Review of Best Practices in Documenting Newborn Screening Refusals for States

April, 2015

Supported in part by a grant from HRSA H46MC24089

Jeremy Penn, Ph.D.
Eric Sondreal, M.P.H.
North Dakota State University

http://tinyurl.com/NBSrefuse

NEWBORN SCREENING: TOWARD A UNIFORM SCREENING PANEL AND SYSTEM

Newborn Screening Steering Committee

Jose Cordero, MD, MPH
Centers for Disease Control and Prevention
Health Resources and Services Administration

E. Steven Edwards, MD
Past President
American Academy of Pediatrics

R. Rodney Howell, MD
American College of Medical Genetics
University of Miami School of Medicine

Jennifer L. Howse, PhD
President
March of Dimes Birth Defects Organization

Michele A. Lloyd-Puryear, MD, PhD
Maternal and Child Health Bureau
Health Resources and Services Administration

Marie Y. Mann, MD, MPH (Project Officer)
Maternal and Child Health Bureau
Health Resources and Services Administration

Tricia Mullaley
Genetic Alliance

Peter van Dyck, MD, MPH
Maternal and Child Health Bureau
Health Resources and Services Administration

Michael S. Watson, PhD (Project Director)
American College of Medical Genetics

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.

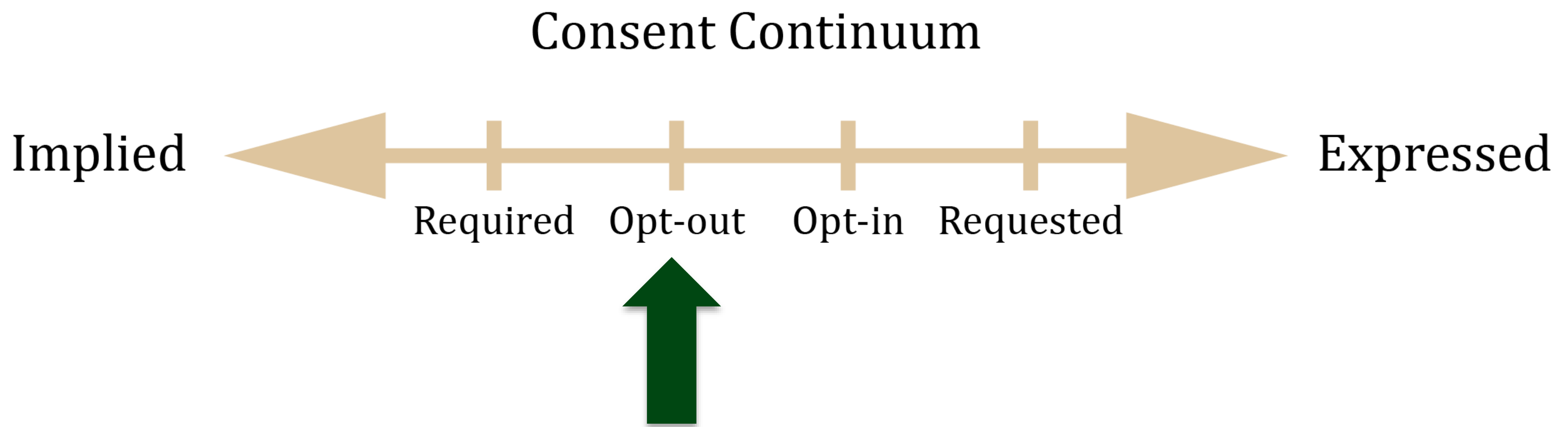
	Number of States	Percent of States
Refusal for any reason	15	29%
Refusal for religious reasons	33	65%
No provision for refusals	3	6%

Refusal provision	No State Form		Optional State Form		Required State Form	
	n	%	n	%	n	%
Refusal for any reason	5	10%	6	12%	4	8%
Refusal for religious reason	12	24%	6	12%	15	29%
No provision for refusals	3	6%	0	0%	0	0%
Total:	20	39%	12	24%	19	37%

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



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

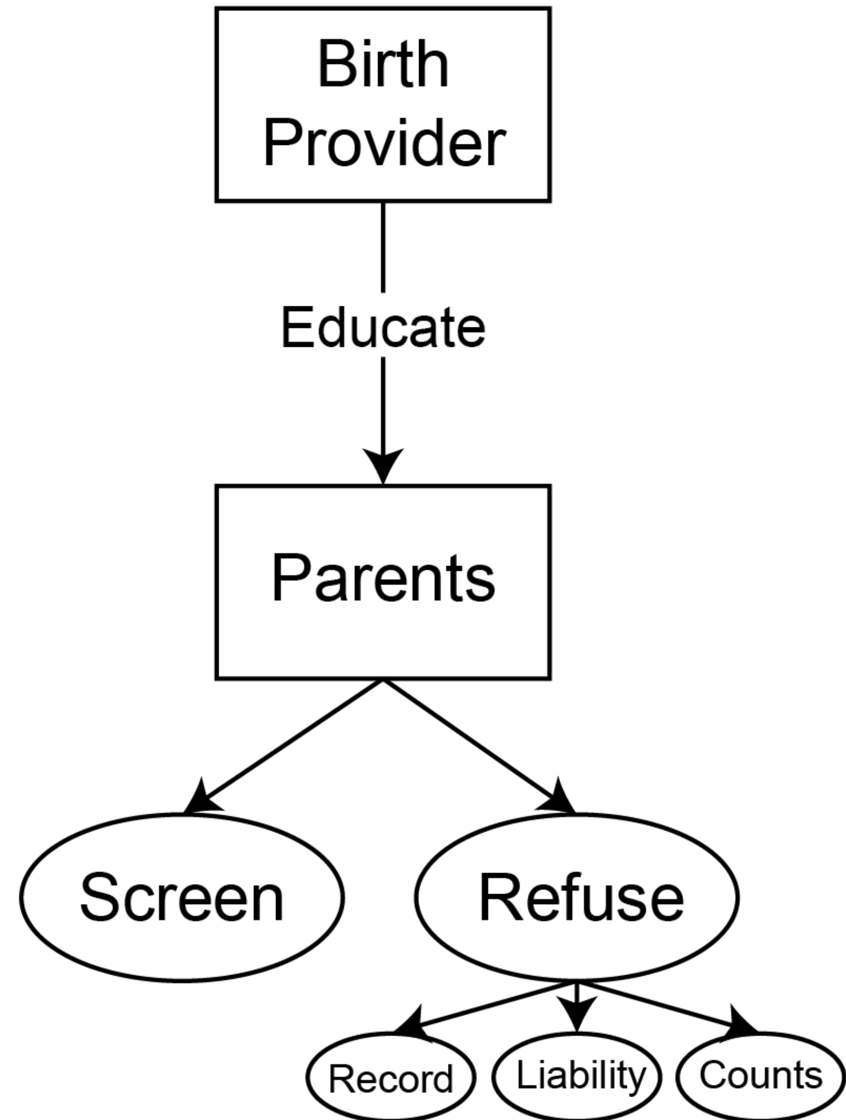
Those with required form agreed significantly more strongly than those with no form that:

