

REDUCING LABORATORY QUACKERY AND OTHER FORMS OF UNNECESSARY LABORATORY TESTING

Michael Astion, MD, PhD

Professor and Director of Reference Laboratory Services

University of Washington Department of Laboratory Medicine
Seattle, WA

Now you've all had a couple of drinks. But you know I like to speak to a crowd of people who've had a bunch of drinks and are sitting in the dark. When you're sitting in the dark, you know in the complete dark, the beauty of it it's easier to see the light. And so today I'm going to talk about a topic that isn't talked about too much which is frank quackery. But I'm going to give the whole continuum of unnecessary lab testing including lab tests that are real lab tests but are used in the wrong setting. And this comes up for all lab managers at some point because you have to deal with your send out list which consists of, and you have to manage it, and you have to also decide what you're going to bring in and what you're going to leave out. And well end of show, that's... oh this is I see. This is my lecture. And ok. So that's my lecture and as most of you've heard me speak before, I've given myself the honorary HTBE degree which has never been more relevant in this economy. So I remain happy to be employed. And it's an old joke but it's come back, it's still got some legs on it.

And this is the University of Washington, the Department of Lab Medicine is actually off to the side here. This is the main campus. That's Mount Rainier. And we're actually as you might expect we are actually below ground, we're a couple of stories below ground but we get to see that. And some of the material here was developed a few years ago with the help of Jim Hernandez from Mayo, Brian Jackson from ARUP, people I'd interviewed and talked about ideas with and Kim Riddell from Group Health was also on our faculty and has done some interesting stuff that I'll talk about related to report cards.

And I'll just give a slide on general healthcare trends as it effects utilization, some definitions. Talk a little bit about what quackery is versus other forms of what I call nonstandard lab testing, put it in the context of evidence based medicine and talk about why it's growing and while it will continue to grow. And look at some common characteristics for identifying nonstandard lab testing and talk about some interventions to decrease it. And I won't kid you, I'm not that optimistic about, I'm optimistic about the ability of your practice for those of you who are practicing either in a large or small hospital or a reference lab. I'm optimistic about your ability to not participate in it but I'm not optimistic about you know or even trying to decrease its growth for the general public through direct to consumer testing. And that's as I'll show you is because of the internet, you know and I just think that genies out and we're not going to do much about that.

So in general as you know, we spend about 2.3 trillion and about you know the lab industry depends on how you count if whether you count anatomic pathology or not but anyway it's

several tens of billions. And most testing is spent on chronic diseases, so even though we talk about omics and genetics and the fact is that most people who are sick are older and most older people who are sick have a chronic disease rather than something exotic. And the other important trend as it relates to utilization is the growth of what I call, it's like a parallel system which used to not matter to most of us, but we participate most of us here participate in what I call regular healthcare. You know you get up, you put on some kind of usually tailored clothing after taking a shower and you get into some car and then you go to a place that's like a hospital where people are you know behaving in normative fashions and you order regular lab tests and you might call each other doctor and people come there and they have tumors and they're removed, or they get new organs. That's what I call regular healthcare. All the regular, you're seen by an M.D. and that M.D. doesn't stand for mountain doctor it stands for medical doctor. And that person might frequently be wearing a tie. Then there's this separate area of that's grown and it didn't matter for a while to people like us because there was no overlap. There's a sort of insane crazy healthcare where people are taking creams and lotions and having their colons cleaned and they're not getting vaccinated and they have diseases which are not defined by conventional medicine like dysbiosis which is the idea that your gut critters need to be balanced. And it used to not matter but now they overlap. And that's what I'm going to talk about. It's actually bled into regular healthcare, the idea, and this is the idea that we're all sick. And the myth of, and in here, in the overlap, is what we call the wellness movement. The wellness movement. Everybody's for wellness and everybody's for screening for diseases that are a) are diseases and b) that you can screen for. But it turns out that there's a lot of myths around wellness and that there aren't that many diseases that you can actually screen asymptomatic people for. And it's an irony but true that we've never had more lab tests and yet we've never recommended fewer. In fact my over 26 years in medicine, the number of lab tests has grown and the number of lab tests that are recommended for well people on well patient visits and that will be paid for has actually gone down quite dramatically. We don't do chemistry panels on all patients who come in for ambulatory care now. In fact it won't be reimbursed in many cases. So anyway so there's this overlap and so the irony of the wellness movement is it literally makes everybody sick. It literally, you cannot get a specimen sent to Spectracell Diagnostics for nutritional testing without having a positive test. You know same for a lot of other labs. So that's a real irony of the wellness movement.

Now quack is a pretender to medical skill and quackery is actually fraudulent and it promotes products and services that have questionable or unproven or proven to be detrimental type of scientific basis. So that's quackery.

