

Financing Newborn Screening: Sources, Issues, and Future Considerations

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Newborn screening (NBS) programs are population-based public health programs and are uniquely financed compared with many other public health programs. Since they began more than 45 years ago, the financing issues have become more complex for NBS programs. Today, almost all programs have a portion of their costs paid by fees. The fee amounts vary from program to program, with little standardization in the way they are formulated, collected, or used. We previously surveyed 37 of the 51 dried blood spot screening programs throughout the United States, and confirmed an increasing dependence on NBS fees. In this study, we have collected responses from all 51 programs (100%), including updated responses from the original 37, and updated our fee listings. Comments from those surveyed indicated that the lack of a national standardized procedural coding system for NBS contributes to billing complexities. We suggest one coding possibility for discussion and debate for such a system. Differences in Medicaid interpretations may also contribute to financing inequities across NBS programs and there may be benefit from certain clarifications at the national level. Completed survey responses accounted for few changes in the conclusions of our original survey. We confirmed that 90 percent of all NBS programs have a fee paid by parents or a third party payer. Sixty-one percent reported receiving some funds from the Maternal and Child Health Services Title V block grant, 33 percent reported some funding from state general revenue/general public health appropriations; and 24 percent reported obtaining direct reimbursement from Medicaid (without passing through a third party). A majority of programs (63%) reported budget increases between 2002 and 2005, with

increases primarily from fees (72%) and to a lesser extent from Medicaid, the Title V block grant, and state general revenues.

KEY WORDS: financing, NBS, public health

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Newborn screening (NBS) describes various tests that occur shortly after birth that have the potential for preventing catastrophic health outcomes, including death. Historically, NBS has referred to biochemical testing for inherited disorders, generally metabolic in origin. One can expect normal or near normal health outcomes if the conditions are detected and treated early. A broader definition of NBS includes other testing methods such as an audiologic assessment for newborn hearing screening. In this report, we have used the traditional biochemical test definition, although many of the concepts and discussions can apply equally to newborn hearing screening. We present an overview of newborn screening financing issues and survey results to better illustrate the complex issues that may not be generally understood. We also suggest policy strategies that need further discussion.

There is currently no national NBS finance or program policy in the United States; however, NBS is statutorily required in all states and some territories.^{1,2} There is general recognition that individual NBS programs differ in their screening panels, services, costs, and financing methods. And, there is recognition of a need for increased national NBS uniformity to provide more equitable neonatal health benefits across the country.^{3,4}

When NBS for phenylketonuria began in the 1960s, state legislatures provided funding to reduce the number of persons with mental retardation cared for in publicly funded institutions.⁵ This saved money by reducing lifelong institutionalization at state expense. As NBS programs expanded to more conditions, cost savings arguments became more complex and state legislatures began to require programs to be self-supporting. Now most programs have fees that support all or a part of their screening program.

We previously described⁶ the extent to which various federal activities that have resulted in sporadic funding support of NBS activities over the years.⁷⁻¹⁰ As a result of Title V block grant consolidation and decreased federal funding in the early 1980s, fees increased in the 1980s as a means of NBS program sustainability.¹¹ Between 1983 and 1985, 12 states added NBS fees, and by 2001, 13 programs reported fees as their only source of NBS funding; 19 others used fees to support at least 60 percent of their NBS expenditures.¹²

Currently, no federal funds are appropriated specifically for state NBS programs, although Title V Maternal and Child Health (MCH) Services Block Grant funds can be used for NBS at the state's discretion.^{6,13,14} In addition, funding from the Health Resources and Services Administration (HRSA) Maternal and Child Health Bureau through Special Projects of Regional and National Significance (SPRANS)² has been used actively over time to support various NBS activities. SPRANS funds were used to establish a National Newborn Screening

and Genetics Resource Center (NNSGRC) in 1999 to provide a national contact point for NBS issues and information. A SPRANS initiative in 2004 also funded seven regional collaboratives and a coordinating center to address issues of technology, infrastructure, and manpower resulting from NBS expansion.²

NBS programs routinely report their fees to the NNSGRC, and these are available for public review (<http://www2.uthscsa.edu/nnsis>); however, national data on funding sources and costs for related services and activities are not routinely available. The 2003 Government Accountability Office report noted that in 2001 more than \$120 million (64% from fees, 19% from state funds, 10% from Medicaid, 5% from MCH block grant funds, and 2% from other sources) were spent to screen 4 million US newborns (an average of \$30 per infant screened).¹² No breakdown of costs for individual NBS system components was included. Currently, 46 programs (Table 1) use fees as a primary source of program funding, with this number likely to increase during 2007.

