

Recommendations for Effective Newborn Screening Communication: Results of Focus Groups With Parents, Providers, and Experts

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ABSTRACT

OBJECTIVES. The aims of this study were to determine parent and provider knowledge and awareness of newborn screening; to gather opinions from parents, providers, and newborn screening professionals about the content and timing of newborn screening education; and to use consensus data to formulate recommendations and to develop educational materials for parents and providers.

METHODS. We conducted 22 focus groups and 3 individual interviews between October 2003 and May 2004, with English- and Spanish-speaking parents of infants <1 year of age who had experience with initial testing, retesting, or false-positive screenings; health professionals who provide prenatal care or health care for newborns; and state newborn screening program health professionals.

RESULTS. Parents and providers had limited knowledge and awareness about newborn screening practices. Parents wanted brief to-the-point information on newborn screening and its benefits, including the possible need for retesting and the importance of returning promptly for retesting if initial results are abnormal. Parents wanted the information orally from the primary care provider. Parents, providers, and newborn screening professionals all thought that an accompanying concise, easy-to-read brochure with contact information would be helpful. All focus group participants thought that parents should receive this information before the birth of the infant, preferably in the third trimester of pregnancy. Providers wanted a brief checklist of information and resources to prepare them to educate parents effectively.

CONCLUSIONS. We recommend prenatal and primary care providers be more involved in educating parents about newborn screening. Professional societies and state health officials should work together to encourage parent and provider education. User-friendly patient and provider education materials, such as those we developed, could form the basis for this educational approach.

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Key Words

newborn screening, parent education, health communication

Abbreviations

AAP—American Academy of Pediatrics
HRSA—Health Resources and Services Administration
ACOG—American College of Obstetricians and Gynecologists

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EACH STATE IN the United States operates a newborn screening program to test neonates for selected genetic and other disorders. State programs differ not only in the disorders for which testing is performed but also in the information given to parents and the process of reporting results, contacting parents, and referring them for care when an infant's test results are abnormal.¹⁻³

Newborn screening communication practices were recently addressed in a study by Kim et al,¹ who surveyed the program staff of all state newborn screening programs. Those investigators found that often the responsibility for informing parents about the testing is not clearly defined. Less than 50% of the states responded that primary care providers had some responsibility for informing parents about newborn screening, and only 25% indicated that they encouraged or required prenatal providers to educate parents. Most commonly, states reported that parents are informed about newborn screening procedures immediately before testing. Kim et al¹ concluded, "States should work with families, primary care physicians, and prenatal health care professionals to develop well-defined systems for pretesting education of parents." There are no national guidelines, however, for the content of parent and provider education about newborn screening, and each state does not have a comprehensive plan for dissemination of such education. In addition, few data exist on the knowledge and needs of parents and health care professionals for education in this area.^{1,2}

The American Academy of Pediatrics (AAP) Newborn Screening Task Force recommended in 1999 that each state design and implement parent education efforts regarding newborn screening.² Although written educational materials regarding newborn screening now exist in 49 of the 51 US states/territories, their effectiveness may be hampered by dissemination problems and lack of reading ease.⁴ The issue of reading ease is particularly important, because a recent report by the Institute of Medicine indicated that 90 million US adults have difficulty understanding and acting on health information and that a great deal of written information for patients is unnecessarily complex and not understandable by large proportions of the population.⁵

The AAP task force recommended that "studies should be done to broaden the understanding of the ways in which communication can be done effectively for the benefit of consumers."² The task force also recommended that "public health agencies (federal and state), in partnership with health professionals and consumers, continue an educational process" to advance these goals.²

This study was designed as a step toward meeting the AAP task force recommendations. Specifically, the purposes of this study were to determine parent and provider knowledge and awareness of initial newborn

screening and follow-up testing; to gather feedback on the content and timing of newborn screening education from parents, primary care clinicians, and state newborn screening professionals; and to use the information obtained to make recommendations regarding the content of information about newborn screening and the methods through which this information should be communicated to parents.

METHODS

Study Design

This study used a qualitative research design that involved conducting 22 focus groups and 3 individual interviews between October 2003 and May 2004. The study methods were reviewed and approved by the Louisiana State University Health Science Center Research Subjects Review Board and the institutional review board of the Health Resources and Services Administration (HRSA).

Focus Group Subjects

Subject Selection

Subjects were selected through purposeful sampling, a method through which participants are selected because they have certain characteristics that make them representative of the groups whose opinions and experiences are being sought.^{6,7} Participants included English- and Spanish-speaking parents of infants <1 year of age who had experience with initial testing, retesting, or false-positive screening results; health professionals who provide prenatal care or health care for newborns (pediatricians, family physicians, obstetricians, nurse practitioners, physician assistants, nurse midwives, and nurses); and state newborn screening program professionals.

Parents

We recruited parents for the focus groups from Louisiana, Maryland, and New Mexico. These states were chosen because they represent different geographic areas of the country, they provide ethnic diversity, and we were able to identify coinvestigators to collaborate with us in the execution of the study.

At each site, local collaborators identified programs that served parents of children <1 year of age. Some of the programs served predominantly middle- and upper-class clientele, whereas others served predominantly low-income clientele. The local collaborators worked with staff members in each program (clerks, nurses, and program directors) to coordinate the focus groups. These staff members received a \$100 honorarium to recruit parents, to remind them about the focus groups, and to arrange for necessary meeting rooms.

