Review of Best Practices in Documenting Newborn Screening Refusals for States

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Executive Summary[*]

Documentation of newborn screening refusals is a critical – but underutilized – aspect of program evaluation and improvement for newborn screening programs. Perhaps one explanation is the lack of clear information on how to best document newborn screening refusals. The purpose of this project was to examine states' processes for documenting newborn screening refusals and to identify best practices.

Data were collected through an electronic survey, phone interviews with five states, examination of publicly available materials and refusal forms, and a focus group with parent advocates.

Findings showed great variation in the processes states used to document newborn screening refusals. Some states required use of a detailed state form while other states did not even provide an optional form and made no effort to track refusals.

Best practices identified included requiring use of state-level common refusal form, using the form as part of a communication process including follow-up with parents and providers, providing options for parents and education in the form itself, and collaborating with multiple groups throughout the form development process. Effective refusal documentation appeared to result in fewer refusals by allowing for parents to change their minds and provided information programs could use to make improvements.

> "Documenting newborn screening refusals is considered an element of good practice in evaluating newborn screening programs."

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[*] The views and opinions expressed in this paper are those of the authors and do not necessarily reflect the policy, position, or views of HRSA, Heartland Genetic Services Collaborative, or North Dakota State University.

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Introduction

Newborn screening saves or improves the lives of more than 12,000 babies each year (1) and is an important part of the Ten Great Public Health Achievements (2) from 2001-2010. However, every year a small number of babies are not screened because their parents refuse screening, putting them at risk for disability or death.

Forty-seven states and the District of Columbia allow parents to refuse newborn screening. Thirty-three allow refusal for religious reasons and 15 allow refusal for any reason. However, only 34 of these states make an effort to track and document refusals at the state level (see Table 2), leaving 14 states – covering 39% of the U.S. births per year (3) – that allow refusals but do not track them at the state level.

Documentation of newborn screening refusals is considered an element of good practice in evaluating newborn screening programs (4) and, when done well, can serve the goals of newborn screening programs by facilitating communication, by identifying potential areas for improvement, and by providing information to policymakers.

Unfortunately, there is little information available to states about how to effectively document refusals. The purpose of this project was to identify best practices in documenting newborn screening refusals and to develop recommendations for practice that can be adopted by newborn screening programs.

Informed Consent or Refusal Only?

Discussions regarding newborn screening refusals would be incomplete without considering the issue of informed consent. Informed consent for participation in research and as a patient's right to understand and agree to any medical procedure in advance (unless certain conditions are met) are cornerstones of the practice of medicine. Principles of informed consent typically include (5):

A. For research projects, a statement that the study involves research.
B. Explanation of the purpose of the activity and procedures that will be followed.
C. Description of any foreseeable risks and efforts that will be taken to minimize risks.
D. Description of benefits.

E. Disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous.
F. A statement about describing what records will be kept confidential.
G. If more than minimal risk is involved, statement about treatments or remedies that may be available.
H. For research projects, amount of remuneration / compensation provided to participants (if any).
I. Information on who to contact for answers to pertinent questions about the procedures and the patient's rights.
J. A statement that participation is voluntary and that refusal will involve no penalty or loss of benefits.

Only one state requires informed consent for newborn screening while the other 50 programs either have no provision for refusals or operate under opt-out methods only. Figure 1 provides an illustration of the range of consent options available. (Note that under the 2015 Newborn Screening Saves Lives reauthorization, all states will be required to obtain informed consent for research use of the bloodspot cards (see (6) for a detailed discussion) but there is no requirement for states to use informed consent for screening itself.) In addition to a range of consent options, states vary in how they educate patients with regard to newborn screening. In order to make a truly informed decision, regardless of where the state is located on the consent continuum, patients must have full understanding of the procedure and its risks and benefits.

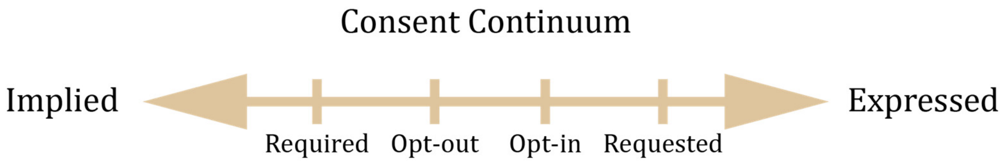

FIGURE 1. CONTINUUM OF CONSENT.

While the purpose of this project was not to delve into the issue of whether or not informed consent in an opt-in approach should be required for newborn screening (for other articles on this issue see (7), (8), and (9)), the principles of informed consent and informed dissent (or refusal) are sufficiently related to necessitate mention here. To avoid any confusion, this project focuses on informed dissent (which will be called "refusal" in this paper) in an opt-out setting.

