Two Ethical Principles for Brokers to Follow

Massachusetts CE course #C19400, 8 ethics credits

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Introduction

This text reviews two ethical business principles outlined in the Bible (Torah) that apply to today's health insurance brokers. Brokers who follow these principles in their customer dealings are commonly perceived as acting ethically; those who do not, act unethically.

We use the Bible as a core statement of ethics because countless thinkers throughout the generations have also done so. Acting according to the Bible's precepts has become synonymous with acting ethically throughout Judeo-Christian history and culture.

We do not in this course advocate for or promote religion, any specific religion or religious observance in general. That is not our purpose. We are agnostic about all those issues.

Our purpose here, instead, is to glean time honored, traditional, universal ethical principles from Biblical writings and apply those lessons to today's American health insurance brokers.

The two principles we will discuss in today's course:

- 1. *Lifnei iver* or **'Do not place a stumbling block before the blind'** from Leviticus 19:14 and a fascinating follow up, 'hochei-ach tochi-ach' (both expressions badly transliterated Hebrew) from the Book of Isiah, meaning roughly 'rebuke your neighbor when he errs out of love and concern', and
- 2. **Don't 'let the buyer beware' but instead 'do your fellow a favor'** from Genesis 23, the first commercial transaction described in the Bible.

We will discuss each of these principles in turn and tie their various lessons to modern health insurance broker and client interactions.

Why Continuing Education Classes?

First, an introductory comment on the purpose of continuing education classes. CE classes are not the venue to teach or learn regulatory details and provide policy form updates in our opinion. The continuing education regulatory constructs and requirements preclude this: most Massachusetts brokers only take CE classes once every 3 years, insufficiently regular and routine to use these courses as resources to keep current on plan and regulatory details.

Instead, CE classes can help brokers think more broadly about how our healthcare system functions and the role health insurance policies play in it. Brokers can step back from their day-to-day, detail-oriented activities to contemplate their larger role in ameliorating client problems. That is our point of departure, less regulatory detail, more systemic contemplation.

I hope that viewpoint resonates with readers and that this course helps brokers, at least a little bit, provide better services to their clients.

Disclaimer

We at HealthInsuranceCE, are not a Biblical scholars which will undoubtedly become painfully clear shortly. Instead, we are more conversant with healthcare system functions, problems and reforms. I hope this lack of Biblical study and training doesn't interfere too terribly with the main thesis of this text.

Widespread Applicability

The ethical issues raised in this course apply equally to advisors working in all forms of health insurance including:

- Medicare, our national single-payer healthcare system for the elderly that currently insures about 50 million Americans,
- Medicaid, our national single-payer healthcare system for low-income people, that currently insures about 60 million Americans. Medicaid actually comprises 50 different systems, each single payer within its own state, each managed by the individual states and each funded 50/50 by the feds and each state. Medicaid recently expanded in most states under the Affordable Care Act.
- Commercial insurance, the private coverage purchased by employers for their employees, that currently insures about 150 million Americans,
- The Veteran's Administration Healthcare System, the government program that covers military veterans and
- The various other fill in programs designed to cover people left out of the above list of health insurance programs.

Education, Not Advocacy

This is an education course, not an advocacy exercise. Our goal is to stimulate broker's thinking. We hope this course will help you consider your own ethical standards.

We'll outline in this course a very activist ethical position based on our interpretation of Biblical sales ethics from various Biblical stories including Isaiah's remonstrations to his community about the errors of their ways, and Abraham's purchase of a burial plot for his wife, the first commercial transaction in the Bible.

That said, we do not advocate for any particular religion or for any religion at all. I base this course on the Bible because it has served as the ethical basis of western civilization for thousands of years. Living according to Biblical teachings is generally synonymous in our society with living ethically. That's a good enough starting point.

We also absolutely don't advocate for or against any specific medical interventions. Those decisions are entirely between the patient and his or her advisors. I hope though, in this course, to introduce some decision making tools that can help patients explore critical issues more effectively with their care givers. Introducing those tools, in our terms, means acting ethically. That will become clear as this text progresses (hopefully).

Rather that advocating for or against any specific tests, medications or procedures, we'll introduce educational tools that brokers can adopt to help their clients identify necessary and beneficial care as distinct from unnecessary and non-beneficial. We'll show some ways to educate subscribers in a value-neutral way.

Our contention is that brokers who adopt this approach will help their clients / patients get better outcomes with less risk and at lower cost. In doing so, they act ethically.

Not all brokers will agree with this analysis. Some will think that our interpretation of Biblical teachings is flawed. (Still not Biblical scholars.)

Others will argue that the Bible is not relevant to today's health insurance market. They may well be right.

Still others will argue that we set unrealistically high ethical standards for health insurance brokers. I disagree with that.

In fact, I'd argue exactly the opposite: that brokers who adopt the standards outlined in this course will have healthier businesses than brokers who do not. In brief:

- All professional brokers at least the ones I meet in class, and that's well over 1000 in the past few years are well trained and competent.
- All have access to the same prices and data from the same health insurance carriers.
- All know the regulations and / or can access regulatory information online equally easily.
- All are committed to excellent customer service, and all take their professional responsibilities very seriously.
- All teach their clients how to navigate our overly complex *health insurance / payment* system to optimize carrier payments and minimize client out-of-pocket treatment costs.
- But only some a small but hopefully growing number teach their clients how to navigate our mind numbingly insane and complex *medical care and treatment* system to avoid waste and treatment harms.
- Only a few teach clients how to maximize their chance of medical care benefits and minimize their risks of harm. (Most focus on how to maximize the value of insurance payments, not how to maximize the value of medical benefits.)
- Only a few teach clients that more care may be worse for them than less care, that patients generally have treatment options, that some treatments shown

effective in studies may be overused in real life so will likely not generate any benefit to a specific patient, and much more.

I respond to critiques that these ethical standards are unrealistic with this question: if you were a benefits manager for a large company, would you prefer the broker who only spreadsheets and advises on compliance? Or would you prefer the broker who also teaches these critical thinking and navigational skills?

I'd bet on the later.

Nonetheless, regardless of whether you entirely agree with the ethical standards introduced in this course, I hope you will consider them and that you will be a better broker as a result.

Principle #1: Lifnei Iver, Leviticus 19:14 and extensions from the Book of Isiah

Lifnei iver translates as 'before the blind' and defines a prohibition against misleading blind people by use of a 'stumbling block'. Colloquially this ethical admonition is called 'do not place a stumbling block before the blind'.

Clearly placing a stumbling block – a large boulder, tree trunk, chair or table for example – in a blind person's path is unethical. This obviously would not only cause physical and perhaps emotional injury, but equally obviously cause *predictable* injury. The person who places the stumbling block reasonably anticipates that a blind person will walk into it. At first glance, that appears the basis of this admonition.

Why single out blind people? Perhaps there were lots of blind people walking around in Biblical times bumping into things and hurting themselves or, perhaps lots of people put stumbling blocks in front of the blind people who roamed the streets...a sort of juvenile prank gone wild. While perhaps empirically possible, neither of these interpretations rises to the level necessary to include in the Bible as metaphysical lessons for humanity. (Still not a Biblical scholar.)

Instead, according to those who study and interpret this professionally, the Bible uses 'blind' to mean unable to see in a metaphorical sense, meaning someone or group that is unaware, unsuspecting, uneducated, poorly informed, overly trusting or otherwise ignorant of problems or obstacles that may harm them as they try to achieve their goals.

Indeed, classical rabbinic literature refers to *lifnei iver* figuratively as a prohibition against misleading people. One midrash (commentary on the Torah) argues that the recipient of advice is metaphorically blind to its accuracy so would metaphorically stumble if provided with self-serving, inaccurate, or otherwise inappropriate advice and counsel.¹

¹ See the midrash Sifra for more on this or read the summary in Wikipedia <u>https://en.wikipedia.org/wiki/Lifnei_iver</u>

A stumbling block to a blind person thus equates to bias in the insurance or healthcare arena; a biased doctor giving medical care advice that increases his or her billing, or an insurance broker more interested in securing large commissions than in helping clients optimize their insurance protection without overpaying. Dozens of other routine and mundane situations can also exist in healthcare.

Two business ethical implications follow from all this.

Lifnei iver ethical transgressions of co-mission

The first and most obvious involve **actions** or things that people do - ethical transgressions of <u>**co**</u>-mission in other words - things like

• Misleading investors, decision makers or others with phony financial statements or representations. Most insurance brokers don't prepare financial statements for investors, but rather represent either their own business successes or company size to clients, 'financial statements lite' you might say.

Imagine a broker saying 'I have 100 clients like you' meaning white collar businesses with 50 – 100 employees for example, when, in fact, the broker only has 7. 'One hundred' indicates significant experience in that specific insurance market and probably a high degree of professionalism and success. 'Seven' indicates far less experience and related knowledge of that market.

But the client might rely on the broker's representation and make a contracting decision based on it. That misrepresentation misleads the client about the broker's experience and competence and acts like a stumbling block in the path of making a wise decision.

Unethical under the active 'transgression of co-mission' metric introduced above.

- Recommending a policy that generates high commissions but doesn't serve the client's interests as well as a policy with lower commissions. Here the client asks for advice and the broker commits *lifnei iver* putting a stumbling block in the form of bad / self-serving advice before the unsuspecting / 'blind' client. Again, an active transgression of co-mission.
- Telling a client 'that portion of the policy doesn't apply to you; it's just the insurance company's way of protecting itself'. This was perhaps most classically a problem during the HMO era of the 1990s when insurers routinely rejected claims or during the pre-ACA period when carriers could rescind policies. (Rescission means the carrier refunds your premiums instead of paying a big claim, a practice outlawed by the Affordable Care Act.)

Here again, the broker's action placed a stumbling block before the client by misrepresenting an insurance policy's components. Again, an active ethical transgression of commission.

• Other inaccurate statements and recommendations that mislead, misdirect or confuse clients.

Lifnei iver ethical transgressions of o-mission

Second and less obvious and but more problematic, some Biblical scholars have extended *lifnei iver* beyond active placement of that metaphorical stumbling block to passively not removing it.

You should not only not <u>put</u> a stumbling block in the blind person's path in other words – i.e. take an action that causes harm to someone else – but you cannot <u>passively</u> allow someone to be taken advantage of if you (a) know about the problem and (b) are in a position to do something about it.

Torah scholar Nehama Leibowitz puts it this way: ²

even by sitting at home doing nothing, by complete passivity and divorcement from society, one cannot shake off responsibility for what is transpiring in the world at large... By not protesting, "not marking the graves" and danger spots, you have become responsible for any harm arising therefrom, and have violated the prohibition: "Thou shalt not put a stumbling block before the blind..."

Leibowitz's interpretation moves beyond active transgressions of <u>co</u>-mission to passive transgressions of <u>o</u>-mission. You can act unethically, in other words, and violate *lifnei iver* by **not acting** when you see someone making a misguided decision.

Professor Hershey Friedman in his article *Placing a Stumbling Block Before the Blind Person: An In-Depth Analysis* ³ extends this again, concluding that the admonition 'do not place a stumbling block before the blind' is really an ethical imperative requiring people to do everything possible to help the unaware, the unsuspecting, the overly trusting, the uneducated and therefore vulnerable among us.

Friedman's underlying assumption apparently is that people make misguided decisions because they lacked all facts necessary to make wise decisions. They face stumbling blocks in the form of poor information because they trust biased information sources.

Or, phrased differently, people would make wise decisions (wiser at any rate) if they had access to, and understood, all the relevant, necessary facts. Better information in other words.

Applying These Ethical Principles to Health Insurance Brokers

² Quoted in Hershey H. Friedman 'Placing a Stumbling Block Before the Blind Person: An In-Depth Analysis <u>http://www.jlaw.com/Articles/placingstumbling.html</u>

How might these ethical issues arise in healthcare? How might brokers remove the related stumbling block from their clients? Answering these questions allows us to suggest some general client education issues – things ethical brokers should teach their clients - including:

- Teach some key **outcome oriented** questions for patients to ask physicians so clients generate better information. That in turn can lower their medical spending and utilization factors, not to mention, enjoy better medical care. We'll suggest some questions later in this course, and
- Teach about **Cochrane**, a little used by patients, but excellent information source that brokers can advise clients to use.

A quick word about Cochrane and online information sources: All are not equally credible. Some may be biased due to their advertiser requirements. Others may accept conflicted donations, i.e. get funding from organizations with an agenda other than pure research. Still others may be low quality, i.e. not very good scientific reporters.

Cochrane is about the best easily accessible, financially unbiased, scientifically high quality source for typical patients. There are a couple other equally good options like the US Preventive Services Task Force. But in this course, we'll only discuss Cochrane as that alone is a big topic. We'll have much more to say about it later in this course.

As context for Case Study 1 below, consider utilization reports that brokers typically receive about their client's medical treatments and the related *lifnei iver* responsibilities using Friedman's interpretation above.

Case Study 1 Arthroscopic debridement and the broker's ethical responsibilities

We'll take a simple orthopedic example and assume that the broker sees a utilization report indicating that the client had arthroscopic debridement for osteoarthritis of the knee. (We'll assume here for simplicity purposes that the broker sees only 1 report for only 1 treatment for only 1 patient. In real life, of course, brokers might see hundreds or thousands of treatments for clients with dozens or hundreds of insured employees. That doesn't change the essential ethical issues here. It simply complicates and compounds them.)

Arthroscopic debridement (AD) involves surgery to remove damaged cartilage or bone from someone's knee. This is generally done to ameliorate knee pain. Theoretically damaged cartilage and bone fragments cause pain and inhibit proper knee functioning. Debridement should result in less knee pain and, possibly, better knee functioning. Often with debridement - the removal of damaged bone or tissue – doctors also spray jets of fluid to wash and suck out all debris around the joint. This is called lavage or washout. Thus, the broker might see debridement plus lavage on the utilization report.

Debridement always generates physician income because physicians bill fee-for-service. In theory debridement also benefits patients. Might the fee-for-service incentive act as a stumbling block in which physicians give biased advice? Might this increase client utilization and costs without also generating patient benefit?

Might, in other words, the client be the unaware, unsuspecting, overly trusting, uneducated and therefore vulnerable person Friedman described above?

The answer here is clearly yes. Not even a close call.

Here's some additional background data from Cochrane. (See description of Cochrane below). Cochrane says unambiguously in the conclusion to its arthroscopic debridement systematic review that "there is gold level evidence that AD (arthroscopic debridement) has no benefit for undiscriminated OA (osteoarthritis)."⁴

The broker, knowing this, now faces a dilemma. Should he or she act ethically, remove the stumbling block and provide relevant facts to the client? Or should he or she transgress ethically and remain quiet? That answer, from an ethical point of view at least, is clear and obvious. Yes, remove the stumbling block.

More interestingly, what consequences might the broker expect from his or her ethical and non-ethical actions?

If the broker follows the non-ethical approach: No one will know. The client's medical expenses will increase because of the fee-for-service billing. The client's medical risks will increase from having a procedure. But the client's medical benefits will not increase. That's clear from Cochrane's analysis.

If the broker follows the ethical approach: Alternatively, if the broker acts ethically and introduces relevant facts to the client after the debridement expenses and risks, the client might not engage in similarly non-beneficial care in the future. That's clearly in the client's interests. Plus, the broker now has a client more appreciative of his or her services and more likely to engage the broker's services long into the future.

Practicing ethics, in other words, is good for business.

Of course, the client might be annoyed and respond with 'why didn't you tell me that before I wasted my money and suffered the various discomforts associated with surgery without any chance of pain reduction benefit?'

⁴ Arthroscopic debridement for knee osteoarthritis, Cochrane <u>https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD005118.pub2/full</u>

First, the broker might reasonably say 'I didn't know you were planning arthroscopic debridement.'

Second, the broker might offer classes on 'Excellent Sources of Healthcare Outcome Information' or similar, related topics to pre-empt such questions. We'll touch on these later in this course.

What 'similar non-beneficial care' might the broker's intervention eliminate?

In this case, since debridement didn't work to alleviate the patient's knee pain, the client will likely seek other knee osteoarthritis treatments. Here's a partial list of options along with a brief Cochrane comment about each:

- Joint lavage no better than placebo
- Doxycycline minimal to non-existent pain reduction
- Transcutaneous electrostimulation no better than placebo
- Braces and orthoses little to no pain reduction benefit
- Therapeutic ultrasound no better than placebo
- Joint corticosteroid injection possibly some short-term benefit but no evidence of benefit after 6 months

Note that I, as a non-physician, don't know *how* any of these treatments work; I can't comment on the medical technologies or biological / anatomical aspects.

I only know that they don't benefit patients.

Knowing this outcome information - and there's much more available - could save the client significant cost, stress and potentially treatment risk.

The client. of course, could have had any of these other interventions first, instead of debridement. The ethical broker, following the same methodology and process, would have arrived at the same point regardless of which treatment the patient had first.

Understanding Cochrane

Now, finally, a word about Cochrane.

Cochrane, formerly the Cochrane Collaborative, is a huge international network of medical researchers that publishes systematic reviews of medical studies. 'Systematic reviews' compare multiple (generally all relevant) medical studies on a particular topic, evaluate the scientific methodology of each, then summarize the highest quality studies into one review. Physicians typically use Cochrane regularly and many / most medical libraries subscribe to it.

The Cochrane review of arthroscopic debridement for knee osteoarthritis summarized and evaluated 3 random controlled studies on a total of 271 patients.

• One study, the best according to the Cochrane analysts, compared AD plus lavage to a sham procedure,

- The second, with a higher risk of research bias, compared AD to a washout procedure,
- The third, also at a higher risk of bias, compared AD to closed-needle lavage.

After reviewing all three studies – both the study methodologies and results – the Cochrane authors concluded that gold level evidence shows arthroscopic debridement has no benefit for undiscriminated knee osteoarthritis whether resulting from mechanical or inflammatory causes.

Cochrane publishes a library of systematic reviews organized by specialty and subspecialty, updated periodically. It is widely regarded as outstandingly high quality and regularly used by medical researchers and practitioners.

Sidebar - my own Cochrane study. I once showed a course draft that referred to Cochrane analyses to a friend, a fellow centrally placed in the Massachusetts health insurance world with 30+ years of experience working with carriers and brokers. He had never heard of Cochrane but, coincidentally, had dinner scheduled the next evening with an old high school friend, a physician. At dinner, he reported back to me afterwards, he casually asked his friend, 'Ever heard of Cochrane?'

His physician friend replied 'Of course. I use it all the time.'

Cochrane is widely known and used by physicians but virtually unknown and rarely if ever used by brokers and patients. Consider the potential *lifnei iver* ethical issues about this.

The Cochrane organization funds itself by subscriptions to its library and grants from international funding sources. Compare that to other commonly used online information sources that often fund themselves with advertising or rely on grants from commercially incented industry players.

- Can you even figure out who funds them?
- How might their funding sources exert editorial control and introduce bias?

Cochrane does not accept commercial or conflicted funding, i.e. funding from parties that could potentially introduce bias into the Cochrane review process. Here's a partial list of their 2019 funders. It's the All-Star team of international unbiased medical funders. It was easy to find. Just google Cochrane funding sources. (Try this with other information providers.)

