



Presidential Commission *for the* Study of Bioethical Issues

TRANSCRIPT

Incidental Findings in the Direct-to-Consumer Context

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SESSION 5: INCIDENTAL FINDINGS IN THE CLINIC

MR. WAGNER: And welcome everybody back.

This panel is assembled like our prior panel, except focusing in the area of -- in the clinical context. And again, we're delighted to have three speakers representing three different perspectives here.

And our first speaker is Haavi Morreim -- am I saying that -- it's good enough? You know not to challenge me from my prior -- and she is professor in the department of internal medicine in the College of Medicine at the University of Tennessee.

A licensed attorney, assisting clients in selected pro bono cases, Dr. Morreim has authored more -- has authored two books and over 140 articles published in journals of law, medicine, bioethics, including the California Law Review, Vanderbilt Law Review, Journal of the American Medical Association, Archives of Internal Medicine, Hastings Report and the Wall Street Journal.

She has presented hundreds of invited lectures nationally and internationally to such groups as the American Medical Association, American and Tennessee Bar Associations, American Health Lawyers Association, and numerous state medical associations as well.

She does clinical teaching, she does consulting, research, focusing mainly on bioethics and health law with special interest in healthcare's changing economics and in clinical medical research. We are delighted to have you with us, Haavi, the floor is yours.

DR. MORREIM: Thank you very kindly.

Yes, I -- my focus in this, I've been trying to figure out what is distinctive about the clinical setting you know, as opposed to research. And obviously the direct consumer as well. And I also want to dovetail with some of the things that were said earlier today. Dr. Cho was mentioning public health, I'm also interested in that. And as Dr. Sulmasy pointed out, the shotgun approach to diagnostic testing is a very fertile place to go as well.

So basically what I'm trying to do more than anything is kind of to create a roadmap of how clinical side issues differ with respect to incidental findings from research and the other settings. And so this is kind of where I'm going to go. The defaults are not the same -- the definition of "incidental" gets quite interesting here -- and figure out what in the world is a finding, actually can be a question in this setting of clinical medicine. Then looking at disclosure issues and some policy implications.

So with respect to the defaults, really the research setting and the clinical setting have very different defaults, if you will. One is a fiduciary, clearly the physician is, the researcher is not, as I have written before. And I believe you have that paper, or papers, available to you.

In research, the goals are generally pretty focused, narrow and relatively clear. And the tools for exploring those questions are relatively focused and precise, such as you can get it, or as precise as you need to be.

In the clinical setting, if Mrs. Smith comes in and says, "Doctor, I feel so weak and dizzy," the goal may not be very clear, okay? And the tools you use may not be terribly precise until you've gone a fair way down the road.

Another default difference -- and I believe you have in your notes, actually, a quick outline that I provided to Elizabeth Pike yesterday. There is an inherent obligation to be alert and to at least potentially pursue and disclose IFs, if you're a clinician. The default tends to go the other way if you're a researcher. It's kind of what's the rule, what's the exception? They go the opposite direction. And the depth of the relationship obviously is also different.

Here's where we find an interesting contrast, I think, in the clinical setting. If the definition of an incidental finding is not what you were looking for, something other than the intended aim of the test, well, let's think about the clinical setting and that vague scenario that Dr. Sulmasy raised. If somebody comes in with a vague complaint, "oh, Doctor, I feel so weak and dizzy," the doctor may use, for better or worse, a shotgun of testing. At which point, the aim may be nothing more than, well, we'll just see what else crops up.

At that point, it's hard to say that anything is outside the aim, or else nothing is within the aim. I mean, it's hard to figure out what constitutes outside the aim because the aim is so undefined of your testing.

And some examples in the clinical setting are, tests with very low sensitivity and specificity, especially in a low-incidence population. You don't know what you're going to get. Similarly, as mentioned this morning, broad bundles of lab studies, and the bundle varies in part by which insurer the patient has, if any, what they require you to get at the same time, because they don't want to have to go back and pay for the next one individual test, so just get the whole panel. And similarly with imaging studies, by nature, they will cover more than just what you're looking for.

I also want to introduce another category here that I call quasi-clinical. We're talking about workplace screenings that are neither research nor direct clinical. The workplace screening typically is, A, are you qualified physically to do the job, but B, to protect the employer. So that if you claim later you have a workplace disability or a work-related disability or injury, they may be able to say, nuh-uh, you had that when you came in. So workplace screenings are not necessarily for the benefit of the person. Sports physicals similarly have a mixed aim, and they deserve perhaps separate consideration.

So defining a finding. If we're not sure what incidental is, as I noted above, when somebody comes in with a vague complaint, then the tools you use may be very broad. Sometimes when tools are very imprecise, the results are very unclear, and you don't know even if what you have is a finding.

Think for example about some of our screening tests. The PSA. An elevated PSA, tell me what that means? Who knows? Usually the only correct answer. Who knows? Depends on lots of other things that we're going to do and find out in a cascade of further work-up. Newborn screens we talked about before. Some of my genetics friends, just ordinary clinical geneticists say, take any person, get a three-generation pedigree, you're going to find loads of incidental findings and you have no idea what they mean. And maybe it's a finding and maybe it's not. A shadow in mammography in

younger women, is that a finding even? So that's another question that's worth taking into account.

