Participants in studies used as basis for medicare decisions differ from beneficiaries

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The clinical trials used by Medicare for making decisions about coverage for cardiovascular products or services include participants who differ from Medicare beneficiaries in age, sex and country of residence, according to a report in the January 28 issue of *Archives of Internal Medicine*, one of the JAMA/Archives journals.

Cardiovascular disease is the leading cause of death and disability among Medicare beneficiaries, according to background information in the article; expenses for this condition exceed those for any other. “Because Medicare expenditures continue to increase rapidly, it is necessary that coverage decisions be based on data most likely to maximize value and optimize outcomes for Medicare beneficiaries,” the authors write. An independent panel of physicians and other professionals advises the Centers for Medicare and Medicaid Services (CMS) on medical technologies. Panelists review technology assessments prepared for each new medical product or service and then vote on the quality of evidence for health benefits.

Sanket S. Dhruva, B.A., and Rita F. Redberg, M.D., M.Sc., of the University of California at San Francisco School of Medicine performed a meta-analysis of all trials included in technology assessments considered by the CMS advisory panel between 1998 and 2006. For the panel’s six meetings, 141 studies with a total of 40,009 participants were analyzed.

Compared with Medicare beneficiaries, clinical trial participants were an

average of 60.1 years vs. 74.7, 75.4 percent vs. 41.8 percent male and 60 percent vs. zero lived in countries outside the United States. “The trials are conducted mostly in younger, healthier, male, non–U.S. populations,” the authors write. “Medicare beneficiaries, on the other hand, are mostly older women with comorbid [co-occurring] conditions. The clinical trials primarily relied on to inform national coverage decisions simply do not reflect the Medicare patient population. Compounding this problem, data frequently are not reported by age, sex and race.”

Elderly people and women are the most likely to be affected by these disparities and should be included in more clinical trials, the authors note. “The Food and Drug Administration already requests sex-specific data for new drug applications; it certainly would be consistent, and logical, for the CMS to require direct evidence of benefit in the coverage process. Alternatively, the CMS could issue a coverage decision with a requirement that continued coverage after a specified period depends on additional subgroup data, a variation of the newly introduced ‘coverage with evidence development’ initiative,” they write. “Closer linkage of evidence to coverage would promote better value and improved outcomes for the rapidly growing and underrepresented population of Medicare beneficiaries.”

Commentary: Clinical Trial Results Cannot Always Be Generalized

The results of randomized clinical trials are most directly applied to populations of patients similar to those who participated in the study, write Noel S. Weiss, M.D., Dr.P.H., and colleagues at the University of Washington, Seattle, in an accompanying commentary.

“However, as Dhruva and Redberg illustrate in this issue of the Archives, the demographic profile of a trial’s participants and the medical care environment in which the trial is conducted may differ considerably from the target population and practice context in which the trial’s

findings are later used to guide clinical decision making and policy," the authors write.

"Although the measured effect of a particular therapy on a health outcome in the study population included in a given trial will, in many instances, closely reflect the effect of that intervention on the corresponding outcome in other settings, this extrapolation should not be made reflexively," they conclude.

Source: JAMA and Archives Journals

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