



# The missing minorities

Minority groups in the US are shying away from participation in clinical studies, with the result that their medical needs often remain unmet. **Karen Politis Virk** outlines the language and cultural barriers, and proposes ways to encourage enrolment in these patient populations

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**T**he inadequate representation of ethnic and racial minority groups in clinical trials taking place in the United States is currently of great concern. Although minority groups should not carry an unfair burden in clinical research, they also should not be excluded from participation in clinical trials.<sup>1</sup> Research has shown that genetic factors, including race, greatly influence disease propensity and an individual's response to treatment.<sup>2</sup> Despite this, genetic differences are not adequately taken into account in clinical research. Furthermore, despite the prevalence of commonly studied diseases among many populations, ethnic and racial minority groups in the US continue to be under-represented in clinical research.

Several factors are responsible for the low enrolment of minorities in US clinical trials. Among the most important factors, as various studies have shown, are an insufficient number of minority investigators, language barriers, cultural perceptions, religious beliefs, poverty, and illiteracy. While many pharmaceutical companies are making an effort to include minority groups – by employing more ethnically and racially diverse clinical investigators and hiring more healthcare providers with access to minority populations – there is a continued disparity in minority participation compared to other populations in the US.

## The importance of diversity

According to US FDA regulations, clinical trial participants should best represent the population for whom the medication undergoing testing is intended. Because of the under-representation of US minority populations, since 1988 the FDA has required that in order to ensure the safety and efficacy of new drug applications, studies should include subgroups according to population demographics. The FDA further specifies that these subgroups should adequately represent different ages, genders, races and ethnicities.

Patient characteristics are often associated with markers of disease prevalence and severity, and influence how an individual absorbs, metabolises and ultimately responds to medications. The lack of diversity in clinical trials makes it difficult to determine whether a new drug works equally well for everyone. In particular, a specific drug may not work as well in some people because, for example, they have a different version of a protein needed to activate the drug inside the body. If physicians know that a particular drug is less effective in people with a certain genetic makeup, they can prescribe a different treatment for those individuals. Clinical trials can often reveal such differences if they include the full range of people who will use the drug being tested.

### US minority populations

The US government considers Hispanic or Latino to be an ethnic characteristic rather than a race. The following five are racial categories as defined by the US Department of Health and Human Services: Caucasian, African American, Asian, Pacific Islander, and Native American. In the context of this article, the term 'minority' is used to refer to persons whose ethnic characteristics or racial category form a minor percentage of the US population, ie. Hispanic or Latino, African American, Asian, Pacific Islander, or Native American.<sup>3</sup>

In July 2005, the US Census Bureau reported that the total population of the US was 296.4 million. Of this, 42.7 million were Hispanic, 39.7 million were African Americans and Caribbean African Americans, and 14.4 million were Asian Americans. Minorities in the US currently represent one-third of the country's total population. Hispanics, or people of Latin American descent (sometimes referred to as Latinos), are the largest minority group in the country. Asian Americans form the third largest minority, and primarily include people of Chinese, Indian, Korean, Vietnamese, Cambodian and Filipino descent. In addition, some of these groups are growing rapidly. Hispanics, for example, accounted for nearly half of the US population growth during the period 1 July 2004 to 1 July 2005.<sup>4</sup> Significant growth has also been observed in the Asian American population. As this growth continues, the number of minorities participating in clinical trials should reflect the increase.

### Barriers to minority participation

Recent studies have shown that numerous factors determine how well clinical trial participation is accepted within a community, and that certain barriers inhibit minority group participation in clinical research. The barriers include economic factors such as transportation or child care costs; language factors, especially illiteracy and lack of English proficiency; negative cultural attitudes about clinical studies; and limited access to routine and preventive healthcare. Inadequate health insurance coverage is a major medical barrier to preventive healthcare, although clinical trial participation for uninsured patients may provide an opportunity for treatment.