So we raise the question, if a test result has no readily discernable meaning or significance, obviously how aggressively should we pursue this vague finding to figure out whether it even is a finding, let alone a significant finding.

So now into disclosure issues, those are fairly familiar. Certainly very familiar to the Commission. Again we look at the defaults. In the clinical setting, distinguishing here between whether to disclose and what to disclose, if you do. In the clinical setting, obviously the default is, yes, we generally will disclose, if there's any reasonable possibility that it's significant. Your presumption, your default is to disclose unless it's otherwise contraindicated.

On the other side, for research, you're required justification to disclose usually. But there are good justifications out there.

In the quasi-clinical setting, probably your presumption is going to be closer to the clinical setting than to the research setting. But I confess, I have not thought that through in enough detail to figure that out. I think it is worthy of separate consideration.

And then under the heading of what to disclose, again, you look at your defaults. On research what you will disclose is if you find something that's reasonably well verified or is going to be important if you can verify it. In clinical, I suggest a good standard to start with is, what would a reasonable person -- look at the law standard. What would a reasonable person in the same or similar circumstances want to hear about? Plus if you know the patient well enough to know that that person would want this information, by all means, disclose in the clinical setting.

Quasi-clinical standard, again it's probably the reasonable person is the good place to start. But you're probably not going to have the clinician's added information of this individual person would want to know this, unless the person has actively said that.

So on to the policy implications, to wrap up here. In a sense what we're doing -- I kind of realized yesterday evening, what we're doing is we're reframing some very familiar questions. By what standards should care be provided? In other words, how aggressively do you work up

something that you see in your broad scatter shot? That's a very familiar question, but we're kind of reframing it.

And by what standards should the quality of care be assessed, whether legally or for the extra remuneration we are now seeing in value-based purchasing of healthcare. By what standards do we identify the quality of care? And I think we can look at it in three areas. Preventive screening, and how aggressively do we want to screen people when we know that we will get a boatload of unclear information at the other end? PSA being a classic example.

Mammography not just in younger women, frankly. A nice piece by Gilbert Welch that came out as kind of a counter point just a couple of weeks ago in the Wall Street Journal pointing out, if I recall correctly -- take this with a block, not a grain of salt, because my memory may not serve me. But for basically for a thousand women, you identify -- it may be four of them will have it, you'll be able to pick up three -- and I'm getting my numbers mixed up. But in order to pick up another woman at age 50 or above who has breast cancer, you're going to have to screen something like ten thousand women or a thousand women for ten years, to pick up one more, if I recall his data. Forgive me, I should have had that more in hand.

Regular diagnostic work-ups where you're using tools that you know are going to produce lots of incidental findings, how much should you use those tools? And for pursuing diagnosis induced incidental findings?

Then we look at med-mal issues, which really are driving a lot of the clinical shotgun approach. What I would invite both clinically and the malpractice setting to look at is population and evidence basis for pursuing something, and cost effectiveness. And I would love to see our med-mal standards bring population issues into account.

One of the problems that is well known in med-mal litigation is it tends to focus on the individual and sine qua non causality with this individual have done better, but for. I think we need much better to recognize a population focused and evidence-based reasoning for using diagnostic tests, for pursuing odd findings and so forth. And to help physicians avoid getting into a

self-fulfilling prophecy, namely, you know, so long as physicians excessively pursue odd findings, that can be the standard of care simply because it's done standardly.

So I thank you for your attention.

MR. WAGNER: Thank you for your getting us started on this particular session.

Our next speaker is Dr. Danielle Ofri, Associate Professor of Medicine at New York University School of Medicine. She practices medicine at Bellevue Hospital where she and her medical team -- where she did her medical training -- excuse me -- and have been taking care of patients there for two decades. She is editor in chief and cofounder of the Bellevue Literary Review, the first literary journal published from the medical center. She is author of four books about life in medicine, the newest of which is "What Doctors Feel," is the title. "What Doctors Feel," how emotions affect the practice of medicine, which will be published in June. Is that right?

Dr. Ofri writes regularly for the New York Times about medicine and the doctor/patient relationship and her essays have appeared in many leading newspapers and medical journals, have been selected for best American science writing and twice for best American essays. She is the recipient of the John P. McGovern Award from the American Medical Writers Association for preeminent contributions to medical communications.

Welcome, it's good to have you here.

DR. OFRI: Thank you.

And I appreciate the introduction about distinguishing the research from clinical practice. And one of the biggest distinctions I see is that research focuses on populations. But in clinical medicine we take care of individuals. And I'm going to share a story of one individual patient of mine. She's a very long-term patient, I've cared for her for more than a decade.

