Providing Newborn Screening Specimens for Research

Legal Issues Faced by State Health Departments

Session 1
April 26, 2012
Agenda

- NBSTRN Overview and Introduction
- Speaker Introductions
- Session 1 Topics

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Goals of the Hunter Kelly Newborn Screening Program

- Identify, develop and test the most promising technologies
- Increase the specificity of newborn screening and expand the number of conditions for which screening tests are available
- Develop experimental treatments and disease management strategies for additional NBS conditions, and other genetic, metabolic, hormonal and or functional conditions that can be detected through NBS for which treatment is not yet available
The mission of the Newborn Screening Translational Research Network (NBSTRN) is to improve the health outcomes of newborns with genetic or congenital disorders by means of an infrastructure that allows investigators access to robust resource for newborn screening research.
Scope of Work

1. Network of State NBS Programs and Clinical Centers
2. National Research informatics system
3. Repository of dried blood spots (virtual)
4. IRB, consent, policy expertise and support
5. Facilitate research on new technologies
6. Facilitate research on effectiveness of treatments and long-term outcomes
7. Statistical leadership and clinical trial design expertise
8. Facilitate timely dissemination of research findings
9. Recruit steering committee to make recommendations
Speaker Introductions

- Bradford Therrell, Jr, Ph.D.
  - Director, NNSGRC
  - TX Dept of Health Bureau Laboratories
  - Professor, Department of Pediatrics, University of Texas Health Science Center at San Antonio
  - ISNS
  - SACHDNC
Speaker Introductions

- Michelle Huckaby Lewis, M.D., J.D.
  - 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
Speaker Introductions

- Denise Chrysler, J.D.
  - University of Michigan School of Public Health, Network for Public Health Law – Mid-States Region
  - Michigan Dept of Community Health
  - Michigan BioTrust for Health
  - Community Values Advisory Board
  - NBSTRN
Session 1 Overview

- Newborn screening and secondary use issues
- Challenges in storing and using residual dried blood spots
  - Role of the law, state variations, public concerns
- Case example – how Michigan has handled many of these issues
- Questions and Answers
Introduction to Newborn Screening and Biobanking

Bradford L. Therrell, Jr., Ph.D.
Professor/Research, Department of Pediatrics
University of Texas Health Science Center at San Antonio
Director
National Newborn Screening and Genetics Resource Center
Presented: April 26, 2012
Brief Review of Newborn Screening Situation in the US

- State Based – No National Law
- Policies are not harmonized – 51 Different Programs
- National recommendations – Sec. of Healths Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC)
- Recommended core panel of 31 conditions (incl. SCID + CCHD)
- Secondary panel – 26 conditions (incl. other T-cell abn.)
- Various others conditions tested at state discretion – LSDs, Toxoplasmosis, HIV, G6PD
Brief Review of Newborn Screening Situation in the US

- Two screens are required in 9 states and strongly required in several others (~25% of newborns receive a required second screen)
- Conditions required vary
- Methods of financing vary including fees and reimbursements from Medicaid
- Infrastructures vary
- Laws, rules and regulations vary
- Residual blood spot storage, retention and use policies vary
U.S. Newborn Screening Requirements – 2011
(Ascending Number of Required Disorders)
U.S. Newborn Screening Fees – 2011
(Ascending Number of Required Disorders with Fees Overlaid and Normalized)
Current Newborn Screening Residual Specimen Storage in the U.S.
~ 44% Newborn Pop. Stored for ≥20 yrs. (14 jurisdictions)

~ 56% Newborn Pop. Stored for ≤ 5 yrs. (37 jurisdictions)
Storage, Retention and Use of Residual Dried Blood Spots

Overview of the Issues

- Storage of residual DBS by screening labs
- Retention times for residual DBSs
- Uses of residual DBSs (and the restrictions)
- Policies impacting dried-blood spot (DBS) use (privacy issues)
- Public relations: media, parents (privacy issues)
- National (multi-state?) DBS repository: actual or virtual?
Newborn-Blood Storage Law Stirs Fears of DNA Warehouse

By Alexa Meneghini

An obscure bill that sailed through Congress and was signed into law last month is sparking fears of a nationwide DNA warehouse potentially open to abuse by law enforcement agencies or health insurance companies.

The Newborn Screening and Genetics Act of 2000, H.R. 2875, N.Y. S. 398, signed into law on April 24, empowers a committee to provide guidelines to all states on how — and for how long — they should store blood, if present, of newborns born in the state. The act requires that the guidelines be reviewed and revised at least once every five years. The act also establishes a national database of newborn screening results.

