Providing Newborn Screening Specimens for Research

Legal Issues Faced by State Health Departments

Session 6
September 27, 2012
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Agenda

- Speaker Introductions
- Wrap up of Series
- Recap - Sessions 1 - 5

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Speaker Introductions

Fred Lorey, MS, PhD

- Chief, Program Development & Evaluation branch, Genetic Disease Screening Program, California Department of Public Health
- College of William and Mary
- University of California at Davis
- ACMG, SIMD, ASHG
- SACHDNC, NBSTRN
Speaker Introductions

Aaron Goldenberg, PhD, MPH

- Assistant Professor, Case Western Reserve University, Department of Bioethics
- Assistant Director, Center for Genetic Research Ethics and Law
- Co-Director, Bioethics Masters Degree Program, CWRU
Speaker Introductions

Michelle Huckaby Lewis, MD, JD

- Berman Institute of Bioethics
- Genetics and Public Policy Center
- Research on retention and use of NBS samples
- Capitol Hill
- White Task Force on Health Care Reform
- Johns Hopkins and Georgetown
Sessions 1 - 2

- Newborn Screening Translational Research Network (NBSTRN)
- Issues surrounding newborn screening and secondary use of specimens
- Existing state laws and public opinion about residual dried blood spots
- Biorepository development and the role of “the honest broker”
- State laws governing ownership and control and genetic privacy
- Impact of current legislation/ litigation on Public Health programs
- Clinical Utility of retained specimens after screening and diagnosis
Sessions 3 - 4

- HIPPA regulations and requirements for consent and de-identification
- Application of general principles to specific concerns re DBS and research
- Management of privacy in a large Public Health program
- Federal regulations and governmental protection of human research subjects
- Michigan BioTrust for Health
- Common Rule – Advanced Notice of Proposed Rule Making
Introduction to the issues
Models: (Charitable trust, Open results, Shared ownership)
Advocacy-run biobank
Considerations from Massachusetts experience
Key Considerations

- NBS most successful public health endeavor in the US
- Informed utilization of de-identified DBS provides the basis for scientific investigation to improve NBS and to ensure continued QA/QI for state public health laboratories
- Continuation of NBS must be guarded by appropriate concern for bioethical and legal issues, while promoting studies to improve understanding, prevention and management of heritable disorders
Webinar Series

http://www.networkforphl.org/newborn_screening/
Or from www.nbstrn.org
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Definitions and Abbreviations

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<th>Term</th>
<th>Meaning</th>
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<tr>
<td>CBDMP</td>
<td>California Birth Defects Monitoring Program</td>
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<td>CDPH</td>
<td>California Department of Public Health</td>
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<td>MCAH</td>
<td>Maternal, Child and Adolescent Health Division</td>
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<td>GDSP</td>
<td>Genetic Disease Screening Program</td>
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<td>PNS</td>
<td>Prenatal Screening</td>
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<td>NBS</td>
<td>Newborn Screening</td>
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Birth Defects Monitoring Program Background

- The Birth Defects Monitoring Program is located within the Center for Family Health’s, Maternal, Child and Adolescent Health Division.
- The mission of the Division is to:
  - develop systems that protect and improve the health of California’s women of reproductive age, infants, children, adolescents and families.
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History

- 1980-1982 - NBS DBS stored at -20C without any data link
- 1982-present – NBS DBS stored at -20C and dessicated with unique identifier code only
- Currently 16 million NBS DBS
- 2008: Legislation introduced to begin storing portion of prenatal maternal serum samples
- Currently approximately 1 million serum samples stored
- 2012 – move of NBS DBS to new facility with automation
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History

- Until 2008, authority for use of DBS for anonymous research was located in California Health and Safety Code
- The code also stipulates the DBS become the property of the CDPH when testing is completed.
- Parents have an opt out choice to have their child’s specimen marked not for research or to be destroyed upon written request.
- HIPPA requires that the program be able to identify if a specimen has been used in anonymous research. This is tracked in database.
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(g) The department, health care providers, researchers, and local health departments any entities approved by the department, and researchers shall maintain the confidentiality of patient information and blood samples in accordance with existing law and in the same manner as other medical record information with patient identification that they possess, and shall use the information only for the following purposes:

(1) Research to identify risk factors for children’s and women’s diseases.

