Informing Parents About Newborn Screening: Hidden Problems, Practical Solutions

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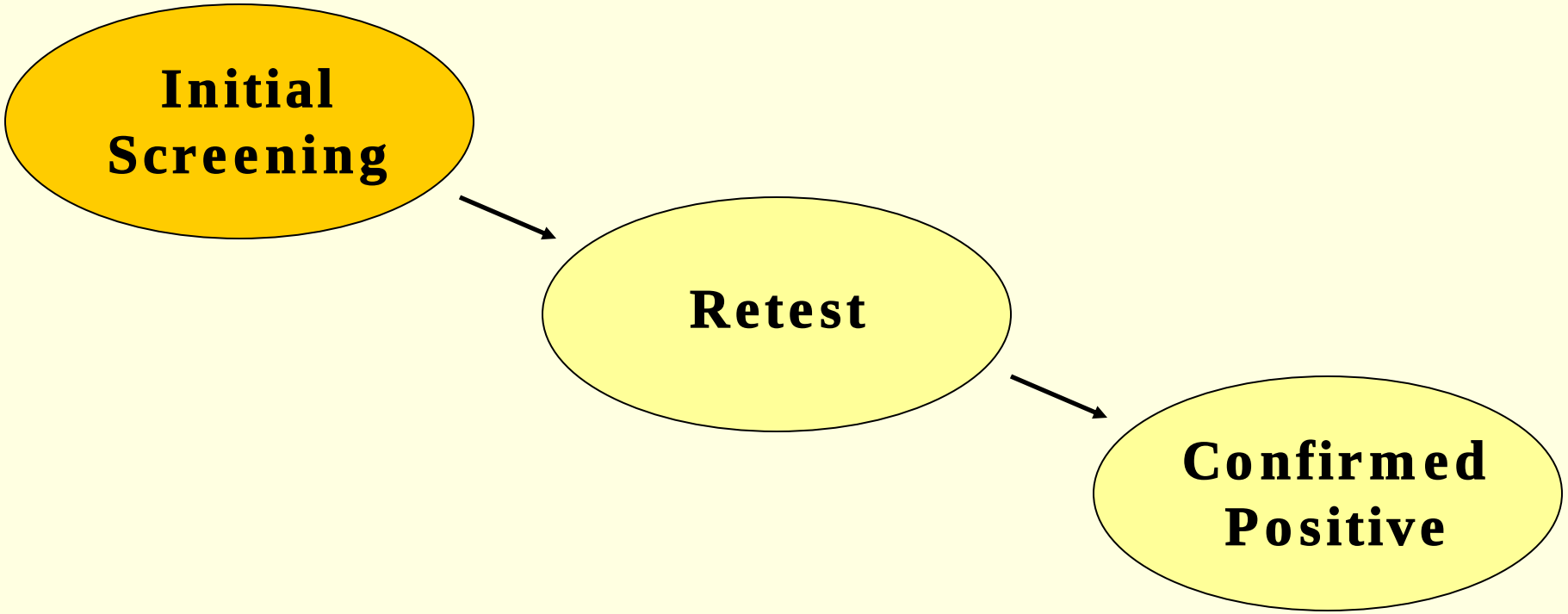
Quality: Top health care issue 21st century*

Newborn Screening Communication

- knowledge-based
- patient-centered
- systems minded

*IOM Quality Chasm: 2001

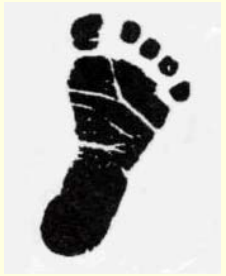
NBS Communication Stages



Parent informational & psychological needs vary

NBS Parent Education Background

- ✓ NBS parent education materials available in 49 of 51 states - mostly given in hospital
- ✓ No national guidelines for content or dissemination
- ✓ AAP-NBS Task Force recommends families be educated during the prenatal/ perinatal periods
- ✓ Prenatal NBS education is **rare** (class has limits)
- ✓ Pediatricians rarely discuss initial screening with parents



NBS Communication Challenges

- ✓ New technology/rapidly changing environment
- ✓ State programs differ (disorders screened, info given, process of reporting results)
- ✓ Parents/ public lack basic knowledge
- ✓ Hospital birth visit a “fog” for most parents
- ✓ Primary providers may lack up-to-date information, patient education materials, time
- ✓ Best practices yet to be identified

Hidden Barriers to Informing Parents about NBS

Patients/ providers/nurses/ state programs:

✓ Agendas/ communication styles/ knowledge level differ

Patients:

✓ Education/ Literacy/ Language

✓ Health Literacy:

Capacity to

- Obtain, process, understand basic health information and services
- Make appropriate health care decisions (act on information)
- Access/ navigate healthcare system

Education in the U.S. today

School drop-out rates

Russia	2%
Japan	5%
U.S.A. (16th)	29%
U.S. cities	35-45%
U.S. black students	*50%*

14% 9th graders finish college in 6 years

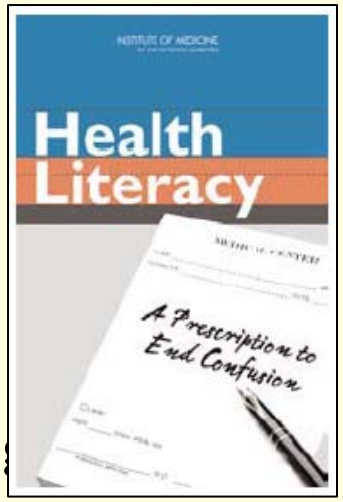
Job requirements in U.S.

20%	4 year college
65%	Assoc. degree
15%	minimum skills

½ of h.s. students can eventually get a job that supports a family

Health communication

Hot national topic



IOM: 2004 Report

- 90 million adults have trouble understanding and acting on health information
- Complex text must be simplified and attention paid to culture and language

Healthy People 2010

- Improve health communication/health literacy

JCAHO (1993); Balanced Budget Act (1997)

