Transparency Metrics

For high deductible and self insured clients

Gary Fradin

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Preface

I'm a huge fan of medical care. I've seen the following during the past several years, a partial list from my own family and small circle of friends:

- My father recovered from a major heart attack 20 years ago well enough to ski in the Colorado Rockies until almost age 80. His pacemaker has provided a quality of life that would have been unimaginable years ago or in most other countries today.
- A close middle-aged friend had a cancerous kidney removed about 8 years ago and now lives a full, complete and virtually unrestricted life (rugby disallowed). His doctors expect him to enjoy normal longevity.
- An adolescent child of a friend had severe learning and emotional problems that threatened her ability to remain in public middle school. Medication and therapy helped address those problems and she ultimately graduated from a top college with honors.
- A child of another friend was born so prematurely at 3 pounds that she hadn't even developed ear ridges: her ears were completely smooth for her first day or so of life. She ultimately graduated from an Ivy League university, went into professional business management and experienced no physical or mental repercussions from her very premature birth.
- I had urinary frequency problems in my early 50s that negatively affected my quality of life and probably would have shortened it without a medical intervention. One 'garden variety' procedure – a TURP – later and I returned to long distance bicycle riding, skiing and all regular activities.

The point of this list: I've seen medical care at its best and have benefited greatly from it. I'm no anti-medicine churl.

HOWEVER, I've also seen medical care harm people. I've seen men suffer from impotence after prostate surgery or incontinence after colon surgery, women suffer the negative psychological effects of mastectomies, kids become zombies from too much medicine, elders become exhausted and depressed from endless tests, follow ups, more tests and more follow ups, and much more.

When I see these, I ask myself if the treatments were necessary or not. Certainly *living* with incontinence is better than *dying* fully continent. But living with *unnecessary* incontinence doesn't help anyone.

Recent medical care book titles include **Overtreated**, **Overdosed** and **Overdiagnosed**. The fundamental medical problem in this country has switched over the past 20 years or so (especially post Obama's healthcare reform) from sick people have too little medical care to healthy people have too much. It's causing us to go broke and some may do **More Harm Than Good**, the title of another recent book.

After studying this issue for years, I was left with the question that I heard repeatedly during my one and only Harvard Business School class (I studied Regional Planning on the other side of the river): What are you going to do about it? And specifically, what can patients do about it?

- How can patients differentiate necessary from unnecessary care?
- How can they tell if they're *overtested* or appropriately tested, *overdiagnosed* or appropriately diagnosed, *overtreated* or appropriately treated, *overdosed* or appropriately dosed?
- How can they tell if they're receiving good, high quality medical care; poorer, low quality care; or unnecessary care?

As I lecture, research and write, I'm increasingly convinced that most consumers lack the necessary metrics to compare medical care interventions and make wise choices. I worry that in our market-driven, litigation oriented, fee-for-service based medical industrial complex, the incentives to overtreat outweigh the incentives to treat conservatively, that the historically tried-and-true 'less is more' approach is disappearing from American medicine.

I'm also increasingly convinced that health insurance brokers have the opportunity, the incentives and the responsibility to teach their clients appropriate medical decision making mechanisms. Brokers shouldn't teach *which* medical decisions to make – they're not qualified or licensed to do this - but rather *how* to make wiser decisions, the metrics to use and processes to follow.

I wrote this book to show brokers how to teach their clients *the right questions to ask* about their medical care and to give clients *the necessary skills* to make wise medical decisions. I hope it helps.

A word about my writing style. I'm sometimes sarcastic, sometimes skeptical, sometimes cynical, sometimes angry and sometimes outraged but I'm never negative. I'm always optimistic that medical care will help sick people.

I hope that comes through to the reader.

A word about me: I'm not a doctor. I've have taught healthcare economics to insurance brokers for the past decade. I was motivated to write this book, in part, to address the questions that arise regularly in class and the ignorance of many about how our medical care system actually works. If brokers who sell health insurance for a living don't know much of this information, then regular consumers who are professionally unexposed to these issues probably know even less.

I see my own PCP regularly and value his advice, have tests rarely but when I deem them necessary, and see specialists even more rarely because I'm pretty healthy. I approach medical care with caution but also with the belief that if and when I get sick, it will help me.

Again, I hope that sentiment comes through.

Gary Fradin

March, 2013

Introduction

Healthcare today is so complicated that patients need to understand two very different types of information to make wise decisions.

The first is '<u>how</u> medicine works'. Your doctor is your advisor here. He/she knows you (hopefully) and knows the technical aspects of medicine – cellular physiology, anatomy, biochemistry, surgical protocols and all the rest – which she brings to bear on your case. Your doctor knows the newest tests and technologies, can discuss how treatments, therapies and medications work and how they may affect you. He/she diagnoses, prescribes, operates and refers you as necessary.

Your doctor is trained in medical technology. Doctor-patient discussions typically focus on medical technology and types of appropriate medical interventions.

This is the information we normally associate with medical care and medical advice. But it's only one of the two bodies of knowledge you need to make wise medical care decisions.

The second is '<u>how well</u> medical care works'. This focuses on medical *outcome* information. Expertise in the '*how well* does it work' field doesn't require a medical degree. You just need to ask the right questions to help you decide, for example

- which diseases pose significant mortality risks to you and which do not
 - a corollary to this: which *screening tests* may be worthwhile, based on your own disease risks, and which may be superfluous and unnecessary
- which *medications* will likely work best on patients like you, and which worst
- which screening tests may actually present more *false-positive risks* than *mortality gains* to you
- which specific surgical technique generates the *lowest mortality rates* for patients like you
- which surgeons and surgical teams get the best results for patients like you
- which *hospitals* are best for patients like you. For example, which are best for coronary care, which for orthopedic, which for diabetic and
- many similar issues

Some examples of 'how well does it work' measurements include knowing:

- the Number Needed to Treat for various medical interventions so you can choose the medical treatment that most likely will *benefit* you
- the **Number Needed for Harm** for various medical interventions so you can choose the medical treatment that most likely will *not harm* you
- your **Starting Risk** of developing or dying from various diseases so you can understand preventive medicine's potential impact
- which medical measures are valid and useful disease specific mortality rates for example – and which sound good but actually provide useless information like 5-year survival rates
- how closely test indicators cholesterol or blood pressure numbers, for example – correlate to patient health events like heart attacks or strokes, to avoid receiving too little, or too much, medical care
- the difference between observational studies and high quality double blind comparative ones, so you base your medical decisions right information. For example, you probably wouldn't want to base your coronary medication decisions on studies performed in Glasgow, Scotland, as it is 'the world's heart attack capital' and information derived from studies of Glasgow residents is probably less applicable to you than you would like ¹
- which high quality data sources exist so you can evaluate hospital and treatment outcomes to choose the one that most likely will benefit you and least likely to harm you... and much more.

There may be a third body of useful information – medical care prices. These seem to me tertiary to the 'how' or 'how well' details. I've yet to hear a parent say 'I want the second or third best medical care available for my sick child in order to save some money.' Rather, people generally say 'I want the best care for my kid, regardless the price' indicating the relative importance we place on medical care quality and price. I'll have much more to say about prices later.

¹ BBC News, Glasgow: The World's Heart Attack Capital, May 7, 1999. Note that the Adult Treatment Panel III (ATPIII), the expert committee that advised on cholesterol medications in the early 2000s used the West of Scotland primary prevention study, in part, as a justification for its recommendations. We'll discuss this at some length in Chapter 4.

One reason why doctors typically have less expertise in the '*how well* does it work' arena: they have less academic training in evaluation protocols, the skills necessary to answer these types of questions.

A second reason: doctors need to master such a huge amount of '*how* does it work' information that they simply don't have time to master the *how well* techniques and keep up with the *how well* studies and information.

A third reason: the skill set required to answer the *how well* questions is not the skill set that makes one a great physician.

A great surgeon, for example, is generally one who performs lots and lots of surgical procedures. Practice makes perfect in surgery, as many studies have shown: the more procedures a surgeon performs annually, the better the patient outcomes.

Wise patients want a surgeon who's at the top of his/her game, performs lots of procedures, is up on the most current techniques, and practices his/her craft to perfection. That's different from one who keeps up on all the '*how well*' metrics and studies.

Asking your physician *also* to develop expertise in outcome metrics and methodologies, to keep current on the Number Needed to Treat studies for lots of medications (often only tangentially related to his/her surgical skills) and to know which hospitals have the best risk-adjusted patient outcomes for your specific medical condition may be asking too much.

That information is somewhat outside your physician's core area of expertise.

Here's the thesis of this book: the patient can acquire the tools necessary to determine medical care quality, the *how well does medicine work* information. This can improve their medical decision making skills tremendously and lower their medical costs and risks.

One specific thing this book will do: teach the questions to ask about medical care. When patients ask the right questions, they generally get useful information both from their own online research and from their physicians.

But when patients fail to ask the right questions, they often get lots and lots of information that's – at best – only marginally useful. At worst, they get the wrong information, 'wrong' in terms of not serving usefully as the basis for medical decision making.

You need to know several of these medical care quality metrics to make wise medical decisions. Most are easy to understand and grasp but too rarely make it into real life patient-doctor discussions.

As an indicator of our failure to include the *how well does it work* information enough in the typical doctor-patient relationship, note that 'up to about a third of medical care is devoted to services that do not provide any detectable benefit' according to many high quality medical research studies.²

One reason for this: we rely too much on our doctors to advise us on both the *'how'* and *'how well'* information.

That's why patients need to learn how to ask better questions and participate better in your medical decision making. Your doctor can help of course, as can other medical professionals. Remember that, in the end, the medical decisions about your care are really yours. The better you understand the *how well* information, the wiser your medical decisions.

Indeed, studies show that when patients learn the '*how well does it work*' information, they often disagree with their physician's recommendations!

The Dartmouth Atlas of Healthcare, a publication of the Dartmouth Institute for Health Policy and Clinical Practice (perhaps the leading US research institution studying the 'how well does it work' information and part of Dartmouth Medical School) puts it this way:

When patients are fully informed about their options, they often choose very differently from their physicians.

And the patient's decisions are often less risky and less expensive, at least according to Laura Landro, a health columnist in the Wall Street Journal:

² This paraphrase 'up to about a third...no detectible benefit' comes from Elliott Fisher, Healthcare in America: Is More Better? Annals of Internal Medicine, February 2003. Fisher is a very highly respected researcher at the Dartmouth Institute for Health Policy and Clinical Practice, one of our foremost healthcare research institutions. He also used the phrase 'no detectable benefit' in his article Associations Among Hospital Capacity, Utilization and Mortality, Health Services Research 34:6 (February 2000). Others suggesting the same amount of waste include, for example, Skinner, Efficiency of Medicare, National Bureau of Economic Research, August 2005, Fisher, The Implications of Regional Variations in Medicare Spending, Annals of Internal Medicine, 2003;138:288-298, Maggie Mahar, Money Driven Medicine, interview with Jack Wennberg of Dartmouth Medical School, page 159, Catherine Arnst, 10 Ways to Cut Healthcare Costs Right How, Bloomberg BusinessWeek, November 12, 2009 and *Dartmouth Medicine*, spring 2007 issue among many, many other references.

When patients **understand their choices** and share in the decision-making with their doctors, they tend to **choose less-invasive and less-expensive treatment** than they would otherwise have received. ³

A 2012 Dartmouth Institute study goes even farther, making this point about customer satisfaction:

Health care may be one of the only fields in which increasing customer satisfaction **actually costs less**.⁴

A corollary of this point may well be that the most sophisticated, well informed and demanding medical care customers are the least expensive. I suggest this corollary, not the Dartmouth folks.

All this leads to the US Institute of Medicine's conclusion:

Health outcomes improve when patients are engaged in their own care. People are eager to play a strong role in their own health care **when given the right tools**.⁵

This book will help you develop those tools.

A special note to health insurance brokers and other benefits advisors: You may find that the information in this book helps you develop client educational programs – at least, I hope you realize that.

In fact, some advisors who have attended my lectures or read drafts of this book have commented that this may be the future of the health insurance brokerage and advisory business. I'll discuss this in some detail in Chapter 3.

The argument, in brief:

- Your clients want and need the '*how well* does it work' information and *they will find a way to get it*
- If you don't provide it, your clients will get it from someone else your competitor, perhaps.

³ Landro, Weighty Choices in Patient's Hands, Wall Street Journal, August 4, 2009, emphasis added

⁴ Mulley, Stop the Silent Misdiagnosis, BMJ, November 8, 2012, emphasis added

⁵ Patients Charting the Course, US Institute of Medicine, 2011

As a licensed health insurance broker myself, I understand the vast scope and complexity of what advisors do. My message is, unfortunately, that you probably need to learn this new information too.

My sense about the market: brokers who ignore information about medical care quality - and fail to help clients understand these issues - may well be left behind.

Chapter 1: The Transparency Quality Problem

Medical quality describes the extent to which medical care improves your health.⁶

- *High quality care* improves your health, and does so more than alternative types of care and more quickly and efficiently;
- Low quality care improves your health, but much less, and less quickly and efficiently;
- Unnecessary care does not improve your health at all.

You want the highest quality necessary care because this will help you the most.

You want to avoid unnecessary care because it can't help you (it's unnecessary!) but can harm you through side effects and medical errors, and costs you money.

Remember: *all* medical care contains some element of risk, even medical care as benign as taking a baby aspirin or putting on a Band-Aid. Someone, under some set of circumstances, can be harmed by these activities. With unnecessary care, you face all risk downsides without the benefit upside.

Americans, unfortunately, get too much unnecessary care. At 'up to about a third' of all medical spending, unnecessary care is the biggest single line item of our healthcare expenditures – bigger than

- Cancer care about 4% of all medical spending
- Coronary care around 9%
- Diabetes care close to 4%
- Elder care Medicare costs about 20% of total healthcare expenditures.

Shannon Brownlee, author of **Overtreated** - called 'the economics book of the year' in 2007 by the New York Times – puts it this way: *We spend between one fifth and one third of our healthcare dollars on care that does nothing to improve our health*.⁷

⁶ This comes from the Institute of Medicine's definition 'the extent to which health services provided to individuals and patient populations improve desired health outcomes.' See PeerPoint Medical Education Institute, http://www.peerpt.com/website/index.php?option=com_content&view=article&id=10&Itemid=10

⁷ David Leonhardt, No. 1 Book, New York Times, December 19, 2007

The Congressional Budget Office estimates that up to 30 percent of care delivered in the United States goes toward unnecessary tests, procedures, doctor visits, hospital stays and other services that may not improve people's health – and in fact, may actually cause harm. ⁸

This chapter will present examples and vignettes about medical care, each showing an aspect of medical care quality. **These are not definitive analyses of various medical interventions!** Rather, they're designed to expand on the *high quality – low quality – unnecessary care* typology.

I want to introduce readers to the '*how well* does it work' lens discussed in the Introduction, rather than the '*how* does it work' one. In each vignette, ask yourself these questions:

- How much does this medical practice actually help patients?
- Is it necessary?
- Is it high or low quality medical care?

And consider whether some medical interventions can be *necessary* but *low quality* despite being commonly practiced and perhaps, the best available at the time.

An International Perspective

American healthcare expenditures per capita have grown faster than per capita healthcare expenditures in other developed countries like Canada, Britain or France.

Today Americans spend far more on medical care, per capita, than do residents of these other countries.

We use only this 3 country comparison because charts with more countries become quite difficult to read. The situation we describe, however, would be roughly the same regardless the first world countries we use.

Here's a chart of medical care expenditure increases over time, showing US spending growing the fastest: $^{\rm 9}$

⁸ http://choosingwisely.org/wp-content/uploads/2011/12/about_choosingwisely.pdf

⁹ Both charts based on OECD data. We used this data source for all our charts, for consistency purposes. Note that we could have used data provided by the World Health Organization, which shows about the same things.



Healthcare expenditures: \$ per capita

Our spending follows an almost perfect logarithmic curve and nothing – not government regulations, new programs, new plan designs or anything else we've tried – seems to affect the slope of this curve. See how, for example, Nixon's introduction of HMOs in 1973 to control costs didn't affect the cost curve; Clinton's attempts to reform healthcare in the 1990s didn't either; and W. Bush's introduction of Health Savings Accounts – if anything – exacerbated, rather than mitigated, the cost per capita spending increases.

American medical outcomes, however, as measured by longevity or infant mortality rates, don't correspond to expenditure increases.

Look at longevity gains over time. You can see on the next chart that our longevity gains are about the same as Canada, Britain and France – actually slightly worse - even though our expenditures far exceed theirs:



I show this longevity data because longevity is one of three benefits a medical care system can provide. Here are those three benefits:

- Live longer. We can measure this;
- Enjoy lower infant mortality rates. Again, we can measure this;
- Live better generally defined as having less pain, greater range of motion and less depression. We can't measure this very well. However, it's hard to believe that a large population say 310 million Americans or 62 million Britons living with less pain, greater range of motion and less depression will die younger, on average. That's why we suggest that longevity data encompasses some aspects of living better.

In sum, a medical care system can help you be born, live well and die old. That's about it.

The US infant mortality rate reduction, though clearly significant over time, falls in lockstep with Canada, Britain and France, despite our much higher medical expenditures. Here's that comparative chart, again using OECD data:

Infant Mortality Deaths per 1000 live births, OECD data



One way to interpret these charts: Americans spend more on medical care than these other countries without benefiting from that spending. That's a definition of low quality medical care and unnecessary spending.

This has tremendous economic implications. The \$4000 or so that we spend unnecessarily on medical care compared to Britain, France or Canada is money that we can't invest in our educational system, spend on new plants and equipment or use to develop new transportation systems. Its money that our foreign competitors can invest in their economies to help them outperform us.

As a more frightening example, compare US healthcare spending and longevity to China and India. In which economy's future would you prefer to invest? ¹⁰

	2011 medical spending/capita	2011 Life Expectancy at Birth
US	\$8000	78
China	\$ 300	74
India	\$ 130	65

We spend almost \$8000 more per capita than the Chinese but only live about 4 years longer. That may suggest we live only a little bit 'better', medically speaking. I wonder what would happen if they spent \$600 or \$1000 on healthcare? Or if the Indians

¹⁰ Data from OECD and World Health Organization 2011 reports

increased to \$500 or \$800 per person. We would still face a huge economic disadvantage with, likely, little or no longevity advantage.

The simple, probably obvious point of this international perspective: unnecessary medical spending harms us economically. This can have tremendous implications for our future, and for that of our children.

But unnecessary medical spending can also harm us medically, perhaps even more than economically. We'll show some examples of this in the next few vignettes, coming shortly.

Let's dig deeper to discover some other aspects of unnecessary medical care and compare the number of MRI exams per thousand Americans to MRIs per thousand Britons, Canadian or Frenchmen (women).



MRI Exams per Thousand Pop, OECD data

Some MRIs are clearly useful. That's indisputable. Based on the longevity and infant mortality data presented above, having about 50 scans per thousand of population seems about right. That's about what other advanced countries – with slightly better infant mortality and longevity data – have. We currently do about double that.

Here's a very rough estimate of the economic costs of those additional or unnecessary MRIs: \$30 billion annually.

The calculation: MRIs cost about \$2000 each, according to New Choice Health, a website that compares medical care prices. ¹¹

That's \$2000 for each of the 50 unnecessary MRIs per thousand of us...and there are about 310 million of us!

One more international chart – pharmaceutical consumption per person.



Pharmaceutical Consumption \$ per capita, OECD data

This chart shows Purchasing Power Parity consumption, not official exchange rates. This means – at least theoretically, or as best the OECD researchers could calculate – drugs cost the same in all four countries. Again, at least theoretically in this comparison, an individual aspirin costs the same amount of money in the US, UK, France and Canada, so this chart reflects the number of drugs or number of prescriptions taken per capita in each country.¹²

¹¹ <u>http://www.newchoicehealth.com/MRI-Cost</u>

¹² I'm not an international economist and this is only a quick and dirty definition of Purchasing Power Parity. Conceptually, the same basket of medications costs the same in each country using PPP calculations.

In fact, Americans have increased the number of pharmaceutical prescriptions per capita from about 7.3 in 1992 to 12.6 in 2009. ¹³

We spend about \$300 per capita more than Canada, the second biggest pharmaceutical consumer on earth. Assuming that they consume about the right amount – remember, they live slightly longer than us and enjoy slightly better infant mortality rates – then we annually waste about \$90 billion or so on unnecessary pharmaceuticals.

We'd better not calculate our waste compared to the British: they spend about \$600 less per capita annually than we do!

We could show lots of similar charts, indicating that Americans have more medical interventions – hip replacements, cancer screening tests, dialysis etc – than almost anyone else. Rather than belabor that point, however, let's try to figure out what all this means.

We *hope* that all our medical spending – scans, pharmaceuticals etc, at rates far higher than other countries - makes us healthier over time so we live to a ripe old age. The assumption: years of high quality medical care should prepare us to live longer lives. In other words, if all those screening tests, preventive medications, hip replacements, MRI scans etc help us, then we will – presumably – reap some longevity benefits in old age.

So let's compare life expectancies of various countries at age 65.

The good news: all have gone up over time.

The bad news: they've all gone up at about the same rate. American's don't seem to enjoy any significant medical aging benefits from all that preventive care; we live about as long at age 65 as countries that spend far less than us, who have fewer MRI scans, medications, hip replacements, etc.

Here's how our Life Expectancy at Age 65 compares to other countries. This chart shows the number of years after age 65 *men* live. The female chart looks about the same, only a few years higher.

¹³ Kaiser Family Foundation, Prescription Drug Trends, May 2010



Life expectancy at age 65, number of years, males

No big differences among countries here. It looks like all that medical spending – about \$4000/person/year more than Britain, France or Canada – didn't generate much benefit at all.

Two Harvard Medical School scholars who studied all these activities – Julius Richmond, a former US Surgeon General and Rashi Fein, Professor of Medical Economics Emeritus – reached this conclusion in their 2005 book **The Health Care Mess:**

The various health gains [since World War II] were largely the consequence of progress in applying our knowledge of health promotion and disease prevention than of improved clinical care.¹⁴

In other words, public health investments generate more health improvement 'bang for the buck' than clinical care does. Yet we have, over the past 50 years or so, invested far more in clinical care and less in public health. We're now reaping the rewards – or lack thereof.

¹⁴ Richmond and Fein, The Health Care Mess, page 92

We have decided that relatively easy access to specialists and hospitals is critical to enjoying good medical outcomes, and have invested accordingly. Unfortunately, our infant mortality and longevity outcomes suggest that our decision was a poor one and that we have invested unwisely. In fact, some commentators suggest that such easy access actually contributes to *poorer* medical care outcomes.

Here, for example, is Kenneth Thorpe, former Assistant Secretary of Health and Human Services, paraphrased: ¹⁵

The typical Medicare beneficiary sees two primary care physicians and five specialists working in four different practices...system fragmentation...providers rarely coordinate. *That structural gap explains a significant portion of excess mortality*.

'Excess mortality' means premature deaths, or deaths before the average life expectancy of a particular demographic. It comes, according to Thorpe, in large part from our easy access to excessive medical care – specialists primarily, but also equipment and treatments. All these specialists don't coordinate medical care among themselves very well. That, according to Thorpe, leads to excess mortality.

Thorpe's conclusion is echoed on the Dartmouth Atlas of Healthcare website. The Atlas is a series of medical utilization maps based on Medicare expenditures, complied by researchers affiliated with Dartmouth University Medical School. The website commentary states bluntly that

Increasing the number of physicians will make our healthcare system worse, not better [because]

Physicians in high-supply regions are more likely to report concerns about inadequate continuity of care, inadequate communication among physicians, and greater difficulty providing high quality care.

And certainly most important, patient outcomes are not better in regions with a very large supply of physicians ¹⁶

Indeed, one very highly respected Dartmouth physician-researcher, Elliott Fisher, has quantified the medical harms of having excessive medical resources among the Medicare population:

¹⁵ Thorpe, Chronic conditions account for rise in Medicare spending, Health Affairs, April, 2010

¹⁶ http://www.dartmouthatlas.org/keyissues/issue.aspx?con=2940

For every 10% increase in spending, relative risk of death increased. ¹⁷

The most expensive US regions he studied had a 2 - 6% higher mortality rate than the lowest spending regions. The reason for this higher mortality rate?

The most reasonable explanation for the higher mortality rate is that the additional medicine patients are getting in the high cost regions is leading to harm.¹⁸

Let's tie this back to our international perspective. Our demand for increasing amounts of medical services, compared to the British, French or Canadians, ends up harming us in 3 different ways:

First, we spend lots of money unnecessarily. This harms us economically;

Second, we fail to invest in public health to the extent that we should. This leads to poorer longevity outcomes than we would like;

Third, we invest excessively in medical care and services, which leads to excess mortality – in other words, harms us by decreasing our life expectancies.

This is a long way of saying that much of the medical care we enjoy today is either unnecessary – it doesn't generate any benefits for us – or is of such low quality that it's virtually unnecessary.

What we need is a set of metrics that help us decide which medical care to have – which, in other words, is high quality – and which to avoid. Our next few vignettes will shed some light on those issues.

Where You Go is What You Get: Unnecessary Care By Geography

The Dartmouth Atlas tracks medical utilization – expenditures, surgical procedures etc in various US geographical regions. One example of geographic utilization differences: Medicare women in Connecticut are about twice as likely to have mastectomies as Medicare women in Massachusetts.

Here's a chart showing mastectomies per 100,000 Medicare women in 2007¹⁹

¹⁷ Fisher, Implications of Regional Variations in Medicare Spending, part 2.

¹⁸ Brownlee, Overtreated, page 50

¹⁹ Dartmouth Atlas



And here's a map showing the same thing:



Interestingly, Springfield Massachusetts and Hartford Connecticut – two population centers – are only about 25 miles apart. People sometimes live in or near one but work in or near the other. They may even move from one to the other.

The Dartmouth researchers have not identified any significant epidemiological differences between Connecticut and Massachusetts female Medicare beneficiaries – at least not that would explain this mastectomy difference.

And I, a Massachusetts resident with relatives in Connecticut, have not noticed any major differences between the women in these two states either. (That's an amateur opinion, not a professional one.)

Connecticut women don't have twice as much breast cancer as Massachusetts women: the breast cancer incidence is about the same in both states.²⁰

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

Breast Cancer Incidence per 100,000 Women 2003 – 2007

Absent significant demographic or epidemiological differences between the two populations, what can explain the breast cancer treatment differences?

The answer appears to have two parts.

First, Connecticut women go to Connecticut hospitals, while Massachusetts women go to Massachusetts hospitals.

Second, Connecticut oncologists prefer treating early stage breast cancer by mastectomy more frequently than Massachusetts oncologist, who may prefer lumpectomy or watchful waiting.

That provider preference difference explains the mastectomy rate differences far better than the alternative, that Connecticut women are sicker.

²⁰ Breast Cancer Facts and Figures 2011 – 2012, American Cancer Society

Hypothetical Doctor-Patient Discussion

When the Connecticut woman asks 'Doc, what do you recommend?' she'll more likely get a mastectomy answer than will a Massachusetts woman. That's the obvious implication from the Dartmouth Atlas.

But a more profound, less obvious implication comes in answer to her next question: 'I'd like a second opinion. Who do you recommend?'

The Dartmouth Atlas suggests that physicians practicing in the same region will likely have similar medical preferences or similar approaches. Dartmouth and other researchers have done a number of studies indicating that this is, in fact, the case. Thus another Hartford oncologist may also recommend mastectomy... as might a New Haven oncologist.

The profound message from these Dartmouth Atlas maps is that oncologists in Connecticut might agree with each other 100% of the time....but disagree with equally competent Massachusetts oncologists 50%!

For this reason, a second opinion for a Connecticut woman in Hartford or New Haven may be less useful than a second opinion in Springfield or Boston, Massachusetts.

Similarly, a woman in Massachusetts might ask 'Doc, what do you recommend?' and receive a lumpectomy recommendation, or perhaps a 'watch and wait' suggestion. Her second opinion request from a Massachusetts oncologist may agree with the initial recommendation 100% of the time....but disagree with a Connecticut oncologist 50%!

Of course, the key question to ask: do Connecticut women exhibit better breast cancer outcomes as measured by their breast cancer mortality rate or average age of breast cancer death than Massachusetts women who have half as many mastectomies?

The apparent answer: **no!** According to the most recent data available from the American Cancer Society, the breast cancer mortality rates per 100,000 women in both states were **the same**. Here's the ACS data from their Breast Cancer Facts and Figures, 2011-2012: ²¹

²¹ http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-030975.pdf

Breast Cancer Mortality Rates per 100,000 Women, 2003 – 2007

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

From this analysis, it appears that about half the mastectomies performed in Connecticut are unnecessary: they increase patient costs and risks without generating any patient benefit. But they may lead to the 'excess mortality' that Thorpe identified, both for clinical reasons (infection, physician error, etc) and care coordination reasons, and do more harm than good. (Unfortunately, we don't have the requisite data to determine this.)

A wise Connecticut consumer / patient wouldn't shop for the *least expensive* mastectomy. The wise consumer would ask a host of quality related questions first to determine the necessity of that mastectomy prior to engaging in the price considerations. We'll go into that process in great detail later in this book.

More care = more cost and more risk, without evidence of better patient outcomes

Mastectomies are far from a special case. Here's a map showing back surgery rates per 1000 Medicare beneficiaries in Florida.



Beneficiaries in Fort Myers, the most southwestern region in Florida are about twice as likely to have back surgeries as are beneficiaries in Miami, the most southeasterly region.

Again, as in the Connecticut / Massachusetts mastectomy case, researchers have not identified significant enough patient medical differences between the two populations to explain the differences. They're both composed of retirees, generally transplants from the northeast and Midwest.

And again, these maps can help someone decide where to go for a second opinion.

Here's a third map, with an accompanying comment from the New York Times. This map shows angioplasty rates in various Ohio regions on Lake Erie – that's the big body of water in the middle of this map.



People living in Elyria Ohio - the small dark region on Lake Erie – have about 31 angioplasties per 1000 Medicare beneficiaries - about 4x the national average.

They're about 50% more likely to have angioplasties than in Cleveland - the region completely surrounding Elyria – which performs about 21 angioplasties per 1000 Medicare folks.

And they're about twice as likely as people living in Akron about 50 miles away, which performs about 17.5.

The New York Times looked into this rate discrepancy and found:

nearly all the procedures at the Elyria hospital are performed by a group of cardiologists who dominate coronary care in this city and have an unabashed enthusiasm for angioplasties, the highly profitable procedure in which they specialize ²²

The Times continues

The Elyria cardiologists do not perform bypasses [an alternative invasive coronary procedure]. Because they are not surgeons, the North Ohio cardiologists must refer a patient to another doctor if they conclude that bypass surgery is that patient's best option...

Which raises questions about the physician's economic incentives to treat or refer out.

Again, though, we have no indication that Elyria residents are medically much different from Cleveland or Akron residents so *need* angioplasties more frequently. And no evidence that Elyria residents end up healthier as a result of all these angioplasties.

But we have significant evidence that Elyria cardiologists benefit financially from this treatment variation!

The message from these maps – and there are dozens more published on the Dartmouth Atlas – is twofold.

First, you can learn if you're in a high or low utilization region for a specific medical treatment;

Second, you can decide where to go for a second opinion.

John Wennberg, founder of the Dartmouth Institute for Health Care, estimates that much of Medicare's spending – and likely all US healthcare spending - falls into this *preference-sensitive* category. ²³ Wise and well informed patients who understand the geographic treatment variation issues can make different medical care decisions from patients who are less well informed.

Some Costs of Regional Treatment Variation

The Dartmouth Atlas tracks Medicare spending per capita in different US regions, in addition to tracking specific treatment differences. Medicare spending on similar populations can vary by up to \$8000 or more per person per year!

²² Abelson, Heart Procedure Off the Charts in an Ohio City, New York Times, August 18, 2006

²³ Wennberg, Tracking Medicine, page 9

Let's compare spending on Medicare beneficiaries in Miami, Florida and Minneapolis, Minnesota. These two populations are approximately similar: everyone is over 65 years old.

But Miami beneficiaries have consistently cost far more annually per capita than Minnesota beneficiaries *without any indication either of poorer health or better outcomes!*

Researchers have not determined that Miami Medicare beneficiaries are sicker than their Minneapolis equivalents – and they've looked! ²⁴

Nor have they found that Miami beneficiaries live longer or are more satisfied with their care.

They have only established that Miami beneficiaries cost more.

Here, for example, are the 1996 and 2008 Medicare spending amounts per beneficiary in each city:

	<u>1996 Spending/beneficiary</u> ²⁵	2008 Spending ²⁶
Miami	\$8414	\$15,568
Minneapolis	\$3341	\$ 7,380

These spending differences actually *grew* by \$3115, from \$5073 to \$8188 per capita over this 12 year period; the situation is getting *worse* over time. The far higher costs - with virtually identical patient outcomes - is one indication of the size of our unnecessary problem in Miami.

Here are some 2008 Medicare spending rates in various regions. Remember, Medicare payments per procedure vary only slightly by region, based on some minor cost of living differences.²⁷

• Rapid City, South Dakota \$6,462

²⁴ Elliott Fisher, The Implications of Regional Variations in Medicare Spending, Parts 1 and 2, Annals of Internal Medicine, 2003

²⁵ ibid

²⁶ Dartmouth Atlas. 2008 is the most recent year for which this data was available as of date of this book

²⁷ Downloaded from Dartmouth Atlas Dec 2012

- Grand Junction, Colorado \$6,683
- Birmingham, Alabama \$10,092
- McAllen, Texas \$14,362....almost 2.5 times the Rapid City cost per person. This suggests that McAllen beneficiaries receive about 2.5 times as many medical interventions or treatments per person, per year.

But, perhaps more astonishingly, here are some next door regions with virtually identical costs of living and populations, but vastly different Medicare spending per person:

- Ft Lauderdale, Florida **\$10,642** next door to Miami, Florida **\$15,568**
- Reno, Nevada **\$7256** next door to Las Vegas, Nevada **\$10,274**
- Sayre, Pennsylvania **\$7648** next door to Wilkes-Barre, PA **\$10,203**
- Bloomington, Illinois **\$7588** next door to Joliet, Illinois **\$10,158**
- El Paso, Texas \$7866 demographically almost identical to McAllen, Texas \$14,532 (similar poverty rates, income rates and percent Hispanic) ²⁸

The Downside of Excessive Low Quality / Unnecessary Care

Remember Kenneth Thorpe's comments about excess mortality rates and Elliott Fisher's conclusion that *mortality rates increase as medical care spending also increases*, both from the last section.

Those and similar studies suggest that people living in Miami, for example, face various medical care risks that people living in Bloomington, Illinois or Reno, Nevada do not. One way to phrase that: Miami folks use more 'low quality' or unnecessary medical care than Bloomington or Reno folks.

This, somewhat counter-intuitively, puts Miami Medicare recipients at higher mortality risks. Ditto for Las Vegas, Wilkes-Barre, Joliet and McAllen recipients.

Of course we want everyone to access as much high quality, necessary care as they need. That's the purpose of having a healthcare system in the first place. How can we decide what care is high quality and what low? Or what care is unnecessary?

We're beginning to make some progress answering those questions.

²⁸ Atul Gawande, The Cost Connundrum, New Yorker, June 1, 2009

One answer: determine if you're in a high or low utilization region. You can get some indications of this on the Dartmouth Atlas website, or you can ask your doctor;

A second answer: go to a region with a different utilization rate for your second opinion. In other words, if you're in a high back surgery region, try to get a second opinion from a low back surgery region.

We'll now turn to hospital based metrics to learn about high quality, low quality and unnecessary care at the individual hospital level.

Low Quality and Unnecessary Care by Hospital: Case study of C-section rates and similar things

Caesarean sections as a percent of all deliveries vary significantly by hospital. But infant mortality and maternal infection rates do not!

C-sections also cost significantly more than vaginal deliveries – about \$3500 more.²⁹

Here are the 2010 C-section delivery rates as a percent of all deliveries from various Massachusetts hospitals with at least 1000 annual deliveries: ³⁰



²⁹ Estimate from the Boston Globe, May 17, 2011, page 1

³⁰ Massachusetts Department of Public Health report, March 2010
Rates vary from about 48% in Caritas, Methuen to about 22% in Leominster. There's no evidence of significantly different maternal or infant health from the highest to lowest rates here: Baystate Medical (32% C-sections) and UMass Memorial (28% C-sections) are the major teaching hospitals in western and central Massachusetts, respectively, and receive the majority of high risk patients in their regions. Caritas, Methuen and Melrose-Wakefield do not.

Instead, hospital organization, staffing and routines define the different C-section rates more than patient need. Rates vary for a number of reasons, according to Dr. Lauren Smith, the then-Medical Director of the Massachusetts Department of Public Health, including

how do they **organize the staffing** of their labor and delivery units, what are **the resources that might be available**...are there **residents or attending physicians**, **how many delivery rooms** or operating rooms do they have.³¹

Most states exhibit roughly similarly discrepant C-section rates. Rather than show lots of similar charts here – you can do your own research for your own state – we'll present some analyses.

First, from New Hampshire. The State of New Hampshire Insurance Department looked into the C-section variation problem in New Hampshire hospitals: the C-section rate there varied from about 15% of all deliveries at one hospital to 47% at another. Here's part of the New Hampshire report: ³²

There are no obvious reasons that explain why c-sections are higher at one NH hospital versus another, *and*

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 status (for deliveries) and c-section rates.

Second, from New York. A 2011 study of 30,000 births in 10 upstate New York hospitals without specialized neo-natal intensive care units but with varying C-section rates showed

³¹ Boston Globe, June 7, 2010, Cooney, emphasis added

³² A Commercial Study of Vaginal Delivery and Cesarean Section Rates at New Hampshire Hospitals, April 1, 2011, New Hampshire Insurance Department

no difference in outcomes for babies born in the hospitals with the highest Csection rates and those with the lowest (based on Apgar scores, need for assisted ventilation, or need to move to intensive care hospital)³³

In other words, hospitals performing higher rates of C-sections don't service sicker populations or generate better outcomes. This is an example of low quality or unnecessary medical care: the patients could have achieved the same medical outcomes without as many C-sections, at lower costs and with less risk.

Our national rate of C-sections has risen fairly dramatically over the past 15 years – from about 21% of all deliveries in 1998 to about 32% in 2007 - though some evidence suggests that the rate of C-section increases is mitigating more recently. Here's the 1998 - 2007 chart: ³⁴



Caesareans per 100 Births

During this same period – when our C-section rate increased by 11 per 100 live births, from 21 to 32 - our national infant mortality rate dropped by about 5/100ths of 1%, from .0072 to .0067 per 100 live births. 35

In other words, comparing 2010 to 1996:

³³ Bakalar, Childbirth: More Labor Interventions, Same Outcomes, New York Times, April 25, 2011

³⁴ Menacker & Hamilton, NCHS Data Brief #35, March 2010, Dept HHS

³⁵ OECD Health Data, 2010

- We performed about 480,000 additional C-sections in 2010
- We enjoyed about 5000 fewer infant deaths. These were not all attributable to C-sections. During those 14 years we developed better maternal care, improved delivery technologies and NICUs among other things. How many of these 5000 kids survived because of the 480,000 additional C-sections is open to question. ³⁶

An interesting question from our high quality – low quality – unnecessary care perspective: why the sudden and fairly dramatic C-section increase? Part of the answer may be economic – higher hospital revenues. Part may be defensive medicine on the part of obstetricians, and part may be hospital organization, as we discussed above.

But part may also be the near-universal use of fetal oxygen sensors. These measure the baby's heart rate during the delivery process. If it goes down, this may indicate that the baby is not getting enough oxygen - a threat to the baby's health. Obstetricians monitoring the fetal heart rate may decide to perform an emergency C-section as a result.

Thus, the argument goes, fetal heart monitors save babies lives and help physicians deliver healthier babies – both clearly benefits of medical care – at the risk or expense of some additional C-sections. Many would say that's a fair trade-off.

Dr. Gilbert Welch of the Dartmouth Institute for Health Policy and Clinical Practice and the White River Junction (Vermont) VA Hospital, quantified this in his excellent book Overdiagnosed. He described several studies on a total of 37,000 women which indicated little, if any, infant benefit from fetal heart monitors. ³⁷ Fetal heart monitors don't generate lower infant mortality rates, better Apgar scores, fewer babies with cerebral palsy or less need for intensive care, according to Welch's research. The only measureable benefit: a lower seizure rate, 1 per 1000 as compared to 2 per thousand from women delivering without fetal monitors.

³⁶ Here's my calculation, based on the 2010 National Vital Statistics Reports Vol 60, No 2 and the OECD infant mortality rate data: There were 4 million deliveries in the US in 2010. 32% (1.28 million) were C-sections. The 12% increase between 1996 and 2010 was 480,000 C-sections/year. Our infant mortality rate in 1996 was 7.3 per 1000 live births; in 2010 it was 6.1, for a reduction of 1.2 deaths per 1000 live births over the 14 year period.

³⁷ Welch, Overdiagnosed, page 105 - 107

And, interestingly, the US Preventive Services Task Force – the 'gold standard' for clinical advice according to many – recommended *against* routine fetal heart monitoring in 1996 due to the lack of evidence of effectiveness and has not changed its recommendation since.

But fetal heart monitors have had one major impact: an absolute C-section rate increase over time according to Welch.

How do we classify the near universal use of fetal heart monitors? Low quality care? Unnecessary care? Harmful care? The exact label may matter less than the more poignant question: what can a pregnant woman do to help herself?

Some Key Questions about Fetal Heart Monitors and C-sections

I take no position on whether any particular woman should have a C-section or not. Nor on whether or not she should use a fetal heart monitor. Those are individual decisions for each woman to make with her doctor's advice.

But I do have some suggestions about <u>how</u> to make those decisions...in other words, what questions to ask. My thesis and the thesis of this book: asking the **right** questions can help you make wise and well-informed decisions, while asking the **wrong** questions doesn't help you as much.

Here are some of the *right* questions to consider asking about C-sections:

- What are the C-section rates at my local hospitals?
- What accounts for any differences?
- Are there any significant *infant outcome differences* among the hospitals in my region: in other words, do hospitals with higher C-section rates deliver babies with higher Apgar scores, lower infant mortality rates, lower seizure rates, lower ICU admission rates or lower infant <u>re</u>admission rates?
- Do higher C-section rates lead to different *maternal outcomes* such as higher infection or hospital readmission rates?

And some questions about fetal heart monitors:

- What is the rate of fetal heart monitor use in my various local hospitals?
- What could account for any differences?

- Do babies born from mothers who use fetal heart monitors have lower mortality rates, higher Apgar scores, lower ICU admission rates or lower seizure rates than babies born from mothers who don't?
- Do mothers like <u>me</u> with <u>my</u> health and medical status who use fetal heart monitors have higher C-section delivery rates? Healthier babies?

These questions differ from those often asked, such as

- Do I need a fetal heart monitor? And
- Should I have a C-section?

I suggest that asking the *quantity* questions ('what's the C-section rate at the different hospitals?') and the *outcome* questions ('do babies born in high C-section rate hospitals do better?') may help you more when you make your decisions. Remember, you want to choose high quality medical care that likely benefits you rather than low quality or unnecessary care that's perhaps more likely to harm you.

C-section variation is not an isolated case

Across the country, *different* hospitals treat *similar* patients *differently*. This holds for lots of different procedures, ranging from deliveries to coronary care and to orthopedic.

Here, for example, as rates of Coronary Artery Bypass Graft (often referred to as heart bypass surgery) in various New Jersey hospitals per 1000 Medicare beneficiaries in each region. This particular chart shows a low of 2 CABG procedures per 1000 Medicare beneficiaries in Mount Holly, and a high of 5.5 procedures per 1000 Medicare folks in Holmdel. Note that Cape Ann Court House (about 2.7 procedures/1000 Medicare folks) and Bridgeton (4.5 procedures) are geographically right next to each other.

Remember: all these people are Medicare beneficiaries living in New Jersey. Most simply use their local hospital for their medical care. I downloaded this data from the Dartmouth Atlas website in October, 2012.



Bypass Surgeries per 1000 Medicare Beneficiaries by Hospital, NJ

This chart suggests that patients arriving at a hospital with chest pains and related coronary problems are more likely to get bypass surgery in Holmdel and, perhaps, more likely to have angioplasty, medications or other treatments in Mount Holly.

This data comes from Medicare and likely, though not definitely, applies to the non-Medicare population also. We have, unfortunately, relatively poor non-Medicare comparative data like this which makes hospital choice decisions unnecessarily speculative.

Here are some questions a wise patient might ask his doctor – or research online - about CABG procedures at particular hospital:

- How many CABG procedures does the hospital perform per 1000 people living in the hospital's catchment area? You can get some of this information from the Dartmouth Atlas of Healthcare, though that is specific to the Medicare population.
- What is the risk-adjusted mortality rate for CABG procedures in this hospital? This information can come from the US Department of Health and Human Services website <u>www.hospitalcompare.hhs.gov</u>, although that site provides riskadjusted outcome data for a relatively small number of procedures and only for Medicare patients.
- What is the risk-adjusted 30 day readmission rate for CABG procedure patients in this hospital? Again, some information is available from <u>www.hospitalcompare.hhs.gov</u>.

• You can ask the same questions, and do the same research, about other types of medical care. The Dartmouth Atlas provides surgical procedure rates for about 2 dozen different procedures, often on an individual hospital basis.

The key care-quality issues here:

First, high quality care means appropriate care. The Dartmouth Atlas shows rates for various procedures at various hospitals. This can help you decide if a particular hospital overtreats – thus exposing you to unnecessary risk – or undertreats, exposing you to potentially poorer outcomes. This can help you determine 'appropriateness'.

If two nearby hospitals, serving the same population, show vastly different surgical procedure rates, you can conclude either that one overtreats or the other undertreats. You and your doctor will need to decide which.

Second, better care generates better patient outcomes. The hospital with the lowest risk-adjusted mortality rate provides better care than the hospital with the highest. Reputations, gleaming hospital facades and nice waiting room cafes generally don't say much about care quality; risk adjusted outcomes do.

Once you learn these metrics, you and your doctor can have a useful, well-informed discussion about how to proceed.

Care Quality by Medication

High quality medical care, as we've discussed, benefits you more than the alternatives. *Low quality* medical care may benefit you, but less effectively and with more risk. *Unnecessary* medical care doesn't benefit you at all.

Let's use ZETIA, a cholesterol lowering medication manufactured by Merck, as an example from which we can draw interesting lessons. How would you categorize it? ³⁸

ZETIA lowers cholesterol. Its print advertising says, 'if you diet and take a statin, ZETIA can help lower LDL (bad) cholesterol even more' and

In a clinical study, people who added ZETIA to their statin medication reduced their bad cholesterol on average by an additional 25% compared with 4% in people who added a placebo.

³⁸ See for example, Parade Magazine, September 11, 2011, back page. ZETIA sales estimate from Justine Cadet, 'Merck's Q4, FY10 net income drops, Feb 7, 2011, cardiovascularbusiness.com.

These ads apparently build on our national understanding that bad cholesterol is a risk factor for heart disease and heart attacks, so lowering your LDL will reduce your heart disease and heart attack risks. The apparent, though not formally stated progression:

Taking ZETIA leads to lower bad cholesterol which leads to less heart disease and fewer heart attacks

ZETIA's 2010 sales exceeded \$2 billion despite the fact that, again quoting its ads 'ZETIA has not been shown to prevent heart disease or heart attacks.' In other words, real world tests proved the theoretical progression above false.

I'm hard pressed to call ZETIA 'low quality medicine' since the patients didn't achieve their goals: less heart disease or fewer heart attacks. It's best categorized as *unnecessary* medical intervention – a treatment that generate no patient benefit but only increases patient costs and risks.

Two reasons why people take unnecessary medications

First, patients – and, unfortunately, too often their physicians too – confuse their 'numbers' with medical care outcomes. Ask yourself why you take a medication: do you want *lower cholesterol* or *fewer heart attacks*. **They're not the same!**

Most people, I suspect, want to avoid heart attacks. If they need to lower their bad cholesterol to achieve this goal, then they'll lower their bad cholesterol. But if cholesterol doesn't actually impact their chance of having a heart attack, then they'll ignore their cholesterol number. The ultimate goal is avoiding a heart attack. Lowering bad cholesterol is simply a means to this end. Is it a *necessary* means to the end?

Researchers call lower cholesterol a *test indicator* that seems to suggest something about your chance of actually having a heart attack. One advantage to using test indicators like cholesterol: they're very easy to measure. ZETIA actually performs quite well in this regard as it lowers the cholesterol levels of people taking it.

The key question, of course: how closely does the *test indicator* - lower bad cholesterol in this case – correlate to the medical event – *having a heart attack.* Research suggests that bad cholesterol levels correlate very, very, very loosely with heart attack rates.

In the ZETIA example, the cholesterol indicator doesn't correlate at all, at least according to their print ads.

Some cholesterol-lowering medications correlate better. Statins, according to a detailed analysis published in Bloomberg BusinessWeek, prevent about 1 heart attack over

about 4 years per 100 people who take them.³⁹ (This statistic applies to people without heart disease or a history of heart attacks.)

Lipitor is one such statin. Its tablets are 'proven to lower LDL ("bad") cholesterol' and its website suggests that 'if you have high cholesterol, don't kid yourself about your risk for heart disease. Talk to your doctor about your risk and if LIPITOR is right for you.' ⁴⁰

Lipitor's 2007 print advertising campaign shows the correlation between the cholesterol *indicator* and heart attack *events*: **about 3%.** Quoting Lipitor's December 4, 2007 Wall Street Journal ad (next page), '3% of patients taking a placebo or sugar pill had a heart attack compared to 2% of patients taking Lipitor.' High cholesterol didn't lead to heart attacks in 97 out of 100 people. And Lipitor was only effective in preventing heart attacks in about 1% of patients who took it. See the small print, lower left of this ad:



³⁹ Carey, Do Cholesterol Lowering Drugs Do Any Good?, Bloomberg BusinessWeek, January 16, 2008

⁴⁰ http://www.lipitor.com/

Our point here: patients often confuse *changing a medical indicator* – cholesterol for example – with *reducing your risk of heart attack*. You need to know how closely the indicator correlates with the medical event to make a wise decision. In the cholesterol example above, about 99 out of 100 people who take cholesterol lowering medications do not receive any heart attack reduction benefit, mainly because 97 weren't going to have a heart attack in the first place. Two others still had heart attacks.

One question if/when your doctor says that 'your numbers are high' and 'I suggest you reduce them with medication':

How closely do the numbers correlate with actual medical events?

You need that information to make a wise decision. (We'll discuss this in much more detail in Chapter 4: A Four Step Process for Making Medication, Test and Treatment Decisions. I just want to introduce the issue here.)

The **second** reason why people take unnecessary medications: they rely on direct-toconsumer medical advertising. Research suggests that every \$1 spent on medical ads generates about \$4 in medical sales. ⁴¹

Direct-to-consumer advertising is regulated by the Food and Drug Administration. Surprisingly, FDA regs don't require information about *how well* drugs work, which, of course, adds to the type of confusion we just discussed about ZETIA and Lipitor effectiveness. Here's verbiage directly from the FDA website: ⁴²

Print product claim ads may make statements about a drug's benefit(s). ('May' not 'must')

Broadcast product claim ads may make statements about a drug's benefit(s).

That's it. No other requirement demonstrating *how well* the drug works or *how frequently* patients benefit. Perhaps as a result of this **nearly a quarter of patients assume that only 'extremely effective' drugs can be advertised!** ⁴³

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⁴¹ Brownlee, Overtreated, page 187

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072077.htm#ris k_disclosure

⁴³ Woloshin, Value of Benefit Data in Direct-to-Consumer Ads, Health Affairs, April 28, 2004

In fact, nearly 1 in 3 American adults has discussed a specific drug seen in an advertisement with his/her physician; nearly 1 in 8 ended up with a prescription as a result.⁴⁴

The FDA does, however, require much more information about drug risks. That's why drug ads list lots of potential side effects and harms.

These FDA requirements allow for some remarkably well written medical ads, often citing test indicators as medication benefits. No one teaches them otherwise. So we take lots of ZETIA and Lipitor – but heart disease remains the #1 killer of Americans.

Lots of money for some pretty unimpressive outcomes. Low quality medicine – or unnecessary?

Orthopedic surgery and the need for comparative studies

Not only are some drugs unnecessary, but some surgical procedures are also. Would you call arthroscopic knee surgery to treat knee osteoarthritis or spinal fusion surgery low quality? Or unnecessary? See the examples below.

'There is no evidence that arthroscopy cures or arrests the osteoarthritis' according to a study published in the New England Journal of Medicine. ⁴⁵

Here's their evidence: Researchers at the Houston VA hospital conducted a double blind, random, placebo-controlled trial to assess the efficacy of arthroscopic surgery to relieve knee pain and improve physical functioning in patients with osteoarthritis. Some patients received real surgery, others did not – just glorified skin punctures. Neither they nor the doctors following them knew which was which.

The same surgeon performed all the procedures to ensure against surgical skill differences. He was, at the time, the orthopedic surgeon for an NBA basketball team and was previously the orthopedic surgeon for the US Olympic Men's and Women's basketball teams.

Some results, according to the NEJM:

⁴⁴ Brownlee, Overtreated, page 187

⁴⁵ Moseley et al, A Controlled Trial of Arthroscopic Surgery for Osteoarthritis of the Knee, New England Journal of Medicine, July 11, 2002

- No significant difference between the placebo group and the others in selfreported ability to walk and bend at one year or at two years;
- Objectively measured walking and stair climbing were poorer in the treatment group than in the placebo group at two weeks and one year;
- At some points during follow-up, objective function was significantly worse in the treatment group than in the placebo group.

According to the Journal, in the early 2000s (and perhaps continuing today), we perform some 650,000 such procedures annually at a cost of about \$5000 each.

Spinal fusion surgery. No evidence shows that spinal-fusion surgery is superior to other surgical procedures for common spine problems, and such surgery leads to more complications, longer hospital stays and higher hospital charges than other types of back surgery, according to the Back Pain Patient Outcomes Assessment Study produced for Health and Human Services back in 1994.

No rigorous, independently funded clinical trials since 1994 have negated this conclusion according to researchers Sanjaya Kumar, chief medical officer at Quantros, and David Nash, dean of the Thomas Jefferson School of Population Health at Thomas Jefferson University in their 2011 Scientific American article.⁴⁶

Yet the number of spinal fusion surgeries performed in this country rose from about 100,000 to 300,000 between 1997 and 2006, with each costing around \$50,000.

Are Kumar and Nash right? What's the recent evidence?

I reviewed a 2011 study published in Spine Magazine that compared 725 people on workers compensation due to back problems who *received* spinal fusion surgery with 725 also on workers comp for the same reasons, who *did not*. ⁴⁷ The study conclusion:

Fusion for the diagnoses of disc degeneration, disc herniation, and/or radiculopathy...is associated with significant increase in disability, opiate use, prolonged work loss, and poor return to work status.

Two years after surgery, only 26% of the spinal fusion patients had returned to work, while 67% of the non-spinal fusion folks did within 2 years of their injury.

⁴⁶ Kumar and Nash, Healthcare Myth Busters, Scientific American, March 25, 2011

⁴⁷ Nguyen et al, Long term outcomes for lumbar fusion, Spine, Feb 15, 2011

11% of the spinal fusion patients had permanent disability while only 2% of the nonsurgery group had.

The spinal fusion surgery group missed a total of 1140 days of work, compared to only 316 days for the other group.

Wolters Kluwer, an international legal, tax, finance and healthcare advisory conglomerate, summarized this study to their clients: For patients with chronic low back pain

'spinal fusion surgery leads to worse long-term outcomes—including a lower rate of return to work—compared to nonsurgical treatment' ⁴⁸

Dr. Nguyen, the study leader, said that the results of this study are 'consistent with previous studies. The result we've provided is nothing new.' ⁴⁹

If the results are nothing new, then why do we perform so many procedures annually? We can ask the same question about arthroscopic knee surgery and many other procedures.