The legislation was prompted by the 1998 report of the Institute of Medicine, which found that newborn screening for genetic disorders is widely underutilized and that more information is needed to improve the accuracy and effectiveness of screening programs.

The Newborn Screening and Genetics Act of 2000 establishes a national database of newborn screening results. The law requires that newborns be screened for a variety of genetic disorders and that the results be reported to a central repository.

The law also requires that newborns be screened for a variety of infectious diseases, including hepatitis B and HIV. The act also provides for the development of an electronic medical record system that will allow health care providers to access newborn screening results electronically.

The Newborn Screening and Genetics Act of 2000 has been hailed as a significant step forward in the field of newborn screening. The law has been praised for its comprehensive approach to newborn screening, which includes federal funding for research and education, as well as the establishment of a national database of newborn screening results.

The law has been controversial, however, because of concerns about privacy and the potential for misuse. The American Academy of Pediatrics has called for strict safeguards to protect the confidentiality of newborn screening data.

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Texans unknowingly donate children's blood to research

Medical privacy advocates, ethicists say parents should be asked for consent before newborns' screening samples are kept.

By Mary Ann Roser
AMERICAN-STATESMAN STAFF

Sunday, February 22, 2009

For almost seven years, the state has been indefinitely storing blood from nearly all newborns in Texas without their parents' consent for possible use in medical research.

The blood is collected as part of a 44-year-old state-mandated newborn screening program in which hospitals, birthing centers and midwives draw blood from a baby's heel — parental consent isn't required for that, either — so the state can test for a host of birth defects. The state either discarded the blood after six months or, more recently, stored it for three years before destroying it.

But starting in 2002, the state health department began collecting and keeping blood indefinitely for current or future medical research, a practice that has been the subject of a legal challenge in Minnesota.

Five dots of blood are collected on paper for the screening and then stored.

Under the health department's policy, the samples can be used by the medical community for things like cancer research, birth defects studies and calibration of lab equipment, said Doug McBride, spokesman for the Department of State Health Services.
“Whole blood absorbed into filter paper and then dried offers an excellent means for creating a repository (bank) of samples for DNA investigations.”

These guidelines provide scientific information for policy development by state health departments considering appropriate use of newborn screening specimens after screening tests are finished. Information was collected, debated, and formulated into a policy statement by the Newborn Screening Committee of the Council of Regional Networks for Genetic Services (CORN), a federally funded national consortium of representatives from 18 regional genetics networks. Newborn screening programs vary widely in approaches and policies concerning residual dried blood spot samples (DBS) collected for newborn screening. Recognition of the epidemiological utility of DBS samples for HIV seroprevalence surveys and a growing interest in DBS for DNA analysis has intensified consideration of issues regarding retention, storage, and use of residual DBS samples. Potentially these samples provide a genetic material “bank” for all newborns nationwide. Their value as a resource for other uses has already been recognized by scientists, administrators, and judicial officials. Programs should promulgate rules for retention and use of residual newborn screening DBS samples based on scientifically valid information. Banking of newborn samples as sources of genetic material should be considered in light of potential benefit or harm to society.

BACKGROUND

The Council of Regional Networks for Genetic Services (CORN) is a federally funded project to improve the quantity, quality, and availability of cost-effective genetic services in the United States. CORN was developed in 1985 in response to the need for an organization that could coordinate activities among federally funded genetic service networks encompassing the entire United States and could implement programs of national significance that emerge from regional initiatives in priority areas such as quality assurance, data collection, and education. Two delegates from each of the 30 defined networks serve on the CORN steering committee with additional representation from the Alliance for Genetic Support Groups, national sickle cell disease programs, and certain other organizations involved in genetic services. CORN members constitute a unique organization of genetic service providers, public health personnel, and consumers. In its goals...
Some Reasons for Retaining Residual DBSs:

- Reconfirmation of newborn screening analytical results
- Legal accountability (e.g., number of punches taken for analysis, the existence of a sample and its adequate collection)
- New method evaluations and comparisons
- Epidemiological or other public health surveys
- Special health related studies for patient or family
- Forensic studies
- Future DNA testing

“Additionally, storage and secondary uses have been documented to occur without parental consent.”

“In the absence of uniform guidelines there is an urgent need to develop policies that address the issues of DBS storage and their secondary uses, and the ensuing ethical, legal, and social dilemmas.”