NBS programs originated primarily as public health laboratory activities, and therefore as fees developed, they were invariably associated with laboratory services. Fees were charged for laboratory tests or for specimen collection devices (kits) essential to the screening process. Initially, little attention was paid to nonlaboratory activities such as education, tracking, and follow-up since the needs with phenylketonuria screening were minimal. As testing panels expanded, screening support activities also expanded, but funds were usually appropriated internally in health departments from other funding sources such as Title V funds or state general revenues. Slowly, fees have become more inclusive of funding elements for other NBS system components.

Lack of national harmonization regarding NBS fees and services has resulted in a wide range of fee policies and billing strategies. Reasonable fees and timely cost recovery are issues both for screening programs and specimen submitters. With specimen collection kits, charges occur before the birth and the billing/payment cycle must be designed to accommodate the cash flow needs of specimen submitters and third party payers. As an alternative, a few NBS programs bill submitters periodically (usually monthly) for their screening services. Inability to pay for NBS does not prevent its being done and various accommodation mechanisms exist. In cases where NBS includes two or more specimens, a linking system sometimes allows one fee to cover additional specimen analyses. Second and subsequent screens often occur at physicians' offices or in outpatient laboratories, further complicating the billing/payment process. Billing issues arise whenever a cost increase is needed. Negotiated third party

TABLE 1 • Newborn screening program fees—2005 and 2006 (unless indicated, fee covers initial screen and any subsequent screens)

State	Fee October 2005	Fee October 2006	State	Fee October 2005	Fee October 2006
Alabama	\$139.33	\$139.33	Missouri	\$25.00	\$50.00
Alaska	\$55.00	\$55.00	Montana	\$39.34	\$42.70
Arizona*	\$20.00	\$30.00 (first screen) \$40.00 (second screen)	Nebraska	\$30.75	\$35.75
Arkansas	\$14.83	\$14.83	Nevada*	\$60.00	\$60.00
California	\$78.00	\$78.00	New Hampshire	\$18.00	\$40.00
Colorado*	\$53.25	\$59.00	New Jersey	\$71.00	\$71.00
Connecticut	\$28.00	\$28.00	New Mexico†	\$32.00	\$32.00
Delaware*	\$64.00	\$78.00	New York	No fee	No fee
District of Columbia‡	No fee‡	No fee‡	North Carolina	\$10.00	\$14.00
Florida	\$15.00	\$15.00	North Dakota	\$36.00	\$42.50
Georgia§	No fee	No fee	Ohio	\$45.15	\$55.16
Hawaii	\$47.00	\$47.00	Oklahoma	\$58.23	\$98.70
Idaho	\$23.00	\$25.00	Oregon*	\$54.00	\$54.00
Illinois	\$47.00	\$47.00	Pennsylvania	No fee	No fee
Indiana	\$62.50	\$74.50	Rhode Island	\$59.00	\$110.00
Iowa	\$56.00	\$77.00	South Carolina	\$42.00	\$42.00
Kansas	No fee	No fee	South Dakota	\$18.53	\$99.99
Kentucky	\$14.50	\$53.50	Tennessee	\$47.50	\$47.50
Louisiana	\$18.00	\$30.00	Texas*	\$19.50 (each screen)	\$19.50 (each screen)#
Maine	\$47.00	\$52.00	Utah*	\$31.00	\$65.00
Maryland	\$42.00	\$42.00	Vermont	\$33.30	\$33.30
Massachusetts	\$54.75	\$54.75	Virginia	\$32.00	\$53.00
Michigan	\$55.72	\$56.83	Washington	\$60.90	\$67.50
Minnesota	\$61.00	\$61.00	West Virginia	No fee	No fee
Mississippi	\$70.00	\$70.00	Wisconsin	\$65.50	\$69.50**
			Wyoming	\$45.00	\$70.00

*A state that requires two newborn screens on every newborn—unless indicated, single fee covers both screens.