Language and cultural barriers interfere significantly with the recruitment of minority populations for clinical research. More specifically, clinical research has been shown to under-represent ethnic and racial minority groups because of inadequate proficiency in the local official language.<sup>5</sup> In the past, many countries including the US did not take the participant's language or race and ethnicity into consideration when enrolling subjects for clinical trials. More recent research has indicated the importance of native language communication, and awareness of this issue has increased.

The process of informed consent in particular is a critical barrier because of inadequate English language skills among many racial and ethnic

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minority groups. For this reason, informed consent forms must be provided in the patient's native language, and clinical trial information must be explained in terms that all participants can clearly understand. The need to accommodate those who are not proficient in English is clear, especially as minority groups with limited English proficiency are growing: aside from English, Spanish is currently the number one spoken language spoken in the US, and Mandarin Chinese has quickly become the second.

Community outreach programmes have a major role to play in overcoming language and cultural barriers in clinical research. Improved enrolment rates of minority populations have been observed due to more effective communication through community-based focus groups and the use of culturally appropriate educational information translated into native language(s). Distribution of materials about the prevalence of certain diseases, available prevention programmes and access to clinical trials has been shown to significantly facilitate greater racial and ethnic minority participation. It is critical, however, that translators are native speakers and experts in the field of clinical research.

### Inadequate representation

Many studies indicate that the lack of adequate minority participation in US clinical trials is strongly related to language and cultural barriers, as the following two examples show.

#### *Hispanics in AIDS and cancer studies:*

Although racial and ethnic minority groups in the US comprise approximately one-third of the US population, they represent 67% of new AIDS cases. There is further disparity between minority clinical trial participation and the number of individuals infected with HIV among certain minority groups. Clinical trial participation among Hispanics is particularly low compared to the incidence of HIV infection: only 11% of Hispanics undergoing treatment for HIV participate in clinical trials, compared to 62% of Caucasians.<sup>6</sup>

Statistics for minority group participation in cancer studies are similarly concerning. Cancer is the second leading cause of death among Latinos in the US. Certain cancers are reportedly high among Latino populations, including breast, cervical, stomach, gall bladder and liver cancer. Breast cancer, in particular, is the leading cause of cancer death among Latina women. Moreover, Latina women have the third highest breast cancer mortality rate in the US, partly because they tend to be diagnosed at more advanced stages.<sup>7</sup> Despite this, Latina women account for less than 2% of

clinical trial participants in breast cancer research.

One recent study of the barriers to Latina participation in breast cancer clinical trials indicated that 'the most influential group-specific social factor contributing to the low participation rates of Latinas was lack of English proficiency'.<sup>8</sup> Participants in the study rated native language communication very high and expressed their preference for bilingual healthcare providers or interpreters. In addition, study participants indicated that the healthcare providers' race or ethnicity was less important than the presence of someone with whom communication in their native language was possible. Fifty percent of the women who participated in the study confirmed that because they could not read or write in English, they did not feel confident navigating their way through the hospital without an interpreter.

The rate of invasive cervical cancer in Hispanic women is almost twice that of non-Hispanics in the US, due largely to poor preventive care in this patient population. In addition to economic factors and education, poor quality Spanish language translation of educational information proved to be the greatest barrier to trial participation.

One study that addressed the barriers to disease prevention among Mexican immigrant women found that education pamphlets designed for these patients were confusing and irrelevant.<sup>9</sup> Among the problems identified were differences in terminology differentiating cervical cancer from cancer of the uterus. (Cancer that originates in the cervix or neck of the uterus is distinguished from uterine cancer which originates in the body of the uterus.) The Mexican women in this study commonly misunderstood the Spanish pamphlet translation explaining the importance of pap screening in the prevention of cervical cancer and as a method of screening for cancer of the uterus. Improving patient information materials and informing patients of the importance of clinical trial participation can help overcome such barriers.

