Current State Policies and Practices: Storage and Use of NBS Samples

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Overview of Presentation

- Role of State Health Departments and the Legislature
- Authority Over Storage and Use
- Access
- Secondary Use
- Parent Education

Role of State Health Departments and the Legislature

- As of May 2010, laws and/or regulations in at least 18* states discuss storage *and* use issues to some degree
- CA, IN, IA, ME, MA, MI, MN, MS, MO, NE, NH, ND, OK, SC, TX, UT , WA, WI

* State policies that refer to storage and use of information or test results only without specifically discussing specimens not included

Role of State Health Departments and the Legislature

- Examples of Recent State Legislation Introduced
  - 2010 NH 1164 (Passed both chambers)
  - 2010 TN HB 3174/SB 3143
  - 2009 MN HF 1341/SF 1478
  - 2009 TX HB 1672 (Signed by the Governor)

Role of State Health Departments and the Legislature

- State Newborn Screening Programs Reported Length of Storage to the National Newborn Screening Genetics Resource Center – 1 month to indefinitely
- National Newborn Screening Information System (NNSIS)

http://genes-r-us.uthscsa.edu/

(See NNSIS, General Reports, Laboratory Specimen Information, Select 2009)

Authority Over Storage and Use

- Tools for providing the state health department with some control over and responsibility for storage and use
  - Ownership of residual dried blood specimens
  - General declaration of authority over storage and use or responsibility for developing a system to manage residual dried blood specimens

Authority Over Storage and Use

- Tools for providing parents/legal guardians/children over the age of 18 with some control over the storage and use of residual dried blood specimens
  - Consent for research use
  - Dissent for research use
  - Allow storage of specimen but not for research use
  - Request destruction of specimen
  - Request return of specimen

Access

- After the newborn screening process, state laws and regulations may allow the following to access specimens:
  - State health department
  - *Approved* researchers
  - Other approved entities

Access

- HOWEVER, the type of information available in conjunction with research use varies:
  - Anonymized
  - Coded, Double-blinded
  - Personally identifiable information with consent
  - Personally identifiable information with justification in approved study proposal

Secondary Use

- Types of allowable research range from:
  - Newborn screening-related research
  - Research on maternal and child health issues
  - Public health research
  - Medical research

Secondary Use

- Examples of state practices
  - Michigan – Community Values Advisory Board
    - "1) studying the incidence of different gene variants for an inherited condition (hereditary hemochromatosis); (2) developing additional laboratory screening methods (sickle cell diseases); and (3) searching for new disease markers (childhood leukemia)" Q & A Newborn Screening Dried Blood Spots and Michigan's Biotrust Initiative, http://www.michigan.gov/documents/mdch/FAQbooklet_269087_7.pdf

Secondary Use

- Minnesota
  - http://www.health.state.mn.us/newbornscreening/research.html
  - Newborn screening studies (quality assurance/quality improvement for existing tests and evaluation/feasibility of new screening tests)
  - Non-newborn screening studies

Secondary Use

- Texas
  - Quality assurance and quality control
  - Research Uses
    - http://www.dshs.state.tx.us/lab/nbsBloodspotsUse.shtm
    - Information on studies from 2001-2010

Parental Education

- Information provided to parents may include:
  - No information although health department is authorized to store and use residual dried blood specimens
  - Notification that specimens may be stored and used for secondary purposes
  - Options for parents regarding storage and use of specimens
  - Information on the benefits of storage and use of specimens

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