Here's one answer: **patients ask their physicians the wrong questions!** Most patients ask questions like

- Do I need this procedure?
- Will this procedure help me?
- Do you generally get good results from this procedure on patients like me?
- What risks do I run?

These questions all suffer from the same problem: they ask about *observational* – not *comparative* – outcomes.

Comparative studies compare a group of people who had a procedure with a group of people who did not.

Observational studies only look at the group that had the procedure.

The problem with relying only on observational data: you don't have a benchmark. For example, asking 'do you generally get good results from this procedure?' fails to define

⁴⁸ http://www.wolterskluwer.com/Press/Latest-News/2011/Pages/pr15feb2011.aspx

⁴⁹ Salamon, Spinal Fusion Surgery May Leave Some Back Pain Patients Worse Off, Health Day, http://www.emanuelmedicalcenter.org/body.cfm?xyzpdqabc=0&id=148&action=detail&ref=37625

'good results'. 'Good' to one person may be 'bad' to someone else. A comparative study, by contrast, identifies better or poorer results.

That's why we suggest asking these questions when your doctor recommends a treatment or procedure:

- What comparative studies did you rely on to make that recommendation? followed obviously by
- What were the results of those comparative studies?

This will help you differentiate better and poorer outcomes, in our terminology higher and lower quality medical care....and even unnecessary care, like the arthroscopic knee surgery example above.

As a general rule, we suggest you ask this question whenever your physician recommends a medical procedure. Asking can't hurt you but may help steer you toward higher quality treatments.

Remember: comparative studies define 'better' and 'worse' medical care. You need 2 groups for a comparative study: one that got the treatment and the other that didn't.

Comparative studies may still lead to low quality care: the need for baseline

Comparative studies, as we showed in the knee and back surgery cases, only define 'better' or 'poorer' care; they fail to identify whether or not the 'better' care is really very good at all. (It might just be better than some really low quality care.)

A leg amputation example can illustrate this. This Dartmouth Atlas map shows leg amputation rates in various regions per 1000 Medical enrollees from 2003 - 2007: ⁵⁰

⁵⁰ http://www.dartmouthatlas.org/data/map.aspx?ind=158



Medicare enrollees in eastern Massachusetts have about .78 amputations/1000 enrollees, compared to similar folks in western Massachusetts who have about 1.2, or about 40% more per thousand. We have scant evidence either of significant demographic differences among the enrollees in these two regions or of better patient outcomes in western Massachusetts as measured by life expectancy, for example.

Many, if not most leg amputations result from diabetes. It's tempting to suggest, therefore, that folks in western Massachusetts have low quality diabetic and orthopedic care, while people in eastern Massachusetts have high quality care.

But that may not be true. *Both* regions may exhibit low quality care, with western Massachusetts simply exhibiting somewhat poorer quality. High quality care is actually exhibited in Madrid, Spain – a region with roughly comparable diabetes rates to Massachusetts and that spends far less on medical care. ⁵¹

Madrid's female amputation rate is about .05 per 1000 Boston's amputation rate is about .78 per thousand – 15 times higher!

⁵¹ 'Roughly comparable' based on Spain's 13% diabetes rates and the US 8%, suggesting that Madrid's diabetes rate may actually be higher than Massachusetts. See Soriquer, Prevalence of diabetes mellitus and impaired glucose regulation in Spain, Diabetologia, January 2012 for the Spanish estimate and The American Diabetes Association Data from the 2011 National Diabetes Fact Sheet on http://www.diabetes.org/diabetes-basics/diabetes-statistics/ . For the amputation rates, see 'Renzi, et al, An international comparison of lower extremity amputation rates, Annals of Vascular Surgery, 2006

We know, for example, that about 90% of lower limb amputations are completely preventable, but result from poorly controlled diabetes. ⁵² The Madrid area medical care system is organized to treat diabetics more effectively than the Boston area system – and far better than the western Massachusetts, central Pennsylvania or West Virginia systems. Madrid seems to suggest that only a very small number of leg amputations are really necessary, provided patients receive high quality diabetic and podiatric care. That's why they exhibit lower amputation rates. ⁵³

Interestingly, some studies in Sweden suggest that even as the Swedish obesity rate has *increased* (obesity being a prime cause of diabetes), the Swedish leg amputation rate has *decreased*. ⁵⁴ This indicates the disconnect between obesity and leg amputations; higher obesity rates do not necessarily need to lead to higher leg amputation rates, though they appear to in this country.

High quality medical care can disconnect obesity/diabetes on the one hand from leg amputations on the other.

The wise patient, when asking the comparative study question (*What comparative studies did you rely on to make that recommendation?*) should understand the potential pitfalls of this question. You don't want to compare two low quality medical interventions while ignoring some much higher quality options.

The highest technology screening tests may sometimes be low quality medicine

We saw earlier in this chapter that Americans get about 50 more MRI scans per thousand of population than our French, British or Canadian friends, at a cost of about \$30 billion per year. This admittedly huge economic cost may pale compared to the human and medical costs.

In the medical screening world, the more we look for medical abnormalities, the more we find. The more we find, the more 'further investigations' we do, the more 'suspicious findings' we generate, the more exploratory procedures we perform and the more we treat....*but not necessarily, the healthier we get.*

Our scientific and engineering radiological capabilities may exceed our medical diagnostic capabilities, so having more powerful scanners may lead to confusion,

⁵² http://surgery.arizona.edu/sites/surgery.arizona.edu/files/pdf/SALSA.pdf

⁵³ Renzi made a special note of this in his study.

⁵⁴ <u>http://www.nature.com/ijo/journal/v28/n2/full/0802553a.html</u>, <u>http://www.cardiab.com/content/11/1/18</u>

misdiagnoses and overdiagnoses – that means identifying a harmless medical abnormality and pathologizing it. Once identified, the (scared) patient generally wants treatment, or at least, further investigation into exactly what the abnormality really is.

One example of diagnostic confusion: radiologists disagree with each other about the correct diagnosis up to 25% of the time, or more depending on the specific issue. ⁵⁵ Perhaps more surprising, cardiologists in one study disagreed with *themselves* between 10 - 23% of the time. In other words, the same cardiologist, reviewing the same scan at a different time, had a different interpretation. ⁵⁶

Having more scans may, thus, be lower quality medical care than having fewer.

There's a strange and disconcerting issue underlying this:

First, as our technologies improve we find more and more abnormalities. This is to be expected. But

Second, as our technologies improve, *our definitions of 'dangerous findings' change and expand,* sometimes quite dramatically.

I'll explain this with an analogy. Let's look at some maps and assume that a 'lake' on each of these maps is a medical abnormality. ⁵⁷ I assume everyone knows what a lake is. We'll define it as a body of water completely surrounded by land.

Here's a view of Florida from a distance or, to push this analogy, the equivalent of using some old radiological equipment. You can just make out 1 small lake in south central Florida.

⁵⁵ Berlin, Accuracy of diagnostic procedures: has it improved over the past 5 decades?, American Journal of Roentgenology, May 2007

⁵⁶ Newman, Hippocrates' Shadow, footnote, page 58

⁵⁷ This clever example comes from Welch, Overdiagnosed, Chapter 3. He used Utah as his example.



Now let's get closer, maybe using more modern radiological technology. You can see a big lake in south central Florida and some evidence of a few others in central and northern Florida, though these are somewhat vague and confusing – 'suspicious findings' to push the medical analogy – and perhaps worthy of further investigation.



Closer still, maybe using quite modern screening equipment:



Wow – one very big lake west of Port Saint Lucie, and lots of other, smaller lakes. Remember that *we haven't changed the geography* of Florida. We've only changed our viewing technology.

But the big problem arises when we get even better viewing technology. Is this a lake? It's a body of water completely surrounded by land:



Well, perhaps it's a 'gulley' or a 'pond', maybe not a lake. As we look more closely, our definition begins to change. Is a 'pond' a 'lake' and a dangerous medical abnormality...or something innocuous?

Lake...pond...or something we haven't yet defined?



Or this?



Maybe this is a lake, and maybe it's not a serious medical abnormality. But once identified, it has to be understood – and maybe treated.

The big problem arises as our technologies get really, really powerful and identify abnormalities that appear – and perhaps disappear! What kinds of investigation do you do then?



Or



Let's apply this 'lake identification problem' to shoulder MRIs:

In 2011, Dr. James Andrews, a Florida sports medicine orthopedist, evaluated MRI scans of 31 perfectly healthy baseball pitchers. ⁵⁸

These were pitchers who had no shoulder pain and were not injured. They were professional athletes – young, strong men at the height of their physical strength and abilities.

⁵⁸ Kolata, Sports Medicine Said to Overuse MRIs, New York Times, October 28, 2011

Dr. Andrews found abnormal shoulder cartilage in 90% of them and abnormal rotator cuff tendons in 87%. As he said to the New York Times *if you want an excuse to operate on a pitcher's throwing shoulder, just get an M.R.I.* because the scans are so powerful and easily misinterpreted. This can lead to unnecessary and even harmful treatments...harmful if the surgery goes poorly or the patient acquires an infection for example.

One shudders to think of the impact these MRI results have – diagnoses of abnormal cartilage and rotator cuff tendons – on the pitcher's psyche after, perhaps, a few bad outings.

More scans and better scanning technology may generate more medical information but lower quality care. A second example: ⁵⁹

The Journal of the American Medical Association reported on a study of 380 patients with chronic lower back pain who were randomized to receive either spine X-rays or MRIs. The study's hypothesis: patients receiving MRIs would enjoy better treatments and less pain over time due to the more accurate diagnosis.

Physicians monitored patient disability and pain for a year. They found that, though both groups reported reductions in pain 'bothersomeness', there was no pain reduction *difference* between the X-ray and MRI groups.

There were, however, more diagnoses in the MRI group and this group cost slightly more for scans, physician visits and physical therapy (about \$2380 vs. \$2059. Remember these were 1999 prices). 10 patients in the MRI group had spine surgery vs. 4 in the X-ray group.

A physician who reviewed this study in 2010, Dr. Joshua Quass, Director of Trauma Services at St. Luke's-Roosevelt Hospital Center in New York City, suggested what it means:

- Patients with low back pain but without pathological features are not helped by having an MRI, and
- MRIs result in increased cost, possibly more procedures and no change in patient long-term pain, disability or functional status

High quality medical care, thus, doesn't necessarily mean 'using the newest piece of equipment'. Rather, high quality care means 'getting meaningful results from my

⁵⁹ MRI vs. Plain X-Ray Imaging for the Evaluation of Chronic Lower Back Pain, TheNNT.com, article dated August 25, 2010.

medical tests.' Paraphrasing Mae West 'too much of a good thing may be too much.' My caution: be sure you need the scan before you have it.

Here's one way: ask your doctor the outcome question 'how many patients actually benefit from the screening test?' In the example above, back pain patients did not benefit by having MRIs as compared to X-rays. Focusing in patient outcomes can help you differentiate necessary from unnecessary tests. Remember that unnecessary tests don't help you, but expose you to costs and risks.

I feel sorry for those baseball pitchers.

Lakes, Shoulders, Backs...and Cancer

Let's tie our lake, shoulder and back surgery examples to cancer screening. The more we look for cancers – and the better our cancer screening technologies – the more we find **but not the lower the mortality rate** by very much!

See below, charts published in the BMJ, 2012, showing the increased rate of cancer diagnosis per 100,000 people (the green lines) and the pretty flat rate of mortality from those cancers (the red lines). ⁶⁰ Remember as you read this: over the 30 year time period shown in these charts, treatments have improved. What percent of the mortality reduction is attributable to better screening? What percent to better care? We simply don't know!

Look at the breast cancer lines in particular. How closely does the increase in breast cancer *diagnosis* correlate with the reduction in breast cancer *mortality*? What's going on here?

⁶⁰ Moynahan, Preventing Overdiagnosis, BMJ, 2012:344



Here are some overall breast cancer numbers:

- About 40 million women screened annually ⁶¹
- About 140,000 diagnosed with breast cancer
- About 1000 deaths avoided. This estimate comes from subtracting the number of annual breast cancer deaths in 2006 (40,921) from the number in 1996 (43,091), about 2200.⁶²

Dr. Otis Brawley, the Chief Scientific and Medical Officer at the American Cancer Society, attributes this decrease mainly to three things: mammography, better breast awareness and better treatments. ⁶³ Applying a roughly 1/3, 1/3, 1/3 impact, mammography seems to save about 800 lives per year. I rounded up to 1000 to be generous.

In our terminology, mammography may be *necessary* but *low quality* medical care. Many women may feel a need to determine if they're at risk of dying from breast cancer but we haven't, unfortunately, developed very good tools to determine this. Mammography may be the best available, but it's not very good.

This raises a troubling question: when you have a medical risk of significant concern, is it better to have a low quality, quite ineffective screening test, or to avoid the screening test due to its limitations?

That's a very personal 'preference-sensitive' decision (Wennberg's terms, from our Connecticut and Massachusetts mastectomy example above) best made by a well-informed patient with her physician.

⁶¹ Parker-Pope, Mammography's Role as Savior Tested, New York Times, October 24, 2011. Same source for the annual diagnosis estimate

⁶² Saenz, Trends in breast cancer mortality in the United States, Population Reference Bureau <u>www.prb.org</u>. This number is lower than Gilbert Welch's estimate, published in the Parker-Pope article referenced above. Welch based his estimate on 10 and 20 year risks. I based mine on actual death reductions, some of which may have been misreported. Perhaps the 'real' number is somewhere in between. Even using Welch's higher estimates, however, the mortality impact of mammography is very low.

⁶³ American Cancer Society, Behind the Science videos, discussion between Dr. Len Litchfield and Dr. Otis Brawley <u>http://www.cancer.org/research/researchaccomplishments/behind-the-science-videos</u>

A New England Journal of Medicine study reported in November, 2012 sheds some light on the ineffectiveness of screening mammography.⁶⁴

The rate at which women present with late stage breast cancer has fallen by only about 8 cases per 100,000 women since the 1970s, from about 102 to 94 cases per 100,000 women.

But during this time period, the rate of **breast cancer detection** has increased from 112 to 234 cases per 100,000 women.

In other words, we identify and diagnose over 100 more women per 100,000 with early breast cancer today, but this has only a minor impact on the number of women developing **late** stage breast cancer.

We don't know exactly why the reduction in late stage diagnoses. Perhaps some is due to mammography and perhaps some due to 'better breast awareness', Otis Brawley's term. We can't, unfortunately, assign causality here.

By expanding our mammography rate, and by improving the screening technologies, we're apparently diagnosing and treating harmless little swimming pools, but missing the streams and gullies that will become major, deadly cancers, to completely mix our metaphors. But we're not helping women live much longer!

The *average age of breast cancer death* has remained flat over the past decade or so. It was 68 in 1996 and 68 in 2006. ⁶⁵ We would expect that if mammography was very effective in identifying important cancers and saving lives, the average age of breast cancer death would increase over time.

Mammograms are not risk free. We don't know exactly how many deaths are *caused* by mammography screening. Dr. David Newman, Director of Clinical Research at Mount Sinai Medical Center in New York, estimates that mammography radiation causes 1 breast cancer case (not 1 breast cancer death) for every 10,000 women screened annually for 10 years. ⁶⁶ At about 40 million women screened annually, mammography itself may thus increase breast cancer incidence by 4000 cases annually with an unknown number of associated deaths.

⁶⁴ Bleyer, Effect of three decades of screening mammography on breast cancer incidence, NEJM, November 22, 2012

⁶⁵ Saenz, ibid. 2006 data from SEER Stat Fact Sheet, National Cancer Institute downloaded October 2012

⁶⁶ Newman, Hippocrates' Shadow, page 37

Breast cancer *treatments* – mastectomy, chemotherapy, etc – may also cause some deaths. Steven Woloshin and his colleagues at the Dartmouth Institute estimate that for every breast cancer death avoided by screening, about 100 women get 'false positive' indications that they may have breast cancer and require a follow-up biopsy, and between 5 and 10 have more aggressive breast cancer treatment. ⁶⁷ If any of those women die from physician error, medication problems, hospital acquired infections or other treatment complications, their deaths might not be classified as breast cancer. We simply don't know this number.

What quality rating would you give mammography? I can't answer that question for you. You should consider the 'how well does it work' question for yourself. All I can suggest is that mammography is not an obvious example of high quality, highly effective medical care that clearly works well.

This is clearly a fertile topic for women to discuss with their doctors. My suggestion: ask the outcome question 'how many patients benefit from having screening tests like mammograms?' (You can ask the same question about lots of different screening tests.)

Be sure when you ask the outcomes question that you remember the lessons from our past few vignettes:

- From our ZETIA and Lipitor discussion: most women won't die of breast cancer. So learning that many women have mammography but don't die of breast cancer isn't particularly enlightening.
- From our spinal fusion discussion: you want to use comparative studies of women who had, and didn't have, mammography. Simply using observational studies only of women who had mammography isn't enough. You want to focus on the difference between breast cancer mortality rates for women who *don't* have mammography and women who *do*.

I'll have lots more to say about this in Chapter 4.

April 4, 2012 for the first time in history...

Nine of the top medical societies in the US published lists of tests, procedures and treatments performed by their own members that are generally unnecessary. Donald Berwick, former head of Medicare and Medicaid, suggested that April 4, 2012 may go

⁶⁷ Woloshin, Benefits and Harms of Mammography Screening, Journal of the American Medical Association, January 13, 2010

down in history as the first time medical societies recommended in favor of patients and against the economic interests of their own members. ⁶⁸

The initiative called Choosing Wisely (<u>www.ChoosingWisely.org</u>) was sponsored by the American Board of Internal Medicine Foundation with assistance from Consumer Reports. The original participating medical societies:

American Academy of Allergy, Asthma & Immunology American Academy of Family Physicians American College of Cardiology American College of Physicians American College of Radiology American Gastroenterological Association American Society of Clinical Oncology American Society of Nephrology American Society of Nuclear Cardiology

Since, several more societies have joined this effort, including

American Academy of Hospice and Palliative Medicine American Academy of Neurology American Academy of Otolaryngology–Head and Neck Surgery American Academy of Pediatrics American College of Obstetricians and Gynecologists American College of Rheumatology American Geriatrics Society American Geriatrics Society American Society for Clinical Pathology American Society of Echocardiography American Urological Association Society of Cardiovascular Computed Tomography Society of Hospital Medicine Society of Nuclear Medicine and Molecular Imaging Society of Thoracic Surgeons Society for Vascular Medicine

Here are 7 of the easiest-to-understand initial recommendations along with the explanations from the website. You can find the entire list on ChoosingWisely.org.

I've also included price estimates for some procedures. These came from the New Hampshire state medical price calculator, <u>www.nhhealthcost.org</u>. No particular reason for using New Hampshire data other than it's available and easy to use. I assume, but haven't verified, that these prices are fairly representative of prices nationally.

⁶⁸ Comments at the Pioneer Institute Hewitt Lecture, April 5, 2012, poorly paraphrased

1. Don't do imaging for low back pain within 6 weeks, unless red flags are present. American Academy of Family Physicians.

Red flags include, but are not limited to, severe or progressive neurological deficits or when serious underlying conditions such as osteomyelitis are suspected. Imaging of the lower spine before six weeks does not improve outcomes, but does increase costs.

Low back pain is the fifth most common reason for all physician visits.

Typical costs of an MRI for the lower back, according to the New Hampshire price list: about \$1000.

2. Don't order annual electrocardiograms (EKGs) or any other cardiac screening for low-risk patients without symptoms. American Academy of Family Physicians.

There is little evidence that detection of coronary artery stenosis in asymptomatic patients at low risk for coronary heart disease improves health outcomes. False-positive tests are likely to lead to harm through unnecessary invasive procedures, over-treatment and misdiagnosis.

Potential harms of this routine annual screening exceed the potential benefit.

Typical costs of an EKG in New Hampshire: about \$1000

3. Don't perform Pap smears on women younger than 21 or who have had a hysterectomy for non-cancer disease. American Academy of Family Physicians.

Most observed abnormalities in adolescents regress spontaneously. Therefore Pap smears for this age group can lead to unnecessary anxiety, additional testing and cost. Pap smears are not helpful in women after hysterectomy (for non-cancer disease) and there is little evidence for improved outcomes.

4. Don't perform stress cardiac imaging or advanced non-invasive imaging in the initial evaluation of patients without cardiac symptoms unless high-risk markers are present. American College of Cardiology

Asymptomatic, low-risk patients account for up to 45 percent of unnecessary "screening."

Testing should be performed only when the following findings are present: diabetes in patients older than 40-years-old; peripheral arterial disease; or greater than 2 percent yearly risk for coronary heart disease events.

Typical stress test costs according to the New Hampshire site: about \$4000

5. Don't do imaging for uncomplicated headache. American College of Radiology.

Imaging headache patients absent specific risk factors for structural disease is not likely to change management or improve outcome. Those patients with a significant likelihood of structural disease requiring immediate attention are detected by clinical screens that have been validated in many settings. Many studies and clinical practice guidelines concur. Also, incidental findings lead to additional medical procedures and expense that do not improve patient well-being.

6. Don't order sinus computed tomography (CT) or indiscriminately prescribe antibiotics for uncomplicated acute rhinosinusitis. American Academy of Allergy, Asthma and Immunology.

Viral infections cause the majority of acute rhinosinusitis and only 0.5 percent to 2 percent progress to bacterial infections. Most acute rhinosinusitis resolves without treatment in two weeks. Uncomplicated acute rhinosinusitis is generally diagnosed clinically and does not require a sinus CT scan or other imaging.

Typical CT scan for uncomplicated sinusitis in New Hampshire: about \$900

7. Don't routinely prescribe antibiotics for acute mild-to-moderate sinusitis unless symptoms last for seven or more days, or symptoms worsen after initial clinical improvement. American Academy of Family Physicians.

Symptoms must include discolored nasal secretions and facial or dental tenderness when touched. Most sinusitis in the ambulatory setting is due to a viral infection that will resolve on its own.

Antibiotics are prescribed in more than 80 percent of outpatient visits for acute sinusitis. Sinusitis accounts for 16 million office visits and \$5.8 billion in annual health care costs.

At best, these and the other recommendations identify *low quality* medical care; in low quality care, some patients receive at least some benefit. At worst, they identify unnecessary care – that's the care that Elliott Fisher defined in our Introduction as generating 'no detectible patient benefit'.

What a tragedy for thousands – or tens of thousands – of us to pay the economic costs of this care and to risk the side effects without any hope for benefit. I hope the

ChoosingWisely campaign remains alive, expands and helps all of us choose our medical care most wisely.

Remember: these recommendations weren't written by some odd-ball researchers aiming to make names for themselves. They were written by the specialty society itself, advising its members not to perform certain tests and procedures...and informing patients to avoid them also.

Avoiding Unnecessary Care or getting the Cheapest

Shopping for your medical care based on price has serious problems.

- You don't want the cheapest unnecessary care because it won't benefit you;
- You probably also don't want cheap, low quality care when more expensive, high quality care is available;
- You certainly don't want the *most expensive* unnecessary care, by making the mistake of equating higher medical costs with better medical quality

We have a dichotomy in our medical care decision making due largely, I suspect, to our lack of quality metrics and outcome data.

On one hand, everyone wants the 'best' medical care for themselves and their family.

On the other hand, we want the least expensive care we can get. Much of the current so-called 'transparency' discussion in insurance and government circles revolves around medical prices. Carriers increasingly try to steer their clients to the lowest cost providers; many are developing pricing tools so patients can see actual medical prices before buying.

In my experience, brokers, regulators and politicians define transparency as knowing prices and quality... *and then proceed to discuss prices only*. We somehow assume that all hospitals are of equal quality, all specialists equally competent and all physician recommendations equally valid and all treatments equally beneficial.

But as we've shown, in this chapter: those assumptions are wrong up to about 1/3 of the time!

That's why I suggest choosing your medical care based on quality considerations first and then – if you find two providers of high quality care – consider price. But I write this very hesitantly, for I wonder how often people actually do their quality analysis first, and how often they simply jump to the cost considerations.

I worry about

- a Connecticut woman who finds two mastectomy providers with equal mortality and infection rates, who then chooses the cheapest likely *unnecessary* mastectomy;
- a New Hampshire man who finds two cardiologists with equal reputations and experience, who chooses the least expensive, *unnecessary and potentially harmful* stress test;
- an Elyria patient who compares prices among Cleveland and Elyria cardiologists and chooses an Elyria cardiologist due to the lower price, then gets an *unnecessary* angioplasty (and hopefully doesn't acquire a hospital-based infection in the process);
- a Fort Myers, Florida resident with back pain who shops wisely and for the best, least expensive back surgeon and gets *high quality, low cost unnecessary* back surgery;
- A western Massachusetts man who chooses the cheapest vascular surgeon in town and then gets an *unnecessary*, entirely preventable leg amputation;
- a man who buys Zetia from the local big box store because it's on sale, develops headaches, nose and throat infections and diarrhea ⁶⁹ ...and then *still* has a heart attack;
- a woman who chooses the least expensive local hospital to deliver her baby, and then has an unnecessary, emergency c-section from which she develops an infection;
- an arthritic man who chooses arthroscopic knee surgery to address his knee osteoarthritis from the cheapest orthopedic practice in town;
- a fellow who goes to the most expensive orthopedic surgeon in town for his spinal fusion surgery, figuring that 'the most expensive guy must be the best' and gets expensive unnecessary surgery and a permanent disability...
- and so on and so forth, for far too many treatments to list here.

⁶⁹ See Zetia side effects on MedTV <u>http://cholesterol.emedtv.com/zetia/zetia-side-effects.html</u> and WebMD <u>http://www.webmd.com/drugs/drug-64336-</u> Zetia+Oral.aspx?drugid=64336&drugname=Zetia+Oral&pagenumber=6

Sure, if two providers offer the same price for the same quality, go ahead and choose the cheapest....but be sure you need the treatment and be sure the quality is really the same!

Some concluding comments

Spending money on medical care unnecessarily hurts us both economically and medically.

Let's run with our earlier estimate that 'up to about a third of all medical spending is wasted on unnecessary care' and see what it may mean for each of us.

First, remember that the typical or average employer-based health insurance policy costs about \$10,000 per year, divided between the employer and employee contributions. The 'up to about a third' estimate suggests that up to \$3300 of that goes to unnecessary medical care and is wasted.

By eliminating waste, we could save up to about \$3300 per policy per year. That's money that could better be spent doing something else since it doesn't deliver any medical care value.

Second, remember that many employees have 'sick days' or days on which they miss work for medical reasons. The 'up to about a third' estimate suggests that up to about a third of those sick days are wasted on unnecessary care, tests or treatments.

This costs business a great deal of money in unnecessarily lost productivity.

And **third**, perhaps the key message from all the charts and discussion so far: *our traditional method of choosing medical care doesn't work very well.*

What's our traditional method? Asking your doctor what to do. 'Doc, what do you think I should do?' or 'Doc, what would you do if you were me?' or more simply 'Doc, tell me what to do.'

As we've already seen, that approach has led to *more medical expenditures* than other countries that are demographically and economically similar to us with *no better (but sometimes poorer) medical outcomes* than them.

In other words, simply asking our doctor what to do leads to excessive and unnecessary medical care – or medical waste – up to about a third of the time.

Many people read the preceding sentence and think it doesn't apply to them because 'I always ask good questions' or 'I do lots of research before agreeing to any medical intervention' or 'I'm skeptical so take my doctor's advice with a grain of salt'.

I hear these comments all the time **but I don't believe them!** I sometimes follow up on those comments with a – hopefully nicely phrased - question like

- What's your starting risk of dying from that disease? or
- What's the Number Needed for Harm of that treatment? or
- I wonder if you're in a high or low utilization area for that care? or
- Have you reviewed double blind comparative studies or relied solely on observational data? or
- Did you use relative or absolute mortality reduction estimates?'

I generally get a blank stare in response.

I remember a study of 1,000 audiotapes of doctor-patient discussions which found that patients who *claimed* they participated in their medical decisions actually simply agreed with their doctor's initial recommendation after asking a few questions and without much discussion about options or much weighing of the risks and benefits. I suspect that's what many people mean by 'participating'.⁷⁰

The undirected, often anxiety fused research that most of us do these days is called 'infoxication' by Gary Schwitzer, editor of MedicalNewsReview. Infoxication – rhymes with 'intoxication' - has nothing to do with Fox TV, but lots to do with excessive noise, factoids, sketchy data, poorly framed issues, poorly formed conclusions and generally poor quality research. In fact Schwitzer has reviewed 1700+ medical news articles over the past several years based on their reporting quality. His results:

- About 70% of articles failed to quantify medical *harms*, but often minimized them ('side effects were generally minor and infrequent')
- About 70% of articles failed to quantify the medical *benefits*, but often exaggerated them (by using relative percentages of improvement, not absolute, for example or say this is a 'medical breakthrough' or 'game changer')
- Most also failed to evaluate the quality of the evidence reported, often failing to differentiate between
 - o corporate press releases,
 - potentially biased industry-funded observational studies and double blind randomized, comparative data, or

⁷⁰ Paraphrased from Braddock, The Emerging Importance and Relevance of Shared Decision Making to Clinical Practice, Medical Decision Making, September / October 2010

• failing to differentiate between correlation and causality. ⁷¹

Undirected medical research that fails to focus on the key questions has turned today's patients from <u>un</u>informed to <u>mis</u>informed. The 'tools' that the Institute of Medicine discussed in our Introduction are exactly the tools that most of us lack when doing our web searches or talking with our doctors – the tools that address the '*how well* does it work' questions.

We need to do something *in addition to* reading lots of poorly researched and presented articles and asking our doctor what to do, to ensure that we avoid unnecessary medical care.

⁷¹ From Schwitzer's talk at the MIT Faculty Club, December 4, 2012
Review Questions

answers on next page

1. How do American healthcare expenditures compare to Canadian or other first world countries?

- a. We spend far more on healthcare per capita than any other country
- b. We spend about as much on healthcare as any other country
- c. We spend far less on healthcare than any other country

2. Americans get more MRIs and take more medications than almost any other people. How does this affect our longevity?

- a. We live longer than any others
- b. We live about as long as any others
- c. We die younger than any others

3. How does our more extensive birthing technology – fetal heart monitors, radiological equipment and experience with C-sections – affect our infant mortality rates, compared to other countries?

- a. Our infant mortality rates are higher than most developed countries
- b. Our infant mortality rates are about the same as most developed countries
- c. Our infant mortality rates are much lower than any other developed countries

4. Some regions of our country perform more surgeries – mastectomies, heart bypasses, back surgeries for example – than other regions. How does this impact on resident's quality of live and longevity?

a. Residents in regions that perform more surgeries live longer than residents in regions that perform fewer

b. Residents in regions that perform more surgeries live about as long as residents in regions that perform fewer

c. Residents in regions that perform more surgeries live less long than residents in regions that perform fewer

5. Is access to cancer screening tests, like mammograms, a good thing, as measured by breast cancer longevity?

a. Yes, having more mammograms leads to women living longer

b. No, having more mammograms doesn't appear to help women live longer

6. What is the big deal about the ChoosingWisely campaign?

a. It is no big deal, just a bunch of dissatisfied physicians making noise

b. It is a really big deal because this is the first time in history that medical societies were advising patients not to use the services provided by the society's members.

7. Can a consumer usefully do his/her own medical research online?

 a. Yes, because there are so many articles available
 b. No, because most articles fail to quantify either the benefits or harms of medical care, but generally exaggerate the benefits and minimize the harms

8. What do most people mean by 'participate' with their doctor in their own medical decision making?

- a. Ask lots of 'common sense' questions
- b. Ask intense questions like 'what would you do if you were me?'

c. End up agreeing with their doctor's initial recommendation after asking a few questions

9. What is one particularly insightful question that a Connecticut woman who is diagnosed with early stage breast cancer might usefully ask her physician?

- a. Do I really have breast cancer/
- b. What do you recommend I should do about it?
- c. Do you think I should have a second opinion?
- d. Can I have a referral to a Massachusetts oncologist for a second opinion?

10. Here's a hypothetical: a 65 year old man, former high school and college football player who has stayed in good physical shape ever since, has developed a sore right knee. It's uncomfortable but doesn't affect his quality of life very much. His orthopedist recommends knee surgery. What is one particularly insightful question he might usefully ask the orthopedist?

- a. What are my options?
- b. What are the surgical risks?
- c. How long until I regain full use of my leg?
- d. Am I in a high or low knee surgery region?

Review Questions

correct answers in bold

1. How do American healthcare expenditures compare to Canadian or other first world countries?

a. We spend far more on healthcare per capita than any other country

- b. We spend about as much on healthcare as any other country
- c. We spend far less on healthcare than any other country

2. Americans get more MRIs and take more medications than almost any other people. How does this affect our longevity?

a. We live longer than any others

- b. We live about as long as any others (We actually live *slightly* less long, so b or c are both technically correct.)
- c. We die younger than any others

3. How does our more extensive birthing technology – fetal heart monitors, radiological equipment and experience with C-sections – affect our infant mortality rates, compared to other countries?

a. Our infant mortality rates are higher than most developed countries

b. Our infant mortality rates are about the same as most developed countries. (Actually *slightly* higher, so a and b are technically correct)
c. Our infant mortality rates are much lower than any other developed countries

4. Some regions of our country perform more surgeries – mastectomies, heart bypasses, back surgeries for example – than other regions. How does this impact on resident's quality of life and longevity?

a. Residents in regions that perform more surgeries live longer than residents in regions that perform fewer

b. Residents in regions that perform more surgeries live about as long as residents in regions that perform fewer (Actually *very slightly* less long, so b and c are technically correct)

c. Residents in regions that perform more surgeries live less long than residents in regions that perform fewer

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Chapter 2: The Insurance Industry Response

Fully understanding the quality issues we discussed in Chapter 1, and facing rapid healthcare cost increases in the early 2000s, the insurance industry had some decisions to make. Should it

- focus on *quality* and educate patients how to choose high quality necessary care and avoid unnecessary care, or
- focus on *costs* and incent patients to make medical care decisions based on price, thus hoping to control healthcare inflation, or
- both?

This chapter will describe two major industry activities post-2000s: the introduction of Consumer Driven Healthcare aimed at controlling costs and of HEDIS quality measures aimed at improving quality.

These are not the only programs developed. Rather, they are examples of the *types* of programs implemented by carriers over the past decade, both in terms of form – how the programs are designed - and their impact. Both failed to much positive impact. Other, similarly designed programs have had pretty much the same (non)impact. It's a sad and disturbing story.

The evidence

Here are some cost impact indicators:

America's healthcare spending patterns both before and after introduction of so-called Consumer Driven Healthcare in 2003 didn't change much:

- American healthcare spending has averaged 2 3x the overall rate of inflation since about the 1970s.
- The US overall inflation rate averaged about 3% per year from 2002 2012.⁷²
- US healthcare premium increases averaged about 6.2% between 2002 and 2009

 about double the overall inflation rate.
 ⁷³ Just like our historical experience.

⁷² <u>http://www.usinflationcalculator.com/inflation/current-inflation-rates/</u>

⁷³ OECD Healthdata 2011.

- In 2010, employer based coverage premiums grew at about double the general inflation rate.⁷⁴
- Reuters estimates that in 2013, healthcare costs will inflate by 7.5%, about 3x the overall inflation and economic growth rate, about the historical average. ⁷⁵

Not much of a spending brake there. ⁷⁶

The *quality* gains of these insurance programs were even less profound. Here's some fairly upsetting data:

• About 18,000 Americans die annually due to lack of health insurance according to 'Care Without Coverage' a seminal study by the Institute of Medicine in 2002.

That's 18,000 out of the approximately 50 million Americans who lack health insurance.

 About 187,000 Americans die annually due to harm from our medical care system (errors, infections, inappropriate care etc), according to a Health Affairs study in 2011. ⁷⁷ (Other credible research estimates range from about 98,000 to 200,000)

That's out of about 250 million insured.

Your chance of dying from no insurance is about .035%.

But your chance of dying from medical system harm is about .**075**% according to the 2011 Health Affairs estimate.

Here's that comparative chart:

⁷⁴ Nussbaum, Healthcare costs rise faster than US inflation rate, Bloomberg Businessweek, May 21, 2010 <u>http://www.bloomberg.com/news/2012-05-21/health-care-costs-rise-faster-than-u-s-inflation-rate.html</u>

⁷⁵ Morgan, Healthcare costs to rise 7.5% in 2013, Reuters, May 31, 2012 <u>http://www.reuters.com/article/2012/05/31/us-usa-healthcare-costs-idUSBRE84U05620120531</u>

⁷⁶ Some individuals and companies did, however, generate premium savings by switching to the higher deductible plans. In the first year, according Consumer Driven Healthcare by Amy Lischko, a Pioneer Institute publication released in December 2012, the average premium reduction was about 15% as compared to remaining with traditional insurance. Plus companies with Consumer Driven plans tend to have lower year after year premium increases.

⁷⁷ Goodman, Health Affairs, 2011

Relative Chance of Death from no health insurance and from the medical care system

Data from 2002 Institute of Medicine, Care without Coverage and the 2011 Health Affairs article estimate.



Remember: The uninsured mortality rate comes from a 2002 study; the healthcare systemic harm data comes from a 2011 estimate. *This trend may be worsening...*

The interesting question here: why have both our cost control and quality improvement programs so far failed to achieve their objectives? What are their structural flaws?

My premise: the same flaws exist in a myriad of similar initiatives undertaken by the industry recently. People who understand them can make better medical care decisions than people who don't.

I'll explain why in detail below. But here's a brief summary:

- 1. Medical pricing information, without quality indicators, is only marginally useful. Patients almost instinctively understand this which is why they don't all flock to low cost medical care providers *even when prices are known*. The upside of saving a little money pales in comparison to the downside of injury or death.
- Patients want quality measures that tell them whether or not they will get well, whether a medical treatment will help them. Other indicators – compliance with some set of guidelines or a procedural checklist – don't tell them. So-

called quality metrics that don't tell patients if they will get healthier are about as useless as price metrics without quality information.

Our starting point: the 2004 NCQA report

The National Council on Quality Assurance, a managed care industry association, published the following in its 2004 Annual Report, clearly identifying the need to improve the quality of our nation's medical care. I choose 2004 because it was the first year after the introduction of Health Savings Accounts in the Medicare Modernization Act of 2003 and because the 2004 NCQA report so eloquently framed these issues:

The disparity between the care most Americans receive and the care delivered through the nation's best plans results in from 42,000 to 79,000 premature deaths each year...

...thousands of preventable second heart attacks, kidney failures and other conditions...

...more than \$9 billion in lost productivity and nearly \$2 billion in hospital costs could be averted through more consistent delivery of best-practice care...

...more than 14,000 heart attacks and strokes could be prevented each year through better diabetes management alone.

This report followed on the groundbreaking 1999 **To Err is Human** study by the Institute of Medicine that documented, for example

preventable medical errors cost the US economy between \$17 billion and \$29 billion annually plus thousands of preventable annual deaths.

These errors include diagnostic, treatment, preventive and systemic problems.

The IOM believes that faulty systems, processes and conditions, rather than individual physician mistakes cause these medical errors.

These preventable errors account for up to about 100,000 unnecessary deaths per year.

Both statements describe a poor quality medical care system that includes huge amounts of unnecessary care, expense, preventable injury and death, all of which has a significant financial impact.

How did the insurance industry respond to these types of wake-up calls? In part by introducing process metrics like the HEDIS system that I'll describe later, and in part by

introducing Health Savings Accounts, a tax codification of the trend toward high deductible health plans, the so-called Consumer Driven Healthcare, aimed at controlling medical care inflation.

Consumer Driven Healthcare

Consumer Driven Health Care aims to treat medical care purchasing like all other consumer purchases such as cars and homes. It does this by requiring consumers to spend their own money on medical care, up to some specified annual deductible.

Consumer engagement starts – and generally stops – with deductibles. Few plans include meaningful medical care quality metrics like the Number Needed to Treat or Number Needed for Harm. Few consumers know their Starting Risk of developing various medical problems, or the Modified Risk offered by medications, therapies or tests. Even fewer can understand which medical claims - from medical ads for example - are meaningful and which are not.

The industry has, so far at least, failed to teach consumers how to choose high quality medical care over low and avoid unnecessary care altogether. Lacking this knowledge, consumers continue to spend their money unwisely on medical waste - up to, about, 1/3 of the time - regardless the deductible or the tax treatment thereof.

Here's what price-based medical decision making overlooks: **better outcomes almost** always cost less than poorer ones.

One reason for this: better medical quality leads to fewer missed diagnoses, hospital readmissions, unnecessary tests and unnecessary procedures. This suggests that wiser medical consumers – i.e., those who make the most well-informed medical care quality decisions – are generally the *lowest cost* medical consumers, not the 'penny-wise, pound foolish' folks who shop based on price.

Dissuading people from choosing *quality* care by motivating them to choose *cheaper* care may well take us in the wrong direction.

Medical care prices are, of course, important.

Pricing information is *most appropriate* for medical commodities like radiologic scans, pharmaceutical products, and routine tests and procedures. In these, the care quality is either approximately the same - many hospitals use the same type of MRI machine, for example - or unknowable. How can a patient determine the quality of one physical therapist as compared to another? They can generally only determine the friendliness.

Pricing information is *least appropriate* for complex, expensive, highly individualized, potentially life threatening medical interventions. Would an elderly patient suffering from congestive heart failure, decreased kidney function, Parkinson's disease and diabetes - who needs his pacemaker removed and upgraded - choose the least expensive facility?

Or an obese, diabetic woman suffering from COPD and lupus choose the least expensive facility for her double mastectomy?

I suspect these people would want the *best* facility because the risks are so high.

These individualized, non-routine interventions are the ones with the most potential to save money. But they're the ones for which we're least able to get meaningful pricing information.

In general, I submit that price is a secondary consideration in medicine, one that wise patients should only consider after they have determined the care quality. Here's how the wise patient would make an informed medical decision, at least conceptually:

First, decide which medical care *treatment* offers the best outcomes for people like you. Spinal fusion surgery or back therapy, for example; mastectomy or watchful waiting.

Second, decide which *hospitals and physicians* provide that treatment the best, as measured by outcomes for people like you,

Third, if you find two hospitals or physicians that generate the same outcomes for the same treatment, then sure, choose the least expensive.

Of course, medical decisions are often rushed so you can't go through this sequence in detail. Often these data don't exist for your particular medical need so you need to estimate. But the key point remains: *choose high quality, necessary medical care based on outcomes for people like you as a first consideration, and relegate cost issues to a secondary role.*

So- called Consumer Driven Healthcare tends to flip this process on its head.

Consumer Driven Healthcare Defined by Deductibles (largely)

In common insurance lingo 'consumer driven products' are those with \$1000 or more annual deductibles. Each consumer spends that \$1000 as best he/she sees fit – for physician visits, medications, tests or therapies. Only after satisfying the deductible does insurance begin to pay. Then, depending on the specific plan design, insurance pays all of the additional medical expenses, or part up to some set amount.

Some other aspects of so-called Consumer Driven Healthcare include tax benefits of Health Savings Accounts, Health Reimbursement Accounts and Flexible Spending Accounts. These allow consumers to spend <u>pre-tax</u> money on healthcare, effectively reducing the cost by about a third. Another way of saying this: the government picks up about a third of the cost via foregone taxes. The economic effect: reduce the cost of unnecessary medical care.

Whenever we reduce the cost of anything – candy bars, gasoline or unnecessary medical care – consumers buy more of it. For this reason, the tax benefits included in so-called Consumer Driven Healthcare may incent patients to consume even *more* unnecessary care than they would have otherwise.

In theory, when people spend their own money they shop more wisely and get better value than they would if they only spent the carrier's money. This is the same theory that underlies other consumer products, ranging from refrigerators to cars to tennis racquets.

Unfortunately, the theory fails in healthcare due primarily to the lack of medical *quality* information – the necessary first step to wise medical care decision making. The lack of quality info makes medical decisions different from, say, car purchasing decisions.

The car buyer can compare various cars before deciding which to purchase. Large or small, good gas mileage or poor, lots of luxuries or few, good crashtesting rating or not, high resale value or low, built-in GPS units, etc...and price too, of course!

But the medical purchaser generally has very little similar information. How effective is this intervention compared to that? Or this medication compared to that one? Which doctor has the best outcomes for people with my illness? Which hospital?

You don't need a medical degree to compare the effectiveness of different medical treatments. You just need the information. But we generally lack it.

For this reason, I suggest that today's so-called Consumer Driven Health Care is really nothing more than cost shifting to sick people. **These plans have virtually nothing to do with consumerism.** And they can't, since patients have virtually no useful medical care quality information today upon which to make wise medical care decisions.

The insurance industry favors price over quality information: some examples

To help patients spend their deductibles wisely, insurance carriers, private companies and some states have developed and promoted pricing tools – lists of medical treatment prices from various local providers that, theoretically, help patients shop for the best deal.

Some of these are extremely detailed, showing, for example, what an individual consumer will pay based on his/her deductible payments so far this year, how much your employer will pay, what types of follow up care you may need and what they will cost, etc.

I'll show you some simple examples. To avoid any confidentiality or related issues, I'll use a public pricing site, the New Hampshire state site, nhhealthcost.org. I chose it because it was easy to use.⁷⁸

The first chart shows sample total costs (deductible + insurance payment) for arthroscopic knee surgery. Note the huge price difference among providers: ⁷⁹

<u>Facility</u>	Total Cost
Concord Ambulatory Surgery Center	\$3,431
Franklin Regional Hospital	\$5,118
Cheshire Medical Center	\$6,644
Parkland Medical Center	\$7,717
Weeks Medical Center	\$9,873

We have no quality information - infection rates, speed of return to normal health, 30

79

⁷⁸ I downloaded all this information on December 6, 2012, posing as an Anthem subscriber with HMO coverage. Anthem was one of the carrier options and HMO one of the plan options. I chose both at random.

http://www.nhhealthcost.org/insuredWizardUserInput.aspx?procedure=2&procedureName=Arthroscopic+Knee+Surgery+(outpatient)

day readmission rates, etc. Nor do we know for which patients this is necessary surgery and for which unnecessary.

Remember the Houston VA study from Chapter 1, with the New England Journal of Medicine concluding that there is no evidence that arthroscopy cures or arrests knee osteoarthritis.

But we know that prices for this procedure range from \$3431 to \$9873. That's a lot!

Radiology prices also vary hugely. Here are sample prices for a pelvis MRI, same subscriber, downloaded the same day:

Facility	Total Cost
Derry Imaging Center	\$1,486
St Joseph Hospital	\$2,574
Exeter Hospital	\$2,758
Speare Memorial Hospital	\$3,381
Monadnock Community Hospital	\$3,868

Again, no quality information – rates of false positives, misdiagnoses, overdiagnoses etc. No information on number of call backs, unnecessary further investigations, etc.

And no indication of the number of *unnecessary* pelvic MRIs performed.

But an impressive price discrepancy.

Some patients – presumably – will choose the lower cost provider to save money.

- Others may choose the *higher* priced treatments, assuming that the most expensive is the best.
- Still others may choose the one closest to home, regardless the price, especially if they have already satisfied their deductible.
- And others may follow their doctor's advice, regardless of price.

I'm not sure what all this has to do with medical care quality – the 'up to about a third generating no detectable benefit' – as we have no reliable, similarly detailed outcome metrics to combine with these prices.

I'm also not sure exactly how consumers will change their behavior when faced with this pricing information. But some industry folks are developing ways to address that behavioral issue.

When prices become known, new plan designs become available

Once prices for lots of procedures – and for bundles of procedures – become available, carriers and brokers can design *reference based pricing* plans. That's likely the next new thing.

Reference based pricing takes the deductible concept a step further:

- The *deductible* applies to all your medical care. Once you pay it, the care is free for the rest of the year, though some plans may still call for a co-insurance payment up to some specified amount.
- *Reference based pricing* says the insurer will only pay the lowest price in the region after you satisfy your deductible. The insurance subscriber is responsible for all or part of any excess if he/she chooses a different provider.

The low price provider may change by treatment. In our examples above, Derry was the low price pelvis MRI provider and Concord the low price arthroscopic knee surgery vendor. Whichever provider is the lowest price becomes the 'reference' for that treatment.

These plans are still very new and we don't have evidence of their effectiveness. Creative carriers and brokers will almost certainly develop variations on this theme.

The fundamental problem with prices: you need to understand what they tell you

Prices serve a variety of supplier goals including profit generation and customer attraction (marketing). I'll use an automotive analogy to introduce all this and then show how hospitals do the same things. Here's the example:

An independent auto mechanic advertises oil changes for \$19.95.

Meanwhile the large dealer up the road charges \$34.95.

Is the independent better or worse at oil changes? We don't know. But by charging \$19.95 he's probably trying to attract new customers who will like his work and use his services for brake jobs, tune-ups and other higher priced, more profitable work.

In other words, the \$19.95 oil change is part of his marketing strategy to get people in the door with the low priced item and then upsell them: 'You know, your brake pads are pretty thin. I could replace them while I do your oil change.' Retailers do this all the time: attract new customers with cheap, low margin items and then sell them higher priced expensive stuff. Two points here:

First: there are lots of auto repair competitors, so consumers can quite easily research their options. You can't make too much of an auto repair mistake as you're normally only spending a few hundred dollars at most. A bad decision probably just means you overspend by a bit. Pretty small risk to the consumer. *Not so true of complex medical issues where poor quality care can literally kill you.*

Second, auto repairers are notorious for upselling unnecessary services, at least in the common public perception, so consumers are 'defensive shoppers,' constantly on their guard to avoid getting ripped off. George Castanza articulated this in a 1995 Seinfeld episode, describing his dealings with an auto repair facility: ⁸⁰

Well of course they're trying to screw you! What do you think? That's what they do. They can make up anything; nobody knows! "Why, well you need a new Johnson rod in here." Oh, a Johnson rod. Yeah, we'd better put one of those on!

Could hospitals do the same thing, upsell patients? Attract them in and then provide lots of additional, perhaps unnecessary but high margin billable services?

Item: Emergency room physicians at Carlisle Regional Medical Center in Pennsylvania had targets for how many patients to admit. According to the New York Times investigation, published in November, 2012: ⁸¹

doctors said that hospital administrators created targets for how many patients they should admit. More admissions translated into more dollars for the hospital.

⁸⁰ http://www.imdb.com/title/tt0697702/quotes

⁸¹ Creswell and Abelson, A hospital war reflects a bind for doctors in the US, New York Times, Nov 30, 2012

...one of the physicians recalled getting phone calls in the middle of the night questioning why he had not admitted an older patient whose hospitalization he could easily have justified. "The pressure to admit was so high," he said.

Item: 60 Minutes reported on December 2, 2012 that Health Management Associates, the 4th largest for-profit hospital chain in the country *relentlessly pressured its doctors to admit more and more patients -- regardless of medical need -- in order to increase revenues.*⁸²

The Emergency Room admission benchmark was 15% in some places, 20% in others and 50% for Medicare enrollees, with hospital administrators emailing ER docs messages like:

- Only 14 admits so far!!! Act accordingly...
- I will be blunt...I have been told to replace you if your [admission] numbers do not improve.

Sounds like upselling to me.

ER is a low margin business, like oil changes. Inpatient admissions - far more profitable. Like Johnson rods.

Hospitals can make millions off of free services

Just image the potential impact if hospitals *compete* with each other on advertised prices, but *compensate* their doctors based on admission rates or surgeries performed.

Item: On September 12, 2012, Westerly Hospital in Westerly, Rhode Island offered free PSA screening from 5 - 6 PM. ⁸³ 'Free' is the ultimate low cost.

Now...why would a hospital give its services away for free? And why PSA screening in September 2012, *four months after the US Preventive Services Task Force recommended <u>against</u> PSA screening for prostate cancer?*

Dr. Otis Brawley, Chief Scientific and Medical Officer at the American Cancer Society suggested an answer in an interview: ⁸⁴

⁸² 60 Minutes, Hospitals: The Cost of Admission, December 2, 2012

⁸³ <u>http://www.westerlyhospital.org/hospital-offers-free-psa-screening-on-sept-12/</u>

⁸⁴ <u>http://www.whale.to/cancer/psa_screening.html</u> . Brawley reports a similar story in his book How We Do Harm, pages 228 - 9

We at Emory have figured out that if we screen 1,000 men at the North Lake Mall this coming Saturday, we could bill Medicare and insurance companies for \$4.9 million in health care costs [for biopsies, tests, prostatectomies, etc].

But the real money comes later--from the medical care the wife will get in the next three years because Emory cares about her man, and from the money we get when he comes to Emory's emergency room when he gets chest pain because we screened him three years ago.

Questioner: You're saying that screening creates long-term customers. So, did Emory Healthcare decide to go ahead with the free PSA screening on Saturday?

Dr. Brawley: No, we don't screen any more at Emory, once I became head of Cancer Control. It bothered me, though, that my P.R. and money people could tell me how much money we would make off screening, but nobody could tell me if we could save one life. As a matter of fact, we could have estimated how many men we would render impotent...but we didn't. It's a huge ethical issue.

Seems that Westerly Hospital made a different decision.

I'm left to wonder if publishing price lists will still leave as unnecessary about half the Connecticut mastectomies...or perhaps increase the rate of unnecessary mastectomies if radiologists are compensated based on mastectomy rates or a similar metric.

I just don't see how all this pricing information cuts down on our rate of unnecessary care or switches people from low to high quality treatments.

I <u>do</u> see how this can cut some hospital and treatment costs, but I hesitate to guess whether this means better care or worse. Will hospitals routinely admit more patients in the 'gray area' between definitely needing admission and definitely not to maintain their income...like our ER examples above? Will others do *more* investigations to find *more* microscopic abnormalities that require *more* low quality care, perhaps like Westerly Hospital? Will our overall medical inflation rate actually *rise*?

Shopping for medical care based on price requires people to understand what those prices actually mean. I'm not sure many do.

I worry about the tyranny of the unintended consequence.

Spurious quality assertions: Using 5 year survival rates to justify high mammography prices

Here are some New Hampshire mammography prices. As you review these, remember Dr. Brawley's comments and ask yourself 'if I ran a high priced hospital, how could I

keep my mammography prices high to maintain my income while also maintaining my volume?'

I probably wouldn't want to compete on mammography *price* as that could mean foregoing \$300 or more per mammogram with a potentially significant negative impact on my bottom line. (\$300 per mammogram, 11 mammograms/day, 6 days/week is about a million dollars per year.)

Facility	Total Cost
St Joseph Hospital	\$273
Woman's Life Imaging	\$291
Elliott Hospital	\$313
Cottage Hospital	\$371
Memorial Hospital	\$555
Androscoggin Hospital	\$673

One suggestion (I'm sure creative hospital marketing people will come up with dozens more): a hospital might decide to attract mammography patients by advertising an *'over 95% 5 year breast cancer survival rate'*.

That sounds pretty good. People might pay more to use this facility based on the quality it apparently has and the peace of mind it offers. It's a good marketing campaign that might even increase patient volumes while the hospital maintains high prices.

But the 95% 5 year survival rate tells nothing about the hospital's breast cancer treatment *quality*; survival rate statistics are spurious, misleading at best and bogus at worst. Here's why:

The 5 year survival clock starts when the breast cancer is diagnosed. Over time, we have diagnosed smaller and smaller abnormalities, earlier and earlier in the breast cancer's life.

In fact, between the mid 1990s and mid 200s, we diagnosed breast cancer about 1 full year earlier, according to the National Cancer Center's SEER data.

Average age of breast cancer diagnosis mid-1990s: about 62; ⁸⁵ Average age of breast cancer diagnosis 2006: about 61. ⁸⁶

Unfortunately, the average age of breast cancer death was the same in 1996 and 2006: 68.⁸⁷

Screening starts the 5 year clock earlier. Screening identifies an abnormality before it becomes symptomatic. It may take a year, 2 years, 5 years or more to become symptomatic, if ever. Identifying an abnormality – breast cancer, for example – by screening *automatically* adds all the pre-symptomatic time to the survival time.

