Reimbursements

Beth Brooks: So, I'm just going to introduce myself very briefly. I'm Beth Brooks. I'm the president and founder of Decision Driver Analytics.

I started Decision Driver back in 2006 for the express purpose of providing health economics and market access services to the medical device industry.

I'm a Mathematician by training, but I've been working as a health economist for more than twenty years now. So, I've kind of seen it all, in terms of the mistakes that companies have made with respect to reimbursement and market access.

And, then, I've seen a lot of really good success stories, too. So, I'm hoping to share a little bit of all of that with you. And, now, I'm going to turn it over to April to introduce herself.

But, before I turn it over to April, I did want to say that I started Decision Driver back in 2006 but in 2016, just a year ago, Decision Driver merged with Translational Technologies International, which is the company that April founded.

The reason that we merged is because over the years, with my expertise in health economics and our company's expertise and market access, we found that very often, we were needing clinical study design expertise from outside of our company. The company that we worked with was April's company, Translational Technologies International. She brings that study design expertise.

We worked together so closely on so many opportunities that we finally, last year, decided to join forces and merged our companies together. So, we are now a TPI company at DDA. I am very pleased to bring April to 10x for the first time, even though we've been working together for years.

April Zambelli-Wiener: Okay, thanks. Good morning, I'm April Zambelli-Wiener. I'm an Epidemiologist and Statistician by training. My background is in clinical research at Johns Hopkins. I left Hopkins to enter the private consulting world about 15 years ago and I've been doing that ever since.

TTI is a research methodology company, so we design and implement the full range of studies: clinical studies, observational, registry, small formative qualitative studies. We support the full range of activities that are required for both the implementation and evaluation of healthcare technologies and, also, Public Health and healthcare programs.

So, as I said, I'm very happy to be here for the first time and very excited to share our collective experiences, supporting our med device clients and sharing the things we've learned together over the years.

Nic Anderson: So, I'm Nic Anderson. I think you and I met via Joe right. Joe introduced Beth to me a few years ago and I remember hanging up the phone and I called my wife. Do you remember that episode from friends when Joey meets his identical hand twin? It was like I met my identical health economist twin.

She gets me. She gets what I'm talking about, and so, at the time, for the last seven years, I was a payor. I determined what Intermountain Healthcare was going to buy and not buy and reimburse and not reimburse.

So, anything coming through Intermountain Healthcare in Salt Lake went by me and our medical director, which is pretty much me. He would just say, “Nic you figure it out and then tell me what you think.”

I've written 150 some-odd health technology assessments, these big book reports on your technologies. When a company has a new treatment for BPH or breast cancer or a new… some of them weren’t products, necessarily. Some of them were procedures, you know, “should we be paying for sleeve gastrectomy for the treatment of gastroparesis.” I'd write a big 60-page thing on that, amalgamate all the data and say, “Here's what the data says and here's how much it would cost us. Here's how much it would save us.”

A couple years ago, I was approached by my neighbor. He said, “Come over. I want you to meet my friend who's a plastic and reconstructive surgeon at Johns Hopkins and he's got a new technology. He's gonna go raise 50 million dollars, tomorrow. Will you come with us? Let's talk.”

Two years goes by. They called me in January and said, “Will you come join us as the director of market access for Polarity TE. We can grow back full-thickness flesh for burn victims, their own full thickness skin.”

I'm now on the other side of the table. I was a payer for seven years. Now, I'm on the other side, trying to convince payers to pay. So, you're getting kind of the both sides, all sides, with it right here.

In most companies you have a Director of Sales and Marketing. If you work for a carpet company or a microphone company, you'd have a Director of Sales and Marketing. In Biotech, Medtech, Pharma you have Directors of Market Access. And then on the side, I do health economics consulting, market access consulting, and I'll leave it at that.

Beth Brooks: So, we really decided to focus this workshop on dispelling some reimbursement myths. You know, Nic and I did an abbreviated version of this a little over a year ago, at another one of Joe's events that was focused more on the marketing side. I think we had 20 minutes and we threw up seven myths. I think those are the same top seven that we're going to hit here today.

And we'll talk about things that we have seen over the years that a lot of medical device companies think, in terms of how reimbursement works, that really aren't true at all. I loved hearing the "train wreck" terminology in the back, because that's exactly how I describes my first medical device company clients.

Back when I started the Decision Driver in 2006, almost all of them came to me, as what I would describe as train wrecks, having not given a thought to reimbursement. You know, quite the opposite of what we just also heard, that we don't even develop the technology if we don't think there's a reimbursement pathway.

Many of our clients previously have not even thought about reimbursement until they tried to sell to the marketplace, after FDA approval. So, that Train Wreck Terminology is one that I have used quite frequently.

But we have a bunch of myths that we're going to talk through with you today. I think we stopped at 17 or 18, although we could have kept going. We're going to throw the myths up, talk about them a little bit, and then we have, I think, about eight case studies to talk through that hit on a number of those myths in a little bit more detail. But again, we want this to be an interactive session.

So, if you go ahead and pull down the content… The issue here is that, if you believe the myth, you're going to make mistakes. And you can make really big mistakes that will ruin your company, if you happen to have a start-up company.

But even if you come from a larger well-established company and you have a new product technology that maybe used in a new area or the reimbursement rules change a little bit, as they are changing a little bit right now, making mistakes can be very costly. So, understanding what some of these myths are, and how to avoid falling into those traps, is really important.

So, that's really what we want to talk about today. How can we help you dispel those myths and then dispelling the myths, helps move you forward.

Myth #1 FDA Clearance Equals Market Access.

This is the train wreck scenario. If you believe this myth, that if I have FDA clearance, I have access to the marketplace, that's not a good place to be, because it's just simply not true.

Nic, you and April, both feel free to chime in at any point.

I had most of my first clients in 2006, that's what they thought. My hurdle, and that's why we have the hurdles, my hurdle is to get FDA approval, then everything else will fall into place.

No. You jump over that hurdle and you're either met with a higher hurdle of coverage or adoption by the providers or, I used to describe it as, clearing the hurdle and slamming into the brick wall, that's the payer system. Nic, please feel free to chime in.

Nic Anderson: Of the 250 technologies that I said I reviewed, we denied coverage for 67% of them and they were all FDA cleared. Mull that over for a minute.

That includes technologies from every major medical device manufacturer we all know, we can let them be nameless, right? Of a 150 technologies, now not all of those were technology, some of them, like I said, were procedures, but so, let's say, 112 over 115 or whatever, that were medical technologies that were FDA cleared, 2/3 of them I denied coverage for them, because they were neither safe nor efficacious. They say, “I thought that’s what the FDA did. I thought the FDA already told us it was safe and efficacious.”

April Zambelli-Wiener: Yeah, and I just wanted to chime in. Whether you haven't had to generate data because there's a predicate device or you have had to do a study for FDA approval, often you know it's not the kind of data you're gonna need to demonstrate value. So, it's best to be thinking about those things from the beginning, because that's where you get economy.

When you can design these studies, to the extent possible, to be incorporating economic and patient reported outcomes, even knowing that our clinical trials are typically limited, and may not still be the only data that you need to generate, and we're gonna talk more about that later, but it's good to have a roadmap from the very beginning that sort of encompasses all of these things. And that's how we help our clients save a lot of time and money.

Beth Brooks: This is related, you know, some of these slides, you know, obviously the myths are related to one another.

Myth #2 FDA clearance means that your technology is no longer considered experimental / investigational / not medically necessary.

I use that language very specifically because that's the language that you see in negative coverage decisions. We're not covering this procedure, this technology because it's experimental, investigational, not medically necessary.

I have had numerous clients come to me and say, “Well, we're FDA-approved. Maybe we just need to tell the payers that we're FDA approved. We're not experimental. We're not investigational. We're FDA approved.”

They know that. You’re experimental from their perspective. You've shown that you're safe and efficacious, likely over a very short time period, but to a payer where you know this technology is gonna be released into the marketplace for use by physicians and patients that it's likely not been tested in and they need to know what the long-term safety or the long-term effectiveness, which is different, its effectiveness in actual uses. You are absolutely experimental and investigational.

So, no, don't schedule the meeting with the payer to just tell them you're FDA approved. They know that, and they still think that you’re experimental and investigational. And that goes to the point that April just made, about having the right data to show that you're safe and effective and cost-effective in actual use, is really what the payers are looking for.

Myth #3 our technology costs less so the payor coverage and payment will not be an issue. We're good to go.

Again, I’ve heard those very words, we're good to go, we cost less, we have a CPT code, we're good. There's gonna be no problem with this. No, that's not how it's viewed by the payers, again.

I've had numerous clients again who…”Well, we cost less’ We don't work quite as well. Maybe our diagnostic is not quite as sensitive and specific as the gold standard, but it really costs a lot less, so they're gonna really like it.”

No. That's just not how they view it. So again, it's another myth. “If I can just get my costs lower and be essentially equivalent, we're not gonna have a problem.” Not the way they view it, again. They're still going to go back to, “We need to see your evidence.”

Nic, I know one of the topics that we've both talked about a lot, is the number needed to treat or the number needed to diagnose. So, if your sensitivity and

specificity it's just a little bit lower than the standard of care but you cost less, the payer looks at it as, ”How many patients do I have to treat to diagnose a cancer? And, how much does that cost me? If I have to run more tests and more patients to find one cancer, than with the current standard of care, all of a sudden, my cost is increasing beyond what I think on a case-by-case basis.” So, this is a very different way that the payers are looking at it and again it comes down to the data that you have to support your technology.

Nic please.