#### ***Asian Americans in cancer studies:***

As mentioned earlier, Asian Americans are currently the third largest ethnic/racial minority group in the US, and one of the fastest growing. Despite the fact that cancer is the leading cause of death among Asian Americans (not heart attack/stroke as in most other groups), they continue to be under-represented in clinical trials. According to statistics, Vietnamese American women experience the highest incidence of cervical cancer, Korean Americans experience the highest incidence of stomach cancer, and Chinese men have the highest incidence of liver and nasopharyngeal cancer.<sup>10</sup> Breast cancer incidence rates for Asian American women have been increasing, and are reportedly higher in US-born Asian Americans. More recently, breast cancer rates among Japanese American women appear to be increasing at rates greater than those of non-Hispanic white women. Similarly, prostate cancer incidence rates are increasing among Asian American men.<sup>10</sup>




Several studies indicate that the low rate of recruitment of Asian Americans in cancer clinical trials can be greatly attributed to language and cultural barriers. Negative cultural perceptions of clinical research as being potentially unsafe greatly influence Asian American subjects. Another major cultural barrier in this population is the predominance of family decision-making. In many Asian cultures, decisions about a family member's healthcare are commonly made by the senior male member(s) of the family.

A pilot survey of barriers to the recruitment of Asian American women in cancer studies cited language problems, lack of culturally relevant cancer information, and complex protocols.<sup>11,12</sup> Asian oncologists who communicated with their patients in their native Asian language reportedly had greater success rates in this study. Several Asian American women with cancer who received care from non-Asian oncologists were found to need language and cultural support through interpreters or patient navigators.

Cervical cancer rates among Vietnamese American women are five times higher than among the general US female population. A significant number of Korean Americans have never heard of a pap smear test. Only 48% of Filipino women and 41% of Korean women in the US receive pap smear tests within the recommended timelines. Despite the high incidence of cervical cancer among these women, their participation in clinical trials is low, largely due to the perception by many Asian cultures that clinical trials are potentially unsafe. One study specifically looked at factors that interfere with the preventive screening and recruitment of Asian American women in cervical cancer clinical trials. In addition to cultural perceptions, language barriers were found to interfere significantly both with preventive care and participation in clinical trials.<sup>13</sup> Despite the high correlation between lung cancer and smoking, this habit has not decreased among many minority populations. In particular, smoking among Asian American males is high. Because cancer awareness among some Asian American male populations is inadequate, their participation in smoking cessation programmes and clinical trials does not reflect the large number at risk of cancer. This highlights the how crucial it is to develop culturally-appropriate programmes in native languages for these populations.<sup>14</sup>

### Summary

The inadequate representation of large racial and ethnic minority groups in US clinical research has prompted efforts to identify the barriers to medical access and participation. Many factors have been shown to interfere with appropriate access of minority groups to disease-prevention programmes and clinical trials. These include educational, economic, cultural and language barriers. Establishing disease treatment and prevention educational programmes for minorities, encouraging clinical trial participation through focus groups, and recruiting community leaders who are native speakers to participate in community meetings, are effective ways to overcome language and cultural barriers. Another important step is to hire bilingual staff, professional translators and local interpreters to assist healthcare providers in ensuring that all relevant study information is clearly communicated to their patients. Study materials should be translated in a linguistically- and culturally-appropriate manner by professional translators using localisation strategies.

Cultural beliefs, traditions and social and family values that may prevent a subject from feeling comfortable with trial participation must be taken into account. Understanding cultural differences among minority populations in the US and providing quality information in relevant native languages will help achieve greater diversity in clinical trial participation and improve healthcare overall. Although language and cultural barriers are not the only reason for poor representation of US minorities in clinical research, they are certainly among the most important to overcome. 

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#### Karen Politis Virk MS

Director

Biotech and Pharmaceutical Research

Language Connections

Boston, MA, US

Tel: +1 617 731 3510

Fax: +1 617 731 3700

E-mail: [karen@languageconnections.com](mailto:karen@languageconnections.com)