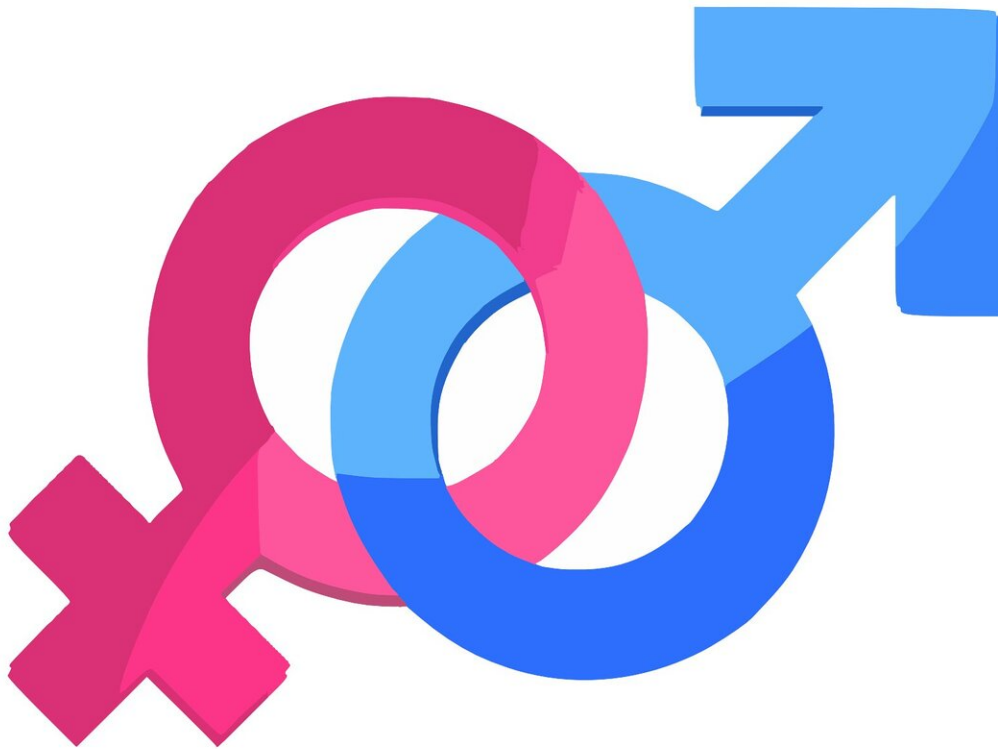


Mitigating the effects of gender bias in clinical trials

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The development of drugs and other medical treatments usually begins with basic research, followed by experiments in the laboratory, pre-clinical trials and, finally, clinical trials that confirm both the treatment's efficacy in humans and its safety. Clinical trials are long and expensive processes that seal the fate of the proposed treatment—whether it will receive approval from the FDA or other authorities or be rejected. As a result, they play a central and critical role in the development of medical treatments.

A new article by researchers at the Henry and Marilyn Taub Faculty of Computer Science at the Technion—Israel Institute of Technology, in collaboration with Dr. Eric Horvitz of Microsoft Research, describes a specific bias that affects the implementation of these trials' findings: underrepresentation of women in many clinical trials. The article, which was published in the *Journal of the American Medical Informatics Association (JAMIA)*, depicts this bias and presents a special tool that can help compensate for this [gender gap](#), thereby improving [medical treatments](#) for women.

According to Technion Ph.D. candidate Shunit Agmon, who conducted the research together with Technion alumna and visiting professor Dr. Kira Radinsky, "Nowadays, we know that different population groups react differently to a given treatment—in particular, women can have a different reaction than men to a treatment. For example, Zolpidem, a drug used to treat sleeping problems, clears more slowly in women and therefore it is important to prescribe a smaller dose for women than for men—which was discovered only after the drug was released to the market. The underrepresentation of women in clinical trials creates a problematic bias that harms the quality of women's healthcare, including misdiagnosed diseases and adverse drug reactions."

Gender bias in clinical trials is not new, and it has in fact worsened following traumatic events, including the Thalidomide affair—a drug

that caused numerous birth defects when prescribed to pregnant women to alleviate morning sickness. That tragic episode, which took place in the early 1960s, led to a drastic decline in [female participants](#) in clinical trials.

In 1993, laws were passed in the United States that mandated the inclusion of women in these trials and the analysis of results with regards to gender. Yet, female underrepresentation remained a prevalent phenomenon, especially for trials that took place prior to 1993. Agmon points out that other population groups are also underrepresented, including certain age groups, ethnic groups, and other demographics. In some cases, there is also an underrepresentation of men, such as for diseases that are considered more "feminine," such as fibromyalgia.

In recent years, machine learning models have been introduced to the world of medicine, aiming to improve medical diagnosis, treatment, and prevention. However, Agmon claims that "many of these models are based on biased trials and therefore they 'inherit' their biases, and in some cases even amplify them."

The researchers explored this issue using machine learning tools, including natural language programming (NLP), and vector representation of words (word embeddings) – approaches that enable computers to "understand" texts. They used these methods on 16,772 articles from the PubMed database and allotted each one a "weight" based on the percentage of women in the clinical [trials](#) described in each article. This way, they developed an algorithmic tool that enables gender-sensitive use of clinical literature. This algorithm corrects the gender bias and improves the treatments' suitability for female patients.

The algorithm succeeded in substantially improving predictions for women in various situations, including length of hospitalization, re-hospitalization within a month, and correlation between various diseases.

Although the model focused on improving predictions for [women](#), it also significantly improved overall clinical predictions (for men as well).

The researchers expect the JAMIA article to increase awareness of the problems of underrepresentation in research in general and in [clinical trials](#) in particular and will lead to additional solutions to improve the quality of personalized medicine.

More information: Shunit Agmon et al, Gender-sensitive word embeddings for healthcare, *Journal of the American Medical Informatics Association* (2021). [DOI: 10.1093/jamia/ocab279](https://doi.org/10.1093/jamia/ocab279)

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