Beyond Deductibles

How Medical Literacy Programs
Reduce Healthcare Spending
and Improve Employee Health

Gary Fradin

Nothing in this book should be interpreted as medical advice.
The information presented here is for illustrative purposes only.

Medical literacy: the ability to obtain, process, and understand basic health information.

- **12 percent of adults have proficient health literacy**
- **Low health literacy is associated with higher healthcare costs**

Definitions and estimates from
US Department of Health and Human Services
'Quick Guide to Health Literacy Fact Sheet'

Medically literate employees cost less!

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Acknowledgments

No book, I've come to learn, is the work of only one person. Authors learn from their research, personal experiences and, most importantly in my case, from friends and colleagues.

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Many other professional friends and colleagues offered their own insights and encouragement as I grappled with this topic and its presentation. Authors always worry that by listing some people they'll leave out others, so with that proviso clearly in mind, I'd like to thank for their support: Jeff Rich, Kerry Stefano, Sue Donahue, Karen Bacon, Bill Stuart, Tom Hamel, Joe Lawler, Allen Shaughnessy, Seamus O'Hara, Tracey Messina, Bob Was, Bob Landry, David Mudd, Jim Scammon and Trygve Halverson. All helped in ways they might not appreciate but I certainly do.

Finally, last and foremost (!), I thank my wife Marjorie for her edits, insights, perspective, patience and most importantly, her ongoing love and support. This book and my entire life would be far less complete, satisfying and meaningful without having her in it.

The Author

I teach healthcare economics to health insurance brokers and have spent 15 years studying

> **Healthcare slippage** or *things that go wrong but shouldn't in American healthcare* and
>
> **Patient education** or *why and how well informed patients generate better outcomes at lower costs and with less risk.*

I've given over 500 lectures and written six books on these subjects:

- Moral Hazard in American Healthcare, 2007
- Healthcare Problems and Solutions, 2008
- Understanding Health Insurance, 2010
- Transparency Metrics, 2013
- How to Talk to Your Doctor, 2014 and
- Consumerism and Value Creation in American Healthcare, 2015

Based on this research and experience, I've concluded that **the best way to reduce healthcare spending is to improve patient literacy.**

This book explains why and how. The potential benefits are overwhelming to patients, employees, employers and our entire healthcare system.

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I hold a Bachelor's Degree in Politics from Lancaster University in England, a Master's in International Relations from London University and a Master's in Regional Planning from Harvard.

In a former life, I worked for CARE in Chad, Africa. I think that's where I honed my 'let's get it right because the costs of getting it wrong are too high' orientation.

A Message to CEOs, CFOs and Benefits Administrators

This is a self-help book for self-insured companies.

Successful and sustainable healthcare cost control programs require that you teach your employees how to identify and avoid unnecessary, ineffective, wasteful and low quality medical care.

Attempts to control expenses *with* plan design changes or ancillary programs but *without* this educational component never live up to their billing.

Here's a condensed 50 year history of commercial health insurance:

- **Cost sharing** or 'major medical' in the 1970s was inflationary so replaced by
- **First dollar coverage** or HMOs – the opposite of cost sharing - in the 1980s and 90s. People found these plans too restrictive so replaced by
- **High deductible plans** - the opposite of first dollar coverage - post 2000. People complain about the deductible size and have trouble differentiating necessary and beneficial medical expenditures from unnecessary and wasteful.
- **None of these programs integrated the necessary educational component into their fabric.** Any would have been far more successful with it.

You've probably tried

- **Wide hospital networks** figuring more competition leads to lower costs and
- **Narrow hospital networks** figuring more carrier control leads to lower costs,
- **Defined benefit plans** to give employers more plan design latitude and

- **Defined contribution plans** to give employees wider choice, and
- **Several other things that didn't work out too well** …but never with a fully integrated employee education component.

The unwritten assumptions behind all these plans and design changes: the right financing program will motivate employees either to (a) use better medical care, (b) use less medical care or (c) use less expensive medical care.

History has conclusively shown these assumptions wrong.

Your employees will always find a way to access the medical services that they believe will improve their health *whether or not that belief is valid.* Attempting to influence their behavior with financing restrictions annoys them, doesn't work and doesn't improve their treatment outcomes or health.

The fundamental axiom that any *effective* healthcare financing program honors

Good health is cheaper than bad health. That's universally and patently true.

So is its extension: the more quickly and efficiently you can turn an employee from sick to healthy, the less it costs, especially if you factor in absenteeism and presenteeism.

Better care quality – better outcomes in other words – is cheaper than poorer care. (Yes, I understand that some MRIs cost less than others. But I wonder how many are necessary and actually improve employee health.)

If your employees choose medical care based on likely outcomes, *they'll* get healthier and *you'll* save money. It's the best possible win-win.

But if your financing program tries to get them to choose medical care based on other criteria … not so much.

This presents a new focus

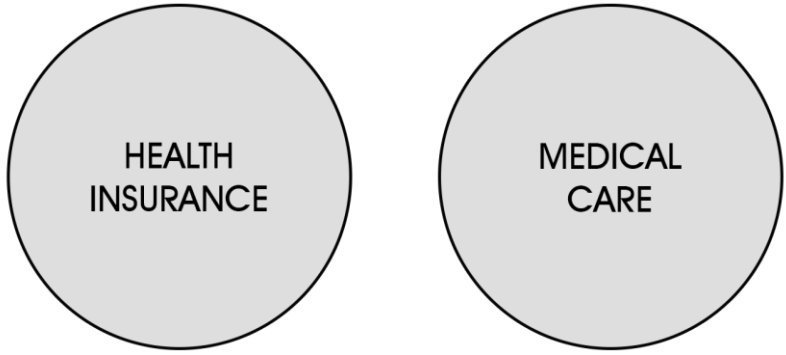
I suggest that corporate healthcare programs have as their #1 priority teaching employees how to choose care based on the outcomes they're likely to enjoy.

Design and develop that program first. This book can help.

Then design a financing system to enhance and support your educational effort.

Don't do it the other way around.

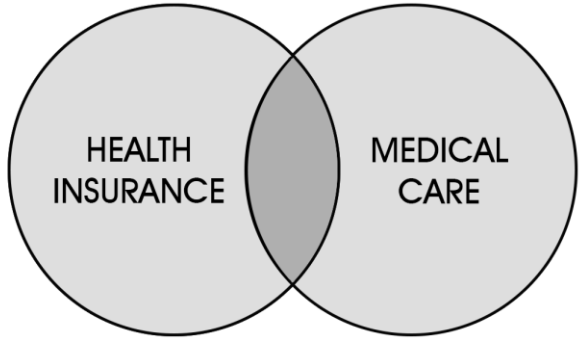
The Old School approach currently in effect



Corporate engagement programs focus on understanding insurance coverage. Employees ask ‘is the service covered?’ and often conclude that ‘if it's covered, I want it.’

The New School approach proposed in this book

The interesting work takes place in the overlap.



Corporate engagement programs include medical literacy. Employees learn to ask ‘is the service covered, *does it benefit me* and *do I want it*?’

What this book is about and why you need to read it

Millions of well insured Americans get too many tests, take too many medications and have too many medical interventions. Our currently in-vogue benefits programs – deductibles, HSAs, wellness programs, etc. – haven't stemmed that tide.

Instead, I'll show you how to identify and avoid unnecessary, excessive, ineffective and low quality medical care.

I'll teach you the **Five Most Important Questions to Ask Every Doctor, At Every Appointment, About Every Medical Intervention**.

- If ***you*** learn, understand and ask these questions, you'll get better medical care with less risk. And you'll save a bunch of money along the way.
- If ***your company*** adopts this approach, it will save money and help its employees enjoy better outcomes with less intervention risk.

Too much care – and the wrong care - is bad for your health, both medical and financial. We currently waste according to many, up to $1 trillion annually. *That's almost Russia's total GDP!* [1]

Consider these estimates.

- David Cordani, CEO of Cigna claims that slippage or 'things that don't work the way they're supposed to' accounts for at least 25% of all medical spending but 'probably much more'.[2]
- Aetna's website says that 'wasteful spending likely accounts for between one-third and one-half of all US healthcare spending'.[3]
- The Dartmouth Atlas, generally considered the bible of healthcare utilization analytics, suggests that up to about 1/3 of all US healthcare spending generates no patient benefit views this 'as an underestimate given the potential savings even in low cost regions'.[4]

The specifics may shock you. We Americans annually, for example,

- get **36 million prescriptions** for a blood pressure lowering medication that doesn't prevent heart attacks or save lives,
- spend **$250 million** on a back procedure that works no better than a placebo,
- spend **$3 billion** on a knee procedure that can work less well than a placebo,
- spend over **$2 billion** on a cholesterol lowering drug that has not been shown to prevent heart disease or heart attacks according to its own advertising,
- *and much more*.

I'll name names and provide details. I'll also discuss some common medical procedures and show you that, for example,

- **A quarter**, maybe more, of the mastectomies in Connecticut generate no patient benefit.
- **Half**, maybe more, of the back surgeries in Fort Myers Florida generate no patient benefit.
- **30%** or maybe even half of the c-sections in Florida, New Jersey and Louisiana provide no patient benefit.

This excess can lead to patient harms caused by medical care. Consider this trend:

- The **1999** Institute of Medicine report 'To Err is Human' found that up to 98,000 patients die annually from medical errors.

- **Seventeen years later**, a 2016 Johns Hopkins study found that over 250,000 Americans die annually from medical errors.[5]

All this leads to a dismal healthcare summary:

- Americans spent **$328 billion more** for healthcare in 2015 than 2013.[6] That's about $1000 more per person.
- But we **lived slightly less** long in 2015. For the first time in decades, our national life expectancy actually fell despite the increased medical spending.[7]

This gross inefficiency puts enormous responsibility on individual patients to choose healthcare wisely.

Step 1 of that process is acknowledging and understanding the problems.

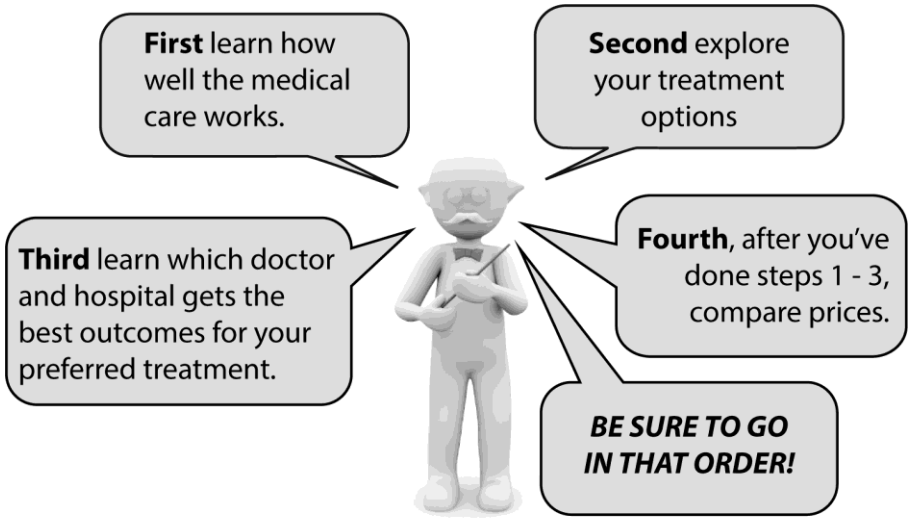
Step 2 is learning how to make wise medical decisions.

How to make a wise medical decision

Follow this process to get better outcomes with less risk and at lower costs:

- First, determine how well the medical intervention works.
- Second, evaluate your treatment options. You almost always have them.
- Third, determine which doctor and hospital generates the best outcomes for your preferred treatment alternative.

- Fourth, if you find two or more equally excellent providers for your preferred option, consider price. **But consider price fourth, only after you've completed the first three steps!**



Asking the *right* questions gets you the information necessary for wise decisions.

But asking the *wrong* questions gets you … something else. Maybe useful information, but maybe just *some* of the most important information, maybe irrelevant (even if true) facts, maybe impressions, maybe incorrect information, maybe noise, who knows.

Obtaining the relevant information is a skill that most of us lack. In fact, according to the US Department of Health and Human Services, only 12% of Americans are medically literate, meaning they have the skills necessary to assess likely treatment benefits and harms [8] though

I suspect the real number – the percentage of people who understand and use the tools described in this book – is actually much lower.

Less medically literate folks have higher hospitalization rates and medical costs, and poorer health outcomes. This medical literacy problem arises because most of us haven't been taught how to approach medical investigations. This book will correct that problem.

The Goldilocks Rule
not too little, not too much, but just right

Too little medical care leads to *undertreated* patients and poorer-than-optimal outcomes.

Too much medical care leads to *overtreated* patients, higher-than-necessary treatment risks, higher-than-necessary medical costs and potentially poorer-than-optimal medical outcomes.

Inappropriate medical care leads to suboptimal outcomes, excessive costs, patient dissatisfaction and sometimes lawsuits.

Appropriate medical care minimizes your chance of medical harm but maximizes your chance of medical benefit.

Why can't I simply follow my doctor's advice and skip the rest of this book?

You always should consider your doctor's advice! But temper it with our questions for two main reasons:

First, doctors generally worry more about undertesting and undertreating than overtesting and overtreating patients. (This highlights a difference between advice *giving* and advice *receiving,* a situation I'll discuss in Question 4.)

