Explore Adoption Strategies with Government Officials
Facilitators:
John Windle, University of Nebraska Medical Center
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(__) Happy to kick us off. Before we dig in on the content we should run an introduction. I direct Pew's Health IT work which includes our interoperability, patient matching work and also our patient safety work.

(__) from FDA CDER, Biologicals.

(__) VANGUARD Coordinated Registry Network. MDEpiNet

(__) DCRI informatics and I am here, simply, to run the WebEx, the purpose of which is to record the session and that's about it. I don't think there's gonna be anything displayed.

(__) from the University of Nebraska and been working with Jimmy for a number of years through starting off with CCHIT and then going on the ACC Informatics Task Force. He's a CO-PI on my ARC grant. So, nice extension of that collaboration.

- Hi, I'm ___, I'm with the the American Society of Clinical Oncology. I am their Associate Director of Quality and HIT Policy.

- (___): I work for ESAC, Inc. We're a consulting company that works with various ONC projects. One of them is the Women's Health Technology Coordinated Registry Network.

- (___), I'm with ONC where I head up the DCQM and USCDI work. Previously with CMS where I headed up the Meaningful Use Program and other quality programs.

- (___), I'm with the American Society of Anesthesiologists, here on behalf of our registry the Anesthesia Quality Institute.

- (___)and I'm with the PRIME Registry of the American Board of Family Medicine. I have to say, I have only been in the registry side two months. I'm coming from (___) side with the ECQMs and actually worked a lot with ONC and CMS on trying to get that program up and going. Happy to be here.

- (___): I'm gonna move over here because I can't sit next to Bev, but center of gravity's over there at OSC, do you mind?

- Pretty clear where he thinks the heavy is.

- No, I know where the important things are moving. But, I know him, I don't know you all.

Very well. (___) and I have been tasked on moderating this panel for this session and want it to be interactive. We will have a readout of this during the back to the broader group. At some point you should decide who that person should be. (___) really been the brain behind this session. But our goal is, generally, here today, John please add anything, is to discuss and figure out if it's appropriate for government to be involved in advancing the use of these common data elements and if so, what levers can be used in order to help advance adoption.
I build on that, also, trying to understand where the gaps are, that you need other people to fill and how we get towards that sort of process. That's the introduction. As we look at this, and then we have some catalysts for discussion. One of the things we talked about is I think there's universality of the importance of patient safety, quality, people are not gonna argue, go nowhere for a less safe environment, work for lower quality. What comes out of that is then, there's a data collection piece of it, the data structures. From my work in the American College of Cardiology where we have a lot of registries, the burden of data collection is getting larger and larger. Specifically in my research, it's worth looking at data flow, workflow and cognitive support. As we get at this, the question is, really, I guess in economics, it's perhaps the issue of the Law of the Commons, which is, everybody agrees that patient safety and quality is important, but then there's not good rules on the grazing of those Commons to understand the consequence to the clinicians or I'll just say the clinician burden or the difficulty of computing the data to be collected as you go along. I think the context of this is, the more we can have common, agreed-upon data elements and standards, the easier the transmission becomes and the less rewrites and those sorts of things as we go forward. Then the question comes up, well, I guess from an environmental scan, there's a lot of work that's already been done in this area. The question is, what can we learn that's good from this and then, most importantly, what are the gaps that remain and how do we close those gaps.

I think we should be mindful and take some lessons learned from the Meaningful Use Program. I think there was a of lot similar goals in interoperability. We were wanting to meet provider needs. But there were a lot of unintended consequences because of that, that has created other issues. I think it's worth taking a look at that and how Meaningful Use Program rolled out. How those regulations impacted the different industries. Who had the burden and who had the responsibility, I think, got mixed up. What was intended, were the providers had the responsibility, but not necessarily, the control, the vendors had the control, and made a lot of money off of it and the burden was laid on providers and that was not intended. I think there needs to be a lot of thought into that and look at some lessons learned from how regulation pushed that program to make sure that some of the things were mindful, at least, of the consequences.

I think that's a really important point. I was saying to somebody at lunch that my experience, I have about a decade in government now and I've done everything from the very beginning of Meaningful Use, pre-stage one-stop, through transition of programs from things like BQRS to MIPS. My experience is that everybody thinks that government providing a direction for things is a great idea, until the moment that we do it. Then there are a multiplicity of voices that raise, many times, very excellent reasons why that's an issue. Some of those issues come in because of, you allude to it, I think, in some of these questions, usually whatever our jurisdiction is is obviously statutorily decided and fairly narrowly focused. Do you start off with the reason that providers, under Meaningful Use, got hit with most of the burden is because the read of the statute, by all of the lawyers, and I don't think they were wrong here, is that that is what the statute gave the regulatory body power over. There was no ability to tell vendors specifically what they needed to do. There was no ability to say, and this is what I think of what I think of some of these things with data elements, we think about certification. We're fairly limited to the programs to which this applies. Much as I think it would be fantastic to look at important critical supplemental systems, like lab systems and so on, and be able to define some of those standards in a way that would increase interoperability in probably a dramatic way within the industry, we have absolutely no statutory purchase in those areas. Sometimes when you look at these the levers are fairly concentrated and that's, sometimes, the challenge on our end. I think often people think, well, if CMS,
for example, would require this, then all of the, the other folks who are doing quality measurement programs, for example, will follow suit. Because one of the major issues, I think everybody knows, is when you have physicians, I think the average is 18 different quality reporting programs that they have to do. If we could just align, if we can harmonize. It should be easy, right, because there are certain quality measures everybody collects, right. There’s blood pressure, HbA1c, or whatever it happens to be. We’ll just get everybody to use the same measure. CMS went through an effort to try and do exactly that. Even some of these in the electronic area, but there’s no leverage with those commercial payers to make them take that. Organizationally there’s really no incentive for them to adopt. As you think about how we can help proliferate, I think that’s other thing in my mind is some of those levers are not as big as we might think.