†Fee of \$89.00 to begin January 1, 2007.

‡No fee is directly charged to patient. DC Government pays the fee to the contracting laboratory.

§Fee of \$40.00 expected to begin from January 1, 2007.

||Fee of \$48.00 for double kit when screening occurs prior to 48 hours of age.

¶Fee includes \$44.50 laboratory surcharge.

#Fee of \$29.50 to begin November 1, 2006 (Medicaid fee to increase to \$29.50).

**Fee includes \$30.00 laboratory surcharge.

reimbursements, including Medicaid, may not easily accommodate NBS rate increases, particularly if they occur during a predefined contract period.

Fee income is usually handled in one of two ways—either placed into state general revenues or maintained in a dedicated NBS account. Funds placed into general revenues may require competition for their use and some programs have been “fiscally challenged” as a result.¹⁵ Dedicated or restricted accounts, while still subject to political considerations, are less likely to be diverted for other uses. In either case, the amount of the fee and the way fee income is used create ongoing NBS policy issues.^{5,16} Some programs utilize the services of contracted laboratories, and these laboratories may collect the fees. In such cases, a portion of the fee revenues may be returned to the NBS program for support services.

Few programs have budget items that reflect adequate funding for all six of the NBS system components (education, screening, follow-up/tracking, diagnosis, treatment/management, and evaluation).¹⁷ No national procedural testing codes exist to guide reimbursement and variable Medicaid interpretations contribute to nonuniform fees. Funding differences generally reflect the variation in state fiscal policies, public health infrastructures, and medical care capacities. Some programs provide full reimbursement for metabolic formula, whereas others do so on a sliding scale based on family income. Some programs automatically link newborns with NBS-identified conditions to publicly funded services, whereas others do so only on demand. Support for nutritional and genetic counseling, comprehensive educational programs for professionals, consumers, and policy makers, and long-term

data collection for assessing and improving the NBS system is minimal in most programs.

Charges for NBS are usually reimbursed as part of global payments for maternity/perinatal services (eg, hospital fees for birth). Medicaid coverage for NBS is allowed and is reimbursed to the birthing facility or directly to the NBS program. There is not a national reimbursement standard, however, and NBS fees are sometimes reimbursed directly to policy holders by third party payers.

Since the American Medical Association has not yet developed Current Procedural Technology (CPT) codes for NBS, there is no uniformity in payment of billing practices. This likely contributes to a lack of uniformity in NBS procedural descriptions, fees, and charges. However, it can equally be argued that a lack of national NBS testing uniformity has contributed to the lack of CPT codes.

Over the past 10 years, the biggest change in NBS has been the introduction of tandem mass spectrometry (MS/MS) into the screening laboratory. Since with MS/MS testing, a single laboratory process results in simultaneous detection of multiple conditions, nonlaboratory costs (ie, educational, diagnostic, treatment, and administrative) have disproportionately increased. In turn, NBS fees have increased. Although fee increases usually accommodate ongoing MS/MS program costs, start-up funding to purchase equipment for MS/MS is often an issue requiring separate funding strategies such as one-time appropriations.

● Methods

In 2004, we developed a one-page questionnaire of questions designed to inform about the basics of NBS program financing.⁶ This questionnaire originated from financing information obtained in a multistate case study of NBS funding experiences. The questionnaire was pilot tested and refined before distribution using the assistance of three state NBS programs. Initially, the questionnaire was sent by e-mail to all 51 US NBS programs addressed to staff members identified by the NNSGRC as those individuals most likely to answer the questions in an informed way. Following a second round of e-mails, the response rate was 72.5 percent (37 state programs responding).

Building on those data, we sought to complete collection of survey information from all remaining programs. In February 2006, a year after the initial survey was completed, we contacted the 14 programs from which responses had not been received, first by e-mail and then by telephone if a response was not received within 2 weeks. Because we recognized that these data may be different from that obtained from the other

programs a year before, we revalidated the original 37 responding programs. Revalidation included preparation of a spreadsheet with information from the original 37-program survey and the more recent 14-program survey. The spreadsheet was distributed by e-mail to all 51 responders for correction and validation. If an e-mail response was not received within 2 weeks, telephone contact was made. This process resulted in validated responses from all 51 respondents (100%).

