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Meeting Name: Consent Management Working Group

Call In:

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Meeting Materials:

Meeting Date: 8/16/24

Meeting Time: 10:00-11:00am

Agenda Topic	Time
<p>Attendees: Lyn Snow, Kevin Fredrick, Jane Wilson, Erin Crites, Roberta Lopez Karen Haneke, Jackie Ackerman, Justin Man, Melissa Gillespie Gabby Burke, Kathryn Lofy, Cory Hussain</p>	2-3 mins
<p>Accessible: Discuss what it means for the consent process to be accessible to all users, including healthcare providers and patients.</p> <p>Cory Hussain: One of the things we came up with is a framework for our consent form. There was a paper published in 2019 on how to ask questions. One of the key points was that anything you ask must meet three criteria: Accessibility, readability, and actionability. We want to create a framework within this group where our consent form for CoSHIE, or if we decide on a universal consent form for health information exchange that includes both HIE and social health information exchange, adheres to these criteria. I'll start with accessibility and then cover the other two. Afterward, we'll brainstorm on all three.</p> <ul style="list-style-type: none">• Accessibility means the form is accessible to the end user, the person asking the questions, and the people who need this information. These are the three groups we need to focus on.• Readability involves the standards for consent forms. The form should meet legal requirements but also be understandable, ideally at a 6th to 7th-grade reading level. For patient education, instructions on medication or lab work should be at a 3rd-grade reading level, but that's not recommended for consent forms. So, we need to ensure our consent forms are at a 6th to 7th-grade reading level.• Actionability means the form should clearly define what actions need to be taken, what information can be exchanged, who can see it, and what it can be used for. <p>Before we dive into these, I want to share that I've been using generative AI extensively, and Karen Haneke and I had a pre-meeting about this. I used a generative AI system to plug in the social health information exchange data exchange standards, which is public</p>	17 mins



information, along with two to three consent forms from health information exchanges, like CORHIO and Contexture. The AI-generated an elegant, 6th-grade reading-level CoSHIE consent form that I'd like to share with the group. It covers everything a client or patient and provider would need to know.

Cory Hussain: This is just a prototype; it is not final. It's a brainstorm. The system first explains what CoSHIE is and why it's important. It's elegant and succinct; explaining that sharing this information helps us better understand your needs and provide more complete care. Then, it details what information will be shared—basic information, social health information, and general health information. It clearly defines sensitive health information and substance use information. It explains who can see this information—only approved health and social service providers.

We may need to elaborate on the approval process. This includes doctors, nurses, social workers, care coordinators, mental health professionals, and substance use treatment providers, among others. It's essential for people to know how long their information will be kept. We need to define how long different types of information are stored. The form also explains how sharing information helps the patient by improving care coordination and reducing the need to repeat information to different providers. It assures patients that their information is safe and only accessible to authorized individuals.

The form emphasizes that patients do not have to agree to everything; they can choose what information to share. It also covers how patients can change their minds later and how to opt-out. It provides contact information for any questions. Finally, the form includes a confirmation section after patients review everything. I'll send this out to the group.

I created this with the help of AI. Do you all see what I'm getting at? I saw someone ask if this working group is designing a consent form to be used with CoSHIE. Yes, we're developing the basics, the infrastructure for the form. Our job is to support organizations by providing a toolkit with recommended questions and components. They can modify it, but if many organizations in Colorado—rural and urban health networks, service providers, and CBOs—agree that what we've created is excellent and requires little to no modification, then we've done our job well. I'm going to stop sharing now and go back to our framework.

Let's brainstorm on what should define accessibility, readability, and actionability in our consent forms. Please, everyone, share your ideas. You've all been in this space for a long time and have encountered many forms. Let's start with accessibility. What are the key components we should include for accessibility in our consents? This is a living document, so we can continue to update it.

Jane Wilson: Digital accessibility requirements are essential. The form needs to meet the Web Content Accessibility Guidelines (WCAG) for digital accessibility.

Cory Hussain:
Anything else? What about people who don't have digital access?



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Karen Haneke:

Yes, we'll need a paper version as well. We should discuss the best approach for administering this when it's a paper consent.

Cory Hussain: That's a great point, Karen. So, when we talk about administering the consent form, who is responsible for it?