I’ll add to that, a different government perspective. Start with a little story. I started my career at the CDC and those were the days when every part of the CDC was giving State Health Departments PCs. It was a different machine for every program. They couldn’t use one machine. We’re in the same situation right now. We have categorical mandates across the agencies, also piping to the same institutions that have to comply. It’s not only within CMS, it’s across government. It’s been a long, thank God for that we have ONC now, as a focus for all this. Before we didn’t. We don’t have a forum where these issues were mediated. Our former commissioner at the FDA, Dr. Califf, convened such a process. Wasn’t really his job, exactly, but because of his stature in the field, people went along for it, which I was thrilled to see that. That they weren’t just following bureaucratic lines. That was a beginning of a discussion that would lead to this harmonization. I think the problem is created in large, in part, not just the lack of regulatory focus on this, but the categorical needs of government, of various government agencies.

I think you can’t forget the human factor. A lot of us are here because we want to do the right thing. We see a need, we have skills or interests that can assist in moving that bar forward. But we can’t forget there’s also the other human factor that’s looking at this is a money maker, a potential business opportunity. I think that in the same way that the Meaningful Use program created all these big EHR systems who are now trying to control data, block interoperability. I see that the registry has been flying under the radar a little bit. There’s not as many vendors or those businesses in the registry domain. I am concerned about, as we begin to push, there is a business opportunity there. We don’t have say, vendors, at the table here, they’re not as this conference, they’re not giving input, they’re not part of this discussion. They’re not being partners right now, that I see anyway. I’m not sure how to navigate that. But I do think, let’s not be naive to think that everybody's gonna be trying to do the right thing. There’s a business opportunity there too.

One of the things is in May, the American College of Cardiology hosted a HIT summit. We had, probably, 70 vendors there. What’s surprising, we did pre surveys from vendors and then various stakeholder groups like the standards organizations, the healthcare organizations, subspecialty societies related to cardiovascular medicine. All of them saw the same problem and honestly everybody was trying to come to a solution. Now, I'm old enough and cynical enough that yes, if there is a financial way to drive things that's ultimately, you know, no margin, no mission stuff. But I don't think there's evil anywhere. But I think it is that kind of issue of, I think if the vendors are looking for direction. What I'm hearing and again, if I misunderstand because I'm outside the beltway, but it really sounds like regulation, statutory things, and the categorical needs don't allow that big vision, strategic thought process. If you're a business, you say, here's our vision here's our mission, "Here's our statement "and this is what we're going to do." That's what's missing.
I mean, I think that that's part of what ONC, obviously, was created to do is that. But part of that is also a recognition that we are across governments, we are totally compartmentalized. That is not a horrible criticism of the bureaucracy, somebody else can do that. It's the nature of the statutory authority. I mean, it happens that way, it evolves that way. You end up again, with things like this.

There's no such thing as government collaboration between their federal agencies is an unnatural act between unwilling partners. Many people still feel, I mean, I was raised that way, I hate that. But many people still function that way. ONC has created a forum within government to bring people together, which I think has been very salutary, but it does. I think convening is a big part of it. But, as Robert says, "statute is statute." We're given money to do X.

- I know you have been cognizant.

I'm gonna ask you a question, then I'll follow up with a little story. Does ONC have the authority, capability, to develop a pathway for certification of domain-specific data elements?

Within certain parameters, yeah. I think, within something that applies to a specific program that is available through something on HA. That is almost always a CMS program. We can develop data elements or we can adopt data elements and standards. But the requiring of them....

I'm not saying requiring. I'm saying certification.

Certification is required. Part of that is...

So, certification, if I'm right, you just certify a set of data elements that are domain specific. Vendors who are going to work in that domain would then need to use that set.

Yeah, I mean we have to find a way to tie it to a program.