And earlier this year she had abdominal pains on a weekend, and so chose to go to a local E.R. Now I don't know how detailed a history and physical were done, or whether they tried to call me, her primary care doctor, but I could have told them, she's had these non-specific pains for, you know, ten years or more. Her lab tests, endoscopy, physical exam, findings have all been normal,

and these pains tend to flutter in times of emotional stress.

However, she walked into the emergency room of a medically advanced country with abdominal pains so was absolutely given a CT scan. The scan, as I could have predicted, was entirely negative for a serious pathology. But she came to my clinic the following week in a panic convinced that she had cancer. Incidentally noted, the report read, is a two-centimeter nodule in the right adrenal gland. The dreaded "incidentaloma".

I reassured her that it was exceedingly unlikely that she had cancer. Benign nodules of the adrenal are as common as scabies and far less annoying. Ninety-eight percent of the time or more, they are benign adenomas, which do nothing but take up space. But in one to two percent of the cases, they can be problematic. An adrenal mass can be bad in one of three ways. It can over-produce adrenaline-type hormones, it can over-produce cortisone-type hormones, or rarely it can be cancerous.

Luckily my patient's adrenal mass was reassuringly small and smooth bordered and she had no symptoms of adrenal disease. Nevertheless, once the incidental finding had been given life, so to speak, it was no longer incidental. So I checked on our local medical reference for these standard of care valuation of the adrenal incidentaloma, and there were quite a number of tests required to rule out the bad effects of adrenal misadventure.

So first was the 24-hour urinary metanephrines to test for the adrenalin producing capacity of the adrenal. I don't know if you're familiar with the 24-hour urine collection, but it's quite exacting in its instructions. You have to get up in the morning, discard your first morning's void and then collect every subsequent drop of urine for the next 24 hours at work or at home or at play in a large gallon jug. Through the night, including the next morning's void, and then keep refrigerated.

Next was the overnight dexamethasone suppression test to evaluate the cortisol producing capacity of the adrenal. For this, the patient gets a prescription for one tablet of dexamethasone, go out, buy the prescription and then take it at 11:00 p.m. specifically on the night before the morning of the day they'll go to the hospital for the 8:00 a.m. blood test on an empty

stomach. And if that's positive, you have to do the high dose dexamethasone test, another prescription for another tablet, 11:00 p.m. on only the night of the day before you take the test. Alternatively, three consecutive days with 24-hour urinary collections.

Then with the possibility of cancerous growth, the third adrenal havoc. You need surveillance CT scans at zero, six months, one year, and two years. The patient I had spoke only Bengali, so this was done via interpreter and with excessive arrows and circles on a piece of paper. By now, as you can imagine, we had run well over our allotted fifteen minutes. The patient was completely overwhelmed, I was frustrated, the patients in the waiting room were quite annoyed.

But mainly, I was angry. I was livid that some random doc in some E.R. somewhere in Queens had ordered a CT scan. And now the fallout was in my lap. I never would have ordered the scan, but now I was being compelled to take on this gargantuan evaluation and assume responsibility for it.

As a primary care doctor, I feel as though I have a finite amount of medical capital with a given patient at a given visit. And given the limits of time and attention, the reality of how many prescriptions a patient will actually fill, let alone actually take, there's usually only one or two things I can realistically focus on in one visit.

This incidental finding from tests that I hadn't ordered had used up all my medical capital with this patient. And frankly, we were in overdraft by now. By the time we finished addressing the meaning of the incidentaloma, the specifics of the urinary 24-hour urine collection, the overnight dexamethasone suppression test, the surveillance CT scans for the next two years, she had already forgotten my definition of what the adrenal gland was. And forget about the rest of her healthcare issues.

Have any of you begun to wonder about the risks of these additional tests? I started poking in literature and came across this very interesting study that estimated the chance of uncovering a malignant tumor in a patient like mine was roughly equal to the chance of causing a fatal cancer from all the radiation. You know, that really gave me some pause. Additionally, each

additional scan is another opportunity for incidental findings, opening yet more Pandora's boxes of medical evaluation.

Now I work in an academic medical center and we teach students and house staff. So I thought about an educational system. Our reliance on imaging and technology steadily is overshadowing our confidence in history taking and physical examination. We no longer trust ourselves to evaluate our patients with our hands, with our eyes, with our ears, and the trust out of that that connect all three. This intellectual orientation is now being passed on to our students who will be our doctors.

And then I thought about cost. The evaluation of my patient's incidentaloma easily would cost \$1000 or more. Tens of millions of CT scans are done every year in this country. Now I'm not the fastest back of the envelope calculator, but it doesn't take much to see how quickly the cost of incidental findings will add up.

So as a clinician, I wondered, how much my regard for society's obligations with regard to cost played into the decision for my patient and her individual care? So what should I have done? Should I have followed the standard of care guidelines and done everything in the kitchen sink, or gone with my instinct and the probability that it was most likely benign?

The truth is that, for doctors, these two choices are not equally weighted. We have a bias toward doing something as opposed to doing nothing. It feels right even if it's wrong, which in many cases it surely is. And our patients almost uniformly want us to do something. Both doctor and patient are enthralled in this overwhelming medical imperative to act. Remaining still, old-fashioned watchful waiting requires a fortitude that few doctors are able to muster.