Storing Newborn Blood Spots: Modern Controversies (2004)

Linda Kharaboyan, Denise Avaré, and Bartha Maria Knoppers

Storage Newborn Blood Spots:

Modern Controversies

Through in existence for over thirty-five years, due to the increasing panoply of possible tests. Newborn screening programs are drawing public attention. Many jurisdictions have mandatory newborn screening programs for treatable disorders. Disorders are detected through tests on blood spots drawn from a newborn’s heel soon after birth and verified through a diagnostic test with follow-up. Unfortunately, most parents, these blood spot cards are also stored thereafter. Indeed, while dried blood spots (DBSs) are primarily used for screening for health problems, experience demonstrates that they can be made useful in various contexts unrelated to screening.

Newborn dried blood spots have taken on a new life as a result of developments in genetics and the increasing ability of bioinformatics to link DNA information with clinical data. Additionally, storage and secondary uses have been documented to occur without parental consent. In the absence of uniform guidelines, there is an urgent need to develop policies that address the issue of dried blood spot storage, secondary use and the ensuing ethical, legal, and social dilemmas.

Internationally, regionally, and nationally, governmental, professional, and consumer organizations have contributed to the debate on the storage and retention of newborn screening residual blood samples. Despite all these efforts, a consensus of opinion on any one issue has yet to be reached. We will compare current guidelines and policy documents that apply to banking DBSs and assess the similarities and differences as concerns consent to storage, length of storage, and access to stored samples. Our comparison examines countries from different regions of the world and offers different socio-political contexts for examining the rationale for storage and issues of confidentiality and consent. As novel uses of newborn spots emerge, and as researchers and public officials contemplate mechanisms for the retention of DBSs by newborn screening laboratories, it is crucial to outline current purposes and lengths of storage and adequate consent requirements for the secondary uses of archived blood spots in research or otherwise.

Banking Residual DBSs: Purpose and Length?

Purpose of Storing

Since the late 1960s, newborn screening to detect congenital metabolic disorders has been standard paediatric procedure in newborn care in most industrialized countries. Early detection of pre-symptomatic disorders such as Phenylketonuria (PKU) and Congenital hypothyroidism (CH) has prevented chil-

Residual Newborn Screening (NBS) Specimens

A statement of position:

- Residual Dried blood spots are a valuable national resource that can contribute significantly to the health of children.
- NBS blood spots are stored with rigorous control and respect for privacy and confidentiality.
- “Parents should have the option to have their child’s specimen stored in a national repository for research.”

Source: http://www.acmg.net
Danish Biobank

Statens Serum Institut
Copenhagen, Denmark
Danish Biobank
-20 deg C with desiccant

Bent Norgaard-Pedersen
Statens Serum Institut
Copenhagen, Denmark
Blood Spot Biorepository
Michigan BioTrust for Health
Thailand NBS Biobank

Source: Wiyada Charoensiriwatana - 2011
Armed Forces DNA Repository

- Includes specimens from all branches of the armed forces & coast guard
- Includes mission specific DOD employees and civilian contractors
Repository Samples Used for Pentagon Victim Identification

Victims
Army: 24 (18)
Navy: 36 (28)
Civ: 65 (2)
AA #77: 64 (1)
Total: 188 (49)
Newborn Dried Blood Spot Screening: Residual Specimen Storage Issues
Bradford L. Therrell Jr and W. Harry Hannon
*Pediatrics* 2012;129;365; originally published online January 16, 2012;
DOI: 10.1542/peds.2011-3416

Public Attitudes Regarding the Use of Residual Newborn Screening Specimens for Research
Jeffrey R. Botkin, Erin Rothwell, Rebecca Anderson, Louisa Stark, Aaron Goldenberg, Michelle Lewis, Matthew Burbank and Bob Wong
*Pediatrics* 2012;129;231; originally published online January 16, 2012;
DOI: 10.1542/peds.2011-0970

Citizens' Values Regarding Research With Stored Samples From Newborn Screening in Canada
Yvonne Bombard, Fiona A. Miller, Robin Z. Hayeems, June C. Carroll, Denise Avard, Brenda J. Wilson, Julian Little, Jessica P. Bytautas, Judith Allanson, Renata Axler, Yves Giguere and Pranesh Chakraborty
*Pediatrics* 2012;129;239; originally published online January 16, 2012;
DOI: 10.1542/peds.2011-2572
Committee Report on Retention and Use of Residual Specimens from Newborn Screening

Genetics in Medicine, July 2011
Thank you!
Providing Newborn Screening Specimens for Research Webinar Series