Nic Anderson: Okay, this is that back-of-the-envelope health economics that drives the three of us crazy. “Well, my cost-effectiveness ratio went down because my cost is less, even though I have worse outcomes than…” Well, if it was that easy, there wouldn't be a whole industry of health economist out there, in this space. I mean, this is that back-of-the-envelope staff. They know if you're a worse technology, you're a worse technology, so it has to be superior. It has to be cost effective it has to have many of these boxes checked.

Myth 4 Clinical data from the FDA equals sufficient data for payor coverage and payment*

Beth Brooks: In any of these, where you see a little asterisk at the end of the myth, it means that's gonna be specifically covered in a case study later. There's going to be a specific client, a specific example, that we'll talk about that addresses that issue. That's just sort of the flag for me to be quiet about it, a little bit more, and not talk, because I can talk a lot. All three of us, unfortunately for you, can talk a lot.

I did want to say, though, if I'm talking more than my fair share, it's because last year I saddled Nic with this whole workshop, because the week before the workshop, I got pneumonia. And both my physician, and my husband said “No, you're not traveling to San Diego to give a workshop.” So, Nic ended up with less than a week to prepare the whole workshop by himself, so I promised I'd make it up to him by talking more today.

We're seeing a theme. Clinical data from our FDA submission, that resulted in our FDA clearance, equals sufficient data for payer coverage. No, it doesn't. You know what the payers are looking for is typically very different from what the FDA is looking for. FDA wants to know you know, in short-term, are you safe and efficacious. Payers need to know a lot more than that. And again, we'll be addressing this specifically in one of the case studies. But, April, a word...

April Zambelli-Wiener: Yeah, just a couple of comments. I think it's important to remember that you know our CTs are good for answering certain questions. And

usually, it's short term, acute safety and its efficacy, not effectiveness, not real-world effectiveness.

And, while there are things you can do to incorporate certain end points into your RCTs, as you're going through the FDA process. It's important to know that you have options.

You know, people tend to think of the RCT as the gold standard and the only way to address questions. It's not. It's the right methodology for certain questions and for other questions it's not the right methodology.

It's good to know from the beginning, you have a lot of different options which we're going to talk about. They can range from retrospective studies, administrative claims databases and EMRs.

You can do formative small-scale studies, where you can gather important data, Micro costing data, that can be inputted into economic models. So, we'll talk about those more. I don't want to belabor the point, but just to know that there are a lot of different options. Okay.

Myth #5 Immediately after obtaining FDA clearance, we are going to seek formal coverage determinations. Our technology is groundbreaking, and this will eliminate any roadblocks with our customers.

Beth Brooks: This is one of my favorites. The reason this is a very bad idea and, Nic, I know you want to speak on this, is because if they say no, which they almost certainly will, when you first get FDA approval, they've said no for everybody. It means, no local Medicare provider can say, “Yes, we'll try it in this patient population.”

It means that's a national decision, they cannot cover it. And then all of the private payers, BlueCross, BlueShield, says, “Well, they're not covering it, I'm not covering it.” So, it's the fastest way to kill your technology to do that.

Nic Anderson: You just said it. This might be worth it at this point, realizing the different players in health economics and in reimbursement and in making money in general in medicine.

I want to say this, really quickly, Beth, before we go on to number six, that it's worth everyone going through this exercise. When you get back to your office, on your whiteboard, in your office, write Payer, Hospital, Physician, Patient. And then start drawing down silos. And saying, “Here's all the reasons why the payer would love my technology. Here's all the reasons why the payer would hate my technology.

Here's all the reasons why the payer couldn't care less about my tech… why they would say, well this thing that you've told me is so great about your technology, I just don't care."

One, as a payor, that I was always frustrated with was Operating Room Time. "I took your operating room time, with my new technology, from one hour to 45 minutes." What do I care as a payer? I have to pay the bill anyways. I don't get billed by the minute. Maybe I do for anesthesiology or something but the $20 you're saving me on anesthesiology isn't worth the $5,000 you're charging me for your technology.

And then do the same thing for the hospital. Here's why the hospital would love me, hate me, and couldn't care less. Why the physician would love me, hate me, and couldn't care less. Why the patient would love me, hate me, and couldn't care less.

And then stand back and have the gut-wrenching moment when you look at this and go, "Really, who is my customer? Really, who is it that is going to love me and pay me for that love, right?" That's what ultimately, a lot of this comes down to, correct me if I'm wrong, is you know immediate… the FDA said they love me.

The FDA gave me that signature, from a government agent in Washington DC. Well, what do you think? Does the CMS care? Does the private payer in Salt Lake City or in Phoenix or in New York City care? No, those are two totally different people with different incentives and different zeitgeists altogether.

Payers pay for a patient to get better, so they don't have to keep paying for that patient to get better. That's not what the FDA does. And that's not what physicians necessarily do. And that's not what patients necessarily care about. Patients don't write checks.

So, this activity of putting things in silos, it sounds elementary, and like, "Well, Nic, of course, I know what the…" No you don't. Write it up on a board and spend three or four weeks revisiting that and going, "Now that I come to think about it, I only shave off operating room time. Now granted, I take it from three hours to two hours, but why would a payer care?"

Payers don't care. The CPT code for that procedure is the same amount of money whether it's three hours or two hours, even though I cut 33% of the operating room time. Who would care about that? The physician would. The hospital would. So, that's the argument you need to make to them. You need to find some other argument to make to the payer, because operating room time probably isn't going to cut it.

So, Beth this is facility versus non-facility, yes…exactly right. The physician would. Is the physician behaving as a part of the hospital or is he or she behaving independently, depending on position? You get into the OPP schedule, physician fee schedule and all that kind of stuff.

Beth Brooks: right… You have different arguments for different customer segments. So, we'll talk about this, as well, but in some cases, you don't care about the payer at all. You don't care about Blue Cross Blue Shield, at all, because Blue Cross Blue Shield is paying a lump sum to the hospital for a procedure under a DRG and your technology falls under that DRG, so the payer really doesn't care.

It's the facility that you have to convince, why they should adopt and use your technology. They can be completely different arguments and even in a case where the payer does care, very often in traditional reimbursement, fee-for-service reimbursement, a provider may really want to use your technology, if they feel it will drive utilization in their practice. “I have a point of care diagnostic that I can use that I could get paid for, that benefits me in my practice and I also think it benefits my patients, but it benefits my practice.” So, they're all about that argument. And the payer is thinking of it that way, but from the opposite perspective of, “That's gonna drive utilization, which means I'm gonna pay more money.” So, you have two arguments, very often, in that traditional fee-for-service environment, that are at odds with one another.

Your argument, to the provider, is you can do this test in your office and you can make money off of it. You know that's great and drives utilization and at the same time you know that story is exactly what the payer is fighting against. Where the payers going, “That's gonna drive utilization, which means, I'm gonna spend more money.” And until they have the evidence that the increase in utilization is going to save them money in other areas, because you're diagnosing a condition earlier which allows for an easier treatment protocol and improved patient outcomes over time, until that evidence is there, the payers going to deny coverage, which is going to keep the provider from using it. So, those things really fit together in a very complicated network.

What's changing a little bit is that if you're falling under a value-based reimbursement where you know it's a capitated environment, or there's an arrangement between a provider and a payer to say, “Look if you can manage this patient with diabetes well, and keep them healthy, and keep costs low we'll share in profits,” that aligns those two perspectives. So, now the physician is not thinking, “I want to make more money on a case-by-case diagnostic basis,” but, “How can I reduce overall healthcare costs.” That aligns those perspectives.

But in a traditional fee-for-service, very often, those are two different arguments that you're making. They are at odds with one another and so you have to figure out how to make that work. So, that's a great question.

It's very very important to think about “Who is your argument for?” If you're making that argument to the physician, you better be thinking about how the payers gonna view it and be gathering the evidence that's gonna let the payer feel okay about it, or, they're just going to deny it.

April Zambelli-Wiener: I just wanted to add a comment to kind of extend on Nic's suggested activity, which I think is a great one. But when you take that step back and you look at the board, also, ask yourself “How you know those things?”

We're gonna talk a little bit more about that. But, are you relying on a single key opinion leader? Have you been drinking the Kool-Aid for four years? Look you know you have great technologies. These technologies are amazing. But, you need to make sure that you have the right story. I cannot tell you how many times we have worked with clients where they said, “Well we know this is the story.” “Well, how do you know it?” “Well, we just know, okay?”

For a small investment, let's see if you actually know. And nine times out of 10, it's not the value story. We go to the providers and they're like, “We don't care about that. But we care about this over here.” You know it is better to find that out early, than after you've invested a lot of money in studies.”

Nic Anderson: Sometimes, it’s an excellent question. And I think, sometimes, it would really shock you.

So, just this morning, we were sitting out here in the lobby and I gave this story.

There was a technology and I can't even remember where I was. I don't know if this was in Intermountain or what, but, they had a way to inject trans-rectally into the colon, methylene blue. It would selectively stain polyps and adenomas in the colon. It was like a half a gallon of methylene blue. They'd inject it, and then the methylene blue would spill out on the table and on the floor in the operating room.

And they had the value analysis team. I was on that for Intermountain. There was about six of us on the VAC committee for Intermountain Healthcare and I was one of them. Maybe, that was where I heard this and heard the story. But, in the VAC committee, was the head of facility services or something like that, probably a Bachelor's Degree-type guy… that was sitting in the room.

They all went around, so the colorectal surgeons, right… They are saying “Yeah, this is great. I love this thing. You know how many polyps I miss? I'm sure I miss 100 polyps a year doing this. Can you imagine how many people died because I just can't see all the polyps. This would be great.”

And they went to the hospital administrator that said, “Yeah, I mean this stuff's cheap. Methylene blue is free. And then the label that you put inside the methylene blue and stir it up and is only $100 or whatever.”

