

Newborn screening:

Empowering nurses to improve quality and safety

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Article purpose

The purpose of this article is to empower registered nurses to improve quality and safety in newborn screening (NBS). The article presents an overview of the NBS system and discusses the risk of deadly delays in reporting results, the need for a culture of safety and the new federally recommended schedule to prevent these delays. The article also addresses psychosocial aspects of NBS.

Objectives

After reading this offering, the learner will be able to:

1. Describe why NBS is a system and not simply a test.
2. Explain what is meant by a culture of safety and why it is important in NBS.
3. Describe the new federal schedule to achieve timeliness in the NBS system.
4. Explain how nurses can ensure a culture of safety for NBS, guarantee sample quality, prevent transport delays and manage psychosocial aspects of NBS.

Deadly delays in newborn screening

Timeliness is critical to prevent deadly delays in newborn screening (NBS). During pregnancy, a mother's metabolism clears abnormal quantities of compounds that cross the placenta from an affected baby. Once the umbilical cord is clamped, maternal metabolism is no longer a factor, and the baby begins to accumulate abnormal toxic metabolites. For some disorders, including those associated with the inability to metabolize fats (fatty acid oxidation disorders) and the accumulation of organic acids (organic acidemias) and ammonia (urea cycle disorders), the baby is at risk of dying within the first weeks of life.

The Milwaukee Wisconsin Journal Sentinel (Gabler, 2013) published a series of articles drawing attention to what it called "deadly delays" in NBS. These delays include hospitals batching samples for several days before sending them to the laboratory and laboratories being closed on weekends and holidays. The NBS community owes a great debt to the reporters who drew attention to this problem that initiated changes to improve the NBS process.

One *Journal Sentinel* article (Fauber, 2013) illustrates the importance of NBS by telling the stories of two babies born in Colorado with medium chain acyl-CoA dehydrogenase (MCAD) deficiency, a fatty acid oxidation disorder that can result in significant hypoglycemia, seizures and

death. Baby Noah was born on a Friday. His NBS sample was drawn on Saturday morning, but it was not sent to the testing laboratory until Monday. The lab was closed on the weekend, and hospital staff did not know that the lab had a drop box that would have allowed the sample to be processed at 6:00 AM Monday morning. Noah died on Tuesday, and his NBS results came back on Wednesday. Baby Kelly, another newborn with MCAD deficiency, was born on a Tuesday. His NBS results were reported on Friday, and he lives without disability or medical sequelae.

A second *Journal Sentinel* article (Gabler, 2014) reports the story of Baby Juniper, a Utah newborn with MCAD deficiency who may owe her life and well-being to attention drawn to timeliness in the NBS system. Juniper was born on Sunday, October 5, 2014 in a rural hospital that previously sent its NBS samples by U.S. mail, a process that resulted in about half of the hospital's specimens requiring 5 days or longer to reach the state laboratory. Three days before Juniper's birth, Utah began a program to fund overnight delivery of samples from rural hospitals to the state lab. Juniper's sample was drawn on Tuesday when she was 2 days old. The lab received it Wednesday, and her health care provider received the results on Friday when Juniper was 5 days old. If her hospital had not had overnight delivery and because of lab closure on weekends and Columbus Day, Juniper may have been 11 days old by the time her health care provider received her NBS results. She may not have been alive at that time, as a similar delay was far too long for Noah Wilkerson. Juniper's story shows the value of identifying problems (such as timeliness) in NBS and proactively developing solutions to prevent deadly delays, a process of continuous quality improvement.

March of Dimes NBS Quality Awards

In partnership with the Association of State and Territorial Health Officials (ASTHO), the March of Dimes established the NBS Quality Award to acknowledge state health officials with achievements in NBS. These achievements include decreased sample transit times (beginning at 72 hours with a target of 24 hours) and full

transparency of NBS data so parents can know the NBS performance of their planned birth hospital.

The inspiration for and the first recipient of the award is Will Humble, MPH, Arizona Department of Health Services Director. Mr. Humble saw his state's NBS data in Ms. Gabler's (2013) *Journal Sentinel* article and determined that his state needed to do better for the health of its babies. He immediately established a policy of full transparency for transit times from hospitals to the state laboratory with a target of 95 percent of sample transit times within 72 hours. For more information about the March of Dimes NBS Quality Award, visit marchofdimes.org.

