for MSM, including social gathering sites (dance clubs, cafes, and bars), work sites (such as snack bars, gift shops, hair dressing salons), representative social organizations (nongovernmental or civil organizations in the gay community or in the general community with MSM as members). Recruiters established a routine for visits from Thursday to Sunday, with different time schedules for each type of recruiting site; dance clubs and bars were visited between 11 : 00 pm and 3 : 00 am, cafes were visited between 3 : 00 pm and 9 : 00 pm, and work locations between 9 : 00 am and 8 : 30 pm. Individuals interested in participating were asked to fill out a questionnaire to screen three of the inclusion criteria: age, number of sexual partners, and no previous female partners. The potential participants who met these three criteria were invited to make an appointment with the physician in the study clinic to establish whether they were free of anal-genital lesions.

Recruitment monitoring

The recruitment team also developed a mechanism for the continuous monitoring of screening and recruitment activities. The recruitment team met once a week with the objective to evaluate the recruitment rate. In these meetings the team identified effective and ineffective recruitment strategies, defined how to reinforce particular messages and how to avoid or resolve conflicts that some young people had with participating, and decided how to avoid potential losses or drops in the recruitment rate over time.

Ethical considerations for study recruitment

In addition to these technical aspects, special considerations were given to the ethical aspects of the recruitment process. Basic ethical principles for recruitment of study participants included respect for persons, beneficence, and justice [17]. With respect to the MSM study group, respect for persons and justice seem of particular relevance. This group often suffers discrimination; hence, confidentiality and providing safety from abuse was critical. Regarding confidentiality, the potential participant received information about how the study results were to be used; who had access to study data, and for what purposes the results were reported.

Based on these general principals, the recruitment team defined ethical guidelines for interaction with the participants, with a particular focus on confidentiality. First, a statement about maintaining confidentiality was included in the informed consent letter, guaranteeing the rights of participants to maintain control over access to information about their health status. Second, those participants who preferred to use a pseudonym in the MSM community were allowed to maintain it. Third, for the clinical screening of potential participants after-hour clinical appointments were offered in case participants felt more comfortable visiting the clinic at this time to ensure that they would not encounter people that they knew. Since the clinic was established as part of a larger research project on prevention of STIs many women and men were seen in the clinic for general counseling. Despite of the fact that there was no particular stigma attached to using this particular clinic, some potential participants expressed a preference for after-hour visits.

Other points included in the ethical guidelines for interaction with the participants were:

- Promoting communication: making sure that the participants have sufficient time and opportunity to obtain all the information they require about participation and about any clinical events (possible adverse events).
- Ensuring dignified treatment: guaranteeing that study participants are treated with full respect for their dignity and their rights as persons.
- Prompt attention: respecting clinic appointments.
- Basic comfort at the study site: clean bathrooms, waiting rooms, and medical offices, with adequate seating and space, in addition to the general quality of study site facilities.
- Counseling: a trained and experienced health care provider to offer counseling when giving participants STI test results.

In addition to these ethical guidelines, the recruitment team drafted a 'Bill of Rights' (Table 2) in order to make explicit the respect and acceptance by the recruitment team and all researchers involved in the study towards the participants. The study coordinator drafted the Bill of Rights and local leaders from MSM activist groups were invited to give feedback. All of them gave very positive comments and some leaders were very enthusiastic and wanted the bill to be published widely. It was put on the wall of the recruitment center, serving as a reminder to all study recruiters.

Community engagement was sought through contacting local leaders in MSM activist groups in the state of Morelos. Meetings with the leaders were

Table 2 Bill of Rights for MSM participants in clinical trial

1.	I have the right to respect for my integrity, well-being, and personal interests.
2.	I have the right to health, to receive care for my physical well-being.
3.	I have the right to not be discriminated against.
4.	I have the right to respect for my sexual preference.
5.	I have the right to confidentiality, that any information I provide in any form not be distributed or discussed with anyone other than myself.
6.	I have the right to receive sufficient and accurate information on which to base my decisions and choices related to the study.
7.	I have the right to be treated by each member of the study team in accordance with established professional ethics.
8.	I have the right to be addressed and treated with kindness by study personnel.
9.	I have the right to not be mistreated by the study staff, with words, attitudes, or actions.
10.	I have the right to medical care free of violence.

held in order to inform them about study objectives and provide printed information. Many of the local leaders were very positive about the study and invited the study coordinator to speak at meetings and to distribute flyers.

Finally, as one of the fundamental premises of research ethics, the study protocol guaranteed the provision of treatment for any STI detected during the study, independent of whether the participants were later excluded from the study because they were HPV- or HIV-positive. Treatment and care was provided at the University Medical Center of the State University of Morelos. Referrals were made to health facilities for further treatment (especially for HIV-positive men).

