Consent Policy Design Group

Guiding Principle

Compilation of Responses from Design Group Members & Suggested Recommendations

September 24, 2019

Principles	Accept	Accept with Changes	Don't Accept	Unable to Respond	Proposed Changes
1. Consent policies should require patients be provided clear and unambiguous information about health information sharing choices under applicable State and Federal law. The information should be translated for non-English speakers and should conform to the Web Content Accessibility Guidelines[1] developed by the Web Accessibility Initiative (WAI), part of the World Wide Web Consortium (W3C).[2]	2 SB, NS	2 RR, PC			(PC) And should conform with the most recent TEFCA guidelines (policy) including the concept of meaningful choice
Recommendation: Accept with changes. *Consent policies should require patients be provided clear and unambiguous information about health information sharing choices under applicable State and Federal law.*					
2. consent policies should require Connecticut's Office of Health Strategy to develop an educational resource tool kit on health information sharing, leveraging and adapting content from recognized	3 SB, NS, PC			1 RR	(RR) See comments. (PC) Shouldn't be dependent on funding. IAPD funding should include funds to cover this component

[1] https://www.w3.org/WAI/standards-guidelines/wcag/

[2] https://www.w3.org/WAI/

Deleted: Connecticut and Federal statutes

Commented [R1]: These 2 sentences are 2 totally different concepts and requirements and should be divided into 2 different principles.

Deleted: Dependent upon funding availability

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third-party resources.[3] Educational content should be reviewed and approved by the Health IT Advisory Council, and should not only include information for patients, parents and guardians, but also for providers, pharmacies, labs, health plans, state and local government agencies, and employers.					
Recommendation:					
3. Information and educational resources on consent policies should be distributed broadly by Health Information Alliance, Inc. (HIA) throughout Connecticut and be made widely available and easily accessible through a variety of sources including the Health Information Alliance, all health and human services agencies and departments in the state of Connecticut, and organizations participating in HIE services in Connecticut.	3 SB, NS, PC		1 RR		Internal Review: I can see the value in having HIA disseminate this, but not as the sole source of this info. People aren't initially going to go there, or even know they should, to look for this. OHS should be the lead in working with stakeholders to develop a comprehensive and sustainable plan for managing consent education.
Recommendation:					
4. A review of consent policy considerations should be conducted by HIA, Inc. for each HIE use case before an HIE use case is put into production, with a use case-specific consent policy developed if indicated from the review.	2 SB, NS	1 PC	1 RR		(PC) Refer to #1

[3] Adapted, with permission, from the CARIN Alliance Trust Framework and Code of Conduct (https://www.carinalliance.com/our-work/trust-framework-and-code-of-conduct/)

Deleted: to the extent possible

Commented [R3]: I have no idea who this organization is and how it relates to State policy. Why would we as the State rely on distributed resources of a private organization, and in particular of one organization over another? Shouldn't it be the State that determines our educational resources to support the State's official HIE and the functions the State decides are appropriate to run through the HIE?

Commented [R4]: Why? And would this review need to be funded? Wouldn't that need to go out to bid to then determine if in fact this is the right organization to do this review?

Commented [R5]: Why wouldn't this be reviewed by an internal State committee, similar to this Consent Design Group, filled with Subject Matter Experts and including appropriate Legal Counsel to review compliance with applicable laws and best practices in both privacy, patient choice, patient experience and quality?

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Recommendation:					
5. Notification of a healthcare organization's participation in electronic health information exchange should be included in the Notices of Privacy Practices (NPP), as required of healthcare organizations by Health Insurance Portability and Accountability Act (HIPAA). This inclusion in the NPP should be standard practice across the state of Connecticut, whether the exchange of health data is facilitated by: a. a national consortium; b. an association of healthcare providers or hospitals on behalf of their members; c. a group of healthcare organizations operating under single tax ID for healthcare payment under an accountable care arrangement; d. a group of healthcare organizations using the same electronic health record system vendor; or e. entities incorporated or designated for the purpose of facilitating electronic exchange of health data.	3 SB, NS, PC		1 RR		
Recommendation:					
6. Consent policies should result in the lowest possible burden on providers responsible for their implementation and maintenance.	2 SB, NS	1 PC		1 RR	(PC) But provide ample information for patient understanding and questions.
Recommendation:					