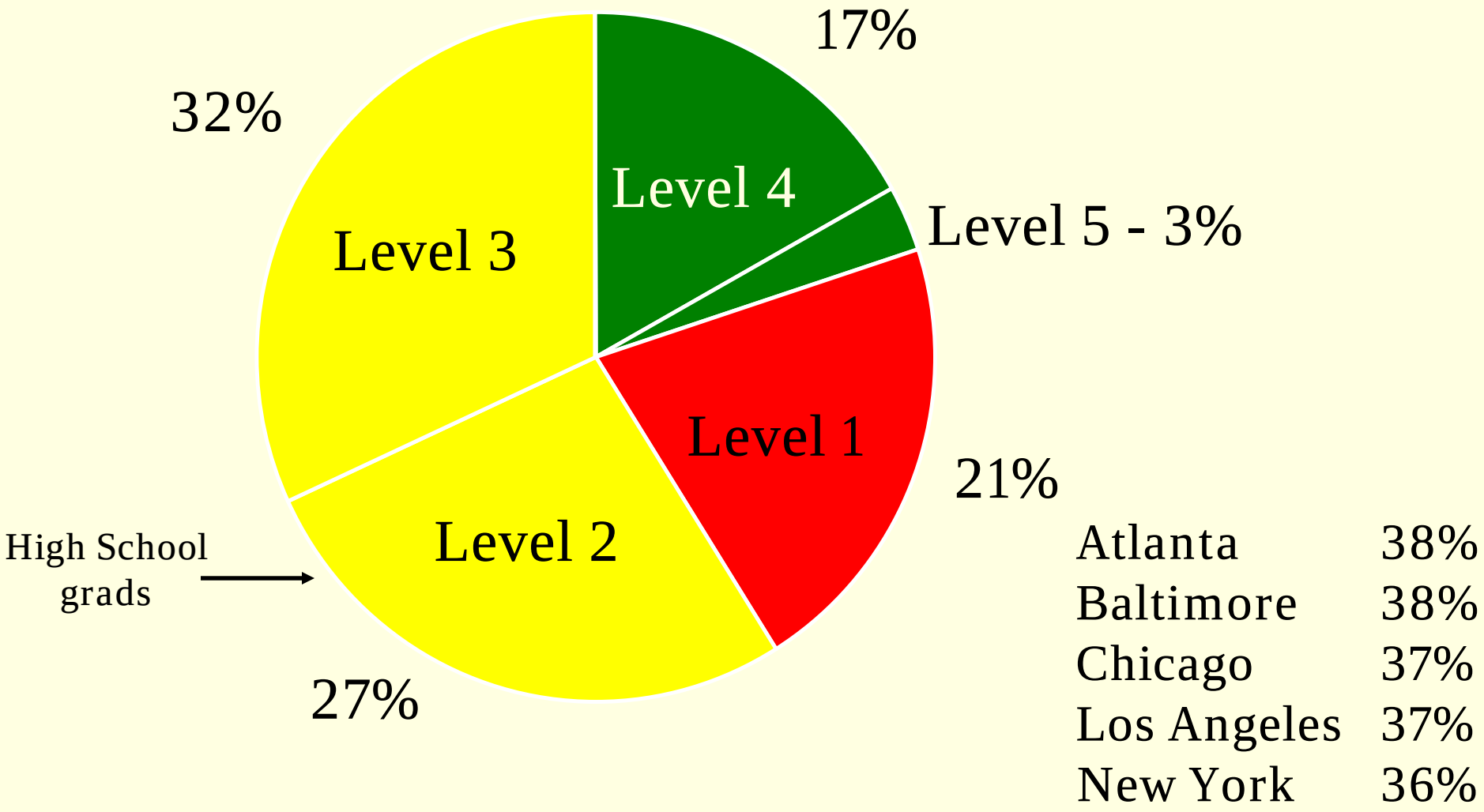
- Patients must be given info they can understand

National Adult Literacy Survey

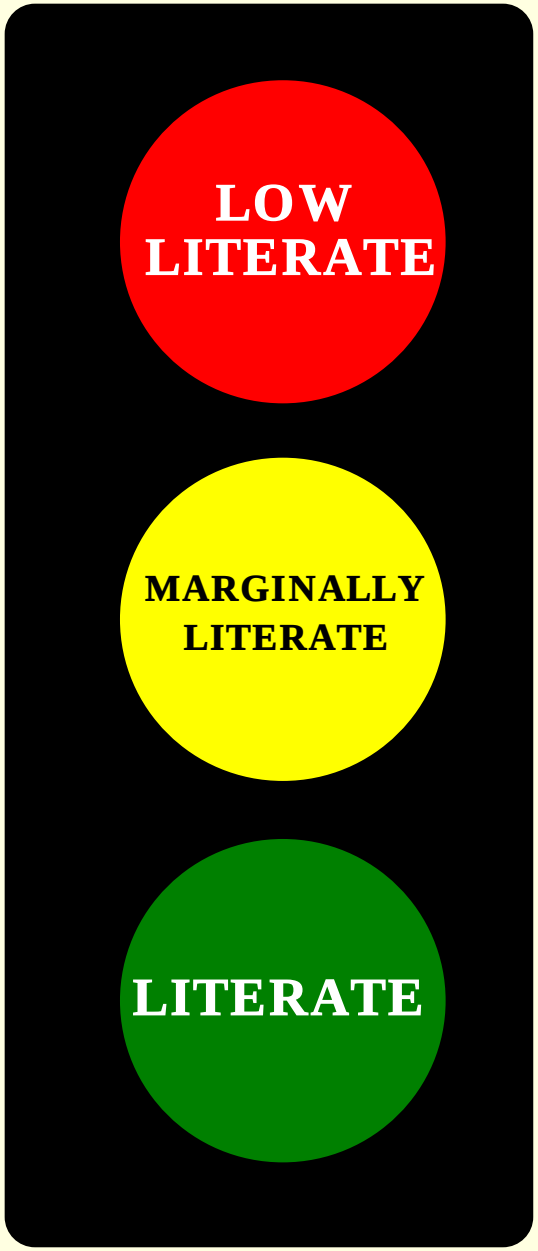
n = 26,000

- Most accurate portrait of literacy in U.S.
- Scored on 5 levels
- Levels 1 and 2 cannot:
  - Use a bus schedule or bar graph
  - Explain the difference in two types of employee benefits
  - Write a simple letter explaining an error on a bill

1993 National Adult Literacy Survey



Atlanta	38%
Baltimore	38%
Chicago	37%
Los Angeles	37%
New York	36%



Who's at Level 1 nationally?*

Medicare recipients	42%
Medicaid recipients (over 1/3 births)	41%

Low literacy LINKED to:†

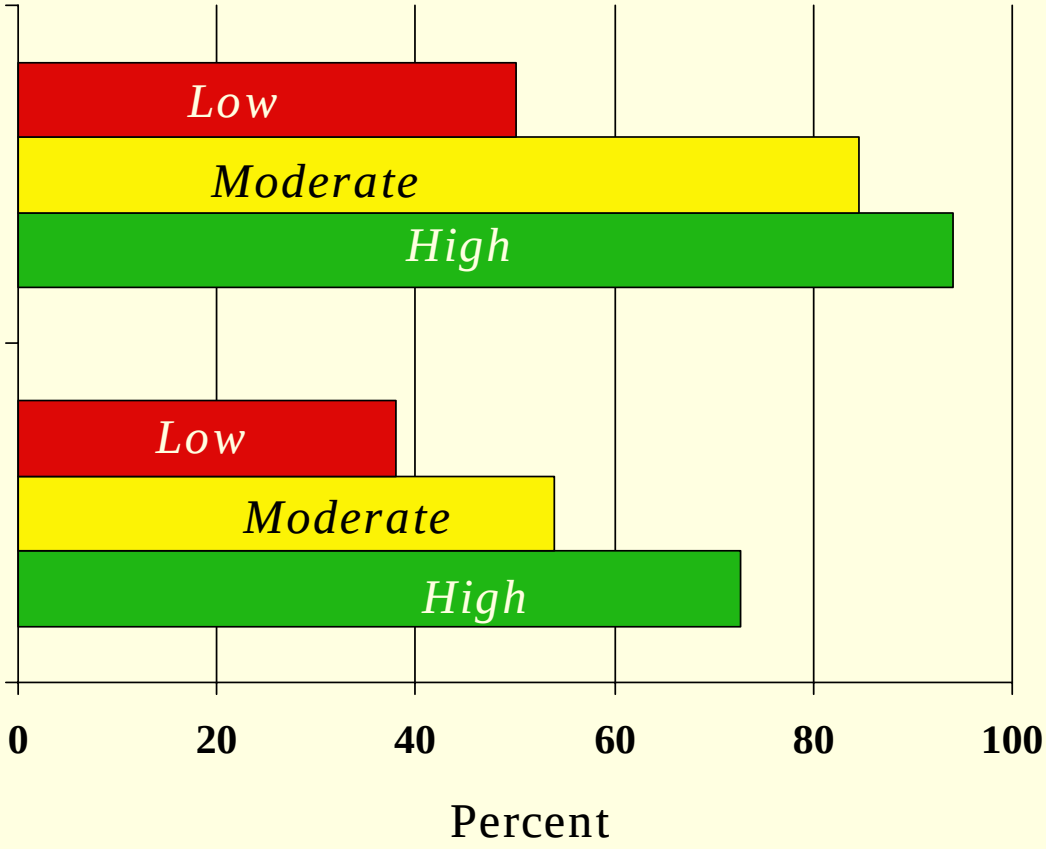
- poor health
- lower quality care
- medical errors
- poor outcomes
- disparities

