



**HIT Policy Committee
Clinical, Technical, Organizational and Financial
Barriers to Interoperability
Virtual Hearing
Transcript
August 14, 2015**

Presentation

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Interoperability Task Force; it's a longer name, but we'll just go with Interoperability Task Force. This is a public meeting and there will be time for public comment at the end of today's meeting. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Paul Tang? Bob Robke?

Bob Robke – Vice President, Interoperability – Cerner

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Bob. Christine Bechtel? Josh Mandel?

Joshua C. Mandel, MD, SB – Research Scientist – Boston Children's Hospital

Good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Josh. Julia Adler-Milstein?

Julia Adler-Milstein, PhD – Assistant Professor of Information, School of Information; Assistant Professor of Health Management and Policy, School of Public Health – University of Michigan

Here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Julia. Larry Wolf?

Larry Wolf – Health IT Strategist – Kindred Healthcare

Good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Larry. Mike Zaroukian?

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Information Officer – Sparrow Health System

Here; good morning.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Mike. Micky Tripathi? And Stan Crosley? Okay, so normally this is where I get to hand it off to Paul, but unfortunately Paul has had some travel trouble and is on a plane. So I'm going to try and step in for Paul. So first of all, let me thank all of our presenters for agreeing to participate in today's virtual hearing. We have a number of folks who were invited at the last minute so we greatly appreciate you dedicating your time to us and I'm sure that we'll have a very fruitful discussion.

Just a reminder for those who haven't been involved in the past; what we typically do is we have each presenter on the panel present, most panels today are three presenters...three or four presenters; so we'll have all of them go. And then what we do is we open it up to the task force to ask questions. So for the task force members, we'll use the hand-raising feature which will just put you in the queue to ask questions and we'll just go down the list of questions or those who have their hand raised, I should say. And typically that's where we get a great deal of discussion, are able to dive a little bit deeper into the conversation and the presentations that we heard. So I'm looking forward to a great conversation.

So before we do that though, I just wanted to remind everybody of the specific charge questions that we were given, which I think will help focus our discussion today, which is really to focus on the financial and business barriers to interoperability. Caitlin or Lonnie, can you go forward a couple of slides, actually. Yeah, thank you. So just to review, these were the specific charge questions that we were given by Jodi.

So, as we've discussed in the past, there are a number of different barriers to interoperability, but we really want to focus on the financial and business barriers that exist in the ecosystem; identify where those barriers lie and with which stakeholders. Talk about the impact of the barriers and the practices on the ability of stakeholders to interoperate; which of these are being addressed by initiatives underway today? Where can progress be made? Where do the gaps still exist? And then what actions need to be taken to address these financial barriers and business practices?

So just keeping these in mind as we go through today's discussion I think will be very helpful. Because at the end of the day, what we're hoping to get out of this meeting and next week's meeting are recommendations to help answer some of these questions. I'm leaning on Julia, who has helped a great deal...this hearing, so Julia, if you have any other comments to add, that would be welcome as well.

Julia Adler-Milstein, PhD – Assistant Professor of Information, School of Information; Assistant Professor of Health Management and Policy, School of Public Health – University of Michigan

Sure, maybe I'll just add two brief comments. So I think the first is that as we have our discussion today, I think it will be really helpful to try to stay focused on financial and business barriers, even though they oftentimes interact with other domains and the task force is certainly thinking about other domains. So for example, the financial and business barriers can impact the approach to governance, but if we can try to sort of stay upstream and really focus on those financial and business barriers today, I think that will really help us accomplish our goals.

And the second is to recognize that financial and business barriers may vary by stakeholder type or geographic location or wherever it may be and so I think it would also be really helpful to us to get a sense for sort of when you're describing phenomenon, to give us a sense for sort of where you've seen that play out if you've seen variation there. Because I think we hear different things from different people, including some people who would say that this is the key barrier to interoperability and that it really stems from misaligned incentives and the fact that there is profit to be made from lack of interoperability. To other places where they say this is really not an important barrier and we shouldn't focus that much time.

So I think we really need these hearings to help us figure out not just which of those two scenarios it is, but sort of in what places might one of those be the case and other places that might not be the case, so that we can think about effective strategies. And maybe just the third point I'll add is that it really will be valuable to us to speak frankly about these topics. I think a lot of times what I hear is that, you know, they're sort of the back room discussions about this and then there's sort of what's said publically and obviously everyone is under different constraints in terms of what they can say, but I think that to the extent that you are really able to give us a sense for how these issues play out, it really will help inform our work and making sure that we pursue strategies that are really likely to make a difference. So maybe those are some hopefully helpful points to add before we dive in.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thanks so much, Julia. So I think we are ready to dive in. One thing I just want to clarify, we have today's virtual hearing and then we also have one next Friday. We did shorten today's meeting to end at 12:30 and then we're going to have an administrative call with just the task force members from 12:30 to 1 to finalize the list of invites for next week. So again, that will be short notice for some of those folks, but just want to clarify in case there was any confusion.

Okay, so with that, I think we're ready to get into Panel 1. So, Panel 1 is John Blair from MedAllies, Jitin Asnaani from CommonWell and Dave Cassel from Carequality. So just a reminder, we'll have all three presenters go and then we'll open up to questions from the task force members. We did ask each presenter to try and limit your comments to 10 minutes; if you go shorter, I'm sure that will be welcome as well and if you go longer, I may have to ask you to finalize your remarks. So with that, we'll turn it over to you John.

A. John Blair, III, MD, FACS – Chief Executive Officer – MedAllies; President – Taconic IPA

Okay thanks Michelle and I appreciate being asked to speak here, although on short notice. I'll try to cover what you've asked me to cover. There were specific questions that I was given; I assume everybody that also were supposed to be addressed with the other comments on the slide before in mind. So I'll try to hit those questions, the specifics. And the first was what strategy would you recommend for achieving interoperability across the country? And actually sorry, can you hear me okay?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

We can hear you okay, John and I'm sorry, just for the task force members, on the agenda that we sent out, there were questions and those are the questions that John is referring to; so, sorry.

A. John Blair, III, MD, FACS – Chief Executive Officer – MedAllies; President - Taconic IPA

Okay, so strategy that I would recommend is first and foremost to focus on Direct, that's something that I've been very involved with, probably before it ever started. I came from a clinical perspective and trying to meet the needs of several advance primary care practices in a region in New York and Direct came out of that for us and is very much a part of what we're currently doing on our Comprehensive Primary Care Initiative contract with CMS for the regional...the New York Region and at this point, we've implemented probably, I don't know, close to 200 practices to Level 3 NCQA recognition and when you get to interoperability between care settings, it has turned out to be probably the best tool that we've ever found. So I would focus on Direct in terms of getting that completed. There are many bumps still in the road, but it's significantly improved in just a year, so that's the first comment.

The next is a single strategy sufficient or is it more likely that a hybrid strategy will be needed? I do not want to imply with my first comment that I think Direct is the strategy, I do not believe a single strategy is sufficient. I think that if you look at all of the different use cases in clinical practice and in healthcare, there's just no way that a single strategy can meet all those; you think about just on the business side EDI, claims transaction; that's a whole piece that goes on. With interoperability you have e-Prescribing that's now maturing; you have lab orders and results that are...improving with the focus on standards.

You also, I think, definitely need a query or a look-up type of component which Direct doesn't get at. So, I think that we need to focus on the push with Direct for transitions of care. We need to continue on a query strategy, whether it's the...what's been evolving with the e-Health HIway and that effort or whether it's CommonWell or whether it's the whether it's the promise of FHIR. I don't know how that'll play out, but I do think that's going to be necessary...it's necessary.

The next question is what's the role of your organization's approach in the global strategy? So we evolved into running a Direct network nationally; it was not our plan at all. We've been very New York focused on very advanced primary care and working with Geisinger for years on pushing out their integrated delivery network accomplishments to an open community but in doing so, got into Direct.

At this point we are running a national network that has...that we've been running for abo...a little over a year and at this point our bringing on about 100 provider organizations a week. We have, I think, probably over 3500 ambulatory groups and about 300 hospitals, close to 60,000 providers. So certainly that speaks to the ability to roll this out and get providers active and get an infrastructure out there and that's...and so to me, that's been pretty phenomenal. I would have never guessed this kind of, oh, getting this many people active this quickly.

The next thing and I will come back to where I think the real problems lie right now, which gets into the incentives and training. But, the next question is, what are the strengths and limitations of your organizations' approach and how might these...might other strategies complement it and what I would say is, this is reminiscent to me of the early days of e-Prescribing. I remember again in the New York region where we'd done the advanced primary care work, really pushing on e-Prescribing. And early days, the biggest problems were the software at the edges catching up and becoming usable for end users.

The next problem though was really getting these different organizations, ambulatory practices to work with pharmacies, pharmacies to do this and you really were moving to a new situation where it wasn't just something within your organization, be it a small or a large organization, but really needing to work with different components of the healthcare system. And we're that...we're there right now with transitions of care and Direct; we...if it's rolled out now, there's enough infrastructure in place that all of this is about now helping the providers figure out how they work with other providers that they've worked with for years, using a technology that now starts to integrate them.

Once you lay that out and explain it and help them across different care settings and put some training in, it's unbelievable. We have seen usage go up 10-fold when you add that effort to the infrastructure. So that's the thing I would add is a way to get these organizations working with each other. I mean a lot of times I don't even know who to call in other organizations they've been working with for 10 years, to arrange how to start this wor...happening.

The next question, is there a good business model supporting this? I would say that the business model is driven by the patient-centered medical home and the advanced primary care work that we do. As I said, we are the sole source contractor for CPC in New York and if you look at milestone 6 and 9, we have incorporated Direct to meet those milestones around transitions of care and when that...when it becomes clinically relevant, it becomes a non-issue. Even very particular providers that want things to work virtually perfectly will compromise on some of the clunkiness and embrace this. So it needs to be driven by a clinical interest and I also think there need to be financial incentives so that they can afford to make these efforts work.

How would it fit or complement business models or other approaches? Again, it's really the underwrite to make these changes has to be driven by an interest in getting ready for the value-based purchasing models. The providers that do believe this is coming and that are making the efforts to put...to get buy-in in the culture of their practices for this and that have the leadership are interested in getting this working and that's where we see success. So, it's ultimately going to have to be driven by a reimbursement model that rewards coordination of care because transition of care is a foundational building block and that's where what I'm talking about comes into play.

The last question is what would you recommend to facilitate your business model to remove barriers? I think I've covered that. I think that it's about the new, evolving reimbursement models. I think we have way underestimated the need across the country for providers to understand how to coordinate these implementations with their clinical trading partners. And I see that in some of the SIM Programs, the Statewide Innovation Models; some states are really putting some dollars behind the technical assistance like CPC has, and I think that that's going to be important. So, I'll conclude there. Thanks, Michelle.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you, John. Next up is Jitin and Jitin has some...yeah, okay.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

Sorry. Thanks Michelle and thanks for having me hear. I have a handful of slides, which I think where Michelle was going. I'll go through some of them really quickly and others I'll spend a bit more time on. My intention hopefully today is to share a little bit about CommonWell Health Alliance. I'll do that briefly up front. I presume most on this call already know something about the Alliance, and then spend more of the time sharing with you sort of the model that we use to think about successful data exchange. Parts of that are the business model, parts of it are other pieces, so I'll try to focus as much as I can on those pieces which I think are particularly critical for data exchange to occur.

So first off, going to slide 1, just to level set, CommonWell Health Alliance is an independent, not-for-profit trade association really focused on one...with one vision which is, patient data should always follow the patient, regardless of where care occurs and access to that data should be build-in to health IT at a reasonable cost. So really that's the vision of the Alliance.

Over the last...going to the next slide, over the last 2-1/2 years, our state of progress can be simply stated as, in 2013 we announced an intent to build a CommonWell Health Alliance. We launched the Alliance and within that year had built a working service that was ready for initial deployment. In 2014, we ran those initial deployments in earnest and began scaling our membership. As we formed in 2013, we had a very small handful of industry participants, HIT vendors, but the intention was always for it to be an open alliance, so in 2014, we got to the place where we could open up membership and allow any organization that believed in our mission to join us.

And now in 2015, we're deploying nationally. We have specifications, we leverage standards, everything is up on the web in an open forum so that others can learn what we're doing to a great amount of detail. And over the course of this year, we are going live in 5000 provider sites across the nation as well as creating new use cases for new care settings beyond acute and ambulatory care settings, which are currently supported by our use case; so that's CommonWell Alliance in the...in a nutshell.

On my next slide I want to start talking about the way we think about data exchange and what are some of those big buckets of things that need to work for data exchange to happen in reality. And this is not necessarily a linear process, but we think of four things that need to happen. The first is that you need to have a problem that you're...a real problem that you're trying to solve and that in solving it you'll create value relative to the cost of solving it.

The second is knowing what the solution is that's going to solve that problem. What's interesting in health data exchange today is that you...proposition is sensible and coming to a solution is also sensible, but because it's...creating a health solution is such an intricate combination of technology and policy pieces and components, often times what you have at the end of solution design is not something that solves the original problem that you began with. And so you completely need an iterative process between these two steps to really ensure that you're solving the problem you intended to solve.

But even if you solve the problem, it's no use unless it's actually in the hands of the customers who need to...who can use the solution to improve care or whatever your organizations mission happens to be. And so distribution is the third big step. And then the fourth step is even if the user does have access to that solution, at the end of the day a user, whether it's a provider, a social worker or a patient or who have you, is a human being. And human beings will use something that's actually...well, creates value in the first place, but is actually easy for them to use.