- NIHR, the National Institute of Health Research in the United Kingdom. The NIHR is the research arm of the UK's National Health Service.
- Den danske regering/The Danish Government (Rigshospitalet Research Committee), a Danish specialty hospital.
- Bundesministerium für Gesundheit (BMG) Federal Ministry of Health, Germany

- National Institutes of Health (NIH), part of the U.S. Department of Health and Human Services, is the nation's medical research agency
- South African Medical Research Council (South Africa)
- Health Research Board / Public Health Agency, Health and Social Care Research and Development (Northern Ireland)
- World Health Organization
- Foreign, Commonwealth and Development Office (UK)
- Direction générale de l'offre de soins (France)
- Ministry of Health, Social Services and Equality (Spain)
- Chief Scientist Office (Scotland)
- Ministry of Health (New Zealand)
- Ministry of Health, British Columbia (Canada)
- McMaster University (Canada)
- Norwegian Agency for Development Cooperation (Norway)
- Health and Social Fund, Lower Austria (Austria)
- Amsterdam University Medical Center (Netherlands)
- Institut National du Cancer (France)
- Ministry of Health (Austria)

Some ethical lessons from this brief case study of arthroscopic debridement. First, a well-informed broker, practicing *lifnei iver*, can save his or her client money, time and risk while strengthening the client-broker relationship. A win-win in this treatment specific case.

Remember that debridement is but one of many different treatments that generate little to no patient benefit. Cochrane lists hundreds (thousands?). Some research suggests that up to about a third of all US healthcare spending generates no patient benefit. This approaches \$1 trillion annually, meaning brokers have a tremendous opportunity to save their clients money by reducing their amount of ineffective, non-beneficial care.

A well-informed broker, practicing *lifnei iver* as outlined in this simple example, could save a client thousands of dollars annually and perhaps even more, plus pain and risk.

Second and more broadly, though, this case shows why brokers should teach clients to learn about medical care outcomes, not processes, not fancy names, not new-fangled-inventions. We'll give another case study example below.

Outcome focused patients who ask '*how well* does that treatment work?' not '*how* does that treatment work?' tend to enjoy better outcomes, choose less risky and less invasive treatments and cost less.

Cochrane is one specific tool to help patients research outcomes. Cochrane's systematic review summaries are available online for free; anyone can find them.

Follow Up: Introducing A Key Outcome Oriented Question for Patients to Ask Their Doctors One way brokers can practice *lifnei iver*

One potential challenge Cochrane poses – a minor issue in my opinion – is their use of medical terms and jargon. 'Arthroscopic debridement', for example, is not only a big and somewhat intimidating word but is also often abbreviated as 'AD'. Patients might get intimidated or confused, but it's an easily solvable problem. If and when confused, simply ask your doctor 'what does Cochrane say about your proposed treatment?' That's an invitation for your doctor to look it up.

In my experience, doctors welcome insightful questions like this and are eager to engage with thoughtful patients who ask.

The simple, non-threatening question 'what does Cochrane say about your proposed treatment?' opens the door to an outcome-based discussion. Outcome-based issues should be the primary focus of all patient-doctor treatment discussions. Cost and insurance coverage issues, while important, are secondary. Have you ever heard anyone say, 'I choose the ineffective treatment for my child because it was cheaper?'

Instead, I regularly hear 'I don't care what it costs. I want the best care for my kid.'

Remember:

- 1. Patients see doctors to improve their health, obviously. The wise patient first learns *how well* a specific treatment will likely work. Cochrane, almost uniquely in the medical reporting business, provides that information in universally highly credible detail.
- 2. The outcome-based, Cochrane focused discussions may indicate that the treatment doesn't work or doesn't work well enough for a specific patient to choose. In that case, discussions of cost or insurance coverage are meaningless; neither matter for a treatment that doesn't work well enough for a patient to choose.
- 3. Cochrane may not cover a specific treatment under discussion. The treatment might be too specialized for Cochrane's more general audience. But the outcomebased question 'what does Cochrane say' opens the door to follow up 'if it's not addressed in Cochrane, what other outcome-based studies exist?'

A variation on this question: 'what do high quality, outcome-based comparative studies show about this treatment?'

The important concept here: wise patients start their outcome-based questions by referencing Cochrane and / or their own, similar research. That will indicate to their doctors that they're interested in clinical outcomes as reported by high quality, unbiased sources. The follow up questions above will reinforce that.

The broker's educational, ethical role here is to teach clients the right questions to ask and, of course, explain why outcome oriented questions are the best place to start. I hope you can see how a discussion of outcomes differs from a discussion about costs and insurance coverage.

Let's conclude with the 3 main takeaways from this arthroscopic debridement case study:

- 1. Many treatments generate no patient benefit but serve only to raise patient costs and risks.
- 2. Brokers who (a) help patients focus on outcomes, (b) teach clients how to research treatment outcomes and (c) encourage them to discuss their researched outcome information with doctors act ethically and, in doing so, develop stronger client-broker relations.
- 3. Cochrane is an excellent source of treatment outcome information and one that ethical brokers can teach their clients to use.

Case Study 2 Aduhelm and the broker's ethical responsibilities

Let's consider now a more systemic situation instead of a specific treatment one and use the 2021 FDA approval of Aduhelm for Alzheimer's disease as our example. Aduhelm is the brand name for aducanumab. We'll refer in this course to Aduhelm as it is more commonly recognized in the lay community.

This case study was written in July, 2021 shortly after the FDA approved Aduhelm despite vociferous objections. While the FDA may reverse or modify its decision, the essential ethical and educational issues raised in this case study remain important and valid.

In this case the broker can act *a prioi* – before the client spends money - not *a posteriori*, after the client wastes money on non-beneficial care, as most likely occurs in the arthroscopic debridement case above. The Aduhelm situation shows how brokers, acting ethically, can advise clients before they waste money, time, resources, and emotional energy on non-beneficial care.

This case also allows us to introduce 2 new components of a medical literacy program, concepts that patients rarely understand but often confuse... to their detriment:

- 1. Surrogate endpoints vs. patient events
- 2. Statistical significance vs. clinical significance

There are many more, equally important concepts for patients to understand of course. Rather than provide a complete medical literacy program here though, our purpose is simply to introduce some notions that ethical brokers can address in their client education programs. These concepts are samples or examples. We simply want to show that various tools exist to help patients make wiser medical treatment decisions and, in the process, reduce their medical spending and treatment risks. ⁵

In doing so, the broker acts ethically according to the *lifnei iver* principle.

Imagine how the quality of your client's medical decisions might improve if they learn about and then access these tools.

Imagine the impact on their medical spending.

Imagine the impact on your client retention.

All good results of from acting ethically.

Brokers, of course, can't practice medicine. But brokers can teach clients how do their own homework and medical research better (*everyone* uses google). Brokers can also help clients frame discussions with doctors to avoid potential information biases if only due to information left out by the doctor.

In other words, the ethical broker can help clients frame discussions with their doctors with the goal of helping clients avoid being unintentionally unaware, unsuspecting, overly trusting, uneducated and therefore vulnerable... just as Biblical scholars Leibowitz and Friedman suggested earlier ago in this text.

Some background on Alzheimer's disease and Aduhelm

Alzheimer's disease is the most common form of dementia, a general term for memory loss and other cognitive problems serious enough to interfere with daily life. Alzheimer's disease accounts for 60-80% of dementia cases. ⁶

Alzheimer's is a progressive disease in which dementia symptoms gradually worsen over several years. During early states, memory loss is mild, but is late-stage Alzheimer's, individuals lose the ability to carry on a conversation and respond to their environment. Alzheimer's is the sixth-leading cause of death in the United States. On average, a person with Alzheimer's lives 4 to 8 years after diagnosis but can live up to 20 years, depending on various factors.

Alzheimer's has no treatment or cure.

Or, at least, that was true until the FDA approved Ahuhelm in June, 2021. Biogen, Adhuelm's manufcturer, plans to price it at \$56,000 per patient per year.

Aduhelm, according to the FDA, doesn't actually stop or even slow the progression of Alzheimer's disease, at least for most people, most of the time. Dr. Sam Grandy, director of the Mount Sinai Hospital Center for Cognitive Health summarized Aduhelm this way

⁵ For more on medical literacy and specific patient decision making tools, see **Beyond Deductibles** and **How to Be a Patient**, both by Gary Fradin and both available on www.lulu.com.

⁶ This description comes from the Alzheimer's Association website <u>https://www.alz.org/alzheimers-dementia/what-is-alzheimers</u>

in the New York Times: "no one was improved by Aduhelm and patients' cognition always continued to decline at some rate."⁷

Data analysts have found, however, that a small subgroup of patients may receive benefit from the drug.

• Is that significant either statistically or clinically? We'll get to that below. These are two concepts that ethical brokers can teach their clients.

The FDA approved Aduhelm based on its ability to remove brain plaques called betaamyloid, that supposedly contribute to the disease. In other words, the FDA used a surrogate metric – beta-amyloid – instead of actual patient experience to approve the drug.

- How do surrogates metrics and patient events correlate? Why might one be credible and the other not so? These are two additional concepts that brokers can teach their clients, the differences between surrogate metrics and patient outcomes. We'll discuss below.
- What ethical issues does this raise for brokers?

Insurers balked at covering Aduhelm because of the huge price, \$56,000 per patient per year. Michael Sherman for example, chief medical officer at Point32Health in Massachusetts claimed that Biogen should cut the price to \$5,400 given the drug's questionable benefits and potential risks. ⁸

• Is price a relevant factor in *lifnei iver* ethics? Does one put a stumbling block, from an ethical perspective, before a blind person at \$56,000 per year, but not at \$5,400 ... or the reverse? We'll get to that too.

This brief overview frames our *lifnei iver* discussion about the broker's ethical role in the Aduhelm roll out. We'll adopt Professor Friedman's yardstick, the admonition that 'do not place a stumbling block before the blind' is really an ethical imperative demanding that people do everything possible to help the unaware, the unsuspecting, the overly trusting, the uneducated and therefore vulnerable among us.

Key educational concepts that bear on *lifnei iver*: surrogate endpoints vs. patient events and statistical significance vs. clinical significance

Let's look at some typical stumbling blocks before patients that the Aduhelm case introduces and focus here on vocabulary. Words can act as stumbling blocks by confusing people. I'll define some terms here, words common in medical research to show that.

⁷ Cleveland Clinic and Mount Sinai Won't Administer Aduhelm to Patients, Belluck, New York Times, July 14, 2021

⁸ Boston Globe, June 23, 2021 "State's Second Largest Health Insurer Slams Biogen"

'Endpoints' or 'events' are the outcomes measured in a study. These come in two flavors, surrogate and patient.

- **'Patient events'** or **medical events** are actual patient experiences like heart attacks, strokes and death.
- **'Surrogate' endpoints** or **metrics** are biomarkers like cholesterol levels or amyloid beta plaque reduction, that *seem to indicate* something about the likelihood of a patient having an actual medical event.

The FDA sometimes uses surrogate endpoints to approve drugs when either (a) the patient events take a long time to study like strokes, (b) the surrogate is easy and inexpensive to measure or (c) the relationship between the surrogate metrics and patient events are well understood and strong, like controlling blood pressure and having or dying from a heart attack.

No relationship between surrogates and patient events is perfect. Take the high blood pressure mentioned above, one of the clearest and most compelling surrogate-event combinations. Some people with high blood pressure never have or die from a heart attack. In fact, according to the US National Cancer Institute, high blood pressure only kills about 4 sixty-year-old American men per 1000 over 10 years.⁹ Way more than 4 sixty-year-old American men per 1000 have untreated high blood pressure; the American Heart Association estimates that about 25 - 30% of all Americans suffer from the condition ¹⁰.

That would suggest that 250 or more 60-year-old men per 1000 *have* high blood pressure while only 4 *die* of it over 10 years. Some researchers call that correlation - between the surrogate metric 'high blood pressure' and the patient event 'death' – weak, even very weak. Nonetheless, the surrogate endpoint of 'high blood pressure' often stands for 'dying from a heart attack' in studies and treatment guidelines.

In addition, researchers sometimes use surrogate endpoints because they're relatively easy and inexpensive to measure. This can also be problematic. Consider the classic case of beta blockers (atenolol in particular), a blood pressure lowering medication.

Beta blockers clearly lower blood pressure, the surrogate metric. Lower blood pressure *should* lead to fewer heart attacks, the patient endpoint, at least in theory. But Cochrane's 2017 systemic review found that atenolol had little to no effect on heart attacks or mortality. ¹¹ Somehow, atenolol manages to lower blood pressure without reducing the number of heart attacks.

https://knowyourchances.cancer.gov/big_picture_charts.php

⁹ Know Your Chances Risk Chart, US National Cancer Institute

¹⁰ <u>https://www.heart.org/en/news/2018/05/01/more-than-100-million-americans-have-high-blood-pressure-aha-says</u>

¹¹ <u>https://www.cochrane.org/CD002003/HTN_beta-blockers-hypertension</u>

Patients who read this sometimes conclude that 'the study must be wrong' since the theory is so compelling. That's another stumbling block; too often in medicine, patients rely on theory, not evidence.

That's also why Cochrane is so important. Its systemic reviews include *all* relevant studies and consider both the research methodologies and outcomes.

For some psychological reasons that I don't understand and can't explain, patients too often ignore study outcomes in favor of simplistic logic and medical theory. Another stumbling block.

With the above discussion about surrogates and patient outcome endpoints as background, switch focus back to Aduhelm. Here the FDA relied on the surrogate endpoint of amyloid beta plaque reduction in the approval process, not on actual patient symptom changes. Amyloid beta plaques are hard substances that clump together between brain neurons in Alzheimer's patients. These inhibit normal brain functioning.¹²

The FDA said the surrogate endpoint amyloid beta plaque reduction is "expected" to predict a clinical benefit, despite the failures of dozens of amyloid-targeting drugs over many years.¹³

The FDA, interestingly, instructed Biogen, Aduhelm's manufacturer, to complete a patient symptom follow up study by 2029. 'Patient symptoms' are a fancy way of saying 'events' like developing Alzheimer's disease, having Alzheimer's disease progress on some recognized, objective scale or dying from Alzheimer's disease.

This suggests questions within the FDA about how well amyloid beta plaque reductions correlation with patient Alzheimer's patient symptom reduction.

It also suggests that doctors and patients won't know how well Aduhelm actually works until 2029, eight years after the FDA approved the drug and, presumably, eight years after clients start demanding coverage for it from their health insurance carrier.

The ethical question for the broker: Should you explain all this to your clients? After all, clients want benefits advisors to help them control healthcare spending while they enjoy better clinical outcomes.

The ethical broker says 'yes, I should explain all this to my clients'. The ethical broker understands that patients who confuse surrogate endpoints with patient events increase their chance of making unwise treatment decisions. Surrogate endpoints often show more benefit than do patient event measurements. Clients who rely (unknowingly) on surrogates may choose non-beneficial care more than clients who rely on patient endpoints.

¹² <u>https://www.brightfocus.org/alzheimers-disease/infographic/amyloid-plaques-and-neurofibrillary-tangles</u>

¹³ Sachs, The FDA's Approval of Aduhelm, Health Affairs, June 10, 2021

The unethical broker says 'no, I do not need to explain all this to my clients'.

The unethical broker takes the 'I only arrange financing for healthcare. My clients can choose whatever medical care they want. Their medical choices are not my professional responsibility'.

The problem with the unethical position: utilization and therefore medical spending will likely increase among people who rely on surrogate endpoints. This runs counter to the broker's responsibility to help clients control their healthcare spending. You simply can't control medical spending very well if clients mistakenly waste money on non-beneficial medical care.

In this case, as with arthroscopic debridement earlier in this course, good ethics equals good business practice.

Why the FDA relied on surrogate endpoints and the underlying ethical issues

Why did the FDA rely on surrogate endpoints, not patient endpoints? This topic allows us to introduce an entirely new set of issues that ethical brokers can teach to their clients.

Some background: ¹⁴ In 2015, Biogen started two randomized controlled trials, called EMERGE and ENGAGE, to test the effectiveness and safety of aducanumab, the more technical name for the product that would ultimately be branded and marketed as Aduhlem. In its 2019 data analysis of patient endpoints, Biogen found that the EMERGE trial showed positive results for patients taking a high dose of aducanumab.

The ENGAGE trial did not generate similar positive patient endpoint results.

The EMERGE study's results were statistically significant according to the researchers who ran it. *Were they also clinically significant?*

Let's introduce and define the two terms, statistical and clinical significance.

• *Statistical significance* means the result didn't happen by accident or wasn't a fluke. In common use, statistical significance means that another research study, using the same methodology, would likely generate similar results.

'Not statistically significant' means the results may have happened by chance and another research study, using the same methodology, might not generate similar results.

Statistical significance applies to the study methodology and data quality.

Researchers who evaluated Aduhelm determined that the outcomes didn't happen by chance meaning other studies on the same product, using the same research methodology, would probably generate about the same results.

¹⁴ This analysis comes from Garber, Alzheimer's drug sets a dangerous precedent, Lown Weekly, June 14, 2021

• *Clinical significance* means the medication in question impacted either a large enough number of patients, or impacted patients strongly enough, to warrant physician and patient attention. An outcome that *slightly* benefits 1 patient in 10,000 isn't clinically significant but one that *greatly* benefits 39 in 100 is.

Applying this to our current case study, an outcome that changes Alzheimer's symptoms on the Clinical Dementia Rating Scale (CDRS) by 5 - 8 points probably is clinically significant, i.e. warrants physician and patient attention. The Clinical Dementia Rating Scale runs from 1 - 18 with higher numbers indicating more severe illness.

Aduhelm generated a 0.39 point symptom reduction.¹⁵

Not clinically significant in our opinion (though a specific patient, armed with these facts might arrive at a different conclusion).

Thus, a *statistically* significant study might not be *clinically* significant.

The client educational message here: Patients who misinterpret the endpoint results (statistically but not clinically significant) will be more likely to make unwise treatment decisions. They might confuse the two terms and choose a statistically significant treatment that doesn't generate much, if any, patient improvement.

Should an ethical broker teach these four concepts – surrogate endpoints vs. patient events, statistical significance and clinical significance – and many others (how many do you want in 1 ethics course?) to their clients?

Rather than answering that question here, I leave it open-ended. What would you do?

If you were a client, what would you want your broker to do?

Sidebar Some other key medical literacy concepts for ethical brokers to teach their clients

I decided to list some other key concepts for ethical brokers to teach their clients rather than leave readers hanging, wondering 'what else is there in the patient education arena?' Each is worth its own course.

- How to present disease risks and interpreting treatment benefits relative vs. absolute risk data, 'big' vs. 'small' risks and improvements.
- Screening vs. diagnostic tests meaning and role of each.
- Evidence quality double blind comparative vs. observational studies, long term vs. short term studies, large vs. small studies, etc.

¹⁵ Ibid.

- How reporting bias and conflicts of interest impact studies and guidelines who and what are behind the study and report and what impact does this have.
- Disease mongering and overdiagnosis, i.e. medicalizing normal human functions, equating risk factors with diseases, identifying innocuous abnormalities as 'stage 1 cancer', etc.
- Red flag words breakthrough, game changer, promising, dramatic, etc. that have no clinical meaning but may influence patients.
- The non-medical context of disease risks, utilization drivers and treatment outcomes fee-for-service billing, patient socio-economic status, loneliness and isolation, etc.
- Second opinion role, necessity and impacts.
- Treatment variation why different doctors treat similar patients differently, and how to protect against both undertreatment and overtreatment.