- As trainees, they're upbraided for having too little information about their patients not too much information, so learn to overtest.
- As doctors, they're typically paid to do more not less, so may overtreat.
- As caring human beings, they want to do *something* to relieve your suffering, not nothing.
- As professionals operating in our legal system, they're more likely to be penalized for *not* doing something than for doing something extra.

One result is that about a third of patients annually receive one or more useless tests or treatments.

- Dr. Atul Gawande, a famous Boston area surgeon, found that 7/8ths of his patients had. [9]
- Millions more, he writes, 'receive drugs that don't help them, operations that don't make them better and scans and tests that do nothing beneficial *but often cause harm*.'

Second, many doctors assume they know what patients want, their risk / reward tradeoff decisions. But studies show doctors can get this wrong.[10]

- One, for example, showed that most doctors assume breast cancer patients rate 'living as long as possible' as their primary goal. But only 59% of patients agreed. Doctors were wrong about 40% of the time.
- A second showed that 40% of men with benign prostate disease opted against surgery once they were fully informed of surgical risks and benefits.
- A third showed that almost 20% of patients suffering from chest pain diagnosed as stable angina opted against surgery when fully informed of their treatment options and likely outcomes.

A fundamental cause of these problems is 'information asymmetry' or 'your doctor knows more about medical care than you do so thinks he or she understands your treatment goals and preferences too.' Gawande writes

> We can recommend care of little or no value because it enhances our incomes, because it's our habit, or because we genuinely but incorrectly believe in it.

Patients often *want* to do their homework but don't know how. Some attempt to become mini-MDs through online research**.** That almost certainly won't protect against unnecessary, excessive or inappropriate care; the research is clear.

Instead this book will show you how.

It will put you onto a level (or, at least, a more level) field so you can participate more wisely and effectively in your own medical decision making.

The 5 Question Checklist
Medical Literacy in Practice

*If you **understand** these questions, you're medically literate.*
*If you **ask** them, you're ahead of the curve.*
*If you get them **answered**, you've maximized your chance of benefit and minimized your risk of harm.*

In a typical appointment, you and your doctor discuss a medical problem and your doctor recommends an intervention.

Ask these 5 questions about that recommendation:

- **Has it been tested for the outcomes that concern me?**
- **Out of 100 people like me, how many benefit and how many are harmed?**
- **Is it overused?**
- **Would most physicians make the same recommendation or might some suggest something different?**
- **How many patients like me do you treat annually?**

These deceptively simple questions are based on extensive research and analysis. The better you understand them and the more you integrate them into you medical thinking, the better care you'll get.

Ask them of *every* doctor, at *every* meeting, about *every* medical intervention.

You can use this list as a script. Feel free to share it with your doctors.

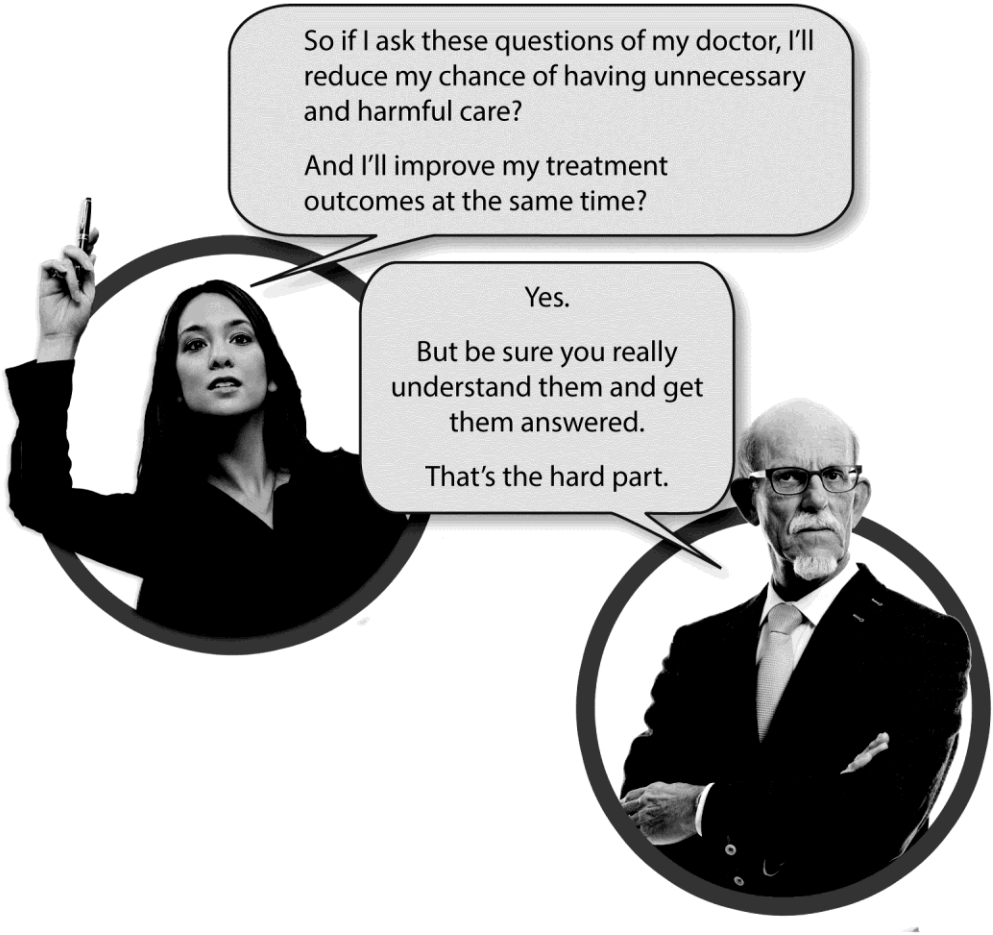
'DECEPTIVELY SIMPLE'

My youngest son explained a screen pass to my wife during a Patriots game one day. It took him about 15 seconds and my wife seemed to understand.

'Of course,' he added, 'Bill Belichick would spend an hour explaining the same thing. At the end of his explanation, you'd really understand screen passes.'

Really understanding screen passes adds to your enjoyment of football games.

Really understanding these questions can save your life.


So if I ask these questions of my doctor, I'll reduce my chance of having unnecessary and harmful care?
And I'll improve my treatment outcomes at the same time?
Yes.
But be sure you really understand them and get them answered.
That's the hard part.

Question #1

Has it been tested for the outcomes that concern me?

Determining which medical interventions work and which do not

Testing determines how well a medical intervention works in real life, on real people.

When testing, medical researchers typically divide a large group of people in half to make 2 identical smaller groups. They give one group the treatment but not the other.[11]

Then researchers watch both groups for a time period, say 5 years, and note medical differences like the number of heart attacks, deaths or strokes. They attribute any differences to the intervention.

Simple! (Actually not simple at all. Medical research methodology is very complicated and worthy of many books, each much longer than this.)

But what happens if you don't have 5 years available? Say that a new blood pressure lowering drug just came on the market, looks promising and you, a person with high blood pressure, have a doctor's appointment the next day.

Your doctor may say 'this is the newest generation of blood pressure lowering medications and has been configured to reduce the side effects of the old drug. I suggest you try it and see how you tolerate it.'

In theory the new drug works well. But it hasn't been tested yet in real life, on real people, for years.

How well does it work?

Dr. Vinay Prasad, assistant professor of medicine at the Oregon Health and Sciences University, studies that issue. He asks 'how well do medical interventions work if they haven't been tested over long time periods on real people?'

How well, in other words, did medical theory hold up to subsequent testing?

Prasad and his team conducted a fascinating study.[12] They reviewed every article in the New England Journal of Medicine between 2001 and 2010 and pulled out those that studied and tested an established medical practice, one commonly used on patients like intensively lowering blood sugar in Type 2 diabetics to reduce cardiovascular events … interventions, in other words, that made medical sense and that the medical community embraced.

363 studies qualified.

Prasad then asked 'Of those 363 studies, how many *affirmed* the practice?' i.e. found that it benefited patients.

38% affirmed the practice, 40% negated the practice, (found it ineffective or harmful) and 22% were ambiguous.

Dr. Prasad's research shows that if you base your medical decisions on biology, physiology, anatomy and logic – *but not on test results* – you are wrong about as often as you are right.

We'll call this Prasad's Law and refer to it throughout this book.

According to Dr. Prasad, rather than focusing on outcomes, patients often

> gravitate toward the nuts and bolts — what does it do, how does it work?
>
> But the real question is: Does it work? What evidence is there that it does what you say it does? What trials show that it actually works?
>
> You shouldn't ask *how* does it work, but *whether it works at all*.[13]

PRASAD'S LAW

Medical interventions that haven't been subjected to real life testing are ineffective or harmful about half the time.

Prasad's Law explained by Dr. Prasad[14]

Dr. Vinay Prasad

Why is this the case?

Our bodies are enormously complicated and our understanding of medical risks, causality and treatment impacts is surprisingly limited. Sometimes (often?) rather than using the most *important* biological or anatomical factors in our medical theories, we use the most *easily accessible and measurable*.

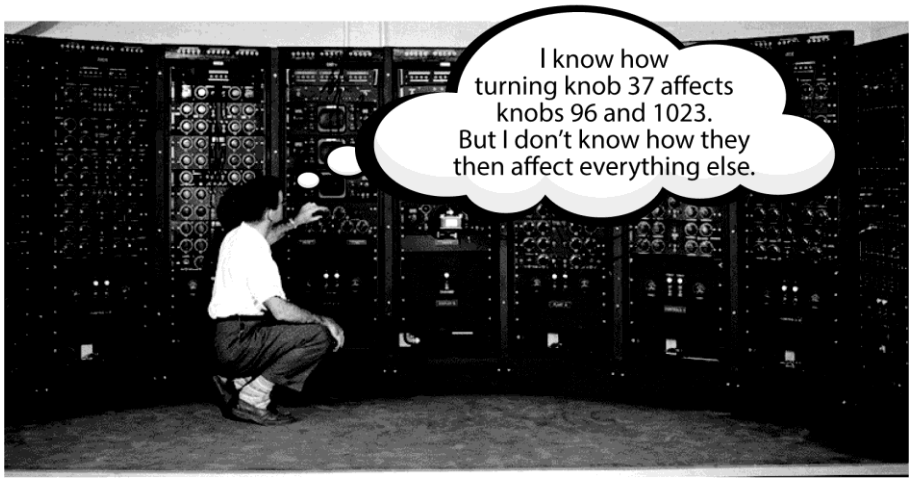
Here's an analogy to illustrate:[15]

> Assume that our bodies are controlled by a wizard located in our brain, more or less like the fellow behind the curtain in the Wizard of Oz.
>
> The wizard in our brain has a wall of knobs that control body parts and functions - one controls cholesterol levels,

another blood pressure, a third bone density, a fourth eye ball pressure, etc.

If each knob is 1 inch in diameter and 1 inch apart (so the wizard can get his fingers around it) **the wall is six and a half feet high and half a mile long!**

Turning any one knob affects the value of some others, which in turn affect still others.



We simply can't anticipate all the initial effects, rebound effects, interactions and modifications from turning a knob or two.

Medicine rarely works in the simplified 'if A causes B, and B causes C, then A causes C' scenario. That's why we need to test.

Wise patients always ask 'has it been tested for the outcomes that concern me?'

If it *has been* tested, then your doctor can tell you how well it works. All physicians today can access extensive databases of medical studies…in their offices…in real time so they can answer this question.

If answers exist.

Asking this question may motivate your doctor to refresh his or her memory and look for new studies that have been published since the last time he or she checked.

You and your doctor can then decide if the intervention works well enough for you. I'll show you how in the next section.

But you may learn that the intervention *has not been* appropriately tested. In that case, you know your chance of benefit is only 50/50. Prasad's Law tells us that.

And even if it benefits you, it might not benefit you very much.

Examples of medical care that *should* work, but doesn't;
Case studies that illustrate the power of asking this question

I'll present 6 case studies to show the power of asking 'has it been tested for the outcomes that concern me?' and why you need to ask this question about every medical intervention:

- Extended release niacin, a 'good cholesterol' boosting drug
- Atenolol, a blood pressure lowering drug
- Ezetimibe, a cholesterol lowering drug
- Vertebroplasty, a back surgery technique
- Arthroscopic knee surgery, a knee osteoarthritis remedy
- Rest after heart surgery, an historical example to tie everything together

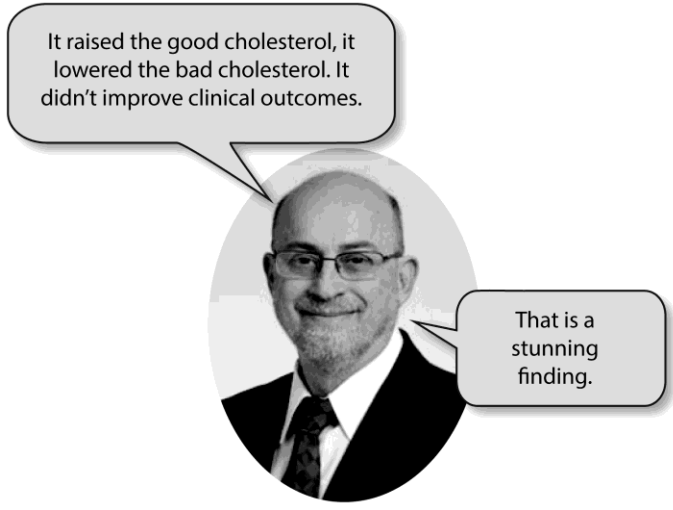
Extended release niacin. Niacin, a B vitamin, has been shown in tests to raise good (HDL) cholesterol. More good cholesterol is associated with a lower heart attack risk, so artificially raising it should benefit patients.

