## **EPISODE 17:** Dr. Michael Astion and PLUGS – a Laboratory Stewardship Program to Foster Precision Medicine Best PracticesDr. Michael Astion | June 2019

Karan Cushman: Welcome to [*The Precision Medicine Podcast*](https://www.interventioninsights.com/precisionmedicinepodcast)*,* sponsored by Trapelo. This is the podcast where experts come to discuss the problems oncologists, reference labs, and payers face, as precision medicine grows, and consider solutions for advancing the quality of patient-centered cancer care.

Jerome Madison: Welcome to The Precision Medicine Podcast. Jerome Madison here, and today we're talking to Dr. Michael Astion, Medical Director for the Department of Laboratories at Seattle Children's, and also co-founder of PLUGS, Patient Centered Laboratory Utilization Guidance Service. Dr. Astion, welcome to The Precision Medicine Podcast.

Michael Astion: It's good to be here, Jerome. Thanks for inviting me.

Jerome Madison: I heard you speak at The Precision Medicine Institute in New Orleans this year, and you were talking about the need for collaboration of labs, payers, and providers, or healthcare systems. At some point during your conversation, I found myself looking around the room, because I wanted to know who else was going to jump out of their chair and shout, "Amen." That was me, because we here at Trapelo, we want to lead the conversation. We're one of very few who are talking about this very topic of collaboration of these three parties, but then you started talking about the work that PLUGS does, and the work that you guys have been doing there. I just thought it was phenomenal, and wanted to share more of that, and have this conversation.

Jerome Madison: Off the top, could you share what is PLUGS, and what kind of work does the organization do in healthcare?

Michael Astion: Sure. Well, like you said, PLUGS is the Patient Centered Lab Utilization Guidance Service, and it's a member-based organization founded and quarterbacked by Seattle Children's Hospital. Generally what it does, it's a program of Seattle Children's Hospital that supports what people refer to as laboratory stewardship. Now, laboratory stewardship used to be called ... people used to refer to it as utilization management, or test utilization management. But, when people hear the term test utilization management, especially laboratories, when they hear that, what they're thinking is, "I'm not going to get paid."

Michael Astion: When patients hear it, they think, "This is not going to be a covered benefit. I'm going to be out-of-pocket." When care providers hear it, they're like, "Someone is going to tell me, Dr. Big, what I have to order." So, we've tried to change the conversation, by pushing this idea of stewardship, which is management of a resource. We've piggybacked that on the ... We borrowed it from any microbial stewardship, which is the idea of using antibiotics better for the good of a population.

Michael Astion: And so what PLUGS does is it supports four things. One, is ordering the right test. Two, is retrieving that test because one of the largest sources of patient harm, and litigation in the lab industry is failure to retrieve a test. So, that's two, three interpreting the test correctly in three and four fair payment. When we say fair payment, we mean that it's fair to all parties. It's fair to the patient first, it's fair to the laboratory, and it's fairly the insurance company. Those are the four aspects of laboratory stewardship that PLUGS aims to pursue and improve amongst the members.

Jerome Madison: What is your hope that the stewardship programs will ultimately do for institutions?

Michael Astion: Well, I think that the institutions right now, besides the corporate sponsors, there's 92 members, most of which are hospital-based laboratories, or commercial laboratories. Many times these labs are part of larger health systems like Inner Mountain is a member, and Kaiser is a member and these large health, a lot of large health systems are members. But, what we're hoping to do is that they'll stand up ... We help them stand up. These members, stewardship system, so that their providers can better order, retrieve, interpret tests, and align with insurance companies to get fair payments.

Michael Astion: So, to service the members, we do four things. One is provide basic stewardship tools how to build a stewardship program, how to perform a stewardship committee, how to choose projects to improve stewardship, anything, it could be simple, like how to decrease duplicate test orders, or can be complicated like how to completely control your precision medicine, ordering, interpretation and spend.