Right, so I'll tell you the quick story. We look at central venous access devices, right, and infections. Currently, the quality of infection data is extraordinarily low and CDC is moving away from gathering catheter specific data for microbiologic data, regardless of source. We're gonna get even further away. In the year that penalties were instituted for elevated CLABSI rates the rate of blood cultures in patients who have catheters declined precipitously. Because if there's no positive culture, there's no penalty. You can pull the line out of your patient with antibiotics, you can behave as if there's a catheter related infection, but we just don't know. Now that the data that we have is driving all kinds of quality assurance programs and penalties and so forth. But it's meaningless, worse than meaningless. If there were common data elements in that domain including the pathway to achieve a diagnosis of catheter-related, bloodstream infection, then physicians, for example, who are seeing a patient with fever and Reiter's, but don't draw cultures, but do pull the catheter, but don't culture the catheter tip, but do treat them with antibiotics give every evidence that they believed that there was a catheter-related infection without appropriate due diligence to discover and report it. Should CMS be paying for that service? Well, CMS doesn't have choice now because they can't identify it. They can't identify quality versus non-quality and they can't relate it to outcomes accurately. But an ONC pathway to certification of those domain specific data elements, would permit those things to be performed.
I think you've got a couple of challenges. I don't disagree with you, I think you got a couple of challenges there. I will start by saying, so I headed up the group that does most of the quality measurement within CMS quality measurements value-based incentive group. They do IQR, they do MIPS they do post care, 27-some quality programs. I will tell you it is my absolute personal opinion that we do not have quality measurement as an industry at all in this country. What we have is quality reporting. In the same way that there is a business case there is a business case within government itself. I would argue this is probably is within third-party payers as well. Although, in third-party payers it's tied more explicitly to dollars. There's a business case for maintaining the status quo. Because the reward for folks on the CMS end is not a reduction in whatever associated costs. That's not the way they're primarily measured on those programs. The measurement of those programs and CAUTI, CLABSI are a great example of this, is can they show a reduction over time in that area. That's really... What goes into it, what the elements are are less important than that overall number that they are able to demonstrate. The performance within that program is primarily one that rewards participation rather than outcomes. It's very difficult, the challenge on that end, is getting a culture shift in those areas. To where you would look at those different elements. On the ONC side, the challenge for us is that certification is necessarily tied to those programmatic measurements. I mean, a vendor is not gonna take up certification requirements which are primarily voluntary, unless, they are gonna be selling that product to somebody who is using as part of a program. You can certainly add some of those elements but it is difficult. I mean, it's difficult all the way down the line right. But primarily the difficulty is in convincing an organization or providers to purchase a product that has data elements, they're paying extra, beyond what they would pay for something that is not tied to a program that they have to use. It's not tied to reporting that they have to do. Why would I pay this extra amount for it? Sometimes you will get some internal things where you will get people who will push for certain things because from a workflow perspective it works. But in a large healthcare organization or a hospital organization, bean counters let that go so far, I mean, let's just be honest here. I think that's the challenge. It's a chicken and egg argument.

True, so if you were able then to offer participating institutions indemnification or whatever word would be appropriate from penalty, by virtue of participation, then you've got a economic lever for that.

I think that is 100% right. You have to either, and we have pushed in the past, we continue to push now. I think, with CMS especially, in areas like MIPS and IQR and that's really relevant, I think, to thinking of things here. In what ways can we incentivize, right. Because that's really what it always comes down to it. In what ways are you, as an organization or a provider incentivized to be able to adopt what that is. Whether that is a bonus score or indemnification within IQR or an associated program, that's really where your bread and butter are pushing things like that.

True Because currently, we're incentivizing provision of low quality data. And low quality practice, right?

But we have lots of low quality data. That's the important thing.

This is a really important important thread to run on, which is, we've talked about some of the challenges of government leading the way in these areas. But also, there have been some successes. What are some of the successes, and the characteristics of those successes, that then can we potentially use to inform any recommendations on government actions to advance these common data elements.

One that's near and dear to Ben Moskowitz's heart is UDI, unique device identified for devices. FDA worked with ONC, they got it as a required element for a certified EHR. Unfortunately, that doesn't
mean it has to be collected. There it sits in the data model, you can you can fill it if you want. It's absolutely essential it's there. It was a great collaboration. I think the other really good collaboration I know of is the CMS, FDA collaboration around the TVT, transcatheter valve therapy where data requirements for safety and efficacy from the FDA and data requirements for national coverage decision were coordinated. As opposed to lagging by years, it happened within a couple days. The FDA and CMS invested in ACC and that apparatus the linked registry network to predict, to provide data for both sources and it was tremendous success.

How would you characterize why those were so successful? And how can we apply those characteristics to these common data elements?

On those, of course, contacts with the government. Bureaucrats who knew bureaucrats. Friendly enough, working together enough. That's how it happened actually.

But the uptake is in the dollars right. I mean, when you look at the end of the day the reason that hospitals participate in the Meaningful Use hospital program, now that a lot of CMS, I didn't mean to say Meaningful Use. The reason that there's the uptake on the physician and physician organizations side is because of first, the incentive dollars that were associated with it, and then the potential for penalties, and now, again, the MIPS bonus. I think all of those things drive those organizations to get certified products that actually now have that UDI that are included in it. I think when you look at some of this you have to look at within the programs is there a way to provide additional incentive in scoring in some of those areas. Is there, sometimes it's a scoring bonus, although I'm starting to get leery of them, there are an awful lot of scoring bonuses these days. I'm not sure how robust a program it is when you can score.

Incentives also works inside government. I really like the PCORI Trust Fund out of ASPE which is a program that has, its money that came from PCORI, but where the money came from is less important than how ASPE coordinated across government and gave money only if proposals came jointly from multiple agencies to build real world evidence systems. That incentivized programs to bring people together. Kind of unique, I mean that government usually gets no money, it has no leverage. The purpose of that government, that level, I worked at that level for 10 years. The purpose at that level government is to coordinate but you got agencies that don't wanna coordinate if they don't have any incentive. They don't have much power, very little leverage over the individual agencies. This was a unique program. Usually, agencies fight to the death for the dollar between the agencies. They don't want the money to go to that level.

The confusing thing, Greg, about that trust fund program is that non-government participants are not permitted.

Well, it's by design. It's to get government agencies to work together. The money flows through that consortium of government agencies to contractors or private entities. But the purpose of ASPE is to coordinate government agencies within HHS.

Coordinate around what?
Real-world evidence and patients of PCORI, patient-centered outcomes research, that's the purpose of it.

Right, but the research is not coming from the agencies, the research is coming from the clinical community.

We've got PCORI and we've got NIH for that. The government, this is something to coordinate government.

But PCORI, particularly, doesn't fund research that hasn't already been done. Patient engagement, there's no predicate research. How do you get funding from PCORI through PCORnet to generate meaningful progress? And nobody who's in the field working on it can participate in the trust fund project so you've closed the door to support where there's funding that should work to knit government together, to lift a program up that's of national import.

