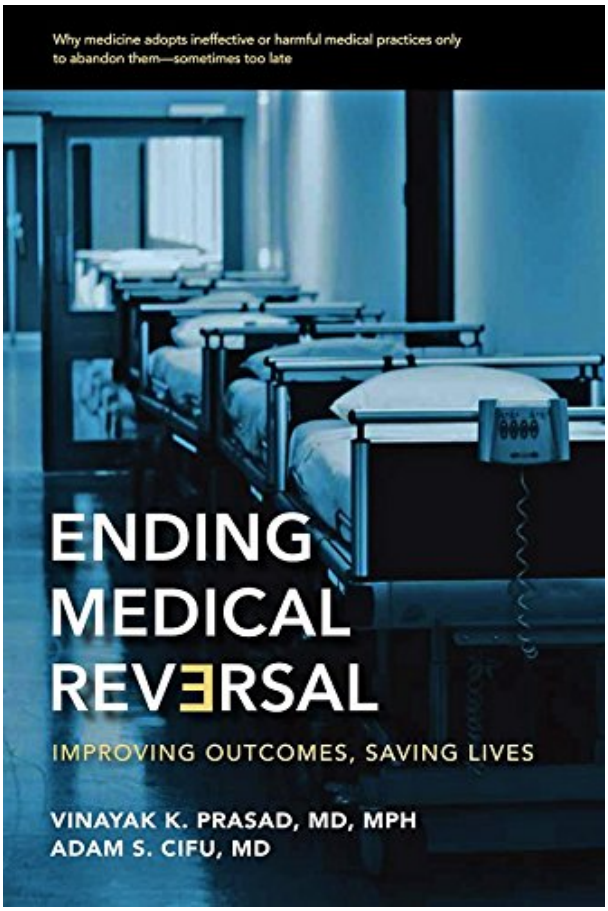
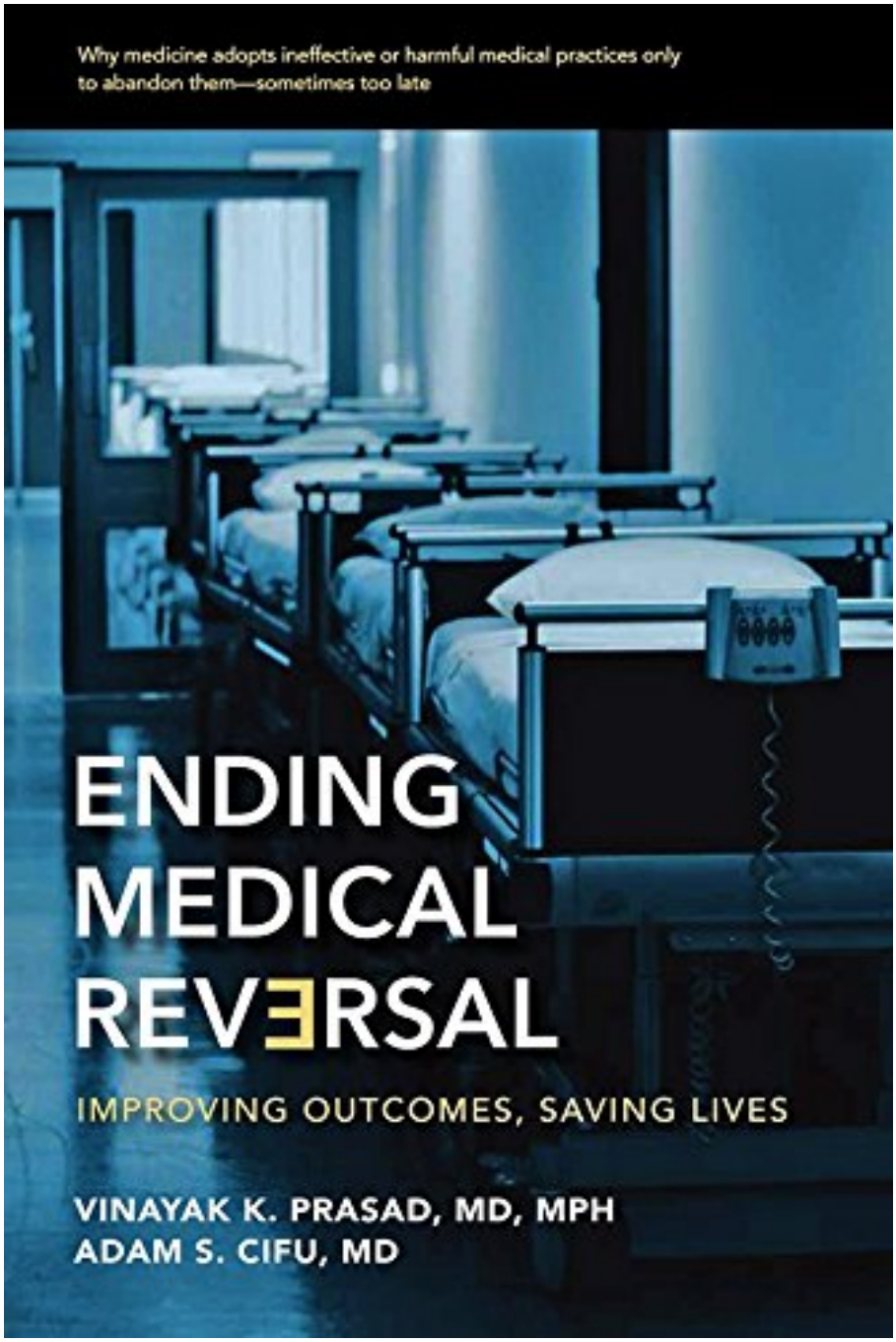
ENDING MEDICAL REVERSAL BY VINAYAK K., MD, MPH PRASAD, MD, ADAM S. CIFU





