Primary Care Cures

Episode #33 – Kristine Ashcraft

Ron Barshop: You know, most problems in healthcare are fixed already. Primary care is already cured on the fringes. Reversing burnout, physician shortages, bad business models, forced buyouts, factory medicine, high-deductible insurance that squeezes the docs and is totally inaccessible to most of the employees. The big squeeze is always on for docs. It's the acceleration of cost and the deceleration of reimbursements. I want you to meet those on this show, that are making a difference, with host, Ron Barshop, CEO of Beacon Clinics. That's me.

Ron Barshop: So what would overhaul the healthcare game called preservation that the bigs seem to own and manage and run?

Ron Barshop: Well, one group uses telehealth to onboard 100% of its patients. Their inpatient and outpatient costs are 40% of their peers, four years now. And they have a Google rating of 4.8. I know a consultant also who sets an achieves a goal of 1.5 million take home for independent PCPs using about 50 different ancillaries. The ecstatic patients are delighted because of the convenience alone, if not for the outcomes. So he's sending a worked up patient to a specialist.

Ron Barshop: Direct primary care in its infancy, was born about 10 years ago and it squeezes out the middles like coders, brokers and carriers and even offers drugs at wholesale and other procedures at cost. The tests are free and the take home for that doctor can be double and outcomes can sore because they've squeezed out the middles.

Ron Barshop: A fourth model I've seen out there is direct to patient price transparency offerings and surgery and imaging like our last guest and in labs. And there are new PBMs that are popping up out there that are offering total transparency and very thin margins.

Ron Barshop: And the sixth is ANI enabled radiologist selection, lab testing, ECG scans and blood cancer screening. These are all turning the tables on the system essentially bringing the costs down, bringing the patient and the doctor closer in a relationship. So there's also a certifying transparent out of the box solution for creative brokers with the Health Rosetta. And another is giving a hand to inaccessible patient assistant programs to obsess free drugs for the customer, for the patient, surgery, births and more.

Ron Barshop: Today we have a national expert on pharmacogenetics, it and food and cancer and allergy genetics and gut biome analysis are upending the front end testing and primary care in other areas. They're soon going to become the standard of care in my opinion, because they remain like a fingerprint, largely unchanged. Your DNA doesn't change and it's uniquely you. And it tells us what drugs and foods and vitamins we're wasting our money on. So we're going to learn all about that today.

Ron Barshop: These are my guests since we launched primary care cures eight months. These docs and entrepreneurs aren't afraid of the future. They're embracing the future. They are apple cart tipper overs. They're troublemakers that are captains of destruction of the middles and the bureaucrats because they like messy space and messy is good. And healthcare is very messy. So my guests love fixing healthcare and are living the fix.

Ron Barshop: We welcome today Kristine Ashcraft. She is a molecular biologist with an MBA by training and she is also CEO and founder of an innovative company called YouScript. A precision medicine early adopter, Kristine was recently named one of the 25 leading voices in precision medicine. Can't wait to hear more about that. Kristine has authored multiple publications on the clinical and economic benefits of pharmacogenomic testing. They're both accurate, I guess. I learned the second. And one even lauded her work as one of the most influential publications at an AMA convention.

Ron Barshop: She's been interviewed by the New York Times, by the Wall Street Journal, NBC Nightly News among many, many other press and has spoken at South by Southwest, near and dear to my heart because it's in Texas, and numerous precision medicine conferences. She's recognized by the industry as one of the really important practitioners and spokes people and thought leaders. So welcome Kristine to the show.

Kristine A.: Thanks so much Ron. I appreciate you asking me to join you.

Ron Barshop: So I'm pretty excited about what you've done here. I think maybe my introduction to you is I heard a story about an adverse reaction to Prozac. A young man had led to his death and because of a prescription was completely accurate but apparently there's unnecessary deaths due to prescriptions that don't jive with your system every five minutes in America.