(2) Research to develop and evaluate screening tests.

(3) Research to develop and evaluate prevention strategies.

(4) Research to develop and evaluate treatments.

(h) (1) For purposes of ensuring the security of a donor’s personal information, before any blood samples are released pursuant to this section for research purposes, the State Committee for the Protection of Human Subjects (CPHS) shall determine if all of the following criteria have been met:
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Newer Biobank Regulations Introduction

- In 2008, new legislation added storage and use of prenatal maternal serum specimens and updated all research regulations including newborn screening or any other blood samples.

- The regulations cover requests for:
  1. newborn blood spots,
  2. pregnancy blood samples,
  3. and/or any associated data.
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Perinatal Biobank Regulations - Executive Summary

- California maintains a large and diverse Biobank of pregnancy and newborn blood samples and data.
- California has the potential to establish a renowned biomedical resource, contributing to advancements in medical knowledge and therapies.
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Perinatal Biobank Regulations - Executive Summary

- California’s specimen bank is unique:
  1. No other state compares in number & quality of specimens collected.
  2. Potential linkage with statewide prenatal screening program data, birth defects data, developmental disabilities data, and cancer data.
  3. Only large historic repository of blood from pregnant women available to researchers.
  4. Represents a culturally, geographically and genetically diverse population.
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Perinatal Biobank Regulations - Executive Summary

- It is the duty of the California Birth Defects Monitoring Program and the Genetic Disease Screening Program to:
  1. Establish guidelines for invoicing, charging, and collecting from approved researchers an amount necessary to cover certain expenses associated with research application requests including:
   a. data linkage,
   b. retrieval,
   c. data processing,
   d. data entry,
   e. re-inventory,
   f. shipping of blood specimens
   g. data management.
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Perinatal Biobank Regulations - Executive Summary

2. Adopt regulations specifying the protocols and conditions under which blood specimens will be released for research purposes;
3. Establish fees to be collected from researchers for provision of specimens and data.

“Assembly Bill (AB) 2599 (De Leon), Chapter 680, Statutes of 2008”
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Perinatal Biobank Regulations - Executive Summary

- Governor Schwarzenegger has recognized the importance of Newborn and Prenatal repositories and has ordered that GDSP and CBDMP:
  1. make these resources available to researchers,
  2. and recoup costs already being expended for processing and storage of these specimens.
- To comply, CDPH needs to establish regulations to implement and establish protocols for releasing blood to researchers.
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Executive Summary Protocols

1. The protocols must:
   a) comply with current federal and California state statutes and regulations,
   b) must establish guidelines for charging fees,
   c) address issues of research feasibility,
   d) address issues of research approval,
   e) and insure subject confidentiality, privacy and consent.
Questions & Answers About the Storage of Newborn Screening Bloodspots

- Why is my baby’s blood spot collection card stored by the Genetic Disease Screening Program (GDSP)?

The main reason GDSP stores the used blood spots is to develop new tests to add to the newborn screening testing panel and to provide quality control for testing on an on-going basis. When the Newborn Screening Program began in the early 1980s, we tested for 3 disorders. The stored specimens were used anonymously to develop the new tests, which now number over 80. Newborn Screening blood spot cards are not “DNA cards”. Your child’s DNA is not analyzed for our initial screening tests and his/her “DNA profile” is not stored. There is no personal information on the dried blood spot card, only a unique non-identifying number.
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What if I do not want my baby’s blood spot collection card used by the Genetic Disease Screening Program? What are my options?

- Why is my baby’s blood spot collection card stored by the Genetic Disease Screening Program (GDSP)?