And there is frank quackery in the lab, things that have been known forever to be completely useless like hair testing for allergy would be an example or anything related to entities which are not actually clinically defined by normal healthcare like the idea of dysbiosis or these vague diagnosis whose main purpose is to separate people from their money and a lot of this exists in alternative medicine and another good example of this which CLIA has actually talked

about, was actually talked about by regulatory bodies is live blood cell analysis as performed by naturopathy and the chiropractors and the reason is these things aren't tests is that no two people do it the same way, there's no reproducibility, there's no standard. So for me I think a test is not a test. If we send my hair somewhere and we send it to 13 places for the same test and they come back with 13 different answers but they're all positive, and then we re-mail my hair and they come back again but the same lab is positive but in a new way, that's not a lab test to me. That's just a crap shoot. And so that's frank quackery. And that's a small part of what goes on but it's important. And I'll talk about that. And more important though is this sort of non, other nonstandard tests, tests that are not ready for prime time and may become ready or may never become. So you know recently we've had Oversure, which had to be pulled from the market. And there's all kinds of genetics susceptibility testing for nutritional deficiencies, toxins, cardio vascular disease, Alzheimer's disease. It's a whole idea of susceptibility testing. And that you're going to do something about it. Someone recently susceptibility testing will tell you what exercises to do. It's called DNA fit. I'm not lyin'. Same group also did for nutritional, the idea that you can get what you need from food. You need these tests and they're expensive. Proprietary testing for irritable bowel syndrome. There is clinically if you look, if you do an evidence based review, there are no tests for irritable bowel syndrome. It's a clinically defined entity. But you wouldn't know that if you went to the Prometheus Diagnostics website. You would think that there is actually autoantibodies testing for irritable bowel syndrome and that perhaps this is even autoantibody disease. IgG allergy testing. So conventionally IgG we review as protective. Allergists, a normal allopathic allergist's view this as protective but Naturopaths view this as the gain and then the entire area of food intolerance or things related to food is ripe for quackery. The idea that I've been poisoned or that there are things in my environment that my systems for chemical for balancing out chemicals are easily overcome by just simple paint or fertilizer on my lawn that I'm not all that I'm cracked up to be, that I cannot resist, there's something wrong with me and I need help from this kind of testing that my normal way and my host factors are absolutely useless and I need this kind of testing to guide what I eat and how I protect myself from this scary environment. The idea that berylliosis is an actual entity but usually you have to work at a smelter to get even cadmium toxicity and perhaps we all have it. That's what's pushed by these, these are real tests. Cadmium testing is a real test. Heavy metal testing is a real test. But do we all need heavy metal testing? Probably not. And then there's legitimate tests in the wrong clinical setting and that's what the massive wellness panels that are pushed now and they're advertised a lot in churches, synagogues, mosques, pushing this myth of wellness. It's extended out that we all need a bird lover allergy panel. I mean I don't have a bird, I'm not around birds. The only thing I really ever see is a pigeon. And then tests for inherited genetic diseases where those no family history or any other testing done in extremely low pretest probability where the symptoms are vague and the people who want the testing have more money than sense.

And so you know the good news about lab testing of course is that if you are sick, it's incredibly beneficial. You know if you have a tumor, if you're having your organs transplanted, if you have any infectious disease, it's very very important to have lab tests. But what if for wellness, it's a more limited set. This is examples of common overutilization which is the idea of order tons of stuff for well visits, especially thyroid testing for everybody. The idea that I'm a little hot I'm a little cold, I'm gaining a little weight, I'm losing a little weight, I'm a little bit angry, I'm apathetic. Could all be my thyroid, I'm wet, I'm dry. Tumor markers, the idea that you can read all the NACB stuff right on the AACC web site. What are tumor markers for with the exception of PSA which is still controversial. These are used for following, you know monitoring tumors but not for case finding but you wouldn't know that from the public. Why are we ordering, Pete Brian Jackson gave me this example from ARUP, looked at you know there's not even at the most ardent advocate of PSA testing which say we should screen 85 year olds and yet when he looks at the ARUP database there are plenty of 85 year olds getting screening tests. ANA testing is a tremendously overutilized testing and it's almost all, I'll tell you the single biggest one over utilized now in the autoantibody, it used to be ANA for the autoantibody lab, now it's celiac disease and the idea, you know 1% of the population it's arguable, but let's say you believe the high end, that 1% of people have celiac disease. That's fine, I'm OK with that, with 0.5% I'm fine, and I'm OK with that, but you know when you go to my kids' school for every you know for every person who actually has celiac disease, there appears to be 10 who think they have celiac disease. And they're sending your test to particular labs that tend to give a positive result for celiac disease. Kids come over to your house now, you can't feed them. Parents give you a list of things they can and cannot eat. Now I say to the people, this is a play date. I'm not here to take directions from you. It's not a management course, it's a play date. What I'll be serving is popcorn, pizza the usual things you serve kids. Your kid will be getting spring water. Spring water, that's all they'll be served. "Ah Dr. Astion, your kids are having birthday cake and pizza!". I'm like, well your mother's crazy and so you're having spring water. Would you like another glass of water. I'll cop you a break, I'll put ice in it. And then so now I actually have a case where I actually make the parent bring a bag of snacks because the kid, she thinks the kid has 20, the allergy testing at MetaMetrix Stage Diagnostics, there's a long list of lab. Nova Diagnostics, they only produce positives, and if you test me for 500 things, I'm gonna have one. And so the kid has all these things and comes with an eppy pen and I say, this is no lie, and so I make the kid bring their own snacks in a bag. This is what I've dealt with the parent. Bring them in a bag and then bring them out. And I feel sorry for the kids who really do have a peanut allergy. Because it's a real allergy and it can kill you. But every one of those, there's a bunch of people that think they have these things and it's driven by this nonstandard testing more than anything else.