Karen Haneke: The system is currently set up for care providers in various roles—physicians, social workers, and others. They would be in a session or in person with the individual when entering the CoSHIE system and discussing data sharing. We initially thought about having a button for the care provider to print out a version and do it in person. But we'd appreciate the work group's feedback on what makes sense at the points of care for accessing this consent. We also need to discuss the easiest way to upload the consent, and we'd appreciate any comments or guidance.

Cory Hussain:

It seems like accessibility has several components: accessing the form, administering it, and recording it. Correct?

Karen Haneke: Yes, that's correct.

Cory Hussain:

So, in terms of accessing the form, you mentioned care providers. My question for the group, and I'll go to Roberta and then Kevin, is who should have access? Is it just care providers, like we have for health information exchange, or do we allow clients to access the form asynchronously without a provider present? Something to consider. Roberta?

Roberta Lopez :

I hope I'm not taking the conversation back too far, but I recently joined the group. Are we talking about providers using the consent forms we develop or the state develops, or are providers using their own consent forms? As a provider, I'd want to use my own form, consult my own attorneys, and have a form specific to my data collection. I'm not sure about the relationship between the provider and the state. Should we provide our form, or should providers use their own? I ask because providers are deeply involved with their data, and their consent forms may be tailored to their specific needs, unlike a general form that might not address certain data types.

Cory Hussain:

So, are you saying that different data types collected at different places require different consent forms because of variations in data collection across organizations? Is that correct?

Roberta Lopez:

Yes, for example, substance use disorder data requires a different level of consent than



general health data, HIPAA-protected data, or criminal history data. Providers who work with this data regularly might be best suited to develop or use their own consent forms that have been vetted by their counsel.

Cory Hussain:

Roberta, I understand your point, but I'm thinking more from a patient or client-centric perspective. The autonomy and ability to exchange information should lie with the client. They need to clearly understand what they're consenting to. We want to move away from the idea that only certain people are experts in obtaining consent. The goal is to standardize the questions so that clients, no matter where they are, can clearly articulate what information they want to share. Whether they're at a food bank, a healthcare facility treating substance use, or with a care team, they should understand the data requirements for information exchange. This approach streamlines the consent process for everyone connected to CoSHIE, eliminating the need to consent at multiple locations for different types of information. Currently, clients may need to consent separately at a food bank for social health information and at a substance use provider for substance use information, leading to silos and significant burdens. I've experienced situations where I couldn't determine if a patient has universally consented, so I had to chase them down for signed release forms to obtain HIV or syphilis results. If there were one consent form that covered all necessary information, and the patient understood and agreed to it, we wouldn't face these issues. It would be stored and accessible as needed.

Roberta Lopez:

I'd like to follow up. In a perfect world, patients would be educated enough to understand what they're consenting to, but they often aren't. They rely on providers to provide them with the correct release of information forms that comply with data release policies. Providers are ultimately responsible if they don't have the proper release, and they can't shift the burden to the patient by saying, 'You signed this, so we're off the hook.' Different types of data require different notices in the release forms.

Cory Hussain:

Absolutely, I agree. Our group needs to work with providers to create a framework that clearly explains these categories. You're right; we can't mandate a single form for everyone. However, if we create something really good, people will use it as a framework. Certain facilities dealing with substance use disorders might explain the type of information being exchanged, but I believe that if we define and simplify the language, any organization could do the same. For instance, if I'm a healthcare facility providing sexual health information, I should be able to explain CFR Part 2 substance use disorder information to a patient when obtaining consent for sexual health information. The current consent forms in healthcare are full of legal jargon, including our own from CORHIO. They're very technical, and while that's necessary, the patient-facing side needs to be simplified and easy to understand. For example, if a



form mentions 'step program enrollment,' it should define what that means within the context of CFR Part 2 data. That's the vision I have.

I agree with you, Roberta, that we currently rely on the expertise of organizations that handle specific types of information to explain the consent process. However, as we develop this, we need to avoid situations where only certain organizations can obtain consent for specific information. Imagine a patient sitting with me, discussing their healthcare needs, and I have to tell them they need to go back to another provider to consent for exchanging data. That places an unnecessary burden on the patient. Instead, I should have a toolkit that explains the necessary information in plain language and allows me to obtain that consent.