Commented [R6]: It is higly unlikely large organizations that participate in numerous HIE's and similar exchanges will be able and/or willing to modify their NPP's each time a new use case or exchange process is added. Healthcare Organizations should instead be required to at a minimum state in the NPP's that the organization participates in HIE's and similar exchanges, and have a location (e.g., a designated website) that could list the various HIE's and exchanges they participate in over time, with links to further explanations and guidance from the entity, OHS's resources and other information about exchanges and who to contact with questions or concerns. Including this specific requirement could result in certain organizations deciding not to participate in this specific HIE, particularly where other HIE's are available that would eventually connect to this HIE in all likelihood anyway.

Commented [R7]: This is a great statement in theory, but depending upon the size and perspective of the provider, I'm not sure we can define what constitute a burden for them.

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7. Clearly written information about consent policy changes should be provided by to patients, parents and guardians, state and local health and human service agencies, and all licensed healthcare entities in a timely manner when policies or practices have changed, adhering to the principles of broad dissemination and accessibility of information described above. [3]	3 SB, NS, PC			1 RR	Internal Review: Seems closely related to #3. Maybe consolidate this message?
Recommendation:					
8. Mechanisms, including digital tools, for expressing consent policy preferences should be user-friendly and easily accessible.	3 SB, NS, PC			1 RR	(PC) Implies everyone has access to and basic literacy to use digital tools. Should there be a paper option
Recommendation:					
9. Consent policies should explain what will happen to the patient's data after they withdraw their consent. [3]	4 SB, NS, RR, PC				(PC) Implies a mechanism to withdraw consent not previously noted.
Recommendation: Accept as written.					
10. Consent policies should require third-party vendors and contractors be contractually bound by Business Associate Agreements (BAAs) to publish privacy policies of any organization facilitating electronic health information exchange in Connecticut, and prohibit use or disclosure of patient information (including de-identified, anonymized or pseudonymized data) for any undisclosed purposes without express consent from the patient. [3]	2 SB, NS			2 RR, PC	(PC) Does this suggest they may exchange information outside the bounds of the acted use cases or HIPAA allowed uses? Need more info to sign off.

Commented [R8]: Again, why would this be provided by HIA rather than OHS?

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Commented [R9]: Yes, I agree. This should go without saying. But without clarity as to how this would be accomplished and what it might look like from the Privacy-By-Design perspective, it is hard to say whether what mechanisms would be appropriate. It is also not clear from how this is worded what "digital tools" would mean. Does that mean there is a way for an individual patient to login to the HIE and consent? Is this a datafeed that happens on the Healthcare Organization's side that blocks a patient's information from going to the HIE is affirmative consent is not received? Or if we are going via an opt-out methodology (and again, we have not determined as group whether a recommendation for opt-out vs. a recommendation for opt-in is more appropriate for consent for this HIE or other exchanges using State tools), how that would be addressed digitally or electronically? We do not have enough information as a group to even say whether this very basic thing that we probably could all agree to as a group as a recommendation is even appropriate.

Commented [R10]: This is not a Consent policy requirement; this is a HIPAA Privacy regulatory requirement. Why would this even go in a consent policy?

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Recommendation:					
11. Consent policies should require safeguards be followed consistent with the responsible stewardship associated with protection of a patient's health information against risks such as loss or unauthorized access, use, alteration, destruction, unauthorized annotation, or disclosure. [3]	3 SB, NS, PC			1 RR	
Recommendation:					
12. Consent policies should address sensitive and specially protected data, including, but not limited to, mental health, substance abuse, and HIV status data, in alignment with federal and state statutes.	3 SB, NS, PC			1 RR	(PC) This should be a shall
Recommendation: Accept with changes. *Consent policies shall address sensitive and specially protected data, including, but not limited to, substance abuse treatment, HIV status, sexually transmitted disease data, as well as age-related privacy protection for minors, in alignment with federal and state statutes.*					
13. Consent policies should be aligned with certain national interoperability initiatives, including the Common Agreement (CA) under development as part of Trusted Exchange Framework and Common Agreement (TEFCA), to support the ability to exchange data with entities outside the state.	3 SB, NS, PC			1 RR	
Recommendation:					
14. Consent policies should be reviewed annually (or biannually) to ensure it is aligned with these principles and complies with any changes in best practices or federal or state law.	3 SB, NS, PC			1 RR	
Recommendation:					
	4				