Niacin doesn't lower total cholesterol like commonly prescribed statin drugs.

Cardiologists have prescribed various niacin products for years. One, Niaspin manufactured by Abbott Labs, generated about $900 million in 2009 sales.[16]

Then in 2011, the AIM-High trial of niacin effectiveness showed that, while extended release niacin *is* associated with higher HDL levels and lower triglyceride levels, there was no significant reduction in cardiovascular events.[17]

In 2013, a second study, this time of Merck's niacin drug Tredaptive found the same thing: no difference in coronary event rates between people taking Tredaptive with a statin, and those just taking the statin.[18] Dr. Steven Nissen, Chief of Cardiology at the Cleveland Clinic, summarized the Tredaptive study findings:[19]



Dr. Steven Nissen

Two studies on two different niacin based drugs arrived at the same conclusion: niacin doesn't reduce rates of heart attacks or strokes.

This is an example of Prasad's Law: interventions that appear to make biological sense and that are adopted before publication of comparative tests are proven ineffective or harmful about half the time when they finally are tested.

Atenolol, a blood pressure lowering drug.

High blood pressure is a common condition in which the long-term force of the blood against your artery walls is high enough that it may eventually cause health problems such as heart disease. High blood pressure can damage the heart and coronary arteries and lead to heart attacks, strokes and death, among other events.[20]

Lowering blood pressure, therefore, *should* reduce the number of heart attacks, strokes and deaths. So strongly do physicians subscribe to this theory that they write millions of blood pressure lowering medication prescriptions annually, worth billions of dollars, including 36 million prescriptions for Atenolol in 2010.[21]

Atenolol recorded $161 million in 2014 sales.[22]

Unfortunately comparative study hard outcomes do not always support the theory.

Start in 2002 with publication of the LIFE study on two of the most commonly prescribed blood pressure lowering medications called beta blockers, Losartan and Atenolol.[23] Atenolol placed 2nd in preventing heart attacks and strokes.[24]

Was that because Losantan was superior or because Atenolol was actually ineffective?

That question was answered in a 2004 meta review (a compilation that integrates results from several different studies to develop a single conclusion) in the Lancet entitled 'Atenolol in hypertension: is it a wise choice?' [25]

Those reviewers found that

> there were no outcome differences between Atenolol and placebo in the four studies, comprising 6825 patients, who were followed up for a mean of 4.6 years on all-cause mortality, cardiovascular mortality, or myocardial infarction [heart attacks].

The PubMed abstract summary concludes:[26]

> Our results cast doubts on atenolol as a suitable drug for hypertensive patients.

The theme was then picked up in the March 15, 2005 issue of The American Family Physician, a publication of the American Association of Family Physicians. Dr. Henry Barry's article 'Should Atenolol Be Used for Hypertension?' concluded that, though atenolol *did* lower blood pressure,

> *It does not appear to reduce the rates of cardiovascular mortality or morbidity.*

Let's summarize:

DEFINING `BENEFIT'

Studies can report two different types of outcomes.

One, called 'test outcomes' tells how well you do on a test, say for cholesterol or blood pressure.

Niaspin, Atenolol and Zetia (coming next) score well here.

The other called 'patient events' or 'hard outcomes' measure events like heart attacks and strokes.

Niaspin, Atenolol and Zetia don't score well here at all.

Beware of relying on test indicators. They may correlate very weakly with patient events … *if they correlate at all.*

Focus instead on patient events.

- One major, high quality comparative study in **2002** concluded Atenolol is 'inefficient'[27]
- A large meta study in **2004** concluded 'no outcome differences' as compared to a placebo and cast doubts on Atenolol as a suitable drug for hypertensive patients.
- At least one article in a professional publication in **2005** seriously questioned the use of Atenolol.
- **Five years later**, docs wrote 36 million Atenolol prescriptions and **nine years later** Atenolol achieved $161 million in annual sales.

Medically literate folks – the ones who ask the questions in this book – could have saved those millions of dollars by avoiding Atenolol.

Would they have made wise decisions?

In January 2017, Cochran released an update on beta blocker research.[28] Cochran researchers reviewed *all* relevant beta blocker studies published through June 2016, most of which focused on Atenolol. Their conclusions were entirely in line with the research discussed above, specifically that beta-blockers have little to no effect on heart attacks or mortality and are inferior to other anti-hypertension drugs.

I hope you're beginning to understand why you need to ask 'has it been tested for the outcomes that concern me?' about *every* medication. Even for medications that have been around for a long time.

Ezetimibe, a cholesterol lowering drug. Lower cholesterol is associated with fewer heart attacks. Ezetimibe, typically marketed as Zetia, blocks cholesterol absorption in the small intestine, unlike the more commonly prescribed statins that block absorption in the liver.

- Some patients can't tolerate statins.
- Others might not achieve their desired cholesterol reduction goals with statins and lifestyle changes alone.

Ezetimibe offers benefits to both types of patients. Consider this statement on Zetia's website, zetia.com from about 2011 – 2016. [29]

> *Adding Zetia to a statin is proven to help reduce cholesterol more than a statin alone.*

Zetia's sales exceeded $3 billion annually from 2013 - 2016.[30]

But read the next sentence on Zetia.com, this one in bold:

> **Unlike some statins, Zetia has not been shown to prevent heart disease or heart attacks.**

The New York Times review of Zetia's 2008 clinical trial, for example, concluded that no trial has ever shown that it can reduce heart attacks and strokes.[31]

Note the difference between cholesterol lowering (Zetia has been shown to be good at this) and heart attack prevention (Zetia has not been shown to be good at this).

Then in 2014, the IMPROVE-IT study showed a 'modest' though statistically significant benefit of Vytorin (combination of Zetia and Zocor, a statin) over a statin only, but just for a very select group: patients who had already suffered a heart attack or experienced chest pain.[32]

This underscores the need to ask your doctor regularly 'Has it been tested for the outcomes that concern me?' Be clear about the outcomes that concern you – heart attack reduction or cholesterol lowering. They're not necessarily the same.

- Patients who conflated the two and focused on Zetia.com's first claim that Zetia reduces cholesterol might have opted to take the medication but then only have received the cholesterol lowering benefit, not the heart attack reduction one. *On the other hand*
- Patients who relied only on the website's second sentence 'Zetia has not been shown to prevent heart disease or heart attacks' - and who had previously had a heart attack - might have missed the heart attack prevention benefit discovered in 2014.

See why being medically literate is so important?

Vertebroplasty to relieve back pain Let's switch focus now from medications to procedures. Consider vertebroplasty, a procedure to inject medical grade cement into fractured vertebra (back bones) to reduce back pain.

In 2008, the US market for vertebroplasty was $245 million.

Then in 2009 the New England Journal of Medicine published two studies comparing vertebroplasty to a control or placebo group that received lidocaine (a topical skin numbing agent), massage and aromatherapy to reproduce operating room smells.

- The Australian study found 'no beneficial effect' of vertebroplasty compared to the control group.
- The Mayo study concluded that patient improvements were similar in the placebo and experimental groups.[33]

Vertebroplasty, in other words, worked as well as, but no better than, the safer and far cheaper placebo.

The market for vertebroplasty then shrunk. Unsurprisingly.

But what of all those patients who spent millions on vertebroplasty in the early 2000s? They undertook surgical risks without any potential

benefits – the subsequent comparative studies proved that. At best they received no benefit; at worst were harmed.

They and their doctors had relied on biological analyses, not comparative study results, in their treatment decision making.

And their employers, in the self insured arena, paid hundreds of millions.

'FEELING BETTER' AS AN OUTCOME

Some patients in the vertebroplasty placebo group reported less back pain even though they only received a topical skin numbing agent and a back massage.

Dr. David Kallmes, lead author of the Mayo study, summarized his findings: Patients in the placebo group who reported improvements 'did not respond to simple local anesthesia – they responded to local anesthesia that they thought was a vertebroplasty.' ***Eisner, Sham-Wow, Orthopedics This Week, August 11, 2009***

When you ask about pain reduction, be sure the treatment benefits exceed placebo benefits.

****

Placebo-based patient improvements are a poorly understood but apparently real and potentially impactful phenomenon, worthy of discussion with your physician.

Surgery for Knee Osteoarthritis Knee osteoarthritis is a degenerative disease that causes pain, stiffness and decreased knee function.

Arthroscopic surgery, including lavage (removal of particulate material such as cartilage fragments and calcium crystals) and debridement (surgical smoothing of articular surfaces and osteophytes) was the widely used treatment in the early 2000s despite the fact that, according to the New England Journal of Medicine in 2008 'scientific evidence to support its efficacy is lacking'.[34]

Estimates of the number of knee arthroscopies performed annually in the US vary, and not all address osteoarthritis so we'll have to estimate the size of this problem:

- A 2002 New England Journal of Medicine study estimated 650,000 procedures at $5,000 each, creating a $3.25 billion market.[35]
- A 2014 NEJM study estimated the market at 500,000 knee arthroscopies at about $20,000, generating a $10 billion market.[36]
- Vinay Prasad in his 2015 book Ending Medical Reversal estimated the market at 700,000 patients spending $4 billion.[37]

How poorly does the scientific evidence support the efficacy of arthroscopic surgery to treat knee osteoarthritis?

- A 2008 New England Journal of Medicine published study concluded that they 'failed to show a benefit of arthroscopic surgery for the treatment of osteoarthritis of the knee.'[38]
- This followed a 2002 comparative study which concluded 'At no point did [the] arthroscopic-intervention group have greater pain relief than the placebo group.'
- The 2002 study concluded 'This study provides strong evidence that arthroscopic lavage with or without debridement is not better than and appears equal to a placebo procedure in improving knee pain and self-reported function.'[39]

Those disagreeing with these study conclusions present the usual 'weak study methodology' case, primarily, I would suggest, to protect their incomes. Even at our lowest market estimate - $3 billion – that's certainly a big incentive for lots of people to protect their turfs.

These studies raise some uncomfortable questions:

- Why, after the 2002 paper, did doctors continue to prescribe this procedure and patients have it?
- Why after the 2008 study did both parties continue to use it?

This is an extension of Prasad's Law that says treatments adopted absent testing are proven ineffective or harmful about half the time. Here we have treatments used *even after* studies showed no patient benefit, underscoring the need for you to ask this question and insist on a clear answer about *every* medication and procedure.

Asking encourages your doctor to check (again?).

Never hurts but may help.

A lot!

Rest after heart surgery, an historical example to tie all this together.

We'll start in the early 1900s with Dr. James Herrick's advice then fast forward to today's protocols.

Herrick was an extraordinarily influential coronary care researcher who received impressive accolades from both the Association of American Physicians and the American Medical Association.

In his major 1912 paper, Herrick wrote that, after having a heart attack or heart surgery 'the importance of absolute rest in bed for several days is clear'.[40]

Herrick's recommendations were adopted by most hospitals. Over time they extended Herrick's advice of absolute bedrest from several days to a few weeks.

Indeed, thirty four years after Herrick's paper, Dr. Thomas Lewis published his own coronary care textbook *Diseases of the Heart* and elaborated on Herrick's prescription:

> Rest in bed should continue for 4 – 6 weeks to ensure firm cicatrisation of the ventricular wall … Patients have lost their lives … by neglect of these precautions.[41]

Lewis' justification came from pathological studies showing that it can take 6 to 8 weeks for firm scarring of the lesion to occur. Rest for that amount of time was considered necessary to minimize ventricular rupture risks.[42]

Dr. Paul Woods, another coronary care authority, reinforced that message in his textbook *Diseases of the Heart and Circulation* in 1959, 13 years later, recommending 3 – 6 weeks of bedrest or more depending on the severity of the heart attack.[43]

Thus at least three medical textbooks written between 1912 and 1959 agreed: post heart attack and heart surgery, patients should rest, pretty much for as long as possible.