Methods

State newborn screening coordinators were identified through a web search. Coordinators were sent a paper letter informing them of the study and asking them to notify the researchers if they no longer served in this capacity. Coordinators were then contacted through email and asked to participate in a web survey that asked questions about documentation of newborn screening refusals in their state. Coordinators received up to three follow-up emails. Coordinators who did not respond and did not decline were called by the researchers to see if the survey had been sent to the correct place or if they had any questions or concerns about the project. A $5 incentive gift card was offered for completing the survey although only ten participants (24%) accepted the gift card. The final response rate was 82%.

We gathered 93% of the newborn screening refusal forms for states that had a required or optional form. If the form was not available on the internet, we requested a copy from the coordinator. Refusal forms were analyzed by key characteristics. We shared three refusal forms, representing a range of characteristics, with a focus group of six parent advocates for discussion.

Five states were selected to participate in hour-long in-depth interviews over the phone. The participants for the in-depth interviews were selected because there was some aspect of the refusal documentation process identified in the survey that was unusual or intriguing and because they were willing to participate in the interview. Participants in the phone interviews received a $10 gift card. Finally, information on refusal documentation practices was gathered from states that did not complete the survey by examining those states' policies and administrative rules.

Results

Refusal Provision and Documentation

Most states (63%) allowed refusal of newborn screening only for religious reasons (see Table 1), while fewer (31%) allowed refusals for any reason. Only 3 states (6%) did not have any provision for refusals. However, for these three states we did not investigate the extent to which newborn screening is enforced (that is to say, these states could fall into the undocumented refusal category if screening is not enforced).

There was a wide range in refusal documentation across the various refusal provisions. A total of 17 states allowed refusal for newborn screening but had no state refusal form in place to document refusals. However, some of these states did make other efforts to track newborn screening refusals (see Table 2).

Table 1. State refusal provision by documentation form type.

	No State Form		Optional State Form		Required State Form		Total	
Refusal provision	n	%	n	%	n	%	n	%
Refuse for any reason	5	10%	6	12%	5	10%	16	31%
Refuse for religious reasons	12	24%	6	12%	14	27%	32	63%
No provision for refusals	3	6%	0	0%	0	0%	3	6%
Total:	20	39%	12	24%	19	37%	51	100%

Efforts to Track Refusals by Other Methods

As shown in Table 2, 4 states (8%) that did not have a required state form to use in documenting newborn screening refusals used other methods to attempt to track refusals. For example, one state compared birth certificate data with newborn screening records to see how many babies were and were not screened in the state. Another state asked hospitals to report when screening was refused. In another state the birth provider was asked to submit a blank bloodspot card to show screening was refused.

One state with an optional form did not use the form to track refusals at the state level. The form was provided as informational guidance for hospitals and providers to use.

Table 2. Effort to track refusals by documentation form type.

	No State Form		Optional State Form		Required State Form		Total	
State makes effort to track refusals	n	%	n	%	n	%	n	%
Yes	4	8%	11	22%	19	37%	34	67%
No	13	25%	1	2%	0	0%	14	27%
No provision for refusals	3	6%	0	0%	0	0%	3	6%
Total:	20	39%	12	24%	19	37%	48	100%

Views on Documentation of Newborn Screening Refusals

As shown in Table 3, documentation of newborn screening refusals is viewed as a critical aspect of quality control and improvement and has importance in states for legal reasons. Respondents agreed less strongly that their current newborn screening refusal documentation process provides accurate and meaningful information about refusals. Only 47% of respondents agreed that the current refusal documentation process meets the needs of their state. Only 12% of respondents identified substantial barriers to changing the newborn screening refusal documentation process.

Table 3. Views on documentation of newborn screening refusals.

	Disagree / Strongly Disagree	Agree / Strongly Agree
Accurate documentation of newborn screening refusals is a critical aspect of quality control and evaluation for newborn screening programs. (n = 40)	0%	83%
Accurate documentation of newborn screening refusals is important in my state for legal reasons. (n = 37)	11%	73%
Documentation of newborn screening refusals in my state informs efforts to improve the newborn screening program. (n = 35)	6%	71%
The current newborn screening refusal documentation process provides accurate information about newborn screening refusals in my state. (n = 36)	25%	50%
The current newborn screening refusal documentation process provides meaningful information about newborn screening refusals in my state. (n = 36)	28%	58%
The current newborn screening refusal documentation process meets the needs of my state. (n = 36)	28%	47%
There are substantial barriers (e.g., legal, legislative, political, etc.) in my state to making changes to my state's process for documenting newborn screening refusals. (n = 35)	46%	12%

Views on documentation of newborn screening refusals were compared between states with different documentation processes (required form, optional form, no form). No significant differences were found between states with optional forms and states with either required forms or no forms. On five items there were significant differences between states with required forms and states with no form. Respondents from states with a required form agreed significantly more strongly than respondents from states with no form that:

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

While there may be other factors involved, such as the rate of refusal of newborn screening in states and attitudes toward newborn screening in states, this provides some evidence of benefits for states that have required refusal documentation forms. States with no refusal form may use this result to support efforts to develop a required refusal documentation form.