Commented [R11]: Again, these are HIPAA Privacy Rule, HIPAA Security Rule, Part 2, etc. requirements anyway. Why would this even be part of a consent policy? Why wouldn't we just say in a consent policy that all applicable requirements of Federal and State law will be followed by participating organizations utilizing the HIE as part of the resource guides and informational tools OHS and the entities would provide to patients?

Commented [R12]: Again, in theory I agree with this concept, but we would need clarity on the use cases where specially protected data would pass through the HIE in the first place. Many of the regulations involving these specially protected data categories specifically require affirmative consent (i.e., authorization, explicit opt-in, etc.) to share data. This would be again then be a regulatory requirement, not a consent policy nicety.

Commented [R13]: It is hard to comment on this proposed principle without clarity as to what is meant by the term "be aligned with…."

Commented [R14]: Is annually practical? A specific consent process should be reviewed each time a new use case is to be implemented. The over-arching policy should also be reviewed when new use-cases are contemplated to make sure everything still lines up. But I think saying annually or biannually, as opposed to something like, as a minimum when new use cases or regulatory changes may impact consent, provides more flexibility and is probably more manageable. Also, who would do this review? Would it be OHS? A consent process committee?

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15. Consent policies should provide a clear procedure for addressing complaints by individuals regarding the use of their data.	SB, NS, RR, PC				(PC) Should thid be a special Board or Committee? Internal or external?
Recommendation: Accept as written.					
16. OHS should consider pursuing regulations that define requirements for compliance with consent policies.	3 SB, NS, PC			1 RR	
Recommendation:					
17. Consent policies should require that patients have sufficient time to review educational material before making a consent decision.[4]	3 SB, NS, PC			1 RR	
Recommendation:					
18. Consent policies should require a consent decision is not used for discriminatory purposes or as condition for receiving medical treatment[4].	4 SB, NS, RR, PC				
Recommendation: Accept as written.					
19.					
20.					
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24.					
25.					

Commented [R15]: What does this mean? Why would there be a time crunch for a patient to decide? Again, whether we do an opt-in or an opt-out may matter here. If sharing is not going to be automatic, then a patient should be able to take as long as they like to decide. If the process is going to be automatic based upon a decision to put this simply in NPP's and then let patients opt out either affirmatively, or by choosing not to receive healthcare at an organization that participate in this and/or exchanges, then this time element becomes irrelevant.

[4] Adapted from ONC, HealthIT.gov Meaningful Consent Overview (https://www.healthit.gov/topic/meaningful-consent-overview)

In Reference to Guiding Principle #1:

Susan Israel - The public needs to be informed whether CT is an opt-out state for transparency and in order for the "unambiguous information about health sharing choices," name the groups (who) will be seeing their data (identified or unidentified) and where the data would be sent and stored temporariiy or permantently. It must be stated for which data the patients can exercise consent vs what are automatically sent by their providers by virtue of recievnig medical care:

1) identify and care mapping data
2) identity quality control
3) clinical care summaries with diagnoses and medications
4) empanelment
5) quality data measurement output
6) public health beyond communicable diseases
7) opioid medication that includes psychiatric drugs which are also controlled substances
8) outpatient and inpatient discharge summaries
9) identified tumor registry
10) lab and imaging data
11) individual electronic health record longitutidal data
12) Surecripts data (from which there is an opt-out?)

Obviously, there is the tension of patient rights to opt-out of an electronic health infomation exchange for their mandated data to go to OHS/CT. But the removal of patient right of consent for the sharing of their data for TPO which includes oversight was removed by HHS in 2003 without Congressional approval. CT taking so much private medical data (including the APCD) and the HIPAA rules certainly stretch what the government is "allowed" to do under the 4th amendment.