Roberta Lopez:

I think some providers may tell patients they need to handle this themselves, but often, providers will request the information on behalf of the patient. The patient just needs to sign the form, and the provider handles the rest. The risk lies with the provider, who must ensure they have a proper consent form signed before releasing information.

Cory Hussain :

Absolutely, I agree. Even now, with health information exchange, the risk should lie with us, not the patient.

Roberta Lopez :

If we shift the burden to the patient to understand and fill out a form, how can we expect them to know their rights? It's unrealistic to assume patients will fully understand their rights compared to providers who deal with this day in and day out. I have to jump to another meeting, so I'll let that point go. I appreciate you indulging me in this.

Cory Hussain :

Thanks for the input, Roberta. Just to circle back to accessibility, we're looking at who accesses the form, who administers it, and who records it. Go ahead, Karen.

Karen Haneke:

It reminds me of work we did about seven years ago in the accessibility realm. Technology providers often claimed it was too difficult to make things truly accessible, particularly in the visual realm with assistive technologies. While I understand the challenges Roberta mentioned, we need to believe that these problems can be solved. Individuals should be able to understand the consent they're providing around their health information, and we can't consider this an unsolvable problem. Focusing on the framework you've put together is important, even if it's just to establish a baseline understanding. On the note of accessibility, we should also consider how to access this information based on different accessibility needs. The Accessibility Advisory Council under OIT has found that providing information digitally is the most accessible way when done correctly. Mobile access is the most effective digital method for people who use assistive technologies. The key is to let people know how they can access the



information in a way that suits their needs, whether digital or paper. It's not about choosing between digital or paper; it's about providing both and explaining how to use each option.

Cory Hussain:

I love that idea. It's not an 'or' situation but an 'and.' We should allow people to choose how they access and complete the form, whether digitally or on paper, and provide clear instructions for both. Kevin?

Kevin Fredrick :

I'd like to add to that. I'm on the technical team assisting with this, and we're thinking about a technology-first approach. We're considering providing an interface or portal that a patient can access in various ways—maybe a provider gives them a QR code or sends a text message that links to the portal for consent management. There could be many variations. The advantage is that patients can use their own tools if they prefer, or a provider could give them an iPad or paper document. The consent form can be pulled back into the system in a machine-readable format, making it easier to disseminate. We're also focusing on ensuring the form can be translated accurately, with appropriate context, and that definitions are clear. The same approach applies to paper forms, which can be coded to be easily integrated back into the system. We're looking at the broad spectrum of technology to make the process as accessible and user-friendly as possible. We also want to ensure that patients are making well-informed decisions when they give or remove consent. It's an opportunity to help educate patients and assist them in making positive choices for their healthcare and access to services.

Cory Hussain :

Completely agree. Jackie?

Jackie Ackerman :

Hi, Cory. I'm new to the team with Resultant, and I've been working closely with Gabby and Karen for the past two weeks. I attended the MESC conference this week, where there was a great session on consent management and various pilots that are currently underway. I wanted to gauge the group's interest in looking at some of these other pilots that are further along in the process. I can share the links in the chat if you're interested. I'm not sure if you've already looked at them, but I don't want to repeat the information. Some of the topics you've discussed today came up in that session, and it might be helpful to learn from what others have already figured out. If you're interested, I'll share the links in the chat so we can have more reference material.

Readable: Define the readability standards for the consent form

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Cory Hussain :

That would be great. Jackie also shared one of the presentations from that conference, and it was insightful to see what other organizations are doing. We're not the only ones in this space, and it's valuable to learn from others' experiences. They've done pilots, and we can look at the results. For example, QHN is already functional and has an elegant consent form that's working well. We want to emulate that success. Moving on to readability, I want to discuss how consents are handled for medical procedures. A study showed that when patients are given written forms outlining risks, they often glaze over and sign without understanding. However, when a video is provided, they understand the procedure ten times better. Roberta mentioned shifting the burden, and I agree. We should consider using educational videos to accompany our consent forms. For example, we ask questions about race and ethnicity, which can be loaded terms. We faced challenges with poor data on race, ethnicity, and language. To address this, we found a video that explains these concepts using jelly beans. It was effective, and we shared it with patients before asking those questions. I'm wondering how great it would be to accompany our consent form with an educational video. We could explain what CoSHIE is and the different components, and we could use infographics to make it easier for patients to understand. Imagine giving someone an iPad to watch a short video before they consent. We could make it bilingual, in English and Spanish. Readability isn't just about what you can read; it's about how you learn. Many people rely on visual cues for learning, and we need to adapt to that. The world has changed, and we shouldn't just hand people a form and ask them to read it. We need to provide an educational platform that makes sense in today's environment. What are your thoughts?

