All In Webinar:
Navigating Consent

Tuesday, July 26, 2017

Learning Objectives

- Provide opportunities for communities to connect with thought leaders—each coming to the topic of consent with different expertise and perspectives

- Address participants' questions related to consent and recommend various approaches or resources

- Respond to specific use cases from communities on addressing consent

- Stimulate active discussion that will help communities figure out concrete next steps

Panel Introductions

Jane Thorpe, JD, George Washington University
Became involved in data issues when working for CMS and ONC, where she focused on speaking about how access, exchange, use of patient information could support a wide range of community and regional efforts and activities, including health information exchanges, collaborative care, and patient engagement. At George Washington, her departmental focus is in health information and intersection with the law. She has been working lately on comparative maps at the state level on various policy issues including consent requirements and mental/behavioral health.

John Wilbanks, Sage Bionetworks
He is looking for ways to bring for-profit innovation and financial engines into health information space. He has been working for several years on participant-centered consent, which uses design and technology to improve to delivery and evaluation of informed consent. Has developed open-source tools available on EDM currently being used by 28 research projects and counting. He became a sub-awardee for the Precision Medicine initiative, and serves as the co-chair of the consent working group. He is involved in research that is regulated by the Common Law and HIPPA at the national level.

Jennifer Bernstien, JD, MPH, The Network for Public Health Law
She is focused on using the law as a tool to promote health information exchange and developing solutions to increase data sharing. She is currently working on high-level/multi-state data sharing initiatives around immunizations. She looks at federal laws like the Common Rule, FIRPA, and HIPPA, but also at laws at the state and local level with public health agencies. She is very aware of the frustrations that arise trying to share data across boundaries, geographic and sectoral.

Carrie Hoff, San Diego County
She has worked for the past five years on an effort to move the County of San Diego Health and Human Services Agency towards person-centered service delivery and implement a multi-sector information exchange that includes mental health, alcohol/drug services, child welfare, adult protective services, probation, self-sufficiency programs, public health nursing, and housing. The initiative brings in data from public programs that can be very sensitive, so she has extensive experience running into data sharing barriers.

What are the two biggest struggles or mistakes you have seen organizations make with respect to consent?

- **Jane Thorpe**

    1. Consent is regulated by a number of different legal frameworks. Many federal and state laws and regulations address how patient consent should be obtained and what it should include. It can be challenging to create a uniform consent form that meets the needs of various federal and state laws.

    2. You may be doing work that doesn't require active consent from patients, but there may be something you want to do later that actually does require consent, like conducting research. Try to think through as much as possible what your activities will be down the road because if they do trigger consent, you should build that into the front end of your activities.

- **John Wilbanks**

    1. People struggle with "technical debt," or shortcuts that were taken when developing software that are very costly to update or fix after launching. For example, if an IRB form stored as a PDF, everyone is invested in that document, creating network effects where people are scared to do things differently because the cost of abandoning the default is so high.

    2. Another issue is the immense amount of health information being created by technology. Google knows how long you spend at fast food restaurants and gyms. Credit card companies know what you're buying at the store and when you spend at health care facilities. This is all unregulated data that is out there and can't be bottled back up to make tidy consent possible. We need to make consent compatible with this newly digital world.

- **Jennifer Bernstein**

    1. Organizations are not specific enough in making the request/what their data requirements are, so that further complicates understanding what legal barriers or facilitators there are. Sometimes you can find alternative data sources/proxy data that is not bound by the same legal requirements. Mapping the flow of data is critical: who sends, who receives, what they do with it, and who they send on to all have considerations along the way.

    2. Many organizations think that more data is always better. However, legally-sensitive data may open up more issues and can require considerable resources – staff training, employing privacy officers to oversee compliance, investing in computer systems to meet security standards, and legal and security audits.

- **Carrie Hoff**

    1. Remember that information sharing is very context-heavy: don't approach your analysis in abstract, be concrete. Determine where to use notification of practices vs. requiring individual consent. Having a network of groups that are sharing information on the same individuals and developing common practice notifications can be a very powerful.

    2. People often bundle too many questions into data collections. Unbundling helps parse out what to do in each situation. Separating data into supplemental screens and applying role-based/partitioned access makes it easier to drive the actions you want certain people to take.

What are the most effective strategies you've seen for empowering people to understand how their information is being used?

- **John Wilbanks:** Do interviews and see what people care about and what their worries are. When you decide consent needs to be obtained, spend time thinking about how to make the process of informed consent more effective—both for the person who is providing informed consent and for the professional that is working to obtain it. Learning tools, decision support tools, guidelines, and FAQs can be very powerful tools for decision-making. The more people understand the benefits and risks of participating, the more engaged they will be over time.

How do you overcome and manage situations with a lot of technical debt?