Yeah, I think that's gonna be a challenging approach though, for most government agencies. There are certainly agencies that do some of that type of funding, like HRQ will sometimes do some things like that. But by and large, within HHS, CMS is an insurance company. They do not think of themselves as funding the type of research that leads to, they will adopt those things, they will look into it, they will start doing some models that are based on evidence based studies. But they are not gonna fund the research that is behind it. I think that would take, rightly or wrongly, I think that would be a real culture shift for them.

Can I go back and circle this back to something you said, which I think is sentinel to this discussion. Which is the difference between quality measurements and quality reporting. Is there a way to build out quality measurement as a rewardable outcome? Because, sitting as a clinician, with value-based care, coming, sitting on a taskforce on performance measures of hypertension where I'm down enough in the weeds to go, oh my god, our fuzziness around the data is pretty high. People think as long as the words 130 over 80 appear we're good, if it's 138. Then you go, well now because you've put money in there, people are going to be incented. To your point, how do we go back and is there a way to get into, "Hey, you're doing a great job measuring the data." And then make it a secondary use of the data, rather than the primary use. Is that feasible?

On a fundamental level, yeah absolutely. I think there's a lot of challenges to it. I think one of the challenges is there is an industry that is built on the way that quality measures are currently expressed. We can all talk about different ways of looking at all of these things, but when push comes to shove, there are essentially six places, six very small places, within this entire country. I think it amounts to something like 95-100 people, nationwide, who actually build quality measures. Whether those are electronic or whether those are chart abstracted. Those hundred people really only understand one particular way of looking at quality metrics. They have a particular challenge, and it's not just theirs, but they get paid a certain price. They have a particular challenge for looking at improvement. Some of that is related to the status quo of their business model, but some of it is also related to the way that measurement occurs as ascribed by the organizations. CMS has annual reporting and for certain programs it is statutorily mandated to have an annual application of some type of payment adjustment or positively or negatively. That is despite the fact there are a number of conditions that probably are not best assessed on an annual basis. Especially when we look at chronic care and probably the two visits a year that you have, if you're lucky with your endocrinologist, is not the best way to tell whether you are improving overall. Then we get into the issues of, right now most of those things are not
population-based they're looked at on an individual patient level and they're extrapolated upward. That may not be the best method of assessment. There's a challenge with the way things are in that model. I think you also have a challenge, to be perfectly frank, from the physician and healthcare organization, whether that's a hospital or large organization. On the one hand, I have absolutely heard physician and physician organizations scream that none of these quality measures accurately assess true quality and they would like measures that are relevant to their practice. On the other hand, the moment that you try to get rid of a top-down measure on which everybody scores over 95%, well you're killing their children. And that can't be let go. Everybody wants an accurate assessment, but nobody wants accurate assessment. Everybody wants to be accurately assessed as long as they score 95% and above. That is part of the challenge that I think you run into. Honestly, that's part of what you see within the programs. When people go internally within government to structure some of those programs is people are walking a little bit of a line between how do we assess versus how do we not--

Okay, but there's another model. The professional society model. John knows about that. They subject themselves, hospitals subject themselves to registries and accreditation. You see your data of your hospital, and meaningful data, to the physicians compared to your peers. But it's private information, everyone doesn't see it just you see it. Everyone thinks, of course, they're doing the best job and they realize, oh my gosh, they're not. They realize somebody else is doing better, then they figure out why and things improve over time. It's been demonstrated in multiple areas. In bariatric surgeries at American College of Surgery. People went to the wild west of bariatric surgery, it turned out there were a lot of deaths over time. They were able to decrease complications by the same kind of process. I think, maybe the strata-- it's intuitively appealing in a data-oriented society that everyone could see there to hospital's scores. But for the reasons you say, I mean.

There's a challenge with government doing that. Everything that we take in is public information, it all findable.

Yeah, there's a huge disconnect between you're talking about there's like the M&M conference version of internal specialty society registry. Where you quite nakedly assess yourself. But it's internal to you and you're really using that for real quality improvement. Versus this is gonna show up on Physician Compare with none of the caveats. People here, most patients really don't know what they're looking at. They're saying, I wanna be 95%.

As a national strategy, I think that the professional society strategy is something we should embrace more. I think that's proven. You can measure these things and you can get the data on think these things, it's a question of how you share the data and you use the data. I think that's the lesson I get from it.

If we take it by analogy, when I was Associate Dean for continuing medical education, it was very clear that we've certified the certifying bodies of continuing medical education. Not the individual meeting and not the individual. Does that sort of model potentially work where the government certifies the specialty societies for overseeing things or that sort of stuff? And then, your participation in those societies now becomes your gateway to to reimbursement.
Certainly a possibility, but not under the way the statutes are currently. We definitely talk about, and we can give specific statutory authority to agencies to the physician.

