

Clinical practice guidelines: Trying to get them right the first time

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The common thought in the medical community is that the randomized, controlled trial is the gold standard in medical research. Findings from these studies are thought to be most reliable and are often endorsed by guideline-making organizations and brought into medical practice. But, Penn Medicine researchers caution that the rapid adoption of one or two studies as the basis for clinical practice, even if they are randomized controlled trials, can lead to misinformation and potential harm. Using the case of Beta-blockers, they show how clinical practice guidelines are too often adopted quickly then overturned in the ensuing years. Their work is published in the current issue of *BMJ Quality and Safety*.

"We wanted to study this phenomenon to better understand the kinds of problems that guideline-makers encountered in making reliable guidelines and how processes might be improved in the future," says lead author, Mark Neuman, MD, MSCE, assistant professor of Anesthesiology and Critical Care and Senior Fellow in the Leonard Davis Institute of Health Economics at the Perelman School of Medicine at the University of Pennsylvania.

In the late 1990s beta-blockers, drugs commonly given to patients to reduce blood pressure, were hailed as a breakthrough for reducing life-threatening post-surgical cardiac complications in high-risk surgical patients as a result of two small high-profile randomized studies. So much credence was placed in these studies by the [medical community](#) that the American College of Physicians called attention to one of them as 'an important publication that we think should alter current practice'.

In 2001, the U.S. Agency for Healthcare Research and Quality (AHRQ) followed, rating this the second most relevant practice for improving [patient safety](#), and a year later the American Heart Association (AHA)/American College of Cardiology (ACC) called for wider preoperative Beta-blocker use.

Then, the evidence began to crumble.

Two larger retrospective studies in 2005 failed to reproduce the earlier, much celebrated results. In addition, three randomized controlled studies in 2005 and 2006 cast further doubt on earlier findings: none of them observed any difference in postoperative outcomes with preoperative initiation of Beta-blockers versus placebo.

By 2006, the ACC/AHA had downgraded its recommendation regarding the preoperative initiation of beta-blockers and in 2009 the recommendation was downgraded further.

The AHRQ in its second edition of "Making Health Care Safer," in 2013 did not list Beta-blockers among its 22 "strongly encouraged" or "encouraged" patient safety practices. Over 15 years the hailed paradigm-shifting practice – considered a symbol of safe medical care – fell out of favor as accumulating evidence called attention to previously overlooked potential harms.

The researchers contrast the debate over Beta-blocker use with that of hormone-replacement therapy (HRT) for women. From the late 1970s to the late 1990s retrospective studies led HRT to be recommended to treat the symptoms of menopause and prevent heart disease in older women. But, [randomized controlled trials](#) in 1998 and 2002 showed that HRT increased heart disease, stroke and cancer risk. Again, the recommendation was overturned.

"We believe that there are several pressures causing the early endorsement of these treatments as best practices, specifically in the case of Beta-blockers," says Neuman. "First there was an overly high degree in the confidence in the results of limited randomized trial evidence; second, the medical community was looking for a way to minimize post-surgical adverse cardiac outcomes in high-risk patients in need of surgery and the early studies fit this need; third, guideline-making organizations, and the medical specialty as a whole face real political pressures to codify best practices for quality measurement. These pressures, we believe, can lead to the premature endorsement of trial results as best practices.

"The hope is that we can openly discuss episodes like the beta-blocker story as a start towards understanding how to do better in the future," says Neuman.

"This story became extremely important since the ACC/AHA published new Guidelines of Perioperative Cardiovascular Evaluation within the last two weeks and the controversy regarding the evidence surrounding perioperative beta-blockers was a critical reason for the update," said senior author, Lee A. Fleisher, MD , Professor and Chair of Anesthesiology and Critical Care and Senior Fellow in the Leonard Davis Institute of Health Economics at the Perelman School of Medicine at the University of Pennsylvania.

Provided by University of Pennsylvania School of Medicine

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