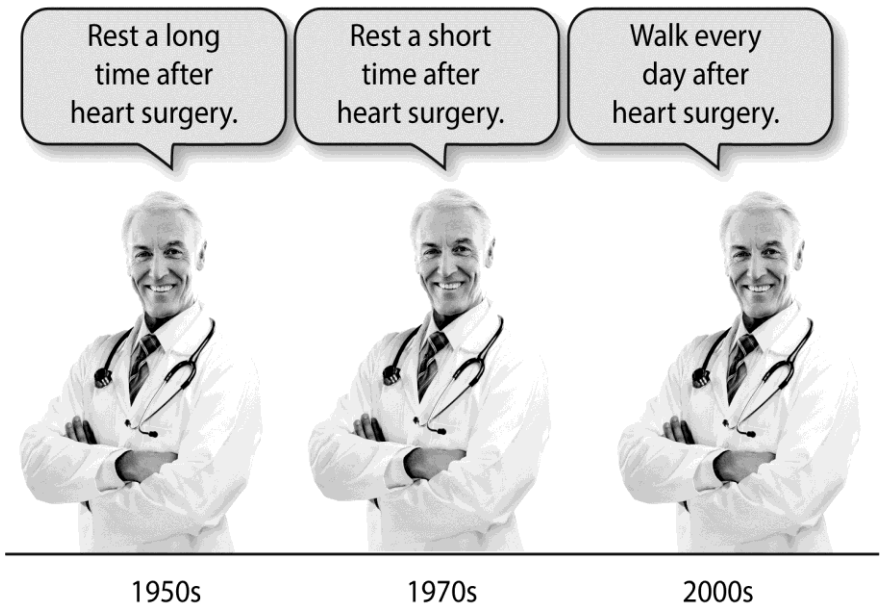
But by the 1960s medical opinion reversed. Eugene Braunwald, author of his own 2007 cardiology textbook, claims doctors began to realize that

> Prolonged bed rest, which had been routine since Herrick's day, could actually be harmful in some patients by leading to venous thrombosis and fatal pulmonary thromboembolism. In uncomplicated cases, the duration of absolute bed rest was shortened to about five days.[44]

Patients who asked 'what do you recommend doc?' in the ***1940s and 50s*** would have received the long bedrest recommendation.

But patients who asked the same questions in the ***1960s and 70s*** would have received the short bedrest advice.

And today, patients are advised to walk every day during the first 6 – 8 weeks post heart surgery, the exact opposite of Herrick's, Lewis's and Woods' recommendations.



How can ‘rest’ and ‘don’t rest’ both be right? They obviously can’t. At least one is wrong. Drs. Herrick, Thomas and Woods offered their *best guesses* backed up with biological justifications. In effect, they said ‘our best guess is that the risk of ventricular rupture exceeds the risk of venous thrombosis and fatal pulmonary thromboembolism.’

Their guesses were really testable propositions which, apparently, weren’t actually tested until relatively recently. When tested, they learned that thrombosis risks exceed ventricular rupture risks. Thrombosis and embolism risks are so high in fact that today’s patients are advised not even to stand in one place for more than 15 minutes! [45] The exact opposite of Herrick’s, Thomas’s and Woods’ advice.

That’s why wise patients don’t research *why* a specific medical recommendation makes sense. Doctors and scientists can justify a wide range of (often conflicting) recommendations, just as we’ve seen here. Prasad’s Law tells us that absent testing for specific outcomes of concern, those recommendations are wrong about half the time.

Instead of relying on theory, wise patients rely on test data, the facts.

The tragedy of this story is that some heart attack recovery patients presumably died in the last century *from following the established protocols and textbook advice*.

They didn't ask if the recommendations had been tested.

****

Dozens, hundreds, perhaps even thousands of other 'makes sense but doesn't work' situations exist. Here are some relatively-easy-to-understand additional examples of Prasad's Law from his book *Ending Medical Reversal*.

Estrogen replacement to reduce heart attacks in postmenopausal women. Testing showed no heart attack rate reduction.

Coronary stent insertion to prevent heart attacks in patients with stable angina. Testing showed no impact on heart attack rates over time.

Prophylactic antibiotics for people with persistent Lyme disease symptoms and a history of Lyme disease. Testing showed no symptom reduction.

Lowering diabetic's blood sugar (A1c) below 7% to prevent heart attacks with an intensive drug regimen. Testing showed an increase in mortality rates.

Calcium plus vitamin D to reduce the risk of hip fractures. Testing showed no hip fracture rate reduction but an increase in kidney stone risk.

Withholding birth control pills for women with lupus to reduce the rate of lupus flares. Testing showed no increase in flares.

Saw palmetto for benign prostatic hyperplasia. Testing showed no benefit measuring multiple outcomes despite more than 2 million men using it.

****

ChoosingWisely, a program organized by the American Board of Internal Medicine Foundation to combat wasteful, unnecessary and harmful medical care lists 300+ more examples of medical practices that, according to testing, should not be used. *ChoosingWisely* is a wonderful resource for well informed patients. Here are a few examples for illustration purposes.[46]

Don't automatically use CT scans to evaluate children's minor head injuries.

Avoid doing stress tests using echocardiographic images to assess cardiovascular risk in persons who have no symptoms and a low risk of having coronary disease.

Don't perform EEGs (electroencephalography) on patients with recurrent headaches.

Don't routinely treat acid reflux in infants with acid suppression therapy.

Don't recommend prolonged or frequent use of over-the-counter (OTC) pain medications for headache.

Don't routinely prescribe antibiotics for inflamed epidermal cysts.

Don't use systemic (oral or injected) corticosteroids as a long-term treatment for dermatitis.

****

When you ask 'has it been tested for the outcomes that concern me?' you may learn how well it works. In that case you and your doctor can determine if the benefits are substantial enough, and risks low enough, for you to have the treatment. I'll show you how in the next section.

But you may learn that the treatment has not been tested in real life, on real people.

In that case, remember Prasad's Law.

Applying Prasad's Law to long term medication use

Some medications may have been tested for 1 year, say, but be prescribed for longer. What are the 8, 15 or 20 year effects, both positive and negative? We often don't know.

This is a version of Prasad's Law. In this case, the untested treatment is the *time horizon.* A medication with few side effects over 6 months may have major side effects over 10 years.

You can rephrase the testing question to 'Has it been tested for the length of time that I'm likely to be on it?'

WHY TIME MATTERS

A 6 month trial of 8,000 people using the arthritis drug Celebrex showed lower rates of stomach and intestinal ulcers and related complications than two other arthritis drugs, diclofenac and ibuprofen.

Some doctors and patients presumably made medication decisions based on those facts.

But the full 12 month test showed Celebrex's safety advantage disappeared since most of the ulcers and complications occurred in the second 6 months.

****

In the 1990s, after a total of 42 clinical trials, the FDA and approved several new antidepressants including Prozac, Paxil, Zoloft, Celexa, Serzone and Effexor.

Patients may take these drugs for years.

But the majority of those 42 trials lasted just 6 weeks.

References: Okie, Missing Data on Celebrex, Washington Post, Aug 5, 2001 and Drug Firm May Not Call Celebex Safer, Washginton Post June 8, 2002, Angell, The Truth about Drug Companies, page 108 (Celebrex) and 112 (antidepressants)

Summary of Question 1

What We Have Learned So Far

Comparative tests tell us how well medical interventions work.

Wise patients ask '**Has it been tested for the outcomes that concern me?'** and base their medical decisions on comparative test results. I'll show you how in the next section.

Importantly, we also learned that interventions that make biological and anatomical sense are shown to be ineffective or harmful about half the time in comparative tests.

Patients who base their medical decisions on biology and logic – but not test results – are wrong about as often as they're right.

Question #2

Out of 100 people like me, how many benefit and are harmed?

Determining *how well* care works from medical tests

Once you learn that a treatment has been tested, you and your doctor can discuss the impact. Use this phrasing:

- Out of 100 people like me, how many benefit? And
- Out of 100 people like me, how many are harmed?

This tells you how well the treatment works in *testing* circumstances. We'll discuss how well it may work in *real life* circumstances in the next chapter.

****

Ask '**out of 100**' to get a number for your answer. '16' conveys more information than 'some', 'many', 'a few' or 'quite a few'.

Some patients may decide that 16 people benefiting is good enough to have the treatment while others say 'only 16? That's not very many.' Different people can reasonably disagree.

Statements like 'this treatment cuts your risk by 36%' don't answer the question! 36% *of what*? Percentage answers may confuse more than they illuminate.

Remember that Prasad's Law applies if your doctor can't answer the *'of what'* question above.

Ask about '**people like me**' because treatments can have different impacts on different demographic groups. Consider these examples.

> **Age:** The American Academy of Pediatrics recommends against prescribing cough and cold medications for respiratory illnesses in children under 4 saying 'these products offer little benefit to young children and can have potentially serious side effects'. [47] They're apparently fine for 6 or 8 year olds though.

… out of 100 people … these medications work, but

… *like me* … not if you're under 4 years old

Gender: In 2014, the Food and Drug Administration cut the recommended dose of Ambien, a sleep aid, in half for women after determining that men and women metabolize it differently. Women, it turns out, have more of the drug in their bodies the next morning, putting them at higher risk of impaired driving.

… out of 100 people … the medication works, but

… *like me* … not so well for women

Other patient differences exist but we don't always know how frequently. You and your doctor may have to estimate the impact on people like you.

Identify the **benefits** of interest to you. If you take a heart attack prevention medication ask 'out of 100 people like me, how many avoid a heart attack by taking this medication?'

- Remember our discussion of Atenolol and Zetia in the last section.

If you want to reduce your back pain, ask 'out of 100 people like me, how many enjoy less back pain as a result of this procedure?'

- Remember our discussion of vertebroplasty and knee surgery in the last section.

Beware of listing 'lower my cholesterol' or 'lower my blood pressure' as the benefit you hope to achieve. We discussed earlier how these 'test benefits' may or may not correlate closely to 'patient' or 'event' benefits. Focus on the benefits you hope to achieve.

And be as specific as possible.

ONE PATIENT'S EXPERIENCE ASKING THE 'OUT OF 100 PEOPLE LIKE ME' QUESTIONS

Sean, a middle aged insurance professional told his story in class one day. He had previously attended several of my lectures and apparently they had an impact.

Sean had been brought up in conservative Ireland and learned that there are two types of people you never question: your priest and your doctor.

Fast forward several decades. He moved to Massachusetts, built a successfull business and had his own family. One day he took his daughter to the doctor for a minor issue. I don't know what it was.

The doctor prescribed treatment and Sean remembered the lectures and plucked up the courage to ask, 'Doc, out of 100 kids like her, how many benefit from this treatment.'

The doctor's answer was apparently satisfactory.

But more importantly for our story is what happened next. The doctor, as Sean recounted the story, shook his hand and introduced him to the other physicians in the practice saying (and this is a direct quote)

I have 1700 patients in my practice. Sean is 1 of only 4 who have ever asked me how well medicine works.

I asked Sean for permission to use his story. His email response:

Please feel free to quote me. If it helps 1 person then it worked.

Some case studies to indicate the power of asking this question

Out of 100 **people like me, how many benefit and are harmed?**

Consider antibiotics to treat pediatric ear infections, a quite common childhood problem. Ear infections can be painful to the child and frightening to the parents who, not unreasonably, want to do something to help.

Ear aches are sometimes viral and sometimes bacterial. Doctors often prescribe antibiotics.

This intervention – antibiotics to treat pediatric ear aches - has been studied so Prasad's Law doesn't apply.

A meta review – that's a compendium of several individual studies – of 15 studies on 4100 kids concluded that 6 in 100 who took antibiotics reported less ear pain after 2 – 7 days; 94 in 100 did not enjoy less ear pain as a result of the antibiotics. [48] Most had a complete recovery within 2 – 7 days without the medication.

But 11 in 100 who took antibiotics suffered uncomfortable side effects like diarrhea.

- Out of 100 kids who take antibiotics to treat ear infections, how many benefit by enjoying less ear pain in 2 – 7 days? **6**
- Out of 100 kids who take antibiotics to treat ear infections, how many are harmed by diarrhea or other uncomfortable side effects? **11**

Now you have sufficient information to discuss this intervention with your pediatrician. Does it work well enough for your child? Some parents may decide yes, others no.

But in both cases, it's an informed decision made by a parent in light of the facts.

Dozens of similar cases exist. One website www.TheNNT.com lists about a hundred. ChoosingWisely www.ChoosingWisely.org takes a slightly different approach and lists hundreds more. Both sites will provide good information for you to discuss with your doctor.

Out of 100 people *<u>like me</u>* how many benefit and are harmed?

We already discussed how age and gender can impact outcomes. I'd like to explore a different, infrequently discussed but vitally important *like me* category: social status.

I'll define social status ambiguously as a combination of wealth, income and sense of control over your life, analogous to the way former US Supreme Court Justice Potter Stewart defined pornography: you know it when you see it.

The Whitehall studies in Britain first identified and quantified social status' impact on health. These studies tracked disease and death rates by job and rank in the British civil service and their conclusions have been reproduced in other studies, in other countries.[49]

Whitehall found that low social status folks had higher disease and death rates than high status folks. Surprisingly – and this is the big deal - this was not *only* due to measureable factors like cholesterol, blood pressure, blood sugar, smoking, obesity or exercise rates.

After correcting for those factors, *the lowest status folks were about twice as likely to have heart attacks, develop other diseases and die as the highest status ones*.

Whitehall also found a gradient: the higher you are on the social status scale, the lower your disease and death rates and the reverse, the lower you are on the social scale, the higher your disease and death rates.