This needs a legislative approach is what I'm saying, I agree. There are different ways the government could be involved. We could give financial incentives to registries of professional societies and we could provide standards by which they should follow. There's all sorts of levers, the way the government could promote that activity. Now, there's also another approach here and I will tell you, this is my own little hobbyhorse and I pushed this a little bit and CMS did not get a whole lot of uptake, so I don't know. One of the approaches to this is, currently, we take a comparative training in this physician and hospital. Compare how much can we get everybody on the same core set of measures and participatory indicators so that we can compare them and say, "You're doing great, you're not doing so great." Which is the inherent nature of trying to come to the positive and negative spread of payment adjustment. We could abandon the notion of trying to get to strictly comparative indicators in favor of looking-- this takes, I think a much more mathematical approach. Which is why I think it's a little less intuitive. Essentially, we could look across organizations, hospitals, physicians, and look for improvement. We don't care what the particular indicator is within this realm of indicators that we are able to track. What we want to see, over a given period of time, is improvement. Yeah, I mean, does that mean that everybody is gonna tackle the lowest hanging fruit first? Well, of course they are. Many of them aren't even doing that now so what's that gonna hurt. But eventually you get to a point I would say, where you exhaust the lowest hanging fruit. Because the amount that you are improving is not statistically significant. You have to look at other indicators. There are ways within that system to incentivize priorities. You could look at CAUTI and CLABSI and say these are high priority clinical conditions. If you prioritize improvement in these areas, using these particular indicators, you can do X. That also ties in then, I think, with the notion of data elements individually, because then you don't have to necessarily be tied to a certain expression that you have in a quality measure. Right now you could be tied to a series of key indicators that are data elements.

Underpinning the whole enterprise of publicly protected data, though, is an economic model. People vote with their feet. Most communities the United States don't have any ability to vote with their feet. There's only one system for them anyway. I think, this whole enterprise it is founded on a, I don't know, maybe a New York City model. I'm not sure where. But it's an economic model where people mark with their feet. It just doesn't help in healthcare with the structure.

I agree, I mean, one of the fallacies is that you have a huge, moveable population. If you wanna get into us through the front door I have an opening in February to see me. I'm not looking for more business, therefore, in a model that's very much flat, there's not a lot of ways to move that. I don't think you want to. When I was in Continuing Ed, one of the early decisions I made is, do I wanna go after the 95% of doctors that are trying to do the right thing or do I wanna go after the 5% of doctors that are the problem? I decided my life was much happier going after the 95% and, I think, that's part of what I'm hearing is we need-- for healthcare in the US to grow the vast majority of clinicians need to rise with it. Because you can't, that there isn't that excess capacity to move, in a sense, 25% of the bad players out. There's no place for them to go. I wanted to ask a question back to this, because it circles back to variation in practice. Is there a way to, because I think about specialty societies, I think about incentives, reducing variation in practice is a positive and less negative way to move things forward. Is that a feasible strategy?

I think it's a demonstrated strategy. It is more feasible.
There are path codes using pathways. We've built, and are building a whole payment model around pathways. The idea being that pathways they do give you a lot less variation. Just pick a number, 80%, whatever, that patient should be on pathway. But that allows plenty of flexibility for people not on pathway and that allows you to look at value and quality and value. We really do see that as being an incredibly important part of value-based, and quality-driven healthcare moving forward. We haven't--we’ve tried talking to CMS and others, we haven't, to date, gotten a lot of enthusiasm, but I know in talking with members from other specialties that they also are seeing that. A lot of our members use pathways with private payers. This is not like a weird thing that nobody's doing. ---- and other organizations develop pathways and clearly, it is working in the private and the commercial sectors. I mean, we just see pathways is tying together, if you will, the cost and the quality categories.

I tend to agree with that approach. I think that the reason behind the snickering the reason you haven't gotten a lot of enthusiasm is because the worlds of quality and payment exists completely separately in CMS. There is quite literally a payment division that sits in an entirely different building than the people who do quality. Although occasionally, we come together at ice cream socials, we actually very rarely even meet together in the same policy spaces. This goes back to what we were talking about earlier, statutorily, those things exist in different places. What may seem obvious and somewhat doable outside, actually, once you begin combing through some of the Byzantine structural things, it actually is, it might be very difficult to implement something along those lines. Although something like CMMI under their authority might be a direction to go. Clearly, philosophically, they're trying be more flexible.

That's a great point that there are some opportunities that we have today, essentially leverage, one of which potentially is CMMI. Before getting to CMS, what about within ONC? The acronym of the day has been for USCDI, the common clinical data set. Some of the data elements in the common clinical data set have an associated standard like drugs, RxNorm, others don't. The USCDI also not have an associated standard. Given the work the DCRI team has put together, which builds on the USCDI, what are some opportunities to leverage that policy to advance some of these standards in the EHR space and the data exchange space so that they could be better utilized?

I think, this was brought up earlier by the gentleman the end of the table. We've been very supportive, we have legitimately been supportive of ONCs work as a convener, as facilitator. Someone did comment on the transit exchange framework but, I think, if we could somehow work with ONC on domain specific areas, that would be incredibly helpful. Because, I mean basically, now you’ve got oncologists are either in big systems, using primary care records where they're putting everything in a free text node and it's never recoverable or they paid literally a million dollars for an oncology physician CMR that doesn't interact with anything else. If we could, somehow, bring these specialty areas under that rubric, that would be fantastic.

(__) mentioned, well, what do want us to do. Give people the rules, or give them concept and a pathway to build the rules? They've decided to hand out the rules for data elements that they've selected. But I think, there's a real case to be made for pushing some prototypes through at different conceptual levels, to provide a pathway to lower the barriers for others to follow suit. Once you've got a format to fill in, people can do that. They have the clinical expertise, they have the programmatic expertise to target the key elements and develop them and implement them. But right now, people don't have the wherewithal to do that. So, there's this huge barrier between content expertise and implementation. We need some prototypical support to develop a pathway and then we need to capture that pathway so that we can use it as a guide for others to follow along. Then find a way to provide incentives to give them a reason to follow along.
There's one prototype that's pretty close, SHIELD. Laboratory data has been digitalized for over 30 years. However, it's still not at the point that it's really, truly, semantically interoperable. There's an effort that's being coordinated by FDA for no good reason other than Mike Waters is doing it and he's a great guy. They're putting together federal agencies, multiple private settings, multiple big payers, and labs around having LOINC, Livid, UDI, OMOP all the different standards that are associated with lab, communicating and coordinating. It's also connected with the next layer up with I understand is part of SHIELD too. That's an activity that's very close to being successful at the most basic level about having true semantic interoperability across the nation. Implementation is less of a problem because labs are so highly digitalized already and moving towards common standards is less of a problem. So, there's a good example.