Overview of NBS

NBS touches each of the 4 million babies born every year in the United States (Martin, Hamilton, Osterman, Curtin & Mathews, 2015). It was developed in Massachusetts in 1963 as a state public health initiative to provide early identification of and dietary intervention for phenylketonuria (PKU). Robert Guthrie, PhD conceptualized sending dried blood specimens from babies' heel sticks to a centralized state laboratory for screening for phenylalanine.

The goals for NBS continue to be those initially identified by Guthrie for PKU, but they are now expanded to include early identification of a broader array of conditions to permit presymptomatic intervention and unnecessary disability and death. These conditions make up the Recommended Uniform Screening Panel (RUSP) for NBS (Table 1). The tests are screening tests. After a positive screen, a positive follow-up diagnostic test is required before a baby is identified with a disorder.

Because of the historic importance of PKU to NBS, some call the NBS system the "PKU test" even though current NBS includes a recommended 32 disorders. This miscommunication has led to incorrect follow-up testing of individuals with disorders other than PKU, with diagnostic testing performed for PKU rather than the correct disorder.

Table 1. Disorders included in the RUSP

Organic acid metabolism disorders (accumulation of acidic metabolites result in acidemia)	<ol style="list-style-type: none"> 1. Isovaleric acidemia (IVA) 2. Glutaric acidemia (GAI) 3. Hydroxymethylglutaric aciduria, also called 3-OH 3-CH3 glutaric aciduria (HMG) 4. Multiple carboxylase deficiency (MCD) 5. Methylmalonic acidemia, mutase deficiency (MUT) 6. 3-methylcrotonyl-CoA carboxylase deficiency (3MCC) 7. Methylmalonic acidemia, Cbl A and Cbl B forms (Cbl A,B) 8. Propionic acidemia (PROP) 9. Beta-ketothiolase deficiency (BKT)
Fatty acid oxidation disorders (disruption of fat and energy metabolism)	<ol style="list-style-type: none"> 10. Medium-chain acyl-CoA dehydrogenase deficiency (MCAD) 11. Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD) 12. Long-chain hydroxyacyl-CoA dehydrogenase deficiency (LCHAD) 13. Trifunctional protein deficiency (TFP) 14. Carnitine uptake defect (CUD)
Amino acid metabolism disorders (inability to metabolize amino acids properly)	<ol style="list-style-type: none"> 15. Phenylketonuria (PKU) 16. Maple syrup urine disease (MSUD) 17. Homocystinuria (HCY) 18. Citrullinemia (CIT) 19. Argininosuccinic acidemia (ASA) 20. Tyrosinemia type I (TYR I)
Hemoglobin disorders (abnormalities in the oxygen-carrying protein, hemoglobin)	<ol style="list-style-type: none"> 21. Sickle cell anemia 22. Hb S/beta-thalassemia (Hb S/Th) 23. Hb S/C disease (Hb S/C)
Other disorders (miscellaneous)	<ol style="list-style-type: none"> 24. Biotinidase deficiency (BIO) 25. Congenital hypothyroidism (HYPOTH) 26. Congenital adrenal hyperplasia (CAH) 27. Galactosemia (GALT) 28. Hearing loss (HEAR) 29. Cystic fibrosis (CF) 30. Severe combined immunodeficiency (SCID) 31. Critical congenital heart disease (CCHD) 32. Pompe disease (GSD II)
U.S. Department of Health and Human Services (DHHS) Advisory Committee on Heritable Disorders in Newborns and Children, 2015	

The NBS system and the need for a culture of safety

NBS is not a test but a system (McCabe & McCabe, 2009; American Academy of Pediatrics [AAP] Newborn Screening Task Force, 2000). Table 2 lists identifies steps in the NBS system process. This complex system should include the understanding and application of a culture of safety (McCabe, 2014).