If you decide not to allow the GDSP to store your child’s dried blood spot, you may request that the specimen not be used for research by our laboratory. Please submit this request in writing to: Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Richmond, CA 94804.
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Aaron Goldenberg, PhD, MPH
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Bottom Line
- NBS important and primary purpose for collecting DBS
- Distinguishing NBS and secondary uses
- Law, ethics, and policy must all be considered
- Proceed cautiously
- Protect NBS
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State Law & Secondary Uses

- Consult state law regarding retentions, uses, requirements, protections
  - Include laws regarding NBS, genetic & health information privacy, data, discrimination
- Great variability among states
- Few states have addressed secondary uses comprehensively
- Strong policies needed
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Federal Law & Research Using DBS
- Federal protections human research subjects
- HIPAA privacy rule
- De-identified data
  - Research that might harm/is objectionable to a group
  - Proposed changes to Common Rule
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ANPRM-Proposed Changes to the Common rule

- “Reforms would require written consent for research use of biospecimens, even those that have been stripped of identifiers. Consent could be obtained using a standard, short form by which a person could provide open-ended consent for most research uses of a variety of biospecimens”  
  (From HHS ANPRM Table-hhs.gov)

- Implications for Newborn Screening Programs and other public health efforts that collect samples that may be used for research bloodspots may be released for anonymous research without parental consent in a number of states.

- Concerns about potential effects on NBS generally
Recommendations -- Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children

- To States - Policies reviewed by legal counsel that address:
  - Access to DBS, including after NBS test completion
  - Disposition of dried blood specimens remaining after NBS
  - Procedures for secondary uses that are transparent and comply with applicable laws
  - Procedures should include consent or dissent requirements and privacy protections
  - All state NBS programs have proactive education programs to educate parents, healthcare providers, and the public about NBS and potential uses of DBS
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Recommendations -- Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children

- To HHS Secretary -
  - Improve efforts to educate public and healthcare providers about NBS and the retention and use of specimens
  - Facilitate national dialog to develop national standards for retention and secondary uses, consent or dissent, and privacy protections.
  - Explore the utility & feasibility of establishing a voluntary national repository of residual dried blood specimens, in which parents may choose to participate
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Parental Attitudes
- Studies, surveys of parents
- Portrayal of parents’ attitudes in media
- Addressing parents’ fears
  - Discrimination
  - Privacy & security
  - Improper use
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Privacy Protections

- Consent
- De-identification
- Anonymize DBS
- Honest brokers
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Consent

- Ownership & control of specimens
  - Donated tissue cases: Moore, Catalonia, Greenberg, Havasaupi Tribe
  - NBS DBS cases: Bearder (MN) & Beleno (TX)
- Informed consent ("opt-in")
- Dissent ("opt-out")
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The Community

- Transparency
- Stewardship
- Trust
- Education & dialogue
- Public asset to benefit community
  - Defining & measuring
  - Reciprocity
  - Control of results of research, commercial products
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What do you think?

- What challenges do you face?
- What questions do you have?
- What resources would be helpful to you?
- Are there further webinars that you recommend?
- After the webinar is completed, with these question in mind a survey will load in your web browser
Michelle Huckaby Lewis, MD, JD
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Overview of Litigation Re DBS Retention and Use - Texas

- Families brought a class action lawsuit against state DOH on behalf of all infants born in state
- Claimed that the practice of retaining and using de-identified DBS w/o explicit parental consent violated constitutional right to privacy and right to be free from search and seizure
- When lawsuit was initiated, no consent req’d and parents not given option to refuse
- New law passed to implement opt out procedures
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Texas

- Parties settled-part of settlement agreement was to destroy 5 million DBS
- Then it was reported that DOH had given samples to U.S. Armed Forced Pathology Lab
- Plaintiffs claimed that this information had been withheld from them during settlement negotiations
- A second lawsuit was filed-held to be moot b/c law had changed
- Tx law changed again, now requires consent
- Legal issues never adjudicated
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Minnesota

- Bearder v. State of Minnesota
- 9 families sued state alleging multiple claims
- Plaintiffs initially lost at district court level and on appeal
- Minnesota Supreme Court held that state practice of retaining DBS and using them for secondary research w/o explicit parental consent violated genetic privacy provisions of state data practices act (opt out mechanism was not ok)
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**Minnesota Genetic Privacy Act**

- GPA restricts the collection, use, storage and dissemination of blood samples collected pursuant to nbs statutes
- Ct held that “an individual’s blood samples are biological information subject to protection” under the GPA
- DNA w/I sample that brings sample w/I protection
- Genetic info includes the biological info itself, not just the analysis of the info
Impact of Decision

- QA: commissioner’s power to conduct health studies does not include unlimited authority to use genetic info obtained fr newborns for screening purposes in those health studies.
- “Use of genetic information for purposes other than the screening of newborn children and for follow-up services requires informed consent.” can’t peform qa activities w/o consent
- Only dissemination permitted is reporting of results
- Remedies-only impact families in that lawsuit.
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Concerns of Plaintiffs

