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In Need of Aging

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Excluding people with multiple chronic illnesses, or comorbidities, from clinical research trials may limit the applicability and usefulness of research results, some scientists worry.

In most randomized clinical trials—widely considered the best way to test treatment safety and efficacy—researchers lay out precise conditions, called eligibility criteria, for participants. A colorectal cancer treatment trial, for example, might limit volunteers to those above age 18 with non-metastatic disease who have never had radiation or chemotherapy.

There are reasons for such restrictions, including recent treatment that might interfere with current tests. But some groups of patients, such as older patients with several illnesses, may be excluded unnecessarily from cancer trials. As a consequence, clinical trial results may not be broadly applicable, and some groups of patients may be barred from participating in important and possibly lifesaving research.

Cancer is primarily a disease of older people, yet people above age 65 are routinely excluded from trials, one team of researchers reported in the *Journal of Clinical Oncology* after analyzing dozens of research papers. One cited study found that patients who were 65 or older accounted for just 25 percent of participants in a set of clinical trials, although they represent 63 percent of cancer patients in the general population. Desire to participate didn't appear to be the issue, as only about one-third of eligible older patients are selected for trials, according to another study.

Surveys of physicians in the United States and Canada found that the most frequent reasons for excluding older patients was worry that comorbid conditions could impact the response to treatment and older patients would experience worse side effects from drugs. Other reasons included transportation difficulties, which may prevent patients from making appointments, or life expectancies of older patients are too short to justify participation. By contrast, studies have refuted the belief that older patients don't tolerate chemotherapy or radiation well, and others show that even younger patients have comorbid conditions, which are not always disclosed.

Excluding people with comorbidities from clinical trials can affect the generalizability of results, other researchers reported in early 2006 in the *Annals of Family Medicine*. A treatment shown to be effective in a selective group of patients may not work well for others, although the published results of clinical

trials do not always make clear for whom the treatment is likely to be most effective.

Researchers suggest clinical trial investigators increase the acceptance of older cancer patients into studies, including those with comorbidities, and design cancer trials to specifically take other chronic illnesses into account.