- **Jennifer Bernstein:** Consent is the gold standard, with some exceptions. If an individual has a right to their own data, then they also have a right to share that data with third parties as they see appropriate. Consent is an opportunity to engage people and get buy-in. Most people are very happy to share their personal health data if they see the benefit it will have to themselves or to the community at large. In the public health context, when you look at states that have different data schemes (eg. opt in vs. opt out), generally most people are happy to be under either scheme as long as they feel they have an informed choice.

When is consent required and what is the best process for an organization trying to figure out whether it is or not?

- **Jane Thorpe:** Think through what activities you're planning on engaging in and what steps might naturally follow from those activities. Are your efforts related to public health, treatment, research, payment? The nature of your activities will determine whether or not you need consent. Think about what kind of organization you are, the nature of your research, what data you will need, and what the data will be used for. Communities should also get feedback from consumers, providers, compliance professionals, etc. on the front end to prevent challenges down the road.

With a huge array of federal and state consent laws, do you have suggestions for good sources to start the process of determining consent?

- **Carrie Hoff:** On a practical level, over the course of my work, there really wasn't a cut and dry answer to getting consent. The conversations that I had with attorneys, compliance officers, and privacy officers, it really came down to degrees of risk and looking at what made logical sense. As you start looking into the laws, they are very fine-tuned depending on what type of service delivery model you're using. For example, during one project, we realized that sharing if a person is a veteran simultaneously revealed they were in a drug treatment program, which violated the 42CFR part 2 federal regulation on substance abuse confidentiality. Technology allows us to ask those pointed questions without revealing sensitive information.

- **Jennifer Bernstein:** The questions that come up in a public health context vary widely. A lot of data sharing falls under exceptions under HIPPA for public health activities, but often we decide to use data later on for other purposes, like for research or in primary care settings. It's important to think proactively about other potential uses of information, and those are the areas where consent becomes important. We might be able to collect information for a public health registry, but then using that information in other ways beyond traditional public health reporting changes the conversation and the legal analysis. State laws are often more restrictive than HIPPA, especially in substance abuse/mental health laws. Be able to articulate what your potential uses are, where you're going to get the information, and how you will use the information once you have it. Once you do the factual analysis, look for the legal expertise that can help you answer whether it's possible and what consent procedures need to be in place.

How do you determine whether you need to get consent for the data you want to collect?

- **Carrie Hoff:** We were looking at sharing data to deliver person-centered services. In looking at services that have law enforcement touch points (child welfare, probation, adult protective services), our organization made the determination that it really wasn't a matter of the customer permitting the sharing, but we did want to notify of the practice of sharing for the purpose of better care. There was also a similar theme with our housing and self-sufficiency programs. In these programs, once participants are determined to be eligible, they receive a monetary benefit (housing assistance, cash aid). The three types of data sets that the customer could make a determination to increase sharing around were mental health, alcohol and drug services, or medical/physical health information. Based on our service delivery model, we determined that an employee needed to have access to that information to perform their job duties, that couldn't be restricted by the customer.

Is sharing mental health information more difficult than sharing physical health information?

- **Carrie Hoff:** I wouldn't say that the alcohol and drug data or mental health data was any more difficult than physical health. What it came down to for us is that sharing at the identifiable level is allowable if it's for the care of the individual person or family. We discussed what it means to be involved in collaborative care across disciplines and provided training and common practices around that. By collaborating across disciplines, it reduced the risk that we were sharing information without knowledge of what was happening in another entity with that data.

- **Jane Thorpe:** Don't shy away from mental health, but just be cognizant of the fact that there may be an additional level or protection or an additional step, depending on the state that you're operating in.

What's piece of final advice you'd like to share?

- **Jane Thorpe:** Think through the role that your organization plays because that will impact what laws and regulations you are triggering. Take a multi-stakeholder approach to developing these policies and procedures and get buy-in from the consumers and stakeholders that will be using the consent forms.

- **Jennifer Bernstein:** Be specific. Really understand what you want from the data and what your issues/areas of concern are.

- **Carrie Hoff:** Push yourself and your colleagues to question your assumptions about what gets bundled in a package. Not every piece of information is governed in the same way. Data mapping can really help you unlock where there are points of flexibility.

Additional Resources Shared During the Webinar

- HealthInfoLaw.org offers keys to understanding the laws that govern health information and the implications they can have across health care and beyond. A project of the George Washington University's Hirsh Health Law and Policy Program, the website is designed to serve as a practical online resource to federal and state laws governing access, use, release, and publication of health information.