And it's particularly in this sort of wellness crowd and now there's a continuum of evidence-based healthcare from things that we all buy into regarding lab testing like in troponin being useful in heart attack, you know lipids being good for cardiovascular disease risk assessment. The things that are clearly dangerous like avoiding conventional cancer testing around cancer

and instead getting the anti-malignin antibodies from Onco Lab in Massachusetts the only provider and the only one who's ever published on the anti-malignin antibody test as a screen for all of cancer or all of this other stuff, comprehensive stool analysis, etc. This is clearly leading us in the wrong direction and this is the tough area. Legitimate tests in wrong setting, massive well patient testing being the best example but you know do we all, this idea that we all need hormone testing which we don't need. So this is the toughest area for management from a conventional if you're working in a conventional lab like mine.

Now the reason there is so much nonstandard testing and overutilization in the U.S. is Google and patient pressure, would be the first. Marketing pressure by these firms. You know they push hard, they put sometimes the larger ones will put sales staff in your hospital and they'll market directly to physicians. And then an important factor is patient and physician misunderstanding about how to interpret lab tests. So patients in general, I'm making a generality here, but tend to view lab tests interpretation in a much more black and white fashion than care providers that know that it's gray, they know there can be false positives. Patients tend to view things more black and white. Like in my family, if you know if you have an albumin and the reference range is 3.5 to 5, and you had a 3.3 and you Googled it, you tell them I've got them starving. And you know I'd say Mom, you know everybody in our house is 75 pounds overweight, I just don't think, look, look at my albumin. Look at it. Your sister Googled it. Or my ALT is one point above the range there, I think someone's slipping something into my drink. This is how my family thinks. Very black and white. People tend to become their false positive.

Now if you're sick like I said, lab tests, I don't want to downgrade the importance of laboratory testing for sick people and in a conventional way for monitoring for, you know you can't have hepatitis C hepatitis without having a positive hepatitis C test. So I don't want to downgrade it.

But see, most care, this is known to most care providers, conventional care providers is denied by most alternative medicine providers, and unknown to most patients that there's really no lab test for headache or for most of the things that bother us in ambulatory care common complaints. You know I got the low back pain, I got the neck pain, I got the hair loss. What are the lab tests for that? What's the lab tests for that, what's the lab test for my headache, for most forms of fatigue and mood disorders. And these are the things, these symptoms of being alive and annoyed and having in-laws and children who don't behave, and an annoying job. These things that prove to you that you're alive, these semantic complaints that are being initiated by your emotional state perhaps you know these things, there's just no test for these things, and there's no evidence based body you can go to to find any testing. But if you look at my friend Mehmet Oz who I went to medical school with, and Oprah, and all these web sites push the beliefs that there are tests for these things when in fact there's not. And I wish there was. I wish there were tests for these things but the fact is that if you're a scientist, and now people say to me it's because I've given this lecture to hostile audiences. This is like

preaching to the choir this crowd. But I've given it in front of naturopaths and they always say the same thing: you do not think outside the box. And I say that there's a difference, my response is there's a difference between you know thinking outside the box, not thinking about side the box and not thinking. If I mail my hair to 13 places and they all come back positive in different ways, that's not lab testing. That's crazy. That's not outside the box. That's outside of normal human experience. That is not thinking. So when it comes to common concepts, I can give you some common lab concepts and how patients see them. You'll see why this feels nonstandard testing.

So we know what a cutoff is and providers know that you know that some patients are above the cutoff and have a false positive result. But patients in general think oh my god, it's above the cutoff I'm sick. Below the cutoff, I'm well, and in quackery the cutoff is set so low, that the test is either always positive or positive disproportional set time. So now we have a lot of, in Washington state we have a lot of these patients who want to have Lyme disease. They want to have Lyme disease. Now in Washington state, it's not like New Jersey or Connecticut, we don't have Lyme disease, very infrequent. So it's so infrequent, we don't even, we're a huge lab. We have 1700 tests on the menu. We don't even do the test. We send it out to Mayo. But what you know the patients who want to have positive tests. Why? Where do they want it sent? IGNEX. They want it sent to IGNEX so they can get a positive result. And this is true of a lot of different things. If people want a heavy metal test, they ask us to send it to these labs where they intercalate, they give an intercalating agent and then measure metals. And you know how many people would be positive when you intercalate for mercury and then measure mercury. 100%. So I say to those patients a) we won't send it out for you there and b) you have the disease you want. I'm giving it to you and you don't have to test. Save your money and go get your intercalation therapy because that's what they want. Or in the case of Lyme disease they want the IV antibiotics. I've had people in my own groups, these groups you know at school where they ask me these things and they want to get into a fight because they know I'm a conventional medical doctor and I say god bless you, go get your intravenous antibiotics. Don't you don't have to send your test. You've got, I'm so sorry you've got that disease. I'm so so sorry. So the cutoff is set unbelievably low. And some of the labs are frank to admit it. Specter Cell Lab admits that on average, patients will have between one and four, the average American has between one and four nutritional deficiencies. We look well nourished to me. We look well nourished to me.

And similarly with regards to reference ranges, in terms of how patients see a reference range, you know they will, you know view it more, using Google and stuff will view it more dramatically you know providers, most providers know that 5% of people will be outside of reference range even if they are perfectly healthy and that the more tests we order the more likely we are to find one outside the reference range. If you have 24 independent tests, there's a 71% chance that you would have one outside the reference range, this is just math, it's not laboratory science and of course so now what happens when you have, have you seen

the size of these wellness panels. There was the one, I forgot the name of the company up from Austin Texas, but I don't know there must be hundreds of things in that panel. And then when you get a 500 antigen allergy panel, you're going to get a positive, my friend.

