

**New York eHealth Collaborative Policy Committee Meeting**  
**September 25, 2018**  
**12:00 noon – 4 p.m.**  
**Meeting Notes**

A meeting of the SHIN-NY Policy Committee was held on September 25, 2018. Present either in person or via telephone were:

Art Levin, Center for Medical Consumers, Co-Chair Policy Committee  
Nance Shatzkin, Bronx RHIO  
Dr. Tom Mahoney, Common Ground Health  
Steve Allen, HealthLink  
Cindy Sutliff, NYeC  
Bob Belfort, Manatt  
Alex Dworkowitz, Manatt  
Mary Beth Conroy, NYS DOH (SPARCS)  
Callie Wells, Manatt  
James Kirkwood, NYS DOH  
Dan Tietz, AIDS Institute  
Dr. Glenn Martin, Queens Health Network  
Valerie Grey, NYeC  
Jonathan Karmel, NYS DOH  
David Nardolillo, OPWDD  
Deirdre Depew, NYS DOH  
Jeannette Rossoff, NYeC  
Eric Boateng, NYeC  
Linda Adamson, NYSTEC  
Tatiana Ledneva, NYS DOH  
Amy Warner, Rochester RHIO  
Dr. John-Paul Mead, Cayuga Medical Associates  
Jessica Eber, NYS OMH  
Evan Brooksby, HANYS  
Zeynep Sumer King, GNYHA  
Tom Check, Healthix RHIO  
Geraldine Johnson, NYS DOH Public Health  
Charles Gonzalez, AIDS Institute  
John Fuller, AIDS Institute /HIV Registry

The meeting was called to order by Mr. Levin at 12:00 noon.

**I. Welcome and Introductions**

Mr. Levin welcomed the Committee members, highlighted the need for efficiency, and introduced Mr. Kirkwood.

## **II. DOH Update**

Mr. Kirkwood said funding had been secured from CMS in a timely fashion and contracts had been approved. Mr. Kirkland discussed a QE's successful pilot project for medical record review with PPSs under DSRIP, which is set to expand to new members this fall. Mr. Kirkland also discussed the 2020 upcoming requirements for querying state prescription drug monitoring programs, and a pilot with Rochester RHIO to test how this may be possible by connecting EHRs to ISTOP. Mr. Kirkland expects expansion of this model in the future.

## **III. NYeC/SHIN-NY Enterprise Update**

Ms. Grey provided an update of 2020 Roadmap Strategy Highlights, including that NYeC has implemented New QE Performance Based Contracts and awarded High Gap Closure projects to help QEs attain certain targets. Progress is being made on these metrics, quarterly report cards have been developed, HITRUST certification is being prioritized this year, and new performance metrics have been developed for 2019-2020.

Ms. Grey also noted that SIM quality measurement awards are imminent and NYeC is working with DOH to create a plan to connect SHIN-NY to the all-payor data base. Additionally, NYeC has issued an RFP to analyze and assess options for engaging in a national network. Additionally, an interoperability and innovations pool has been created with certain QEs to undertake QE data sharing, claims integration, and operationalizing the wire-once concept. Ms. Grey explained that NYeC plans to move forward with an FHIR standards assessment, and a NYeC Technology Innovations Advisory Group will begin later this year.

In discussing the future focus of NYeC, Ms. Grey explained that focus will remain on delivering and executing on the roadmap, working on a longer-term sustainability plan, and beginning to engage in scenario planning.

## **IV. Report Out on Research Subject Matter Expert (SME) Roundtable—General Overview**

Mr. Levin introduced and summarized the purpose of the research roundtable, explained that the meeting materials detailed the discussion to follow, and highlighted the value of hearing various SME perspectives. The key takeaways from the roundtable were: (1) agreement that de-identified and identifiable data can be valuable in research studies; (2) requirement to obtain written consent and IRB approval is a barrier to research; (3) enthusiasm to explore use of de-identified data to identify study participants; (4) re-identification fear was discussed, and HIPAA alignment was discussed as a potential solution; and (5) some experts thought it may be useful for the SHIN-NY consent form to reference the use of the patient's data for research (an all-in-one form).