Michelle Huckaby Lewis, M.D., J.D.
Genetics and Public Policy Center, Berman Institute of Bioethics
Johns Hopkins University, Washington, DC
April 26, 2011
Overview

1. Overview of state laws
2. Views of the public
3. Recommendations of the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children
“State Laws Regarding the Retention and Use of Residual Newborn Screening Blood Samples”

- State statutes and regulations related to NBS from all 50 states + DC were accessed online between Nov 2008 and Dec 2009
- Reviewed by 2 independent reviewers
- To determine the extent to which the retention and use of DBS were addressed
## State Laws

<table>
<thead>
<tr>
<th>Policy</th>
<th>Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retention &amp;/or use of residual DBS</td>
<td>20</td>
</tr>
<tr>
<td>Use of information related to DBS</td>
<td>13</td>
</tr>
<tr>
<td>DBS becomes property of state</td>
<td>4</td>
</tr>
<tr>
<td>State retains control over use of DBS</td>
<td>10</td>
</tr>
<tr>
<td>Purpose for which DBS may be used specified</td>
<td>13</td>
</tr>
<tr>
<td>Research using DBS is prohibited</td>
<td>1</td>
</tr>
<tr>
<td>State may charge a fee for use of DBS</td>
<td>4</td>
</tr>
<tr>
<td>DBS may be released for anonymous research without parental consent</td>
<td>7</td>
</tr>
</tbody>
</table>
State Laws (cont.)

<table>
<thead>
<tr>
<th>Policy</th>
<th># of States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidential info may be released with parental consent</td>
<td>14</td>
</tr>
<tr>
<td>Parents must be informed of scope of info to be released</td>
<td>4</td>
</tr>
<tr>
<td>Parents must be informed to whom the info will be released</td>
<td>2</td>
</tr>
<tr>
<td>Parents must be provided info re retention of DBS</td>
<td>8</td>
</tr>
<tr>
<td>Parents must be told of potential use of DBS</td>
<td>7</td>
</tr>
<tr>
<td>Parents must be informed they may request destruction of DBS</td>
<td>3</td>
</tr>
<tr>
<td>Parents told they may be recontacted if research reveals information that may be important to child’s health</td>
<td>1</td>
</tr>
<tr>
<td>Parental consent req’d under certain circumstances to release DBS</td>
<td>6</td>
</tr>
<tr>
<td>Opt out permitted</td>
<td>7</td>
</tr>
<tr>
<td>Parents may request destruction of DBS</td>
<td>5</td>
</tr>
</tbody>
</table>
Conclusions

- Despite growing interest in research use of DBS, few states have addressed these issues in a comprehensive manner.
- States have developed disparate policies re these issues.
- Need for development of more comprehensive policies is clear.
- Maintenance of public trust in NBS and the research enterprise is paramount.
Public Views


- Diverse set of 3855 respondents were recruited using 3 methods: focus groups, paper or telephone surveys, and a Knowledge Networks panel

- Some viewed educational video about retention and use of residual DBS

- All were surveyed using a 38 item questionnaire
## Public Concerns

<table>
<thead>
<tr>
<th>Question</th>
<th>Response Choices</th>
<th>Mean +/- SD response</th>
</tr>
</thead>
<tbody>
<tr>
<td>How concerned would you be if health departments saved leftover blood samples from infants after testing is done?</td>
<td>1. Not at all 2. Only a little 3. Somewhat 4. Very</td>
<td>2.6 +/- 1.15</td>
</tr>
<tr>
<td>Should health depts use these leftover blood samples to maintain the quality of existing tests for newborns?</td>
<td>1. Definitely 2. Probably 3. Probably not 4. Definitely not</td>
<td>1.92 +/- 0.95</td>
</tr>
<tr>
<td>Do you think it would be alright for these leftover blood samples to be used for important research?</td>
<td>1. Definitely 2. Probably 3. Probably not 4. Definitely not</td>
<td>1.85 +/- 0.93</td>
</tr>
</tbody>
</table>
## Public Concerns (cont.)

