

# Moving Forward and Using APHL Educational/Legal Toolkits

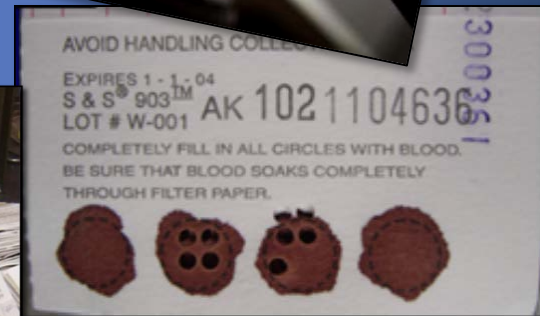
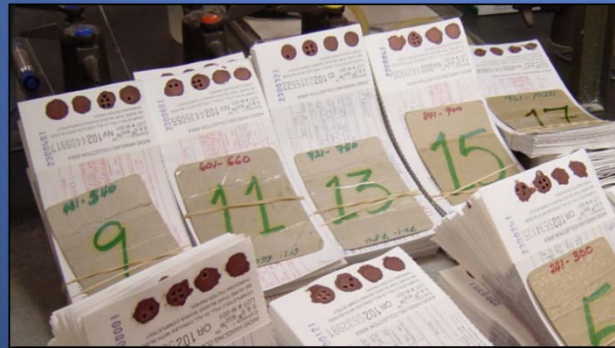
Public Health & Legal Alliance: Lessons Learned from  
Newborn Screening Litigation

APHL Annual Meeting  
June 3, 2014

# Looking Back

# Litigation

- Texas
- Minnesota



Residual Dried Blood Spot Specimens

# SACHDNC Committee Report:

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*Considerations and recommendations for national guidance regarding the retention and use of dried blood spot specimens after newborn screening.*

*Genet Med* 2011;13(7):621-624. Therrell, et.al.

# 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

APHL Newborn Screening & Genetics  
in Public Health Committee

Residual Dried Blood Spot  
Task Force

# 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

Respondents	Findings - Policy
85%	Written policy on the use of residual DBS
83%	Reviewed by legal entity or attorney general
45%	Addressed in newborn screening legislation
85%	Written policy for destruction of residual DBS
69%	Reviewed by legal entity or attorney general
31%	Addressed in newborn screening legislation
53%	Consent or dissent policy for use of residual DBS for research

# Survey Highlights



Response Rate: 34 of 50 states

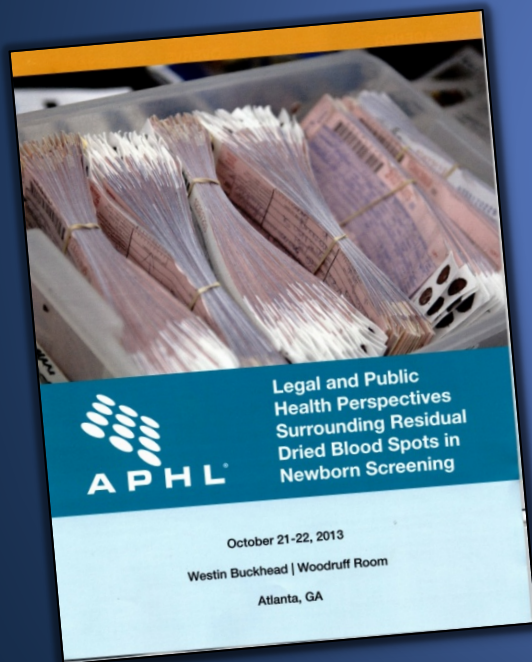
Respondents	Findings - Education
85%	Educational materials for healthcare professionals
26%	Potential uses of residual DBS
15%	Prenatal - For families regarding storage and use of residual DBS
24%	Postnatal - For families on storage and use of residual DBS
21%	Prenatal - For families regarding long-term storage of residual DBS
35%	Postnatal - For families on long-term storage of residual DBS

# 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

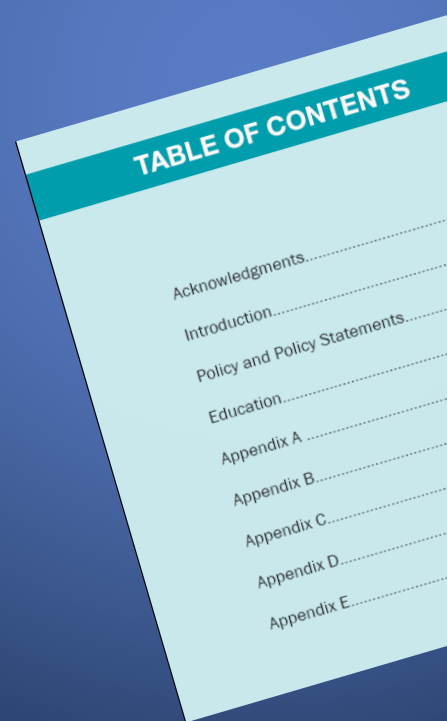
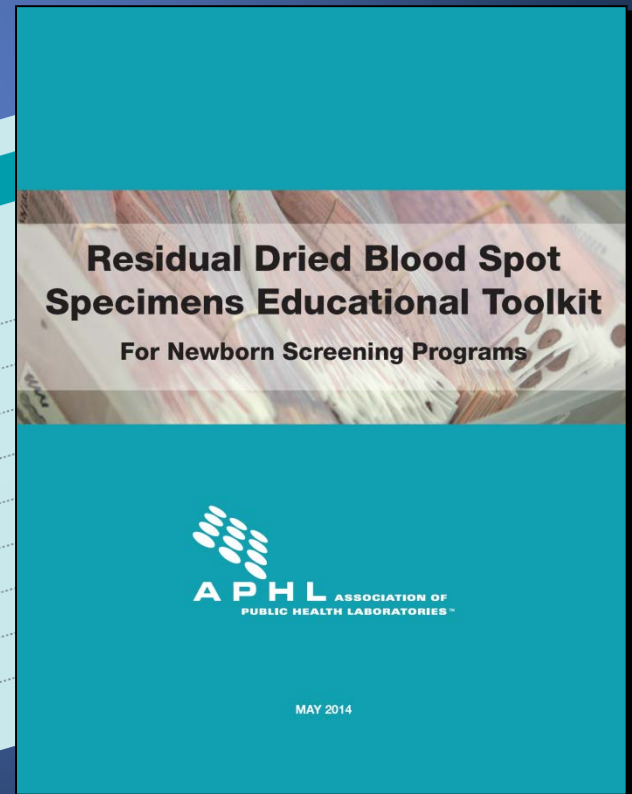