This increases 5 year survival rates at even *poor quality* hospitals, because most of the women diagnosed wouldn't die within 5 years anyway. Diagnosing more women with small, young, asymptomatic cancers will increase your 5 year survival rate - by definition - regardless of your medical care quality.

You can, thus, improve your 5 year survival rates (or 10 or 20 year rates) by

- diagnosing cancer earlier but without treating it better or without extending the woman's life at all. Women may still die at the same age, but just live longer with the (earlier) cancer diagnosis. This is apparently the case in the US, or
- diagnosing cancer no earlier, but providing better cancer treatment and extending the woman's life through better care, or
- both

Knowing only the 5 year survival rate doesn't tell us which of these 3 situations occurred. That's why 5 year (or 10 year, or any number of year) survival rates may not tell us *anything at all* about the hospital's cancer treatment quality.

But a hospital that advertises these to an unsophisticated public may make lots of money! *Caveat emptor.* ⁸⁸

⁸⁵ Glockler, Cancer survival and incidence, The Oncologist, December 2003

⁸⁶ National Cancer Inst, SEER Stat Fact Sheet: Breast downloaded Oct 2012

⁸⁷ The 1996 estimate comes from Saenz, Trends in Breast Cancer Mortality, Population Reference Bureau, December 2009; the 2006 from SEER Stat Fact Sheet, ibid.

⁸⁸ Latin for Let the Buyer Beware. Fine advice if the buyer has the relevant tools to beware with!

When is an 'abnormality' a 'dangerous abnormality'? Defining DCIS as 'dangerous cancer' can boost your 5 year survival rates

More insidiously, using 5 year survival rates may put marketing pressure on hospitals and carriers to widen our definition of 'cancer' beyond utility and label more women as having cancer; it's a way to create more patients.

Today, for example, about 25% of breast cancer diagnoses are for DCIS – ductal carcinoma in situ – an abnormal collection of cells in the milk duct. ⁸⁹ It's a low grade tumor, something between normal breast tissue and breast cancer, not really what we think of as life threatening breast cancer.

Some cancer specialists including Dr. Brawley of the American Cancer Society want to remove 'carcinoma' from the name – i.e. **not call it cancer at all** - out of concern 'that we are scaring a whole host of people that have ductal carcinoma in situ who make rash decisions because it's called 'carcinoma'–decisions that they wouldn't make if it was more adequately described for what it truly is.'

An expert panel of the National Institutes of Health agrees, recommending that the word 'carcinoma' be deleted from this diagnosis.⁹⁰

But hospitals, presumably, want to keep the name as-is to advertise their spectacular 5 year survival statistics and attract patients. Indeed, as our radiologic equipment detects smaller and smaller abnormalities, maybe some of these will be called a new type of 'cancer' under pressure from hospital marketers and lobbyists, something analogous to our search for lakes in Florida.

A hospital, knowing all this, can advertise its (potentially non-existent) high quality medical care and charge high prices to unsuspecting patients.

*Prices tell us nothing about quality...*or lack thereof. Caveat emptor indeed!

⁸⁹ This discussion comes from Gary Schwitzer's discussion of January 14, 2010, Why don't journalists pay more attention to DCIS? On HealthNewsReview.org <u>http://www.healthnewsreview.org/2010/01/why-dont-journalists-pay-more-attention-to-dcis/</u>

⁹⁰ Kolata, 'Cancer' or 'Weird Cells': Which Sounds Deadlier? New York Times, November 21, 2011

Which hospital to choose for your delivery? You need to know lots more than price to make wise decisions

Hospital A charges \$4000 for a normal, vaginal delivery and \$8000 for a C-section. Hospital B charges \$4500 for the vaginal and \$8500 for the C-section. Both have similar delivery volumes and first class NICUs.

Hospital A is obviously cheaper and is, perhaps, the reference hospital in a reference based pricing system.

But Hospital A performs 48% of its deliveries by C-section, while Hospital B only performs 21%. The same woman would be far more likely to deliver by C-section at Hospital A.

Here's the correct way to calculate the average delivery costs at both hospitals (go ahead and try):

- Cost of vaginal delivery times the % of vaginal deliveries plus
- Cost of C-section times the % of C-sections plus
- Number of extra days in the hospital for C-sections times the cost/day plus
- The infant and maternal readmission rate for C-sections times the cost per day times the % of deliveries by C-section **plus**
- The infant and maternal readmission rate for vaginal deliveries times the cost per day times the % of vaginal deliveries **plus**
- Etc, etc, etc

That's why I suggest that shopping for medical services based on price is far more difficult than it initially appears and the effort may not bear any fruit at the end anyway.

The Insurance Industry Developed Some Medical Care Quality Measures

Of course, pricing information along with medical care quality information can be very useful to patients. Unfortunately, we have, today, little useful quality information.

The health insurance industry responded to the Institute of Medicine's *To Err is Human* report and the NCQA studies showing big treatment quality differences among hospitals and physicians by developing new sets of **process guidelines**. These are like manuals designed to improve clinical practice.

The National Committee for Quality Assurance (NCQA) in particular developed the Healthcare Effectiveness Data and Information Set – HEDIS - basically instructions for how to provide high quality medical care to various types of patients.

Today, according to the NCQA website, the HEDIS tools is used by more than 90 percent of America's health plans to measure performance of their contracted hospitals and physicians. Because so many plans collect HEDIS data, and because the measures are so specifically defined, the NCQA claims, HEDIS makes it possible to compare the performance of health plans on an "apples-to-apples" basis. ⁹¹

The NCQA publishes lists of carrier rankings based on their contracted hospital and physician HEDIS scores. (I should point out that HEDIS is but one of a handful of measures. Another commonly used metric is CAHPS, the Consumer Assessment of Healthcare Providers and Systems, which also measures process compliance and has the same fundamental flaws as HEDIS, which I'll describe below.)

Note that HEDIS measures *inputs*, not *outcomes*. Inputs are what the doctor does to the patient. Outcomes are how the patient actually did. HEDIS assumes that similar inputs lead to similar outcomes. We'll see...

Here are some of the 2013 HEDIS measures.⁹²

Measure	Commercial Patients	Medicaid Patients	Medicare Patients
Assistance with smoking cessation	Х	х	х
Flu shots for adults over 50	Х		х
Annual monitoring for patients on persistent medications	x	Х	Х

Others, perhaps less compelling:

⁹¹ <u>http://www.ncqa.org/HEDISQualityMeasurement.aspx</u>

⁹² http://www.ncqa.org/Portals/0/HEDISQM/HEDIS2013/List_of_HEDIS_2013_Measures_7.2.12.pdf

Measure	For Commercial Patients	Medicaid Patients	Medicare Patients
Breast cancer screening	Х	Х	X
Cervical cancer screening	Х	Х	
Colorectal cancer screening	Х		X
Use of Spirometry Testing in the Assessment and Diagnosis of COPD	x	х	X

One specific concern: breast cancer screening with mammography is controversial, to say the least. The US Preventive Services Task Force only gives this a B recommendation, not A, concluding that *there is a moderate certainty that the net benefit is moderate.* Not exactly a ringing endorsement.

The USPSTF recommends *biennial*, not *annual* mammograms due to the risk of false positives and breast cancer overdiagnosis, in women 50 – 75. HEDIS recommends *annual* mammograms, perhaps downplaying the false positive and overdiagnosis risks.

The Preventive Services Task Force makes no recommendation about mammograms for women 75 and older saying *the USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women 75 years or older.* ⁹³ HEDIS recommends it for all Medicare women, apparently seeing the current evidence differently.

And the Preventive Services Task Force actually *disagrees* with HEDIS about spirometry testing for COPD, recommending *against* screening adults for COPD using spirometry. HEDIS says 'do it to increase your scores'; the USPSTF advises against saying the incremental benefits are judged to be no greater than small' and 'fair evidence indicates that spirometry can lead to substantial overdiagnosis of COPD.⁹⁴

I certainly can't tell you whether spirometry testing is a good or bad thing and, apparently, neither can the medical community. But doing it is necessary to get a good HEDIS score.

⁹³ http://www.uspreventiveservicestaskforce.org/uspstf09/breastcancer/brcanrs.htm

⁹⁴ http://www.uspreventiveservicestaskforce.org/uspstf08/copd/copdrs.htm

The fundamental point here: getting a high HEDIS score may not indicate medical care excellence. It may only indicate that your doctor checked the relatively easy-to-check boxes on one particular table of relatively easy-to-measure physician activities.

Annual mammograms are simply easier to track from a bookkeeping and customer satisfaction perspective; biennial tests are more nuanced, harder to explain and track. 'If some screening is good, then certainly more screening is better,' I've heard asserted pretty frequently. HEDIS apparently acquiesces to, rather than fights this type of superficial reasoning. Ditto for COPD screening.

Michael Porter, Harvard Business School's great strategy professor, suggests a fundamental fallacy with this entire approach to medical quality measurement: ⁹⁵

Much more relevant is information about providers' actual experience levels, the treatments they use...and, most importantly, the results they achieve.

Porter's concern – and yours, if you want good medical care – is that process compliance in medicine doesn't always translate to outcome similarities.

Process compliance means physicians treat similar patients similarly; *Outcome* tell us how well patients actually did.

In medicine *similar medical processes* can lead to *different patient outcomes*.

(Sorry if this is difficult to grasp, but it's really important to understand.)

A classic example of the difference between process compliance and patient outcomes comes from Atul Gawande's study of cystic fibrosis.⁹⁶ All CF treatments at all 117 specialized CF treatment centers across the country use exactly the same protocols for treating CF patients. All CF physicians have the same specialized training. According to the theory underlying HEDIS, all CF patients should therefore enjoy about the same outcomes – lung function and longevity, for example.

Unfortunately, patient outcomes vary significantly by CF treatment center, with some consistently *over* performing and others consistently *under* performing the norm. Gawande graphed this as a classic bell curve of outcomes.

⁹⁵ Porter and Teisberg, Redefining Healthcare, page 54

⁹⁶ Gawande, The Bell Curve in Gawande, Better

Interestingly, Gawande learned that at least one facility regularly outperformed the norm, year after year. HEDIS type process metrics assume that this doesn't happen.

How can 117 facilities following exactly the same treatment protocols generate a bell curve of patient outcomes? Here's Porter again:

There are simply too many dimensions of process to track and too much heterogeneity among patients. Focusing on just a few visible process steps creates a checklist that providers can address, but oversimplifies the problem. ⁹⁷

In fact, we may use for our checklists only the *easiest to measure* processes not the *most important*. I suspect that's what HEDIS and similar checklists do.

Some other problems with HEDIS checklists

First, the HEDIS type checklists, as any process oriented checklists, become institutionalized, bureaucratized and resistant to change. The new medical information that constantly becomes available – the latest mammogram studies, for example – may not make it onto the HEDIS lists.

Or may make it after a lengthy time delay, during which even newer, potentially critically important data, becomes available. Process oriented checklists are often, if not always, at least somewhat out of date.

Yet physicians are often reluctant to deviate from the approved checklist. Their hospital administrators may sanction them for this.

Second, the designers of HEDIS type lists may become susceptible to industry lobbying. We have numerous examples in the medical care industry where experts who write regulations and who make recommendations are paid by pharmaceuticals or other suppliers to recommend their products.

A classic example is the 2003 Adult Treatment Panel III, which lowered the definition of dangerous total cholesterol to 200. Eight of the 9 panelists had financial ties to pharmaceutical companies, most to companies that manufactured cholesterol-lowering drugs. ⁹⁸ (I'll discuss this in much more detail in the next chapter.)

One wonders how the designers of HEDIS style lists might be equally affected.

⁹⁷ Porter, op cit, page 87

⁹⁸ http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04_disclose.htm

The quality information patients really want

How will this treatment affect me? Will I get better? Will I be harmed? We call these outcome measures and the insurance industry is remarkably poor at providing these.

Outcome measures describe how well patients actually do. What percent of lung function do patients at a particular cystic fibrosis facility actually have? What is the average life expectancy at each CF facility?

- How many heart bypass patients need readmission to Hospital C within 30 days of discharge, and how many to Hospital D? How many TURP or hip replacement patients?
- Do patients having carpal tunnel surgery from Surgeon G return to work more quickly or less than patients of Surgeon H?
- And, even more basically, how many heart bypass surgeries, kidney removals, rotator cuff surgeries or hip replacements does a given hospital perform each year? We have evidence that higher rates of a specific surgery by a specific medical team generate better outcomes, suggesting that the *quantity* of surgeries performed by a surgical team is a reasonable indicator of medical *quality*....but we generally can't even get the quantity information! And HEDIS style lists don't provide it.

Porter gives this depressing summary:

In only a few isolated disease areas - notably cardiac surgery, organ transplants, cystic fibrosis and kidney dialysis - is broad-based results information available

and

most physicians lack any objective evidence of whether their results are average, above average, or below average.⁹⁹

Fairly astonishing, don't you think? This industry sector costs about \$2.7 trillion per year and represents about 16% of the American gross domestic product. But we lack data indicating which medical professionals are the best, which are average and which are the worst.

In other words, most patients have no idea how good their physicians and hospitals are. Remember that half are below average, because, by definition, 'average' means that

⁹⁹ Porter, op cit, page 55

patient outcomes from half of all surgeons and at half of all hospitals are above it and *half are below*. Here's Porter's take on this:

it is human nature for most people to believe that they are above average, which cannot be true $^{\rm 100}$

meaning you can't just ask your doctor if he/she is above average because there's no data to support the answer.

Perhaps as a result of this mind-boggling lack of care quality information, the definition of a 'good' health plan is one that offers easy access to a wide range of physicians and the 'best' offers *really* easy access.

This may be because of our poor outcome data. You want to try one doctor but, since you really don't know if he/she is any good, you want the option to change.

Interestingly, we compare country healthcare systems on cost, longevity and infant mortality, but we compare carriers on provider network size, access ease and HEDIS scores. In doing so, we forget Kenneth Thorpe's comments about 'excess mortality' and Elliott Fisher's findings that easier access and more medical spending leads to slightly higher mortality rates, slightly poorer outcomes.

Private information sources and social networking enter the void

To escape these problems, people sometimes look at so-called consumer oriented physician rating services or social networking websites. A lot of these exist, all with about equally mediocre quality information.

HealthGrades, for example, claims that more than 200 million consumers use it to research and select a doctor or hospital and that it's America's most comprehensive source of information on hospitals and doctors. ¹⁰¹ Atul Gawande once looked up his own HealthGrades report card:

They don't tell you that much. You will learn, for instance, that I am certified in my specialty, have no criminal convictions, have not been fired from any hospital, have not had my license suspended or revoked, and have not been disciplined for misconduct....it sets the bar a tad low, doesn't it?¹⁰²

¹⁰⁰ Porter, ibid

¹⁰¹ http://www.healthgrades.com/about

¹⁰² Better, page 207

I looked up my own PCP and learned the following:

- 79% of patients would recommend him
- He's 'very good' at scheduling appointments, at office environment and at office friendliness
- Most patients report that he listens well, helps patients understand their condition, spends enough time with patients and that they trust him.

I suspect my auto mechanic would get the same write-up. Surely there's something about medical competence and patient outcomes that's relevant here!

Here's what I didn't learn, for example:

- Does he generally refer to aggressive specialists who operate as soon as possible on patients, or to more conservative ones who prefer to watch and wait?
- What percent of the orthopedic patients he refers for surgery need to be readmitted within 30 days of hospital discharge? What percent of cardiac? Urologic? Other?
- What percent of his female patients have mastectomies? What's the average age of death of his patients with breast cancer? With prostate cancer? What percent of his male patients over age 65 have prostatectomies?
- What percent of his Medicare patients have leg amputations?
- What percent of his patients maintain their Body Mass Index within a couple of points through their 50s and 60s? Develop diabetes? Keep their blood pressure low-to-moderate? Have heart attacks? Maintain a full range of physical functioning and exercise regularly?
- What tests does he perform at annual physical? How open is he to discussing specific tests?
- And lots more similar info.

Now that's some really useful information on which to base a physician choice decision. Too bad it's all unavailable.

Social Media Steps into the Void

Patient satisfaction and feedback, so useful for restaurant and hotel choice, is growing in medicine. Unfortunately, this may make the unnecessary care problem worse!

Choosing your physician based on patient satisfaction scores can actually lead to more unnecessary care, according to analyses in Forbes and amednews, a publication of the American Medical Association.¹⁰³ Here's why:

Doctors, in order to satisfy their patients and get a good score, overtest, overprescribe and overtreat. Patients, often believing that more medical care is better medical care, like this excess. The more a doctor tests, the better that doctor is. The more easily a doctor prescribes, the higher the patient satisfaction.

Researchers have found that the people who are most satisfied with their doctors get more prescriptions, are more likely to be hospitalized, and have higher death rates than patients who are less satisfied with their care. ¹⁰⁴ According to medical researcher Joshua Fenton of the University of California at Davis who studied more than 50,000 adult respondents,

Doctors may order requested tests or treatments to satisfy patients rather than out of medical necessity, which may expose patients to risks without benefits

The impact? Quoting the UC Davis Press Release:

'For every 100 people who died over an average period of nearly four years in the least satisfied group, about 126 people died in the most satisfied group' despite the fact that 'more satisfied patients had better average physical and mental health status at baseline than less satisfied patients'.

Dr. Brenda Sirovich of Dartmouth Medical School commented on this apparent paradox:

Numerous studies have found that patients are consistently highly satisfied with one of the most common downsides of medical care–false-positive test results and the downstream events that follow ¹⁰⁵

meaning that doctors can intervene compassionately and brilliantly, perhaps even heroically, but often unnecessarily because the patient wasn't sick to begin with. That's what a false-positive test result means.

¹⁰³ Falkenberg, Why Rating Your Doctor Is Bad for Your Health, Forbes, January 21, 2013 and O'Reilly, Patient Satisfaction, When a Doctor's Judgment Risks a Poor Rating, amednews.com, November 26, 2012

¹⁰⁴ Patient Satisfaction Linked to Higher Healthcare Expenses and Mortality, UC Davis Health System, February 13, 2012

¹⁰⁵ Falkenberg, op cit

Websites like Angie's List, Press Ganey, Gallup and National Research Corporation publish patient satisfaction ratings of physicians. Forbes estimates that about 1/3 of all US physicians receive annual incentives based, at least in part, on the results of those and similar surveys. Caveat emptor.

Let's tie all this together

The health insurance industry now requires that people spend their own money on medical care, perhaps \$1000 or more annually, before insurance kicks in. We call this Consumer Directed Health Care.

The industry has developed process compliance metrics to show consumers the 'quality' of various doctors and hospitals.

Quick vignette: An 85 year old female friend-of-a-friend recently changed PCP. The new one - who received top marks on HealthGrades including for appointment scheduling, office environment and office friendliness – looked at her chart and said 'you're out of date for your annual mammogram'.

Annual mammogram for an 85 year old woman?

Check the box ... just like HEDIS wants.

Neither the prices now available, nor process metrics like HEDIS, mean very much about medical outcomes, which is the only meaningful measure of how good a medical provider really is.

The insurance industry has failed to address the 'up to about a third of medical spending generates no detectible benefit' problem. Prices and process metrics fail to tell us which treatments are effective, which low quality, which unnecessary and which may do more harm than good.

Two orthopedists, one in Fort Myers, the other in Miami, charge the same and get the same HEDIS and HealthGrades scores. The Fort Myers doc has higher patient satisfaction ratings.

But half the back surgeries done by the Fort Myers doc are unnecessary! We know this from the Dartmouth Atlas.

Nor does the industry tell us which physicians are higher quality – above average in Porter's terms – or below. Which generate excellent patient outcomes and which mediocre?

In fact, the insurance industry doesn't even help patients determine which questions to ask! Does 'appointment scheduling efficiency' mean anything at all about patient care or outcomes? Should I spend my deductible on someone having a good HEDIS score...or someone who says the system is nonsense and, as a result, has a poor score but perhaps quite healthy patients? Should I rely on patient satisfaction surveys?

Let's conclude. If the insurance industry that developed Consumer Driven Healthcare and HEDIS type process metrics actually provides any useful patient education and decision support, then one of three things should happen:

- American healthcare spending would *decrease* relative to healthcare spending in other countries since our outcomes are not superior to theirs. That has not happened. The trend is getting worse.
- American outcomes, as measured by longevity and other factors (infant mortality for example) would *improve* relative to other countries since our spending exceeds theirs. That also has not happened over the past decade.
- Healthcare systemic harms would decrease relative to the harm caused by a lack of access / lack of insurance, since consumers would spend their healthcare money more wisely. That also has not happened. Remember the mortality rates for uninsured Americans vs. insured folks who die from medical error that we presented at the beginning of this chapter.

Our health insurance industry has failed to help patients differentiate high cost, low quality medical care from the opposite. Today's patient may have a vague idea of medical care costs but absolutely no idea the quality.

Consumer Engagement

Health outcomes improve when patients are engaged in their own care. People are eager to play a strong role in their own health care *when given the right tools* according to the US Institute of Medicine.¹⁰⁶

Who, in our medical care landscape, can help consumers acquire the 'right tools'?

¹⁰⁶ Patients Charting the Course, US Institute of Medicine, 2011

I submit that a key candidate is the health insurance broker:

- Doctors are too busy to teach 'tools' while they diagnose, prescribe and treat,
- Carriers, for the reasons explained in this chapter, have basically dropped the 'right tools' ball, and
- Hospitals, also for some reasons discussed above, tend to operate out of economic self interest and would be poor candidates to play this educational role.

Brokers, on the other hand, are the professionals who design benefits program at most companies and who communicate it to employees. Part of the broker role could be employee education – providing the 'tools' described by the Institute of Medicine, above.

Let's turn, in the next chapter, to a discussion of the broker's role in consumer engagement. It's probably not what you expect!

Review Questions answers on next page

1. What is Consumer Driven Health Care?

a. Having consumers make medical care decisions based on price only

b. Having consumers make medical care decisions based on quality only

c. Having consumers make medical care decisions based on prices and quality together

2. What is the correct process of making a medical care decision?

a. Learn the prices first, and then choose the best quality from among the low cost providers

b. Learn the quality first, and then choose the least cost provider from among the top quality providers

c. Learn the necessity first, then learn the quality, then choose the price so you only get necessary, high quality, low cost medical care

3. What do medical care prices tell us about quality?

- a. In general, the highest priced providers are the best
- b. In general, the lowest priced providers are the best
- c. Medical prices tell us nothing at all about medical care quality

4. If two providers have the same quality HEDIS scores but Provider A charges \$1000 while Provider B charges \$2200. Which would a wise consumer choose?

a. This example provides insufficient information for a wise consumer to make an informed choice. We don't know if the procedure is necessary or not and we don't know anything about the patient outcomes from either provider.

b. The wise consumer would choose Provider A because it's less expensive

c. The wise consumer would choose Provider B because it's more expensive, indicating that it's probably better quality

5. What's wrong with using process measures to indicate medical care quality?

a. Process measures only tell us *how* the medical treatment is performed; they don't tell us *how well* the patients did

b. There's nothing wrong with using process measures to learn medical care quality. In fact, medical care providers who use the same process almost always get the same patient outcomes

6. How closely do process measures like HEDIS correlate to patient outcomes?

a. They correlate almost exactly

b. They may correlate well for some procedures and not for others, but, as we have such little patient outcome information, we are unsure exactly which outcomes correlate closely to medical care inputs. Cystic fibrosis patient lung capacity and longevity, for example, varies significantly among providers even though all use exactly the same processes

7. Which, below, do most patients really want to know?

- a. Will I get better?
- b. What are the comparative HEDIS scores at my local hospitals?
- c. How well does my doctor stack up on the HealthGrades ranking?

8. What does 'upselling' mean? How might a medical care provider upsell?

a. Upselling means charging more for hospital rooms on higher floors. A hospital might convince patients that having an attractive view from their window will speed their recovery from, say, eye surgery

b. Upselling means admitting more patients in the gray area between definitely needing to be admitted and definitely not needed to be admitted. An emergency room doctor, for example, might have an hospital admission quota, or be required to admit a certain percent of ER patients into the hospital.

9. What does 5 year survival rate really mean?

a. It means that the treatments have helped most patients live at least 5 more years

b. It doesn't mean very much of anything since the 5 year survival rate clock starts when the cancer is identified. By identifying smaller and smaller cancers through better and better screening technologies, we automatically increase the 5 year survival rates of cancer patients without necessarily having any impact on their date of death

c. 5 year survival rate means that people who read this book from cover to cover are extremely likely to live for at least 5 more years. You can increase this to10 years by buying a second copy.

Review Questions correct answers in bold

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Chapter 3 Consumer Engagement

policy vs. outcome considerations

Brokers and other insurance professionals use terms like 'consumer engagement' and 'informed consumer' in two very different – and sometimes opposing – ways. This can create confusion among subscribers and patients, and even among brokers themselves.

To *risk management professionals* – and the medical community - 'informed consumer' means someone who understands treatment options, risks, benefits and trade-offs. An informed consumer - to risk management folks, for example - might prefer a treatment that *differs* from the one recommended by his/her physician.

A case-in-point: an oncologist might recommend a mastectomy for a woman with early stage breast cancer, based on *his* analysis of the risk-reward tradeoffs. Meanwhile the patient might prefer to watch-and-wait before operating based on *her* analysis. Both analyses may be factually correct, but the doctor and patient value the risks and rewards differently. We saw an impact of this in our Chapter 1 discussion of mastectomy rates in Connecticut and Massachusetts.

An informed consumer, from the risk management or medical point-of-view, thus takes an active role his/her own *medical decision making* and is able to make wise medical care decisions.

To *compliance oriented insurance professionals,* 'informed consumer' means a subscriber who understands the component parts of the health insurance policy and the associated regulations about how to use it.

An informed insurance consumer - to the compliance professional, for example - might prefer to compliment a Health Savings Account with a Flexible Spending Account rather than a Health Reimbursement Account, based on some set of specific medical spending habits and needs. Or the informed insurance consumer might prefer a lower-cost policy that pays for medical services on a reference-based model rather than a higher-cost plan that pays everything over the deductible.

This type of informed consumer is one able to make wise *coverage choices* and use the insurance policy most effectively.

This interview highlights these two different definitions of 'informed consumer'.

The interviewer, Todd McDonald, owner of Aisling Partners, a brokerage firm in Worcester Massachusetts, articulates the *compliance definition*. He wants to help insurance customers understand policy provisions and tax implications so they can use their policies most effectively.

Todd initially wants to leave the consumer alone to decide which medical care is necessary and which providers appropriate; he doesn't, initially, adopt the risk manager perspective. He suggests that the traditional broker advisory responsibility ends when the consumer understands policy provisions.

Meanwhile I use the *risk manager's - or medical – definition* of informed and engaged consumer. I suggest that consumers who are well informed about medical care options will make better choices for themselves, meaning better outcomes at lower costs.

I also suggest that the process of becoming a 'well informed medical consumer' is one that can be taught and learned, though admittedly, it rarely is today. My comments focus on the types of education one needs to become well informed about medical purchasing and suggest that choosing care based on medical quality metrics generally results is lower total care costs, and probably lower insurance costs too.

The savings available from making informed *medical* choices, I suggest, likely trump the savings available from making informed *insurance* choices.

I also wonder who in our medical care system can teach consumers to become well informed about medical care. Doctors? Hospitals? Carriers? Brokers? Or some other entity.

As you read this interview, ask yourself if either definition of 'well informed' is *sufficient* in our evolving healthcare system and market...or if we need to combine *both*.

Todd ultimately suggests that wise and innovative brokers will need to combine both definitions of informed and engaged consumers in order to maintain their advisory role. You can sense his discomfort – and also his excitement – about exactly how to do this.

Do you agree with Todd? Do you think he's being too aggressive, defining the broker's future roll too expansively? Or do you think he's being too conservative by not defining the broker's role expansively enough?

This interview was sponsored by the Massachusetts Association of Health Underwriters and was taped on May 25, 2012. We thank MassAHU for permission to publish this transcript.

Transcript

Todd McDonald: Good morning, I'm Todd McDonald, President of Aisling Partners, a benefits consulting agency located in Worcester Massachusetts and I'm joined by Gary Fradin, President of TheMedicalGuide.

This morning we're going to spend some time talking about consumer engagement. What does it mean? What is it? So welcome Gary.

As I take a look back in time and think about the notion of Consumer Engagement and Consumer Driven Health Plans, I keep wonder 'what is it'? Ten years ago we saw the introduction of annual deductibles, high deductible health plans sometimes called CDHC or Consumer Driven Healthcare, I think that was the introduction of consumerism in healthcare. The challenge was the lack of data, the lack of information and so forth. So Gary, in your mind, what is consumer engagement?

Gary Fradin: Great question. You started off with a hard one.

I think consumer engagement means helping healthcare consumers – patients – make medical decisions the same way they would make car-buying decisions, or refrigeratorbuying decisions. Use the same types of criteria, ask the same types of questions and bring all the skills that we have developed as a society that make us great consumers to medical care. I think we'll have tremendous benefits, both for the patients and for healthcare costs.

So I'd say consumerism in medical care means the same thing as consumerism in automobiles and other products.

TM: And in automobiles, for those of us buying a new car, you can go online, you can research, you can find out what a dealer paid for the car, the mark-up and all of that.

I think the challenge that we've had in healthcare historically is the lack of information, the costs and quality. So let's talk a little bit about that. What you say seems to be straight-forward, seems to make sense to me in the role that I play as a benefits advisor to companies.

Why is there such a challenge to make it happen? What are the barriers to entry to consumer engagement when it comes to this type of consumerism?

GF: Barriers to entry. Tough question.

There are probably lots of barriers to entry. The one that strikes me as most significant is the fact that we have relatively lousy outcome data about medical care. We simply don't know what works well, what works badly, and exactly *how well* it works.

It's like buying a car if you don't know the miles per gallon. Maybe we can get some pricing information. But if a car dealer tells you a car gets good gas mileage, does this mean 16 miles per gallon or 41?

In medical care, we hear things like 'that's a risk factor for having a heart attack' or 'that's a risk factor for cancer' and this is a good treatment. Well...*how much* of a risk factor, *how good* of a treatment and how will it affect <u>me</u>? Those are questions that we're increasingly starting to focus on and we're developing some data to help us get those answers.

TM: What's interesting in the role that I play with clients is that consumer engagement really plays out around product design. The various health insurance carriers have created over the past several years, new products designed to engage the consumer. Deductibles, co-insurance and things of that nature. We have products today designed to get consumers to make decisions, to learn where providers fall within certain tiers for example, limited networks.

So from a product standpoint there's this notion of consumer engagement, working with employers and employees to understand product.

From your perspective and the topic that we really want to get into today, beyond insurance products, beyond 'where do I go, what hospital is in-network', you're talking about consumer engagement at the physician level, at the choice level, is there an overabundance of prescriptions, of unnecessary medical care. Let's talk a little bit about that from your perspective.

GF: Let me make a couple points because you're raising critical issues here.

One is that researchers estimate, based on lots and lots of medical studies, that we waste up to 1/3 of all medical spending on unnecessary medical care. That's care that can't help you – because it's unnecessary – but costs you money and could potentially actually harm you.

The lowest range of estimates that I've seen is 20%. That's from Donald Berwick who ran Medicare for a couple of years. The commonly accepted estimate of medical waste is up to about 1/3 of care that generates 'no detectible benefit'.

That estimate hasn't changed despite plan design changes. We still waste up to about a third.

My comment about plan design changes is that carriers and regulators have tried to organize our healthcare delivery system to become more efficient and cut down on unnecessary care through iteration after iteration after iteration over the past over the past 20 or 30 years, and we have always seen healthcare inflation running about double CPI (the Consumer Price Index inflation rate) or about double the GDP growth rate. We haven't seen that fall significantly despite plan design changes.

I don't think this is a regulatory issue – reducing unnecessary care – and I don't think it's a plan design issue, although high deductibles seem to have some impact. I think the way to reduce unnecessary spending is to educate consumers, educate patients and show why it's in their interest not to get unnecessary care. It doesn't benefit them – it might hurt them.

TM: Let's talk about that a little bit. My firm provides advice and guidance to clients. We do it at the employer level and at the employee level. We have benefit communication meetings and so forth. From your perspective, what are the tools and resources available? What tools exist to engage consumers outside of products, outside of plan designs?

GF: I think that those tools are being developed. We're starting to get the relevant data about quality so people can make medical decisions based on care quality, not necessarily price.

Nobody wants to get bad quality care. Forget price for a moment. I have yet to hear a parent say 'times are tough, we're cutting back on medical care quality for our kids'. I've never heard that. I always hear parents say 'I don't care what it costs, I want my kid to get the best care he or she can get.'

One tool that we've been working on a lot is called the Number Needed to Treat. Teaching consumers to ask their doctor 'what's the Number Needed to Treat with this medication, this medicine or this screening test?' NNT simply tells you how many people have to have a medical procedure or take a medication in order for 1 person to benefit.

TM: Can you give an example.

GF: Sure, I can tell you about cholesterol lowering medications. Lots of people think that high cholesterol leads to heart attacks.

Study after study after study has suggested that people with high cholesterol – using all kinds of different definitions of 'high' cholesterol, these are generally industry funded studies – suggest that about 3 people out of 100 with high cholesterol will have a heart attack in the next 4 or 5 years. Roughly, approximately 3 out of 100. Some studies show somewhat higher rates. These are folks who don't have heart disease.

If you reduce your cholesterol with a statin, you bring that number from about 3 having a heart attack out of 100 to about 2 having a heart attack out of 100.

In other words, you have to give 100 people a statin for about 4 years to prevent 1 heart attack. The Number Needed to Treat is about 100.

Let me make 2 points going in 2 different directions here. Some commentators have suggested that insurance not pay for interventions that have a Number Needed to Treat greater than 20. An NNT of 20 means that only 5% of people benefit. So if you learn the Number Needed to Treat, you can learn how efficient or how effective this medical intervention is, so you can choose.

The sister, or cousin if you will, of Number Needed to Treat is Number Needed to Harm.

TM: NNH?

GF: Yes, NNH. Obviously that tells you how many people have to take the medication for 1 person to be harmed.

Let me tie all this together and refer to what Dr. David Newman of Columbia Medical School claims. Knowing the Number Needed to Treat and Number Needed to Harm is basic medical literacy. If you don't know these numbers and you can't discuss them, then you're medically illiterate. It's sort of like an accountant saying 'you made money, but I don't know what your earnings per share were, or exactly how much you made'.

TM: So is your expectation that individual consumers should know their own NNT and NNH information and should know these facts and be able to go into a physician and discuss them?

I guess I'll use myself as an example. I happen to have had, 2 days ago, my annual physical. I went in and had my 12 minutes with my doctor and part of the discussion was, ironically, around cholesterol. There have been a lot of articles about cholesterol and statins and the danger of them.

I thought I was being a good consumer, I thought I was engaging by simply asking my doctor and challenging the notion of whether or not I should remain on a statin. And my doctor's comment to me was that the belief still is that the rewards of being on a statin outweigh the risks.

My doctor went on to say 'if it's of any help, Todd, I too am on a statin and have been, so I would not be prescribing something to you that I myself am actually not engaged in taking.'

From my standpoint as someone who is in this industry and do what I do, I felt that I had become a better consumer, that I engaged in the process more by asking questions and actually challenging the notion of remaining on this, asking about the risks and rewards. I'm not sure that many people take the step that I took.

But I get the sense from our discussion certainly that there's more to do, more questions to ask and that I should be armed with NNTs and NNHs and so forth. Is that true?

GF: I think so.

First, let me make one point very strongly: if you're comfortable with your doctor, do what your doctor says. I in no way want to make people uncomfortable. That is dysfunctional all the way through.

But I hesitate to rely very much on your doctor's story about himself. Your doctor may have different risk tolerances from you. He may have different orientations. Different family background and genetics. He may or may not exercise the same as you. He may have all kinds of different risk factors. And his decision criteria may not be the same as yours.

To some extent, and I don't want to belittle doctors, I'm not trying to do that, but to some extent this is like when you buy a used car and you go to a dealer with lots and lots of high quality used cars. You look at a Ford Taurus. The salesman says 'well, I drive a Ford Taurus' suggesting a personal endorsement for how good this car is. OK, but I don't know how he made his decision. Does he drive young kids around? Does he schlep hockey equipment? Is his wife a baker and he makes deliveries for her? Did he get a particularly good deal on a used Taurus, when, perhaps, he would have preferred a Honda Civic? I don't know how he made his decision.

And I don't know how your doctor made his statin decision. Lots of studies suggest that when patients are well informed about their treatment options, they often choose differently from their doctors. That's why I think you have to know what the outcome numbers are.

Remember, doctors learn how to calculate the Number Needed to Treat and Number Needed to Harm in medical school. But they don't talk to patients about it because they figure that in 12 minutes, they don't have time to teach this to a patient.

But if you go in and ask the question, and say 'I will take a medication that you prescribe, but I want to know the NNT, I want to know the Number Needed to Treat so I know how well it works. In fact, I want to know the Number Needed to Treat for 2 or 3 different options, and then I want to choose the best. And I don't want to take a

medication if you don't know how well it's going to work for me.' That's how I would offer for consumers to engage with their doctors.

TM: And I like it. I truly do. The question is how to get consumers to be able to take that step, to have the comfort and the confidence to be able to challenge their physician, question their physician – and I don't mean that in a negative or derogatory sense – but to give them the comfort and the confidence.

Is there data or resources – are there any tools available that I could use, prior to having gone to my physical 2 days ago, any resources that I could have reviewed or tools that I could have evaluated to make me a better consumer and a more engaged consumer, by asking particular questions?

GF: Sure. In fact we have a website that does this in quite a bit of user friendly detail.

Let me go through four simple questions that we sometimes suggest people ask prior to, or during, their appointments about preventive medications, simply as an example here.

Question #1: Out of 100 people like me, how many will have the bad medical event without taking medication? In other words, out of 100 people with high cholesterol like me, how many will have a heart attack? In the statin example, we said about 3. If your total cholesterol level is 350, it might be 5. It might be 6. If your total cholesterol level is 202, it might be 2. Remember, you're asking 'out of 100 people <u>like me</u> how many will have the bad event?' You want to know *your* risks, not necessarily average or theoretical risks.

Question #2: Doc, if I take the medication, if I have the screening test, if I have the medical intervention, then **out of 100 people like me, how many will** <u>still</u> have the **bad event?** Because we know that medicine doesn't work perfectly all the time.

Question 3: Out of 100 people like me, how many actually benefit from the medication by avoiding the bad medical event? Get the number.

And Question #4: Out of 100 people like me, how many are harmed?

These are simple questions. You would ask these of a car dealer, in a different form of course. You would ask these if you're buying a refrigerator. You would ask these types of questions about many different products.

TM: I think that's the key. When you say 'ask'...we're a society that has just taken advice, taken whatever is said by our doctor, trusting it, doing whatever is prescribed, and I think we're at a day and an age where it's so complex.

In the health insurance world, we engage around products, tiers, networks, HRAs, HSAs, FSAs, and so on. For many of us, when we think of consumer engagement, we think of doing a better job of educating the consumers on product and product design.

You're talking about a completely different, though interwoven piece, saying that the consumer or the patient needs to ask questions and understand *medically* what steps need to be taken.

GF: Yes. Let me turn this into a question for you. We're entering a high deductible world where people are starting to spend their money 'more wisely'.

High deductibles give you the opportunity to spend your money more wisely. Somebody has to educate people about *how* to spend their money more wisely.

Where in our healthcare distribution system does that entity lie?

- Is it physicians you have 12 minutes per year. Is that the right entity?
- Is it the hospital are they going to teach you which questions to ask about your medical care?
- Is it the insurance carrier? The problem with the carrier is we all know why a carrier would tell you about unnecessary care. They want to save money. Or, at least, that's the cynical public perception.
- Is it the employer, who's probably pretty busy making widgets, especially during a recession. They don't have a lot of extra resources to teach about medical care.

Where in our healthcare distribution system – our medical distribution system – is there an entity that can take on the responsibility of doing this teaching so we can reduce the 33% waste factor, besides the broker?

TM: I don't think there is, and I think that of all the stakeholders, the various people involved in the process, none others of them have the ability, the bandwidth, the time to do that, and I think you make a very valid point.

It's just an interesting dynamic that for 20 years I've been in the business. We provide advice and guidance and council to employers, more and more to employees, now the notion of wellness which engages a whole different element to all this.

Now all of a sudden, in the role that we play, thinking about education and engagement at a completely different level. To talk about NNTs and NNHs, what questions to ask

your provider. It's a completely different way to proceeding, a completely different approach. And at the same time, critically important.

GF: Let me ask you a question.

TM: Please.

GF: You said that at your physical a couple days ago was the first time you pushed back and challenged your doctor. Why? You've had a physical presumably every year for many years. Why now? What happened this year?

TM: A little more knowledge, a little more understanding. Certainly the likes of folks like you. News and information is becoming greater. I don't simply want to take the status quo as many of us have done, when the doctor gives a prescription we take it without asking.

I think the notion of statins and harms and long term effects have really resonated with me and have caused me to push back on that particular item.

I think in general, we can all agree that our healthcare system is flawed, at many levels.

You mentioned waste before, 33% waste. Above and beyond all of that, for me to go in once a year for my personal health, and literally have about 12 minutes to ask questions, review data, update personal information and all that to me is challenging and troubling. I need to become my biggest and my own advocate for my own healthcare.

And I think getting back to your original question 'why this year?' I think because more information is available. We are changing and I think there's a dynamic going on in our industry where we need to challenge where we need to be, in the role that we play providing advice and guidance beyond product, beyond solution, beyond all of that to provide advice and guidance at the employee level.

GF: I think it's really interesting when you make the point about more information becoming available. That resonates with me. More and more information is becoming available to consumers. I think we run the risk of having information overload. The question is 'what information is really useful?' What information is bogus or biased or not terribly useful? How does a consumer figure that out?

TM: Gary, that's a complete struggle for me and I'm sure for just about every consumer. What is the right information? If I read the Harvard Business Journal, that's one piece of information. If I read another article, another book...it's very challenging to know what

information is accurate. From which stakeholders does this information come and is there any bias or connection back to a provider or manufacturer?

Maybe I can turn this back to a question for you. As a consumer, how do I navigate my way through the various information channels to arrive at what I think is good, solid accurate information so that I can make good, solid, accurate personal choices?

GF: I think that's the question that highlights the broker's role.

A broker clearly can't give medical advice. They're not licensed for this. And a broker can't say 'here is a procedure that works and here is a procedure that doesn't work' according to some study. That's not the broker's role.

It seems to me that the broker's future role and the growth of this part of the business is teaching people the questions to ask. If you ask the right question, you have a pretty good chance of getting the right answer. But if you don't ask the right questions, then you may get all kinds of misinformation or confusing information or biased information.

We at TheMedicalGuide try to simplify this by, for example, asking the 4 questions that we discussed a few minutes ago to determine Out of 100 people like me, how many will be harmed?, Out of 100 people like me how many will benefit?

We try to simplify the process by teaching people to ask questions about the Number Needed to Treat and Number Needed to Harm. I should probably add that we teach questions to ask about lots of different kinds of medical interventions.

I guess my feeling is that if brokers can put on consumer engagement programs and courses for their subscribers that help people ask the right questions of their doctors, then we've gone a big step. We've made progress. And Step 2 I can't tell you about yet. I don't know what it is!

TM: Going back to your question - when you have all these stakeholders and providers being part of the equation, who is best served to do it – for someone who spent 20 years in this business, I have an initial challenge, internally, to think that I am the one, and my firm is the one, to provide consumer engagement at a level that gets so specific to medical care and so forth.

At the same time, I can see the validity to this and that many of us can't hide behind the notion that consumer engagement is teaching and educating about product and all of the elements that go along with that. It's a challenge. It's a shift in thinking for me.

GF: Do you think, as a business owner, you can avoid getting involved in this kind of consumer education?

TM: I don't. I truly don't.

The question is when? How quickly? How broad of a spectrum? How deeply? It's a challenge. I say this openly, it's really a shift. It's a mental shift to think of the role that we play and how we will engage the consumer at a completely different level.

At the same time, it's tremendously exciting.

And then beyond all of that, the complexities to everybody. As we sit in the roles that we play as advisors to employers and employees, you have new products – with all sorts of functionality and limitations, with tiers and networks, and the account based elements of HSAs, HRAs and all that. It has become so complicated. My point being that complexities at the product level and at the distribution level are just immense and enormous, and then you fold in another component and layer.

I guess trying to understand it and articulate it, and taking it back to the role that we play, I have to wonder and ask 'how do we do this?' What is the first, best step for us to do it? I guess I'll put that to you. There was a question, or at least a thought of a question in all that.

GF: I think it's very thought provoking. I don't have an answer. As you were talking, I was thinking about that famous Chinese curse or blessing 'May you live in interesting times.' Yes, it is tough to navigate the future.

Look, it's always tough to navigate. It's always tough to run a small business. I guess the first step I would say to brokers who want to get into this brave new world is to become familiar with some of these consumer aids, these medical decision making aids, to become familiar with this part of the business, and on a case-by-case basis work it in. I wish I had a better and more complete answer.

TM: But I think that your answer is representative of the stage we're at in the development of all this. I truly do.

One of the things that comes to my mind, and I certainly want to garner your perspective on, is this notion of cost and quality. It's at times such a nebulous thing, where many carriers, going back to the product designs, and consumer engagement at the product level, is about cost and quality.

Your thoughts on cost vs. quality, the importance of it. Is cost a real driver and issue or do you believe quality prevails, that someone is going to request and require quality without much notion of cost?

GF: I think transparency is clearly both. You have to know price. You don't want to get the same quality for \$2000 that you can buy for \$600.

But I think that the first step, the driving force, is quality. Everyone wants the best medical care they can get for themselves and their family. One of the reasons that so many people use expensive hospitals is that we equate higher costs with better quality care. Or high credentials with better quality. Or medical school affiliation with better quality. I think people want quality. Then, if you find 2 procedures that have the same NNT and the same outcomes, then sure, go for the least expensive one.

I would warn people against assuming that you can learn something about the care quality from the price, because you can't. A broker once said to me 'this quality information is too complicated. If you assume the quality is all the same, then you can shop based on price'. My response was 'besides that Mrs. Kennedy, how was your trip to Dallas? I heard you had a nice breakfast.'

The ballgame is quality. And price is a secondary consideration. I have yet to meet a person who wants poor medical care, and I have yet to meet someone who wants the cheapest *un*necessary medical care. I only meet people who want good, necessary care.

TM: I think you bring up a great point, and the challenge that we see every day is also the waste in care. People don't want bad care, but I think it still goes back to waste. It goes back to that 33% waste factor, it goes back to how the system is currently structured, and I think that is a tremendous challenge. The complexities of the system. Waste continues to be an issue.

But getting back to your NNT, unnecessary care ideas, are these regional? National? International? Is this about how our healthcare is structured here or is it relevant beyond state and even national boundaries?

GF: I think all healthcare consumers in all countries have the same questions. I think all parents want good care for their kids, all sick people want good care for themselves, and if you're in a government funded system, a privately funded system, or a mixed system, you as the consumer still have the responsibility for asking the right questions and getting the best care for yourself. So I don't think the structure of the system matters for consumer responsibility and engagement. I think people are all the same – they all want good medical care. No one wants to have unnecessary care that won't help them but might harm them.

Research is currently being done on all these different kinds of metrics all over the world, with researchers having the same fundamental question: how can we identify

good, high quality, necessary care as opposed to poor, unnecessary, low quality, wasteful care. Everyone is interested in the same thing.

My guess would be that there will be an explosion of knowledge in this whole quality arena in the next decade or so. The early adopter brokers who start to educate their clients now, start to learn the programs now, start to learn what this is all about now will put themselves in an awfully strong position as all of this evolves to capitalize on it and grow their businesses in the future.

TM: I think that's a great point. I think that's something that brokers like me need to be mindful of. We have been, and continue to be moving away from product based sales, product based advice and guidance to become a true benefits consultant. I think it's a tremendous opportunity personally for those willing to engage.

GF: It's exciting.

TM: It's tremendously exciting. I think we as brokers have a role to play and I think a unique one. The other stakeholders that we don't believe are equipped to participate in this consumer engagement process, my hope is that that changes at least in some capacity. We really need them to be part of the equation in some way, shape or form, so this becomes a collaboration.

GF: I would agree with that.

TM: This has been a tremendous dialogue.

GF: Yes, it's been interesting. You asked good questions.

TM: Thanks. Hopefully this has been useful to the people watching who want to learn more about the consumer engagement process.

We've discussed a tremendous spectrum of what it means and what it is. Historically, engagement has been around product – how can we engage consumers around products, so they best utilize the plan that they have chosen.

But today we've discussed taking this to a different level and really getting to the medical aspect of consumerism and consumer engagement...asking questions, understanding outcomes, a completely different aspect to the world of healthcare as it stands today. Gary, thank you for your time, your comments, your insights...

Review Questions answers on next page

1. What does the medical care industry mean by 'well informed consumer'?

a. Someone who understands treatment options, risks, benefits and trade-offs

b. Someone who understands deductibles, copayments and other components of his/her health insurance policy

c. Someone who has done lots of online research about his/her medical condition

2. What does the *health insurance* industry generally mean by 'well informed consumer'?

a. Someone who understands treatment options, risks, benefits and trade-offs

b. Someone who understands deductibles, copayments and other components of his/her health insurance policy

c. Someone who has done lots of online research about his/her medical condition

3. About how much impact does *plan design* have on the amount of *unnecessary medical care*?

a. Very little, as evidenced by the fact that we still waste up to about a third of all healthcare spending on care that generates no detectible benefitb. A great deal, as evidenced by the fact that we have cut our rate of unnecessary medical care dramatically over time

4. What impact has plan design had on the rate of medical inflation over time?

a. Very little impact. We still spend see medical spending growing at about 2 to 3x the overall inflation rate

b. Very big impact. The medical inflation rate has fallen below the overall inflation rate in the past few years

5. What does this statement mean from your doctor: "I too take a statin to control my cholesterol"?

a. That you and your doctor have exactly the same medical conditions and exactly the same orientation to care, so you too should take a statin
b. That statins are good for almost everyone

c. It doesn't mean much of anything since you and your doctor may have different genetics, exercise routines, diets, orientations to care, treatment preferences and risk tolerances

6. Which professional entity seems best positioned to teach consumers how to choose their medical care more wisely?

- a. Doctors
- b. Nurses
- c. Health insurance brokers
- d. Pharmaceutical salespeople

7. This interview suggested a new frontier in employee engagement and education. What is it?

- a. Teaching employees which medical information is useful and which is not
- b. Developing fixed commission products
- c. Selling more disability and voluntary products

8. Which activity will likely have the greatest impact on medical care cost reduction?

a. Teaching employees how to avoid unnecessary medical care

b. Developing narrower provider networks with higher barriers to switching from one network to another

- c. Expanding the use of HRAs
- d. Restricting access to primary care physicians

9. A broker once said 'this quality information is too complicated. If you assume the quality is all the same, then you can shop based on price'. What's wrong with this?

a. Everything. Quality is the ballgame. No one wants the least expensive, poor quality unnecessary medical care

b. Nothing. This is a quick and dirty way to summarize medical care purchasing to employees with high deductible plans

10. Over the course of this Interview, how does Todd McDonald's position change?

a. He's initially skeptical about having brokers inform patients about how to use the medical care system – preferring to inform patients only about how to use their health insurance – but by the end, he's excited by the opportunity to engage employees on a whole new level. He suggests that this may be a key future component of the 'benefit advisors' role

b. He thinks the broker's role is and always will be to teach about how to use their benefits but not to engage consumers about how to use the medical care system and to ignore the existence of, and impact of, unnecessary medical care.

Review Questions correct answers in bold

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Chapter 4 Sickness Metrics and some cost implications for your clients

We commonly define 'sick' in this country by a number. For example

- If your diastolic blood pressure (the top number) is 150, we say you have hypertension
- If your total cholesterol is 240, we say you have high cholesterol
- If your fasting blood sugar is 145, we say you have diabetes

People whose numbers indicate that they are 'sick' access medical care to make them well.

This Chapter will discuss some issues raised by numerical definitions of sick. Remember as you read this: our medical care system can help you – often tremendously – if you're really sick. But it can't provide much benefit to you if you're healthy. Our tendency to define health by numbers may conflate the two.

Unfortunately, far too often, these numerically-labeled sick people are really healthy and medical interventions actually make them *worse* off.

The dictionary defines sick as 'ailing', 'affected with nausea', 'inclined to vomit' and similar.¹⁰⁷ Numerical definitions, such as we commonly use today, flip this definition on its head. Numerical definitions mean 'you have a likelihood of having a future bad medical event'.

You no longer need to be ailing or affected with nausea to be sick. In fact, you can work, play tennis, ski, socialize and feel fine but be 'sick' at the same time!

Once, however, you exceed the 'sickness number' – for example, total cholesterol over 220 or so - your doctor can prescribe medications for you and your carrier will, by and large, pay. There are potentially millions of dollars in play based on the numerical definitions of sick. As the definitions expand – and label more people as sick - so too do the potential markets for pharmaceutical and other medical products.

Numerical disease definitions therefore have both medical and financial implications.

Defining sick by a number presents two key problems:

• Who decides which numbers qualify as sick? and

¹⁰⁷ Dictionary.com

• How accurately do these numbers predict your likelihood of having a future medical event?

Let's address each of these.

We increasingly define 'sick' by a number.

That number indicates a likelihood of you experiencing a future medical event.

How closely do these numbers actually indicate future medical events? Stay tuned...

Who decides which numbers indicate sickness?

By and large in this country, the Department of Health and Human Services relies on ad hoc Expert Committees for advice on these matters.

Congress established a system to create and operate Expert Advisory Committees for many different branches of the federal government in the Federal Advisory Committee Act of 1972. ¹⁰⁸ These committees report to various cabinet secretaries. There are hundreds of such committees advising the government on lots of different issues including ¹⁰⁹

- The Advisory Committee on Cemeteries and Memorials
- Task Force on Lead Based Paint Hazard Reduction and Financing
- The Advisory Committee on Presidential Libraries
- Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, and
- Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, among hundreds more.

Members are appointed by the appropriate Cabinet Secretary, for example in medicine by the Secretary of Health and Human Services, and generally include recognized experts in the field.

¹⁰⁸ Originally Public Law 93-463, updated over the years

¹⁰⁹ http://www.fedgate.org/comlist4.htm

One such expert is Dr. James Gavin III, MD, PhD, Chairman of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus that issued its report in 1997. Here are some highlights from his resume: ¹¹⁰

- Clinical Professor of Medicine, Emory University Medical School and Indiana University Medical School
- President of the Morehouse School of Medicine
- National Chairman of the National Diabetes Education Program
- 'Living Legend in Diabetes' award winner from the American Association of Diabetes Educators

Dr. Gavin is clearly an expert in his field and, based on his resume, seems appropriate to serve on an expert committee that evaluates diabetic care in this country.

He also worked with, owns stock in and received payments from pharmaceutical companies that manufactured medications and devices for diabetics, including ¹¹¹

- Amylin Pharmaceuticals, from which he received \$236,578 in 2011,
- Baxter International, from which he received \$239,021 in 2011, and for which he served as Director since 2003, ¹¹²
- ARCA biopharma, in which he owned 25,000 shares in 2006.

He was Chairman of the Board of Equidyne Corporation as of 2003, a company that manufactured and marketed a needle-free drug injection device at the time. ¹¹³

All of this may suggest a problem since Dr. Gavin could benefit financially if his committee made certain recommendations about diabetes treatment - for example, if his committee recommended using the drugs manufactured by Amylin, Baxter or ARCA.