Over and above specific disease risk factors, Whitehall concluded, there is something about social status *independently* that impacts people's health. Harvard School of Public Health Professor Nancy Kreiger, whose own work affirms Whitehall's conclusions, put it this way:

> An individual's health can't be torn from context and history. We are both social and biological beings—and the social is every bit as "real" as the biological. [50]

In line with this analysis, a major 2016 study in JAMA, the Journal of the American Medical Association found that the life expectancy gap

between the richest 1% of Americans and the poorest was about 12 years on a gradient similar to Whitehall's. In an accompanying editorial, Nobel laureate Angus Deaton emphasized the impact of income and social status on health and castigated traditional medical thinking:

> The finding that income predicts mortality has a long history… the mortality gradient by income is found wherever and whenever it is sought…**but the medical mainstream emphasizes biology, genetic factors, specific diseases, individual behavior, health care, and health insurance.** [51]

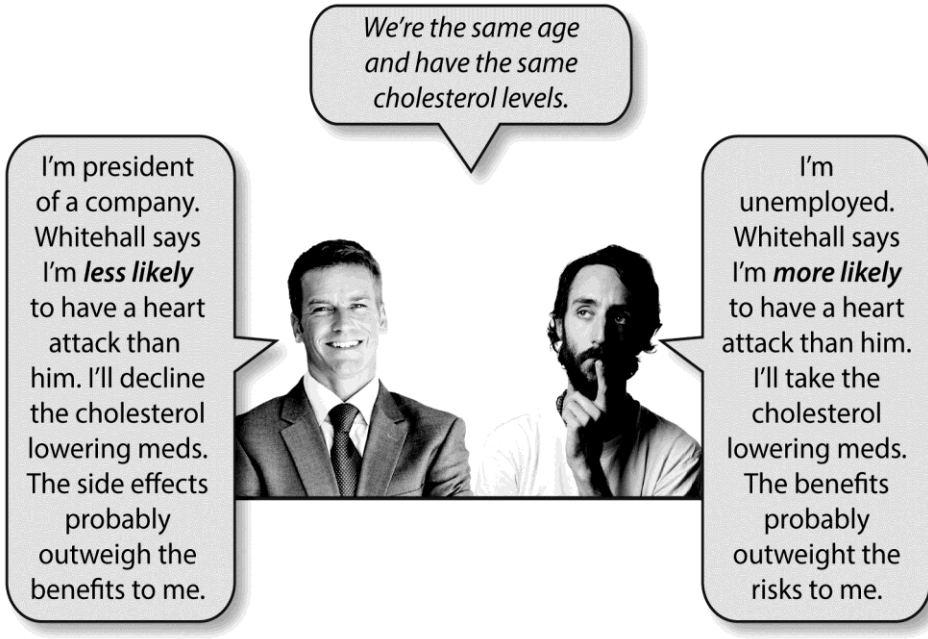
Consider the medical impacts of your own social status. Imagine your doctor says 'your cholesterol level is slightly high. The guidelines suggest lowering it. I'll prescribe a medication.'

- If you're a *low* status person (thus facing higher than average heart attack risks) you may be undermedicated, leaving you exposed to *disease* harms.
- But if you're a *high* status person (thus facing lower than average heart attack risks) you may be overmedicated, exposing you unnecessarily to *medication* harms.

Try to include social status factors in your 'like me' discussions with your doctor along with age, gender, general health status, family history etc. One good information source is the 2004 report 'Work, Stress and Health: The Whitehall II Study'. Share it with your doctor. It's surprisingly easy to read and it may change the way you think about medical care.

It certainly did for me.

Consider the two men on the next page, both of whom have slightly elevated cholesterol. Which, if either, are *you*?



'Out of 100 people like me…' or 'The guidelines say…'
Case study of hypertension

The American Heart Association recommends that people over 60 years old begin treatment for high blood pressure when their readings exceed 150/90. [52]

But out of 100 people like that, how many benefit by following those guidelines?

Some answers come from a 2009 Cochrane report that summarized 15 trials totaling 25,000 subjects over age 60 with moderate to acute hypertension followed for average 4.5 years.[53]

> *Out of 100 people over 60 years old with moderate to acute hypertension, how many avoid cardiovascular disease or death over 4.5 years?*
>
> *Answer: About 4*

Here are Cochran's numbers:

- Risk of cardiovascular death or disease *without taking* hypertensive medication: 14.9/hundred. This is the control group.
- Risk of cardiovascular death or disease among patients *taking* hypertensive medications: 10.6/hundred. This is the test group.
- Medication benefit: 4.3 fewer deaths or diseased patients/hundred (4.3%)

I don't know how many, if any, were harmed by the medication.

Which question gives you the best information and best helps you make the wisest decision: 'Out of 100 people like me, how many benefit?' or 'What do the guidelines say?'

It's your call.

Summary of Question 2

What We Have Learned So Far

Question 2 builds upon the lessons of Question 1.

Question 1 was '**Has it been tested for the outcomes that concern me?'** We learned that comparative tests identify the benefits and harms of a medical intervention.

- Importantly, we also learned that medical interventions that have not been subjected to comparative testing are ineffective or harmful about half the time. We called this Prasad's Law.

Question 2 showed how to quantify the benefit and harm impacts. We learned to ask

- **Out of 100 people like me, how many benefit?** And
- **Out of 100 people like me, how many are harmed?**

We also learned

- Why to ask 'out of 100' and not to accept answers like 'this treatment reduces you risk by 36%'.
- Why to ask about 'people like me', including about people in your socio-economic demographic.
- Why 'patient outcomes' always matter but 'test outcomes' may not.

Question #3
Is it overused?

Sometimes beneficial care is overused so may not benefit *you*

This question acts as a yellow warning light to wise patients: proceed but proceed cautiously.

****

Testing sometimes shows that a treatment works well on a narrowly specified group of patients but, in the real world, doctors may offer it more widely, perhaps hoping to benefit even more patients.

Examples include mastectomies, back surgery, c-sections (I'll discuss these three in some detail below), tonsillectomies, antibiotic prescription, prostate surgery, MRI use, coronary angioplasty and many more.[54]

This results in **treatment variation** meaning that different doctors may treat similar patients differently.

Vast amounts of research into this phenomenon have identified three significant issues.

First, about 85% of the time, two or more treatments can generate the same patient outcomes.[55]

TREATMENT VARIATION

Treatment variation means that similar patients get different care from different doctors or hospitals.

The Dartmouth Atlas of Healthcare, the epicenter of variation research, concludes 3 things about treatment variation:

- It accounts for up to about 1/3 of all medical spending, perhaps $1 trillion annually.
- It arises primarily from physician orientation differences, not patient health differences
- Patients receiving more care, or care above the minimum available in any US region or hospital, do not enjoy better outcomes or longevity, only more cost and risk.

Mastectomy or lumpectomy for early stage breast cancer, surgery or physical therapy for back pain, injections or physical therapy for frozen shoulder, etc. Though the outcomes may be the same, the process, pain, risk, recovery period, family impact and cost can vary widely.

Second, when faced with care options, many patients delegate decision making to their doctors. This forces the doctor's preferences, not the patient's, to define the treatment decisions and doesn't always serve the patient's best interests.

We'll explore some implications in Question 4, the next section.

Third, the higher the supply of medical services in a region, the more frequently patients access those services: the more hospital beds, the more hospitalizations, the more MRI units, the more MRI tests, the more orthopedic specialists, the more orthopedic surgeries etc.

We'll discuss some implications in this section.

Excessive utilization raises costs and risks but doesn't improve patient outcomes. It may even worsen them since patients expose themselves only to potential treatment harms, not benefits.

We'll explore three case studies of treatment variation. Two are based on Dartmouth Atlas of Healthcare information: early stage breast cancer treatment in Massachusetts and Connecticut and back surgery in south*western* and south*eastern* Florida. The third is hospital baby delivery patterns, specifically c-section rates.

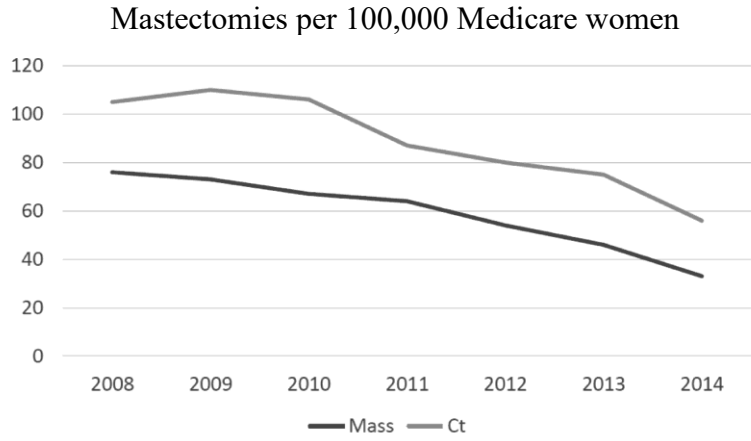
These are 3 of dozens I could have chosen. As you read them, consider how patients who have the more aggressive, excessive and overused treatments may actually end up worse off.

Case Study: Mastectomy Rates in Massachusetts and Connecticut

Female Medicare beneficiaries in Connecticut, using Connecticut hospitals, get about 40% more mastectomies per 100,000 than do

similar women in Massachusetts. This has been roughly constant since 2008.

Here's a chart showing the mastectomy rates each year from 2008 – 2014, the most recent years for which data are available on the Dartmouth Atlas. The Connecticut rate is the top line, Massachusetts the bottom .[56]



How can we determine if these surgical rate differences are driven by *patient* health differences or *physician* treatment orientation differences?

We'll first consider patient differences. The American Cancer Society tracks cancer incidence and mortality rates by state. They show that the breast cancer incidence rates for 2011 per 100,000 women are virtually identical in both states: [57]

	Non-Hispanic White	African American	Hispanic
Connecticut	139	113	127
Massachusetts	137	109	104

Hispanics are about 10% of each state's population so their incidence difference would play a minor role in the overall statistics though it might raise other questions.

Based on breast cancer incidence rates alone the treatment variation appears driven by physician orientation, not patient disease rate differences.

Did the Connecticut women benefit from more mastectomies?

The American Cancer Society also tracks breast cancer mortality rates in each state. That's the rate at which women die of breast cancer. Again, they're virtually identical in both states.

Here are the rates for 2011-2012, again per 100,000 women:

	Non-Hispanic White	African American	Hispanic
Connecticut	24.0	27.4	12.1
Massachusetts	23.5	27.3	12.1

If the higher rate of mastectomies in Connecticut from 2008 – 2011 generated patient benefit, we would expect to see lower Connecticut breast cancer mortality rates in 2011-2012 than in Massachusetts. We don't see that.

Women asking the standard treatment questions – is this a good treatment? Do you get good results? Would you recommend this treatment for your wife, daughter or sister? – would get the same answers in Massachusetts and Connecticut.

But the Connecticut women wouldn't avoid those additional mastectomies.

The higher mastectomy rate in Connecticut generates no patient mortality reduction benefit. It only raises patient risks and costs.

Asking the ‘is it overused in this hospital or region’ question would help motivate physicians and well informed patients to review these kinds of data.

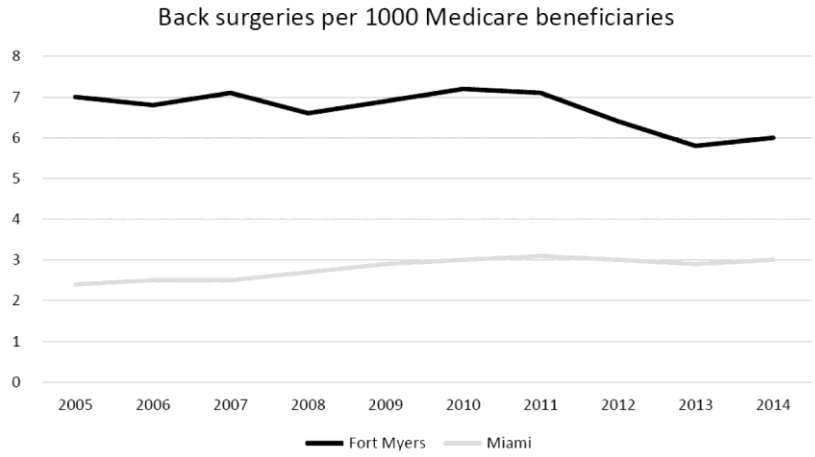
Follow up with ‘out of 100 women like me, how many benefit and are harmed by mastectomies?’

Really well informed women might also ask ‘would most physicians make the same treatment recommendation or might some suggest something different?’ I’ll introduce that question in the next chapter.

***This way overstates the case to make a point:** different doctors can make very different treatment recommendations. Not all Connecticut oncologists recommend mastectomy and not all Massachusetts oncologists recommend against mastectomy. Try to find a second opinion doc who would offer a different opinion from your first doctor. Be sure to ask them both the same questions.

Case Study: Back Surgery in Florida

Medicare beneficiaries in southeastern Florida, around Miami, are about half as likely to have back surgery as Medicare beneficiaries in southwestern Florida, around Fort Myers. See this chart with Fort Myers on top and Miami on the bottom from 2005 – 2014, again the most recent years of data on the Dartmouth Atlas website.



Are retirees in Miami *medically different* from retirees in Fort Myers? John Wennberg, founder of the Dartmouth Atlas and professor emeritus at the Geisel School of Medicine at Dartmouth, answers with a resounding 'no' saying

> There is no epidemiologic evidence that illness rates vary as sharply from one health care region to another as does surgery.[58]

Do retirees in Miami *prefer* more aggressive care than retirees in Fort Myers? In other words, do Miami patients routinely ask for physical therapy for their back pain while Fort Myers patients typically ask for surgery?