Michael Astion: So, the first thing we do is we help the member stand up their stewardship systems by providing tips, tricks, policies, procedures, educational materials, meetings by WebEx where people can share best practices with each other. That's number one. Number two, we align with insurance company. So, we help insurance companies write policies, we help them pick out fraud and abuse, and we generally just try to align with them because they have problems too and the idea is if we help solve their problems, then they'll be more aligned to look at our members differently, and perhaps give them the benefit of the doubt on medical necessity. So, that's the second thing is insurance alignment.

Michael Astion: The third thing we do is publish voluntary checklists of stewardship standards. So stewardship, their standards around how to form committees, how to do interventions to improve test ordering, standards around the data, how to handle the data when you're doing these interventions, and then their standards around how to improve your stewardship system. So we have checklists for each of that. Then the fourth value proposition of PLUGS is to help particular clients who do not have genetic counselors to help them with precision medicine. And we provide a case management, a fee for service case management service with a trusted partner, which is Metis Genetics.

Michael Astion: So those are the four things we do in the industry for members, and it's been very popular, and it's really caught on I think insurance companies are particularly interested in this more collaborative approach.

Jerome Madison: Yeah, it's a very robust offering for a group to offer a member institution. What problems did you see or experience that inspired you guys to create a solution in the marketplace for this? I guess how did PLUGS formally get started as an organization?

Michael Astion: Yeah, PLUGS is really a grassroots thing. PLUGS started, it actually started in pediatrics, with patient complaints about uncovered benefits for genetic testing. As you probably know, although reimbursement for genetic testing is improving in the United States, historically, it's been poor and to this date, it still lags behind. It's hard for insurance companies to keep up to date. With the explosion of genetic tests, they need to make policies for the tests, it's very expensive and difficult to make policies, and so payment has lagged behind. So, PLUGS started, first, there were complaints in my own institution, letters from patients complaining about $5,000 bills that were uncovered benefits.

Jerome Madison: Yeah.

Michael Astion: They were shocked, and at the same time, this was happening at institutions around the country. And we had a meeting, just a regular meeting of the Children's Hospital Association back in 2012, and in an open forum, this came out. All these patient complaints, and all the problems with genetic test ... PLUGS started in genetics. All these problems with genetic test ordering, and the problems that the care providers are ordering the wrong tests, and the problems of not getting paid, which are related.

Michael Astion: So we basically cooked it up just around a dinner one night about six institutions cooked up this idea that we should, instead of complaining about it, we should share tips, tricks, policies, procedures, ideas, get people together, start creating solutions, and start to cooperate with insurance companies, instead of just calling them stupid or unethical. Let's start to get on the same page and realize that most people just want to do a good job. So that's how PLUG started with six institutions, and then we figured out a membership package. We did a collaboration with the business school here at the University of Washington, figured out how to put together a business plan that we thought could work long term, and then it really just took off. Because this problem goes all over the country. So, it started in genetics, and then it spread to all areas of testing.

Jerome Madison: Yeah, I think here's some data that was published in the Journal of Applied Laboratory Medicine, 2016. It was sharing information that reflects exactly what you've been mentioning that laboratory testing is really the single highest volume medical activity. Somewhere estimated over 13 billion tests performed each year. You mentioned genetics, about 30% of genetic tests are ordered inappropriately-

Michael Astion: That's right.

Jerome Madison: About 5% of those genetic tests are frank medical errors.

Michael Astion: That's correct.

Jerome Madison: What are some case studies about how the stewardship program has been rolled out there at Seattle Children's or other places where you've been able to save time, money and account for these errors?

Michael Astion: Yeah, well, there's a bunch of publications now on that very topic, including one from us. There's Cleveland Clinic, ARUP, and Prevention Genetics, and others now that have ... Or, other bunch of places that have published on putting together stewardship systems for genetic testing, and then improving the quality of the test order.

Michael Astion: The work, the first I ever saw a place really take an active position on it was the University of Utah, ARUP labs. It was a small publication by Chris Miller, and then we ended up interviewing for a piece in clinical laboratory news. But they took the courageous approach of starting to review the genetic tests submitted to their reference lab, and they found this 30% figure, which is held up pretty well over time.