And certainly there's a legitimate fear of lawsuits. If I didn't do the standard of care and was sued, well, I wouldn't have so much as a legal toothpick to stand on. But if we dig deeper down as I think we should, because I think that we doctors are far less rational when we tell ourselves and everyone else that we are, there are potent emotional forces at work.

Much of what bolsters a doctor's sense of self is the ability to exert control over our

environment. Taking action is a concrete affirmation of our ability or our illusion of ability to affect the outcome. Conversely, sitting still, living with uncertainty is profoundly unsettling. It threatens the very core of our being as doctors. If we're not doing anything then we aren't much better than the shamans who preceded us or the guys hawking Herbalife on TV.

I mean, what happens if something goes wrong? If a bad outcome occurs while in heroic pursuit of cancer, all might be forgiven. But what if the bad outcome occurs while doing nothing? To have ignored something on a CT scan then have a bad outcome? Well, that's unforgivable. Not just in the legal system, but in the doctor's deepest recesses.

So it's not only impossible for a doctor to ignore an incidental finding. Once noted, it compels us to act. And the rate of incidental findings seems to increase exponentially each year as you perform fewer and scantier histories and physical exams. A CT scan seems so much faster, so much easier, so much more accurate. But the downsides, as we are seeing today, are legion.

The adrenal nodule on my patient's CT scan was an incidental finding, something most likely to remain comfortably in hibernation for the rest of her waking days. But it had completely steam rolled our visit that day, greedily soaking up our time, her ability to comprehend and my entire medical capital. It initiated a cascade of expenses and risks, not to mention a torrent of anxieties and confusions, all most likely for naught.

But her diabetes, her arthritis, hypertension, depression, cholesterol, they all ended up with the short end of the clinical stick. And an outcome that is surely not incidental.

Thank you.

MR. WAGNER: Quite an illustration. Thank you.

The last speaker, before we go to questions for this session, is Carol Krucoff. She is an award winning journalist who served as the founding editor of the health section of the Washington Post where her syndicated column "Body Works" appeared for twelve years. She currently works with Duke Integrative Medicine in Durham, North Carolina. She has written for numerous national publications, including the New York Times and Reader's Digest. She is author of the book "Healing

Yoga for Neck and Shoulder Pain" and co-author, with her husband, Dr. Mitchell Krucoff, a cardiologist at Duke, of "Healing Moves, How to Cure, Relieve and Prevent Common Ailments Using Exercise."

While receiving clinical care for a post-marathon injury, Ms. Krucoff was notified of a finding incidental to her clinical care, a slow-growing brain tumor.

Welcome, we look forward to hearing from you.

MS. KRUCOFF: Thank you.

Few conditions capture attention like a brain tumor, and I am grateful for this opportunity to speak to you today about mine which was discovered as an incidental finding that I learned about during a routine annual checkup in the spring of 2004, just after my 50th birthday.

I was sitting on the exam table in a hospital gown, basking in my doctor's praise for how fit and healthy I kept myself while she flipped through my medical records. "Let's get your cholesterol checked," she told me. "Oh, and you'll need to get a repeat MRI to monitor that little brain tumor."

I felt my heart bang against my ribs. "What brain tumor," I stammered.

My doctor looked at me aghast, "I'm so sorry," she said. "I thought you knew." She proceeded to explain that an MRI taken six months earlier, when I'd been hospitalized for severe hyponatremia had revealed a small acoustic neuroma, which is a benign tumor on the eighth cranial nerve. The reason I didn't remember having that MRI was that I'd been in a coma at the time.

Do I press this one? Which one? There.

In honor of my 50th birthday, I'd flown to Jamaica with a friend to speedwalk the Reggae Marathon, which was great fun until I became dizzy in the last mile. The first aid staff thought I was dehydrated and they gave me several cups of water, however, my problem was that I'd already been drinking too much water resulting in dangerously low sodium levels.

It's a lovely picture coming up.

I collapsed just over the finish line, had a seizure, was put on a ventilator and air

ambulance back home to Duke University Medical Center. My husband, who is a cardiologist at Duke, and our two children, didn't know whether I would live, die or be permanently disabled. Waking up in the neuro intensive care unit four days later, with no idea how I'd gotten there was an overwhelming experience.

I was very grateful to be alive and to hear that I was expected to make a complete recovery. I was quite weak and my memory of the events was impaired. I don't remember crossing the finish line, for example, although they mailed me that picture several weeks later. But I was surprisingly relaxed and happy. I call it a sort of post-traumatic bliss syndrome.

I only vaguely recall the doctors telling me that, when they did an MRI to see if the hyponatremia had damaged my brain, they discovered as an incidental finding a very small acoustic neuroma about three millimeters, the size of three grains of sugar. It didn't really register that this was something potentially dangerous or that I needed to do anything about. My husband didn't seem to think it was very important, and I certainly never heard it called a brain tumor.