Again ‘no’ but this time from Dr. James Weinstein, former Chairman of the Orthopedics Department at Dartmouth’s Geisel School of Medicine who has studied treatment variation for years:

> It's highly improbable that Medicare retirees living in Fort Myers prefer back surgery two times as often as residents of Miami. [59]

What causes the treatment variation? Wennberg again provides the answer:

> Doctors decide who needs health care, what kind, and how much.[60]

And the key patient benefit question: Do retirees in Fort Myers benefit from the extra back surgeries? In other words, do Miami retirees suffer unnecessarily from receiving too few back surgeries?

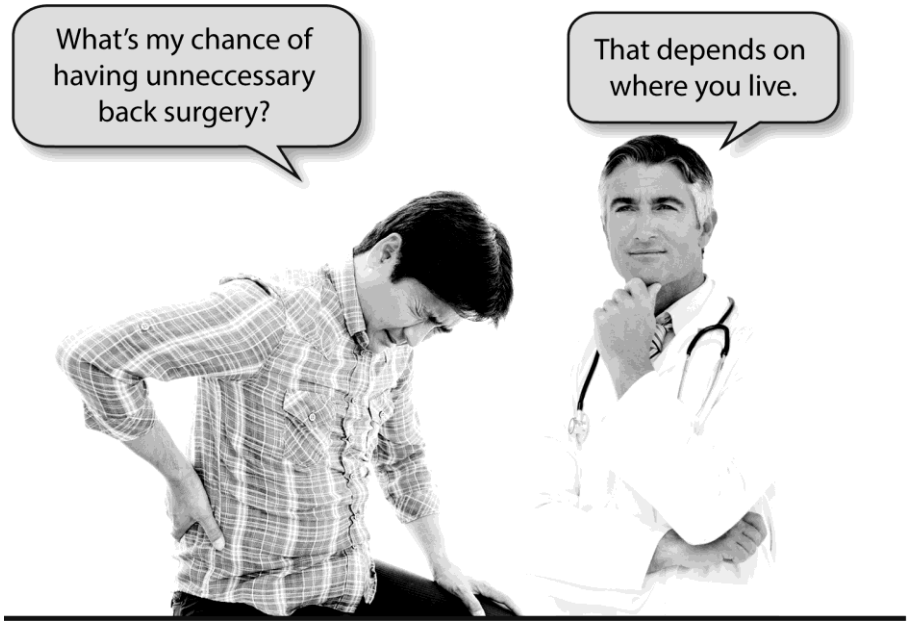
Though I was unable to find solid academic studies that specifically answer this question (!), Dr. Elliott Fisher and his Dartmouth colleagues addressed this issue in general in their massive 2003 study, ‘The Implications of Regional Variations in Medicare Spending’.[61] One observation, paraphrased for readability here:

> For every 10% increase in medical spending, the relative risk of death increased.
>
> In none of the regions studied did the higher per capita expenditures lead to a statistically significant mortality decrease.

In other words more care, or care above the minimum available in any US region, led to more harm not more benefit.

Wise patients don’t stop their questioning when they learn that a treatment is beneficial, as spinal surgery and mastectomy sometimes are.

Wise patients want to ensure that the treatment provides benefit to *them*. That takes additional questioning.



Acceptable and Unacceptable Answers to 'Is it overused?'

Acceptable answers include 'yes', 'no' and 'I don't know'. All can lead to a useful, additional discussion.

Unacceptable answers include 'we never perform unnecessary back surgery.' Fort Myers orthopedists and Miami orthopedists would say this about as frequently!

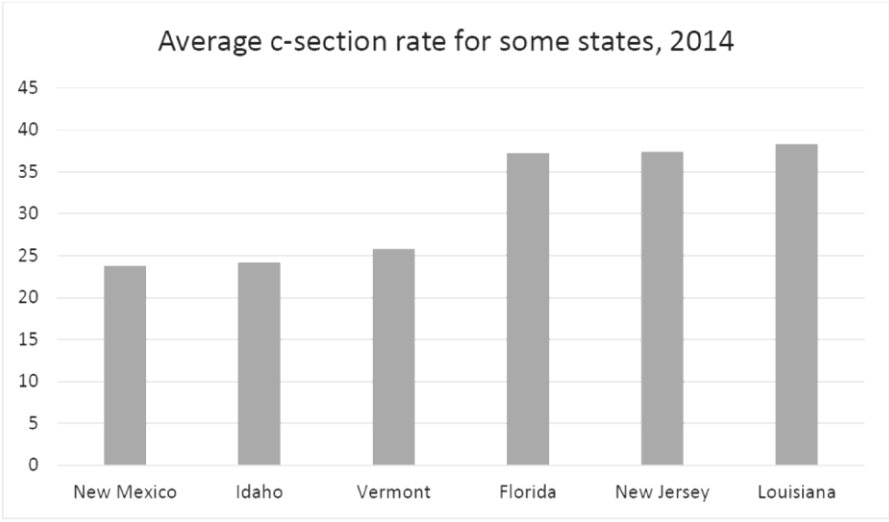
So would Connecticut and Massachusetts oncologists.

See the somewhat-famous-party-trick discussion coming up for further explanation.

Case study: C-section delivery rates at different hospitals

C-section rates vary tremendously among hospitals and regions. Some hospitals routinely deliver 40% or more of babies by c-section while others deliver 20% or less.

Similarly some states exhibit far higher average c-section rates than others.[62]



Why? Do patients differ dramatically in these states? Do outcomes?

We'll start our analysis with a 2011 New Hampshire Insurance Department study 'A commercial study of vaginal delivery and cesarean section rates at New Hampshire hospitals' that showed c-section rates varied between 15% and 47% of deliveries by New Hampshire hospital. That study concluded

> There are no obvious reasons that explain why c-section rates are higher at one NH hospital than another …
>
> there does not appear to be a relationship between c-section rates and health status among hospitals …
>
> statistics show essentially no relationship between hospital population health and health status and c-section rates.

The NH study did not note outcome differences among hospitals suggesting similarity. (Major outcome differences would have been headline news and almost certainly included in this study.)

That raises the question: Do hospitals that perform more c-sections on similar populations generate healthier babies?

A second 2011 study addressed that, this time of 30,000 births at 10 upstate New York hospitals without specialized neo-natal intensive care units but with varying c-section rates. It found no difference in outcomes for babies born in the hospitals with the highest c-section rates and those with the lowest when outcomes are measured by Apgar scores, need for assisted ventilation, or need to move to intensive care hospitals.[63]

Two studies, both showing different c-section rates by hospital without apparent patient health reasons or outcome differences.

Fast forward to 2013 and consider the conclusion of a Harvard School of Public Health study of 228,000 births in 49 different Massachusetts hospitals:[64]

> The same woman would have a different chance of undergoing a c-section based on the hospital she chooses …
>
> Certain hospitals' high rates of cesarean births have more to do with characteristics of the hospitals themselves than with characteristics of their patients.

Harvard goes on to issue this caution:

> While c-sections can be a lifesaving procedure for an infant in distress, or when there are multiple births or other labor complications, c-sections that are not medically necessary can put mothers and babies at avoidable risk of infection, extend hospital stays and recoveries, and increase health costs.

Again a beneficial medical intervention is overused and when 'not medically necessary' (Harvard's words) puts patients at unnecessary risk.

The same year, 2013, a different study by Dr. Katy Kozhimannil and

others of 817,000 births in 593 hospitals nationally arrived at the same general conclusion.[65] Kozhimannil found that c-section rates varied from 7 to 70 percent of all deliveries by hospital and suggested that *provider practice patterns* were a key driver of this rate variation.

Surgical variation rates were not, according to Kozhimannil

> explained by hospital size, geographic location or teaching status…
>
> The scale of this variation signals potential quality issues that should be quite alarming to women, clinicians, hospitals and policymakers.[66]

More or less like the New Hampshire study, the New York study and the Harvard study.

Four different studies arrived at the same conclusion: c-sections benefit some patients but are overused so may not benefit – and may even harm – others.

To summarize:

- The hospital that you choose has a significant impact on your likelihood of delivering by c-section.
- Hospitals with the highest c-section rates don't necessarily serve the sickest, most at-risk populations.
- C-section rates vary significantly even among low risk mothers.
- Hospitals performing the highest rates of c-sections do not generate better outcomes than hospitals performing lower rates.

These treatment variation situations get replayed for dozens of procedures including

- tonsillectomies
- coronary stent insertions
- heart valve replacements
- referrals for CT scans
- hip replacements
- radical prostatectomies, and others.

Dartmouth researchers estimate that if you add all the excesses above the minimum, for lots and lots of procedures, you'll arrive at about 1/3 of all medical spending. I'd recommend that anyone interested in this topic visit the Dartmouth Atlas website and click around. It's packed with fascinating, potentially life-saving information.

A somewhat famous medical party trick story showing that even great doctors in great hospitals practice differently

John Wennberg, more or less the godfather of treatment variation analytics in this country, performed a party trick of sorts to show how doctors practicing at highly regarded hospitals can treat similar patients differently.[67]

He used Boston, home to Harvard Medical School affiliated teaching hospitals, and New Haven, home to Yale Medical School affiliated hospitals, as his case study.

Wennberg learned that Boston area patients spent about 40% more time in the hospital:

- A Boston patient suffering from gallstones would be 40% more likely to be hospitalized than a similar patient in New Haven.
- A patient hospitalized for surgery that required 1 night in a New Haven hospital would often have spent 2 nights in a Boston hospital.

He wondered if the New Haven docs felt they undertreated patients or if Boston docs thought they overtreated. When asked, doctors in both cities claimed to treat patients appropriately.

Which were right? They can't both be.

To answer that question, Wennberg presented his findings at New Haven and Boston medical conferences, but *he accidently-on-purpose switched the data*!

He showed the Boston docs that their patients spent 40% *less* time in the hospital and therefore received less care than New Haven patients, and vice versa, and asked for explanations.

- The Boston docs came up with lots of reasons why the New Haven ones erred by overtreating their patients, admitting too many to hospitals and therefore exposing them to unnecessary treatment risks and financial costs.

- The New Haven docs explained why the Boston ones erred by undertreating their patients, admitting too few to hospitals and therefore exposing them to unnecessary disease risks.

Wennberg then admitted his data mistake and went through the (presumably uncomfortable) analysis of the doctors' faulty reasoning.

The bottom line: though doctors all want to treat appropriately – and claim to - they are often unaware of their own assumptions and treatment patterns.

That's why wise patients always ask our questions and demand answers…

Even from the most experienced doctors who graduated from the most famous medical schools and work at the most prestigious hospitals!

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Summary of Question 3

What We Have Learned So Far

Question 3 builds upon the lessons of Questions 1 and 2.

Question 1 was '**Has it been tested for the outcomes that concern me?'** We learned that comparative tests identify the benefits and harms of a medical intervention.

- Importantly, we also learned that medical interventions that have not been subjected to comparative testing are ineffective or harmful about half the time. We called this Prasad's Law.

Question 2 showed how to quantify the benefit and harm impacts. We learned to ask

- **Out of 100 people like me, how many benefit?** And
- **Out of 100 people like me, how many are harmed?**

Question 3 moved us out of the laboratory and into the real world. We learned that sometimes beneficial medical interventions are overused. We learned to ask

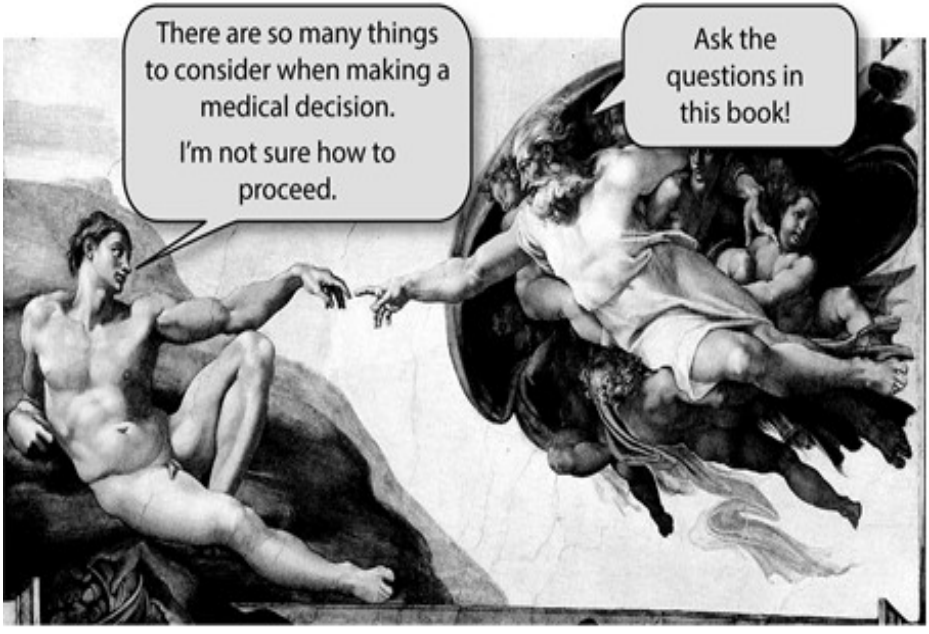
- **Is it overused?**

Appropriate answers include ‘yes’, ‘no’ and ‘I don’t know’.

Inappropriate answers include ‘we never perform excessive or unnecessary treatments.’

