National Cancer Policy Forum Workshop

Enabling 21st Century Applications for Cancer Surveillance through Enhanced Registries and Beyond

Policy Opportunities for Advancing Progress

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Data Governance of “Registries”

- Registries are a tool that can be used for multiple different purposes – the uses and identifiability of the data drive, as well as ”who” is collecting/maintaining/using the registry, dictates current policy. For example:
    - HIPAA may apply if registries are used by “covered entities” or business associates
        - Treatment use cases vs. research vs. public health
        - Doesn’t apply to HIPAA de-identified data
    - State privacy laws
    - Common Rule (human subjects research rules) if research + identifiable data
    - NIH Guidance
- Guidance from regulators can help ease uncertainties around registry creation & use.

Patient Organizations Increasingly Driving and Funding Research

- Patient organizations expanding their roles, including developing patient registries and funding scientific research.

- Nearly 700 deals with an estimated aggregate value of $2.4 billion have been publicly announced between patient organizations and life sciences companies over the past 15 years.

- Following passage of the 21st Century Cures Act (2016), “seismic shift” in how patient organizations collaborate with life sciences companies and facilitate research.

Supporting Patients Through Research Collaboration: Interactions Between Patient Organizations and Life Sciences Companies, IQVIA Institute for Human Research (2023).

21st Century Cures Act (2016)

- “Interoperability” initiatives (Title IV) prioritized sharing of electronic health information:
  - Technical FHIR API requirements for certified electronic medical record technology
  - Prohibitions on “information blocking” (regulations from HHS Office of the National Coodinator for Health IT (ONC))

- Information blocking rules should unlock the sharing of electronic health information in major ways.

- Essentially, the rules establish penalties for interfering with the sharing of electronic health information for any legally permissible purpose.
  - Sharing with patients is a major priority of these initiatives.

Example: Citizen Health Platform

- Worked with the Leukemia and Lymphoma society to quickly power a study on the efficacy of COVID-19 vaccines in their patient community
  - Greenberger et al. “Antibody response to SARS-CoV-2 vaccines in patients with hematologic malignancies,” *Cancer Cell* (July 21, 2021) https://www.cell.com/cancer-cell/fulltext/S1535-6108(21)00389-5.

- Powering the research registry for the Cholangiocarcinoma Foundation
  - Abstract: Real world patterns of oncogenomic testing in cholangiocarcinoma: pilot of a novel study approach. *Mayo Clinic Individualizing Medicine Conference*.
- Working with patient advocacy groups to explore barriers to clinical trial participation. Increasing clinical trial participation of Black women diagnosed with breast cancer. *J. Racial Ethn. Health Disparities*. (2023)