* NALS, 1993 † AHRQ Evidence Report 2004

Low Literate Diabetic Patients Less Likely to Know Correct Management*

***Need to Know*:**
symptoms of low blood sugar (hypoglycemia)

***Need to Do*:**
correct action for hypoglycemic symptoms



*Williams et al., Archive of Internal Medicine, 1998

Video

- 90 million Americans have trouble understanding and acting on health information
- Health information is often complex & unfamiliar to people of all education levels
- It’s easy to make a mistake

Mismatched Communication

Provider Process/ State NBS Program: Giving information

Patient Process: Understanding, remembering, and acting on information

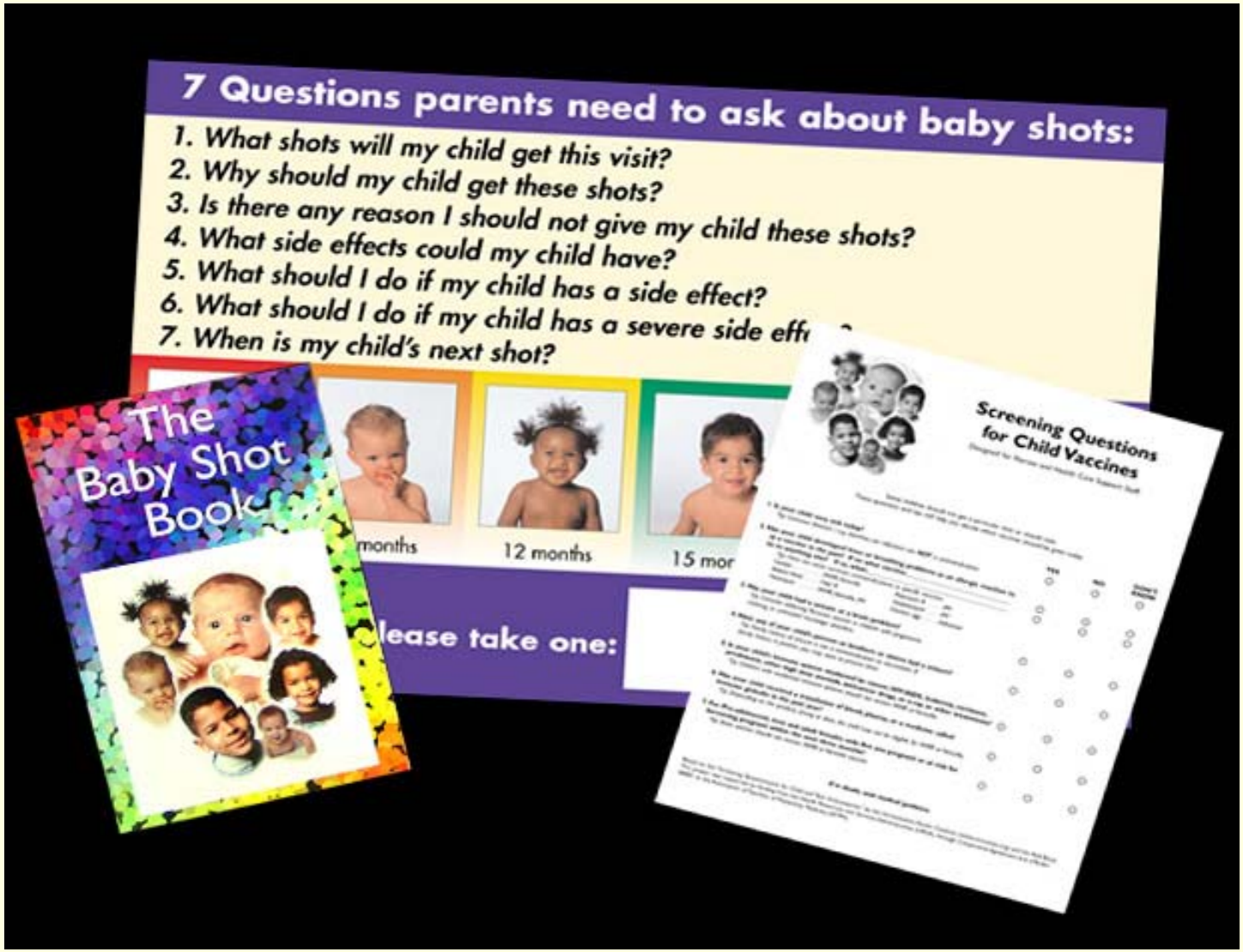
Patient Education: What We Know

- ✓ Written materials, when used alone, will not adequately inform
- ✓ Simplified materials are necessary but *will not* solve communication problems
- ✓ Focus needs to be on “need-to-know” and “need-to do”
- ✓ Work with patients to identify best practices