And it came around to the janitor guy. And he goes, “Do you guys have any idea how long it's gonna take me to clean up the methylene blue that's spilled out of a patient's butt all over the floor in the operating room? You guys are already on my case for cleaning it up. We have 50 surgeries a day and I can barely get the room clean.” And it was him that shot it down.

So again, maybe, that's another column. Why would facilities management hate your product? If you're a pain in the butt to use your product… If it's really difficult to go to the central processing and get your kit, and then haul it down to the operating room, and then do this and this and this… That's another decision-maker, that… Now, there's only so many of these verticals you can do. It can get ridiculous, but, it is worth going through this process.

Sometimes, it's a high-power position that's sitting in that room that says “This is stupid. I'd never use it.” And they give no data. There's no discussion. There's nothing. “This is stupid. I would never use it. You know seven words and it sucks all the wind out of the room. And everyone goes, “Alright, well, I guess that’s it”

Despite the fact they have great health economics, they would really work. That's where having good messaging comes into play. It could be anywhere, from that high-power position, all the way down to the janitorial staff, that says yes or no. It might be the janitorial staff that goes, “Look this thing… I bet you guys could do 12 extra surgeries today because I don't have to clean up this mess.”

Beth Brooks: That's a great question. And if you go ahead and go to the next myth, I think I can talk about it a little bit more, based on this one.

Myth #6. Direct Facility Sales equals Easier Market Access

So, it seems to be that this was true, a long time ago. That if you didn't have to worry about the payer and it was really just, let's say, a surgical supply that was going to be used during a procedure and it was really just the facility’s decision, “Do I utilize your supply versus another supply?” That used to be easier.

Because, you could just get the surgeon to like it, and the surgeon would go to bat and say “You know I really just like the way this feels. I just like this technology.” And they would adopt that technology. That's not true anymore.

The surgeon will be a part of that value analysis committee, and their opinion will be heard. But it is not the only opinion in the room. You have all of these other factors. You have Purchasing. You have Infection Control. You have Supply Management. You have OR management. I mean you can have all those players around the table. And, you know they all bring their perspectives.

If the Purchasing person is in charge of… You know, their incentive is based on keeping their supply costs low, guess how they're going to vote on fancy new expensive surgical supply. You know, you have to understand that that’s how that works. And so, I would say, today direct facility sales is not easier than when you have to go to a payer. It's pretty much the same game. You just have to understand, “What information do they need to see? And what are those perspectives?”

And again, it can be something… We have an example of her client we're working with right now, where you they currently have a reusable supply, a reusable technology that's used in the facility and there are planning to cannibalize their own market with disposables. Still, the decision can come down to things as simple as, “I hate the way your disposables are packaged. I don't understand how to select which technology I should use. Why don't you color code them better. It's a pain for me.” It's, “I can't figure out how to store it... I can't figure out how to get it to the operating room in the right way.” It can be things like that that just kill the technology. And, so again, you know those perspectives and understanding that is very important.

And to April's point about, how do you figure that out? You have to go talk to the people you know. You have to talk to them and not ask them leading questions. You don't go to them and say, “wouldn’t you really like the disposable better than the reusable, because you wouldn't have to sterilize it.” They’d say, “Yeah.” You asked it that way, versus asking in a completely other way. Let them tell you. “Well, but you know the thing that I really don't like about disposables is… they’re always packaged in a really stupid way… and it irritates me… and it causes me problems during my day… and it makes me make mistakes.”

So, it's just really important to understand that you really have to gather the right information and really understand how your technology is going to impact a facility across all those different segments.

April Zambelli-Wiener: I just wanted to add that qualitative research is a whole science, and a lot of our clients don't realize that. That how you ask a question is

highly correlated with the answer that you get. And there's a whole science around doing that the right way.

So, sometimes, people think that they're getting the information that they need just from talking to people, when you actually need a little more rigor around it to make sure that you're getting true objective responses. Then you know things you can analyze and really draw consensus from.

Beth Brooks: So many of my clients have come to me over the years and they regard the payer as the enemy. ‘How can we trick the enemy’ or just using that very negative language about how are we gonna get around… They get a look on their face, and you can just tell they hate even thinking about it. Don't think of the payer as your enemy. They're your customer. You know you have to give the customer what the customer wants. So again, another message, “Don’t think of the payer as the enemy.” Think of understanding their perspective. Understanding why they're asking for what they're asking for. Then that shapes the way you go about approaching that problem. It really makes a big difference. Understand why they need the data that they need. Then do what you can to get it to them. April, I'm gonna let you talk about this one.

Myth #7 No one knows our technology’s value story as well as, or better than, we do. After all, it’s our technology!

April Zambelli-Wiener: I think that I already covered this, but again, I think this derives from the few sources, and probably others that I mentioned, which is you have one or maybe a few really strong KOLs who are driving the message. When you've got founders involved, this is your baby. You're passionate about it. and So it can be very easy to just slip into a knowing mode of, “I know what all those answers are.,” that Nic was talking about.

So, this just speaks to the importance of taking the time and using the right methodology to just get some answers from your potential customers about what your value story actually is, so that you can appropriately allocate resources and design your marketing and your research program. We're going to give an example of this one.

Beth Brooks: But again, we've all seen this a million times. And one of the things that I love working with medical device clients, is how passionate they are about their technology. That's one of the things that's just so satisfying about working in this space is you meet people and they're so excited about their technology, they're so passionate about it, it's really hard not to get excited about it and want to help them. But sometimes, they're excited and passionate about it for all the wrong reasons. They think they have the best thing since sliced bread and you're like, “Uh,

No.” And you can see immediately all of these reasons why it's not going to work. So, it really is important to try and filter yourself a little bit, to understand that your perspective can be can be skewed just because you're too close to it.

Just like we all can think that what we've written is really clear. How often have we written a report or written something where you think it's crystal clear and somebody reads them, “Like I need to know what you're talking about.” It's because you're too close to it. So, I think that's just important to remember why that qualitative research is really important.

Nic Anderson: Something, too, it is semantics, but it does help frame a lot. Technology is not a product. Technology doesn’t equal a product. Technology is just a raw thing that has no emotions, sitting on your bench top. That’s just the technology. It may have a patent wrapped around it. It may have some KOLs that have seed thoughts about it. The product is what you're selling. That it takes years sometimes to get from the technology all the way down to the product. To the point, sometimes, you can get so enamored with the brilliance of your technology, that you end up forgetting the fact that with each of the little value points that you've pointed to that you say we can shave an hour off of surgery and the patient can leave the operating or the ambulatory surgical center one day sooner and this and this and this… behind all of those great things that your technology will eventually turn into a product and that product will eventually do all those things that you just said. There's CPT codes and Hick Pix codes and DRG codes and ICD-10 codes that might not let you capture that value.

So, the fact that you shave an hour off, I'm just gonna pick on that for the rest of the day, let’s change whatever it is for your technology that's applicable, right. That's great you shave that off, but there's no way to capture that value though. The hospital might not be able to capture it, the payer might not be able to capture it, and neither could the physician, or the patient. Nor will you be able to quantify that, in any meaningful way, that illustrates clinical utility. What difference does it make if the patient's in under anesthesia for two hours versus an hour 45 minutes? Are you gonna be able to show a clinical outcome measurement by getting that patient off of anesthesia 15 minutes sooner? So, there might not be a way for you, even though your technology says you will be able to do all these things and maybe your product at the end of the four years of R&D and getting it out there, can actually maybe do some of those things, is the billing and coding mechanism going to let you capture those values? So that's another thing worth realizing. You might go out and say, “I can save you this and I know I can shave 15 minutes off of this and I can help physicians identify 7% more of these, yes, but is any of that capturable? Your technology might be able to pull it off, but your product might not. Your product involves CPT codes and DRGs and ICD tens and all of that. All of that is wrapped up in your product and it will dilute some of the majesty of your product. Your product

can indeed do all those things, but your technology can't, but your product can. Your product includes the whole healthcare industrial complex wrapped up into it that might squash some of the benefit of your technology.

Myth #8 Randomized Clinical Trials (RCTs) are the only studies payors will consider when making coverage decisions. Providers prefer prospective RCT evidence, too.

Beth Brooks: Yeah, this is another myth is that our RCTs are the only studies that payers will consider when making coverage decisions. And that providers prefer perspective RCT evidence as well. So, this runs a little bit counter to one of the other myths… is why do we need any data? We have FDA approval. But once you move past that then people think well it has to be an RCT. It has to be a prospective RCT. That's the only thing that anybody's gonna look at and that's really not true. And that's a hopeful uplifting message. See, we moved right into that.

You didn't even know we were gonna do that because, look, we work with a lot of startup companies. We work with a lot of companies, that, this is their first product. And when they get up to get approval, they don't have any revenue. They don't have any money coming in. They've got investors, but they don't have a lot of money. Some of them don't have any money and so the idea of running a large perspective RCT to get coverage, this is just like “We just can't do it. So, what do we do?” Well, there are things that you can do. There are incremental steps that you can accomplish, that will build payer coverage. We'll talk about that more in a couple of case studies, but there are ways to do this. If your Mentronic … if your Boston Scientific, if you're a large company, you can afford to run an RCT, right away. You can afford to run a five-year long RCT, while you're launching your product.

They don't always do it, but, they could if they needed to. But they don't always because they don't always have to do that. So, they know there are other ways to get there. And the disadvantage that you're in, when you're a startup, is, you don't have that experience bank to draw on. You think it's either all nothing. If I can't do that, then I'm not gonna do anything at all. I'm just going to try these other tactics to get into the marketplace. But there are things you can do to build your evidence and work towards fair coverage. Is there anything that you wanted to add to that, or we can wait until the case studies?