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Review

Every doctor should read this book.

(JAMA Internal Medicine)

Dr. Prasad and Dr. Cifu offer a five-step plan, including pointers for determining if a given treatment is really able to do what you want it to do, and advice on finding a like-minded doctor who won’t object to a certain amount of back-seat driving. Of course, there are no guarantees that their tips will endure forever, but they probably have a longer shelf life than most medical advice.

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An outstanding, genre-defining work, this book will be read by students, educators, policymakers, scientists, scholars, medical skeptics, and health-care pundits alike.

(John Henning Schumann, MD, host of Public Radio Tulsa's Medical Matters)

An important book that frames medical reversal in a compelling way. Readers will be drawn to this clearly written account.

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When I describe Ending Medical Reversal as revolutionary, I don't use the term lightly. Go out and read it?right now.

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[A]n excellent and realistic discussion of some of the horror stories that occur in medical practice....The examples are quite interesting and certainly educational for all readers. Highly recommended.

(Choice)

Ending Medical Reversal goes far in teaching medical students and practicing physicians alike how to learn on our own.

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This has to be on the reading list for medical and nursing students.

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About the Author

Vinayak K. Prasad, MD, MPH, is a practicing hematologist-oncologist and internal medicine physician. He is an assistant professor of medicine and public health at Oregeon Health & Science University. Adam S. Cifu, MD, is a professor of medicine at the University of Chicago. He is a practicing general internist, medical educator, and the coauthor of Symptom to Diagnosis: An Evidence-Based Guide.

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We expect medicine to progress in an orderly fashion, with good medical practices being replaced by better ones. But some tests and therapies are discontinued because they are found to be worse, or at least no better, than what they replaced. Medications like Vioxx and procedures such as vertebroplasty for back pain caused by compression fractures are among the medical "advances" that turned out to be dangerous or useless. What Dr. Vinayak K. Prasad and Dr. Adam S. Cifu call medical reversal happens when doctors start using a medication, procedure, or diagnostic tool without a robust evidence base—and then stop using it when it is found not to help, or even to harm, patients.

Drs. Prasad and Cifu narrate fascinating stories from every corner of medicine to explore why medical reversals occur, how they are harmful, and what can be done to avoid them. They explore the difference between medical innovations that improve care and those that only appear to be promising. They also outline a comprehensive plan to reform medical education, research funding and protocols, and the process for approving new drugs that will ensure that more of what gets done in doctors' offices and hospitals is truly effective.

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Most helpful customer reviews

17 of 18 people found the following review helpful.
Wasted Money, Temporary Placebo Gains, Deliberate Deception
By Loyd Eskildson
The book reports how/why doctors continue to used medical practices, sometimes for decades, that are later shown to be of no benefit to their patients. Time and again, we 'learn' that a new practice will help extend life, then that it does not. (Estrogen-replacement therapy after menopause, placement of coronary stents to open narrowed/blocked coronary arteries, cupping - topical suction, lobotomy. Vioxx, flecainide, losartan, routine mammography for women in their 40s) The authors assert that while there are instances of good

hypotheses failing to live up to expectations - such should happen in a lab/controlled clinical trial - not in clinical medicine. They believe medicine can do a better job recommending practices that actually work.