A provider wants to take care of their patient, but if the fastest and easiest thing for them to do is still to send a FAX, then regardless how great their data exchange capabilities are, they'll still send a FAX because if it's not easy to use and not easy for them to get the job they need to get done in the 15 minutes they have with the patient.

I'd like to just...to make this a little bit more concrete, I'll just superimpose what CommonWell has done and then I'll share my take-aways from it; if you go to the next slide. Along these four dimensions, in value proposition, and so CommonWell's value proposition, what we're trying to solve is, person-centered query and retrieve of documents and data. That's the initial use case we started out with to date. And our solution is two-fold; one is, there's a set of centralized services that manage patient consents and IDs, locate record and facilitate query and retrieve.

And the second component is that every participant on our network creates one and only one interface; one interface to the network that gives them access to everybody else in the network. And that is the solution we created and because, going on to distribution, because we've...we're a vendor-led Alliance in the first place, even though we broadened out since then and will continue broadening out, the access, that single interface, is built into health IT. So if you're a provider who uses an EHR and the EHR is a member of CommonWell, sometime today or tomorrow, you're going to have access to CommonWell Health Alliance services, so you're going to be able to use the service.

Now if we've done the right job in that fourth step, user experience, then you have a service built into your EHR that your users actually want to use and do data exchange. The one piece that we get almost for free, so to speak, is because we are built into the EHR or built into the health IT system, you know, in the post-acute care space or whoever it is that's built an access to CommonWell services, at least we're in the middle of the workflow in the first place and then it's just a matter of iterating on that experience between the care provider and the patient.

Let's go to the next slide. So, if I think about these as the four building buckets and what we've done and I now take a step back and say, well, what is it that enabled CommonWell to emerge? The thing that strikes me right away is that the incentive alignment has been huge for the Alliance. If you think about the panelists today, we have representation for Direct, for CommonWell, for Carequality and none of these organizations was even possible 3 years ago; well call it 3-1/2 years ago. They're possible now because of a few things and in my mind those few things are, for CommonWell specifically, well and maybe for all of them, it's incentive alignment to the fact that the evolving payment models, which John alluded to as well. Meaningful Use Stage 2 incentives to adopt certain standards and to exchange data have certainly played a factor.

For CommonWell specifically, the political will of the founders, members and subscribers has been key. If...there was nothing that pushed a group of CEOs 2-1/2 years ago to form the Alliance; there was no government...specific government force, no specific government mandate, what there was was a realization that this should be the right thing for the industry, for the patients, for the clients and ultimately if everybody's happy, then it's for their businesses. And they came together to form the CommonWell Health Alliance.

If I look at...going beyond to those positive alignments of incentives. There've also been meaningful consequences to not being interoperable and this is starting to serve as a floor. For example, the discussions that have occurred and the potential ramifications in the future associated with data blocking is certainly a big part of just a realization of the industry that we need to move from a place where data exchange is an option to data exchange is just a way of doing business. The importance of interoperability in government contracting; we've seen that come out in various government contracts where the focus has been on interoperability, and that's a very good signal for the rest of the industry.

I will say that a number of the building blocks that have already existed in health care or with a push forward through Meaningful Use have been extremely valuable. For us as an alliance to get together and ask a number of EHR vendors to build an access to our services was greatly facilitated by the fact that everybody had already built the C-CDA. As we look towards doing more interesting things with EHRs and bringing in other types of health IT systems, such as those that power pharmacies, labs and others, they don't have C-CDA and the opportunity to use something like FHIR is extremely important and extremely valuable to the service.

There have also been some policy precedents for health information exchange; things like BAAs that have existed, HIPAA that's existed. I'm not saying any of these things are necessarily perfect, but they do serve as building blocks which we've been able to leverage in scaling our service from essentially 30 sites at the beginning of this year to 5000 to the end of this year.

And finally, people; I can't underscore this enough. At the end of the day, great health information exchange, health data exchange activities don't occur because a committee came together and said let's do this. It occurred because leaders, individuals who think they can make a difference come together and say, we can do this together, and this is how we're going to do it and we're not going to stop until it's done. And that's a big part of the Alliance; it is this just will to see the right thing happen, regardless of, you know, just regardless of the necessary specific mandate to make it happen.

And that feeds right into my last slide which is around...oops, sorry...which is the recommendations. I'll skip through the first two very quickly, I mean, I'm not...I've always recommended that ONC and CMS continue strengthening the building blocks of, you know, the standards, clarification on HIPAA, especially those that cause the most confusion along viability, etcetera. And simplify certification by taking advantage of the fact that if somebody is participating in CommonWell Health Alliance for real data exchange, there's really no amount of certification investment you can make that's going to replicate the clarity with which you know that this person really can exchange data. There's just...there's no tool set you can build that can just replicate that.

But the one I'd really like to emphasize today is that providing strong and focused guide posts for behavior is really important. Things like making data exchange a part of participation of federal programs, things like treating data blocking harshly. To be clear, there are techn...there are real technical challenges, real historical business practices, relative business priorities that are legitimate causes of illiquidity. The fact that in today's day and age some vendors, and even some providers, continue to exploit these points of friction, that is what I think is unethical and needs to be dealt with harshly by government.

And then the last part and I think this underscores a point that John made as well, at the end of the day, a number...there are going to be a number of strategies that help interoperability to happen. Interoperability is a very broad term and I think...I don't think there's any way we can have a preconceived set of strategies which we believe is going to do the job. I think you have to let innovation thrive and set a context in which that can happen. Michelle, I think I ran one minute, 15 seconds over my time limit, but hopefully...so thank you for not dinging me.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you, Jitin. Dave, if you're ready, we'll turn to you now.

Dave Cassel, MS – Director - Carequality

Absolutely. Well, thanks first of all for the opportunity to share today from Carequality's experience. I think I'll be able to build a little bit on what both John and Jitin have shared. I think it's interesting as you look at the concepts here of business models and financial and policy barriers and it reminds me of the tension that I've always seen in healthcare between what I'll call the market forces and mission forces.

And I think actually by and large the healthcare industry makes some really admirable efforts to align the expectations with the needs of good patient care. And there is always a tension there and it isn't always resolved perfectly, but I think that the industry can be commended really for its overall will as Jitin put it, to do the right thing. And that will, as you'll see here as I go along, has been essential for care equality as well.

One of the things that I think is worth pointing out, and this also builds in with what Jitin said, the business side can't be ignored and the reality is that interoperability does carry a cost. Somebody, somewhere is facing a cost to make these connections work, whether that's a vendor investing development time in implementing new standards or ways of connecting or whether that's a provider dedicating staff time to actually implementing what their vendor has provided. Somebody's going to be facing a cost.

And in order for them to do that, we need to make sure that there's sufficient value. You know, it seems like it's an obvious statement a little bit but at the same time, we need to be realistic. Those of us who really dedicate our lives to interoperability sometimes can live in a little bit of a bubble, but we need to be realistic about the actual value that we're providing and always looking not only to lower costs, which absolutely is something we should be doing, but also to increase value. Because no matter how many barriers we remove, the costs are still going to be there in some way, and we need to make sure that there's sufficient reason to face those costs.

So, with that said, a little bit on Carequality. Carequality is an initiative of the Sequoia Project which is a not-for-profit with a public service mission. The aim of Carequality, the sole aim is to advance interoperability. And our specific approach to widespread interoperability is to make it possible for the members of different data-sharing networks to connect to one another. I often use the analogy of a cell phone. I get my service from a particular network, happens to be AT&T in my case, largely because I'm grandfathered in to a good data plan, but I can make calls to anyone, regardless of their particular provider. And we take a very similar approach in connecting networks in the Carequality structure.

One quick note there, we do define networks very broadly; a network might be a state or regional HIE, it might be centered on a particular service provider, it could be a vendor that provides the structure for its customers to connect, but otherwise wouldn't necessarily be typically considered a network in the traditional sense. As you can imagine with that variety of players, it's been an interesting process to reach consensus on the principles, but underlie the structure for connectivity. We do have a very broad community of stakeholders including our initiative members, but also many others who volunteer their time to ensure that we have broad stakeholder representation.

And so as that group came together, the first conclusion that it came to was that in this sort of widespread exchange ecosystem with lots of different players coming together that we envision everybody first needed some way to trust each other. So the Carequality community developed what we call the principles of trust. And the principles of trust outlined the core characteristics of an equitable exchange relationship to serve as the foundation for Carequality's governance structure. Now those are very fine sounding words, but the next conclusion the community reached was that principles are all well and good, but nobody's going to trust anybody else until the principles are translated into legally binding terms that all the parties agree to. And I think the primary reason that underlies that, and there are lots of different surface reasons, but I think at the end of the day, the reason there is that you need those legal requirements in order to align the policy and business requirements among all the different players.

So, as we were approaching the specific requirements for Carequality and how we would go about setting up a framework that would allow these different networks to connect, the two questions that are most relevant to this topic anyway that we ran into that were the funniest were, when can I charge a fee? And do I really have to exchange with everyone? Now the answers to those questions can vary by use case in Carequality's framework, but in what you might call the prototypical health information exchange use case, where clinical documents are being requested for treatment purposes, the answers that the community arrived at were that you cannot charge a fee for access to patient records and yes, you really do have to exchange with everyone, obviously with a caveat that you don't have to violate the law or go against the patient's wishes.

The community did not arrive at these answers lightly and it actually was the second question that informed the first. Essential to Carequality's founding was the recognition that we need to break through the selective exchange paradigm which I'll share records here but not there, you know, kind of the current state that Jitin was referring to with some of the historical reasons for illiquidity in health information; trying to break through that. So again as Jitin stated there are legitimate technical reasons and legacy policy and business approaches that are real reasons why connection doesn't occur today.

With the Carequality framework, we've been able to make a lot of progress in standardizing on those areas, for those who adopt the framework. And what we were left with was business drivers and specifically the desire to charge a fee as a key remaining reason for selective exchange. And basically similar actually to what Jitin was talking about with his conclusions, the conclusion that the Carequality community reached was that charging fees for access to records when needed for treatment was inconsistent with Carequality's principles.

Now, as you might imagine, there was and still is some concern about this. You know, one of the points that I make regularly is that you are still able to charge fees, you know, you can charge fees to your own members to be part of your network and receive connectivity services and you can look at other services you provide. You can even charge fees for access to individual records if that purpose is not for treatment. But ultimately, at the end of the day, if your business model is to charge others for access to patient records that are needed for treatment, that's problematic under what the community has agreed to and it's really impressive to see, I think. And again, it gets to that will that Jitin was referring to; there really is a will out there to make this approach work, and it's somewhat up to us to make the value match up with the willingness to proceed and to re-evaluate business models and approaches.

Finally, and I'll try to make up a little bit of time here, I want to circle back to the statement I made in passing really about the fact that you can't require organizations to release information in violation of applicable law or against the patient's wishes. Now that obviously is a necessary statement to have in there, a necessary requirement but, given the variety of state laws, the variety of the ways different organizations are covered under those laws, they can be pretty challenging to come up with any sort of centralized policy that makes sure that there isn't a gap there. So there is a potential policy barrier, I think, that needs to be addressed around all the different myriads patient consent policies.

A couple of our founding members on the Carequality side are already planning to pilot a fairly simple technical approach for streamlining patient authorization. And I hope that their work can eventually be adopted by the community as a whole, but it's still a bit in process there.

So to summarize the key take-aways; first of all, there are different business models among those providing interoperability services and the differences are a potential barrier. Standardized policy requirements enforced in a legally binding framework like we've put in place for Carequality can resolve or at least mitigate that challenge.

Secondly, the will really does exist to move beyond selective exchange and to encourage business models that align with that goal. And one of the responsibilities that we have as those who really set the tone for interoperability and make it happen is to ensure that the value is there to match that will and justify it.

And finally, local autonomy with respect to patient opt in and authorization policies is obviously a good thing. But it also represents a possible policy barrier. It's not insurmountable; there are reasonable approaches to mitigating the risk but they still need to be proven in a widespread, multi-platform implementation. So, I'll stop there. I think I ended up not necessarily cutting it short, but thanks again for the opportunity to share with you today and look forward to the questions and discussion.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you, Dave and thank you to all three presenters. At this time we'll open it up to task force members to ask any additional questions that you may have. Just a reminder, we're going to use the hand-raising feature so if you could raise your hand to put yourself in the queue that would be wonderful. And first off is Julia.

Julia Adler-Milstein, PhD – Assistant Professor of Information, School of Information; Assistant Professor of Health Management and Policy, School of Public Health – University of Michigan

Okay, that was terrific; I thought those presentations were just each individually extremely enlightening, as well as nicely complementary. So I wanted, you know, sort of thinking back over the comments you made, I certainly got the sense that it feels like today incentives are much more aligned than they were a few years ago. And I think it would be helpful to us to get a sense for like is this just a matter of time and sort of are incentives continuing to head in the right direction or at the rate that they are changing, it could still take us a long time? Because I think there's a difference between saying, you know, we'll never get there versus we will get there but at the pace things are going, that could take 5 years, 10 years.

So I think maybe then the specific question I'd like to get a sense for is, using the metaphor of sort of market versus mission focus and what I took away is that they are more closely in alignment, but not perfectly in alignment. So if you had to say today, where do you run into incentives that impede either what you can do or the speed with which you can do it? Can you give us sort of some, each of you maybe one or two concrete examples of sort of where you are today, where you see sort of incentive misalignment or lack of market forces that either impede what you can or the speed with which you can do it?

