

Governance Design Group Session #3 Meeting Summary

Meeting Date	Meeting Time	Location – Zoom Web Conference
Thursday, June 14, 2018	10:00am – 11:30am EDT	Webinar link: https://zoom.us/j/815997759 Telephone: (408) 638-0968 or (669) 900-6833 Meeting ID: 815 997 759

Design Group Members			
Lisa Stump, MS, RPh, Yale New Haven Health		Bruce Adams, JD, Office of the Lieutenant Governor	X
Patricia Checko, DrPH, Consumer Advocate and Public Policy Professional	X	Commissioner Roderick Bremby, Department of Social Services Representative (supported by Polly Bentley and Joe Stanford, as needed)	X
Jake Star, VNA Community Healthcare & Hospice	X	Bill Roberts, JD, Office of the Attorney General (on assignment from Shipman & Goodwin)	X
Design Group Support			
Michael Matthews, CedarBridge Group	X	M.J. Lamelin, HIT PMO	X
Chris Robinson, CedarBridge Group	X	Sarju Shah, HIT PMO	X
Jennifer Richmond, HIT PMO	X	Kelsey Lawlor, HIT PMO	X
Grace Capreol, HIT PMO	X	Dino, Puia, HIT PMO	X

Minutes		
	Agenda Topic	Notes
1.	Welcoming Remarks – Meeting Overview and Objectives	Jennifer Richmond thanked everyone for their participation in today's meeting. Everyone was very engaged last week.
2.	Recap of Prior Meeting (June 6) and Approval of Meeting Summary	<p>Jennifer provided a high-level recap of what was discussed last week. Michael gave an overview of the Trusted Exchange Framework and Common Agreement (TEFCA) and the national interoperability initiatives, such as Carequality, CommonWell, and the eHealth Exchange. We also gave an example of the chain of trust in use by the Michigan Health Information Network Shared Services (MiHIN). We reviewed the major components of a Trust Agreement – we will be spending more time on this today. Michael has some exercises prepared around the Trust Agreements, and other topics. We also had some building block exercises and started to dig into the critical success factors.</p> <p>Jennifer emphasized that the first two sessions of the Design Group focused on the foundational building blocks of the next phase of work, which is to emphasize the construction process. Everyone participated in this with the critical success factor exercise. Today we will get into this more with exercises focused on the characteristics of a neutral and trusted entity and the critical elements of a Trust Agreement. These sessions going forward will have a lot more time allotted to discussion and questions from members. This participation will really help us to develop our recommendations by the end of the Design Group.</p> <p>Design Group members also received some documents from the Chesapeake Regional Health Information System for our Patients (CRISP),</p>

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		<p>ConnectVirginia, and the Trust Framework Analysis. Jennifer asked members if there were any questions around these documents.</p> <ul style="list-style-type: none"> • Pat Checko – kudos to you and thank you for putting together this wonderful document. <ul style="list-style-type: none"> ○ Jennifer Richmond – Grace put a lot of work into this document as well. It is helpful for you all to see the different components, as well as national and state examples. Thank you for your comment. • Jake Star – are we expecting to get into these agreements in any detail in our sessions? <ul style="list-style-type: none"> ○ Jennifer Richmond – this was really to get you familiar with what the documents look like and what exists in other states. Michael do you have any other comments? ○ Michael Matthews – yes, we will be addressing these documents and the components of each document. This will be more for the specific scope of the agreements and policies and procedures, as opposed to specific content. We will be discussing the various elements deeper in the conversation. ○ Jennifer Richmond – we also have some additional examples of Trust Agreements that will be provided. This will include MiHIN and New Jersey. <p>Michael asked if the Design Group members had any suggested changes to the Design Group Meeting Summary (Session 2) that was distributed.</p> <ul style="list-style-type: none"> • Bruce Adams – I want to abstain from this vote, as I was not able to attend the last meeting. • Pat Checko initiated the motion to approve the Meeting Summary and Jake Star seconded the motion. The approval was unanimous. <p>Michael covered the proposed meetings and topics (slide 3). We have gotten through two meetings so far. Today’s meeting will be focused on some additional exercises. Meeting 4 will also include some building block exercises and we will bring the process to conclusion in Meeting 5.</p>
3.	<p>Building Block Exercises and Discussion</p> <ul style="list-style-type: none"> • <i>Critical Success Factors (confirm previous discussion)</i> • <i>Characteristics of a Neutral and Trusted Entity (exercise and discussion)</i> • <i>Elements of a Trust Agreement (exercise and discussion)</i> 	<p>Currently, in the Building Block Exercises (slide 4) we have covered the critical success factors during Meeting 2. Today we will go through three more exercises: the characteristics of a neutral and trusted entity, the elements of a Trust Agreement, and the policies and procedures table of contents. There will be five additional exercises that will be covered during Meeting 4 and Meeting 5.</p> <p>As a reminder, we previously covered the “Network of Networks” model (slide 5). As we get deeper into the various agreements, documents, and other artifacts, it is important to keep this conceptual model in mind.</p>

