

Quality Improvement Workgroup

September 8, 2010

Hosted via Webex

Participants: John Moeschler, Wendy Smith, Leah Burke, Tom Brewster, Patrick Miller, Monica McClain, Karen Smith (minutes); **Absent:** Rosemarie Smith, Mary Beth Dinulos, Mira Irons

Agenda:

- Updates by all
 - CPHS waivers
 - Business Association Agreements
 - PSO update
 - Next steps for next 3 months
 - Other items?
 - Schedule next meeting
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Patrick provided a brief update of the registry, which is all set to go. He and GVT (vendor) will resolve a few minor browser issues by tomorrow, but the form itself and the patient enrollment screen are complete. Sheila Upton at DHMC will back-enter John's forms. Next steps for development include a dashboard, more in-depth reporting module, and improved in-box functions. Patrick and Monica will meet this Friday re: language for BAA and IRB paperwork. Patrick asked that people continue to use the data sheet until we bring your site up electronically.

John reviewed progress to date regarding obtaining approval for the project.

Work on a Patient Safety Organization (PSO) has been "painfully slow".

- Dartmouth continues to consider it as they have for 10 months.
- ACMG has said (for 8 mo) they will be a PSO for purposes of MOC work they need to do; John is in contact with them but doesn't know how soon it will happen.

John is considering alternatives.

- establishing our own 5013C
- use ECRI as PSO
- work with **Committee for Protection of Human Subjects (CPHS)** at each institution

Background: The number of QI activities is on the rise. There is a concern that as they become large and global, they potentially become research. If one says the data will be research one day, it's considered research.

John applied to the CPHS at Dartmouth for a letter stating his data registry project is in fact QI work and not research. The committee agreed and provided the letter (sent earlier to the group).

John proposed getting a similar exemption letter from each participating site.

Leah noted she would like to use the same explanation John used in his request.

John will help others compose their requests to their own CPHS committees. He'll send around his application/materials, including these modifications:

- the project *does* include protected health information
- add these data points: first name, last name, middle initial, zip code (Patrick's recommendation allowing for more analysis, such as "females in Boston"; you will still never see a name)

It's important to be clear about the QI work and distinguish it from research. For the project, each entity is involved in its own QI activity. The registry holds the data and analyzes it on their behalf. Data can be shared across sites, but is not co-mingled. The letter gives clarity of relationship.

Establishing Business Association Agreements between institutions was another recommendation, by Michelle Winchester (attorney with expertise in health issues). This specifies the purpose for which the information will be used.

Patrick also suggests establishing HIPAA agreements. UNH already has one with GVT. Patrick is working with Dartmouth to establish one with UNH. As each Center moves forward, UNH will implement a BAA with the Center. We can work with the Centers' Privacy Officers or other appropriate staff and use the Dartmouth-UNH BAA as a model for language (forthcoming).

The group agreed to think of proceeding in parallel paths:

- 1) continue to develop PSO
- 2) apply for CPHS exemption letters / simultaneously work on Business Association Agreements
 - a. use language provided by John and the Dartmouth exemption and letter as an example
 - b. be ready to execute Business Assoc Agreement upon receipt of CPHS letters at each site
 - c. when letters are in place, use GVT technology to begin using registry

Wendy and Leah thought it made sense and wouldn't be a problem to get CPHS letter; working on the business agreement could be more of an obstacle (Patrick suggested talking to HIPAA privacy officer). Tom has less of a patient base as new referrals to a clinic so may not participate. John said Mary Beth is part of the Dartmouth activity; Mira wrote and said she doesn't see many referrals for DD but would be interested at the point they add other conditions.

Patrick will work with Monica about language to use.

Next face to face meeting

John, Wendy, Leah, and Rosemarie are going to ASHG meeting in November. Karen will help facilitate evening meeting for them on Thurs, Nov 3, from 6:30 -9:30. (This avoids overlap with other committee meetings on Wednesday eve.)