* *IOM: Report on Health Literacy 2004*

* *AHRQ Report 2004*

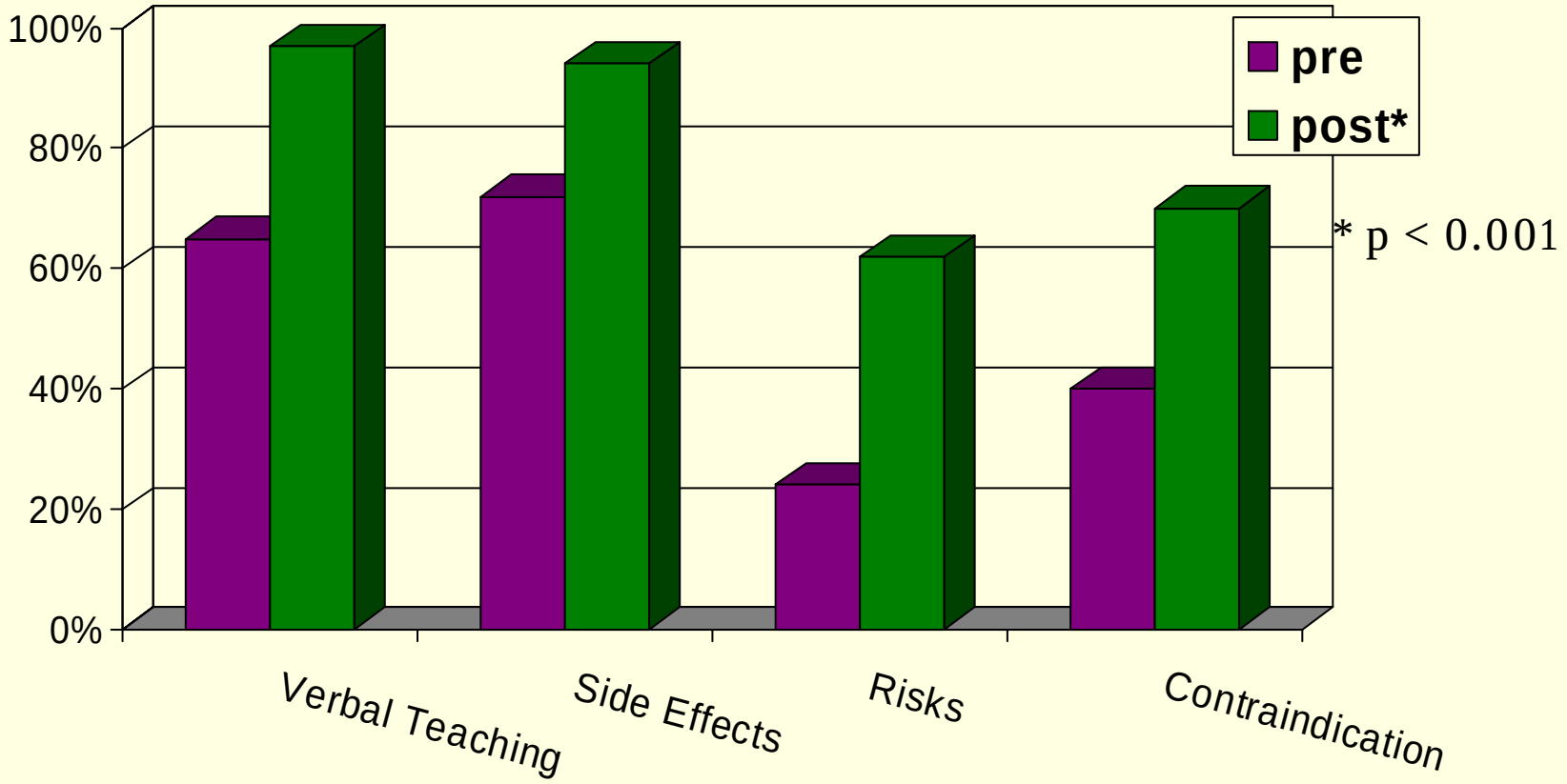
Vaccine Communication Materials



T Davis. Ambul Peds; Fredrickson, Davis. Pt Ed Counsel

Vaccine Communication

Pre and Post Materials



T Davis et al, *Ambulatory Pediatrics*, 2002

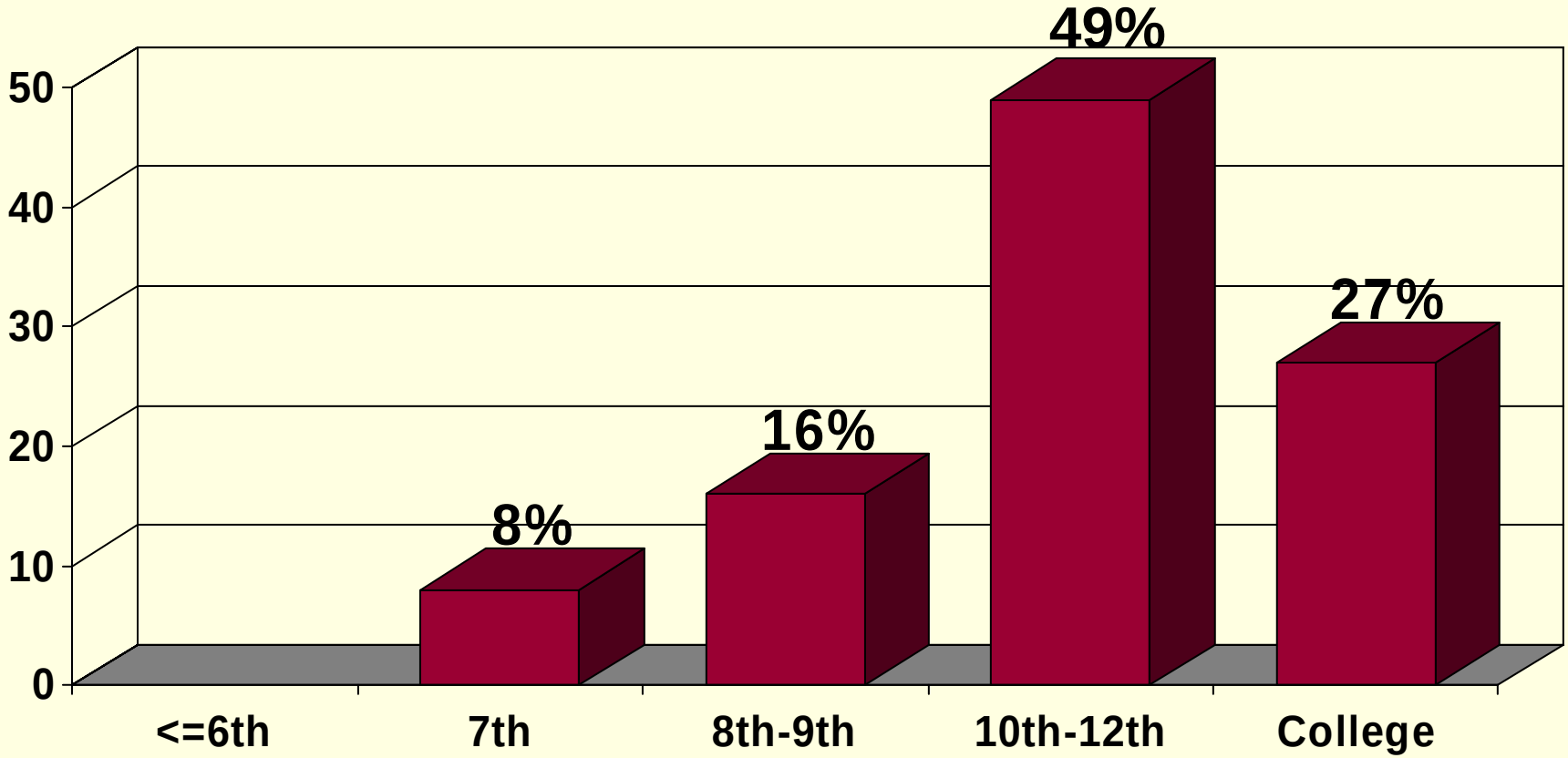
HRSA Contract

- ✓ Evaluate user-friendliness, including readability and cultural appropriateness, of NBS parent education materials in English and Spanish (49 programs)
- ✓ Conduct listening groups of key stakeholders
- ✓ Develop pamphlets in English & Spanish for parents
- ✓ Work with NNSGRC to develop and evaluate educational tools for prenatal providers & toolkits for state programs

Davis T, et al. *Pediatrics*, in press.