Undertreatment means receiving insufficient care and being harmed by the disease; overtreatment means receiving excess care and risk being harmed by the treatment.

These are all potentially fruitful areas of patient education but, unfortunately, lie outside the scope of this particular ethics course.¹⁶

Cost as an ethical differentiator

Michael Sherman, chief medical officer at Point32Health claimed that Biogen should cut Aduhelm's price from \$56,000 to \$5,400 given the drug's questionable benefits and potential risks. ¹⁷

• Is price a relevant factor in *lifnei iver* ethics? Does one put a stumbling block, from our ethical perspective, before a blind person at \$56,000 per year, but not at \$5,400 ... or the reverse?

Yes, I understand that more people can afford \$5,400 but that's an economic issue, not a *lifnei iver* ethical one.

To address the ethical issues in pricing a medical treatment, we need first to contextualize price as a stumbling block. We'll approach this from three perspectives:

1. How important is price in a patient's medical decision making? This question focuses on the role of health insurance or third-party-financing.

Today about 90% of Americans have health insurance, meaning other policy holders fund the treatment, not the patient him or herself after the relatively

¹⁶ For a more in-depth discussion of these issues, see Gary Fradin's books **How to Be a Patient** and **Beyond Deductibles**, both available on <u>www.lulu.com</u>.

¹⁷ Boston Globe, June 23, 2021 "State's Second Largest Health Insurer Slams Biogen"

small deductible and co-insurance if any. We'll explore some ethical issues about this below.

2. What responsibility does each individual patient have to protect other people from paying excessively high premiums? This question focuses on each patient's responsibilities toward others and the broker's role here, if any.

Does Aduhelm's high price, in other words, place additional ethical responsibilities on each patient who might access it and therefore on the brokers who design policies to cover it? This important ethical issue falls somewhat outside the typical *lifnei iver* parameters but is fertile ground for discussion. We'll touch on it below.

3. How important is the benefit-to-harm tradeoff in determining price? This question gets to the signal prices send to potential consumers. In most of our economy – hotels, restaurants, cars etc. - high prices equate to high quality, low prices to lower quality.

In the Aduhelm case, we have relatively low reported benefits but comparatively high risks (see below). Should an ethical insurance carrier insist on low prices to encourage utilization, thus optimizing the potential benefits...or high prices to discourage utilization?

Which action fits within the *lifnei iver* context?

We'll address each of these issues in turn.

The importance of price in medical decisions. Healthcare is a relatively inelastic service, meaning people access approximately the same amount regardless the price. This is, obviously, because health insurance funds most individual medical care so individual patients do not factor price into their consumption decisions once their annual deductible has been reached.

Or for treatments that exceed the annual out of pocket maximum, like Aduhelm.

Aduhelm's price, at either Biogen's \$56,000 or Michael Sherman's \$5,400 exceed almost every individual plan deductible.

Thus <u>from our purely *lifnei iver* ethical perspective</u>, Aduhelm's price does not place a stumbling block before the blind.

Dr. Sherman's comments appear aimed at achieving a different goal, either protecting Point32Health's financial position or avoiding raising premiums company wide. While both of those goals may be laudable, neither fits within our current ethical context.

Does Aduhelm's high price place additional ethical responsibilities on brokers? There is a relatively weak argument under *lifnei iver* that it does, but a much stronger argument under a different ethical concept, fairness. The relatively weak *lifnei iver* argument goes along these lines. If Aduhelm becomes widely used at the \$56,000 price point, this will force insurance carriers to raise premiums on everyone. That, in turn, will force some people to drop health insurance due to cost. The lack of health insurance is a stumbling block to people who need medical care.

Thus indirectly, brokers who fail to educate their clients about Aduhelm's true benefits (or lack thereof) may place a stumbling block before other policy holders. The indirect nature makes this ethical obligation relatively weak.

A far stronger obligation falls under the fairness ethical standard which defines ethical behavior as treating everyone equally regardless their station in life.¹⁸ Ethicists could argue that it is unethical / unfair for some people to cost the healthcare system huge amounts of money - \$56,000 per year for many years - while receiving little benefit in return. That, if seems to us, is a far stronger ethical argument but one that falls somewhat outside the scope of *lifnei iver*.

Different ethical issue. That's why we simply mention it here.

How important is the benefit-to-harm tradeoff in determining price? In most of our economy, high prices signal better quality. Higher cost hotels provide more comforts and better services than lower cost hotels. More expensive TVs provide better pictures than less expensive TVs, and so on.

Thus pricing Aduhelm at \$56,000 per year suggests that it works relatively well. Pricing it at \$5,400 per year suggests that it works relatively poorly.

Dr. Sherman suggested that Aduhelm should cost \$5,400 per year based on his valuation of the medication's benefits and harms. While he might be correct in the classical pricing sense, I think he got the *lifnei iver* / stumbling block ethics backwards, primarily because of our excessively complex and insanely incentivized health insurance system.

At \$5,400, carriers will be less inclined to restrict access to Aduhelm. More doctors, figuring 'the carrier pays and my patient wants it' will prescribe it. Doctors who do so, parenthetically, will get higher patient satisfaction grades from frightened, poorly informed patients, than doctors who do not. Talk about crazy incentives!

More patients, as a result, will figure 'it the carrier pays, it may work for me' and take it.

This gives a false hope of benefit. Based on the initial studies, very few patients actually enjoy symptom improvement. Most only subject themselves to the risks and potential harms of Aduhelm. How common are these?

According to the Lown Institute's summary:

¹⁸ <u>https://www.scu.edu/ethics/ethics-resources/ethical-decision-making/thinking-ethically/</u>

1% more patients taking aducanumab (Aduhelm) experienced a serious adverse event that researchers attributed to the drug, compared to patients taking placebo (0.7% of placebo group vs 1.7% of aducanumab group). If all 6 million Americans diagnosed with Alzheimer's each year took the drug, that would result in 60,000 more serious adverse drug events each year.

The aducanumab group also reported higher rates of headache (19.6% vs 15.2%), falls (14.1% vs 11.8%), and diarrhea (8.2% vs 6.8%), compared to the placebo group. Applied to 6 million potential aducanumab users, this would result in 252,000 more cases of headache, 84,000 cases of diarrhea, and 138,000 more falls each year.¹⁹

Overall, up to 40% of all Aduhelm patients had side effects including dizziness and small brain bleeds.²⁰

At the \$5,400 price point, carriers remove the price stumbling block, at least in large part. They would, presumably and consequently, impose *fewer* restrictions on utilization so more people would take the drug and experience these adverse events.

But at the \$56,000 price point, carriers impose a price stumbling block. They would, presumably and consequently, impose *more* restrictions on utilization so fewer people would take the drug and experience these adverse events.

Remember that Aduhelm shows virtually no clinical, statistically significant patient event benefits. That's why regulators relied on surrogate endpoints.

In this weird case where insurance finances a consumer product, placing a stumbling block before people who seek this kind of treatment – where the patient harms apparently exceed the benefits – becomes ethical!

Clearly this is not what the original ethicists considered when developing the *lifnei iver* guidelines. They assumed, presumably, that the blind person chose a path toward greater benefit that the stumbling block would inhibit. In our current upside-down case, however, the drug seems to do more harm than good, so the stumbling block would save people from Aduhelm's harms.

That's why Dr. Sherman, while probably on strong *economic* grounds, gets the ethical issue of Aduhelm backwards. The correct ethical position under *lifnei iver* is to raise the drug's price to restrict access and protect policy holders from the higher likelihood of harm than benefit.

At least, that's what the evidence shows to date.

¹⁹ Garber, Lown Weekly June 14, 2021, op cit.

²⁰ Saltzman, Alzheimer's Drug is Hit By Another Rejection, Boston Globe, July 24, 2021 <u>https://edition.pagesuite.com/popovers/dynamic_article_popover.aspx?artguid=4d0ac9e0-8c44-41f4-9f8f-d555947b4bdb&appid=1165</u>

Summary of *lifnei iver*

We started by defining the ethical *lifnei iver* principle from Leviticus as 'do not place a stumbling block before the blind'. This definition evolved in two different directions.

First and most obviously, don't inhibit people from obtaining truthful information necessary to make a wise decision by lying, shading the truth, misleading clients or providing self serving information when people ask for your advice. We called these 'ethical transgressions of co-mission'.

Second and less obviously, don't *passively* allow someone to be taken advantage of if you (a) know about the problem and (b) are in a position to do something about it. We called these 'ethical transgressions of o-mission'. Under this interpretation, *lifnei iver* is really an ethical imperative requiring people to do everything possible to help the unaware, the unsuspecting, the overly trusting, the uneducated and therefore vulnerable among us.

Under this second definition, we explored how price can sometimes be, and sometimes not be, a stumbling block, depending on the benefit-harm trade-off that each individual makes and the impact of third-party payments. Some tools to help people make those trade-off decisions include understanding surrogate endpoints, patient outcomes, statistical significance and clinical significance. Other decision tools also exist.

But one question, at least, remains: **how strong is the ethical admonition against the transgressions of o-mission we discussed above?**

And related, why did Biblical ethicists develop this doctrine in the first place?

Extensions from the Book of Isaiah: Why Biblical ethicists discuss *lifnei iver*

Hochei-ach tochi-ach roughly translates as 'we must rebuke our neighbor'. The Book of Isaiah continues in the next verse "You shall not take revenge nor bear a grudge... but you shall love your neighbor as yourself."

What's the big deal about rebuking? Why must we do it? Who in the health insurance field should do it? Who and how should they rebuke? Let's discuss.

In the Book of Isaiah, Isaiah himself delivers a remarkable verbal thrashing of his neighbors and community. He doesn't just type messages into his Facebook echo chamber; instead, he goes into the streets and confronts people. He tells them to change "to unlock the shackles of evil; to loosen the thongs of the yoke; to send forth crushed souls to freedom," as translated into English from the original text.

He claims to have received divine instructions "Tell My people of their rebelliousness; Proclaim their wrongs..."

Imagine hearing that directed at you from a member of your own community. Talk about making people feel uncomfortable!

Everyone must have disagreed with, even hated, Isaiah. As the rabbi and scholar Abraham Joshua Heschel put it, paraphrased here 'To the patriots, he seemed pernicious; to the pious multitude, blasphemous; to the men in authority, seditious.' ²¹

This notion of speaking out against wrongs – rebuking in other words – is perhaps most succinctly and poignantly summarized in modern times, in Ted Kennedy's famous eulogy of his brother Bobby in 1968. Read this as an updated summary of the *hochei-ach tochi-ach*, the notion that we must rebuke our neighbor. Bobby, Ted said, was someone who

saw wrong and tried to right it, saw suffering and tried to heal it, saw war and tried to stop it.

Someone, in our terms, who lives up to Isaiah's *hochei-ach tochi-ach* ethical standard.

Why is this so important ethically? Why rebuke?

Commentators suggest that rebuking keeps us from hating, from nursing a grudge that could explode into vengeance, from engaging in destructive activities. Rebuking can address small problems before they escalate into large, costly ones, and diffuse potentially destructive motivations that destroy relationships.

Rebuking, in other words, shows you care, at least enough to engage in potentially difficult and upsetting discussions.

In business terms, it's cheaper to rebuke a client than lose the account.

I once had a vaguely related experience like this, a discussion with a new boss. I worked for CARE in Chad, Africa at the time and was an outspoken (obnoxious?) 20-something. I liked my old boss, a very experienced professional who was moving to a different position in the company and had worked closely with him.

I often, in our current context, rebuked him. I prefer today to call it 'asking good questions' and 'suggesting potential pitfalls' but that's probably just with the ameliorative benefit of hindsight.

The new boss questioned the old boss. 'Why', he asked, 'do you tolerate this from Gary?'

The wise old boss responded, 'It's cheaper to hear it from him than to make a mistake in the real world.'

Interestingly, the scholar Abraham Joshua Heschel said much the same thing about Isaiah and the other Prophets: "The striking surprise is that prophets of Israel were tolerated at all by their people." Somehow, apparently, society realizes that squeaky wheels – rebukers in our terms – perform a useful function.

²¹ Comments and interpretation from sermon by Rabbi Ken Carr at Temple Chayai Shalom, October 9, 2019

In business or economic terms, rebuking can be efficient, low cost and effective. Rebuking can take many forms for a health insurance broker:

- He or she can say 'I see on your utilization report that you have many treatments of suspect quality' and then discuss some sub-optimal medical decisions that the client has made. Having arthroscopic debridement is one, taking atenolol probably another.
- He or she can say 'I see that you didn't get a second opinion before deciding on [some specific treatment]' and then discuss how second opinions can improve patient satisfaction with care and reduce medical spending.
- He or she can say 'Did you discuss Cochrane with your doctor prior to making [a specific medical decision]?' That opens the door to discussion of Cochrane and the role of outcome studies in general.

Let's tie this into our previous discussion of *lifnei iver*:

- Brokers shouldn't put a stumbling block either actively or passively before their clients.
- This can often revolve around information quality like medical outcomes.
- We introduced several case studies to show types of stumbling blocks and types of ethical broker interventions.
- Now we introduce a different justification for removing stumbling blocks, the notion of rebuking those you care about. Rebuking your client (i.e. removing a stumbling block) when you see him/her or it making a poor decision, can diffuse potentially big problems in the future.

A Tale of 3 Brokers

Consider this hypothetical but potentially realistic interaction with a client suffering from knee pain who considers having arthroscopic debridement for knee osteoarthritis.

Broker #1 could say nothing, ignore the ethical discussions above and take the position that 'I just arrange healthcare financing. How the client uses that financing is up to him or her.'

The client could then complain about a premium increase the next year. Then Broker #1, explaining the increase, could explain that the knee surgery caused part of the increase. The client could then complain 'and I didn't even benefit from the surgery!'

The client then asks for competitive quotes from new brokers, one of whom says 'Oh, arthroscopic debridement doesn't work. I could have told you that and saved you time, money and a premium increase.'

Broker #1, the 'how-the-client-uses-his-insurance-policy-is-up-to-him' one, loses the account.

Enter **Broker #2** who rebukes the client to show that he or she actually cares about the client. Broker #2 could speak out about arthroscopic debridement – that's from *lifnei iver*.

And the client could reply 'I'm busy, maybe some other time.'

Broker #2 then lets it drop.

Sure, Broker #2 tried.

Sure, Broker #2 acted somewhat ethically and told the client that he or she was making a mistake.

Sure, Broker #2 attempted to remove a stumbling block and followed *lifnei iver*.

But Broker #2 didn't act ethically under *hochei-ach tochi-ach*, the 'we must rebuke our neighbor' standard. #2 is more like the Facebook 'post to the echo chamber' person, less like the prophet Isaiah. He or she said what they had to say and moved on.

Under *hochei-ach tochi-ach*, though, the broker should insist, tell the client 'I must teach you and your staff about Cochrane, I must give you tools to make wiser medical decisions to save you time, money and risk.' Then, of course, the client and broker discuss mechanisms to do this. That's **Broker #3**.

A tale of three brokers.

- Broker #1 who doesn't practice *lifnei iver* **or** *hochei-ach tochi-ach*.
- Broker #2 who attempts to practice *lifnei iver* **but not** *hochei-ach tochi-ach*.
- Broker #3 who practices both *lifnei iver* and *hochei-ach tochi-ach*.

Which are you? Which broker will likely enjoy the highest account retention? Which will likely be the most successful?

I know how I would vote.

Continuing Education classes and hochei-ach tochi-ach

How do insurance continuing education classes fit into *hochei-ach tochi-ach*, the notion that we must rebuke our neighbors when we see them acting in error?

Consider these summary observations about our system from various commentators over the past couple of decades:

• In **2005**, Harvard Medical School Professors Rashi Fein and Julius Richmond – the latter a former US Surgeon General – representing the medical school perspective called the American healthcare system a '**mess**'.²²

²² The Healthcare Mass, Richmond and Fein, 2005

- In **2010**, Harvard Business School Professor Regina Herzlinger, speaking at a Massachusetts health insurance association meeting and representing the business school perspective, called our health insurance system '**insane**'. ²³
- In **2011**, Otis Brawley, Chief Medical Officer of the American Cancer Society, representing the medical practitioner's perspective, summarized American healthcare as "**How We Do Harm**".²⁴
- In **2014**, Ezekiel Emanuel, principal author of the Affordable Care Act, representing the public policy perspective, called our healthcare system '**terribly complex**, **blatantly unjust**, **outrageously expensive**, **grossly inefficient and error prone**.'²⁵
- In **2017**, Elisabeth Rosenthal, Editor in Chief of Kaiser Health News, representing the medical journalist's perspective, titled her book about American health insurance "**An American Sickness**".
- In **2018**, Jonathan Engle of Columbia University's Mailman School of Public Health, representing the public health perspective, called American healthcare "**uniquely dysfunctional**".²⁶
- In **2020**, Princeton economists Anne Case and Angus Deaton the later a Nobel Prize winner representing the economic perspective, called American healthcare a "**calamity**".²⁷

Thus commentators across the board - representing medical schools, business schools, medical practitioners, public policy experts, journalists, public health schools and economists – claim our healthcare system delivers poor value, delivering suboptimal outcomes while costing more than any other country.

Yet most health insurance Continuing Education classes focus on regulations and policy forms, including insurance deductibles, Health Savings Accounts, Health Reimbursement Accounts, tax implications of various insurance programs, supplementary insurance, state and federal regulations and mandates, HIPAA and the like, all routine things that brokers deal with daily and weekly.

That is, perhaps, appropriate only in a very narrow sense.

In the larger sense, this approach ignores the deep flaws in our healthcare system. American healthcare and health insurance delivers suboptimal outcomes – our life expectancy, for example, lags other advanced, developed countries – while costing too much. Typical Continuing Education classes ignore the bigger picture, astonishingly to me, coming as I do, from the *hochei-ach tochi-ach*, we must rebuke, orientation.

²³ From my notes on her lecture, December 2010.

²⁴ Title of Brawley's 2011 book

²⁵ See the title of Ezekiel Emanuel's 2014 book about the Affordable Care Act "Reinventing American Healthcare: How the Affordable Care Act Will Improve our Terribly Complex, Blatantly Unjust, Outrageously Expensive, Grossly Inefficient, Error Prone System"

²⁶ See Jonathan Engle, Unaffordable, published in 2018

²⁷ Anne Case and Angus Deaton, Deaths of Despair

This strikes me as an opportunity for the Massachusetts Department of Insurance to practice rebuking within the educational arena, *hochei-ach tochi-ach*. But, sadly, it doesn't.

Here is one data set to highlight the poor quality of our expensive healthcare system and the rebuking opportunity available within the Continuing Education framework. See below the American life expectancy at birth data from 2019, the year before Covid. (The years during and shortly after Covid were obviously abnormal.)

In 2019, according to the US Centers for Disease Control, Americans enjoyed a life expectancy at birth of 78.8 years, on average.²⁸ That compares to:

- **82** years in Austria, Belgium, Canada, Greece, Ireland, the Netherlands and New Zealand, all countries that spend far less on healthcare per capita than we do,
- **83** years in Australia, France, Israel, Italy, South Korea, Norway, Spain and Sweden, also countries that spend far less than we do, and
- **84** years in Japan and Switzerland, ditto on the healthcare spending front.