Mostly, I was grateful to have recovered completely from this life-threatening experience. Before my doctor shocked me with this news, I had been feeling wonderful. I was back to my full schedule of jogging, teaching, yoga and writing. So hearing about this incidental finding came out of the blue. I recall very little of what my doctor said that day, other than the tumor was non-cancerous and slow-growing. But that if it grew, I might need brain surgery.

Driving home, I was exactly the same person I had been that morning, except suddenly everything was different. Now I was someone with a brain tumor. I immediately went on the internet and learned some helpful and some frightening facts. Most of the tumors are slow-growing, some grow rapidly. They can result in hearing loss, balance problems, tinnitus and headaches, and if they grew too big could be life threatening.

So as directed by my doctor, I scheduled an appointment with Duke's acoustic neuroma expert who asked that I have another MRI and a hearing test before I saw her. That MRI reported the tumor unchanged from the previous and my hearing test found no loss of hearing in my right ear, the

side of the tumor, but did find some mild hearing loss in my left ear. Go figure.

My strongest memory of that first appointment was this physician describing in great detail the pros and cons of various surgical approaches she might use to remove the tumor. She also mentioned the option of radiation. When she finished, I asked her if, since I had no symptoms, I could just skip the brain surgery and radiation for now and do nothing?

She said, acting early when the tumor is small optimized the chances of preserving my hearing. However, since it was so very small and I was having no symptoms, it was reasonable to watch and wait. She recommended I make another appointment with her and have another MRI and hearing test in six months, and to call if I developed symptoms earlier.

I joined an acoustic neuroma support group and met some lovely people who had tumors surgically removed, including one woman whose surgery to remove a two millimeter tumor that had been asymptomatic left her with constant headaches and facial pain. I also logged on to the discussion forum of the website of the Acoustic Neuroma Association and read some horror stories of botched treatments as well as some wonderful examples of excellent results.

After several months of almost daily trips to the discussion forum, I became overwhelmed by the anxiety, angst and suffering these posts aroused and I signed off permanently.

I have now been watching and waiting for nine years. Over that time I've had nine MRIs. The first three at six month intervals, the next two at one-year intervals, the last four about 18 to 20 months apart. I'm scheduled to have my next one in August which is a little past the 18 months recommended, but the whole experience is so anxiety provoking, I hope you'll understand why I have procrastinated.

I called my insurance company, Blue Cross/Blue Shield, to find out the price of the MRIs and was told that each cost \$3579. I am grateful to have health insurance with a co-insurance payment of \$160 for each MRI. The charge for the hearing test and doctor's appointments is about \$960 of which my payment is 50.

Fortunately, I've had no symptoms, although in the early years, any time I felt dizzy or

had trouble hearing, I'd worry. At one point, the tumor did grow slightly, about one millimeter, so I was referred to a radiation oncologist. After meeting with him, I opted to again continue waiting. I researched top experts in radiation and sought second opinions. Were my tumor to grow, I would likely choose this option. But as these technologies continue to rapidly improve, waiting again seems to make sense, especially since treatment could negatively impact the hearing in my right ear, which at the moment hears fine, while my left ear has hearing loss.

And I've had other health issues to deal with. In 2008 I had open-heart surgery to replace a congenitally abnormal aortic valve and repair a resulting aneurism. And I've had several pre-cancerous lesions removed from my left eye. So I watch and wait here, too, seeing my cardiologist and my eye doctor periodically for tests.

For the most part, I try to completely forget that I even have this little brain tumor. Had I not learned about it as an incidental finding, I would have been blissfully ignorant. As a health journalist, I had always thought there was great benefit in early detection. However, my experience has made me question the wisdom of learning about an anxiety if all -- of learning about an abnormality if all it offers is anxiety, as well as potential harm from treatments for something that might never affect my health.

In 2005 -- here it is -- I wrote an article for the New York Times about my experience, and one of my sources, Dr. H. Gilbert Welch, put it this way: have we done people a service if all we do is worry them? Worry itself may be harmful. As a yoga teacher, I am a firm believer in the mind/body connection. And one of my teachers calls worry "meditation on a bad outcome." So I do my best not to worry about my little brain tumor. Easier said than done, especially as the date for my next MRI approaches.

Since I'm one of those people who believe that everything happens for a reason, perhaps I was meant to go through this to learn lessons of patience, compassion and gratitude, and to share my experience with you today to help shape recommendations to make the process of dealing with incidental findings more skillful.

From a patient's perspective, here are some recommendations. Please keep me informed in simple, direct language of what's been found and its implications for my health.

Train providers with good communication skills to ensure that they present this information compassionately and clearly with patience and honesty.

Consider adding a support person to the health care team, such as a social worker or psychologist, to help the patient and their family process the information and decide on a course of action.

Unless it's clearly a medical necessity, don't rush to treatment. Recognize that treatments may have risks and sometimes watching and waiting is the best option.

At this point, I'm glad I've chosen to watch and wait. At my last appointment in 2011, this same doctor who had initially talked about using the middle fossa surgical approach to remove my tumor now said, we're learning that many of these little tumors don't really amount to much. I am very much hoping that this is true with mine.

