Scenarios used in breakout discussion sessions at 2012 European Summit on Trustworthy Reuse of Health Data, May 14-15, 2012.

First breakout: Opportunities and trust

Scenario 1

Children with attention deficit-hyperactivity disorder (ADHD) are frequently treated with medications that have simulant effects on the heart. Although these medications are generally thought to be safe, case reports from Canada and the United States included cases of sudden death, heart attacks, and strokes in children under treatment for ADHD. A retrospective analysis of multiple data sources including electronic health records, health registries, and pharmacies provided data for 1,200,438 children ages 2 to 24 was conducted to determine the risk of cardiovascular events for children taking ADHD medications.

Background

This scenario is adapted from an article N Engl J Med Nov 2011. Many believe that large clinical databases are necessary to provide evidence-based recommendations for rare diseases. This scenario also stresses the need for large data sets to analyze rare outcomes in relatively common clinical situations. In contrast to scenario #3 (which you will see on Tuesday) this type of analysis is not real time, involves the integration of multiple data sources that may not share any standards.

Questions for Breakout group

1) Could such a study be conducted across the EU?  
2) Will any single European country have enough patients for such a study?  
3) What are the barriers to conducting such a study?  
4) Should data from EHRs be centralized to facilitate such a study?  
5) Who needs to give permission for such a study?  
6) Who needs to give consent for such a study?

Second breakout: Governance

Scenario 2

A successful vendor of Electronic Health Records (EHRs) wants to develop new revenue streams while decreasing the costs to physicians of purchasing and maintenance of their EHR. Their idea is to sell the data collected by their EHRs and return some of the revenue as discounts or offsets to the initial purchase price or the ongoing maintenance costs of their EHR. Their plan is to ask the physician or office manager to participate in the program. If permission is granted, they will poll at midnight the EHR (via the Internet) and download an anonymized patient record for each patient seen during the previous day. The data will be aggregated and cleaned at central storage facility. The company will then seek commissioned studies for €50,000 on this dataset, thus avoiding the
transfer of data outside the company.

**Background**

This scenario is actually about an existing company in the United States. The discussion of monetization of data was the most difficult discussion we had in the two previous meeting in the United States. However, every time an item of data is moved from one location to another (e.g. a data transaction) money also moves. The infrastructure providers profit, the software providers profit, and the consumers of the data benefit. While we don't think about improved healthcare as a "profit," poor quality health care costs our society money. This example just makes explicit the monetization of data. Again the discussion will be uncomfortable for some and lively.

**Questions for the Breakout**

1. Should this be allowed?
2. Who needs to give permission to access the EHR?
3. Does the patient need to provide informed consent?
4. Should patients be aware their data is being sold?
5. Should any of the monetary benefit accrue to the patient?
6. How much is patient data worth?

**Third breakout: Policies that will facilitate reuse of health data**

**Scenario 3**

There is a new strain of Flu that has surfaced in China. There is growing concerns that it will spread through out Europe given the increase in trade and interaction with all parts of Asia - that coupled with the fact that there are more than 10 flights a day from China to De Gaulle, Heathrow and Frankfurt. The European Commission wants to set up bio-surveillance system that can aggregate all of the chief complaints and other clinical data from every emergency room across Europe, monitoring the information steams for "hot spots".

**Background**

In contrast to scenario #1 on Monday, this is a massive multinational undertaking (investment.) This scenario posess many technical and logistic problems not addressed in scenario #1. The data needs to be transmitted real-time and up-front standards need to be in place. In the United States such an undertaking has consumed over $250 million and still much work remains.

**Questions for the Breakout**

1. Can this be done (now)?
2. What policies would be needed to make this possible?
3. What challenges are there concerning multiple languages, systems, and data streams
4. Who's going to pay for the system?
5. Who governs the use of the collected data for other than public safety?
6. Who governs the re-use of the data gathered? Can the data be used for other purposes other than surveillance?

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