Methods to Apply Results from Randomized Trials to Patients in Clinical Practice

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What was the project about?

Randomized controlled trials, or RCTs, look at how well treatments work. But people who take part in RCTs may differ from patients who receive care in clinics. For instance, patients who take part in RCTs may be less likely to smoke or may have fewer health problems. These differences can affect how well a treatment works. As a result, a treatment may work differently for a patient receiving care in a clinic than it did for patients who took part in the RCT.

Researchers can use statistical methods to account for differences in patient traits and behaviors. In this project, the research team developed and tested new methods to account for these differences. They used the methods to apply RCT results to patients receiving care in clinics.

What did the research team do?

The research team combined data from an RCT with data from patients receiving care in clinics. The team looked at two ways of combining the data:

- **Nested design.** The RCT data were inserted, or nested, within data from patients receiving care in clinics.
- **Non-nested design.** The team added data from patients receiving care in clinics to the RCT data.

The research team then created three types of statistical methods to analyze the data from both

study designs. The team used the methods to look at how well the treatment would work for the patients receiving care in clinics. The team tested the accuracy of the methods using data created by a computer and data collected from patients.

Patients and healthcare providers helped advise the study team.

What were the results?

All three types of methods worked correctly if enough data were included from the patients receiving care in clinics. If enough data weren't available, then the findings from the RCT couldn't be applied to clinic patients.

What were the limits of the project?

The methods need further development if data from patients receiving care in clinics are incomplete or have errors. To use the methods, researchers need to make sure that they have data on the patient traits that may affect how well a treatment works.

Future studies could explore ways to use the methods with other health problems and different data sets.

How can people use the results?

Researchers can use these methods to apply RCT results to patients receiving care in clinics.

To learn more about this project, visit www.pcori.org/Dahabreh365.