Long-term Follow-up Data Collection and Use in State Newborn Screening Programs

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Objectives: To describe and analyze the types of data-related policies and practices that currently exist among state newborn screening (NBS) programs in relation to long-term follow-up (LTFU) and oversight for newborns with confirmed disorders.

Design: A 19-question online survey.

Participants: Thirty-five state NBS programs.

Main Outcome Measures: Whether LTFU is performed, collection and use of LTFU data, and variety of LTFU data collected.

Results: Survey findings reveal data-related challenges faced by state NBS programs in their ability to perform ongoing oversight, evaluation, and quality assurance with respect to LTFU for newborns with confirmed disorders. Of the NBS programs surveyed, 56% reported collecting no LTFU data. More than two-thirds of state NBS programs surveyed do not use LTFU data at all or use it only minimally. Most programs that collect any LTFU data from providers (physicians, nurses, and allied health professionals) do it through verbal communication or paper forms rather than electronically. Almost half of the programs collecting any LTFU data do so only once a year. A lot of variety exists in the types of LTFU data collected across programs. Most of the 15 programs that reported collecting LTFU data use it to track the clinical outcomes of patients, assess the needs of patients and their families for services, and track and identify individuals lost to follow-up across time.

Conclusion: The results generally point to a need for greater alignment of state NBS program data practices and policies with the data requirements for essential public health functions, such as quality assurance, program evaluation, and cost-benefit analysis.

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Newborn screening (NBS) is expanding in the United States. Most states are in the process of increasing their testing panels to a recommended 29 core disorders, and some states now test for as many as 50 disorders. This testing expansion is not without controversy. Debates involve the cost-effectiveness of testing for rarer disorders, the ethics of testing for incurable or poorly understood diseases, the need for consistent informed consent/dissent policies across states, and the importance of ensuring timely, appropriate care through infancy and adolescence for individuals with diagnosed disorders.1-3 The expanded testing now under way, despite concerns, has great benefit associated with it, especially for newborns with disorders that can be identified early, treated, and managed in effective ways.4

Long-term follow-up (LTFU) is an important part of the NBS system. This system also includes education, screening, follow-up of abnormal results, and diagnosis. Although most emphasis in the system is on testing and short-term follow-up, increased attention is being given to the activities of LTFU.56 These activities are conducted past the point of confirmatory diagnosis and may include a variety of oversight, care coordination, and direct service activities. Primary care and specialty providers (physicians, nurses, and allied health professionals) are responsible for treating newborns with disorders diagnosed through NBS. These providers constitute the “medical homes” identified in the literature as important to realizing the full value of NBS as a public health endeavor.7 However, an issue of increasing debate is whether the state and federal governments should become more involved in ensuring that an activity that costs taxpayers and the health care system millions of dollars annually reaches its full potential. This places emphasis on determining the ideal role that government entities, such as state NBS programs, should play in the activities of LTFU. A 2005 guideline published by the...
Clinical and Laboratory Standards Institute defines NBS LTFU as follows:

“Long-term follow-up is a mechanism for determining if the newborn screening system is accomplishing its intended goal of improving health outcomes. Long-term follow-up refers to an infrastructure with the capacity for periodic monitoring of selected outcome indicators appropriate for evaluating the efficacy of newborn screening. Data obtained through long-term follow-up can be useful in improving and refining the newborn screening system. Long-term follow-up may include facilitation of services to ensure coordinated, comprehensive health care.”7(p11)

In addition, the American Academy of Pediatrics, the Council of Regional Networks for Genetic Services, the National Newborn Screening and Genetics Resource Center (NNSGRC), and the Secretary’s Advisory Committee on Heritable Disorders have also identified activities in the areas of care evaluation, outcomes research, medical management, and quality assurance as appropriate elements in a fully functional NBS system.3,8,9

Previous research6 shows that LTFU policies and practices across state NBS programs are highly variable. Many state programs perform no LTFU activities, and those that do face significant challenges because of a lack of quality assurance mechanisms and appropriate resources.6,12 If state NBS programs take a more active role in LTFU in the future, their ability to access timely and reliable patient and provider-related data is critical. The public health functions outlined previously herein and advocated for by organizations such as the Clinical and Laboratory Standards Institute and the American Academy of Pediatrics require that specific types of data be collected and analyzed across time. Table 1 outlines the types of data required for various follow-up activities to be performed, whether at the federal, state, or local level.

