AMERICAN MEDICAL ASSOCIATION ACADEMIC PHYSICIANS SECTION

Resolution: APS-03
(X-##)

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Subject: Increasing Female Representation in Oncology Clinical Trials

Referred to: Reference Committee ___

Whereas, females have historically been underrepresented in biomedical research, including in oncology clinical trials; and

Whereas, previous studies have found that females comprised only 34.7-38.6% of participants in cancer prevention and treatment trials from 1990-2010, a proportion far less than the actual incidence of cancers among females; and

Whereas, more recent literature relating to this topic documents that females remain underrepresented, especially as compared to the magnitude and proportion of their disease burden in surgical and other invasive oncology trials, and anal canal, bladder, bone/joint, esophageal, head/neck, kidney, stomach, and thyroid cancer trials; and

Whereas, the resulting generalizability of cancer clinical trial findings remains hindered by the persistent failure to proportionally enroll female participants relative to their disease burden, a factor which continues to limit women’s access to novel therapeutics and potentially improved survival through trial participation; and

Whereas, current research also shows that industry-funded oncology clinical trials had greater odds of proportional female representation than U.S. government and academic-funded oncology trials, suggesting success of the Food and Drug Administration (FDA) exploratory committees investigating female participation (for nearly all industry-funded trials) over simple mandates for female participation as put forth by the National Institutes of Health (NIH) (for most government and academic-funded trials not overseen by the FDA); and

Whereas, existing AMA policy encourages increased outreach and education only for minority and female physicians to promote minority and female patient recruitment in clinical trials, despite this being an issue that impacts all physicians and their patients; therefore, be it

RESOLVED, That our AMA amend H-460.911, Increasing Minority Participation in Clinical Research, by addition as follows:

Increasing Minority and Female Participation in Clinical Research H-460.911

1. Our AMA advocates that:
   a. The Food and Drug Administration (FDA) and National Institutes of Health (NIH) conduct annual surveillance of clinical trials by gender, race, and ethnicity, including consideration of pediatric and elderly populations, to determine if proportionate representation of women and
minorities is maintained in terms of enrollment and retention. This surveillance effort should be modeled after National Institute of Health guidelines on the inclusion of women and minority populations.

b. The FDA have a page on its web site that details the prevalence of minorities and women in its clinical trials and its efforts to increase their enrollment and participation in this research; and

c. Resources be provided to community level agencies that work with those minorities and females who are not proportionately represented in clinical trials to address issues of lack of access, distrust, and lack of patient awareness of the benefits of trials in their health care.

These minorities include Blacks/African Americans, Hispanics, Asians/Pacific Islanders/Native Hawaiians, and Native Americans.

2. Our AMA recommends the following activities to the FDA in order to ensure proportionate representation of minorities and females in clinical trials:

a. Increased fiscal support for community outreach programs; e.g., culturally relevant community education, community leaders' support, and listening to community's needs;

b. Increased outreach to female all physicians to encourage recruitment of minority and female patients in clinical trials;

c. Continued minority physician education for all physicians and physicians-in-training on clinical trials, subject recruitment, subject safety, and possible expense reimbursements, and that this education encompass discussion of barriers that currently constrain appropriate female and minority subject recruitment and methods for increasing trial accessibility for patients such as community partnerships, optimized patient-centered locations for accessing trials, and the ready availability of transportation to and from trial locations and child care services;

d. Support for the involvement of minority physicians in the development of partnerships between minority communities and research institutions; and

e. Fiscal support for minority and female recruitment efforts and increasing trial accessibility through optimized patient-centered locations for accessing trials, the ready availability of transportation to and from trial locations, child care services, and transportation, child care, reimbursements, and location.

3. Our AMA advocates that specific results of outcomes in all clinical trials, both pre- and post-FDA approval, are to be determined for all subgroups of gender, race and ethnicity, including consideration of pediatric and elderly populations; and that these results are included in publication and/or freely distributed, whether or not subgroup differences exist.

Fiscal Note:

Received: TBD

References:


Relevant AMA Policy:

**H-460.911 Increasing Minority Participation in Clinical Research**

Our AMA encourages increased outreach to female physicians to encourage recruitment of female patients in clinical trials, and advocates that The Food and Drug Administration (FDA) conduct annual surveillance of clinical trials by gender, race, and ethnicity, including consideration of pediatric and elderly populations, to determine if proportionate representation of women and minorities is maintained in terms of enrollment and retention. [BOT Rep. 4, A-08 Reaffirmed: CSAPH Rep. 01, A-18]

**H-460.965 Viability of Clinical Research Coverages and Reimbursement**

Our AMA encourages legislation that would allow sponsors of clinical trials to cover non-clinical, ancillary costs (including transportation, lodging, meals, and child care) for trial participants. Currently, insurers are required to cover the direct medical or “routine costs” of treatment ordinarily incurred during a clinical trial, and trial sponsors generally cover the expenses for procedures or medications that are necessary for the research study. However, patients are often responsible for ancillary costs, which may lead to varied participation rates between higher- and lower-income patients, patients in rural areas, and other underrepresented groups. [Amended: Rep. Prelim, A-22]