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<ul style="list-style-type: none">• <i>Policies and Procedures</i> <i>Table of Contents (exercise and discussion)</i>• <i>National Perspectives</i>• <i>State Perspectives</i>	<p>Last week we covered the critical success factors. We want to revisit the outcome and confirm this with members (slide 7). Michael reviewed the critical success factors that were developed and validated by members and asked if there were any other additions from members. Michael asked if we were missing anything after another week of reflection. There were no additional comments / additions from Design Group members.</p> <p>Characteristics of a Neutral and Trusted Entity: The next exercise will cover the characteristics of a neutral and trusted entity. We have pulled out the relevant references to a neutral and trusted entity from the Environmental Scan (slide 8) and Public Act 17-2 (slides 9 and 10). From the Environmental Scan, the following items were highlighted: accountability, an engaged board of directors, foundational trust agreements that establish clear rules of the road, sound policies and procedures, business decisions driven by value creation, judicious use of public and private resources, and the effective engagement with the State of Connecticut. Public Act 17-2 contained several aspects that are relevant to this conversation, including: the responsibilities of the Health Information Technology Officer (HITO), the entity’s governance falling to a party “other than the state,” the entity’s board composition, and typical activities / compositional components of the entity.</p> <p>On the next slide (slide 11), Michael pulled together some relevant points from Public Act 17-2 and the Environmental Scan. Michael reviewed the starting set of characteristics and asked members if there are any comments or questions about the existing list. To start, Michael asked members how they feel about the bullet point that says the entity “may be organized as a nonprofit entity” and whether the “may” needs to be changed to “should.”</p> <ul style="list-style-type: none">• Jake Star – I think that “sound policies and procedures” may include a lot of different items. Some of my suggestions may fall under this bullet point.<ul style="list-style-type: none">○ Michael Matthews – this is a fair point, we will talk about some of the policies and procedures at a later point in this meeting.• Pat Checko – are there currently any HIEs that are for-profit?<ul style="list-style-type: none">○ Michael Matthews – there are, such as the regional HIE that I ran in Virginia was a for-profit entity. The general rule is that most of these HIEs serve the public good and are organized as a not-for-profit. The IRS has shifted its view on the review of HIEs over the years. Previously, they were confused by the concept of an HIE and whether they should have tax-exempt status. It has gotten easier for state-supported or state-sponsored HIEs. The Sequoia Project achieved tax exempt status under the argument that it is relieving a burden of government.
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		<ul style="list-style-type: none">○ Pat Checko – in legislation they are more often permissive, rather than authoritative. The will of the Advisory Council is that this entity should be a not-for-profit, so I would certainly be in support of adding the word “should.”● Bruce Adams – the reason we made this a permissive word is so that we would not have to go back to the legislature down the road if we determine the HIE could have a function that received profit. We didn’t want to have to go back.<ul style="list-style-type: none">○ Michael Matthews – this makes a lot of sense to me. It is good to have flexibility.● Jennifer Richmond – the studies that we have done show that about 70% of HIEs are not-for-profits and the rest reside in a state agency.● Bill Roberts – I want to make comment about the potential benefit of a for-profit status. When we think about the future work of an HIE entity, the primary benefit of keeping “may” in the language is that it would provide greater flexibility in years to come regarding side businesses, such as providing consulting services to other HIEs and members of the HIEs or selling some other ancillary services. Absent those ancillary services, I do not see any benefit of the for-profit status. With a not-for-profit status you do have IRS challenges, and there is more paperwork, although the community benefit would be quite easy to fulfill. There may also be benefits in respect to obtaining state, federal, and private grants.<ul style="list-style-type: none">○ Bruce Adams – that is right. Consulting was the primary benefit we were thinking of down the road. Because this whole thing is enshrined in statute and the government has taken on the burden, I believe this entity would be able to claim tax-exempt status under the theory of relieving burden. There are a couple of avenues to achieve a c(3) status.● Michael Matthews – given these comments, what do people think?<ul style="list-style-type: none">○ Bill Roberts – in light of the future potential of consulting services, I think this is the key factor in my mind. If the group does believe there is potential of having consulting services, I recommend keeping the “may,” but if this is not a five-year goal, then “should” is likely more in line with the goals of the organization.○ Michael Matthews – could a not-for-profit entity have a for-profit arm?<ul style="list-style-type: none">▪ Bruce Adams – yes, this is possible.
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- Bill Adams – I worry that if we say the HIE should be tax-exempt, this may prevent us from being not-for-profit and for-profit at the same time.
 - Bruce Adams – this makes sense to me.
- Michael – let me see where people are. There are some considerations in favor of “may” and some in favor of “should” but at this point, barring these future deliberations, that “may” will give us more flexibility as we go into deeper conversations in the future. Is it the will of the group to have the “may” continue?
 - Jake Star – I am in favor of “may.”
 - Pat Checko – as we write up this report, we may want to add a footnote or explanation for how we made this decision.
 - Michael Matthews – this is a good idea.

