From: lesleybenne@aol.com <lesleybenne@aol.com>
Sent: Sunday, March 15, 2020 3:13 PM
To: OHS.HITO <HITO@ct.gov>
Subject: RE: Feedback on DRAFT Consent Design Guiding Principles

Thanks for this opportunity to provide feedback on the The Final Report and Recommendations of the Consent Design Workgroup.

My name is Lesley Bennett. I am a Stamford Resident, advocate for patients with chronic illnesses, former co-chair of the SIM Practice Transformation Task Force (PTTF) and member of the HIT-Med Rec & Polypharma committee (MRPC). While I sincerely appreciate all the hard work and vigorous discussions that members of the Design Group had before issuing this report, I am appalled that the *Guiding Principles and Recommendations* in this report seem to be more focused on **providers and business** in our state rather than on the needs of the **PUBLIC** and on **safeguarding patients' confidential information and privacy.** According to the leading Health Informatics Professional Organization (AMIA), *"Patient Safety and Quality of Care are at risk if the (HIE) informed consent process does not **emphasize patient comprehension."*** Consent for Connecticut's HIA needs to be patient-centered!

In my opinion Recommendation #6 needs to be deleted from the list of recommendations and guiding principles! Recommendation #6 clearly states that *"**CONSENT POLICES should result in the lowest possible burden on providers responsible for their implementation and maintenance!!!!*** The next phrase in this principle ("...*without compromising the need for sufficient patient understanding and ability to exercise meaningful consent.*") does little to address the issue of what constitutes a ***BURDEN*** on the provider or what constitutes the standard a provider must meet for an effective and meaningful consent process. The process for obtaining ***Meaningful Consent*** is not an issue that can be left up to each provider or health system. Consent must be focused on the needs of patients (patient-centered) not the wants and wishes of providers, and it must be a standardized process that is fully documented in the Design Group's Recommendations and Guiding Principles . I understand (through my work on the PTTF) that many providers feel overburdened by paperwork and new duties being added to their work due to the HIE (am I am willing to help advocate for more compensation to enable the hiring of more personnel). However, do Design Group members realize that professional medical (AMA) and surgical organizations are currently having problems with health care providers effectively communicating with patients to obtain meaningful informed consent for invasive medical/surgical procedures? A recent AMA report shows that >40% of the patients who signed an informed consent for an invasive procedure did not remember or understand what they signed. In our current healthcare system there is a great deal of pressure on providers to just obtain a patient's signature on an informed consent before a procedure. There are a number of physicians who take this process very seriously and have a very effective process for communicating with patients in order to reach a meaningful informed decision...*but* there are also a number of providers who rush through the process focusing only on the patient's signature and not on effectively communicating the risks/benefits of the procedure. According to AMA there are 3 major factors involved in obtaining meaningful consent: (1) **Patient-related** factors such as emotions, health literacy, cognitive/physical abilities, language barriers, ethnicity etc; (2) **Information-related factors** such as is the info presented in electronic, written, or oral format etc: and (3) **Provider-related** factors such as how well a provider communicates with a patient and understands the procedure/process. In the case of HIE, many providers in our state do not understand this system yet and are not capable of deciding what consitutes a meaningful HIE consent process . While I understand the the consent process will place a time/cost burden on providers, the Design Group should not compromise PATIENT SAFETY and the Quality of Care a patient receives by making recommendation #6.

With regard to Recommendations 1 and 18: at the very I feel that least patients must be allowed to opt-out of the HIE. Since we are now at a time when genetic testing is being added to many patient records(and on the verge of GENOMIC Medicine being incorporated in EHRs), I would like to see the state adopt a combo opt-in and opt-out consent process similar to the one being used for the MA HIway. The Guiding Principles & Recommendations for our HIE should include a clear statement of what part of a patient's personal data can be included in the HIE

without express consent, what information a patient can "opt-out" from having included in the HIE, and what information will be considered "sensitive" (such as mental health and genetic info) requiring express informed consent. Since the platform for the HIA allows for the creation of a *Business Framework*, I feel that the Guiding Principles must address the issue of how all this data can and will be used--for instance should it be used for research or can it be used in a "*for-profit*" endeavor...and if this data is used in a *for-profit* endeavor, how will patients be compensated? Safety of the data and what steps the HIA will take to protect the safety and confidentiality of patient data need to be clearly defined--along with a clear explanation of what constitutes patient privacy and confidential patient data. Since several of these issues may need to be addressed by statute, I feel it may be time for the HIT Advisory Council and OHS to involve members of the CGA not only in Public Hearings at the LOB and around the state on HIR consent issues but in looking at what statues that may be needed to protect confidential patient information and patient rights.
Thanks,
Lesley Bennett
30 Soundview Drive
Stamford, CT 06902
203-829-7650

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Sent: Monday, March 16, 2020 10:13 AM
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Thanks. I would also like to add that I believe that more "consumers" who are patients (CT residents who actually use healthcare frequently and understand/use electronic health record info and/or advocates from organizations representing those with chronic illnesses (not health policy advocates) need to be added to the HIT Advisory Council. Currently there are 5 openings on the 2020 roster listed on the public website-- 3 Chair appointees and 2 CGA appointments that I hope could be filled by patients or patient advocates.
Thanks
Lesley