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Recruiting Older Subjects Necessary for Accurate Study Results

Enrolling older Americans in clinical trials can be difficult, but their inclusion is necessary to get accurate study results, according to a study by researchers at the University of Michigan.

Americans over 65 account for 34 percent of healthcare expenditures, but more than half of clinical trials in the U.S. exclude patients based on age or age-related conditions. This can lead to several problems, Donna Zulman, lead author of the study, told *CTA*.

"Ideally, the study population will reflect the population in the real world," she said. "So, if the trial is for a condition that is common in an older population, and the treatment would benefit this population, then researchers have an obligation to make sure these patients are recruited to the trials"

FDA Concerns

The FDA has also expressed concern about the participation of older patients. A 2009 draft guidance from the agency and the International Conference on Harmonisation suggests that trials for new drugs should enroll at least 100 geriatric patients to detect clinically important differences between populations (*CTA*, Dec. 12, 2009).

There are a number of reasons older patients aren't enrolling in trials, Zulman said.

"Older patients tend to be more complicated, have poor health status or certain comorbidities or complicated health issues like cognition that make it harder for them to participate," Zulman said.

Those same comorbidities may make patients more susceptible to side effects and create difficulties interpreting study results.

Older patients also may have more difficulties traveling to study sites and following up with trial requirements, Zulman said.

Insurance can complicate the matter too, as many older patients rely on Medicare, according to Anne Forsman, manager of oncology clinical trials at the Essentia Institute of Rural Health in Duluth, Minn. Medicare often won't cover unapproved new drugs even in a trial setting, particularly if there is an approved treatment for the condition.

However, "it's more trial design than anything," Forsman told *CTA*.

"I believe there should be more trials designed for older Americans," she added, "but a lot of times, the older patient just doesn't fit the study's criteria for inclusion," she added.

Despite the difficulty of designing trials that can accept older patients, it's worth the effort for clinical researchers, according to Zulman.

"It's critical that we understand how drugs and interventions work in these patients, Zulman said. "Trials need to include patients who are representative of our aging demographics." — Wilson Peden

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