Michael asked the group if anyone disagrees with any of the characteristics listed on the slide. There were no further comments from members.

Michael then asked the group what additions members had for characteristics of a neutral and trusted entity.

- Bruce Adams – I think stakeholders should have vocal support of the HIE entity. This needs a team mentality. “Consensus-driven approach” is a good way to say this.
 - Michael Matthews – I think this is an important consideration.
- Jake Star – I was trying to figure out if contracting and purchasing practices would fit under policies and procedures.
 - Michael Matthews – it probably will, but it can also be listed here. I think there will be some overlap. Let’s add “contracting and purchasing practices.” Could you state how that should be worded?
 - Jake Star – how the HIE goes about contracting and purchasing should be transparent.
- Jake Star – I think the HIE should be certified or audited from an information security perspective. This would include some sort of external review.
 - Michael Matthews – this is on the minds of every healthcare governing body right now. Cyber security is a very important issue.
- Jake Star – my last addition goes off of value-creation. I use the word “balance” because value for one sector could create cost for a different sector. This can’t be built on value-creation for one specific sector only.

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- Michael Matthews – very good. Let’s add “balanced value creation across stakeholder groups.”
- Pat Checko – this probably flies in the face of Jake’s addition, but we keep talking about the consumer as the North Star, and I don’t know if it would be a good idea to say that the development and utilization of an HIE would set the outcomes for consumers at the higher level as a driving principle. Do we need to have a principle of better health outcomes?
 - Michael Matthews – yes, let’s capture that item as “clear and tangible benefits for consumers and patients.”
 - Jake Star commented this is not in conflict with his early suggestion.
- Pat Checko – in terms of Jake’s suggestion relating to audit and certification, as TEFCA matures and we opt to become part of this, would this be one of the things that are required?
 - Michael Matthews – quite possibly, but I don’t want to be reliant on what may or may not be included in TEFCA. In some respects, one way to look at TEFCA is as the floor, not the ceiling. Think of this in terms of HIPAA compliance. States can have more stringent requirements for privacy and security. TEFCA may adopt the same approach.
 - Pat Check – I am not sure if “certification” is the right word here.
 - Michael Matthews – that is an interesting point. People have talked about certification of HIEs in the past, and some have attempted this, but there is not currently a default standard or specified standard to be in business. TEFCA may come closer to this. The question with TEFCA will be: why would someone participate in this type of framework? Are there incentives or penalties? There has been speculation that the proposed rulemaking for information blocking will contain a waiver if there is participation under the TEFCA framework.

Michael asked if anyone disagreed with any of the suggestions made by the group. No additional comments were provided by members.

Elements of a Trust Agreement:

Michael provided a recap of some slides that were covered during Meetings 1 and 2. The purpose of Trust Framework was discussed (slide 14). The major components of a Trust Framework were also reviewed (slide 15). Michael also provided a recap of the Trust Framework Analysis that was conducted

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by Jennifer Richmond and Grace Capreol (slide 16), and the key differences between Trust Agreements (slide 17).

Michael introduced the exercise for determining elements of a Trust Agreement (slide 18). Michael added the elements of a Trust Agreement from slide 15. In the future, we may have some of the folks from Velatura add to this discussion during Meeting 5. MiHIN's agreements are structured in an interesting way – there is a master agreement, with use case agreements executed separately underneath the master agreement. Michael asked if there are any questions about the elements listed on the slide. There were no comments from the members. Michael asked if there is any disagreement with the inclusion of any items.