So medical professionals deal in the concept of predictive value. Alright positive which is the test has come back positive what's the probability that I have the disease or the test has come back negative, how happy should I make the patient. And the, but from the patient's point of view, positive tests are usually viewed as positive, and negative negative. Not everybody. Some people have a more subtle view. But that's the big difference between providers and patients. And I can tell you from having lectured to you know physicians, naturopaths, nurses, that plenty of care, now in Washington state to be a care provider, you basically we have a very low threshold, you just have to declare yourself a care provider. I am a healer. Boom. That's it. So you know instead of having to spend your life studying in a basement while your father worked his ass off 24 hours a day so you could go to medical school so that you can you know work for 20 years, be on top of your craft and finally understand these concepts. You know you just *raspberry* you declare yourself a provider and you're thinking outside the box, and you're ordering dysbiosis testing and comprehensive stool analysis, IgG allergy testing, testing for all kinds of metals and you're as smart as me. That's basically, that's the idea. Even though I went underground for 20 years to study. You know. That's just kills me. My dad worked in a, my dad owned a candy store. He worked. This guy worked. And I said dad, now everybody can order lab tests now. Nothing special. Direct to consumer. I said you want to know your genetic susceptibility what exercises you should be doing.

So this is an example of, I'll show you, I'll illustrate how this works and why these things are driven to, how quackery and nonstandard testing works. So here's three cases and you can say to yourself in your own mind, is this low, medium, or high test probability to disease. Are these patients likely to have lupus? 40-year-old man presents with burning feeling on urination, new girlfriend has lupus. After googling, he wants a conventional ANA test and an alternative test he saw on a naturopathic web site. Is he likely to have lupus. His chance of having lupus are about 1 in 100,000. It's not an infectious disease that you get from your new girlfriend. Now here's a 40-year-old woman presents with progressive fatigue, hair loss, malar rash, oral mycosis. She has lupus. Whether we test or not, she has lupus. She has high pretest probability. And in the middle is a 40-year-old woman presents with one month of fatigue, hair loss, describes a lupus-like facial rash, but it's not currently present. So this is the person that lab testing helps. This is the most helpful. This we would never trust a positive. This we would never trust a negative. And this is the one where that may help us a little bit.

And this is what the positive predictive value curve looks like for a test with a sensitivity of 95 and aspecificity of 85, which is like the lupus test on a fairly typical day. Sensitivity is probably a little higher and specificity is a little lower. And so the test has come back positive here. So this is the probability that the patient has the disease. Probability that the patient has the disease. This is the pretest probability of the disease. So given everything we know about the

patient but we haven't tested yet, what's the probability in the physician's estimation that the patient has the disease. So in our googling guy with the burning pee, his pretest probability is down here. The gal with all those lupus, her pretest probability is here. So if this was HIV testing down here would be cloistered nuns. Over here would be you know received massive transfusions prior to 1980. You know of sharing needles with people known to have HIV. That would be high pretest probability. Right. So this is where quackery's practiced. Low pretest probability of any specific disease because it's likely that you've unless you're working in a smelter or downwind with a smokestack in your face without an occupational health exposure, you're unlikely to have a variety, with the exception of lead poisoning, are unlikely to have heavy metal poisoning, so that's you down here. Low pretest probability, vague symptoms. This is where quackery's practiced because when the tests come back positive, the probability that you have the disease is almost zero and so you can virtually assure the patient if you were a normal doctor that they don't have the disease being tested for and that's why you don't test. And this curve is now born out in hundreds of thousands of people with regard, this is why we don't do massive wellness screening and why the evidence based U.S. Preventive Service Task Force, ICSI, whatever you look at, they are supporting less and less testing because when the pretest probability is low, very few tests are good enough to produce any meaningful positive predictive value. So why do people have positive tests when they're negative? Million reasons. Errors, overlap between the disease and healthy state is the biggest one, interferences.

Here, now you make the test better. This red line. Now you got a test that's 95% sensitive, 95% specific. Look how crappy this test is in the low pretest probability setting. If you have a pretest probability of 0.5%, you know 5 in 1,000, right, 5 in 1,000. A positive test virtually assures that you are negative. And this is why wellness screening is a myth. Even for, this would be a perfect test, 100% sensitive, 100% specific. There's no such test. The whole laboratory testing process can't produce, even if the test was theoretically perfect, the fact that we shake and bake the specimen, you have your Uncle Elmo doing the phlebotomy and he's right out of prison, university of prison, and he's shaking and he's putting the wrong label on it and choosing the wrong tube and spinning it at the urine speed, leaving it outside for the courier at 118 degree heat, who picks it up, goes down and hits every pothole on the way to my lab. We haven't, the lab hasn't even had the chance to make an error yet. So you can't see this curve. These are the curves you see in the best case, pretest probability so what has good enough to test in a well patient. Well, turns out, what, lipid screening. Lipid screening. Pap smear for a woman. Fecal occult blood if you're over 50. PSA is controversial. This is why the data, this curve is just, this math is born out by reality.

