PROJECT INFORMATION

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Statistical Methods to Test If a Treatment Is Not Worse Than Standard Treatment

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Organization

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What was the project about?

Researchers usually design studies to find out if a new treatment works better than no treatment or better than a treatment that is currently used. But sometimes researchers may want to know that a new treatment is not worse than one that's in use. These studies are called non-inferiority, or NI, studies. Researchers conduct NI studies when a new treatment has other benefits such as fewer side effects, even though it may not work better than the one in use. NI studies can provide useful information, but they are hard to design and conduct.

In this study, the research team tested different statistical methods for NI studies that compare treatments.

What did the research team do?

The research team created three Bayesian methods and a traditional method for use in NI studies that compare two treatments. Bayesian methods account for findings from previous studies, which can make results of NI studies more accurate. Traditional methods don't use past findings.

The research team compared the accuracy and precision of the four methods. The team first looked at the methods using test data. The test data included information on patients' health and treatments created with a computer program. Then the team tested the methods using real data from a previous

study that compared treatments for skin infections. The real data had actual information about the patients' health and treatments.

What were the results?

With the test data, the Bayesian methods worked similarly to the traditional method.

Using the data from a previous study, the Bayesian methods performed better than the traditional method.

What were the limits of the project?

Using findings from previous studies may not work if patients in previous studies had different traits than those in the planned NI study. Also, the new methods are for studies that collect patient data once. The findings may not apply to studies that collect data from the same patients at several points over a long period of time.

Future research could create methods for testing in NI studies that collect data over long periods of time.

How can people use the results?

Researchers can consider these results when designing NI studies.

To learn more about this project, visit www.pcori.org/Ghosh302.