

Analysis: Commonly used drugs are rarely studied in primary care patients

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Drugs most commonly prescribed to patients seen by primary care physicians are not often tested in the patients who go to these clinics, where most people receive their care, say investigators at Georgetown University Medical Center (GUMC) and Yale School of Medicine.

The study, published in the September edition of *Journal of General Internal Medicine*, looked at drugs for conditions that are commonly treated in primary care settings, such as acne, hypertension, and diabetes.

The finding suggests primary care [patients](#) are being treated with drugs that have not been tested in settings where they are being seen, precluding the possibility that equally effective less dangerous drugs are not being used, says the study's main author, Dan Merenstein, MD, a professor in the Department of Family Medicine at GUMC. He is also director of research programs in family medicine.

"I think it is most important that the studies be done in primary care settings if they are to be used in this patient population," Merenstein says. "For example, studying an antibiotic for sinusitis in an ears, nose and throat specialty practice office is totally different than studying it in a primary care setting."

Merenstein explains that by the time a patient sees a subspecialist, they often have already received numerous courses of antibiotics and have a more severe bacterial disease. The patients seen in primary care offices for sinusitis often have viruses or less severe bacterial infections.

"Sinusitis is the number one reason antibiotics are prescribed in the outpatient setting in the U.S., most often inappropriately," he adds.

"When a patient is at the point of seeing a specialist, their condition is usually much more severe than what a primary care physician would typically see. For example, by the time someone reaches the endocrinologist for their diabetes, they have a very different severity level of their diabetes than we see in primary care," he says. "Therefore, the treatment will be very different."

The findings were made by examining 151 clinical studies (resulting in 129 published studies) of 40 different agents for all new drugs approved by the FDA between 2005-2012. Researchers found that none of the studies were conducted only in primary care patients, and only 8 percent included some primary care patients in the mix of participants. The rest of the study patients were overseen by subspecialists or other non-primary care physicians, not in a primary care setting.

Researchers also determined that only about 30 percent of studies were conducted in the United States. The other studies may have included some U.S. patients or were conducted outside of the country. Almost 22 percent of the studies included no geographical information.

Merenstein says that, while [primary care physicians](#) don't need to lead all of the trials that test drugs they might prescribe, they should be represented in advisory boards of the National Institutes of Health, should be considered for study grants and, most importantly, primary care patients need to be included in trials of drugs that will be used in primary care settings.

"The NIH has funded only one very small study of sinusitis in a primary care setting, and family practitioners represent only 0.16% of NIH advisory committee members," he says. "I would like to see the FDA

and NIH make it a priority to study conditions seen in primary care settings, in [primary care](#) settings."

More information: Jason R. Crossley et al, Review of clinical trial settings of drugs commonly used in primary care and approved between 2005 and 2012, *Journal of General Internal Medicine* (2018). [DOI: 10.1007/s11606-018-4486-7](#)

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