A. John Blair, III, MD, FACS – Chief Executive Officer – MedAllies; President – Taconic IPA

So this is John, I'll...I can take...I'll take that first, Michelle, is that okay?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Sure, thank you.

A. John Blair, III, MD, FACS – Chief Executive Officer – MedAllies; President – Taconic IPA

So I think what you said is right, market mission is coming closer, but I think we're probably 5 years away from where we ought to be; I'm thinking about the 2019 timeline for the reimbursement model to be really playing out. And so I think that a year into that you're going to be where you...at the point you spoke of. I do see, and again, I deal with over 5000 providers in the Eastern part of New York and it's a community, it's a community it's not large IDNs.

They are now starting to become aware of this, where things are headed; they are starting to focus on this. The early adopters that we started with 10 years ago who wanted to do more advanced primary care were in it from the beginning, for care reasons. Now there's a greater awareness, but we're far from them really jumping in universally to push on this. So I would say we're heading in the right direction, the thing that we can best do is more and more educate the providers as to where things are really going.

The other thing I would say is I hear this constantly now when we talk about Direct, that we did this for MU2, we are now putting this into our interoperability strategy. I hear it constantly now. So I do believe that we're heading for what you spoke of, I'd say we're 5 years away from that.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

I...

Dave Cassel, MS – Director - Carequality

The...oh, go ahead, Jitin.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

No, you go ahead.

Dave Cassel, MS – Director - Carequality

Well the...I would say, I think the incentives really are coming together and a lot of that has been...both the...there are the two angles to it; one is the payment models and gradual movement from volume to value and emphasis on outcomes and patient care coordination. It has had an impact, you know, that's going to probably I think realistically take some time. You know, how do you transform an industry? It obviously is going to take some time.

But the other...the flip side there is, there's such a clear signal to all parties involved in healthcare that interoperability needs to happen or it's going to be made to happen and you might not like the way it's made to happen. I think that has created such a demand really for valuable interoperability services that if anything, we're going to potentially face a backlash to not being able to meet that demand with sufficient value in the short term. So it may be interesting to see how that plays out.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

Hi, this is Jitin. I will...let me...I'm going to actually resonate a lot of what Dave and John both said, but particularly what Dave said; but I'll add some other detail to it as well. So when I helped co-launch the S&I Framework and the Direct, and when I was co-leading the Direct Project 5 years ago at ONC, there were a number of EHR vendors...a number who participated and a number whom I just couldn't get in to come and participate; despite the fact it was an open forum. Fast-forward 5 years to now and a number of those organizations have jumped in with both feet in things like CommonWell and Carequality or both, along with other organizations, eHealth Exchange, DirectTrust and the like.

And so I absolutely agree with both John and Dave that the incentives are getting there, we are certainly in a positive direction where movement is really happening. And the culture of the industry is changing; everybody realizes that this has to happen...almost everybody realizes. I'll still say that CommonWell is still in the early phases in terms of we have 31 members, there are probably a lot more who are...will join us over the course of time.

And when we talk to potential members, potential vendors about joining us, there are a number of great reasons why they say they'll join a little later or they'll join now or they're trying to figure it out. But sometimes you run into these reasons which give you pause for concern. At least three different vendors I talked to indicated that this just doesn't line up well with the way they think about business and one in particular, actually went as far as to say, look, this intermediates a major source of income for us which is the interface. We charge heavily for interfaces and it's a major driver of revenue for our organization so, this just is not something we really want to get into until we have no choice. That was a small to medium sized vendor who conveyed that.

And so, I think we still are in a circumstance today where it's just not taken for granted that we're going to move to a place where interfaces need to be either cheap or free, depending on their nature and their purpose, but particularly centered around clinical care. And...but again, like I said, directionally it's in the right place, we haven't crossed all the bridges that there are in the road and we haven't hit...you know cross...you know smoothed over all the bumps, but we're getting there.

A. John Blair, III, MD, FACS – Chief Executive Officer – MedAllies; President – Taconic IPA

Yeah, this is John; just one quick comment. We keep talking about, and I'm doing it, too, but we keep talking about vendors and policy levers and everything; I mean I came out of this as a physician, practicing for 20 years, leading a 5000 provider group. I mean I've come at this from providers, day-to-day doctors and their staff. To me, this is about their incentive; interoperability is going to happen no matter how much technology we do, if, you know, when the providers want to do it, one for care and two for reimbursement.

And to me the biggest thing that's happened is those that are sa...that are starting to realize they've got to do coordination of care and the transition of care component is critical to that. Once they believe that that's necessary for them to do to practice well and to give good care, it all...all of this...all of the difficulties and obstacle fade away.

Dave Cassel, MS – Director - Carequality

I would agree with that and just one point of clarification, when I'm talking about value, that's exactly what I'm referring to is we need to make sure that there's value that we're actually providing to meet the demands on the part of the providers.

A. John Blair, III, MD, FACS – Chief Executive Officer – MedAllies; President – Taconic IPA

Yeah, I mean you look at all of the new things that are coming out of medical home and now starting to get reimbursement for that. Providers, now that they know it's going to get compensated, are more than happy to do those things to give their patients better care.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

This is Michelle; we have a number of questions in the queue so I'm going to go to our next question. The only thing is Julia, I see your hand raised; do you have a follow up to your first question?

Julia Adler-Milstein, PhD – Assistant Professor of Information, School of Information; Assistant Professor of Health Management and Policy, School of Public Health – University of Michigan

Nope, why don't you let others go, I have a different question.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay, thank you. Mike Zaroukian?

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Information Officer – Sparrow Health System

Yes hi. So my thanks to the three of you as well, on short notice for putting together such great and I would agree, complementary presentations. I'd like to take it in a little bit different direction, sort of testing the interoperability considering the three thoughtful and again I think complementary approaches.

So as an example of looking at the business and financial drivers, how would each of you view the barriers and facilitators of your own organizations interoperating with each other? And what strategies would you propose to work synergistically together to expand interoperability with each other in the current environment? So for example, making sure it doesn't matter whether a provider is part of a CommonWell organizational approach or a Carequality approach, using Direct, etcetera to be able to exchange with those who chose the others approach; what would make this more feasible today? What would make it more desirable, feasible and successful in the future?

A. John Blair, III, MD, FACS – Chief Executive Officer – MedAllies; President – Taconic IPA

All right, this is John; I'll jump in again first then I'll quit after this, jumping in first. So I think these are different use cases to a degree so they really cannot be interoperable; they're different use cases. Now, and this is where I think Carequality really has...I like the concept; when you move from thinking about the architecture and infrastructure as being interoperable to thinking about the use cases as starting to overlap. For example, maybe a query via Direct and then something coming back via, you know a CommonWell approach or some other approach. I think when the use cases start to overlap, that's when you ask this group on the panel how do you work together. I'll stop.

Dave Cassel, MS – Director - Carequality

Yeah, I think that's valid. The Carequality framework is actually meant to be very extensible and as John alluded to, to address a variety of different use cases and technical architectures and really is kind of a governance overlay; I know we're not supposed to talk about governance today, but kind of a governance overlay on top of these different use cases. The...he's exactly right as well that to varying degrees there are different use cases there.

I think that ultimately CommonWell adds a data-sharing network as opposed to sort of CommonWell the Initiative, is definitely one of those that we see down the road being connected into the Carequality framework. And there are some technical things and just considerations that we need to figure out and it's something that Jitin and I actually meet regularly to talk about. But as far as Direct goes, you know it hasn't been an immediate priority for Carequality because there has been a lot of other work in that area, but we certainly wouldn't rule out looking at a Direct messaging related use case in the future.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

Hi, this is Jitin. I'll add on, I absolutely agree with both the previous comments. The way I think about it is there are some cases where the use cases are so very different; so Direct is clearly following a push-based use case or a push-based technology which lends itself to a number of use cases, which makes sense with push. CommonWell is approaching it from the point of view of query and retrieve, which is a different technology or different mindset that requires...that implies a different set of potential use cases.

And the...so in some cases, they may or may not converge and it may not make sense for them to converge anyway; the one place, and this is more to Dave's point, is that there is...CommonWell and Carequality for sure, we spend regular time trying to figure out how and when we will eventually intersect. One of the things that we're very cognizant of, and I think both parties are very cognizant of is right now thinking about interoperability between networks is a little bit like thinking about cell phone portability in 1997. In short it doesn't matter because nobody's really doing exchange at any volume that makes you think that this is...that it's worthwhile spending time doing inter-network connectivity today.

Now, that doesn't go for the entire industry; there are certainly places where there is exchange happening and they're connecting through things like eHealth Exchange or through Carequality where it makes sense. But by and large, there is no, you know, if you take an analogy from another industry, there is no clear Verizon and clear AT&T and clear T-Mobile for whom their networks, it's time for them to collaborate.

So that's a continuously monitored target and a place where we're very active in making sure that we don't reach a world where if you join Verizon you can only talk on the Verizon network; if you join AT&T, you can only talk on the AT&T network. That's the noble goal that Carequality is going to help us make sure we don't get to and that's why we collaborate actively. But we're still not there yet, we're still 97, 98, 99 for cell phones; it's on the horizon but we're not there.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. Our next question is from Larry Wolf. Larry, if you're speaking, you're on mute.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Thanks, is that okay?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Yes, thank you.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Okay, so I'll begin with echoing everybody's thanks, this has really come together on a really short timeline and I appreciate everybody's flexibility. And given that depth of what you've had to say, clearly this is something important on an ongoing basis; you didn't just throw this together in the last two days, this is, you know, we're talking about a lot of work that's taken in most cases several years to get where we are. So I think there's a real appreciation of the timeline and trajectory and I think some of the comments about how much has happened in the last year, really speak to how much things are in change including, perhaps, expectations.

So I think actually what we're seeing, and this is eventually getting to what I'd like you guys to comment on, what we're seeing is in fact rising expectations. The conversation around data blocking, the conversations around did we really get, as a nation, the value from the investment in health IT. I think a lot of that comes out of a rising expectation that interoperability should be easy, should be quick and that we should have it now or we should have had it yesterday.

And so where I'm going with this is that interoperability inherently is really about some level of cooperation among many organizations and a lot of what you've been talking about are kind of the upside, right, of the improvements in patient care that might happen. And I wonder if there are things that are downside things that are shared pain where interoperability is the answer to the shared pain? And that the pain might be something that would rally vendors and providers together in a way to sort of move this forward. So do you have a sense of things out there today that we could talk about as that kind of shared pain, shared need? You've touched on some of this, so maybe it's just a reframing of some of the things you've already said.

A. John Blair, III, MD, FACS – Chief Executive Officer – MedAllies; President – Taconic IPA

Okay, this is John; I'm breaking my promise because I've got to get off actually I've got a hard stop right now. So Larry, I'll quickly say this and I've got to hop. I completely agree with what you just said, all of that. And I'll go back to where I live, which is day-to-day with providers from solo practitioners to 500 provider multispecialty groups, systems to small hospitals, etcetera and as we've been...and we've been at this for 15 years on our community transformation work, and when we started the Comprehensive Primary Care Initiative about oh I think 33 months ago on the CMS project, there were 9 milestones.

And one of them was very specifically around coordination of care and we outlined I think three or four different ways that providers could accomplish that milestone. We developed implementation guides that are now part of the CMS documentation that's being used across the country. And at that point, Direct was just beginning, it was something that I had hopes for and so the other was FAX, mail, all sorts of work arounds with communication over phone; but they had to accomplish those milestones. And we had to shoehorn that in to the way things worked in the community.

Now, three years later, they're universally using Direct. If we look at our national network, our transaction volume across where this focused effort is is 10 times higher than our national network. And so what it's...what this has done is it has, to your point, certainly made it much easier than those other three options that we have built into our implementation guides now. This is what's chosen first and foremost and a lot of comments about how much easier it is now, the solo practitioner can send off to his 15 different specialists over Direct a C-CDA and then get it back after consults and all of the meds that have changed are highlighted and he can port it into his EHR. Those kinds of things are what we need to speak to. As to the new paradigm that's come, if you're going to do coordination of care, there's a lot easier way to do it.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

Hi, this is Jitin; I'll add a couple of different perspectives as well to this. Two perspectives come to mind; there are actually...there's actually a lot of pains to be solved across all the dimensions of stakeholders from providers to vendors and everything in between and around those and not the least being patients. But I think there are two pains in particular that I've seen having driven activity, particularly over the last 12 months, in my mind and I've only been at CommonWell full time for the last 5 months, so maybe some of this a pre-bias.

But there are two in particular; one is the reality is that building an interface is expensive and we do not have enough money in our national budget to build point-to-point interfaces across the country. It's just...it's not possible; 5000+ hospitals, I don't even know how many ambulatory patient settings, pharmacies, labs, etcetera; there's just no way you actually connect the world through interfaces and they're expensive. You have to use...you have to use the same engineers who could otherwise be improving your analytics product, to build an interface; it's a complete waste of money.

So there's certainly that push, just coming from the vendors. Now I need to satisfy my providers and their needs for care management, population health, you know, the higher standards for quality that they're expected to care at. And I just...I don't...I literally don't have money and enough engineers in Silicon Valley to pull out and do this work. So I need a more scalable solution. So that's one pain where we're seeing that folks are looking; that's why a number of...that's part of the reason a number of vendors have come together to form organizations like Carequality and CommonWell, not to mention Direct and others.