Results

In total 723 MSM were initially contacted over a period of four and a half months, most of them through MSM community meetings (326), followed by bars and dance clubs (107) (Figure 1). Of these 243 completed the screening questionnaire. Based on the results from the screening questionnaire, 151 were eligible, and 141 of these men were interested in participating and were invited to receive a clinical examination. Out of 131 who fulfilled all inclusion criteria, 98 were interested in participating. Finally, 73 agreed to sign the consent form and were recruited as study participants.

Discussion

Overcoming barriers to participation in clinical trials evaluating the effectiveness of HPV vaccines in MSM constitutes a challenge, particularly in developing countries such as Mexico where discrimination of MSM and social stigma in relation to treatment of STIs exist. Nevertheless, due to their risk of acquiring HPV, participation of MSM in universal vaccination schemes and hence clinical trials is warranted. There are two pertinent issues to consider in the recruitment of this study group: first it is a hard-to-reach population and, second, MSM are often subject to discrimination. In order to address these challenges and to thereby boost the recruitment rate, we used generally recommended strategies – such as the constitution of the recruitment team and its training, attention to recruitment sites, and monitoring – and a novel ethical framework for recruitment that consisted of guidelines for recruiters, with a particular focus on confidentiality and a Bill of Rights as an explicit expression of respecting persons.

In recent years, several reviews have looked at which type of recruitment strategies yield the largest number of study participants. Among others, three key strategies which have been identified – (a) appropriate composition and training of the recruitment team, (b) selection of recruitment sites, and (c) community engagement – are of particular importance.

(a) Appropriate composition and training of the recruitment team monitoring, and community outreach were found to be particularly relevant to successful recruitment [4]. We regard the special training of the recruitment team and monitoring of recruitment over time as important factors in our recruitment success. We set up a team of recruiters with clearly assigned responsibilities and lines of authority, as this had been found to be relevant to recruitment success [1]. In addition, the team's psychologist supported the identification of those potential participants, who would most likely adhere to study protocol.

(b) Previous studies about recruitment strategies for MSM have discussed the importance of appropriate recruitment sites depending on the location and organization of the MSM community. Predominantly, bars and dance clubs have been chosen [18,19] as these are commonly visited by MSM and provide a safe place for social gatherings [20]. In addition, the time–location approach is relatively effective in