¹¹⁰ <u>http://www.forbes.com/profile/james-gavin/</u>, downloaded December 24, 2012. The committee's report is available in the Diabetes Care Journal issue of January, 2003, http://care.diabetesiournals.org/content/26/suppl 1/s5.full#ack-1

¹¹¹ Ibid. I couldn't determine Dr. Gavin's financial relationships with pharmaceutical companies in the late 1990s and earlier 2000s during my web searches.

¹¹² http://www.baxter.com/about_baxter/corporate_governance/company_leadership/gavin.html

¹¹³ http://www.aetna.com/foundation/aahcalendar/1993gavin_bio.html

The 1997 committee, of which Dr. Gavin was chair, recommended lowering the threshold for diabetes from fasting blood sugar >140 mg/dl to > 126. People with fasting blood sugar between 126 and 140 were now categorized as 'sick' whereas they had previously been 'not sick'. This redefinition created about 1.6 million new diabetics. ¹¹⁴

It also increased the market for diabetes drugs by about 1.6 million potential customers. Companies like Amylin, Baxter and ARCA could sell more of their products as a result. Presumably their stock value and revenues would increase and, as a result, Dr. Gavin would benefit.

None of this is, of course, illegal, and I don't necessarily want to single out Dr. Gavin, who I don't know and have never met, personally. He's an example of the type of expert we use in this country – people who can gain financially if they provide certain kinds of advice.

This combined role – expert and investor – makes many uncomfortable.

The government requires experts to disclose their financial situations so observers – in our case physicians, patients and researchers - know of any potential bias in the expert's reports. The apparent theory: requiring this financial disclosure will ensure that the report writers will go out of their way to write objectively and readers will understand the potential biases and compensate for them when considering the expert's advice.

This situation – where experts have a financial interest in the impact of their report – occurs in virtually all the medical expert committees that advise the government on medical affairs. Here's another example:

Many of the experts who wrote and updated the Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III or ATPIII)¹¹⁵ – that's the report that lowered the definition of 'dangerous total cholesterol' to greater than 200, written and updated in 2002 and 2004 – were compensated by companies that manufactured cholesterol-lowering or other coronary related drugs. Here's the financial disclosure information from the complete list of experts who wrote the 2004 version: ¹¹⁶

¹¹⁴ Estimate of the increased number of diabetics comes from Gilbert Welch, Overdiagnosed, page 23

¹¹⁵ <u>http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf</u>

¹¹⁶ ATP III Update 2004: Financial Disclosure at

<u>http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3upd04_disclose.htm</u>. This is a public document. I downloaded it entirely to avoiding casting aspersions on any individual. I couldn't find a financial disclosure statement for the 2002 report; I don't think it exists.

Dr. Grundy has received honoraria from Merck, Pfizer, Sankyo, Bayer, Merck/Schering-Plough, Kos, Abbott, Bristol-Myers Squibb, and AstraZeneca; he has received research grants from Merck, Abbott, and Glaxo Smith Kline.

Dr. Cleeman has no financial relationships to disclose.

Dr. Bairey Merz has received lecture honoraria from Pfizer, Merck, and Kos; she has served as a consultant for Pfizer, Bayer, and EHC (Merck); she has received unrestricted institutional grants for Continuing Medical Education from Pfizer, Procter & Gamble, Novartis, Wyeth, AstraZeneca, and Bristol-Myers Squibb Medical Imaging; she has received a research grant from Merck; she has stock in Boston Scientific, IVAX, Eli Lilly, Medtronic, Johnson & Johnson, SCIPIE Insurance, ATS Medical, and Biosite.

Dr. Brewer has received honoraria from AstraZeneca, Pfizer, Lipid Sciences, Merck, Merck/Schering-Plough, Fournier, Tularik, Esperion, and Novartis; he has served as a consultant for AstraZeneca, Pfizer, Lipid Sciences, Merck, Merck/Schering-Plough, Fournier, Tularik, Sankyo, and Novartis.

Dr. Clark has received honoraria for educational presentations from Abbott, AstraZeneca, Bristol-Myers Squibb, Merck, and Pfizer; he has received grant/research support from Abbott, AstraZeneca, Bristol-Myers Squibb, Merck, and Pfizer.

Dr. Hunninghake has received honoraria for consulting and speakers bureau from AstraZeneca, Merck, Merck/Schering-Plough, and Pfizer, and for consulting from Kos; he has received research grants from AstraZeneca, Bristol-Myers Squibb, Kos, Merck, Merck/Schering-Plough, Novartis, and Pfizer.

Dr. Pasternak has served as a speaker for Pfizer, Merck, Merck/Schering-Plough, Takeda, Kos, BMS-Sanofi, and Novartis; he has served as a consultant for Merck, Merck/Schering-Plough, Sanofi, Pfizer Health Solutions, Johnson & Johnson-Merck, and AstraZeneca.

Dr. Smith has received institutional research support from Merck; he has stock in Medtronic and Johnson & Johnson.

Dr. Stone has received honoraria for educational lectures from Abbott, AstraZeneca, Bristol-Myers Squibb, Kos, Merck, Merck/Schering-Plough, Novartis, Pfizer, Reliant, and Sankyo; he has served as a consultant for Abbott, Merck, Merck/Schering-Plough, Pfizer, and Reliant.

The process of having advisors gain financially if they give a certain kind of advice raises questions about the expert's objectivity and incentives. As I write this, I remember Upton Sinclair's pithy comment ¹¹⁷

It is difficult to get a man to understand something when his salary depends on him not understanding it.

How impactful is the financial relationship between experts and industry? One scholar who has looked into this, Professor David Diamond of the University of South Florida,

¹¹⁷ Sinclair Lewis, *I, Candidate for Governor and How I Got Licked*, page 109

suggests that Dr. Grundy, Chair of the ATPIII Expert Committee, received about \$150,000 annually from each of 10 different pharmaceutical companies for a \$1.5 million total. ¹¹⁸ That's 1.5 million pretty good reasons to 'understand something' in Upton Sinclair's words.

Diamond also quotes Dr. George Mann, Professor and Nutritional Biochemist at Vanderbilt University as saying

No sensible person can avoid the conclusion that the NCEP (National Cholesterol Education Project) is an expensive fraud perpetuated by avaricious business enterprises and dishonest scientists.

Who's right here? Did the Experts do a really good job and issue an objective, high quality report about cholesterol? Is their definition of 'sick' being total cholesterol above 200 appropriate? Or did they write a poor report to satisfy their industry paymasters? Do financial disclosure statements matter? What impact does the industry affiliation of so many experts really have?

Three scholars, Daylian Cain, George Loewenstein, and Don Moore from Carnegie Mellon University writing in the Journal of Legal Studies suggest that Upton Sinclair and Professor Diamond were on to something with their observations and that, in fact, financial disclosure may actually make matters *worse*, not better, by leading to *more* corrupt advice that otherwise.¹¹⁹

Disclosure, they found, can *increase* the advice bias because it leads advisors to feel morally licensed and strategically encouraged to exaggerate. After all, they've already told you that they're biased.

In fact in an experiment, Cain and the others found that disclosure led to 'greater distortion of advice' and the *more* an expert disclosed, the *greater* the distortion.

Here's an analogy. Salespeople sometimes put on 'educational' seminars. Attendees understand the goal: the salesperson wants to sell his/her product. They understand that the salesperson may use data selectively, may emphasize certain information and may ignore information that doesn't show his/her product in a good light.

¹¹⁸ David Diamond of the University of South Florida and J.A. Haley Veteran's Hospital, Myths and Misinformation About Saturated Fat and Cholesterol: How Bad Science and Big Business Created the Obesity Epidemic, <u>http://www.cas.usf.edu/news/Diamond_USF.pdf</u>

¹¹⁹ Cain, et al, The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest, Journal of Legal Studies, Jan 2005

Using the terms from the Journal of Legal Studies article, salespeople feel *morally licensed and strategically encouraged* to exaggerate: they've already given you fair warning. Wise attendees are, therefore, appropriately skeptical of the presentation's validity because they understand that someone is trying to sell them something.

Financial disclosure statements are somewhat similar. They tell the public that the expert may be biased and use data selectively, may emphasize certain information and ignore other that doesn't help make his/her case.

In other words, experts who file financial disclosure statements announce that they may try to sell you something. The financial disclosure statement can turn their expert report into a sales presentation, or at least can give the wise consumer that indication.

Cain's research suggests that once the financial disclosure form is filed, the expert may feel morally licensed and strategically encouraged to exaggerate. The expert may figure that wise readers will discount his/her conclusions because they now know they're biased so the expert needs to *overcompensate*.

I don't know if Cain is completely correct here, but I doubt that many people read expert medical committee reports sufficiently skeptically.

But my bigger concern: financial disclosure, such as we currently require of our committee experts, may fail to solve the biased presentation problem created by conflicts of interest *and may sometimes even make matters worse* to quote Cain and his colleagues.

The experts who make up Expert Committees often have financial relationships with pharmaceutical and similar medical device companies.

This can give the appearance that the experts have an incentive to expand the market for the pharmaceutical's products.

The disclosure of this financial relationship probably doesn't suffice to protect the public from biased analysis.

How closely do the 'numbers' relate to sickness?

The expert committees that define sick have an explicit, narrow focus: not to miss anyone who could possibly benefit from diagnosis and treatment. If expert committees err, they err on the side of caution by setting expansive disease definitions. **Sometimes they miss a broader perspective.** Here's an example, showing how 'healthier' people (according to one number) can actually die more frequently. ¹²⁰

The National Institutes of Health had a randomized blood sugar reduction trial starting in 2003.

- 5,000 people received so-called 'intensive' drug therapy to reduce their blood sugar level below 126;
- 5,000 others had less intensive treatment aiming for more modest sugar level reductions.

The intensive therapy group got their average fasting blood sugar level down to about 116 (below the diabetes threshold and therefore 'healthy') and the other group got their level down to about 130 (above the diabetes threshold and therefore 'sick').

But the healthier, intensive therapy group members died at a higher rate! In addition, hypoglycemia requiring assistance, and weight gain of more than 20 lbs, were more frequent in the intensive-therapy group.

The researcher's conclusion:

the use of intensive therapy to target normal glycated hemoglobin levels for 3.5 years increased mortality...These findings identify a previously unrecognized harm of intensive glucose lowering in high-risk patients with type 2 diabetes.

In 2011, the BMJ published a summary of 13 studies on the impact of reducing the blood sugar levels in 33,000 people.¹²¹ According to James Wright, a co-author of the BMJ study:

One would expect that lowering glucose levels to normal would make people live longer; but we could find no reduction in mortality in these trials. If anything, mortality was increased by 4% in the people treated intensively.¹²²

¹²⁰ <u>http://www.ncbi.nlm.nih.gov/pubmed/18539917</u> Same reference for the Researchers Conclusion. See also Welch, Overdiagnosed, page 19 for an easy-to-read description of the same study.

¹²¹ Boussageon, et al, Effect of intensive glucose lowering treatment on all cause mortality, cardiovascular death, and microvascular events in type 2 diabetes: meta-analysis of randomised controlled trials, BMJ, July 26, 2011, <u>http://www.bmj.com/content/343/bmj.d4169.full</u>

¹²² <u>http://medicalconsumers.org/2011/08/08/risks-of-diabetes-2-treatment/</u>

In other words, defining sick by one number may miss other factors that can play a very important role in one's health.

The disease number, or indicator, may focus very narrowly and miss the bigger picture.

This can create a situation where healthier people – based on one definition of sickness – actually die more frequently.

Another example: High cholesterol How closely does 'dangerous cholesterol' correlate to heart attacks?

The Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) – an expert committee – defined 'dangerous' or borderline high total cholesterol as >200 mg/dl.

This was a decrease from the previous definition of dangerous total cholesterol being > 240.

The experts concluded that people with total cholesterol > 200 could benefit from taking statins, cholesterol lowering drugs developed in the 1980s and 90s. As the report authors state:

Two major primary prevention trials with statins were the West of Scotland Coronary Prevention Study and the Air Force/Texas Coronary Atherosclerosis Prevention Study ... In both trials, statin therapy significantly reduced relative risk for major coronary events.¹²³

Note this wording '*significantly reduced relative risk*'. I'll explain what that's important. It's one of the tricks of the salesperson-acting-as-expert trade.

¹²³ Report Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report, pages II-31 and II-32.

Why did the expert committee use relative risk information? Because relative risk reductions make statins look better.

Here's an example. Take 2 groups of 1,000,000 people each. One group takes a medication, the other doesn't.

In the *non*medication group, 2 people die. In the medication group, 1 person dies.

That's an absolute reduction of 1 death in 1,000,000 people who take the drug. Maybe not a very big deal.

But it's a *relative* reduction of 50%, from 2 to 1 death. That sounds like a really big deal!

Good salespeople *always* use relative statistics because relative statistics *always* exaggerate their product's impact.

But truly objective experts should know the difference.

Caveat emptor. Those financial disclosure statements really mean something.

Based on the ATPIII report, physicians began diagnosing their patients with total cholesterol >200 as appropriate for statin medication and began prescribing it.

Unfortunately, the data behind the committee's conclusion are squishy and I'm not sure justify the conclusions. Remember, these may have been financially biased people. Let's take a close look at their data.

West of Scotland Pravastatin Study

This was one of the two primary prevention studies referenced by this expert committee in their statin advice. This study divided men living in and around Glasgow, Scotland into two groups: 3293 with high cholesterol who did not take pravastatin, and 3302 with high cholesterol who did. Their average total cholesterol was 272. About half smoked. In all relevant aspects the 2 groups were the same, or as close as the researchers could get them.

Over the 5 year study, 52 men in the control group died of a heart attack as did 38 in the statin group. That's a reduction of 14 deaths in about 3300 men attributable to statins, or about 0.4% (that's 4/10ths of 1%), just about at the statistical margin of error.

But it's a *relative* reduction of about 29%.

A note about the statistical margin of error: researchers tried to divide the study participants into two groups that were identical in all aspects except that one group took the statin while the other took a placebo. All other risk factors – age, smoking, weight, exercise levels, etc – were supposed to be split 50/50 between the two groups.

Unfortunately in the real world, researchers can't guarantee an exact 50/50 risk factor split. They may have achieved only 49/51 split of some important factor, or perhaps 49.5/50.5.

For this reason, outcomes showing less than about half a percent difference may fall within the margin of error and may not be valid. In the West of Scotland example, the mortality reduction was just about ½ of a percent, suggesting that statins may have a mortality reduction impact, but that it's a very, very small one.

Sorry if all this statistical stuff seems intimidating or boring, but wise consumers need to understand it. After all, we're trying to turn you from an *uninformed* to an *informed* patient!

Here's how you calculate the 29% relative reduction: ¹²⁴

- 52 men in the control group died of a heart attack. That's about 1.7% of the participants in this group
- 38 men in the statin group also died of a heart attack. That's about 1.2% of the participants in this group
- The different between 1.7% and 1.2% is about a 29% *relative* risk reduction. You arrive at this by subtracting the 1.2% who died in the statin group from the 1.7% who died in the control group (the difference is 0.5%), and then dividing this by the 1.7% starting risk in the control group. Got it?

¹²⁴ Nortin Hadler, Worried Sick, page 35

Relative reductions show the difference in *percents* of people who died of heart attacks; absolute reductions show the *actual number* of people who died.

That's why relative data always show the product has more impact.

Professor Nortin Hadler of the University of North Carolina Medical School gives this warning, written entirely in capital letters in his book Worried Sick. ¹²⁵

NEVER LET ANYONE TALK OF RELATIVE RISK REDUCTION WITHOUT DEMANDING A STATEMENT OF ABSOLUTE RISK REDUCTION.

According to the West of Scotland study, you need to give 142 men (with average total cholesterol of 272, half of who smoke) statins for 5 years to prevent 1 cardiovascular death. ¹²⁶ We have little additional data on these men and we don't know, for example their fruit and vegetable consumption rates, their average daily exercise, the impact of second-hand smoke or a variety of other factors that could affect their proclivity to have a heart attack.

I'm not sure if reducing the mortality rate by 0.4% (that's 4 tenths of 1%) over 5 years qualifies as a major or important medical success - as the committee *appeared* to claim - or not. I also don't know how this applies to people with total cholesterol of 210 or so who don't smoke, exercise a bit and eat their vegetables, like many of newly classified 'sick' Americans.

But I'm pretty sure that evidence from a study in western Scotland doesn't apply very well to most Americans!

Glasgow, the main population center in western Scotland, was the world's heart attack capital in the 1990s according to a 1999 BBC report.¹²⁷ (The West of Scotland study took place in the early 1990s.) Talk about choosing a population to fit your needs!

¹²⁵ Ibid. page 37

¹²⁶ For a clear explanation, see Dr. Robert Lemmon's analysis on <u>http://bittersweetmedicine.com/2010/03/26/overrated-medications-series-no-2-statins-for-primary-prevention-of-cardiovascular-diseases/index.htm</u>

¹²⁷ http://news.bbc.co.uk/2/hi/health/337109.stm

The Whitehall studies

More significantly, other research suggests that the ATPIII experts ignored a key factor for heart attacks and other diseases: <u>stress</u>. Lots of medical studies discuss the impact of stress including the very long term Whitehall studies. ¹²⁸ These suggest that a long term feeling of hopelessness – the feeling that you've lost control over your life and that nothing you can do will reverse this – actually correlates more closely to coronary event rates than does the population's cholesterol level.

Stress, for our purposes, means that long term feeling of hopelessness. This kind of stress is more prevalent among lower income people than higher income.

We too often equate stress with making big business management or political decisions. Studies suggest that this *doesn't* have the heart attack impact of the stress caused be a feeling of hopelessness, the feeling that no matter what you do, you won't improve your lot in life.

Call is 'stress', call it 'long term frustration' or call it 'status'. It's the same thing for our purposes.

Whitehall and similar studies show that *high stress people*, using the stress definition above, with high cholesterol have more heart attacks than *low stress people* with the same cholesterol levels!

Whitehall actually uses the word 'status' rather than 'stress'. They suggest that low status employees – janitors, traditional secretaries, low income customer service reps, laborers, etc – often feel trapped in their jobs and unable to move up the income or status ladder. The Whitehall studies were based on the British civil service which was far more stratified than is the American population.

I prefer to use the word 'stress' and identify it as *a feeling of loss of control over your life.* I think this is easier to understand than 'status' which often means different things to Americans than it did to the Whitehall researchers.

¹²⁸ This was a conclusion from the long term Whitehall studies of British civil servants. For a good explanation see this explanation by Dr. Michael Marmot, director of the Whitehall project http://globetrotter.berkeley.edu/people2/Marmot/marmot-con3.html . Interestingly, the first Whitehall study was published before the West of Scotland study began, suggesting that the authors knew that information and perhaps chose greater Glasgow as the epicenter based on it. Hmmmm....

Sir Michael Marmot, director of the Whitehall studies, suggests that the often discussed risk factors like smoking, diabetes, obesity and cholesterol may only explain about **1/3** of the difference in heart attack rates between high stress and low stress populations, more or less between high income and lower income people. Stress itself seems to explain the other 2/3.¹²⁹

One proxy for this type of stress – the feeling of hopelessness described by Whitehall – is the long term unemployment (or underemployment, if you can find it) rate in a community. The long term unemployed and underemployed in American or Britain are not completely destitute folks who are homeless or starving to death. Rather, the unemployed receive assistance payments, perhaps housing subsidies and various other types of government assistance, or at least they did in Scotland in the 1990s.

Instead, their stress comes from their lack of ability to find a good job offering upward mobility. High unemployment depresses overall wages; even employed folks are often short of money, living under the grinding financial and emotional stresses of lack of self-worth, lack of self-esteem and lack of any optimism about the future. Whitehall suggests that all this contributes to higher rates of many diseases including heart attacks.

The New England Journal of Medicine published a commentary in line with the Whitehall conclusions in 2004, just after release of ATPIII, called 'Class – The Ignored Determinant of the Nation's Health'. They use the word 'class', Whitehall used 'status' and I use 'stress' to mean about the same thing: the constant feeling of that you come up short day-after-day, month-after-month and year-after-year.

The Journal commentary claimed, among other things

- Differences in rates of premature death, illness and disability are closely tied to socio-economic status,
- People in lower socio-economic classes die earlier than do people at higher levels,
- Unhealthy behavior and lifestyles alone do not explain the poor health of those in lower classes,
- Even when behavior is held as constant as possible, people of lower socioeconomic status are more likely to die prematurely, and
- There is something about lower socioeconomic status itself that increases the risk of premature death.

I wonder why ATPIII ignored this entire line of research.Source: Isaacs, et al, Class-The Ignored Determinant of the Nation's Health, NEJM, September 9, 2004

¹²⁹ Ibid.

We can suggest that, based on the Whitehall and similar studies, a population exhibiting very high rates of long term unemployment and underemployment will have a higher rate of heart attacks than a similar population of fully employed people.

Furthermore – and here's the startling suggestion both from Whitehall and the NEJM commentary, among others – **that's true** even if the cholesterol levels are the <u>same</u> in both groups!

Whitehall suggests that the variation is about 2 to 1: for every heart attack in the fully employed, satisfied population, the high unemployed / high stress group will have about two. That means someone with total cholesterol of 272 who's *unemployed* over a long term may be about twice as likely to have a heart attack as someone with 272 cholesterol who's *employed* and enjoying his/her job.¹³⁰

The Glasgow situation

What was the long term unemployment situation in western Scotland during the term of the West of Scotland study? Glasgow and its environs had very high unemployment, with 25% of the population described as 'economically inactive' for years. ¹³¹ In other words, a prime geographic site for lots of heart attacks.

That's probably a key reason why Glasgow was the world's heart attack capital and, perhaps, why it was chosen for this study.

Yet even among this group of very high stress, heavy smoking, extremely high cholesterol men, only about 7.5% had a heart attack of any kind during the 5 year study, let alone a fatal heart attack.

There were 248 coronary events (heart attacks or coronary death) in the placebo group.¹³² That means 92.5% of men taking the placebo *didn't* have a heart attack.

In other words, high stress, high cholesterol and the other risk factors *didn't* correlate to heart attacks 92.5% of the time even among this very high risk group of people.

¹³⁰ For a detailed discussion of this point, see the various Whitehall studies and commentaries. I've taken some liberties describing the Whitehall studies to keep this section short.

¹³¹ BBC, ibid.

¹³² Shepard et al, Prevention of Coronary Heart Disease with Pravastatin in Men with Hypercholesterolemia, New England Journal of Medicine, November 16, 1995

Most other cholesterol studies show a lower heart attack risk among the placebo group, probably due to their subjects having lower economic stress factors. Bloomberg BusinessWeek, in its January 16, 2008 cover story for example, suggested that about 3% of high cholesterol people will have a first heart attack in the next 4 or so years, but doesn't identify either the cholesterol or population stress levels.¹³³

All this suggests a very weak correlation between cholesterol and heart attacks, certainly not the 'significant' one referenced by the expert committee...and it sheds some light on the potential conflict of interest among the experts.

Conclusions drawn from studies of people who are *very different* from you may not mean very much about your own, individual, risk of having a future medical event. The Whitehall studies explain why.

Even among the west of Scotland population, though, over 90% of people with key heart attack risk factors *didn't* have heart attacks.

This helps put the impact of these risk factors in perspective.

Air Force/Texas Coronary Atherosclerosis Prevention Study

The Air Force/Texas Coronary Atherosclerosis Prevention Study – the other primary prevention study mentioned in ATP III as justification prescribing statins to people with total cholesterol >200 - presents a somewhat different problem. ¹³⁴ (I'll describe this more briefly.)

In this study, again using two groups of very similar people, the group taking lovastatin had fewer first heart attacks, coronary events or need for hospitalization for cardiovascular disease. In fact, as compared to the placebo group, the lovastatin group had 25% fewer fatal and non-fatal coronary and cardiovascular events. Relative reductions, of course, but so far, so good.

Unfortunately, *the people taking lovastatin died at the same rate as the people taking the placebo*. Here's the quote directly from the study:

The overall mortality rate was similar in each group, with 80 deaths among participants treated with lovastatin and 77 deaths among participants treated with

¹³³ See, Carey, Do Cholesterol Drugs Do Any Good? Bloomberg Businessweek, January 16, 2008.

¹³⁴ Downs, et al, Primary Prevention of Acute Coronary Events With Lovastatin in Men and Women With Average Cholesterol LevelsResults of AFCAPS/TexCAPS, JAMA, May 27, 1998

placebo (4.6 and 4.4 per 1000 patient-years in participants treated with lovastatin and placebo, respectively).¹³⁵

Two groups of similar people died at similar rates, though one had fewer fatal coronary and cardiovascular events. How can this be?

The short answer: I don't know. Maybe a fluke.

The longer answer: there's a difference between the *coronary death rate* and the *overall death rate*. Some people, for example, may have a heart attack, survive, become weak afterward and ultimately die from pneumonia. Their cause of death would be listed as pneumonia, not a heart attack.

This may have been the case in the Air Force/Texas Coronary Atherosclerosis Prevention Study. I couldn't determine that from the data. But the teachable lesson from this study is this:

A wise consumer needs to know both the *disease-specific* mortality rate and the *overall* mortality rate to determine if the medical intervention really saves lives.

In this case, fewer heart attacks and coronary disease did not lead to fewer deaths. I don't know why. But before assuming that lovastatin will prolong my life, I would want to know both mortality rates, the disease specific and the overall rate.

You need to know both the disease specific mortality rate and the overall mortality rate to determine if the medical treatment in question really saves lives.

Some treatments may reduce the coronary mortality rate while increasing the pneumonia mortality rate.

Are cholesterol numbers *high quality* information, *low quality* or *unnecessary*? Are statin interventions high or low quality medical care? Based on the studies referenced in ATP III and the associated recommendation to take statins, I'd be hard pressed to call either 'high quality'. As we've seen

• Over 90% of the very high cholesterol men in greater Glasgow did not have a heart attack during the West of Scotland study. What do you call a medical

¹³⁵ Ibid.

indicator that does not impact over 90% of the people who have it? I'd call it low quality.

- Few of the very high cholesterol West of Scotland men avoided dying from coronary disease by taking statins, perhaps only about .4%.
- Even fewer avoided death from any cause in the Air Force/Texas study by taking statins.

ATP III, by classifying as 'dangerous' total cholesterol >200, may or may not have saved many lives. The two studies referenced by ATP III indicate that it did not.

But it certainly did spur sales of statins...

Which may have been the expert's goal in the first place.

Unfortunately, the problems plaguing cholesterol numbers as a high quality indicator of a future coronary event also plague other diseases that we define by numbers. Caveat emptor!

A third example: PSA screening numbers and prostate cancer cases

PSA, or Prostate Specific Antigen, tests commonly indicate the presence of prostate cancer. These tests measure the amount of a specific protein (or antigen) per milliliter of blood.

Physicians use various cut-off numbers as 'dangerous' or 'abnormal' test results.

- Some think that a PSA number of 4 or higher is dangerous.
- Others suggest that PSA numbers of 2.5 or lower are not dangerous.
- Results between 2.5 and 4 often fall into the gray area.

Physicians determine the existence of prostate cancer with a biopsy, removal and examination of some prostate cells. If any are cancerous, then, by definition, the patient has prostate cancer.

Researchers have studied the relationship between PSA test results and biopsy results. They discovered that prostate cancer exists in men with virtually all PSA numbers.
Here's the approximate relationship between PSA test results and biopsy results: ¹³⁶ ¹³⁷

- PSA <1: approximately 8% of men had biopsy evidence of prostate cancer;
- PSA between 1 and 2: approximately 16% of men had biopsy evidence of prostate cancer;
- PSA between 2 and 3: approximately 24% of men had biopsy evidence of prostate cancer;
- PSA between 3 and 4: approximately 26% of men had biopsy evidence of prostate cancer;
- PSA >4: approximately 30% of men had biopsy evidence of prostate cancer

Thus having a low PSA number does not necessarily indicate the absence of prostate cancer and having a high PSA number does not necessarily indicate the existence of prostate cancer.

About 70% of men with PSA numbers greater than 4 had no biopsy evidence of prostate cancer.

When men get a high PSA test result, they then tend to get a biopsy. That determines whether or not they really have prostate cancer.

The PSA test, in other words, acts mainly to identify those at highest risk and who therefore need a biopsy. It's a 'rule out' type of medical test: it rules out men who most likely don't have prostate cancer and for whom, therefore, a biopsy is probably unnecessary.

In other words, the costs and risks of a biopsy for men with low PSA numbers are higher than the prostate cancer risk, or so goes the theory.

This leads to the next questions: how accurate is the biopsy, and what exactly does it tell us? ¹³⁸

In the standard prostate biopsy, physicians remove 6 samples of prostate tissue. The prostate, remember, resembles a golf ball and physicians worry that a cancer growing in

¹³⁶http://www.nejm.org/doi/full/10.1056/NEJMoa031918

¹³⁷ <u>http://www.amazon.com/Overdiagnosed-Making-People-Pursuit-</u> Health/dp/0807022004/ref=sr_1_1?ie=UTF8&qid=1309023059&sr=8-1

¹³⁸ This discussion comes from Welch, Overdiagnosed, page 49. See chart, page 50 in particular.

the southern hemisphere may be missed by a biopsy in the north. Ditto for the east and west. Theoretically samples taken from 6 different regions represent a pretty good cross section of the prostate and provide pretty accurate information.

A man is deemed 'prostate cancer free' if none of the 6 samples contain cancerous cells.

But studies of men deemed 'prostate cancer free' at 6 samples showed that men actually *had* prostate cancer with 11, 12 or 13 needle biopsies about 25% of the time! The message here: the harder we look for prostate cancer, the more we find....even in men in their 20s, almost 10% of whom had biopsy evidence of prostate cancer! ¹³⁹

That information comes from a fascinating study by pathologists at the Cleveland Clinic who examined prostates of 525 men killed in accidents. The rate of prostate cancer increased with age, so that by their 70s, some ³/₄ of men had prostate cancer.

The message: lots and lots of prostate cancer exists, and the more you look for it, the more you find. Arbitrary PSA numbers are only very, very, very loose indicators of prostate cancer...as are an arbitrary number of needles (6, 11, 12 or 13) for prostate samples.

The fundamental question to consider with your doctor about all these numerical types of tests: is the relationship between *test scores* – your disease sickness number, like your PSA number - and *sickness itself*, strong enough to warrant the test?

In the PSA example, they may not be.

And second: if the test and subsequent follow-up, like a prostate biopsy, confirms that you're at risk, *do our currently available treatments work well enough to use them*?

¹³⁹ Ibid, page 48

Interestingly, the age adjusted prostate cancer mortality rate fluctuated fairly dramatically between 1975 and 2009.

- It *rose* almost every year from 111 per 100,000 men, age adjusted in 1975 to 142 per 100,000 men in 1993. Why did it rise? We're not sure.
- It then fell back to 110 per 100,000 men in 2000, and continued to fall to 79 in 2009. Why did it fall? Also not completely clear.

The question each man should answer: Do the treatments work *well enough* to have the PSA screening test?

Today's answer – or the answer in 2014 or 2016 – may differ from the 1993 or 1999 answer. Will the mortality rate rise again as it did from 1975 – 1993? No one knows!

Source: National Cancer Institute SEER data 'Age-Adjusted U.S. Mortality Rates By Age At Diagnosis/Death Prostate, All Races, Male 1975-2009' <u>http://seer.cancer.gov/faststats/selections.php?#Output</u>

The answer to our 2 questions above ----- (1) is the relationship between test scores and other sickness indicators strong enough to justify the test, and (2) do currently available treatments work well enough to use them ---- perhaps even more than the actual numbers themselves, is worthy of discussion.

You could ask the same question about cholesterol and other numbers.

Some indicators, like PSA screening numbers, correlate very weakly to sickness. In the PSA situation, about 70% of men in the 'dangerous PSA level' did not have biopsy evidence of prostate cancer.

The wise patient should consider how closely test indicators like PSA screening numbers correlate to diseases before having the screening test. That can help avoid unnecessary tests leading to unnecessary medical care that may do more harm than good.

What screening and sickness numbers really mean

Medical sickness numbers roughly indicate the likelihood that you will experience a particular medical event. For example:

- If your total cholesterol number is 210, you're *somewhat more likely* to have a coronary event than if your total cholesterol is 190;
- If your PSA is 3, you're *somewhat more likely* to have prostate cancer than if your PSA is 2.

Medical numbers do not indicate certainty.

- If your total cholesterol is 240, you will not *definitely* have a coronary event;
- If your PSA is 4, you do not *definitely* have prostate cancer.

Medical cut-off numbers are arbitrary. As they change so <u>may</u> your risk of developing a disease.

For example, we define elevated cholesterol as greater than 200. This does not mean that someone with 201 is very sick, while someone with 199 is completely healthy.

- Someone with 201 total cholesterol may be *very, very, very, very slightly* more likely to develop heart disease than someone with 199;
- Someone with199 total cholesterol may be *very, very, very, very slightly* more likely to develop heart disease than someone with 190;
- Someone with 215 total cholesterol may be *very, very, very, very slightly* more likely to develop heart disease than someone with 205.

This is true of PSA test results and prostate cancer also.

- Someone with a PSA of 2.5 is not necessarily completely prostate cancer free.
- A rising PSA number does *not necessarily* indicate the presence of prostate cancer.

The same situation exists for blood sugar test results and diabetes, T-score results and osteoprosis, blood pressure results and hypertension / heart attacks, etc.

Scores above a particular number do not necessarily define sickness, and results below a number do not necessarily define good health.

These 'test indicators' often correlate very, very loosely with actual patient disease presentations.

How much does the medical number tell us? How much does your risk rise as your number rises? At what point should you become concerned? That depends on the specific disease, the number...and on you.

- For some people, the fact that about 3 in 100 people with high cholesterol will actually have a heart attack in the next few years is a *strong enough* indicator to have their cholesterol checked regularly and take medication; ¹⁴⁰
 - For others, the same indicator is *weak*, so they don't have their cholesterol checked regularly or don't take medication.
- For some people, statins which reduce coronary mortality in high cholesterol folks by perhaps 0.04% over 5 years work *well enough* to take;
 - For others, the same statin impact is so *poor* that they refuse to take them.
- If you determine that the test result is too poorly correlated with actually being sick, you may decide not to have the test itself;
- If you determine that the medication or treatment impact is so low as to have no real impact on your health, then you may decide not to take that medication.

These decisions are yours. Your doctor, acting defensively, may want to prescribe statins if your total cholesterol exceeds 200 or so. But you, acting in your own interests, may disagree.

Remember this quote from the Dartmouth Atlas in our Introduction:

When patients are fully informed about their options, they often choose very differently from their physicians.

And remember that all medical interventions contain risk. If you decide on medical care that you really don't need (due to, for example, the weak correlation between test results and patient health), you face all the treatment risks without much chance of benefit. There's some evidence that this is the case with prostate cancer screening, diabetes screening and cholesterol screening among others. *Caveat emptor.*

¹⁴⁰ This estimate comes from the Lipitor ad in our chapter The Medical Quality Problem

We're creating more sick people

Various expert committees have redefined sickness by numbers, with the trend over time to lower the threshold and create more sick people. Here's an estimate about the impact of this on just 4 diseases from Dr. Welch of the Dartmouth Institute: ¹⁴¹

Condition	# Sick People, Old Definition	# Sick People, New Definition	New Sick People
Diabetes (blood sugar decreased from 140 to 126)	11,697,000	13,378,000	1,681,000
Hypertension (Systolic BP decreased 160 to 140, Diastalic from 100 to 90)	38,690,000	52,180,000	13,490,000
Hi Cholesterol (total chol decrsd from 240 to 200)	49,480,000	92,127,000	42,647,000
Osteoporosis (T score decrsd fr -2.5 to - 2.0)	8,010,000	14,791,000	6,781,000

According to Welch's estimate, redefining just these 4 diseases with lower threshold numbers has created about 64 million new sick Americans over the past 20 or so years. These are all folks appropriate for medication, which may explain part of our medication utilization increase over the past 20 years. Other diseases have followed this pattern.

Some Non-Numerical Disease Definitions

This numerical-type analysis misses a whole other class of diseases that aren't easily converted to numbers: psychiatric illnesses. These are defined by the Diagnostic and Statistical Manual of Mental Disorders which is updated about every 15 - 20 years by the American Psychiatric Association. We're currently using version 4, called DSM IV which came out in 1994, with DSM V due out in 2013.

DSM IV listed 365 recognized psychiatric disorders. Interestingly, DSM III, published in 1980, only listed 226 disorders. That's a 139 disorder increase between 1980 and 1994. More disorders mean more diagnoses, more treatments, more prescriptions for psychiatric drugs and more income for psychiatrists and pharmaceutical companies.

¹⁴¹ Welch, Overdiagnosed, page 23

In addition to increasing the number of recognized disorders, DSM IV broadened the definitions of many DSM III disorders. This defined more people as having the disorder and therefore being appropriate for care and medication.¹⁴²

Attention deficit hyperactivity disorder (ADHD), for example, was redefined in DSM IV to nearly double the number of children diagnosed and appropriate for prescription medications, including stimulants like Ritalin.

As a result, perhaps, the number of stimulant prescriptions tripled among preschoolers in the 1990s.

Some critics wonder if the redefinitions in DSM IV represent scientific advances in patient care or successful lobbying by medical interest groups.

Louis Menand, writing in the New Yorker for example, asks if expanding definitions of mental disorders is anything more than a 'blatant pathologization of a common personality trait for the financial benefit of the psychiatric profession and the pharmaceutical industry'. ¹⁴³

Edward Shorter, author of Before Prozac, accuses the DSM of accelerating the trend of 'making variants on the spectrum of everyday behavior into diseases: turning grief into depression or apprehension into anxiety.¹⁴⁴

DSM authors would, of course, disagree.

Let's review the history of Paxil, a drug approved to treat Social Anxiety Disorder to understand the genesis of these criticisms.

Social Anxiety Disorder, originally *recognized* in 1980 and included in DSM III, was not fully *defined* until the late 1980s and DSM IV. ¹⁴⁵

Cohn & Wolfe, an ad agency working for SmithKline Beecham, the huge pharmaceutical company, used the disorder definitions circa DSM IV to launch an advertising campaign

¹⁴² Shannon Brownlee, Overtreated, page 182

¹⁴³ Louis Menand, Can psychiatry be a science?, New Yorker, March 1, 2010

¹⁴⁴ Alex Beam, On My Mind, Boston Globe, March 16, 2010

¹⁴⁵ http://www.socialanxietyinstitute.org/dsm.html

for Paxil in the mid-late 1990s as 'the first and only FDA-approved medication for the treatment of social anxiety disorder.' ¹⁴⁶

Here's an overview of that effort from bioethicist Carl Elliott of the University of Minnesota:

Pharmaceutical companies who are marketing psychopharmacological treatments have gotten into the business of selling psychiatric illness. The way to sell drugs is to sell psychiatric illness.

If you are Paxil and you are the only manufacturer who has the drug for social anxiety disorder, it's in your interest to broaden the category as far as possible and make the borders as fuzzy as possible.

In other words, if Cohn & Wolfe's advertising program could suggest to more Americans that they suffered from social anxiety disorder, then SmithKline Beecham could sell more products.

Perhaps as a result of this campaign, some 13% of Americans reported being affected by social anxiety disorder by 2001, making it the 3rd most common mental disorder after depression and alcoholism - even though the National Institutes of Health claims the real number of sufferers is closer to 3.7%.

Did the other 9.3% of the population - perhaps 28 million people - *really* have social anxiety disorder? Did the medication benefits exceed the risks...*and the costs*?

Paxil's annual sales exceeded \$1.2 billion in 1999. Ask yourself if this passes the smell test. And remember: some 68 million Americans suffer from mental illness or substance abuse. 38,000 of them committed suicide last year. ¹⁴⁷

I don't doubt that some people really do suffer from social anxiety disorder and that medication really can help them. But I suspect, as a lay person who's been in many different social situations - some of which really are anxiety provoking - that the number of clinically ill people is closer to the National Institutes of Health estimate than Paxil's and that we're overdoing this by quite a bit. I doubt, as a lay observer, that this disorder caused many of our 38,000 suicides or destroyed many families.

¹⁴⁶ Shankar Vedantam, Drug ads hyping anxiety make some uneasy, Washington Post, July 16, 2001, page A01

¹⁴⁷ Estimates from Kevin Cullen, Boston Globe, January 11, 2013, page B1

Dr. Baruch Blumberg, the Nobel Prize winning scientist who saved millions of lives by helping develop a vaccine against hepatitis B provides this context:

Vaccines are not an attractive product for pharmaceutical companies in that they are often used once or only a few times and they ordinarily do not generate as much income as a medication for a chronic disease that must be used for many years. ¹⁴⁸

Applying Blumberg's thought to our Paxil example: pharmaceutical companies educate about, and advertise for, the conditions that generate income for them – not necessarily the diseases that impact much of the population. That's why Dr. David Kessler, former commissioner of the FDA suggests that *consumers who make health decisions based on what they learn from television commercials ultimately take medicines they may not need*, ¹⁴⁹ - in our terms, may consider themselves sicker than they really are.

Two summary thoughts:

- 1. Most physicians and researchers agree that psychiatric medications can help people who are *definitely* afflicted with mental disorders;
- 2. Many question, however, whether the risks and costs faced by those *not definitely afflicted* exceed benefits.

Expanding the *number* of mental disorders and the *definitions* of those disorders – often by people who stand to gain financially from this process - can blur the distinction between those *definitely afflicted*, and those *not definitely afflicted*, with a variety of cost, risk and patient benefit implications.

Conclusion

High quality medical care can help people who are definitely sick. But even the best medical care won't help someone get healthier if they're not sick to begin with. Healthy people who have medical care to treat them get no benefit from it because they're healthy, not sick.

They do, however, face all the negatives from medical care, including the costs and risks.

¹⁴⁸ Segelken, New York Times, April 6, 2011

¹⁴⁹ Brownlee, Overtreated, page 186

We have, in this country, a proclivity to define sickness with a number. This has turned millions of us from healthy to sick but has not always served us well. In the diabetes example above, treatment made people healthier on the blood sugar scale while killing them more frequently. On balance, that's a pretty big net negative.

In the statin example, we found that an expert committee composed of people who stood to gain financially from their recommendations advised widespread use of statins based on weak evidence of their effectiveness, while ignoring other, potentially far more important, medical issues like stress. Indeed, the entire ATP III ignored lessons from the Whitehall studies. They based their recommendations – largely, though not entirely - on the highly select, unique population in western Scotland that's quite unlike the typical American population.

In the PSA screening example, we identified a very unreliable prostate screening test that generates inaccurate results some 70% of the time. We wouldn't tolerate this level of inaccuracy in other aspects of our lives. But poorly informed patients had these tests annually for years and often based their treatment decisions on them.

We saw how our reliance on numerical definitions of 'sick' has turned over 60 million of us from 'healthy' to 'sick' over the past 20 years, to the economic benefit of the pharmaceutical industry but perhaps not to the medical benefit of the patients.

And we saw how experts writing the various DSM manuals may succumb to financial pressures when defining psychiatric illnesses. Social anxiety disorder the 3rd most important mental illness in America? I don't think so.

This isn't to say you should ignore medicine – far from it. If you're actually sick, medicine can help you tremendously.

But the numbers we've discussed so far in this chapter, and the mechanisms by which we arrived at them, don't present a compelling case for their being a basis of sickness definitions.

Other numbers, by contrast, may be far more meaningful. We'll show how asking the right questions can generate useful information, numbers, in other words, that you can rely on to make wise medical decisions.

Review Questions

Answers on next page. Some questions may have more than 1 correct answer.

1. Who generally determines the 'number' that defines sickness in this country?

a. The President of the United States

b. The President of the American Medical Association

c. An Expert Committee appointed by the Department of Health and Human Services

2. According to this chapter, what is the purpose of financial disclosure statements?

a. They identify which members are rich and which are poor

b. They identify which members may have a financial interest in the results of their study so may not be totally objective experts

c. They identify which members may act as salesmen for a product or class of products

3. When experts file a financial disclosure statement, does this tend to make them more *cautious and objective* in their recommendations and conclusions or more *biased*?

- a. More objective
- b. More biased

4. In 1997, an Expert Committee lowered the threshold for diabetes from fasting blood sugar greater than 140 mg/dl to fasting blood sugar greater than 126. People with fasting blood sugar between 126 and 140 were now classified as 'sick' and deemed appropriate for blood sugar lowering medication. What was one effect of this?

a. Lots of people lived longer and healthier lives

b. About 1.6 million people were reclassified from 'healthy' to 'sick', thus expanding the potential market for blood sugar lowering medications
c. The mortality rate of people taking medications to lower their blood sugar increased, since they were aiming at a lower number

5. If a medication 'significantly reduces relative risk' does it also impact a large number of people?

a. Yes, of course!

b. No, not necessarily. A 'significant relative risk reduction' may reduce the mortality rate from 2 in a million to 1 in a million. That's a 50% relative risk reduction (from 2 to 1) that only helps 1 person per million who take the medication.

6. In 2002, the ATPIII Expert Committee redefined dangerous total cholesterol from greater than 240 to greater than 200. This increased the potential market for statins by about 42 million people. How solid was this Expert Committee's analysis?

a. It was outstandingly well done

b. It was shoddy, relying too much on relative risk and benefit analysis c. It was shoddy by failing to account for the social stress-type causes of heart attacks. These may, in fact, account for 2/3 of the heart attacks in the West of Scotland study

d. It was shoddy by failing to acknowledge in the Air Force/Texas study that statins had no impact on reducing overall mortality rates

7. How important is the total cholesterol level in predicting heart attacks?

a. It is a very strong predictor, since most people with 'dangerous' or high total cholesterol will have a heart attack in the next 5 years
b. It is a very weak predictor, since, according to the West of Scotland study, 92.5% of people with average 272 total cholesterol, half of whom smoke and many of whom are 'economically inactive' (i.e. very highly stressed) will <u>not</u> have a heart attack during a 5 year period.

8. What is the key question to ask your doctor when you learn that you are 'sick' according to a test indicator?

- a. Which medication will make me 'healthy' the fastest
- b. Which medication will make me 'healthy' the cheapest
- c. How closely do test indicators correlate with actual medical events?

9. What has been the trend over time in definitions of psychiatric illness?

a. We have tightened all mental illness definitions over time so fewer and fewer people are being diagnosed and ill appropriate for medication

b. We have increased the number of recognized psychiatric disorders over time, from 226 in 1980 to 365 in 1994

c. We have expended the definitions of various psychiatric disorders like Attention Deficit Disorder to include more people

Review Questions Correct answers in bold

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Chapter 5

A four-step process for making medication, test and treatment decisions

This chapter will introduce a four-step decision making process for patients to use when deciding about having medical tests or treatments, and about taking drugs. It's basically a series of questions to ask your doctor and to use when doing your own medical research:

- It's easy-to-use and understand, though we sometimes lack all the data needed to answer the questions
- It's easy-to-share with your doctor, something a wise patient should definitely do
- It's replicable, so you can repeat it over and over whenever you're faced with a decision about tests, treatments or drugs, and
- It's easy-to-teach, so brokers and other advisors can use this chapter as a basis for their client engagement programs.

Studies suggest that very few Americans understand this process, discuss these issues with their physicians or include them in their own medical research. Those who do, I suggest, tend to get better medical care, with less risk, at lower cost.

Here are the decision process components:

- 1. Determine how likely you are to suffer a specific bad medical event. This introduces starting risk measures. You need to know how likely you are to suffer a specific medical event in order to understand how much medicine can help you.
- Determine how much medicine can help you. This introduces risk reduction measures. You need to know your starting risk first – your chance of having a bad medical event *without* treatment – and then compare it to your chance of having the same even *with* medical care. The difference between the two is the amount that medical care can benefit you.
- 3. Determine how much medicine can harm you. This introduces some medical harm measures. Use the same process as above: determine your chances of harm absent a medical intervention and compare it to your chance of harm with medical care. That tells you how likely medicine is to harm you.

4. **Compare medical options.** This introduces Number Needed to Treat and Number Needed for Harm metrics. I'll explain below in detail.

Step 1: Learn your Starting Risk

of having various medical events

Starting risk is the first important number you need to learn. It tells how likely you are to have a particular medical event. Starting risk compares you to a large group that shares your risk factors.

For example, about 1 non-smoking male out of 1000 in his 30s will die of stroke.

The starting risk for this group of having a stroke is about 1 out of 1000 over 10 years, or 1/10th of 1%. ¹⁵⁰

But about 90 male smokers out of 1000 in their 60s will die of lung cancer.

The starting risk for this group is about 90 out of 1000 over 10 years, or 9%.

It is thus more likely that a male smoker in his 60s will die of lung cancer than that a male non-smoker in his 30s will die of stroke.

- As a general rule, the higher the starting risk, the more likely a medical intervention (like stopping smoking) will help you.
- The opposite is also true: the lower the starting risk, the less likely a medical intervention will help you.
- Knowing your starting risk for various medical problems can help you prioritize your medical care choices.

A starting risk of 1/10 of 1% may strike some as unimportant and not worth worrying about. But a starting risk of 9% may strike them as very important and worth worrying about a lot and acting on aggressively.

You have different starting risks for lots of different medical events, including having a first heart attack, dying from prostate cancer, losing your leg to diabetes or having a stroke. Your own starting risks of having a future medical event can change over time. Here are some examples:

¹⁵⁰ <u>http://www.vaoutcomes.org/papers/Simple_Charts_Men.pdf</u>

Starting Cancer Mortality Risks, Never Smokers Number of Women Who Will Die over 10 years per 1000 women ¹⁵¹

Age	Lung	Breast	Colon	Ovarian	Cervical
50	1	4	1	1	<1
60	3	7	3	3	1
70	7	9	7	4	1

Thus about 1 non-smoking women will die of lung cancer in her 50s, per 1000 women, while about 7 similar women will die of the same disease in their 70s.

The Journal of the National Cancer Institute, referenced below, lists both male and female starting mortality risks from various types of cancer at various ages. Other charts and research lists starting risks for various other medical events.

One advantage of knowing your starting risk

or why starting risk is so important

Once you know your starting risk of facing a certain medical event, you can determine how much medical care can help you.

But if you don't know your starting risk, then you can get very confused, very quickly.

Here's a standard example of this problem, articulated by Dr. Otis Brawley, Chief Scientific Officer of the American Cancer Society: ¹⁵²

mammography combined with good treatment saves lives. It decreases the risk of death by somewhere between 15 to 30%.

If you know your starting risk of dying from breast cancer, then you can determine what a 15 - 30% risk reduction actually is. If you don't know your starting risk, then you have no idea what a 15% mortality risk reduction really means.

• Assuming Dr. Brawley is correct, for women in their 60s, the mammography risk reduction is about 2 lives saved per 1000 women screened over 10 years.

http://www.cancer.org/research/researchaccomplishments/behind-the-science-videos

¹⁵¹ This data comes from Woloshin, et al, Risk Charts, Journal of the National Cancer Institute, Volume 94, Number 11, June 5, 2002

¹⁵² This quote comes from a Behind the Science video interview of Dr. Brawley by Dr. Len Lichtenfeld on the American Cancer Society's website

According to our starting risk chart, about 7 women per 1000 in their 60s would die of breast cancer without mammography. 15-30% of 7 is about 2.

• Again, if Dr. Brawley is correct, for women in their 50s, mammography saves about 1 life per 1000 women over 10 years. Do you see why?

If you don't know your starting risk, you have no idea what a 15-30% reduction means:

- 5 women per thousand?
- 400 women per thousand?
- At what ages?

We often, in this country, describe risk reduction as a percentage, as Dr. Brawley did above. Absent starting risk information, you can't decide if the percentage reduction is a big deal or not.

According to Dartmouth Medical School researcher Steven Woloshin and his co-authors of *Know Your Chances*, **starting risk data can be hard to find!**

- Nearly 70% of abstracts in medical journals did not indicate the starting risk (Abstracts are the part of journal articles that most busy doctors read);
- 45% of press releases issued by major medical journals did not indicate starting risk;
- 97% of direct-to-consumer ads for prescription drugs did not indicate the starting risk.

One effect of this: doctors and patients think medications work better – have more beneficial impact – than they often really do. Woloshin, et al, Know Your Chances, page 52

Here's an easy question to ask your doctor about your own starting risk for various medical events:

Out of 100 people like me, how many will have [the medical event in question] in the next 5 years?

You can phrase it like this:

- Out of 100 non-smoking men like me, how many will die of lung cancer in the next 5 years? or
- Out of 100 women with my cholesterol level, how many will have a first heart attack in the next 10 years? or
- Out of 100 men my age and with my physical characteristics, how many will die of prostate cancer in the next 5 years?

You can ask lots of similar questions about lots of medical events.

Remember to ask about people <u>*like you*</u>. If you're a good natured, 45 year old athletic fellow with 210 total cholesterol who's concerned about your risk of having a heart attack, *people like you* are also good natured, middle aged athletic guys with similar cholesterol levels.

People like you are not 65 years old, depressed, highly stressed, obese, heavy smokers with 272 total cholesterol. These people face different heart attack starting risks than you do.

That's the problem of extrapolating data from the West of Scotland and applying it *to you*.

Asking questions in this form – *out of 100 people like me* - avoids many of the problems we discussed in the last chapter:

- You won't get confused about what a 15 30% reduction means or if it's 'a significant relative reduction'
- You don't need to understand the population bias in the West of Scotland study
- You don't need to analyze the methodological problems with PSA screening test studies

Asking in this form also helps focus your doctor's comments on you – 'out of 100 people *like you*'.

And asking helps you prioritize your medical concerns:

- You would want to get treatment for medical events that will affect 50 out of 100 people like you over the next 5 years, but
- You might not care much about medical events that will only affect 0.01 out of 100 people like you over the next 20 years.

Be sure to get your answer in the same form as the question that you asked. Here are some appropriate answers:

- 3 out of 100 people like you with your cholesterol level, emotional state, coronary history etc. will have a first heart attack in the next 5 years, or
- 0.1 out of 100 men like you your age and health status will die of prostate cancer in the next 10 years.

The form of your doctor's answer matters.

Comments like 'about 14%' or 'cholesterol is a significant risk factor for heart attacks' or 'prostate cancer can be a very aggressive form of cancer' <u>don't answer your starting risk question!</u>

Unfortunately, we don't always know the exact answer to these questions. But only by asking can you begin to get the information you need to make a wise medical treatment decision.

Key idea: you should always start your discussions about medical tests, treatments and medications with the starting risk question:

Out of 100 people like me, how many will have the bad medical event if they <u>don't</u> take this medication, have this test or have this treatment?

You may decide that your starting risk is so low that you won't benefit enough from the medical intervention to have it.

Step 2: Learn how much medicine can help

Medical treatments, unfortunately, don't work perfectly. Sometimes a blood pressure lowering medication will help you avoid a stroke and sometimes it won't. Sometimes women who get annual mammograms still die of breast cancer. Sometimes people who religiously take their statin medications still have heart attacks.

Here's how we suggest you ask this question:

Out of 100 people like me who take the medication [or have the screening test, or have the surgery], how many will <u>still</u> have the bad medical event?

For example:

- Out of 100 people like me who take statins, how many will *still* have a first heart attack in the next 5 years? or
- Out of 100 women like me who have annual mammograms, how many will *still* die of breast cancer? or
- Out of 100 men like me who have PSA screening tests, how many will *still* die of prostate cancer?

Key idea: Once you know how many people like you will have the bad medical event *without* a medical intervention, you can ask the next question:

Out of 100 people like me who have the medical intervention, how many will *still* have the bad medical event?

Be sure to phrase your question exactly like this. Some people try a shortcut version and ask, for example *'out of 100 people like me, how many don't have a heart attack if they take a statin?*' The problem with this phrasing: many people wouldn't have had a heart attack in the first place. The statin didn't help them.

You need to compare the number of people who had heart attacks *without* statins to the number who had heart attacks *with* statins. That's the only way to determine the statin impact...and why you need to phrase your question correctly.

You need to clarify what you mean by 'have the bad medical event'. There are two possible answers.