The second part that I see is there is, you know, it's...we've been talking about interoperability now for years as an industry and I think the illusion of interoperability is, it's starting to become more apparent. We've...if you talk to...don't...I'm doing a tour right now, not really a formal tour but an informal tour of going through, meeting doctors in various states to figure out what it is...how it is that interoperability is changing the way they practice medicine. And a really interesting fact is that I meet these doctors, some of them in states whose HIEs are so well known and so touted and you see them on...you see their doctors practices or hospitals listed on the HIE side.

And you go talk to the doctors and it's a very different experience; they're not able to get the data they want; sometimes there's no data to be gotten, sometimes they have no idea that they were connected in and you realize that well, there is actually a big disconnect between what people say they're doing for interoperability and actual interoperability affecting patient care. And that sort of disillusionment, especially now as interoperability becomes an important part of being able to take care of your patient population, is starting to drive some of those organizations. Sometimes a provider, sometimes their provider organizations, you know the CEOs of their health systems and sometimes the HIEs themselves, towards looking for solutions which will actually enable real patient care to happen across the boundaries of organizations.

So I think there's a maturing of the industry that's happening as people realize that experiments...and some of the experiments in the past are not working and some of the experiments in the past just need to be iterated upon.

Dave Cassel, MS – Director - Carequality

Briefly, because I know we probably need to move on; I would agree with that and I think the...ultimately the biggest driver is around patient care coordination and just the need to overall shift from volume to value and looking at patient outcomes; all these obviously being critically important. But Jitin, in his comments there, referenced population health management, care management, analytics; all of these things that we need to do, and all of them require interoperability and so the demand is there.

The great thing about vendors, you know, being for profit, that has arguably some downsides in some areas to some minds, but it does mean that they respond to market forces including demand. And where there is sufficient demand from the providers, that demand will ultimately be met, you know, there may be winners and losers. But I think I would agree overall with the assessment there that Jitin just gave that the market is gradually maturing and it's not yet mature by any means, but we're going to see, I think, some interesting structural shifts over the next few years that ultimately, I think, will result in greater value, greater connectivity.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay, this is Michelle; we're running into the next panel. It is on the same topic so I'm hoping that we'll be able to make up some time a little bit. We have two more questions in the queue so if we could try and get through those as quick as possible and then we'll move on to our next Panel. So Josh has a question and then Julia.

Joshua C. Mandel, MD, SB – Research Scientist – Boston Children's Hospital

All right thanks and I'll try to make it really quick. I think Jitin actually just provided a great lead-in for this question which is the disparity between the networks that people are in theory hooked up to and what they can actually do with those networks today and what they're aware of. And actually one of the comments that Dave made really sparked this question for me which is, he said he was on AT&T so he could call anyone in the country on any phone system. But the state that we're at today with health IT seems more like, I've got a phone number for you and I'm trying to send an e-mail to your phone number and it just doesn't work and the end user is often unaware that this is like the problem in the first place.

So I'm wondering, for the data sharing networks where customers are often vendors or health care provider organizations, to what extent are there business practices in place or under way to actually educate the end user physicians and clinicians who are working with these systems to give them expectations about what they should be able to do and how they can start to investigate when things don't work.

Dave Cassel, MS – Carequality Initiative Lead – The Sequoia Project

It's an interesting question...this is Dave. You know, and there isn't any single answer. There's a lot of variety out there among the different data sharing networks and Jitin kind of alluded to this as well, some are successful and have a lot of real widespread connectivity and others do not. And I think the...it's interesting to look at how the different models play out and, you know you can maybe draw some conclusions.

But ultimately at the end of the day, if a provider has to work too hard to take advantage of a connection, they're less and less likely to use it. And if they go out there once and they have a bad experience, they're going to be less likely to do it a second time. If they try to use the connection a second time and they have another bad experience, they're probably never going to try to use it again because it gives no value to them, as they see it. They're very busy, they're pressed, a lot of requirements weighing on them as well. They just don't have time for these things that don't work. And so that's where I talk about it gives them value.

It's...the demand is there, we just need to supply an actual product that's if you will, that will meet that demand and provide sufficient value. And I think working with vendors, it's something that both Carequality and CommonWell do, to really build things into the workflow, to make sure that standards are there so that you know how to get your EHR users connected; that's essential. Being able to ultimately make it easy for the end users because it is hard to train; if you make it complicated, these are very busy people with lots of demands, lots of things that they have to be accountable for besides the intricacies of understanding a health information exchange's rules and who is actually participating, who's not.

That's why we just need to break down those barriers and get to that point. And we're not there, you know we're definitely not there and Carequality is just at the start of really making inroads into making this work. But we do need to get to that point where you can just call each other. I think we'll get there, but it's a process.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

Hi, this is Jitin; I'll add on, too. I totally agree with that, I'll add in a couple of details that we've learned from our experiences here that hopefully complement exactly Dave's answer, which I spot-on agree with. There are...as I said at the beginning, there's value proposition, solution, distribution and user experience and the reality is, until you actually get distribution solved such that you have the ability to put a health data exchange platform of some sort in front of your user, you can hardly start being able to figure out the user experience.

One of the things we have done is because we are a vendor-driven network and our solutions are built into vendor products, really like just any feature in the EHR. When our vendors distribute the newest version of the EHR or the CommonWell-enabled version of the EHR, they decide to do a CommonWell specific release, then they provide the same education as they would for any other type of EHR functionality that's released. It's not a separate process, it's not something they're...the providers in the orga...sorry, not providers, the management within the provider organization needs to specifically carve out. It's just another feature in the EHR that complements the work they're doing already.

So what we're trying to do is get from our individual vendors, and this is where I think all three of us panelists said that the will power is what's amazing in the industry right now and for us within CommonWell, what we see is that our...a particular vendor will roll out, get some feedback from users as to what is working, what is not working and they'll come and share that with the whole Alliance, both the successes and the failures. So as other people roll out, they're getting the benefit of knowing what kind of education is working and not working with clients. What type of workflows are working and not working with clients. What sort of policies are working and not working in terms of how CommonWell fits into whatever policy that they've already organized with their providers for the use of their EHR.

And so there's this tremendous sharing that's starting to happen and I think we're at the very tip of it and probably going to learn...probably more rough lessons than easy lessons, but that iterative process at the end is key to this. And it does include just getting experience from the actual user behavior, do they click on the button that allows them to share or not, and the feedback from the user in terms of what that experience looks like. And we get it through our vendors, different models we get it through different mechanisms including directly in some cases. But that's how we're incorporating the feedback, again, as really thinking about this as just another feature of the EHR.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay and quickly, last question to Julia and quick 30 second question and answer, hopefully.

Julia Adler-Milstein, PhD – Assistant Professor of Information, School of Information; Assistant Professor of Health Management and Policy, School of Public Health – University of Michigan

Yup, absolutely and this may just be the beginning of a discussion but both Jitin and Dave talked about, I think and the words used were sort of in focus, guideposts for behavior; Dave used the term standardized requirement; sort of a sense that we need to come up with some rules of the road for what is considered ethical behavior with regard to sort of information sharing and interoperability.

And I would just love to have you help us think about like how do you actually operationalize that idea? And...because I think there is a sense of like there are bad business practices out there right now and is there a way to come up with sort of a code of conduct that, you know, should it be voluntary, transparently reported? I mean, what could we do there to really make that idea have some teeth?

Dave Cassel, MS – Director - Carequality

Well, and I can address that I think briefly. We discussed that at some length in the Carequality community and we came to the conclusion that there was no warm and fuzzy answer; that ultimately you need to set out the business requirements and you need to make them legally binding. So in order to gain entry into this community of exchange between all the different networks, you need to agree to these practices and these policies and if you don't, then you aren't allowed to come in.

Jitin Asnaani, MBA – Executive Director – CommonWell Health Alliance

Yeah, I'll build on that. As...any data sharing network needs to ensure that it has policies in place, otherwise it's just technology without the right things in place to make that technology work in a clinical context. Our policy reflects what I call the two for tang...the two to tango policy which is, if you are subscribing to CommonWell services, that means you have access to the data from everybody else in the network and that means that everybody else in the network has access to your data, too.

For the use cases prescribed, it's not wholesale access to be authorized and for the use for direct patient care today is our only initial use case. And that is...and so if you don't sign up for the services, if you don't participate in CommonWell for those services, then you don't get the benefits nor do you expose yourself in terms of actually being able to allow others to access your data. So my perspective is, just the policies of being part of a data sharing network will kind of enforce that over time.

But there is a flip side, and I do...I will underscore what I said previously which is, there are...I think we're at the time now or we're rapidly getting to the time now, something I couldn't say 5 years ago, that it should just be expected that there will be that real world impediments to data blocking will no longer be an excuse for data blocking. And I think what government needs to do is ensure that it's treated seriously enough, beyond just wrist slap, something that actually gets the provider organization and/or the vendor, depending on where the issue lies and it can certainly lie at either place, to participate in an economy that's no longer going to accept data blocking as a potential business strategy.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Well thank you both Dave and Jitin, and I think we lost John. We really appreciate you being able to participate and provide such thoughtful responses. We're going to switch over to Panel 2, same topic we just had to break them up into two panels. I think all three presenters are on, but let me just check; Ann, are you on the line?

Ann O'Malley MD, MPH - Senior Fellow - Mathematica Policy Research

Yes I am can you hear me?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, yes. And Tim, I heard you earlier. And Peter I believe...

Tim Pletcher, MHA, PhD - Executive Director - Michigan Health Information Network Shared Services (MiHIN)

And I'm still on.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And I believe is still on...yup. Okay, Peter?

Peter DeVault, MS – Vice President – EPIC Systems Corporation

I'm here as well, thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay, great. All righty, well we'll let Ann kick us off.

Ann O'Malley MD, MPH - Senior Fellow – Mathematica Policy Research

All right; well thanks very much, Michelle and the entire committee for the opportunity to share our research findings related to provider competition in health information exchange. Between 2008 and 2015 at the center for studying health system change and at Mathematica Policy Research, we've done a series of studies examining the use of health information technology in physician practices to foster coordination of care and team work across clinicians and inter-professional staff. Most of these studies have been funded by the CommonWell Fund and Robert Wood Johnson Foundation.

As part of this work, we conducted in-depth interviews with 221 mostly primary care physicians and nurses and specialists in 115 practices ranging in size and ownership type from across the United States. And through this work we've heard from on the ground clinicians who are really battling it out every day, as well as other stakeholders including EHR vendors, medical executives and national thought leaders about facilitators and barriers to using HIT to improve coordination of care with lack of interoperability being a chief barrier.

I was asked to speak today specifically about findings on competition as a barrier to interoperability; whether or not this is the pervasive versus market-specific phenomenon, and what might help provider interest in interoperability. As you know, challenges to health information exchange are pervasive; they are not just a market specific phenomenon. There are some exceptions in a few markets with robust health information exchange. In some cases these are geographically isolated areas or markets served by a single, integrated health system; however, for most patients and providers, they live and practice in areas where this level of integration is absent and thus, they face major barriers to health information exchange. Competition is part of the story and it poses challenges to interoperability in both indirect and direct ways.

So first I'll kind of run through the indirect challenges to health information exchange. The first one includes misaligned payment incentives. In our interviews over the years we have heard that many primary care clinicians and specialists, as well as community support and social services, would very much like to exchange information to improve patient care. They really, they do want to see care for patients be of high quality and they understand that speaking to the other providers who share care for that patient is critical to doing that.

They've told us, however, that the current fee-for-service payment system does not promote this activity. Instead fee-for-service payment encourages clinicians and hospitals to continually increase the volume of more lucrative procedures and diagnostic testing and other resource intensive services to maximize revenues. Thus exchanging clinical information to better coordinate patient care is a low priority because coordination and data exchange activities have not historically been reimbursed, at least not in a manner that can overcome the volume-based incentives.

There are some exceptions, for example staff model HMOs, some closed systems where provider's incomes are not strictly determined by RVU or productivity incentives. And similarly, in new models of care such as ACOs, there is an effort to get both primary and specialty care providers, as well as hospitals, on the same page to better coordinate care for patients and shifts the focus towards shared accountability for patients and away from the volume incentives in traditional fee-for-service payment.

The second indirect challenge is something that's been referred to a little earlier by the first panel, and that is a culture that does not emphasize information sharing and accountability for the whole person or the whole patient. Again, this is in part a function of misaligned fee-for-service incentives and the increasing fragmentation of care across an ever-growing number of subspecialists.

Clinical culture has shifted away from a sense of shared accountability for the whole person. As a result, providers are not part of integrated systems that share electronic health records and they are not typically part of projects that encourage coordination. And in those cases, where they're not part of those types of things, they may not really understand the benefit or importance of communicating with one another to ensure that a patient receives well-coordinated care.

The third challenge is a lack of systemic communication processes across different types of providers including primary care clinicians, specialists, community based services and social service agencies. A common example of this in a clinical setting is the unreliable communication between primary and specialty care clinicians about patient referrals and consultations. When providers are using the same EHR, they can access the patient records; but providers on different EHRs typically cannot exchange information electronically and still resort to faxing long referral and consultation notes from their records. And clinicians continue to complain, in the real world, that these referral and consultation notes generated by EHRs are long and repetitive and make it extremely challenging to pull out the important clinical kernels from the large amounts of copied, pasted and templated text.

We know that the C-CDA is a step toward trying to systemize this type of clinical information exchange, but something providers continually reinforced for us during our interview is that they want to maintain the nuanced, free text fields where they clearly can state the reason for the referral or what their critical assessment of the patient is; that's something providers really value is pulling out that thinking piece that clinicians need to do. And that that is something that really needs to be maintained as standards and processes are implemented for EHRs and for data exchange.