Stephanie Pugliese :

I love it. I was waiting for our work group members to chime in, and I saw Erin go off mute.

Erin Crites:

This is a great idea for the general population, but when it comes to our folks in jails or correctional facilities, we face different challenges. Access to technology is limited, and only some have a consistent mobile device or internet access. Time constraints also make it difficult to provide lengthy educational experiences. While the video idea is ideal, it's unlikely to be feasible in these settings. We also need to consider rural areas where high-speed internet is still unreliable. It sounds strange, but it's a reality for some of our rural communities, including criminal justice entities and first responders. While I love the idea of a video for most people, we need to consider the limitations for professionals and consumers in these other areas.

Cory Hussain:

Exactly, Erin. We have a large population that doesn't have digital access due to poverty or other reasons. We've invested in an advertising campaign with posters and



infographic sheets that distill the information down to simple visuals, like four pictures on a page, to help people understand. We must also consider those who can't read, are visually impaired, or have difficulty understanding due to language barriers or educational background. We need to create a toolkit that includes this component and other options for them. We need educational material that is so simple that even someone with a third-grade education can understand it. For example, showing an image of someone with food insecurity alongside a bowl of food and explaining how CoSHIE can help connect them with resources. We need low-tech options that respect our clients. Many of the people with health-related social needs face significant barriers, including education and access to technology. We need to ensure we're reaching these people. Once we have a prototype, we can get community input by showing them the infographic and asking if they understand it. This needs to be an iterative process where we continuously improve. I'm not a fan of developing everything behind closed doors and then launching it only to find out it doesn't make sense to anyone. Small pilots can help us work through this and ensure people understand what they're seeing.

Erin Crites:

In my experience, some people in the justice system will sign anything put in front of them because they fear negative consequences or not receiving services. They often don't ask questions. We need to ensure that, even if this isn't part of the consent form itself, the rollout process makes it clear that services can still be received even if they don't consent to everything. We need to be upfront about what's voluntary and what's not, especially for justice-involved populations. They often struggle to distinguish between requirements from a government entity and their own autonomy. We're not always good at explaining that distinction, and sometimes, we take advantage of their lack of understanding because it's easier to get things done. However, it should always be the individual's choice to consent, and they should understand what they're consenting to. The provider shouldn't assume the patient or client understands; they need to provide the information in a way that's accessible. I like the idea of piloting this with individuals who have lived experience and can provide objective feedback on how they would have responded to this form in the past and how they perceive it now.

Actionable: Determine how the consent framework can be designed to be actionable and effective in real-world scenarios

Cory Hussain:

Erin, you've set a challenge for us—to develop autonomy for people who have had their autonomy taken away. If we can meet that challenge, we can ensure autonomy for everyone. If we can explain autonomy to individuals who don't have it and give them the ability to opt-out and question, then our work is starting at the most basic level.

Readability is about reaching that level of understanding, especially for people who can't even read. If we can create a form or explanations that make sense to those with

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limited education and provide a toolkit for providers to explain it, then we're on the right track. We need to start with the most challenging population when creating this consent.

Erin Crites:

It's a big question for a Friday morning! But focusing on the patient is key. However, in my world, if we don't also focus on the individuals facilitating the conversation, then focusing on the patient or client doesn't always matter. Gatekeeping happens with information, especially in correctional facilities. We need to explain to people what services they might be eligible for and be upfront about the efficiencies they might experience upon release from jail. For example, if they sign the consent form, we can share assessment information from the jail with community providers who can help them upon release. They can choose what to share with community providers. It's important to show them that their information is being used to benefit them, not against them. They have a history of their information being used against them, so building trust is crucial.