And year of evidence based medicine now these things are no longer recommended in well patients. And when I say well, I'm talking about the vague symptoms of daily living. We all got a little something. I haven't been able to touch my toes in 20 years. I don't consider that an illness. I don't have hair. I have a headache a lot. The three most important substances

in my life are coffee, Tylenol and Pepto Bismol. And I'm not lying. I would never travel without those three substances. I'm more likely to not wear clothes than to have those three things with me. I need those things. So now we don't, this is from the U.S. Preventative Service Task Force. We recommend almost nothing now except for lipid screening. And lipid screening is your go-to move. A) you could save a person's life and B) it gives you something for those patients who want lab testing. In a very, which is a very real phenomenon. In a survey by Protrask and colleagues, patients do rate their visit higher, quality of visit in internal medicine higher if they have a procedure or test done. And so cholesterol is your chance to do that. It gives gravitas to the patient's visit. To come in and say well, you know you have, you've got a little TMJ thing and occasionally you feel a little light headed, I got nothing for ya. I got nothing for ya. That's no good. But if you can give them for a woman you can say well I got a, maybe I can give you a mammogram. I got your lipids. At least it gives you something.

Quackery or usually false positive results that are bogus for tests that either completely bogus like live blood cell analysis were not ready for use like Oversure for screening for ovarian cancer, or that are real but shouldn't be ordered in asymptomatic or vaguely symptomatic patients. That's the entire wellness panel. A man does not need to know his testosterone. An asymptomatic man or a man who's just say angry, which is the typical man, does not need to know his testosterone. But a testosterone, if you look even at university direct access testing sites like Ohio State which I love, I love Ohio State, but they offer the male wellness panel and it is male hormones. Similarly female wellness panel and female hormones. But there is no basis, and it's more likely to deceive and lead to what they call a cascade effect, my colleague Rich Dale, a cascade affect of unnecessary medical technology where the next thing you get is god knows what. Another test, or an MRI, thank god that went away because that was a deadly combination where you had the quack test followed by the total body imaging and most of those places went away for the same exact math reasons, you know the radiologists realized that everyone has a little something, everybody has what they call an incidental-oma. Everybody has like an extra this or that or a little thing and it's not cancer. But if you send everybody to a screening things, they are all cancer.

This is just a small example that I collected. I got a grant when people saw that I was studying this, I got a grant from insurance industry to you know make lists of these things are these are the common ones. Parasitology profile especially big in women's health magazines where you you know actually do your own stool testing and mail this thing in. And then it because you shouldn't have parasites or you should have a balance. Irritable bowel antibodies. Nonstandard organisms so things that are really contaminates, you know fungus and stuff. Stealth virus testing is big now. There's an outfit in New Jersey. Quack Lyme is big, that's IGNEK. Candida causes everything. There's a whole, there's a whole industry around yeast. And the idea that we're supposed to be sterile like sort of the lysolization of life. Hair analysis of all sorts. I actually saw that there was a positive article written about hair

analysis in Clinical Lab News. I say bullshit to that. And the reason is not because it's not theoretically possible to do perfect hair testing. I'm. It's theoretically possible to do glucose testing the way we're supposed to which is glucose tolerance testing, you know timed glucose tolerance testing. Theoretically it's better. But we can't do glucose tolerance testing very well because timing, no likes to eat that stuff, we've got to label the specimens. Right. Same hair can be a perfect specimen, but it's not. So I'm living on a place called planet earth. So there's not going to be hair allergy testing while I'm on planet earth. In heaven, there's hair allergy testing. Hair analysis of all sorts of suspect with the exception if I see hair ordered in our lab and it doesn't have arsenic next to it, red flag for me because I'm dealing in reality, not theoretical. Trace minerals, metals, nutrient deficiencies, this is big. This is big. People think that they're not getting enough nutrients, antimalignant antibodies, ..., salivary hormones, bioidentical hormones, adrenal stress panels, genetic risk is the big bunny and that's the big one. Detoxification capacity, the idea that you don't have what it takes in your liver to deal with life. Urine neurotransmitters. There's so many more. That's just a short list.

Here's eight warning signs that a lab test is quackery. Claims to rule in a syndrome that's not well accepted like emotional problems, stealth viruses, or dysbiosis is the big one, this general feeling that I don't feel good around here, which for me is forever. But that doesn't make this a disease. Just because I've never figured out what I got going here doesn't mean, and then I view it as part of regular life and that doesn't make this a disease. And no two people, no two naturopaths define that the same way. There is no naturopathic evidence based body where people would agree to that. Claims to rule in a syndrome for which there's no labs test. So these things are syndromes, fibromyalgia is a syndrome, autism is a syndrome, terrible effect on families, irritable bowel syndrome is real, but there's no lab test for those, or involves anything that involves a huge panel of bundled tests that's greater than \$400, the hair on the back of my neck stands up. Or if you send it out, and the tests always come back positive. I would say that's a red flag.

