

SCIENCE FACT OR SCIENCE FICTION: CAN MEDICINE BE PERSONALIZED WITHOUT SEX AND GENDER?

In contrast to a reactive, “one size fits all” approach to health care, personalized medicine is proactive and tailored to each individual. Health researchers and clinicians are increasingly looking to personalized medicine to help predict, prevent and treat disease more effectively. However, in our urgency to make medicine more precise, have sex and gender been overlooked?

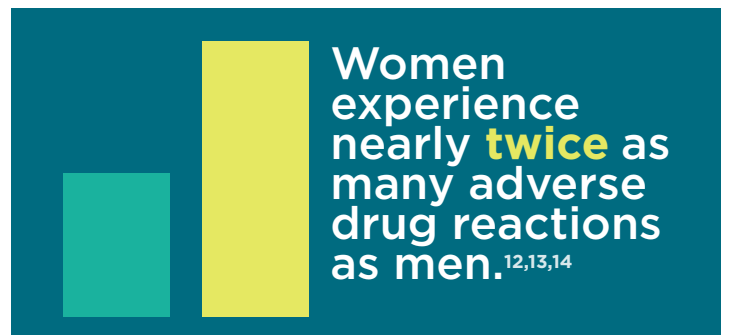
WHAT MAKES MEDICINE PERSONAL?

The traditional western health-care model recommends a particular treatment based on the ‘average’ patient. This approach may lead to successful results in many, but will be less effective in others and could even be harmful in some cases.¹ Personalized medicine is a rapidly developing field in which personal information, including genetics, biology and lifestyle factors, is used to prevent disease and determine the most effective course of treatment.²

Areas in which personalized approaches are particularly promising include cancer treatment, cardiovascular diseases, neurodegenerative diseases, psychiatric disorders, diabetes and obesity, arthritis, pain and Alzheimer’s disease. In all of these fields, a personalized medicine approach is expected to lead to better health outcomes, improved treatments and a reduction in adverse drug reactions.³

WHAT IS PHARMACOGENOMICS?

Within personalized medicine, the emerging field of pharmacogenomics studies the effects of genes on a person’s response to particular drugs. One of the goals of pharmacogenomics is to develop effective, safe medications and doses tailored to variations in a person’s genes.⁴



GETTING PERSONAL WITH SEX & GENDER

Research suggests that sex (biology) and gender (socio-cultural) are important factors in adverse drug reactions,⁵ cardiovascular disease,^{6,7} immune disease,⁸ respiratory illness,⁹ diabetes¹⁰ and mental health.¹¹ In fact, research shows that women experience nearly twice as many adverse drug reactions as men.^{12,13,14} However, many clinical trials do not sufficiently account for sex and gender differences,¹⁵ which leaves researchers and clinicians with significantly less information about 50 per cent of the population.

PERSONAL MATTERS OF THE HEART

Almost 40 per cent of Canadians between 18 and 79 years old have high blood cholesterol levels, one of the major risk factors of cardiovascular disease.¹⁶ While heart disease is often perceived by the public to be a men’s health issue, more women than men in Canada die from heart disease and stroke.¹⁷ Research shows that both sex and gender differences in cardiovascular diseases influence risk factors, help-seeking behaviours and diagnoses.¹⁸

Dr. Marie-Pierre Dubé at the Montreal Heart Institute is working to raise awareness among the genetic research community about the importance of incorporating sex and gender in personalized medicine and pharmacogenomics, especially for drug trials.

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“We have strong biological evidence supporting the fact that drugs may work differently in men and women. Data from drug trials need to be analyzed separately for men and women in order to investigate differences in drug response.”

-Dr. Marie-Pierre Dubé

Over three million Canadians are prescribed drugs called ‘statins’ to lower cholesterol.¹⁹ Given that sex and gender were often overlooked in initial trials, Dr. Dubé is using genetic profiles of the tens of thousands of patients who have participated in cardiovascular drug trials with statins to see if sex and/or gender are affecting drug response. She estimates that up to 40 per cent of people may not be using these drugs optimally either because they were prescribed an inappropriate dose or because negative side effects may lead them to stop taking the medication. Both sex and gender play a role, she argues, as men and women metabolize drugs differently and gender can influence how drugs are prescribed and used.^{20,21}

In an ongoing project, Dr. Dubé is developing a tool to help clinicians analyze whether increased muscle pain, a side effect frequently reported by women, is in fact caused by statins. She hopes this tool will help clinicians better target prescriptions for cholesterol medications to women.^{22,23}

X-MARKS THE MISSING DATA

Dr. Dubé says that one of the greatest challenges in re-analyzing clinical studies for sex and gender is that only around 30 per cent of participants in clinical trials are women.²⁴ She uses large data sets to reach statistical significance; but points out that, because of women’s low participation in trials, data is still hard to come by. “Clinical trials need to be done differently to appeal to more women,” she says. Dr. Dubé suggests ongoing communication and feedback with participants, as well as alternative recruitment techniques as first steps to achieving greater female participation.

CONCLUSION

To be truly personalized, health-care approaches must account for both biological and socio-cultural differences to determine how disease and drug outcomes differ for men, women, boys, girls and gender-diverse people.

Applying a sex and gender lens to personalized medicine has the potential to create opportunities for more targeted and effective health interventions. After all, what’s more personal than the sex you were born with or the gender you identify with?

ABOUT THE RESEARCH

Dr. Marie-Pierre Dubé is the Director of the Beaulieu-Saucier Pharmacogenomics Centre at the Montreal Heart Institute, a professor of pharmacogenomics and genetic epidemiology at the Université de Montréal and a CIHR-funded researcher. Dr. Dubé has conducted several pharmacogenomic studies of clinical trials in cardiovascular disease.

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