Thank you.

MR. WAGNER: Carol, thank you. Another compelling story, but from a different perspective. We so appreciate it. In fact, thanks to all three of you.

The floor is open for questions or comments.

Nita?

DR. FARAHANY: Carol, thank you for being willing to share your story.

I will start by telling you I have a slightly similar story, which is as an incidental finding, they discovered that I had papillary thyroid cancer a few years back. And much like the description you've given, it's incredibly slow growing, many times never detected during a person's lifetime, with unclear kind of advice for how to proceed. But I decided I couldn't live with the anxiety of having every six months to have to have a ultrasound done, and this and that done, and went the surgical approach.

But you know, I could have done what you've done, which is waited and watched, and

some people, you know, recommend that approach. But what you said struck me, which is you would have remained blissfully ignorant. And so I'm hoping you could expand a little on your experience as to whether or not you would have preferred to remain blissfully ignorant?

Because I've often pondered that same thing, would I have preferred to simply never know? And would I have been better off by simply never knowing, because I would still have my thyroid and I wouldn't have anxiety and I -- you know, et cetera. And yet at the same time, I also -- you know, it could have exploded much like yours could, you know, progress. It could have become a health danger, et cetera.

So I was hoping you could just, you know, kind of expand a little bit. Do you really wish that you simply had never been told?

MS. KRUCOFF: That's such a good question. And I think I might have to wait until the end of my life to answer that. If it does grow, I will be very glad to have been doing these monitorings. If it never does grow, it will have been a big pain in the ear.

(Laughter.)

MS. KRUCOFF: So it's -- again, I -- if the question turns into a recommendation, do I wish they hadn't told me, my answer is definitely no. If they know, I want to know. Definitely I want to know.

Do I wish that I hadn't had my head stuck in a MRI machine? Yeah, part of me does. But again, I don't know what the future holds, and it might grow and it may save me from a diagnostic misadventure later in life. It's a really good question, but one in our era that, I guess, more and more people are going to be asking themselves.

DR. FARAHANY: So if I could just follow up on that? So it certainly hasn't enhanced your life so far by knowing, but you would rather the knowledge?

MS. KRUCOFF: If it's known, if there are doctors out there, if there are people out there who know, I would rather the knowledge. I would want to know. I wouldn't want to be shielded for my own protection. That's my decision, this is my brain.

DR. ARRAS: Thanks so much. This is irresistible. I've got to follow through.

So are you saying then that -- so just to switch from Nita's question, like my question would be, do you think that physicians are -- or others are obligated to tell once they know? And you're telling us that you think they should have an obligation to tell, no matter how -- you know, no matter how significant the finding? Because you know, what I'm -- this is very difficult, you know, because what I'm hearing is that this has put you through a lot, right? A lot of anxiety?

And this is the reason why I have signed out of the PSA adventure. I don't want to hear about it, you know. I don't want to be offered the test anymore, I don't want to hear the results. So is your preferred solution then to have a negotiation between you and your physician about what kinds of things you want to be told? Because I can easily imagine some people saying, well, you know, given this enormous hassle that you're talking about, and the mountains of anxiety that you're talking about, maybe it would be a perfectly reasonable position for a lot of people to just not hear about it.

MS. KRUCOFF: Well, I guess I would answer that by saying, it depends on, are we talking about an acoustic neuroma, or are we talking about something else? So I wouldn't want to presume to answer for everything for everyone. I can just answer for myself.

And I think it's very important to know, and I chose to -- possibly because I'm married to a physician who is fantastic in helping me kind of sort through. But I paralleled my situation with this other woman I met in the support group who had a two millimeter tumor that was not giving her symptoms, and she couldn't bear the thought of living with it. So she had the brain surgery.

Now if I knew, say, to enter Nita's observation, that that brain surgery would cure it, would take it away completely, I might have done something. But there's no -- with acoustic, it could grow back. I mean, it's not like you do this, you're cured, it will never happen again, or you don't.

So it's an "it depends" situation. But from my case, especially with the ability to have a wonderful physician, my husband who I could talk with about this, rushing to treatment did not really -- for something that was completely asymptomatic, where the treatment has risks, it could grow back after the treatment, you know, watching and waiting seemed to be the most reasonable

option. And I just sat next to a woman at a dinner on Saturday night who had an acoustic -- who said, excuse me, she couldn't hear me very well because she had an acoustic neuroma radiated in her right ear, but hers had been growing rapidly. So sometimes they do grow rapidly. So you just don't know.

So I'm glad I don't have your job, coming up with these recommendations. It's not easy. But from a patient's perspective, if the doctor knows something that might be significant to my health -- now the PSA may be another total issue. But this was something that could be significant to my health, I want to know about it.

DR. ARRAS: The problem with the PSA is that, in most cases, its significant to your health but in a bad way.

MS. KRUCOFF: Right, okay.