Huge inter/intra laboratory variability. I talked about that with hair. This is one I use. Tests do not appear in a search of any of those or we have a thing called a care provider tool kit at the University of Washington. So if I use the top seven things in the care provider tool kit, like I, you put this biosis which is commonly accepted by naturopaths, into any of these things, you will get nothing. Nothing. For hair you will only get arsenic. Tests offered as special by chiropractors and naturopathics especially if they tell you that there's a conspiracy by doctors to withhold them from the public. Or offered by one of the, any one of these labs, I'm not saying that these labs, some of these labs do real testing, but all these are suspect. They're all suspect and anything to Genova, anything to Prometheus. They have real tests here and you have to use them for certain things that they have proprietary. But they are the masters of bundling real tests with not real tests or bundling real tests with tests that are proprietary for which they own, they're the only ones who publish data and which are nonstandard. I'm not saying they are quackery, but they're not ready for prime time but by bundling, a good

example would celiac disease, you need usually one test tissue transglutaminase, but hard to get it from them like that. Not only that, another thing that on websites that worries me is when they have on the websites forms that you can fill out to overcome insurance denials, that you can just basically download them and fill your name in. IGeneX, Doctor's Data, Medical Diagnostics, this is stealth viruses, MetaMetrix allergy, many others, Sage, ALCAT, there's a huge list. Now most of these are small, but these two guys are big. These guys do over \$200,000,000 a year testing and my guess is that \$100,000,000 of it is BS. They're the masters and that's why they'll be publically traded. Now if I was my cynical, I would invest in them, because I believe that this cannot be stopped honestly. It can because people are demanding these kind of tests and also they're tricky because they have some tests that are needed. And then I'd like to make a special note about vap testing, lipid particle counting and the Berkeley. Now the Berkeley I love. I love the Berkeley because it's driving so much business to the University of Washington because when the Berkley heart multitest panel for cardiovascular disease risk is positive, a lot of times it, no one knows how to interpret it and so it drives testing into our cardiology clinic. But we've had experts come in and review data, John Brunzell from the University of Washington, Kevin O'Brian, have asked the cardiologists to look at this stuff and they, interestingly from Brunzell's lab, John Brunzell at the University of Washington is one of the world's experts on lipids testing and it's people from his lab who actually are doing these things. And he never uses these tests clinically. So this isn't quackery, these are real tests. It's just do these \$450 heart panels add sufficient value to a regular lipid panel or some stuff with apolipoproteins that add value to make them worth \$450 rather than paying \$50. And the answer is no. According to every evidence based thing that we've been able to put together and appeal to the experts.

And in a typical nonstandard lab sequence, this is the thing to look at that's a red flag, where that the diagnostic tests or test battery is link to advice or products and that the monitoring never ends. Repeat testing sell more products. That's the typical sequence.

And this is actual quotes from one web site, which I didn't put what the web site is but they actually asked these questions. Are you chronically tired, angry, anxious, overweight, hair thinning. Yes I am. Then they make broad claims. You may have one of these things. A gut flora imbalance, stealth infection, nutritional deficiency, metals, the same themes I've talked about, food allergy, early genetic susceptibility, hormone imbalances, you may need bio identical hormones and then they sell you a test.

Onco Lab is the sole provider of antimalignant antibody tests, and these things are usually linked to nutritional supplements, which I don't even care, I mean all you're doing is performing a cashectomy on people, I mean people would be better off spending the money on fruits and vegetables and they are more enjoyable, especially in the summer, but so I don't care about this, I don't care about creams, or even half of these things, teas, but this is the stuff where people start getting hurt. You don't need anything put in your colon, ever, unless you're very very sick. You know in my family if you say the word colon, you're thinking

cancer. We were afraid of the word colon. Now people talk about their colons you know like over par, and you know, I live on the west coast and it's crazy there. Because I'm actually kind of a left of center human being. But compared to my neighbors, I'm like right of Ronald Reagan. They're into all this stuff. These people, there's, you could get you colon cleaned as easily as you can pick up a bagel, pick up a dozen bagels. In the state of California, it's as easy to get your colon cleaned as it is to get you know gas in your car. So quackery is often what I call colonocentric and the colon is supposed to be dirty. That is the God's intended purpose for your colon, and the proof of that, the proof of that, I would just say is obvious. Certain things just need no experimental base at all. Do not clean your colon on a regular basis.

Here is an example actually from a web site, am I suffering from all these things, I may have mineral balance or metal poisoning, very common one. Test to by, this is my favorite, these guys are since out of business. I used to have the web site. Yeah. Tracemineralanalysis.com. This one was the best because you actually wrote the check to a guy, his name. Now this one is a little weird because all the other labs I'm talking about are CLIA certified. But this guy was not CLIA certified, but you wrote your check to him, which I got a kick out of. I don't know if he poured it down sink or he had a little analyzer in his basement.

And this has been written, medical toxicologist are particularly up in arms about this because they feel that patients are being preyed upon by unscrupulous practitioners especially if you carry diagnosis like chronic fatigue syndrome, or fibromyalgia, they are, and autism. People are very ripe you know you need hope that you're in pain, or your kid is in difficult shape, most of you have probably experienced families with who have autism and how horrible, you probably have friends who have fibromyalgia. These are very tough syndromes but that doesn't mean there's lab tests for them. And they are preyed upon unfortunately. And there were thousands of web sites when I googled trace mineral analysis in '07 and again before this.

This is actually the study I referred to from Barrett about the hair where they actually mailed hair from healthy teens to 13 labs and got the results I discussed. This was repeated again in 2001 and repeated again in the German study more recently. And that's why you know I know hair could be great but it isn't great. It could be great. I could win the Olympics in pole vaulting. But I'm not gonna win it. And hair could come along. But it would take a special lab to do hair. Takes a special lab to do hair well.