Michael Astion: Many of the errors are, they're not going to cause patient harm, except that our pocketbook, it's a duplicate test, or it's a slightly inferior test, too big a bundle, too small bundle, et cetera. But then there's this 5% or 6%, that are, you're just ordering the wrong test. It's very hard for a physician, for anybody to keep up with the number of tests. When I started in lab medicine, there were only two tests you either tasted the urine, or you looked at it under a microscope. And now, yeah, now there's thousands of these genetic tests, and it's very hard. It's hard for providers to keep up, it's for insurance companies to keep up their policy writing engines to account for them.

Michael Astion: And so the stewardship systems that have been stood up now ... Oh, I would say at least a third and maybe a half of PLUGS members have them now. Usually use laboratory genetic counselors, the basis of them to review all genetic tests above a certain threshold. Sometimes it's a financial threshold like $1,000, or sometimes it's medical threshold, a basket of tests is chosen that is frequently miss-ordered. For us, we review every genetic test, except for factor five live, and that approach is also common.

Michael Astion: We have a lab genetic counselor systematically review the case, and in our hands, we're still correcting about 25% of the cases submitted. This has happened all over, and usually what you find is this 25%, 30% correction rate, there's 5% medically significant error rate. And then tremendous cost savings, because about 10% of the tests don't need to be done at all, because they're duplicates, or the patient doesn't have a pedigree, or medically a reason to make the tests medically necessary.

Michael Astion: So when you don't send those tests out, either the lab or the patient accrues the benefit financially, and so these programs tend to pay for themselves. So when patients can pay, then they accrue, they don't have to pay for tests that are unnecessary. It wouldn't be a covered benefit when you order a duplicate, for example, a duplicate genetic test, and when patients can't pay, who pays? Well, the lab pays, we still have to pay our send out bill. If we send out a test to the university or to commercial genetics lab, we have to pay that send out bill and if the patient can't pay us, then we have to somehow pay for it. The way you do that is you call shift into the price of all your tests. So really everybody pays.

Michael Astion: So in those cases when we don't send out a test, that accrues right back to the lab budget, and that's how you can afford a lab genetic counselor. So, the reason the lab stewardship movement was built on the back of genetics, is because it's one of the rare places where patient safety meets good, you know, a positive financial gain, and then the rest of stewardship was built on that back. That's why genetics really ignited the lab stewardship movement.

Jerome Madison: You've actually, you mentioned this earlier, helping insurers revise their policies for covering genetic and genomic tests. How are they seeing this problem as the era of precision medicine, it's kind of comes like tsunami, all these tests on the market? How are they responding?

Michael Astion: Well, genetic ... Insurance companies aren't all the same. I mean, there's different ways to divvy them up. I think for the purposes of stewardship one easier way to think about them is small plans versus large plans. So if you take, in the United States, a disproportionate amount of health insurance is administered by United Healthcare, Aetna, Cigna, Humana, and Anthem. They have it also a disproportionate share of the underwriting profits, and they cover the rest of the industry. The other 200 plans don't cover as many human beings as those five big insurance companies.

Michael Astion: So the problem that the small plans have is different than the big plans. So I'll just start with the big plans, because they're easier because you basically asked me about trends. So the trends over time, with the big plans is that they're covering slowly more and more in genetic testing. Big plans usually have the resources to do evidence reviews, or pay for evidence reviews, they often are excellent policy writing houses. So you can go for example, and many of them make them all members of an insurance plan have access to the medical policies that are governing their healthcare, the payment for their health care. But many of these companies make those policies publicly available.

Michael Astion: So for example, you could go online right now and look at Aetna's medical policy, all the medical policy bulletins for genetic testing. So, big plans, advantage, they got resources, they review evidence, and over time, as the evidence accumulates, they will start giving favorable coverage decisions, when there's an evidence based. The disadvantage of big plans is that they move very slowly, because they're large, like any big company, they move slowly.