The policy options considered were: (1) to do nothing; (2) to remove QE review for certain de-identified data; (3) no consent for patient contact; (4) to revise consent forms to be more inclusive of the research agenda; or (5) to move to complete HIPAA alignment. Mr. Levin noted further discussion on these proposals would occur later in the meeting.

Ms. Sutliff added that these policy options were taken to the Tiger Team to review them in depth, the Tiger Team discussed these various options, and the Tiger Team decided on three topics as most promising, to be discussed by the Policy Committee.

## **V. Statewide Planning and Research Cooperative System (SPARCS) Presentation/Q&A**

Mr. Levin introduced the SPARCS model and introduced Ms. Conroy, who explained SPARCS. Ms. Conroy gave a background on the SPARCS database; explained the content, which includes de-identified, limited, and identifiable data; and discussed the administrative review necessary to access these various types of data, which is most stringent for identifiable data. To access identifiable data, a researcher would have to receive approval by SPARCS staff, the Data Governance Committee, and the Commissioner.

Ms. Grey asked about the makeup of the committee. Ms. Conroy replied that there are two independent individuals from the data protection review board, and the rest are individuals across DOH. Ms. Conroy discussed recent changes to the committee meetings, including that researchers are no longer required to attend in person, and a quorum is no longer required to vote. Mr. Karmel added the committee is advisory, and the commissioner has the ultimate decision-making power, so therefore the committee is not subject to the open meeting laws.

Mr. Levin asked what patient consent is required by the researchers in order to grant access, and Ms. Conroy answered that requests can be denied if there is no IRB approval, exemption from requirement for IRB approval, or evidence of waiver of patient consent as a part of IRB approval.

Dr. Martin asked if the committee ever disagrees with an IRB approval, and Ms. Conroy answered no. Dr. Martin asked if there have been data breaches associated with SPARCS, and Ms. Conroy answered no. Ms. Conroy also noted that there have been examples of the committee sending a letter asking for a second appearance if a researcher is seeking to expand the scope of their research after receiving the data. The SPARCS program monitors this closely, generally hearing about such expansions secondhand.

## **VI. De-identification of Data Process Presentation/Q&A**

Ms. Ledneva introduced her discussion of de-identification of data by explaining that the increased need for health data has led to attention on de-identified data, and the goals of using and sharing personal information while protecting patient privacy. Ms. Ledneva discussed the HIPAA safe harbor requirements for de-identified data and when expert determination is required to determine if data has been de-identified, commenting that in her opinion, it is always useful. Ms. Ledneva walked through the 8 steps DOH uses to de-identify data, including (1) determining the focus of the data risk; (2) classifying the variables as direct vs. indirect identifiers; (3) determining acceptable re-identification risk threshold; (4) determining the data risk; (5) determining overall risk; (6) anonymizing the data via data masking or de-identification; (7) assessing data utility; and (8) documenting the process.

Ms. Eber requested permission to share the PowerPoint presentation with colleagues at OMH, which Ms. Ledneva granted.

Mr. Levin asked if there had been any instances of re-identification, despite de-identification efforts, and Ms. Ledneva stated she was not aware of any data breaches of any of their data sets.

## **VII. Outcomes Discussion: Key Takeaways, Proposed Policy Changes and Discussion**

After a break, Mr. Dworkowitz recapped the Tiger Team meeting and discussed the three options identified by the Tiger Team.

The first option would give more discretion to QEs regarding de-identified data. Mr. Dworkowitz explained that under this proposal, QEs could keep their current policy (requiring IRB approval and QE Committee approval for use of de-identified data, which is above and beyond HIPAA). However, QEs could also choose to eliminate the QE Committee approval for de-identified data, if they so choose. The QE would be required to make publicly available their policy on sharing de-identified data. The same could apply for limited data sets, except that, under HIPAA, a QE is required to enter into a data use agreement with the researcher.