First, you may mean 'lower my total cholesterol' or 'lower my blood pressure'. This is probably <u>not</u> what you really want. We know, for example, that cholesterol lowering medications really lower people's cholesterol. That's what they're designed to do.

But as we pointed out in our discussion of the West of Scotland Study in the last chapter, lowering your cholesterol correlates very, very weakly to avoiding a first heart attack or dying from coronary disease.

Scholars sometimes call 'lower cholesterol' or 'lower blood pressure' or many similar measures *test indicators*. These are numbers that seem to indicate something about your chance of having a heart attack or dying of heart disease. But unless that number correlates very strongly to an actual medical event, it's probably not very meaningful to you. In the cholesterol case, it's a very, very weak correlation.

Second, you may mean 'avoid a first heart attack'. This probably *is* what you mean. It's sometimes called a 'patient outcome' or 'medical event'. Other patient outcomes include

- Dying of breast cancer
- Dying of colon cancer
- Having a stroke
- Losing your leg to diabetes
- And many, many more

This patient outcome information is often more difficult to obtain than test indicator information. You may, for example, ask your doctor 'out of 100 people like me who take statins, how many still have a first heart attack?' and your doctor may say 'I don't know exactly, but having lower cholesterol is a good thing for you.'

Again, that doesn't answer your question. Dr. Newman is very firm on this point: ¹⁵³

Push hard if necessary. Do not allow confusion to stand.

You need to know how much the health interventions you undertake have the potential to help you.

Here's how Lipitor answered the two questions that we have just introduced, the

- Out of 100 people like me, how many will have a first heart attack if they *don't* take Lipitor, and
- Out of 100 people like me, how many will *still* have a first heart attack if they take Lipitor?

¹⁵³ Newman, Hippocrates's Shadow, pages 213 and 218



See the small print, bottom left. It's well done and very clear: ¹⁵⁴

Out of 100 people, 3 would have had a heart attack *without* Lipitor and 2 *still* had heart attacks with Lipitor. (Oh, that other drug and treatment information was as user friendly!)

You're now ready to answer the key benefit question, a simple subtraction:

Out of 100 people like me, how many benefit from the medical intervention?

This follows directly from your starting risk question 'out of 100 people like me, how many will have the bad medical event without a medical intervention?' and your second question 'out of 100 people like me, how many still have the bad medical event if they have a medical intervention?'

¹⁵⁴ This ad ran in the Wall Street Journal on December 4, 2007, among other places.

Benefit means 'avoid the bad medical event'.

- If 3 out of 100 people like you will have a heart attack *without* taking a statin, and
- If 2 out of 100 people like you will *still* have a heart attack even if they take a statin, then
- 1 out of 100 people like you who takes a statin actually benefits by avoiding a heart attack.

You can use these questions to assess the benefits of lots of different medical interventions. Try it with your own doctor. You may be surprised by his/her response....as he or she will probably be impressed with your questions.

Step 3: Learn how much medicine harms

Patients face a number of potential harms from medical interventions. You need to understand the risks and weigh them against the chance of benefit to make a wise and informed medical decision.

We'll consider 4 different medical harm categories:

- 1. Random, systemic errors
- 2. Predictable treatment side effects
- 3. False positives, or indications that you have a disease when, in fact, you don't
- 4. Overdiagnosis, or being diagnosed with a medical condition that won't become symptomatic or ultimately harm you.

Systemic errors

The 1999 Institute of Medicine study To Err is Human found that at least 44,000 and as many as 98,000 people die in hospitals every year as a result of medical errors that could have been prevented. ¹⁵⁵ Quoting the IOM report

Medical errors can be defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Among the problems that commonly occur during the course of providing health care are adverse drug

¹⁵⁵ Institute of Medicine, To Err is Human, <u>http://www.iom.edu/~/media/Files/Report%20Files/1999/To-Err-is-Human/To%20Err%20is%20Human%201999%20%20report%20brief.pdf</u>

events and improper transfusions, surgical injuries and wrong-site surgery, suicides, restraint-related injuries or death, falls, burns, pressure ulcers, and mistaken patient identities.

Other researchers have defined errors differently and used different research protocols to arrive at higher harm rates. For example:

- A 2011 Health Affairs study suggests that the real rate of patient harms in hospitals is up to 10x higher than the Institute of Medicine estimated in 1999¹⁵⁶
- Another 2011 Health Affairs study suggests that adverse medical events medical care that causes harm or injury separate from the underlying medical condition – may cause up to 187,000 hospital deaths each year and up to 6.1 million injuries ¹⁵⁷
- The Centers for Disease Control estimates that approximately 1.7 million hospital acquired infections occur every year in American hospitals, resulting in 99,000 deaths.¹⁵⁸
- Dr. Lucian Leape, a highly respected professor at Harvard Medical School who has studied hospital safety for years, was asked in 2008 'How much of a problem is patient safety?' ¹⁵⁹

His answer: The unsettling fact is that no one knows.

These are all national, large scale statistical studies and observations. To bring this to a more personal level, let's review the very good reporting on medical harm in Las Vegas done by the Las Vegas Sun in 2010. This resulted from a 2 year investigation into Nevada hospital practices.¹⁶⁰

The Sun divided its analysis into 4 main sections, each describing a different way hospitals harmed their patients:

¹⁵⁶ Classen, Global Trigger Tool, Health Affairs, April 2011

¹⁵⁷ Goodman, The Social Cost of Adverse Medical Events, Health Affairs, April 2011

¹⁵⁸ CDC At Work: Preventing Healthcare-Associated Infections, <u>http://www.cdc.gov/washington/~cdcatWork/pdf/infections.pdf</u>

¹⁵⁹ To Err is Human – To Delay is Deadly, SafePatientProject.org, <u>http://safepatientproject.org/safepatientproject.org/pdf/safepatientproject.org-ToDelayIsDeadly.pdf</u>

¹⁶⁰ Do No Harm: Hospital Care in Las Vegas, a five-part series in the Las Vegas Sun

- 1. Preventable injuries that patients suffered in the hospital
- 2. Hospital acquired infections
- 3. Punctures and lacerations
- 4. Systemic failure

The Sun's series revealed, among other things: ¹⁶¹

- the dangers patients have unknowingly encountered as they enter delivery rooms, surgical suites and intensive care units, including thousands of cases of injury, death and deadly infection associated with stays in Las Vegas hospitals, *and*
- the public has not known the scope of the problems, even though the state has been gathering inpatient data since 1986.

The result: In a state where gamblers can easily access the odds on any video poker machine, hospital patients have had no way of knowing how frequently harmful outcomes occur where they receive their most sensitive health care.

The Sun's investigation and data analysis from 2008 – 9 revealed:

- 3,689 cases where patients suffered preventable harm while under a hospital's care. In 356 of the incidents, patients died in the facilities. ¹⁶²
 - Preventable harms include bedsores, central line infections and patient falls, almost all of which are preventable.
- 2,010 patients were infected with drug resistant bacteria. ¹⁶³
- 710 accidental punctures or lacerations more than half during elective procedures. In 38 cases, the patient died in the hospital. ¹⁶⁴

¹⁶¹ These are direct quotes from the June 27, 2010 article 'A breakthrough in medical transparency'

¹⁶² Allen, Why We Suffer, Las Vegas Sun, Nov 14, 2010

¹⁶³ Allen and Richards, A Hidden Epidemic, Las Vegas Sun, August 8, 2010

¹⁶⁴ Allen and Richards, Patients at Risk Under the Knife, Las Vegas Sun, September 19, 2010

All medical care contains an element of risk, as we have been suggesting. When patients need care and when that care will very likely benefit them, the risks may well be reasonable, appropriate and acceptable.

But when the care is *unnecessary* or of *very low quality* – meaning the patient has a very low chance of benefiting - the risks may be unreasonable and unacceptable. That's for each patient to decide, of course. *But they certainly need to ask the right questions and get complete answers to make that decision!* The Sun's investigation showed how poorly patients understand the hospitalization risks they run.

I've tried to explain, in this initial discussion of harm, that patients face unpredictable, random, systemic risks from any hospitalization or medical intervention. The message: don't get hospitalized or access medical interventions thoughtlessly; be sure you need them.

In the next section, we'll discuss some predictable risks that arise from specific medical treatments.

Key idea: all medical care contains an element of patient risk.

One type of risk is *systemic harm*, much of which is avoidable. The Las Vegas Sun documented over 3600 specific examples of avoidable patient harms in Las Vegas hospitals in 2008 and 9.

Treatment specific, predictable harms

Each medical intervention contains some *predictable* side effect harms in addition to the systemic risks we discussed above. Let's first consider a simple case, side effects of statins.

Statins, as we have seen in the Lipitor ad, reduce the rate of heart attacks in patients with high cholesterol or other risk factors from about 3 in 100 to about 2 in 100. In other words, about 1 in 100 people who take statins actually benefit from them by avoiding a heart attack.

Remember that when calculating the benefits we asked 2 questions:

- 1. Out of 100 people like me, how many will have a heart attack in the next few years if they *don't* take a statin? And
- 2. Out of 100 people like me, how many will *still* have a heart attack if they take a statin?

Wise patients use the same format to calculate harms.

One statin side effect is diabetes. According to a 2010 Lancet report on 13 statin trials with 91,140 participants, 4278 developed diabetes during a mean of 4 years. ¹⁶⁵ The Lancet conclusion: treating 255 patients with statins for 4 years resulted in one extra case of diabetes.

In other words, statins generate about 0.4 cases of diabetes per 100 users over 4 years.

We can now compare statin benefit and the diabetes harm:

Benefit: 1 heart attack avoided per 100 users over 3.5 years per Lipitor's ad

Harm: 0.4 cases of diabetes *caused* by statins per 100 users over 4 years from the Lancet article

In essence, the various Lancet studies asked and answered our questions:

- Out of 100 people who *don't take* statins, how many will develop diabetes? And
- Out of 100 similar people who take statins, how many will develop diabetes?
- The difference is 0.4 people per 100 who will develop diabetes by taking statins.

Some other statin side effects include muscle pain, cognitive impairments and sexual dysfunction. I won't bore you with the underlying research data but will jump to the conclusions. Bloomberg BusinessWeek's seminal 2008 article summarized these risks as affecting about 10 - 15% of statin users. ¹⁶⁶ Is this a big or small, significant or insignificant risk?

John Carey, author of that Bloomberg BusinessWeek article has an astute observation about words like 'significant', 'very rarely' and 'insignificant':

Drug makers usually dismiss a 1 in 100 side effect as completely insignificant. ¹⁶⁷

¹⁶⁵ Sattar et al, Statins and the risk of incident diabetes, Lancet, February 27, 2010

¹⁶⁶ Carey, Do cholesterol drugs do any good? Bloomberg BusinessWeek, January 16, 2008

¹⁶⁷ John Carey, Nieman Reports, Spring 2009
<u>http://www.nieman.harvard.edu/reports/article/100950/Diving-Into-Data-to-Tell-Untold-Medical-Stories.aspx</u>

In our example, researchers have documented about half as many cases of diabetes caused by statins as heart attacks prevented. But the 1 in 100 heart attack reduction is 'significant' while the 0.4 in 100 diabetes increase is 'small'.

Here's another example, the Mayo Clinic's write up of diabetes risks from statins: ¹⁶⁸

It's possible your blood sugar (blood glucose) level may increase when you take a statin, which may lead to developing type 2 diabetes. The risk is small...

'Small' diabetes risk. Meanwhile, still according to the Mayo Clinic

Statin therapy significantly reduces the incidence of heart attack, stroke, and cardiovascular death.

I think John Carey was on to something.

I looked up 'statin side effects' on the Mayo Clinic site and learned that

The most common statin side effect is muscle pain. You may feel this pain as a soreness, tiredness or weakness in your muscles. The pain can be a mild discomfort, or it can be severe enough to make your daily activities difficult....

Very rarely, statins can cause life-threatening muscle damage called rhabdomyolysis

But I didn't learn <u>how frequently</u> any of this occurs and especially not how frequently in people like me. I also don't know what 'very rarely' means to the Mayo Clinic writers. That's why I find information on educational websites like this less valuable than the comparative outcome information like I presented from the Lancet, above.

Ref: http://www.mayoclinic.com/health/statin-side-effects/MY00205

A wise patient asks our key questions and insists on getting answers. Remember the logic:

1. Out of 100 people like me, how many will have a heart attack if they don't take a statin? (Answer: about 3 per Lipitor ad)

¹⁶⁸ <u>http://www.mayoclinic.org/medicalprofs/statin-intolerance-clinic.html</u>

- 2. Out of 100 people like me, how many will *still have* a heart attack if they take a statin? (Answer: about 2 per Lipitor ad)
- 3. Out of 100 people like me how many benefit from taking statins? (Answer: about 1 per Lipitor ad)
- Out of 100 people like me, how many are harmed by taking statins? (Answer: about 0.4 develop diabetes from Lancet study and 10 – 15 report other problems from Bloomberg BusinessWeek article.)

Now, and only now, are you an informed patient, able to decide whether or not to take a statin!

Key idea: an informed patient can quantify the benefits and risks of each medical intervention.

In calculating harms, you need to use the same logical progression as you did to determine benefits.

Comments like 'rarely' or 'insignificant' don't help you become well informed!

Let's turn next to a more complicated example, prostate cancer screening tests (PSA).

PSA screening can help identify asymptomatic prostate cancer. That's early stage prostate cancer that men don't feel and that presents no symptoms. Sometimes these are very slow growing cancers that will never harm the man. Other times these may be faster growing, more dangerous cancers. Physicians have difficulty determining which is which.

Once identified, most men want to do something about the cancer and, generally since about 1990, remove the prostate. Few take the 'watch and wait' approach as it's so stressful. Some opt for radiation or other measures.

We have, therefore, a standard, chronologic progression from *screening* to *diagnosis* to *treatment*. Screening generally leads directly to treatment when cancer is identified. Treatment harms thus equate to screening risks, since we can predict that a certain percent of the men screened will be treated and a certain percent of them will be harmed.

This is a more complicated situation than the statin example above because of the chronologic progression. In the statin example, you take the pill and have the benefits and harms. It's a one-step cause and effect.

In the PSA example, you have the test, then make a treatment decision and experience the benefits and harms. It's a two-step cause and effect. The screening itself doesn't cause the harm – it's a simple blood test. But the result of the screening does.

What is that predictable percent of men who will be harmed by prostate treatment? One good estimate comes from a major European study of PSA screening and its effects. ¹⁶⁹ According to this data, which presents PSA screening in the most positive light of the various studies in the past couple decades, about 1400 men need to have regular PSA screenings to save one life.

- The life saving benefit of PSA screening is about 1 in 1400 men, or about 7/100ths of 1%. Remember, that's from the most favorable study.
- Others have found no life saving benefit from PSA screening. ¹⁷⁰

The European study found that to prevent one death, 48 men would need to be treated for prostate cancer. Many, historically, have chosen radical prostatectomy. This surgical procedure has the following rates of predictable patient harms: ¹⁷¹

- About 50% of men experience sexual dysfunction two years post surgery
- About 1/3 have problems urinating two years post surgery.
- A few, perhaps one or two per thousand, die in the hospital after surgery.

PSA testing, thus, predictably leads to sexual dysfunction or urinary incontinence in about 1 in 60 men screened, or about 1.7%. Another 1 in 1000, or .1% die from the surgery.

Are the impotence and incontinence risks low enough to have the screening? Are they 'very rare' or 'insignificant' screening side effects?

¹⁶⁹ Schroder et al, Screening and Prostate Cancer Mortality in a Randomized European Study, New England Journal of Medicine, New England Journal of Medicine, March 26, 2009

¹⁷⁰ Can prostate cancer be found early? American Cancer Society http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-detection

¹⁷¹ Welch, Overdiagnosis, page 58

Or are they so high that men want to avoid the screening test?

These are, of course, individual decisions. Here are the numbers: Of the men screened

- .07% of men benefited, in the most optimistic case, by having their life saved, while
- 1.7% of men were harmed by incontinence or impotence.

Remember John Carey's observation from the previous section: 1.7% of men *harmed* by PSA screening is roughly the same percent as the 1% of people *helped* by taking statins.

- Remember how statin proponents claimed this is a 'significant relative reduction'.
- Beware of PSA proponents who claim that the 1.7% risk of incontinence or impotence is 'small' or perhaps 'significant but small'.

Key idea: in addition to the *systemic* harms, each specific medical intervention has its own rate of side effects. These are often known by the medical community.

In the PSA example, one large study showed that 1 in 1400 men screened will have his life saved while 1 in 60 will have his life harmed by incontinence or impotence.

Other studies have shown no life saving benefit from PSA screening but suggest the same predictable treatment harm rates.

Note that these predictable side effects differ from the random, systemic harms identified in the Las Vegas Sun series. The wise, informed patient would therefore ask two very different questions of his/her physician:

- 1. What are the harm rates infections, bedsores, falls of the *hospital* that you're referring me to?
- 2. What are the predictable harm rates of the treatment that I'm facing?

We may not have the exact answers and, according to the Las Vegas Sun researchers, much of the systemic risk information is hard to get. But as I type this, I hear Dr. David Newman in my mind's ear:

Push hard if necessary.

If your physician doesn't have the answers, don't be afraid to ask them to find the answers.

You need to know how much the medical interventions you undertake have the potential to harm you. ¹⁷²

False positive and overdiagnosis harms

False positives are test results indicating that a patient has a medical problem when, in fact, the patient does not. A positive test result – whether a true or false positive – often leads to medical care. In the false positive result case, that care is unnecessary.

Overdiagnosis means you are diagnosed with a medical abnormality that will never become symptomatic, harm you or shorten your life. Overdiagnosis is a relatively new medical phenomenon.

Key idea: Patients receiving care based on a false positive or over-diagnosis can't benefit because they weren't sick to begin with.

But they face all the medical care costs and risks.

I'm discussing both of these together in this section because they act the same way: they both make someone believe they're sick and cause them to have unnecessary medical care.

False positives can result from many causes, including simple physician error. Remember our earlier discussion of a study suggesting that when cardiologists are (secretly) given the same EKG multiple times, they disagreed with themselves more than 10% of the time? ¹⁷³ An X-ray, MR, EKG or other may look like a serious medical abnormality one image reader but not to another.

False positives and overdiagnosis can also result from our increasingly powerful screening technologies. We discussed this in an earlier chapter, using the Florida lake identification problem as an example. To push the analogy:

¹⁷² Newman, Hippocrates' Shadow, pages 213 – 218. I changed the second last word of the third quote from 'help' to 'harm', since this section discusses harms.

¹⁷³ Newman, Hippocrate's Shadow, page 58

- A doctor may identify as a 'lake' a flooded plan that disappears after a few days, or a pond, swimming pool or swamp that looks like a lake in some key ways but really isn't *really* a lake. That's a false positive.
- Or the doctor may identify a really, really, really small lake that only appears on the newest, highest technology imaging machine. That's more in the overdiagnosis category.

Here's a chart showing the rough impact of false positives and overdiagnosis caused by mammography screening over a 10 year period, per 10,000 patients: ¹⁷⁴

	<u>Age 40 – 49</u>	<u>Age 50 - 59</u>
Breast cancer deaths avoided	5 (out of 10,000 over 10 yrs)	7 (out of 10,000 over 10 yrs)
False positive results requiring	600 - 2,000	500 - 2,000
a biopsy	(out of 10,000 over 10 yrs)	(out of 10,000 over 10 yrs)
Unnecessary treatment including mastectomy, lumpectomy and radiation	10 – 50	10 – 70

In order to avoid 1 breast cancer death for women in their 50s, according to this data, up to 10 women would need to receive treatment. Nine would not benefit because they were not going to die anyway, but they face all the treatment costs and risks.

In other words, false positives and overdiagnosis put many more women at risk of having treatment than their starting risk of dying from breast cancer.

Ray Moynihan, a former Harkness Fellow (that's roughly the Commonwealth equivalent of a Rhodes Scholar) listed some false positive and overdiagnosis estimates in a 2012 Health Affairs article. Here's part of his list: ¹⁷⁵

- Asthma a Canadian study suggests 30% of people so diagnosed may not have asthma and 66% of those may not require medications
- Attention deficit hyperactivity disorder widened definitions have led to concerns about overdiagnosis. Boys born at the end of the school year have 30% high

¹⁷⁴ This information comes from Woloshin, 'The Benefits and Harms of Mammography Screening' Journal of the American Medical Association, Jan 13, 2010

¹⁷⁵ Moynihan, Preventing Overdiagnosis, Health Affairs, May 29, 2012

chance of diagnosis and 40% higher chance of medication than those born at the beginning of the school year

- Breast cancer systematic review suggests up to a third of screening detected cancers may be overdiagnosed
- Gestational diabetes expanded definition classifies almost 1 in 5 pregnant women
- High cholesterol estimates run as high as 80% of people with near normal cholesterol may be overdiagnosed. Many of these people are treated for life
- Lung cancer 25% or more of screening detected lung cancers may be overdiagnosed
- Osteoporosis expanded disease definitions mean many low risk women get treated and experience a net harm
- Prostate cancer up to 60% of men whose prostate cancer is detected by PSA exams may be overdiagnosed
- Pulmonary embolism our increased diagnostic sensitivity leads to detection of very, very small emboli. Many may not require anticoagulant treatment

Key idea: Our false positive and overdiagnosis rates may be very, very high, perhaps a quarter to half of some disease diagnoses.

The false positive and overdiagnosis trends may be worsening as our imaging and other technologies improve faster than our understanding of medical abnormalities.

Summary of the Harms section

The wise patient, when faced with a treatment decision, would ask his/her physician

Out of 100 people like me, how many will be harmed by this medication, test or procedure?

Those harms include

- Random, systemic harms
- Predictable drug or treatment side effects and
- False positive or overdiagnosis disease definitions

I suggest that the conclusion to our Harms section is this: there's no such thing in medicine as 'erring on the side of caution'. There are only benefits and risks of *having* a test, taking a medication or having a procedure...and the benefits and risk of *not*.

Our questions will help you determine which way you want to proceed.

Step 4 Understanding the Number Needed to Treat

To some extent, medicine today is like baseball as depicted in the movie Moneyball – an industry in search of evaluation metrics.

Movie or baseball buffs may remember that Billy Beane, the General Manager of the Oakland Athletics, needed to find undervalued baseball players due to the financial constraints he faced. He developed new metrics to evaluate ball players, used them to assemble his team, and then set a major league record for consecutive wins.

Could we do the same in medicine?

Our 'out of 100 people like me' series of questions is one attempt to measure medical effectiveness. These questions will help you determine benefits and risks of various medical interventions. They'll help you and your physician have a better discussion and help you become a more well-informed patient. Consider this series of questions as one new medical effectiveness metric.

Some members of the medical community use a different metric. Many doctors learn it in medical school. It's called the Number Needed to Treat or NNT.

The Number Needed to Treat tells how many people need to have a medical intervention for 1 person to benefit. It's conceptually very easy to understand. You'll understand it from our Lipitor example (again!). Remember the Lipitor ad data:

- 3 out of 100 people who *didn't* take Lipitor had a heart attack during a 3 ½ year period
- 2 out of 100 people who took Lipitor *still* had a heart attack during the same period
- So 1 out of 100 people who took Lipitor benefited by avoiding a heart attack.

The Number Needed to Treat in this example is 100. You need to give Lipitor, according to the information in its ad, to 100 people in order to avoid 1 first heart attack.
Key idea: the Number Needed to Treat (NNT) tells how many people need to have a particular medical intervention for 1 person to benefit from it.

Remember: 97 of the people who took Lipitor weren't going to have a heart attack in the first place so the Lipitor didn't help them avoid one. (Unfortunately, we don't know exactly who those 97 people were.) That's why we can't say, for example, 'person #54 took Lipitor and didn't have a heart attack, so the Lipitor worked' and have a Number Needed to Treat of about 1. We need to account for all the people who weren't going to have heart attacks in our NNT calculation. Lipitor didn't help them.

- The best way to do this: compare a large group of people who took Lipitor with a large group of similar people who did not. Note the number of heart attacks in each. Then determine how many people needed to take Lipitor in order to prevent 1 heart attack.
- Simply observing that most people who took Lipitor didn't have heart attacks gives the wrong information!

Let's try another example using the PSA screening information we discussed above. According to the European study, 1410 men need to be screened for prostate cancer using PSA tests to save 1 life.

The Number Needed to Treat is 1410. ¹⁷⁶

Some commentators refer to the Number Needed to Screen. It's the same general idea. The NNS or NNT tells you how many people need to have a particular screening test to avoid 1 death. (We'll shortly compare this number – the benefit number – to the harm number. Stay tuned.)

Remember, the European study showed the most impact from PSA screening. Other studies showed less, or none. The NNT in those cases would be higher, with some scholars estimating that it's actually infinite.

What does an infinite Number Needed to Treat mean? It means that you need to treat an infinite number of people in order to benefit 1. In other words, the treatment generates *no patient benefit at all*.

¹⁷⁶ Some researchers have developed a Number Needed to Screen metric for cases like this. It uses the same logic.

Higher NNT numbers indicate that the treatment is less effective; lower NNT numbers indicate that the treatment is more effective. Do you see why?

NNT information isn't necessarily exact. Various studies can show different NNTs, though generally within an order of magnitude. That's how I suggest you read NNT (or Number Needed to Screen) numbers. In our PSA example, the Number Needed to Treat to avoid 1 prostate cancer death is a very large number, perhaps as low as about 1400 and perhaps much higher.

For all practical purposes, it doesn't matter much if the real NNT is 1200, 1400, 1600, 2000 or 2200. It's really, really big, and your chance of having your life saved by PSA screening is really, really small.

This obviously raises the question of harm. If your chance of benefit is really, really small, might your chance of harm be larger? That's the real utility of NNT calculations: they allow you to compare your chance of benefit with your chance of harm.

Now let's use the mammography numbers from earlier in this chapter. We quoted a study earlier showing that if you screen 10,000 women in their 50s for breast cancer using mammography, you'll save 7 lives.

Can you calculate the Number Needed to Treat here? It's about 1428. That's 10,000 women screened divided by 7 lives saved. Again, not necessarily exactly 1428, but a very large number, indicating at any individual woman's chance to have her life saved by mammography is very, very small.

The Number Needed to Treat is a powerful tool. It allows you to compare your medical options based on the likelihood of benefit. Dr. Newman says it's an honest assessment of the value of healthcare interventions and is basic literacy for patients and doctors. ¹⁷⁷ In other words

If you're not familiar with Number Needed to Treat concepts and calculations, you're not medically literate!

(That's why I roll my eyes when people tell me that they're a wise and informed patient unlike everyone else. I've yet to meet someone who knows the NNT of any of the medications or tests he/she has.)

¹⁷⁷ Newman, op cit, pages 217 and 218

A sister concept to the Number Needed to Treat is the Number Needed for Harm or NNH. This is exactly the opposite of NNT: it tells us how many people need to have a medical intervention for 1 person to be *harmed*.

One definition of being a well informed patient: knowing the NNT and NNH of your various medical treatments.

Someone who doesn't know these is simply not a well informed medical care consumer.

Again, let's review our statin discussion. We learned that 0.4 people out of 100 who take statins develop diabetes. The Number Needed for Harm here is about 250. Can you see why?

We also learned that researchers estimate 10 - 15% of statin users suffer muscular, cognitive or sexual problems. The Number Needed for Harm here is about 8. (I divided 100 users by 12.5, the midpoint between 10 and 15%.)

• Is the number needed for muscular, cognitive or sexual problems caused by statins exactly 8? Probably not. But if the research in Bloomberg BusinessWeek is correct, the real NNH here is probably somewhere between about 6 and 15.

Note the confidence range around our NNT and NNH estimates. For small, single digit numbers, the relevant range is plus or minus a few, perhaps plus or minus 3 or 4.

But for large triple or quadruple digit estimates, the range is much bigger. Our mammography NNT range may be 1000 – 1800, for example. That's a guess on my part but a relatively educated one. Remember: NNTs and NNHs suggest orders of magnitude.

As the underlying NNT and NNH gets larger and larger, so too does the relevant range of estimates.

An NNT of 1 means that everyone using the medication or intervention benefits from it. This is a very effective medical treatment.

An NNH of 1 means that everyone using the medication of intervention is harmed by it. This is a very harmful medical treatment. You would probably want to avoid it.

• The lower the Number Needed to Treat, the better the medical intervention works.

• The lower the Number Needed to Harm, the more the medication harms.

Here are some NNT calculations, purely for example purposes: ¹⁷⁸

Intervention	NNT
Aspirin to prevent a first heart attack or stroke, average risk population	1667
Aspirin to Prevent Cardiovascular Disease in Patients with Known Heart Disease or Strokes	50
Rapid Defibrillation for Cardiac Arrest to prevent death	2.5
Oral anticoagulants in non-valvular atrial fibrillation for primary stroke prevention (no prior stroke)	25
Topical antibiotics for clinical care of bacterial conjunctivitis	7
Glucocorticoid steroids for bacterial meningitis (to avoid hearing loss)	21
Antibiotics for treatment of acute bronchitis in adults	infinite (no benefit found)
Steroids for croup (for respiratory improvement)	5
Terbinafine to treat fungal nail infection over 24 weeks	3
Antibiotics to prevent infection from dog bites	16
Droperidol to treat post operative vomiting in children	4

And here are some combined Numbers Needed to Treat and Numbers Needed for Harm, again as examples only: $^{\rm 179}$

¹⁷⁸ The first 8 examples come from <u>www.TheNNT.com</u>. The last 3 from <u>http://www.medicine.ox.ac.uk/bandolier/painres/download/whatis/NNT.pdf</u>

Intervention	NNT	NNH
Hormone replacement therapy to <i>prevent</i> hot flashes	3	
Hormone replacement therapy to <i>cause</i> breast cancer or a nonfatal heart attack		667
Mammograms to prevent death, women in their 50s	1428	
Mammograms to cause a cancer scare (false positive) over 10 years		2
Mammograms to cause a surgical procedure on a noncancerous breast (13 years)		5
Vioxx to prevent a serious gastrointestinal problem	200	
Vioxx to cause a heart attack, stroke or related event		59

Look at the Hormone Replacement Therapy numbers above. Many women stopped this medical intervention in the 1990s and early 2000s after hearing that hormone replacement therapy is a risk factor for breast cancer.

The numbers above suggest that while it *is* a risk factor, it's a relatively small one (large NNH). Meanwhile, hormone replacement therapy works pretty well to prevent hot flashes: the NNT is only 3. This kind of analysis suggests that a short term use of hormones may generate substantial benefit while posing some, though relatively little, risk. Maybe something worth discussing with your doctor.

Key idea: A wise patient who knows the NNT and NNH numbers can make an informed medical decision.

An unwise patient who only knows that hormone replacement therapy is a risk factor may miss out on some quite substantial benefits.

¹⁷⁹ From Newman, Hippocrates' Shadow, page 193. The mammography NNT comes from our discussion, above.

On the other hand Vioxx sold very well in the 1990s and early 2000s, marketed as a pain killer with fewer gastrointestinal bleeding problems. True, but only 1 in 200 people benefited by having fewer stomach bleeds. That's an NNT of 200, a pretty small benefit.

Vioxx caused heart attacks, strokes or related events in 1 out of 59 users. An NNH of 59.

When the Number Needed to Treat is larger than the Needed for Harm, watch out! The intervention may do more harm than good.

These NNT and NNH numbers, hopefully, put to rest poorly considered medical decisions based on ambiguous notions of 'risk factors' or 'fewer stomach bleeds'. The wise patient needs to know *how much* of a risk factor is hormone replacement therapy for causing breast cancer? The answer: not very much.

How much stomach bleeding did Vioxx avoid? Again, not very much. That's why knowing the Number Needed to Treat and Number Needed for Harm separates the medically literate from illiterate, the informed from uninformed patient.

- Yes, Vioxx was a pain killer with fewer stomach bleeds, just like advertised.
- But no, it didn't prevent very many stomach bleeds. That's what an NNT of 200 means.

Dr. Nortin Hadler from the University of North Carolina suggests that NNTs over about 50 are pretty poor medical interventions:

'Anything over an NNT of 50 is worse than a lottery ticket; there may be no winners' ¹⁸⁰ especially when you value in the harms.

Remember: an NNT of 50 means that only 2% of people taking the medicine or having the intervention actually benefit from it. That's a pretty low bar and a pretty good indication that any specific individual won't benefit. After all, 98% don't.

Vioxx's NNT of 200 mean that very, very, very few people would benefit and that you, an individual taking the product, likely won't. After all, 199 out of 200 Vioxx takers don't.

Hadler also suggests that insurance only pay for treatments with relatively low NNTs: ¹⁸¹

¹⁸⁰ Carey, op cit

• For 'hard outcomes' like death, stroke or heart attack, he suggests that insurance pay for interventions with NNTs up to about 20.

An Number Needed to Treat of 20 means that 19 out of 20 people who have the intervention *don't* benefit from it.

• For 'soft outcomes' like 'feeling better', he suggests that insurance only pay if the NNT is less than about 5.

An NNT of 5 means that 80% of people *don't* benefit from the intervention.

I wonder the impact on our insurance premiums if we adopted Hadler's recommendations. (Probably big)

And I wonder the impact on our health status if we adopted them. (Probably small, but that's just my opinion.)

Some concluding thoughts

As we struggle to control our healthcare spending without compromising patient care, we need new metrics to measure medical care effectiveness.

Our 4 question series is one kind of metric:

- 1. Out of 100 people like me, how many will have the bad medical event without a medical intervention, like a medication or a screening test?
- 2. Out of 100 people like me, how many will still have the bad medical event if they take the medications or have the screening test?
- 3. Out of 100 people like me who take the medication or have the screening test, how many actually benefit?
- 4. Out of 100 people like me who take the medications or have the screening test, how many are harmed?

The Number Needed to Treat and Number Needed to Harm analysis is another really useful metric.

¹⁸¹ Hadler, Worried Sick, page 223

http://books.google.com/books?id=fra7RRmHYdIC&pg=PA223&lpg=PA223&dq=hadler+nnt+20&source= bl&ots=dOtVo3mnX2&sig=Bwd9xvmgbTOzOucn9JezSpY5ZTY&hl=en&sa=X&ei=RctbT9rPKYL50gH6p9 CTAw&ved=0CCIQ6AEwAA#v=onepage&q&f=false

Both aim at the same thing, identifying your chance of benefitting or being harmed by a medical intervention.

Unfortunately, we often lack the data necessary to use these metrics exactly. But, being an eternal optimist, I think we're moving in that direction.

Here's an invitation to those who have actually read this entire chapter: use these metrics when you next need medical care. Ask your doctor, for example, for the NNT and NNH of a medication he/she prescribes. Or ask the 'out of 100 people like me' questions.

I have done this the past few times I've visited a doctor. Each time, the doctor was intrigued – actually taken aback - and responded with very open and honest answers. Each verbalized to me that they appreciated my questions. Their reactions were quite positive.

Let me know if you have the same experiences!

Digging Deeper

How ATPIII addressed the NNT issues: for people really interested in this issue

The authors of the ATPIII report included Number Needed to Treat metrics in their analysis. I include this section to demonstrate that the medical community really uses these metrics, though, perhaps because report writers sometimes feel compelled to show that they understand and use them, sometimes badly.

This is a pretty complicated and turgid section, aimed specifically at brokers who really want details. Others can feel free to skip to the next chapter.

The NNT numbers that we show below demonstrate that medical interventions have more impact on sicker people than on healthier. For example, statin medications will more likely help people with total cholesterol of 300 than people with total cholesterol of 205. That's, perhaps, the main lesson of this section. When you, a patient, ask your physician about NNTs and NNHs, make sure the answer applies to you. As the numbers below indicate, the NNT for preventing a first heart attack varies depending on many factors, including your own total cholesterol level and other risk factors.

I included this section primarily to show that NNT numbers are becoming more common in the medical literature, and because we've previously discussed the ATPIII report. I don't think these specific numbers mean very much because they rely on so heavily on unproven assumptions.

The first assumption: researchers can extrapolate data from a 5 year statin study like the West of Scotland study and draw meaningful conclusions about 15 years of statin use. That's highly spurious at best, and probably closer to nonsense.

A second assumption: people will actually take their statin medication every day for 15 years. This assumes a patient compliance rate that's much higher than for most medications. In fact, nearly 3 out of 4

Americans report that they don't always take their medications as directed and 1 in 3 never even fill their prescriptions! ¹⁸² Nonetheless, I decided to include this information because people might see it in the literature and I thought it useful for readers to see how NNT numbers are used and abused. Note in this particular example: the ATPIII authors ignored any Number Needed for Harm analysis at all, which raises questions about the objectivity and orientation of these experts. We've already discussed that.

Here are some NNT estimates from the ATPIII study. These are estimates of statin benefit for people at age 65 who take statins for 15 years: ¹⁸³

For people facing a 10% chance of having a heart attack or dying from coronary heart disease according to the Framingham Heart Study risk estimator, the Number Needed to Treat to avoid *dying of coronary heart disease by age 80* is 42. For the same population, the Number Needed to Treat to avoid *dying of coronary heart disease or of having a heart attack by age 80* is 21. For the same population, the Number Needed to Treat to avoid *dying of coronary heart disease or of having a heart attack by age 80* is 21. For the same population, the Number Needed to Treat to avoid *dying of coronary heart disease or of having a heart attack by age 80* is 21. For the same population, the Number Needed to Treat to avoid *dying of coronary heart disease or of having a heart attack, unstable angina, angioplasty or bypass surgery by age* 80 is 10.

For people facing a 20% chance of having a heart attack or dying from coronary heart disease according to the Framingham Heart Study risk estimator, the Number Needed to Treat to avoid *dying of coronary heart disease by age 80* is 20. For the same population, the Number Needed to Treat to avoid *dying of coronary heart disease or of having a heart attack by age 80* is 10. For the same population, the Number Needed to Treat to avoid *dying of coronary heart disease or of having a heart attack by age 80* is 10. For the same population, the Number Needed to Treat to avoid *dying of coronary heart disease or of having a heart attack by age 80* is 10. For the same population, the Number Needed to Treat to avoid *dying of coronary heart disease or of having a heart attack, unstable angina, angioplasty or bypass surgery by age 80* is 5.

There. I've shown that experts writing Expert Committee reports really use NNT numbers. Though, I suspect, their analysis is quite incomplete.

¹⁸² Report from the National Campaign to Improve Drug Medication Adherence <u>http://www.nclnet.org/images/PDF/adherence%20campaign%20overview%20dec%202009.pdf</u>

¹⁸³ Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (ATPIII) Page II-33 http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf

Review Questions answers on next page

- 1. What does starting risk mean?
 - a. That's the amount of medical risk you have over your lifetime

b. Your chance of having a particular medical event without a medical intervention

c. Your chance of being harmed by medical care

2. Why should you ask your doctor questions for which he/she likely doesn't have an answer?

a. You shouldn't. It may make your doctor feel badly

b. Asking good questions can help you and your doctor work as a team to find the answers

c. If you don't ask the right questions, you almost certainly won't get useful information

3. Why is it important to know your starting risk of having various medical events like heart attacks or dying of colon cancer?

- a. So you can anticipate your future medical expenditures
- b. So you can buy the right kind of health insurance

c. So you can understand medical claims like 'this medication reduces your chance of having a heart attack by 36%'

4. What is a useful way to ask your doctor about your starting risk of having a specific medical event?

a. Doc, do you think I'll have a heart attack?

b. Doc, out of 100 people like me, how many will have a heart attack if they don't take cholesterol lowering medication?

5. Can you make a wise medical decision without knowing your starting risk?

- a. Yes
- b. No

c. It's always best to defer these kind of questions to my doctor

6. What is a good way to learn how much a medical intervention can help you?

a. Ask your doctor 'do you think this medical intervention will help me?'

b. Ask your doctor if it's more likely, or less likely, that a specific medical

intervention will help you

c. Ask your doctor 'out of 100 people like me, how many will still have the bad medical event if they have the medical intervention?'

7. What's another good way to learn how much a medical intervention can help you?

a. Ask a nurse 'do you think this medical intervention will help me?'

b. Learn the Number Needed to Treat for that medical intervention

8. What's a good way to learn how much a medical intervention can harm you?

a. Ask your doctor 'do you think this intervention will harm me?'

b. Ask your doctor if he/she generally gets good outcomes from a specific medical intervention

c. Ask your doctor 'out of 100 people like me, how many are harmed by this medical intervention?'

9. Which statement below conveys the highest quality medical information?

a. '3 out of 100 people like you will have a heart attack without taking statins but only 2 out of 100 will still have a heart attack if they take a statin'

b. 'statins reduce your risk of having a heart attack by 36%'

c. Statins reduce cholesterol levels and high cholesterol is a risk factor for having a heart attack

10. What does the phrase 'significant relative risk reduction' mean?

a. It means that a medical intervention saves lots of lives

b. It means that a medical intervention helps lots of people

c. It doesn't mean very much of anything at all, especially if you don't know the starting risk

11. What do the phrases 'this medication generates significant patient benefit' and 'this medication rarely has major side effects' mean?

a. They mean that the medication in question helps many more people than it harms

b. These phrases don't mean very much of anything, since people use words like 'significant' and 'rarely' to mean different things about benefits and harms, depending largely on whether they're selling a medical service or not

Review Questions correct answers in bold

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Chapter 6

Metrics and Indicators for Hospital and Physician Choice

In addition to choosing your medication, test or treatment – by using our 'out of 100 people like me' questions or by determining the various Numbers Needed to Treat and to Harm – you need to choose your doctors and hospitals.

There are various ways to do this - some appropriate, some not. Here are a few inappropriate ways to choose your providers:

- Choose the one with the biggest Yellow Pages or google ad
- Choose the most famous, biggest or oldest one
- Choose the one affiliated with the most prestigious local medical school
- Choose the one closest to your home or work
- Choose the most expensive one, or
- Choose the one with the most credentials and awards.

These are all inappropriate criteria, in my opinion, because they don't tell you the key fact that you want to know: *will they help me get better*? Patient outcomes don't necessarily correlate with advertising, fame, size, cost, location or credentials. In fact, patient outcomes are a completely separate category.

This chapter will suggest some ways to choose doctors and hospitals. You may feel a bit uncomfortable as we go through this exercise. The reason: many people want to trust that their doctor and hospital will make them well. After all, they're frightened or in pain, facing potentially lethal risks. Patients often feel a need to trust that their care giver is really good.

The questions and the issues we raise here may undermine some of that trust.

Which provider is 'best'?

Hospitals have different strengths and weaknesses:

- Some may be particularly good at cardiology, for example, while others are very strong in urology or nephrology
- Some may be excellent at routine, non-controversial treatments, while others are much better at cutting edge interventions

 Some may have low readmission rates for some procedures but higher rates for other

The wise patient learns how to differentiate among the various strengths and weaknesses of each hospital to maximize his/her chance of benefitting from a hospitalization.

Doctors also have different strengths, weaknesses and orientations:

- Some doctors may be particularly risk averse, so advise their patients to have extensive and regular screening tests
- Others are more concerned about false positives or overdiagnosis so use screening tests more judiciously
- Some specialists are more aggressive and prefer to operate as soon as possible to treat abnormalities before they grow or spread, while others may prefer to watch and wait, to ensure that surgery is absolutely necessary

Many medical interventions are judgment calls. The wise patient understands this and chooses doctors whose judgments match his/her own.

Hospitals differ by patient outcomes

Here's a list, for example, of the 4 Massachusetts hospitals with the lowest risk adjusted heart failure mortality rates during the period June 1, 2006 and July 31, 2009, as reported by Medicare's hospitalcompare.gov website: ¹⁸⁴

- 1. Southcoast Hospital, Fall River (the lowest)
- 2. Brigham and Women's Hospital, Boston
- 3. Ana Jaques Hospital, Newburyport
- 4. Faulkner Hospital, Boston

And here are the 4 Massachusetts hospitals with the lowest risk adjusted pneumonia mortality rates for the same period:

- 1. Norwood Hospital, Norwood (the best)
- 2. Falmouth Hospital, Falmouth
- 3. Boston Medical Center, Boston

¹⁸⁴ Risk adjustment discounts illness severity differences among patients, so avoids penalizing some hospitals for treating sicker patients. The variation among these hospitals is pretty small, generally within the margin of error. Expanding this list to exceed the margin of error shows pretty much the same thing: that hospital outcomes differ by disease and patient type.

4. Mount Auburn Hospital, Cambridge

Medicare publishes similar lists of patient outcomes by disease, for most hospitals in all states.

What do you notice about the Massachusetts list? Different hospitals! If you're suffering from pneumonia, you probably want to go to Norwood Hospital, not Southcoast. But if you're suffering from heart failure, you might want the reverse.

Other states and disease types demonstrate similar outcome patterns. When choosing a hospital, you want the hospital that's best for <u>you</u>, with your disease and medical needs, not for someone suffering from a different medical problem.

The key questions to ask

A wise patient wants to learn, before choosing a hospital: What are your outcomes for *patients like me*?

- Patients like me have my medical problems and presentation.
- *Patients like me* do not necessarily share my race, creed, color, religion, income state, political views or other, similar medically irrelevant characteristics.

Finding outcome data may be difficult, much like finding NNT or NNH data. But only by asking the question can you begin to get an answer, and sometimes by asking the question your doctor or other advisor may direct you to a useful information source.

It doesn't hurt to ask and you may make a better hospital choice as a result.

Absent outcome data, an easier-to-find outcome indicator: the *quantity* of patients like you

Unfortunately, as we've oft discussed so far in this book, we don't often have exactly the patient outcome information that we need to make wise and informed medical care decisions. That's likely the case for you: you may not learn the various *outcomes for patients like you* from one or a set of hospitals.

Fortunately we have a pretty good proxy for that information and one that's relatively easy to find. It's the *quantity* of a specific procedure performed by a hospital. In other words, the more heart bypass surgeries a hospital performs the better the patient outcomes...in general, by and large, most of the time.

Though not a hard and fast rule, much medical research suggests that quantity often equals quality in medicine, with higher quantities generating better patient outcomes and lower quantities generating poorer.

Thus, a good proxy for our outcomes question: **How many patients like me do you treat annually?**

Here are some research examples:

 'High-volume providers have significantly better outcomes for vascular procedures' according to Killeen and his colleagues in their 2007 Journal of Vascular Surgery article. ¹⁸⁵ In fact, they found that

The reduction in the risk-adjusted mortality rate for high-volume providers [hospitals] was 3% to 11% for elective abdominal aortic aneurysm(AAA) repair, 2.5 to 5% for emergent AAA repair, 0.7% to 4.7% carotid endarterectomy, and 0.3% to 0.9% for lower limb arterial bypass procedures.

• 'Unadjusted mortality rates were significantly higher at low-volume hospitals' according to a 2003 Health Affairs article. ¹⁸⁶ This article went on to suggest that

hospitals that perform more than a threshold number have significantly lower mortality than do hospitals where fewer procedures are performed ...

Volume threshold levels have been recommended as the basis for evidencebased referrals ... and

in the absence of other information on quality of care, volume of procedures is a reasonable standard for selecting hospitals.

 'Evidence exists that high-volume hospitals (HVHs) have lower mortality rates than low-volume hospitals (LVHs) for certain conditions' according to a 2000 study published in the Journal of the American Medical Association. ¹⁸⁷ Unfortunately, however

¹⁸⁵ Killeen et al, Provider volume and outcomes for abdominal aortic aneurysm repair, carotid endarterectomy, and lower extremity revascularization procedures, Journal of Vascular Surgery, March 2007

¹⁸⁶ Elixhauser et al, Volume Thresholds and Hospital Characteristics in the United States, Health Affairs, March 2003

¹⁸⁷ Dudley, et al, Selective Referral to High Volume Hospitals: Estimating Potentially Avoidable Deaths, Journal of the American Medical Association, March 1, 2000

few employers, health plans, or government programs have attempted to increase the number of patients referred to HVHs.

Specifically, this study found that

Mortality was significantly lower at HVHs for elective abdominal aortic aneurysm repair, carotid endarterectomy, lower extremity arterial bypass surgery, coronary artery bypass surgery, coronary angioplasty, heart transplantation, pediatric cardiac surgery, pancreatic cancer surgery, esophageal cancer surgery, cerebral aneurysm surgery, and treatment of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS).

In fact, among patients admitted to California hospitals in 1997 for these procedures

we estimated that 602 deaths at LVHs could be attributed to their low volume.

Some hospital safety and quality research organizations have established benchmarks or thresholds for the recommended number of annual procedures. A wise patient learns and uses them.

Based on these and similar studies, consider asking your referring physician

1. What is the recommended annual threshold number of procedures like mine for a hospital? and

2. What are the annual volumes of procedures like mine at the various hospitals you're considering referring me to?

(You can ask the same of your surgeon. We'll address some 'how to choose a physician' topics later in this chapter.)

In the absence of high quality outcome data, answers to these questions can help you make a much better hospital choice decision.

Why is volume so important for hospitals and surgeons?

We know that practice makes perfect in lots of different fields, from violin playing to baseball hitting. Not surprisingly, practice makes perfect in medicine also.

But the two main reasons why practice makes perfect in medicine may surprise you. In fact, practice doesn't really improve the surgeon's cutting and suturing skills much after

residency. Those skills are somewhat like bicycle riding: once you attain proficiency, you don't get much better over time.

Instead, the two reasons why practice makes perfect in medicine are unique to the medical field.

First, the surgeon's experience dealing with similar patients helps him/her identify and treat patients who are 'out of bounds' much more quickly, often during the surgery itself. Dr. Gawande described this eloquently in his article The Computer and the Hernia Factory. ¹⁸⁸ In it, he claims that the keys to surgical perfection are

...routinization and repetition: survival rates after heart surgery, vascular surgery, and other operations are directly related to the number of procedures a surgeon has performed...

When I'm in the operating room, the highest praise I can receive from my fellow surgeons is 'You're a machine, Gawande.'

He used Shouldice Hernia Hospital in Canada as a case study. Shouldice only performs hernia surgeries, and it performs more of them than any other institution in the world.

Hernia surgery is a relatively simple procedure that typically takes about 90 minutes and is typically performed by a general surgeon. The US failure rate, as measured by hernia recurrence, ran about 10 - 15% during the time of Gawande's study. ¹⁸⁹

But at Shouldice, hernia procedures only took about 30 - 45 minutes, and the failure rate was less than 1%. ¹⁹⁰

The reason according to Gawande: practice and repetition. Each Shouldice surgeon repairs 600 – 800 hernias annually, more than the typical American general surgeon would do in a lifetime. This allows Shouldice surgeons to act like machines, to operate in an 'automatic mode', more or less like driving a car.

The fascinating thing about acting in the so-called automatic mode is that we ignore routine details and events *but focus on abnormalities*. A surgeon or surgical team with lots of experience with particular types of patients can differentiate unimportant, routine

¹⁸⁸ Gawande, Complications, pages 38 - 41

¹⁸⁹ This is probably 1990s era data. Gawande's original article on this topic appeared in the New Yorker in 1998.

¹⁹⁰ I heard Gawande discuss this in Brookline, Massachusetts in 2007. At that time he estimated the Shouldice failure rate at between 1/10th of 1% and 1%.

factors from really important abnormalities more quickly and effectively than surgeons or teams with less experience.

Paraphrasing Gawande, the automatic mode frees the surgeon to focus on the key, really important details and to identify serious abnormalities almost instinctively. Because of this, he says that 'a surgeon for whom most situations have automatic solutions has a significant advantage.'

We've all probably had similar situations while driving. You, as an experienced driver, don't pay much attention to the colors of the cars nearby, nor the make or model when everything is routine.

But sometimes you *start* to slow down, almost instinctively, almost before you *decide* to slow down. The car in front of you did something peculiar and you react. Even before you can verbalize it, your experience takes over. You're operating in the automatic mode.

Sometimes you just know that the car in front of you will make a left hand turn. Not because of a turn signal indicator but because of something else, almost an instinct on your part. It may take a second or two for the rational side of your brain to kick in, but you've already started to drive defensively. Again, the automatic mode takes over because you've done this so many times in the past.

Sometimes an experienced driver on a wintery Vermont road almost instinctively slows down before an oddly colored bit of road. Is it harmless tree shading? Water? Or dangerous black ice? The experienced driver adjusts automatically, almost instinctively, before the rational side of his/her brain kicks in; he/she has seen this before.

That's why 50 year olds, with slower reflexes, drive more safely than 17 year olds with faster reaction times. The 50 year olds' experience puts him/her into an automatic mode, able to focus on abnormalities rather than harmless routine details. The 17 year old, lacking sufficient experience, can't quickly determine which events are normal and harmless, and which abnormal and dangerous. That's the learning process that explains why practice makes perfect in driving.

The same holds for surgeons and surgical teams.

- The experienced surgeon almost automatically, almost instinctively adjusts to abnormal patient needs, provided he/she has operated on a sufficient number of similar patients.
- An operating nurse, with years of experience assisting with a particular procedure, more quickly identifies an 'out of bounds' patient than a younger

nurse, or one with less experience dealing with a that procedure or type of patient.

To belabor this point: imagine that you're a gynecologist performing your first ever heart bypass surgery (for some inexplicable reason). You know that there will be some patient bleeding and you observe some. Is it the right amount? Too much, indicating that the patient is suffering? Too little, indicating a problem in the making? You only know the right amount through experience.

And, according to Gawande, if you're operating in the automatic mode, you don't focus on the amount *unless it's the wrong amount*.

Second, hospitals that perform the same procedures over and over have perfected their treatment *systems and routines*, the patient hand-offs and information exchanges all along the line from patient admission to pre-op to operating room to recovery room to post-op to discharge and to rehabilitation. Hospitals with fewer patients have less well developed systems and routines.

To some extent, those systems operate automatically, more or less like very experienced surgeons. The operating room nurse expects to get certain information from the pre-op nurse, which the pre-op nurse routinely and almost automatically sends. Ditto for the recovery room nurse from the operating room nurse. If the 'sending' nurse makes a mistake and leaves out something vital, the 'receiving' nurse can immediately ask about it.

In hospitals with less well-entrenched patient and information flows, the sending nurse may omit some vital information that the receiving nurse doesn't identify. That's the fundamental problem of dealing with a very diverse patient body and performing low quantities of lots of different procedures.

The Leapfroggroup – odd name for a high quality patient safety organization – has published hospital annual threshold recommendations. They recommend, for example, that hospitals perform a minimum of 450 heart bypass surgeries per year, 50 abdominal aortic aneurysm repairs per year and 120 aortic valve replacements per year to maintain optimal patient safety. ¹⁹¹ Leapfrog recognizes that hospitals need to perform a minimum number of each procedure to routinize their procedure-specific systems.

In 2007, the Annals of Surgery published a study of the impact of those annual hospital threshold volumes on mortality rates from 5 procedures: coronary artery bypass graft

¹⁹¹ Leapfroggroup Fact Sheet: Evidence-based Hospital Referral *EBHR) http://www.leapfroggroup.org/media/file/Leapfrog-Evidence-Based_Hospital_Referral_Fact_Sheet.pdf

(CABG), percutaneous coronary interventions (PCI), elective abdominal aortic aneurysm repair (AAA), pancreatectomy (PAN), and esophagectomy (ESO). ¹⁹² The conclusion:

For all 5 procedures, hospitals that did not meet Leapfrog Group volume thresholds were associated with significantly higher odds for in-hospital mortality when compared with hospitals that met Leapfrog Group volume thresholds.

Physician volume and hospital volume of a given procedure are the two best predictors of a patient's likely surgical outcomes.

Do other indicators correlate as well with patient outcomes?

Patients sometimes want to select hospitals based on criteria other than *outcomes for patients like me* or the *quantity of patients like me*. Among the most prominent of those criteria: the technology available.

Yes, better technology may lead to better patient outcomes. But no, it may not lead to better outcomes *for you*. The reason: hospitals and physicians need to gain experience with the new technology in order to use it most effectively.

- One example: some hospitals have recently acquired robots to assist in prostate cancer surgery. Robots are the new technology.
- Unfortunately, studies show that physicians aren't proficient with these and able to remove all the malignant cells until they've performed more than 1600 procedures with the robots. ¹⁹³
- You don't want to be patient #15 or #225 or even #500!

