Scientists teaching machines to make clinical trials more successful

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Yizhao Ni, Ph.D., a researcher in the Division of Biomedical Informatics at Cincinnati Children's Hospital Medical Center, stands in the institution's research data warehouse. Ni and his colleagues are mining electronic health record data and blending human and artificial intelligence to find better ways to recruit patients for clinical trials. They report research results on April 27 in the *Journal*

of the American Medical Informatics Association identifying key reasons why people decline to participate in clinical studies. Credit: Cincinnati Children's

Scientists are teaching computers to figure out why people accept or decline invitations to participate in clinical trials. Recruiting sufficient numbers of participants is a current challenge in medical research that can compromise results or stop some studies altogether.

Researchers at Cincinnati Children's Hospital Medical Center report April 27 in the *Journal of the American Medical Informatics Association* they are using so-called "machine learning" technologies to predict whether patients will participate.

"Challenges with patient recruitment for clinical trials are a major barrier to timely and efficient translational research," said Yizhao Ni, PhD, lead author and a researcher in the Division of Biomedical Informatics at Cincinnati Children's. "The ultimate goal of our research is to impact patient recruitment strategies to increase participation in clinical trials, and to help ensure that studies can be completed and the data are meaningful."

The authors report in their study that their automated algorithm was significantly better at predicting patient participation response than the program that simulates current recruitment practices.

In the study, about 6o percent of patients approached with traditional recruitment practices ultimately agreed to participate. Researchers predict that their new automated algorithm could push acceptance rates up to about 72 percent. As Ni and his colleagues further develop and refine the algorithm, their goal is to increase the acceptance rate beyond 72 percent.

The authors worked from previous studies that identified categories of objective and subjective factors that influence successful patient recruitment. Age, race, education, socioeconomic level, financial resources and required time commitment are examples of objective factors. Subjective factors include attitudes about medical research, family influence, seasonality, or whether a person's health condition has suddenly deteriorated.

The new study confirms that patients are less likely to participate in randomized studies, multi-center trials, more complex trials, and trials that required follow-up visits. The paper also identifies new recruitment challenges that should be analyzed in future studies.

Even with growing new intelligence on why people accept or decline clinical trial invitations, study authors indicate it is difficult to manually process this new information in busy medical clinic environments. This makes current recruitment practices somewhat random - with little time or ability to account for individual patient preferences or biases. An automated system capable of analyzing and interpreting these factors can also develop precise patient-directed recruitment strategies to improve participation.

The machine-learning algorithm developed by Ni and colleagues basically analyzes, compares and interprets different data sources to predict specific patient decision making. To test their algorithm, researchers collected data from 2010 through 2012 involving clinical trial recruitment in the Emergency Department of Cincinnati Children's - a busy and challenging environment with 70,000 annual patient visits.

Study authors write that patient recruitment in the Emergency Department is now done on a per-patient-visit basis. Clinical research coordinators attempt to match patients with appropriate clinical studies based on the study's specific goals and guidelines, and then approach

those patients for enrollment.

For purposes of the current study, the researchers attempted to collect data on the Emergency Department's process. For scoring, each Emergency Department patient invited into a clinical trial was counted as an "encounter." Patients accepting invitations were labeled as "+1"; decline responses were labeled "-1." The researchers counted data that included 3,345 patient encounters for a diverse set of 18 different clinical trials.

At the same time, the researchers collected demographic, socioeconomic data and clinical information from different sources to help build patient profiles. This information was fed into the machine learning algorithm, which processed the data through programs for predictive modeling, comparison, analysis and prediction.

Researchers then compared the effectiveness of their algorithm to a "random-response-prediction program" that was developed to simulate the current recruiting method in the medical center's Emergency Department. Those results were then validated by comparing them to the "acceptance" and "decline" responses recorded from the in-person Emergency Department encounters.

Researchers stressed the algorithm requires additional development and testing before it can be used clinically.

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