Staff members approached parents enrolled in their program who had a child <1 year of age and asked them to participate. Middle- and upper-class parents were re-

cruited from mother's day out programs at churches and from a nursing mothers support group at a suburban obstetric practice. Low-income parents were recruited from Medicaid case-management programs, Healthy Start programs, or other neighborhood programs. Three parents who had experience with false-positive newborn test results were identified from state newborn screening program records, and staff members for those programs contacted parents and asked them to participate. During the focus groups for parents with experience with initial screening, we identified some parents who had been notified that their infant needed to be retested and subsequently was retested. All parents were informed that they would receive a stipend of \$25 to compensate them for time spent in the focus group interviews.

Health Care Providers

Collaborating coinvestigators and state newborn screening directors recommended pediatric, family medicine, and obstetric practices in Louisiana, Maryland, New Mexico, and Texas. These practices were located in urban, suburban, and rural areas and included private, community/public, and university settings. All of the physicians, nurse practitioners, and physician assistants who worked in the practices were included in the focus groups.

Nurse midwives were recommended by the president of the American College of Nurse Midwives. The midwives were located in urban areas in Georgia, Maryland, and Texas. Newborn nursery nurses were recruited by a hospital administrator in Ohio.

State Health Department Representatives

The HRSA chief of the Genetic Services Branch of the Maternal and Child Health Bureau recommended representatives from state newborn screening programs in Maryland, New Mexico, and Louisiana. We then contacted and recruited the individual responsible for patient education in each of those programs.

Focus Group Structure

All focus groups were conducted in English except for 2 sessions with Hispanic parents in New Mexico; those 2 sessions were conducted in Spanish by a coinvestigator who is a native Spanish speaker. The principal investigator led all other focus groups and individual interviews except groups in Ohio and a group in Shreveport, which were led by a coinvestigator. Each focus group also had a coleader and 2 note-takers except for the Spanish-speaking groups, which had 1 leader and 1 note-taker.

The sizes of the groups ranged from 2 to 12 individuals, not including the investigators. Each focus group session lasted ~1 hour, and each subject participated in only 1 session.

Focus groups with parents were held at the usual

meeting sites of the programs from which parents were recruited (churches, clinics, and community centers). Most focus groups with health care providers were held in their offices, clinics, hospitals, or other locations that were convenient for the providers. Focus groups with the health care providers were conducted in person, when possible. In a few instances, interviews were conducted by telephone; specifically, we conducted a telephone focus group with nurse midwives in Georgia and individual telephone interviews with nurse midwives in Maryland and Texas and with an obstetrician in Louisiana who was in solo practice. The focus groups with state newborn screening professionals were conducted at their state office buildings or at a site that was convenient for them.

All sessions except for the Spanish focus groups and the telephone focus groups and interviews were audio-taped. As noted, parents participating in the focus groups received a stipend of \$25. We provided physicians with a \$100 stipend and other health care providers with \$50, to compensate them for time spent during focus groups and interviews. We provided focus group participants with a snack or meal.

Focus Group Content

Development of Moderator's Guide

In the initial stage of this project, we assembled a team of individuals with expertise in newborn screening, children's health care, patient education, risk communication, and ethics and with previous experience conducting focus groups.⁸⁻¹³ After examining current pertinent literature,^{1-3,14-23} the team drafted a focus group moderator's guide with scripted questions.

Next we assembled an advisory board composed of representatives of 6 national professional organizations that were recommended by the chief and a public health analyst of the Genetic Services Branch of the Maternal and Child Health Bureau, HRSA. The 6 organizations are listed in Table 1. The representatives were either the organization's president or a health professional in charge of the organization's newborn screening policy or guideline committee.

Members of the advisory board reviewed the draft of the moderator's guide and made suggestions for revisions. Then the revised guide was pilot tested among a small group of providers and parents, and final revisions

TABLE 1 Organizations Represented on the Committee That Reviewed Focus Group Scripts

American Academy of Family Physicians
AAP
American College of Nurse Midwives
ACOG
Association of Women's Health, Obstetric, and Neonatal Nurses
Society of Teachers of Family Medicine

were made on the basis of the results of pilot testing. Appendices 1 to 3 show the final scripted questions for parents, providers, and health department representatives, respectively.

Parents

In the parent groups, scripted questions elicited parents' awareness of, knowledge about, and experience with newborn screening. All questions to parents were posed in a nonjudgmental manner. Group leaders probed for the sources and content of written and oral newborn screening information that parents received, their most trusted sources of health information and whether and where they sought information, their opinions about informed consent and the variability of diseases screened by their state, and their concerns about the newborn screening process. Parents were also asked what information they wanted and how they wanted it delivered (ie, when, in what format, and by whom). Parents were shown newborn screening brochures from their state and other states and asked to give specific feedback on the content, wording, graphics, layout, and organization. Parents whose child required retesting were asked to describe how they were informed of the need for retesting, the subsequent process of retesting, and suggestions for improvement.

Health Care Providers

In the provider focus groups, scripted questions asked what the providers knew about the newborn screening information parents received and the process of getting the information to parents. Providers were also asked what they discussed with parents about newborn screening, what they thought parents wanted and needed to know, and their usual timing and format of delivery. Other questions sought information about how often parents asked about newborn screening and what types of questions parents asked.

Providers were asked about their experience with their state's newborn screening program, including the number of their patients who had false-positive results, the number of patients who needed to be rescreened, and the number of patients for whom a genetic disorder was identified through newborn screening. In addition, providers were asked what they thought they needed to know about newborn screening and how they would like to learn it. The leader probed for providers' responses to questions about continuing education on newborn screening and about receiving information and patient education materials from their national professional organizations.