I think, there is an opportunity with USCDI, I think, we've done a lot of talking today about USCDI as if it is this decided thing. But let's keep in mind the only thing that ONC has released thus far, I'm keenly aware, of this being directing some of them. The only thing we've released so far is a draft proposal of an idea for notions, we haven't even released a draft, this is what the elements would look like. for people to respond to. We are still very much in infancy on that and what that process will look like. And how it trickles down to industry. I think, there is opportunity now and, I think, opportunity in the near future to provide some inputs, on, not just potential elements for USCDI, obviously, through an annual process. But also in the annual process itself. I mean, some of what's, how that decides what goes in to the programs as a whole and what gets accepted versus what gets put into new versions of certification, what that looks like. I think there's an opportunity to look at some things that may be able to touch into some of the specialty areas that, perhaps, are not as widely adopted in some of their areas, but at least it serves as something of a guide as to what the actual standards are available or what that set of terms may be for that area.

I think I hear two pathways that, I see, on one side, we're talking about having the functionality available. That they're coded in a specific way that that data is flowing back and forth. Then I'm also hearing adoption. So that's more on the provider actually using those fields. So, just so that I'm clear, what, are we looking at both? Are we wanting to enforce both or are we just talking about, let's make sure that the technology is in place so that we can have that flow and then we'll work on adoption.

I think, trying to save some measure of cognitive dissonance. As a clinician, I think, the clinicians need to define what's important and, I agree, it has to be done at the level of domain specificity. But, I think especially through the medical societies and if there's domain-specific information that this is what I'm pursuing and then there is a format through ONC to standardize that, encode it, whatever we wanna say, put a casing around it. That makes a lot of sense. Because then some of this gets into behavioral economic kind of stuff, which is if you own the data and it's yours, you're gonna believe it. That's why a lot of these things work, is because the folks in the cath lab know that they're looking, they know which point they are and they're enough competitive to go, what do you learn? If you look at door-to-balloon that's another example where you took something that was all over the map and then, in a very focused way, they said, "If you wanna improve outcomes, "get it down to this timeline." People were not proscriptive about how you got there but there were best practices that emerged. And pretty quickly, it came in into a commonality and, I think, that's another example where that domain specificity can be translated into a workable, viable improvement in patient safety and quality.

I will say there is importance to us as a regulatory agency that adopts these things to get a consensus. This is sometimes challenging. I think, why you see this proliferation, this thousand flowers bloom, and I
smiled when I heard that phrase because that's the exact phrase that a former national coordinator used all the time about this. It wasn't an unfortunate side effect of the philosophy, it was the philosophy. The overriding portion of this was this notion that the market decides consensus and that would get adopted. Now, you know, Criticize that however you want to and we can talk about it later in the corner and I'd be happy to criticize with you. I think, one of the things that we definitely look at as we're moving forward with this is some consensus also. I think, not just the clinician side also some of these other stakeholders.

Again, I mean, I'm not arguing that random, you know... Change management says anything that increases my burden I'm going to oppose. There has to be a return on investment. And that's why I'm saying, I think, to a certain extent, the specialty societies have a little bit of a cushion, because they have that trust. There's that value proposition that goes with it that says, "Hey, if you do this," and if we go back to the TAVR for example nobody's saying I'm not gonna collect the TAVR data because everything's aligned. To me it actually is that.

Over 90% of procedures are collected in that procedure. But, let me follow up on that example because, I think, it's an important limiting case. I'm publishing a paper on the subject, so I'm sensitive to the issues. It's terrific and it works, however, the current way in which you collect data is so burdensome that it creates a rate limiting step. It works in cardiology because volume's high, profits are high, it's a highly organized field. If we can drive down the cost of data collection it's a model that could be used in other other areas. And, currently the state of the art, and again cardiology is a rate limiting step because there's so much data that's needed in cardiology space, but they've met... And Jimmy Tcheng is the master. He's structured data capture. They've decreased the burden of data collection and improved quality of care, and quality of data by streamlining, building the data collection into the re-engineered workflow. We're back to EHRs, we're back to digital systems that are-- Right now, about 70% of data that's needed for studies of Cardiology are collected from here. Jimmy's met image of the swivel chair data collection. It's... only about 20% of it is in the EHR. The rest of the data that's necessary to make meaningful decisions, is in this machine, that machine, that log, that log and every hospital's different too. So, unless we crack that egg, the data's not gonna be there for, you know, it's not gonna be there.

But one of the things that my research has done, is we've gone to eight different sites, around the country with seven different EHRs. The fundamental thing, we use a simulated patient who goes in and does this, and you see a lot of variation. But, fundamentally, cardiology's practiced the same across the country and independent of the EHR. Which means, best practices can be established. And yes, there is a burden, initially, towards building that standardization into the workflow. I think, if you go to Duke, and I've actually been a simulated patient going through a STEMI at Duke. Interesting, slight digression. I was asked five times in the ER about was I sexually abused because, apparently, as a 68 year old male coming through with chest pain that's the place to gather that information. At Parkview Health, I was asked three different times if I'd been outside the country in 21 days because, apparently, Ebola was still a thing in Fort Wayne, Indiana in 2018 because they hadn't taken it off the list. But, it is the right way to get things. If we go back, one of Jimmy's point's gonna be can we start with a hundred things and get them right and streamline it. I think, what is interesting about this conference is there's commonalities that do go across the process. There's still some issues of governance and, I think, I wanna get back to, is there a better governance model or do we stay federated and have these meetings and let Pew buy our lunches or how do we move forward? I think, there's some commonality coming out.

