

Few treatment guidelines for heart disease are based on rigorous study

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Less than 10 percent of the treatment recommendations U.S. doctors rely on to manage care for heart patients are based on evidence gained from multiple large, randomized clinical trials—the gold standard for obtaining scientific data.

In fact, the proportion of well-supported recommendations for heart care



has actually declined compared to 10 years ago, when an earlier analysis found a similar dearth of rigorous studies supporting treatment guidelines. The latest study, led by the Duke Clinical Research Institute, appears online March 15 in *JAMA*.

"In 2009, there was a call for improvement in the clinical research enterprise after that earlier study highlighted several deficiencies," said senior author Renato Lopes, M.D., Ph.D., a cardiologist and professor of medicine at Duke.

"But really, despite some initiatives and a greater focus on conducting randomized controlled trials, the chasm between <u>evidence</u> and the need for evidence has not improved," Lopes said.

"As a matter of fact, the proportion of U.S. recommendations from cardiovascular guidelines supported by high quality evidence actually decreased from 11 percent to 9 percent in the last decade," Lopes said. "To deliver the <u>health care</u> that our patients deserve, clinical research must be transformed."

Lopes and colleagues, including former FDA commissioner Robert M. Califf, M.D., examined the evidence supporting more than 6,300 treatment recommendations issued by the American College of Cardiology and the American Heart Association (ACC/AHA), and the European Society of Cardiology (ESC).

These treatment standards are used to define and manage such basic cardiovascular conditions as <u>high blood pressure</u> and high cholesterol, and adherence is widely considered to improve patients' outcomes.

The quality of the data that buttress the recommendations are important to minimize any inherent study biases and confounding factors, which could then affect real patients in real-world circumstances.



Guideline writing committees categorize recommendations by the level of evidence supporting them: Level As are based on evidence gained from multiple randomized control trials; Level Bs are supported by a single randomized control trial or non-randomized studies such as observational analyses; and Level Cs are set by expert opinion. The researchers recorded the level of evidence assigned by guideline writing committees in current guideline documents.

According to their review, the Duke-led team found that just 8.5 percent of ACC/AHA recommendations relied on Level A evidence, while 50 percent of studies had Level B data and 41.5 had Level C.

"Patients should have an expectation that the science behind the care they receive is solid and will result in improved outcomes," said lead author Alexander Fanaroff, M.D. "Progress in reducing cardiovascular mortality has decelerated over the past several years, so improving the evidence base for <u>treatment guidelines</u> could help forestall this trend."

Califf noted that technology has advanced greatly in the past decade, and more should be done to incorporate the growing ability to capture data and improve clinical research.

"Changes in computing and the widespread use of electronic health records have taken away the technical limitations to a much more efficient and scalable clinical research system," Califf said. "We need to make the changes in the way the system works so that patients and clinicians can have assurance that their decisions are based on high quality evidence."

Provided by Duke University Medical Center

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