April Zambelli-Wiener: That's one of the benefits of the great proliferation of science that's out there and in PubMed. I don't know how many of you are familiar with the hierarchy of evidence, but now, at the top is systematic reviews and meta-analysis of RCTs but also observational studies. So, we do a lot of that for our clients. Making use of existing data. What can you do with what already exists. Sometimes, it's really not obvious. Sometimes it is, but sometimes it’s not.

Same with administrative claims databases. There's a lot of proprietary data sets, as well as publicly available data that can be used by itself, or in mixed methods designs, where you're drawing on some data that you have from your smaller scale studies and pulling in other available data to create that value story.

So, there's a lot of creativity that can go into this that will still be accepted by your clients and by the payers, if you've done your homework, and you have a road map, and know where you need to go.

Myth #9 We are a start-up company. We cannot afford to conduct meaningful studies.

We've already addressed that one. Don't even need to say anything else. We're a start-up. What we can we do? There are things that you can do. It doesn't have to be all or nothing. There are always lots of different ways that we can get there. So, let's move on.

Myth #10 Investor-initiated (or sponsored) studies at high-profile sites will always provide the best data for market access.

And this is another one that we see a lot is, we have startup company clients like, "You know we can't afford to sponsor a study." We've got lots of physicians out there, a lot of them at really high impact facilities. We have positions of Mayo who are excited. We have physicians at the Cleveland Clinic who are excited. We have physicians at the Children's Hospital of Philadelphia who are excited about our technology and they want to run studies. So, we don't have to sponsor anything. We're just gonna let them do the study they want to do and we're going to use their data."

That can work sometimes and it can really, really, really not work sometimes, several reasons. One is you have no control over their timeframe. You want to do this fast. And you want to get the information out there fast. They are typically not interested in fast or they just can't operate quickly because of the environment that they're in. They may also want to study something that really is not of interest to you. And you don't think it's going to impact your position with the payers or with the providers. If they have total control of it, they're gonna collect the data that they want to collect and then they'll publish it and sometimes it hurts you rather than helps you.

We've seen that a couple times where we've had clients come to us and say you know, "We did this investigator-initiated study. We thought it was a good idea, and now they published this. And this publication just kills them. And they're, "What are we going to do now?"

Or it could even be a case where, it's a sponsored study, but they picked these high-profile sites that all start wrestling over control. And there wasn't enough put in in terms of clinical study coordination, of their managing the data process and it can just cause a lot of a lot of headaches. April, you may want to address that more.

April Zambelli-Wiener: That's a fantastic situation to have, whether you have all these clinical sites, who are excited about your technology, and interested in working with it or you want to engage them and pull that kind of thing together.

Invest in coordination, independent in coordination, whether it's within your company, or an external. And don't think that you can't afford it, that that's only something that happens for huge large scale clinical trials, because there is just a small amount of protocol development, codes dictionaries, training of the sites, on how to collect data and then managing that data.

The return on investment will be tremendous. We've been brought in to rescue situations that have gone, luckily, not all the way down the path.

But, you've got sites, they're using completely different coding ontology. They're collecting all different data, in all different ways. You're gonna end up with not a lot of usable data out of that situation. And for a small investment, you have, really, a treasure trove of data that you can use to support your value story.

Myth 11 At product launch, we must keep our market as large as possible*

This is a good one, kind of shifting gears a little bit. But, at product launch, we need to keep our market as large as possible.

So, think about a technology that as you're going through you know startup activities and getting investments you want to go out and say to investors this is a huge market. This technology is an asthma. Think about how many asthma patients there are. Think about how huge this market is. This is a, however many gazillion dollar market, and that's what you want to say to your investors.

As you're thinking that, think about how the payers are going to think about that. So, they see new technology unproven technology and huge patient populations, what do you think their reaction to that is going to be? “No, No. So, this is going to hit a huge percentage of my covered lives and this is unproven” and, for them, it just increases their risk.

So, at market launch, we're very often telling our clients, if you're moving into an area like asthma or diabetes or you know some highly prevalent condition, think

about it at launch, ways that you can make that market smaller. How do you define the patient population that this technology would most benefit, where you can prove to the payer that in that small sub segment this has benefit and build gradual coverage in that way.

Nic Anderson: So, because this is exactly… a payer, we have a budget. I have a 500 million dollar budget this year. Your health economic argument might be over four years you'll capture all this money, but today I got a budget right now. I get you'll save me money in the long run. So that's exactly this. Now, that you complimented me on analogies I'm hesitant to use one, but an analogy I have used is pretend you're the best college professor in the world. You teach Ochem you got hundred students in your classroom and so your total addressable market for your Ochem professing is one hundred. But, you've got seven students that show up drunk every day. Well now you only look 93% efficacious. So what if you could have used April services to taper down.

You want to be able to say, “I got a hundred people.,” because a hundred times a thousand dollars that you charge for your technology is a ton of money for your investors. The problem is it’s multifaceted. One, the payer would look at the huge thing of a hundred people and say, “I can't afford to treat a hundred people with your new thing. That's 40% more expensive than I'm currently paying, because I got a budget, right now, I'm a company. I only have a seven hundred million dollar a year budget for your diabetes or whatever. You'll blow that out of the water.”

And the other thing is to say, “I want to taper it down to this, to the diabetics, or the uterine cancer patients that are gonna most benefit from my technology.”

So, it takes your bell curve from being washed out by these drunk students that are killing your bell curve. You trim them off and all of a sudden everything looks better.

Your technology looks infinitely better because you're getting rid of those people and you're making it within the budget mechanism of a payer. So, you win two times.

Then over the next three and four and five years, go ahead and include some of these people. Bring them back in. But for the time being say, “I am only for type one diabetic patients that do not have foot ulcers.” Even though you could perfectly work well in patients that do have foot ulcers But, that's such a huge thing it spooked payers. They might end up kind of ruining your data a little bit.

You might work them in, but, try to taper them off for now and say, “I'm only going for here,” so it's the camel’s nose under the tent, right? Just begin right here. You'll make a huge return for your investors in the short term, and, then, next year, expand a little bit and expand a little bit and expand a little bit until you get all those patients.

Myth #12 When it comes to Health Economics analysis, big and complicated is better.

Beth Brooks: When it comes to health economics analysis, big and complicated is better.

So, this is another, maybe, heartwarming, uplifting story. We have a number of clients who come in and they say, “Our technology impacts these 20 different areas within the hospital. It's going to help with their sterilization cost, and it's going to help with their transport costs from the supply room, and it's going to help with…” And they've got 20 different areas where it's gonna help. “And we want you to build a model that shows all 20 of those areas and how that works into the value proposition.”

And, my response to that is, “Okay, but, it also looks like you're throwing the kitchen sink at it. It makes it less believable. If your value proposition depends on each and every one of those 20, what happens if one of those 20 elements doesn't apply in my situation? Does the whole thing fall apart there? They start to get suspicious when you make it too complicated. Sometimes, you have a technology or a situation, an indication, where it has to be complicated to tell your story and it's justified. You have to do that. But, a lot of times, maybe, there's three things that your value story really hinges on.

Make your value story on those three things, and use the other 17 as what I just call color commentary. “Here's our economic argument. It's based on these three very believable and supportable and proven propositions.”

Put the health economics model together about that, and then say, “And we haven't even considered these other 17 things that also would swing it in this favor.” That's much more compelling to someone to see it like that, than the kitchen sink story.

April Zambelli-Wiener: And a lot of times, remember, you're going in, you're sending your sales people out with a tool to take to the facilities, in this case, thinking about the facilities, facility perspective.

You have a base case in your model, but, they want to enter their own data for certain parts of that model, and you walk in with this four-tabbed spreadsheet that blows their mind. They're not gonna be very receptive and happy. That's a big burden on them.

We've seen clients go in with just… It's a whole training process just to get them to understand the spreadsheet and the model and that's not where you want to be with your client. So, doing that research again to really understand what's driving the value story, it's really important.

Myth #13 Our technology will be paid based on its value to the healthcare system.

Beth Brooks: Okay, this is another one. “Our technology will be paid based on its value to the healthcare system.” This myth arises from complete misunderstanding

about how technology is valued and how a CPT code, for example, is given a payment level.

They'll come in and say, “This technology is going to eliminate the need for these three procedures downstream, so I'm gonna be able to get a premium payment for this from the payers.”

Nope, that's not how it's valued. It's valued on the resources that go into that procedure. So, it's the supply itself that's being used. But it's nursing time and physician time and expertise. And those actual time and cost values go in and build that payment.

It has nothing to do with cost avoided. That's not the way it's evaluated at all. So, very often they're like, “… I can charge ten thousand dollars for this because, I'm gonna save twenty thousand.”

No, if your procedure is simply to a non-invasive in the office point-of-care procedure, that takes very little time and experience on the part of the physician, it doesn't matter how much you're saving downstream. You're gonna be valued based on what's happening in that procedure, so, it's just a misconception.

We had a client a number of years ago. This one's not a case study, so I'll expand on it a little bit. They came in with these market estimations that they were going out to their potential investors with. And it was based on garnering this premium payment for the technology because of cost avoided. I'm going to say, “You ought to stop that. Because, that's not the way it's going to be valued. Here's how the payment is actually valued. This is what you can control. You can control how much you charge for your technology, but if your technology is like a pushpin, you can't charge $20,000 for that. See, there are things you can control, in it in terms of how you price your technology, but you can't control how they're then value the resources that go into that procedure.”

So, we told them, “You gotta stop it. That's totally messing up your market assessment. You got to go back and look at this again. And look at it more realistically and then move forward from there.”

They weren't happy with us. But, you know, once they did their research and they realized we were right, they're like, “Okay, so, we've got to kind of start from scratch here.” So, that's it. That's a really very common misconception that we've seen.

Myth #14 It is much easier to demonstrate the value of a diagnostic technology versus a treatment technology.

Ok this is one, “I think there's a couple of diagnostic folks in the room. It's easier to demonstrate value of a diagnostic than a treatment technology.