Far better to ask 'what are your outcomes for patients like me'. In the end, you probably don't care which technology the hospital uses - you care whether you get healthy or not.

Sometimes patients want to use the nearest *teaching hospital*, figuring that a medical school relationship indicates higher quality care.

¹⁹² Allareddy, et al, Specificity of Procedure Volume and In-hospital Mortality Association, Annals of Surgery, July 2007

¹⁹³ Cortez, Doctors Need 1600 Robot Aided Prostate Surgeries for Skills, Bloomberg.com, Feb 16, 2011, <u>http://www.bloomberg.com/news/2011-02-16/doctors-need-1-600-robot-aided-prostate-surgeries-for-skills-study-finds.html</u> and Bankhead, Long Learning Curve for Robotic Prostate Removal, MedPage Today, February 16, 2011 <u>http://www.medpagetoday.com/MeetingCoverage/ASCOGU/24908</u>

In fact, teaching hospitals may excel at cutting edge care for complex, non-routine patients. But their outcomes may not surpass community hospitals for hip replacements, gall bladder removal, TURP surgeries or other routine procedures. We saw that in our Massachusetts example above. The lowest mortality rate hospitals did not include the great Harvard Medical School affiliated teaching hospitals.

Other patients want to choose a famous surgeon, perhaps the head of the department or author.

- The surgeon him/herself, however, is only one member of a large team that includes operating room nurses, recovery room nurses, patient floor nurses, residents, the discharge team and the follow-up / rehab team.
- All these people need to work together to achieve excellence.
- A brilliant surgeon working with a mediocre post-discharge team may generate patient outcomes as poor as a mediocre surgeon working with a great team.

Far better to ask 'what are your outcomes for patients like me?'

Indicators other than *outcomes for patients like me* or the *quantity of patients like me* may not provide the information that a wise patient really wants.

This holds both for your *hospital* choice and for your *specialist* choice.

Remember: if you need to be hospitalized or need to choose a specialist, ask the key questions we've discussed above:

- The outcomes question
- The quantity question and
- The threshold number question

Should you defer medical decisions to your doctor?

Many patients say 'My doctor knows best. I'll simply ask him/her what to do.' Maybe – or maybe not – a good strategy.

Remember four things about relying exclusively on your doctor for medical research and advice. *First*, your doctor is only human. He/she may not be completely up-to-date on all 13,000 medical diagnoses, 6,000 medications (all of which have side effects), 4,000

different medical and surgical procedures and the thousands of research articles published annually in medical journals. Your doctor may appreciate your input.

Second, you may have different risk or treatment preferences from your physician. You may be

• More concerned about a specific medical problem than your doctor.

An elderly person may want to take Vitamin D supplements to avoid a bone fracture due to loss of bone density, while her physician may fear kidney damage from excessive Vitamin D more....or the reverse.

• More fearful about certain outcomes than your doctor.

You may fear breast deformation from a double mastectomy more than your doctor, while he/she may fear the side effects of radiation after lumpectomy more...*or the reverse*

• More concerned about some aspect of your treatment than your doctor.

You may fear the pain of knee replacement surgery more than your doctor, while he/she may fear chronic, low level knee pain more than you...or the reverse.

In other words, your doctor's subjective judgments – the risk vs. reward calculation – may differ from your own. This may affect his/her advice.

Third, current liability laws, insurance regulations or hospital bureaucratic routines may impact your doctor's advice. We sometimes call this 'defensive medicine', defensive for the doctor in a lawsuit but perhaps offensive to a patient with a different risk-reward calculus.

Fourth, the average physician visit lasts only about 20 minutes. That may be *sufficient* for your medical exam but *insufficient* for your doctor to educate you about the benefits and risks (NNT and NNH) of your various treatment alternatives or to discuss the most recent studies about your condition.

For all these reasons, the more research and preparation you do before your doctor's visit, the more likely you are to get the medical care and outcomes you desire.

Remember: some 85% of all medical care requires a choice. Physical therapy or surgery, mastectomy or lumpectomy, prostate removal or radiation, one medication or another.

- Dr. John Wennberg, founder of the Dartmouth Institute for Healthcare a very highly regarded research institute at Dartmouth Medical School – estimates that only about 15% of our medical interventions are so clearly superior to alternatives they require no choice on the part of the doctor or patient.
- This quite small number comprises services that, in Wennberg's words, are 'known to work better than any alternative and for which the benefits of treatment far exceed the side effects or unintended consequences.' ¹⁹⁴

The other 85% or so of medical care involves treatments for which reasonable options exist. Wennberg calls these preference-sensitive treatments, or medical interventions in which someone could reasonably prefer one option or another.

The question we'll address in this section: **whose preferences**? Who makes that choice? What's the doctor's role...and what's the patient's?

Different values

Let's consider the fact-value distinction. That's a fancy way of saying that you and your doctor can make different decisions based on the same set of facts.

Your doctor, being highly trained in medical treatments and technology, can supply you with lots of medical facts. These include diagnoses – a set of facts about why you're ill – and treatments – facts about how various interventions work, including, perhaps, some facts about how well treatments work.

But your doctor can't tell you which treatment you *prefer*. In fact, your doctor might prefer a treatment different from the one you would.

Your doctor may be more risk averse than you. Or more blasé about certain medical risks. Or more worried about missing a potentially dangerous cancer than treating a harmless abnormality unnecessarily. Or more concerned about post-operative pain, or long term implications than you are...Or the reverse of any of these.

In other words, you and your physician may value these factors differently. Your doctor knows the facts. You have a set of concerns, or values. You need both the facts and the values to make a wise medical decision.

When you ask your physician's advice, he/she will likely respond based on his or her value structure, not necessarily based on yours. We'll present an example, below.

¹⁹⁴ Wennberg, Tracking Medicine, page 8

An early-stage breast cancer example

Many treatment options for early stage breast cancer exist including:

Watch and wait. Some breast cancers grow aggressively, while others grow very slowly, if at all. Your oncologist may suggest that, based on her values, you watch and wait to see if this is an aggressive breast cancer or not. She may worry more about harming your breast unnecessarily and you suffering related psychological harm as a result.

You meanwhile may be frightened about having breast cancer and want treatment right away. You may find watching-and-waiting too stressful.

Mastectomy (breast removal). This is, perhaps, the most aggressive intervention. It may offer the psychological satisfaction of knowing that 'the doctors got everything' including lymph nodes, thus reducing the chance that the doctors missed some cancer and that it regrows.

On the other hand, complete breast removal may lead to self-image problems in the future.

- Your doctor may value the certainty that you are completely cancer free very highly and consider the self-image problems as secondary.
- You, on the other hand, may be very highly interested in your appearance and feel more comfortable with another cancer treatment option that preserves your breast intact.

Lumpectomy (removal of the cancerous cells only). A less invasive procedure than mastectomy, lumpectomy leaves far more of the breast intact. It often requires multiple post-operative radiation sessions.

- Lumpectomy may leave the patient with the psychological fear that the 'doctors missed something' or with the psychological satisfaction of having an intact, healthy, cancer-free breast.
- Lumpectomy also requires post-operative radiation.

You may prefer the satisfaction of keeping your breast intact, but your physician may worry more about the process of, and long term effects of, radiation.

Science doesn't help us much here. Breast cancer mortality rates seem about *the same* for mastectomy and lumpectomy patients. And many studies suggest that we overtreat

early stage breast cancer, suggesting that watching and waiting may be a good option *scientifically* though perhaps not *emotionally*.

Here are 1996 quotes from oncologists in Rapid City, South Dakota who gave advice to patients about how to treat their early stage breast cancer.¹⁹⁵ We'll use this to introduce some key questions for you to ask your doctor about his/her medical advice.

As a prelude to these comments, note that researchers had determined in a 1970s era randomized controlled study – that's <u>20 years earlier</u> – that mortality rates were the same for mastectomy and lumpectomy. ¹⁹⁶

• 'As far as I'm concerned, the gold standard is still mastectomy. Everything has to be compared to that. It is my personal bias that mastectomy does better.'

This oncologist believed his own observations trumped the scientifically controlled comparative study. Did he even know about the 1970s comparative study?

Whenever your doctor recommends a treatment or cautions you against one, ask

What <u>comparative studies</u> did you rely on to make that recommendation?

This will help ensure against your doctor relying too much on his/her own biases.

Also, that question may trigger a literature review. Your doctor may discover some new studies that can help you.

• Another surgeon said that Rapid City women preferred mastectomy, suggesting that western women are less concerned about their body image than are women elsewhere in the country.

This doctor verbalized *his impression* of his patient's self image value. Did his patients share that self image value?

¹⁹⁵ Wennberg, Tracking Medicine, page 44

¹⁹⁶ Wennberg, Tracking Medicine, page 43.

When your doctor makes a statement like 'western women your age are less concerned about body image than are younger women in New York or LA', he/she expresses his or her own values. Ask yourself if you agree.

Another form of this statement: 'most patients prefer' or 'it's more important to do this than that'.

In all these cases, the doctor states his/her values and preferences, or sense of how other people value their options.

Those values may not be yours.

A third Rapid City doctor answered the question 'what would your wife do?' with (paraphrasing)

'she is a nurse and we have discussed it, and she would have a mastectomy which doesn't require radiation'.

This doctor also tells patients that

'radiation requires time-consuming, tiring daily trips to the hospital for six weeks, and that 'scatter' from it may touch the lungs and ribs' increasing the risk of secondary cancer.

This surgeon placed a higher value on avoiding 'time-consuming, tiring daily trips for 6 weeks' to 'keeping your breast intact'. Would you agree?

When a doctor answers the 'what would you do if you were me?' question, listen very carefully to his/her reasoning. Are you willing to make the same trade-offs? Do you value the medical facts similarly?

In this case, the doctor clearly wants to avoid 'time-consuming, tiring daily trips for 6 weeks'. In his opinion (and, apparently, his wife's) that 6-week inconvenience is a bigger problem than living the rest of your life without a breast.

He's also concerned about radiation scatter. What question would you follow up with here? (Answer below.)

The follow up question about radiation scatter: *What comparative studies did you rely on to make that recommendation?* See the 'comparative study' text box above. You want to ensure that scatter is a significant problem before accepting this doctor's line of reasoning.

Interestingly, since mastectomy and lumpectomy outcomes were the same, we might expect rates of mastectomy and lumpectomy also to be about the same. It was in many locales in the 1990s. In Rapid City, however, *nearly all the patients chose mastectomy*.

The bigger picture

Physicians *giving* medical advice may have different orientations, incentives and values than patients *receiving* their medical advice. Here's a simple chart identifying some of the potential differences:

Physician Concerns	Patient Concerns
Success	Success
Fear of lawsuits	Pain
Local, regional and hospital norms	Recovery process and time
Professional preferences	Personal impact
Professional expertise	Family impact

In preference-sensitive cases, treatment options exist. The patient receives the care that *someone* prefers. That 'someone' could be the physician, the patient, or both. According to lots of research, when the treatment reflects the patient's preferences, he/she gets enjoys better outcomes, often from less invasive treatments and often at lower costs.¹⁹⁷

Where should you go for a second opinion?

Where you go for your medical care may determine what you get. Remember our discussion of Massachusetts and Connecticut mastectomy rates much earlier in this book. Similar women, facing similar medical problems, received different care depending on where they went for treatment.

Patients who understand this can choose their 2nd opinion physician more wisely than patients who don't. One obvious criteria for your 2nd opinion choice: a physician working in a region that treats people differently from your own.

¹⁹⁷ See our Introduction for some quotes about this, and our chapter on The Quality Problem.

• For example, a wise Connecticut woman might get a second opinion in Massachusetts. Or a wise Rapid City woman in Denver.

You can find good indicators of which regions treat similarly and differently on the Dartmouth Atlas of Healthcare. This Atlas is a series of medical utilization maps. The big caveat: they only use Medicare data and, if you're not a Medicare beneficiary, you'll have to assume that non-Medicare treatment follows the same patterns. This is likely, though not definitely, the case.

John Wennberg's great insight is that physicians in the same practice, region or hospital, will likely treat similar patients similarly. He calls these 'surgical signatures'.

But physicians in different practices may treat similar patients differently. They have a different surgical signature.

For a valuable second opinion, consider a physician in a different region, affiliated with a different hospital, or at least in a different practice. You'll have a better chance of disagreement among physicians that way. And a higher certainty that, if both physicians agree, you're probably making the right treatment decision.

What about Primary Care Physicians?

Primary care physicians function quite differently from specialists:

- Specialists see sick people and aim to make them healthy. We can quantify this, or use volume indicators as a proxy for specialist outcomes.
- PCPs generally have large caseloads of healthy people and aim to keep them healthy. We need 'health maintenance' indicators to determine PCP quality. I'll suggest a few below.
- PCPs also refer patients to specialists. I'll suggest some referral indicators below.

One set of 'health maintenance' indicators includes questions like these:

- What percent of his/her patients maintain their Body Mass Index within a couple of points through their 50s and 60s?
- What percent develop diabetes? What percentage of his/her Medicare patients have a leg amputated?

- What percent keep their blood pressure low-to-moderate? (All PCPs tell patients to eat right and exercise. But how effectively does a PCP do this? What indicator appeals most to you?)
- Have heart attacks?
- Maintain a full range of physical functioning and exercise regularly?

I've listed only some questions as suggestions. You may want to ask others: the percentage of male patients who have prostatectomies. Or the percent who accept / decline PSA screening tests. (This can indicate whether or not the PCP discusses testing risks and benefits with male patients.) Or the percent of patients over 50 who have colonoscopies as opposed to CAT colonographies.

The important message here: you, as a wise consumer, can feel free to ask the questions that concern you. Your PCP may not know all the answers. But by asking these questions you may get to know your PCP better and decide how comfortable you feel accepting his/her advice.

As second set of questions concerns your PCPs referral patterns. Does he/she, for example

- Refer to aggressive specialists who like to operate as quickly as possible, or to more conservative specialists who prefer to watch and wait.
 - Remember our preference-sensitive discussion above. Do your preferences match your PCPs? Ask how your PCP normally deals with early stage breast or prostate cancer, arthritic knees, high cholesterol patients and other routine medical problems.
- Refer to excellent specialists? What percent of his/her orthopedic referrals, for example, need readmission to hospital within 30 days of discharge? What percent of his/her cardiac patients report satisfaction with their specialist?

Vignette: my friend who had a cancerous kidney removed, had referrals to two surgeons. The referrals came from the widely recognized 'elder statesman' of the local urological community who had, in fact, trained both surgeons.

One surgeon, the elder statesman told my friend, would want to operate as quickly as possible; the other would want to wait as long as possible to be certain that surgery was necessary. Both generated outstanding results.

As my friend reported back to me, both surgeons lived up to their billing. Neither was 'better' or 'worse'. He decided based on surgical *process* not surgical outcomes. He felt very alone while making that decision, worried that he failed to consider some key issue.

A helpful Primary Care Physician – which my friend did not have – could have aided in this decision making process and not left my friend all alone to make this difficult choice.

A third set of questions concerns your PCP's use of your Annual Physical time. Lots of test? Lots of talk? If lots of tests, which tests? How open is your PCP to discussing test risks, like false-positives or overdiagnosis? And, perhaps even more fundamentally, does your PCP think that we can unnecessarily diagnose certain conditions?

In the 1960s and 70s, two large randomized controlled trials were conducted, and both studies showed little positive impact – people who had physicals did not seem to live longer or have less illness than those who did not have physicals. Dr. Ateev Mehrota, assistant professor at the University of Pittsburgh Medical School, in Laura Blue, Time Magazine 'Is an Annual Physical Really Necessary, June 4, 2008.

There's no strong evidence base for the periodic health exam. Bonnie Darves, Rethinking the Value of the Annual Exam in ACPInternist, a publication of The American College of Physicians, 2010

Current evidence does not support an annual screening physical examination for asymptomatic adults. Prochazka et al, Support of Evidence-Based Guidelines for the Annual Physical Exam, Archives of Internal Medicine, June 27, 2005

How does your PCP respond to comments like these? And, perhaps most importantly, **do you and your PCP respond the same way?**

And **a fourth consideration**: how comfortable do you feel talking to your Primary Care Physician?

We sometimes have emotionally-charged medical concerns that are difficult to admit. Drug dependence, sexual dysfunction or perhaps emotional problems. A good, caring Primary Care Doctor may be able to help...but only if you, the patient, feel sufficiently comfortable discussing these difficult issues.

Two questions in this arena to ask yourself about choosing a PCP:

- Are you comfortable discussing difficult issues with him/her? And
- If so, do you find the quality of his/her advice truthful and helpful?

Asking these types of questions can help you choose a Primary Care Physician who treats you as you would like to be treated. I hope this section empowers your to ask important questions of your (potential) PCP.

Conclusion

Medical care quality differs by hospital and by physician. Some hospitals treat certain diseases *better* than others; some physicians treat certain patients *differently* from other physicians.

You certainly want the best care. But you also probably want the right care, 'right' for you, based on your own preferences.

I've tried to outline in this chapter, some key questions to ask and issues to consider, so you get both of these.

Your hospital choice includes learning the *outcomes for patients like you* from various hospitals. If you can't satisfy yourself with this data, a good fall back consideration is the *volume of patients like you* treated at each hospital.

If possible, get a threshold estimate from the Leapfroggroup or a similar hospital evaluation organization to help you decide which hospitals are safest for a patient like you.

Choosing a hospital based on its fame, size, medical school affiliation or location probably won't help you access the 'best' for your particular needs. But choosing based on outcomes for people like you, may.

Your physician choice includes finding a physician who understands your own medical care values. Most physicians, I dare say, are technically very proficient. But they don't all make the same treatment recommendations for similar patients.

Dartmouth's Wennberg says it this way:

When patients delegate decision making to their doctors, physician opinion rather than patient preferences often determine which treatment a patient receives. ¹⁹⁸

Listen carefully when your doctor talks and try to differentiate his/her factual statements from his/her personal values.

In my own case, I'm fortunate to have found a Primary Care Physician who does this. He says, point blank, probably because I demand it, 'I'll tell you the facts and answer your factual questions, and I'll share my professional observations with you, but I'll leave my opinions out unless you ask. And if you do, I'll identify them as 'my opinions' not 'medical facts'. Your treatment decisions are up to you. I'll honor whatever you decide.'

Admittedly, there's a huge gray area between medical facts, his professional observations, and his personal values/opinions. We discuss that, and the discussion process makes me more comfortable with his advice.

I like to make decisions on facts and honesty, and I'm quite comfortable hearing 'I simply don't know the answer to your question or what to recommend. '

Of course, I may be a more demanding patient than most, 'demanding' in that I want medical facts whenever available but not his personal values. I want to learn from his experience and wisdom but I don't want him to play God. He's a fine fellow who I like and respect. But he's not me.

You, the reader, may or may not share my comfort level with ambiguity or my desire to exclude a physician's personal opinions, so your PCP choice criteria and interactions may differ significantly from my own. The main point: the better you understand the role of facts and opinion, and the better you understand your own medical decision making requirements, the more likely you are to get the care you desire.

¹⁹⁸ Wennberg, Tracking Medicine, page 9

I've tried to show some key questions that patients can ask, and issues to consider, so they get the treatment that they prefer.

Among the questions about hospitals:

- What are your outcomes for patients like me?
- How many patients like me do you treat annually?
- What is the advised threshold number of patients like me?

Remember to try to learn the treatment tendencies of each hospital. Different hospitals can treat similar hospitals differently: some have far higher rates of bypass surgery or angioplasties than others who service the same population. A good initial information source: the Dartmouth Atlas.

Among the questions about specialists:

- What are your outcomes for patients like me? (for surgeons and specialists)
- How many patients like me do you treat annually? (ditto)
- What comparative studies did you rely on to make that recommendation?

And the critical filter of your doctor's comments:

• Is that a recognized medical fact or your opinion?

Among the questions for your Primary Care Physician:

- Are you more concerned about *missing a potentially dangerous abnormality* or about *overtesting* and risking false positive results and overdiagnosis?
- Do you refer to aggressive specialists who like to operate as quickly as possible, or to more conservative specialists who take a 'watch and wait' approach?
- How do you prefer to use our annual physical time: lots of tests? Lots of talk?

And, perhaps the key question about your Primary Care Physician: When you face an emotionally difficult medical issue, one that's hard to talk about:

• Are you comfortable discussing this with your PCP?

I hope these questions help you choose better – more appropriate for you – medical care.
Review Questions

Answers on next page. Some questions may have more than 1 correct answer.

1. What is the best indicator of your likely outcome from a hospitalization?

- a. The hospital outcomes for patients like you
- b. The size of the hospital
- c. The prestige of the hospital
- d. The location of the hospital, specifically its proximity to your house

2. What is a *pretty good* indicator – though probably not the best – of your likely outcome from a hospitalization?

- a. The volume of patients like you that the hospital treats annually
- b. The fame of the surgeon who does the operation
- c. The medical technology available
- d. The credentials of the nursing staff
- 3. What is a 'threshold quantity'?

a. The minimum number of a given procedure necessary to generate optimal patient outcomes

b. The maximum number of a given procedure that a hospital is licensed to perform

c. The maximum number of a given procedure that a hospital can, theoretically, perform

4. Which indicator, below, correlates most closely with patient outcomes for a particular procedure?

a. The volume of patients who annually receive that procedure from a hospital or specialist

b. The technology used for that procedure

c. The quality of the medical school with which the hospital or specialist is affiliated

- d. The size of the hospital or fame of the specialist
- 5. Is mastectomy or lumpectomy a better treatment for early stage breast cancer?
 - a. Mastectomy is almost always better
 - b. Lumpectomy is almost always better
 - c. That depends on what a wise, well informed patient decides in conjunction with

her physician

d. That depends on what the doctor prefers

6. Do physicians and patients always share the same decision making criteria?

a. Yes, always. The physician always ignores every issue except what's best for the patient

b. Yes. Physicians are highly trained to make these decisions

c. No. Treatment options exist, according to Dartmouth's John Wennberg, up to 85% of the time. Patients and physicians may have different opinions about which treatment each prefers

7. Why might it be important for a patient to understand his/her physician's values?

a. The physician may value 'identifying small abnormalities' more than he/she fears the risk of false positive test results, and may, therefore, advise more medical testing than the patient feels comfortable with

b. The physician may fear false positive test results more than he/she values 'identifying small abnormalities' and may, therefore, advise fewer medical tests than the patient feels comfortable with

c. The physician may prefer aggressive interventions as early in the disease cycle as possible, while the patient may prefer to take a 'watch and wait' approach

d. The physician may prefer to take a 'watch and wait' approach, while the patient may prefer an aggressive intervention as early in the disease cycle as possible

8. What's the key difference between a specialist and a Primary Care Physician?

a. The specialist is more sophisticated

b. The PCP provides less help to patients

c. Specialists deal with sick people and aim to make them healthy; PCPs have large caseloads of generally healthy people and aim to maintain their health

Review Questions

Correct answers in **bold**. Some questions may have more than 1 correct answer.

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a. The hospital outcomes for patients like you

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- d. The credentials of the nursing staff
- 3. What is a 'threshold quantity'?

a. The minimum number of a given procedure necessary to generate optimal patient outcomes

b. The maximum number of a given procedure that a hospital is licensed to perform

c. The maximum number of a given procedure that a hospital can, theoretically, perform

4. Which indicator, below, correlates most closely with patient outcomes for a particular procedure?

a. The volume of patients who annually receive that procedure from a hospital or specialist

b. The technology used for that procedure

c. The quality of the medical school with which the hospital or specialist is affiliated

d. The size of the hospital or fame of the specialist

5. Is mastectomy or lumpectomy a better treatment for early stage breast cancer?

- a. Mastectomy is almost always better
- b. Lumpectomy is almost always better

c. That depends on what a wise, well informed patient decides in

conjunction with her physician

d. That depends on what the doctor prefers

6. Do physicians and patients always share the same decision making criteria?

a. Yes, always. The physician always ignores every issue except what's best for the patient

b. Yes. Physicians are highly trained to make these decisions

c. No. Treatment options exist, according to Dartmouth's John Wennberg, up to 85% of the time. Patients and physicians may have different opinions about which treatment each prefers

7. Why might it be important for a patient to understand his/her physician's values? (All answers here are correct.)

a. The physician may value 'identifying small abnormalities' more than he/she fears the risk of false positive test results, and may, therefore, advise more medical testing than the patient feels comfortable with b. The physician may fear false positive test results more than he/she values 'identifying small abnormalities' and may, therefore, advise fewer medical tests than the patient feels comfortable with

c. The physician may prefer aggressive interventions as early in the disease cycle as possible, while the patient may prefer to take a 'watch and wait' approach

d. The physician may prefer to take a 'watch and wait' approach, while the patient may prefer an aggressive intervention as early in the disease cycle as possible

- 8. What's the key difference between a specialist and a Primary Care Physician?
 - a. The specialist is more sophisticated
 - b. The PCP provides less help to patients

c. Specialists deal with sick people and aim to make them healthy; PCPs have large caseloads of generally healthy people and aim to maintain their health

Chapter 7 19 Educational Modules

This chapter presents 19 modules for brokers to use in their client education programs. Each modules makes one key point and teaches employees one key question to ask their own physician(s).

These modules are specifically designed to do some or all of these three things:

- First, teach you, the broker, about healthcare system inefficiencies. These modules review some of the information presented previously in this text.
- Second, the broker can use these modules as part of your existing client education program.
- Third, brokers can design their own educational programs around these modules.

The modules build on each other, so the information in early modules is often used in later ones. They're all formatted similarly, more or less as conversations between a somewhat skeptical patient and a teacher (you, the broker?).

These modules were originally developed by **TheMedicalGuide** (<u>www.TheMedicalGuide.net</u>), a password protected educational website that teaches people how to identify and avoid unnecessary medical care. On TheMedicalGuide website, users click on the patient comments – underlined in this text – to advance pages. That process will become clear very quickly.

We present all references in the Summary at the end of this chapter.

Module #1: Understanding Medical Claims

This module shows employees which medical claims are meaningful and which types of medical data to believe.

Employees who know this material will more likely make wise medical decisions – in other words, choose medical care that can benefit them. Employees who do not know this material will more likely based their medical decisions on the wrong information, often to their financial or health detriment.

Most of this and future modules follow the same format: an exposition or introductory statement, followed by a series of questions to lead the reader / student through the thought process.

These Modules are designed as conversations between a knowledgeable narrator and a skeptical, occasionally sarcastic patient. The patient's questions are often those posed in real life.

Introductory Statement of the Problem:

Sometimes we see ads that claim '*this medication reduces your heart attack risk by* 33%' or '*this test reduces breast cancer mortality by* 20%'.This Module helps you understand the answers...*which is harder than you may think*!

An Example

About **3 in 100** folks *with* high cholesterol but *without* heart disease will have a heart attack in the next few years. Statins – cholesterol lowering medications like Lipitor and Crestor – reduce this to about **2 in 100**. **Thus statins prevent about 1 heart attack per 100 patients.**

> How many heart attacks do statins prevent? (Yes, it's a trick question.)



Two answers

Answer #1: statins prevent about 1% of heart attacks. In fact, they prevent about 1 heart attack per 100 people who take them.

Answer #2: statins prevent 33% of heart attacks. In fact, they cut the number of heart attacks from about 3 to 2 in 100.

<u>1% or 33%?</u>

How many?

1% is based on 100 people who take statins.

3 would have had a heart attack; 2 had heart attacks; 1 benefited

1 = 1% of 100 Where does 33% come from?

What's 33%?

33% is based on the number of people who had heart attacks.

3 would have had heart attacks without statins; 2 had heart attacks; 1 avoided it

1 is about 33% of 3!

l'm confused!



We can make up lots of different numbers. Here's an easy way to discover the most important number for *most* people. Pose this question to your doctor:

Out of 100 people like me who take this medication, how many will avoid a first heart attack?

You can also ask about screening tests, other medications, surgical procedures, therapies, etc.

Ask in exactly this form!

What about the answer?

Form matters! Be sure to get your answer in the same form.

For example:

1 out of 100 who take this medication will avoid a heart attack or 15 out of 100 who have this screening test will avoid dying of cancer Answers like 'about a third' or '40 – 50%' may measure other things and confuse you!

Why are there so many different numbers?

Lies, damn lies and statistics

Sometimes researchers and reporters themselves wonder how to report medical claims:

Should they quote *percentages* or *absolute numbers*? Should they show *bigger numbers* to generate more discussion or *smaller numbers* to be conservative?

Sometimes corporate marketers use numbers to promote their products. Beware!

A 33% reduction has more impact than a 1% reduction.

Here's an analogy to help you.

The lottery ticket analogy

Would you buy a second lottery ticket?

Consider two statements:

#1: If you buy a second lottery ticket, you double your chance of winning. Your chances of winning increase by 100%

#2: If you buy a second lottery ticket, you increase your chance of winning by about 1 in one million...or by .000001%

Both statements are *true*. But ask yourself:

If I'm *selling* lottery tickets, which would I use? or If I'm *buying* lottery tickets, which would I consider?

The same is true for medicine!

Most medical claims are true, but.....

Some may be *misleading!*

Your problem as an informed medical consumer: **Decide which numbers are meaningful.**

We've tried to simplify all this by suggesting 1 simple question to ask.

What was that question again?



The Question Out of 100 people like me who take this medication, how many will benefit?

A Rule of Thumb about the answer

A Rule of Thumb

If the answer is 80 out of 100 people benefit, then you probably will also.

But if the answer is 5 or fewer, then you may want to consider other options.

Click here for The Bonus Question

The bonus question

Once you learn how many out of 100 benefit, you can follow up with how many out of 100 <u>are harmed</u>?

Then – and only then – can you determine if the medical intervention is more beneficial than harmful, or more harmful than beneficial!

Make sure your harm question is answered like this:

x out of 100 who take this medication are harmed by it.

Your Homework

Homework

The next time someone says 'this is a good medication' or 'this test reduces your risk', ask

Out of 100 people who have it, how many benefit?

You may be surprised by the answers!

Module #2: How to choose a hospital

Choosing the best hospital for your care can improve your chances of enjoying a good outcome. But choosing the wrong hospital may increase your risk of being harmed.

People choose hospitals based on many different factors: geography, reputation, referrals, friend's experiences, etc. Some of these factors are relevant to patient outcomes while others are not.

We suggest in this module one particular criterion for choosing a hospital. Consider whether or not you find it useful. And consider whether or not your clients might.

Introductory Statement of the Problem

Hospitals differ!

Choosing *wisely* can improve your health greatly; Choosing *poorly* may harm you.

This Module helps you choose your hospital wisely.

How would a wise consumer choose a hospital?

Outcomes for people like you

We suggest choosing hospitals based on outcomes for people like you.

...outcomes for people like me...

What are outcomes?

Outcomes mean 'how well patients did'.

Some good outcomes:

Successful surgery Complete patient recovery Timely discharge without readmission

Some bad outcomes:

Patient infections Readmission shortly after discharge Death

Who are people like you?

'People like you' are people who have your medical condition.

For example:

If you have kidney failure, 'people like you' also have kidney failure If you have liver disease, 'people like you' also have liver disease

Who are <u>not</u> people like you?

People like you are not

Your age, occupation, socio-economic status, demographic group, or

People hospitalized for a different medical problem from you

Why does this matter?

You want great medical care

A hospital might be excellent at treating one kind of patient but relatively poor at treating another.

What you really care about is how well the hospital treats you -

not how well they treat people who are *different* from you.

For example

Some Massachusetts hospitals

Here are the 4 Massachusetts hospitals with the lowest *heart failure* mortality rates:¹⁹⁹

#1: Southcoast Hospital, Fall River (the best)
#2: Brigham and Women's Hospital, Boston
#3: Ana Jaques Hospital, Newburyport
#4: Faulkner Hospital, Boston

¹⁹⁹ These are risk adjusted mortality rates, as reported by the US Dept of Health and Human Services for Medicare patients between June 1, 2006 and July 31, 2009. Risk adjustment discounts illness severity differences among patients, so avoids penalizing some hospitals for treating sicker patients.

But here are the 4 Massachusetts hospitals with the lowest *pneumonia* mortality rates:

#1: Norwood Hospital, Norwood (the best)
#2: Falmouth Hospital, Falmouth
#3: Boston Medical Center, Boston
#4: Mt Auburn Hospital, Cambridge

Different hospitals!

Why not just choose a hospital for its technology?

Technology

Great technologies run by poor operators may cause more harm than good.

For example, doctors who perform robotic-assisted prostate cancer surgery aren't proficient and able to remove all the malignant cells until they have done the procedure more than 1,600 times.

You don't want to be patient #15, or #38 or #200!

What about a famous surgeon?

Fame

The surgeon is only one member of your medical team. Other members:

Operating room nurses Recovery nurses Patient floor nurses Residents The discharge team The post-discharge team ... and more

All need to work together for the best patient outcomes.

A brilliant surgeon with a poor post-discharge team may generate poorer outcomes than an average surgeon with an excellent team.

The only way to know how well your medical team works together: **determine***outcomes for patients like you*.

Remember...

Medicine is a Team Sport



You need the entire team - people, processes and technologies - working together on your behalf.

Choosing a hospital based only on a *component* of that team -- the surgeon, medical school affiliation, technology or other - is unwise.

It's analogous to betting on a football team only because of its quarterback; A winning football team also needs a good defense, coach, receivers, kicker etc.

A medical team with lots of experience working together may outperform a set of outstanding individual components....just like in football.

That's why we recommend choosing hospitals based on *outcomes for people like you.* That tells you how well the medical team works together.

How can I learn outcomes for people like me?

Sources

Ask your doctor!

When your doctor refers you, ask *what are their outcomes for people like me?...* and explain why you're asking.



Remember: You'll probably need to lead the discussion since your doctor's busy and **most people don't ask!**

Module #3: How to choose a specialist

Some 70%+ of all physicians in this country are specialists.

We have, today, specialists for virtually every body part, from brain surgeons and psychiatrists for the head to podiatrists and orthopedic surgeons for the feet. Indeed, when we have a medical problem, we can often choose among many different physicians within the same specialty. For example, if you have a coronary problem, you may have a choice of several different cardiologists.

How can a wise medical consumer decide? We offer one criterion below. As you read this, consider if you find it useful yourself. And consider whether or not your clients might also find it useful.

Introductory Statement of the Problem

Specialists differ! (and not just by specialty)

Some have warm, wonderful bedside manners; Others are quieter but excellent diagnosticians.

Some perform lots of tests; Others test less.

Some embrace new medications and technologies quickly; Others adapt to change more slowly.

This module focuses on one simple question:

How should a wise consumer choose?



Outcomes for people like you

We suggest choosing specialists based on their *outcomes for people like you.* (Sound familiar?)

In the last Module, we suggested choosing *hospitals* based on their outcomes for people like you ...

This month, we make the same suggestion about choosing specialists.

What are outcomes again?

Outcomes mean 'how well patients do'

Some outcome questions:

How quickly do patients like you *return to their prior health status*? How often does surgery *help* patients like you? How often does surgery *harm* patients like you?

outcomes for people like me...

Who are people like me?

People like you

People like you have your medical condition.

For example, if you have minor back pain - that only affects your tennis game - people like you also have minor back pain. But if you have major, chronic back pain that affects your ability to walk, people like you also do.



You want to choose a doctor who's really good at treating patients like you... not patients who are different from you.

How can I get outcome information?

Unfortunately...

We don't have very good information about patient outcomes by physician.

Harvard Business School's Michael Porter put it this way:

'In only a few isolated disease areas - notably cardiac surgery, organ transplants, cystic fibrosis and kidney dialysis - is broad-based results information available.'

Porter goes on to say

'most physicians lack any objective evidence of whether their results are average, above average, or below average.'

So what can I do?

Ask your specialist two questions

Question #1: What outcome information do you have about your own patients?

Be sure to use the word *outcome*.

Some specialists may keep detailed records and will share them with prospective patients if asked.

Beware of Porter's warning about doctor's impressions of their own competence: 'it is human nature for most people to believe that they are above average, which cannot be true' (Some specialists *must* be below average.)

The second question

Question #2

How many patients like me have you treated?

Many studies suggest that *the more experience* a doctor has treating patients like you, *the better the outcomes*.

In other words,

experience treating patients like you is often the most important indicator or your likely outcome.

the Bonus question

When your PCP gives you a referral... Ask the same 2 questions!

What are this specialist's *outcomes for patients like me*? and How many *patients like me* has this specialist treated?

Your questions may surprise your PCP but...

they may help him/her make the best referrals to you.

The moral of this story

Ask good questions

Whenever you consider a specialist for medical care, ask the **outcome** question (what are your outcomes for patients like me)

and the *quantity* question (how many patients like me have you treated?)



The answers may guide you to better care... and better health.

Module #4: How to choose a Primary Care Physician

Most insured employees have a primary care physician. This is, in part, a holdover from the old managed care days, when the PCP served as gatekeeper and a necessary source of referrals to specialists and hospitals.

Today the PCP can serve a different role: an advisor who knows you and knows your overall medical condition.

As a result, we suggest that the criterion for choosing a primary care doctor differs from the criteria for choosing a specialist: they perform different functions. As you read this module, consider how it may help you choose a good PCP...and how it may help your clients also.

Introductory Statement of the Problem

The last 2 modules suggested definitions of a good hospital and a good specialist.

Good hospitals and good specialists get good outcomes for patients like you.

Today's question:

Can we apply the same criterion ... outcomes for patients like you ... to PCPs?

No! (In our opinion) Primary care doctors are different.

Different?



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Keeping you healthy vs. returning you to good health

Primary Care Physicians are generally more responsible for *keeping you healthy* than for *returning you to health after an illness*.

Hospitals and specialists are generally more responsible for returning people to good health or for managing chronically ill people.

PCPs typically have large caseloads of healthy people and aim to keep them healthy.

... keep me healthy ...

How should I - a healthy person - choose a PCP to keep me healthy?

Choose someone you can partner with We suggest choosing your PCP based on how he/she <u>relates</u> to you.

Physicians have different personalities, styles, approaches, values and medical philosophies.

Choose someone you respect and can speak honestly with.

A true partner

The human connection may be key

Dr. David Newman of Columbia Medical School puts it this way:

Find a doctor who understands that the human connection is a healthcare tool.

The human connection allows you to discuss your health, treatment issues and concerns... because you have lots of treatment options, choices and decisions to make.

Lots?

Yes!

Some excellent PCPs refer to aggressive specialists who like to operate as soon as possible;

others to conservative specialists who prefer to watch and wait before surgery

Some prescribe the newest medications as soon as they are FDA approved; Others are more cautious and prefer to wait Some give lots of tests to avoid missing a disease diagnosis; others give fewer tests to avoid inaccurate results or too much radiation

> Some like to talk more and test less; Others are just the opposite

Some prescribe cholesterol-lowering medications when your total cholesterol hits200; Others wait until it's 220, 240 or even higher... And some don't prescribe it at all!

There are often not *right* or *wrong* approaches. Instead there are advantages and disadvantages for you and your PCP to discuss

... if you have a real PCP partner...

Partner in your care

A true patient-PCP partnership helps you decide which approaches work best *for you*.

Aggressive or conservative? More tests or fewer?

Ask yourself: Do you and your PCP really partner in your medical decision making?

Many people report that they do ...

<u>But...</u>

They probably don't!

Research suggests that what most people describe as *participating* really just means *agreeing with their physician's recommendations after a brief discussion*.

Research also suggests that optimal medical decisions - and the best medical outcomes - often come when patients participate fully in a shared decision-making process.

Not when they delegate decisions to their doctors.

You need to feel comfortable with your PCP to engage in these discussions....

An analogy

Different diets work for different people

Some follow the Scarsdale diet, others the Atkins diet, or the South Beach diet, the Cabbage Soup diet, the Carb Lover's diet, the Glycemic Index diet, the Grapefruit diet, the Zone diet, the Mediterranean diet, the Park Avenue diet, the Sonoma diet, the Mayo Clinic diet, the Big Breakfast diet, the Morning Banana diet, the Protein Power diet ... or something else.

Lots of different diets generate about the same result --- weight loss.



The question isn't which work? But

Which work for you?

You and your PCP partner should answer that question together

We are used to thinking that a doctor's ability depends mainly on science and skill, suggests Dr. Atul Gawande of Harvard Medical School. But these may be the easiest parts of care.

The human connection with your PCP may be even more important than your doctor's technical skills in *keeping you healthy*.

The human connection helps you get the care that's most appropriate for you.

A test of your PCP partnership

Here are two ways to test your relationship with your PCP

First, are you comfortable asking your PCP difficult questions? A difficult question is one that you're perhaps embarrassed to ask or one that is more personally revealing than you're normally comfortable with;

And second, if you do ask your PCP a difficult question

Do you believe his / her answer?



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If not, maybe you need a new PCP.

Module #5: How can you tell if medicine works?

This module refers back to some of the information discussed in the first module.

There, we discussed which numbers apply to you, and suggested asking this question to your doctor: out of 100 people like me, how many will benefit from this medication, test or therapy?

In this module, we discuss the types of information that can usefully answer that question. In particular, we explain the difference between *observational* evidence and *comparative* evidence.

- The latter is useful and meaningful, and can help you make wise medical decisions.
- The former is far less useful and may well be biased.

As such, relying too heavily on observational evidence may ultimately harm the patient, but adding unnecessary costs and risks to his/her medical treatment.

Introductory Statement of the Problem

It's obvious when medicine works - a sick person becomes healthy.

We see this every day. We call these *observations*. We *observe* that someone got healthier.

But how do we know if medicine really helped ... or if the person would have gotten healthier anyway? For example...

A knee pain question

Let's say your knee hurts when you walk.

- If you rest, your knee will get better.
- If you rest and eat bananas, your knee will get better.

Was it the rest or the bananas that made your knee get better?



My knee got better. Do I care?

Yes!

If you don't know why your knee got better, you might get unnecessary knee surgery!

Oh, come on now...

Here's a study from the New England Journal of Medicine

Some people in pain from an arthritic knee had surgery, recovered and felt better.

Pain gone. The surgery worked. Yay!



But some *other* people with arthritic knee pain had *fake* surgery, recovered and their knees also felt better. **Oops.**

That was exactly the situation at the Houston VA when, in a controlled experiment, a surgeon performed both real and fake procedures on different people.

The goal: see if real arthroscopic knee surgery works better than a placebo to reduce arthritis pain.

The result, quoting from the NEJM: arthroscopic surgery 'is not better than and appears to be equivalent to a placebo procedure in improving knee pain.'

What?

The study's conclusion means

Arthroscopic knee surgery provides no benefit for arthritis pain.

But surgeons perform some 650,000 such procedures every year!

The underlying point

You need comparative information to make a wise medical decision Simply *observing* that some people's health improved is not enough.

You need to compare a group of sick people that *was* treated medically... with a similar group of sick people that *was not*.

Which group got better? The answer tells us how well medicine works.

Why is that?

Lots of things can help a patient get better ...

including general health status, family supports, medical care, etc

Only a *comparison study* shows the specific impact of medical care.

Any other examples?

Back surgery

A large Ohio-based study of people out of work because of back pain compared

* 725 folks who had spinal fusion surgery with

* 725 similar people who had *more conservative treatments* including exercise and physical therapy but no surgery.

The results

The spinal fusion surgery group was worse off!

Only a quarter of the spinal fusion folks returned to work after 2 years compared to 2/3 of the other group Total days off from work was almost *4x greater* in the spinal fusion group: 1140 vs. 316

These results, according to the study's lead author, are "consistent with previous studies. The result we've provided is nothing new" according to the New England Journal of Medicine, and has been known for years.

If the results are nothing new, then how well have we learned them?

We do more spinal fusion surgeries today than ever before

We *increased* the number of spinal fusion surgeries performed in this country from

About 100,000 in 1997, to About 300,000 in 2006

Each surgery costs about \$50,000.

Lots of money for poorer outcomes.

And we've known this for years. Hmmmm

The main point again

Observations vs. comparisons

The back surgeons *observed* that their patients (some, at least) got better after surgery, so concluded that spinal fusion surgery works.

But the comparative study suggests that it works less well than alternatives.

Why do we perform so many procedures that work so badly?

We don't know!

Maybe some physicians aren't familiar with the comparative studies.

Maybe some disagree with the study methods or conclusions.

Maybe others simply don't believe the evidence, thinking that their own (observational) results are better than those studied.

Maybe some find other reasons.

For whatever reasons, results of high quality comparative studies may not impact your own medical care --- quite possibly to your detriment.

How can you protect yourself?

One thing to do: ask the right question



Ask, whenever your physician recommends a procedure, medication or test:

Can you tell me what *comparative studies* you rely on to make that recommendation?

Ask exactly this question, and make sure you use the words 'comparative study'.

The information should look like the knee surgery and spinal fusion studies we referred to in previous slides.

Remember that comparative studies involve 2 groups of similar people, one of which has the medical intervention and the other of which doesn't.

Beware of observational studies only as justification!

Another thing to do

Research outcomes

You can find lots of outcome information on various websites.

We encourage you, when you do a web search, to include the word outcomes.

For example, search for spinal fusion surgery **outcomes**, not just spinal fusion surgery. Look for articles about comparative studies.

Then discuss your research with your doctor.

You'll probably have a better discussion than you would have had otherwise.

Let us know!

Module #6: Understanding Annual Physicals

Some 60 million Americans get annual physicals.

Many people – employees, patients, consumers and physicians - believe that annual physicals are necessary for good health. But recent evidence suggests that this may not be the case, and that, in fact, some aspects of the annual physical may actually cause more harm than good.

This module asks some fundamental questions about the annual physical and, in particular, discusses two very different ways that patients can use them.

As you read this, ask yourself which way works best for you, and which way have you used annual physicals in the past. Consider also the impact that this discussion might have on your clients.

Introductory Statement of the Problem:

Lots of Americans get annual physicals.

Physicals account for about 8% of all doctor's visits and cost about \$8 billion per year.

But do physicals do any good?

Specifically...

Is there any evidence that people who have physicals live longer than people who do not?



Some background

About 60 million Americans get an annual physical, ...typically consisting of some or all of these tests:

Blood pressure Heart rate Respiration rate Lung function Complete blood count Cholesterol Urinanalysis Electrocardiogram Chest X-ray Stress test ... and often more.

Which are necessary?

We don't know!

In fact

there's no medical board that tells doctors which tests to perform at your annual physical!

Really?

Really! 'No major North American health-related organizations recommend the routine annual exams'

Professor Ateev Mehrotra of the University of Pittsburgh Medical School.

Why is that?

Lack of evidence about benefits

In the 1960s and 70s, two large randomized controlled trials were conducted, and both studies showed little positive impact — people who had physicals did not seem to live longer or have less illness than those who did not have physicals. Dr. Ateev Mehrotra, assistant professor at the University of Pittsburgh School of Medicine, 2007

There's no strong evidence base for the periodic health exam The American College of Physicians, 2010

Current evidence does not support an annual screening physical examination for asymptomatic adults The Archives of Internal Medicine, 2005

The annual physical gets a thumbs-down from public-health researchers who find no real evidence to support its effectiveness, despite tradition and widespread use. Dr. Benjamin Brewer, Wall Street Journal, January, 2009

Why do so many physicians give annual physicals?

Because they do

It's what I was taught and it's what patients have been taught to expect Dr. Barron Lerner, an internist and historian of medicine at Columbia University's College of Physicians and Surgeons

Why pick that fight? Why try to explain 10 years of evidence-based medicine so the patient will understand? Dr. Stewart Rogers, an internist at Moses Cone Hospital in Greensboro, NC

Patients will think they have not gotten their money's worth if there is no laying on of hands.

Dr. Steven Woolf, professor of family practice at Virginia Commonwealth University

The coverage of the physical is something [insurance] companies do as a result of requests from our customers Larry Akey, a spokesman for the Health Insurance Association.

But certainly there is some benefit to seeing your doctor regularly!

Yes!

Time together helps you and your PCP build a good working relationship.

How you use your time together matters

Partnering or testing

Annual meetings with your doctor can promote the true partnership that we discussed in Module #4 (How to Choose a PCP).

Excessive testing, however, may not enhance that partnership and *may even harm you*.

Testing may harm me?

Maybe...

There's an old adage in medicine: the more you test, the more you find.

Today's medical testing technologies often identify 'false positives' --- *indications* that you have a medical problem when, in fact, you **do not**.

But once discovered, doctors and patients often want to *do* something ... more tests, or possibly treatment or medications for a problem that doesn't exist.

'Doing something' may be more harmful than doing nothing.

Says who?

The US Preventive Services Task Force

The USPSTF is part of the Department of Health and Human Services. It conducts scientific evidence reviews of many preventive health care services and develops clinical recommendations.

The USPSTF's recommendations are considered the "gold standard" for clinical preventive services by, among others, the Journal of Family Practice, the New York State Department of Public Health, the Annals of Internal Medicine, United Healthcare, the American Academy of Family Physicians, the Centers for Disease Control and the journal Health Affairs.

What do they recommend?

Some tests can help you...some can harm you...and some are in between. Here's a sample

Screening for High Blood Pressure The USPSTF **recommends** screening for high blood pressure in people over 18 years old. Screening for Coronary Heart Disease

Recommends **against** routine screening with resting electrocardiography, exercise treatmill or electron-beam computerized tomography ... in adults at low risk because of the false positive risk

<u>Screening for Chronic Obstructive Pulmonary Disease</u> Recommends **against** screening adults for chronic obstructive pulmonary disease (COPD) using spirometry because of the false positive risk

Screening for Skin Cancer

The current evidence is **insufficient** to assess the balance of benefits and harms of using a whole-body skin examination for the early detection of cutaneous melanoma, basal cell cancer, or squamous cell skin cancer in the adult general population. The USPSTF cannot determine if the **risks** of misdiagnosis and overdiagnosis exceed the**benefits** of early detection, or vice-versa.

But my doctor recommends all these tests, and more!

How you relate to your PCP matters

Do you partner with your PCP in your own medical decision-making?

If so...

Discuss with your PCP how best to use your annual meeting time together.

lots of tests? lots of discussion? which tests? which topics?

The answers

If you discuss these issues thoroughly...

... and you don't *automatically* do what your doctor wants after, perhaps, a short discussion...

then you probably have a good partnership.

And you'll probably make good decisions together.

<u>But...</u>

If you don't have a satisfying discussion...

then you may have the wrong doctor.

Whatever his / her position on testing or annual physicals...

It may not work well for you.

OK - So now give me the bottom line ... are annual physicials good or bad?

That depends on what you and your PCP partner decide <u>together</u>.

(Remember...we aim to *empower* you, not *tell you what to do*. Becoming a wise consumer isn't easy. Good luck)

Module #7: Which medical risks matter most?

We have, these days, far more information about medical diseases than we have ever had before.

- One advantage of this: we can treat more diseases than previously.
- But one disadvantage: we look for more diseases than previously.

Recent studies have suggested that the more we look for diseases, the more we find, and the more we treat.

This raises a fundamental question for a wise consumer: *which diseases should I worry about the most?*

Unless a consumer can answer this question, then all diseases are equally important. That can lead to excessive and unnecessary care, or care that provides little or no benefit but increases the patient's costs and risks.

This module introduces the idea that some diseases (or medical risks) are more important than others, and more worthy of medical attention.

As you review this module, ask yourself which diseases matter most to you. We also encourage you to discuss this with your physician to help you and your doctor focus on the most important disease risks.

Introductory Statement of the Problem

Some people worry too much about their health and get too much medical care.

Others worry too little, and don't get enough care.

You want to get just the *right amount* of medical care...

not too much or too little.

This module helps you decide which diseases to worry about ... and which not to.

I don't understand what you mean. Can you give me an analogy?

You wear a bike helmet when you ride a bike. But you don't wear one when you walk.

The reason: bike riding is more dangerous!



You *instinctively* know this and adjust.

Wearing a helmet is annoying and costs money. Plus it makes you look like a dork.

You won't wear it unless the risk justifies the cost ... even if wearing a helmet while walking is safer!

<u>Hmmm</u>

Here's another example:

You wear a seat belt to drive your car but not to sit at your kitchen table.

Why?

Car driving is more dangerous, so you adjust.

You wouldn't wear a seat belt at your kitchen table even if this reduced your chance of falling off your chair and hurting yourself by 30 - 40%!

The reason: your chance of falling off your chair is so low that a 30 – 40% risk reduction is infinitesimally small and essentially meaningless.

How does this relate to my medical care?

You face lots of disease risks

Just like you have different risks in normal life from walking to bike riding to car driving -

so you have different **medical risks** for every disease from heart failure to skin cancer, and athletes foot to head trauma.

Our question today: which medical risks are *high enough* to worry about and seek preventive medical care for....like wearing a bike helmet or seat belt?

OK, tell me

Your chance of having a first heart attack, or dying from a specific disease or developing some other health problem <u>without</u> medical intervention is called your **starting risk.**

We'll describe the starting risks for some well-known diseases in the next few slides.

Which - if any - would you worry about ... and seek preventative treatment for?

We'll tell you the names later...no peeking!

Go for it

Disease #1 rarely shows symptoms, but doctors can determine if you're **at risk** with a simple blood test.

The test gives you a number.

If your number is *above* a certain point, then you're *at risk*. If it's *below*, then you're *not at risk*.

About 97% of the at-risk folks *still* do not develop this disease.

In other words, about 97% of people with a high test number are not harmed by it.

Of the roughly 3% who are harmed by this disease, very few die of it.

Would you worry about it?

What is Disease Number 1?

Disease #1 is a first heart attack

The at-risk population is people with high cholesterol but without heart disease.

About 3% of people with high cholesterol but without heart disease will have a non-fatal heart attack in the next few years.

Did you think this was a high enough *starting risk* for people with high cholesterol to worry about?

OK, now I understand what you're doing. What's Disease #2?

Disease #2 kills about 5 out of 1000 people over 10 years.

About 995 out of 1000 people do not die of it and generally are not harmed by it.

Would you worry about getting this disease?

Would you choose to be tested for it ... if the test itself posed some danger?

What is Disease Number 2?

Disease #2 is breast cancer

About 5 women per 1000 in their 50s will die of breast cancer.

About 995 will not die.

Did you think this is a big enough *starting risk* to worry about?

I'll tell you later...maybe. What's Disease Number 3?

Disease #3 kills about 1 or 2 out of 1000 people over 10 years. It otherwise generally doesn't harm you.

About 998 out of 1000 people are not killed by it.

Would you worry about this disease? Would you get tested for it *if the test itself posed some danger*?

Disease #3 is prostate cancer

Between about 1 and 2 men per 1000 in their 50s will die of prostate cancer over the next 10 years.

About 998 or 999 out of 1000 men in their 50s will not die of it.

Did you think this was a big enough risk to worry about?

I'll get back to you on that one too. Any more?

Disease #4 is a fatal genetic disease.

If *1* parent has the gene, the offspring have a 50% chance inheriting it; If *both* parents have the gene, the offspring will probably inherit it.

Although everyone who *inherits* this gene doesn't *develop* the disease, **people who develop the disease all die of it within about 3 years.**

Would you worry about it?

Would you get tested and choose your spouse (in part) to avoid passing it on?

Hmmmm....I might, actually. What is this disease?

Disease #3 is Fatal Familial Insomnia

It was first discovered in Venice in 1765.

Since then, about 100 people have died of it while hundreds of millions of people were unaffected.

Your chance of developing this disease is about 1 in 100 million (give or take a few million).

Did you think this was a big enough starting risk to worry about?

What diseases should I worry about?

We can't tell you when to worry

That's for you and your doctor to decide.

Some people worry that a 1 in 100 million risk - fatal familial insomnia for example - is high and want to take precautions.

Others think that a 30 in 1000 risk - of a non-fatal heart attack among high cholesterol folks - is low and don't worry about it.

Though we can't tell you what to worry about, we can help you in 2 ways.

The first way?

We'll help you frame discussions with your doctor

You and your physician can discuss your starting risks of various diseases and together decide which are worthy of medical attention.

