RuSH: Sickle Cell Surveillance and Registry Program

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Centers for Disease Control and Prevention
Outline

- Background / Goals / Partners
- Site Selection
- Data gathering / Data elements
- Evaluation of data collected
- Next Steps: Future expansion of Surveillance and Development of Registry
- Questions
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In the United States, SCD affects approx. 72,000 to 84,000 (104,000 to 138,900) or 89,000.

Among newborn American infants, SCD occurs in approximately:
- 1 in 400 Blacks
- 1 in 1,400 to 1 in 36,000 Hispanics
- 1 in 80,000 Whites

Over 3 million Americans have sickle cell trait:
- 1 in 12 (or 8%) African Americans

1 Hassell, K (2009) AJPM (in press)
Domestic Statistics

- The total healthcare cost associated with sickle cell disease is 1.1 billion annually (1)

- The number of hospitalizations among adults with sickle cell disease (SCD) in 2004 was 83,149 (2)

- The total hospital costs for hospitalizations principally for SCD were approximately $488 million (2)

- Among those hospital stays principally for SCD, 66 percent were paid by Medicaid and 13 percent were paid by Medicare (2)
Current Challenges

- Three decades shorter life expectancy
- Significant pain and other complications
- Growing population
  - More adults
  - Changing demographics
Current Challenges

- Unknown Prevalence
- Lack of access to specialty care/quality care especially for adults
- Lack of understanding of risk factors and complications over the lifespan
- Lack of understanding the overall impact and barriers to diffusion of effective interventions
- No national coordination of services
- Lack of community awareness
Stakeholders

- Federal Partners
- Sickle Cell Disease Association of America (SCDAA) and other SCD CBOs
- Thalassemia CBOs
- Post-ASPHO SCD Summit Surveillance Action Committee
- States
- SCD and Thal Consumer Community
A collaborative effort between NHLBI and CDC working with other Federal and state agencies

- Interagency agreement – CDC and NHLBI
- 4 year pilot project
- Two Phases: Planning and Implementation
- Phased implementation plan.
RuSH Objectives

- Develop a hemoglobinopathy surveillance system that will
  - Fill a need for generating statistically sound estimates and to store bio-specimens for use in genetic and genomic analyses
  - Provide data for population-based and clinical studies, health services planning, and policies
- Create an infrastructure that enables the development of registries to monitor health outcomes of hemoglobinopathy patient populations
- Establish a bio-specimen repository for hemoglobinopathies
Definition of Public Health Surveillance

“The ongoing systematic collection, analysis, and interpretation, of data on specific health events affecting a population, closely integrated with timely dissemination of these data to those responsible for prevention and control.”

- Centers for Disease Control and Prevention
Why do we need public health surveillance?

- Assess burden of disease
- Monitor trends in health
- Identify emerging risks
- Develop, implement, and evaluate disease control and prevention programs
Uses of Public Health Surveillance

- Planning of programs and services for SCD
  - Characterization of the affected population
    - Number of affected individuals
    - Location and types of utilized services/facilities
    - Spectrum of complication and issues experienced/services needed and gaps in services available
      - Nature and number of providers
  - The effectiveness of services, prevention efforts and intervention on populations
Objectives of Surveillance System

- To describe the ongoing pattern of disease occurrence and to link with public health action

- Primary
  1. Prevalence of hemoglobinopathies by genotype including patients not born in US
  2. Incidence of hemoglobinopathies using NBS data plus immigrants
  3. Demographics characteristics and geographic distribution
Objectives of Surveillance System

**Secondary**

1. Disease severity, co-morbidities, and chronic disease complications of persons with hemoglobinopathies;
2. Disease and treatment-related infections;
3. Reproductive and pregnancy outcomes of hemoglobinopathy patient populations;
4. Mortality rates, including case fatality rates for hemoglobinopathies and complications;
5. Health care utilization, costs of care, and the geographic variation of specific services
Committee and Working Groups for RuSH

RuSH States and Project Staff

Clinical and Laboratory Working Group

Data Harmonization Working Group

Community Partnership and Education Working Group

CDC/Division of Blood Disorders

CDC RuSH Oversight Committee

NIH/NHLBI

NIH RuSH Monitoring Committee
RUSH TIMELINE 2009 – Planning Phase

January
RuSH Steering Committee Meeting

February
RuSH

Stakeholder Calls
Analyzed RFI Responses

April
FOA for Surveillance Released

June
FOA’s recievied

July
FOA’s Reviewed

August
FOA’s Approved but unfunded

December
CDC – NIH IAA for RuSH

Ongoing

• Monthly CROC Meetings
• CDC Weekly RuSH Team Meetings
• Montly CDC-NHLBI Meetings
RUSH Steering Committee
January 13-14, 2009

Key Recommendations
- Learn from experience
- Avoid duplication
- Modify list of conditions
- Distinguish surveillance from registry approaches
- Considering state qualifications and readiness
- Consider and be responsive to the ethical, legal, and social issues (ELSI).
Community-Based Organizations (CBOs)/Advocacy Groups Panel - Themes

- CBOs should be involved early to start educational process and build trust with clients. They should also be apart of process throughout project.

