

Clinical Trials: The Current Challenge.

By Valandra L. German, MPH

The heterogeneous population of the United States calls for the importance of multi-ethnic clinical trials. Because the underlying foundation of the United States is based on social equity, justice, and respect for the human existence, equal recruitment and retention to clinical trials is essential. The Texas Medical Center, comprising over 40 institutions, can set a precedent to ensure no disparities exist for clinical trial enrollment, regardless of funding source or insurance status.

Currently there are significant disparities with respect to cancer and asthma surveillance and treatment. For example, disparities have been noted in surgery for non-small cell lung cancer, and screening mammography. The underserved populations include people of low socio-economic status, people living in rural areas, elderly, as well as ethnic peoples of Latino/Hispanic, Asian/Pacific Islander, American Indian/Alaska Native, and African American descent.

The emerging trend in clinical trials, at least with respect to ethnic minorities, is that the number of minorities participating has stabilized, whereas clinical trial participation in the general population has been rising. Thus, the percentage of minority participation is decreasing. Because treatment efficacy is ascertained through clinical trial participation, disparity in clinical trial enrollment and retention, may have broad implications.

Recruitment and retention of these populations is important for several reasons. Clinical trials are used to test hypothesis regarding treatment and prevention. Adequate representation allows generalizability of findings, and allows for ethnic-specific analyses and data presentation. Cancer clinical trials are often used to gauge efficacy of treatment. Typically, only about 3-5% of cancer patients participate in clinical trials. Because the underserved population is disproportionately affected by cancer and asthma, their lack of participation is of serious consequence.

There are significant benefits to participation, from both a research and patient standpoint. From a research perspective, the structure of clinical trials should include underserved populations based on the hypothesis. If burden of disease is higher in a specific population, the study should over-sample this population. A second approach assumes there are no racial or ethnic differences, so the study sample composition should reflect the census. Alternatively, the study using the second approach can reflect the demographics of the region (i.e, proportional sampling); although this may confine study results to a specific locale, the findings will more accurately reflect the disease burden on the local population.

Participation in clinical trials is also beneficial on the individual level. A study conducted by Comis et. al., found in a survey of approximately 6,000 cancer patients, the majority report it as a positive experience. Also, the physicians who participate in clinical trials have been found to take better care of their patients.

Systematic reviews pinpoint barriers stemming from lack of opportunity, lack of awareness, and lack of acceptance. It is possible to overcome these barriers. Studies demonstrate awareness increases with the provision of culturally relevant education, and provision of transportation. Acceptance increases with altruism, perceived benefits of participation, and incentives. Evidence shows that media and clinic based strategies are successful vehicles of transmitting clinical trial information.

Effective recruitment and retention must focus on individual and structural-level dimensions. On an individual level, one must ascertain the personal and socio-cultural characteristics impacting decision-making. Examples of structural-level dimensions include accessibility to where the trial is held, as well as physician knowledge about the trials.

In a survey of Texas primary care physicians, hindrances to participation include: perception of enormous amounts of clinical trial paperwork, lack of knowledge of clinical trials available, lack of knowledge about the set-up of clinical trials, and lack of information to ascertain risk-benefit ratio for individual patients.

Given the plethora of information on the research and individual benefits of participation in clinical trials, it is not a question of whether to participate. If the mission of the Texas Medical Center truly is to “promote the highest quality health status for all people and...highest possible standards of patient and preventive care, of research and education, and of local,

national and international community well-being,” then it is our obligation to step in and ensure a more equal representation of the underserved population in clinical trials. Together, we can use media and clinics as outlets for information dissemination, tailor the strategies to increase awareness and acceptance on an individual level, and work towards decreasing structural obstructions. Ultimately, a good clinical trial is one whose study sample composition is based on the hypothesis; and, with cancer and asthma trials, that quite possibly may require changing current recruitment and retention practices for underserved populations. ●

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