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# Policy and Policy Statements

- 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.*





# Disposal of Specimens

- 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



Who?

What?

When?

- Transparency

Where?

How?

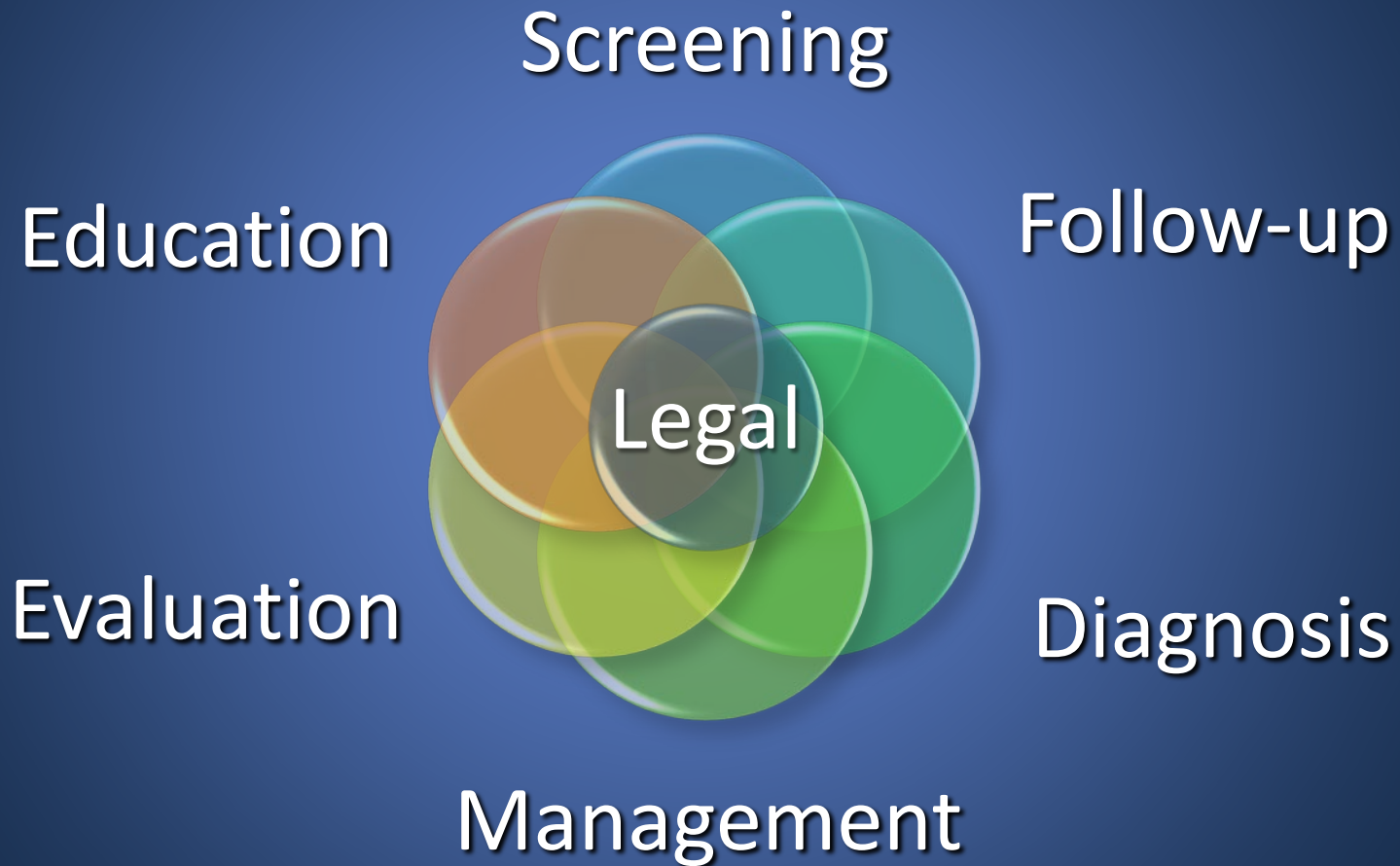


# ➤➤ Moving Forward ➤➤

- Collaborative relationship with legal representatives
- Strengthen legislation



# System Components





# *Questions*

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