Your starting risk tells you which diseases are more dangerous or less important.

Absent starting risk information, you can't tell - all diseases are equally important!

This can confuse you and lead to unnecessary worry and medical care.

The second way?

We'll help you understand the impact of medical care

You can estimate medicine's impact once you know your starting disease risks.

Remember our bicycle helmet example:

- You wear a helmet when riding because your starting risk is *high enough* to justify the expense, hassle and look;
 - But you don't wear a helmet when walking because the starting risk is too low...even if wearing a helmet could benefit you. You know that almost instinctively.

Medical care is like the helmet. It can work well, but has costs and side effects. You only want to get medical care when your starting risks are high enough to justify it.

If you don't know your medical starting risks, you'll likely overestimate - or underestimate - medicine's beneficial impact.

How should I proceed?

Discuss all this with your doctor

Whenever you consider medical care - a screening test, medication, surgery etc ... ask your doctor 'what is my starting risk'?

Here's a way to phrase this:

Out of 1000 people like me, how many will have a first heart attack? or die of breast cancer or suffer a broken hip, etc

Be sure to get your answer in this form:

Out of 1000 people like you, about x will have a first heart attack.

Remember today's message: knowing your starting risk is a necessary step to making wise medical decisions.

Module 8 - Introducing NNTs

Physicians often counsel their patients with statements like this: 'this medication is very effective' or 'this test is very reliable'.

A wise patient might respond 'how much better is it than another medication or test?'

We have not, until recently, had a way to compare the effectiveness or reliability of various medications, tests or procedures. But recently researchers have developed a new scale for measuring the effectiveness of tests, medications, procedures and therapies.

The scale is called the Number Needed to Treat or NNT. This tells us how many people need to take a particular medication, or have a test, for one person to benefit.

As you read this module, ask yourself if you have ever been in a situation where you could have used this information. Or indeed, if you have ever asked your doctor which medication works best only to receive ambiguous answers like 'this one is very good, but so is that one. I suggest you try them both to see which you prefer.'

Consider whether or not you find that answer very satisfying. And consider how knowing this information can help you make wiser medical care decisions.

Introductory Statement of the Problem

Many people think that medications, screening tests, surgical procedures or other medical treatments work 100% of the time.

In other words, they think that you take a medication and you get better or you have a screening test and know if you have cancer.

You may believe this yourself.

Unfortunately, it is not true!

Some medical treatments work better than others

Some medications work better than others.

Some screening tests are more reliable than others.

Some therapies and surgeries are more effective than others.

You may have heard people say, for example...

Sleeping pills

'Over-the-counter sleeping pills don't put me to sleep'

In fact, sleeping pills work for some people but not for others.

Our question today:

How can you tell how well medications work?

Introducing the Number Needed to Treat (NNT)

The **Number Needed to Treat (NNT)** tells how many people need to take a pill (or have a medical treatment) for 1 person to benefit.

For example

Heart attack prevention

You have to give statins to about 100 people to prevent 1 heart attack.

The Number Needed to Treat with statins is about 100.

or

You have to give the Mediterranean Diet to 23 people to prevent one heart attack.

The NNT of the Mediterranean Diet is about 23.

This comparison tells us that the Mediterranean Diet is about 4x more powerful for preventing heart attacks than statin medications.

We can get the Number Needed to Treat for lots of procedures

Some examples

CT lung cancer screening in high-risk smokers to avoid lung cancer death: NNT = 217

High blood pressure medicine for preventing heart problems, over age 60, 1 year: NNT = 100

Lowering salt intake for preventing heart problems after a heart attack or stroke: NNT = 42

Quitting smoking for preventing death or heart attack after a heart attack or stroke: NNT = 8

Hormone replacement therapy for preventing hot flashes: NNT = 3

Vitamin D for preventing bone fractures in elderly folks: NNT = 36

Steroids for toddlers with the croup to help them breath more easily: NNT = 5

MRI compared to X-ray to evaluate chronic lower back pain: NNT = infinite (no benefit found from the MRI)

These estimates come from the website <u>www.TheNNT.com</u>.

What is a good Number Needed to Treat?

We don't have a consensus

Some people think that an NNT of 10 is bad

An NNT of 10 means that 1 out of 10 patients benefit from the treatment, and that 9 out of 10 do not.

Other people think that an NNT of 50 is good

An NNT of 50 means that 1 out of 50 patients benefit from the treatment and that 49 out of 50 do not.

One author - Professor Nortin Hadler of the University of North Carolina - suggests that insurance not pay for any treatment with an NNT of more than 20!

An NNT of 20 means that a treatment is only effective 5% of the time.

How can knowing the Number Needed to Treat help me?

First

You can decide - with your doctor - if a medication, test or therapy is *worthwhile* for you.

An NNT of 2 is probably worthwhile. An NNT of 2000 is probably not.

Second

You can compare

You may have several treatment options, like statins or dietary changes to prevent a heart attack.

The Number Needed to Treat (NNT) tells you which work best.

The NNT is basic medical literacy



The Number Needed to Treat is a way for doctors and patients to share information

Here's Dr. David Newman's suggestion:

Ask for it.

In fact, demand it.

You need to know how much the health interventions you undertake have the potential to help you and which ones matter most.

Concluding thought

Knowing the Number Needed to Treat <u>defines</u> an informed medical consumer

Knowing NNTs = being an informed consumer

Various lists of NNTs exist, from a variety of sources, including TheMedicalGuide.

We hope you use them to become a wise and informed medical consumer.

Module #9 - Introducing NNHs

The same logic that describes the Number Needed to Treat can describe the opposite: the Number Needed for Harm.

This provides a standard measurement and way for physicians and patients to evaluate the potential harm from a medication, test or medical procedure.

- A low NNH (Number Needed for Harm) indicates a greater likelihood of being harmed by the medication, test or procedure.
- A high NNH (Number Needed for Harm) indicates less likelihood.

A wise consumer can compare both the NNT (Number Needed to Treat) and the NNH (Number Needed for Harm) to determine which medications, tests or procedures he/she feels most comfortable having.

Introductory Statement of the Problem

The last module introduced NNT - the Number Needed to Treat - to identify medical treatment effectiveness.

The NNT tells how many people need to have a particular medical intervention for 1 person to benefit.

This module introduces the rest of that story....the NNH, or Number Needed for Harm.

The NNH tells how many people need to have a particular medical intervention for 1 person to be *harmed* by a side effect or other problem.

A wise consumer needs to know both

Medicine both helps and harms

A medication may settle your upset stomach but give you a headache.

Or a sleeping pill may help you sleep but leave you thirsty.

NNT and NNH information tells us how frequently medicine helps and harms.

Our old friend, statin medication

Statins both help and harm

Last month we discussed how some people with high cholesterol but no heart disease take statin medications to avoid heart attacks.

That Number Needed to Treat was about 100.

In other words, about 100 people with high cholesterol but no heart disease need to take statins to avoid 1 heart attack.

Today's question:

how many of those 100 people are harmed?

The Number Needed for Harm of stating

About 1 in 255 people who take statins for 5 years develop diabetes.

The NNH for developing diabetes is, therefore, 255

Any other harms?

About 3 – 10 out of 100 people who take statins suffer myalgia or muscle pain because of statin use, according to the Forbes article below.

Other people report sexual side effects and/or memory loss or other cognitive impairments though we don't have hard numbers on these.

We summarize all this by suggesting the Number Needed for Harm of statins is about 9.

That's a very rough estimate. Here are some easy-to-read references on statin harms:

- Statin Use and Risk of Diabetes Mellitus in Postmenopausal Women in the Women's Health Initiative, JAMA Internal Medicine, 2012;172(2):144-152. doi:10.1001/archinternmed.2011.625.
- How concerned should statin users be about diabetes risk?, Kotz, Boston Globe, January 10, 2012
- The Latest Statin Scare, Haiken, Forbes, Feb 29, 2011
- Do Cholesterol Drugs Do Any Good? BusinessWeek, January 16, 2008

We encourage you to review these and other articles and to discuss with your own doctor.

Statin summary

Compare the NNT and NNH of statins

For every 1 person who avoids a heart attack, 11 suffer harm.

The Number Needed to Treat (NNT) to avoid 1 heart attack: about 100.

The Number Needed for Harm (NNH) including myalgia, diabetes, sexual side effects and cognitive impairment: about **9**.

Remember: this is for people with high cholesterol but *no history* of heart disease. The numbers change for people with high cholesterold *and* heart disease or who have *already* had a heart attack.

What should I do next?

Discuss this with your doctor

You and your doctor may decide that the benefits outweigh the risks... or the opposite.

Remember:

You can't make an *informed decision* without knowing both the **NNT (Number Needed to Treat)** and the **NNH (Number Needed for Harm)**.

Some other comparisons

Hormone replacement therapy in menopausal women

Many menopausal women suffer from hot flashes. Hormone replacement therapy can both prevent hot flashes and increase the chance of developing breast cancer.

Absent NNT and NNH numbers, doctors and patient have difficulty deciding if the benefits exceed the risks, or vice versa.

But with NNT and NNH numbers, a woman can make an informed decision.

Here are the numbers:

Number Needed to Treat (NNT) to prevent hot flashes: 3

Number Needed for Harm (NNH) to cause breast cancer or a nonfatal heart attack:667

Vioxx, a painkiller with fewer stomach bleeds

As effective...and safer?

Vioxx, a painkiller that is easy-on-your-gastrointestinal system, sold over \$2 billion annually because it was safer than aspirin or ibuprophen....until it was pulled from the market in about 2004 due to patient harms.

Here are the NNT and NNH numbers:

Number Needed to Treat (NNT) of Vioxx to *prevent* a serious gastrointestinal problem: **200**

Number Needed for Harm (NNH) of Vioxx for *causing* a heart attack, stroke or major coronary event: **59**

Researchers estimate that 60,000 people may have died from taking Vioxx.

Now...do you think you should discuss NNTs and NNHs with your doctor about all your medications?

What about screening tests, therapies and surgeries?

All medical interventions contain some element of risk

A wise consumer learns the NNT and NNH before beginning treatment.

Here's the simple question to ask your doctor:

What is the Number Needed for Harm from this test, medication, therapy or surgery?

I may not get a clear answer

Few patients ask

Answers like it's very safe or it's risky may not satisfy you.

That's why we introduced the Number Needed for Harm (NNH).

Knowing this can only help you.

Conclusion

Here's Dr. David Newman's advice: ask questions

Push hard if necessary. Do not allow confusion to stand.

When a physician continues to speak in ambiguities, it is often a sign that medical science doesn't have a concrete answer to your question.

Ask if this is the case....

In the long run, both you and your doctor will be happy you did.

Module #10 – What is Unnecessary, Dangerous Medical Care

that raises health insurance costs without benefiting patients very much?

Unnecessary medical care, by definition, cannot help you but can raise your medical costs and risks. The wise medical consumer seeks to avoid it.

Many medical researchers estimate that unnecessary care accounts for up to 1/3 of all medical spending in the US.

This module summarizes the information in modules 8 and 9, about NNTs (Number Needed to Treat) and NNHs (Number Needed for Harm) to develop a definition of unnecessary care.

As you read this, consider whether you yourself, or anyone you know, has ever complained about having unnecessary medical tests or procedures *after the fact*.

And then consider whether or not they would have preferred to have this information in advance.

Introductory Statement of the Problem

Unnecessary care accounts for up to 1/3 of all US medical spending.

Avoiding unnecessary care can only help you.

But having unnecessary care can harm you, either financially or medically.

This module provides a new definition of unnecessary care that you may wish to discuss with your own doctor.

Let's review the last 2 modules:

Two modules ago, we introduced the Number Needed to Treat (NNT) to help you determine *how much a medical treatment can help you.*

The last module introduced the Number Needed for Harm (NNH) to help you determine *how much a medical treatment can harm you.*

Now, we'll tie this together and ask

What is *unnecessary* medical care?

OK, what it is?

A simple definition

Unnecessary medical care has a high NNT (Number Needed to Treat)

and

a low NNH (Number Needed for Harm)

What does that mean?

Explanation

High NNT means few people benefit

Low NNH means many people are harmed

What is NNT (Number Needed to Treat) again?

Number Needed to Treat is a very powerful measure

It tells how many people need to be treated for 1 person to benefit. Here are some:

Cholesterol-lowering medications to avoid 1 heart attack in high cholesterol folks without heart disease, NNT = about 100:

CT lung cancer screening in high risk smokers to prevent 1 lung cancer death, NNT = about 217

Quitting smoking to prevent death or heart attack after a heart attack or stroke, NNT = about 8

What is a high NNT?

Here's one suggestion

Professor Nortin Hadler of the University of North Carolina thinks that health insurance not pay for treatments with NNTs greater than 20.

An NNT of 20 means that the treatment only benefits 1 out of 20 people who have it; 19 out of 20 do not benefit from it.

Stated differently:

A treatment with a Number Needed to Treat of 20 only benefits 5% of patients.

Do you agree with Professor Hadler that this is high?

People disagree

Some people think an NNT (Number Needed to Treat) of 20 is too stringent. They might prefer an NNT of 40, 50 or maybe even 100. An NNT of 100 means that 99 out ot 100 patients do not benefit from a particular medical intervention.

Others think a Number Needed to Treat of 20 is too lenient.

They might prefer an NNT of 15 or even 10. An NNT of 10 means that 9 out of 10 patient do not benefit from a particular medical intervention.

We certainly can't tell you which is correct!

We only suggest that you - together with your doctor - answer this question:

At what Number Needed to Treat is medical care so ineffective that I don't want it?

10? 20? 50? 100? or more?

Decide for yourself...

With your doctor's help, of course

But once you decide which NNT is too high to provide benefit to you....

avoid those treatments!

That's Step 1 of Avoiding Unnecessary care: avoid treatments that probably won't benefit you!

What about harm...the NNH?

The Number Needed for Harm is also a powerful measure

It tells you how many people need to have a medical treatment for 1 person to be *harmed.*

Here are some NNH measures:

Statin medications, NNH = about 11 That means 1 in about 11 people who take statins are harmed by them

Hormone Replacement Therapy, NNH to develop breast cancer = about 667 That means 1 in about 667 women who take Hormone Replacement Therapy develop breast cancer

PSA screening for prostate cancer, NNH = about 60 for impotence or incontinence That means 1 in about 60 men who are screened regularly end up impotent or incontinent

The NNH rule of thumb

The lower the NNH, the greater the risk

An NNH (Number Needed for Harm) of **5** means that 1 in 5 people who have a medical treatment are harmed by it.

An NNH of **10** means that 1 in 10 people who have a medical treatment are harmed by it.

An NNH of **667** means that 1 in 667 people who have the medical treatment are harmed by it.

What do you think is high or low?

Where would you set the bar?

This is Step 2 to avoiding unnecessary care

Decide this with your doctor: At what Number Needed for Harm is the care too dangerous for <u>me</u>?

5? 10? 667?

Step 2 of Avoiding Unnecessary Care: avoid care that will likely harm you.

The unnecessary care equation again

Unnecessary Care =

High Number Needed to Treat + Low Number Needed for Harm.

Now....the Bonus Factor!

Avoid medical care with very high Starting Risks...

Starting Risk tells how likely you are to develop a medical problem. Remember module 7?

For example, about 3 in 100 people with high cholesterol but no heart disease will have a heart attack in the next few years. Their starting risk is about 3 in 100.

> But about 1 in 100,000,000 people will die of fatal familial insomnia. Their starting risk is about 1 in 100,000,000.

Starting risk tells you which diseases are more likely to affect you...in other words, which diseases are important.

Absent Starting Risk information, all medical problems are equally important... which may lead to you being treated for problems that would probably never affect you.

What constitutes a high starting risk?

That's for you to decide with your doctor!

Some people think a 3 in 100 starting risk --- of heart attack, for example --- is low and don't worry about it.

Others think a 1 in 100,000,000 starting risk - of fatal familial insomnia for example - is high and want treatment for it.

Our suggestion: decide with your doctor what starting risks are high enough for you to worry about...

and then avoid medical care for the rest!

What do you mean...I should avoid medical care?

If you and your doctor decide that a particular disease Starting Risk is too low to worry about...

Then don't get treatment for it!

That's the Bonus Step to avoiding unnecessary medical care.

The summary

To avoid unnecessary medical care:

Avoid treatments with **high NNTs** (Number Needed to Treat) and **low NNHs**(Number Needed for Harm) ...

Especially those with high Starting Risks!

<u>Now...</u>

Let's put everything together....

If you have a true partnership with your PCP (from Module 4) ...

and

You use your Annual Physical time to discuss your concerns about unnecessary medical care (from Module 6) ...

Then you can frame your unnecessary care discussion around NNTs, NNHs and Starting Risks.

<u>But...</u>

If you haven't laid the groundwork...

If you don't have a true partnership, and you use your Annual Physical time differently ...

Then you may not have the thorough unnecessary care discussion ...

And you may not be as wise and empowered a medical consumer as you would like to be.

Module 11 – Understanding Medical Ads

Direct to consumer medical advertising generates about \$4 in pharmaceutical sales for every \$1 spent. It's a very powerful driver of healthcare spending.

- The extent to which patients understand the advertising is the extent to which they will more likely make wise spending decisions
- But the extent to which patients get confused by the ads or make their decisions based on an incorrect analysis of the ad message is the extent to which patients may make poor spending decisions.

Remember that US patients spend about twice as much on medications as other developed countries like Canada, Britain, France and Germany – without evidence of much benefit, as measured by life expectancy, for example.

Understanding Medical Ads

Americans get much of their medical education from TV, radio and print advertising.

This discussion helps you understand what the ads say and mean ... which may be different from what you think!

Medical ads are very effective

About a third of all patients ask their doctors about a medication they saw advertised....

And most of the time, their doctors give them a prescription in response!

Advertisers know this

So they place lots of direct-to-consumer medical ads

Total value of direct-to-consumer medical ads 1996: \$985 million

Total value of direct-to-consumer medical ads 2005: \$4.2 billion

What do they advertise?

- 1. Drugs that target common, life long, non-lethal conditions that don't just 'go away' like sleep or nasal problems for example....
 - 2. Drugs that address conditions of well-insured consumers, like Medicare beneficiaries.

Really?

Really!

Here are two examples:

First, common occasional heartburn became **GERD** (gastroesophegeal reflux disorder) helping Prilosec become the 3rd best selling drug in the world in 2002.

Is heartburn really the 3rd most important disease in the world?

Second, shyness became **social anxiety disorder** in the mid-1990s. Paxil *'the first and only FDA-approved medication for the treatment of social anxiety disorder'* sold over \$1 billion in 1999.

A billion dollars to treat shyness?

What is the common feature here?

Diseases that fit drugs

Dr. Marcia Angell of Harvard Medical School and a former Editor of the New England Journal of Medicine put it this way:

Once upon a time, drug companies promoted drugs to treat diseases. Now it is often the opposite. They promote diseases to fit their drugs.

If you don't believe this...

try watching the evening news on TV, with a critical eye on medical products advertised. Jot down the kinds of drugs and medical conditions you see advertised the most. **Do these strike you as the most important medical problems in America today?**

What do drug ads generally say?

The first message

You're sick and at risk ... so beware

and

It's normal to be sick and at risk

Lots of people have your medical condition and it's dangerous. You needn't feel weird about taking this medicine. It's OK

Here are some wording tip-offs

'millions of Americans suffer from' or '10% of Americans report problems with'

One study found that about 2/3 of all drug ads rely on this type of emotional appeal to patients.

And second...

We can help.

What do ads typically leave out?

How well the drug works!

In fact, the US Food and Drug Administration only requires ad information on drug **side effects** (i.e. potential harms), not **main effects** (i.e. potential benefits).

This leads many patients to assume - often incorrectly - that the drug works better than it really does.

In addition, and for reasons only understood by them, nearly a quarter of all patients assume that only 'extremely effective' drugs can be advertised to consumers!

What do most patients really want to know?

How well the drug will work for me.

Remember the questions from Module #1?

Out of 100 patients like me, how many will benefit from this drug?

and

Out of 100 patients like me, how many will be harmed by this drug?

Statements like 'this drug works', 'lots of people have this medical problem' or 'this drug can help' don't tell you!

Even an ad that uses real data may not help too much

Here's an ad that's better than most. It ran on Dec 4, 2007 in the Wall Street Journal

What this ad says ... and appears to say

This ad says 'Lipitor reduces your heart attack risk'

It appears to say 'Lipitor reduces your heart attack risk by a lot'

36% is a big number. It gets your attention. It's impressive.

But it gives a misleading impression.

The misleadling impression

the misleading impression is that lots of people avoid heart attacks by taking Lipitor.

But the ad actually says that 99% of people who take Lipitor won't avoid a heart attack because of it. See the small print on bottom left

'3% of people taking a sugar pill or placebo had a heart attack compared to 2% of people taking Lipitor'

That means... Only 1 out of 100 people taking Lipitor actually avoids a heart attack.

Does that mean Lipitor fails to benefit 99% of the people who take it?

Yes - according to this ad!

1 out of 100 people actually benefit by avoiding a heart attack, while 99 out of 100 do not.

Would you take a medication that fails to help 99% of people who take it?

Two additional points

First, since Lipitor uses these numbers, we assume this shows Lipitor's best case.

One wonders what other studies may show about Lipitor...*perhaps that it works even less well.*

Second, Lipitor is not completely effective. While it prevents 1 heart attack in 100 users, *it fails to prevent 2 other heart attacks.*

How can you protect yourself from misunderstanding a drug ad?

Ask the two key questions from Module #1

Out of 100 people like me, how many will benefit from taking this drug?

and

Out of 100 people like me, how many will be harmed by taking this drug?

Then and only then can you determine if the medication is worth taking.

Your homework from today

The next time you see a drug ad...

Look for the answers to those two questions.

Then decide if you really have enough information to proceed!

Module 12 – Where You Go is What You Get

Treatment variation describes the likelihood that the *same* patient will be treated *differently* by different physicians and hospitals. Some researchers estimate that the cost of treatment variation is up to about 1/3 of all medical spending.

This Module introduces the notion of treatment variation. As you read this, consider how your own physicians and hospitals express their preference for one medical treatment vs. another.

Where You Go is What You Get

Sometimes we hear patients say

'my doctor prefers knee replacements to physical therapy for people like me' or

'my doctor thinks mastectomies are much better than lumpectomies for early stage breast cancer'.

This Module shows a surprising geographic distribution of treatments, suggesting that

where you go

for your care often determines

what medical treatment you'll get

For example

Women in Connecticut are twice as likely to have mastectomies as women in Massachusetts

The <u>Dartmouth Atlas of Healthcare</u>, a series of medical care utilization maps, shows variations in the way medical resources are used in the US. Here's a chart showing mastectomy rates in various Connecticut and Massachusetts regions for Medicare beneficiaries:



And here's a map showing the same thing:



Are Connecticut and Massachusetts women very different from each other?

No!

In fact, they have almost exactly the same breast cancer incidence rates:

Breast Cancer Incidence per 100,000 Women 2003 – 2007

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

What about patient outcomes?

Breast cancer mortality rates are about the same in both states!

Here are the rates per 100,000 Women, 2003 – 2007

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

What explains the different mastectomy rates?

Where they go for medical care

Connecticut resident women generally go to Connecticut hospitals for cancer care, while Massachusetts resident women generally go to Massachusetts hospitals.

The **hospital choice**, rather than the **illness itself**, explains the different mastectomy rates! That seems odd. Why would Connecticut hospitals treat differently from Massachusetts hospitals?

Physicians and hospitals in a region often develop certain treatment expertise and preferences – mastectomy surgeries, for example.

The more they do, the more their routines become entrenched... and the more mastectomies Connecticut doctors will do next year and the year after, as compared to Massachusetts doctors.

This is particularly true of conditions that have multiple treatment options and for which the medical community has not clearly settled on the 'best' – like treatment of early stage breast cancer.

Another example

Back surgery in Florida

Here's a map showing back surgery rates per 100,000 Medicare beneficiaries in Florida



Note how people living Fort Myers – the most southern region in *western* Florida – are about 3 times more likely to have back surgery than people living in Miami – the most southern region in *eastern* Florida.

These treatment rate differences have existed for at least 15 years, as tracked by the Dartmouth Atlas.

Are Fort Myers and Miami Medicare folks very different from each other?

No again!

Most Medicare enrollees in both regions are transplants, often from the Northeast and Mid-West. They generally move near their friends and family, or for cultural or other social reasons.

Researchers have not identified 'back strength' or 'back health' as a key criterion in retiree location decisions.

Researchers have also not identified better medical outcomes in Fort Myers, whether outcomes are measured by longevity, greater range of motion or greater satisfaction with medical care.

Hmmm....I begin to see a pattern

Coronary care in Ohio

This map of western Pennsylvania and Ohio shows that people living in Elyria Ohio - the small dark region on Lake Erie - have angioplasties about 4x more often than the national average.



They're about 50% more likely to have angioplasties than in Cleveland - the region completely surrounding Elyria - and about twice as likely as people living in Toledoor Akron, both about 50 miles away.

The New York Times looked into these discrepancies and concluded

'nearly all the procedures at the Elyria hospital are performed by a group of cardiologists who dominate coronary care in this city and have an unabashed enthusiasm for angioplasties, the highly profitable procedure in which they specialize'

Remember: people tend to get medical care at the hospital closest to where they live.

Elyria residents, choosing Elyria hospital, are more likely to have angioplasties than Cleveland residents choosing Cleveland hospitals.

Lessons for patients

First

Wide disagreement often exists among physicians about the best way to treat patients.

There is often not a universally accepted better or worse treatment protocol.

But there may be better or worse treatment protocols <u>for you</u> based on your personal situation, family supports, preferences and other considerations.

<u>And</u>

Second

Where you go for your care - and your **second opinions** - matters.

Two orthopedists in Fort Myers Florida may agree on your back care treatment plan 100% of the time...

But disagree with equally competent Miami orthopedists 2/3 of the time!

How can I protect myself?

Use the available resources

Among the best:

The Dartmouth Atlas of Healthcare

We also encourage you to ask your own physician if you're in a **high utilization region** for your specific medical condition or a **low one.**

The question may surprise him/her --- but may help you get the medical care that's most appropriate *for you*.

Module 13 – Better Safe Than Sorry?

People sometimes think that screening and other medical tests are risk-free and provide a level of safety against having a future bad medical event, like dying of cancer or having a heart attack.

Consequently, they may justify having screening tests by figuring they're 'better safe than sorry.'

This Module takes exception to that line of reasoning showing that, in fact, there are benefits and risks of *having* medical tests and benefits and risks of *not having* them.

The wise consumer considers both before deciding which tests, if any, to have.

Better safe than sorry?

When it comes to screening, a doctor who says 'Let's err on the side of caution,' may actually err on the side of reckless ignorance and grave harm.

That's not just any doctor talking...that's Dr. Otis Brawley, Chief Medical and Scientific Officer of the American Cancer Society and a nationally renowned expert on cancer screening tests.

His question: is it safer - more cautious - to have have screening tests or not to?

First, do no harm

All medical interventions, including tests, contain some element of risk so can harm you.

Screening risks include *false-positive* results and *overdiagnosis*.

What is a false-positive?

False-positives are test results indicating that you have cancer when you really do not.

The US National Cancer Institute estimates that false-positives occur, for example, in 50% of women screened for breast cancer annually for 10 years and that 25% will have biopsies.

False-positives can lead to anxiety and potentially other harms from biopsies, such as infections, physician errors, etc
What is overdiagnosis?

'Overdiagnosis' is the identification and treatment of insignificant abnormalities that will never harm you.

Sometimes these disappear on their own, never grow or never hurt you.

Some abnormalities are really dangerous and others are not

Why not consider any abnormality as a dangerous one and treat it?

Treatments can harm you!

For example, treatment of breast abnormalities can result in

breast deformity, lymphedema, thromboembolic events, new cancers, or chemotherapy-induced toxicities according to the National Cancer Institute.

The Institute estimates that about 33% of breast cancers detected by mammography represent overdiagnosis.

The rate may be rising as we use increasingly sophisticated screening technologies.

What does all this mean for me?

You may be diagnosed with a non-existent or meaningless medical abnormality.

The BMJ - a highly regarded medical research journal - published charts in 2012 comparing the *increased* rate of various cancer diagnoses with the *decreased* rate of cancer deaths.

The results may surprise you.



Many more cancers diagnosed but only a few additional lives saved.

How can I protect myself?

Ask the questions we introduced a few Modules ago

But this time, phrase the questions slightly differently:

Question 1:

Out of 100 people like me, how many will die of cancer (be specific: breast, prostate, thyroid, etc) in the next 10 years if they *don't* have a screening test?

'100 people like me' share my age, general health, family history and other risk factors. That's the best comparative group to determine your cancer risk.

Question 2:

Out of 100 people like me, how many will *still* die of cancer (specify breast, prostate, thyroid etc) in the next 10 years if they *have* the screening test?

Question 3:

Out of 100 people like me, how many will *avoid* dying of cancer (again, specify the type you're concerned about) in the next 10 years by having the screening test?

Question 4:

Out of 100 people like me, how many are *harmed* by the screening test, including by false positive test results or by overdiagnosis?

What should I do with the answers?

Discuss them with your doctor.

<u>Remember</u>

There are risks and benefits of *having* screening tests, just as there are risks and benefits of *not having* them

The question isn't 'How can I err on the side of caution?'

Instead, the right question is...

Do I prefer the risks and benefits of *having* the test or of *not having* it?

Remember

There is no such thing as erring on the side of caution...

Because....

There are only risks and benefits of each medical decision you make

Answering the 4 key questions above will help you quantify the various risks and benefits.

Then you can best decide how to proceed.

Module 14 – Are You Sick?

Medical care can benefit sick people by turning them into healthy people. But medical care can't benefit healthy people much – if at all – because they're healthy to begin with.

- The dictionary defines sick as 'feeling nauseous' among other things.
- Our medical community, however, has increasingly defined sick with a number that very roughly indicates your likelihood of having a future medical event.

Today you can feel fine – not nauseous at all – but be sick at the same time!

As our numerical sickness definitions have evolved, we have consistently created more and more sick people in this country. Those newly defined sick people add costs to our healthcare system – once identified as 'sick' they need treatment – but they don't as often benefit.

As you read this Module, consider some insurance payment implications of our current and evolving definitions of sick. Consider also some medical and psychological implications on our newly created sick people.

Are you sick?

The dictionary defines 'sick' as

affected with a disease, ill health, ailing, queasy or nauseated

as in

He was home sick in bed with the flu

But today doctors and patients increasingly define sick as a number.

For example

You're 'sick' if, for example

Your fasting blood sugar exceeds 126;

Your systolic blood pressure exceeds 140 and/or your diastalic pressure exceeds 90;

Your total cholesterol exceeds 200;

Your T-score is less than -2

As a matter of fact...

You don't have to be home in bed to be 'sick'!

You don't even have to feel lousy

You can ski, swim, run, play tennis or work hard and be sick at the same time!

How can you feel great - but be sick - at the same time?

That's exactly the point of this Module.

You may be healthy...but get labeled as sick.

My doctor says that numbers indicate my underlying medical condition and changes in the numbers indicate that I get healthier or sicker over time

Maybe.

Some gross numbers may indicate an unhealthy medical condition.

And a rapid change *may* indicate a serious problem.

But many commonly used numbers indicate little or nothing about your 'underlying medical condition'

<u>Oh?</u>

Our concern: defining sick by numbers may lead to overdiagnosis of sickness.

In other words, defining sick by numbers may lead to unnecessary worry and treatment

What is overdiagnosis and unnecessary treatment?

Overdiagnosis means diagnosing a medical abnormality that will never cause you harm.

Unnecessary care is care that cannot help you - because you're not sick to begin with - but can only harm you.

Identifying 'sick' by numbers can lead to both.

Why?

Two reasons.

First, the disease indicator or number - total cholesterol for example - may correlate only very, very loosely with disease events, like heart attacks.

One way to understand this: see the number of people with so-called high cholesterol who *don't* have heart attacks.

What is a loose correlation between a disease indicator and a disease event?

A sickness indicator that doesn't affect most of the people who have it.

For example, the West of Scotland Study tracked 7000+ people for 5 years. This is a very well-known study, and one that served as a basis for recommending statin medications to people with high cholesterol.

The West of Scotland folks had average total cholesterol of 272.

44% smoked.

Yet only about 8% of these people had a heart attack during the study.

Over 90% did *not* have a heart attack.

That's what we mean by 'weak correlation'

And the second reason why a sickness number may lead to overdiagnosis and unnecessary care?

We lower the threshold numbers defining sickness over time, creating more 'sick' people.

What does that mean?

Dangerous total cholesterol was 280 in the 1980s and 1990s before it was lowered to 240 and most recently to 200 in 2004.

That means someone with 220 total cholesterol was *healthy* in the 1990s but *sick* after 2004.

Diabetes, osteoporosis and other disease indicators have similar threshold lowering histories.

As the threshold numbers go down, the number of 'sick' people goes up.

Here's a chart showing this developed by Dr. Gilbert Welch of Dartmouth Medical School and the White River Junction (Vt) VA Hospital

Condition	# Sick People, Old Definition	# Sick People, New Definition	New Sick People
Diabetes (blood sugar decreased from 140 to 126)	11,697,000	13,378,000	1,681,000
Hypertension (Systolic BP decreased 160 to 140, Diastalic from 100 to 90)	38,690,000	52,180,000	13,490,000
Hi Cholesterol (total chol decrsd from 240 to 200)	49,480,000	92,127,000	42,647,000
Osteoporosis (T score decrsd fr -2.5 to - 2.0)	8,010,000	14,791,000	6,781,000

Just expanding definitions of 4 diseases – diabetes, high cholesterol, high blood pressure and bone density - created over 60 million new 'sick' people in this country!

<u>Wow</u>

Here's the concern: Once someone is identified as 'sick', they worry and may start medical treatments, like taking medications, for their 'problem'

Drug sales increase along with disease definition expansion.

But people may not get much healthier.

In fact, some may actually be worse off.

Really?

Yes!

In 2011 researchers analyzed 13 studies of over 33,000 diabetics and concluded

"One would expect that lowering glucose levels to normal would make people live longer;

but we could find no reduction in mortality in these trials.

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If anything, mortality was increased by 4% in the people treated intensively."

Treatment increased mortality. Why?

Because we are complex organisms comprised of millions of interactive parts both physical and emotional.

Adjusting one part - blood sugar, for example - may have an as-yet-not-understood impact on other parts.

That's why the 2003 Heart, Blood and Lung Institute 'ACCORD' study of blood sugar lowering in diabetics concluded

'despite detailed analysis, we have been unable to identify the precise cause of the increased risk of death...

We believe that some unidentified combination of factors tied to the overall medical strategy is likely at play'

What do you mean by a combination of factors?

Dr. David Newman suggests a graphic answer:

Image that each of our internal substances, chemicals or body functions is controlled by a Wizard of Oz who adjusts these with knobs.

One knob decreases our cholesterol. Another increases our iron. A third adjusts our blood clotting factor.

If the knobs are one inch in diameter and arranged an inch apart, with forty rows, the panel reaches six and a half feet in height and half a mile in length - more than seven football fields long.

We just don't exactly know how changing one knob affects another, perhaps 2 football fields away.

That's the 'unidentified combination of factors' that led to a mortality increase in diabetics who lowered their blood sugar intensively.

Setting their blood sugar knob correctly made another knob go haywire!

What should I do with this information?

First, take a deep breath.

Remember that some indicators can help your doctor track your health.

And second?

Discuss all this with your doctor.

Remember the questions we keep repeating

Out of 100 people like me, how many will benefit

and

Out of 100 people like me, how many will be harmed....

Ask your doctor how many benefit from 'knowing their numbers'... and from which numbers.

You can also ask

How many out of 100 are *overdiagnosed* and treated *unnecessarily*? How many out of 100 are *correctly diagnosed* and treated *appropriately*?

Final thought

If you and your doctor have a thoughtful and thorough discussion of these issues, then you'll probably make good decisions together.

But

If you don't have a good, thorough discussion... If you only *agree* with whatever your doctor recommends.... Or if your doctor is *uncomfortable* with your questions....

Then you may find yourself inappropriately labeled as 'sick' and subject to overdiagnosis or unnecessary treatment!

Good luck.

Module 15 – What Types of Advice Does a Physician Give?

This Module helps people understand the different between medical *facts* and medical care *opinions*. It also helps people understand how best to use their physician's advice.

- When, for example, does your physician tell you medical facts i.e. statements that the medical community has, by and large, accepted as true?
- And when does he/she offer his/her own opinion statements that may work only for him or her?

You, as a discerning patient, may or may not agree with your physician's opinions.

But you should definitely pay attention when he/she introduces facts.

Patients often ask

Doc, what do you think?

or

Doc, what should I do?

Sometimes patients ask because they're worried and want to be comforted.

But other times, patients seek information, advice or opinions.

If so, they may be asking the wrong questions

Physicians are experts on likely outcomes, likely effects and side effects.

But patients are experts on their preferences - the trade-offs they prefer to make

Outcomes --- Preferences. What are these?

Doctors know medical facts.

They're trained to understand biochemistry, medical data and patient reports.

They're not trained to understand your medical fears, concerns, hopes and trade-offs.

My medical fears, concerns, hopes and trade-offs?

Doctors sometimes offer their own *personal opinions* about the treatment you would prefer or desire....

and their opinions may differ sharply from yours.

Give me an example

Remember the Where You Go is What You Get discussion in Module #12 above?

We showed that Medicare folks living in Fort Myers, Florida are about 3x more likely to have back surgery than those living in Miami, for example.

<u>So?</u>

Doctors in Fort Myers shared an *opinion* that back surgery is often the treatment-ofpreference for certain patients.

Meanwhile, doctors in Miami shared a *different opinion* that back surgery is often *not* the treatment-of-preference.

Outcomes, as measured by longevity or patient satisfaction with care, are about the same in both places.

Researchers sometimes call this *preference-sensitive care*.

Dr. John Wennberg, founder of the Dartmouth Institute for Health Policy and Clinical Practice, estimates that preference-sensitive care encompasses about 25% of all medical spending.

Your question again

Doc, what should I do?

Doctors in Fort Myers tend to answer one way, with their preferred approach

Doctors in Miami tend to answer another, with a different preferred approach!

Another example

Mastectomy or lumpectomy for early stage breast cancer?

Researchers learned, **in the 1970s**, that survival rates were the *same* for both surgical techniques.

By 1996 - about 20 years later - lumpectomy accounted for about half of breast cancer surgeries in many regions.

This was not surprising since lumpectomy and mastectomy outcomes were about the same.

But lumpectomy accounted for almost none of the breast cancer surgeries in Rapid City, South Dakota.

<u>Why?</u>

Here are some comments from **1996** interviews with Rapid City surgeons – 20 years after the lumpectomy / mastectomy studies showed similar outcomes:

As far as I'm concerned, the gold standard is still mastectomy....It is my personal bias that mastectomy does better

Radiation (necessary with lumpectomies) requires time-consuming, tiring, daily trips to the hospital for six weeks

Another Rapid City surgeon suggested that Western women are less concerned about their body image than are women elsewhere in the country.

Personal bias...avoid time consuming trips....less concern about body image. Those sound like opinions to me.

Yes!

In these cases, physicians substituted *their own opinions* for professional advice

Some women may prefer 6 weeks of daily radiation to life without a breast;

others may be far more concerned about their body image than their surgeon thinks.

Remember: this is just one of many preference-sensitive medical decisions.

What are some others?

C-sections with huge variations in state and hospital rates

Othopedic procedures such as hip replacements, knee replacements and back surgery

Early stage cancer treatment especially for breast and prostate cancer

Coronary procedures such as medication vs. angioplasty vs. bypass surgery

In all these cases, treatment options involve tradeoffs

for example, more invasive care, at higher risk, only *sometimes* with potentially better outcomes

Do you want these tradeoffs including risk, pain, recovery time and cost to reflect **your values** or **your doctor's opinions**?

So what should I do?

First, remember that your physician is only human.

He / she probably *really* wants to help you and wants to share the lessons learned from treating lots of patients like you.

So be aware of this human tendency to offer help.

Can you give me an analogy?

We all like to make vacation recommendations.

When a friend asks for advice, we generally wax poetic about the romantic beach in Jamaica, beautiful views in Colorado, dynamic night-life in Las Vegas or delicious food in Miami.

We want to share our experiences with others. It's a human characteristic.

But when we describe the quiet beach, do we think 'hey, you never said you like quiet beaches'

or when we describe that fantastic French restaurant do we consider whether or not our friends like heavy food?

We tend to assume that our own preferences are our friends' too.

Just like physicians, when we ask for their advice.

And second?

Remember that your doctor can offer both excellent advice and personal opinions.

They are different.

You definitely want his / her advice about medical technologies and processes.

You may or may not want personal opinions.

Let's give the last word to Dartmouth's John Wennberg

Informed patients often prefer a form of treatment other than the one their physicians actually prescribe

and

When offered a clear explanation of the treatment options, informed patients often choose the less invasive treatment

Beware of substituting your doctor's personal opinions for your own.

It's hard to do!

But the rewards may be huge.

Good luck.

Module 16 – Some Disease Starting Risks

Starting risk is the first important number you need to learn about your chance of having a future bad medical event.

It compares you to a large group that shares your risk factors and tells you how likely you are to have a heart attack, die of colon cancer or have a stroke absent medical care.

Some researchers suggest that knowing your starting disease risk is the first step to being an informed medical consumer, meaning that people who do not know their starting risks are simply not well-informed.

This Module shows the starting risks of having several different future medical events for various populations.

Starting Risk means your chance of dying from a particular disease *without a* medical intervention like screening tests, medications or surgeries.

Modified Risk means your chance of dying from the disease with medical interventions.

This Module will give you some Starting Risk numbers for various diseases.

Why do I care about Starting Risks?

Knowing your Starting Risk can help you in two ways:

First, it can help you decide if your chance of having a future bad medical event (e.g. having a stroke, dying from colon cancer, having a child who develops fatal familial insomnia) is high enough to worry about.

Second, it can help you understand the impact of medical services.

Explain, please

If your Starting Risk of dying from a disease is 1 in 5 people over 10 years, then you should probably worry about this disease a lot, and get medical care to reduce that risk.

But if your Starting Risk of dying from another disease is 1 in 100,000,000, then you may decide that your risk is too low to worry about.

OK, I understand that. What about helping me understand the impact of medical services?

We sometimes hear that a particular medical treatment reduces your chance of dying from a specific disease by 20% or 30%.

You need to know your Starting Risk of dying in order to understand whether a 20 or 30% reduction matters to you.

Do you remember why you don't wear a seat belt at the dinner table, even if it reduces your risk of falling off your chair by 20%?

The reason: your chance of falling off a chair is so low that a 20% risk reduction is virtually meaningless.

Here's a medical way to understand Starting Risk: men don't have mammograms.

Though some men do develop and even die from breast cancer, their Starting Risk is so low than the risk reduction benefits from mammography are deemed too small to justify their costs and risks.

OK, so I need to know my Starting Risks for various diseases. Will you tell me?

Yes. We'll provide Starting Risk numbers for lots of different diseases.

We'll use the Risk Charts published in the Journal of the National Cancer Institute.

You can also find these in Know Your Chances by Dr. Steven Woloshin of Dartmouth Medical School

OK, thanks

Here are the risks of dying from various diseases over 10 years per 1000, 50-year old non-smoking women:

Heart Attack	Stroke	Lung Cancer	Breast Cancer	Colon Cancer	Ovarian Cancer	Cervical Cancer	Pneumonia	Influenza	Aids	Accidents	Any Cause
4	2	2	5	2	1	1	1	<1	1	2	42

and here are the risks of dying over 10 years per 1000, 50-year old non-smoking men

Heart Attack	Stroke	Lung Cancer	Colon Cancer	Prostate Cancer	Pneumonia	Influenze	Aids	Accidents	Any Cause
12	2	2	2	1	1	<1	1	4	62

Some of these numbers seem awfully low, like the ovarian, cervical and prostate cancer rates

As you age, your mortality risks increase.

Here's the chart for 60 year old non-smoking women showing death rates per 1000 over 10 years

Heart Attack	Stroke	Lung Cancer	Breast Cancer	Colon Cancer	Ovarian Cancer	Cervical Cancer	Pneumonia	Influenza	Aids	Accidents	Any Cause
14	4	5	7	4	3	1	2	<1	<1	2	105

What does this mean to me?

These charts can help you determine which diseases pose the greatest threats to you, and whether those threats are big enough to worry about.

What do you mean by that?

Here's a breast cancer example

Age	# die/1000 over 10 yrs	# not die / 1000 over 10 yrs	% not die
50	4	996	99.6%
60	7	993	99.3%
70	9	991	99.1%

Do you think this Starting Risk is high enough to worry about?

At age 50? 60? 70?

Yes, I think so...although my chance of not dying is pretty impressive

OK, that's your opinion. Other people may agree or disagree.

Our point is that once you know your actual Starting Risk, then you can make a wise and informed decision about whether or not to seek medical care that may mitigate it.

Here's the same chart but this time showing prostate cancer mortality risks.

Age	# die / 1000 over 10 years	# not die / 1000 over 10 years	% not die
50	1	999	99.9%
60	4	996	99.6%
70	14	986	98.6%

Do these strike you as high enough to worry about?

Maybe. I need to think about it. What should I do with this Starting Risk information?

Discuss it with your doctor.

He / she may be unaware of your actual Starting Risks and may find this information useful when prescribing tests and treatments to you.

When you have these discussions, we encourage you to remember two things.

First, remember to include both your Starting Risk of *dying* and your Starting Risk of *not dying*.

You may find that expressing these as the number of people who will not die helps you grasp the risk.

A '2 in 1000 risk of dying over 10 years' is the same as saying '998 people will not die'

And the second thing to remember?

You need to decide which Starting Risks are high enough for <u>you</u> to worry about, and which are not.

Some people think that a 98.6% chance of *not dying* (prostate cancer in 70 year old men, for example) is so high that they don't worry about the disease and skip screening for it;

Others think that a 99.9% chance of not dying (cervical cancer in 50 year old women, for example) is low, so they have every screening test available.

Who can help me decide which disease starting risks are high enough to worry about?

That's an individual decision and people can disagree on the answer.

But your doctor can help you think about all this, provided you feel comfortable talking with him or her about these issues.

Good luck.

Module 17 – Overdiagnosis

Overdiagnosis is a relatively new phenomenon in our healthcare system. It means that you are diagnosed with a medical abnormality that will never harm you.

Our increasingly powerful radiological and other screening tools can, today, *identify* abnormalities perhaps better than our physicians can *understand* them.

Once diagnosed, however, most patients seek medical care. This can increase medical spending unnecessarily and generate more harm than benefit. Remember: many overdiagnosed patients are not 'sick' in the first place, if 'sick' means you have a medical problem that will harm you.

As you read through this Module, consider the diagnoses you and your family members have had, and ask yourself if you've ever been overdiagnosed.

Do I really need this test?

Today's concern:

People without symptoms may be diagnosed with a disease that will not cause them to experience symptoms or early death.

The more we test, the more of these irrelevant abnormalities we find.

This is often called 'overdiagnosis' and it's a big problem today.

OK – please explain more

As we use increasingly power testing technologies - MRI, CT, Ultrasound, X-ray and others - we identify more and more medical abnormalities.

'Abnormalities' include muscle tears, disks touching nerves, fetal 'bright spots' in the heart or intestine and cancerous cells.

Unfortunately, we're sometimes not able to understand *exactly* what the abnormality is ...

Or even if it's meaningful or dangerous!

In fact the definition of 'abnormal' may change as our technologies get more powerful!

Give me an example

Here's an analogy that may help.

Imagine that we're looking at the earth and want to count the number of lakes in Florida.

(Make pretend that a lake is a medical abnormality.)

OK, it should be pretty easy to count the lakes in Florida

Well....maybe.

Remember that a lake is 'a body of water completely surrounded by land'. Try to count the number of lakes in each picture below.



Here's a view of Florida from outer space

How many lakes do you see?

I think I see one, but not very clearly

OK, you see 1 lake in Florida.

Now let's look more closely, say from a lower altitude.



How many lakes do you see now?

I see one large lake clearly and possibly a few others south of Jacksonville

OK - you see a few lakes.

We're not changing Florida's geography....but we're using better and better technology to find lakes.

How many do you see this time?



I see one really big lake and a whole lot of small lakes between Tampa and Palm Bay.

The harder we look - and the better the technology we use - the more lakes we find.

But if we look really, really closely, we may confuse ourselves about exactly what a lake is.

We started off looking for 'a body of water completely surrounded by land'.

Is this a lake?



Yes, this is a lake. Definitely. <u>At least, I think so.</u> <u>Actually, I might prefer to call it a pond</u>

A pond is not exactly a lake.

What about this?

It's still a body of water completely surrounded by land



No, not in my opinion. I see a swimming pool. I think that a swimming pool is not a lake. Now we're getting into opinions and interpretations, just like in medical diagnoses. Here's one more picture. 'A body of water completely surrounded by land'



No. Definitely not a lake. It's a temporary flood. It will disappear after a few days

But it was a body of water completely surrounded by land when we looked at it.

And that's a big problem for medical diagnoses.

The 'lake' appears....then, upon further investigation, disappears.

Why?

Did the patient really have a medical abnormality?

This opens the door to lots of follow-up testing and investigation.

Remember: we didn't change the number of lakes in Florida.

We only changed the *technology* used to look for lakes... and the amount of *effort* put into finding lakes. The same problem exists in medicine. It's sometimes called the disease *detection* vs. disease *incidence* problem

What does that mean?

It means that the harder we look for diseases, the more we find.

We *detect* more medical abnormalities (thereby labeling more people as sick) as we look harder and use better technologies.

But we haven't changed the *incidence* or frequency with which people have medical abnormalities.

This sometimes leads to patient benefits....and sometimes patient harm.

Can you give me an example?

A Florida sports medicine physician named Dr. James Andrews suspected that MRI screenings might provide misleading information.

So he invited 31 perfectly healthy baseball pitchers to his facility for shoulder MRIs.

None of these professional athletes was injured or had shoulder pain.

But the MRI results showed:

- * 90% had abnormal shoulder cartilage and
 - * 87% abnormal rotator cuff tendons.

"If you want an excuse to operate on a pitcher's throwing shoulder, just get an M.R.I.," according to Dr. Andrews.

Wow. That can really mess with their heads, especially if they have a bad outing

Exactly.

Here's a summary of the problem, according to Dr. Christopher DiGiovanni, a professor of orthopedics and a sports medicine specialist at Brown University:

"It is very rare for an M.R.I. to come back with the words 'normal study'. I can't tell you the last time I've seen it."

That's because, just like finding lakes in Florida, the harder we look for rotator cuff injuries or other medical abnormalities, the more we find.

And, just like our definition of 'lake' became an opinion in the Florida lake pictures (a 'pond' or a 'pool' or a 'swamp', not really a 'lake'), so our definition of rotator cuff injury, canerous cell or other medical abnormality may also become an opinion.

That seems a stretch

Not really. Here's a study for you to consider:

195 pregnant women were referred for ultrasound or magnetic imaging of their fetuses for suspected ventriculomegaly, a fetal brain condition.

Multiple physicians reading the scans independently *agreed* on 60% of the ultrasound diagnoses and 53% of the magnetic images.

In other words, they disagreed on their diagnosis over 40% of the time!

<u>Oh my...</u>

Those types of disagreements among physicians have been noted for years.

One study of EKG interpretations by 10 experienced cardiologists found that they disagreed with each other's diagnosis about 2/3 of the time.

In fact, when the cardiologists were given the *same* EKG results multiple times, they disagreed with *themselves* more than 10% of the time.

This is scary information. How can I protect myself?

Our advice remains remarkably constant:

Find a physician with whom you can communicate and discuss your concerns with him or her.

Don't automatically *have* every test available; and **don't** automatically *avoid* all tests altogether.

Remember: there are benefits and risks of testing, just as there are benefits and risks of *not* testing.

Try to use this information when you talk to your physician.

We hope it helps!

Module 18 – Some Key Sources of Medical Info for Consumers

Patients today access many different medical information sources including newspapers, websites and journals. Many of these are quite good; some may be biased; and some may be poorly researched and presented.

This Module will introduce two reference sources that we have found quite useful.

- The first, the US Preventive Services Task Force, tells how well various medical interventions work.
- The second, the Dartmouth Atlas of Healthcare, tells how frequently patients get different medical treatments by state, region and often by hospital.

These are not the only sources of useful medical care information, but they are two of the best – and we don't want to overwhelm you with too many recommendations.

Using these two sources can help you identify and avoid unnecessary medical care and therefore help you control your healthcare spending and treatment risks.

Here's a good place to start when you're facing a medical decision:

The US Preventive Services Task Force

The USPSTF is an independent panel of non-Federal experts in prevention and evidence-based medicine.

It conducts rigorous, impartial assessments of the scientific evidence for the effectiveness of a broad range of clinical preventive services, including screening, counseling, and preventive medications, and it makes Recommendation Statements.

How can I find their recommendations?

Here's the link to their A-Z recommendations page <u>http://www.uspreventiveservicestaskforce.org/uspstopics.htm</u>

Or you can type US Preventive Services Task Force into your browser. The site is pretty easy to navigate.

How do they give recommendations?

The USPSTF gives grade recommendations for various medical tests and procedures ranging from A - D.

An 'A' recommendation means the USPSTF recommends the service, saying 'there is high certainty that the net benefit is substantial.'

A 'B' recommendation means the USPSTF recommends the service, but there is only *'high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.'*

The USPSTF sometimes gives a **'D'** recommendation, meaning it recommends against the service because there is moderate or high certainty that the service has **no net benefit** or that the **harms outweigh the benefits**.

And sometimes the USPSTF gives an 'I Statement' meaning the current evidence is *insufficient to assess the balance of benefits and harms* of the service.

How well are their recommendations received?

The US Preventive Services Task Force recommendations are called 'gold standard' by many healthcare organizations including

The American Academy of Family Physicians The Society of Teachers of Family Medicine The US Department of Health and Human Services, Agency for Healthcare Research and Quality The Journal of Family Medicine The New York State Department of Health The Nebraska Academy of Family Physicians United Healthcare Harvard Pilgrim Health Care and many others

In fact, the Patient Protection and Affordable Care Act of 2010 (ObamaCare) specifically grants to the US Preventive Services Task Force the power to determine which tests are appropriate for insurance coverage and which are not.

Tests receiving an A or B recommendation from the USPSTF are covered with no patient out-of-pocket costs, per Title IV of PPACA.

What are some of USPSTF recommendations?

The examples below come from the list of dozens of USPSTF recommendations.

We listed one 'A' recommendation, one 'B' recommendation, one 'I statement' and one 'D' recommendation **for illustration purposes only**, and *not because we consider these the most important recommendations.*

Cholesterol Screening

The USPSTF strongly recommends screening men age 35 and older, and women age 45 and older for lipid disorders. An **'A'** recommendation

Breast Cancer Screening

The USPSTF recommends biennial screening mammography for women aged 50 to 74 years. A **'B'** recommendation *and*

The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women 75 years or older. An 'I statement'

Prostate Cancer Screening with PSA Tests

The USPSTF recommends against PSA-based screening for prostate cancer A 'D' recommendation

Some doctors follow these recommendations while others apparently do not

The USPSTF only makes the recommendations.

Physicians may choose to follow them or not.

And you, as a patient, may also choose to follow them or not!

If your doctor doesn't follow these recommendations, ask why. He/she may have a very good reason.

Our unscientific polling of physicians indicates that most physicians welcome discussions of this issue by well-informed patients.

Reviewing and understanding the USPSTF recommendations that apply to you is a big step toward becoming well-informed.

What is the second reference source that you recommend?

Our second excellent source of medical information is the Dartmouth Atlas of Healthcare, <u>http://www.dartmouthatlas.org/</u>

For more than 20 years, the Dartmouth Atlas Project has used Medicare data to document significant variations in how medical resources are distributed and used in the US.