DR. GUTMANN: So what I'm hearing is, don't over-test, but don't under-test either. There isn't an asymmetry here, right? I mean, if you over-test, that's wasteful and anxiety producing. If you under-test, you may miss lifesaving diagnoses. It's a little bit -- so what we have to do is somehow get more specific than that.

Dr. Ofri's story was one of over-testing, at least the way you presented it, it was. But there are also stories we can give of under-testing where people didn't find out things which if, caught early, would have been able to save their lives.

So I'm wondering whether there is -- and your story of having a husband who was a wise counselor suggests that there is no substitute for wise counsel for superb doctors, advisors, who can give you the evidence-based but also wise, which is more than evidence, advice. And then ultimately the patient needs to decide. So I would just like your reaction to -- you made the recommendation to train providers with good communication skills, which you all have in high relief, all three of you.

But I'm wondering whether that's enough? I'm not saying that you suggested that's enough, but good communication skills are necessary. But it sounds like you all either are examples of or relied upon somebody who had very excellent judgment. And is there any substitute for that?

DR. MORREIM: If I may, I mean, I find myself going back to the distinction between, in the first place, into incidentaloma generating work-ups? And then after that the question, how aggressively to pursue something when you do find an incidentaloma.

Some of my colleagues in Memphis have found that E.R.s in Memphis use the CT scanner a logarithmic leap above even other E.R. physicians in most other cities of comparable size. And so needless to say, you can imagine a lot of needless CTs, which Dr. Ofri began with, that generate all sorts of incidentalomas and so forth. That may be a particularly important place to begin.

DR. GUTMANN: That's don't over-test, and there's incentives for people who have insurance to be over-tested. But people who don't have insurance can get under-tested.

DR. MORREIM: Yeah.

DR. GUTMANN: So we've got to get the incentives right.

DR. MORREIM: And evidence, frankly. The basis. Because it wasn't until relatively recently that our research focus -- I mean, up until, you know, the last decade or two, our research focus generally speaking has been testing exciting new things. And it wasn't until relatively recently that we finally have incentives to test and do serious research on what we don't need to do.

MR. WAGNER: Interestingly, we have two comments from the floor that bear on this point. And they wonder out loud -- actually one is an example -- of whether or not these are decisions, these conversations are decisions that should take place only between the patient and the clinician. As you said, you had a wise advisor.

Actually, one comes to us from a Ph.D. student, *Alyssa Forrest -- Alyssa, raise your hand if you're out there? In fact, we met, we had a chance to chat.

And she wonders if the determination of whether to disclose incidental findings might be done better by an independent oversight board charged with making and conveying to the participants such decisions.

And just flowing right into that, some of us had a chance also to meet Federico DeMontivo. Federico, actually a distinguished guest, he and I share the title of vice president -- vice

president – vice-chair of our respective bioethics boards. His just happens to be in Spain.

But he notes that in his country, there is -- because of this new context that so much in medicine -- so many medical cases that we're talking about are about predisposition to disease before the actual -- before the disease becomes symptomatic, as it was your case, or if we're talking about genetics, the same thing, predisposition.

The value of autonomy may be different. He suggests the same thing that Alyssa suggests, that apparently there is in Spain now two legal instruments to protect the patient. The first is, in the case of genetic predispositions, counseling provided in every case. And also the opinion secondly is hospital bioethics commissions, which opine on these situations.

What are your thoughts of sort of third-party intervention, formal advice and intervention?

MS. KRUCOFF: I certainly love the idea of a support person, a counselor, a psychologist, a health coach. But someone to help the patient and their family navigate. That makes a lot of sense to me.

DR. OFRI: I still think initially it all has to be between the doctor and the patient, because there's a context, not just medically, but based on a history of knowing the patient's preferences. When you talk about opting out of the PSA and the right not to know, that's actually quite large. I think it comes up very often. And we have to prioritize. The patient may have already existing illnesses versus things that are propensities. And we have limited resources, time, intellectual energy, emotional capacity. I know my patient has, you know, coronary artery disease, that will probably kill her before this incidental finding.

MR. WAGNER: Wouldn't that argue that you would have been helped by a panel that could have actually helped the patient understand that it's not just your opinion versus hers, and a nodule on a scan? But that there's a larger context in which she should determine --

DR. OFRI: Absolutely. I think it would be a wonderful adjunct. It's hard to imagine how that would be outside of a clinical setting. Because the reality is that you do have existing

coronary disease, and that's a disease whose trajectory we can trace, as opposed to one that we can't.

So while it would be a lovely adjunct I wouldn't want to replace or detract from. But would it, in terms of resources, time and money, I'm not sure.

MR. WAGNER: Yeah. You could have said, let's take this to the such-and-such board.

DR. MORREIM: In terms of third parties, I'm not thinking so much about an independent ethics advisory board in this sense as your ACO, now a reborn HMO. Because we are -- I remember the '90s so well, and the guidelines of care were not always well constructed, let alone well adhered to or well imposed. 1-800-nurse-from-hell became the watchword of the day for utilization management.

Today what we're going to see, and are beginning to see, is the accountable care organization in many iterations and forms. But A, the quality guidelines, financial guidelines, will have a lot bigger say than we're accustomed to in deciding how much you can do to generate incidentalomas.