The present study examines the capacity of state NBS programs, as it relates to data, to fulfill aspects of the LTFU definition as outlined by the Clinical and Laboratory Standards Institute, the American College of Medical Genetics, and other organizations. Whereas other state-level entities may be involved in NBS LTFU, state NBS programs are in a strategic position to play a prominent role in LTFU data collection and analysis because they are the central repository for testing and short-term follow-up information on each newborn screened. The following research questions are addressed in this study: (1) What is the scope of LTFU data collection and use among state NBS programs? and (2) What are the policies and practices related to LTFU data collection and use among state NBS programs?

**METHODS**

**SURVEY AND SAMPLE**

A 19-question online survey was developed and administered during fall 2005 to 35 state NBS programs. Surveys were completed by the designated follow-up coordinators in each program, as identified by the NNSGRC.12 The survey focused primarily on the practices and policies in state NBS programs related to LTFU data collection and use. The LTFU data were generally defined for respondents as data involving patients, patient care, and providers past the confirmatory diagnostic phase (ie, after an individual is diagnosed as having a disorder). Respondents were asked whether they collected 1 or more of 9 types of LTFU data, such as details of visits with specialists and primary care providers, treatment regimens, and developmental progress.

**Table 1. Data Needs for State Newborn Screening Programs According to Specific Public Health Functions Applied to the Case of Newborn Screening**

<table>
<thead>
<tr>
<th>Public Health Function</th>
<th>Data Needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessing quality of care and access to care across different populations with disorders (eg, non-Hispanic white vs Hispanic or privately vs publicly insured)</td>
<td>Data related to visits with providers (physicians, nurses, and allied health professionals), such as frequency of visits and identification of current primary and specialty care providers for affected individuals; patient treatment regimens; clinical outcomes (eg, the developmental progress of the child); and children lost to follow-up</td>
</tr>
<tr>
<td>Integrity of the primary care–specialty provider relationship (eg, communication adequacy between the 2 relative to patient progress)</td>
<td>Identification of current primary and specialty care providers for affected individuals, visit data, and children lost to follow-up</td>
</tr>
<tr>
<td>Patient access to providers/medical home across time</td>
<td>Identification of current primary and specialty care providers for affected individuals, visit data, and children lost to follow-up</td>
</tr>
<tr>
<td>Evaluation of care to affected populations</td>
<td>Aggregate and patient-level data on medical management and treatment regimen for affected individuals and visit data</td>
</tr>
<tr>
<td>Outcomes research to assess the cost-benefit analysis of screening for different disorders</td>
<td>Billing data on cost of care for affected individuals across time and clinical outcomes (eg, the developmental progress of the child or existence of comorbidities)</td>
</tr>
</tbody>
</table>

Public health functions were generally obtained from the Institute of Medicine,11 then were applied specifically to the case of newborn screening as elaborated on by the American Academy of Pediatrics,3 the Council of Regional Networks for Genetic Services,5 and the National Newborn Screening and Genetics Resource Center.12

Additional survey questions included information about the state NBS program location (eg, within or outside of a health department or family health unit), the number of specialty centers for different categories of disorders in a state, the use of funding for LTFU, state NBS program definitions of the term medical home, whether LTFU data are collected by the NBS program, a description of the types of data collected, the methods used by programs to collect LTFU data, uses and storage of LTFU data, and largest sources of funding for follow-up. A copy of the complete survey is available from the corresponding author. The survey items were developed through an iterative process that involved qualitative interviews conducted during the same period with follow-up coordinators in the 35 state NBS programs, discussions with the director of the NNSGRC, and review of the literature on NBS. This article presents findings from the survey only. This study was approved by the State University of New York at Albany institutional review board (protocol 04-323).

Fifteen state NBS programs did not participate in the survey. During an earlier survey conducted by the first author (T.H.) in January 2003, these programs indicated that they did not want
to participate in a second survey. Analysis of the 15 states that were not sent a survey indicated that there were no significant mean differences with states completing the survey in the NBS program budget, number of employees in the NBS follow-up component of the program, number of statewide births, number of conditions tested, or geographic location. Several variables from the earlier survey, which was also completed by state NBS follow-up coordinators, were added to the current data set for the 34 state NBS program respondents, including perceived resource adequacy for follow-up activities, number of full-time employees involved in follow-up in the state NBS program, and type of LTFU model used by NBS programs (eg, contracting LTFU out completely vs performing LTFU completely “in-house” in the program itself). Three additional variables were added to round out the data set. The number of live births in each state was obtained from the National Center for Health Statistics. The current NBS fees charged and the number of required conditions for testing in each state as of October 2005, when the survey was conducted, were obtained from the NNSGRC.13

STATISTICAL ANALYSIS

Statistical analysis was performed using a software program (SPSS 13.0; SPSS Inc, Chicago, Illinois). Analyses were conducted using a combination of univariable and bivariable statistical operations, including descriptive statistics such as frequencies, means, and standard deviations; correlation analysis using Pearson and Spearman coefficients; and analysis of variance using independent-sample t tests. For categorical and nonnormally distributed variables, nonparametric techniques were used, including cross-tabulations using the \( \chi^2 \) measure of association and, for median comparisons, use of the Mann-Whitney test. The latter test compares 2 subgroups of cases in terms of whether their ranked locations in relation to some test variable in the larger combined set of cases are equivalent to or significantly different from each other.