Table 4. Views on documentation of newborn screening refusals by requirement status.

	Required form		Optional form		No form	
	n	M	n	M	n	M
Accurate documentation of newborn screening refusals is a critical aspect of quality control and evaluation for newborn screening programs.	16	4.88***	9	4.33	14	3.86***
Accurate documentation of newborn screening refusals is important in my state for legal reasons.	16	4.44*	9	4.11	11	3.18*
Documentation of newborn screening refusals in my state informs efforts to improve the state newborn screening program.	16	4.19	8	4.25	10	3.80
The current newborn screening refusal documentation process provides accurate information about newborn screening refusals in my state.	16	3.69*	9	3.33	10	2.50*
The current newborn screening refusal documentation process provides meaningful information about newborn screening refusals in my state.	16	4.06**	9	3.33	10	2.60**
The current newborn screening refusal documentation process meets the needs of my state.	16	3.75*	9	3.44	10	2.60*
There are substantial barriers (e.g., legal, legislative, political, etc.) in my state to making changes to my state's process for documenting newborn screening refusals.	15	2.47	9	2.22	10	3.10

Note: This table does not include states that do not have a provision for refusals.
Note: Some states that do not use a standard form may attempt to examine refusals / missed screens another way (e.g., through review of birth certificate records).
*$p < 0.05$, **$p < 0.01$, ***$p < 0.001$

The Refusal Form

The next six tables, Table 5 to Table 10, provide information about the refusal forms from 20 newborn screening programs that answered these questions on the survey. The tables starting with Table 11 were developed by analyzing the available refusal forms themselves.

In most states the refusal form was developed by the State Department of Health, although many other participants were identified.

Table 5. Development of refusal form.

	n	Percent of states reporting
State Department of Health	12	63%
State Committee	5	26%
Don't know	4	21%
Legislative process	3	16%
Always used this form	3	16%
Borrowed from another source	2	11%
Legal / litigation process	2	11%
Newborn Screening Program	2	11%

Note: The total is more than 100% because some states reported more than one development source.
Note: Total number of responding states was only 19 for this question.

Refusal forms were all available in English, and only 30% of the states also had a version of the form available in Spanish.

Table 6. Languages in which refusal form is provided.

	n	Percent
English only	14	70%
English and Spanish	6	30%

Refusal forms were typically completed by a parent or parents and in many cases also require some information be provided by a physician or attending caregiver or some other hospital staff member.

Table 7. Person who typically completes the refusal form.

	n	Percent
Parent(s)	17	85%
Other hospital staff member	14	70%
Physician or attending caregiver	12	60%
Note. Total is more than 100% because some states reported more than one person who completes the form.		

Half of the respondents said refusal forms were completed 24-48 hours after birth which aligns with the timeframe in which the first newborn screening sample would be collected. Surprisingly, the other half of respondents said refusal forms were completed at various times.

Table 8. Timing for completion of refusal form.

	n	Percent
24-48 hours after birth	10	50%
Unknown or various times	10	50%
Prior to birth	0	0%

Paper mail was the most common form submission method, although many respondents also indicated use of fax. Only 10% of respondents reported use of the internet or a web form.

Table 9. Submission of refusal form to newborn screening program.

	n	Percent
Paper mail	17	85%
Fax	16	80%
Scanned and emailed	12	60%
Internet (web form)	2	10%
Note: Total is more than 100% because some states reported more than one submission method.		

Refusal forms were made available through a variety of sources, most commonly through the State Department of Health website.

Table 10. How refusal forms are made available.

	n	Percent
State Department of Health website	15	75%
Direct request	11	55%
Packets sent to hospitals / birthing facilities	9	45%
County health departments	2	10%
Sent directly to parents after home births	1	5%
Electronically accessed by hospital	1	5%
Supplies mailed to midwives	1	5%
In practitioners' manual	1	5%
Web-based	1	5%

Note: Total is more than 100% because some states reported more than one way the form is made available.

Information on the Refusal Form

An attempt was made to gather refusal forms from all states that had either optional or required refusal forms. A total of 27 refusal forms were analyzed (refusal forms for the other 4 states that had an optional or required form could not be located or were not made available for review).

Contact Information

Contact information requested on the refusal form varied. All forms required information about the parent and the child, although what information was requested varied. Most forms requested information about the delivery provider and a few forms requested information about the pediatrician or provider who would be providing well-baby care after the delivery.

Table 11. Contact information on refusal form for parents.

	n	Name only	Name and address	Name, address, and phone number
Parent	27	52%	41%	7%

Most refusal forms asked only for the baby's name and date of birth. Some refusal forms requested information about the baby's medical record number, address, or other demographic information. In states with larger populations, having only the baby's name and date of birth could make it difficult to identify the specific baby, as names can change or may be similar between babies born around the same time.