Table 2. NBS system process

1. Education of health professionals
2. Pre-test education of parents
3. Sample acquisition for blood spot-based tests, such as for PKU and MCAD deficiency, or performance of functional testing, such as for hearing loss and pulse oximetry for critical congenital heart disease (CCHD)
4. Blood spot transit to centralized laboratories in or designated by state health departments (to be collectively designated as state laboratories in this article)
5. Testing in the laboratory
6. Result reporting to designated provider(s)
7. Provider informing parents of the results
8. If results are positive and the designated provider(s) do not include subspecialists, then referral to subspecialists with expertise in follow-up
9. Diagnostic testing of babies with a positive NBS result to determine if the result was a false positive or a true positive
10. Management of babies with confirmed positive tests through the neonatal period, infancy and across the lifespan

For professionals involved in the laboratory testing, the system includes:

- Oversight of testing
- New test development
- Continuous quality improvement
- Dissemination of information regarding quality and safety

The complexity of the NBS system is evidenced by the number of steps in the process and the variety of individuals involved, including babies, parents,

nursery staff, general and subspecialty physicians, state health department staff and federal and state policy makers.

Human-designed complex systems like NBS require a culture of safety to prevent failure, which in the case of NBS means delayed or missed diagnoses (McCabe & Howse, 2013; McCabe, 2014).

The Centers for Disease Control and Prevention (Holtzman, Slazyk, Cordero & Hannon, 1986) showed that many opportunities for errors exist in the NBS system in the form of missed cases; most of these errors are due to human factors. These findings demonstrate that NBS is a target-rich environment for error, similar to hospitals and the nuclear power and aviation industries (Mort, Demehin, Marple, McCullough & Meyer, 2013; Ruchlin, Dubbs & Callahan, 2004; Sutcliffe, 2011). The high reliability organization (HRO) paradigm is a key feature of system safety that protects high-risk environments like NBS by anticipating adverse effects and resiliently containing adverse events (Ruchlin et al., 2004; Sutcliffe, 2011). Anticipation of risk and probability of error leads to the employment of continuous quality improvement to protect the system and to provide optimal outcomes.

Nurses can become empowered to prevent potentially deadly errors in, and to create a more robust environment for, NBS by understanding the complexity of the system and the roles they play in it (McCabe, 2014; McCabe & Howse, 2013; Sutcliffe, 2011). Sensitivity to the NBS process allows nurses to respond to small errors by adjusting and preventing problems from cascading and compromising the system. Nurses can acknowledge system vulnerabilities, such as delays that they can prevent during sample acquisition in the nursery and transit from the nursery to the state laboratory.

Sample quality is another aspect that nurses can work to optimize. The Clinical and Laboratory Standards Institute (Hannon et al., 2013) describes what constitutes an adequate NBS sample (Table 3). Poor samples result in delays due to the need to acquire a repeat specimen when the state laboratory declares it inadequate.

Table 3. Taking an adequate NBS sample

1. Clean the baby’s heel with an alcohol swab and let air dry.
2. Use a sterile lancet to prick the outer aspect of the heel.
3. Drop a full drop of blood onto the circles of the filter paper card. A second drop may be applied to completely fill the circle. (Routinely check the expiration date on filter paper cards.)
4. Let the card dry at least 3 to 4 hours in ambient temperature.

Often nurses are involved in follow-up when the laboratory identifies a positive NBS sample. In some states, lab staff notify the primary care provider and specialist simultaneously when a NBS result is abnormal; in other states, lab staff notify the primary care physician who must then contact the specialist (Summar, Kirmse & Monaco, 2014). Experience in the Mid-Atlantic region of the United States indicates that states in which the primary care provider is the intermediary has “a significant increase in the time to diagnosis and treatment of patients who had serious inborn errors of metabolism” (Summar, Kirmse & Monaco, 2014, page 1). The authors describe this as a weak point that could be addressed more quickly and effectively by involving the specialist as an immediate contact in the event of an abnormal screening test result.