State Newborn Screening Professionals

State newborn screening program staff members were asked to describe their current programs. In particular, they were asked about the process through which par-

ents and providers are notified about test results and the need for retesting; the patient education that takes place; what patient education materials were developed, how they were developed, and the distribution process for those materials; what they think parents and providers need to know about newborn screening; system barriers; and recommendations for improved patient education about newborn screening.

Data Analysis

After each session, project staff members in attendance at the focus groups discussed and summarized the content and key findings of the group. This information was typed and reviewed by the investigators to identify main themes. In addition, 2 investigators who did not attend the focus group reviewed the audiotapes and identified themes expressed in the tapes. These themes were then discussed among the investigators until a consensus was reached about the main themes.

All themes identified by the reviewers were categorized according to the structure of the moderator's guides or additional information identified during the focus groups. The groups and themes were condensed into a single set of themes that applied to each of the 3 groups, ie, parents, providers, and state newborn screening program professionals. These themes are presented below. In cases in which there was variation within groups in response to a theme, these variations are reported. Representative statements from individual subjects also are provided.

RESULTS

Study Groups

The focus groups and individual interviews involved 51 parents, 78 health care providers, and 9 state newborn screening professionals. Tables 2, 3, and 4 display demographic characteristics of the participants.

In total, the interviews generated 12 hours of audiotape. Eighty percent of the tapes had adequate audio quality for use for analysis.

Five main consensus themes emerged from the focus

TABLE 2 Parent Demographic Characteristics (n = 51)

Ethnicity/race, n (%)	
White	22 (43)
Black	22 (43)
Hispanic	7 (14)
Gender, n (%)	
Female	48 (94)
Male	3 (6)
Age of child	6 wk to 1 y
Age of parent	16–39 y
Insurance, n (%)	
Private	23 (45)
Medicaid	23 (45)
No insurance	5 (9)

TABLE 3 Provider Demographic Characteristics (n = 78)

Ethnicity/race, n (%)	
White	64 (82)
Black	9 (11)
Hispanic	3 (4)
Asian	2 (3)
Gender, n (%)	
Female	43 (55)
Male	35 (45)
Age, y	
	23–72
Health profession, n (%)	
Obstetrician/gynecologist	11 (14)
Pediatrician	17 (22)
Neonatologist	2 (3)
Family physician	24 (31)
Nurse midwife	4 (5)
Nurse practitioner	4 (5)
Physician assistant	5 (6)
Labor and delivery nurse	11 (14)

TABLE 4 State Newborn Screening Professional Demographic Characteristics (n = 9)

Ethnicity/race, n (%)	
White	6 (67)
Black	2 (22)
Native American	1 (11)
Gender, (%)	
Female	6 (67)
Male	3 (33)
Age, y	
	35–60
Health profession, n (%)	
Medical doctor	3 (33)
Registered nurse	4 (44)
Social worker	1 (11)
Laboratory supervisor	1 (11)

groups, namely, (1) knowledge and awareness of initial newborn screening information, (2) knowledge and understanding of the process of informing parents and providers of the results of newborn screening, (3) informed consent and costs, (4) recommendations for how newborn screening information needs to be communicated to parents, and (5) recommendations for what parents and providers want and need to know.

Theme 1. Knowledge and Awareness of Initial Newborn Screening Information

Parents

Overall, parents in the focus groups demonstrated little knowledge about newborn screening. Almost no parents were familiar with the term “newborn screening,” although some were familiar with terms such as “heel-stick test” or “PKU” (phenylketonuria). Even those familiar with the term “PKU,” however, were often unaware that a phenylketonuria test involved >1 test. “Since I had heard it called the ‘PKU test,’ I thought that was the only disease tested for. I had no idea they were testing for other conditions.” Some parents confused

newborn screening with testing for jaundice, prenatal laboratory testing, and hepatitis B immunization.

Very rarely did parents say they sought or received information about newborn screening before their infant was born. Although many recalled receiving a newborn screening brochure in a packet of information given to them during the hospital stay after delivery, very few reported reading it or remembering the information in the brochure. Even fewer actually recalled being told anything about newborn screening while in the hospital. If they were told anything, it was that their infant had a “blood test.” “The hospital visit was a fog; the only thing I wanted to know was ‘is the baby OK?’ ”

In Maryland, where signed consent for newborn genetic screening is mandatory, most parents remembered signing a form that acknowledged that their infant would have a “heel-stick test.” However, they retained very little of the other information about newborn screening that was provided in the consent form and associated paperwork. “The nurse just brought in a bunch of brochures and papers I needed to sign.”

Only parents who had delivered infants in >1 state knew that different states tested for different conditions. Very few knew that additional screening was performed in other state health laboratories or was available in their state through private laboratories. After learning this, some parents were curious regarding why this was so. For others, it made no difference; they said they trusted their providers to advise them about the diseases for which their infants should be tested.

Language was a major barrier for Spanish-speaking and bilingual respondents. Those parents reported that their health care providers often spoke little or no Spanish and that most written information provided to them was available only in English. Newborn screening is referred to as “blood test” in Spanish, which makes it easily confused with several other procedures performed on newborns. Even when newborn screening was explained in the Spanish focus groups, there was confusion about its meaning.

Health Care Providers

All health care providers knew that parents received information about newborn screening in the hospital, and none was surprised that parents were told very little. Providers reported that parents seldom ask about newborn screening, and many providers assumed that parents were not interested in learning more. “Parents typically don’t ask about what happens to their baby in the hospital. They are more interested in the practical things like breastfeeding or crying [when they take the infant home].”