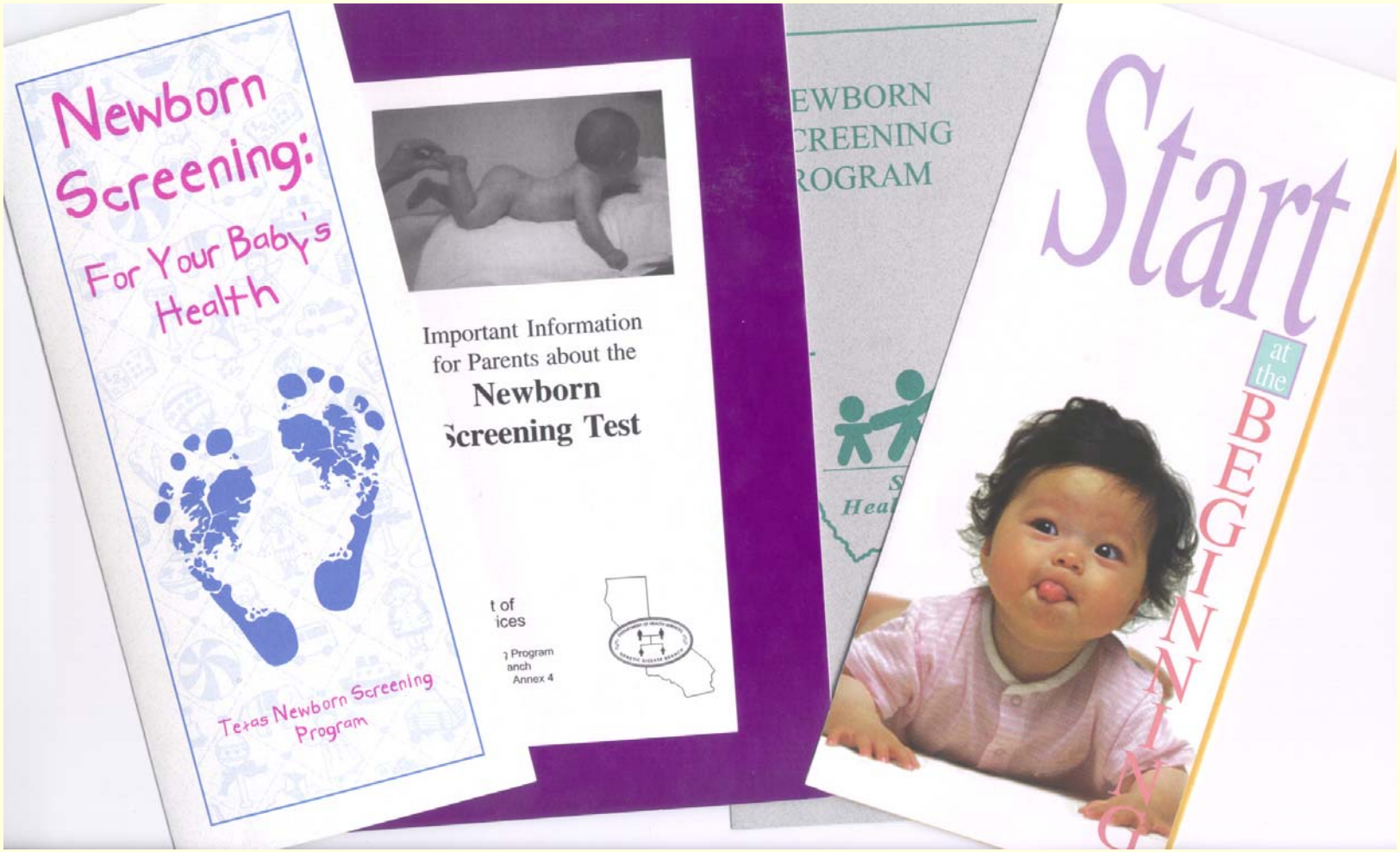
Arnold C, Davis T, et al. *Pediatrics*, in press.

Brochure Readability



Gold Standard Readability: $\leq 6^{th}$ Grade

Do Current Materials Work?



Readability is the tip of the iceberg.

Is the layout user-friendly?

1. Is the layout user-friendly?

First impressions are important!

Does the pamphlet:

- Have ample white space?
- Limit paragraphs to 4 to 5 lines?
- Use bullets, boxes, indentation, bolding, vertical lists?
- Use bifold rather than trifold format?
- Use font that is 12 point or larger?
- Avoid use of ALL CAPS, *italics* and *specialty* fonts in large blocks of text?

Parents sometimes worry about the health of their unborn baby. Many don't put those fears to rest until they are finally able to hold their newborn, count the fingers and toes, and see for themselves that their baby is perfectly healthy.

Usually, a newborn who *looks* healthy, is healthy. But sometimes, that may not be true. A baby may have "invisible" problems which could lead to mental retardation, abnormal growth, dangerous infections ... and even death.

Early detection of these "invisible" disorders is the goal of the Department of Health and Environmental Control's Newborn Screening Program (law requires this testing).

Through this program, all newborns are tested soon after birth for several genetic and chemical disorders. These disorders include *Phenylketonuria (called PKU), Congenital Hypothyroidism, Galactosemia, Congenital Adrenal Hyperplasia (called CAH), Medium Chain Acyl Co-A Dehydrogenase Deficiency (called MCADD), and Hemoglobinopathies.* The tests are done on a small sample of blood taken by pricking the baby's heel. Early treatment can give an infant with one of these disorders the best chance for a healthy, productive life.

"What is each of these disorders?"

PKU is a disorder that keeps the baby's body from being able to use certain parts of the proteins (amino acids) found in milk and formula. This amino acid (phenylalanine) builds up in the baby's system and can damage growing brain cells, causing mental retardation. Doctors can give babies with PKU a special formula and diet low in phenylalanine.

Congenital Hypothyroidism means that the thyroid gland is not working properly. If untreated, a baby with Congenital Hypothyroidism will not grow or function normally and may develop severe mental retardation.

Galactosemia is a condition where the baby cannot use a sugar (galactose) found in cow's milk-based infant formula and breast milk. Babies who are not treated can develop life-threatening infections and mental retardation. This disorder can be treated by feeding the baby soy-based infant formula.

In babies with **CAH**, the body's adrenal gland does not work normally. Untreated babies will not grow or mature properly. Some of these babies may even die.

The body uses a sugar called glucose as the main energy source. When the glucose cannot be used, fat is broken down for energy. **MCADD** is a disorder where the body is unable to use certain kinds of fat to make energy. Because they cannot use fat for energy, babies with **MCADD** may get very sick if they have an illness that makes them not want to eat. They can have trouble breathing and have seizures. Their hearts may even stop beating if their blood sugar gets too low. The main treatment for MCADD is to make sure the baby eats every few hours.

Hemoglobinopathies are genetically caused hemoglobin disorders such as Sickle Cell Anemia. These disorders can cause many problems *including misshaped red blood cells*, anemia, severe pain and high risk for serious infection.

"What if my new baby seems very healthy? Are these tests really necessary?"

The tests are necessary. Most babies who have PKU, Congenital Hypothyroidism, Galactosemia, CAH, MCADD or Hemoglobinopathies seem healthy at birth. Most are born into families who have no history of genetic or chemical disorders. Blood tests are the only way these disorders can be found in the early stages.

"These disorders seem rare. Why is there a state law requiring screening?"

PKU, Congenital Hypothyroidism, Galactosemia, CAH, MCADD and Hemoglobinopathies are uncommon, but they are also very serious. Testing every baby at birth is the best way to make sure all babies who have these disorders are found quickly and treated as soon as possible.

"What does it mean if I'm told my baby needs a second test?"

Retesting may be needed for a number of reasons. Sometimes a retest is needed simply because enough blood was not collected the first time. Babies whose first blood sample is taken before they are 24 hours old should also have a second test as a precaution.

Also, the tests are very sensitive to make sure a baby who really has one of these disorders will not be missed. Because of this, a few normal babies will have false positive results and will need a second test. While taking your baby in for repeat testing can be scary, it is important that every baby has a thorough screening. As a general rule, only when a baby's test is unusual for a second time will your

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 tests?

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

Ask about results when you see your baby's doctor.

Do illustrations convey the message?

2. Do illustrations convey the message?

A picture may be worth a thousand words – but which thousand?

Are pictures and captions:

- Serving a purpose (they are not just decorative)?
- Clear and realistic?
- Familiar and likely to be understood?

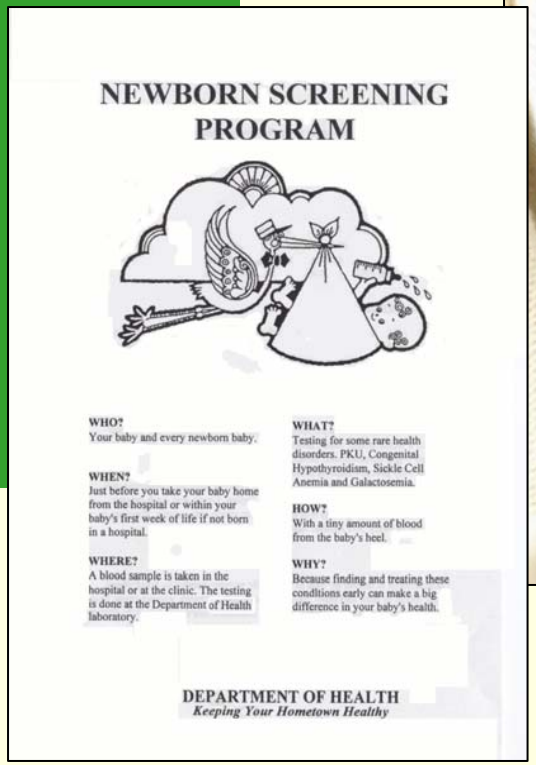
Is the message clear?