The questionnaire included five questions and a matrix of four additional informational items. All programs were first asked to indicate all sources of program funding during the past 3 fiscal years (fees, Medicaid, state general revenues, Title V block grant, and/or other). Programs in which a fee was collected (either by the program or the screening laboratory) were asked to indicate whether fee monies went into a direct budget line (ie, not the state general fund) and to enumerate all of the items within the NBS program supported by fee funds (laboratory, short-term follow-up to diagnosis, long-term follow-up following diagnosis, program administration, and/or other). All programs were asked to indicate whether there had been funding changes over the past 3 to 5 years (budget increased, decreased, or remained unchanged) and to comment on who (governor, health department staff, advisory group, or consumer advocates) was most responsible for changes in NBS policy during those years. Finally, all programs were asked to complete a matrix, indicating trends in state funding allocated to the NBS program (more, no change, less, don't know) for (1) fees; (2) Medicaid; (3) MCH block grant; and (4) state general revenues.

● Results

Overall, the completed responses from all 51 NBS programs accounted for very few changes in our basic conclusions based on the original survey of 37 programs. Ninety percent (46/51) of all programs reported that a fee is now collected (from health providers, laboratories, hospitals, parents, etc). Sixty-one percent (31/51) reported some funding from their Title V block grant; 33 percent (17/51) from state general revenue or general public health appropriations; and 24 percent (12/51) from direct Medicaid payments (not associated with hospital fee payments). Only 14 percent (7/51) reported receiving funds from other sources (eg, private insurance payments, Supplemental Nutrition Program for Women, Infants, and Children [WIC] funding for formula foods).

In response to financing trends, the majority of programs (32; 63%) reported that their NBS budget increased between 2002 and 2005. Fees accounted for most of the budget increases with lesser contributions

from Medicaid, MCH block grant, and state general revenue funding. Of the 46 programs ($n = 46$) charging a fee, 33 (72%) reported a trend toward fee increases; 11 (24%) reported no change; 1 reported a decrease (in return for an increase in direct Medicaid funding); and 2 gave no response. Regarding trends in Medicaid funding ($n = 51$), 24 programs (47%) reported no changes; 10 (20%) reported a trend toward increases; 1 (2%) reported a decrease; and of the remaining 16 (31%), half indicated that they were unsure and half gave no response. Regarding Title V block grant funding trends, 21 programs (41%) reported no changes; 10 (20%) reported a trend toward increases; 9 (18%) reported a trend toward decreases; and of the remaining 11 (22%), 3 indicated they were unsure and 8 gave no response. Regarding trends in general revenue funding, 21 programs (41%) reported no changes; 5 (10%) reported a trend toward increases; 7 (14%) reported a trend toward decreases; and of the remaining 18 (35%), 15 (30%) gave no response and 3 were unsure.

Virtually, every NBS program has changed its administrative policies in recent years, particularly as it relates to the screening panel. Responding to our request to identify the single entity most influential in recent program policy changes, most responders chose not to follow the directions, and indicated more than one choice. Because not all who answered did so in the same way, the responses were not definitive. Nonetheless, it is informative that approximately 60 percent of survey responses indicated that health departments (31; 61%) and advisory groups (30; 59%) were responsible for policy changes, while one-third (17; 33%) attributed changes to advocacy group action. Fourteen responses (27%) indicated that the governor's office or the state legislature was most responsible for program policy changes.

As NBS is a system of services and activities, not just a screening test, a number of different program services/activities must be supported within the financing structure. With each program policy or procedural change, certain core activities such as program administration, laboratory testing, and follow-up must be present (and funded) for the rest of the system to function. All 46 programs with a fee reported using some of their fee revenues to support laboratory costs (directly or through contracts). Seventy percent reported financing short-term follow-up (from screening to diagnosis) and program administration/management from fee funds. Slightly less than half (46%) reported financing some aspects of longer term follow-up, case management, or family support beyond diagnosis through their fee. Thirty-seven percent of programs reported using fee monies for some program activity other than laboratory, follow-up, or program administration listing as examples: genetic or nutritional counseling, sub-

sidies for formula and/or foods, and limited medical treatment.