<table>
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<tr>
<th>Comparison</th>
<th>Frequency and percentages</th>
</tr>
</thead>
<tbody>
<tr>
<td>More important to allow notification of parents if something important is learned versus provide greater privacy protection</td>
<td>2441 (64%) notification vs. 1386 (36%) privacy</td>
</tr>
<tr>
<td>Better to keep samples unless parents contact the health department to have them destroyed versus keep samples only if parents sign a form</td>
<td>1448 (38%) opt-out vs. 2383 (62%) opt-in</td>
</tr>
<tr>
<td>With privacy safeguards in place, allow the samples to be used for important health research versus do not allow the samples to be used for important health research</td>
<td>2167 (71%) allow vs. 904 (29%)</td>
</tr>
</tbody>
</table>
Conclusions

- Retention and research use of DBS was acceptable to the public
- Opt-in approach was preferred
- Need public education and transparency about these issues
Recommendations by the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children

- Recognized concerns in some consumer communities regarding: 1) the potential uses of DBS and 2) patient privacy
- Recommendations were developed “to assist in policy improvements that can protect the individual’s privacy and allow for important public health uses of residual newborn screening specimens.”
- Recommendations have not been adopted by the Secretary of HHS
Access

- “All state NBS programs should have a policy in place that has been reviewed by the state attorney general or other appropriate legal authority that specifies who may access and use dried blood specimens once they arrive at the state-designated NBS laboratory, including further access after NBS tests are completed.”
  - The potential research value of DBS “has increased the need for national harmonization of specimen storage and specimen access polices for both legal and ethical reasons.”
  - “Identifying a standard set of key issues to be addressed in a comprehensive policy regarding access and use” of DBS “should facilitate greater uniformity among programs.”
Disposition

“All state NBS programs should have a policy in place that has been reviewed by the state attorney general or other appropriate legal authority addressing the disposition of dried blood specimens remaining after NBS. Policymakers should consider the value of the specimens as a promising resource for research, the importance of protecting the privacy and confidentiality of families, and the necessity of ensuring the public’s trust.”
Education of Healthcare Providers

- “All state NBS programs should develop a well-defined strategy to educate healthcare professionals who provide patients with prenatal and postnatal care about NBS and the potential uses of residual NBS specimens.”
Compliance with Federal Regulations

- “All state NBS programs should create policies that are in compliance with federal research regulations, assure that parents are aware of these activities, and consider whether documentation of parents’ wishes and willingness to participate are required.”
  - “The state attorney general... should review this process.”
  - The use of DBS for standard program uses are components of the NBS program and do not require additional consent.
  - “Once the use of a residual NBS specimens [sic] moves beyond the state NBS mandate and related standard program uses, each state needs to consider whether separate or blanket consent/dissent processes for approved studies are required from parents... For using residual NBS specimens.” (emphasis added)
Education of Families

“All state NBS programs should work proactively to ensure that all families of newborns are educated about NBS as a part of prenatal and postnatal care.”
Role of Secretary of HHS

- “The Secretary of HHS should help improve efforts to educate the public and healthcare providers about NBS and the retention and use of specimens.”
National Dialog

“The Secretary of HHS should facilitate a national dialog among federal and state stakeholders about policies for the retention and use of residual NBS specimens, including model consent and dissent processes.”
Voluntary Repository

“The Secretary of HHS should explore the utility and feasibility of establishing a voluntary national repository of residual dried blood specimens, in which parents may choose to participate.”
Overall Conclusions

- Public is generally supportive of research use of DBD
- Need for comprehensive policies is clear
- Need for greater transparency re policies related to the retention and use of DBS
- Policies must maintain public trust in both NBS programs and the research enterprise
Michigan’s Experience:
Legal Issues Faced by State Health Departments

Denise Chrysler, J.D., Director
The Network, Mid-States Region
Presented April 26, 2012

The Network
for Public Health Law
Outline

- Michigan’s storage and use of NBS blood specimens for research
- Addressing legal, ethical and policy issues for research uses
- Key points
... After Newborn Screening (2006)

- Blood spots stored 21 ½ years
- Over 3 million DBS representing 99.5% of children born in Michigan since 1984
- Stored in records center
- Used to evaluate, develop NBS tests
- Occasionally, researcher would request DBS (consent not required for de-identified DBS)
- 2006 – Began to explore feasibility of providing improved storage conditions and making DBS more widely available for health research
... After Newborn Screening Today

- Michigan BioTrust for Health initiative
- Blood spots stored indefinitely in Michigan Neonatal Biorepository, preserved, available for research
- 135,000 DBS added each year
- October 1, 2010 informed consent required for research use; opt out available for DBS collected prior to May 1, 2010
Michigan Public Health Code

- Health agencies: authority and responsibility to promote research to improve population health
- Authorizes Department to establish retention and disposal schedule
- Allows specimens to be used for medical research during retention period
  - Research preserves confidentiality
  - Consistent with federal law to protect research subjects
- Explanatory pamphlet informing public of retention period and that specimens may be used for medical research
Data Use Is Part of Blood Spot Use

Bloodspots + Data = Research Goldmine

Honest broker provides linkages
Public Health Databases

- **Birth Records**: Birth date, birth weight, sex, mother/father age, address, maternal prenatal care and behaviors.

