DD19-1906 Capacity Building for Sickle Cell Disease Surveillance

Session 4: State Agency Engagement and Approval and Data Types

December 19, 2019
Acknowledgements

Sickle Cell Data Collection in Georgia is made possible by support from the Centers for Disease Control and Prevention (CDC-RFA-OT13-1302), and by support from the CDC Foundation with funding from Bioverativ, Global Blood Therapeutics, Pfizer, and the Doris Duke Foundation.

The content of this presentation is the sole responsibility of its authors and does not reflect official views of the Centers for Disease Control and Prevention, the Department of Health and Human Services, or other supporters.
General Lessons on Engagement

• Personal relationships with State Agency Officials are the most important asset in this work. Stay positive and flexible.
• Engage with program or other agency staff first to get their buy-in and understanding before engaging with *legal* teams.
• Do your best to meet with the right people before you start any official agreement process.
Engaging with State Public Health Agencies

• Multiple items to discuss with Public Health Agency Partners; may require more than one meeting.
• Public Health Authority to conduct SCD surveillance on their behalf.
  – Best contact is likely the State Epidemiologist or equivalent.
• Determine what state-level data (including identifiers) they already have access to for other public health activities (surveillance activities are the most relevant).
  – NBS, vital records
  – Possibly hospital/ER discharge data, Medicaid administrative data, State Employee Health Plan data, All Payer Claims data, etc.
• Discuss mechanisms already in place to have covered entities (including other State Health Agencies like Medicaid if they aren’t part of the same Department) report SCD cases based on State surveillance infrastructure.
  – Is SCD currently reportable? Is there a system in place to report other diseases and SCD could be added, etc.
• Discuss IRB needs for surveillance (this activity is exempt, but some States may still require an IRB application).
State Public Health Authority

- A “public health authority” is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. See 45 CFR 164.501.
HIPAA & Public Health Agencies

- The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to **protected health information** to carry out their public health mission.

- **General Public Health Activities.** The Privacy Rule permits covered entities to disclose protected health information, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. This would include, for example, **the reporting of a disease** or injury; reporting vital events, such as births or deaths; and **conducting public health surveillance**, investigations, or interventions. See 45 CFR 164.512(b)(1)(i).
Engaging Other Data Stewards

• For disclosures (under HIPAA) to a public health authority, covered entities may reasonably rely on a minimum necessary determination made by the public health authority in requesting the protected health information. See 45 CFR 164.514(d)(3)(iii)(A). For routine and recurring public health disclosures, covered entities may develop standard protocols, as part of their minimum necessary policies and procedures, that address the types and amount of protected health information that may be disclosed for such purposes. See 45 CFR 164.514(d)(3)(i).
Surveillance vs. QI vs. Research

• Giving the lead entity public health authority to perform SCD **surveillance** on behalf of the State is the most efficient and sustainable option because it gives all other data partners an official/legal way to share PHI with the lead entity.
  – In this scenario the State Public Health Authority actually owns the data.
  – This can be accomplished through a letter from a State Health official, a Business Associate Agreement, and/or a Data Sharing Agreement.

• Exemptions to HIPAA also include sharing data for quality improvement purposes and frequently this can be done with data collected for other purposes without engaging with patients directly; some may interpret this to mean that covered entities can only perform QI on the patients they serve not everyone in the State with SCD.

• If this activity is considered a clinical registry of all SCD patients then depending on how data will be collected it may be considered research and require patient consent.
Engaging with Medicaid Agencies

- Similar to other entities who steward administrative data like APDs or Hospital/ED claims.
- Probably need to target Medicaid Directors, Medicaid Medical Directors, a Data/Policy Director or another person who may have a personal relationship with someone on your surveillance team.
  - First approach is under surveillance if public health authority is granted
  - Second approach would be under a QI exemption
    - This will likely require the use of the lead entity’s IRB
Engaging with Health Service Providers

- **Contact with providers caring for SCD patients**
  - First approach is under surveillance if public health authority granted; through case reports or other mechanism that is standardized in your state.
  - Second approach would be under a QI exemption and will require a DSA and possibly a contract if funds are transferred.
    - Determine how data will be shared back with clinical reporters to help improve the quality of care for their patients.
  - Third approach could be under a clinical registry but would likely need patient consent...likely outside the scope of this project.
    - There are options for the clinical entity to share limited data from their registry with the lead surveillance entity and then partner on papers and QI projects under public health or QI IRB exemptions.
Data Types and Why You Might Want Them

California Sickle Cell Data Collection Program
Considerations for Data Sources to Include in Surveillance

- Programmatic goals
  - Incidence and prevalence
  - Access to care
  - Utilization of healthcare resources
  - Treatments and outcomes

- Resources needed
  - $$$
  - Time to request and wait to obtain
  - Personnel expertise and time (linking vs prelinked)
  - Storage/Software

- Accessibility of data
  - Public vs non-public
  - Availability/permissions
DATA TYPES AND SOURCES
Newborn Screening

- Incidence information
- Variables
  - Date of birth, sex, other identifiers
  - Genotype
  - Link to mother (findable in other data sources)
  - Link to hospital of birth
  - Geographic info
  - Pediatrician and/or hematologist referral info
- Universal in all states now (?) but info does not cross state borders
- Can be hard to access
- Identifiers can be hard to link (name changes, no SSN or MRN)
- Information typically only valid for first weeks of life
Administrative Health Care Data (Hospital Discharge, ED)

- Longitudinal
- Necessary for prevalence, healthcare utilization, treatment, outcomes
- Variables
  - Identifiers? and demographic
  - Dates of service
  - ICD codes
  - Procedure/treatment codes
  - Site of service
- Often a ‘public’ version with no identifiers available
- May be trackable over time with record linkage number
- Does not include outpatient care, drugs
Vital Records Birth

- More information about birth, setting, family, geography than NBS
- Variables
  - Identifiers? and demographic
  - Pregnancy information
  - Birth information
  - Newborn health status
  - Geographic
  - Parental information
- No information about diagnosis (happens after birth)
- Linkage can be challenging
Vital Records Death

- Confirmation of death
- Circumstances of death
- Variables
  - Identifiers and demographics
  - Circumstances of death
  - Cause of death (lots of errors or simplification)
  - Geographic information
  - Decedent’s history (employment, marital status, education)
- Diagnosis of SCD may or may not be included
- Linkage is simple
- Because deceased, obtaining of identifiers is typically simple
Health Care Claims Data

- Medicaid, Medicare, private payer, state health plans
- Necessary for outpatient care, Rx
- Adds significantly to prevalence information, outcomes, utilization, treatments
- Variables
  - Enrollment
  - Identifiers
  - All claim information (incl plan type, which may tell you more)
- Managed care may mean not all encounters and care are included
- May duplicate hospitalization/ED data
- May be challenging, time consuming, costly to obtain
Clinical Case Reports

- Additional source of genotype
- Assess access to quality care
- Variables
  - As you determine and clinical center agrees to
- May be unnecessary if complete data available from other sources
- DUAs can be challenging at clinical sites
- Cost?
Others

- Immunization
- Education/School
- Opioid Registry
- Social Services
- WIC
Mary Hulihan (CDC): ibx5@cdc.gov
Susan Paulukonis (CA): Susan.Paulukonis@cdph.ca.gov
Angie Snyder (GA): angiesnyder@gsu.edu

For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.