

Women are overmedicated because drug dosage trials are done on men, study finds

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A new study by University of Chicago and University of California, Berkeley researchers suggests that women are being widely overmedicated—and suffering excess side effects—because drug dosages are calculated based on studies done overwhelmingly on male subjects.

"These drugs are optimized from the beginning to work on male bodies," said Prof. Brian Prendergast, a UChicago psychologist and co-author of the study. "We need to immediately reevaluate the widespread practice of prescribing the same doses to men and women."

Scientists and [medical professionals](#) have long known that women experience more [adverse side effects](#) than men, even when [drug](#) dosages are adjusted for body weight. These side effects can range from headaches and nausea to bleeding and seizures. But for decades, women were excluded from [drug trials](#) due to the false belief that hormone cycles would skew test results.

"For much of the time it's been practiced, biomedical science has been done by men, on men," said Prendergast. "It even starts in the [petri dish](#): Most cell lines used in early tests are male, and then drugs are tested on male lab animals."

Since 1993, the National Institutes of Health has mandated that trials should be run on both men and women. They strengthened these requirements after a seminal study in 2014, coauthored by Prendergast, which showed that female mice's hormone cycles did not skew drug test results.

However, a large proportion of studies still underrepresent women—and the trials that do include them often don't analyze the data for [sex differences](#), or even publish that data so that others can. In addition, thousands of drugs remain on the market that were approved before the 1993 ruling.

In the new study, published June 5 in the journal *Biology of Sex Differences*, Prendergast and co-author Irving Zucker of UC Berkeley combed through the publicly available data for clinical drug studies. They found 86 drugs for which there was clear evidence of sex

differences in how the body broke down the drug. For nearly all of these drugs, women metabolized them more slowly than men, leading to higher levels of exposure to the drug; in 96% of cases, this resulted in significantly higher rates of adverse side effects in women.

The medications they studied include such common drugs as aspirin, morphine and heparin, and widely prescribed antidepressants such as sertraline and bupropion.

Every human body reacts slightly differently to any given drug. In women, the drugs tend to linger longer in the blood and tissues than they do in men, for example; the liver and kidneys also generally process drugs at different rates. This remains true even when the dosage is adjusted for the weight of the patient.

"The reasons for these big differences is not fully understood, but this is a really striking result and a wake-up call," Prendergast said.

The two authors lay out a set of recommendations to address the crisis. For example, they call for the FDA to post the gender breakdown of study participants in trial data for future analyses, and to specifically label drugs that are already known to have sex differences. The information should also be discussed and included in medical education, the authors said.

"There are a lot of drugs that are prescribed on a 'one-size-fits-all' basis, and it's clear that this doesn't always work," Prendergast said. "Especially for drugs that we already know have a wide therapeutic range —meaning there's a wide range of doses that are still effective—we could do a lot better job of titrating dosages with sex in mind."

This means that, whenever possible, doctors would start with prescribing a smaller dose for [women](#), and gradually increase to reach a balance

where the medication is working as intended, but without significant side effects.

"We have an opportunity to do this better," Prendergast said. "This information needs to be widely available."

More information: Irving Zucker et al. Sex differences in pharmacokinetics predict adverse drug reactions in women, *Biology of Sex Differences* (2020). [DOI: 10.1186/s13293-020-00308-5](https://doi.org/10.1186/s13293-020-00308-5)

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