Speaking of commonality. Given a level of agreement, do we have agreement here, where, despite the challenges with government running the show on some of the standard information that the USCDI,
which is is a sense, still presents an opportunity that we should be leveraging to potentially encourage ONC to adopt the common data elements, both ones that are cross specialty and then, eventually, domain-specific. Is there agreement in the room on that? Objections?

Do they have to be serial goals or can they be parallel? Can we work on domain-specific data element sets at the same time we’re...? Because if we make it a serial process we’re gonna be generations down the road before we make make meaningful...

I think, it also allows the establishment of best practices. I’m curious, after what Tom did in his analysis, if you look what it takes to make medications interoperable there are things, for instance, within EPIC that they need to figure out, which is how many different tables can you store that don't talk to each other. But that's an EPIC-centric problem that's not a bigger issue. But what surprised me coming out looking as we did this analysis, is it's actually possible and should be expected in 2018 that medicines can flow from prescription to registries, untouched by human hands. Those standards are there, they're just not adopted. My suspicion is that’s more out of ignorance than anybody going, no, I don't wanna follow any standards, we're cowboys here. I just wanna.

I have to push back on that because coming from that clinical informatics side at a large health system, academic medical center and trying to meet the regulations for Meaningful Use, our providers were doing all the right things but it was the lack of our vendors to support the data flow itself that made our providers look bad when actually they were functioning very well.

Is it because the nature of the 10 thousand tables that Julia Skapik and talked about.

Yes, and that's just that one vendor. You can't get the data out. I am very, I have a hard time, I will not support, yeah.

The APIs in USCDI helps solve. I mean, you eventually grow this common pool and then using the API and leveraging certifications, you were able to at least extract that.

I think, that's where who's getting the stick and who's getting the carrot. That's where my concern is.

But it also cuts this other way too, right. I saw a little bit of this looking at some of the data elements downstairs and deciding. You can't leverage USCDI for what you feel like leveraging and then say but we're gonna ignore these eight that we don't like. You're in or you're not, because that's the point of standardization. If you're going to sit there and you're going to say, "Now we’re gonna push our own version "of a different standard because we don't care about "this thing over here, that's not useful for registries." That's how we get to a point where you say, "Oh, there's only overlap of eight elements here." "You're not able to support these other things because you decided to tailor them." The same when we get to quality measures where you go, no, no, no, we wanna look at this, slightly tweaked, in a different way. I think that's, as we look at some of that thing, some of those things, in the registry area, especially as registries begin to be leveraged for things far beyond what they were originally designed for. They're now being used for reporting and the individual quality measurement reporting. In some cases actual, individual, new measurements. It becomes increasingly important, I think, to push that notion of a set of standards USCDI for the registries as well.

We were talking a little bit before about the burden of data generation on clinicians and other participants. In part, I think, we're victims of our success. If you start out with aortic valve replacement
as a business model for registry development you're willing to pay $1,000 per patient for boots on the ground to translate data. But it's not a sustainable model for other domains. But that's what has driven most of the financial success. There's no incentive for those people making a lot of money, off $1,000 per patient gig to use structured reporting and automated data extraction to reduce the burden and increase the reliance on workflow. We need to get into messier, lower delta opportunities because that's the only way that they're gonna survive is having very low cost to participate. If we focus on, forgive me, cardiology and orthopedics and vascular surgery we're never gonna get there. We need to look beyond those domains that have generated the greatest success so far to take it to the next step. Similarly, I think, we need to look at some messier issues about interoperability, like patient engagement and the ability of the patient to move their data around at will without special effort. That's a little bit of a hurdle to mount. But if we don't spend some more time focused on developing standards, because we can't interpret, individually, every patient generated piece of data. We have to have standards for patients to contribute their data to reduce the cost of incorporating, integrating patient related information with clinical data and real-world experience. I'm just saying the low-hanging fruit has gotten us this far, but now we're gonna have to climb the tree if we're gonna get more success that we need to sustain the thing on a broader level.

I agree with what Rob said, if ONC is involved and they're setting standards, say, for registries, what registries should include, what and how they should built or how the data should be flowing, that's one thing. I think, that's a great idea, similar to what they did with the EHR vendors about having to be certified, so you must meet these standards. That make sense.

- Though we should be clear, that's not the business model that we're going after. Let's be clear, with USCDI we're not going to go and say, "Okay, well vendors you have to do this "and registries have to do this and these people..." We're going towards a model, and USCDI is the latest expression of this, in which we say, "Hey, this is the standard school. "This is what everybody should be drawing off of." It's the minimum bar. Whether you're a registry, or a vendor or whatever you happen to be, this is gonna look the same for everybody 'cause that's how we get to interoperability because we're all using the same expression of the language.

- I agree with that.

- I just want to add, I was in an interoperability forum two weeks ago, and that's one of the issues that was talked about was the differentiation between interoperability standardization adoption. Where if you have five different standards, somebody's gonna say well, we wanna make this interoperable, well, you're gonna come up with another standard and then you're in the same quagmire that you are before. It's just, standard upon standard. The issue that should be brought up is you have these standards, now how are you gonna make them enable them and adopt them. Because you have them there, it's just the adoption and enabling of that amongst everybody is the issue. Because if you just keep on saying "Well, we'll make another standard, we'll make another standard" it just leads to the same issue.