Michael Astion: So just to give you an example, recently Aetna made a positive coverage decision with reasonable inclusion criteria for covering exosomes. We were pressuring them and talking to them that they're really slow, they got to move it, they're way behind. They had exosomes as investigational and experimental long after exosomes were useful for a fair number of patients. So that's an example on the big plan side.

Michael Astion: The small plans, they don't have the resources to write the number of policies that are needed. So when you don't have a medical policy, and you're a small plan, usually one or two things happen. Usually you don't cover for genetic testing, you just call it investigational or experimental, or you go to the other extreme, and you cover everything until you start to see as you look at your spend that you're going broke.

Michael Astion: So what small plants have had to do, and remember, in the United States, small plans, on the whole, are much less profitable. They're the ones that are struggling the most, they're getting bought up, they struggle to make an underwriting profit from the conventional health insurance industry. And so they've had a purchase, their biggest disadvantage is they can't keep up their medical and administrative policies, and so they have to purchase these policies, a lot of times from third party providers, and a nice third party industry has awoken and formed to provide the policies and procedures to administer genetic tests.

Michael Astion: So these are companies like ... And we're most involved with is Evercore, but there's Avalon and Hayes, and I'm a DNA direct ... Not DNA direct, Informed DNA and some others, but the space has got people in it now, and the small plans have to piece together something so that they can keep up. So those are the big trends of what's happening. Most insurers want to do a good job, and essentially, if they can keep up, but they want to pay for medically necessary testing without being ripped off by fraud and abuse, and waste.

Jerome Madison: Yeah. Are you seeing that there is a level of understanding with payers? Because you've spoken about germline testing preventative, versus those that are somatic mutations that may be acquired for other autoimmune diseases like cancer.

Michael Astion: Right.

Jerome Madison: Is there a distinguishing line between them because many of their policies address NGS testing as a whole? Is there a need for different policies?

Michael Astion: Yeah, well, there's ... I mean, the best insurers have a very nuanced policy books for different ... you know, that go into cancer, genomic profiling by tumor type and age. I mean, it can get very, very nuanced on the cancer, on both the germline side and the cancer genomic profiling side. So and that's why small ... And small plans can't produce that kind of nuance, so they have to purchase it from a organization that can.

Michael Astion: The one thing I would say that I think is really important, like if you're a provider of genetic tests, like we are or our university partners, or if you're a commercial lab either providing cancer genomic profiling or germline testing, or both. A lot of times you perceive the insurance companies as blocking or not wanting to pay, as not being fair, and there's definitely cases of that, there's no doubt, but you have to ask yourself why? The usual answer is, "Oh, they're a bunch of greedy, horrible people, who are unethical and don't care about patients." That's like the usual response. The PLUGS approach is much, much different than typical people, those kinds of names.

Michael Astion: One of the big reasons that insurers are a little loath to quickly cover, especially when there's just say one paper out there or something is just based on a principle, or the only data that's out there is internal data submitted by the commercial for profit laboratory company. One of the reasons they're a little loath to cover is that we're afraid to admit in our field, in the clinical laboratory field, that there's a lot of over testing a lot of quackery, and a lot of waste, a lot of fraud, waste, and abuse. And these insurers have tuned their systems, their claims adjudication systems, to block fraud, waste, and abuse.

Michael Astion: Now, when you tune your system to block fraud, waste, and abuse, what happens is that you end up blocking a lot of useful testing too. They're not doing it in response to being unethical, their systems make sense relative to the claims that they're seeing. Now, how do I know what I'm talking about? Well, for the last dozen years, we've been working with large insurers, and reviewing gigantic claims databases, and we've gotten to see as a university the fraud, waste, and abuse that's out there in many domains of lab testing, including genetics, both cancer genomic profiling and germline. Where the bundles ... Where the tests are too big, and way beyond the evidence, and the price is too big relative to what the patient needs.