The fourth kind of indirect challenge is something that the earlier panel has touched on, which is the absence of a viable business plan or standard organizational structure for data exchange. This likely contributes to suboptimal rates of health information exchange. There was a recent review by Dr. Kruse and colleagues which noted that in the absence of a national infrastructure for data exchange, even providers who want to share information to coordinate care for patients will continue to face numerous barriers.

So now I'd like to turn to the sources of direct competition that pose challenges to health information exchange. And we've heard about two primarily in our research. The first is electronic health record vendor competition, which is overt and from the providers' perspectives that we've interviewed over the last 7 years, including in Primary Care Redesign Projects, this is really a leading barrier to health information exchange.

As you all know, EHR vendors are selling a tool or a service so they understandably have few, if any, incentives to support interoperability, reinforcing what many providers have told us. An EHR vendor that we interviewed told us, "even if you want to interface, there's someone selling a similar product in the same market. Everyone talks about interoperability, but we need the cooperation of other vendors to interface with their systems." Dr. Sheikh and others recent work suggests that federal stimulation of competition by mandating vendors to open up their application program interfaces would help to overcome this problem.

The second major challenge is one of competition between hospital systems. At the Center for Health...Studying Health System Change, we conducted numerous site visits across the United States as part of the community tracking study. And during our 2010 site visits, sponsored by Robert Wood Johnson and the National Institutes of Health Care Reform, we learned about growing employment of physicians by hospital systems. Hospitals, as you know, have become increasingly consolidated in markets over the last decade and this consolidation as well as other challenges that physicians face has led to increased employment of first specialists and now primary care physicians by these large hospital systems.

Hospitals' primary motivator for employing physicians is frankly to increase hospital market share and garner referrals from primary care providers to the hospital specialists and lucrative diagnostic testing procedures and inpatient admissions. Health information exchange within a hospital system can be enhanced if all the clinicians within that system used the same electronic health record, but there is no guarantee that those hospital systems and their employed physicians will work together to coordinate care, without care processes being well-defined within those institutions and the providers having their lives made easier in ways that will encourage them to coordinate care.

Furthermore, hospital consolidation and increased hospital employment of physicians does not encourage communication with providers outside of their systems. Competition between hospital systems, coupled with misaligned fee-for-service payment incentives which reward volume, create little incentives for hospitals to try to exchange data with physicians or other systems outside of their own business entity. Quite simply they want to keep the lucrative services performed within their own systems.

So, this leads us to the third question of, driving provider interest in HIE. Maximizing clinician's interest in health information exchange to improve quality and coordination of care for patients requires EHR vendors to more openly share their program interfaces. It also requires a cultural shift among clinicians and hospitals to improved communication and information sharing about patients for whom they provide care. Key to this shift is removing disincentives under current fee-for-service payment that discourage providers from taking the time to exchange information more routinely and in a more timely fashion.

Until reimbursement changes, providers will be less willing to alter their clinical workflows to improve communication and engage in HIE to sufficiently prioritize shared, coordinated care for patients. Modifying reimbursement to encourage coordination of care will likely drive clinicians to better...to demand better EHR functionalities and infrastructure so that they can exchange information needed to properly care for patients. Adding additional policy levers such as encouraging health information exchange among clinicians include things such as training...clinicians-in-training learning the value of such communication and this could be reinforced by maintenance of certification requirements for clinicians in practice.

We know that ONC has worked hard to standardize data elements for meaningful use of EHRs, but in addition to meeting Meaningful Use requirements, providers need to modify clinical workflows and to do this, they need the support of robust exchange infrastructure and a reimbursement system that emphasizes clinician buy-in, or encourages clinician buy-in to coordinate care. Until there's progress among these multiple tracks, it is doubtful that any single standard or endorsement of a particular care process will motivate providers to fully participate in health information exchange.

Again thank you for the opportunity to share our research findings with you as you develop HIT and infrastructure to improve the population's health.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you, Ann. Tim, if you're ready?

Tim Pletcher, MHA – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

I'm ready; can you hear me okay?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

We can thank you.

Tim Pletcher, MHA, PhD – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

Okay. Well thank you very much for the opportunity; my name is Tim Pletcher, I'm the Executive Director for the state designated entity for Michigan called the Michigan Health Information Network and we're what's considered a network of networks. And my mission is kind of a microcosm of this larger strategy challenge that's in front of the committee; we're trying to get all the different stakeholders to share information. And frankly we feel we've been quite successful and have landed on a model that has allowed us to sort of advance on a number of fronts. And my goal is to really share what I think is reusable from our model that may align with what Ann just said, because that has absolutely been our observation and really what the earlier panel commented on, there's absolutely nothing there that I think we would disagree with.

The first thing that I want to comment on is this idea that the data sharing infrastructure has to have high trust. It has to have high trust for a variety of reasons, but the simple one is the sort of liability chain is very, very real and the bigger organizations are actually very concerned more and more about breaches and disclosures and misuses. And so the legal connectivity and the legal integration is almost more important than the technical integration and upholding that chain of trust and following the liability is actually really critical. Similarly, the data...the technical integration, which is where a lot of our standards, C-CDAs, FHIR, etcetera, are poised.

Where we think there also needs to be some standardization is around the sort of financial components. So for example, in Michigan unlike the DURSA, which hopefully many of you are familiar with, which is kind of a one-size data sharing legal framework; in Michigan we have what we call a two-tier data sharing framework. And the first component is sort of like a master agreement, not at all dissimilar from a DURSA kind of content. For those of you in IT who've made purchases, the difference here is we have a master agreement and then under the master agreement, we have different purchase orders that relate back to the master agreement.

We do the same thing in Michigan for data sharing where we have a master agreement for really being part of the ecosystem and then we have sub-legal agreements that are use case specific. And by having a two-tier system where there's a master agreement that sort of outlines what good behavior looks like, and then it points to sub-agreements that are use case focused, you can create an environment where people are held a little bit more accountable and you are able to align incentives and overcome some of the competitive aspects.

And so what we've done is not said there's a one-size fits all, but really said, the issue for interoperability is articulating the path to prioritize what we're all willing and able to do. And so what we focused on is really identifying the portfolio of use cases that everybody needs to do and what order we're going to do them. And for us, the master legal agreement gets you into the club, it then points to the list of use cases you might begin to participate in and each use case has with it a value proposition. And the value proposition articulates, by stakeholder class, who benefits, who loses or why do we care about this kind of data sharing.

And that value proposition is then linked to an actual second legal agreement that's use case specific that defines the conditions of use, the expectations of use, helps prepare the business development people, who are thinking about it for competitive reasons, helps the individuals who are in risk management understand some of the concerns about privacy or security. And then there's another document sort of associated with every use case and we call that the implementation guide. And the implementation guide provides sort of context for how to implement the standard or standards if there are multiple ways to solve the problem with sort of concrete guidance around the when to send something.

So for example, maybe we have a statewide ADT use case that says please send your ADT messages when a patient's been discharged. The implementation guide would have very specific guidance sort of when to suppress the diagnosis code, when to include the diagnosis code, but the actual standard would be an HL7 standard underneath. This has led us to believe that we've, in our environment, have to really raise the interoperability dialogue in conversation to where we're not focused on just technical integration, but where we really begin to talk about use cases as chunks of information functionality.

And the idea is that if we talk about a use case such as notifying folks about when their patients have been...experienced a transition of care, the emphasis is not on the C-CDA or the CCD or the FHIR protocol, it's on the situation that we want to make sure people are sharing information. And what we then do, for every type of use case, is we really identify the policy lever or the financial incentive or disincentive, the so called carrot or stick that goes along with implementing the use case.

So what we've found in Michigan is if we're unable to pay or punish people for certain kinds of data sharing, that it goes to sort of a very low level in the priority queue. And by aligning use cases with financial incentives, very concretely aligning them or having very specific rules saying you must participate in this use case or you're ineligible for some program. It takes the conversation from you should share data because it's good to you should specifically share consistently this type of information and in a very specific scenario and then you can measure not are they using Direct, but are they specifically doing referrals. Are they specifically notifying folks when they transi...have a transition of care? Are they specifically notifying people when they do a major change to the care plan? And it's completely using all of our detailed technical specs, but it's providing a larger functional context for when you do that sharing.

So what I believe is really required at a national level to make it scale is a similar kind of framework and a similar kind of identification of, these are the common use cases that we expect people to always be able to do. And then underneath them, potentially even give them options for the different transport mechanisms or the different standards that we have for interoperability, to make that available.

Sort of moving on from that, the next area that I think everyone pretty much agrees that care coordination is huge around the interoperability data sharing space. But I think there's another front that has opened up that's not, perhaps, getting the same level of attention that is linked to everything we're doing in health information sharing. And that other front is around quality, performance measurement and outcomes analysis and as we look across the quality space, there is a huge amount of opportunity for streamlining things and alignment.

But what's interesting is to do a very, very good job of running quality reports, you really need to link all the patients, link all the doctors, link all the structures that people are participating in in a consistent way. And there's a bridge that gets built between notifying people for care coordination purposes and making sure that patients being linked to doctors, being linked to care coordinators, being linked to ACO type structures, which you need to deliver data from care coordination. It's the same infrastructure that you need to do very good quality reporting.

And so things like your health provider directory, things like your common identifier or common linking mechanisms to uniquely identified doctors and patients, things like your standard reports are again, different use cases, but follow the exact same model that you need for sharing information from a clinical...purely clinical perspective. The reason the quality and performance reporting though is really powerful is because it brings along with payer community. And the way that health care reform has gone is that you really can't decouple the sort of administrative payment side from the clinical care side.

So one of my observations is that we've put an expectation that doctors will send Direct messages when they're doing referrals to specialists. But we've done nothing to encourage health plans and doctors to use Direct to share almost the same kind of information when they're trying to get paid. And if you do an analysis, you'll see that the payer community and the clinical community interact a lot, but they're motivation is happening on sort of custom portals or on faxes. And we haven't done anything to sort of close the loop to sort of drive up interoperability with the payer side of the house, which would help us get economies of scale to sort of push yet another reason why it's the best option for a clinician to use some of the interoperability standards. Because if the people they get their money from are asked to use the same kind of infrastructure.

I'll go ahead and stop there; those are sort of my big points which were, use cases that are more functional, a two-tier solution for our legal framework, so there's the master agreement component and the use case component; and then really thinking of interoperability as extending to those who pay or regulate care so that they're included in our interoperability framework.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thanks, Tim. Peter?

Peter DeVault, MS – Vice President – EPIC Systems Corporation

Sure, so first of all I'd like to thank Dr. Tang and the other members of the task force for inviting me to participate. When I talked to Paul the other day, he asked me to spend a little time discussing the current ecosystem and its likely evolution, in addition to the business and financial considerations. So I'll combine those in my comments.

We've come a long way in the last several years. Care Everywhere is EPIC's health information exchange platform that went live all the way back in 2008. It includes about a thousand hospitals and more than 25,000 clinics, which are all connected to each other using the industry standards that we're all familiar with. In turn they are connected to over 500 health systems and 27 HIEs on more than 50 different vendor platforms using those same standards.

This ability to connect has tangible outcomes. Just in July of this year, so in a one month time period, these healthcare providers shared more than 16 million patient records, about a quarter of which were with non-EPIC systems. The growth has been explosive over the last two years and to play off the comment made earlier, Care Everywhere probably is the Verizon to eHealth Exchange is AT&T and a lot of our customers use both.

So contrary to what we hear on blogs and in some political channels, interoperability is happening, but it's not ubiquitous and in many cases, the form of interoperability that our industry currently makes possible is not what we envisioned might be most valuable for patients and providers. And that's really what we're discussing this morning. So in the next few minutes I'll describe where I think the industry is going and what it will take for us to get there and what might make that sustainable.

So first let's consider where data lives. Just as sites of healthcare are becoming more dispersed, moving away from hospitals and medical centers and into the community, so the location of data is becoming more distributed. The notion that there will be a master database in the sky that houses all data all the time in one place, whether at a regional, state or a national level seems impossible when said out loud. But that's largely been the premise of the HIE strategy to date. That isn't to say that HIEs don't have a place, they certainly do, but that they cannot be islands because patient care does not respect political boundaries, HIEs need to be able to communicate with each other.

And the same is true of networks that are not geographically bound, such as Care Everywhere, the eHealth Exchange or a Surescripts clinical information network. We need to think of networks not only as being competitive with each other, which can usefully be the case in some instances, but as being complementary to each other. They can serve different purposes for different constituencies, but the networks need to interoperate as well.

I would submit that there will always be multiple networks; there will always be multiple sources of information such as HIEs. And so a critical part of our national strategy needs to include the policy and technical means for these networks and HIEs to interoperate. That's why the work of Carequality under the Sequoia Project is so important to be recognized as such. Importantly for our discussion today, having multiple networks in competition with each other, but able to communicate with each other will help keep long-term costs down.

We need to think beyond just EHR systems, yes, EHRs hold a lot of valuable data but not all valuable data. As an example, consider public health registries. Too often registries are a one-way street for health info...they take data in, but they don't let it out. Last we counted, fewer than half of the state's immunization registries can be queried electronically.

Other examples include payers. CMS knows every place a Medicare or Medicaid patient has been seen; that's crucial information if you're trying to assemble relevant pieces of a patient's medical history, but you can't query CMS to find that out. The same is true of every other payer and their patients. Payers would make natural record locator services because they already have that information.