3. Is the message clear?

- Is the message obvious on the cover, title, and headings?
- Are key messages easy to pick out?
- Does pamphlet get to the point quickly?
- Does pamphlet easily inform the readers of what they need to know and do?

Does cover graphic:

- Target expectant parents?



NEWBORN SCREENING PROGRAM

WHO?
Your baby and every newborn baby.

WHEN?
Just before you take your baby home from the hospital or within your baby's first week of life if not born in a hospital.

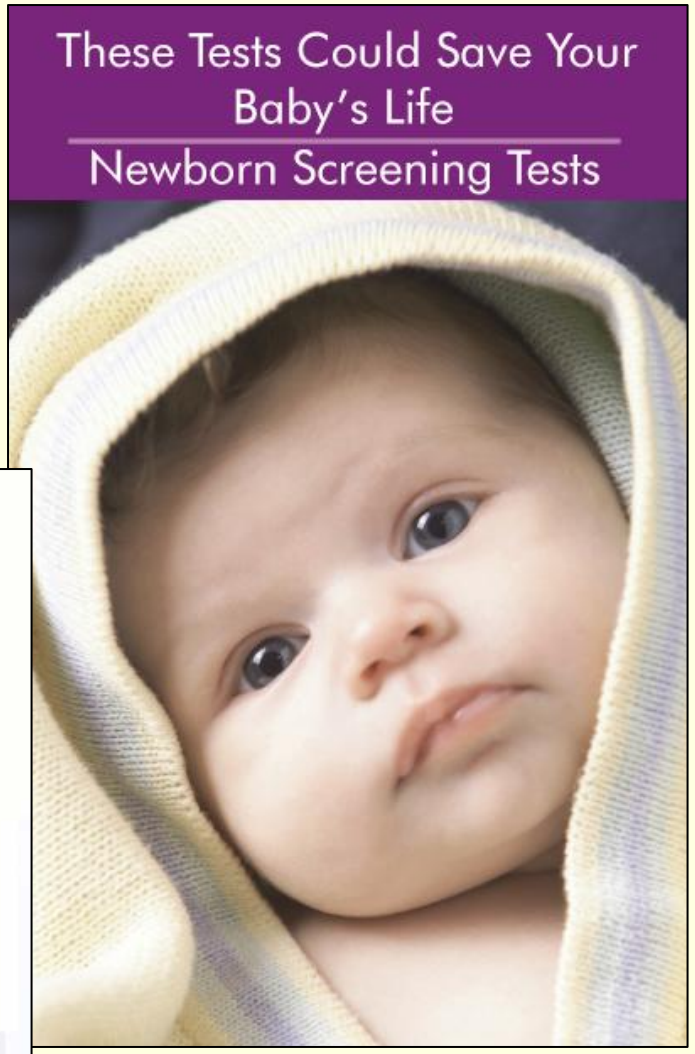
WHERE?
A blood sample is taken in the hospital or at the clinic. The testing is done at the Department of Health laboratory.

WHAT?
Testing for some rare health disorders. PKU, Congenital Hypothyroidism, Sickle Cell Anemia and Galactosemia.

HOW?
With a tiny amount of blood from the baby's heel.

WHY?
Because finding and treating these conditions early can make a big difference in your baby's health.

DEPARTMENT OF HEALTH
Keeping Your Hometown Healthy



Is the information manageable?

4. Is the information manageable?

Does the pamphlet:

- Focus on "need to know" rather than "nice to know"?
- Stick to a few key messages to avoid information overload?
- Limit the use of graphs and statistics?

Why does my baby need to be screened?

Routine newborn screening can determine if your baby has any of the following conditions: PKU (Phenylketonuria), Hypothyroidism, Galactosemia, Sickle Cell Disease or CAH (Congenital Adrenal Hyperplasia). These are rare, but serious conditions which can cause brain damage or even death if not treated. Even if your baby looks healthy, he or she may have one of these conditions. If any of these conditions go untreated, serious problems will arise. Therefore, (state) law requires that all newborn babies be tested. The blood tests will identify babies who need more testing, counseling and treatment. It is critical to detect these conditions as soon as possible. A few days or weeks could make the difference between life and death or disability.

(College Reading Level)

Why does my baby need Newborn Screening tests?

* Most babies are healthy when they are born.
* A few babies look healthy but have a rare health problem.
* Babies who are born with these diseases seem normal at birth.
* We test all babies to find the ones who may need treatment.
* If we find problems early, we can help prevent serious problems like mental retardation or death.

(7th Grade Reading Level)

“Meant for Me”

5. Does the pamphlet make the reader feel "this information is meant for me"?

Does the pamphlet:

- Use a personal, conversational tone rather than a textbook or bureaucratic one?
- Foucs on parent rather than on the NBS program?
- Use familiar words, situations and pictures?
- Address the reader; personalize information (*"your baby"* not *"the baby"*)?
- Show cultural sensitivity?

Newborn Screening is offered to families with new babies as a service through the Department of Health. The initial screening tests are performed by the Department of General Services, Division of Consolidated Laboratory Services (DCLS) which is located in (city). DCLS also performs repeat tests on infants up to six months of age. This service makes it possible to find out whether newborn babies might have disorders that may result in serious problems if treatment is not started soon after birth. Every infant in (state) is tested a few days after birth unless a parent or guardian objects on the grounds that the test conflicts with their religious practices.

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.*

Avoid a Common Mistake

Most patient education materials sequence information using:

Medical model

- Description of problem
- Statistics on incidence and prevalence (tables)
- Treatment forms and efficacy

Is more helpful to use:

Newspaper model

- Gives most important information first

Health belief model

- Your baby may be at risk
- There is something you can do about it
- Your baby will get personal benefits if you do

Focus Group Research

6 states n= 138

22 focus groups & 3 interviews:

- English- & Spanish-speaking parents of babies recently screened
- Parents of babies who had a false positive
- Pediatric & prenatal care providers
- State newborn screening professionals

Parent Demographics

(n = 51)

Ethnicity/ Race		
Black	22	(43%)
White	22	(43%)
Hispanic	7	(14%)

Insurance		
Private	23	(45%)
Medicaid	23	(45%)
No Insurance	5	(9%)

Sex		
Female	48	(94%)
Male	3	(6%)

Age of Child 6 wks- 1 yr

Age of Parent 16-39

Provider Demographics

(n = 78)

Health Profession

Family Physician	24	(31%)
Neonatologist	2	(3%)
Pediatrician	17	(22%)
OB/GYN	11	(14%)
Nurse Midwife	4	(5%)
Labor and Delivery Nurse	11	(14%)
Physician Assistant	5	(6%)
Nurse Practitioner	4	(5%)

Ethnicity/ Race

White	64	(82%)
Black	9	(11%)
Hispanic	3	(4%)
Asian	2	(3%)

Sex

Female	43	(55%)
Male	35	(45%)

Ages 23-72 (range)