An error in NBS, like all failures in complex human-designed systems, is a failure of the system and not a failure of an individual (McCabe 2014; Ruchlin, Dubbs & Callahan, 2004). Therefore, the culture of safety is non-punitive because it is more important to identify errors so they can be prevented than to ascribe blame, which may hinder reporting of future errors. A culture of safety is most effective when it focuses on reporting, justice, flexibility and learning (Ruchlin, Dubbs & Callahan, 2004). To achieve justice, the system must work within a non-hierarchical environment. For example, a new nursing student may see a potential error risk in the nursery. She reports what she has seen. The nurses in the unit respect and consider the student’s input on merit and do not dismiss it because of the student’s status in the

staff hierarchy. They use the incident as a moment for teaching and learning and incorporate this new knowledge into their everyday routines.

Nurses associated with the NBS system must feel empowered to reinforce the attributes that create the culture of safety—the culture that is blameless, non-hierarchical, just and flexible and that supports learning. Through this reinforcement, the integrity of the NBS system is optimized.

Recommended schedule to achieve timeliness and prevent deadly delays in NBS

The Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (DACHDNC), in response to the *Journal Sentinel* series on deadly delays in NBS, developed a schedule for heel stick testing for time-critical conditions (Table 4).

Table 4. Schedule for heel stick testing for time-critical conditions

- Sample collected: When appropriate but no later than 48 hours after birth
- Transit time to laboratory: As soon as possible; ideally within 24 hours of collection
- Sample testing and results reported: Immediately but no later than 5 days of life (by 7 days for all other conditions)

DACHDNC, 2015

Using this schedule, results are reported by 5 days of age for disorders with risk of acute and life-threatening early presentation. The sample collection time of 24 to 48 hours permits the accumulation of signature metabolites in the blood after the umbilical cord is clamped and before toxic metabolites rise to pathogenic levels. Unfortunately, some babies with fatty acid oxidation, organic acid and urea cycle disorders present with metabolic decompensation before 5 days of age; therefore, it is important for providers to consider metabolic disease in the differential diagnosis of sick babies, particularly those with rule-out sepsis.

For all other disorders, such as PKU and hypothyroidism, in which the results are not as time-critical, the DACHDNC recommends that results be reported by 7 days of age.

Role of the nurse in the NBS system

The nursery has a critical role in the NBS system, and nursery staff need to understand the system and their roles within it. While it is ideal to educate families about NBS before a baby is born, this often does not occur leaving the nursery as the place for pre-test education. The nursery also is the site for heel stick blood spot sampling; even if the sample is obtained by phlebotomy staff, nursery and mother-baby nurses need knowledge of what constitutes a quality sample to prevent the laboratory from declaring the sample inadequate, requiring a repeat specimen and causing a possible deadly delay.

Table 5 presents guidelines to assure appropriate dried blood sample quality. For functional testing, such as hearing and pulse oximetry, the nursery staff performs or assists with NBS.

Nursery and mother-baby staff also need to understand their roles in timely sample acquisition and transit initiation. For example, samples drawn too early may disqualify them for certain testing and require repeat specimens to be drawn later; early sampling may lead to inadequate accumulation of metabolites resulting in false negative results and missed babies for conditions like PKU (McCabe, McCabe, Mosher, Allen & Berman, 1983). If a baby is to be discharged before 24 hours of age, staff obtain a NBS bloodspot before discharge; however, a repeat specimen is required (Hannon et al., 2013).

Ideally NBS samples are obtained between 24 and 48 hours of age. Samples accumulated over multiple days to save shipping costs, a process known as “batching,” can result in deadly delays.

Some nurses may consider NBS tests to be low priority because the sampling is routine and the frequency of individual conditions is low. The nursery is a busy environment with frequent admissions and discharges and the ever-present potential for severe, acute disorders, such as hypoglycemia and sepsis. This setting may

lead to babies not having their blood drawn or functional tests performed for NBS, not because of a conscious decision to deprioritize NBS but simply because other events take priority over NBS. Nurses can help reinforce to their colleagues the importance of NBS for parents whose babies receive positive results and have conditions identified in a timely manner.