- Jake Star – where would change management come into play for this agreement? For example, permitted purposes might change over time. How would a new permitted purpose be added to the Trust Agreement?
 - Michael Matthews – thank you, we need to capture the amendment process on this list. Bill and Bruce might weigh in on this, but I think the amendment process would be included in the Trust Agreement, and then there would be a policy and procedure around the change management process.
 - Bill Roberts – I agree.
 - Bruce Adams – I also agree.
- Pat Checko – at the same time we are building the HIE, we are simultaneously creating the eCQM database as a separate process. Do we need to look at whether or not there is or should be a specific relationship between these two projects? Is this a use case issue?
 - Michael Matthews – to me, this is more than a use case issue an important point. In our next meeting we will discuss corporate governance versus data governance. We will show the overall roadmap of activities, including where eCQM and data analytics fit and the data governance over these activities. This would be governed in the “purpose and scope” item on the list, but we will come back to this at our next meeting to discuss overall corporate governance versus data governance.
- Pat Checko – I do not see anything about data retention on this list, but that may be a policy and procedure. In one example it stipulated seven years.
 - Michael Matthews – yes, this is typically addressed in the policies and procedures. In the future, there will be a more intense discussion around data retention.

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- Jennifer Richmond – another area where you might see retention and data reuse is within the permitted uses.
- Bruce Adams – I am sure there will be a lot of boiler plate language that goes into this. One thing that comes to mind is a savings clause. We don't want the whole thing to fall apart over one change. The idea should be that if a piece of the agreement is invalidated somehow, then the rest of the agreement still stands.
 - Michael – is this the only boiler plate language that comes to mind? I was wondering if you and Bill could provide a list of 4 or 5 items that could be included.
 - Bill Roberts – I think we could include a miscellaneous section, which would include the savings clause, as well as notice, counterparts, governing law, and a number of other items. I think this is a great point to add.
 - Bruce Adams – in Connecticut, in most of these contracts we assert our sovereign immunity. So, if Connecticut, as a state, participates, then we need them to be able to claim their sovereign immunity.
 - Bill Roberts – yes, I would imagine there would need to be separate provisions under the bullet point “allocation of liability and risk.”
 - Pat Checko – it may be worth looking at what was done in Rhode Island.
 - Michael Matthews – Bruce and Bill, thank you for taking this homework assignment. If you could forward this to me and Jennifer when you are finished, we will incorporate this into our confirmation slides for next week.

Michael asked if there were any additional comments or additions. There were no additional comments from members.

Policies and Procedures Table of Contents:

Michael provide an example of policies and procedures from ConnectVirginia (slide 20). There are a number of usual suspects included on this list, such as attestations of compliance, user suspension and termination, etc. You get involved in granular items such as time-out provisions, log-in and log-off procedures, password management policies, etc. The management and operation of the HIE will include help desk and training, and there will be policies and procedures around this, such as training requirements. The deletion of report is included, as well as who is allowed to become a node. Also included are dispute resolutions, how to handle sensitive data, consent models, and other topics that will take lengthy conversations to resolve in the future.

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The next example is from CRISP in Maryland (slide 21). The list is not all that different from Virginia. There is information on user requirements, training requirements, password management, user access and patient access policies, permitted purposes, data retention and reuse, data consumption, systems hardware and network configurations, etc. I am mostly focused on HIE-related policies, but as you can see there are also items such as how one gets nominated to the board and what the term of service is associated with that service. There will also be financial policies and procedures, or policies around independent financial audits.

The next example is from the New York eHealth Collaborative / State Health Information Network of New York (SHIN-NY), which is a similar list (slide 22) containing privacy and security, oversight and enforcement, minimum core services technical requirements, and qualified entity organizational requirements. There will always be an insurance and liability provision.

This exercise will be split-up into three sections. The first section will be the policies and procedures related to privacy and security (slide 23). Michael called on Jake first to start, based on his earlier comments.

- Jake Star – in term of privacy and security, it comes back to the audit aspect. Is your security audited and certified? I interpreted the word “audit” by itself differently; this is auditing a participant. I am talking about auditing participants to make sure they don’t just have a collection of policies as proof of their security. They need evidence. New York is going after HITRUST at the state and regional level.
 - Bill Roberts – are you talking about participants or the HIE itself?
 - Jake Star – I think the HIE needs to be certified, but some participants, depending on their situation, may need a certification as well. There needs to be a minimum standard.
 - Pat Checko – would this be a part of verifying participation capability in the first place?
 - Jake Start – absolutely.
 - Pat Checko – do you want to be able to do this initially and on an ongoing basis?
 - Jake Star – if I am a participant, I need to be able to agree to do this on a regular basis. My systems were audited three years ago, and I can show you the certificate, but do I still have security on my system?
 - Michael Matthews – to speak to Pat’s question, there is a whole application process to determine qualified entities. If the application is approved, then there would be an onboarding and credentialing process, which needs to be

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cleared before the entity is activated. There is the possibility of a two-phase process. I think Jake, based on the points you were making, I wonder if can add one bullet point that says, “auditing and monitoring” with two sub-bullets that say “HIE entity” and the other says “HIE participants.”