Next let's consider standards. A lot of time is spent saying we need more standards to interoperate; yes and no. Today we have a handful of transport standards, including two flavors of Direct in the XDS and XCA profiles developed collaboratively within IHE and we have a document standard in the form of a C-CDA. None of these are what might be considered cutting edge technology; that's okay because we can improve on these standards and create new ones as an industry.

People mean different things by standards. Some standards like the metric system are relatively immutable, it's a done deal. Other times standard just means the way things are currently done. That's true of our transport and document standards and even the fact that document exchange is currently the way most health information exchange happens.

The future will be different. Rather than pushing huge amounts of data around every time someone touches a patient, we will move to a highly distributed environment in which data is available and pulled together as needed. We're already starting to see this change in the development of FHIR under HL7. Different networks and vendors will innovate differently and contribute to the development of new standards. Standards are living things that need to grow organically or disruptively. They should not be locked down in a political process.

But in order to move to this highly distributed and highly connected world, some other things need to happen. We need to know where data lives, to whom it belongs and whether it's okay to access it. Specifically we need a standard model for patients to express and publish their consent and we need reliable means to identify patients. We need a national patient identifier. We can limp along without it and constraints do often lead to innovation in limited ways, but we need to come to terms with this at some point.

Finally, a few words on value and sustainability; some of you know that several months ago we at EPIC put a 5-year moratorium on charging our customers for Care Everywhere. We did this in part to help jumpstart the interoperability economy and to quell some of the noise around our efforts. What you may not know is that we employ about 115 people to care for that network and support our customers in its use. Those are 115 jobs with good salaries and benefits. Good, usable, interoperability takes real ongoing effort.

Our customers also incur costs for their interoperability efforts. One example is in the storage capacity to house copies of all the data coming in and out of their systems. A typical customer of ours spends tens of thousands of dollars for storage with the largest spending hundreds of thousands. We built Care Everywhere to save lives and that's also why all of our customers participate in it, and we're passionate about improving interoperability. But even in a world founded completely on altruism and the desire for the best patient care; these costs must be taken into account and balanced against the value derived from specific forms of interoperability.

And so what I would recommend is that we need metrics to measure interoperability, its costs and the value derived from it. With metrics and appropriate transparent reporting, which we don't have today, we can determine how much progress is being made and whether it's the right kind of progress. And we can determine what forms of reimbursement and healthcare arrangements are leading to the outcomes we desire. That's the only way our ongoing efforts will be not only successful, but sustainable across the industry. And with that, I'll conclude my comments.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you all. Just like with the last panel, if the task force members could raise their hands with any questions that you may have. We don't have any questions in the queue yet...Josh Mandel.

Joshua C. Mandel, MD, SB – Research Scientist – Boston Children's Hospital

So one question for anyone who is interested in responding to it but it was sparked by something that Tim said is...has to do with incentives and how well incentives are aligned with the thing that they're actually trying to achieve. So one of the examples that Tim gave were programs where you said, for example, you must use a particular technology for this particular use case, in order to be eligible for incentive payments.

And it struck me that this is of course a powerful way to motivate actors in this space, but it also shares some of the same kinds of risk that we see in clinical studies where instead of measuring the outcome that's directly of interest you measure a surrogate endpoint. And in particular my concern with this kind of incentive program is you wind up promoting a kind of exchange where the data do flow from point A to point B the way they're supposed to, but they might not be as complete as you would want or as precise or you have little error.

And the question is who has an incentive to fix those little errors and make sure that the data really are as complete as they could be if the primary motivation is to be eligible for incentives? And this is obviously a deep problem, but I'm curious whether anyone has a perspective on how we can push towards the kind of exchange we want to see and not just the kind of exchange that allows people to check boxes to be eligible for programs.

Tim Pletcher, MHA, PhD – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

If I may take the first crack at that, I can give you an example; is that fair? So we...when I went and asked all the hospitals in our state to participate in the statewide ADT use case, meaning, anybody with an active care relationship with a patient could see it, not just the ones that the ho...not just the providers that the hospitals owned or liked, but anyone with a need for it. The answer I got back was no.

But when we reached out to sort of Blue Cross and said, hey, could you take 10 of the 100 points that you give hospitals for their big population health incentive infrastructure, you know, incentives, could you link 10 points of that to hospital participation in the statewide ADT use case, which Blue Cross did. Within 18 months I had 93% of all admissions in the entire state coming and hospital CIOs who said, it'll be a cold day, really begging for slots to get into the queue to make it by the deadline.

The next year we added sending discharge med rec type information out with their CCDs and also improving the quality of the ADT message, the consistency, the quality, the distribution of the master data, mapping tables so people could interpret that data. And we added it as a use case. Coming up we'll...we're looking at adding in what we call common key in Michigan which is a linking infrastructure and participation in active care relationships, which is basically patient-provider attribution. But I think we've got a laddering mechanism that gets the flow going and then continues to leverage what looks like basic conformance data quality assessment to make sure that the caliber of that data remains usable for the folks downstream.

But there is something that Dave said for Carequality is really important which is, we're really trying to drive with this kind of approach, the separation of, you know, we don't want people to just send it to who they like, we want it to be able to have people send information to whoever's really entitled to get it, or ultimately, folks be able to query it if they're entitled to have it. And we really think that given this huge overwhelming amount of work everyone has to do, the only way to get the prioritization around concrete things is to say, here's what we're going to pay you for or here's what you'll ultimately be punished for if you don't do.

And then what that does is it gets...we use the standards underneath the hood to sort of get people comfortable with sending CCDs or sending ADT messages or whatever the format is. That continues to break down the barrier and we try to kind of layer each new use case on top of the next, so you get kind of network effects as you really implement more and more use cases.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Hi Michelle, this is Paul, I can't get in...the website's not letting me in, could I get in the queue please?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Sure. Mike Zaroukian?

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Information Officer – Sparrow Health System

Yeah, so hi. Thanks. I'm going to leverage my own primary care in Michigan roots to sort of look at Tim from my HIM and then Julia from her experience as well, but I'm wondering if we could discuss something that at least at this provider's level in our community and perhaps through Michigan has been somewhat of a business and financial driver?

We have a model in Michigan, the Michigan Primary Care Transformation Demonstration Project, which is a care coordination initiative that has for many of us, I think, sort of jump-started the process of thinking about care coordination. And the natural consequences that flow from that such as want...having a greater interest in retrieving data and finding a way to pay for people to do that.

With the current care management codes, CPT codes that are new for 2015, and with that kind of a demonstration project having been successful and then thinking about how some of the levers for driving the demand that harmonizes the desire for interoperable information and the ability to support and be incented for the actual use of it. Does anyone see an opportunity there to maybe leverage the actual evidence? I think to Peter's point, the notion where there are metrics showing that actual interoperability was used to help drive some of these improvements in care coordination goals, etcetera?

Tim Pletcher, MHA, PhD – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

So I...I'm going to jump in. The use cases literally help you quantify and measure, because you can begin to say, okay, if we're sending out alerts to people that there are transitions of care happening, and now we're tracking when our providers beginning to receive those alerts. And now if you can actually uniquely identify patients and link information, specifically in groups like the Michigan Primary Care Transformation Project, you can say, our providers now billing the transition of care and the care coordination billing codes; did that increase and how does that compare to the folks who are not participating in these use cases?

And then ultimately since outcomes are a fascinating space all by themselves, you can take those process metrics of, are...what are people billing for and look at their relationship to your ultimate measures of outcome, which may be readmission rates or total utilization. But there's basically a strategy to get to metrics that help you kind of close the loop on are you doing the right things? At least that's what we're trying to do here.

Ann O'Malley MD, MPH - Senior Fellow – Mathematica Policy Research

This is Ann; I'll just pipe in to kind of build on that response. Through various primary care redesign demonstrations that we evaluate at Mathematica, including the Comprehensive Primary Care Initiative, what we've heard from providers, and this is public information from our first annual report, is that when they see data that what they're doing and the information they're exchanging is actually improving clinical outcomes for patients, then they buy into the process and then they believe in it. And it hopes to get other providers to join the wagon.

My...I guess my concern with this, I think it's a noble idea and there may be some intermediate process measures you can show clinicians to kind of convert them to the value of HIE, but things like hospital readmissions and even honestly acute hospitalizations, the index hospitalization, are relatively rare events and so it's...it will be very challenging just from a sheer number within a small system or within a practice or even within a large system to demonstrate those kinds of effects and to link them directly to, look, you participated in this information exchange and look what happened. I think it'll be extremely tricky. There...it would be nice to do that, and maybe on a national scale that can be done, but I just know just from the research literature that we need pretty big sample sizes, particularly for rare events and for things like cost in hospitalizations to really demonstrate the linkage there.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay, we'll go to Paul, but before we do I just want to note we've moved the ONC presentation to next week so that we have a little more time for discussion. So, to you Paul.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay, thank you. And this actually is similar to what Mike was just asking about. Peter DeVault ended his presentation with an ask for metrics for interoperability and by the way, I want to thank everyone for their presentations, it was very helpful I think and laid out some really ground facts about what people are doing and what's really going on. To give a very good example of what he's been doing in some of the add-ons to the oth...what he called Care One Agreement and the emphasis on care; they found it to be very helpful, when Peter talked about EPIC's experience.

My question is, like Tim said, we don't want to have metrics where you just check the box; it strikes me that a lot of the "interoperability metrics" are, in a sense they're check the box; I did send and I did receive. How can we get closer to measuring meaningful exchange? So I'm going to give two sort of wild examples, they're just top of my head kind of thing, but...and it may not be practical. But in some sense when you look at a review let's say on Amazon, one of the questions they ask, was this review helpful? And that actually helps the next person. You can imagine, well once I got some information from outside the organization, was that helpful to your decision making? It could be one subjective kind of question and potentially if people did answer, it would be very useful, it would measure was this meaningful?

Another example would be, you know, we in clinical decision support, if you're about to order something and a clinical decision support alert or reminder pops up, and you then don't finish that, you could infer that that alert did affect your decision making. Wouldn't it be nice if we across the board could measure the user's behavior...I was about to order, I was looking up something and I got this information from another system and that changed my workflow in a sense, you saw the order discontinued or not completed, you saw them when they were looking up some information that they actually clicked on that, that would be, you know, you'd infer, just like Google does, that that was of interest to you.

It would be interesting to see. That latter example was sort of a process measure that reflects that this may be different than your thinking and then the former did this help is a subjective, but also it tries to start the same thing; did this extra information help your thinking? Because we also know that overloading a provider trying to make a decision with lots of information isn't necessarily better and sometimes it's worse. So any thoughts you have in assessing that piece, you know, this measurement of effective...of meaningful exchange in the provider's clinical workflow.

Peter DeVault, MS – Vice President – EPIC Systems Corporation

Paul, this is Peter; that's exactly what I had in mind talking about the value of interoperability for providers and patients. I do think there's a really big space between sort of check the box, did you send, did you receive measures and outcomes measures....outcomes measures which are so far downstream and hard to isolate individual variables to determine what lead to those. And perhaps it's on us as EHR vendors to help build in some of those capabilities where, did the provider actually incorporate the outside medication into the medication list? Did they use a diagnosis as a visit diagnosis that was...that originated at another organization? You know, we could go on and come up with quite a list of those things and then we'll have to figure out which ones would be most useful to have and which ones would be the best proxies for determining value.

Tim Pletcher, MHA, PhD – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

At the expense of talking too much, you know one of the things that we think lies at the heart of being able to build an assessment and evaluation infrastructure is getting sort of accurate patient provider attributions. And in Michigan we've focused really hard in building out something we call the active care relationship infrastructure where folks, providers essentially declare their patient rosters on a regular basis.

And when you begin to aggregate those, you begin to see who all of the providers are who have an active care relationship, essentially making up the care team, and we're now really working to map what does an active care relationship with a facility like a hospital look like? What does an active care relationship with home health, with a skilled nursing facility? But this idea of really understanding the path that the patient is taking through the larger ecosystem, allows you to kind of more quickly narrow down, well what really did happen sort of medically as they traversed.

And potentially in real time, where you can even begin to say, okay quickly show me who has an active care relationship with this patient, and begin to use that as either an alerting infrastructure or using it as a short list, narrow path record locator service to say, okay, who do I go query with great precision to say what I need to get back. And I think those are foundational components along with, I forgot who said it, a way to uniquely identify the patient, which we call Common Key, to make sure you're accurately identifying providers and patients. You can then use that as a legitimate platform to do the next level of assessment. But I think maybe said in reverse, without that, I'm not sure how you can ever adequately measure outcome.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

...going to ask just a little drill down on that, that's a very interesting thought to have people actively declare on a regular basis. How often is the regular and what characteristic do you use to cause that info...cause them to spend that effort to do that, which seems like very valuable information?

Tim Pletcher, MHA, PhD – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

It's a formal use case in Michigan called the active care relationship, we abbreviate it ACRs, but that's because patient provider attribution service sounded terrible and scary, so active care relationship sounded better. But basically providers are incentivized to do that once a month and we're now, like I said, working on trying to advance that so it happens more and more regularly. For groups like home health or pharmacy, etcetera; there's a different time window but we're trying to figure that out. But we believe that is a crucial component to sort of connecting all the dots and traversing, from a care coordination perspective, where do...even if you have to do a human in the loop and pick up the phone, that will help circumvent a lot of process. And it works great for sort of broad decision support where you need to push data out to folks, everyone with an active care relationship, for example.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

And then with your care coordination perspective, what thoughts do you have on the measures of meaningful exchange?