We've got a case study that addresses this. This is not true. A lot of our clients come to us and they say, “Well, known sensitivity and specificity… it's really easy to

compare it against sensitivity and specificity of current diagnostic. So, you'll be able to see the value proposition. It's cost effective. It's not cost effective." Then, you show that to the payers, and they say, NO. We've got a case study where we'll talk about that. They're really much more interested in, "Does it really change physician behavior?"

Or, payers are typically worried about, in the case where there's a new diagnostic, is this really going to be a new diagnostic that they want to use.

But then, they're so used to using this other one they're going to use that one, too. And so, you're overusing. You're double-paying for the same diagnostic, essentially.

Or that you'll use the diagnostic and then it won't change your behavior. "Well, this diagnostic tells me that this is early diabetes. I'm just making something up, but I don't really believe it because I've never used this before, so I'm not going to do anything different.

So, you're paying for technology, but it's not changing the physician's behavior. So, if it doesn't change the physician's behavior, it can't change patient outcomes. So, again payers are very well aware of this and they're very skeptical of new diagnostics, and in some ways, more so, than with treatment technology.

Myth #15 We're in good shape because our technology has a CPT code so we know it will be covered and paid!

We have a CPT code. We know we fit under the CPT code, so we're good. Again, we're good. We've got this covered."

That CPT code might not be covered, which means you're not covered. So, you're falling under that CPT code could be a really bad thing. It might be much better if you needed a new CPT code where you can build your own coverage from that point forward.

If you have kind of a "me to" technology that falls under an existing CPT code and that CPT code is not covered, for lack of evidence, guess what. Your technology will not be covered for lack of evidence.

So, it's really one thing doesn't have to do with the other. Reimbursement has three different elements. There's the code. Then there's payment that's associated with that code. And then there's coverage. If you don't have all three of those things put together in a way that works for your technology, having a code alone doesn't do anything for you.

Myth #16 Today's reimbursement environment is tougher than ever.

Beth Brooks: This one is warm-hearted and uplifting, again. The myth is "Today's reimbursement environment is tougher than ever."

I don't think that's true. Is it tougher than it was 30 years ago? Yes, it's tougher than it was 30 years ago. Is it tougher than it was 10 years ago? No, it's not tougher than it was 10 years ago, because we have new opportunities now that didn't exist 10 years ago with the value-based reimbursement.

And again, you know we don't, any of us, know exactly what's going to happen with the Affordable Care Act. Things are kind of up in the air. And, I know a lot of people are worried about that. Is the whole thing going to change again?

We're just figuring out this new environment. But, that's not necessarily a bad thing. Value-based reimbursement has been introduced. Accountable care organizations have been introduced. It provides an opportunity to move out of that fee-for-service environment that, almost necessarily, has your different customer segments competing with one another, like we talked about a while back, where the provider wants to utilize more and the payer wants them to utilize less. And you've got those two competing perspectives.

That is tough to manage. In value-based reimbursement, at least everybody's aligned. Everybody's trying to improve outcomes and lower cost. Everybody's aligned. That's one story that you can tell.

We're also in an environment where, because of this value-based reimbursement scenario, everybody's still trying to figure that out a little bit. And you have payers that are more willing to engage in pilot engagements with small segments of the population.

Again, we'll talk about this in a case study, maybe, they don't want to adopt your technology for all their asthma patients, but, the subset of five percent of asthma patients that's costing them 80 percent of their spend in asthma. Are they willing to look at new technology that might benefit them? Yes, they are. And conduct pilot studies and give you limited coverage so that you can prove your point.

So, there are opportunities now that didn't exist 10 years ago. So, I think that's going to continue, regardless of the details that happen. I don't believe that value-based reimbursement idea is not going to go away.

Nic, I know, is going to talk a lot about digital health and how digital health is going to be shaking everything up moving forward as well. [59:31.3] [2:03:41.3]

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Case Study 1: Understand your customer’s needs & barriers to adoption

- Client type: Biopharmaceutical start-up
- Indication / Technology: Ophthalmology / drug-device combo

- Problem: Asked to conduct study to determine true facility-perspective costs associated with non-compliance with steroid eye drop regimen

April Zambelli-Wiener: This is a client who came to us with an ocular technology for post-surgical management. They came to us wanting to design and implement a very large multi-site study to demonstrate their value.

Their story was very compelling that they told. Patients were non-compliant with their post-surgical prescription regimen. This was an insert that would take that whole patient compliance element out of the picture. They had the anecdotal justification. These patients suck a lot of provider resources when they start having complications, due to non-compliance they're taking up chair time. It's a bundled payment situation and so on.

But we still ask the question. Sounds good, but how do you know that? Are you sure? Because, you're about to invest a whole lot of money in a study to show that. And, it really was just kind of one KOL and something that had been rising up through the ranks of the company.

So, they agreed to conduct a small formative research study to validate these assumptions. We used a nationally representative sample of surgeons all over the country kind of checking all the different boxes and developed a very rigorous interview guide and administer this study. It also included a couple site visits, just to actually talk to some of the other staff members in the surgical centers and get their perspective.

Question from audience: (inaudible)

April Zambelli-Wiener: Because, they were going to have to absorb the cost of the insert. So, it would be something that the providers themselves … So, great question. I think there was variability in the literature on the compliance issue itself. But the real issue was, “Did the physicians or providers feel that there was a financial burden to them, from patient non-compliance?”

Beth Brooks: It is a great question. It shows sort the complexity of the environment that you're moving into with your technology. So, in this case, this was a technology, a procedure that was not going to be separately payable. So, this was a bundled payment environment. This ophthalmologist was going to get the same payment level whether they inserted this technology at the end of the surgical procedure or they didn't.

So, the question from the provider perspective is, “Why would I do that? Why would I do more? Why would I take more of my time during the procedure to do this and I'm not going to get paid more for it. And I'm going to have to buy your technology, out of pocket. So why would I do that? Why would I buy your technology out of pocket, not get paid more for it, have to spend more time with the patient?”

And so, our client came to us and the reasoning that they had come up with was, “Well the physicians may not realize it but non-compliant patients, with their post-surgical regimen, do cost them money, because if they're non-compliant then they have poor outcomes. They come back to the facility. And they require more follow-up visits, which comes off of the bundled payment. They're not paid more. It's they're like 90-day global payment. So, if they come back five times versus two times, that does cost the facility money. They may not think about it that way currently, but, the idea that the client had was that if we could just build this story about non-compliance with post-surgical regiments on the patient's part, that we can build this cost story for them that would let them see, “Okay, yeah, you're going to have to spend more money. You're not going to get paid more. But, your facility… it's going to work out for you, because you're not going to have all these excess visits, and it's not going to be eating into your bundled… global payment structure.

So, that's a little fuller setup of the scenario. And where they were thinking their story was going to live with the facilities, right?

April Zambelli-Wiener: Thanks. So, what we did was a smaller qualitative study to really understand what was going on. And, you know what was really interesting is, that this didn't turn out to be the value story at all.

Almost uniformly, the surgeons felt that this was not a concern or an issue. Not only did they think that non-compliance wasn't a big issue, they thought you would have to be severely non-compliant for it to actually have any impact either on the health outcomes of their patients or on their on their practices because they had sort of mechanisms in place for dealing with people over the phone. And not having to have them come back in. And so, it really wasn't sucking a lot of their resources.

But, what did emerge from, again, having those nice open-ended questions asked in the right way, was that there was a whole other value story. And the value story was about the prescription itself and the fact that different patients respond differently to different prescriptions or steroids essentially. And that there was always a tension between, what was best for the patient, and what would actually be covered by their insurance company.

And so, they had entire staff just mobilized around this entire issue of who can get samples. What can I sample them? What's being covered by their insurance company? Is it the right one for them? Then they come back, it's the wrong one. What's covered is the wrong one, and now they have to figure out how to get them the right one. They said, “If you could just eliminate this whole prescription issue for me, that, I would care about.” And so, as a result of that small study, the company has now reorganized around their whole marketing and research strategy, just from the findings of that one well-done formative study.

Beth Brooks: Well, it just it makes me laugh every time I think about presenting this research to the client. We weren't face to face with them. We're on the phone with

them. We're talking to them. We're presenting the results of this research. And there was a dead silence… Crickets… on the other end… I mean, it was dead silence and we're trying to get him to talk. And we're trying to get him to say... Nothing. I mean there was just dead silence. It was like not going over well.

Later, we had someone that we were a little bit closer to inside the company, we said, “Okay, what was going on in the room, you know, when this…

And he said, “They were just floored. It wasn't that they were unhappy with the research. They were happy with the research, because they felt like it kept them from making a really big mistake, in terms of spending several hundred thousand dollars for a study to get at the cost of non-compliance. That would have been a non-story. But, it just rocked their world. This was what they thought the story was, and then that wasn't the story. So, they were just floored.”

It took them a while to recover from that. And it was about, maybe, two months before they even reached out to us again. I mean, it was just absolute radio silence after this call. And then they finally came back, and they're like, “Okay, yeah, we appreciate that. And now we're redoing things. And now we'd like you to publish this research that you did.”

So, we're working on a manuscript with them currently and they're trying to recover and create their new market proposition, while they continue with the FDA approval process.

They're not there yet, but it really was just a case where, had we let them go down that wrong path. They really could have invested a lot of money that wouldn't have gotten them anywhere. And then you know they're going to have to start over again. Once they hit the market with that story.

April Zambelli-Wiener: That's a great question. Well, qualitative research is a little different than quantitative research, right? So, the sample sizes required are a lot smaller, because the data is a lot richer. The way it gets analyzed is different so often times, ten or less. A dozen or less is sufficient to be able to draw conclusions.