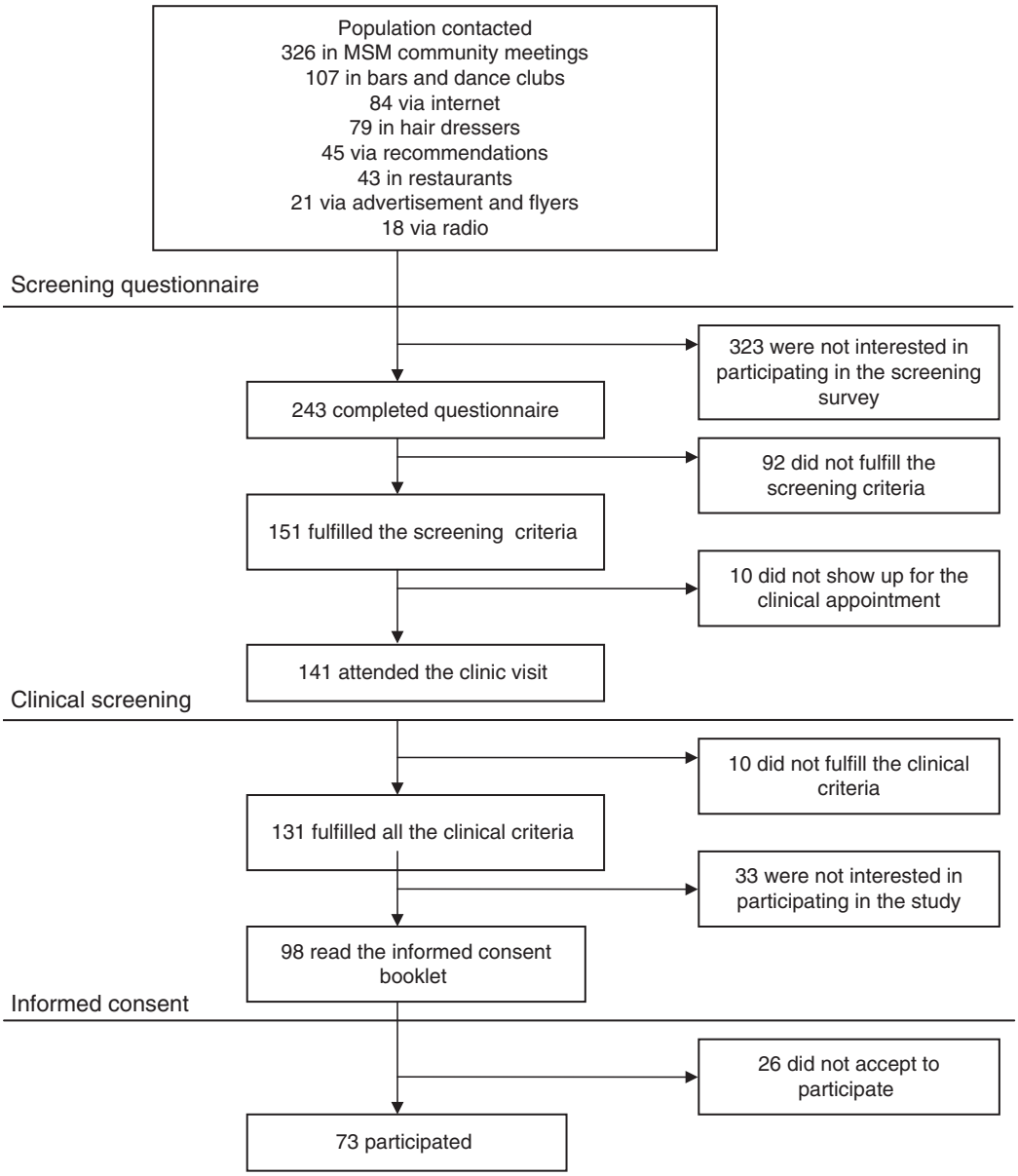

Figure 1 MSM recruitment report

providing access to a high number of eligible participants in a short timeframe [21,19,14]. Some recent publications conducted in Latin America, Africa, and Asia look at different methods of recruiting such as time–location sampling and respondent driven sampling [12,13,22]. However, as these were surveillance studies or cross-sectional sero-surveys recruitment is in general less difficult than for clinical trials. Our results show that bars and dance clubs as recruitment locations in Mexico are effective as they yielded the second highest recruitment rates, after MSM group gatherings. In our experience, the change in recruitment sites was a relevant aspect not only to achieve a higher rate of participation, but also to increase the participants' confidence that the research team would protect their rights.

(c) Community engagement was another critical element in the recruitment process. It has been found that recruiters should, if possible, match the study population in terms of age, race, and other personal characteristics so that potential study participants can identify with the recruiters, thus enhancing trust [23]. Some of the recruitment team members had similar sexual preferences without identifying themselves as belonging to the MSM. This facilitated a better

understanding of the study population and choosing appropriate recruitment strategies. Furthermore, the Bill of Rights played an important part in establishing a collaborative relationship between MSM leaders and the study coordinator. The Bill of Rights received unanimous positive feedback and created trust between the study coordinator and local leaders. This trust contributed to local MSM leaders facilitating access to the MSM community under their guardianship [24]. It also seemed that many members of the MSM communities were more inclined to talk to the study coordinator after he spoke at MSM meetings as opposed to other social events.

Homophobia exists in Mexico and in many regions of the world [25], and therefore, we regard two ethical considerations as crucial for recruitment success: first, the guarantee of confidentiality and second, an explicit statement of respect for persons [26].

With respect to confidentiality, as many men who have sex with men conceal their sexual preference and participation in a trial might risk disclosing their preference to family members, friends, or colleagues, privacy was one important request by the potential participants. We responded to this request for privacy in three ways. First, we changed the initial recruitment place from the university campus to more anonymous sites such as bars and cafes. Second, we offered after-hour clinic visits to those participants who preferred it. Third, we allowed study participants to maintain their pseudonym with which they were known in the MSM community.

Regarding the respect of persons, Bills of Rights have been developed in other countries and contexts. For instance, it is obligatory to give potential study participants a Bill of Rights before they agree to participate [27]. This includes presenting their rights as research subjects in a language easy to understand for most people. Our objective was to develop a Bill of Rights as an explicit manifestation of the respect that all research staff and health care personnel showed to all participants, while recognizing and combating the discrimination to which they may be subject. This was a unique way of preparing the recruitment team to interact with MSM. In addition, feedback from local leaders was particularly helpful for developing the Bill of Rights.

Recommendations

Success in recruiting subjects for controlled clinical trials is often the limiting factor in determining whether or not a trial can proceed [28,29]. Recruiting MSM in a developing country such as Mexico presents multiple challenges. Because of the difficulties that might be involved in recruiting MSM for research projects – as a hard-to-reach population and, particularly, the risks involved in their revealing their sexuality – recruitment methods need to be carefully tailored to this study group and adhered throughout the study process. This includes a careful preparation of the recruitment team and sensitization towards a group that suffers discrimination.

As a result of the recruitment strategies described above, recruitment was nearly three times the stated goal. Community engagement, confidentiality, and explicitly expressing respect for the person were of particular importance to create an environment in which the participants were treated with dignity. The development of a Bill of Rights was a novel approach to explicitly expressing respect for study participants.

Conflict of interest

Dr Eduardo Lazcano Ponce is Research Grants and Consultant (Merck and Co., GlaxoSmithKline) and Dr Jose Luis Viramontes is the Director PPD, Mexico City, Mexico and Ex-Clinical Research Director at MSD, Mexico.

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