Medical reversal/disbelief is strongest when involving how people feel - eg. vertebroplasty, coronary stents (for the first three years), arthroscopic knee surgery to repair degenerative meniscal tears (700K/year),

Seven states in the career of a medical innovation,' pre-Evidence Based Medicine (EBM), per John McKinlay: A 'promising report' in which a medical innovation is publicized based on its promise. 2)The innovation is adopted. 3)Patients and payers accept the innovation as standard. 4)Data begin to become available - however, those supporting the innovation come only from insubstantial studies that support the innovation in the most superficial way. 5)The RCT makes an appearance. 6)Then denial, if its use is not supported - entrenched interests deny the innovation may not be effective. 7)Acceptance.

While EBM has filled journals, they often avoid big questions or favor one side such that they are not useful.

Surrogate end points are objective ones that can be easily and directly measured (eg. improved bone density vs. fracture rates, lowered blood pressure vs. decreased rate of strokes, antiarrhythmic drugs decreasing the number of premature ventricular contractions but not survival after a heart attack, hospitalization rates). However, they are invisible to the patient.

Summarizing to this point, we have seen reversal for practices meant to make us live longer when evidence supporting that practice was weak or flawed - this included times when the evidence relied on surrogate end points. For practices meant to make us feel better, we have also learned how powerful the placebo effect is, and noted reversals when treatments were later tested using appropriate controls, such as sham procedures.

Screening recommendations have also be reversed. In many reversals involving screening are the worst kind - they are performed on healthy people and thus affect an enormous number of them who simply want to stay that way. An ineffective screening test can turn millions of healthy people into patients. Recommendations for PSA tests, mammograms for women in their forties, Pap smears, etc. have all been revised.

In studies of CT-scan screening for lung cancer in those between ages 55 and 80 with a heavy-smoking history is the only screening test to-date that makes you live longer - and even here am many as 96% of abnormal findings are false alarms. In studies of colorectal cancer with 30 years of follow-up, for every 10,000 people, 192 die of colon cancer in the unscreened arm, vs. 128 in the screened arm. However, looking at overall mortality, 7,109 out of 10,000 die in the unscreened group vs. 7,111 in the screened group - not a significant difference.

Most experts agree that all cancer screening leads to some amount of over-diagnosis. When we screen for prostate cancer, we end up treating about 40 cancers for every cancer that will kill. For mammography, the best studies suggest that if a mammogram finds breast cancer and it is treated, there is a 13% chance this will have saved a life.

Each year in America, we spend hundreds of billions on screening tests and their downstream costs. In 2011, two articles were published, finding that gown-and-glove precautions did not decrease transmission of VRE or MRSA in ICUs - an intervention generating additional costs w/o benefits. However, gown-and-glove precautions were adopted largely on the basis of 'single-center, before-and-after studies. The proof from such a study tends to be tenuous because that center may be idiosyncratic - a unique demographic of patients or bacteria, or an unusually enthusiastic proponent who changes the culture in ways not reproduced elsewhere. Before-and-after studies are also problematic, and the initial data behind most systems interventions.

However, one's intervention is never the only thing changed (Hawthorne effects) - and per the author, we have yet to see a very large, well-done randomized trial confirming that eg. a checklist is truly what makes the differences. Another - rapid-response-teams for cardiac arrests were demonstrated in the 2005 MERIT trial in 23 Australian hospitals to not improve patient outcomes. Yet, gown-and-glove precautions and RRT are widely accepted, despite not working.

'Door-to-balloon' time was considered an important objective. A 2013 study found that between 2005 and 2009, door-to-ballon times were significantly reduced across the nation - the number of patients waiting longer than 90 minutes decreased from 40.3% to 16.9^. Mortality, however, was unchanged. Explanations - perhaps we were not targeting the right metric (instead focus on total time), or decreasing door-to-balloon time might be an example of diminishing returns. A final example - in 2001 a single-center unblinded RCT found that lowering blood-sugar levels to normal levels could improve survival in a SICU. (A novel strategy because one of the body's responses to critical illness is to raise blood-sugar levels.) This quickly became a new standard until a 2009 multicenter (42 hospitals) RCT found the practice increased deaths by 2.6 percentage points at 90 days.

Prasad then points out that while doctors often recommend treatments that do not work, patients also do - on their own. Glucosamine and chondroitin ($700 million in 2004) - a 2006 RCT found no difference in pain; this was followed by a 2010 review of data from 10 different trials that reached the same conclusion. Echinacea - nearly 20% of Americans reported using Echinacea in the past 30 days, mostly to reduce the duration of cold symptoms. A 2005 RCT study concluded it did not reduce symptom duration; this was later supported by 7 randomized trials - only one of which reduced symptom duration compared to a placebo. (The authors also examined 12 studies that looked at Echinacea to prevent colds - none of the studies showed an effect.)