And what, exactly, does that mean?

The Dartmouth Atlas researchers have divided the US into 306 Hospital Referral Regions and 3436 Hospital Service Regions.

A **Hospital Referral Region** consists of a major acute care hospital - often a teaching hospital - and the community hospitals that refer patients to it.

A Hospital Service Region is the geographic region served by a community hospital.

The Dartmouth folks then note the frequency at which patients receive various medical services like back surgery, knee surgery, mastectomies and a couple dozen other medical procedures in each region.

The information is pretty surprising and very useful to patients.

Can you give me an example?

Sure.

We actually discussed this in Module # 12 Where You Go is What You Get.

Here's a simple example: Medicare men in Rochester, New York get about 3x as many prostate surgeries as Medicare men in Buffalo, New York - about an hour away.

The Rochester men get about 255 surgeries per 100,000 men; The Buffalo men get about 79

Here's a map from the Dartmouth Atlas with this information: (it's easier to read on their website, in color)



Remind me why this is a big deal

These Dartmouth Atlas maps show that **where you go** for your medical care has a great influence on **what medical care you will get**.

Demographers have *not* identified huge differences in the medical conditions of men in Rochester and Buffalo.

Instead, they note that Rochester men generally go to Rochester hospitals, and Buffalo men to Buffalo hospitals.

Rochester hospitals apparently prefer prostate surgery for early stage prostate cancer, while Buffalo hospitals prefer other treatment protocols.

That's what the Dartmouth researchers mean by 'where you go is what you get'.

How can I, a patient, use this information?

You can use this info in two different ways.

First, you can determine if you're in a high or low utilization region.

Patient outcomes, as measured by, for example, mortality rates, don't vary nearly as much as treatment frequency.

So learning that you're in a high utilization region may be a caution flag, suggesting a useful topic to discuss with your physician.

Why a caution flag?

A caution flag because more hospitalizations increases your likelihood of acquiring a hospital-based infection or of physician error, according to the Atlas.

The Dartmouth folks also warn about inadequate continuity of care and communication among physicians in high utilization areas, leading perhaps to *poorer* patient outcomes.

Poorer outcomes?

One of the senior scholars at Dartmouth Medical School, Dr. Elliott Fisher, published a major analysis of Medicare spending and treatment patterns called **The Implications of Regional Variations in Medicare Spending.**

Here are some of his conclusions:

'We found no evidence to suggest that the pattern of practice observed in higherspending regions led to improved survival, slower decline in functional status, or improved satisfaction with care.'

In other words, more care does not generate better patient outcomes

and

For every 10% increase in hospital expenditures among Medicare patients, the relative risk of death within 5 years *increased*.

In none of the regions Fisher analyzed was an increase in spending - meaning an *increase* in medical care - associated with a *decrease* in mortality rates.

Are you saying that more medical care may lead to poorer patient outcomes?

That's one of the potential lessons from the Dartmouth Atlas.

And that's why we suggest that learning whether or not you're in a high intensity medical care region is so important!

You said there is a second reason for learning if you are in a high or low volume region. What is this reason?

Knowing this information can help you decide where to go for a second opinion.

In the Rochester - Buffalo prostate surgery case, for example, an informed consumer in Rochester may want to get a second opinion in Buffalo about the need for prostate surgery.

The Dartmouth map shows that physicians in the two cities will disagree about treatment recommendations up to 2/3 of the time, so going outside your region may be a useful exercise.

Wow. Fascinating. Is the Dartmouth Atlas easy-to-use?

Unfortunately no.

It's useful and fascinating, and provides critical information to informed patients. But it's not even as user-friendly as the US Preventive Services Task Force website!

We suggest, however, that clicking around the Atlas website is a very useful endeavor for people who really wish to become informed about their medical treatment options.

Any other recommendations about good sources for patients to use?

There are lots of valuable web resources and some really terrific books available.

But, rather than provide a long list of resources, we decided to stop at 2. That's a manageable number for most people.

We encourage you to review these two websites - the **US Preventive Services Task Force** and the **Dartmouth Atlas** - as key steps to becoming a well informed consumer.

Can I be an informed consumer without using these tools?

Not in our opinion:

Using these two tools is part of our definition of being an informed medical consumer.

Remember: The better informed you are about your medical care, the more likely you are to enjoy good outcomes.

We invite you to contact us with questions or comments about our recommendations, and to ask for more.

We have plenty to offer!

Good luck.

Module 19 – What do 5-year Survival Rates Mean?

Some medical outcome metrics are useful and others not. We suggest that 5-year survival rate information falls into the latter category.

Though we often use them – including in many of the most highly respected journals and by many of the most highly respected research institution – it is such a flawed measure that it probably fails to provide any useful information at all.

This Module explains why you don't want to use it.

What do 5-year survival rates mean?

<u>That seems obvious, at least to me.</u> It means that people live for at least 5 years with a disease.

Yes....more or less

People often use this measure to compare treatments or see if we're improving our cancer care over time.

For example, former Vice President Al Gore claimed that 5-year survival rates for all cancers improved in the early 1990s to over 60%. That's up from 51% in the early 1980s

And Senator Kay Bailey Hutchinson argued for increased breast cancer screening claiming:

When detected early and when confined to the breast, the 5-year survival rate for this disease is over 95%...this is a remarkable statistic and represents a dramatically improved picture than that of even a few years ago.

Sounds good to me

Except that cancer *mortality* rates actually rose in the 1980s.

And many researchers wonder if mammography actually saves any lives at all.

If 5-year survival rates mean anything, then cancer mortality rates should have *fallen* in the 1980s!

Our question today:

What, if anything, do 5-year survival rates really tell us?

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OK, you tell me

The 5-year survival rate means, as you said earlier, that someone lives for at least 5 years with a disease, generally cancer.

But remember: you can extend the survival rate in either or both of two ways:

Either you can extend life, so that instead of dying at age 70, someone now lives to age 72.

or

Or you can find the cancer earlier so that instead of diagnosing it at age 66, you now diagnose it at age 64.

Or both.

Which do we find in this country: people dying older? Or people being diagnosed younger?

I would guess that people die older. Right?

Not exactly.

In the **1990s**, the average age of breast cancer diagnosis was **62**.

The average age of breast cancer death in 1996 was 68.

So women survived for an average 6 years with breast cancer.

But during the period **2005 - 2009**:

The average age of breast cancer diagnosis was 61

The average age of death from breast cancer was still 68.

Women survived an average 7 years with breast cancer... but they still died at the same age, 68.

We extended the survival rate by a year without extending women's lives.

<u>Oh my</u>

This situation - longer survival rates without longer lives - occurs with other cancers also.

Here's a prostate cancer survival example:

In the early 2000s, the US prostate cancer 5 year survival rate was over 99%

The UK prostate cancer 5 year survival rate was about 81%

But the age adjusted mortality rates were virtually identical!

The US rate: 23.6 per 100,000 men The UK rate: 23.8 per 100,000 men

Why?

In both the breast and prostate cancer cases, more screening led to earlier diagnoses.

But the earlier diagnoses didn't translate into longer lives.

The earlier diagnosis only translated into more years of living with a cancer diagnosis!

(There is some evidence that people are living longer with metastized cancer today than previously, but that's a different issue.)

Why do survival rates not correspond closely to longevity gains?

Survival rates require a cancer diagnosis - that starts the survival time clock

The more we screen, the more survival rates increase.

Survival rates always rise as cancer screening increases.

Let's say this again:

If screening helps people *live longer*, survival rates **rise**; If screening has *no effect on longevity*, survival rates **rise**; If screening, for some reason, causes people to *die younger*, survival rates **rise**.

Please explain

Screening, by definition, finds a cancer earlier, before the physician or patient would otherwise find it...in technical terms, before it becomes symptomatic.

So - by the definition of screening - the more we screen, the more we extend the survival rate, simply because we start counting earlier.

We gain all the 'pre-symptomatic' time during which few, if any people, die of the disease.

OK, I understand. Anything else?

Our current screening technologies can identify incredibly small cancers today - smaller than we could have identified a decade or two ago.

That's what happened in our breast cancer example from a couple slides ago:

1990s technology only allowed us to see breast cancers of a certain size. We averaged identifying them in women at age 62.

But the 2005 technologies allowed us to identify smaller, younger cancers. That's why we averaged identifying them in women at age 61, at least in part.

We didn't increase the amount of cancer in women, nor did we extend their lives very much, if at all.

But we increased their average survival rate from 6 to 7 years.

<u>Wow</u>

So if you want to learn whether or not cancer *screening* leads to longer lives, or whether or not cancer *treatments* help extend lives, you need to ask the right question.

The correct question to ask isn't 'What's the 5- year - or 10-year - survival rate?'

A far better question is

What's the average age of death from this cancer?

If the average age of death goes up, then we're extending lives.

Does that tell how efffectively screening works?

Partly, but not entirely

If you want to learn whether breast cancer screening extends the lives of those screened, ask this:

What is the average age of breast cancer death for women who have mammograms and for women who do not?

That isolates **screening** from **treatment** improvements.

This reminds me of the Comparative Study Module, #5 above!

Exactly!

You've been paying attention

Module #5 How Can You Tell if Medicine Works explained why you need to have *comparative* information to determine if - and how well - medicine works.

'Comparative studies' compare a group of people who had the medical intervention - in this case, the cancer screening test - with a similar group that did not.

Results of comparative studies are far more reliable and credible than results of observational studies.

Or of survival rate studies.

OK, interesting. I think I understand all this. Is there an overall morale to this story?

Yes, there are two.

First, we have several good measures that tell us how well a medical intervention, like cancer screening, works.

Those measures include comparing the average age of death for people who had the screening tests and people who did not.

One measure that does <u>not</u> tell us anything about screening effectiveness is the 5-year or 10-year survival rate.

If the survival rate information tells us anything at all - which is doubtful - it tells us that more people get screened and the screening identifies younger, smaller cancers earlier in the disease cycle than older identification methods.

5-year and 10-year survival rates don't tell us anything about whether or not screening saves lives.

And the second morale?

People who quote 5- and 10-year survival rates don't know what they're talking about!

Since these are not credible measures, people who use them are also not credible.

Beware and be forewarned. As yourself:

If these people aren't credible about survival rates, are they credible about <u>anything</u> they say... or are they just trying to sell you something?

Better information and better information sources exist.

We encourage you to use them.

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Summary and References

These 19 modules can serve as a client education platform for brokers to use as part of their client engagement program. They addressed the following issues:

Module 1: Understanding Medical Claims. This module helped people know which statistics are meaningful to them when buying medications, or when considering a medical test, therapy or procedure. This is important because people often get confused about medical claims. This module helps people compare the benefits and harms of a particular medication, test, or therapy.

References:

http://www.businessweek.com/stories/2008-01-16/do-cholesterol-drugs-do-any-good

Module 2: How to Choose a Hospital. The hospital's track record of treating patients with your medical condition is the single best indicator of your likely outcome of a hospitalization. Other indicators - technology, famous surgeons, teaching hospital vs. community hospital - do not predict your outcomes as well.

References:

http://www.medicare.gov/hospitalcompare/

http://www.bloomberg.com/news/2011-02-16/doctors-need-1-600-robot-aided-prostate-surgeries-forskills-study-finds.html

http://www.medpagetoday.com/MeetingCoverage/ASCOGU/24908

Module 3: How to Choose a Specialist. The single best indicator of a specialist's results for a particular patient is his/her track record with other, similar patients. Unfortunately, we generally have poor public information about outcomes by specialist. Some specialists, however, may keep their own records. A wise consumer can ask. Absent that information, the next best indicator of a specialist's results is the number of patients he/she has treated. In medicine, patient outcomes often (but not always!) correlate with the number of times a specialist has treated similar patients.

References:

http://www.amazon.com/Redefining-Health-Care-Value-Based-Competition/dp/1591397782/ref=sr_1_1?ie=UTF8&qid=1329171962&sr=8-1

http://books.google.com/books?id=f_WvEIY55eUC&pg=PA52&lpg=PA52&dq=unaccountable+after+panc reas+surgery+by+surgeon+experience&source=bl&ots=z3pYzWGRtd&sig=fprC2Xe6TyAdWJTYOuX7jjO T3Ps&hl=en&sa=X&ei=xyh4UPPLHcXs0gHjIIHQDg&ved=0CCcQ6AEwAA#v=onepage&q=unaccountabl e%20after%20pancreas%20surgery%20by%20surgeon%20experience&f=false **Module 4: How to Choose a PCP.** The role of the primary care physician differs from the role of the specialist much of the time. The specialist's main responsibility is either to return a sick person to better health, or to manage a chronically ill person. The PCPs main responsibility is to keep relatively healthy people healthy. As such, the criterion for choosing a PCP differs from the criterion for choosing a specialist. One useful way to consider choosing a PCP is the human relationship factor, and the trust level a patient has for his/her primary care doctor.

References:

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http://www.webmd.com/diet/evaluate-latest-diets

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Module 5: How Can You Tell if Medicine Works. Comparative studies compare a group of people who had a particular medical intervention with a similar group of people who did not. This is the best way to determine how much the medical intervention helped. Other kinds of studies do not tell us how important a medical intervention is, compared to, for example, strong family support, a positive mental outlook, some genetic predisposition or other factors.

References:

<u>http://www.dartmouth.edu/~library/biomed/services/lgr/docs/Direct_to_Consumer_Advertising.pdf?mswitc</u> <u>h-redir=classic</u>

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http://www.amazon.com/The-Truth-About-Drug-Companies/dp/0375508465

http://vedantam.com/socialanxiety07-2001.html

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http://content.healthaffairs.org/content/early/2004/04/28/hlthaff.w4.234.short

http://www.kevinmd.com/blog/2010/09/dtc-advertising-history-fda.html

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072077.htm#ris k_disclosure

Module 6: Understanding Annual Physicals. People can use their annual physicals in one of two different fashions. Some choose to have lots of tests and to watch as their test results change over time. Others choose to spend their annual physical time primarily talking with their physician. There are advantages and disadvantages of both. The most relevant factor: how comfortable both the patient and the physician feel with the use of their annual physical time together.

References:

http://www.time.com/time/health/article/0,8599,1735156,00.html

http://www.webmd.com/a-to-z-guides/annual-physical-examinations

http://men.webmd.com/news/20070924/annual-physical-exam-unneeded-expense

http://www.time.com/time/health/article/0,8599,1735156,00.html

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http://www.nytimes.com/2003/08/12/health/annual-physical-checkup-may-be-an-emptyritual.html?pagewanted=all&src=pm

Module 7: Disease Risks. Patients face different risks of developing various diseases, like heart disease, cancer or fatal familial insomnia. Some people worry about a 1 in 100,000 risk and seek medical care to prevent that. Others do not worry about a 1 in 100 risk. The wise patient understands his or her own disease risks and decides which to worry about and seek treatment for, and which not to. Absent this information, all diseases are equally important. This may result in the patient receiving too much - or too little - medical care.

References:

http://www.businessweek.com/stories/2008-01-16/do-cholesterol-drugs-do-any-good

http://www.vaoutcomes.org/our_work/risk-charts/

http://www.world-of-lucid-dreaming.com/fatal-familial-insomnia.html

http://en.wikipedia.org/wiki/Fatal_familial_insomnia

Module 8: NNTs. The Number Needed to Treat tells how many people need to take a medication or have a test, procedure or therapy for 1 person to benefit. Patients and physicians who know NNT data can answer two key questions. First, how well does this medical treatment work? Second, which medical treatment works best? The lower the NNT, the better the medical treatment works.

References:

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Module 9: NNHs. The Number Needed for Harm tells how many people need to have a medical test, procedure or therapy, or need to take a medication, for one person to be harmed. Patients and physicians who know NNH data can answer two key questions. First, how much harm (or risk) does this medical treatment pose? Second, which medical treatments pose the least patient risk? The higher the NNH, the less risky the treatment.

References:

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http://www.searcylaw.com/files/ofcounsel05 1.pdf

http://www.amazon.com/Overtreated-Medicine-Making-Sicker-Poorer/dp/B0026IBY1S/ref=sr 1 1?ie=UTF8&qid=1331644114&sr=8-1, pages 210 – 212

Module 10: Unnecessary Care. This module ties NNT and NNH information together. As a general rule, care with a high NNT is less beneficial than care with a low NNT, because care with a high NNT generates less benefit to any individual patient. Also, as a general rule, care with a low NNH poses more risk to any individual. Wise patients may elect to avoid care with a high NNT and a low NNH.

References:

http://books.google.com/books?id=fra7RRmHYdIC&pg=PA223&lpg=PA223&dq=hadler+medicare+nnt+2 0&source=bl&ots=dOu_n8lnT0&sig=ZG4CKYKmAWZtNgch-DmTnwKN7Cs&hl=en#v=onepage&q=hadler%20medicare%20nnt%2020&f=false

Module 11: Understanding Medical ads. Direct to consumer medical advertising generates about \$4 in pharmaceutical sales for every \$1 spent. It's a very powerful driver of healthcare spending. The extent to which patients understand the advertising is the extent to which they will more likely make wise spending decisions. But the extent to which patients get confused by the ads or make their decisions based on an incorrect analysis of the ad message is the extent to which patients may make poor spending decisions. Remember that the US patients spend about twice as much on medications as other developed countries like Canada, Britain, France and Germany – without evidence of much benefit, as measured by life expectancy, for example.

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http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(01)06254-7/abstract

http://content.healthaffairs.org/content/early/2004/04/28/hlthaff.w4.234.short

http://www.kevinmd.com/blog/2010/09/dtc-advertising-history-fda.html

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072077.htm#ris k_disclosure

Module 12: Where You Go is What You Get: Treatment variation describes the likelihood that the same patient will be treated differently by different physicians and hospitals. Some researchers estimate that the cost of treatment variation is up to about 1/3 of all medical spending. This Module introduces the notion of treatment variation. As you read this, consider how your own physicians and hospitals express their preference for one medical treatment vs. another.

References:

http://www.dartmouthatlas.org/

http://www.nytimes.com/2006/08/18/business/18stent.html?pagewanted=all

Module 13: Better Safe than Sorry? People sometimes think that screening and other medical tests are risk-free and provide a level of safety against having a future bad medical event, like dying of cancer or having a heart attack. Consequently, they may justify having screening tests by figuring they're 'better safe than sorry.' This Module takes exception to that line of reasoning. In fact, there are benefits and risks of having medical tests and benefits and risks of not having them. The wise consumer considers both before deciding which tests, if any, to have.

References:

http://www.amazon.com/How-We-Do-Harm-America/dp/0312672977/ref=sr_1_1?ie=UTF8&qid=1345655448&sr=8-1&keywords=how+we+do+harm, page 242

http://www.cancer.gov/cancertopics/pdq/screening/breast/healthprofessional/page1

http://www.bmj.com/content/344/bmj.e3502.full?ijkey=tzRK2ncLto2JJ9I&keytype=ref

Module 14: Are You Sick? Medical care can benefit sick people by turning them into healthy people. But medical care can benefit healthy people much – if at all – because they're healthy to begin with. The dictionary defines sick as 'feeling nauseous' among other things. But our medical community has increasingly defined sick with a number that very roughly indicates your likelihood of having a future medical event. Today you can feel fine – not nauseous at all – but be sick at the same time! As our numerical sickness definitions have evolved, we have consistently created more and more sick people in this country. Those newly defined sick people add costs to our healthcare system – they need treatment now – but don't as often benefit. As you read this Module, consider some insurance payment implications of our current and evolving definitions of sick. Consider also some medical and psychological implications on our newly created sick people.

References:

http://www.amazon.com/Overdiagnosed-ebook/dp/B004C43EW6 page 23 http://www.nejm.org/doi/full/10.1056/NEJM199511163332001#t=abstract http://www.nhlbi.nih.gov/guidelines/cholesterol/index.htm http://bittersweetmedicine.com/2010/03/26/overrated-medications-series-no-2-statins-for-primaryprevention-of-cardiovascular-diseases/index.htm http://medicalconsumers.org/2011/08/08/risks-of-diabetes-2-treatment/ http://www.nhlbi.nih.gov/news/press-releases/2008/accord-clinical-trial-publishes-results.html

http://books.google.com/books?id=WdWqPHgu3c8C&pg=PA202&lpg=PA202&dq=hippocrates+shadow+ bayes+theorem&source=bl&ots=PgXHVZl8y1&sig=zKS7uF1LHZEK-1L_JfJsmasMvy4&hl=en#v=onepage&q=hippocrates%20shadow%20bayes%20theorem&f=false

Module 15: Some Disease Starting Risks. Starting risk is the first important number you need to learn about your chance of having a future bad medical event. It compares you to a large group that shares your risk factors and tells you how likely you are to have a heart attack, die of colon cancer or have a stroke absent medical care. Some researchers suggest that knowing your starting disease risk is the first step to being an informed medical consumer, meaning that people who do not know their starting risks are simply not well-informed. This Module shows the starting risks of having several different future medical events for various populations.

References:

http://jnci.oxfordjournals.org/content/94/11/799.full.pdf

Module 17: Overdiagnosis. Overdiagnosis is a relatively new phenomenon in our healthcare system. Overdiagnosis means that you are diagnosed with a medical abnormality that will never harm you. Our increasingly powerful radiological and other screening tools can, today, *identify* abnormalities perhaps better than our physicians can *understand* them. Once diagnosed, however, most patients seek medical care. This can increase medical spending unnecessarily and generate more harm than benefit. Remember: many overdiagnosed patients are not 'sick' in the first place, if 'sick' means you have a medical problem that will harm you.

References:

http://www.amazon.com/Overdiagnosed-Making-People-Pursuit-Health/dp/0807021997/ref=sr_1_1?ie=UTF8&qid=1348696704&sr=8-1&keywords=welch+overdiagnosed page 108

http://www.nytimes.com/2011/10/29/health/mris-often-overused-often-mislead-doctorswarn.html?pagewanted=all&_r=0

http://radiology.rsna.org/content/247/2/516.full

http://books.google.com/books?id=WdWqPHgu3c8C&pg=PA58&lpg=PA58&dq=newman+hippocrates+sh adow+ekg+reading+1958&source=bl&ots=PgXJS3HaE3&sig=g1OlgeyvuKUb51BipcD2QQtoens&hl=en& sa=X&ei=gH9jUMCsDYLr0QHA2IGoAg&ved=0CCAQ6AEwAA#v=onepage&q=newman%20hippocrates %20shadow%20ekg%20reading%201958&f=false

Module 18: Some Key Sources of Medical Information: Patients today access many different medical information sources including newspapers, websites and journals. Many of these are quite good; some may be biased; and some may be poorly researched and presented. This Module will introduce two reference sources that we have found quite useful. The first, the US Preventive Services Task Force, tells how well various medical interventions work. The second, the Dartmouth Atlas of Healthcare, tells how frequently patients get different medical treatments by state, region and often by hospital. Using these two sources can help you identify and avoid unnecessary medical care and help you therefore control your healthcare spending.

Module 19: What do 5-Year Survival Rates Mean? Some medical outcome metrics are useful and others not. We suggest that 5-year survival rate information falls into the latter category. Though we often use it – including in many of the most highly respected journals and by many of the most highly respected research institution – it is such a

flawed measure that it probably fails to provide any useful information at all. This Module explains why you probably don't want to use it.

References:

http://books.google.com/books?id=SAXI2PASXNkC&pg=PA138&lpg=PA138&dq=gilbert+welch+cancer+i n+books+kay+bailey+survival+rates&source=bl&ots=jpFd7MvdO4&sig=bopo9qE2urlcwSN6PIDiX1DPHT g&hl=en&sa=X&ei=IZh1UKGDNei40AH8soGYDw&sqi=2&ved=0CCwQ6AEwAw#v=onepage&q=gilbert% 20welch%20cancer%20in%20books%20kay%20bailey%20survival%20rates&f=false

http://www.medpagetoday.com/HematologyOncology/BreastCancer/27800

http://theoncologist.alphamedpress.org/content/8/6/541.full

http://www.prb.org/Articles/2009/breastcancer.aspx

http://seer.cancer.gov/statfacts/html/breast.html

http://www.cancerresearchuk.org/cancer-info/cancerstats/types/prostate/?script=true

http://www.youtube.com/watch?v=rcHQEIKhWFc

We hope that these educational modules help brokers and their clients spend their discretionary medical resources and premiums more wisely.

Chapter 8 Some Comments on the Broker's Professional Responsibilities

regarding client education about quality-of-care metrics

Some Background

We know that health insurance brokers have a professional obligation to disclose several things:

First, they must honestly explain policy terms; Second, they cannot leave out important information; Third, they must honestly quote the price.

Does the broker's professional responsibility end with these three obligations? Should a broker provide additional information?

Specifically, do health insurance brokers have a professional responsibility to educate their clients about the workings of our healthcare system...or should the broker 'let the buyer beware' of them?

Let's remember that the ultimate product we sell is healthcare. *Insurance* is simply (simply?) the means of financing healthcare services. We know that our clients will ultimately purchase healthcare services – examinations, operations, medical treatments and the like. Our products facilitate access to, and use of, these services; health insurance is not an 'end' product in and of itself. The 'end' product is medical care.

This raises a key question: can brokers differentiate health insurance from health care?

In other words, can brokers reasonably claim that their jobs involve *only* making financial resources available to clients for medical care, but not the end-use for which clients use this money?

We suggest in this chapter that they cannot reasonably make this claim. Instead, we will suggest that healthcare financing (insurance) is inextricably tied into medical care. The 'benefits advisor' should, in other words, advise on the benefits that clients will access.

The knowledgeable broker – especially one what has read this far in this book - knows that we sometimes *overuse* our medical system. Overtreatment may lead to negative patient results. Indeed, some Dartmouth Medical School researchers, among others, have discovered that mortality rates go *up* as patients receive more and more medical care. Dr. Elliott Fisher's major post 2000 studies showed that hospitals that *spent the*

most and *did the most* for patients had a 2 - 6% *higher* mortality rate. ²⁰⁰ The reason: The additional medicine patients are getting in the high-cost regions is leading to harm. ²⁰¹ More care led to more patient risks from error, infection and fatigue, without any compensating medical advantages.

Here's our potential patient cycle: patients with generous insurance plans may receive unnecessary care. That care, according to Dr. Fisher, corresponds to higher mortality rates. If you, as a broker, take the position that you should 'let the buyer beware', then you know that some of your clients will be harmed by unnecessary care, at least economically if not physically.

A Traditional View of Business Professional Responsibilities: The problem of unequal knowledge

'Do unto others as you would have them do unto you' and 'Love thy neighbor as yourself' are two fundamental ethical dictates of Judeo-Christian religions. We – Americans coming from Judeo-Christian traditions and teaching – believe that we have responsibilities to treat others as we would want them to treat us. This, we often feel, is particularly true of professionals – those we rely on for advice.

What does 'unequal knowledge about the healthcare system' mean?

Brokers typically know a great deal more about our healthcare system than do their clients. They attend industry conferences and events, read industry journals, share ideas with colleagues, take Continuing Education courses and many other things. As a result, brokers are seen by the marketplace as having expertise about the healthcare system that most other people lack.

Does *having* all this professional knowledge *creates a professional responsibility* to share it with clients? In developing our answer, we will rely primarily on traditional Judeo-Christian writings and ethics. These have served as the moral, ethical and professional foundation of western civilization for thousands of years.

²⁰⁰ Elliott Fisher, et. al. The Implications of Regional Variations in Medicare Spending, Annals of Internal Medicine, 2003, several articles. See Shannon Brownlee, Overtreated, page 50 for a summary of relative mortality risks.

²⁰¹ ibid, The Implications of Regional Variations in Medicare Spending Part 2, Annals of Internal Medicine 2003:138, pages 292 - 293

We'll base our position on our interpretation of Biblical sales ethics and the seller's professional responsibilities to the buyer - specifically the story of Abraham's purchase of a burial plot for his wife.

This is the first commercial transaction discussed in the Bible. Some Biblical scholars suggest that this placement indicates that the lesson of this story is of primary,or overwhelming importance for businesspeople. Were some other lesson more important, they suggest, then <u>it</u> would have been placed first and not the full disclosure principle.

(Though we base our discussion on Biblical ethical principles, we do not advocate any particular religion - or religion at all, for that matter. We base this course on the Bible because it has served as a foundation of western civilization for thousands of years.)

Not all brokers will agree with this analysis. Some will think that our interpretation of Abraham's purchase is flawed. Others will argue that the Bible is not relevant to today's health insurance market. Still others will argue that we set an unrealistically high ethical standard for health insurance brokers.

Regardless of whether you agree with our activist position or not, we hope that you will consider the issues rasied.

The First Professional Business Principle in the Bible Comes From Abraham's Purchase of a Burial Plot for His Wife

In the first commercial transaction in the Bible, Abraham laid down the 'full disclosure' commercial principle.²⁰² His purchase from the land seller consists of 5 different steps:

Step 1: Abraham explains what he needs in vague terms – a burial plot for his wife. He does not stipulate where or exactly what kind of burial plot;

Step 2: The sellers offer 'the choicest of our burial places';

Step 3: Abraham considers this (perhaps even goes on a guided tour of choice burial places) then asks for 'the cave of Machpelah...which is at the end of [the sellers] field', and offers to pay 'full price';

Step 4: The sellers confirm that they have exactly what Abraham wants 'the field and cave that is in it';

²⁰² This genesis of this discussion comes from <u>www.torah.org</u> Business Ethics: The Challenge of Wealth, *Parchas Chayei Sarah, Parchas Metzora, Parshas Shoftim* and *Responsa-Vayigash*

Step 5: The buyer and seller ultimately agree on the land and price and transact the purchase in public 'in the presence of the sons of Heth, before all who went in at the gate of his city'.

Note the similarity with health insurance policy sales:

Step 1: the Buyer explains what he/she needs in vague terms – a policy to cover my family's medical needs, perhaps with some specific issues in mind;

Step 2: the Broker says 'we have many quality plans available' and explains them;

Step 3: the Buyer considers several options, then stipulates what he/she wants;

Step 4: the Broker confirms that a specified policy contains the desired benefits;

Step 5: the Buyer enrolls by signing a contract.

It was clear from Abraham's negotiations that he had the opportunity to view the land and cave prior to purchasing. The seller had helped him learn about the land, pointing out the choicest burial place. Indeed, the seller may even have warranted the land: 'none of us will withhold from you his burial place', thereby confirming that this was, in fact, burial property.

The seller apparently understood that Abraham – 'a foreigner and a visitor' – did not know all details about local burial plots.

The seller therefore helped Abraham learn everything that he needed to know so he could make a wise, informed purchase. There was no ambiguity about the land, the location or the use. No confusion about exactly what Abraham bought...because the seller provided such a thorough and detailed education.

'Let the Buyer Beware' is Unprofessional

The lesson about this transaction? Traditional professional standards do not contain any concept of 'let the buyer beware'.

The seller taught Abraham everything he needed to know about local burial plots, made very clear to Abraham exactly what he was buying and made his declarations publicly.

'Let the buyer beware' assumes that all parties to a commercial transaction have the same information regarding price, quality, use, location, comparative markets, etc. This was clearly not true for Abraham, the 'foreigner and visitor'. The seller could have taken

advantage of his lack of knowledge to swindle him – but did not. The seller educated the buyer. This is the business lesson from this story.

'Let the buyer beware' also assumes that all parties have equal abilities to <u>understand</u> the information available. In Abraham's case, he was only able to understand the intricacies of burial plots after being educated by the seller.

Is this concept still valid today?

The answer is yes. The traditional position on client education and disclosure remain valid today - for two main reasons.

First, sellers and buyers rarely have exactly the same information.

The seller generally knows his / her products far better than the buyer. The simple reason: the seller deals in this market – for this product – far more frequently than does the typical buyer. For example, a health insurance broker attends seminars sponsored by carriers or others involved in the field, and reads books such as this one. This gives the broker the opportunity to keep current to better serve his/her own clients. In short, the broker knows more about policies and healthcare than his/her clients typically do.

The Biblical Abraham clearly lacked such independent information about burial plot qualities. Abraham's expertise did not include detailed knowledge of local burial plots, just like the health insurance purchaser often lacks detailed knowledge about networks, tiers, Rx copayments, etc. Abraham relied on the burial plot sellers' expertise to guide him, just like many policy purchasers rely on their brokers.

Second, in the real world, sellers can understand their product information far better than the buyer can.

This is primarily because the health insurance broker has studied healthcare issues in far greater depth than the typical buyer. Even if the buyer has *access* to information, he / she often lacks the *background and context* in which to place that information.

Again, this is similar to Abraham's situation. He was a merchant, with expertise in his own arena – not in burial plots. He was not in a strong position to understand burial plot issues without additional education.

Our clients are similar to Abraham. They are accountants, schoolteachers, fishermen or others, with expertise in their own fields, not healthcare. Lacking the broker's healthcare education and background, they are less able to understand healthcare details and issues than the broker.

Thus for these two reasons – that the broker has *better access* to product information and a *better ability to understand that information* – today's health insurance salesperson has an ethical responsibility to educate the client. Just like Abraham's burial plot seller.

Do Your Fellow A Favor

Traditional professional standards build on this concept and go even further. Many commentaries contain injunctions that forbid the seller from hiding product flaws, and even from creating a false impression. This is covered in traditional ethical concepts of 'faulty sale'.

According to this doctrine, the seller is obligated to make full disclosure of any defect in the goods or services sold. One ethical commentator suggests that 'even where the seller was ignorant of the flaw, the sale may be cancelled' as the buyer cannot be forced to accept a discount as compensation for the defect.²⁰³

Thus, the broker who claims 'I didn't know that the policy contained that' has no good defense: traditional professional standards make the seller responsible to understand fully the implications of each health insurance policy. Over time, traditional business ethics evolved and introduced the higher standard. This became known as '*do your fellow a favor*', exactly the opposite of 'seller selfishness'.²⁰⁴

Now the seller has an even greater ethical burden. Not only must he / she educate the buyer and make full disclosure, but the seller must *do his fellow a favor* and highlight problems with the health insurance policy that <u>may</u> occur.

Is it enough simply to describe the health insurance policy in detail?

Such a description would include a discussion of copayments and deductibles, exclusions if any, available providers, prescription drug coverage, price etc and then show alternative products and describe them. Though this may satisfy some customers, it does not satisfy our traditional professional requirement to 'do your fellow a favor'.

How Much Should Brokers Disclose?

Let's review the doctrine of 'faulty sale', discussed above. That's the doctrine requiring full disclosure of any defect in the goods or services sold, and a cancellation of the sale due to product defects *even if the seller was ignorant of the flaw at the time of sale*. It is

²⁰³ Rabbi Dr. Meir Tamari in ibid. Responsa-Vayigash

²⁰⁴ Ibid.

unclear exactly *how much* information Abraham's burial plot seller provided. He apparently provided a great deal, and probably all that was necessary in that circumstance.

But we get into a gray area when applying these lessons to more complicated transactions like health insurance policy sales.

- Is it a 'product defect', for example, if someone buys a high deductible health insurance plan but does not get any advice about how to spend the deductible?
- Is it a produce defect if someone who buys a high deductible plan asks a broker how to locate better quality medical care, but does not get a satisfactory answer?

We don't know. Traditional commentators seem vague on the issue of 'how much information must the seller provide'. That's why they expanded the discussion to include *do the fellow a favor.* Now we have the ethical tools to address this question.

Dr. Tamari puts the Biblical ethical position like this:

He Who Does Not 'Do His Fellow a Favor' is Not of the Sons of Abraham 205 and Sanctity is achieved ... by doing or sharing with others, irrespective of the utility or reciprocity... 206

A simple, standard example

Let's look at a simple example of 'treating others as you would want them to treat you' - an interaction with a car mechanic.

When I have a question about my car, I ask a car expert – i.e. my local mechanic. I seek his advice because he has had years of experience working with cars. He has an expertise that I do not share. He can differentiate serious from minor problems and advise me if and when to get my car fixed. A good mechanic answers my questions when I ask them. He treats me as he would want to be treated were conditions reversed.

But here's a slightly more complicated case: when my mechanic changes my oil and notices a problem with my car, I expect him to inform me. My local mechanic recently told me, for example, that – since I was coming up on 100,000 miles - I should schedule

 ²⁰⁵ Dr. Meir Tamari, Parshas Shoftim <u>http://www.torah.org/learning/business-ethics/shoftim.html</u>
 ²⁰⁶ Ibid.

a tune-up and install new brake pads. I appreciated his advice: he treated me well, which means 'he did unto me as I hope I would do unto him' were conditions reversed.

I would be very unhappy with a mechanic who told me after a serious accident 'Yes, I noticed that your brake pads were worn out, but I decided not to tell you'. Here the 'expert' did not share his expertise. I thought that he would 'do unto me as I would do unto him' were conditions reversed and he let me down.

Note some issues with this lack of disclosure:

- 1. Since he did not tell me that there <u>was</u> a problem with my car, I assumed that there was, in fact, <u>no</u> problem;
- 2. The underlying issue here is definitional. I define a good mechanic as one who looks out for my interest. Part of his job is to be my 'car advisor' and offer advice about how best to maintain my car.
- 3. He, apparently, defines his job much more narrowly, simply as fixing things that I ask him to fix, but no more.
- 4. His definition of 'good mechanic' puts an enormous burden on me. I must ask after every oil change for example, a number of specific questions about my car's operation. Are the brake pads good? Is the air filter working properly? Does the head gasket leak? Are the brake rotors in good condition? Are the tires balanced?

Unless I ask, he will not disclose.

My interest in developing a long term relationship with this mechanic is very weak. I don't trust him to look out for my interests. I worry that I may fail to ask the right questions and have an avoidable accident as a result.

As a result, I will probably switch to a different mechanic. After all, they just fix cars. They all use the same parts. They all – more or less– repair things that have broken. I will switch because I define 'good mechanic' as someone who looks out for my interest, who helps me be proactive in maintaining my car and who fixes things that brake.

The fundamental issue between me and my mechanic: I want him to share his expertise with me, in addition to fixing my car.

Insurance Broker Professional vs. Unprofessional Behavior

Several years ago I had a poignant interaction with an insurance professional over this *information disclosure issue*. The situation:

I had considered changing a liability insurance policy (written by an out-of-town agent) so got a quote from my long-term local P & C agent. He informed me by phone that he had a better policy at a lower price than my current plan. He summarized some key points and said he could bind it on my verbal approval. I trusted him, so agreed.

He also suggested that I cancel my existing policy, which I also did.

After a detailed policy review (a week or two later) I decided that the new policy was not as comprehensive as the previous one. I re-activated the old policy with the out-of-town agent, and informed my long-term local agent by email that I wanted to terminate the new one.

He never cancelled my new policy. Instead, several months later, he told me that neither I nor the other broker had submitted the cancellation request on the correct form. (It then took numerous phone calls and significant upset to correct the problem.)

Note the different definitions at work here. My local agent defined his job as getting quotes, processing bills and filing the correct forms. He took the 'let the buyer beware' approach, apparently thinking that the burden of looking out for my interests fell on me or on others. He would sell me the policies that I requested, and nothing more.

I defined his role as 'looking out for my interests', or 'doing to me as I would do for him were roles reversed' - which included informing me that I needed to file a specific form to achieve my cancellation goal. I had no way of knowing which form to file absent his input; he had specific expertise and product knowledge that he failed to share with me. He 'let the buyer beware' to an upsetting end.

This destroyed my ability to trust his advice. What other information, I wondered, would he also leave out? What avoidable harms might I endure? What unnecessary problems would I face? In short, why should I pay him to advise me when he takes the 'let the buyer beware' approach?

Needless to say, he fairly quickly lost my home and auto insurance accounts!

Translating These Ethical Standards to Health Insurance Policy Sales

The broker who simply describes the health insurance policy by defining the terms and conditions appears to act 'selfishly'.

Here's why: The broker knows that his/her clients don't have access to good medical shopping information. He/she knows this because clients often complain that they don't know how best to spend their discretionary medical monies.

We suggest two types of evidence for this: **First**, numerous studies from highly respected medical researchers indicate that up to 1/3 of all medical spending is wasted on unnecessary care.²⁰⁷

Second, well informed brokers regularly read anecdotal comments about unnecessary medical testing, medications etc in the popular press and hear them in industry forums. Here are some sample headlines found during a quick google search for 'unnecessary medical care':

- Doctors estimate \$6.8 billion in unnecessary medical tests, Washington Post, October 31, 2011 ²⁰⁸
- New research shows how some common tests and procedures aren't just expensive, but can do more harm than good, Daily Beast, August 114, 2011²⁰⁹
- 13 common medical tests you may not need, Boston Globe, January 18, 2012 ²¹⁰

Thus the broker is aware of these product flaws and is responsible, under the ethical guidelines discussed above, to inform his/her client. The question for the ethical broker becomes, not 'should I educate my clients about these problems?' but 'how should I educate them?'

If the Broker 'let's the buyer beware', then who will 'do his clients a favor'?

In the 1990s, carriers restricted access to medical care as part of their cost containment programs. Patients needed referrals – which were not always accepted by the carrier. Carriers limited access to expensive specialists, limited the number of physician visits / condition, or limited the types of medications covered.

²⁰⁷ See, for example, Overtreated by Shannon Brownlee, Overdiagnosed by Gilbert Welch, analysis on the Dartmouth Atlas of Healthcare, Understanding Health Insurance by Gary Fradin (approved for CE in many states) and numerous articles by Professors Skinner, Welch, Fisher and Wennberg of Dartmouth Medical School.

²⁰⁸ <u>http://www.washingtonpost.com/national/health-science/doctors-estimate-68-billion-in-unnecessary-</u> medical-tests/2011/10/28/gIQANpEXZM_story.html

²⁰⁹ <u>http://www.thedailybeast.com/newsweek/2011/08/14/some-medical-tests-procedures-do-more-harm-than-good.html</u>

²¹⁰ <u>http://articles.boston.com/2012-01-18/health-wellness/30634462_1_medical-tests-cervical-cancer-osteoporosis-screening</u>

The American public perceived this as an attempt to improve carriers' financial positions rather than to improve patient outcomes – and objected to these inappropriate restrictions.

One result: today's insurance policies allow easier, even unfettered (in the case of many PPO or POS type plans) access to the hospital or specialist of choice. Post-2000, many carriers have acquiesced to consumer demands for easier access to care. Today many insured Americans can get access to all the medical care available.

Patients delegate medical decision making to physicians

Purchasing medical services is different from purchasing most other services: The Impact of Trust

John Wennberg, the founder of the Dartmouth Institute for Health Policy and Professor Emeritus at Dartmouth Medical School addresses the underlying issue here. Purchasing medical services, he suggests, is vastly different from purchasing goods and services in most markets. 'The doctor-patient relationship is different,' he suggests 'because of the asymmetry of information.'

The consumer – your client:

Does not know what he or she truly needs; it is the physician who knows the nature of the patient's illness and can select the right treatment [as a result] patients delegate decision making to the seller of the services.²¹¹

Key Idea: Purchasing medical services differs from purchasing most other services. In medicine, the service supplier (physician) knows far more about the technical aspects of our problem than we do, due to his/her extensive training. As a result, we rely on our physician to (a) diagnose the problem; (b) design a treatment program; and (c) implement that treatment option. We often delegate decision-making responsibility to him/her.

Arnold Relman, Professor Emeritus of the Harvard School of Public Health and a former editor of the New England Journal of Medicine, echoes Wennberg on the asymmetry of medical information between patient and physician: ²¹²

²¹¹ Wennberg, Tracking Medicine, page 23

²¹² Arnold Relman, A Second Opinion, 2007, pages 22 - 23

Patients usually know much less about the diagnosis and treatment of their disease or injury than their doctors do. Furthermore, because of illness or injury they may be in no condition to evaluate their options.

As a consequence they cannot independently decide what medical services they want in the same way consumers choose services in the usual market...

The penalties for making a mistake in the health care market are usually higher than in others.

Patients must therefore trust their physicians to decide what services they need.

Imagine doing this with your home repair contractor! We might call it 'license to steal' if the homeowner said 'tell me what I need and I'll buy it all.'

But in medicine we accept that the service seller (physician) will identify the problem, design the solution, implement the solution, get paid for his/her efforts and that the patient will agree.

Our medical system does not pay anyone to disagree with the physician

By analogy, our legal system requires both a prosecution and defense attorney to question witnesses. That way neither has too much power.

In our medical system, however, patients only get one point of view ---from providers who earn money by providing care. This is Wennberg's key point. Your doctor plays the equivalent roles of police investigator, prosecutor, defense attorney and judge. This puts enormous advisory power in the hands of one person – and, interestingly, a person who has an economic interest in the patient's decision.

Our system does not pay anyone to oppose the provider's point of view.

Carriers might also play that role – but the managed care experience of the 1990s has turned popular opinion against trusting carriers too much.

Second opinions might fulfill the role...but probably do not. Physicians in the same group practice, hospital or region tend to treat patients with similar protocols, and disagree far less than perhaps they should. This is very well documented in the healthcare literature.

No one, it seems, will do your clients a favor....except you, the broker!

How Should a Professional Broker Proceed?

Here's some some general advice for how best to do your fellow a favor. ²¹³

Some general advice for professional health insurance brokers: **First**, educate yourself about our healthcare system, so you understand both *insurance policy and regulatory details* and *healthcare system operational issues*.

1. Educate yourself about our healthcare system.

The professional broker has a responsibility to 'do your fellow a favor'. The more you know about our healthcare system, the better you can educate your clients.

Today's bookstores are full of insightful and useful books about healthcare. Hopefully, this course was one. Some that I have found particularly useful (also quite engaging and easy to read):

Overtreated, by Shannon Brownlee; Best Care Anywhere, by Phillip Longman; Should I Be Tested for Cancer?, by Dr. H. Gilbert Welch; Overdiagnosed, by Dr. H. Gilbert Welch; Know Your Chances, by Dr. Steven Woloshin, et al Tracking Medicine, by Dr. John Wennberg How We Do Harm, by Dr. Otis Brawley Hippocrates' Shadow, by Dr. David Newman

Here's typical feedback from brokers who have attended my lectures on these subjects or read these books: they contain fascinating and very useful information. Some brokers use that information in their normal professional work.

2. Help your clients ask questions.

Patients – your clients - sometimes are intimidated by physicians; sometimes awed by them or sometimes tongue-tied in front of them. The better you educate your clients about the inner workings of our healthcare system, the better they'll be able to ask important questions of their physicians.

²¹³ Some of this advice comes from the Afterward of Overtreated. See Brownlee, op cit pages 308 - 310

Second – provide your clients with good information so they can ask good questions of their physicians.

3. Give general, but not client specific advice. Talks about metrics and give plenty of examples – but always indicate that they're examples, not medical advice.

Third – give general advice about our healthcare system's operations, not specific medical advice (unless you are licensed to do so).

Summary

Consider the idea that educating your clients about medical outcome metrics *is good customer service*. The more you treat your clients as you would like them to treat you (were conditions reversed), the more satisfied they will be with your service.

'Customer service' in this regard is much more than answering telephones promptly, responding to emails and processing the myriad of forms that health insurance brokers process. It is also more than generating quotes for health, life, disability and dental coverage.

Customer service begins to mean 'help your customers navigate our healthcare system.' This may be far more important than answering phones promptly.

Imagine how satisfied a client will be with your service when she learns from you about the relative risk of Caesarian births at local hospitals. Absent that knowledge, she might have had an (unwanted) Caesarian; her lack of information may have reduced her ability to plan and increased her risk of a procedure that she did not want. Armed with information, however, she can make more informed decisions about where and how to deliver her baby.

Alternatively, imagine how pleased a different woman may be to learn that some hospitals perform very low rates of (desired) Caesarian births. She may use your information in discussions with her obstetrician, and alter her choice of delivery hospital as a result.

Imagine how satisfied another client will be when they begin a conversation with their cardiologist armed with data about the relative rates of angioplasty performed in your region compared to the national average.

Now ask yourself the chance that a client who is so satisfied with your services will switch to another broker at the next policy renewal. I suggest that your client retention rates will increase as you embrace the 'do your fellow a favor' ethical standard.

Professionalism, defined in part by 'do your fellow a favor' is good customer service. I hope the ideas introduced in this book will help you better understand the workings of our healthcare system and better teach your clients how to identify and avoid unnecessary medical care. If so, then we all benefit.

Review Questions answers on next page

1. Can a professional broker 'let the buyer beware'?

a. Yes

b. No

c. Only if the broker is certain that the buyer will not make bad medical care choices

2. Which is a higher and more professional standard: 'let the buyer beware' or 'do your fellow a favor'?

- a. Let the buyer beware
- b. Do your fellow a favor
- c. They are equally professional
- d. Neither is very professional at all

3. What does 'unequal knowledge between the buyer and seller' mean?

a. It means that the buyer knows more product details than the sellerb. It means that the seller knows more product details than the buyer and that the seller has a better context within which to understand those product detailsc. It doesn't mean very much of anything, since the internet makes everyone's access to information about the same

4. Is the problem of unnecessary medical care an insurance issue and relevant for brokers to understand?

a. Yes. Unnecessary medical care increases your clients' costs, which are always relevant to brokers.

b. No. Unnecessary medical care is the physician's and patient's problem, not the broker's

c. Some brokers may choose to educate their customers about this problem, but most probably will not because it's outside their normal set of business activities

5. Reflecting back on the Interview (Chapter 3) and this discussion of the broker's professional responsibilities, what is one thing a progressive broker might choose to do?

a. Learn more about the actual workings of our healthcare system by, for example, reading the books recommended in this chapter

b. Sell more voluntary benefits, as these can fill gaps in your client's insurance

c. Diversify your portfolio since you don't yet know all the implications of national healthcare reform

6. What is another thing a progressive broker might choose to do?

a. Use the educational modules in Chapter 7 to teach your clients how to use our medical care system more productively

b. Get out of the health insurance market because it will become too competitive once all the Exchanges and other sales outlets get up and running

c. Sign very long term contracts – say 10 years or more – with clients so you will be certain of your future cash flow

d. Go to law school, since insurance is becoming increasingly litigious

7. John Wennberg, above, talked about the asymmetry of information between the doctor and patient. What role can education about outcome metrics have on this asymmetry?

a. Though the doctor will always know much more about medicine than the patient, the patient can guide the discussion to the areas of his/her main interest by asking good questions. We have proposed, in this book, some questions to ask about tests, medications and treatments

b. Since the patient will never know as much about medicine as the doctor, the wise patient will delegate all decision making to the doctor

c. The best thing a wise patient can do is get a medical degree. Otherwise he/she really can't have a wise and informed discussion with any doctor.

8. Do you agree that consumer education about the metrics discussed in this book –
Number Needed to Treat, Number Needed for Harm, outcomes for patients like me, etc
– are part of the definition of a professional health insurance broker or not?

a. Yes. I agree with Todd McDonald's position in Chapter 3 that brokers need to understand these new medical care quality metrics and teach them to their clients. I don't think brokers will be able to remain in business unless they embrace these new concepts and metrics

b. No. I think the broker has enough to do by developing benefit plans for companies, getting prices, and keeping the company in compliance with all the state and national regulations. Asking the broker to expand his/her set of responsibilities is too much.

Review Questions correct answers in bold

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c. It doesn't mean very much of anything, since the internet makes everyone's access to information about the same

4. Is the problem of unnecessary medical care an insurance issue and relevant for brokers to understand? (the correct answer to this question depends on your own orientation and what your clients demand)

a. Yes. Unnecessary medical care increases your clients' costs, which are always relevant to brokers.

b. No. Unnecessary medical care is the physician's and patient's problem, not the broker's

c. Some brokers may choose to educate their customers about this problem, but most probably will not because it's outside their normal set of business activities (the answer to this question depends on your own orientation)

5. Reflecting back on the Interview (Chapter 3) and this discussion of the broker's professional responsibilities, what is one thing a progressive broker might choose to do?

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b. Sell more voluntary benefits, as these can fill gaps in your client's insurance
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6. What is another thing a progressive broker might choose to do?

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a. Yes. I agree with Todd McDonald's position in Chapter 3 that brokers need to understand these new medical care quality metrics and teach them to their clients. I don't think brokers will be able to remain in business unless they embrace these new concepts and metrics

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state and national regulations. Asking the broker to expand his/her set of responsibilities is too much.

Chapter 9 Some Concluding Thoughts

'Will this medical intervention make me healthier?'

We're deluged with healthcare information these days, discussions about healthcare reform, the individual mandate, exchanges, marketplaces, insurance regulations and the like. We 'enjoy' a 24/7 national healthcare discussion in the media, laced with emotion and opinion.

Exactly what this cacophony has to do with normal people's medical care decisions escapes me.

- Whether or not you have a well-functioning insurance exchange in your state, you still need to decide about annual mammograms. You need to develop the tools to help you make the right decision *for you.*
- Whether or not we have an individual mandate, you still need to decide how to treat your arthritic knee. You need to ask the right questions of your doctors to get the right information to make the right decision *for you*.
- Whether or not the Federal government subsidizes health insurance for families making up to 250%, 300% or 400% of the federal poverty level, you still need to decide how to use your annual physical time with your PCP. You need some background to make a wise decision that's right *for you*.
- Whether or not healthcare reform adds or reduces our budget deficit, you still need to decide which hospital to use when you get sick. You need metrics to help make the right decision *for you*.

Yes, I understand that a lack of available healthcare financing (we call that 'health insurance') impedes access. I get that.

But access is only part of the problem, and perhaps a small part. I'm as concerned, perhaps even more, about people with access who lack critical medical care decision making tools. This puts them at the mercy of our growing medical-industrial complex, a term coined, I think, by Dr. Arnold Relman of Harvard Medical School and a former editor of the New England Journal of Medicine. We've seen it eat up more and more of our GDP and our salaries over the past 50 years, often on care that people don't need and sometimes don't even want.

Interesting factoids, comparing the amount of time the average American needed to work in order to buy various things:

In 1955, at the average hourly wage, someone had to work 1,638 hours to buy a new Ford Fairlane car.

By 1997, the save average worker only needed to work 1,365 hours to buy a brand new Ford Taurus with tons of technology and features like air conditioning, airbags and power windows that the 1955 Fairlane lacked. That's efficiency.

By contrast, in 1964, our average healthcare spending per person was \$197. The average American worker took home \$2.53 per hour. So the average American worker needed to work 78 hours – about 2 weeks – to cover his/her annual medical care.

By 2007, the average worker needed to work 411 hours - over 10 weeks - to cover the \$6,300 average annual medical care cost. That's inefficiency.

Projecting these trends into the future, by 2054 the average American may have to work 2,970 hours – 74 weeks per year, an impossibility – just to cover medical costs.

The question this raises: when we have the inevitable medical care restrictions, how will you protect yourself? Do you have the necessary tools to choose high quality, necessary care?

These estimates come from Phillip Longman's excellent book Best Care Anywhere about the VA Healthcare System.

That we get overtreated is beyond doubt; that we are overdiagnosed with illness equally true; and that we are overdosed with medications simply a tragedy. The big medical care problem of the future: how to decide which care is necessary and high quality and which unnecessary and inappropriate.

These are often individual decisions that require patients to understand their treatment options and alternatives.

I've tried, in this book, to define and describe both necessary and unnecessary medical care. Aggressive interventions – more care, at more cost and more risk? Or more conservative care, that often takes a 'watch and wait' approach? Neither approach, nor any in between, is often obviously universally right or wrong.

But any approach may be right or wrong *for you*. The only way to determine that, in my opinion, is to develop analytic and decision making tools. I've tried to introduce those in the form of questions to ask your doctor, like

• What are this hospital's outcomes for patients like me? And
• What is the NNT of this or that treatment?

My goal was not to teach you about medicine – other sources such as your doctor provide much more factual information than I can.

Rather, my goal was to help you focus your research and discussion on the key issue that concerns most people: will this medical intervention make me healthier?

I suspect that we're at the very early stages of developing the metrics necessary to answer that question. This book is one attempt. Hopefully in the near term, we'll be more advanced and have better tools and metrics available.

At least, I hope so.