- [The National Network for Public Health Law](link) (NNPHL) offers a number of resources, including a legal assistance library, issue briefs and customized technical assistance. Experienced Network attorneys are ready and able to provide technical assistance and guidance on any legal or ethical issue that arises from the collection, use, storage and/or disclosure of data by public health agencies. For legal technical assistance and support on accreditation of public health agencies, please contact your region.
  - [NNPHL Tool: Checklist of Information Needed to Address Proposed Data Collection, Access and Sharing](link)
- [The Common Rule](link) is the Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and codified in separate regulations by 15 Federal departments and agencies. For all participating departments and agencies the Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance.

Can I avoid having to obtain consent?

- **Jane Thorpe:**
  o Consider reframing consent not as something to avoid, but as an opportunity to connect with patients and consumers in a meaningful way.

  o These are some elements to consider when determining whether consent required: Who/what is requesting information? Who/what is source of information? What type of information is being requested? Is the requested information identifiable? What is purpose of requested use? Who/what is funding requested use? Might there be long-term uses other than the immediate request that may require consent?

- **Carrie Hoff:**
  o Another way to phrase this question is: Is consent the only tool available to enable information sharing? The answer is that there are several tools. First, review the laws and regulations that apply to the data types you are looking to share. Then, identify if the laws and regulations allow for the sharing of information for the care of the client/individual or for 'business purpose.' Next, identify if the laws restrict or prohibit information sharing in specific situations. Also, the laws and regulations will also identify if the data is something that a client has the ability to consent. For data involving public benefits, law enforcement, or protective services, the client may not have the ability to consent to increase sharing beyond the job roles defined by the organization.

  o An important tool you have is your policy and practice approach. If your service delivery approach requires that staff perform certain functions and they need access to information to perform that function, you may have an opportunity to share information and provide clients with a notification of practices. A notification of practices alerts clients to the fact that information will be shared and for what purpose. You can strengthen that with staff training about use of the data.

  o Look at ways you can avoid revealing unnecessary information by sharing the data. In some cases, sharing the data without identifying what system or program it comes from may open up the opportunity to share the data. For example: being able to share a client's primary language is helpful for quality of care. If you are able to share that information without revealing that it was captured in a specific program data system, you have un-hooked the data from revealing enrollment in a program (that may be restricted information). Another example is sharing trend information rather than raw data – I have heard of an organization who worked with their local schools and they were able to reach an agreement that the school would share trend data (e.g., is the student's scores going up, down, or staying steady) rather than the raw data. The organization was able to take meaningful action with the trend data and stay within the boundaries of what is allowable to be shared.

If I have to obtain consent, when does this have to be done?

- **Jane Thorpe:**
  o If consent is required, it should be obtained prior to data collection or as soon as practicable again depending on the circumstances.

- **Carrie Hoff:**
  o Very simply put, the consent should be obtained after information exists and before the information is shared (e.g., you should not obtain a 'consent' from a customer for a future date when information may be collected). Some factors to consider about your process include: when in the service delivery cycle or process should the conversation be held, who in your organization should explain the consent to the client, is your explanation clear to a reader who is not in your profession? When considering these factors, be aware that you may send unintended cues to the client, for example, having a physician have the discussion about consent with clients during appointments versus the front desk staff have the conversation during check in.

How do we coordinate data sharing with organizations that have pre-existing consent procedures?

- **Jane Thorpe:**
    - It is important to understand the relationships/arrangements between all actors playing a role. This will help address questions identified above.

- **Carrie Hoff:**
    - I would recommend that you start by reviewing the pre-existing consent procedure and material to determine if it covers the type of sharing you want to do.

Are there communities that have set up health information exchange jails/prisons or corrections departments, and how have they handled consent?

- **Carrie Hoff:**
    - **Jail and/or prisons** – I believe that San Diego Health Connect has health information exchange with the County jails (Sheriff's Department). Dan Chavez can provide more details about how consent is handled.
        - ConnectWellSD shares information with the Sheriff's Department, with different user access roles for medical staff who work in the jails versus law enforcement staff in other roles. Medical staff who are treating people in the jails have access to information that relates to their health care. We plan to use a notification of practices for our clients to advise them that the County of San Diego shares customer information to ensure quality service delivery and care and to collaborate across programs for shared customers. (Note: ConnectWellSD is still in development which is why I used the future tense).
    - **Department of Corrections** - In San Diego, with ConnectWellSD, we have worked with our Probation Department to understand their standard terms of probation. Some programs have a built-in consent that offenders must sign as part of the terms of probation. We have found opportunities with those populations to enable information sharing based on the consent that is built into that process.
        - Please note: if there is information coming from a law enforcement agency, check about the source of that data. Data that falls under Department of Justice (DOJ) regulations, may require that the person receiving the data meet certain requirements. For ConnectWellSD, users that access data that comes from our Probation data systems must complete an FBI-level background check and training every-other-year. (But not all users need to have access to this law enforcement data to perform their job role, so it is only certain users who fall into this category).