Humans in large, economically advanced, demographically diverse countries can easily live to 83 years on average. The 10 countries listed above – from Australia to Switzerland plus others – prove this. I didn't even compare us just to the best echelon of performers above, Japan and Switzerland.

Americans fall about 5% short of the 83 year level despite spending at least double what these other countries spend on healthcare, either per capita or as a percentage of each country's GDP.

Clearly this presents an educational opportunity – an ethical requirement? - to rebuke.

Unfortunately, depressing as these figures are on the healthcare effectiveness front, they mask the gross *inequality* of our system, something that makes all this look far worse. The CDC reports, again for 2019 that non-Hispanic Black Americans, combined male and female, had a life expectancy at birth of only 72 years on average.

That's a large, distinct and identifiable group of 45 million Americans living, medically, on par with:

• North Korea, Kosovo, Moldova, Surinam, Ukraine and Uzbekistan but behind countries like

²⁸ US life expectancy data from the US Centers for Disease Control 'US Life Expectancy Increased in 2019' <u>https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2020/202012.htm</u>, and the Vital Statistics Rapid Release, Rep[ort #010 of February, 2021 by Elizabeth Arias et. al. See also the Boston Globe summary, July 20, 2021 <u>https://edition.pagesuite.com/popovers/dynamic_article_popover.aspx?artguid=05426cb9-28d8-4050-aab0-5a84029276bb&appid=1165</u>. Life expectancy data for all countries except the US from the World Bank, Life Expectancy in Years <u>https://data.worldbank.org/indicator/SP.DYN.LE00.IN</u>

• Azerbijan, BanglaDesh, El Salvador, Kazakhstan and Syria, all of which had a 2019 life expectancy of 73 years.

Shockingly again, this gets worse. Black males, about 22 million Americans, had a 2019 life expectancy of only 68.3 years. That's almost 20% worse than our (already poor) overall national average, putting them on par with:

- Kiribati, Laos, Rwanda, Senegal and Turkmenistan but behind countries like
- Guyana, Iraq and Mongolia.

I do not print this list to demean any country. Instead, I want to show how American health outcomes compare to far less wealthy countries with far inferior healthcare systems. None of the countries listed above – from Surinam and Uzbekistan to Turkmenistan and Mongolia - enjoy the bounty of healthcare technologies, providers and services available in America.

This highlights the huge inefficiency and inequality in our healthcare services and suggests some educational opportunities available within Continuing Education classes.

My ethical question to CE regulators and providers following from *hochei-ach tochi-ach*, the 'we-must-rebuke-our-neighbors' ethical standard from the Book of Isaiah: How can you ignore this in your CE course requirements? How can you leave these issues out of your 'appropriate' list of topics?

Our Continuing Education regulators *require* ethics courses but *don't follow* the ethical precepts discussed in those courses. At least, not of this one. I wonder what the prophet Isaiah and centuries of biblical ethicists would say.

The Book of Isaiah contains this admonition: "Tell My people of their rebelliousness; Proclaim their wrongs". Harsh, stern words designed to shake people up and get them to improve, yet commands noticeably absent from the Continuing Education platform.

We could, of course, teach brokers about the problems we face. Propose solutions. Expand people's thinking. Stimulate improvements through continuing education. Make our healthcare system better.

I see big a huge missed opportunity here, highlighted by our first ethical principle when applied to our current endeavor, insurance continuing education.

Ethical Principle #2: Do Your Fellow a Favor Avoid *caveat emptor* (let the buyer beware) or *mekach taut* (fraudulent sale)

Our second ethical principle rephrases, redefines and further clarifies our first. This time we'll focus on types of information for ethical brokers to disclose when presenting policy options to their clients. In *lifnei iver* terms, we'll identify some specific ways for brokers to remove potential stumbling blocks from before their (metaphorically blind) patients.

Interestingly from a Biblical perspective – and I'm still not a Biblical scholar – this ethical principle covers similar ground to *lifnei iver*. This seems to suggest that the Bible deemed this whole line of thinking tremendously important, at least important enough to discuss and emphasize it twice.

What disclosure responsibilities do health insurance brokers have both legally and ethically when they present a policy to clients?

First, brokers must honestly explain policy terms.

Second, they cannot leave out important information.

Third, they must quote the price.

But do they also have a fourth ethical requirement – to disclose policy implications, such as likely medical outcomes and medical risks? Should the broker provide clients with information about likely impacts of using their health insurance policies? Should they present clients with data about treatment practices and medical outcomes?

In other words, should the broker explain how insurance policies are often misused by poorly informed patients and how this may cause them harm? Or how the various incentives in our healthcare system combine often to provide more care than many people need, or indeed that is good for their health?

The well informed broker knows that patients sometimes overuse our medical system, meaning get excessive and unnecessary care. Some insurance programs may actually increase the likelihood of this. High deductible plans, for example, may inhibit overuse until the deductible is met, then *dis*inhibit the same behavior after. Subscribers may think 'care is now free to me – or almost free – so I might as well get as much as possible to save money next year.' Rather than generating benefit, this excessive care can only harm the subscriber / patient in two separate and distinct ways.

First in no particular order, excessive care can harm the patient, the employer group and the healthcare system *financially* through both direct and indirect additional costs. The direct costs come from copayments and other out-of-pocket spending like parking, transportation, missed work, hiring childcare and the like. The indirect costs come from increasing your company's utilization experience – or your community's – thus impacting premium cost trends over time.

Unnecessary care, in other words, increases the costs of funding our healthcare system.

Second, unnecessary and excessive care can harm the patient *medically* through error or side effects for example. This by definition. 'Unnecessary care' means care you don't need, that won't make you healthier, from which you won't benefit. But all medical care contains some element of risk, some chance of harm. The patient who receives unnecessary care cannot benefit from it – by definition – but may be harmed by it.

As a general rule, patients should avoid unnecessary care, if only for this 'potential medical harm' reason.

Many people underestimate medical risks or consider that 'low risk' or 'essentially risk free' means 'no risk'. Hmmm...

Consider the sad case of Samantha Reckis, a 7 year old girl living on Cape Cod in 2003.²⁹ Samantha ran a fever over Thanksgiving and her parents gave her Children's Motrin, about as safe and benign a medication as exists. Unknown to anyone at the time, Samantha suffered from an uncommon skin disorder called Stevens-Johnson syndrome that makes your skin feel hot, more or less like a bad sunburn. That's what her parents felt apparently when they touched her skin.

The Stevens-Johnson condition can be exacerbated by exposure to ibuprofen, an ingredient in Motrin. When Samantha's parents gave her Children's Motrin to reduce her 'fever', she had a bad reaction – so bad, in fact that it developed into a condition known as Toxic Epidermal Necrolysis, an extremely rare and painful skin condition. Over the next 9 years, poor Samantha endured multiple hospitalizations and surgeries, lost nearly all of her skin, suffered permanent lung and liver damage and became legally blind.

In February 2013, a Plymouth County jury found that Johnson and Johnson, the makers of Motrin, was at fault for causing Samantha's condition because the company had failed adequately to warn patients of this potential adverse effect. Such a notice, the jury decided, could have alerted Samantha's parents or physicians to stop using the drug and thus reduce the harms caused to Samantha. The jury awarded Samantha \$50 million and each of her parents \$6.5 million, all to be paid by Johnson and Johnson.

This is an extreme example of harms from a standard and safe medical intervention. If Children's Motrin can cause all these harms to a little girl, imagine the potential downsides and potential harms from more invasive and risky interventions.

- Vioxx for example, a drug 'as good as aspirin but with fewer stomach bleeds' led to 12,000 deaths according to a court settlement.
- Menaflex, a bovine based knee cartilage replacement, caused adverse reactions in 42% of patients in pre-approval FDA studies.
- Estimates of the harms caused by medical devices range from a low of 16,000 Americans to a high of 160,000.³⁰ (We have only this wide estimate of device harms due to the lousy data on device harms. But even the low estimate seems pretty high to me.)

Should brokers inform their subscribers of these types of risks? Should brokers tell patients how to protect themselves from harms? Or should brokers adopt the 'let the buyer beware' ethical standard and limit their own responsibilities to selling insurance policy packages?

²⁹ Family Awarded \$63 Million in Motrin Case, Wallack and Lazar, Boston Globe, Feb 3, 2013

³⁰ Jeanne Lenzer, The Danger Within Us for many more examples and details.

Research has demonstrated that above a certain level of care, generally defined as the Medicare norm in low cost regions, the excess doesn't generate patient benefit. As Jonathan Skinner, a Dartmouth Institute of Healthcare researcher summarizes

There is just no evidence that doing more helps. At best you do the same and in some cases you actually do worse [due to infections, errors, sides effects, etc.] ³¹

Other researchers have discovered that patients who receive excessive and unnecessary care actually have slightly higher mortality rates. As Elliott Fisher, Director of the Dartmouth Institute for Health Policy and Clinical Practice learned in his huge early-2000s research study on treatment variation, hospitals that spent the most on patient care and did the most tests and procedures experienced a 2 - 6% higher patient mortality rate. ³² The reason, according to Fisher, is quite simply that

The additional medicine patients get in the high-cost regions leads to the harm. 33

Fisher in his studies noted that for every 10% increase in regional medical spending per capita over the Medicare minimum, the risk of death went up. Slightly admittedly but statistically significantly. Somewhere in the ballpark of children's Motrin risk. (Samantha Reckis' story haunts me.)

More care, in other words, is worse for you than less care. Once Fisher and his cohort discovered this, an entire industry of researchers descended on healthcare statistics to determine which interventions generate the best benefits, which the most harms and, perhaps most importantly, how to determine those outcomes.

One result of this years-long effort is that researchers have learned that patients generally have 2 or more treatment options that generate roughly similar outcomes but that may pose very different risks. Not to mention different costs.

Another is that researchers determined that only a relatively small proportion of medical interventions have been tested to see how well they actually work - how effective they are, in other words.

A third is that researchers have definitively learned that more medical care isn't always better than less.

Fisher actually summarized all this research in a brief Letter to the Editor of the Boston Globe on March 2, 2018 entitled 'Check Your Assumptions at the Door.' Patients should, he recommends

Question widely held assumptions:

³¹ Jonathan Skinner, John E. Wennberg, How Much is Enough", NBER Working Paper 6513, 1998

³² Brownlee, Overtreated, page 50

³³ Fischer, et al, The Implications of Regional Variations in Medicare Spending Part 2, Annals of Internal Medicine 2003:138, pages 292 - 293

That current treatments – including drugs – all have been proven safe and effective (safe, maybe; effective, no) ...

That physicians can tell you what's best for you (they can, but only if they know what is important to you);

Or that more medical care is always better (it's not).

The system is ripe for disruption and new thinking. But it will take a fearless commitment to keeping patients at the center.

Should the broker – the 'benefits advisor' – participate in this 'fearless commitment to keeping patients at the center'... in other words, a client educational process? Or should the broker ignore current research and stick with spreadsheeting and compliance?

Should the broker teach clients how best to use their benefits and specifically their health insurance policies? Or does the broker's ethical responsibility end with arranging medical care financing?

Should the broker stick with a narrow definition of professional responsibility and let the policy buyer beware? Or should the broker adopt a more expansive definition of professional ethics?

What ethical disclosure responsibilities does the broker have?

Review Questions Correct answers on next page

- 1. Which disclosure responsibilities does the health insurance broker have according to this text?
 - a. Policy costs only
 - b. Policy coverages only
 - c. Policy coverages and gaps
 - d. Policy costs, coverages, gaps and some likely implications of using the policy
- 2. Is overuse of medical care a problem in the US today?
 - a. No
 - b. Only for orthopedic care
 - c. Primarily for cardiac care
 - d. Yes
- 3. What is one harm from having employees overuse medical care?
 - a. It increases company utilization and experience modifier thus leading to higher premiums in the future
 - b. Employees will miss too much work on physician visits and the company may lose money
- c. Employees will discuss their medical experiences too often and this may reduce workplace efficiency
- d. Employees will become paranoid about their health and workplace efficiency may suffer
- 4. What is a second harm from medical overuse?
 - a. People will face medical risks without much hope for concomitant benefit
 - b. The US economy will tank
 - c. Americans will perceive themselves as too sick to work and the economy will tank
 - d. Doctors will earn too much money and skew real estate prices
- 5. Is more care generally better than less care?
 - a. Yes
 - b. Only for orthopedic care
 - c. Never for cardiac care
 - d. No
- 6. What have we learned from research into care over-utilization?
 - a. That Americans never overutilize medical care
 - b. That overutilization is a national good thing because it stimulates medical research
 - c. That overutilization of prescription drugs helps most people avoid addiction
 - d. That over-utilization increases mortality rates
- 7. Have all medications been proven safe and effective?
 - a. Safe maybe, effective no
 - b. Safe no but effective yes
 - c. None have been proven safe or effective
 - d. All have been proven safe and effective
- 8. Is this text primarily an educational text, an advocacy exercise or a medical treatise?
 - a. Educational text
 - b. Advocacy exercise
 - c. Medical treatise
 - d. None of the above
- 9. Where does the fundamental ethical standard in this course come from?
 - a. The Bible
 - b. The Koran
 - c. The Buddah

- d. The US Constitution
- 10. This text makes several claims about health insurance brokers. Which below is not such a claim? In other words, which statement below is **false**?
 - a. Today's health insurance brokers are well trained, competent and professional
 - b. All health insurance brokers have access to the same data and pricing
 - c. All health insurance brokers understand the regulatory environment
 - d. No health insurance brokers are interested in their client's well being
- 11. This text makes several additional claims about health insurance brokers. Which below is not such a claim? In other words, which statement below is **false**?
 - a. Only some teach their clients how to navigate our complex medical care system
 - b. Only some teach their clients how to maximize their chance of medical care benefits and minimize their risks of harm
 - c. Only a few teach clients that more care may be worse than less care
 - d. Most have extensive educational programming aimed at expanding medical literacy
- 12. Which type of health insurance broker does the author prefer: one that only spreadsheets and ensures regulatory compliance or one that also teaches basic medical literacy?
 - a. One that only spreadsheets
 - b. One that only ensures regulatory compliance
 - c. One that spreadsheets and ensures regulatory compliance
 - d. One that spreadsheets, ensures compliance and teaches basic medical literacy

Review Questions

Correct answers in bold

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Why Health Insurance Brokers Need Ethical Disclosure Standards

The only effective, sustainable way to control your client's healthcare expenses is to teach them how to avoid unnecessary, ineffective, excessive and low quality medical care. That's my opening position.

Any other attempts to control healthcare expenses - financial engineering, clever insurance plan designs or ancillary programs – fail to reduce healthcare inflation. Here's the depressing historical summary: Over the past 60 years, we've tried

- Cost sharing or 'major medical' in the 1960s. These programs were inflationary so they were replaced by
- First dollar coverage or HMOS in the 1979s through 90s, the opposite of cost sharing. People complained about the restrictions so they were replaced by
- High deductible plans, the opposite of first dollar coverage post 2000. People complained about the deductible size.

We've tried

- wide hospital networks figuring that more competition would lower costs, and
- narrow hospital networks, figuring that more carrier control would lower costs;
- defined benefit plans to allow employers more design latitude and
- defined contribution plans to allow employees wider choice,
- individually underwritten plans to reward healthy people and
- community wide rates to avoid penalizing sick people and
- virtually everything in between.

Some companies have adopted ancillary programs to reduce spending like

- Wellness programs to reduce demand for medical services, but these show disappointing returns on investment if any returns at all, and
- Price transparency programs to help employees spend less for specific medical services, but these have little, if any impact outside of a few commodity services like X-rays and MRIs that are probably way overused anyway. What's the point in getting a less expensive unnecessary scan?

These programs all fail for the same reason: Patients will always find a way to access a medical service that they believe will improve their health. In other words, if patients – i.e. your subscribers – believe they need it, they'll get it.

Even if that belief is false. And there's nothing you can do about it.

The only thing we've never tried: teaching employees how to avoid unnecessary and poor quality care. That's a really promising approach.

And that's what ethical brokers should introduce.

Disclosing data on medical care quality: some ethical issues

This text will introduce medical care quality metrics. It's designed to give brokers and patients – ordinary people not trained in medicine, statistics or econometrics, not professional researchers and not nerds - the tools necessary to choose high quality, beneficial medical care and avoid low quality, ineffective or harmful care.

Once you, as a broker, understand these metrics, you'll be in a position to decide whether or not to teach them to your clients. Anecdotal evidence suggests that the better brokers understand these topics, the more likely they are to teach them to clients.

And the more ethical it makes them.

The wise patient today knows that more care doesn't mean better care. But do most of your subscribers and patients have the skills to differentiate high from low quality care, and better from poorer outcomes? I suspect not. That can put you in an uncomfortable ethical position.

Consider this evidence from the US Department of Health and Human Services. 88% of Americans, they find, are medically illiterate, meaning lack the skills necessary to assess likely treatment benefits and harms ³⁴ though I suspect the real number – the percentage of people who understand and use the tools described later in this text – is actually much lower.

Interestingly, however, virtually everyone I meet either professionally in classes or socially claims to be medically literate and generally sees themselves not only as medically literate but also very well informed about medical care. I think that underscores the problem!

Health and Human Services also claims that medically illiterate patients have higher hospitalization rates and medical costs, and poorer health outcomes, the exact opposite of broker's goals.

Knowing this, can you, as a broker, simply develop plans that raise deductibles without including a complementary education program that helps your subscribers spend their deductibles wisely? Is that really ethical? Would you want someone to do that to you?

'Do unto others as you would have them do unto you.'

How a medically literate consumer thinks

Here's a simple overview of how a medically literate person makes a medical care decision. Ask yourself as you go through this list – how many of your clients follow this protocol? And, if you don't teach it to your clients, who will?

- **First determine how well the medical intervention works** and decide if it works well enough for you. You'll need to understand what a comparative study is, and understand how to interpret the study results. I'll show you how. Different patients can make different decisions based on the same set of facts.
- **Second consider your treatment options.** You have them about 85% of the time. Learn to explore them. Again, I'll show you how.

³⁴ https://health.gov/communication/literacy/quickguide/factsbasic.htm

- Third determine which providers practitioners and hospitals generate the best outcomes for your preferred intervention. I'll show you a simple and useful way to choose. It's better than looking up lots of outdated statistical indicators on lots of hard-to-navigate-and-understand websites.
- Fourth, evaluate your insurance policy to see which providers are innetwork, which treatments are covered, what your copayments are and how to access the care you want.

I submit that an ethical broker will teach subscribers to follow this process, with the likely result that they'll tend to generate better outcomes with less risk and at lower costs.

But deviate and watch spending and risk increase and benefits potentially decline.

The Goldilocks principle

Good, proper and appropriate medical care fits the Goldilocks principle: not too little, not too much, but just right.

- Too little medical care leads to *undertreated* patients and poorer-than-optimal outcomes. Undertreated patients are harmed by their diseases.
- Too much medical care leads to *overtreated* patients and higher-than-necessary costs and medical risks. Overtreated patients are harmed by their care, not their diseases.
- Inappropriate medical care leads to suboptimal outcomes, excessive costs, patient dissatisfaction and sometimes lawsuits.

Overtreatment, and inappropriate care represent about 40% of medical interventions. I'll explain in the 'Slippage' chapter below. Attacking slippage, in other words, becomes a prime focus of ethical broker activities.

