



Presentation to the Association of Public Health Laboratories

Public Health and Legal Alliance: Lessons Learned From
Newborn Screening Litigation

Texas Department of State Health Services

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*The mission of the Department of State Health Services
is to improve health and well-being in Texas.*

DSHS Services

- Family & Community Health Services
- Health Information & Vital Statistics
- Mental Health & Substance Abuse Services
- Disease Control & Prevention Services
- Regional & Local Health Services
- Regulatory Services

DSHS Scope

- Alzheimer's and Ambulances to Zoonosis and Zebra Meat
- Impacts every Texan
- Nearly 7900 client services and administrative contracts
- ~160 DSHS sites

Texas NBS Data

- Average of 397,900 live births annually in Texas (average over 2002-2009)
- 6,130,508 NBS samples received by DSHS during 2002-2009
- 760,000 NBS samples received annually, on average
- Texas Newborns are currently screened for 29 disorders
- 18,000 NBS samples show abnormal results and require follow-up
- 800-900 infants diagnosed with 1 of 29 disorders annually

1963

- Phenylketonuria (PKU) screening pilot project began

1965

- Texas began screening for PKU statewide

2002 (note – started this in July)

- Residual newborn screening specimens were no longer discarded after six months

2005

- NBS program expanded with passage of HB 790, which required expansion of NBS program using the ACMG recommended panel as funds allow

2006

- DSHS established Memorandum of Understanding and Agreement with Texas A&M University School of Rural and Public Health (SRPH) for a long-term storage site in College Station for residual blood spot specimens.
- First NBS specimens were transferred from DSHS Laboratory to SRPH for secure storage
- Added screening for 19 additional metabolic disorders.

2009

February

- HB 1672 filed – Introduced version related to confidentiality of newborn screening information.

March - Federal Lawsuit No. 1

- DSHS and Texas A&M University sued in federal court regarding storage and use of residual blood spot specimens. Lawsuit alleges that Texas law violates the US Constitution, and asserts that consent is constitutionally required for any possible residual use of blood spots and/or associated data, whether or not de-identified.

April

- Specimen destruction request/disclosure form posted on DSHS website

May

- HB 1672 signed into law on May 27, 2009. Created “opt-out” system in Texas regarding residual storage/use.

2009 - Summer to Fall

- DSHS implemented public outreach to notify parents that NBS blood spots had been used for certain QA/QC and research since July 2002, and that parents could request destruction of those spots.

August

- Disclosure/destruction request form was distributed to providers, for distribution to parents when child is born.
- Under implementation of new agency policy, shipments of specimens previously used for QA/QC stopped until IRB approval obtained.

September

- Full implementation of HB 1672 in place at DSHS.

November 2009

- Lawsuit No. 1 settled.
- DSHS agrees to destroy all NBS specimens received prior to May 27, 2009, unless written consent was obtained, once screening is completed.
- 5,300,000 dried blood spots to be destroyed.

2010 Terms of Settlement:

- Post-screening research uses of NBS blood spots posted on DSHS website, along with list of the categories of QA/QC for which residual NBS specimens have been used.
- Destruction of dried blood spots in DSHS possession unless consent obtained.
- April: Blood spot destruction completed, according to schedule in lawsuit settlement.

2010 - Post Settlement :

June

- Newborn Screening Advisory Committee created by HB 1795 (81st) begins meeting

August

- DSHS Commissioner's Directive – Management of Newborn Screening Specimens implemented

October 2010 – Second Lawsuit Filed:

- Second federal lawsuit filed, in same federal court, by same law firm, but with different plaintiffs than first lawsuit.
- DSHS Commissioner named individually and in his official capacity.
- Second lawsuit focused on residual NBS bloodspots which were not destroyed as part of the settlement of the first lawsuit (not in the agency's possession at time of settlement.)
- Second lawsuit sought to have de-identified bloodspots, in possession of researchers and companies conducting QA/QC (e.g. as part of FDA trials) at the time the suit was filed, retrieved by DSHS and destroyed.
- Plaintiffs attempted to make this a class action lawsuit as in first lawsuit (unsuccessful in both cases).
- As in first, this lawsuit sought to have Texas law regarding the NBS program declared in violation of the US Constitution.

December 2010

HB 411 Filed: Original Filed version related to confidentiality of newborn screening specimens and data.

June 2011

HB 411 went into effect: “Opt In”- requires disclosure statement and consent for retention, disclosure and use under certain circumstances and requires destruction of specimens after a certain time if consent not obtained; listed exceptions.

July 2011

Second federal lawsuit dismissed by the federal judge based on a lack of standing; plaintiff would not be able to show an injury-in-fact.

June 1, 2012

- Move from opt-out to opt-in for retention and use of NBS specimens and data

December 2012

- Severe Combined ImmunoDeficiency (SCID) testing implemented statewide

Suggested Approach for Public Health Lab Directors

- Defend the Public Health Purpose of NBS
- Educate your lawyers on the program
- Tell your NBS programs story
- Explain uses and disclosures
- Ask the hard questions and be ready to answer
- Get help with communications
- Reach out to other programs and states
- If litigation filed, learn and understand the case and ask questions
- Review current authority
- Get to know the stakeholders, their concerns and perspective
- Involve your legislators
- Find your best advocate

Conclusion

Thank you for your time and interest!