No physician was aware what hospital nurses tell parents about newborn screening, and none had read their state’s brochure. Although they were not asked specifically to name the diseases for which newborns in

their state were being tested, many health care providers volunteered that they did not know all of the diseases. Furthermore, only 2 providers reported that they had had any parent ask about additional screening (for other conditions), and they themselves were unsure how or to whom they should refer parents for additional testing if the parents asked.

State Newborn Screening Professionals

State health department professionals involved with newborn testing were quite knowledgeable about all of the possible tests, variations in state protocols, state legislation, and national policy issues. One individual indicated, however, that the infrastructure for additional screening was not in place in many states; this made it confusing and difficult for parents and providers to learn about it.

Theme 2. Knowledge and Understanding of the Process of Informing Parents and Providers of the Results of Newborn Screening

Parents

Very few parents recalled being given information on the reporting of test results. If parents were told anything, they were likely to remember a statement such as, “No news is good news; you will be contacted if something is wrong.” Parents were not aware of the length of time it would take to get the results; most thought results came back within 1 day.

Parents differed in their opinions of how much information they wanted about the results of the test. Most did not want to be notified unless there was a problem. These parents felt that, because testing is mandatory, they could be confident that the screening had been completed and that their infant’s provider would contact them if retesting was necessary. “If everything is OK, I don’t really care about the results.” However, a few wanted to be informed of the results no matter what they were. “I want to make sure my baby’s test did not slip through the cracks.” Parents unanimously stated that, if they were to receive information about the results, then they would want to hear about the results from their infant’s health care provider, particularly if retesting were necessary.

Most parents had no idea that the state health department was involved in newborn screening or that the state had a laboratory devoted to performing the tests. Many thought “lab” referred to a private laboratory or the hospital laboratory. Only parents whose infants needed to be retested were aware of the role of the state health department in performing, reporting, and following up on newborn screening.

Parents who were informed by the state health department that their infants needed another test reported feeling “blindsided” because they were not aware that

retesting was a possibility or that the state health department was involved in newborn screening. Parents reported feeling alarmed and confused when they received postcards or telephone calls from the state health department. “If I had known retesting was a possibility, it would not have been as frightening when I got the letter.” “I just kept trying to figure out how the health department got my name and knew I had just had a baby. I was so thrown off by it that I couldn’t concentrate on what she was telling me.”

Health Care Providers

Clinicians who provided only prenatal care (ie, obstetricians and midwives) did not receive notification of newborn screening results. Those who provided care to newborns (ie, those practicing pediatrics or family medicine) reported that they received newborn screening results by mail from the state laboratory and that, if retesting was necessary, they were notified via fax or telephone. Some indicated that they thought that notification about results and the need for retesting was not sufficiently rapid.

State Newborn Screening Professionals

State newborn screening professionals described the most common breakdown in the provider-parent notification system as occurring when children did not have a designated primary care clinician or when parents did not identify their child’s physician while in the hospital. If parents did not provide hospital personnel with contact information for their child’s physician, then the state laboratory notified the hospital from which the specimen was sent and also contacted the parents directly when the results indicated an urgent need for retesting.

Theme 3. Informed Consent and Costs

Parents

For almost all parents, the issue of consent was not important. Because screening is mandatory, most thought they did not need to give consent unless the blood collected would be used for some other purpose. Most were not concerned about the cost of the tests; however, a few parents in the middle-class groups wanted to know whether the tests were covered by insurance, and one mother said that she turned down additional tests because she feared they would be too expensive.

Health Care Providers

Only one health care provider advocated strongly for mandating consent; the others thought it might cause confusion or increase parent refusal. A few felt strongly that the child’s welfare overrode the need for consent. Physicians were not aware of the cost of newborn screening or insurance coverage of tests. They reported

that parents did not receive an itemized list of the hospital charges for having an infant unless they participated in a health savings account, paid out of pocket, or requested an itemized list of charges specifically.

State Newborn Screening Professionals

State professionals also indicated that they thought that informed consent was not needed. Like many primary care providers, they worried that it would cause problems.

Theme 4. Recommendations for How Newborn Screening Information Needs to Be Communicated to Parents

Parents

Parents indicated uniformly that they wanted to hear about newborn screening from a trusted health care provider. Almost all requested a brochure to accompany oral education. "I like to have a brochure because you don't always remember everything your doctor tells you."

Parents unanimously thought, however, that the worst time to receive newborn screening information was during the hospitalization for delivery, because at that time parents are often exhausted and feel deluged with new information. When asked the optimal time, all parents responded that information should be provided during the third trimester of pregnancy, during routine prenatal care. "This is the best time because I am going to the doctor almost every week." "This is a time when you are reading everything you can get your hands on." Some parents suggested that newborn screening information be given at multiple times, such as during a prenatal visit, in a prenatal class, and again as a brief reminder from a nurse during the hospital stay.

Hispanic respondents emphasized the importance of sharing information with family members. Spanish-speaking and bilingual parents wanted brochures in English and Spanish to enhance their understanding and to share with family members. "I want to make sure I get all the information." "I need one in Spanish to show to my family."

Health Care Providers

Most obstetric and family practice physicians, nurse practitioners, and physician assistants were willing to include information about newborn screening in their discussions with expectant parents as long as it did not slow them down. All except 2 agreed with parents that the third trimester of pregnancy would be the ideal time. Those 2 thought the initial educational visit with the nurse or physician assistant would be the most practical time to provide education to patients in their practice. All prenatal clinicians agreed that, if the American College of Obstetricians and Gynecologists (ACOG) recommended that they inform parents about newborn

screening, then they would definitely do so. Most providers suggested including newborn screening on the ACOG prenatal parent information checklist.