The best medical decisions

The best medical decisions come from wise, well informed patients working together with thoughtful, caring clinicians.

- **Patients** know their own hopes and fears and the benefit / risk tradeoffs they are prepared to make. Different patients, when faced with the same set of facts, can reasonably make different care decisions and all be right.
- **Clinicians** have extensive knowledge and experience that can aid a patient.
 - \circ Wise patients avail themselves of this knowledge, experience and counsel.
 - Unwise patients ignore it or delegate decision making to their clinician.

Ignoring clinician counsel deprives patients of potentially valuable insights. That's the 'art' of medical care.

Delegating decision making forces your treaters to assume or guess the benefit / risk tradeoffs you're willing to make. Studies suggest that clinicians often get this wrong.³⁵

The Slippage Problem in US Healthcare

I got this term from David Cordiani, CEO of Cigna, a huge national health insurer, who introduced it in his keynote talk at Yale's annual Healthcare Conference in April, 2015. 'Slippage' is to healthcare what 'breakage' is to shipping and 'spoilage' is to food service – stuff that goes wrong, the inevitable problems at afflict any industry.

We can estimate the amount of slippage in our healthcare system from expenditure data since we so often assign dollar values to medical interventions. Read the expenditure data below as indicators of slippage volume: when I suggest that 40% of *expenditures* are ineffective or inappropriate, I imply that about 40% of *interventions* are ineffective or inappropriate. Not an exact equality but good enough for government work.

Cordani somewhat conservatively pegged slippage at 'at least 25%' of all US healthcare spending but added that the real figure is probably much higher. Consider 25% a low estimate.

That approaches \$800 billion dollars nationally per year or about \$2500 per health insurance policy.

Using a different approach, PLOS arrived at a roughly similar conclusion by surveying physicians about the unnecessary care they provide to their own patients in 2017. ³⁶ In other words, this survey asked physicians about their own behavior and the behavior they observed in their colleagues.

The overall estimates for unnecessary care from this group of 2100 physicians:

- 20% of medical care was unnecessary,
- 22% of prescription medications were unnecessary,
- 25% of tests were unnecessary, and
- 11% of procedures were unnecessary.

Among the specific findings:

- 27% of respondents (physicians) believed that at least 30 45% of overall medical care was unnecessary,
- 30% believed that at least 30 45% of prescriptions was unnecessary,
- 38% believed that at least 30 45% of tests were unnecessary,

³⁵ Mulley et al, Patient Preferences Matter

³⁶ Overtreatment in the United States, Lyu et. al. September 6, 2017 <u>https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0181970</u>

• 16% believed that at least 30 – 45% of procedures were unnecessary.

This strikes me as a big deal.

In 2018 a Washington State survey used yet another approach to put some meat on this slippage / unnecessary care bone. The Washington Health Alliance analyzed utilization and billing data from 2.4 million commercially insured patients who used 47 oft-overused services, and found that 45% of services delivered were wasteful accounting for 36% of medical spending.

Cordani's 'at least 25%' waste estimate might be low.

The Washington study is noteworthy for a couple of reasons. First the Washington Health Alliance, the group responsible for this study, consists of virtually all the hospitals, insurance carriers and large benefits agencies in the state. This report was cowritten by the Washington State Medical Association and the Washington State Hospital Association, essentially the medical establishment in Washington.

Second, the group identified overuse from the Choosing Wisely list. Choosing Wisely is a creative and very useful medical decision making tool that far too few patients know or use.

Choosing Wisely

Choosing Wisely is funded by the American Board of Internal Medicine Foundation that basically asked lots of specialty medical associations to submit a list of service that their members do but that don't generally benefit patients. Among the 70+ organizations that submitted a list: the American Academy of Allergy, Asthma and Immunology, the American Academy of Family Physicians, the American Academy of Dermatology, the American College of Cardiology and many more.

Each partner organization submitted at least 5 services that 'physicians and patients should question' because of the low level of benefit provided (if any benefit at all) and / or high level of patient risk.

Choosing Wisely is a useful, albeit low bar for poor quality care.

The Washington State folks identified 'appropriate' care as care that is

- Supported by evidence
- Truly necessary
- Not duplicative of other tests or procedures already received and
- As free from harm as possible.

They used Choosing Wisely's list as the basis for determining low quality care and waste, defining low quality care as

• Likely wasteful, meaning there are serious questions about the appropriateness of the service, or

• Wasteful, meaning the service was very likely unnecessary and should not have occurred.

Remember that 'likely wasteful' and 'wasteful' care is, while clearly subjective, defined both by Choosing Wisely – i.e. the various medical specialty organizations - and the state hospital and medical establishment. Again, a pretty conservative bar.

Third, the Washington State report focused on 47 commonly overused services of which just 11 common tests, procedures and treatments represented 93% of the overuse. That list includes preoperative tests and lab studies prior to low-risk surgery, too frequent cancer screenings, eye imaging tests for people without significant eye disease, annual EKG tests or cardiac screening for people with low risk of heart disease, and imaging for uncomplicated conditions such as low back pain.

In other words, the Cordani and PLOS systemic slippage estimates are supported by the Washington State details indicating that (a) slippage is a huge financial problem and (b) it comes from a relatively limited number of services.

Brokers thus can focus their educational efforts fairly narrowly and have a potentially great impact on their client's health and finances. Our question: is it ethical to do so? And should they?

Five kinds of slippage

Let's expand on the Washington State definition of low quality care to identify 5 types of medical interventions that can generate patient harm and financial waste:

- Care that doesn't work or works so badly that you don't want it
- **Care that works on some people** but likely not on you for reasons like age, sex, overall health and, surprisingly, socio-economic status
- **Care that works in tests but is overused in real life** so quite possibly won't benefit *you*
- Care that you don't want when you learn of your treatment alternatives
- **Care from low quality providers** (clinicians and hospitals) when higher quality providers are available.

I'll discuss all these in more detail below.

How to avoid slippage

Identifying slippage is Step 1. Avoiding it is Step 2.

My suggested slippage avoidance process: teach your clients *to ask the right questions of their doctors*. I'll discuss those questions later in this text.

I developed this process for two main reasons:

First, extensive research shows that most patients trust their doctors and value the patient doctor relationship. Attempts to undermine or go around it seemed doomed to failure.

Patashnik, Gerber and Dowling argue in their excellent book Unhealthy Politics that physicians are the most credible source of patient information, far more than 'studies' or 'guidelines'. ³⁷ Any attempt to undermine physician credibility, in their and my opinion, will simply fail.

My questions therefore enhance the doctor-patient discussion process. Remember that doctors are all highly trained, have access to all the relevant literature, are experienced you and generally welcome patients sharing their hopes, fears and concerns. At least, that's what physicians report.

Second, very few patients are 'medically literate' and able to understand, evaluate and critic medical studies and reports.

This doesn't mean people are stupid!

Rather, it means they haven't had the necessary training. Medically illiterate folks – even if they're otherwise very well educated – need guidance when googling to understand complex information about medical technology and science.

I don't see the utility of showering medically illiterate folks with data and study conclusions. You end up with 'This study shows surgery benefits but that study shows medication benefits. I'm confused so I'll ask my doctor' and you go to my first reason above.

My questions and the discussions they prompt can overcome those problems. These questions allow your subscriber's physician – their most trusted medical advisor - to interpret complex information and apply it to them.

But who in our complex healthcare system, teaches your subscribers how to talk with their doctors? There's clearly a need as demonstrated by the waste data presented above. Seems to me we as a healthcare system, and brokers as a profession, have dropped the ball on this.

Why Brokers? The problem of advice bias and three types of care

Who advises people NOT to receive medical care or to question routine medical advice and care? In our healthcare financing system, physicians are paid to treat. They have a financial incentive to intervene for they generally do not get paid unless they do

³⁷ Patashnik, Unhealthy Politics, chapter 3

something to the patient. Many studies have shown that surgeons tend to recommend surgery far more than non-surgeons do, and sometimes more than patients need.

But physicians, as Patashnik, Gerber and Dowling argued above, are patient's most trusted advisors.

Thus we see a biased medical advice system. Practitioners generally only make money by providing medical care. No one in our healthcare system is paid to advise patients against medical care. No one, in other words, balances the economic intervention interests of clinicians.

'But my doctor suggested that I not have this procedure' goes the superficial but true counter argument. Put this into a tri-partied context.

- Some care is clearly necessary, meaning that virtually all physicians evaluating the same patient would recommend it.
- Some care is clearly unnecessary, meaning that virtually no physicians evaluating the same patient would recommend it.
- And some care is in the gray area, meaning that some physicians might recommend it while others might not.

The 'my doctor recommended against this procedure' statement probably falls into category 2 above, though possibly category 3 too.

The advice bias problem arises only in category 3, the gray area. Research suggests that this is perhaps the largest of the 3 categories.

How large is each category? In other words, what percentage of medical care falls into each? John Wennberg, founder of the Dartmouth Institute, answers this in his book Tracking Medicine. ³⁸ He calls our category 1 'effective care' defined as services that, on the basis of reasonably sound medical evidence, are known to work better than any alternative. This group of treatments accounts, based on his research, for only about 15% of all medical care.

Wennberg calls our category 3 above, the gray area, 'preference sensitive' care meaning care for which there is more than one option and in which different people can make difference decisions and all be correct. Preference sensitive care requires judgment and individuality to evaluate the risk-benefit tradeoffs.

Consider torn or injured rotator cuffs, for example. A surgeon will likely examine the patient, identify a rotator cuff tear and recommend surgery. But a physical therapist, reviewing the same data on the same patient, might well suggest physical therapy, at least to start. Is one right and another wrong?

That situation arose for a student of mine, a licensed health insurance broker in his 60s who managed to tear his right rotator cuff. 'It was so weak and sore' he told me, 'that I

³⁸ Wennberg, Tracking Medicine, pages 8 – 10, then Parts II and III

couldn't shift the gears on my pick up.' It apparently had a gear shift next to the steering wheel.

He went on to tell me that he visited an orthopedic surgeon who took an MRI, identified the cuff tear, and recommended surgery. 'I would have agreed to surgery' he went on to say, 'prior to hearing your lectures and reading your books.' (See – there actually is some value to continuing education classes!)

'But I asked the surgeon if all physicians would agree with that analysis and recommendation. He answered with a snort that some might suggest physical therapy but that would be a waste of time and that I'd be back in his office shortly thereafter.'

My former student decided to try PT and reported when next I saw him that his shoulder was pain free and that he had regained 99%+ range of motion – it might have been 100% but he wanted to be conservative - in the same time as surgical recovery but without the costs and risks of surgery. 'Thanks' he smiled as he relayed the story.

Wennberg estimates that preference sensitive care represents about 25% of medical spending, making our category 3 larger than category 1, the clearly beneficial group of treatments.

Wennberg goes on to describe supply sensitive care, or the 60% of medical spending that is about the frequency with which patients get treatments. Physician decisions, he claims, are strongly influenced by the capacity of the local medical market. Areas that have more surgeons experience more surgery; areas with more Neo Natal Intensive Care Units have more babies admitted to NICUs; areas with more cardiac catheterization beds have more cardiac catheterizations, etc.

How often should a physician see patient in pain, suffering from a chronic condition or desiring to feel better? Once a month? Once a quarter? Semi-annually? The answer, according to Wennberg:

The doctor will sort it out based on how sick an individual patient is and how many opening he has in his schedule. Specialists tend to fill their appointment books to capacity. ³⁹

Thus a physician might say to a patient 'I'd like to see you again in 3 weeks', but the office booking clerk, seeing that the doctor is booked for the next 6 weeks, asks the doctor if waiting 6 weeks is OK. 'Fine' the doctor replies, raising the question of why he or she originally wanted to see the patient in 3 weeks.

This is sometimes called Roemer's Law, named after a healthcare economist named Milton Roemer who discovered that if more hospital beds exist in a region, there are more hospitalizations.

³⁹ This discussion comes from Maggie Mahar, Money Driven Medicine, page 172, including Wennberg's quote.

And it's sometimes called 'supply induced demand.' A hospital buys a new MRI machine and suddenly lots of patients need MRIs. Or when a new dermatology practice opened near my house, I tried to get an appointment only to learn that they were fully booked for the next 3 months. How was that possible for a new practice? According to Wennberg, they simply saw patients more frequently to fill up their calendars. (I don't know if that was the reason but it certainly seemed likely.)

Wennberg's estimate that 25% of medical spending goes to preference sensitive care and 60% falls into the supply sensitive category highlights the problem of advisor bias. And our current fee-for-service physician payment system exacerbates it. Your physician might consciously think 'I'd like to see this patient again in 3 weeks' and subconsciously 'and I'll get paid to see her.'

Or 'this procedure will probably help the patient' and subconsciously 'and I'll get paid to perform it.'

Does this actually happen? Let me quote conclusions from 3 recent studies on the impact of fee for service payments on physician recommendations:

- On average a 2 percent increase in payment rates leads to a 3 percent increase in care provision, with elective procedures responding most strongly to pricing incentives.⁴⁰ In other words, when physicians get paid more to do something, they do it more frequently.
- When specialists are paid through a fee-for-service scheme rather than on a capitation basis, surgery rates increase 78%. ⁴¹ Again, the more specialists are paid, the more they tend to do.
- Patients seeing fee-for-service ophthalmologists were twice as likely to have cataract surgery as patients seeing doctors in capitated systems. Interestingly the number of cataract surgeries dropped by 45% within 6 months after a studied ophthalmology group of physicians switched to a capitated payment contract. ⁴² Or, in the vernacular, physicians respond to financial incentives.

Thus we see a systemic bias in favor or patients receiving more medical care based on the advice – potentially biased - that they're likely to get. This makes medical service different from, for example, legal services.

⁴⁰ Do Physician's Financial Incentives Affect Medical Treatments? Clemens et al, <u>https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2101251</u>

⁴¹ Shafrin, Operating on Commission: analyzing how physician financial incentives affect surgery rates, Health Economics <u>http://onlinelibrary.wiley.com/doi/10.1002/hec.1495/abstract</u>

⁴² Effect of Physician Reimbursement Methodology on the Rate and Cost of Cataract Surgery, Shrank, 2005 <u>https://www.ncbi.nlm.nih.gov/pubmed/16344447</u>

In court the prosecution and defense attorneys argue different interpretations of the same facts, more or less, in John Wennberg's terms, different preference sensitive interpretations. The judge or jury then decides who is right.

But in medical care, patients only have one interpretation, that of their own physician. Patients generally rely on one interpretation and rarely have the skills to question it. (Yes, patients sometimes get second opinions and these can be incredibly useful. But only if they're used in specific ways. I'll get to that.)

We lack in medicine the 'alternative interpretation' feature that opposing attorneys offer in legal services. Where do patients learn how and when to question tests and procedures, especially common ones – things like the eye imaging tests, cancer screenings and annual EKGs that the Washington State report highlighted as waste?

Carriers might play that role – but the managed care experience of the 1990s has turned popular opinion against trusting carriers too much.

Second opinions are too cumbersome. Who wants to get a second opinion when the doctor says 'let's run this test to rule out' something or other? Or when your doctor says 'it's time for your annual mammogram'? Or even 'your cholesterol level is getting high. The guidelines recommend that I put you on medication to lower it.' 'High' to your doctor may be 'moderate' for the patient, assuming, of course, that the patient is medically literate, an assumption that is incorrect 88% of the time according to HHS.

Even if patients get a second opinion, it may be from another doctor in the same practice who may have an informal – perhaps even unconscious – motivation to support his/her colleague.

That leaves the broker. Should the broker advise clients of potential risks of easy availability of medical care? How much should the broker inform clients about systemic abuses? In sum...

What ethical disclosure responsibilities does the broker have to protect his/her client from unnecessary / excess treatments and the related potential medical harm?

Review Questions Answers on next page

- 1. What is the only effective, sustainable way to control your client's healthcare expenses?
 - a. Promote medical literacy
 - b. Raise deductibles
 - c. Introduce a wellness program
 - d. Ration employee access to medical care
- 2. Roughly what percent of Americans is medically literate?
 - a. 12%
 - b. 50%

- c. 75%
- d. 100%
- 3. Roughly what percent of Americans consider themselves medically literate and well informed about medical care according to this text?
 - a. 12%
 - b. 50%
 - c. 75%
 - d. 100%
- 4. Which statement is true about medically literate patients?
 - a. Medically literate patients have lower hospitalization rates and medical costs
 - b. Medically literate patients have higher hospitalization costs
 - c. Medically literate patients have higher medical costs
 - d. Medically literate patients have poorer medical outcomes
- 5. This text outlined a 4 step medical decision making process. Which below is not one of those steps?
 - a. Determine how well a medical intervention works for your ailment
 - b. Explore your treatment options
 - c. Learn which provider doctor and hospital does that treatment the best
 - d. Pray
- 6. How does this text differentiate undertreatment from overtreatment?
 - a. Undertreatment increases the risk of being harmed by the disease; overtreatment increases the risk of being harmed by the care
 - b. Undertreatment is like rationing
 - c. Overtreatment means you are harmed by a different disease
 - d. Undertreatment costs the healthcare system much more
- 7. About how much slippage exists in US healthcare?
 - a. Less than 5%
 - b. About a third
 - c. More than 80%
 - d. More than 90%
- 8. What is ChoosingWisely?
 - a. A list of treatments that patients and clinicians should question and likely avoid
 - b. A list of really good treatment
 - c. A list of the best medications
 - d. A list of the best hospitals
- 9. What is one lesson from the Washington State study?
 - a. That wasteful and low quality care represent over a third of all medical spending
 - b. That environmental factors drive most healthcare spending

- c. That environmental factors do not drive most healthcare spending
- d. That commercial insurance policies control spending very well
- 10. John Wennberg of Dartmouth identified 3 categories of medical care. Which below is not one of them?
 - a. Necessary and effective care
 - b. Preference sensitive care
 - c. Supply sensitive care
 - d. Alternative, low cost care like herbs and potions
- 11. Which below is most credible to most patients?
 - a. Double blind controlled studies
 - b. Guidelines published by medical specialty associations
 - c. Research studies from famous medical schools
 - d. Recommendations from the patient's own doctors
- 12. What approach does this author recommend for helping patients avoid wasteful care?
 - a. Learn the key questions to ask their doctors so they focus discussions on likely outcomes
 - b. Read lots of medical studies from high quality research institutions
 - c. Learn the guidelines that relate to your medical problems
 - d. Get opinions from others who have had your medical condition treated successfully

Review Questions

Correct answers in bold

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Overview of Disclosure Ethics

The Biblical View of Business Ethics: 'Do not do unto others as you would not like done to yourself' 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.

The Business Ethics Center of Jerusalem defines business ethics as 'the value structure that guides individuals in the decision making process when they are faced with a dilemma of how to behave within their business or professional lives.'43

Ethical business considerations fall into two separate categories.⁴⁴ First, business ethics regulates conduct in direct contact situations, such as with employees, clients or suppliers. These commonly fall into standard categories including employee relations, honest representation and truth in advertising.

These types of ethical issues have an immediacy or personal effect: lying to a customer may induce that person to buy the wrong product. Shading the truth may persuade a client to purchase a policy that benefits the broker inappropriately. In both cases, the only party harmed is the party in direct contact with the unethical broker.

Second, business ethics involves social responsibility. These ethical issues consider how much all of us must take responsibility for society as a whole. Ethical social behavior, for example, includes protecting our natural resources, caring for the poor and providing equal educational opportunities to all.