- CDC needs to clearly articulate how RuSH will benefit the patient and their family.

- Avoid a paternalistic approach - patients need to be empowered and feel that their participation can make a difference in their families’ outcomes.
Local and State Health Partners Panel - Themes

- State infrastructure and capacity varies from state to state
- Lack of continuity of care makes accessing adult population difficult
- Participants emphasized that success of RuSH will rely heavily on CBO involvement and their ability to build trust between patients and providers
Request for Information Summary

- 6 responses
  - 4 from clinical care institutions,
  - 1 from a private non-profit business organization, and
  - 1 from a blood center.
- 5 respondents described 10 existing data sets
- 1 respondent described a database in the development process.
Request for Information Summary

- Populations:
  - SCD, SC trait, and/or abnormal hemoglobinopathies
  - One database included information related to family members.
- 8 data bases contained clinical information.
- 3 databases with linked biospecimens
- The biospecimen collections linked to data bases had specimens from 200-600 patients.
  - The data set with the largest no. of patients had information on approximately 3,500 patients.
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- Monthly CROC Meetings
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Funding Opportunity Announcement

- Two Modules
  - Module A: Surveillance of Hemoglobinopathies in States
  - Module B: Capacity Building and Surveillance of Hemoglobinopathies in States with a High Historically Underserved Population

- Eligibility:
  - State governments, territories, NYC and DC
  - Module A: All states
  - Module B: States with
    - 14% or more of population below U.S. poverty level
    - At least 20% or more racial/ethnic minorities
    - 14% or more of the population who are black or African American
FOA Activities

- Data collection and reporting
- Collaboration
- Data integration
- Dissemination of information
- Evaluation and progress reports
33% of African-Americans
44% of Asian-Americans
RUSH TIMELINE 2009

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RuSH TIMELINE 2010

January
- CDC funds 6 states from FOA

February
- CDC releases 2nd RuSH FOA.
- Awardee face-to-face meeting

March
- Phone Call Start with States

April
- Site visit - CA

May
- Site visit - CA

June
- FOA #2 Applications received
- Site Visit - MI

July
- Site Visit - GA
- New FOA Reviewed

August
- Working Groups Begin
- Site Visits - PA, FL, NC
- Steering Committee Meeting

September
- Funding for new FOA

October

November
- Hemoglobinopathy Learning Collaborative

December
FOA 2010

- State-based Surveillance for Hemoglobinopathies
- Applicants
  - New York
  - Ohio
  - Louisiana
  - Hawaii
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Collaborative Activities Year 1

- Refine state surveillance strategies
- Indicators and Case definition Discussion
- Minimal Dataset Development
- Data Linkage
- Develop Data Sharing and Dissemination Plan
Common Data Sources

- Newborn Screening
- Vital statistics birth and death files
- Medicaid claims
- Hospital discharge data
- Emergency department data
- Clinic-based data for individuals ever in care
- Program Service Data
- Registries
  - Immunization, Stroke, Birth Defects, Cancer
Unique data sources

- WIC
- Medicare
- Other Payers
- Data from CBOs
- Blood Banks
- School Health
- Registries

- Immunization, Stroke, Birth Defects, Cancer
Challenges for RuSH surveillance

- Case definition (who’s in the dataset?)
  - Thalassemia
  - Sickle cell
- Datasharing/data access
- ICD coding validity
  - Need for validation study
- Non-NBS population
  - Thalassemia in most states
  - Adults
- What indicators can you measure?
Working Group Composition

- 10-12 members
- Chaired by 1 member of RSC
- 1 member from each site/awardee
- Additional members selected by CDC and NHLBI based on expertise
  - Data Collection and Harmonization WG
  - Clinical and Laboratory WG
  - Community Partnerships and Health Education WG
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Collaborative Activities Year 2

- Plan Program Evaluation
- Surveillance Evaluation
- Data Validation
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Next Steps

- Fund next 2010 FOA
- NHLBI Nutrition and Diet in Surveillance and Registry Studies of Hemoglobinopathies Meeting
- Hemoglobinopathies Learning Collaborative
- Minimal Dataset Development
- Working Groups
  - Address Challenges
    - Development and refinement of case definition
    - Refinement of indicators
Questions?

http://www.cdc.gov/ncbddd/sicklecell/