

Some clinical trials explicitly exclude gay and lesbian patients

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All clinical trials have guidelines that clearly state who can and cannot participate, but according to the National Institutes of Health these guidelines are typically based on age, gender, previous treatment history, the type and stage of a disease, and other medically relevant factors. However, researchers at Fox Chase Cancer Center have gathered evidence indicating that some trials explicitly exclude individuals based on their sexual orientation. Their findings are published in a research letter appearing in the March 18 issue of the *New England Journal of Medicine*.

By performing exploratory searches of ClinicalTrials.gov—a site containing detailed information on over 80,000 clinical trials sponsored by the National Institutes of Health, other governmental agencies, and private industry—for explicit inclusion and exclusion criteria that required participants to be in heterosexual relationships, Brian Egleston, Ph.D., an assistant research professor of biostatistics and bioinformatics at Fox Chase, and colleagues found that exclusion of lesbians and [gay men](#) from clinical trials in the United States is not uncommon, particularly in studies with sexual function as an endpoint. His coauthors included Fox Chase Cancer Center researchers Roland Dunbrack, Jr., Ph.D., and Michael Hall, M.D.

"Most gay and [lesbian](#) patients are probably unaware that their [sexual orientation](#) is being used as a screening factor for clinical trial participation", notes Egleston. "This is a potentially significant issue, both for patients and the medical research community."

The searches, which included only trials with sites in the United States, showed that 15 percent of the identified studies using the terms "erectile dysfunction," "couples," and "hypoactive" had exclusionary language. In addition, the results indicated that industry sponsored trials, multi-region trials, and Phase III trials were more likely to exclude lesbians and gay men among these studies.

"The trials that exclude gay and lesbian patients tend to be larger efficacy [clinical trials](#). Further, by requiring patients to be in heterosexual relationships, many studies are also excluding unmarried or unpartnered patients regardless of sexual orientation," says Dunbrack.

To ensure that there was not a general pattern of exclusionary language missed, the researchers also looked at 1,019 studies identified by the search term "asthma." This search did not find any studies that excluded lesbians and gay men.

Provided by Fox Chase Cancer Center

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