56th Meeting of the NCI Director's Consumer Liaison Group, February 22-23, 2011
Data Sharing, Privacy, and Informed Consent – Changing the Conversation

The DCLG heard from experts working on issues related to data sharing and approaches to gaining consent to share personal health data. The experts presented compelling arguments that data is not being collected or used optimally across the health care and research systems. Data is often collected by researchers or institutions that are unwilling to share the data or face technical challenges in doing so. Even when data is freely available, the overwhelming amount of information can make it difficult to find the specific data a researcher might need. The DCLG believes that researchers, patients, and advocacy organizations must work together to find workable solutions to these challenges that meet various stakeholder needs.

Informed consent and privacy are complicated issues, and approaches to dealing with these issues can greatly impact data availability for research. There is no standardized approach to consenting patients across the research enterprise. Additionally, privacy concerns result in the creation of a multitude of complex approaches to protect patient privacy. These interwoven issues hamper participation in research and limit data sharing, which ultimately results in unpredictable availability and quality of data for research purposes.

Most current conversations about consent and privacy focus on correcting the current process for collecting consent and protecting privacy. Though these efforts are critical, narrowly focusing the conversation can overshadow a similarly important conversation about existing opportunities for patients to contribute their health information to strengthen research efforts. There is a significant opportunity for the cancer advocacy community to lead the conversation with patients and researchers about how to continue productively and responsibly engaging research participants in unlocking untapped patient data resources for the research enterprise.

A critical component to reaching this goal is actively engaging current and future patients in research. Though there are many hurdles to engaging research participants, the DCLG members discussed the values that would need to be imbued in a data collection and sharing environment for them to encourage widespread participation among their constituents. Outlined below are seven underlying themes that surfaced during the discussion. The DCLG hopes that a broad discussion of these issues will highlight opportunities to promote the development of systems and procedures critical to creating a truly learning healthcare system that facilitates outstanding research and outcomes in the best interest of patients. Additionally, the DCLG believes that the dynamic data sharing environment that exists today must continue to evolve in such a way that promotes data availability for research and allows patients to acquire a greater understanding of and benefit from their data.

Considerations for Building Stronger Data Collection and Sharing Systems

Data as a Resource

Data is a critical resource in the research process as well as for patients to make informed decisions about their care. Given the enormous power of patient medical and genetic information to benefit the common good, promoting the widest responsible access of this data is in the best interest of current and future patients. There are huge amounts of medical and research data available, but it is frequently locked behind institutional barriers and can often only be accessed at a high financial cost, if at all. This does not promote the equitable use of the data for the greatest number of valuable purposes as is in the best interest of patients. Continuing to promote broader access to data while reducing barriers to achieving this access is critical for research and patients.

Data Ownership

Ultimately, data must be owned and maintained by a person or entity. Generally, the patient turns over ownership to the research institution because it is responsible for maintaining the data. It is reasonable to believe, however, that patients empowered with the ability to access and share their own medical data may be more inclined to actively seek opportunities to contribute that information to research efforts. It will be important to consider the dynamics created by pursuing models that challenge the current status quo. Creating a balance where data is well maintained while still allowing data sharing will likely require all parties to compromise in some way, but data sharing is critical and in the best interest of patients.

Interoperability and Portability

Data sharing efforts benefit when data systems are built to capture data in a way that promotes ease of exchange between systems and consistency in data captured. Ensuring such interoperability not only allows the systems to be responsive to current needs, but allows the systems to be responsive to evolving research needs.

When interoperability is achieved, portability can be maximized. When patients move between institutions, their information (whether used for research or patient care) is often difficult to transfer given a variety of approaches to records maintenance and sharing. Optimal data utilization requires that data captured in one environment can be easily moved to another at the request of the patient. This not only promotes data sharing but reduces errors, costs, and the burden on patients to manually enter the same information into multiple systems.

Transparency

Making data available for use by the broad research community requires that the existence of the data is widely known and information about its content and quality is accessible in a

systematic, predictable way. Developing approaches to increasing the transparency of data resources and where they are housed is incredibly important to promoting data sharing.

Reciprocity

Research participants are engaged in a reciprocal relationship with researchers. Generally, there is an expectation that the data will be used to promote goodwill and the best interest of patients, and researchers should always honor that. Beyond that, there are varying levels of expectation for what the research participant wants from the experience. This could range from a full report of the study data to a simple acknowledgement that the research outcomes were met. Additionally, research closely linked to clinical care has the potential to expose patients to the fruits of research earlier than in the past. Currently, however, very little is proactively shared with research participants. There is a need for a greater dialogue to define what a feasible response can and should look like, particularly in light of greater access to health IT.

Privacy

Patients agree to forego a certain level of privacy when consenting to participate in research. When considering privacy issues in research, there is the need to look beyond the technical aspects of data security. It is important to discuss what can be done to create a system where the intentions of researchers can be verified. Such a system must promote trust of and among researchers and reduce concerns of research participants. There are many feasible approaches to address this issue, but a consistent approach could create additional integrity throughout the data sharing environment and reduce burdens on researchers.