And then at that point, there may well be some restrictions on what you get to choose by way of how often do you get your MRI? Do you -- will you have the choice to have it every six months? Will they pay for it if it is not population justified? At which point, the individual physician's role, shades of the '90s again, will be to plead the exception where there is actual justification in this individual's case.

DR. SULMASY: Yeah, along these lines, I'm going to give you two aphorisms. One from Ed Pellegrino, which is "the physician should always practice with therapeutic parsimony and diagnostic elegance". And the second from John Stobo, who once told me when he was my chief, "don't just do something, Dan, stand there, all right?"

Now there's a sense in which a lot of people will say those are just nostalgic sentiments, right? The cat's out of the bag, we're going to do scanning of everybody, we're going to do whole genome sequencing and, you know, this is just nostalgia from the past that you would think this way.

On the other hand, you might want to say, this is exactly the cogent advice we need to

make sense of the task we've got before us. Which do you think?

DR. OFRI: I think it is exactly the advice that we need because we are -- can easily be drowned in information in small clinical issues that can sink the ship. And I think about, you know, when we relayed, for example, the studies on mammography in the 40s and the issue of the anxiety. How can you even worry about some anxiety when you could save a life and a cancer?

But if you've had a patient who's had a false positive on a mammogram, that anxiety is not a small issue at all. And even financially, days missed from work and -- it's enormous. And multiplied out towards tens of thousands and millions, it's quite a bit. So I would say that judgment and counsel are even more important.

The thing I would -- your point, Dr. Gutmann, about where we find the sort of sweet spot of over-testing, under-testing, sometimes it is judgment, and we don't necessarily have the strict evidence. The question for the practicing physician very often is, will that stand up in court? I know that is a very base way of looking at it. If you said, in my judgment it didn't seem reasonable to do this, that's a very hard thing to stand with. And if you think you're going to get sued and sued out of existence, financially and/or psychologically, you might just order the CT scan already.

DR. GRADY: Well, that's just what I was going to talk about. I mean, I loved your story, Dr. Ofri, and I also thought that you described a position where you really didn't have a choice. I mean, once the CT scan was done and there was this finding, and the standard set of things you're supposed to do to follow it are already written somewhere, you know, because of the incentive structure, because of liability concerns. I mean, to choose otherwise would have been very risky for you, I think, in a certain way.

And I think one of the things that I wonder about is, how do we change those incentive structures? Because "don't just do something, stand there" is not something that most of us are very good at anyway. But certainly, unless there's evidence that suggests that just standing there and not doing something is okay to do, we're at risk of being, you know, liable for not doing something we're supposed to do. So how do we deal with that?

DR. OFRI: Well, much of these recommendations are not evidence-based. That's one of the things. But once it says that [inaudible] are up to date, then you feel obliged. This is the community standard of care.

And I think in terms of the educational structure, that we make distinctions between what is evidence based and what are recommendations. And hopefully the legal system will follow that.

But I think in terms of this doctor who didn't know my patient, who did an automatic CT scan, you know, had the system been set up differently and had, perhaps, this doctor had more confidence in their clinical skills or our medical system enabled the patient to contact me on the weekend, it might not have been done.

So I think educating our current students and house staff about being able to trust clinical skills will be a way of avoiding some of these incidental findings because it will be tsunami of incidental findings.

MR. WAGNER: And the last --

DR. MORREIM: If I may briefly --

MR. WAGNER: Yeah.

DR. MORREIM: -- this is one reason I spoke about self-fulfilling prophecies heading into the standard of care. But the other thing that I think is at least worth mentioning here is that the reality is that most lawsuits are not because you didn't do enough stuff. Lawsuits are based on relationships predominantly. And as I have said to my house staff and some others more than once, and feel free to quote me on this, doctors learn about law the same way teenagers learn about sex. They ask each other. And the mythology they create is sometimes fairly similar.

(Laughter.)

DR. MORREIM: Doctors scare each other into saying, well, medical/legally speaking, you've got to do XYZ and you've got to do enough stuff or you get sued. That isn't predominantly why physicians get sued. Relationships which were called for here, and good quality conversations

will ward off -- and but they take the time the doctor has to spend on that.

DR. GUTMANN: And that, just so we practice evidence-based recommendations, there is ample evidence to support what you have just said. There is a ton of evidence that malpractice suits go forward, not because doctors don't do enough tests, enough being as many as possible. But the difference between a malpractice suit and not a malpractice suit, the biggest correlation is the relationship that the doctor has with the patient, and whether the doctor has talked with the patient through a problem in a timely fashion.

Now if you're maximally risk averse, you can do more. But again, there's a symmetry here. If you do too many tests and the tests harm people, it's a risk as well. So maybe we can get more evidence out on this and be helpful in that regard.

MR. WAGNER: Actually, to keep us on schedule, we'll look forward to hearing you back at our final roundtable session. But as you leave the table, thank you. Take our thanks with you.

(Applause.)