- This is the data pool.

- Exactly.

- If you wanna play in the sandbox, the same game that everybody else is playing then you have to use this data pool. If you wanna use parts of that data pool, well, you're gonna talk to some of us and others of us you won't and you're not gonna get to interoperability that way.
In the registry space for devices, there’s two activities there that are trying to solve this problem. One, within cardiology. So, ACC has 10 registries and legacy systems. They’ve come up over the years. They’re trying to get all those registries linked, all of them compatible. Actually, data linked, that you can actually study people in multiple registries across time. That’s a major activity. The other one is MDEpiNet Coordinated Registry Network community of practice, where they’re taking about 15 different registry areas, including cardiology and they’re working on the same principle. Trying to, lessons learned, best practices, shared knowledge and getting people to to harmonize. Those are two activities that, I think, are, at least in the device space, that are healthy, that are moving in the same direction.

Because one of the things that I’m listening is perhaps, the way to balance the general and the specialization and I was thinking about the XML schema that was presented this morning, that Jimmy presented. If ONC says, "Here's common things "that we support and we're gonna give the specialty "societies the ability to use the same schema "to create domain-specific information," does that start us getting towards that commonality? I was trying to figure out the right models, like fax machines, et cetera, et cetera, where the more you do this, the more you go, oh yeah this works for all of us. If I’m an EHR vendor and I know what the schema is then it’s easy. And if everybody is using the same schema then that starts building on it. Is that an option?

It’s like what (__) had presented earlier. How she said, I’m only gonna document blood pressure because that’s all my specialty, say, cares about. But your specialty cares if it was sitting or laying down or left arm, right arm. I’m only gonna document what I care about, but the functionality is there for you and your members to document the things that are relevant your specialty. I see it more, something like that, like what Rob said, you can’t just cherry-pick it. We present it all and then it’s available for all. But you don’t have to use all of it. But it’s there for those who document it and it allows the functionality to flow between whoever has those fields that they’re adopting.

The entire point of ripping the CCDA apart into individual data elements is to foster an interoperable exchange, in specific use cases, that doesn’t require you to send the entire damn fax. I don’t have to send 32 pages when all that Greg wants is blood pressure. I just ask for blood pressure and I can get blood pressure. It can work, if you, as specialists only wanna know about blood pressure and you don’t care about any of USCDI other elements. Great, blood pressure’s the only thing that you care about. But it won’t work if the hosting organization, whether that is a registry, or a vendor, or and HIT or somebody else, picks and chooses among those elements. Because what if somebody decided that blood pressure wasn’t important to them and now they no longer have that. You can certainly pull it apart and have end-users, queriers, receivers, have individual elements but you really don’t get a choice and this is part of the reason that test was proposed the way that was proposed. This idea of an exchange framework in which you agree, all of these data elements. I think, as we look, in this particular aspect, with registries, if you get into a situation in which you say, "Out of these 22 elements "we only think these eight are useful "and then we’re gonna totally change these other seven." You’re not speaking the same language anymore and that is not going to get you further down the line, with interoperability. That’s gonna get you further away.

Wouldn’t that be part of the iterative process of the USCDI, is everyone sees the same two elements every year, whatever. Where people are going, "You know what, "this isn’t really working for us "and people don’t wanna use it?"
Could be.

- And things can drop out, right, in addition to being added.

Oh sure. No, no, no, and that's part of the whole iterative process, to be able to provide a place for input publicly, as well. And hopefully, to put together some objective criteria by which we judge whether something gets added or dropped. We're more likely to see addition than we are to see dropping those particular elements.

- Just for the sake of argument.

Certainly, there's space for evolution of elements as standards move forward or completely change. More often than not they move forward. Different versions, updates to that. More specificity and different elements that you might adopt. There's definitely, yeah, there's absolutely room for change of those.

We're just about at time. Any final thoughts from anyone?

- I'm gonna be totally cynical.

- I think, we continue to see that it's a complex issue.

- I'll be completely cynical. If we had if we had a national health system we could think about national health system. We're trying to develop a national health system for data without a national system. It's a little bit problematic.

- I heard cynical, not utopia. (Laughter)

- There were a couple, the engine that drives this train. At the end of the day that is true of any of the uptake and adoption. Everything you have seen, the only reason we are sitting around this table and having this involved of a conversation is because there were pretty big incentive dollars that were attached to this and now there are, for organizations, pretty large percentages that can be tied to some of the Medicare things. I would think, especially, in this registry sphere about what those, if this, going way back to the beginning, what are those pathways of programs to incentivize? Because that gets to the provider uptake and that's what drives it.

There were a couple examples, maybe eight years ago, of inter-agency meetings. At FDA there was one and they were talking about more, I've never seen it materialize. But you guys have both expressed the fact that individuals within government can capitalize progress and there are resources spread around and there are like FFRDCs that can translate those resources into productivity. It's hard to have a conversation agency by agency because of the thinness of the portfolio conversations. If a round table could be generated that linked us with the agencies, the individuals within agencies, that had energy to move this forward and knowledge of the system to support it, and coordinate funding that might be one way to get.

Very valid point. Obviously, my office is statutorily charged with doing that type of work. If you wanted to make that type of recommendation, that probably would make a lot of sense. To try and pull some of that together, at least brainstorm ways on existing funding that's, you know, prioritized.
- I'd love to work with you on that.

- Great.

- I'd love to be the beneficiary.

- Thanks very much everybody. Great conversation.

- Great idea.