● Discussion

Regardless of the sources of funding, state public health departments and state governments appear committed to maintaining NBS programs, including securing sustainable financial resources. Although the degree to which various components of the NBS system receive financial support may vary from program to program, there is general recognition among programs as to what these components are and the various methods for financing them. Because there is no national policy on public health or healthcare financing, the comprehensiveness of NBS systems and their operations, including financing, continue to vary. These variations result from unevenness in state governments' abilities to finance the NBS system and therefore in unequal NBS services across the country. Both access to screening and treatment are more likely to be determined by state of residency than by condition of child or family.

Differences in NBS systems have been identified in other studies,^{3,4,16} and, while some variations may occur because of philosophical differences, most are directly related to healthcare financing. Implicit in these considerations are the lack of uniformity of NBS screening panels, fee structures (where fees exist), and budgeting methods. Financing differences appear to be in part related to the lack of national CPT codes and variable interpretations of Medicaid reimbursement rules. In programs where no fees exist, similar public funding financing issues must still be addressed. Medicaid funding for NBS is particularly important since, in many programs, Medicaid recipients are a major screening population (>50% in some programs).

In general, there appears to be a need for national guidance on developing public health budgets for NBS systems. In addition, there is a need for more guidance to Medicaid and other third party payers regarding reimbursement for NBS laboratory tests. In some programs, NBS laboratory fees appear to be based on reimbursement schedules for diagnostic tests since fee schedules for screening tests do not exist for payers of Medicaid. Although NBS is an allowed benefit of the Medicaid program, the variable ways in which Medicaid is managed from state to state and region to region contribute to unequal program financing and benefits nationally. Comments from survey responders indicated significant state and regional differences in interpreting Medicaid funding restrictions and cost accounting rules. Further research is needed to address the questions of why and to what extent state Medicaid rules differ regarding fee payments (eg, do

TABLE 2 ● Suggested coding system for newborn screening test procedures*

Screening test	Description of procedure
1 Hemoglobinopathy: full screen	A multianalyte panel that includes simultaneously screening for clinically significant hemoglobinopathies and other hemoglobin variants
2 Congenital hypothyroidism: multiscreen	Testing that utilizes simultaneous analysis of both T4 and TSH (<i>Note:</i> Testing for one analyte is not dependent on testing for the other)
3 Congenital hypothyroidism: two-step screen	Testing for T4 or TSH in combination where the testing for one as a second-tier test depends on the concentration of the other
4 Congenital Hypothyroidism: one-step screen	Testing for T4 or TSH without testing for the other
5 Congenital adrenal hyperplasia: one-step screen	Testing for only the concentration of 17-OHP
6 Congenital adrenal hyperplasia: two-step screen	Testing first for 17-OHP followed by a second-tier test for additional analytes on the basis of the initial 17-OHP
7 Cystic fibrosis: one-step screen	Testing for IRT
8 Cystic fibrosis: two-step single mutation screen	Testing for IRT followed by a second-tier test for a single $\Delta F-508$ mutation on the basis of the initial IRT
9 Cystic fibrosis: two-step multmutation screen	Testing for IRT followed by a second-tier test for at least 20 additional mutations on the basis of the initial IRT
10 Galactosemia: transferase deficiency only screen	Testing for the transferase form of galactosemia only using any CLIA compliant procedure
11 Galactosemia: multiple forms screen	Testing for transferase, kinase, and epimerase forms of galactosemia using a multistep testing process that includes testing for total galactose
12 Biotinidase deficiency screen	A single analyte determination to detect the presence or absence of the condition
13 Metabolic panel (MS/MS): comprehensive screen	Screening for any or all amino acid, fatty acid oxidation, and organic acid disorders detectable from a dried blood spot sample using tandem mass spectrometry (MS/MS) (<i>Note:</i> includes both full or limited scanning)
14 Newborn hearing screening: two-step screen	Utilization of otoacoustic emission and auditory brainstem response technologies in combination to detect possible hearing deficiencies, where the use of one as a second-tier test depends on the results of the other
15 Newborn hearing screening: one-step otoacoustic screen	Utilization of otoacoustic emission technology alone to determine possible hearing deficiencies
16 Newborn hearing screening: one-step brainstem response screen	Utilization of auditory brainstem response technology alone to detect possible hearing deficiencies