Table 12. Contact information on refusal form for baby.

	n	Name and date of birth	Name, date of birth, address	Name, date of birth, medical record number	Name, date of birth, medical record number, address	Name, date of birth, medical record number, birth weight, race
Baby	27	44%	11%	19%	22%	4%

Nearly 20% of the refusal forms requested no information about the delivery provider. The majority that did asked only for the name of the delivery provider. Tracking information about the delivery provider gives the newborn screening program the opportunity to reach out to providers with larger numbers of refusals and provide educational materials or identify strategies for better supporting that provider's patients' newborn screening needs in the future.

Table 13. Contact information on refusal form for delivery provider.

	n	Name only	Name and address	Name and ID number	Nothing
Delivery provider	27	63%	15%	4%	19%

Very few refusal forms asked for information regarding the person who would be providing well-baby checks for the baby outside the newborn period. Having such information can be critical for newborn screening programs in communicating the refusal to important audiences. Pediatricians or other well-baby providers need to know if screening was refused so they can know to not rule out the screened conditions if symptoms appear. Some states reported screening occurring for some families that had initially refused after the well-baby providers had conversations with those parents and were able to convince parents to have the screening done at that point.

Table 14. Contact information on refusal form for pediatrician or other provider for baby.

	n	Name and address	Name and phone number	Nothing
Pediatrician / other provider for baby	27	7%	4%	89%

Finally, regardless of what information is requested, it is important that the requested contact information be very clear so those filling out the form know what information to provide. On some forms, instructions or question prompts were not clear and could lead to confusion on behalf of those completing the refusal forms.

Educational Components of the Refusal Form

Forms were reviewed for a range of educational information and options for parents. For some parents the refusal form could be the only information they have ever received regarding newborn screening. Some states require an information brochure accompany the refusal form, but it is not clear the extent to which that requirement is followed.

Most, but not all, refusal forms described the risks to the baby for refusing screening.

Table 15. Refusal form describes risks for refusing screening.

	n	Yes	No
Describes risks for refusing screening	27	81%	19%

A few refusal forms included statements from reputable groups, such as, "The State of XXXX and the American Academy of Pediatrics strongly recommend newborn screening."

Table 16. Refusal form has statement endorsing screening from reputable group(s).

	N	Yes	No
Has statement endorsing screening from reputable group(s)	27	7%	93%

Most refusal forms included either the full list of conditions screened in the state or a summary of the conditions screened. It was surprising that 44% of the refusal forms made little effort to describe the conditions screened in the state.

Table 17. Refusal form lists the conditions screened.

	n	Yes	Summary only	No
Lists conditions screened	27	19%	37%	44%

Nearly all refusal forms included a statement that asked the parent signing the form to certify that he / she had received an opportunity to ask questions or be educated regarding newborn screening. Some states included in the certification statement a note that the parent had received an informational brochure on newborn screening.

Table 18. Refusal form includes a certification statement regarding parent education / chance to ask questions.

	n	Yes	Educated only	No
Includes certification statement that parent has been educated / chance to ask questions	27	26%	63%	11%

Just over half of the refusal forms included a statement that described the state's policy or law on newborn screening refusals and the reason or reasons why parents are allowed to refuse. Such a statement may not be necessary in states that allow refusals for any reason.

Table 19. Refusal form includes a statement about the reasons for which refusal is allowed.

	n	Yes	No
Includes statement that describes allowable refusal reasons	27	52%	48%

A few states provided space on the refusal form for parents to describe the reason or reasons why they refused screening. Several states reported that this space was often either not used or just included a very generic statement, such as "religion."

Table 20. Allows parent to provide a reason(s) why screening was refused.

	n	Yes	No
Allows parent to provide reason(s) for refusal	27	15%	85%

Very surprisingly, given the increased recent attention on the storage and use of bloodspot cards, few refusal forms separated out parents' options for refusing some aspect of the storage or use of the bloodspot card or its use in research and refusal for screening itself. A few states had separate forms (e.g., one to refuse newborn screening, one to request destruction of the bloodspot card after XX days), but these options were not always clear on the refusal form.

Table 21. Separates refusal for screening from refusal for bloodspot storage and research use.

	n	Yes	No
Separates refusal for screening from refusal for bloodspot storage and use	27	7%	93%

Most refusal forms did not provide specific information for parents to use to locate additional information about newborn screening.

Table 22. Provides information on where to go for additional information (e.g., a website).

	n	Yes	No
Provides source for additional information (e.g. a website)	27	22%	78%

Refusal forms varied widely in the information requested from parents and the information provided to parents. Many refusal forms had serious deficiencies, such as missing clear contact information for parents or providers, failing to provide a list of resources for additional information about newborn screening, failing to separate refusal for screening from refusal for bloodspot storage and research use, or even providing a listing or summary of the conditions screened in the state.

Use of Information from Refusal Form

Table 23 summarizes the reported uses of information from newborn screening refusal forms. Most states reported storing the refusal form as part of a long-term record. Otherwise, information from the newborn screening refusal forms did not see substantial use across states, although 50% did report entering some information from the refusal form into databases for future analysis (likely related to evaluation of the newborn screening program).