⁴³ See <u>www.besr.org/DCPage.aspx?PageID=198</u>

⁴⁴ This discussion comes from <u>www.besr.org/DCPage.aspx?PageID=199</u>

This course will deal primarily with the first type of ethical business considerations – the direct contact situations – though we will make some social responsibility types of ethical observations also.

Unequal Knowledge about our Healthcare System

What does 'unequal knowledge about the healthcare system' mean?

Brokers typically know a great deal more about our healthcare system than do their clients. Among the areas of broker expertise:

Underwriting guidelines Regulations Provider cost data (at least rough and crude measures) Outcome data (again, rough and crude measures) Treatment complication data (assuming a well informed broker) And several similar categories.

We will explore the broker's ethical responsibilities to share all available information with their clients.

In developing our overall position on the ethics of disclosure, we will rely primarily on the Torah. Why?

The Torah also known as the beginning of the Old Testament or Five Books of Moses, has served as the moral and ethical foundation of our Judeo-Christian western civilization for thousands of years.

Virtually all the great historical ethicists and philosophers had a deep understanding of the Torah's teachings. These permeate our shared views of right and wrong, morals and ethics, and have done so for a very long time.

Some Judeo – Christian Business Ethical Positions on Disclosure: Start with Abraham's purchase of a burial plot for his wife Sarah

In the first commercial transaction in the Torah or Old Testament, Abraham laid down the 'full disclosure' commercial principle.⁴⁵

The story of Abraham purchasing a burial plot for his wife Sarah is instructive from our ethical viewpoint. The haggling over land takes five steps in Genesis 23: 3 - 20:

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';

⁴⁵ This interpretation is entirely my own and not entirely in line with typical or traditional religious commentaries. The genesis of this interpretation comes from <u>www.torah.org</u> Business Ethics: The Challenge of Wealth and various commentaries including *Parchas Chayei, Parchas Sarah, Parchas Metzora, Parshas Shoftim* and *Responsa-Vayigash.*

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';

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 employee'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.

Caveat emptor 'Let the Buyer Beware' is Unethical

The lesson about this transaction? That in the Torah there is no 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 ethical business lesson of Genesis 23: 3 - 20.

'Let the buyer beware' also assumes that all parties have not only equal information and equal access to information but also equal abilities to understand the information

available. In the Biblical case, Abraham was only able to understand the intricacies of burial plots after being educated by the seller. Is this concept still valid today? Can 'let the buyer beware' serve as a valid basis for commercial transactions?

The answer is no. Traditional Torah ethics remain valid today for two main reasons.

First, sellers and buyers rarely have exactly the same information. The seller virtually always knows his / her products far better than the buyer. The simple reason is that the seller deals in this market – for this product – far more frequently than does the typical buyer.

Today's health insurance broker, for example, spends his or her entire professional life dealing with health insurance policies. The broker constantly hears customer and market feedback – 'I thought the policy covered this but my claim was rejected' or 'The specialist my doctor recommended wasn't in network' or 'This carrier answered all my questions completely and handled my claim quickly' for example.

The buyer, on the other hand, probably only deals with health insurance issues once or a very few times per year. This puts the buyer at an information disadvantage. He or she simply can't know as much about the products, carriers, markets and nuances as the pro who deals with these issues daily.

This was clearly the case for Abraham, whose expertise did not include detailed knowledge of local burial plots. That's why he relied on the seller's representations and information – he had no other option.

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.

How many of your clients know and understand the systemic information presented earlier in this text?

Thus for these two reasons – that the broker has both *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.

Mekach Tau or fraudulent sale

According to traditional Talmudic law, it is forbidden to sell an item—whether moveable items or real estate—if the item is defective. If this is done without informing the buyer of the defect before he completes the purchase, the seller is perpetrating a fraud. ⁴⁶

The prohibition is not necessarily or only a function of price, i.e. charging full price for a defective product. Instead, it is an issue of the seller misleading the buyer either intentionally or unintentionally. (Sema 228:7)

Sometimes defining faulty products is simple. Selling a broken watch, for example, is clear: if the watch doesn't tell time, then it is faulty. Two issues here. First intent. Did the seller intend to deceive the buyer? If so, then various compensation modes become relevant. Second quality. Even if the seller did not intend to defraud the buyer, then the doctrine of *mekach tau* still holds.

But selling a product designed to maintain your health becomes dicey. What do commentators say about a product that buyers use as designed but that makes buyers less healthy, something like insurance payments for Aduhelm, the Alzheimer's product we discussed earlier in this course? Is the broker who sold the coverage that funded Aduhelm committing an ethical transgression?

Or can the broker claim *caveat emptor*, let the buyer beware, and hide behind the argument 'I only arrange healthcare financing. Not my job to ensure that my client spends the money wisely.'

Do Your Fellow A Favor

The Torah and various commentaries clearly provides the answer. According to this doctrine of *mekach tau*, the seller is obligated to make full disclosure of any defect in the goods or services sold. We have already discussed this.

Rabbi Dr. Meir Tamari, an expert on business ethics, states this clearly and strongly, 'there is no Jewish basis for the "let the buyer beware" concept'.⁴⁷ He continues:

Such philosophy presupposes that all the players in the market possess the same access to information regarding price, quality and comparative markets. They are able and are required to ascertain the truth of the state of the playing field, and if they do not, that is their problem.

The problem, of course, is that no such market exists or can exist. The seller virtually always knows more about the product, the applications - and the misapplications - than the buyer as we discussed above.

⁴⁶ This discussion comes from Mind the Blemish: Principles of Mekach Ta'us <u>https://dinonline.org/2016/03/04/mind-the-blemish-principles-of-mekach-taus/</u>

⁴⁷ Tamari, Honesty in Business Dealings, <u>https://www.besr.org/library/honesty.html</u>

Tamari continues 'if there is a flaw in the goods [or services] one is obliged to reveal it to the buyer' otherwise 'the sale is cancelled [the buyer cannot be forced to accept a discount in lieu of the defect] ... there does not need to be any intent to defraud; even if sold in good faith, the seller still bears responsibility and the sale may be cancelled'.⁴⁸

Thus, the health insurance broker who claims 'I didn't know that the policy contained that' has no ethical defense: Jewish law makes the seller responsible to understand fully all the implications of each health insurance policy.

What about the broker who claims 'not my job to watch how people use their health insurance'?

Rabbi Tamari addresses this in the Business Ethics Guide, Economic Justice in a Jewish Perspective. ⁴⁹ He quotes the Rabbis that 'he who does not *do his fellow a favor*, is not of the sons of Abraham' for 'we force one to act contrary to the selfishness of Sodom'.

This answers our questions above. The seller must first educate the buyer and make full disclosure about the policy's coverage. But second and equally important, the seller must *do his fellow a favor* and highlight problems with the health insurance policy that *may* occur. In other words, highlight ways that people use their health insurance in ways harmful to their health.

Why would Jewish law --- which later became Judeo-Christian ethics – place such a burden on sellers?

There appears some thinking that these burdens ultimately work to the advantage of the seller. If all sellers act ethically as described above, then it becomes very easy to sell products to buyers. The reason: buyers would have a very high degree of confidence in the seller's representations.

Business Ethics = Business Efficiency

In doing this, the Torah advises us to *put business long term financial interests ahead of short term profit goals*.

If everyone followed the Torah's teachings, in other words, we would have a very well functioning business economy. The Torah can be seen as a manual for how to prosper in business. We'll read its various ethical teachings in this light.

Ethical sellers – i.e. those who follow the Torah's teachings - would not have to prove their honesty or credibility. They could concentrate, instead, on selling products. This is very efficient: sellers could focus on their income generating activities (i.e. sales) rather than spending time explaining or justifying their personal ethical standards, or establishing personal credibility. They would thus generate higher incomes.

⁴⁸ Tamari, Honesty in Business Dealings, <u>https://www.besr.org/library/honesty.html</u>

⁴⁹ <u>http://www.besr.org/library/responsa/economic.html</u>

Abraham's burial plot sellers, apparently, had this credibility, as there is no mention of Abe searching for other plot sellers. He did not shop around for a 'better deal'. He was – apparently – satisfied with his seller's ethical positions and chose to do business with him.

The religious laws outlined above ultimately work to the seller's advantage.

Efficiency and Health Insurance Sales

Let's apply this standard to health insurance brokers. If we all *do our clients a favor* and warn them about risks of healthcare systemic abuse and excess, then we may help control healthcare inflation. By *doing our clients a favor*, we may serve the interests of our entire economy by reducing healthcare costs.

In short, we do well for our clients and do well for our country by doing our clients a favor. We also, according to the Torah, do well for ourselves as brokers by adhering to this ethical standard.

Whose Interests Should the Broker Protect?

This ethical disclosure standard seems to require brokers to act against physician and hospital financial interests by educating clients about medical risks, waste and low quality care – teaching them, in other words, how to make wise medical care decisions. Providers, under our fee-for-service financing arrangements, have an economic incentive to treat, and often to overtreat, up to about 40% of the time according to the data presented earlier. Brokers, under this standard, have the burden of countering these physician economic incentives.

Seen in this light, the Torah's teachings may set up a conflict in our healthcare economy. Let's look at the gray area, in which a subscriber may or may not need treatment, and discuss the economic incentives facing each party. (Ethical discussions always focus on gray areas, as these are the difficult cases. There's no ethical dilemma in an easy or obvious case.)

Providers – physicians and hospitals – have an economic interest in treating and make the most money by providing the most treatment. The lens through which they view the patient may – consciously or unconsciously – include their own financial self interest. 'Patients of this type', they may think, 'often improve with treatment.'

Upton Sinclair, and American writer in the early 1900s, summarized this problem succinctly while campaigning for governor of Illinois:

It is difficult to get a man to understand something when his salary depends on him not understanding it.

When in doubt, our economic system tends to motivate providers to treat.

Patients with health insurance generally have little or no *economic* incentive to avoid treatment. They purchased insurance exactly for this situation. They generally

have minimal out of pocket costs, depending on their policy type and deductible situation. Even a \$1000 or \$3000 out of pocket payment pales in comparison to a potentially life saving treatment or to treatment that eliminates a chronic pain.

In addition, patients who are sick or in pain are often scared and want to trust someone who offers relief. The reassuring physician who counsels 'I have treated many patients like you successfully' provides exactly the advice that the patient wants to hear.

Thus, our systematic incentives may induce unnecessary treatment for patients in the gray area. The providers gain, but the patient doesn't pay.

Who Wins and Who Loses in the Gray Area?

This seems, at first cut, a win-win situation. The provider wins – gets paid. The patient wins – gets better. Even if the patient doesn't improve much, he/she didn't pay much. No harm, no foul.

Except for two problems. First, in the US, a great deal of care generates little to no patient benefit, as discussed earlier. But the provider always gets paid. Our 'win-win' becomes 'providers win, patients get nothing' around 30% of the time.

Those odds might be attractive to patients if medical treatments were risk-free - if we never had treatment complications, then reasonable and rational patients might decide that a 70% chance of improvement is good enough. They might discount the 'no benefit' risk and agree with their physician's advice to receive treatment.

Unfortunately, however, medical treatments are never risk-free. This is the second problem. There are always complication risks. Remember Samantha Reckis from earlier in this course? She's the little girl on Cape Cod who went blind from taking children's Motrin. Expanding on this, consider these data points from a large Johns Hopkins study published in 2016:⁵⁰

- 250,000 Americans die from medical errors annually,
- 10% of US deaths are due to medical error
- Medical errors are the 3rd leading cause of death in the US.

In addition, according to a 2018 survey of 6700 physicians, 691 or slightly over 10% reported that they themselves had made a medical error in the previous 3 months. 51

This is not the business efficiency envisioned in the Torah's ethical discussions. This is very inefficient and unethical: one group in our society (providers) wins with every transaction while another (patients) loses fairly regularly.

⁵⁰ Johns Hopkins study released May 3, 2016

https://www.hopkinsmedicine.org/news/media/releases/study_suggests_medical_errors_now_third_leading_cau se of death in the us

⁵¹ Physician Burnout, Well-being and Work Unit Safety Grades, Tawfik et. al, Nov 1, 2018 https://www.mayoclinicproceedings.org/article/S0025-6196(18)30372-0/fulltext

They sometimes lose big time.

The Broker's Education Responsibility

What group in our society can counter the providers? Who can give warnings to patients about risk? Who can give unbiased advice to patients about when to trust providers and when not to? Who can act – in Biblical terms – like Abraham's burial plot seller?

I suggest that the broker has these responsibilities. This is a wider definition of broker duties than is currently common in our industry. But it is the definition that follows from the ethical standards discussed in the Torah.

Is it enough simply to describe the health insurance policy in detail?

Such a description would include a discussion of copayments and deductibles, preexisting condition 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 the Torah's ethical requirement.

The broker also has an ethical responsibility to describe policy implications – the likelihood of benefit and harm from using the health insurance policy.

And the broker has an ethical responsibility under the 'do your fellow a favor' principle to teach clients how to identify and avoid wasteful and / or harmful medical care.

How Much Should Brokers Disclose?

The question posed by Rabbi Tamari in Parchas Shoftim above, in the discussion of *do the fellow a favor* remains: How much should a seller disclose about a product to a customer?

Tamari starts with the religious doctrine of Mekach Taut or 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 unclear from Genesis 23 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 the lessons of Genesis to more complicated transactions, like health insurance policy sales.

Is it a 'product defect', for example, if someone goes to a less expensive and also lower quality in-network hospital and picks up an infection? Or if someone opts for surgery and has a complication, only to learn later that physical therapy might have been a wiser choice? Or if someone takes a heart attack prevention medication, later has a heart attack and subsequently learns that the medication was proven ineffective in comparative studies?

That's why the Rabbis expanded their discussion to include *do the fellow a favor*. Now we have the ethical tools to address this question.

Review Questions Answers on next page

1. What does 'let the buyer beware' mean?

a. That the buyer should beware that the seller is probably lying when he/she represents something

b. That the buyer should beware that the seller is probably taping the transaction to protect him/her self in the event of a fraud accusation

c. That the buyer should beware that the product probably contains hidden defects that the seller is not under any legal or ethical obligation to disclose d. That they buyer must do his/her own product research because the seller feels him/her self under no ethical obligation to disclose product details

2. What does 'let the buyer beware' assume?

a. That the buyer understands that the seller is probably lying when he/she represents something

b. That all parties to the transaction have equal abilities to understand the product information available

c. That buyers have a certain minimum level of intelligence

d. That sellers have less than a certain minimum level of intelligence

3. Is 'let the buyer beware' an ethical or unethical standard?

a. This is an ethical standard

b. This is not an ethical standard. In fact, it is unethical

c. It is only an ethical standard for service type products like health insurance

d. It is generally an ethical standard but is inappropriate for service type products like health insurance

4. What does 'do your fellow a favor' mean?

a. That buyers should help sellers whenever possible

b. That sellers should try to put themselves in the buyer's position, and should educate buyers as they would like to be educated themselves if they were the buyer

c. That sellers should embrace 'the selfishness of Sodom' thus creating a more competitive market

d. That buyers should embrace 'the selfishness of Sodom' thus putting more demands on the seller

5. Is 'do your fellow a favor' an ethical standard?

a. No

b. Yes

c. Only when the buyer figures that the 'favor' is worth less than the product in question

d. Only when the buyer figures that the 'favor' is worth more than the product in question

Review Questions Correct answers in bold

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Some Concrete Ways for Health Insurance Brokers to 'Do Your Fellow a Favor' and to Avoid 'Letting the Buyer Beware'

We discussed the low quality and wasteful care problems earlier in this text. Let's drill down on the issue here as a brief summary.

Our fee-for-service healthcare financing system is weak at generating outcome data - we have fewer follow-up studies than we should. Many argue that this is due to our billing system: providers get paid based on inputs – procedures performed – rather than on outcomes. This can create a disincentive to study care effectiveness. Studies showing that treatments generate poor outcomes may hurt them economically.

Ditto for drug manufacturers, device manufacturers, hospital and other participants in the healthcare system. All exhibit a reluctance to engage in outcome studies.

As a result, medicine today is less scientific than we would like to believe. Here's Shannon Brownlee, author of *Overtreated*, articulating the treatment outcome problem over the past few decades and continuing until today:

Much of what doctors were doing was based more on hunches than good research. There were gaping holes in medical knowledge even when it came to something as seemingly mundane as a tonsillectomy. ⁵²

And here's Harvard Business School Professor Michael Porter on the issue of choosing the 'best' physician or hospital:

Physicians generally lack information on results, or their efficiency in achieving results, that is essential for knowing if they are doing their job well...most physicians lack any objective evidence of whether their results are average, above average or below average. ⁵³

As a result, medical practitioners rely on guidelines or norms. Not always a good idea. Yale Medical School Professor Dr. Sherwin Nuland explains the problems using routine standards or current 'care norms' as decision making justification:

Better watch out or the pendulum swing of medical dogma will bash your head in. It swings back and forth far more often than most people realize and with greater velocity.

Thirty years ago patients with inflammation of ... the colon were routinely treated with a diet low in roughage. There was no uncertainty about this course of

⁵² Brownlee, op cit, page 27

⁵³ Porter and Teisberg, Redefining Health Care, page 54

action...and yet, a few years later, medical opinion reversed: decreased roughage was found not to be a panacea but a cause of the disease.

This new medical discovery was announced in the same assuredness and supported by just as much evidence as had been used for precisely the opposite viewpoint. ⁵⁴

This is sometimes called Medical Reversal, today's in-vogue term to describe how we embrace a treatment for a while only to reject it years later when it's shown to be nonbeneficial or harmful. Nuland summarizes one such incidence above. Vinay Prasad in his brilliant book Ending Medical Reversal lists dozens more including

Estrogen replacement therapy for postmenopausal women to reduce heart attacks, a treatment he claims 'was of no benefit to the heart.... Doctors stopped recommending it not because we discovered something better, but because we never should have used it in the first place.' ⁵⁵

Coronary stent insertion to prevent heart attacks in asymptomatic patients until the COURAGE study showed that stents did not help patients live longer. ⁵⁶

Vertebroplasty or insertion of medical grade cement into brittle vertebra to strengthen the bones and take pressure off the nerves. This became a billion dollar a year business in 2012 even though two 2009 studies showed that patient pain reduction was the same in the placebo and treatment groups. Patients, companies – your clients – spend a billion dollar a year on a treatment works no better than a sham!

And over 140 more in his book's Appendix.

Prasad argues that much of what doctors do is unfounded in science and is, simply, wrong. This can help us focus on the broker's ethical disclosure issue. Should the broker, armed with a company's claims experience and recognizing that some employees have preventive stents or vertebroplasty, inform the client of these issues?

Clearly brokers cannot give medical advice. They're not qualified or licensed to do so and should avoid doing it, despite the fact that I regularly hear about brokers giving medical advice. One, for example, told me in class that clients often ask her how to choose a primary care physician. Her shocking answer, shocking to me at least: look for a PCP with specific training in your issues of concern.

'If you have gastro-intestinal problems, for example, look for a PCP who is trained in internal medicine. If you have orthopedic problems, ask your potential PCPs if they have any advanced training in orthopedics.'

⁵⁴ Sherwin B. Nuland, 'Medical Fad: Brain, Midwives and Leeches' New York Times, June 25, 1995, section 4, page 16.