Ann O'Malley MD, MPH - Senior Fellow – Mathematica Policy Research

Yeah, I mean in terms of your original question, Paul, and what can be measured. I mean I actually think in addition to measuring things that are automatically part of the system, asking patients some way and building that into the system would be very valuable because it's the patients that have the best perspective on how well their care is coordinated. And we've heard from multiple interviews with both providers and patients that when they get a referral by a primary care doc to a specialist and they come to that specialists' office and the specialist already knows their history and they've gotten the shared record and that information has been exchanged, they are tickled pink they don't have to regurgitate their entire history.

So I wonder if there's a way to build in, maybe through patient portals or some other mechanism, patient input as one of the outcomes because that's the ultimate person we're trying to serve and I think the extent to which HIE occurs in a way that benefits patients could really be measured in a meaningful way by asking the patients themselves. And similarly with the attribution issue, you know, Michigan's really gone out of its way to make sure that providers know the patients on their panels and reaffirm that monthly, incorporating the patients into that as well, I think would be helpful; you may already be doing that in Michigan.

But I think the patient voice in this in some way that's systematic and doesn't overburden them would be very valuable. They do complain of survey fatigue, we hear that all the time in various demos that we evaluate, so it would have to be done very thoughtfully, but perhaps there's a way to incorporate them.

Tim Pletcher, MHA, PhD – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

So yes, we're working with that, but we find that it's intertwined with consent and so...

Ann O'Malley MD, MPH - Senior Fellow – Mathematica Policy Research

Right.

Tim Pletcher, MHA, PhD – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

...that expansion of that active care relationship to consent...our consent infrastructure...

Ann O'Malley MD, MPH - Senior Fellow – Mathematica Policy Research

Um hmm.

Tim Pletcher, MHA, PhD – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

...and we're finding in order to do consent, we need Common Key...

Ann O'Malley MD, MPH - Senior Fellow – Mathematica Policy Research

Right.

Tim Pletcher, MHA, PhD – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

...to uniquely identify them before you grant a lot of access and so we're approaching that where we can show to a patient everyone who's got a declared active care relationship. They can expand or contest some of those relationships, but also kind of link it into the overall consent, which you need to do query, which you need...etcetera. But we're at Common Key is the fundamental, rate-limiting constraint for us to sort of really advance that.

Ann O'Malley MD, MPH - Senior Fellow – Mathematica Policy Research

Right.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Okay, our final question to Julia.

Julia Adler-Milstein, PhD – Assistant Professor of Information, School of Information; Assistant Professor of Health Management and Policy, School of Public Health – University of Michigan

Great. So maybe I'm just going to sort with one sort of comment on the measurement piece and then ask my new question. So I think I've, because of my sort of research interest, been very interested in thinking about these, you know measures that may really detect interoperability and I think, you know Peter, I would agree that I think our best shot at doing a good job of measuring them would have to come from the vendors.

And as we've had conversations with the vendors, it does often times come back to, well, there's not a strong incentive today to add a 116th person to really build out these measures and so I would love to hear you speak to again, sort of what are going to be the business drivers for a vendor to be willing to dedicate resources to build out these new types of metrics that I think we all agree are important? So that's one specific question.

The additional question that I'd like maybe Tim to begin by speaking to is, you had said that part of what you did with your use cases was really think about the business case and sort of where incentives were aligned or not aligned and therefore sort of the approach you needed to take you know, across your business cases? It would be very helpful to get a sense of like, you know for this many the incentives were already aligned and it just...that wasn't an issue. And for, you know was it the majority of use cases for which you probably see incentives were not well aligned and you really had to spend time, you know making sure that the stakeholders were sort of on board and willing to restructure payment or whatever it took to align incentives.

And then, was there sort of use cases that you felt like you just could not pursue, even though you felt that they were really valuable because it felt like the incentives were misaligned and it was just not clear that there was a path forward to align them? So I realize those are two different questions so maybe Peter if you could start with the measurement question and then Tim, maybe you can address this sort of what was the distribution of incentive alignment across the different use cases.

Peter DeVault, MS – Vice President – EPIC Systems Corporation

Yes, so I think the question was what would be the business drivers for us or for vendors in general to support the measurement of the kinds of things that I was talking about? When we're behaving well, vendors are pretty simple animals, we like it when our customers like what we do and if we can make interoperability better by measuring how well its being used and how much people like it, whether that's putting a like button next to that huge transition of care document or whatever else it might be collecting, it would be valuable to us if we knew that something was going to be done with that information especially.

Julia Adler-Milstein, PhD – Assistant Professor of Information, School of Information; Assistant Professor of Health Management and Policy, School of Public Health – University of Michigan

Great, so what I heard you say was essentially you would need provider demand for that, I mean, that's when you think...is that the way to distill down what you're saying? And I'm just, you know, again I know certification is obviously the other way to go about this and whether that also seems like a path to which we could get some traction.

Peter DeVault, MS – Vice President – EPIC Systems Corporation

You know provider demand certainly is the biggest incentive for a vendor to do something; they're the ones who are purchasing the product. In addition to that, we have a patient outcomes mission as well, that's why we're in this particular business and not something perhaps more lucrative. So we certainly would like to see our product used to the best extent possible and we know that the current paradigm of huge document exchange at every transition of care is not the ultimate goal; so we would happily participate in developing and measuring these things.

Tim Pletcher, MHA, PhD – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

Okay Julia, you threw a lot at me, so maybe we could take it in small chunks. Let's see, the first...I think the first thing you said, well, let me say something. The way we prioritize use cases, okay, were there's sort of a fundamental component, we believe that the three stakeholder classes are sort of the patient, the provider and the payer, depending on how you classify payers, the government kind of folds into that. And what we were really looking at is where the incentives were aligned.

So the reason we started with ADTs were because it was an easy, mature technical spec, okay, that we knew would happen. We knew that hospitals, as providers, while they don't really...in some cases it's better for them to pay the fines and get the revenue from the volume of readmissions, no one's really in the business for readmissions so...but there was some visibility into trying to reduce hospital readmissions. We knew that payers had a financially vested interest in reducing hospital readmission, but when we looked at the physician landscape, they're margins are so small that the addition of trying to do new work for care coordination is kind of not a wash for them. And so unless there was something that made people want to take their busy workload and adjust it, it wasn't going to work.

For ADTs, the transition of care payments, some of the population health, patient-centered medical home incentives were all kind of aligning so that that use case had all stakeholders aligned on it; it was technically feasible. The same thing was true for the meaningful use public health use cases; populating immunizations, reportable labs, you know syndromic surveillance; those use cases were supported from Meaningful Use, but they're also in the public health code as a requirement for people to do and so we picked those use cases because they lined up well across all stakeholders effectively.

Other use cases like query for a CCD are you know we've got a use case called cross-qualified organization query; we can't get people to sort of pursue that right now because we don't have an incentive that lines up well for somebody stopping their workflow, going out and querying for information. Likewise, there isn't a process for example, in the emergency department where let's say somebody goes to the emergency department, we generate an alert, it tells everyone with an active care relationship hey, your patient just hit the ED.

If all of those people or a subset of them wanted to send information to the emergency department saying hey, you're about to see my patient and I want you to know this, there's no intake process in the emergency department for that kind of automation to occur. So, we could articulate the use case, but there's no work process and then there's no larger framework for trading the incentives for people to build a work process to capture that.

And so we're trying to focus use cases on where people are getting alignment across the multiple stakeholder groups and that there's financial support for it and then things are technically feasible. And that seems to be the sort of home run of things that we can actually get people to adopt...to then get them to do it in scale, we have to make sure that there's, we think, very specific incentives that we can concretely tie back to them actually doing that kind of data sharing. And it could be a penalty for hospitals like hand-off to skilled nursing facilities. It could be extra reimbursement for care coordination. It could be very specific population health incentive or a SIM grant, you know, repayment alignment but we have to find all three or four of those components in order to get it to advance.

Julia Adler-Milstein, PhD – Assistant Professor of Information, School of Information; Assistant Professor of Health Management and Policy, School of Public Health – University of Michigan

Great. Thanks, that's really helpful and I think it's helpful in sort of in shaping the way that I think about this where there may be certain domains in which the incentives are aligned for interoperable information exchange and other areas in which they're not. And so we need to sort of think about that dimension rather than just sort of saying, what are the financial barriers to interoperability; it's really interoperability of what type.

Tim Pletcher, MHA, PhD – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

And it has to be purposeful, I mean, I think that's the most im...what specific concrete purpose we're trying to achieve and it's almost like a level of discipline. Historically we've said, data sharing good, interoperability good and I think the ocean is so big, we just need to apply more discipline to say this specific kind of data sharing should happen, you know right now and here's what we're going to need to do it. And I think with things like the CCD, which is capable of containing an awful lot, we've probably reached really big and we probably need to sort of dial-back our focus to well, this is exactly what I want and I don't just want it, I want it to be of high quality. And I think that quality component versus just access to the information component is a new emphasis that's surfacing.

Peter DeVault, MS – Vice President – EPIC Systems Corporation

Completely agree.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Well Paul, since you're back; we have one more question from Larry. So my question for you is, we need to make sure that we have time for Deven; do we go to Larry's question or move on?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Umm, why don't we go to Larry's question and we'll extend the ti...is it okay for us to extend the time?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Sure.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

That wasn't a good...okay, why don't we go to Deven then, let's...sorry Larry...

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

No, we'll go to Larry, but Larry, you have to be fast.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Okay. I already am off mute; I'll be fast. So this has been brought up a little bit already, so maybe it's a good closure point. So med reconciliation seems like a high value activity that could...that needs information from other care settings, other providers, from the patient. It's got some hurdles. It's been pushed by Joint Commission in various ways in the past, it's gotten a lot of attention in other settings. Quick assessment from our panel about is it a good use case or a bad use case for us to be focused on for the near future?

Peter DeVault, MS – Vice President – EPIC Systems Corporation

Good.

Ann O'Malley MD, MPH - Senior Fellow – Mathematica Policy Research

Good.

Tim Pletcher, MHA, PhD – Executive Director – Michigan Health Information Network Shared Services (MiHIN)

Good, it's...but it could be broken down into chunks, because it's actually pretty complicated. But it is absolutely good and prescription monitoring kind of plays into that as well, so it's doubly good from multiple stakeholders entering.

Larry Wolf – Health IT Strategist – Kindred Healthcare

Thanks.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

That was a great answer, a great question and thank you for the answer. And really want to thank this panel, really excellent information, great recommendations for us to think about and so really appreciate your time on such short notice.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

And Paul, just to confirm, we checked, we can go over. We'll just lose part of our admin call, but that's fine.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

So now to an old friend, Deven.

Deven McGraw, JD, MPH, LLM – Deputy Director for Health Information Privacy – Office of Civil Rights

Hi.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi.

Deven McGraw, JD, MPH, LLM – Deputy Director for Health Information Privacy – Office of Civil Rights

Can you hear me okay?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

A friend that we've had the pleasure of knowing a long time, not an old friend.

Deven McGraw, JD, MPH, LLM – Deputy Director for Health Information Privacy – Office for Civil Rights

Ri...oh, thank you Paul. That's okay; I took it exactly the way that you intended, so, even though I do get older every year, huh; funny how that happens. So I, you know the questions that I saw in the agenda, given that I'm coming from a regulatory agency so I'm not really an organization that has...that is dealing with sort of issues of interoperability from an impl...from an operational standpoint; I thought what I would do is just hit some basic high points about HIPAA and interoperability and HIPAA and state law on interoperability and try to leave as much time as possible for questions that you have in case I didn't cover something that you were contemplating.

Some of this is going to be a repeat for a lot of you who know HIPAA pretty well, but just to bring us all up to speed. HIPAA has some provisions in statute, but mostly consists of regulation, rules on privacy, rules on security for electronic identifiable health information and breach notification rules as well. There are also regulations related enforcement of the entire HIPAA framework.

HIPAA governs not all health data, but just entities that are covered by it per the statute, otherwise known as covered entities, and those are most healthcare providers as long as they're billing electronically using the HIPAA standard transactions, which is most providers but certainly not all. Health plans and entities called healthcare clearinghouses, which take non-standard data and turn it into standard HIPAA transaction code sets and reengineer that process where necessary. HIPAA also...the HIPAA rules also extend to business associates of these covered entities, so a BA is essentially a contractor who receives identifiable health information from a covered entity in order to perform a function or a service on that entity's behalf. And in 2009, the HITECH legislation extended HIPAA accountability to those entities.

HIPAA allows for covered entities to use and disclose identifiable health information, which is known as protected health information or PHI, for treatment, for payment and for a range of activities that are characterized as healthcare operations which includes care coordination, which is also part of treatment, as well as quality improvement activities and entities under...who are covered by HIPAA can do all of this without necessarily needing to get the consent or authorization of the patient before doing that.

However, entities are free as a matter of their own policies to establish consent requirements, even for the sharing of data for what's known as TPO, again treatment, payment and operations. And if they do decide to do that, they have a lot of flexibility about how they would implement such a consent policy. And so, for example, we've seen a lot of health information exchanges across the country implement policies that either require opt in consent for the inclusion of patient data, even though they may be performing only TPO or even just T functionalities. Or they've done opt out for that and that is a matter of policy or maybe enacted as a measure for state law compliance; but it certainly isn't something required by HIPAA and so per HIPAA, if you decide to as a matter of policy do consent, again you have a lot of flexibility there.

HIPAA treats all identifiable data the same in terms of its rules with the exception of psychotherapy notes, which are not all physician notes, but only those that are collected by a psychotherapist in the context of a psychotherapy session. Those do require specific authorization from the patient in order to disclose them, but otherwise HIPAA's rules are the same, regardless of the characterization of the underlying data when you're talking about identifiable data.