We’ll move now to Question 4 ‘**Would most physicians make the same recommendation or might some suggest something different?’** This helps you identify your treatment options.

While always important to ask, this question is particularly critical for patients who learn that the answer to Question 3 is ‘yes, we sometimes perform this procedure too often’.



Question #4

Would most physicians make the same recommendation or might some suggest something different?

How to get and evaluate a second opinion

We learned earlier that patients have care options about 85% of the time. Often two or more treatment processes generate the same patient outcomes.

But the treatment processes can involve quite different pain levels, family impacts, recovery periods, costs and other factors.

Researchers have learned that, for the 85% of care that allows for choice, wise and well informed patients may prefer treatments different from that recommended by their doctors.

And two different patients with the same medical problem can choose different treatments and both be right.

Unfortunately, since patients today often delegate decision making to doctors, *physician preference* rather than *patient preference* often determines which treatment patients ultimately receive. That's not always such a good thing.

Preference-sensitive decision making among patients with access to good information

Various studies have assessed the impact of patient education on preference-sensitive decision making and have generally arrived at the same conclusion: when provided with good information about both outcomes and processes, patients tend to prefer less invasive and lower risk care.

PREFERENCE SENSITIVE MEDICAL CARE

Two patients with the same medical problems can choose different treatments and both be right.

Preference sensitive also means you can prefer a different treatment from what your doctor prefers.

The general trend is about a 20 – 25% shift.

Coincidentally, less invasive / lower risk care tends to be less expensive.

One 2012 study in Washington State found that patients who went through a thorough treatment comparison process had 26% fewer hip replacement surgeries, 38% fewer knee replacements and cost about 15% less than patients who did not go through the same process.[68]

Other studies have indicated

- 20% fewer stent insertions
- 40% fewer prostate removal surgeries
- 40% fewer spinal fusion surgeries for herniated disks[69]

These studies and others suggest that physicians need to diagnose both the *medical condition* and the *patient* to prescribe the appropriate intervention. A classic analysis, Patient Preferences Matter, written by two medical school professors and one business school prof, highlights the impact: [70]

> Health care may be the only industry in which giving customers what they really want would save money.
>
> Well-informed patients consume less medicine – and not just a little bit less, but much less.
>
> When doctors accurately diagnose patient preferences, an enormous source of waste – the delivery of unwanted services – is eliminated.

In other words, when doctors assume they know which treatment process a patient wants, they substitute their own preferences for the patient's.

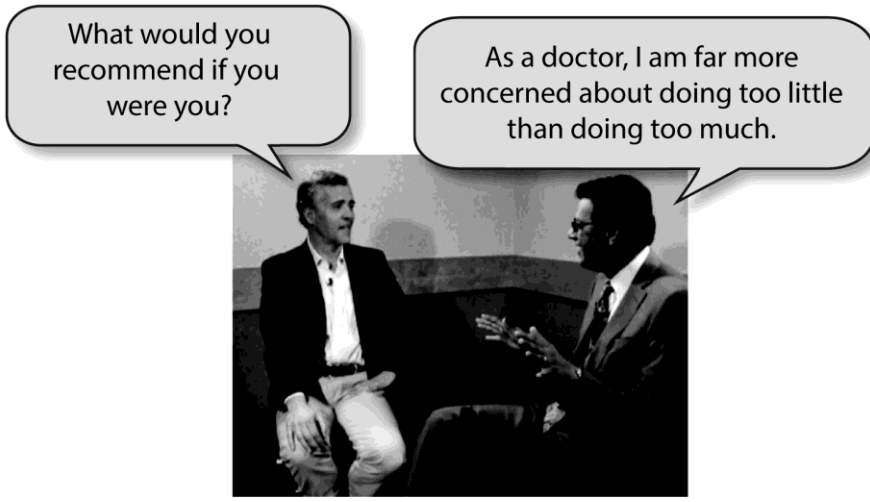
That's not always wise because there's a huge difference between advice *giving* and advice *receiving*. The advice recipient may or may not agree with the advice giver.

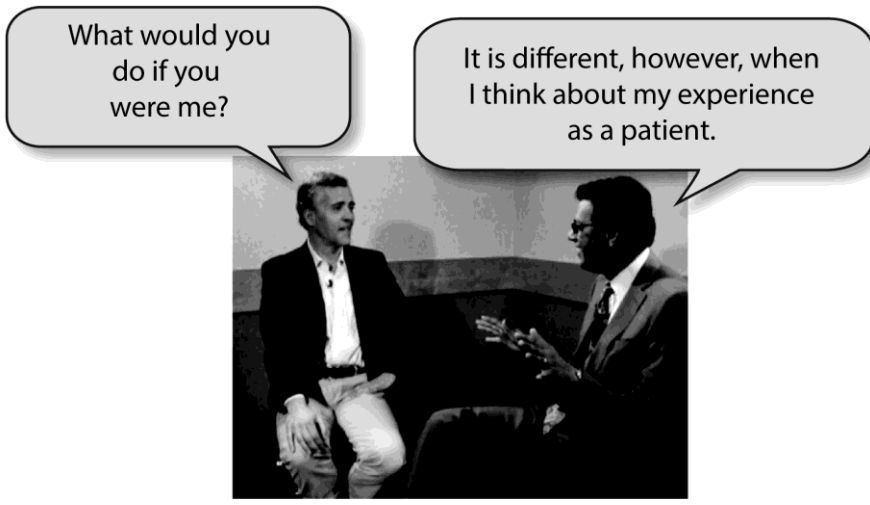
Here's a list of some potential preference-sensitive considerations that affect physician 'advice givers' differently from patient 'advice receivers'. It's not exhaustive. I didn't include 'success' since it's obviously the most important consideration of both doctors and patients.

Some Physician Issues and Concerns	Some Patient Issues and Concerns
Regulations and guidelines	Pain
Fear of lawsuit	Recovery period
Local / regional / hospital norms	Family impact
Income	Self image
Experience with intervention alternatives	Personal preferences (e.g. religious)
Avoid feeling guilty	Cost

The question 'what would you do if you were me, doc?' is unfair. The physician-advice-giver can't remove him or herself entirely from the constraints imposed by that role.

A patient and Dr. Atul Gawande
Direct quotes from Gawande's Overkill article as answers to hypothetical questions [71]





How to proceed after getting a second (or even third) opinion

Once you've had a second (or third) physician make treatment recommendations, use this chart to compare benefits and harms. Try to fill in as many boxes as possible. Include Treatments C and D as appropriate.

	Treatment A	Treatment B
Benefits and harms at intervention		
Benefits and harms over the short term		
Benefits and harms over the long term		

Each patient can define benefits and harms as those most important to him or her, as well as the short and long term. Typically short term means the first few months and long term 3 – 5 years, though you can modify these definitions as you see fit.

Here are some issues in a hypothetical comparison of surgery and physical therapy for illustration purposes only. You may have different concerns.

	Treatment A (surgery)	Treatment B (physical therapy)
Benefits and harms at intervention	* How long will I be hospitalized? *How likely is an infection or other surgical complication? * How much pain will I feel after the procedure and for how long? * How much work will I miss? * Will I be incapacitated and need care from a family member or home health aide? If so, for how long?	* How many sessions will I need? * How much pain is associated with the therapy? *How often are patients harmed by therapy? *When will I know if the therapy is working?
Benefits and harms over the short term	* How long will it take to regain my strength and range of motion? * How many patients report satisfaction with the outcome at 3 and 12 months? * How often do patients need a second surgery?	* How often do patients report satisfaction at 3 and 12 months? * How often do patients quit physical therapy and opt for surgery in the short term?
Benefits and harms over the long term	* How many patients report satisfaction with the outcome at 48 months? * How many need a second surgery within 48 months?	* How many patients who started with PT ultimately end up with surgery within 48 months? * How many patients report satisfaction with the PT outcome at 48 months?

This comparative process isn't limited to surgery and PT: you can use it to compare any medical interventions, though the specific questions in each box may differ.

Try to format your treatment comparisons this way. It will help you focus on the most critical issues and streamline your decision making process.

Feel free to show a chart like this but with your own questions to your doctor. It may facilitate your discussions.

****

Case Study: How John decided on physical therapy for his torn rotator cuff

John, a 69 year old insurance broker, walked up to me in a lecture hall one day with his arms high in the air, smiling and saying 'my shoulder feels fine'.

Odd behavior and greeting in a professional setting. I hadn't seen or talked with him in the previous year or two.

His right shoulder had been so weak, he said, that he couldn't shift gears in his pick-up: he had to reach over the steering wheel with his left hand to shift.

His scans clearly showed a torn right rotator cuff and his orthopedic surgeon recommended surgery. All fairly routine.

COST IMPLICATIONS

The Patient Preferences Matter scholars suggest a 16% or so systemic savings potential. I suspect this estimate is low!

They used British National Health Service costs and practices as a basis for their savings projections.

The British only spend about a third as much as we do per capita on healthcare.

The 16% potential British savings probably translates to a much higher potential savings in the US but I can't guess how much.

But his story then took a surprising turn. I'll quote him:[72]

> 'I probably would have said yes to surgery prior to hearing your lectures. Instead I asked your questions and decided to try PT first.
>
> I regained 95%+ range of motion without pain in same time period as surgical recovery.
>
> Same outcome as surgery at far lower cost, risk and hassle.'

The key questions:

> Out of 100 people like me, how many benefit from, and are harmed by, rotator cuff surgery?
>
> Would most physicians recommend rotator cuff surgery or might some suggest something different?

Interestingly John, a well-educated, knowledgeable, regular attendee at insurance seminars, wouldn't have asked those questions absent specific instruction and a script.

I suspect a similar situation exists for most patients like the Fort Myers back surgery folks and Connecticut mastectomy women we discussed earlier.

They all might have made different choices had they simply been taught to ask the right questions.

This is almost exactly how John looked when he walked up to me in that lecture hall. Slightly older though.

Another patient's experience asking the '*out of 100 people like me*' and the '*would most physicians agree*' questions.

'Preference-sensitive' applies to physicians too!

A fellow called me with this poignant story one day, completely out of the blue. He had attended a lecture and read my book Transparency Metrics.

> I have a good relationship with my cardiologist, so I felt comfortable asking your 'out of 100 people like me' questions. So I did.
>
> He put down his pen, looked at me and said 'no one has ever asked me that. I don't know the answer. Let's figure it out' and he started typing on his computer.
>
> The process of finding answers got me involved and I ended up feeling more comfortable with his treatment recommendations as a result. I feel like I now have an even better working relationship with him than I did before.
>
> I'm also more inclined to comply with his recommendations.[73]

I asked a few questions then he announced 'now I have to tell you about my next experience'.

> I asked my dermatologist the same questions including 'would most physicians agree with your recommendation?'
>
> His response: 'you come into *my* house and ask *me* those questions? If you don't trust my judgment, I think you should get another dermatologist.'

Different doctors for different patients.

Preference sensitive works for physician choice also.

Choose the doctor whose style and professional demeanor work for you.

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Summary of Question 4

What We Have Learned So Far

Question 4 builds upon the lessons of Questions 1, 2 and 3.

Question 1 was '**Has it been tested for the outcomes that concern me?'** We learned that comparative tests identify the benefits and harms of a medical intervention.

- Importantly, we also learned that medical interventions that have not been subjected to comparative testing are ineffective or harmful about half the time. We called this Prasad's Law.

Question 2 showed how to quantify the benefit and harm impacts. We learned to ask

- **Out of 100 people like me, how many benefit?** And
- **Out of 100 people like me, how many are harmed?**

Question 3 moved us out of the laboratory and into the real world. We learned that sometimes beneficial medical interventions are overused and learned to ask

- **Is it overused?**

The answer helps identify at least one critical reason for asking Question 4 **'Would most physicians make the same recommendation or might some suggestion something different?'**

There are several additional reasons for posing this question to your physician including:

- It helps you get a second opinion that differs from the first thus exposing you to a range of treatment options.
- It helps you differentiate personal preferences from medical imperatives.

Once you identify the treatment option that you prefer, you'll want to identify the physician and hospital that does it the best. Ask Question 5 '**How many patients like me do you treat annually?'**

Question #5

How Many Patients Like Me Do You Treat Annually?

The more experience a specialist or hospital has treating patients with your medical condition, the better your likely outcomes

Research has identified a pretty strong (but not perfect!) correlation between the volume of similar patients treated by a specialist or hospital and the outcomes for those patients: The higher the volume, the better your chances.

This is not a perfect predictor but it's about the best predictor currently available.

One classic study on the impact of **hospital volume** on mortality rates was published by Dr. John Birkmeyer of the Dartmouth-Hitchcock Health System and his colleagues.[74] They analyzed the impact of hospital volume on mortality rates for 2.5 million patients who underwent 14 different medical procedures over a 5 year period.

Patients, they concluded, can significantly reduce their operative mortality risk by choosing a high volume hospital. Though the specific mortality rate reduction varied by procedure, Birkmeyer and his colleagues identified a surgical quality gap between high and low volume hospitals.

They concluded three things about this gap:

> First, it is **large** enough to concern patients.
>
> Second, it is **consistent** across different medical specialties and research studies, and
>
> Third, it **makes sense**. High volume hospitals, they reason, tend to have more consistent processes for postoperative care, better-staffed intensive care units, and greater resources for dealing with postoperative complications.