Acupuncture is a popular treatment for pain, dating back over 3,000 years. An effort to summarize all research analyzing acupuncture published (Western Chinese, and Korean scientific literature) between 2000 - 2009 concluded there is 'little truly convincing evidence that acupuncture is effective in reducing pain,' and also enumerated a few examples of acupuncture causing real harm.

Use of multivitamins in a 2009 study of 161K women found no link to declines in cancer, heart disease, or mortality; a 2013 review of randomized trails found no clear benefit on overall survival, heart disease, or cancer.

Recent analyses of randomized trials found that calcium and vitamin D supplementation does not reduce risk of fractures among healthy women, and the U.S. Preventive Services Task Force recommends against the supplements. On the other hand, we've known that calcium and vitamin D supplementation increases kidney stones, and a 2010 group of researchers added heart attacks as another potential side effect.

When it comes to dietary habits, studies are less like science and more like an opinion poll. Most diets are never tested in a randomized trial, and when they are, the main outcome of study is usually short-term weight loss. In PREDIMED (an RCT evaluation of the Mediterranean diet, using randomly assigned patients at high risk for a cardiovascular event) found one had to treat about 90 people with the diet for 5 years to prevent one stroke - yet no mortality differences.

In 2005 John Ioannidis wanted to measure the proportion of important findings in medicine that were later contradicted. He started with studies referenced over 1,000 times published during the years 1990 to 2003. Of those, 45 found a medical intervention effective, and of those 16% were later found ineffective, another 16% less effective than initially believed, 44% supported in future studies, 24% never tested again. The

authors did their own research, using articles in the 2009 NEJM - of the 35 studies examining current standards of care, 46% showed current standards as ineffective. They then extended their study to NEJM articles between 2001 and 2010. Reversals were found in 40%, 38% reaffirmed the benefit of a new practice, and 22% were inconclusive. A project of the British Medical Journal Clinical Evidence completed a review of 3,000 medical practices and found 35% effective, 15% harmful/unlikely to be beneficial/tradeoff, and 50% of unknown effectiveness.

Tracking citations to three major practices found not to work: beta-carotene to prevent cancer, estrogen to prevent Alzheimer's, and vitamin E to lower cardiovascular risk, researchers found that 10 years passed before the research community stopped referencing the flawed practice.

Original analyses of prescribing estrogens for post-menopausal women was cofounded by the self-selected nature of those originally taking the supplements - less likely to have a family history of heart disease, be hypertensive, have diabetes, or smoke; they also were younger, drank more alcohol, and consumed more saturated fats.

A 2012 paper titled 'Empirical Evaluation of Very Large Treatment Effects of Medical Interventions' (Pereira, Horwitz, Ioannidis) examined the proportion of medical trials showing a very large treatment effect (eg. 5X or more). They looked at over 228,000 trials and found only 9% did so. Topics with large effects were less likely to be about mortality and more likely to be about a laboratory value. They then looked at other studies addressing the same questions as those demonstrating the very large treatment effect - 90% of the time, the large treatment effects got smaller when one looked at other studies, thus strongly suggesting the largest magnitude of effect ae more likely statistical flukes. Across all the studies, only one had a large effect on mortality - a method for oxygenating blood of newborns who cannot adequately breathe on their own.

RCTs have intrinsic error rates, added to by early termination of RCTs, publication bias,

Industry-sponsored studies are 4X as likely to reach a positive conclusion; they are also less likely to be published/presented, or published after a delay. When companies hold back evidence (device-makers, drug formulators), the medical literature becomes selectively drawn from a much larger pool. Tamiflu was thought to prevent transmission of the flue, decrease hospitalizations, and save lives - an RCT found it decreased flu symptoms by less than a day - while causing nausea and vomiting, did nothing to prevent transmission of the virus, reduce hospitalization or deaths. Previously, Roche (Tamiflu manufacturer) had published its own meta-analysis, and found large benefits. Their study included only those proven to have influenza (rather than those with influenza-like illness) and focused on those receiving the drug early - different than typical use.

The FDA cannot consider cost as part of its deliberations, nor relative efficacy. Then, in the early 1990s, the FDA pioneered an accelerated-approval program - allowing drugs for serious diseases with few treatment options to gain approval by showing benefit on a surrogate end point reasonably likely to predict clinical benefit. The drug is then given a period of time to prove it benefits a more important end point. However, after a drug is approved, it is much harder to get participants to enroll in a study (no one will pay for a trial if there is no prospect for large returns) and after 20 years one-third of these post-approval confirmatory studies had not been completed.