Kristine A.: It's actually recently updated to every two minutes in America. So yeah, the story you're referring to, Michael Adams Conroy actually started my journey in pharmacogenomics. I started at a lab in 2000 that was originally created as one of the first forensic crime labs in the country in 1987 with a

National Institute of Justice grant. When I joined them in 2000 they were looking for something that leveraged their core competency in providing really high quality DNA testing.

Kristine A.: And way back in 2000 that young man, Michael was on the cover of Fortune and his foster parents unfortunately were originally suspected of intentionally overdosing him because the levels of Prozac were so high in his system. And luckily a smart pharmacist and psychiatrist heard about the case and thought like 1 in 20 patients, he might be a cytochrome P45 2D6 poor metabolizer. Which is an enzyme in the liver that metabolizes a lot of medications we give to patients every day.

Kristine A.: So like good science geeks. We went to PubMed and started looking at just how common these were, how many drugs they impacted, and I easily thought, hey, this is going to be standard of care in five, six years tops. But I do think I had a very, a unique opportunity to talk to a lot of physicians, pharmacists, payers, about widespread barriers to adoption of technology that likely could have saved Michael and that's really where YouScript was born.

Ron Barshop: So just to restate what you said, there's an adverse drug reaction that's completely avoidable if something like YouScript was standard of care. Is that kind of a restating what you just said?

Kristine A.: Yeah, so I can't say that we're going to be able to eliminate every single adverse drug event, but we can certainly start reducing that number dramatically. Yes.

Ron Barshop: Okay, so how many are due to this metabolism instance where the body is not metabolizing the Prozac or other drugs in the proper fashion because of the DNA?

Kristine A.: Yeah, that would be hard to determine exactly. But I can give you just a recent prospective randomized controlled trial. So we did a study in a program that was working to further reduce readmissions. They were actually already in the top 10th percentile for lowest readmission rates in the country and they had pharmacists visiting patients in the home after a hospitalization because medication-related issues are such a common cause of readmission.

Kristine A.: And what we found in the arm that had access to YouScript and this pharmacogenomic testing, in addition to reductions in readmissions in ER visits, there was an 85% statistically significant reduction in death. And so that was though very high risk, high cost patients. I'm a bit of a scientist so it would be hard to theorize. I don't think it would be that high in general, but certainly a significant percentage of the problem.

Ron Barshop: Well, there is one a group that's going to be opposing anything called standard of care with pharmacogenomics, and that's anybody that's selling pharmacy or pharmaceuticals because it seems to me that a percentage of our drugs are simply going to not be necessary or be substituted out, if we had pharmacogenomics tests on everybody, is that sort of accurate?

Kristine A.: Yeah, correct. So when you do pharmacode genomic testing, my analogy is it doesn't necessarily guarantee a bullseye, but right now when we prescribe drugs, we're essentially playing darts with a blindfold on. Pharmacogenomics and YouScripts helps you take that blindfold off. It doesn't guarantee a bullseye again, but it enables you to much more quickly find the correct drug and the safest dose for that patient.

Kristine A.: So patients fall typically genetically into four categories. Normal metabolizer, which is how we prescribe and dose patients, intermediate which means they have about half the capacity. Think of it like a two lane highway. We're pretending everybody has two lanes. Intermediate metabolizers have one, poor metabolizers have no lanes of these highways that commonly process medications. And then there's an ultra rapid metabolizer that has three or more lanes.

Kristine A.: So if we have that information in advance, we're not going to give that poor metabolizer certain medications because they're going to build up in the body and cause a lot of problems. And we're probably not going to give it to the ultra rapid metabolizer either because they process it out so quickly, they don't get any benefit from it. The intermediate metabolizer, we can modify their dose, but what it does is it really moves us from that blockbuster, you know, give everybody this drug first model to finding the right drug and dose earlier.

Ron Barshop: Okay. And then I've also heard you say something that shocked me. You said something like three fourths of all cancer medications are not metabolizing properly in people's body. I mean that just blows me away.