Dr. Martin asked what data this would apply to, and Mr. Dworkowitz explained that these policies would apply to data originating at the participant and entering the QE. Dr. Martin commented that in the future, statewide data should be discussed under the same topic, and that he believes this policy proposal is insufficient, as all de-identified data should go through at least some committee or review. Ms. Sumer King agreed, believing a quality committee review is appropriate.

Mr. Check commented that while he would advocate for a research committee review for his own QE, he believes some QEs would be happy to delegate to the managers of the QE. He believes if the QE governance made that determination, he would defer to them.

Ms. Sumer King said there should be some transparency about the requests that are being made and granted by QEs, and Ms. Sutliff agreed this can be clarified in the language of the proposal.

Mr. Belfort clarified that the proposal would not mean that each request would not need to be evaluated or reviewed by the QE, only that QEs would have the discretion to say, “management may be responsible for fielding ABC requests, but if they have XYZ types of content, they will go to committee,” for example.

Mr. Check added that the initial reviewer should always be a high-ranking official who is able to defend decisions and to make informed decisions, and that there should be “for this purpose only” data use agreements as part of this type of scenario when data use is to be allowed.

Ms. Sutliff added that the Tiger Team will continue to think about the wording of the policy and the policy guidance that would then be provided to the QEs.

The second policy proposal was then introduced by Mr. Dworkowitz, regarding identifiable data. Mr. Dworkowitz explained the SME Roundtable discussed the value of using data in a QE for the purposes of recruiting people for clinical trials. The current barrier is that the policies require written patient consent for use of data for research, but to contact them, the researcher would need a name. The proposal would be that with IRB approval, QE Committee approval, and the data supplier (source) approval, the researcher could receive data with patient information in order to determine who would be appropriate subjects for a given trial. The researcher would not contact the individual directly, but could contact the treating provider and request that the

provider discuss the trial with the individual. Mr. Dworkowitz stated that the data supplier is not required to agree to the data sharing under federal law.

Ms. Sumer King noted that hospital policies would not allow disclosure without data supplier agreement, and that she believes this policy change will have an impact on hospital participation in SHIN-NY if provider data can be used without hospital approval, even if it is technically allowed under federal law. Ms. Sumer King believes hospitals feel they are stewards of the data and provide data to the QE only under a mandate in many cases. She added that breaches would come back to the hospital, further justifying the hospitals' vested interest.

Mr. Belfort highlighted the need to clarify what the policy would mean, as there is an important distinction in whether a researcher can receive data before the QE has limited the data set to potential subjects of a trial, or whether the researcher would only be allowed to receive data after the QE has limited it to potentially relevant individuals. Mr. Belfort stated that HIPAA permits the researcher to do the review to determine which individuals are eligible for a given trial.

Dr. Martin and Mr. Check both added comments that the detailed screening would need to be done after patient consent, as pre-consent reviewers should not be undertaking a comprehensive file review. If a patient is found ineligible after agreeing to join, he/she would be removed from the study.

Mr. Allen commented that he believes the QE would contact the PCPs and try to get consent. The QE would be the conduit to get the data to the provider to get consent. Mr. Belfort commented that if the only policy discussion being considered is allowing the QE to perform review of data and to contact the provider directly, without releasing data to the researcher, a substantive policy change is likely not required, as this would simply be a clarification of current policy, stating that QEs can perform these internal initial screenings. A more substantive policy change would be required if identifiable information could go to a researcher before consent, after limited QE filtering.

Mr. Check wanted to hear how the eight QEs would handle this. Ms. Sutliff proposed the QEs, Manatt, and NYeC meet to discuss how QEs would handle this sort of process.

Ms. Sutliff asked the Committee if they were comfortable with the concept of the QE completing the initial review internally and contacting providers directly. A large majority of attendees in New York City said yes. Mr. Levin asked the Committee if they supported the concept of the researcher receiving QE data, performing the review, and requesting that providers contact the individuals identified. Few attendees responded, and Ms. Sutliff commented the proposals would be sent back to the Tiger Team for review.