Again, if the questions are asked in the right way, and if you've got the right kind of representation in your sample, sometimes you even reach what we call saturation in as little as four or five, where a theme will emerge, because it's an iterative analytic process. Just Like in adaptive trials and things, where you can stop, you can stop in qualitative research, when you reach saturation.

Beth Brooks: There maybe a little bit of difference just in the terminology. The formative research effort that we were talking about is really different from the way you might think of a pilot study. So, the formative research was intended to… is this a good idea at all? Is non-compliance the story? Are we going to be able to find in these facilities medical records about these patients, evidence of non-compliance or evidence and calls back to the facility versus a pilot study.

I think a lot of times you think of this is our protocol, we want to run it in a small you know subset of populations, just to see that it's working okay and that we're able to enroll patients and then we're able to collect the data we want to collect on them.

So from my perspective, I think I would think about those two things a little bit differently. One is a formative research versus our second plan step, had the formative research gone the way we had intended it to do, we would have done a pilot study where we would then design the study protocol to collect the cost of or to assess the cost of non-compliance then run it on just one or two sites before we rolled it out for some more.

April Zambelli-Wiener: Yeah, that's a great point. but to just to address the issue, for economy purposes we kind of were pursuing those in parallel. So, as we were doing the small formative study we were also gathering the necessary information about the feasibility of a pilot study and how that would be implemented so that if it did end up going that way we were prepared to launch that.

Beth Brooks: I think it's a good example of the way we work with a lot of our clients, too. Again, we're used to working with startup companies. This was a startup. And you can't spend two hundred and fifty thousand dollars that you're not sure is a good spend. So, we very often do things in phases. Let's do Phase One that gets us this far and kind of see what that looks like before we launch into Phase Two.

So, again that's a strategy that… whether it's on an individual project like this one or it's gradually building coverage with a series of small studies and different patient populations, it's a strategy that can really work. It can get you there. It's just not taking more, you know, it all in big chunks. It’s just taking smaller pieces.

April Zambelli-Wiener: I just have one other comment. When you have a road map, you can you can get so much economy from every step that you take. I just don't want to under emphasize the importance of stakeholder engagement really early on, and that a lot of times these small studies are really good for that.

One of our sites was Johns Hopkins. We got a lot of support and buy-in from them. They were ready to sign up for the pilot study. A lot of times these clinicians or providers sit on the boards of societies and professional organizations where you're going to want and need their support to advance your strategy and your reimbursement strategy. So, you can accomplish a lot from even a small step like that.

Case Study 2: Importance of study design

- Client Type: Start-up medical device firm
- Indication / Technology: Uterine Fibroids / Minimally-invasive procedure

- Problem: Need to develop study design(s) to demonstrate value of technology as assessed by payors and provide physicians with reasons to adopt.

April Zambelli-Wiener: This is a startup med device firm for a novel treatment for uterine fibroids. So, there's a lot of different technologies on the market you have hysterectomy you have myomectomy…

Beth Brooks: …Uterine artery embolization. There's several different radiofrequency ablation technologies that are on the market, as well.

April Zambelli-Wiener: Right, and then you have full versus laparoscopic. There's a lot of different players, sort of technologies, in this market. So, they had gone down a path of developing a plan that basically said, “This is the endpoint the payers care about,” and it was, I believe, recurrence, right? …Or revision surgery. And that we have to do a randomized clinical trial with 200 subjects per arm. And that just was simply not feasible. So, they came to us and just basically said, “Help! We need to start over, because we've gone all the way down this path and this is not viable.”

So, I think that hits on the whole idea from the beginning, that a big large-scale RCT is always the answer. It doesn't have to be the answer and it doesn't have to be large scale. The other issue is that, that particular primary endpoint, they were never going to differentiate their technology on that endpoint. They just weren't. Their values story was much more complex and really was revolved a lot around patient reported outcomes, disability, absenteeism. Because theirs was an in/out procedure. So, that was not really going to be captured by… especially when you're talking about hysterectomy… was not going to be captured with that kind of trial.

So, one of the things that we did was, we did payor interviews to find out what they cared about and what they were going to want to see in a new technology. We took that with what was published in the literature on the various comparators and figured out where they end, and then some of their preliminary trial data, where they were going to be able to distinguish themselves, and we developed a novel composite endpoint that was going to cover their full value story and provide the payers with incremental evidence of what they were wanting to see.

It would have the recurrence in it, long-term. But, in the short-term, it would generate some more intermediate endpoints, and would definitely allow them to have messaging, have a publication strategy around that. Similarly, when, from a power standpoint, when you have a quantitative outcome or a semi-quantitative outcome, you gain a lot of power. So, by having this composite endpoint we were able to get their arms down to under 50 per arm, which was much more doable.

So that was kind of an example of thinking outside the box. Kind of trying to get away from this idea of a large RCT is the only way to go. Using the formative research, interviewing the payers, developing that roadmap, and thinking a little creatively about endpoints and how to maximize resource dollars.

Beth Brooks: Just to add you know a little color commentary to that story, too, about where they were coming from. They had already conducted several trials in Europe, they're on the market. There's CE marked in Europe. So, they're being utilized there. [They] don't have FDA approval yet but we're currently in their pivotal study for FDA approval. Their FDA study, they had really not thought about the right elements when they designed that study. As we talked about a little bit earlier, the earlier you can think about, what are payers going to want to see, from a length of study perspective, the timeframe that you're looking at, and also the endpoints that they're interested in… The earlier you think about that, so you can build some of that into your pivotal study for FDA, the better.

But they were in a situation. They're like, “Okay, so we know we messed up here. Study already underway, not collecting these endpoints, not comparative in any way, not looking over a long period of time. Okay, so we know that. We know we messed up. So now we know we have to run this randomized controlled trial for the payers, a completely separate study.” But, then they've gone in the completely other direction. So, they hadn't thought about the right stuff for the FDA, and they had designed just smallest study they could, and to get FDA approval, well, now they were going to go the total other direction and design this huge RCT, just for the payers. And then they realize, “But, we can't afford to do that and so, we're stuck.”

I have never had a client come to us with having put so much research and thought into a study design and still have gone nowhere. I mean they've been looking at it for two years. They had Dropbox folders full of research that they had looked at. They had sample size calculations. They had all of this stuff. They had worked with another payer consultant firm and interviewed payors themselves. I had never seen so much information to get to a point of, “We don't know what to do.” And so they said, “Here's all this stuff we have, but we want you to start over. It's here, so you can see what we did. But start from scratch, because we know we can't do this.”

And so, it was really a unique situation where we're like, ”Okay, let's start from scratch and start thinking about it. And one of the things that we found right away was, they were thinking about not only the wrong endpoint, in terms of it… they're not being able to conduct the study. They just simply couldn't afford to conduct that study. They were looking at the wrong comparator. They were comparing to uterine artery embolization, which is accepted and covered, but it's not the gold standard. The payers want comparison to the gold standard, which is hysterectomy. That's really the decision point. It's not… And so we said, “You need to think about this again, just from the comparator perspective.

And then that kind of works more into what April has talked about already, with thinking about this more broadly. Not just about the reintervention rate, but you know what's really happening with these patients. What other resources are being consumed after they have hysterectomy, a major surgical procedure, what's involved with that, from the payer perspective and from the patient perspective, and just

making a more holistic view and then in building this composite endpoint enabled them to really reduce their sample size to a manageable point.

So, I think it was a great example of a client who… they're really trying to do all the right stuff, but really just not understanding how all the pieces fit together because this was their first product. Then, just to add a little more color commentary, they were also entering a market where there was other technology, similar to theirs, that was not being covered because they've done a really poor job with their research effort. So, not only were they coming in with a new technology, they were coming in with a new technology that was being lumped in with other technology that has a bad rap with the payers. So, they had that to overcome as well. You have to show them that you're different. And you're different in the way you're collecting evidence from the very beginning. So, it was just a whole very interesting kind of complex of things happening.

Nic Anderson: While it's on my mind ,real quick, last year I was invited by a company that's here in California, up north, to be part of a payer advisory board, PAB. So, if you've never done one for your technology, it might be worth doing, if the payer is your customer. Now,they might be… I think payers are always part of the customer equation but if your product is primarily… the benefit is going to the payer, you might want to consider doing a payer advisory board meeting, PAB. So, during the National Association of Managed Care Physicians, meeting in Orlando, and then I think they do one in Irvine every year. They flew me down with like six other payers. So, some of us were little local, regional payers and then also Aetna and Cigna were there as well, and the VA.

Sitting next to me was the VA and then Aetna and Cigna over here, and we all sat down. And their chief medical officer, who is a vascular surgeon from Brigham and Women's, Dr. Campbell, he stood up and he was… I've never seen anyone more contrite ever. I mean the guy knew his product inside and out. He's a Harvard trained vascular surgeon, but he stood up in front of us, we had this round shape table, and we sat in there for eight hours. And he stood up there with a pad and paper and said, ”Kate, Joe, What do you think about this? Nic, what do you think? And what do you think we should do for this and this.” Do you have any idea how many people he won over in that meeting? All of us left that meeting going, “Man, those guys are going to hit it out of the park, because we just had the Chief of Vascular Surgery, from Brigham and Women's, standing up there taking notes on what 34 year-old Nic had to say about something.

So they have a really cool invasive… non-invasive coronary artery imaging system and we had the best discussion. And they took notes, all of them did! They had people in their company peppered throughout the room and as we were talking they were all scribbling down notes. Probably, most of the stuff they had already thought of, so this meeting was just a confirmation to them that they were on the right track.

And I remember at one point, after seven or eight hours of this meeting, they put up a slide and they said “Okay, we want to get all of your input. You're all payers from Aetna and Cigna and Intermountain Healthcare and all this. Here's our proposed medical policy. What do all of you think?” And everyone was silent in the room and I raised my hand and I said “Where did you come up with those points? …that you're only going to use this in patients that have never had a heart attack, that are 80% stenotic, that have da da da da da.”