Three variables in the data set had missing data that amounted to greater than 5% of total cases: the number of full-time employees necessary to conduct adequate LTFU, the total number of specialty centers in each state, and the estimated annual number of cases diagnosed in each state before program expansion. These variables were included in the analyses because they were deemed to be important factors that might be associated with particular data collection and use practices in a state NBS program. Rather than use the means for these variables in missing cases, the cases themselves were excluded from analysis.

**RESULTS**

LTFU DATA COLLECTION PRACTICES

Thirty-four of 35 state NBS programs returned a completed survey (response rate of 97%). Fifteen of the 34 programs reported performing some type of LTFU data collection (Table 2). This represents less than half of those returning a survey. Programs that did and did not report collecting LTFU data were compared using a variety of criteria that might shape overall capacity to gather these kinds of data (Table 3). Few differences were found between the 2 groups. Mean NBS fees were almost identical in the 2 groups, as were the mean number of required conditions tested, the median number of annual pretesting expansion cases diagnosed in each state, and the median number of specialty centers in the states.

However, state programs collecting LTFU data reported higher levels of perceived resource adequacy than programs not collecting these data (mean difference, −0.83; 95% confidence interval [CI], −1.67 to 0.02). Two nonsignificant but meaningful findings were the higher mean percentage of in-house LTFU programs in states reporting that they collect LTFU data and the higher number of full-time employees involved in follow-up (long- and short-term) in state programs collecting LTFU data. More than 40% of NBS programs collecting LTFU data conducted LTFU completely in-house compared with only 13% of NBS programs that did not collect any LTFU data (Table 3).

State NBS programs collecting LTFU data varied in the scope and substance of data collected (Table 4). Only 3 state programs reported collecting all 9 types of LTFU data queried in the survey. These states, Maryland, Nevada, and Vermont, are smaller and have fewer diagnosed cases annually than some other states in Table 4 that reported collecting fewer types of data. Two programs in larger states, Illinois and Washington, reported collecting 8 of the 9 types of LTFU data. Most state programs collected at least 6 of the 9 different types of data described in Table 4.

Fourteen of the 15 state NBS programs collecting LTFU data reported that data collection varied by type of disorder, type of provider, or both. This finding suggests that state NBS programs are likely to have inconsistent or incomplete data on visits with providers, treatment regimens, and clinical outcomes (eg, the developmental progress of the child) across patients. The types of LTFU data collected also varied across the individual state programs. Types of LTFU data collected by most state NBS programs were whether the patient has recently been seen by a specialty provider (14 programs), current patient...
USEs of LTFU DATA COLLECTED BY STATE NBS PROGRAMS

The LTFU data are used by state NBS programs in a variety of ways (Table 5). Most programs collecting data reported using it to (1) track the clinical outcomes of patients, (2) assess the needs of patients and their families for services, and (3) track and identify individuals lost to follow-up across time. Fewer programs used LTFU data for conducting research and evaluation studies, such as cost-benefit analyses, or evaluating the performance of specialty providers in their state in caring for individuals with disorders identified through NBS. However, 5 of 15 programs collecting LTFU data (33%) indicated that they either did not use the data for any of the 5 functions listed in Table 5 or used their data for only 1 of the functions. Combined with the observation that 19 of 34 state programs returning a survey indicated that they collect no LTFU data, it can be inferred that 24 of 34 state NBS programs (71%) participating in the study do not use LTFU data at all or only minimally.

Several significant relationships were observed between uses of LTFU data and the types of data collected, the collecting periodicity, and the mode of storage. For example, a higher percentage of programs using LTFU data for research purposes was related to how treatment regimens (14 programs), updated patient clinical data (12 programs), and date of last visit with a specialty provider (11 programs).

Data less frequently collected included the date of the last visit with the primary care provider (6 programs), whether the patient had recently been seen by a primary care provider (8 programs), and contact information for the current primary care provider (8 programs). Almost all of the 15 programs collecting data emphasized LTFU data collection from specialty and not primary care providers. This was surprising given that all 34 state programs surveyed identified the primary care provider either exclusively or in tandem with specialty providers as the appropriate medical home for newborns and children with diagnosed disorders.

