Study finds wide geographic differences in treatment of diabetes, hypertension, depression

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Credit: Anne Lowe/public domain

An international observational study led by Columbia University researchers has uncovered widespread differences in the treatment of patients with common chronic diseases, including type 2 diabetes, hypertension, and depression. Using data from 250 million patient records in four countries, the study demonstrates the feasibility of

performing large-scale observational research to obtain information about clinical practice among diverse groups of patients.

Findings from the study, performed in collaboration with the Observational Health Data Sciences and Informatics (OHDSI) program, were published online today in *Proceedings of the National Academy of Sciences* (*PNAS*).

The study revealed that the vast majority of patients with diabetes worldwide are initially treated with the medication metformin, although there is wide variation in what second-line treatments are given. In contrast, the study found significant variation in first-line treatment of hypertension and even greater differences in the initial treatment of depression. One surprising finding was that 10 percent of diabetes patients, 11 percent of depression patients, and 24 percent of hypertension patients followed a treatment pathway that was shared with no one else in the study.

"We found that while the world is moving towards more consistent therapy over time for the three diseases, there remain significant differences in how they are treated," said first author George Hripcsak, MD, MS, the Vivian Beaumont Allen Professor and chair of Biomedical Informatics at Columbia University Medical Center (CUMC), principal investigator of the OHDSI coordinating center and director of Medical Informatics Services at NewYork-Presbyterian/CUMC. "This suggests that randomized clinical trials—the gold standard in evaluating new therapies—may not capture enough of the information needed to make their results more broadly generalizable to different populations."

Observational research, in which patterns of care are gleaned from large data sets—such as electronic health records, insurance claims, and pharmacy records—have the potential to offer insight into real-world treatment scenarios that may inform clinical trial design and, ultimately,

clinical practice. But analyzing data from a variety of sources is often hindered by disparate models for collecting and storing patient records.

To surmount these hurdles, an international group of scientists formed the OHDSI (pronounced 'odyssey') program, which allows researchers to combine and analyze patient data from widely different sources in the US and abroad. Columbia University serves as OHDSI's coordinating center. Currently, the research collaborative involves more than 600 million patient records from 14 countries.

"Modern randomized trials are currently carried out without a clear view of how current treatments are used," said study leader David Madigan, PhD, executive vice president and dean of the Faculty of Arts and Sciences, professor of statistics at Columbia University, and co-principal investigator of the OHDSI coordinating center. "In the future, before a randomized trial is started, an observational study like ours could be mandatory to determine the appropriate sample size and composition of control groups, among other factors."

The study relied on the OHDSI distributed data network, in which researchers from around the world convert patient-level data to a standardized model that can run a common analysis protocol. Investigators from the 11 research sites participating in the study shared the final, aggregate results, although individual data were excluded to protect patient privacy. Seven of the research sites had completed their analyses within just three weeks of beginning the study.

"While the findings are quite interesting, the important point is that we've shown that large-scale observational research across widely different databases is feasible," said Jon Duke, MD, director of the Drug Safety Informatics Lab and research scientist at the Regenstrief Institute. "And it can be done in a very short amount of time."

Future OHDSI studies will focus on medical product safety surveillance, comparative effectiveness research (making direct comparisons between therapies), patient-level predictive modeling, and other topics. A worldwide request for proposals is planned, in which researchers, citizen scientists, and high school students may propose research questions to be run on the OHDSI network.

"The creation of such a network is a great opportunity, not only to characterize what treatments are actually being used, but also to attempt to identify what treatments are potentially better," said Nigam Shah, MBBS, PhD, associate professor of medicine at Stanford University. "For example, from the wide variation in second-line treatments for diabetes, we can attempt to identify those that are more effective. OHDSI puts us on a path to creating personalized evidence, which is a form of precision medicine."

More information: Characterizing treatment pathways at scale using the OHDSI network, *PNAS*, www.pnas.org/cgi/doi/10.1073/pnas.1510502113

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