Some physicians reported that the most practical use of their time would be to have a nurse or physician assistant give the information to patients. Nurse midwives all reported a willingness to include newborn screening in their patient education; none expressed concern about the time needed to provide this education.

State Newborn Screening Professionals

State newborn screening professionals indicated that they thought it would be helpful for parents to receive a brief, to-the-point brochure (available in several languages) that included contact information. They also recommended the third trimester as the best time to deliver the information and indicated that ideally the education should include prenatal providers.

Theme 5. Recommendations for What Parents and Providers Want and Need to Know

Parents

Parents expressed little interest in obtaining detailed information about how the state newborn screening programs work or medical explanations of the diseases. Most concurred that they wanted to know about specific diseases only if their child was affected. No parents wanted their provider to discuss all of the diseases with them. After receiving an explanation about how the testing system works, parents indicated that they wanted only essential information, ie, (1) that their infant would be screened, (2) that screening would benefit the infant, (3) that the infant might need to be retested, and (4) how parents would be notified about the need for retesting and the need to act quickly.

When parents were shown current brochures, they indicated there was room for improvement. No parent wanted the long explanations or comprehensive information about newborn screening that appear in many current brochures. Parents unanimously requested that the content of pamphlets should correspond to information provided to them orally by health providers. "I don't want a lot of details. I just want it as short and as simple as possible." "Put less information so people will read it. Make it more concise, less overwhelming."

Health Care Providers

Providers thought that the information they give parents orally needs to be limited. "Initially, parents need only very basic and practical information about screening. If you bring up too much, you will just give parents more to worry about." Providers suggested that initial screening information should inform parents that (1) screening will occur, (2) it is done to make sure the infant is

healthy, (3) finding problems early could save an infant's life, and (4) the testing is safe and does not harm the infant. They suggested that parents be given more specific information only if retesting is necessary. "If a parent has a child whose test comes back positive, the patient education is problem specific. The parent only wants to know about that specific disease."

Regarding education for health care professionals, providers in our focus groups thought that clinicians providing prenatal care need to know only cursory information about screening programs, such as why and how screening is performed, the number of diseases for which testing is performed, brief information about each disease (including incidence and treatment), and, most importantly, where to get more information if a parent has a question. These prenatal providers wanted to know enough to give basic information to parents, to answer parents' questions, and to refer them to other sources or subspecialists should the need arise.

Providers caring for newborns wanted enough information to educate and to reassure parents if retesting was necessary. These health care providers were generally comfortable with the knowledge they already had, because they rarely needed to deal with a child who was diagnosed with one of these disorders as a result of newborn screening. They thought that their continuing education time should focus on diseases that are more common than those diagnosed through newborn screening.

If information should be needed about these rare disorders, providers considered the state health department to be a trusted source of information about retesting and positive results. These providers noted that, when they had a patient with positive results, their first call was to the state health department or a trusted genetics expert from the hospital at which they trained or to which they refer patients. They reported that monthly medical newsletters from their professional organizations, review articles in medical journals, and notices from the health department could be additional useful sources of information.

Many clinicians suggested that it would be helpful to have a printed copy (rather than an electronic version) of essential information about newborn screening, including brief definitions of all of the disorders for which there are screening tests, a list of the specific diseases for which testing is performed in their state, and the incidence and treatment of those disorders. They also requested resources for additional information (such as Web sites and toll-free numbers) for themselves and for parents.

State Newborn Screening Professionals

State program professionals thought that clinicians do not need to know details about newborn screening or

the disorders for which screening is performed. They considered the state newborn screening program to be "the safety net for doctors" and thought it was the program's responsibility to provide primary care clinicians with test results, explanations of what the results mean, and what next steps providers should take, including what subspecialists to contact for more information.

DISCUSSION

Summary of Findings

The 1999 AAP Newborn Screening Task Force recommended that research be performed to understand how to improve patient education about newborn screening for genetic and other disorders. Our project, which elicited opinions from parents of newborns, from clinicians, and from state newborn screening professionals, was designed to address the AAP task force recommendations.

Our study confirmed that parents and clinicians have limited knowledge and awareness about current newborn screening practices. Neither group places newborn screening high in the hierarchy of information needed at the time of delivery, which is the time at which newborn screening education is usually performed. Consistent with the task force's recommendations, parents, providers, and state newborn screening professionals in our focus groups suggested that parents be briefly informed about newborn screening and its benefits and indicated that the preferred time for education about newborn screening is during the third trimester of pregnancy.

Although neither parents nor providers were interested in detailed information about newborn screening, there were some key points that they wanted to know. For parents, the most important information was (1) that their infant would be screened, (2) that screening would benefit the infant, (3) that the infant might need to be retested, and (4) how parents would be notified about the need for retesting and the need to act quickly.

As with previous research on patient education, our findings indicated that parents want to receive information orally from a trusted health care provider as well as in a brochure that they can take home.¹¹⁻¹³ Respondents in all of our focus groups agreed that written information should be presented to parents in a user-friendly and easy-to-read format. Our findings are consistent with previous research that found that parents are most interested in information that they deem relevant and practical and that emphasizes what they need to know and do.^{11-13,24}

Clinicians were not interested in time- or resource-intensive training programs on newborn screening. Rather, they preferred short handouts, checklists, review articles, and notices or monthly medical newsletters from their professional organizations that provide to-

the-point information to help them educate parents more effectively. This is consistent with previous studies about communicating with parents regarding childhood immunizations,¹⁰⁻¹³ in which physicians indicated that they wanted only a brief checklist of information that would prepare them to educate parents effectively. The to-the-point information providers requested included a list with definitions of the diseases for which testing can be performed, the specific diseases for which testing is performed in their state, and sources of additional information. They did not want detailed information about the diseases; they requested only a brief statement about each disease, its incidence, and its treatment.