Michael Astion: So our philosophy is to work with insurers and say, "Hey, look, if we weed out, help you weed out fraud, waste, and abuse, and are willing to put together some reasonable evidence based policies with you, review your policies or write some for you, will you be willing to give a more favorable inclination, when certain tests are on the border, but look like they're coming towards, or almost at a level of evidence that supports the test being uncovered benefit?"

Michael Astion: So that's how PLUGS works, is to align, is to not accuse. I'll make one other point for those, I just, it's kind of a long thing there, but if I had to summarize what I would just say, standing on one foot and saying it in 10 seconds, I would say most people do not like to be called unethical or stupid.

Michael Astion: So, I think that if insurers want to work with labs, it'd be nice to not be called that, and for labs to work with insures it would be good for us to take a different attitude. Which is that we're all coming to work to do a good job. There are always a few bad apples out there, but if we work together, we all want to cover the care, the medically necessary care for sick people. The vast majority of us do not want to be painted with a brush of fraud, waste, and abuse. So let's all view each other as like what we like to say in PLUGS, let's view each other as bozos on the same bus. We're all just trying to get by and doing the best we can, let's work together rather than this ridiculous last 20 years of throwing bricks at each other, and calling each other names. That's the underlying PLUGS foundational philosophy.

Jerome Madison: I like the visual.

Michael Astion: You like bozos on the same bus? I got that from a psychiatrist here, actually. Just this idea of looking back, viewing yourselves as better than another person or smarter than another person, it's been very helpful. So, that's how we try to do it.

Michael Astion: I like to tell people who I like to call insurance company executives stupid or unethical. I said, if you want to be in a negotiation with an insurance company, and if you fertilize the ground with, I'm more ethical than you and I'm smarter than you, then you'll grow the green grass of hate. Then you'll never going to get a medical policy. You've got to ... Who works in the insurance industry? It's just physicians, it's no physician's no different than me. Sometimes they go come out of practice and into the insurance company, then back in the practice, sometimes they're moonlighting for an insurance company. It's just the same, it's the same pool of people, and so to call each other names is just ridiculous, I think.

Jerome Madison: Yeah, understood. Well, I'll get you out of here on this. I mean, you're talking about all the great work you guys have been doing. But when it comes to big plans, small plans, in your worldview, what percentage of insurance companies, and I know this is very broad, how many of them have this on their radar to address policy directly focusing on genetic and genomic testing?

Michael Astion: Yeah, well, I would say five, six years ago, maybe a third hadn't even on the radar. Now, I would say nearly all of them do, no matter how small the plan. The reason is, and then the reason for that turns out to be genetics as well. Because you see, years ago, just not that many years ago, but say 5, 10 years ago, lab is a small part of the spend. People, the insurance companies spend, people debate how much it is, but let's just say it's 3% or 4% of the total spend of an insurance company is on pathology and laboratory medicine services.

Michael Astion: So it's such a small amount that it wasn't worth managing. Because they would see that each year, it goes up a certain amount, and that was tolerable. So they would just add it to the fee. In other words, if it went up a few cents per member, if the costs went up a few cents per member per month each year, they would just add that to how much the employer or patient or both had to pay, very simple. So they didn't have a lot of motivation to manage it. It wasn't going up beyond healthcare inflation.

Michael Astion: But then genetics came along, and genetics has had two scary things for insurance companies when they looked at data. The first was the cost per unit of service. In the United States, a typical requisition has about three tests, and bills out at about 45 bucks. Now, that's three tests for 45 bucks, right? So insurance companies are used to dealing with all this high volume stuff where the test costs 11 bucks, 15 bucks, 14 bucks, maybe a crazy test is 70 bucks, here comes genetics 2000 bucks per unit of service, these gigantic cancer genomic panels 3000 bucks. Well, they that's now they're thinking we got to apply something. And then they see that the growth isn't the usual 5% or 6%, it's 22% year over year, the last five, six years in the databases we've seen.