Table 5. Assuring appropriate dried blood sample quality

- Document critical patient information, including maternal conditions, newborn conditions and newborn treatments
- Take the sample after 24 hours of age and before 48 hours of age.
- Collect blood from the baby’s heel on the most medial or lateral plantar surface. Collect enough blood to fill the circles on the filter paper. Don’t oversaturate the circles with blood.
- Use a fresh-flowing blood drop and avoid clots, smearing or contaminating blood.
- If the baby is having a blood transfusion, collect the initial blood sample before the transfusion and a second sample 48 to 72 hours after the transfusion.
- Avoid specimen-to-specimen contact when sending. Use the biohazard flap that covers the dried blood on the filter paper to separate samples. Alternate samples (foot to head) in the mailing envelope.
- Use daily courier shipping.

Hannon et al., 2013

RUSP

The Advisory Committee on Heritable Disorders in Newborns and Children (Advisory Committee) has a formal process for nominating, evaluating and recommending disorders for the RUSP. The Secretary of the Department of Health and Human Services ultimately determines which disorders are added. Selection of a new disorder usually is based on the threat of morbidity and mortality, the availability of a reliable and valid test and the availability of a treatment to prevent morbidity

and mortality. Because NBS is a state-based public health program, the Advisory Committee provides a forum for addressing a national agenda in NBS (AAP Newborn Screening Task Force, 2000). However, NBS is the responsibility of state departments of health, and not all states follow RUSP guidelines. March of Dimes chapters in these states work with departments of health to improve the state NBS program to include RUSP recommendations. All disorders in the RUSP are associated with death or life-long disability if not identified and treated early, for some within the first week of life. This is why delays in NBS can be deadly.

Psychosocial aspects of NBS

Parent anxiety can be acute in the event of an abnormal NBS result. NBS is designed to identify infants who may have a disorder; however, most infants with a positive NBS result do not have the disorder as later shown by a negative diagnostic test.

Parent education about newborn screening serves two purposes: (1) to aid parents in understanding the goals and processes of NBS and (2) to help parents understand the potential ramifications of an abnormal screening result. In general, parents often are underinformed about NBS. To improve parents' understanding, providers need to reiterate information often and, if possible, in different venues. For example, parents can receive NBS education from obstetricians and midwives during prenatal care visits and from hospital staff in the nursery around the time of the baby's heel stick. In the nursery, parents may better retain information about NBS if they receive it during quieter moments after the baby's birth.

For health care providers working in NBS, clear communication and ongoing support are critical in caring for families during the evaluation and aftercare of infants with abnormal NBS results. Researchers continue to look at how provider communication and parents' responses to NBS events can improve services, but more research is needed in this area. Physicians have reported deficits in their own knowledge about NBS

(Kemper, Uren, Moseley & Clark, 2006). In one study, physicians rehearsed delivery of newborn screening results but often used jargon and did not assess parent understanding (Farrell & Christopher, 2013). Parents' responses to NBS events have been studied (DeLuca, Kearney, Norton & Arnold, 2011), but more research is needed in how best to intervene with families.

Continuous quality assurance programs can serve to update NBS information for providers and improve communication between providers and parents for lessening untoward parental psychological responses to newborn screening (Farrell, et al., 2014). State health laboratories and specialty providers are important sources of NBS information for providers.

Providers and parents may benefit from NBS resources listed in Table 6.

Provider education	<ul style="list-style-type: none">• American College of Medical Genetics and Genomics Action (ACT) sheets, acmg.net• marchofdimes.org/peristats• <i>Newborn screening pocket facts</i>; to order visit: marchofdimes.org/catalog
Parent education	<ul style="list-style-type: none">• babysfirsttest.org• marchofdimes.org/newbornscreening• <i>Newborn screening/Pruebas de detección para recién nacidos</i> (booklet); to order visit: marchofdimes.org/catalog
For providers and parents	National Newborn Screening and Genetics Resource Center, genes-r-us.uthsca.edu

Summary

NBS requires a culture of safety that requires champions. Nurses can be those champions. Nurses can optimize aspects of NBS, including maintaining sample quality, ensuring timely sample transport to the lab, communicating testing results to professionals and families and assuring

diagnostic follow-up. Nurses also reinforce a non-punitive, non-hierarchical work environment that is just, flexible and that promotes learning; these attributes are essential to ensure a culture of safety for NBS. Provider and parent education, as well as psychological support of families, can help improve NBS partnerships within an effective NBS system.

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