⁵⁵ Prasad, Ending Medical Reversal, pages 2 – 3

I say 'shocking' because I know of no studies showing that those kinds of PCPs generate better patient outcomes than a control group and neither did this broker. (See why a basic knowledge of comparative studies is useful?)

But I see a potential lawsuit on the horizon. (I'm not a lawyer.) What happens to a client who follows this broker's advice, chooses a PCP and has a bad medical outcome? Might the client sue the broker for poor advice? (I'm still not a lawyer and have no idea is this is realistic or not. But why would a broker open herself to such potential problems?)

I will argue instead that brokers should teach clients how to identify and avoid unnecessary, ineffective and wasteful medical care. Two reasons for this. First, the company hires the broker to help control healthcare costs, to save money on healthcare in other words. Part of this professional responsibility includes helping the company avoid wasting money on ineffective care.

That seems to me part of the broker's fiduciary responsibility, and a core part at that.

Second, under the 'do your fellow a favor' ethical standard, the ethical broker should preemptively educate clients before they waste money on ineffective care. What would Abraham have said if he bought a cemetery plot for his wife and only later learned that the seller knew Abe was purchasing non-cemetery land but didn't say anything in advance? The Rabbis would label that unethical and so, I suspect, would most reasonable people today.

Today's broker knows about healthcare waste, low quality care and care harms based on their own studies and professional education if not only from the data presented in this text. You have the knowledge. Is it ethical to withhold it from your clients? We've clearly seen, under the 'do your fellow a favor' standard, that it is not.

The ethical question has, thus, shifted from '*should* the broker disclose information about healthcare system waste to the buyer?' to '*how* should the broker disclose this information?'

The Process of Disclosure in today's healthcare system

Dr. Prasad echoes many researchers in claiming that clinicians rely on hunches rather than facts far too often. Science gives us facts; hunches give us guesses.

I propose that Step 1 in client disclosure and education starts with explaining how medical science arrives at facts and how to differential facts from hunches. That process – science in other words – relies on comparative testing.

Comparative tests tell us if and how well a medical intervention works in real life, on real people.

When testing, medical researchers typically divide a large group of people in half to make 2 identical smaller groups. They give one group the treatment but not the other. ⁵⁷

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

Here's a simple visual representation of a comparative study for a hypothetical heart attack preventive medicine. The Treatment Group gets the medicine while the Control (or Placebo) Group does not. In this case, for simplicity purposes, I've assigned 100 people to each group. Note that this example is not based on any actual medication and is presented only to show what a comparative study looks like.



Can you determine how well the medicine worked to prevent heart attacks? In this example, the medicine prevented 4 heart attacks per 100 people over 5 years.

Simple! Actually not simple at all. Medical research methodology is very complicated and worthy of many texts, each much longer than this. But this example shows the essence of what a comparative study is. In effect, this example shows how the science tells us how well medical care works.

Scientifically determined outcomes, 'facts' in other words, rely on comparative study data. That's how researchers determined that vertebroplasty worked no better than a placebo to reduce back pain, that estrogen didn't protect postmenopausal women from having heart attacks and that stents in stable patients did not prevent heart attacks....among lots of other things.

⁵⁷ Research methodology is extremely complicated. If you're interested in learning more, check out Know Your Chances by Woloshin et al. It's an easy to read introduction to medical statistics and research methodology.

But what happens if you don't have 5 years available? Say that a new heart attack prevention medicine just came on the market, looks promising and you, a person with some elevated heart attack risk, have a doctor's appointment the next day.

Your doctor may say 'this is the newest generation of heart attack preventive medicine and has been configured to reduce the side effects of the old drug. I suggest you try it and see how you tolerate it.'

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

Dr. Prasad studies that issue. He asks in his research 'how well do medical interventions work if they haven't been subjected to comparative tests?'

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

Prasad and his team conducted a fascinating study summarized in his book Ending Medical Reversal. They reviewed every article in the New England Journal of Medicine between 2001 and 2010 and pulled out those that tested an established medical practice, i.e. subjected an established medical practice to a comparative study. Established medical practices are those commonly used on patients like inserting stents into stable patients and, at least for a time historically, prescribing estrogen to postmenopausal women to prevent heart attacks ... interventions that made medical sense and that the medical community embraced.

363 studies qualified.

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

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

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

We'll call this Prasad's Law at restate it clearly here: Medical interventions that haven't been subjected to comparative testing are ineffective or harmful about half the time. How do we know that they're ineffective or harmful? We learn this when they're subsequently tested, potentially many years in the future.

But that's after patients have used it!

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

gravitate toward the nuts and bolts - what does it do, how does it work?

But the real question is: Does it work? What evidence is there that it does what you say it does? What trials show that it actually works?

You shouldn't ask how does it work, but whether it works at all. 58

He goes on to claim that 'of all those things we're doing currently that lack good evidence, probably about half of them are incorrect.' ⁵⁹

Why is this the case?

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

Here's an analogy to illustrate: 60

Assume that our bodies are controlled by a wizard located in our brain, more or less like the fellow behind the curtain in the Wizard of Oz.

The wizard in our brain has a wall of knobs that control body parts and functions - one controls cholesterol levels, another blood pressure, a third bone density, a fourth eye ball pressure, etc.

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

We simply can't account for all the initial effects, rebound effects, interactions and modifications from turning a knob or two. We don't always know, for example, how turning a knob 2 feet high 100 yards from here affects a level controlled by a knob 3 feet high 300 yards away. And how either of these affects a knob 4 foot high 400 yards away. Or the impact of the last knob change on the first. And so on.

Medicine rarely works in the simplified 'if A causes B, and B causes C, then A causes C' scenario.

⁵⁸ Quotes from Nicholas Bakalar, Medical Procedures May Be Useless, or Worse, New York Times July 26. 2013, italics added

⁵⁹ These are quotes from Dr. Prasad's video

http://www.mayoclinicproceedings.org/cms/attachment/2007391767/2029532458/mmc3.mp4 . Some minor edits for grammar and syntax

⁶⁰ I've adapted this example from David Newman, Hippocrates's Shadow, page 202

Now, as an ethical broker, do you think this is something your clients should know? A meaningful way to 'do your fellow a favor' is to explain what a comparative test is and why using test data as the basis of medical decision making is so important.

Or do you prefer to 'let the buyer beware' and endure the same client decision making mistakes next year as last. And as the year before that.

And then, when your client complains that premiums increases are too high, simply raise deductibles and say 'wellness program' more loudly...just like last year, the year before and the year before that.

Medically well informed patients always ask 'has it been tested for the outcomes that concern me?'

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

If answers exist.

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

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

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

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

Examples of medical care that *should* work, but doesn't Case studies that illustrate the power of ethical disclosure education

I'll present 6 case studies to show the power of asking 'has it been tested for the outcomes that concern me?' and why you need to ask this question about every medical intervention: ⁶¹

- Niaspin, an HDL 'good cholesterol' boosting drug
- Atenolol, a blood pressure lowering drug
- Zetia, a cholesterol lowering drug
- Vertebroplasty, a back surgery technique
- Arthroscopic knee surgery, a knee osteoarthritis remedy

⁶¹ All reference notes for this section appear at the end of this text
• Rest after heart surgery, an historical example to tie everything together

Niaspin, an extended release niacin drug. Niacin, a B vitamin, has been shown in tests to raise good (HDL) cholesterol. More good cholesterol is associated with a lower heart attack risk, so artificially raising it benefits patients, at least in theory.

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

Cardiologists have prescribed various niacin products for years. One, Niaspin manufactured by Abbott Labs, generated about \$900 million in 2009 sales from about 8 million prescriptions. i

In 2011, the AIM-High trial of niacin effectiveness showed that, while extended release niacin *is* associated with higher HDL levels and lower triglyceride levels, this *does not* translate to a reduction in cardiovascular events like heart attacks and strokes. ⁱⁱ

In 2013, a second study, this time of Merck's niacin drug Tredaptive found the same thing: no difference in coronary event rates between people taking Tredaptive with a statin, and those just taking the statin. ⁱⁱⁱ

Dr. Steven Nissen, Chief of Cardiology at the Cleveland Clinic, summarized the Tredaptive study findings: It raised good cholesterol. It lowered bad cholesterol. It didn't improve clinical outcomes. That is a stunning finding. ^{iv}

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

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

Patients who bought and took Niaspin received no heart attack or stroke reduction benefit from it.

They only exposed themselves to side effects like burning, tingling, itching, headaches, stomach upset, intestinal gas, dizziness, and redness of the face, arms, and chest. ^v

Plus the price of Niaspin pills.

Atenolol, a blood pressure lowering drug

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

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

Atenolol recorded \$161 million in 2014 sales.vii

Unfortunately comparative study hard outcomes do not support the theory.

Start in 2003 with publication of the LIFE study on two of the most commonly prescribed blood pressure lowering medications - also called beta blockers - losartan and atenolol. ^{viii} Neither outperformed the placebo.

In an accompanying European Heart Journal editorial, Dr. Franz Messerli, writing for the European Society of Cardiology concluded

the LIFE study should be considered as the final straw that will break the camel's back and hopefully motivate physicians to no longer expose their elderly hypertensive patients to the cost, inconvenience, adverse effects, and most importantly, to the inefficacy of beta-blockers.

That was followed up by a 2004 meta review (a compilation that integrates results from several different studies to develop a single conclusion) in the Lancet entitled 'Atenolol in hypertension: is it a wise choice?' ^{ix} Those reviewers found that

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

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

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

Let's summarize:

- One major, high quality comparative study in **2003** concluded atenolol generates 'no benefit'
- A large meta study in **2004** concluded 'no benefit'
- Physicians writing in various highly regarded journals who reviewed the underlying study data between **2003 and 2005** recommended *against* prescribing these drugs

• Six years later, docs wrote 36 million Atenolol prescriptions and ten years later Atenolol achieved \$161 million in annual sales.

I hope you're beginning to understand why you need to ask if it has been subjected to comparative testing about *every* medication.

And find out what those test results are.

Even for medications that have been around for a long time.

Zetia, a cholesterol lowering drug. Zetia (ezetimibe) lowers cholesterol by blocking its absorption in the intestines, unlike statins that block cholesterol absorption in the liver.

Some patients can't tolerate statins.

Others might not achieve their desired cholesterol reduction goals with statins alone.

Zetia offers benefits to both types of patients: those who can't tolerate statins and those who don't achieve their cholesterol goals from lifestyle changes and statins alone. As Zetia's website, zetia.com, said from about 2011 - 2016 \times

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

Zetia's annual sales ranged between about \$1 and \$4 billion since 2008.

Unfortunately for Zetia users and the people who pay for it, we should also point out the next sentence on zetia.com, the one following 'Adding Zetia to a statin is proven to help reduce cholesterol more than a statin alone', this one written in bold

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

The New York Times review of Zetia's 2008 clinical trial, concluded it xi

... failed to show that the drug had any benefits...[and]

... no trial has ever shown that it can reduce heart attacks and strokes

Our old friend Steve Nissen from the Cleveland Clinic (of Atenolol fame above) called these results 'shocking'. xii

Harlan Krumholz, cardiologist at Yale Medical School went even further, asking 'How can a drug have \$4 billion in sales without any evidence of benefit?' xiii

Vertebroplasty to relieve back pain Let's switch focus now from medications to procedures. Consider vertebroplasty, a procedure to inject medical grade cement into fractured vertebra (back bones) to reduce back pain. It's a minimally invasive procedure with a low complication rate, about 1 - 3%.^{xiv} Complications include soft tissue damage, nerve root pain and compression, pulmonary embolism, respiratory and cardiac failure and death.

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

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

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

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

Dr. Rachelle Buchbinder, lead author of the Australian study, recommended that vertebroplasty not be performed outside of research settings. There are some risks, she reasoned, without any demonstrated patient benefits.

Did any of your own clients have vertebroplasty? If so, are these the clients who demand that you lower their healthcare costs?

See where this goes?

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

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

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

• A 2002 New England Journal of Medicine study estimated 650,000 procedures at \$5,000 each, creating a \$3.25 billion market. ^{xvii}

- A 2014 NEJM study estimated the market at 500,000 knee arthroscopies at about \$20,000, generating a \$10 billion market. xviii
- Vinay Prasad in his 2015 book Ending Medical Reversal estimated the market at 700,000 patients spending \$4 billion.xix

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

- A 2008 New England Journal of Medicine published study concluded that they 'failed to show a benefit of arthroscopic surgery for the treatment of osteoarthritis of the knee' xx
- This followed a 2002 comparative study which concluded 'At no point did [the] arthroscopic-intervention group have greater pain relief than the placebo group'
- In addition, 'objectively measured walking and stair climbing were poorer in the débridement group than in the placebo group at two weeks' (Treatment side effects really matter!)
- The 2002 study concluded 'This study provides strong evidence that arthroscopic lavage with or without debridement is not better than and appears equal to a placebo procedure in improving knee pain and self-reported function.' xxi

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

These studies raise some uncomfortable questions:

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

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

Asking encourages your doctor to check (again?).

Never hurts but may help.

A lot!

Rest after heart surgery, an historical example to tie all this together. We'll start in the early 1900s with Dr. James Herrick's advice then fast forward to today's protocols.

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

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

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

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

Rest in bed should continue for 4 - 6 weeks to ensure firm cicatrisation of the ventricular wall ... Patients have lost their lives ... by neglect of these precautions. xxiii

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

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

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

But by the 1960s medical opinion reversed. Braunwald in an overview of cardiac practices, claims doctors began to realize that

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

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

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

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



1950s 1970s 2000s How can 'rest' and 'don't rest' both be right? They obviously can't. At least one is wrong. Drs. Herrick, Thomas and Woods offered their *best guesses* backed up with biological justifications. In effect, they said 'our best guess is that the risk of ventricular rupture exceeds the risk of venous thrombosis and fatal pulmonary thromboembolism' (if they even knew those risks existed).

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

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

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

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

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

The ethical broker's next step: Help clients interpret test results

Let's return to our simple comparative study example in which 7 people in the placebo group had heart attacks and 3 did in the treatment group. How does a medically literate patient discuss these results?

This presents a golden opportunity for brokers to teach clients how to interpret and discuss treatment benefits with their doctors.

The standard, correct **and useless** way to summarize the tests results is 'this medicine cut the heart attack risk by 57%.' (The math is quite simple: 7 people in the placebo group had a heart attack. 4 people avoided a heart attack by taking the medicine. 4/7 is 57%.)

Though correct, this is not useful for medical decision making.

57% of what?

- In this case, 57% of 7 per 100. (I'm getting confused by all these numbers and I'm writing this stuff!)
- But here's another example of a 57% risk reduction. From 3 in 10,000 to 1.29 in 10,000 over 10 years. That's a 57% reduction.
- Or from 5 in a million to 2.15 in a million over 15 years. That reduction of 2.85 events per million people over 15 years is, again, a 57% reduction.

Preventing 4 heart attacks in 100 people over 5 years may seem like a pretty good benefit.

• But preventing 2.85 heart attacks in a million people over 15 years seems like a pretty small benefit. (If you're not totally confused by now you should consider yourself brilliant.)

Here's a general rule of thumb for reporting test results: whenever you hear expressions like '57% better than', or 'reduces your risk by 57%', ask '57% *of what*?'

- If it's 5 in a million, then a 57% reduction is a pretty insignificant number.
- But if it's 7 in 100, then you probably want to pay attention.

Percentage reductions like 57% better than sound more impressive than they really are. I'd even say that whenever someone quotes study results in this way they're trying to sell you something. That's why retail vendors – refrigerators, clothes, appliances - tend to quote prices in percentage off. It sounds bigger than it is.

- 'Prices slashed by 57%' sounds big.
- 'Prices slashed by \$4.38' sounds small.

It's the same in medicine.

A better way

I propose that brokers teach clients to ask these two simple questions to learn the results of comparative tests:

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

Ask '**out of 100**' to get a number for your answer. '4' for example, conveys more information than 'some', 'many', 'a few' or 'quite a few'.

Some patients may decide that 4 people benefiting is good enough to have the treatment while others say 'only 4? That's not very many'. Different people can reasonably interpret the answers differently. That's the essence of a doctor-patient discussion: apply information to the particular desires of a specific patient.

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

Age: The American Academy of Pediatrics recommends against prescribing cough and cold medications for respiratory illnesses in children under 4 saying 'these products offer little benefit to young children and can have potentially serious side effects'. ^{xxix} They're apparently fine for 6 or 8 year olds - or 30 or 40 year olds – but not for very young children.

... out of 100 people ... these medications work, but

... like me ... not if you're under 4 years old

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

... out of 100 people ... the medication works, but

... like me ... not so well for women

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



An interesting *like me* category that most people don't consider but that an ethical broker should discuss: social status

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

The notion that social status impact disease rates and treatment effectiveness was first introduced in the Whitehall studies during the last 1900s. These studies tracked disease and death rates by job and rank in the British civil service and their conclusions have been reproduced in other studies, in other countries.^{xxxi}

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

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

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

Over and above specific disease risk factors, Whitehall concluded, there is something about social status *independently* that impacts people's health. Harvard School of Public

Health Professor Nancy Kreiger, whose own work affirms Whitehall's conclusions, put it this way:

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

A major 2016 study in JAMA, the Journal of the American Medical Association found that the life expectancy gap between the richest 1% of Americans and the poorest was about 12 years on a gradient similar to Whitehall's. In an accompanying editorial, Nobel laureate Angus Deaton emphasized the impact of income and social status on health and castigated traditional medical thinking:

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

Consider the medical impacts of your own social status. Let's say that after examining you, your doctor says 'your cholesterol level is slightly higher than I'd like. The guidelines suggest lowering it. I'll prescribe a medication.'

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

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

It did for me.

Define the benefits that matter

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

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

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

And be as specific as possible.

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

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

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

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

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

The doctor's answer was apparently satisfactory.

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

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

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

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

Some case studies to indicate the power of asking this question Real life situations that develop from ethical disclosure actions:

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

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

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

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

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

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

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

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

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

Comparing 'out of 100 people like me...' to 'the guidelines say...' Case study of hypertension

The American Heart Association recommends that people over 60 years old begin treatment for high blood pressure when their readings exceed 150/90. ^{xxxv}

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

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

Out of 100 people over 60 years old with moderate to acute hypertension, how many avoid cardiovascular disease or death over 4.5 years?

Answer: About 4

Here are Cochran's numbers:

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

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

This case study shows why the ethical broker doesn't simply 'let the buyer beware' and rely on some set of guidelines but instead 'does his fellow a favor' and teaches a better question to ask.

What if your doctor can't answer these questions?

Prasad's Law! If your doctor can't answer these questions, the medical intervention hasn't been studied thoroughly.

It's ineffective or harmful about half the time. xxxvii

Period.

That's why asking these questions is so important!

An alternative metric that some ethical brokers have introduced

A different version of 'out of 100 people like me, how many benefit and are harmed' has been developed by researchers over the past couple of decades. It's called the Number Needed to Treat (NNT) and Number Needed for Harm (NNH).

The Number Needed to Treat tells us how many people need to take a particular medication, or have a test, for one person to benefit. An NNT of 1 means that if 1 person takes this medication, then 1 person will benefit from it.

But an NNT of 50 means that 50 people need to take a medication for 1 person to benefit. We get NNT data from comparative studies (remember them?)