Given the deficiencies identified in the previous section regarding the elements of the newborn screening refusal forms themselves, such a low amount of use of information from the refusal forms is not surprising. That is to say, since states are not receiving high-quality, actionable information from the refusal forms, they are not able to make better use of the information from the refusal forms. Of course, the connection between the quality of the form and its ability to result in use works the other direction as well. As states see more value in making use of information on newborn screening refusals to improve newborn screening programs the forms themselves will receive increased attention to ensure they meet the needs of the state.

Table 23. Reported uses of information from refusal forms.

	n	Percent
Stored as long-term record	17	85%
Entered into database for future analysis	10	50%
Lab cross-checks with bloodspot cards	4	20%
Follow-up with hospital / provider	4	20%
Identify trends and patterns in refusals	3	15%
Calculate refusals per year and per birth facility	2	10%
Program planning	1	5%
Certified letter sent to parents to inform of risk and offer screening	1	5%
Other	1	5%
Match with database (e.g. birth records)	1	5%
List of refusals	1	5%
Mandatory reporting	1	5%
Referred to birth defect registry	1	5%
Confirm form was received with person who sent it	1	5%
Note: Total is more than 100% because some states reported more than one use of the form.		
Total number of responding states:	20	

Identified Best Practices

1. Have a state-level process to document newborn screening refusals. States that do not have a provision for refusals should have a set of procedures in place to use when refusals occur. Although most states believe the number of refusals is small, there are benefits beyond liability protection for documenting newborn screening at the state level, including:

- Providing clear and consistent information to parents and providers.
- Allowing state newborn screening programs to follow-up with parents, birth providers, physicians who provide well-child care, hospitals, and policymakers, and to develop targeted educational programs. States that followed-up with parents and physicians who provide well-child care reported some conversions of refusals (15% or more in one state).
- Verifying all babies born in the state were screened or refused and were not missed or lost.

In states that do not have a provision for refusals, there should be clear steps to follow when refusals occur. Without a clear process in these states for reporting refusals it will be difficult to enforce required screening.

2. View documentation of refusals as the beginning of a communication process, not the end. As shown in Figure 2, a basic refusal documentation process focuses on counting refusals, protecting the state and providers from liability, and keeping records.

Many states, particularly those with required refusal documentation forms, went well beyond the basic model with one or more enhanced uses of the data from the documentation of refusals. An idealized conceptual model, utilizing enhancements from several different states, is shown in Figure 3. The key difference for these states is recognizing that 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.

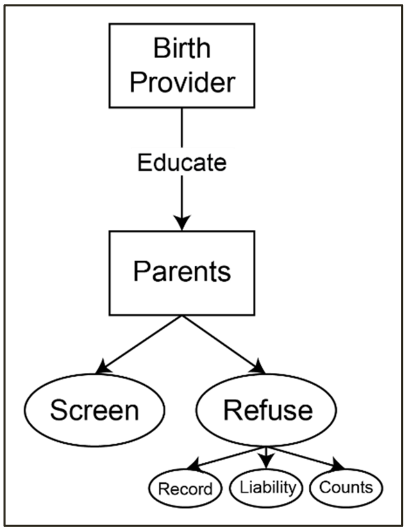

FIGURE 2. DOCUMENTATION OF NEWBORN SCREENING REFUSALS: BASIC MODEL.

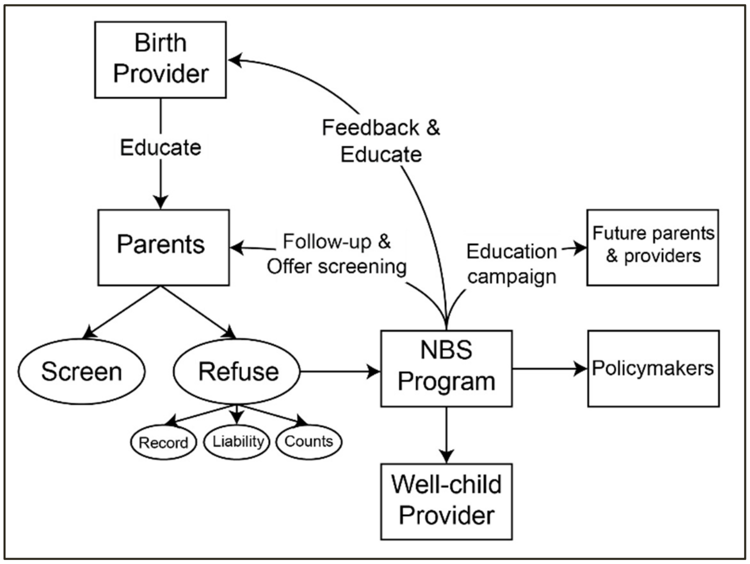

FIGURE 3. DOCUMENTATION OF NEWBORN SCREENING REFUSALS: ENHANCED MODEL.

