Review of Best Practices in Documenting Newborn Screening Refusals for States
April, 2015
Supported in part by a grant from HRSA H46MC24089

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http://tinyurl.com/NBSrefuse
Newborn Screening Steering Committee.
Newborn screening: Toward a uniform screening panel and system. American College of Medical Genetics; 2002.
APPENDIX 4: PROGRAM STANDARDS

Initial Newborn Screening Activities

1. Document complete reporting of all results of all liveborn newborns within three months of the close of the year (target 100%).

   a. Initial screening specimens should be collected after 24 hours, but as close to discharge as possible. Newborns with prolonged hospital stays should be tested before day seven, regardless of reason for hospitalization.

   b. The number of newborns discharged from hospitals without screening and the number of these infants involved in follow-up testing should be documented.

   c. The number of newborns discharged without screening for which screening occurred through follow-up at some later time should be documented.
<table>
<thead>
<tr>
<th>Refusal Reason</th>
<th>Number of States</th>
<th>Percent of States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refusal for any reason</td>
<td>15</td>
<td>29%</td>
</tr>
<tr>
<td>Refusal for religious reasons</td>
<td>33</td>
<td>65%</td>
</tr>
<tr>
<td>No provision for refusals</td>
<td>3</td>
<td>6%</td>
</tr>
<tr>
<td>Refusal provision</td>
<td>No State Form</td>
<td></td>
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<td>-------------------------------</td>
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<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Refusal for any reason</td>
<td>5</td>
<td>10%</td>
</tr>
<tr>
<td>Refusal for religious reason</td>
<td>12</td>
<td>24%</td>
</tr>
<tr>
<td>No provision for refusals</td>
<td>3</td>
<td>6%</td>
</tr>
<tr>
<td><strong>Total:</strong></td>
<td><strong>20</strong></td>
<td><strong>39%</strong></td>
</tr>
</tbody>
</table>
Purpose of Project

- Documentation of refusals is considered good practice for state programs and supports the goals of newborn screening programs
- Wide variation in what states do to document refusals
- Little information available on how to effectively document refusals
A Note about Consent

Consent Continuum

Implied

- Required
- Opt-out
- Opt-in
- Requested

Expressed
Methods

• Survey of state newborn screening coordinators
  – 82% response rate
  – $5 gift card offered

• Collected newborn screening refusal forms
  – 93% of optional or required forms gathered

• In-depth interviews with five states
  – $10 gift card offered

• Focus group with parent advocates on refusal forms
Results
Refusal Forms

Typically:

- Developed by State Department of Health (although many other processes reported)
- English only
- Completed by parents and provider(s)
- Submitted by paper mail or fax
- Available on DOH website
Opportunities for Form Improvement (deficiencies)

• Insufficient contact information requested for parent, baby, birth provider, well-baby provider
• Most (80%) described risks for refusing screening – why not all?
• Few had statement endorsing screening from reputable groups (7%)
Opportunities for Form Improvement

• 44% provided no information on what conditions were screened (not even a summary)

• 52% had no statement that describes allowable refusal reasons (of course not needed in states where parents may refuse for any reason)

• 15% allowed parents to provide a reason for refusal
Opportunities for Form Improvement

- Only 7% separated refusal for screening from refusal for bloodspot storage and use
- 78% did not provide a source for additional information (such as a website)
- Instructions on many forms were poor (e.g., where to send the form, when to use, etc.)
- Use of data from forms often limited to long-term storage (for liability protection?) or entry into database for future use
Best Practices

• Highlighted the value of documenting refusals at the program level

All newborn screening programs should require program-level documentation of newborn screening refusals

(States without a provision for refusals should document refusals so information is available for appropriate follow-up)
Benefits of Having a Required Form

Those with required form agreed significantly more strongly than those with no form that:

- Documentation is critical for quality control and evaluation.
- Documentation is important for legal reasons.
- The current refusal documentation process provides accurate information about newborn screening refusals.
- Documentation process provides meaningful information about newborn screening refusals in my state.
- Documentation process meets the needs of my state.
Basic model for documenting refusals

Challenges:
• Cost / benefit ratio seems high
• Emphasis on counting and protection from liability
• Can be easy to see why some programs wouldn’t want to bother with this
Enhanced Model for Documenting Newborn Screening

Birth Provider

Parents

Screen

Refuse

Record

Liability

Counts

Feedback & Educate

Follow-up & Offer screening

Education campaign

NBS Program

Well-child Provider

Future parents & providers

Policymakers

NDSU
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DIVISION OF STUDENT AFFAIRS
ASSESSMENT
The most important purpose for documenting newborn screening refusals is to facilitate communication between the many stakeholders while record-keeping, liability protection, and counting serve a secondary role.
Gathering accurate data regarding newborn screening refusals allows newborn screening programs to follow-up with parents, hospitals, birth providers, and well-child providers, and reduces the number of babies who are not screened.
Best Practices

• Clear contact information for:
  – Parents
  – Birth center / hospital
  – Birth provider
  – Well-baby provider

• Make the form available in multiple languages

• Ask for the reason for refusal (can also do this at a follow-up after refusal)

• Educate about screening – might be the only NBS document a parent sees
  – Summary of conditions screened
Best Practices

- Include website and phone number for additional information about screening
- Clear instructions on the form
- Separate refusal for screening with refusal for storage/research of bloodspot cards and provide your state’s policy on storage and research use
- Have separate options for refusal for metabolic/genetic, CCHD, hearing
- Use a paper form (or require a portion be printed and given to the parents)
- Do not rely on bloodspot card (insufficient space for all of the information needed and parents do not usually see the bloodspot card)
Best Practices

• Link laboratory records, birth certificate records, and refusals to ensure all babies are accounted for
  – Integrated electronic data systems would be best
  – Want to avoid “misses”
• Work with your state’s legal council
• Collaborate and be transparent about the purpose and use of the form
Next Steps

• Find out what your state’s NBS program does to document refusals (and your state’s policy on refusals!)
• Update your state’s refusal documentation form
• You can request specific feedback from the authors: jeremy.penn@ndsu.edu
• http://tinyurl.com/NBSrefuse to see the paper
• Communicate the change with key stakeholders
• Support additional research on educating providers, follow-up with patients, reasons parents refuse, and using information on refusal to inform policy decisions
• Make use of info from refusal form to improve the program
  – Does your state’s policy on refusals still make sense?

Note: statements in this presentation are those of the authors and not necessarily those of NDSU or HRSA