Mr. Dworkowitz introduced the third policy option, which would be that no affirmative consent would be required for retrospective review, if the researcher had IRB approval and QE Committee approval, and data suppliers have consented to the disclosure.

Mr. Check asked what would occur if the researcher finds actionable details in a retrospective review. Mr. Belfort confirmed the QE can release information back to the source, and could tell the provider who submitted the information about any such discoveries. Dr. Martin commented there must be review, similar to the SPARCS standard. Ms. Sutliff asked whether the requirement for the QE Committee review is enough in his mind, and Dr. Martin commented that it could be, but that if the QE Committee is to be relied on, then certain requirements should be

set for the composition of the QE Committee. Mr. Levin agreed it could be beneficial to require that there be certain skill sets around the QE Committee table. Mr. Check voiced the opinion that the QE board has the ability to define their own committee and felt this was not the role of the Policy Committee. Ms. Sutliff commented that the Tiger Team could draft a proposed definition of QE Research Committee that outlined basic guidelines for its composition. She believes this should move to the Tiger Team before reaching out to the QEs so that the QEs then would have something to respond to.

Dr. Martin suggested data use agreements should be required in all cases, and he raised the future need to decide how to handle these issues with SHIN-NY data, as this model is designed for the individual QE data. Dr. Martin added that the Tiger Team should also consider whether the list of approved projects should be publicly available.

Mr. Levin asked for the sense of the room regarding policy option 3, if SHIN-NY clarifies some requirements for QE board composition. A few attendees responded in favor of the proposal, with no one objecting.

#### **VIII. Proposed Changes to P&P Section 1.2.2(a) Public Health Reporting and Access/Q&A**

Ms. Sutliff gave Mr. Karmel the floor to discuss the proposed changes to P&P Section 1.2.2(a) and Project Ping. Mr. Karmel described the pilot program—if an HIV-positive individual who is not receiving treatment for HIV appears in person in the healthcare system, the provider he/she visits would be notified that the individual is HIV-positive and is not being treated, to provide an opportunity for the individual to be linked back into treatment. The current status is that the Ending AIDS Epidemic Grant ends September 30, 2018, but the pilot demonstrated that this is possible and positive, and the proposed changes would give the green light to begin this project. Currently, providers are able to request the information from DOH, but it is labor-intensive and it isn't automatic. This would automate the process.

Dr. Martin raised concern over distribution of HIV status justified only by the public health perspective, believing there is concern over distributing the information to providers who are not part of the care management process. Mr. Karmel noted we would do this for more communicable diseases if we had the data.

Mr. Allen said the key is that this would currently be allowed under public health law. The policy change is just to allow the alert via the QE. Ms. Sutliff said this is to clarify in the policies for SHIN-NY that a QE can do this. Mr. Karmel agreed.

Dr. Martin stated he is concerned about the lack of boundaries for this policy. A proposal was raised to add "SOLELY for the purpose of linkage and retention under..." Ms. Sutliff requested specific language suggestions to be sent to her.

#### **IX. Discussion of Proposed New Definition of 'Disclosure' for P&Ps**

Mr. Belfort introduced this as a technical change. Mr. Belfort explained that the SHIN-NY policies have been revised to distinguish between transmittals vs. access. The proposed change now is to add a new defined term that combines both "access" and "transmittal" so there is no need to refer to both. Instead, the word "disclosure" will be used. The HIPAA definition is used. Attendees approved with no concerns.

## **X. SHIN-NY 2019 Policy Agenda Areas of Focus Initial Discussion**

Mr. Levin asked the group to review the 2019 agenda. Ms. Sutliff said the policy priorities are in the agenda, and that these priorities work within the 2020 Roadmap, including identifying what policies and procedures need to be adopted or modernized. The internal planning team will come together to do some initial planning in order to present a proposed 2019 Policy Agenda to the Policy Committee at its December meeting.

## **XI. Closing**

Mr. Levin thanked the Committee and concluded the meeting at 3:50 PM.