3. Include clear contact information for parents, birth provider, and provider who will be providing the well-baby checks. Inclusion of a medical record number, or other unique identifier for the baby, is also recommended.

4. Make the form available in multiple languages. Non-English speakers may be at a higher risk for not understanding newborn screening.

5. Ask for the reason for refusal. This is most helpful for states that allow refusals for any reason as states that allow refusals only for religious reasons reported seeing "religion" listed. Asking for the reason for refusal may be more effective through a follow-up phone call or a survey sent with a follow-up letter. Knowing the reason for refusal may allow the screening program to provide a remedy, if possible.

6. Use the refusal form to educate about screening, including a summary of conditions screened and policy on use and storage of bloodspot cards. Don't assume parents received your state's educational materials. Summarizing conditions screened allows the state to add new conditions without having to update the refusal form and was preferred by our focus group.

7. If needed in your state, separate refusal of newborn screening from refusal of bloodspot storage and refusal for research using the bloodspots. Separating screening, storage, and research allows screening to occur for families who are concerned about storage and research issues. An alternative option – such as using a private newborn screening company like PerkinElmer – might be offered as an alternative if parents are concerned about the role of the state. We did not identify any states that specifically mentioned this alternative.

8. Include a website and a phone number that provides additional information about screening. The refusal form might be the only thing some parents see.

9. Include clear instructions on the form, particularly regarding where the form should be sent and who should sign. This will improve accurate form completion and timely submission.

10. Have separate options for metabolic / genetic, CCHD, and hearing screening refusals. Some parents may object to the drawing of blood but may have no concerns about critical congenital heart defect screening or hearing screening.

11. Use a paper form or require a portion of the web form be printed and given to the parent. Web-based forms provide some convenience, particularly for data entry. However, they increase the risk that they could be completed by a birth provider and never read or viewed by the parent (this may also be true for paper forms for parents who cannot read English). In addition, parents will have more time to read and understand the form after they return home and if they change their minds they will need the paper form to be able to make contact with the newborn screening program. If a web-based form is to be used it should include a requirement that parents receive a paper copy of the form. Scannable paper forms, with a copy or portion kept by the parent, may also be an option.

12. Do not rely on the bloodspot card as the refusal document as it is sent to a different place and does not have much space for additional information. Instead, consider sending a blank bloodspot card with a checkbox that screening was refused in addition to a separate refusal form. Using a tear-off section on the bloodspot card (at least one state is experimenting with this) might be another way to do this.

13. Ideally, states should link laboratory records, birth certificate records, and refusals to ensure all babies are accounted for. Integrated electronic data systems are best, but some smaller states did this work by hand.

14. Work with your state's legal counsel to ensure your refusal form is acceptable. Hospitals and providers may wish to use their own "refusal of treatment" form if needed in addition to the state's refusal form.

15. Collaborate and be transparent about the purpose of the refusal form. In a state in the Heartland region during a recent vote on an update to the state's newborn screening law, a legislator stood up with a copy of the state's refusal form and said it served as too severe a "barrier" for parents who wish to refuse screening and that the form should just say "yes or no." This legislator then went on to vote against the updated law, even though the proposed updates had nothing to do with newborn screening refusals or the refusal form. Did this legislator understand the goals of the newborn screening and the risks that are assumed when screening is refused? Did the legislator understand the multifaceted role of the refusal form in educating parents, serving as a communication mechanism, and providing the newborn screening program information needed for program evaluation and improvement? While legislators are very busy and it may be difficult to find ways to reach all of them, this illustrates the importance of building partnerships and collaborations and of using those partnerships and collaborations to support the development and use of a high-quality newborn screening refusal form.

Recommendations

First, documenting newborn screening refusals is a critical aspect of the evaluation of newborn screening programs and supports the goals of newborn screening programs by reducing the number of refusals, by allowing follow-up and conversion after a refusal, and by providing information that can inform policy and program improvement efforts. All newborn screening programs that allow parents to refuse screening should be documenting those refusals with a common, required, program-level refusal form. It is important to remember that refusal forms are part of the newborn screening system, which includes educational materials, a website, communications sent to providers and hospitals, and so on and should reflect a consistent message with these other aspects of the program.

Second, newborn screening programs should be more intentional about using information from newborn screening refusals to inform improvement of the newborn screening program. For example, programs might use information from documented refusals to consider whether or not the state's current policy on newborn screening refusals continues to be appropriate or is being operationalized the way that was intended. States may also wish to reflect on whether or not it continues to be in the best interest of the babies and families in the state to allow refusals for newborn screening[†]. Another way programs could use information from refusals would be to identify the top reasons why parents are refusing screening and to make changes to policies or practices if possible to address those concerns.

[†] An unpublished ethical analysis by the lead author of this paper provides some evidence that states may be justified in intervening in newborn screening refusals.