Limitations

Our findings should be interpreted in light of our study's limitations. First, our purposeful sample, although selected to represent a mixture of geographic locations, ethnic groups, and sociodemographic levels, was not a random population sample. In particular, we studied parents, providers, and state newborn screening professionals from only 6 states, selected mainly because of the availability of collaborators who could access providers and parents who might participate in our focus groups. Therefore, our results cannot be considered representative of the US population or any regional population.

Second, our sample included only 3 parents identified by the state who had actually received false-positive results. Therefore, the recommendations from parents about how to deal with such results are based on the opinions of only those few parents.

Third, the individuals conducting the focus groups were also involved in data analysis. Although themes from each focus group were remarkably similar, a finding that suggests overall validity of the study results, the fact that the same individuals gathered and evaluated the data leaves open the possibility that investigator bias could have influenced the interpretation of focus group data.

Recommendations

On the basis of our study results, it is clear that more attention needs to be paid to patient education materials about newborn screening and the methods used to disseminate those materials. In many states, neither parents nor providers have been involved in the development of materials or plans for dissemination.²⁵ Consequently, neither the materials nor their distribution are provider or parent centered.⁴ More parent and provider input is needed to develop informational materials that are useful for them.

We recommend that prenatal and primary care providers should be more involved in educating parents about newborn screening. However, providers indicated that a directive to provide such education to parents

during the third trimester of pregnancy needs to come from the providers' national professional organizations. State newborn screening programs, federal agencies, and affiliated groups should collaborate with professional organizations to prepare and to motivate health care providers and their professional staff members to provide this education to parents. The educational process should be convenient for providers and tailored to fit into their current modes of practice.

Patient Education Materials

Using the input of providers and parents in our study, a review of current newborn screening brochures,⁴ our previous research,^{10-13,26-28} and patient education and communication literature,^{29,30} we developed a template for a parent education brochure that can be distributed to patients to inform them about newborn screening. A copy of the English version is shown in Fig 1. A Spanish version has also been created. The template for the brochure is available on CD-ROM. Using the CD-ROM version, state newborn screening programs can modify the text to reflect their state's individual policies and procedures and the specific screening tests performed. Similarly, the CD-ROM contains a variety of photographs of newborns from various ethnic backgrounds that can be substituted for those shown in Fig 1, thus permitting users to tailor the brochure electronically to match their population's demographic profile.

Provider Education

We also developed a patient education toolkit that can be used by health care providers. One component of the toolkit is a discussion guide that includes 7 brief points based on what focus group participants thought was the essential oral information to accompany a patient education brochure (Fig 2). In addition, the Newborn Screening and Genetics Resource Center developed a quick reference regarding the various diseases for which testing is performed in state newborn screening programs. This quick reference was designed to give health care professionals a concise, plain-language guide they can use to educate themselves or to answer quickly parents' questions about newborn screening. The provider education materials are undergoing pilot testing in the offices of prenatal clinicians, to determine feasibility and time required for use of the materials, appropriateness and relevance for patients, and satisfaction for providers.

CONCLUSIONS

Parents, providers, and state newborn screening professionals in our focus groups made recommendations about how newborn screening education could be improved. The recommendations include the need for pre-