Lessons Learned from Focus Groups

- Parents and providers had limited knowledge/ awareness of newborn screening- "*not on the radar screen*"
- Parents not familiar with term *newborn screening*
- Physicians did not know what NBS information parents were given in the hospital, none had read state brochure
- All stakeholders felt parents should 1st receive education **prenatally** *"The hospital visit was a fog; the only thing I wanted to know was 'is the baby ok?'"*
- Physician and nurse education before discharge focused on *practical things e.g. breast feeding, crying, car seats*

Lessons Learned from Focus Groups

- Parents wanted 'heads up' about initial & retesting 7-8 months pregnant *"This is the best time because I am going to the doctor almost every week."*
- Parents wanted information orally from their primary provider with a pamphlet to take home *"I like to have a brochure because you don't always remember everything your doctor tells you."*
- Pamphlet needs to be to the point, "*I just want it as short and as simple as possible"*
- Prenatal providers indicated willingness to educate parents
- OB's and FP's more likely to incorporate NBS information if it was on the ACOG checklist

Parent Experiences

• NBS pamphlets often given in hospital with no oral information; pamphlet often "lost" in take home package *"They give you so much information in the packet to take home with you, that you end up throwing most of it away."*

• Opinion mixed on "need to know" if result is negative. Most said, *I don't really care if every thing is o.k.* Others: *I want to make sure my baby's test did not fall through the cracks*

• Did not know state public health department was involved in testing and retesting. "*I just kept trying to figure out how the health department got my name and knew I had just had a baby."*

List/ Description of Diseases

• Parents expressed little interest in detailed information on diseases or NBS program

• Parents did not read list of 32 diseases and descriptions; stopped reading when they realized they could not pronounce the word and had no basic knowledge of the disease, *"I don't want a lot of details." "Put less information so people will read it. Make it more concise, less overwhelming."*

• Parents only interested in description of diseases when baby needed retest, then only in condition being tested *"If my child has a test come back positive, I only want to know about that specific disease."*

• A few highly educated parents requested web links, and computer savvy moms turn to Google 1st when retesting is needed

“Need-to-know” Information for Parents

- **All** babies are screened
- Screening will **benefit** the baby
- Testing is **safe-** not harmful
- The baby may need to be **retested**
- Parents will be **notified if** retesting is needed
- Its important to **act quickly if retesting** is necessary

Cost and consent were not important

Parents more likely to keep high quality materials and throw away copied handouts

To be produced & distributed by AAP. Will be available as an electronic template for states to use or modify

Esta Prueba Puede Salvar La Vida De Su Bebé

¿Por qué mi bebé necesita esta prueba de sangre?

La mayoría de los bebes nacen saludables.

Le hacemos estas pruebas a todos los bebés porque algunos bebés parecen sanos pero tienen un problema de salud raro.

Si encontramos problemas temprano, podemos ayudar a prevenir problemas serios como el retraso mental o la muerte.

¿Cómo se hace la prueba?

Antes de que usted salga del hospital, una enfermera tomará unas gotas de sangre del talón de su bebé.

El hospital enviará la muestra de sangre a un laboratorio especial.

¿Cómo obtendré los resultados de la prueba?

Los padres serán noficados de los resultados si hay un problema.

Pregunte por los resultados cuando vea al doctor de su bebé.

¿Por qué algunos bebés necesitan más pruebas?

Repetimos las pruebas de todos los bebés que salen temprano del hospital.

En algunos estados, todos los bebés reciben dos pruebas.

A veces los bebés necesitan otra prueba porque había un problema con la muestra de la sangre.

Algunos bebés nesesitan más pruebas porque la primera prueba mostró la posibilidad de un problema de salud.

¿ Y si mi bebé necesita otra prueba?

El doctor de su bebé o el departamento de salud del estado se pondra en contacto con usted si su bebé necesita otra prueba. Ellos le dirán por qué su bebé necesita otra prueba y lo que usted tiene que hacer.

Si su bebé necesita otra prueba, hágala de inmediato.

Asegúrese que el hospital y su doctor tengan su número de teléfono y dirección.

•Spanish speaking mothers want pamphlets in English & Spanish *"I want to make sure I get all the information." "I need one in Spanish to show to my family."*

18% of U.S. households do not speak English at home. ***(2000 census)***

Lessons Learned from Providers

- Not interested in time- or resource- intensive training programs
- Preferred short handouts, checklists, brief articles in their professional organizations newsletters.
- Wanted to-the-point information to help them educate parents more effectively.

Providers requested brief information in a handy notebook to prepare them for conversations with parents:

- a list with concise definitions of the diseases screened
- the specific diseases screened for in their state
- sources of additional information

Challenges in Teaching/Reaching Physicians

- CME for NBS is not a *carrot*
- Computers had limited use with most practicing physicians (Family Physicians training residents more likely to use computers)
- Material mailed from professional organizations & the state health department would most likely get to be read by the physicians.

Recommendations

to improve quality of NBS communication

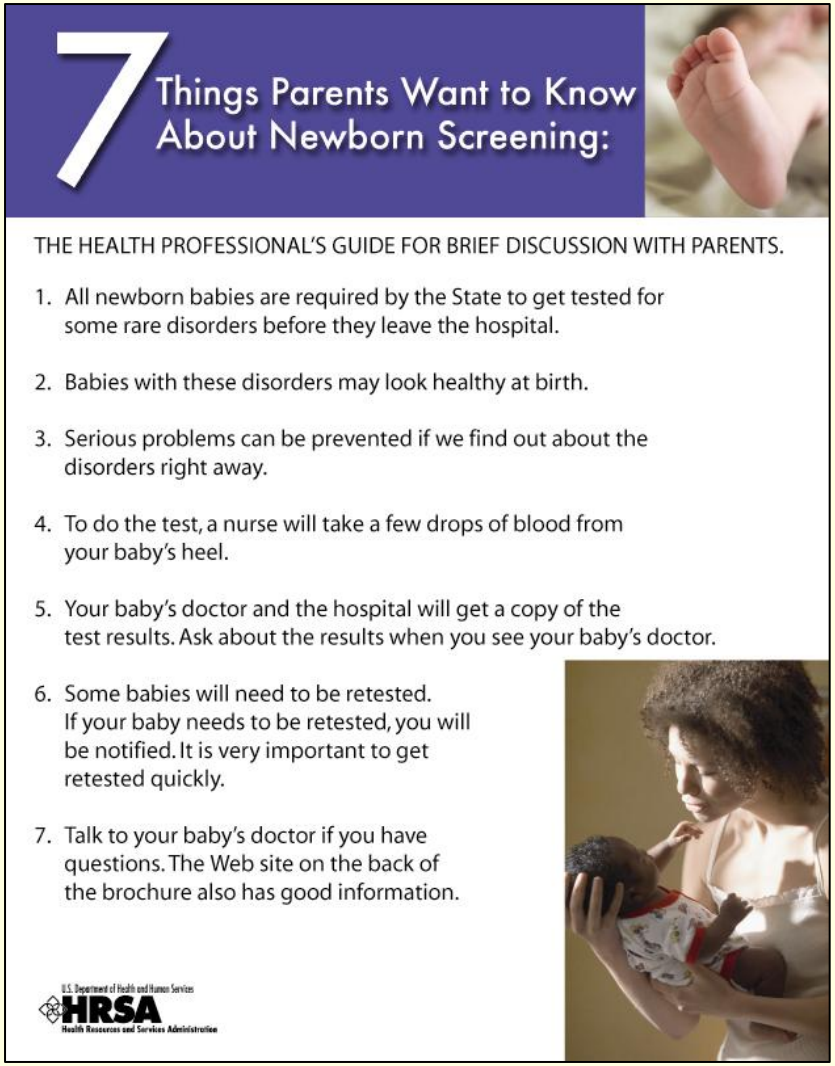
Information needs to be more patient AND provider centered

- Parents and providers need to be involved in development of materials and the distribution plan i.e. *what will be taught, when, where, how, by whom and how often.*

NBS needs to be more systems –minded

- Brief education at multiple times may be helpful *What is the role of office nurse, hospital staff?*
- Providers need to be more *in the loop*
- *Parent education needs to be convenient and practical for usual practice*
- Professional organizations, state agencies, HRSA and affiliated groups should collaborate more to prepare and motivate providers to educate parents

Provider Communication Tools
Brief Discussion Guide



Brief Information to Facilitate Communication with Parents

QUICK REFERENCE TO NEWBORN SCREENING DISORDERS

Biotinidase Deficiency (BIO) BIO is an enzyme deficiency that occurs in about 1 in 60,000 newborns and can result in seizures, hearing loss, and death in severe cases. Treatment is simple and involves daily doses of biotin.