Consider this comparative study of the same heart attack prevention medicine we introduced earlier. Can you estimate the number of people who need to take the medicine to prevent 1 heart attack?



In this hypothetical example, the medication prevented 4 heart attacks per 100 people who took it. Therefore 25 people had to take the medicine to prevent 1 heart attack. The Number Needed to Treat or NNT is 25.

Once you know this, you can compare treatment effectiveness. In fact one group of clever researchers has developed an entire website based on NNT calculations called, not surprisingly, TheNNT.com. This site lists the Number Needed to Treat and to Harm for lots of different interventions.

Here's a sample to show the power of using NNT calculations to choose a heart attack prevention treatment for people without heart disease and who have not had a heart attack.⁶²

- The NNT for statins to prevent a non-fatal heart attack is 104.
- The NNT for statins to prevent a stroke is 154.

Now consider the Number Needed for Harm from statins:

- The NNH for developing diabetes is 50.
- The NNH for muscle damage is 10.

This means that 104 people need to take statins for 5 years to prevent 1 non-fatal heart attack. But 2 of those 104 people will develop diabetes and 10 will experience muscle damage.

This example shows how you can compare benefits and harms from a medical intervention.

Let's now look at how to compare benefit from different medical interventions. This time we'll compare statins to adopting a Mediterranean Diet.

• The NNT of statins to prevent 1 heart attack among people with no heart disease and who have not previously had a heart attack is 104.

⁶² The statin calculation comes from <u>http://www.thennt.com/nnt/statins-for-heart-disease-prevention-without-prior-heart-disease-2/</u>. The Mediterranean Diet calculation comes from http://www.thennt.com/nnt/mediterranean-diet-for-heart-disease-prevention-without-known-heart-disease/

• The NNT of people who adopt the Mediterranean Diet is 61.

In addition, some people were harmed by the statins – we discussed that above – while none were harmed by the Diet. (Remember that I don't give medical advice. These are just some research summaries.)

These metrics, the NNT and NNH, give patients a clear way to compare treatments and to decide which works best, just like the 'out of 100 people like me, how many benefit' question discussed above. Both metrics get to the same answers but some people prefer one to the other. I thought it useful to introduce both in this section.

Review Questions Answers on next page

- 1. What, according to this text, is the basis for many / most medical recommendations?
 - a. Scientifically determined facts
 - b. Physician hunches
 - c. Medical research
 - d. Physiology and anatomy
- 2. How do we determine facts in medicine?
 - a. Through comparative studies
 - b. By analyzing biology and physiology
 - c. By hunches
 - d. By algorithms
- 3. What is a comparative study?
 - a. Divide a large group of subjects in two, then give one of the two groups the treatment and the other a placebo
 - b. Compare different people who take the same medicine to get a good overview
 - c. Compare the effects of medical care on lots of different people
 - d. Study how well a medical intervention works in the real world
- 4. What is Medical Reversal?
 - a. Stop doing something that doesn't work
 - b. Take different drugs to reverse the impact of the initial drug
 - c. Redo or undo a surgery
 - d. Go to a second doctor when you are not satisfied with the first
- 5. How often do subsequent comparative studies lead to Medical Reversal?

- a. About half the time
- b. Less than 5% of the time
- c. More than 95% of the time
- d. Always
- 6. What is a good follow up question when you learn that 'this medication cuts your chance of having a heart attack by 57%'?
 - a. 57% of what?
 - b. Really?
 - c. So you recommend it?
 - d. Would you take it yourself?
- 7. Which is a better metric: Asking 'Out of 100 people like me, how many benefit?' or asking 'What is the NNT of that treatment?'
 - a. Asking 'out of 100 people like me, how many benefit?'
 - b. Asking 'what is the NNT of that treatment?'
 - c. Neither is a good question for your doctor
 - d. Both questions mean essentially the same thing
- 8. If you have a medical treatment that has not been subjected to comparative testing, what is the likelihood that your will receive no benefit from the care?
 - a. 50%
 - b. 4%
 - c. 85%
 - d. 99%
- 9. What is Prasad's Law?
 - a. A penny saved is a penny earned
 - b. Medical interventions that have not been subjected to comparative studies are shown to be ineffective or harmful about half the time when they finally are tested
 - c. The most hospital beds in a region, the more hospitalizations
 - d. Never start a land war in Asia
- 10. Which factor below was shown in the Whitehall studies to impact disease rates and life expectancy?
 - a. Social status
 - b. Childhood exercise rates
 - c. Prenatal care
 - d. Driving distance to your primary care doctor

- 11. If the Guidelines recommend treatment, does this always mean a large number of people will benefit?
 - a. Yes
 - b. No
 - c. Yes for preventive care but no for chronic
 - d. Yes for chronic care but no for preventive

Review Questions

Correct answers in bold

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 - a. Yes

b. No

- c. Yes for preventive care but no for chronic
- d. Yes for chronic care but no for preventive

Integrating These Ethical Standards Into a Discussion with a Benefits Administrator

Consider this situation: A Benefits Administrator for a large company puts the company's benefits out to bid. Two brokers respond. Both offer similar plans at similar prices. Both are experienced. Both are professional. Both offer all the standard services -401(k) administration, FSA administration, wellness programs, etc. Both are impressive.

The Benefits Administrator tries to find some reason to choose one broker over the other. Since they appear to be mirror images of each other, he has little to choose. So he asks both brokers 'why should I choose you?'

Broker A talks about experience: 20 years in the business, a good customer service reputation, intimate knowledge of carriers and plenty of references. Broker A talks about his commitment to clients and interest in helping clients. He even offers to meet with the Benefits Administrator quarterly to provide policy and regulatory updates.

Certainly, thinks the Benefits Administrator, Broker A is fine. There's nothing wrong with him. A solid choice.

Then Broker B comes along. This broker also has years of experience, a good customer service reputation, good relations with the various local insurance carriers and plenty of references. This broker also offers to meet quarterly to discuss policy and regulatory updates. (Both brokers, it seems, value face time with the Benefits Administrator.)

But in addition to all these services, Broker B makes a surprising statement:

My company has a clear business standard that defines our relationship with clients. The ethical standard that we embrace is called 'Do Your Fellow A Favor'. I've studied business ethics and decided that I want my company and my employees to live up to this standard.

Many of my competitors use a different ethical standard. They 'let the buyer beware.'

Intrigued, the Benefits Administrator asks Broker B to continue.

I won't save you any premium money in the short term as compared to Broker A. He's a fine broker who is perfectly capable of running rates and showing alternative policies.

I won't show you any plans that he doesn't. And I offer all the same services as he does.

But in addition to offering everything that he offers, under my 'do your fellow a favor' standard, I'll also educate your employees about how to use our healthcare system.

I'll tell them things about the healthcare system that they probably won't learn from their doctors but that may help them interact with their doctors. I'll help them become wiser consumers of medical care.

The Benefits Administrator starts to yawn as Broker B continues:

Better educated consumers, who shop more wisely, use medical resources more efficiently. In the long run, this may save you money....maybe quite a bit.

The Benefits Administrator suddenly perks up:

You'll save us money? Explain. Give me an example.

Broker B then summarizes:

I noticed that in the past few years, several of your employees had vertebroposty procedures for their back pain. A few others had arthroscopic knee surgery for knee osteoarthritis. (Broker B apparently really did his homework.)

I also noticed that several take Atenolol and quite a few took Niaspin over the years.

All these treatments have been shown in comparative studies to work no better than a placebo.

That means you may have wasted your company's money on ineffective treatments, and your employees exposed themselves to medical risks without receiving any benefit.

'What?' the Benefits Administrator bursts out, shocked. 'How can you say that?' Broker B continues:

As part of our 'Do Your Fellow a Favor' educational campaign, we teach people how to identify and avoid unnecessary and low quality medical care. A key part of that educational process involves teaching employees what a comparative study is and how to understand the results.

I'm happy to include you in our seminars, but for now I'll just summarize some studies. Both of those procedures – vertebroplasty and arthroscopic surgery to treat knee osteoarthritis – have been shown to be ineffective in comparative studies. Neither benefited patients more than a sham procedure.

Ditto for Niaspin and Atenolol.

While we don't tell your employees what specific care to get or to avoid – we're not licensed or trained for that - we teach them the skills to evaluate care quality and to discuss this with their doctor. Studies show that employees who have these skills get better medical care, with less risk and at significantly lower costs.

And they tend to avoid ineffective treatments, like the ones I mentioned.

I, of course, don't know which of your employees had these procedures or which took those medications. I only know that it's highly unlikely that they received any benefit from them.

'So,' says the Benefits Administrator, somewhat stunned 'having this information available may reduce my employee's rate of ineffective care. That could affect our Experience Modifier and save us some premium money in the future. Interesting.'

Broker B continues:

The US wastes about a trillion dollars annually on ineffective and unnecessary medical care. Your company alone probably wastes tens of thousands.

Our 'Do Your Fellow a Favor' program aims to reduce that, not by restricting access but by helping your employees make wiser medical care decisions and talk more effectively with their doctors.

It's a new approach in the benefits arena but one that shows great potential.

And it's risk free: people only participate if they want to. But we're finding that lots of employees really want access to this information and pay attention when we present.

'Interesting,' comments the Benefits Administrator. 'I've never heard of that approach but it seems to make sense to me. We would probably need a custom approach to our employees since we work 2 shifts and have several people off-site.'

Broker B responds:

Each company is different and we always try to fashion the educational process around the company's needs. The information content is similar but our approach varies by client.

In the end, the Benefits Administrator considers the two brokers. One who takes the 'let the buyer beware' approach about dealing with our healthcare system. The other who 'does his fellow a favor'.

Which will help my employees the most, he wonders.

In the end, the Benefits Administrator chooses.....Well, who would you choose?

How Should an Ethical Broker Proceed?

The British think death is inevitable; Canadians think death is preventable; Americans think death is optional.⁶³

Shannon Brownlee summarizes an underpinning of our overuse of medicine in *Overtreated*: ⁶⁴

Our relentless search for wellness through medicine has created a kind of therapeutic imperative, the urge to treat every complaint, every deviation from the norm, as a medical condition.

If we test or intervene with every new development along our normal aging process, we'll abuse our medical system --- and likely generate more unnecessary and counterproductive care, and perhaps higher mortality rates.

We've come to believe that if a test can be performed, it should be performed... [almost] regardless of whether the intervention will improve the patient's sense of wellbeing.

Maybe an old French proverb got it right: the physician's job is 'to cure sometimes; to relieve often; to comfort, always.'

The ethical, sensitive broker understands this and helps clients accordingly.

Clearly no broker can keep current on all healthcare literature and advise clients on all healthcare decisions. That's beyond any human's capabilities.

But, as we have argued in this course, the ethical broker has a responsibility to advise clients not only on policy details but also on likely treatment outcomes, and to help clients chose policies that improve chances of treatment successes.

We have outlined some issues in this course. Many, many more exist.

Hopefully, we have pointed brokers in the right direction, both for ethical advising and for their own future research.

But in this concluding chapter I'd like to offer some general advice for how best to act ethically including practicing *lifnei iver* (removing stumbling blocks from before your

 ⁶³ I don't know the origin of this expression. I first heard it from John Kingsdale, Director of the Massachusetts
Healthcare Connector, at a speech at the Boston Harvard Club sponsored by the Pioneer Institute of 1/15/09.
⁶⁴ Brownlee, op cit, page 206. Same source for the next quote and the French proverb.

clients), *hochei-ach tochi-ach* (rebuking your clients when they erroneously make unwise decisions) and *do your fellow a favor*: ⁶⁵

1. Educate yourself about our healthcare system.

The more you know about our healthcare system, the better you can help your clients.

Today's bookstores are full of insightful and useful books about healthcare. Some that I have found particularly useful include

Overtreated by Shannon Brownlee; **Ending Medical Reversal** by Vinay Prasad **Overdiagnosed** by by H. Gilbert Welch **An American Sickness** by Elisabeth Rosenthal **Know Your Chances**, by Steven Woloshin **Doctored** by Sandeep Jauhar **How We Do Harm** by Otis Brawley **The Quality Cure** by David Cutler **Mistreated** by Richard Pearl

Typical feedback from brokers who have these books is that they contain fascinating and very useful information. Ethical brokers use that information their normal professional work. folks.

I'd also add a few of my own books, though my perception of their quality and value may be biased:

How to Be a Patient Beyond Deductibles Consumerism and Value Creation in American Healthcare Transparency Metrics

Help your clients understand the importance and utility of their primary care doctor. Help them find primary care doctors with whom they can communicate easily.

2. Help your clients ask questions. Help them remember that doctors are guides to medicine, not gods to be believed unquestioningly.

Here are 5 questions I regularly teach people to ask.

- Has the proposed treatment been subjected to comparative tests?
- Out of 100 people like me, how many benefit and are harmed by it in tests?
- Is it overused in real life?
- Would most doctors make the same treatment recommendation or might some suggest something different?

⁶⁵ Some of this advice comes from the Afterward of Overtreated. See Brownlee, op cit pages 308 - 310

- How many patients like me do you treat annually?
- 3. Help your clients use the web appropriately, not excessively. I often encourage people to focus their internet research on 3 sites:
 - ChoosingWisely
 - The US Preventive Services Task Force and
 - Cochrane

These 3 non-financially-conflicted resources present good analyses of likely medical intervention outcomes.

I tend to stay away from other sites.

Help your clients to have the courage and skills to advocate for themselves, for in the end, all healthcare decisions are ultimately their own.

We have, in the Judeo-Christian ethical tradition, thousands of years of business experience. Hopefully some of the ideas in this course will help today's health insurance brokers continue that ethical tradition.

http://www.ncbi.nlm.nih.gov/pubmed/15530629

ⁱ Armstrong, Abbott Doubled Niaspin US Sales Before Trials Cut Use, Bloomberg, June 10, 2013

https://www.bloomberg.com/news/articles/2013-06-10/abbott-doubled-niaspan-u-s-sales-before-trials-cut-use ⁱⁱ This sentence paraphrases the New England Journal of Medicine discussion of the AIM High study http://www.nejm.org/doi/full/10.1056/NEJMoa1107579#t=article.

http://www.reuters.com/article/merck-cholesterol-idUSL1N0BREGB20130227 and For a good summary see CBS News estimate, Study: Heart Drug Tredaptive is Ineffective, Jonathan Lapook, July 29, 2013
CBS News, op cit

^v This list comes from WebMD <u>http://www.webmd.com/vitamins-supplements/ingredientmono-924-niacin%20and%20niacinamide%20vitamin%20b3.aspx?activeingredientid=924&</u>

^{vi} http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/WhyBloodPressureMatters/Why-Blood-Pressure-Matters_UCM_002051_Article.jsp

vii http://www.pharmacompass.com/sales-forecast/atenolol

viii See 'The LIFE Study: The straw that should break the camel's back' by Franz Messerli for a brief summary in the European Heart Journal, March 2, 2003.

^{ix} A meta review is a comparison of several tests. Meta reviewers study, for example, the methodology of each individual test to ensure that researchers didn't goof somewhere along the line.

[×] I had used this example in lectures for several years. When I visited the site in late December 2016, I discovered that it had been replaced with a 'prescribing highlights' pdf in small print.

^{xi} Drug Has No Benefit In Trial, Makers Say, Berenson, NY Times, January 14, 2008

^{xii} Ibid.

xiii Another Vytorin Mess for Merck, Herper, Forbes, Nov 15, 2009

^{xiv} Estimate from Johns Hopkins Health Library

^{xv} For a good summary of those studies, with expanded comments, see Sham-Wow by Walter Eisner in Orthopedics This Week, August 11, 2009, https://ryortho.com/2009/08/sham-wow/

^{xvi} Kirkley et al, A Randomized Trial of Arthroscopic Surgery for Osteoarthritis of the Knee, NEJM, September 11, 2008

^{xvii} Moseley et al, A Controlled Trial of Arthroscopic Surgery for Osteoarthritis of the Knee, NEJM, July 11, 2002
^{xviii} These estimates from Cram, et al, Total Knee Arthroscopy Volume, New England Journal of Medicine, Sept 19, 2014. I was unable to develop a specific number of procedures by year, nor estimate the annual growth rate of knee arthroscopies.

^{xix} Prasad, Ending Medical Reversal, page 22

^{xx} Kirkley, op cit

^{xxi} Moseley, op cit

^{xxii} Braunwald, The treatment of acute myocardial infarction,

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760555/

^{xxiii} Silverman et al, British Cardiology in the Twentieth Century, Chapter 27

^{xxiv} Julian, Ischemic Heart Disease in Dialogues in Cardiovascular Medicine, 2006 <u>http://www.dialogues-</u> <u>cvm.com/document/DCVM40.pdf</u>

^{xxv} Silverman, op cit.

^{xxvi} Braunwald, op cit.

^{xxvii} WebMD, Recovering after heart surgery, <u>http://www.webmd.com/heart-disease/guide/heart-disease-</u> recovering-after-heart-surgery#1

^{xxviii} WebMD, op cit.

^{xxix} ChoosingWisely, American Academy of Pediatrics, <u>http://www.choosingwisely.org/societies/american-academy-of-pediatrics/</u>

^{xxx} CBS News 60 Minutes, Feb 9, 2014 <u>http://www.cbsnews.com/news/sex-matters-drugs-can-affect-sexes-differently/</u>

xxxi See, for example, Isaacs and Schroeder, Class – The Ignored Determinant of the Nation's Health, New England Journal of Medicine, September 9, 2004 <u>http://www.nejm.org/doi/full/10.1056/NEJMsb040329</u>, Drexler, The People's Epidemologists, Harvard Magazine, March-April 2006 <u>http://harvardmagazine.com/2006/03/the-peoples-epidemiologi.html</u>, The Panel Study of Income Dynamics at the University of Michigan

<u>https://psidonline.isr.umich.edu/</u>, and Bradley and Taylor, The American Healthcare Paradox

^{xxxii} Drexler, The People's Epidemiologists, Harvard Magazine, March-April, 2006

^{xoxiii} Chetty, The Association Between Income and Life Expectancy in the United States, JAMA, April 26, 2016. See also Deaton's editorial, On Death and Money: History, Facts and Explanations, same issue, slightly paraphrased with emphasis added.

^{xxxiv} This information comes from Antibiotics for Acute Otitis Media on theNNT.com

http://www.thennt.com/nnt/antibiotics-for-otitis-media/. The underlying studies <u>Sanders S, Glasziou PP, DelMar</u> <u>C, Rover sMM. Antibiotics for acute otitis media in children. Cochrane Database of Systematic Reviews 2004, Issue</u> <u>1. Art. No.: CD000219. DOI: 10.1002/14651858.CD000219.pub2.</u>

Turck D, Bernet JP, Marx J, et al. Incidence and risk factors of oral antibiotic-associated diarrhea in an outpatient pediatric population. J Pediatr Gastroenterol Nutr 2003;37:22-26.

http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/PreventionTreatmentofHighBloodPressure/Ame rican-Heart-Association-backs-current-BP-treatments_UCM_459129_Article.jsp ^{xxxvi} Musini, 2009, Pharmacotherapy for hypertension in the elderly

^{xxxvii} I assume your doctor has internet access and can look up any relevant comparative studies. Though I don't normally give specific advice, I'll make an exception here: if your doctor doesn't use the internet ... get another doctor!