Third, more research is needed to better understand the best approaches for educating providers and hospitals, following-up with parents who refuse screening, and using information about refusals to inform policy decisions.

In closing, documentation of newborn screening refusals appears to be an often overlooked component of evaluation and improvement of newborn screening programs. Effective documentation of newborn screening refusals can facilitate communication, identify areas for improvement, and provide information to inform policy decisions.

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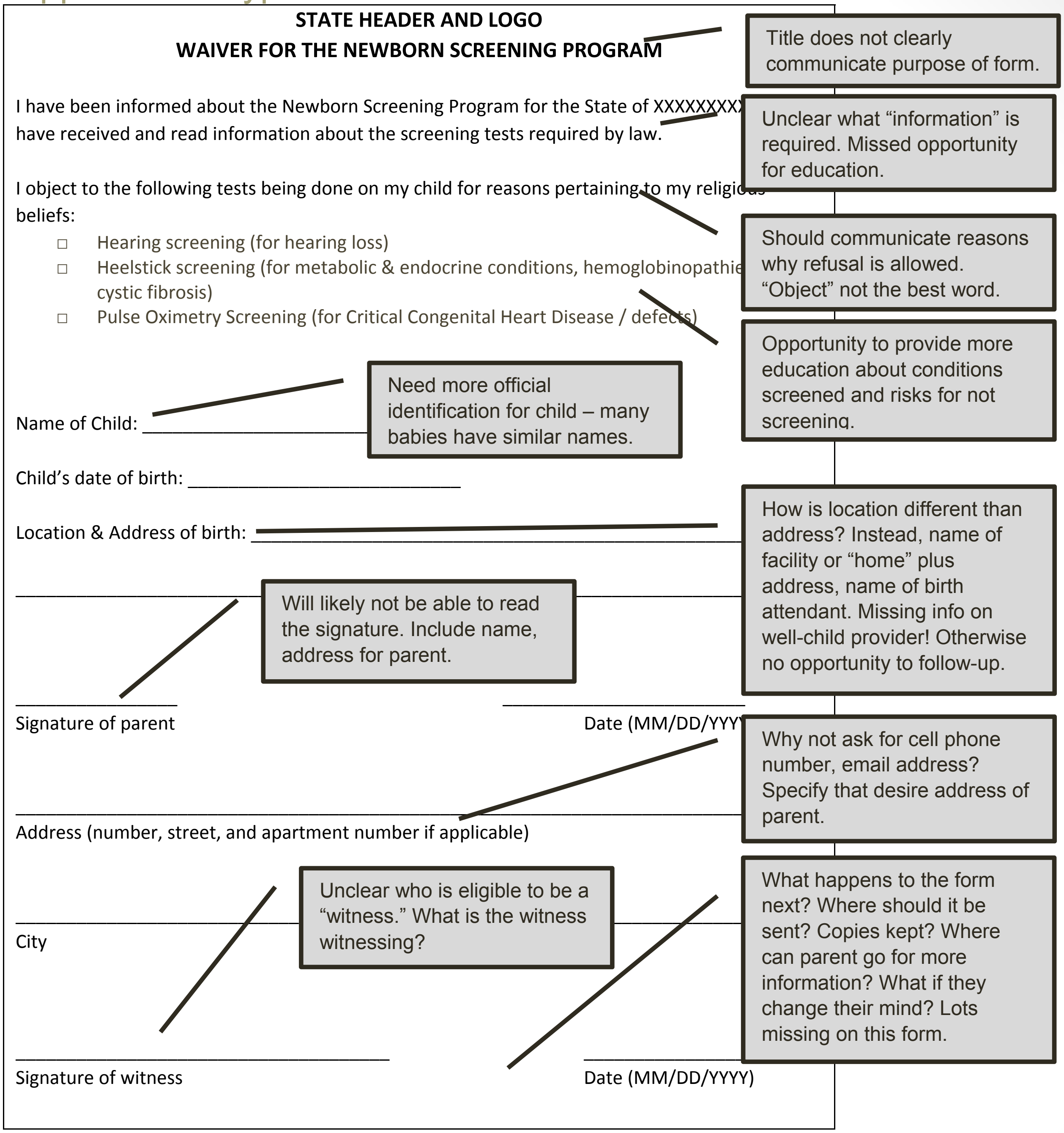
Appendix A: Typical Refusal Form with Annotations



STATE HEADER AND LOGO
WAIVER FOR THE NEWBORN SCREENING PROGRAM

I have been informed about the Newborn Screening Program for the State of XXXXXXXX
have received and read information about the screening tests required by law.

I object to the following tests being done on my child for reasons pertaining to my religio
beliefs:

- ☐ Hearing screening (for hearing loss)
- ☐ Heelstick screening (for metabolic & endocrine conditions, hemoglobinopathie
cystic fibrosis)
- ☐ Pulse Oximetry Screening (for Critical Congenital Heart Disease / defects)

Name of Child: ______________________

Child's date of birth: ______________________

Location & Address of birth: ______________________

____

Signature of parent

Date (MM/DD/YYY

____

Address (number, street, and apartment number if applicable)

____

City

____

Signature of witness

Date (MM/DD/YYYY)

Title does not clearly communicate purpose of form.