Kristine A.: Yeah. Yeah. The treatment failure rate for medications in general is about 50% across all classes of drugs. So that's about 38% of antidepressants, up to three quarters of cancer medications. So the genetic information can be incorporated to really reduce that treatment failure rate. The other reason we see treatment failures is co medication or herbals even, St John's Wort. It's a natural antidepressant. But it could make your really expensive cancer medication not work.

Kristine A.: So what we've done with YouScript is very similar to like the Waze app on your phone. We're looking at everything that can increase or decrease drug exposure, whether it's those drugs, genes or herbals. And just like that Waze app says, hey, this highway's blocked, here's what you can do to

get where you want to go. We provide alternates that will also reduce blood pressure, for example, that are going to avoid those metabolic traffic jams.

Ron Barshop: So does big pharmacy see you as some kind of a threat or will the cardiology groups see you as a threat because they're going to start losing patients because the need for that treatment aren't going to be evidence?

Kristine A.: I would say that it's definitely counter to the blockbuster drug model to use precision medicine. And this is also a problem with precision medicine in general. So we're shifting from a, if a patient has this disease, here's your first line of treatment. If that doesn't work, try this. If that doesn't work, try this. When precision medicine steps in, whether it's pharmacogenomics or another type of genomic application, you're tossing that kind of group mentality out of the window and going for this patient, you go right to what you would typically try fourth. Right?

Kristine A.: That's not how people are trained. So I hate to say, hey, we're against that. We're against how the entire system was designed historically before precision medicine came to the forefront. So it is very much expecting a change in the entire mentality of how people are taught to practice medicine. Right?

Ron Barshop: Do you ever feel the pressure out there from the large groups that don't want what you're offering?

Kristine A.: You know, certainly there is push back that doesn't make a lot of sense to me. So you'll look at the FDA and in the FDA's drug development guidance they say if you have this kind of genetic variation, it should be considered equivalent of a bad drug interaction. Right? And yet we have a mandated drug interaction alerts and work to push those out into the system. But we don't have that same focus on genetic interactions even though the FDA has had that in their drug development guidance for a very, very long time. It's a bit counterintuitive.

Ron Barshop: So I'm going to ask you what the report looks like if I'm a doctor and maybe a separate report that's more patient friendly. But before I do that, I know in nutrogenomix you have different types of screening that you'll do. In other words, you might have a wide array or a broad brush approach and more of this more sort of this precision bombing if you will. Do you have that same world in pharmacogenomics?

Kristine A.: So I think that in pharmacogenomics there are a lot of different tests that you can run and get information on. But in terms of providing actionable evidence-based guidance, there is a limited set of genes that we can currently say, and that means you should avoid this drug and that means

you should get half of this dose. That is going to continue to expand as we learn more and more and it's going to expand very, very quickly.

Ron Barshop: Yeah. So interesting, I see a problem with your model. It's a small problem, but it's a problem. Is I can go for this on my insurance once because they're not going to pay a second or third time. So it's going to be a cost for the second or third time, but you're not that expensive. We'll talk about but so if I get a great answer today, it might not be as great as the answer I'll get next year or the year after, or particularly in five years. Right?

Kristine A.: Right. That is correct. But I would say it's the 80/20 rule. So right now, any pharmacode genomic panel worth its salt will include the core cytochromes, which are responsible for metabolizing most medications that we take. So those additional genes that we learn about are certainly going to matter for a specific cancer medication or a specific anti-psychotic, but I think that a large component of it is covered the first time. And I do think right now they're only going to cover a pharmacogenomics test once, but we're going to see the cost of whole exome sequencing go below the cost of a pharmacode genomic test.

Kristine A.: And we'll see the cost of whole genome sequencing go below the cost of whole exome sequencing. So as that happens, people will not just have a targeted genetic test, but a whole genome sequence available that can be leveraged for whatever use is needed, whether it's pharmacogenomics or otherwise.

Ron Barshop: Is this in the next three to five years or in my grandchildren's lifetime?

