Moving Forward and Using APHL Educational/Legal Toolkits

Public Health & Legal Alliance: Lessons Learned from Newborn Screening Litigation

APHL Annual Meeting
June 3, 2014
Looking Back
Litigation

- Texas
- Minnesota

Residual Dried Blood Spot Specimens
Considerations and recommendations for national guidance regarding the retention and use of dried blood spot specimens after newborn screening.

Recommendations

• Legally reviewed policies:
  • Specifying access and use of DBS
  • Disposition of DBS after NBS

• Strategy to educate healthcare professionals providing pre- and post-natal care

• Create policies in compliance with federal research regulations
Recommendations

• Families of newborns are educated about NBS as part of pre- and post-natal care

• Secretary of HHS should:
  • assist to improve efforts to educate public and healthcare providers
  • facilitate national dialog among federal and state stakeholders
  • explore establishing a voluntary national repository for residual dried blood specimens
Residual DBS Task Force

Members:

• Cheryl Hermerath, Chair - Oregon
• Michelle Caggana - New York
• George Dizikes - Illinois
• Patrick Hopkins - Missouri
• Julie Luedtke - Nebraska
• Fizza Majid - Maryland
• Mark McCann - Minnesota
• Pat Scott - Delaware
• Susan Tanksley - Texas
Residual DBS Task Force

Members:

• Jeffrey Botkin - Univ. of Utah
• Carla Cuthbert - CDC
• Michelle Huckaby-Lewis - Johns Hopkins Univ.
Residual DBS Task Force

Charge:

Use of SACHDNC recommendations
To provide Guidance to state NBS programs
Regarding Policies and practices
For the Storage and use of residual DBS
Survey
Survey

NBS representatives in all 50 states

Focus on:
- DBS policies
- Statutes
- Education materials for parents and providers
**Survey Highlights**

Response Rate: 34 of 50 states

<table>
<thead>
<tr>
<th>Respondents</th>
<th>Findings - Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>85%</td>
<td>Written policy on the use of residual DBS</td>
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<tr>
<td>83%</td>
<td>Reviewed by legal entity or attorney general</td>
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<tr>
<td>45%</td>
<td>Addressed in newborn screening legislation</td>
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<tr>
<td>85%</td>
<td>Written policy for destruction of residual DBS</td>
</tr>
<tr>
<td>69%</td>
<td>Reviewed by legal entity or attorney general</td>
</tr>
<tr>
<td>31%</td>
<td>Addressed in newborn screening legislation</td>
</tr>
<tr>
<td>53%</td>
<td>Consent or dissent policy for use of residual DBS for research</td>
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</table>
### Survey Highlights

#### Response Rate: 34 of 50 states

<table>
<thead>
<tr>
<th>Respondents</th>
<th>Findings - Education</th>
</tr>
</thead>
<tbody>
<tr>
<td>85%</td>
<td>Educational materials for healthcare professionals</td>
</tr>
<tr>
<td>26%</td>
<td>Potential uses of residual DBS</td>
</tr>
<tr>
<td>15%</td>
<td>Prenatal - For families regarding storage and use of residual DBS</td>
</tr>
<tr>
<td>24%</td>
<td>Postnatal - For families on storage and use of residual DBS</td>
</tr>
<tr>
<td>21%</td>
<td>Prenatal - For families regarding long-term storage of residual DBS</td>
</tr>
<tr>
<td>35%</td>
<td>Postnatal - For families on long-term storage of residual DBS</td>
</tr>
</tbody>
</table>
Conference

Legal and Public Health Perspectives Surrounding Residual Dried Blood Spots in Newborn Screening
Conference

Discuss issues from both the scientific and legal community perspectives

NBS and legal community working together in achieving transparency and addressing public concerns
Conference

- Uses and benefits of residual DBS in public health
- Ethical Issues and public attitudes
- Parental perspectives
  - Experiences and lessons learned
  - Human subjects research
  - Genetic privacy laws
  - Introduction of toolkits
Toolkits
Toolkits

1. Legal & Policy
2. Educational
Policy and Policy Statements

- Tips on Writing a Policy Statement
- Policy Language from State Programs
  - Components of Newborn Screening Program
  - Residual Dried Blood Spot Specimens
Education

- FAQs for Retention of Newborn Screening Blood Spots
- Texas Educational Brochure
- Message Pallet
Sample Message Pallet

Newborn screening blood spots—small drops of a baby’s blood—are vital to quality screening. Samples are collected on cards along with the baby’s demographic data. Samples are used to:
- Do repeat screening test if needed.
- Develop new screening tests, e.g., SCID.
- Ensure that testing equipment works properly.
- Improve existing newborn screening tests.
- Check accuracy of positive screening results.
- Check screening quality by comparing test results from stored cards with those from cards sent by CDC.

NBS samples are valuable for:
- Making a diagnosis after unexplained death of an infant.
- In research studies of childhood diseases, environmental exposures (like PCB hazards for children in Love Canal) among pregnant women; exposure of pregnant women to infectious agents, e.g., hepatitis B, toxoplasmosis, rubella, HIV.
- Guiding management of results for newborns by re-testing older siblings’ samples.

Newborn screening blood samples are vital to quality screening. They protect babies’ lives by ensuring accurate and reliable test results.

Some ways states safeguard NBS samples and data:
- De-identify prior to storage.
- Store in locked, secure facilities.
- Allow access by few authorized staff.
- Destroy cards at end of retention period.
- Ensure IRB oversight where research is allowed.
- Require parental consent for use of baby’s card in research.

Can my baby be identified through the DNA in the newborn screening sample alone?
- DNA is in all living organisms and all parts of our bodies: e.g., hair, finger nails, skin, blood.
- A baby cannot be identified through the DNA on a collection card. A second DNA sample is necessary for comparison.
Appendices

• APHL Residual DBS Policy Statement

• Example Policy Language
  • Storage or Destruction of Specimens
  • Access
  • Appropriate Uses
  • Release of Specimens to Another Entity
  • Research or Third-Party Requests
  • Extended Storage and Use: Parental Opt-In or Out
Disposal of Specimens

- Example 1

DBS will be autoclaved and then handled as medical waste, which involves off-site incineration.
Example 2

DBS samples from infants whose parents have chosen to have the leftover NBS samples destroyed are retrieved from the storage freezers by the senior scientist that oversees the sample storage process. The NBS laboratory manager then double checks the sample identifiers with the parent opt-out request to assure accuracy, and then acts as witness to the destruction of the sample into medical waste disposal.
Moving Forward
Moving Forward

- Use of toolkits
  - Finalize Draft
  - Publish
- Formation of new APHL workgroup
Moving Forward

- Communication
- Transparency

Who?  What?  When?  How?

Where?
Moving Forward

- Collaborative relationship with legal representatives
- Strengthen legislation
System Components

Screening

Education

Follow-up

Evaluation

Legal

Diagnosis

Management
Questions

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