OPT-IN OR OPT-OUT
Texas’ Experiences in Implementation of Newborn Screening Residual Specimen Storage and Use Requirements

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Healthcare Providers - Elizabeth Stehel MD, Michael Speer MD, Howard Rosenblatt MD, Alice Gong MD

NNSGRC – Brad Therrell PhD
All specimens stored indefinitely and allowed for external research uses
June 2002 – May, 2009

- All Specimens stored indefinitely
- De-identified specimens allowed for external research uses with IRB approval
- No specific policy
- Destroyed February 2010 per legal settlement
HB 1672 – Opt Out

- All specimens stored indefinitely and allowed for external research uses
  - June 2002 – May, 2009

- Effective immediately

- Unless parent opts out:
  - Specimens stored up to 25 years
  - De-identified specimens allowed for external research purposes

- Strict policy implemented outlining allowable uses and IRB / management approval requirements
HB 1672 – Opt Out

- TX DSHS developed Directive to Destroy form
- Providers required to:
  - Distribute form to parents upon each NBS collection
  - Return form to DSHS if requested by parent
- Parents direct DSHS to destroy specimens within 60 days of request receipt
HB 1672 – Opt Out Statistics

Form Return Rate

- Directive to Destroy
- No Response

<table>
<thead>
<tr>
<th>Process</th>
<th>Estimated Response Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>TX Opt Out</td>
<td>5%</td>
</tr>
</tbody>
</table>
LESSONS LEARNED - “Opt Out”

- **Parents**
  - Often did not know they had completed form
  - Did not understand form
  - Completed form “DO Not Destroy”
  - Did not know what newborn screening was

- **Healthcare providers**
  - No requirement to explain
  - Often did not distribute form
  - Just had parents sign

- **TX NBS Lab**
  - Need time to prepare
    - System and form preparation
    - Submitter education
    - Update kits
  - Non – LIMS processing
    - Labor intensive and error prone
    - Difficult to identify non-compliant facilities
    - Difficult to track specimen status
  - 60 day destruction timeframe
    - Impractical for 2 screen state
    - Impedes QA/QC activities
    - Does not allow parents to change their mind
HB 411 – Opt In

All specimens stored indefinitely and allowed for external research uses
June 2002 – May, 2009

HB 1672
( Opt Out )

2008 2009 2010 2011 2012 2013

HB 411
Passed
( Opt In )

HB 411
Effective
( Opt In )

☐ All specimens stored for up to 2 years and not allowed for external research uses
☐ Parent option to store up to 25 years AND allow external research uses
☐ Codified policy outlining IRB and management approval requirements
☐ New form and process required

Challenge: What happens to specimens retained under previous law and during transition.
Opt In – System Design Goals

- Parent
  - Ensure parents understand their choices
  - Be sensitive to parent / patient privacy
  - Improve general Newborn Screening education

- Healthcare Providers
  - Streamline distribution
  - Maximize return rates

- Texas DSHS
  - Streamline processing (LIMS)
  - Ensure compliance with parental choices
  - Request enough information to match forms to specimens

Not “Opt in” – “Decision” – Make a choice
HB 411 – Opt In

Parent Information Form

- Distributed to parent upon collection of each specimen
- English / Spanish – Front / Back
- 5th grade reading level

Information about specimen storage / use and Decision form

Expanded general Newborn Screening information

Texas Newborn Screening Parent Information

<table>
<thead>
<tr>
<th>Baby’s Last Name</th>
<th>Baby’s First Name</th>
<th>Baby’s Date of Birth</th>
</tr>
</thead>
</table>

Provider: Fill out baby’s information above. Give this form to a parent.

What happens to the blood spot card after testing?

Starting June 1, 2012:

- DHS keeps the blood spot cards in a safe and secure place for up to two years.
- The blood spot cards may be used for:
  - Medical and newborn screening tests are valid for up to three years.
  - Development of new newborn screening tests.
  - Study diseases that affect public health.

If you give your OK, your baby’s blood spot cards will be destroyed up to 26 years, as they may be used for public health research.

Complete, sign, and return the Parental Decision Form.

For more information, call (888) 683-7314 or visit www.deh.state.tx.us/birthscreeningparents.
**HB 411 – Opt In**

**Parental Decision for Storage Form**

- Parents inform DSHS of their decision one way or the other
- Providers required to:
  - Distribute to parent upon each NBS collection
  - Return form to DSHS if requested by parent

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### Explanation of Choices

Parents select 1 of 2 options

### Selection and Signature only required fields

Forms without a signature or a selection will default to ‘No’

### Barcode to streamline processing in LIMS
Custom LIMS Module and Queries

- Generate barcodes
- Kit numbers scanned into system to apply “OK” or “No”
- Generate verification lists for form validation
- Uses linking to apply to all specimens for a patient
- Tracks form receipt dates and applies priority when multiple forms received.
- Create pull list of (OK or No) specimens
- Tracks Destroyed or Not
Logistics of Transition

Complications

- Two laws are essentially opposite
- Providers required to “flip the switch”
- > 1800 Submitting Facilities
- No additional funding
- Minimal requirements on providers
- NBS kits valid for 3 years
  - Some providers ran out of 2010 / 2011 forms prior to June 1
  - Kits with new “Decision” form distributed prior to June 1
- 2 screen state
  - Multiple form distributions
  - Specimens collected before and after June 1
- How to handle invalid forms
EDUCATION – TRANSITION AND LONG TERM

- Official notification letter
- Monthly NBS listserv updates
- Coordination with professional organizations (THA, TMA, TPS)
- Kit order inserts
- Website updates
- Webinars / Onsite Presentations
- CE modules
- Videos
- Brochures / Flyers
HB 411 – Decision Form Statistics

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<td>5%</td>
</tr>
<tr>
<td>TX Opt In</td>
<td>49%</td>
</tr>
</tbody>
</table>

Opt Out Form Return Rate
- Directive to Destroy: 5%
- No Response

Opt In Form Return Rate
- Decision Form: 49%
- No Response
## State to State Comparison

<table>
<thead>
<tr>
<th>State</th>
<th>Estimated Response Rate</th>
<th>% OK</th>
<th>% NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>TX</td>
<td>49%</td>
<td>74</td>
<td>26</td>
</tr>
<tr>
<td>MI*</td>
<td>77%</td>
<td>76</td>
<td>24</td>
</tr>
</tbody>
</table>


### % OK vs. No - Returned Forms

<table>
<thead>
<tr>
<th>State</th>
<th>% OK vs. No - Returned Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>TX</td>
<td>% OK</td>
</tr>
<tr>
<td></td>
<td>36.3</td>
</tr>
<tr>
<td>MI*</td>
<td>58</td>
</tr>
</tbody>
</table>

~750,000 specimens / year

~122,500 specimens / year
Education – Ongoing

- Direct contact with facilities with low and high return rates
- System models
- Educational Brochures
- NBS listserv updates
ISSUES / BARRIERS

Providers:

- Minimal legal requirements.
- May not understand requirements completely.
- Minimum incentive for active collection.
- Active collection creates system inefficiencies.
  - Explanation of the form may be time consuming.
  - Parents may have questions about the form that may be difficult for providers to answer.
  - Waiting for parent to fill out the form may be time consuming.
  - Language barriers.

Parents:

- Form not received.
- Forms given as part of the “discharge packets”. No explanation.
- Not made aware of option to return completed form to provider.
- Low priority to complete and return when caring for newborn.