Kristine A.: I think it's going to occur probably more in the 10 to 20 year timeframe. I would say three to five but I've learned things always take longer than I would like them to.

Ron Barshop: Okay. Well let's talk, Kristine, about your report. Is it a red, yellow, green light report or is it more of a like an ABC report for a patient or is it something that you need an interpreter, maybe a genomics counselor to walk you through it?

Kristine A.: Yeah, certainly not a genomics counselor. So YouScript is an integrated clinical decision support tool. We also have a web based version but it's provider facing and it's meant to be real time because of the evolution of evidence. So what we provide for physicians and pharmacists is a red, yellow, green report with all the genetic information, active medications. The red meaning usually the risks outweigh the benefits. Avoid if possible. Orange is per dosing guidance, so increase or decrease the dose

with specific information. Yellow is just monitor. Greens we're not worried about it.

Kristine A.: But then we also provide one click alternates. So either by class or indication taking all of that information into account in real time, here's what you can do for this patient that would be another FDA approved drug for that indication. So it makes it very easy to optimize a complex regimen.

Kristine A.: For the patients there is a patient facing portal where a patient can just say, hey, you know, my doctor's about to give me Metoprolol, and they'll key that in and it will either say, hey, we think you should talk to a pharmacist or physician about this. There may be problems or we're not foreseeing any issues. If there are problems, the patient that then has the ability to share YouScript access with any of their healthcare providers or pharmacists so they can actually dive in and make recommendations.

Kristine A.: I would like to give more direct access to patients, but the FDA doesn't really smile upon a lot of patient facing information being made available when it comes to genetics.

Kristine A.: I think that right now there's a bit of a battle in our federal government. You have the ONC on one side that's give them everything they have in their electronic health record. Right? But on the FDA side, I think they still tend to be paternalistic. They think that if patients have access to that information, they will change their medications without talking to their healthcare providers.

Ron Barshop: Okay. I don't know if the health care providers are talking to each other. Well, let's give me an example of an optimized drug therapy. I mean maybe something that's at the tip of your tongue where you saw a radical change in somebody's regimen.

Kristine A.: Sure. So I'm still friends with a woman named Elise Astleford. She was a retired minister, the thought that she was in the first stages of Alzheimer's, had to quit her weekly bridge games. She was actually having a drug gene interaction and when that was resolved, her memory issues resolved within just a few days. And she still doesn't have any Alzheimer's like symptoms over 10 years later.

Ron Barshop: Very impressive. And that can be resoundingly part of the standard of care if this were the standard of care. So, you know, it just blows me away just listening to you talk, the FDA seems so deeply concerned with two or three people dying of vaping, which is two or three too many, but a few have died. Now there's many more that have problems with their lungs and pulmonary function. But the issue is small compared to what you're

talking about. Every two minutes something's going wrong because we don't have proper genomics maybe or maybe is some other kind of tests there. Is there anything that could slow that every two minutes death down because of an adverse drug events? What else would slow that down besides your solution?

Kristine A.: Right. Well, I mean the solution there is also to your point, the doctors aren't talking. Somebody needs to be writing heard on the multiple medications and the genetics impacting patients, taking multiple medications and that ideal person is a pharmacist. We have relegated these highly trained people to counting pills in retail pharmacies, and if we retooled them and used them in a clinical capacity, we would see a dramatic reduction in adverse drug events, a dramatic reduction in over prescribing. And I think it's one of the most underutilized resources we have.

Kristine A.: I'd say in addition to the deaths and treatment failures we've chatted about, there used to be a misquote on 289 billion on nonadherence. It was actually 289 billion on non-optimized medications. As of 2016 that's up to 528 billion, which means we spend more on non-optimized medications than we do on the drugs themselves or any major chronic disease. I mean it's literally an epidemic and really needs a huge focus.

Ron Barshop: Is it the pharmas responsibility to fix this problem? Like it seems like they're just producing a product. They're not trying to precisely define the product for all the sub markets in the market.