Patients do have the ability to ask a healthcare provider or plan or any covered entity to restrict uses and disclosures of their data, but generally covered entities have full discretion about whether they grant such a request for a restriction except in one circumstance. And that is with respect to sharing...the healthcare provider sharing data with health plans in a payment context. Per legislation enacted by Congress as part of HITECH in 2009, patients can request that their data not be sent to a health plan in a circumstance where they have paid for the care in full and the provider does not have the ability to say no to that. That is required to be accomplished and we addressed this issue in our most recent regulations and provided some guidance to healthcare providers on how to implement that.

The Privacy Rule also covers issues like disclosing for public health and permits such disclosures without the need for patient consent in circumstances where the data's going to a public health authority and it's for a purpose within the scope of that authority. HIPAA also allows for information to be shared with friends and family members without the need for the patient to affirmatively consent on the front end, unless you have a patient who objects to that, and then the patient's wishes control or the healthcare professional determines that it would not be in the best interest of the patient to make those disclosures. And that's a judgment call that gets made within the purview of their professional judgment.

Those are all permissive disclosures under HIPAA. There are really only two circumstances under which a covered entity must share and that is when the patient or a patient's legal personal representative requests access to or a copy of their health information. That cannot be declined by a covered entity except in very rare circumstances or when the government comes and knocks on the door and is doing an investigation and asks for information. Otherwise what HIPAA sets out is a construct under which information can be shared, but does not require such sharing; again, except in those instances. And as I think most of you are aware, but in case you're not, in the HITECH legislation, Congress enhanced the patient right of access by making clear that patients could get an electronic copy of information that is maintained electronically and that patients can direct that that copy be sent to a third party of their choice, as long as they make that choice clear to the healthcare provider.

And so a lot of people have specu...have asked about whether the patient could essentially be a health information exchange of one, you may remember that term that came up in one of our patient engagement hearings many years ago on the Health IT Policy Committee. And what HIPAA allows is for a patient, yes, to have information transmitted to their care providers, for example.

But that right is within the confines of the patient right of access, which does give the provider up to 30 days under ordinary circumstances to provide the patient with the copy or the access to that information. So while the patient has the absolute right to get a copy of their data, they have an absolute right to send it to whomever...to have it sent directly to whomever that they choose it is within the confines of the patient's right of access under HIPAA. HIPAA also has, as I mentioned earlier, detailed provisions with respect to the security of electronic protected health information and also includes provisions for breach reporting.

So now I'll say a little bit about other laws that may protect the privacy of health information and their interaction with HIPAA. So per the HIPAA statute, HIPAA does not preempt state laws unless they conflict with HIPAA or they are weaker than the HIPAA provisions. So stronger state laws such as those, for example, that would require consent of the patient in order to share any particular type of health information or even health information generally are not preempted by HIPAA and are allowed to stand, and that was a decision made by Congress back in the HIPAA statute, which was enacted in 1996.

There are also federal laws that HIPAA does not specifically preempt that may govern certain types of health data as we have covered in the Health IT Policy Committee previously, or you have covered...it's hard for me not to say we in that context because it hasn't really been that long. The Part 2 rules that are overseen by the Substance Abuse and Mental Health Services Administration that govern data collected in federally supported substance abuse treatment programs and that have the potential to identify or that do identify a person as someone who has received substance abuse treatment services; those Part 2 rules require authorization for disclosure of that data and it has a...the data comes with redisclosure prohibitions that attach to it. So anyone who receives the information from a Part 2 program is subject to those authorization rules with respect to subsequent redisclosure.

Similarly the Common Rule, which covers federally supported human subjects research, has rules that govern when identifiable information is utilized for research purposes, and this is a circumstance where many entities who are HIPAA covered may in fact also be covered by the Common Rule with respect to research uses of their data. Although research is distinct from internal quality improvement efforts; those are not considered to be research under either HIPAA or the Common Rule. And then, of course, FERPA, which...what that acronym means is actually escaping me at the moment, but it covers educational facilities, so student health clinics, for example, are governed by FERPA, which often has more stringent provisions with respect to data that has health implications.

So I'll say a few things about state law even though I want to make it very, very clear that we do not have oversight over state law here at the Office for Civil Rights. And so what I'm about to say is really based on my own experience as a lawyer who's worked in this space for many years prior to becoming the Deputy Director for Health Information Privacy here at OCR. Those state laws that do require consent or authorization often do have exceptions for sharing for treatment purposes, but of course this is not always the case. But even in circumstances where they do allow for sharing for treatment purposes, this is often not well understood by entities that are covered by these laws.

It is also the case, sometimes, that those laws in the way that HIPAA does, are only applicable to certain types of entities who collect and share health information, but that is also not always the case. I have seen laws, for example, there are some laws that govern genetic information in the State of New York that are written like data protection laws where the protections attach to the data regardless of what type of entity has possession of it.

I think there are lots of questions that arise for entities...healthcare entities about what state laws will govern them and what the state laws mean, because there often is not as much guidance as people would desire. And this is often also true of HIPAA, I will admit. But also at the state level, in terms of how the regulators are interpreting those laws, certainly a provider who operates within a particular state is going to be governed by those state laws, but I have definitely received questions, again not in my capacity here at OCR, because we don't have oversight over that, but in my travels and in my work have received questions from people who wonder whether they are covered by a state law by virtue of treating a patient who is resident in another state and whether that's the case or not in part depends on the state's jurisdiction, how its laws are laid out and a number of other questions that may be somewhat dependent on court interpretations in that particular state.

So that's like hitting things that are really high level. I'm very interested to hear what some of your questions are so I can try to give you more information that's more specific to your charge. And I thank you for the opportunity to present to you today.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Thank you Deven; thanks for reviewing the relevant privacy laws. I wonder if you could speak...on the areas of privacy concern, this will draw from your experience and work on the Policy Committee, about what privacy concerns arise related to health information exchange? Or what areas do you think are maybe not as well covered with extant law and maybe things are either federal law, regulation may play...may be needed or local governance may be needed to help data move freely and safely?

Deven McGraw, JD, MPH, LLM – Deputy Director for Health Information Privacy – Office for Civil Rights

Right, so I'm going to take off my OCR hat and put on my former Health IT Policy Committee hat where I served as the Chair of the Privacy & Security working group, including when it was the Tiger Team for many years. We did actually put forward some recommendations to...that were endorsed by the Policy Committee about the need to sort of clarify how HIPAA applies to certain scenar...you know, certain very common data sharing scenarios, like queries for...even for treatment purposes.

And as much as there is guidance out there and the law appears to be very, very clear, certainly to me as an attorney and of course now that I work for OCR and see the gamut of what we've put out in guidance, I think it's very clear that at least for treatment and care coordination, as well as for payment, that data can be shared and should be shared. It is always helpful for entities to have some very specific examples, that's...of circumstances under the Meaningful Use rules about what is acceptable and what is not acceptable and so consequently, okay OCR hat back on, we've been in discussions with the Office of the National Coordinator about how to put out some of those scenarios to make that more clear.

We also on the Health IT Policy Committee have certainly received lots of questions around Part 2 data and the Substance Abuse and Mental Health Services Administration did have a public hearing not too long ago where people raised questions and concerns about the application of Part 2 in a health IT enabled environment. And so they are...that agency has purview over those rules and has an opportunity to consider those, but I would leave questions about Part 2 to them, because that is really under their purview.

But we definitely did hear and think about those issues on the Policy Committee; we made a couple of recommendations to SAMHSA in that regard and we also took up this issue in considering whether certified EHR technology out to have data segmentation capabilities, for example. And so that's how it's come to us.

On the state law issue, you know of course on the Health IT Policy Committee we heard a lot of discussion about this. This is not something that agencies can resolve, not mine, not SAMHSA and it is only an issue that Congress, if it sought to create a single set of rules for the country on health information exchange, it would certainly be within their purview to resolve it. Whether they are eager to do so and to weigh in on what has traditionally been an issue where states have had the authority to weigh in, is not a question that I can answer. But we certainly have talked about that on the Policy Committee; it is not something that's within our purview here at OCR.

And then I guess the last category would be the data that's not covered by HIPAA at all, you know, mobile devices used by patients, personal health records used by patients, social networking sites; that whole sort of consumer-facing spectrum not covered by HIPAA. The Federal Trade Commission is the entity that polices how they handle data through their Unfair and Deceptive Trade Practices Authority. We have talked about that at the Policy Committee level; it's not within my purview here at OCR. Whether HIPAA can or should be extended to those entities is not within the purview of either FTC or my...or HHS, but is another category of work that should Congress see fit to address, it is within their authority to address.

And states also could address that issue and in fact, I...again, I know from my prior experience not necessarily from the job that I currently have, that the State of California a couple of years ago extended its Confidentiality of Medical Information Act to certain types of mobile Apps and PHRs, specifically those that collect clinical and claims data.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Thanks, Deven. I don't have the hand, so Michelle, are there any hands up? Does anybody else have any questions, comments?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Mike Zaroukian just put his hand up.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Information Officer – Sparrow Health System

Yeah, I hesitate to do this, but Deven thank you for your comments. And listening to this and over the source of a number of different committee hearings and workgroups and the like, the repeating message that I've heard that comes back, both of which seem to be related to Congress, the one you just articulated. And since our report on the interoperability barriers is a report to Congress and as a provider, the one thing I think about in terms of simplification is indeed asking Congress to set one set of rules, so there's a single source of truth and no additional business or financial issues to parsing that out state by state would be one thing I think we need to think about and I'd be interested in your comment on that.

The other part is, in a number of hearings there's been a big push on the issue of a national patient identifier and I know that within the government there's not much one can do about that, unless Congress changes its own perspective in that regard. But it feels like that is one of the strong messages we're hearing from vendors and other stakeholder groups. Could you comment briefly on your take on what some of the privacy implications would be of a national patient identifier or can you point us to references in that regard?

Deven McGraw, JD, MPH, LLM – Deputy Director for Health Information Privacy – Office for Civil Rights

Umm, so I'm going to stay in my swim lane on this one because these are matters that I don't control in my current capacity, especially with respect to the...for Congress to enact legislation to cover other data that's not currently covered by HIPAA, for example. Similarly, with respect to the national patient identifier, the HIPAA statute had language tasking HHS with establishing a unique patient identifier, but every year, Congress enacts legislation through appropriations to prohibit us from spending any money to implement that. And I presume they have their reasons for doing so, I'm not going to speculate what they are; it's just that's the...those are the constraints in which I operate and I'm going to leave it at that.

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Information Officer – Sparrow Health System

Understood, thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Okay, well thanks again very much, Deven. And really appreciate your counsel and we'll turn to you often.

Deven McGraw, JD, MPH, LLM – Deputy Director for Health Information Privacy – Office for Civil Rights

Well thank you and very much appreciate the opportunity and if additional questions come up as you are deliberating and coming up with your recommendations, we're happy to try to be helpful where we can.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Shall we open up to public comment please?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Caitlin or Lonnie?

Public Comment

Lonnie Moore – Virtual Meetings Specialist – Altarum Institute

If you are listening via your computer speakers, you may dial 1-877-705-6006 and press *1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press *1 at this time. Thank you.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

So while we wait for public comment I just want to again thank all of our presenters today; we greatly appreciate you taking the time to share your insights with us, especially with such short notice. And it looks like we have no public comment.

So, for our workgroup members, there are only a few minutes left but I would love to get on a quick Admin call to talk about next week's hearing, if that's possible. So we're going to switch lines and go to administrative line and we're also going to open up an administrative web conference. So, thank you all and I will talk to task force members in a couple of minutes.

And it looks like we have a public comment. So don't go yet, Leigh Burchell; just a reminder, public comment is limited to 3 minutes...I'm sorry.

Leigh C. Burchell – Vice President of Health Policy & Government Affairs – Allscripts

Yeah, sorry about that, I pressed it and it didn't work before, so I had to press again when you trying to escape.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Sorry Leigh...okay.

Leigh C. Burchell – Vice President of Health Policy & Government Affairs – Allscripts

So this is Leigh Burchell from Allscripts and I am also Chairperson of the Electronic Health Record Association. I think certainly we know many of you, but as a reminder, we have almost 40 member companies who develop EHRs among other technologies. And we're paying really close attention to the work of this task force, it's a complex issue and it's really fascinating to listen to the conversation. We've done a tremendous amount of work in this area and it's arguably our highest priority as a collaborative group of subject matter experts.

And the reason that I just wanted to chime in, take a couple of seconds is to let you know that we would welcome an opportunity to speak to the task force as an association at one of your future workgroup meetings. We've got some thoughts and suggestions and are happy to answer questions on the topic. We were certainly pleased to see that you invited EPIC today, who is an active member of our Association, but we do believe that there could be even greater value in hearing the consensus positions of a large group of EHR developers who are working on this topic. So just wanted to put that out there and we would love a chance to speak with the task group.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you, Leigh. And thanks again everyone. And for the few minutes we have left, we'll go on an admin call and talk to you all soon. Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation

Thank you.

Meeting Attendance				
Name	08/14/15	08/07/15	07/29/15	07/23/15
Bob Robke	X	X		X
Christine Bechtel	X	X	X	X
Josh Mandel	X		X	X
Julia Adler-Milstein	X	X	X	X
Larry Wolf	X	X	X	X
Michael H Zaroukian	X	X	X	X
Micky Tripathi		X	X	X
Paul Tang	X	X	X	X
Stanley Crosley				X
Total Attendees	7	7	8	10