Almost half of the 15 programs reported collecting LTFU data only once a year. This means that some LTFU data, such as the date of the last visit with primary care and specialty providers or current treatment regimens, are not actually reported to NBS programs in real time but rather at longer intervals after the actual patient visit. Most programs reported receiving LTFU data from providers only in paper form or through verbal communication. One state (California) reported receiving data through a Web-based system, and another, Michigan, was (at the time of the survey) in the planning stages of setting up a Web-based LTFU data collection system. However, no statistically significant relationships were observed between how often a state program collected data and whether they used paper, verbal, or computerized methods for receiving data.

Particularly relevant to how LTFU data might be used to conduct the public health functions described in Table 1, 7 of 15 programs (47%) reported storing the LTFU data they collected only in hard copy form (eg, stored in file cabinets in the program), and another 4 of 15 (27%) stored data through a combination hard copy and electronic database arrangement. The remaining 4 states (27%) stored data only in an electronic database. The latter includes program-created computerized databases using Microsoft Excel or Access and more targeted case management software. The lack of organized electronic databases for patient and provider information in many state NBS programs suggests a lowered level of importance for such data or a lack of expertise in obtaining and using these data (eg, for care evaluation, tracking of patients [such as those lost to follow-up] and medical homes, and outcomes or cost-benefit research).
Table 4. State-by-State Analysis of LTFU Data Collection Policies and Practicesa

<table>
<thead>
<tr>
<th>State Collecting Data</th>
<th>Types of Data Collected, No.</th>
<th>Types of Data Collectedb</th>
<th>Frequency of Data Collection</th>
<th>Primary Data Collection Method</th>
<th>Primary Means of Storing Data</th>
<th>Data Collection Varies by Provider/Disorder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maryland</td>
<td>9</td>
<td>All</td>
<td>Other (some annually, some monthly)</td>
<td>Other (varies by type of data)</td>
<td>Hard copy/database</td>
<td>Disorder</td>
</tr>
<tr>
<td>Nevada</td>
<td>9</td>
<td>All</td>
<td>Other (annually/CSPCN collects)</td>
<td>Other (varies by type of data)</td>
<td>Hard copy/database</td>
<td>Neither</td>
</tr>
<tr>
<td>Vermont</td>
<td>9</td>
<td>All</td>
<td>Other (before clinic visits and as needed)</td>
<td>Verbal communication with providers</td>
<td>Hard copy</td>
<td>Disorder</td>
</tr>
<tr>
<td>Illinois</td>
<td>8</td>
<td>A, B, C, D, E, F, G, H</td>
<td>Annually</td>
<td>Providers complete and submit a paper form</td>
<td>Hard copy/database</td>
<td>Disorder</td>
</tr>
<tr>
<td>Washington</td>
<td>8</td>
<td>A, B, C, E, F, G, H, I</td>
<td>At irregular times</td>
<td>Providers complete and submit a paper form</td>
<td>Hard copy</td>
<td>Disorder</td>
</tr>
<tr>
<td>Arkansas</td>
<td>7</td>
<td>A, B, C, D, E, F, G</td>
<td>Annually</td>
<td>Providers complete and submit a paper form</td>
<td>Hard copy/database</td>
<td>Provider/disorder</td>
</tr>
<tr>
<td>Iowa</td>
<td>7</td>
<td>A, B, E, F, G, H, I</td>
<td>Whenever the patient is seen by the provider</td>
<td>Verbal communication with providers</td>
<td>Database</td>
<td>Provider/disorder</td>
</tr>
<tr>
<td>California</td>
<td>6</td>
<td>A, C, E, F, G, H</td>
<td>Whenever the patient is seen by the provider</td>
<td>Providers enter data using a Web-based application</td>
<td>Database</td>
<td>Disorder</td>
</tr>
<tr>
<td>Texas</td>
<td>6</td>
<td>A, B, C, D, E, G</td>
<td>Annually</td>
<td>Providers complete and submit a paper form</td>
<td>Hard copy</td>
<td>Disorder</td>
</tr>
<tr>
<td>Delaware</td>
<td>5</td>
<td>A, C, E, F, G</td>
<td>At irregular times</td>
<td>Verbal communication with providers</td>
<td>Database</td>
<td>Disorder</td>
</tr>
<tr>
<td>Michiganc</td>
<td>5</td>
<td>A, C, E, H, I</td>
<td>Whenever the patient is seen by the provider</td>
<td>Providers enter data using a Web-based application</td>
<td>Database</td>
<td>Physician/disorder</td>
</tr>
<tr>
<td>Hawaii</td>
<td>4</td>
<td>A, C, E, I</td>
<td>Whenever the patient is seen by the provider</td>
<td>Other (&quot;providers send follow-up medical report&quot;)</td>
<td>Hard copy</td>
<td>Provider/disorder</td>
</tr>
<tr>
<td>Oklahomad</td>
<td>4</td>
<td>E, G, H, I</td>
<td>Annually</td>
<td>Other (&quot;LTFU coordinators submit&quot;)</td>
<td>Hard copy</td>
<td>Disorder</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>3</td>
<td>A, E, F</td>
<td>Annually</td>
<td>Other (&quot;copy of medical record&quot;)</td>
<td>Hard copy</td>
<td>Provider/disorder</td>
</tr>
<tr>
<td>Utah</td>
<td>3</td>
<td>A, G, H</td>
<td>Annually</td>
<td>Providers complete and submit a paper form</td>
<td>Hard copy</td>
<td>Disorder</td>
</tr>
</tbody>
</table>