Kristine A.: I think that it would behoove us to make sure that pharma, not just for new drugs entering the market, but any generics, which are the ones that you see impacted a lot by these genetic variants. Nobody's doing the research in the area. For new pharmaceuticals there are studies that say, hey, this gene is the right match for this drug. The problem is that most of the drugs on the market don't fall into that and they're still causing a lot of problems. So we need to funnel money, coverage and resource into those generic drugs as well.

Ron Barshop: Well, you've entered a lot of hope into this conversation, but you said something awful for your business model. It sounds like you're going to be going down to earning pennies instead of dollars on your product. If that's the case, what are you going to do?

Kristine A.: You know, I think that it's also helping as many people as possible. So even if we just focus on patients taking five or more medications in the United States, there's over 50 million patients now. A hundred million expected by 2040, so even if we only get a dollar per patient to optimize their medications, that's a huge market.

Ron Barshop: So one of our listeners right now just had a friend or a family or member, somebody they loved that just entered cancer treatment. What would your advice be to somebody who just is getting on the front end of dealing with this?

Kristine A.: I would highly recommend getting tested. One of our partner labs, Genalex provides a physician authorized testing and access to YouScript. It's so, so important, not just for cancer patients, but anyone that you love that has to take multiple medications especially.

Ron Barshop: Okay. And insurance is going to cover this for most folks. And if not, the test is not too much. It's under a couple hundred dollars. Right?

Kristine A.: The test is not too much money and if your insurance doesn't cover it, if you have an HSA, you can also use that.

Ron Barshop: Okay. Terrific. All right, well this has been terrific. Now, how are people going to find you, Kristine, if they want to learn more about YouScripts?

Kristine A.: If they want to learn more about YouScript: www.youscript.com is our website. I'm also on LinkedIn for anyone in the health care community that would like to reach out. My name, Kristine with a K. Ashcraft.

Ron Barshop: Yes, and I'm just, I guess one final question. If we can fly a banner over America giving any message, what would your message be to Americans?

Kristine A.: My message to Americans would be that there is an adverse drug event epidemic that's even more important to conquer than the opioid epidemic that gets so much attention. In fact, a big portion of the opioid epidemic is pharmacode genomic variability that isn't properly being managed at the front end. And they really need to push their government and their healthcare providers to start taking this information into account for the safety and quality of life of themselves and their family.

Ron Barshop: That's a long banner, but nobody's done better than that. So that's pretty good Kristine. You know it's interesting. I'm going to ask one last question and break my rule, but it seems to me that physicians fear of genomics and genetics and discussion of it because it's going to bring in risk. It's going to bring in malpractice lawsuits. It's going to bring in a world they don't want to learn about really necessarily. And so it seems like your biggest barrier to entry is the physicians themselves that are just fearful.

Kristine A.: Right. Which is why we have YouScript. We make it super easy for you. You just find an alternate you're comfortable with at the click of a button and we've taken all that complexity of genetics and make it super, super easy for you to act on it.

Ron Barshop: See, now that's a banner right there, baby. I'm going to tell you, we're going to fly both banners from two different airplanes. You're not relegated to one here. All right. Well this has been terrific.

Kristine A.: Ask your doctor if this drug is wrong for you?

Ron Barshop: Yes. But they're not going to know. They're going to know with your help though.

Ron Barshop: All right, Kristine. Well, thank you so much. This has been very interesting and shocking and a wonderful look at your first early start and we're going to watch you closely over the years ahead.

Kristine A.: All right, well thank you so much for the opportunity, Ron. I appreciate it.

Ron Barshop: You bet. Thank you.

Ron Barshop: Thank you for listening. You want to shake things up. There's two things you can do for us. One, go to primarycarecures.com for show notes and links to our guests. And number two, help us spotlight what's working in primary care by listening on iTunes or wherever you get your podcast and subscribing and leave us a review. It helps our megaphone more than you know. Until next episode.