Congenital Adrenal Hyperplasia (CAH) CAH is caused by decreased or absent production of certain adrenal hormones. The most prevalent type is detected by newborn screening in about 1 in 15,000 newborns. Early detection can prevent death in boys and girls and sex misassignment in girls. Treatment involves lifelong hormone replacement therapy.

Congenital Hypothyroidism (CH) Inadequate or absent production of thyroid hormone results in CH and is present in about 1 in 3,500 newborns. Thyroid hormone replacement therapy begun by 1 month of age can prevent mental and growth retardation.

Congenital Toxoplasmosis (TOXO) Infection of the fetus with a parasite ingested by the mother during pregnancy can result in TOXO in the newborn. The transmission rate is about 30% and the national incidence is approximately 1 in 10,000 newborns based on limited screening. Early diagnosis and drug therapy reduces the risk of blindness, mental retardation, or other serious complications.

Cystic Fibrosis (CF) CF occurs in about 1 in 4,000 U.S. newborns and is characterized by progressive lung disease, pancreatic dysfunction, and other organ failures. Confirmatory testing usually involves sweat testing and treatment leads to decreased hospitalizations and better nutritional and pulmonary outcomes. Caucasians are at an increased risk.

Galactosemia (GAL) Failure to metabolize the milk sugar galactose results in GAL and occurs in about 1 in 50,000 newborns. The classical form detected by newborn screening can lead to cataracts, liver cirrhosis, mental retardation, and/or death. Treatment is elimination of galactose from the diet usually by substituting soy.

Homocystinuria (HCY) HCY is caused by an enzyme deficiency that blocks the metabolism of an amino acid that can lead to mental retardation, osteoporosis, and other problems if left undetected and untreated. The incidence is approximately 1 in 350,000 U.S. newborns. Treatment may involve dietary restrictions and supplemental medicines.

Maple Syrup Urine Disease (MSUD) MSUD is a defect in the way that the body metabolizes certain amino acids and is present in about 1 in 200,000 U.S. newborns. Early detection and treatment with dietary restrictions can prevent death or severe mental retardation. There is an increased risk in Mennonites.

Louisiana Newborn Screening Information

In Louisiana, the state mandates screening on all babies for 5 conditions.

Phenylketonuria (PKU)

Hypothyroidism (CH)

Galactosemia (GAL)

Biotinidase (BIO)

Sickle Cell Diseases (SCD)

Beginning late 2004 the program will add a pilot test on all babies for five additional conditions.
The additional tests will likely be mandated in the future.

Homocystinuria (HCY)

Maple Syrup Urine Disease (MSUD)

Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCAD)

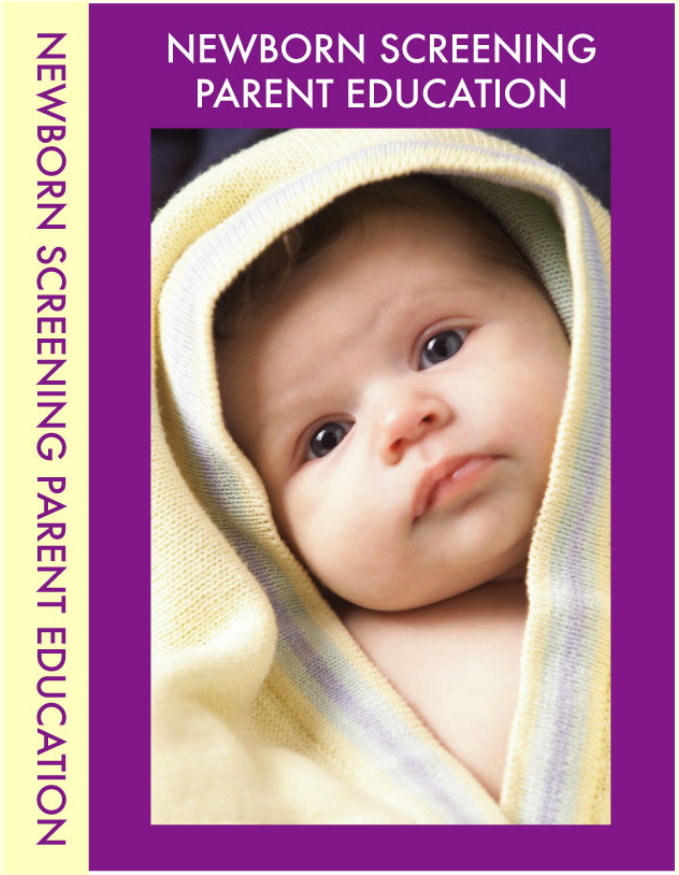
Citrullinemia (CIT)

Argininosuccinate Lyase Deficiency (ASA)

- All mandated screening is done at the Louisiana Department of Health Laboratory
- Some hospitals use a private lab or their own lab to screen.
- There are other screening tests available outside of the mandated program, which parents may wish to investigate.
- Linkages to laboratories providing additional testing are available from the National Newborn Screening and Genetics Resource Center: http://genes-r-us.uthscsa.edu

The state NBS program can provide more information:
Phone: 504-568-5070
Website: http://oph.dhh.state.la.us/geneticdisease/newbornscreen

Provider Notebook to Facilitate Prenatal Parent Education



Pilot to evaluate feasibility & satisfaction

- Materials were mailed to 25 providers in 4 states (GA, LA, NM, TX) 32% FP; 24% OB; 8% Midwives; 2% NP
- Providers used the materials for one month with a total of 240 English-speaking and 130 Spanish-speaking parents (48% Medicaid)

Results of Pilot Parent Education Project

- **92%** reported being highly satisfied with **all** of the materials
- **84%** found the "7 Things" helpful; **80%** were likely to use it on an ongoing basis
- **88%** thought the parent pamphlets were relevant prenatally; **80%** were likely to use them on an ongoing basis

Results of Pilot Project, contd.

- **100%** found the quick reference helpful and thought it contained the right amount of information for them.
- **92%** found state-specific screening information helpful; **only 12%** visited the **state website** listed.
- NBS education using the materials took **2-5 minutes**.

Toolkits for State NBS Programs

- **C.D. in "jewel" case:**
  - Electronic-templates of English and Spanish parent pamphlets that states can tailor to meet their needs
  - Electronic-pictures of parents and young babies
- **Printed guide to developing user-friendly NBS pamphlets**

- To be distributed by the NNSGRC

NBS Education Ideal

- ✓ Parent-centered materials/messages delivered 1st prenatally
- ✓ Messages given multiple times
- ✓ OB and pediatric providers more involved in the system
- ✓ Provider centered “need to know”/ “need to do” education
- ✓ Public awareness campaign may be needed
- ✓ Quality control to ensure consistency and efficacy of education