- 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.

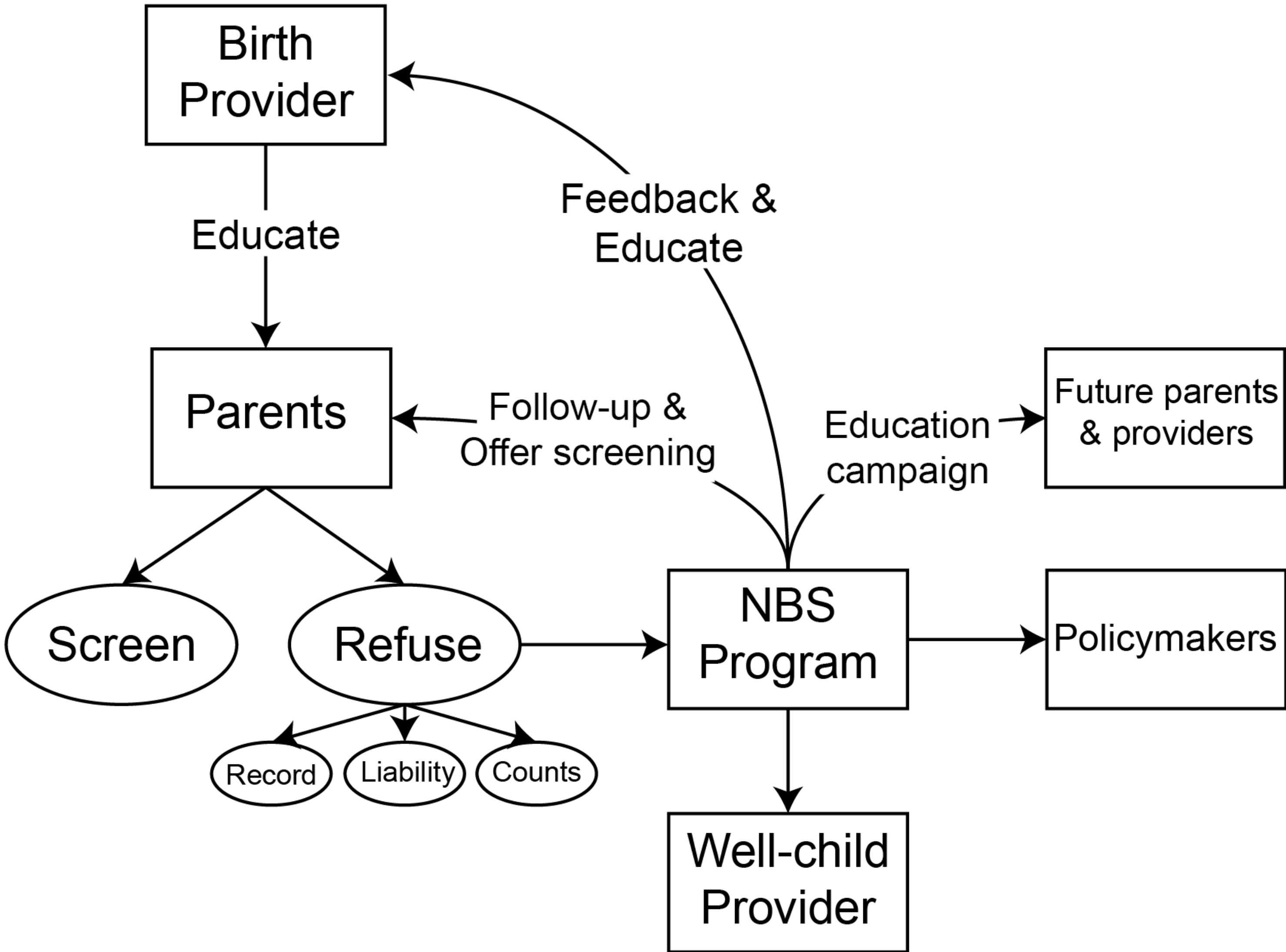
Basic model for documenting refusals

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



Enhanced Model for Documenting Newborn Screening

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.

Well-child Provider

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