I said, “Doctor, where did you get that from?” And he goes, “Well, we just think they're the appropriate end points.” And I said, not in so many words, but, “Have you not heard anything we've talked about for eight hours today? The policy I will create, as a payer, will be based on your evidence. So, what I want to see in your medical policy that you've proposed, they were all these bullet points is a superscript number 2 which leads me to a paper that shows me why you said only patients without heart attacks. Bullet point number 3, superscript number 26, which leads me to, another paper that’s tells me how you came up with that bullet point.”

“The medical policy you want me to go back to Salt Lake City and write on behalf of your company, to cover your technology, under those circumstances, needs to be substantiated by the evidence in those circumstances. If you only have evidence that this works in patients that have never had a heart attack, then, that's the only thing you can put in… that I'll go put in the medical policy. Such-and-such technology works in patients that have never had a heart attack, superscript 22, which leads me to read this paper number 22, that says it only works in patients that have never heart attack. So, it was really funny, during this payer advisory board meeting, that it's worth doing. It's worth the flying in ten payers, pay them all a per diem, put them up in the hotel, rent out a room like this, make it comfortable, have it catered, and let all of us sit there for six hours and tear your technology apart. And, while we're doing that, we're buying in. Then you go do what the payers say, and you come back and go, “Here, guys, I did what you said.” And you go, “Man, that…,” you just got eight payers in a room. They all told you what they wanted. You go, “Great! I'll circle back with you in 24 months.” And then, you get feedback like that.

What if they would have gone out and done this, with all these bullet points of how they wanted me to cover their technology, with no evidence for those bullet points? He was using his clinical judgment in trying to write a medical policy. That's not how medical policies are written. They're written on published evidence.

Case Study 3: The trouble with diagnostics

- Client Type: Start-up medical device firm
- Indication / Technology: Virtual biopsy with potential to eliminate need for physical biopsies

- Problem: Payors were concerned about increased utilization (i.e., virtual biopsy + physical biopsy)

Beth Brooks: You know I think we addressed Case Study 3, kind of as we went through the myths, with the trouble with Diagnostics. Happy to talk about it further with anybody afterwards. But, why don't we skip ahead?

April Zambelli-Wiener: Okay.

Case Study 4: Low cost technology meets high volume, high $$ indication

- Client Type: Medical device firm
- Indication / Technology: Asthma management / Diagnostic tool
- Problem: Despite a low-cost, POC technology, payors were concerned about overuse in a highly prevalent patient population

Beth Brooks: We also talked about this one already, low cost technology meets high volume high dollar value indication. So, just to recap that one, we had a client who had a very inexpensive, like less than $20, point of care Diagnostics slash Management tool. But, it was in a very large indication. You know, lots of patients. Lots of potential for physicians to say, “Wow, I can use this in my office. Why don't I just use it ten times a year in all of these patients?” And, know our client came to us initially and just said, ”This doesn't cost very much. In the current diagnostics that are out there cost 10 times as much. This is going to be a no-brainer for the payers.”

I said, “I really don't think so. I wouldn't put it out there like that.” And they didn't listen to us and they went out and put it out there like that and got no coverage. I mean no coverage. And so ,they came back to us, a year later, and said, “Okay, what were you saying about how we should do this?” And so, we really we really just said, “Focus on the subset of patients where you can show value. Make it a small subset. Make it something that the payers are experiencing pain with these patients already. In this case, I think it was 15% of the population that was costing them 85% of their spend, in this indication. Because, there just were no good options for that. So tell them, “Look, what do you have to lose? But you try this. And so, they took our advice. We developed several health economic models for that specific patient population. We took them out to payers. We were very engaged with that. We got a pilot study with Medicaid in Illinois to try this out in their patient population. And, using that strategy, they started getting favorable coverage within that patient population, and now it's starting to expand.

So, again it's a case of what you told your investors about this huge market, this 20 billion dollar market, is not what you want to come to the payers with. Where the

payers, starting small is a better way to incrementally build coverage. And so that's that covers that one.

Nic Anderson: Payers will say, ”We’ll only cover it in this tiny market,” to that. And, I know that they can't only limit it to that. That's probably another important point to bring up. Some of you can go in with, like I said, “camel’s nose under the tent,” and say we only want CPT code 12345 covered only for patients over the age of 50. That's all we're asking.” And the payor says, “|Man, you’re the first reasonable person I’ve spoken with all week. You know, I thought you're going to come in here and ask for a CPT 12345 to be covered in every single human being. What a breath of fresh air you are, that you only haven't asked for that.” But, guess what. They're bluffing. They can't put an edit in their system for age associated with that CPT code. So, then you could go out if you wanted and tell them, “Look use it in whoever you want. We got coverage for that CPT code.

Now I chaired the committee that actually did this, so I know how many times we got in there and went I get what the mtech committee said. The mtech committee said this will only be paid for patients over the age of 50. But, there ain't anything we can do about this. It's going to get paid. If that CPT code comes in, with this ICD-10 code, it's going to get kicked out for payment. So, we would say in our medical policy, we will only pay for your new technology with CPT code 12345, in patients over the age of 50, hoping that nobody else knew this.

So, if there's real virtue in kind of going small, landing a third base hit, and then over time, go ahead and expand, and try to get prepared to get rid of that “over the age of 50’.

Case Study 5: Simple, effective sales tool for medical supply

- Client Type: Start-up medical device
- Indication / Technology: Innovative small bowel feeding tube for use in critical care settings
- Problem: Feeding tube much more expensive that competitor; however, its placement had been proven to utilize fewer resources

Beth Brooks: And this case today, I can talk about really quickly. This is an example of a technology that was a medical supply, used in hospitals and critical care patients. This client came to us, they had a very innovative, really cool, small bowel feeding tube. I mean, really, one of those technologies, like, that is such a great idea. Why didn't anybody think of that? But, the problem that they were facing is, really cool technology, everybody that they talked to said, “Wow, that is such a great idea. We love it. We would love to use it, but within the hospitals, $40 feeding tube versus $2 feeding tube. And, like, we can't justify this. And so, they were not

getting the adoption that you know it seemed like they should be getting, for that reason.

And we were able to go out and just do a literature review and look at the literature regarding what happened with the placement of the current feeding tubes. And you found out that, well gosh, actually in 80% of cases they go through three or four of them just trying to get them placed right. They don't get it placed right they have to throw it out. They have to get another one. And there was evidence in the literature that showed that. And, it had to be placed using X-ray guidance at the bedside, and there was all these other resources that were being consumed to get this one thing placed. And, if you added up all those resources being consumed, it was more and the $40 feeding tube. And so, we just sort of put it in that context. I mean just a very simple tool that used evidence that was already in the literature and the study data that they had. We put together this one-page little model, that just said, here's Option A standard of care. Here's the new technology. Once all's said and done, here's how the dollar stack up. And it was just one of those, "Oh my gosh. This is fantastic." And they took it out in the field and used it. And we were able to get utilization with the technology. So, it was a case… very simple story. They thought it was going to be a huge issue for them, and there was a really simple solution.

Case Study 6: Prepare for traditional & value-based reimbursement

- Client type: Large, well-established medical supply company
- Indication / Technology: Surgical supply used in complex abdominal aortic aneurysm procedures
- Problem: Purpose-driven supply more expensive that "cobbled together" solutions. No additional payment available to facility

Beth Brooks: Okay, so again, we talked about this a little bit, as well, but I'll use a specific example here. This is sort of the situation that we're in right now. So, we have the traditional fee-for-service reimbursement, which is still the primary way that a lot of procedures are being reimbursed. But, we also have this value-based reimbursement floating around. And the truth is that, almost every hospital has both traditional contracts and value-based contracts going on at the same time. They can have 150 different traditional contracts within their hospital, and 30 different value-based contracts within their hospital. So, how do you sell a supply to that facility that's going to be utilized under a DRG. You know the payer doesn't really care. But the facility cares about how this happens for them. Do you go fee-for-service? Do you go value-based? What do you do with that? And then, the answer is, you've got to show it both ways. So, you need to develop a value proposition that shows it both ways.

So, with this client, this was a… in this case, not a start-up, a very well-established large medical device company, who had, traditionally though, based their sales

process on that Clinical Sell, that I talked about, is not working so well anymore. Where they would get the surgeon to say, ”I really like this technology.” And then the facility would buy it for them. That wasn't happening any more.

So, this was their first foray into developing an economic argument for the facility. And so, what we did is showed, okay, so traditional reimbursement, the facility doesn't care about anything other than that index procedure. ”So, how much do I spend to take care of this surgical procedure?” But, they don't really care downstream, what happens to the patient so much. I mean, they care. But, they don't care, in terms of their terms of their pocketbook. Versus if they're in value-based reimbursement, well, if this patient costs them more over a long period of time, well, then they're going to you know benefit less from that arrangement that they have with payers.

And so, we really developed a tool that could work for them both ways, that hit the Triple Aim of health care that hospitals are really having to meet, which is, trying to reduce costs, trying to improve population health, and you're trying to improve the patient experience of care, all at the same time, which is not such an easy thing to do. And so, this tool really hit on all of those elements. It showed how, over a longer period of time, you could save money, even though the short term, you weren't saving money. Showed how it would improve population health. And it showed how it improved patient experience of care. And just laid it out, and then you can evaluate it from the perspective of whichever type of contract you have. And so again, it's where in the current environment, compared to 10 years ago, we're in a better situation. Because they could make that value proposition longer term to a facility and have it resonate. Whereas, 10 years ago, they were so, “I don't care. It's not saving me money down the road, but it's eating into my profits for that procedure, that doesn't interest me.