- **Disease Surveillance System**: Infectious disease reports.

- **Michigan Care Improvement Registry**: Birth date, address, sex, immunizations received, immunizations overdue, provider who administered, adverse reactions.

- **Birth Defects Registry**: ICD-9 diagnostic codes; procedure codes (already linked with live births) and thus additional variables also available.

- **Newborn Screening**: Birth date, birth weight, specimen date/age, sex, single/multiple birth order, NICU, transfusion status, ethnicity, mother’s address, hepatitis antigen.

- **WIC**: Child and maternal data, pregnancy and post partum health history, breastfeeding, medications, weight, medical/nutritional conditions, marital status, education level.
More Public Health Databases

Cancer Registry
- Patient demographics, cancer site and stage, family history information, laboratory information, method of confirmation, treatment data

Early Hearing Detection & Intervention
- Hearing screen results (pass/fail); confirmed hearing loss (linked with live births and thus additional variables also available)

Children’s Special Health Care Services
- Mother’s name, address, primary enrollment diagnosis (ICD-9 codes), treatment and procedures (CPT codes)

Medicaid
- Birth date, address, racial heritage, diagnosis (ICD-9 codes), providers, procedures (CPT codes), pharmacy claims

Childhood Lead Screening
- Child name, address, test results

Death Records
- Age, birth date and place, death date, immediate and underlying cause of death, ancestry, race, education, occupation, parents’ names, autopsy
So Many Questions ... 

Ownership and control of specimens

1. Who “owns” blood after it has been drawn and tested?
2. What consent – if any – should be obtained to store/use leftover NBS blood spots?
3. What if blood is “anonymized?” “de-identified?”
4. Does it matter whether public health departments provide spots to researchers for free or charge fees?
Ownership?

- Michigan: Law interpreted that state health department conditionally owns DBS; holds them in trust to benefit individual child’s health and benefit population’s health

Control of DBS?

- Opt-out, opt-in, no option
- Biological specimens and genetic information laws
- Informed consent: It’s not easy: Legal, ethical, and practical considerations
Michigan: Research & Choice

Child born –

July 1984 - May 1, 2010
• Spots may be used for medical or public health research unless parent or person over 18 opts out

May 1 - October 1, 2010
• Informed consent pilot at selected hospitals
• Spots not used absent consent

After October 1, 2010
• All parents are asked after delivery whether will consent to research uses
• Spots not used absent consent
More questions ...

- Research using specimens
  1. What are acceptable and unacceptable research uses for leftover NBS blood spots?
  2. If the number of punches are finite, how should spots for rare diseases be distributed?
  3. Should technology be used to increase supply (e.g. amplify components, electronic fingerprints)?
  4. What happens to DBS after research is completed?
Using NBS Dried Blood Spots for Research

A Difficult Balancing Act

Goal: Promote the common good while respecting the individual

Tradeoffs: Individual rights and protections vs. promotion of research
And Still More Questions...

- Ownership and control of research results
  1. To what extent should incidental findings from research be provided to parents?
  2. Should researchers be required to share their research results with other researchers? With the public?
  3. What if research using NBS blood spots results in products and profits (e.g. tests, medications)?
  4. Who should benefit from research? How does the public benefit?
Promoting Research for Population Health

- Promoting research: Two schools of thought
  - Collaborative research communities (sharing research results) Human genome project
  - Harvesting the fruits of your own labor
- Patents on genes
- Preventing monopolies/obstacles to free flow of ideas (BRCA litigation)
- Public transparency and engagement
Key Points

- Legal, ethical, and policy issues are intertwined
- Data use is part of blood spot use
- Choice matters (even if blood spots are de-identified)
- Addressing these issues is neither fast nor easy
Acknowledgements

- Janice Bach, MS, State Genetics Coordinator and Manager of the Genomics and Genetic Disorders Section, Michigan Department of Community Health
- Carrie Langbo, MS, BioTrust Coordinator, Michigan Department of Community Health

References

Question and Answer

Please use the dialog box on the webinar to submit questions
Continuing Education Credits

For information about how to pursue continuing education credits for your attendance at this webinar, contact:

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# Webinar Series

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All sessions at 1:00 pm EST
Thank You

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