

Older adults often excluded from clinical trials

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Older individuals, who constitute a rapidly growing population in the United States, account for a disproportionate share of health care utilization and cost.

Yet more than half of clinical trials exclude people based on their age or age-related conditions, according to a new study by Robert Wood Johnson Foundation (RWJF) Clinical Scholars at the University of Michigan.

"These findings are concerning because it means that doctors cannot be confident that clinical trial results apply to their older patients," says Donna Zulman, M.D., the study's lead author and a Veterans Affairs scholar with the RWJF Clinical Scholars program at the University of Michigan Health System. "Health care providers and patients need better evidence about treatment strategies that improve the health and quality of life of [seniors](#)."

As of 2009, Americans over the age of 65 represented 12.5 percent of the U.S. population—about one in every eight Americans—and by 2030, that number is expected to almost double.

This population accounts for 34 percent of personal health care expenditures, with the majority of spending attributed to individuals with chronic diseases.

Yet in a review of clinical trials published in major medical journals,

Zulman and her colleagues found that one in five trials excluded patients based on their age alone. Furthermore, almost half of the remaining trials excluded individuals using criteria that could disproportionately impact older adults, such as physical frailty or impaired cognition.

The study also found that trials rarely assess how treatments affect function and quality of life, outcomes that are often of great importance to older individuals.

"These practices leave [health care providers](#) in the dark when determining which treatment will best serve the needs of their patients," says Zulman.

"It is rarely appropriate to exclude people from clinical trials based on their age alone," argues Jeremy B. Sussman, M.D., a study co-author and a Veterans Affairs scholar with the RWJF Clinical Scholars program at the U-M. "This is especially true in trials investigating conditions that are common in older adults."

The study authors suggest that clinical trial evidence guiding treatment of older adults would be improved by eliminating upper age limits for study inclusion, by reducing the use of eligibility criteria that disproportionately affect older patients, and by encouraging adherence to recommended analytical methods for evaluating treatment effects by age.

"There's a critical need to ensure that research findings are relevant for our most complex and vulnerable older patients," says Zulman. "Our findings suggest a need for policy change by government agencies like the Food and Drug Administration and the National Institutes of Health to increase the representation of typical [older adults](#) in [clinical trials](#)."

More information: The study, "Examining the Evidence: A

Systematic Review of the Inclusion and Analysis of Older Adults in Randomized Clinical Trials," will be published online in the Journal of General Internal Medicine on February 2, 2011.

Provided by University of Michigan Health System

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