Case Study 7: Maximize existing data

- Client Type: Established medical device firm
- Indication / Technology: Breast cancer / innovative radiation therapy
- Problem: Technology had been utilized in US and in EU; however, very few publication and none clearly demonstrating 5-year recurrence rates to enable comparison to traditional radiation therapies

April Zambelli-Wiener: So, this is an example of just maximizing existing data. This was a company with an established med device firm, with a treatment for breast cancer, intraoperative radiation therapy. The technology had been used for many years. As it says, there were a few publications. And the main issue is, what the payers and the providers were looking for, and used to seeing, was five-year recurrence rates. So, a lot of the studies, as you can imagine, were not five years. That's a really long time to have that kind of follow-up. And so, what we were able to

do was, use some innovative meta-analytic techniques, applied to the existing studies in the literature, and to really predict and project based on the available data what those five-year recurrence rates were. And they were able to show that it was as good as, or better than, the existing standard of care.

Not, as we like to say, no statistical gymnastics, no hand-waving, no tricks. All standard best practices, but not, maybe, the kinds of statistics that most clinicians are used to seeing. So, part of that task was also translating what we did, to a clinical audience, to the lay audience, through different types of messaging, in different publications and presentations. Do you want to add to that?

Beth Brooks: Yeah, what I would say and then we'll answer questions… But, I would say this is another example of the case where the client has… they conducted… or they'd had conducted a lot of investigator-initiated studies. They had a lot of case series data out there. That's what was really comprising the literature. But, what do you do with all that? So, they had all of this evidence that was out there, but, none of it was for the right endpoint. And it was… all the patient populations were a little bit different. We had to do a lot of work to kind of sift through what data could be combined and what couldn't be combined statistically. And so again, it was an example of they had followed this strategy. "We'll just let our investigators publish their own data and that'll help us." And it really wasn't helping them in the way that they had hoped it would. Have any questions?

April Zambelli-Wiener: Well, there were some data points. Yeah there were. So, it wasn't purely predictive. It was building a model based on the existing data which, if there were fewer endpoints at the tails obviously. Yeah, at that the right tail. I think that's point is really important here, too , to just kind of get down into the details of these studies. It's important to know… to have people on your team who really understand statistics, and epidemiology… to really know what are apples, and what are oranges. Because, if you just do a kitchen sink, and think you can just throw everything in there, it's a surefire way to get the wrong answer, most of the time. But we had to align what we were doing with the clinical guidance and really show that the majority of the patient populations, that we were utilizing, lined up with the clinical guidance on which populations were… would benefit from this technology most and so it was a very you know comp… it was it used advanced statistics, but very aligned with the audience and with the clinical guidance.

Nic Anderson: May I ask, is there anybody, right now or in the next six months hiring anybody? You have budget in place, right now, to hire another employee? Okay, so, three, four. If you do, one, either hire a consultancy that has all those employees, but if you have to check a box, right, as my investors are making you hire, and that type of thing, go to your local insurance company, like the one I used

to work for, or go to some insurance company and go into their billing office and steal one of them. Go hire them.

There's a woman, right now, that I'm this close to hiring her, for the skin company I work with right now. She worked on the sixth floor in a cubicle. And that woman, I'm telling you, is absolutely brilliant. And she's the one that you could bring with you, when you use your consulting budget to go hire April and Beth. And you sit down with this woman, my friend, her name's Sandy, and have Sandy come with you. And have Sandy, who's done billing and coding in the trenches, she used to work for United Healthcare and now she's with Intermountain health care.

That it's not always the "best" among us that are going to nail this. I could sit down with Sandy and go, "Sandy, how are uterine fibroids going to be treated? She'll be like "Well, you're da da da da da da da, and she absolutely blow your mind. That if you don't have budget to hire somebody. Hire a consultancy that just is like, "Look, I already know the questions you're gonna ask me. Just, we'll talk to you in six weeks or we'll work with you for six weeks. And the other option is, if you do have to hire somebody that you need with you eight hours a day to talk this through, go poach somebody from an insurance company. I'm not kidding you. Sandy Hill is off the charts. You could sit down with Sandy and she'll be like, "Well, this will never show up, because it'll come in on the utilization benefit, and then Medicare last year came out with this ruling that you got to use J2 of Appendix A. And, you're like, "Who are you? And how did you memorize this? And why would you ever want to memorize this?"

She doesn't. It's her job. And so, go to your local insurance company, some 12-story building, and walk in to the security guard, and go, "Where's your billing department? Can you get somebody to come down here? I want to talk with them. And they're probably making fifty thousand a year. Pay them sixty and they're stoked to leave. And give them freedom. And be like, "Here, help me solve these problems. And your job is to get on the plane and fly out to North Carolina to meet with Beth every week." I'm not kidding you. I'm so close to doing it. She's off the charts.

So, for the premium, payers will sometimes break it out into what's called PMPM, per-member per-month. And so, I'll tell you right now, this is why payers pushed back so hard against autism diagnostics in the United States. For Intermountain Healthcare, it would have been $12 per member per month, in an increase in their monthly premium, if we paid for a diagnostic test for autism. Utah has the youngest population in the United States. My wife and I had our first kid in college, our second in grad school, and our third in business school. We had all our kids by the time we were like 27, right? And, I only have one wife. We have a really funny… have I ever shown you our family photo? I can't even believe I'm saying this on film.

But anyways, that's how this works with… payers will break down sometimes per-member per-month and will lose sleep over 25 cents. Over having to raise your

premium 25 cents per member per month. That can be a deal killer for some payers. In some of these technologies, when we break it out we're like, “This is, like, five and six dollars per member per month, I would have to raise your premium, to cover this one technology.” It ain't gonna happen. And so what ended up happening, is all these autism diagnostic companies went to the government and forced us to pay. Well, there was a reason why we weren't paying. The health economics didn't add up to do a $4,000 chromosomal microarray analysis on every kid in Utah suspected of having autism. I have to raise all of your premiums. So they we wouldn't pay. They went to the state legislature and said I want you to force them to pay. So, now, we have to pay.

Question from audience: (Inaudible)

Nic Anderson: Yes, we do take that into account. But very rarely do we honor it. Maybe, the big plans do, but, local, regional payors don’t do per-member per-month analyses on every single…

Beth Brooks: But, we do hear that. I mean, I we have clients who come to us and say we absolutely need a tool to go to the payer that boils this down to a per member per month impact. So, we absolutely see that and it is usually for the larger payers that want to look at it that way.

Nic Anderson: Now, I’ve got all your heads spinning about… (inaudible) Next year, if you come next year, I’ll tell you.

Question from audience: (inaudible)

Nic Anderson:

That’s a very good question…and again I kind of alluded to it earlier where, we're here in California. Or, if I'm a local payer in New Mexico, I don't care what CMS says. CMS is looking at whole $20 billion market type things. In Utah, where I live, I don't. Furthermore, I don't need the big amalgamated data that CMS has. What I do is, the company I used to work for has two buildings. I worked on the fifth floor here. I take the elevator down. I'd walk over. I'd go up to the second floor at the end of the hallway on the right, in the northwest corner of the building and there sat Julene Wadsworth. And I'd walk over to Julene and I'd say, “Julene, how many asthmatics do we have?” And she go, “We have 1.324 million.” you know, “Okay, how much did we spend on them last year?” ”943 thousand dollars.” “All right, thanks” Right? I mean, that's the most acute data on planet Earth, right? She could pull that for me. If, granted, it'd take her a couple of days. But that's all it would take.

And I can use that data in the data that your sales rep came and told me specifically, when we had a payer advisory meeting at work or something like that. And they had come in and say, “We're gonna charge… We'll only charge you guys 88 dollars, okay? Mike, Mary that I can go do my own very acute for my own health plan for my own population in southern Idaho all the way through Utah. I don't need CMS data

so I could take a CMS policy and go all right I'm gonna use that policy, I'm gonna go to the bottom where the bibliography is, and I'm gonna take all that data. And then I'm gonna go do my own personal analysis for the 750,000 commercial payor members that we had on our health plan.

So, I could look at CMS and go, “Yeah, right, but, you took into account Louisiana, which is the least healthy state, and you took into account California, which is the most expensive state. I don't care about any of that. I only care about our personal members and I can go run that analysis myself with much more granularity than I ever would have got from a big blanket CMS statement.

Beth Brooks: Something can not work well in the Medicare patient population and work well in a in a younger population. So, it can be as simple as that. It's just you're talking about different patient populations. So that, it makes sense for a private payer to pay or not pay and it doesn't make sense for that to be mimicked at CMS. But, having said that, going back to the myth about you should go for a national coverage determination with CMS. If you do that, and CMS says no, it gives the private payers a reason to say, “CMS isn't covering it.” Because, if they don't want to cover it, and they don't want to do a lot of work to say why they're not covering it, they will say, “Because CMS isn't covering it.” So, you can hurt yourself in a whole lot of ways, by doing that. But they don't necessarily fall in line, but, a lot of times you'll see private payers that will give a reason for not covering it and will be based on CMS not covering it.

Audience question: (inaudible)

Beth Brooks: When you have really good data, and you've gotten lots of favorable coverage decisions in smaller environments. So if the local MACs are covering, pretty consistently, the technology or if you have private payers that are covering fairly consistently you've got some favorable coverage determinations and you have really good data. You've got your long-term data, you've got the things that they're looking for, then at that point, you could say, “Okay, I don't want to have to play this payer by payer game all the time.” If you're real confident that you've got the data, you've got a good track record, then it can make sense. Because, then once you have it, once it's favorable, then you're great. Once you have that favorable national coverage determination, you're in a really good spot. You just don't want to go too early. So, I would say you need to have the small successes and know that you have your data before you go there.