Breakout Session Questions

Panel A/ Breakout Session 1: Policies governing data access for personalization of care and research

1. Current policies limit access to, and the use of data for personalization of care. What policy modifications should we push for to clear this bottleneck?

   - For example, doctors can't look up the charts of patients who are not under their direct care. In order to personalize care based on what happened to people who resemble you the most (potentially including family members), we may require a change or clarification in the HIPAA privacy rule to allow front-line clinicians to use aggregate patient data for quality improvement purposes. Similarly, GINA gives special “status” to genetic and genomic information that precludes its use by insurers and employers. This could hinder personalization of care due to imposition of formularies, definitions of medical necessity, etc.

2. What policies are needed to handle the issue of consent for re-use of data for personalizing care and enabling research?

   - Some argue that informed consent should not be waived even in cases of clinical equipoise, the uncertainty within the expert medical community about the preferred treatment. Alternatively, others have argued that patients have a moral obligation to contribute to improving the quality of care in the system. Just as health professionals and organizations have an obligation to learn, patients have an obligation to contribute to and facilitate learning. How do we reconcile these opposing views at the policy level?

3. What should be the policy basis for providers, patients, and vendors to provide access data across medical records systems?

4. What incentives to patients and institutions might [overcome concerns around privacy and market share to] allow defining of cohorts across institutions?
Panel B/ Breakout Session 2: Policies regarding knowledge representation

1. Are policies and/or best practice guidelines needed for initial and future re-annotation and interpretation of genomic and other high volume data for clinical purposes, given that annotation and interpretation is expected to change as scientific understanding grows?

2. Are policies and/or best practice guidelines needed to support representing data and knowledge in electronic clinical systems in a manner that facilitates automated decision support logic as well as representation in human-readable (i.e., documentation formats)?

3. What is needed to incorporate the approaches from #1 and #2 in health IT environments so that knowledge can be applied for screening, patient management, tracking and reporting?

Panel C/ Breakout Session 3: Policies for data integrity and preservation

1. Are there current regulations or other policy issues that have the potential to affect the integrity and persistence of the data needed to achieve the goals of personalizing medicine?

2. Are policies needed to permit data needed for personalized medicine to be safely shared and accessible across ‘distributed platforms’ (Could be multiple healthcare systems, EHRs etc.)

3. What research is needed to identify policy gaps and barriers that impact persistence and integrity of the data needed for personalized medicine and how should this research be funded (or who should have primary responsibility for the funding)?