- Jake Star – this works for me.

- Jake Star – I am not sure if this requires a separate bullet, but both participants and the HIE itself will be using third-parties for their systems. Does there need to be something that requires third-parties to accept the same terms as the participants?
 - Michael Matthews – would they all be considered Business Associates?
 - Bill Roberts – it is possible that some participants will not be subject to HIPAA. Depending on how broad this is, I am thinking of cash-only facilities, school-based infirmaries that are licensed by Department of Public Health. These entities are not subject to HIPAA. I do like the idea of adding a separate bullet related to subcontractors. In the policy itself, we will want to look at the different provisions that will be required.
 - Michael Matthews – we will capture this one as “participant subcontractor requirements.” We will make a specific distinction between participant flow-down requirements and the technology or other contractors who are supporting a participant’s utilization of the HIE.
- Bill Roberts – I have two comments regarding the current bullets. In regard to “permitted purposes” I think we should break this out into “permitted uses” and “permitted disclosures.” It will be necessary to distinguish the purpose based on these two categories. My other edit is related to the bullet point “patient access and rights.” Given the participation of payers, we may want to consider the use of a different term besides “patient.” I think this bullet point should be “individual rights” and explicitly identify what other rights the individuals have. The most common one is the right to amend.
 - Michael Matthews – let’s change the last bullet to “individual access and rights.”
 - Bill Roberts – I think later in the process we should add sub-bullets related to the specific rights we are recommending.
 - Michael Matthews – this will be an interesting conversation, and I don’t want to get too detailed at this point. But there are a lot of nuances that come into play with this area.

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- Pat Checko – I want to pick-up a little bit on the patient access and rights issue. Some of this comes under consent and utilization, but we may need to change some laws to permit access to the third-level sensitive data that we have in the State of Connecticut. Do we want to make a differentiation between what we would call the “standard EHR” and those pieces of high-level confidential data and who can access them? Is this too much in the weeds?
 - Michael Matthews – I think these are issues that will be addressed in the process of actually developing the policies and procedures. Would you like to see a separate bullet point?
 - Pat Checko – no, I just want to flag this, because it will be something we need to deal with in the future.

Michael asked if Joe Stanford or Lisa Stump had comments.

- Joe Stanford – I don’t have any comments at this point.
- Lisa Moon – I agree completely with Pat Checko. I am totally aligned with Pat’s comments related to consumer-mediated exchange. There are plenty of opportunities.
- Jennifer Richmond – thank you, Lisa Moon. Does Lisa Stump have any comments?
 - Michael Matthews – Lisa Stump has not joined the call.

The second part of this exercise is related to the technical and operational policies and procedures (slide 24). Are there any categories that are missing from this list or are you okay with the categories currently listed?

- Jake Star – I am okay with this list.
- Pat Checko – I am also okay with this list.

The third part of this exercise is related to the organizational policies and procedures (slide 25). There can be a lot more listed here, but Michael wanted to create a starter set to spur conversation. We already discussed a number of these items. Information blocking may continue to evolve, but Connecticut can have its own policies aligned with state statutes. Are there any comments or additions to this list?

- Roderick Bremby – I think this list is fairly comprehensive and I do not have any additions at this time. Thank you for walking us through.

Michael explained that at our next meeting we will confirm the outcomes of today’s exercise, and he thanked Bill and Bruce for their willingness to take on a homework assignment.

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4.	Meeting Wrap-up and Next Steps	<p>At the next meeting we will have three exercises: the relationship of the state / HIE entity / Health IT Advisory Council, the relationship of corporate governance versus data governance, and the pros/cons of a new company vs. the designation of an existing company.</p> <p>Jennifer thanked everyone for participating. We will be sending out homework assignments in advance of the next meeting. Also, if there are any comments or questions, please feel free to reach out to Jennifer or Michael.</p>
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Action Item	Responsible Party	Due Date
Development of a high-level list of miscellaneous provisions / boiler plate language for use in a Trust Agreement.	Bruce Adams / Bill Roberts	6/13/18