What is also not acceptable is for a drug company to develop a drug for one indication and then market it for something else - gabapentin is an egregious, but not the most recent, example. In 1993, under the trade name Neurontin, it was approved to be used for the treatment of seizures when combined with other drugs. Its

maker, Parke-Davis, then marketed it for eg. bipolar disorder, pain disorders, etc. AND as a single agent for seizures - despite having previously being rejected for the latter by the FDA. A $430 million settlement followed, but over 20 years later gabapentin is still not approved for most of the off-label uses for which it was initially promoted. (Another reversal-prone situation.)

A bias to 'act now, data later' also contributes to reversal, rapid reporting on new technology is another, along with direct-to-consumer advertising (we're one of only two nations {New Zealand} that permit such). An evaluation of DTC advertising found 10% of those with 'adjustment disorder' symptoms and did not request a medication received one, vs. 39% of those making a general request and 55% making a brand-specific request. Between 1999 and 2005, DTC advertising increased from just under $1 billion to over $4 billion. Another - a medical school emphasis on 'reductionism' (understanding the mechanism by which a drug purportedly works), instead of empiricism (does the drug work).

17 of 18 people found the following review helpful.
Needs to be required reading in medical school
By Miss Barbara
Ending Medical Reversal is a book that should be required reading in medical schools. It is eye-opening for both the medical and lay person in that is asks the big, hard, dirty questions. I've been around long enough to have seen so many of the "Cures du'jures" that are touted to save mankind with its neoteric food regimens or its latest pill only to have these procedures negated in the next year or two. "Sorry, my bad" should not be the modus operandi in the medical field.

Basically, medical reversals are described as medications, procedures or tools that become widespread and then quickly become out of vogue when it's determined that they have no strong or tough evidence that they actually work, in fact many have been proven to cause harm. This book points out that many of the most popular drugs from the formulary in the last 10 years were indeed successful in moving a patient's "numbers" into a more acceptable range BUT they did next to nothing in improving death rates for the disease or syndrome they was prescribed for.

There are many books like this out today that rail at the medical profession, big pharma, and the heath care insurers for their quest to improve diagnostic numbers and not improve the patient's state of health – what makes this book different and commands people to sit up and listen is that the publisher is Johns Hopkins University Press. Yes, the big boys have entered the game.

This is a very readable book for the professional and layman alike. There are a lot of first-hand accounts included that give the book a personal characteristic and reminds the reader that we're talking about real people's lives and how health care choices affects us all. I can't tell you how happy I am to see this book published with the pedigree of knowledgeable authors as Dr.Vinayak Prasad, a cancer specialist, and Dr. Adam S. Cifu from the University of Chicago.

15 of 17 people found the following review helpful.
A plea for evidence-based medicine
By Phelps Gates
This is one of the best books on medicine that I've read in a long time. The format suggests that it might be aimed at professionals, and it does have suggestions on how to improve research and medical education, but the intended audience is the general reader, and there's nothing in the book that's not easy to understand. And the authors are careful to summarize and reiterate their important points.

The book discusses a large number of case studies where it turned out that what doctors were doing was wrong. Some of them have been written about a lot (estrogen replacement, PSA screening, the Neurontin

scandal, etc., etc.), and many others less so. What makes the book worth reading is that it goes into great detail, explaining exactly what went wrong, and how, and how things could have been done better. Sometimes the problem was doing things that ought to have worked in theory but didn't in practice. Sometimes it was relying on studies that were poorly designed, with subtle biases (of many, many types). Sometimes it was deliberate malfeasance, even criminality, on the part of drug company executives. One of the things that medical students are taught (or so I've been told) is that you should never let a patient hear you say "oops!" and there have, alas, been quite a number of "oops" moments in medicine.

The authors make a plea for "evidence-based" medicine. There's something of a tug-of-war in medicine, as in some other scientific disciplines, between reductionism (figuring out exactly what's happening) versus empiricism (discovering what actually works in practice). With reservations, the authors come down firmly on the side of empiricism: it's the job of the clinician to find out, and use, strategies of treatment that have actually been shown to work.

Medical news stories ("a new study shows") appear almost daily in the press, sometimes in garbled form. Just this morning (October 8) there's a study that the headlines say calls for "doubling or quadrupling" daily exercise to prevent heart failure (from 30 to 120 minutes a day). Is this a well-designed study? One might surmise that people who are able and willing to exercise two hours a day are already in better condition. Has this been controlled for? Or do we have another medical reversal waiting to happen? It's hard to say, but reading the book has certainly increased my own ability to evaluate the latest breakthroughs and make more intelligent choices.

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