Unclear what "information" is required. Missed opportunity for education.

Should communicate reasons why refusal is allowed. "Object" not the best word.

Opportunity to provide more education about conditions screened and risks for not screening.

Need more official identification for child – many babies have similar names.

How is location different than address? Instead, name of facility or "home" plus address, name of birth attendant. Missing info on well-child provider! Otherwise no opportunity to follow-up.

Will likely not be able to read the signature. Include name, address for parent.

Why not ask for cell phone number, email address? Specify that desire address of parent.

Unclear who is eligible to be a "witness." What is the witness witnessing?

What happens to the form next? Where should it be sent? Copies kept? Where can parent go for more information? What if they change their mind? Lots missing on this form.

Appendix B: Better Refusal Form Example[ψ]

FORM TO DOCUMENT REFUSAL OF NEWBORN SCREENING

Use this form to document a parent's refusal to have their baby participate in newborn screening offered by the State of XXXXXXX. One copy of this form is placed in the baby's medical record, a second copy is given to the parent, and a third copy is sent to the Newborn Screening Program at XXXXXXXX. A separate form is used for refusal of bloodspot card storage and research. If parents object to the storage and use of bloodspot cards that form should be used instead.

Newborn screening can save your baby's life or prevent serious brain damage. Newborn screening can identify babies with certain diseases so that treatment can be started right away. Newborn screening identifies diseases in the following groups:

- Metabolic (chemical reactions in the body to create energy and build tissue)
- Endocrine (hormones that affect body functions)
- Hemoglobin (red blood cells that carry oxygen)
- Other genetic diseases (Cystic Fibrosis and Severe Combined Immunodeficiency)
- Hearing loss
- Critical Congenital Heart Disease

Babies with any one of these diseases can look very healthy at birth and still have a serious disease. By the time symptoms appear, it may be too late to prevent serious damage to the baby.

Metabolic / genetic newborn screening is done by taking a few drops of blood from the baby's heel. Most babies experience some brief discomfort from the heel stick but it heals quickly and leaves no scar. Hearing screening is done by placing a small instrument in the baby's ear canal for a short time and can be done while the baby sleeps. Critical Congenital Heart Disease screening is done by placing a small device over the baby's toe for a short time and can be done while the baby sleeps. Bloodspot cards are stored for XXXXX and will only be used for research if XXXXX.

All parents must receive a copy of the Newborn Screening Brochure, "STATE NEWBORN SCREENING BROCHURE." If you are unable to pay for newborn screening it will be provided for you at no charge. If you have additional questions about newborn screening call XXX-XXX-XXXX, send a letter to XXXXXXXXX, or visit our website at XXXXXXXXXXXX.gov. If you wish to have the bloodspot card destroyed after screening use form XXXXX from XXXXX.

Newborn screening is required by state law unless the parent or guardian of the child refuses screening for religious reasons. If you have read the "STATE NEWBORN SCREENING BROCHURE" and have decided to refuse screening for religious reasons you must complete and sign the form below.

Name of child:				Medical Record:	
	First Name	Middle Name	Last Name		Number (if known)
Name of parent:					
	First Name	Middle Name	Last Name		

Parent's address:					
	Number and street	Apt. (if needed)	City	State	Zip
Parent's contact:					
	Home Phone Number	Cell Phone Number		Email Address	

Place of child's birth:					
	Name of facility, hospital, or home	Number and street address	City	State	Zip
Primary provider present at birth:					
	First Name	Middle Name	Last Name	Phone Number	

Physician who will be providing well-baby checks:						
	First Name	Last Name	Number and street address	City	State	Zip
	Phone Number					

I have been informed about the Newborn Screening Program for the State of XXXXX and have received the "STATE NEWBORN SCREENING BROCHURE." I understand Newborn Screening can prevent disability or the death of my child. I understand Newborn Screening may be refused only for religious reasons. I have had the opportunity to have my questions answered. I accept all responsibility and liability for the possible consequences of refusing screening.

☐ I refuse to have my child screened for hearing loss.

☐ I refuse to have my child screened for Critical Congenital Heart Disease / Defects.

☐ I refuse to have my child screened for metabolic, endocrine, hemoglobin, and other genetic diseases.

Parent:			
	Signature	Printed Name	Date
Primary provider present at birth:			
	Signature	Printed Name	Date

Send a copy of form to: Address XXXX, Fax XXXXX, Newborn Screening Website for STATE; Form Version and updated date

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[ψ] This is intended to illustrate the best practices and is not intended to be The Form that every state uses. Forms should be carefully reviewed by each state's legal counsel and the newborn screening program before use.