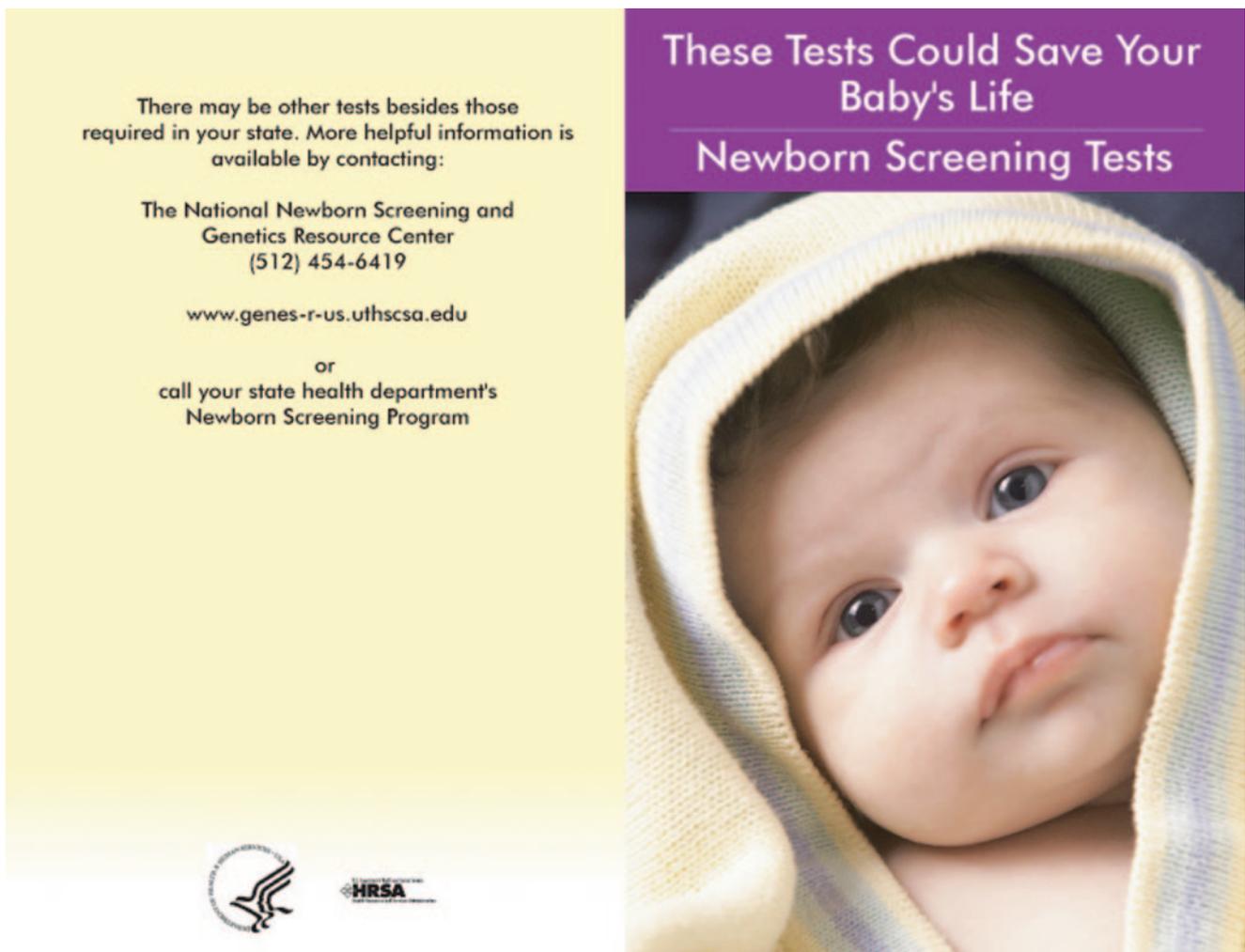


FIGURE 1
Standard brochure template in English.

natal oral teaching with user-friendly materials. Professional societies and state health officials should work together to encourage appropriate parent and provider education about newborn screening. User-friendly patient and provider education materials, such as those we developed and presented in Figs 1 and 2, could form the basis for these materials.

APPENDIX 1. MODERATORS' GUIDES FOR PARENTS (SCRIPTED QUESTIONS FOR RECENTLY DELIVERED OR EXPECTANT PARENTS)

Introduction—everyone give names, etc.
Establish rapport

How old is your infant? What is your baby's name?
How did you choose it?

Scripted Questions

1. Where did you get health information about pregnancy, labor, delivery, and newborns? Probe: where, how, what, and who?
2. Did you go to prenatal classes? Probe: why or why not?
3. In general, what are your most trusted sources of medical information?
4. What information did you receive about what would happen to your baby in the hospital?
5. Have you heard of newborn screening? What does it mean to you? Probe: how did you hear about it (newspaper, magazine, or doctor)?
6. Tell me what you know about the tests done on newborn babies where they stick their heel to draw a little blood.
7. Were you given any information before your baby got the heel-stick/newborn screening test?
 - a. Were you given any written information? What did it say? Was it helpful? How? (If appropriate: what language was it written in?)

Why does my baby need Newborn Screening tests?

Most babies are healthy when they are born.

We test all babies because a few babies look healthy but have a rare health problem.

If we find problems early, we can help prevent serious problems like mental retardation or death.

How will my baby be tested?

Before you leave the hospital, a nurse will take a few drops of blood from your baby's heel.

The hospital will send the blood sample to a newborn screening lab.

How will I get the results of the test?

Parents are notified of test results if there is a problem.

Ask about results when you see your baby's health professional.



Why do some babies need to be retested?

Your baby may be retested if you leave the hospital before 24 hours.

Some States require a second test on all babies.

Some babies need to be retested because there is a problem with the blood sample.

A few babies need to be retested because the first test showed a possible health problem.

What if my baby needs to be retested?

Your baby's health professional or the State Health Department will contact you if your baby needs to be retested. They will tell you why the baby needs to be retested and what to do next.

If your baby needs to be retested, get it done right away.

Make sure that your hospital and health professional have your correct address and phone number.

What if I have questions?

Ask your baby's health professional if you have questions or concerns.



FIGURE 1
Continued

- b. Did a nurse or doctor talk to you about it? Probe: who?
 - c. What did they tell you? Was it helpful? How?
 - d. Did they ask your permission for the heel stick and tests?
8. Were you informed about the results of the test?
 9. If there were no problems, would you want to be informed?
 10. If the test result was abnormal, who would you want to let you know?
 11. Did any of your babies have to be retested?
 - a. How were you informed? Probe: tell me about it.
 - b. What did you like or not like about the way you were informed?
 - c. How would you like to have been informed?
 12. Before they stick an baby's heel, what do you think parents want to know/what would you have wanted to know?
 - a. When? (eg, before birth or at the time of birth)?
 - b. From whom? (eg, physician, nurse, or public health worker)?
 - c. How? (eg, print, talk, or video)?
 13. Do you want to know the diseases tested for? Probe: what information would you want on the diseases? (eg, the number, a general description, a brief description of each, features, cause, and treatment)?
 14. Would you like information on
 - a. Costs?
 - b. How you get results?
 15. What do you want to hear from your provider?
 16. Show examples of state newborn screening patient education materials and get people to critique them;

7 Things Parents Want To Know About Newborn Screening



THE HEALTH PROFESSIONAL'S GUIDE FOR BRIEF PRENATAL DISCUSSION WITH PARENTS

1. All newborn babies are required by the State to get tested for some rare disorders before they leave the hospital.
2. Babies with these disorders may look healthy at birth.
3. Serious problems can be prevented if we find out about the disorders right away.
4. To do the test, a nurse will take a few drops of blood from your baby's heel.
5. Your baby's health professional and hospital will get a copy of the test results. Ask about the results when you see your baby's health professional.
6. Some babies will need to be retested. If your baby needs to be retested, you will be notified. It is very important to get retested quickly.
7. Talk to your baby's health professional if you have questions.