Cory Hussain:

That's exactly where I was going. We gave feedback to Resultant that patients should have access to see who has viewed their information and what information was accessed. Transparency builds trust. The consent form should clearly state that this is protected health information, and only authorized entities can see it. This information cannot be used for nefarious purposes or to incriminate anyone; it's solely for providing services. Especially for incarcerated individuals, the information cannot be used in the legal system unless there's a specific release of information authorization. This is purely for health services. We might need to develop additional layers of information for patients, like a toggle button in an electronic or printout version that provides extra definitions for incarcerated individuals or those with mental health issues.

Erin Crites:

There's also court-ordered treatment, where the provider must report to the court. I don't want to throw more challenges at you, but in this case, having consent on the front end for information to be shared with the court could benefit both the client and the clinician. It could save money by enabling electronic information sharing instead of other, more costly methods.

Cory Hussain :

We only have eight minutes left, so I want to bring this back. We're talking about the client or patient who is consenting, but we also need to consider the care coordinators and others who are facilitating the consent process. How do we explain this to them? What tools can we provide for their own education to understand what we're trying to do? We found that when we asked questions about race and ethnicity, the people asking the questions didn't understand the concepts themselves. That was surprising. So, we need to create a comprehensive toolkit for those accessing these forms. We'll assume they have higher levels of digital access and education, so the toolkit should be



more advanced while still aligned with the same three frameworks we're providing to clients. Any thoughts? We're working on two things simultaneously: the most appropriate framework for clients and the most advanced framework for service providers. We need to hold their feet to the fire. Jane Wilson, you've been in this world for a long time. What are your thoughts?

Jane Wilson :

You mentioned interaction with the legal courts. Would CoSHIE resist a subpoena if someone subpoenaed patient information?

Cory Hussain :

Good question. I'm not sure about the legality of that.

Jane Wilson :

I didn't expect an answer today, but it's something for us to think about. It's a natural progression from the points Erin raised.

Cory Hussain:

Jane Wilson, I can tell you that even though we have an opt-in and opt-out for health information exchange, we don't exchange SUD substance use disorder information currently because of CFR Part 2. If I needed to obtain sensitive information, I would need to get a specific release of information from the patient. I'd have to explain why I need the information, how it would be used, and have the patient sign off on it. So, when it comes to legal matters, I think we'd follow a similar process. You can't just access CoSHIE data unless you have the proper authorization. If someone were to breach it, stealing a username and password to access the data, that would be a criminal act. When we spoke with Resultant, we emphasized the importance of meeting strict data use agreements. For example, if we include mental health or substance use data in CoSHIE, organizations like the Food Bank of the Rockies would never have access to that data. Your level of clearance, like in the Pentagon, must be based on your role and the data you're authorized to view.

Erin Crites :

We need to think about how secondary disclosure could unintentionally reveal information. For example, if a flag for services came from the Douglas County Jail, that would automatically disclose some criminal justice information that the individual may not want to be revealed. We need to consider what that might look like if the source of the information is available. If the jail is the one who indicated a need for food, would the food bank know where that information came from?

Cory Hussain:

In health information exchange, we can see where health information is coming from. So, if you had a syphilis test done at St. Joe's, I can see it.



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Erin Crites :

And if you had a test done at a jail, it would be known that you were in jail. That's another component to consider.

Gabby Burke:

We're almost out of time, but we should keep discussing this. We're already considering how to mask jail data, knowing that providers might be reluctant to accept referrals originating from jails. It's a pattern we've seen in the data. Let's keep thinking about the best way to approach this.

Conclusions and Next Steps

Cory Hussain:

We should also consider how to handle health information from mental health facilities. For example, someone might not want their blood pressure or medication information to be known as coming from a mental health facility. Currently, we can see where someone's medications are from, but in CoSHIE, we might want to hide the source. I think we're out of time, but this has been a great discussion. I hope the agenda was helpful, and I appreciate all the feedback on the framework. Thanks to Jane, Erin, and Roberta for raising important points. If everyone agrees, we can start formulating the framework for the consent form, focusing on accessibility, readability, and actionability for different populations. Thank you all for your input. Have a great day!

2-3 mins

Follow Up:

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