- 1st line of Bearder memorandum: “Defendants violated the public’s trust and violated the public’s right to privacy and bodily integrity.”
- “MDH will do whatever it wishes to effect what it assumes is best for the public.”
- “Plaintiffs fear the use of their blood specimens and test results by government and private entities for unknown purposes.”
- Bearder: objected to Mayo being allowed to keep DBS and perform its own tests on them
Concerns of Plaintiffs

- Objected to Mayo being able to keep results-so DBS AND results
- “This lawsuit is not about ending newborn screening.”
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Minnesota Concerns

- Plaintiffs do not distinguish between QA and research—include QA in research activities that state had undertaken with DBS
- De-identification of samples—Did not matter that DBS were de-identified, argued that the law does not require that the information be about an identifiable individual—need consent even if de-identified
- Plaintiffs said not clear what state means when it says samples have been de-identified—de-identification process and standards not defined
- Concerned that state kept the link, concerned about possible re-identification, did not want state at Honest Broker
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Minnesota Concerns

- Impression that DBS were being sold to private 3rd parties
- Argued that plaintiffs had a property right in their genetic material—but conceded no precedent in Minnesota
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Beleno concerns

- Samples stored “for purposes of undisclosed research unrelated to the purposes for which the infants’ blood was originally drawn, without the knowledge or consent of the infants’ parents.”
- Defendants “never disclosed specifically the purposes or methodologies of such research other than that they are unrelated to the purpose for which the infants’ blood was originally drawn.”
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Beleno continued

- “Plaintiffs are concerned about the potential for misuse of that information and fear the possibility of discrimination against their children and perhaps even relatives through the use of such blood samples and research activities theron.”
- Under current policy, state can use DBS for “cancer research, lab equipment calibration, and other undisclosed matters indefinitely, without the knowledge or consent of their parents.”
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Beleno Pleadings

- Violates “standard, mandatory medical research protocols of first obtaining informed consent from subjects before they are studied.”—but de-identified samples are not considered human subjects research & federal human subjects research protections do not apply
- “Nor have they disclosed what kind of financial interests or transactions are involved, such as taxpayer expense or whether the samples are sold.”
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Beleno Pleadings

- Asked court to compel state to disclose for what purpose they used the DBS of plaintiffs’ children and of the class and disclose all financial transactions.
- Wanted to know what happened to their children’s DBS
- “Plaintiffs do not object to the state’s mandatory newborn screening program so long as safeguards are in place to destroy an infant’s samples within a reasonable period of time.
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From Press Release of Bearder Attorneys

- “Discovery also revealed that a number of proposed contracts for testing of the retained newborn blood samples would potentially benefit third-parties through the right to benefit from commercial applications of their research.”
- “Insisting on written, informed consent for storage and research on newborn blood and DNA continues to be a paramount concern in this day and age where the medical industry is willing to put profits ahead of privacy.”
- “Once the government has control of blood and DNA, there is not telling what may ultimately happen to it.”
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Minnesota Class Action Suits

- Anderson v. State of Minnesota
- Skaja v. State of Minnesota
- Suing for injunctive relief (to require “enforcement of the prohibition on the storage, use, and dissemination of genetic information, w/o informed consent”) and recovery of damages incurred as a result of DOH’s unlawful conduct
- Allege that the state “conducted tests and other research on the Plaintiffs’ genetic information after the initial screening of the blood samples for diseases without obtaining Plaintiff’s written consent.”
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Minnesota Class Action Suits
- This could include pilot studies
- Allege damages greater than $50,000
- Exemplary damage of $1,000-$15,000 for each violation of the GPA.
Concluding Thoughts

- These activists have been extremely successful-at persuading courts and legislatures.
- Activities have been harmful to nbs programs.
- These issues are not going away.
- States need to take their concerns seriously.
- Many instances, reflect lack of understanding, but this points to greater need for transparency and education about QA and research enterprise.
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Question and Answer

Please use the dialog box on the webinar to submit questions
For information about how to pursue continuing education credits for your attendance at this webinar, contact:

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Thank You

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