FIGURE 2
Discussion guide for prenatal providers.

probe for feedback about the cover, content, specific wording, graphics, layout, and organization.

a. Is this brochure something you would pick up and read? Do you think it is clear what the brochure is about?

b. What do you like? Why?

c. What do you not like? Why?

d. What is helpful? How?

e. What is not helpful? Why?

17. After all you have heard today,

a. What do you think are the most important things

that parents need to know about newborn screening?

- b. How should they get this information? When? From whom?

18. Most states do not require that the parents give consent for these tests. Do you think parents should be asked for their consent for these tests on newborn babies? What about permission? If the doctors or nurses had asked your permission, would you have given it? Why or why not?
19. Are you aware that there can be a difference in states and in hospitals in the number of diseases for which babies are screened? What do you think about this?
20. Explain that the dried blood samples can be stored and used later.
- a. Do you mind if that sample is used in the future in a research project?
- b. Would it matter if your baby's blood sample had all identifying information removed?
21. In the future, scientists may be able to test for more diseases. If these tests become relatively inexpensive, states may include these tests in their routine screening. Some of the diseases may not even have treatments yet, and some may not have disastrous outcomes. What do you think of this?

Additional Questions for Parents of Infants with False-Positive Test Results

1. Tell me the story of how you found out your baby tested positive.
2. What were you told? By whom? When? How did you feel? What do you wish they had said or done?
3. What did you do? Where did you go for information? Support?
4. If you were in charge, how would things be run?
5. What information do parents need to know about screening tests? Probe: when? by whom?
6. Do parents need information on all of the diseases? What information do they need?

APPENDIX 2. MODERATORS' GUIDE FOR HEALTH CARE PROVIDERS (SCRIPTED QUESTIONS FOR HEALTH CARE PROVIDERS)

Continuing Education

1. How do you keep updated regarding advances, new practice guidelines, and genetic innovations?
 - a. How do you like to learn new medical information?
 - b. What are the best strategies for delivering infor-

mation to pediatricians/obstetricians/gynecologists/family practitioners in their office, including allied health staff?

- c. Do you have access to computers and the Internet at your job site?
- d. What distance learning modality (Web site, CD-ROM, dial-in telephone conference, or interactive video conferences) do you prefer?
- e. Do you belong to a national professional organization (ACOG, AAP, or American Academy of Family Physicians)? How do you get information from them?

Current Practice

2. Tell me about your state's newborn screening program. What happens? What oral and written education is currently given to parents?
3. What is your role in newborn screening?
 - a. Do you include information about newborn screening in discussions with parents? When?
 - b. What newborn screening information do you give to the parents? Give us an example of what you say.
 - c. Do you use any materials? What?
 - d. How important is it for you or your staff to educate parents on newborn screening?

Newborn Screening Education

4. What do you think parents need to know about newborn screening?
5. Do you think informed consent should be mandatory?
6. Are you aware that different states and hospitals screen for different numbers of diseases?
7. Have any parents asked you about supplemental screening? If parents want more tests, where would you advise them to get more information?
8. Do you have parents who are knowledgeable about newborn screening? How many?
9. Do you have parents who are concerned about states storing blood spots? How many?
10. What do you and the people in this office need to know about newborn screening? Probe: system and diseases screened.
11. Tell me the best way for you to get this information. Probe: from whom, in what form?
12. What are the best ways to convince providers of the importance of adopting and maintaining newborn screening communication in their practices?

13. What tools or strategies would be helpful in delivering newborn screening education to parents?
14. Tell me about your patient education in general. What are the most important issues?
15. Do you use written materials? Probe: who developed them, you, your staff, your hospital system, your professional organization, or pharmaceutical companies?
16. Do you use prompts to remind you to inform parents of various issues?
17. Do you receive patient education information from your professional organization? Probe: how and what?
18. How do you get your mail? Does someone scan it first? Would you likely open mail from your state health department or your professional organization?

Retesting, For Practices That Care for Newborns

19. Tell me about your experience with retesting and positive results. Probe: how many, how are you made aware, and who handles this in your office?
20. Who calls the parents? Tell me what is said to the parents.
21. What resources do you use to find additional information about what a positive test means? Probe: state sources consulted (eg, literature or Internet).
22. Have you ever had a false-positive result? Do you know anyone who has?
23. What happens if there is a false-positive result? Who informs the parent? How do you connect the parent with a specialist? What can be done to improve this process?

APPENDIX 3. MODERATORS' GUIDE FOR STATE NEWBORN SCREENING PROFESSIONALS (SCRIPTED QUESTIONS FOR STATE NEWBORN SCREENING PROFESSIONALS)

1. Tell me about your state's newborn screening program.
2. What is the process of notifying parents and providers of newborn screening results?
3. Are there any barriers to effective notification?
4. What patient education materials are available in your state?
 - a. Who developed them and how were they developed?
 - b. How are they distributed?
 - c. When do parents receive them?
 - d. Do you think the dissemination process is satisfactory?

5. What do you think parents need to know about newborn screening? What is the best way to get this information to them?
6. Should we get informed consent from parents?
7. What do you think health care providers need to know about newborn screening? What is the best way to get this information to them?
8. What are some of the system barriers in the newborn screening process?
9. How can we improve patient education on newborn screening?

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