Other research pretty strongly supports Birkmeyer's conclusions:

> A 2011 study of heart failure patients estimated that 20,000 lives could be saved annually if patients at low volume hospitals switched to high volume hospitals.[75]
>
> A study of bariatric surgery found that hospitals treating more than 100 patients annually had shorter lengths of stay, lower mortality rates and decreased costs.[76] In particular, bariatric surgical mortality rates at low volume hospitals were up to 3x higher than at high volume hospitals for patients over 55 years old.
>
> A 2013 study of high risk patients found those undergoing aortic valve replacement at high volume hospitals enjoyed better outcomes.[77]
>
> Studies of breast cancer treatment, knee surgery and other medical care finds pretty much the same things.[78]

By contrast, studies comparing patient outcomes from newer vs. older technologies, or from academic medical centers vs. other hospitals, do not always find such a gap.

> One such newer vs. older technology study found that physicians need to perform 1600 robotic assisted prostate removal surgeries to achieve excellence. 79 Experience with the technology, often more than the technology itself, correlates with quality outcomes.

We find the same thing for **surgeons** – the higher their volume of a particular type of surgery, the better their outcomes. Dr. Paul Ruggieri summarized the literature on this topic in Chapter 5 of his book The Cost of Cutting:

> The message is becoming clearer with each published study. High volume surgeons operating out of high volume hospitals give patients the best chance for quality outcomes.
>
> Based on the data, the high volume surgeon part of the equation seems to be the most important factor.[80]

Ruggieri, a surgeon, might be slightly biased.

But Birkmeyer, the Dartmouth physician, agrees with Ruggieri's assessment, concluding that patients can improve their chances of survival substantially, *even at high volume hospitals*, by choosing high volume surgeons. [81]

Thresholds

Some organizations publish 'thresholds' or recommendations for the minimum experience a surgeon or hospital needs to achieve excellence. Treating fewer than the threshold number of patients tends to increase mortality rates but treating more doesn't decrease those risks.

The Leapfroggroup, for example, has developed hospital threshold recommendations for several procedures such as

- Coronary artery bypass graft, minimum 450 procedures/year.
- Abdominal aortic aneurysm repair, minimum 50 procedures/year.
- Percutaneous coronary intervention, minimum 400 procedures/year.[82]

Johns Hopkins, Dartmouth-Hitchcock and the University of Michigan go one step further and have developed minimum hospital and surgeon requirements for their affiliated hospitals including[83]

- At least 20 pancreatic cancer surgeries per hospital per year, and at least 5 for each surgeon.
- At least 50 knee or hip replacements per hospital per year, and at least 25 per surgeon.
- At least 10 carotid stent insertions per hospital per year, and at least 5 per surgeon.

John Birkmeyer, the leader of the Dartmouth effort, suggests the impact. If all US hospitals adopted this standard, he says, about half

the hospitals that perform many of these procedures would be prohibited from continuing to do them.[84]

Wise patients choose specialists and hospitals working at or above the recommended threshold.

Why is experience so important?

The common sense answer that 'practice makes perfect' is only part of the reason, and the least important part. Physicians learn the process of cutting, suturing, etc. relatively quickly. Though these mechanical skills may improve slightly over time, this doesn't address the significant mortality reduction evidenced by high volume surgeons and hospitals. Few patients, it seems, die from faulty incisions.

Instead, I suggest that the true benefit of dealing with high volume surgeons and hospitals comes from their ability to identify patients who are 'out of bounds' more quickly and address their problems more appropriately. With volume a surgeon can sense, almost even without testing, that something is wrong.

Without the experience that volume brings, the surgeon is unsure if the patient's blood loss or reactions are within the normal range. This applies at a systemic level to hospitals also: nurses and technicians can develop the same sense from experience.

Atul Gawande wrote insightfully about this process in his article 'The Computer and the Hernia Factory', a study of Shouldice Hernia Hospital in Canada. [85] Shouldice only performs hernia surgeries. Each Shouldice surgeon performs about 700 annually or, over their medical career, perhaps 20,000 similar surgeries. Gawande estimated, in 2002, that Shouldice's hernia surgery failure rate was 'an astonishing 1.0%.' He revised that figure in 2008 to 'closer to 0.1%'.[86]

By comparison, some studies suggest an average 10-year hernia repair failure rate outside of Souldice at around 11%.[87]

With repetition, Gawande found, 'a lot of mental functioning becomes automatic and effortless, as when you drive a car'. This allows

experienced practitioners to focus on novel or abnormal situations and essentially ignore all that is normal and routine. A surgeon, he writes, for which most activities become automatic has a significant advantage.

He described a Shouldice operation:

- The surgeon performed each step ‘almost absently’
- The assistant knew ‘precisely which issues to retract’
- The nurse handed over ‘exactly the right instruments; instructions were completely unnecessary’
- The doctor slowed down only once, to check ‘meticulously’ for another hernia. He found one that ‘if it had been missed, would almost certainly have caused a recurrence’

This ‘almost absent attention to routine features’ but intense focus on potential abnormalities comes only from experience. That’s why higher volumes identify better quality surgeons and hospitals.

Just like why more experienced drivers have fewer car accidents!

When you consider hiring a specialist or using a hospital, be sure to ask the volume question. It just may save your life.

Summary

Let's review what we've learned:

Patients who follow the Goldilocks principle enjoy better outcomes than patients who do not.

- Too little medical care can expose you unnecessarily to disease harms
- Too much medical care can expose you unnecessarily to treatment harms
- Inappropriate medical care can expose you to more risks, higher costs and lower satisfaction than optimal

We introduced 5 questions to ask all doctors about all medical interventions.

> **Has it been tested for the outcomes that concern me?**
>
> **Out of 100 people like me, how many benefit and are harmed?**
>
> **Is it overused?**
>
> **Would most physicians make the same recommendation or might some suggest something different?**
>
> **How many patients like me do you treat annually?**

You can, of course, ask plenty of your own questions too: you may have specific concerns about pain, cost, time off from work, impact on your family, etc.

But I hope you ask the questions listed here. They'll help you differentiate better from poorer care, reduce your chance of receiving unnecessary and non-beneficial care and increase your likelihood of satisfaction with your own medical care.

The next page contains a summary grid of our questions with suggested introductory readings.

Has it been tested for the outcomes that concern me?	If the treatment has been tested, you and your doctor can decide if it works well enough for you to have.	If it has not been tested, it's ineffective or harmful about half the time. This is Prasad's Law.	Prasad's Law can apply to treatments, medications, tests and time horizons.	See Vinay Prasad's ground-breaking book 'Ending Medical Reversal'.
Out of 100 people like me, how many benefit and are harmed?	Try to get a number as your answer. '16' conveys more information than 'some' or 'many'.	Focus on patient outcomes not test indicators when you discuss benefits.	'*like me'*: Disease and mortality rates can vary 2-to-1 based on socio-economic status.	See the 2004 report 'Work, Stress and Health: The Whitehall II Study'
Is it overused?	Patients have treatment options about 85% of the time.	Different physicians and hospitals may treat similar patients differently.	Wise patients get a second opinion from a physician with a different orientation from the first opinion.	The Dartmouth Atlas of Healthcare is a good place to start your research into this topic.
Would most doctors make the same recommend-ation or might some suggest something different?	Doctors sometimes assume that patients share their treatment preferences.	Delegating decision making results in physician preference, not necessarily patient reference, being implemented.	When patients explore all their alternatives, they tend to choose less invasive, less risky and less costly care.	For a good introduction, see the Patient Preferences Matter article by Dr. Albert Mulley and colleagues.
How many patients like me do you treat annually?	The higher the volume, the better the outcomes.	This is a tendency, not an absolute predictor.	This metric applies to specialists, surgeons and hospitals.	See Atul Gawande's article 'The Computer and the Hernia Factory'.

Implementation

I'll make, in this short section, some suggestions about how to implement a consumer literacy program in your company, fully understanding that companies differ culturally and administratively.

The Most Important Implementation Consideration

Repeat, repeat, repeat, repeat, repeat, repeat, repeat, repeat.

Then repeat again.

The material in this book sounds simple but, in my experience, people don't integrate it into their medical consciousness the first, second or even third time they hear it.

I'm a big fan of exposing people to regular educational pieces, say a very short online educational module every month. We've developed this process at www.TheMedicalGuide.net. Each module consists of:

- A 1 minute animated video follow by
- A 'learn more' section that provides additional information and, optionally
- A 3 – 5 question quiz that reinforces the key points from the video. You can't fail - if you select an incorrect answer, the website explains why that answer is wrong and tells you to choose another.

As employees watch video after video, they'll slowly assimilate the information. They'll become like John, the fellow who avoided surgery on his torn rotator cuff by trying physical therapy first.

But he attended several of my lectures and read a couple of my books before the material sunk in.

Incentives

Some creative benefits professionals suggest tying monthly module participation to HRA contributions.

HRAs or Health Reimbursement Accounts are employer contributions to employee health insurance deductibles. Employers can, in certain circumstances, make contributions only for employees who complete a certain number of modules. I've heard several different scenarios.

Other benefits professionals suggest integrating educational programming into their wellness programs. Employees can, for example, get financial rewards for stopping smoking, joining a gym and/or completing a short educational module each month.

'How do I get a reasonable return on my investment?'

Keep your investment low!

At TheMedicalGuide, for example, we estimate that just 1 person making just 1 critical medical care decision more wisely every 3 years will at least cover the 3 year program costs for a 100 person company.

Expect the financial returns to grow over time as employees have positive experiences using these tools and share their successes with fellow employees. Returns in year 3 should exceed year 1 by quite a bit, and year 5 should exceed year 3 by even more.

The bottom Line

Your company may have unique programming opportunities or constraints. I hope that you can find a way to share the information in this book with your employees. It's vital for their medical decision making and your own bottom line.

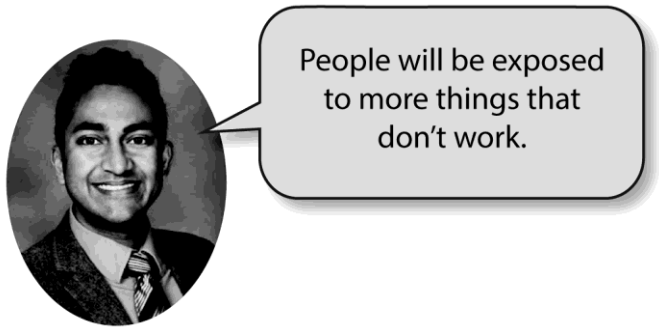
Both you and they can only benefit.

Trends

The burden on patients to ask the questions described in this book will probably grow in the future. Consider these two points:

First, the 21st Century Cures Act that took effect in 2016 lowers evidentiary standards for drug and other approvals. The Act allows for FDA approvals based on 'real world evidence' in addition to – or perhaps instead of - randomized controlled trials.

'Real world evidence' apparently includes observational studies and patient anecdotes [88] though the definition is 'still evolving' according to some proponents.[89] Here's Dr. Prasad's thought about the impact on patients:[90]



Second, the Trump administration seeks faster drug, and presumably other medical device and treatment, approvals, with President Trump aiming to 'slash the restraints' at the FDA.

Will these trends lead to faster development of better, more effective medications as their proponents hope? Or more Atenolols, Niaspins, Zetias, vertebroplasty and treatment variation as their skeptics fear?

I certainly don't know.

But consider yourself forewarned.

And forearmed with the right questions to ask.

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9 Gawande, Overkill, New Yorker, May 11, 2015 for all quotes in this section. I made some minor grammatical upgrades
10 These examples come from Mulley, Patient Preferences Matter, Kings Fund, 2012
11 Research methodology is extremely complicated. If you're interested in learning more, check out Know Your Chances by Woloshin et al. It's an easy to read introduction to medical statistics and research methodology.
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13 Quotes from Nicholas Bakalar, Medical Procedures May Be Useless, or Worse, New York Times July 26. 2013, italics added.
14 These are quotes from Dr. Prasad's video http://www.mayoclinicproceedings.org/cms/attachment/2007391767/2029532458/mmc3.mp4 . Some minor edits for grammar and syntax
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21http://www.clinicalcorrelations.org/?p=4888. I know that Atenolol is conventionally not capitalized but I decided to capitalize it in this book for consistency, like Zetia and Niaspin.
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25A meta review is a comparison of several tests. Meta reviewers study, for example, the methodology of each individual test to ensure that researchers didn't goof somewhere along the line. http://www.ncbi.nlm.nih.gov/pubmed/15530629
26 Ibid.
[27] Messerli, op cit.
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[29] I had used this example in lectures for several years starting in about 2011 but I don't know when the site first became active. When I visited the site in late December 2016, I discovered that it had been replaced with a 'prescribing highlights' pdf. These quotes were taken from the Zetia site on Nov 8, 2016. The 'has not been shown to prevent heart disease or heart attack' statement also appeared in print in Parade Magazine, September 11, 2011.
[30] This includes sales of Zetia and Vytorin, a combination of Zetia and Zocor, a statin. See Merck's Press Release of Feb 2, 2017 'Merck Announces Fourth-Quarter and Full-Year 2016 Financial Results' and Feb 4, 2015 'Merck Announces Fourth-Quarter and Full-Year 2014 Financial Results.
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