*17-OHP indicates 17-hydroxy-progesterone; IRT, immunoreactive trypsinogen; T4, thyroxine; and TSH, thyrotropin.

variations reflect state policy, regional office interpretations, or billing practices?). Items of particular interest include the extent to which reimbursements can be made when fees include nonlaboratory services (such as follow-up/tracking and confirmatory testing); laboratory or nonlaboratory services that might not be necessary for all newborns (such as secondary tests or follow-up to clarify an initial testing result); or adjustments that cover uncollectible costs for services to other newborns. Although states have the flexibility to determine their own payment levels and approaches, knowledge from further research may help in improving the effectiveness and efficiency of Medicaid financing for NBS.

Since the recent release of the American College of Medical Genetics recommendations to the Health Resources and Services Administration for a core panel of NBS tests and their endorsement by the Secretary's Advisory Committee on Heritable Diseases and Genetic Disorders in Children, there has been a tendency for NBS programs to move toward adoption of the recom-

mended core panel of tests. Although not all programs are performing all recommended tests, and not all who are performing them are doing so in the same way, there is still a noticeable movement toward national uniformity. There may now be sufficient testing similarities between NBS laboratories so that development of national CPT codes is feasible. One possible CPT coding structure for consideration and debate is given in Table 2.

When developing the code, we logically and systematically included all of the laboratory screening procedures currently used in the US NBS. Unfortunately, there is not a single analytical process (and thus a single code) that can include all screening processes, particularly when hearing screening is considered. We suggest that even for dried blood spot screening, there are at least 13 procedural codes needed—a reasonable number that is likely to shrink over time as programs become more standardized. Of the 13 suggested codes, a typical dried blood spot program would use up to 7 (hemoglobinopathy, congenital

hypothyroidism, congenital adrenal hyperplasia, galactosemia, biotinidase deficiency, cystic fibrosis, and MS/MS detected metabolic conditions). Although it might be argued that coding on the basis of numbers or groups of procedures in a panel might be equally justified (ie, a single code for 1–9 tests, 10–19 tests, etc), the problem comes in reaching consensus on test groupings and counting rules. For example, there is not yet consensus on the number of conditions that could or would be detected in newborns using MS/MS,¹⁸ some conditions may include phenotypic variations that could be counted separately, and there is no standardized method of counting conditions detected by hemoglobinopathy screening.

Coding choices will invariably exist for certain procedures, sometimes related to cost and sometimes to screening protocol. For example, there are many combinations of ways to screen for congenital hypothyroidism, and these can reasonably be placed into three types of processes, with an appropriate average cost developed for each. Because procedural costs are similar, a single procedure (either thyroxine [T4] or thyrotropin [TSH]) would be one code. The two-step process of using either T4 or TSH followed by second-tier testing with the other test (either TSH or T4, respectively) in selected cases would be another code. And, testing for both T4 and TSH on all newborns would be yet a third code.

We recognize that our suggested coding for NBS procedures need further discussion, debate, and refining, but standardized coding appears to be a key step toward more uniform ways of implementing third party reimbursements.

● Conclusions

It is important to move toward national uniformity not only for decision-making processes regarding screening panels but also for NBS system financing. Families should not have to shop for NBS program benefits because of differing state policies related to basic financing issues. A national NBS CPT coding system could provide structure for laboratory costs/reimbursements. Clarifications of Medicaid Rules as they relate specifically to NBS reimbursements may also be needed. Public-public and public-private partnerships are important to deal with financing issues related to nonlaboratory and patient services. This is particularly important when rapid response to a screening result is needed and the services are most conveniently available through the state NBS system, such as medical follow-up for a rare metabolic condition.

NBS is a complex system that must be financially sustained to maintain the well-documented positive family and societal impacts. Fees—whether paid by fami-

lies, health plans, or other payers—cover a substantial share of the cost for screening in the NBS system nationally. To a large extent, fees do not cover the ongoing care and treatment for conditions diagnosed. Family access is strongly dependent today on finance variations. Finance policies and mechanisms defined at the national level will likely be necessary if national uniformity of NBS services is to be realized.

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