So we'll finish the last part of the lecture on intervention. I don't have much hope for quackery itself. The only hope is to limit the scope of care and that means you can't let everybody, every chiropractor, every naturopath order any lab test and have these special lab tests that don't have to have any evidence base. And now these conversations are occurring, I gave you some web sites where these people debate these things, but I have no hope for these, I have no hope for this at all honestly. But I do have hope for limiting conventional

medical practice because I know that I don't want to deliver a person's baby. I'm an M.D. but I don't want to deliver their baby or do their heart surgery. And I know physicians are willing to limit their scope of practice if motivated to, if given proper incentives to. This group I can't comment on. They seem to want wider and wider scope of practice.

Another intervention that does work in conventional medicine is to shift the patient focus to lipid panels, or to things they need, fecal occult blood and other screening tests. It's not like there's no screening tests. There's just very few. And that can be very helpful to get them to look at things that are important. A third thing that does help is the push-back by insurance companies, now that some of these, once you get bundles that are over \$400, they'll start to look. And so that's, they are starting to make rules and requiring prior authorization for things like 500 antigen panels or denying all kinds of tests, so the insurance industry here, it's one of the rare cases, you know they're our enemy if you are in lab billing like me, but they can be our friend too because when you're managing the send outs list they can be your friend.

And improved provider access to anti-quack resources. There's a lot of anti-quack resources now, both the insurance industry provide them as well as just using evidence based medicine sites and the rules I talked about and then there's quack watch and gene watch. And gene watch is particularly good for all this genetic susceptibility stuff and some of the things going on with direct DNA testing. Quack watch is a little bit more out there but has a lot of useful links.

This is the tough stuff, and I want to finish talking about it. How do we manage our practice, most of us are in conventional medicine. How do we manage the use of legitimate tests but that the setting is wrong? So you know a patient comes in and they're 118 years old, they have numbness. Do we want to order a spinal cerebellar ataxia panel from Athena Diagnostics for \$3,500. Probably not. So how do we say no to that. Or how do we say, let's say a patient needs an ataxia panel. How do we get them to order the you know a few first that are cheap rather than the whole pot? How do we block bundling? And I'll give you some ideas.

Now the first thing that I believe is that it's better to focus on the patient's provider, that it's hard to focus, it's hard to like educate patients. Patients just want the biggest panel usually. It's hard to overcome marketing pressure although we're doing a good job with the pharmacy because we're not letting pharmaceutical reps into our place anymore and they can't sponsor lunch, but I don't see that for lab. Perverse financial incentives is more of a government thing, in other words I have a perverse financial incentive for, I'm actually preaching against my own financial interests at this point in the lecture, because the more vitamin D tests that are not needed that are ordered in my lab, the richer I get. And this is true of everything. We do a lot of celiac disease testing. Not probably 50% of it is unneeded, but I'm making money on 100% of it, not just the half that's needed. So I have a perverse financial incentive to tell you the opposite of what I'm telling you, and to get rid of the perverse financial incentive isn't

easy and it involves government intervention and then paying people for outcomes and all that stuff which is a much more complicated topic.

But this is the sort of tool kit that conventional people can use to manage these tests that are legitimate tests but used in the wrong setting. And it can also be used to manage some quackery. For example, my favorite intervention is forbidding tests, in other words the idea of a lab test formulary. An IgG allergy testing is not on that formulary or in our case we send to 67 send out locations and we define them, and when you ask for a test that's not, to a lab that's not on that, you'd better have a good reason and it better not be on that list that I listed. So forbidding tests is particularly helpful.

And here's some ways I've said no over the years. We don't do that one. That one's not on the menu. I wish I could give it to you. You blame the menu. I wish I could give that to you. Man we should have that damn thing. But it's simply not available. They say bleeding time. Ack, we don't have anyone who can do that anymore. Sorry about that. We don't do that one anymore. And then you know lipid panels are available. So there's a lot of ways to say no in a friendly way. Forbidding tests, it's fantastic. So in our system, we have certain reference labs that are specifically defined as you can't send them there. Genova would be an example of one.

Then there's these other, of all the other techniques vary from what I call gentle through strong. Forbidding tests is obviously the strongest. Computerized reminders when you have computerized physician order entry can be very helpful. I'll show you an example of that. Utilization report cards I like, especially if they're reviewed by the physician's boss, like the medical director. I'll show you an example of that. And then I love this. Which is prior, basically a prior approval by a pathologist or other expert. Or the idea of privileging. The idea that in our system, in our place you can't order a neurogenetic test unless you are either a neurogeneticist, or some neurologists who's seeing neurogenetic patients. That really makes it easy. Really makes it easy. Family practitioner would have to send it to that clinic. Now I have the luxury of having that clinic. But this is true of a lot of tests, it has to come through medical genetics consult. Privileging or acquiring pathologists approval, very very helpful. I think that changing the manual requisition, the strength of the requisition is known to all of you, or the strength of the CPO E template is important.

So this is an example, I'm going to give you an example of each of these. So this is an example of reminders. So you're typing in all kinds of crazy thyroid stuff but if it's screening, you may get this thing, that if you're screening the test, you really only need one test now. People are trying to free text in T3 resin uptakes, this pops up. Or this is a big one at Vanderbilt which is that you're constantly reminded to discontinue standing orders which are rarely needed and rarely improve patient outcomes. And it's hard to turn standing orders on. This is one I always wanted to put in there, like candid camera.