Michael Astion: So now they have a problem because one thing insurance companies are relatively conservative type of businesses. What do you do with those unknowns, that you worry, that they worry that it's going to blow up? Where could it go, lab could become 10%. So that's really what triggered them to look at it, and that's why all of them look at it now. I haven't, at least in our PLUGS world, we haven't really run, and we work with a lot of small plans and large plans around the country and our members cover all the plans, and we don't know have a plan that's that's not controlling genetic testing or looking at it. So, I would say now it's near universally like that, for those reasons.

Michael Astion: So hopefully looking at it, but working in a collaborative way will lead to more beneficial coverage decisions provided labs are willing to play fair, and not overcharged and not over bundle and that kind of thing.

Jerome Madison: Yeah. I think it's not lost on any of the listeners of this podcast that you can't really facilitate precision medicine without testing.

Michael Astion: Right.

Jerome Madison: Greater access to the testing and coverage will continue to spawn innovation to those clinical laboratories out there, and of course, confidence in the providers.

Michael Astion: Yeah, that's true, you need to ... I mean, the test, I'll tell you everything I know about laboratory testing, and I've been at it a long time. In laboratory testing, laboratory testing is phenomenal for sick people. If you are not well, the chances that we have a laboratory tests that can help you both nucleic acid base tests, which is the interests of your company, or other kinds of tests. The chances that it will help you is tremendous. You can't have a diagnosis of HIV without an HIV test. You can't have a coagulopathy without coagulation tests.

Michael Astion: That said, if you're well there's a lot of speculation, there's a lot of wasted testing on well people. The evidence base is weaker, even though people are excited about it. Also, even if you're sick, usually a few well-chosen precision medicine tests are quite a bit better than tons and tons of useless data that you have to try to muck your way through to find some signal amongst that noise. In general, in lab testing, less is more. A few well-chosen tests, with a good evidence based that will get paid for, and it'll help you more than just a sea of unusual speculative testing, where physicians don't know what to do with the results. So, those are just some good rules that I think can guide us. I think there's a good theoretical basis for that, but in practice, that's been our experience as well.

Jerome Madison: Sure. If you are a payer, if you are a health care plan, a medical institution or laboratory and you want to get in touch with Dr. Mike ... Say that again.

Michael Astion: Dr. Mike Astion.

Jerome Madison: Right. So if you are a payer, provider, health care system or someone who wants to get in touch and involved in PLUGS, reach out you can find their information listed on our podcast episode or you can reach out to Dr. Michael Astion at the Seattle Children's Hospital. We want to thank, Mike for joining us on the podcast today.

Michael Astion: Hey, thanks, Jerome. I had a nice time and good luck to you, and thanks for having me.

Jerome Madison: Thank you. We hope you'll tune in for the next episode of The Precision Medicine Podcast. Don't forget you can download transcripts of today's episode at precisionmedicinepodcast.com. Follow us on Twitter, PMP by Trapelo. If you enjoyed this episode, you probably know someone else who would do so please tell them. They'll thank you, and so will we.

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**About Our Guest: Dr. Michael Astion**

Dr. Astion is a clinical pathologist who is Medical Director, Department of Laboratories at Seattle Children’s Hospital and Clinical Professor of Laboratory Medicine at the University of Washington.  His career is divided between clinical service, teaching, and research and development. He has authored more than 20 software titles, 40 peer-reviewed papers, and 40 editorials.  He is the former editor-in-chief of *Patient Safety Focus*, which appeared quarterly for 10 years within AACC’s *Clinical Laboratory News*.  He is currently an editor of *Laboratory Stewardship Focus*, which is also featured inside *Clinical Laboratory* News. He is working actively, through grants and intellectual property held by the University of Washington and Seattle Children’s, with the insurance industry in the United States to create utilization management rules for clinical laboratory testing. In addition, he is one of the founders of PLUGS, the Patient-Centered Laboratory Utilization Guidance Service, a unique service that helps hospital-based and commercial laboratories actively increase the value of lab testing.   Dr. Astion is a frequent speaker at professional meetings, where he lectures on issues related to laboratory test utilization; test interpretation; laboratory economics and outreach; and medical errors. His awards include: