Centering underrepresented populations in pharmacy research

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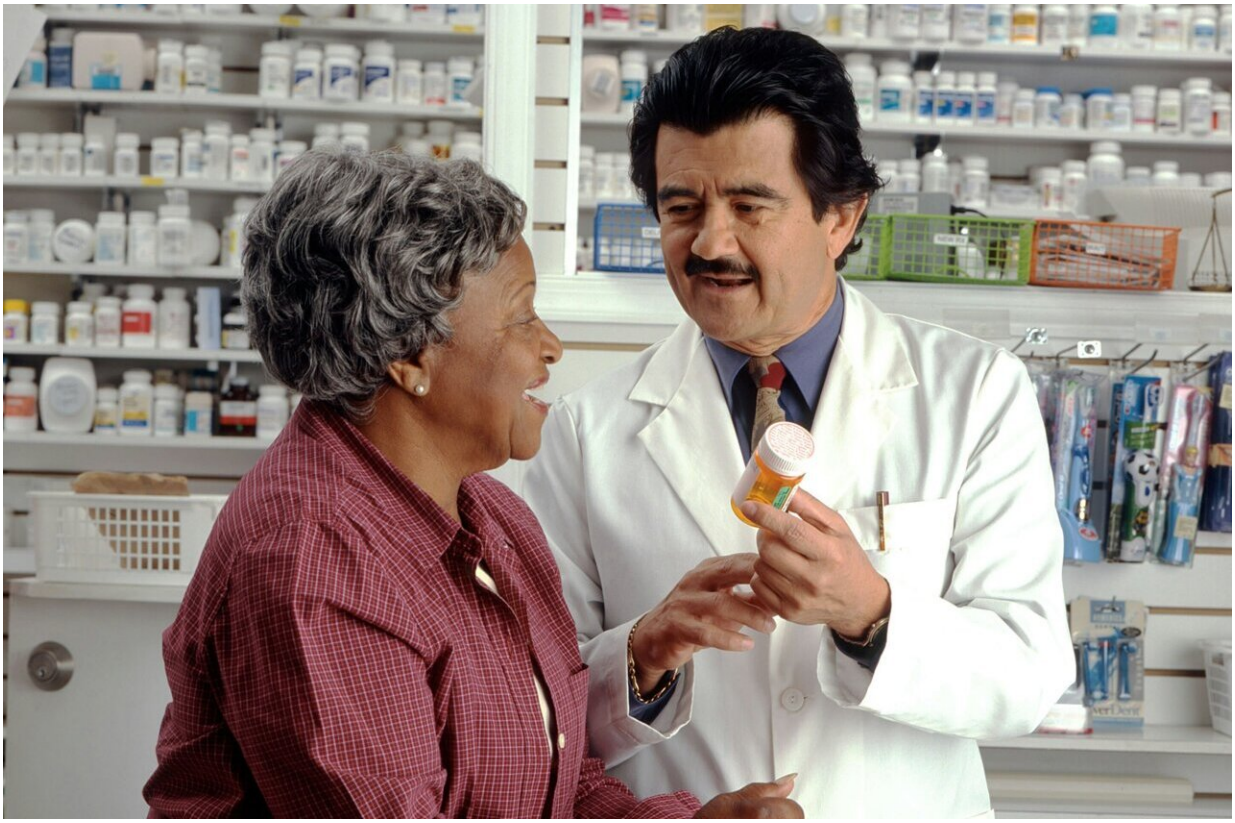

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Underrepresented populations have been historically excluded from clinical trials including women, racial and ethnic minority groups, and pregnant, lactating, pediatric and geriatric populations. While the

importance of including these groups in clinical trials is slowly being recognized and remedied, there are still questions about how currently prescribed drugs affect these populations, including the safety and efficacy of the medications.

"We know that even though we have more policies and regulations suggesting the inclusion of these underrepresented groups, that isn't always translated to what we see as clinicians and who makes it into clinical trials and there's a gap between policy and implementation," says Mira Maximos, Ph.D. candidate in the University of Waterloo's School of Pharmacy. With how significant the gaps are, the need for informed inclusion of minority groups in research is highly important.

Maximos's work, in concert with the Center of Excellence for Women's Health and Health Canada, is fundamental in theoretical research which highlights where limitations are and how to close these gaps in research. Some of this work created a foundation for Maximos's current work with her Ph.D. supervisor, JM Gamble, a clinical associate professor in the School of Pharmacy, centering around penicillin allergy risk stratification and de-labeling with consideration for sex and gender.

The paper, "Sex, Gender, and the Regulation of Prescription Drugs: Omissions and Opportunities," was published in the *International Journal of Environmental Research and Public Health*.

By understanding how sex and gender impact a drug's life cycle, clinicians can optimize dosages and monitoring for better therapeutic outcomes. To improve health and gender equity in research and clinical studies, product monograph and consumer information for medications must be transparent to improve and support sex and gender science, and a clear commitment must be made to data transparency. The gaps regarding underrepresented groups and prescription drugs should be recognized to improve regulations.

The School encourages Maximos and other Ph.D. candidates to integrate pharmacotherapeutic expertise and innovation in basic, applied and clinical research to train future scientists, policymakers and leaders in health science. Waterloo researchers and entrepreneurs are leading health innovations in Canada, by focusing on their research that emphasizes patient-focused care and addresses global health issues.

Maximos's research considers patients and end-users of research, to center their voices and what is important to them. This allows her to look at the outcomes and what directly affects marginalized groups, particularly women.

The impact of conducting research that includes underrepresented groups and missing information about these groups is starting to create a bridge between what we know to be gaps in research, including sex and gender information. "The study shines a light on the gap so we can start to close it," Maximos adds.

The gap makes it harder to know the extent of safety and efficacy of medications and how to apply them to specific populations.

Recommendations from this study were made to Health Canada on how sex and gender can be better included in the life cycle management of drugs, how they can work with manufacturers to improve transparency regarding sex and gender, and how to better involve clinicians in the decision-making processes.

"This research has been very eye-opening. What we considered to be a sex-related adverse effect was actually gender-related. It's gratifying to understand that this is much more complicated than we thought," Maximos says. "We need to understand the balance between the two because you cannot inexplicably remove gender from sex unless you look at sex in a biological variable as an expression of genes. However,

over time, gender becomes intertwined with sex."

Maximos is the recipient of the 2024 Canadian Institutes of Health Research Doctoral Award. She will develop a patient-oriented research program that leverages her clinical expertise in antimicrobial stewardship with her research experience in pharmacoepidemiology and sex- and gender-based analyses.

"Sex and gender advocacy can't be undone from one another; they go hand-in-hand," Maximos says.

More information: Lorraine Greaves et al, Sex, Gender, and the Regulation of Prescription Drugs: Omissions and Opportunities, *International Journal of Environmental Research and Public Health* (2023). DOI: 10.3390/ijerph20042962

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