Now the changes to manual requisitions are powerful, especially it's the best single way to obsolete tests, like single strand DNA, bleeding time, T3 resin uptakes, so changes to manual or CPO E requisitions very very helpful. And if you're still on manual recs, this will not work unless you destroy the old recs. You gotta destroy the old recs, that means literally sending out, because I'm sure you've all had this happen where you get a rec from like 1993. Every week we get some super old 1990s rec because people must hoard them because they still want to order that test. So you gotta have a policy procedure for destroying the old recs.

Now when you change, another thing you can do, and my colleague Kim Reddell does a good job of this, and for primary care, she has a very limited rec. The primary clinics only get a rec with 25 tests on it. The rest have to be written in. This is an example of genetics test and what you want to do is take this off the primary requisition so that they can't, it makes it harder to order these things. And you can do this for each specialty you can make the common tests easy to order and things that you don't think that they should be ordering, hard to order, like neurogenetic testing as in this example.

Here is an example where we didn't change, we didn't actually change the rec, we changed the definition in the LIS. So we have a thing called a chest pain panel that you can check off. Now we tried educating docs that you don't need the CK-MB very much anymore, just you know a second opinion sometimes or you think there's something wrong with the troponin, education did nothing. So behind the scenes we changed the definition. When they check off chest pain panel, it used to be troponin and CK-MB. Know what it is now? Troponin only. Right. And then you get a CK-MB if the troponin is, we have criteria where we'll give you a second opinion, and this is what then happens to the CK-MB order over time when you do the intervention. And that's very very nice. And troponin obviously stays up, CK-MB in red goes down.

And similarly this is ionized calcium and this is published by Wayne Chandler, Dr. Chandler and Dr. Baird from our lab recently in Clinical Chemistry. So here, at this point, in two hospitals, two curves, two hospitals, we changed the definition of an ionized calcium right here to be a total calcium. And an ionized calcium only if the total calcium is less than 8. Over here we're doing continuing education. This is the number of monthly ionized total calciums and note nothing's happening. And this is you can go read this paper, but they did a tremendous amount of work to show that there's no effect on outcomes when you do this, and in fact it probably has a beneficial effect on outcomes and it also had a tremendous financial effect in decreasing calcium gluconate usage. Now it's a very very nice piece of work by Jeff Baird and Wayne Chandler. And this is just changing the definition of an ionized calcium.

I talked about formularies higher level of approval and I'm very very much for this.

And the last thing that I wanted to talk about was lab utilization report cards, which this is from Group Health in Seattle, Dr. Kim Riddell. So you, the idea here, this is a very tough project. But this is very very worthwhile stuff. This is a strong intervention that's hard to do.

So the idea is that you know you come in for a well patient visit, and by that I mean you put, the physicians puts in the insurance codes for well patient visit. And the Group Health leadership looking at the evidence agreed that they're going to set targets, for every 100 well visits, we'd like to see zero comprehensive metabolic panels ordered, less than 11 CBCs and less than 7 TSHs. Now these really they wanted them all to be zero but they tried to make the targets realistic. And this is real data from one clinic and you'll notice that right after this report card went in, so the idea is that the physicians are going to be given a report card and who's going to give them the report card. Their medical director. Why? Because everybody behaves better if they know someone important is watching them. And so everybody comes into compliance. A, B D, and E except Dr. C. Still shotgunning like crazy. Until when? Until Dr. C is given feedback that Dr. A, B, D, E and the medical director all get to see his results. People don't like to look different. And so they correct.

And this is lead to this decrease in CBCs and TSHs. This is 2003, 2004. Kim has data from 2008 and it's still gradually declining over time. There's a long literature on the use of utilization report cards and there's many more than this but utilization report cards work. And report carding is one of the single biggest trends in quality today. You know hospital report, hospitalcompare.gov, all these physician report cards, pay for performances based on report cards.

So in conclusion, nonstandard testing usually involves false positive tests that are either completely bogus or the real test in the wrong setting like massive wellness panels, hormone testing in healthy people, or vaguely symptomatic people. And the cutoffs are usually set low in the case of quackery on the floor, the cutoff for positivity. It's enabled by the internet. And it's exacerbated by ignorance regarding testing principles and that ignorance is large in the public but it's also very frequent amongst alternative practitioners. Very very frequent. It's very, it is the rare alternative practitioner who understand basic stuff like sensitivity, specificity, positive and negative predictive value. And the interventions to decrease quackery, I have no help, I just think it's hopeless in the crazy healthcare system, but in regular healthcare system I think that that list that I gave you the structural interventions, the reminders, the report cards, the deny list, the prior authorizations combined with some pushback by insurance companies can make it so that your practice can maintain some sanity and get some better grip on the send out list so that you know that the stuff you are sending out might benefit a human being rather than sending them down a cascade of unnecessary medical technology which inevitably gives them a false diagnosis. And that's really the danger of nonstandard testing and quackery, besides being an economic waste, there's just so many people who think they're sick and I'm not saying they don't feel, I don't feel well, but we just don't have, you just don't have the disease that you think you have.

I want to thank the management division and AACC for the award and the chance to present this material. It's a real pleasure to be here tonight and I can take questions here at this time.