Abbreviation: CSPCN, children with special health care needs; LTFU, long-term follow-up.

a Based on survey responses from state newborn screening programs. The term provider represents physicians, nurses, and allied health professionals.

b A=Whether the patient is currently being seen by a specialty provider, B=whether the patient is currently being seen by a primary care provider, C=date of the last visit with the specialty provider, D=date of the last visit with the primary care provider, E=current patient treatment regimen, F=changes to treatment regimen, G=updated patient clinical data, H=patient’s developmental progress, and I=contact information of current primary care provider.

c Michigan’s data collection via Internet was in the planning stages at the time of the survey.

d Oklahoma did not provide an answer to the first 4 types of data collected.

data were stored in state NBS programs. A much higher percentage of programs not using data for research stored some or all of their data in hard copy form (91% vs 25%; P=.01), whereas 100% of programs using data for research stored some or all of it in some form of computerized database compared with approximately one-third of programs not using collected data for research (P=.03).

Several uses of LTFU data by NBS programs were also related to state NBS program capacity. In particular, programs using data to assess the needs of individuals and families for services had a smaller mean number of total pretesting expansion cases diagnosed through NBS (mean difference, 188.50; 95% CI, −46.83 to 423.83). In looking at the 9 states that used data for needs or service assessment, 7 could be classified as smaller in terms of number of annual births (ie, Iowa, Nevada, Vermont, Maryland, Arkansas, Hawaii, and Oklahoma). However, programs using LTFU to track the number of individuals lost to follow-up had a higher mean number of employees devoted to follow-up than programs that did not use data in this way (mean difference, −8.73; 95% CI, −15.63 to −1.82).

Finally, NBS program location and whether LTFU was performed in-house or contracted out were related to several uses of LTFU data. Almost 80% of NBS programs physically located in state departments of health did not use LTFU data either to evaluate the performance of specialty providers in their state or to conduct research (P=.09). In addition, regardless of program location, none...
of the state NBS programs doing LTFU in-house used LTFU data for provider evaluation or for research compared with 60% of programs contracting out LTFU (P = .04).

**COMMENT**

The ability to collect and use appropriate LTFU data is important in ensuring that a state NBS system fulfills its public health potential. This study sheds light on the data-related capacity of state NBS programs, as 1 stakeholder in this system, to engage in public health surveillance, oversight, and evaluation of LTFU for newborns with diagnosed disorders in their states. The main conclusion supported by these findings suggests that significant data-related challenges lie ahead in improving the ability of the state NBS programs surveyed to engage in LTFU, should that role be expected of them. Perhaps the biggest finding that supports this observation is that more than half of the surveyed programs reported collecting no LTFU data at present. This renders their ability to fulfill the functions listed in Table 1 questionable.

For the 15 state programs surveyed that collect LTFU data, obstacles exist with respect to their ability to use the data for systematic activities, such as evaluation and quality assurance. For example, with a single exception, LTFU data collection practices vary in programs relative to the type of disorder and provider. This means that reliable data on medical management, treatment regimens, frequency of visits, and medical home access are not available uniformly across all patients and all tested disorders. This makes it more difficult to conduct comprehensive population-based outcomes studies, reviews of provider quality of care, and cost-benefit analyses.

Second, most programs report collecting data from providers through verbal communication or paper forms, which ultimately must be entered into some type of organized electronic database for efficient use in research or large-scale evaluation activities. Only 4 of 15 state programs reported using an electronic database exclusively for storing LTFU data. The apparent lack of technology use in many state NBS programs collecting LTFU data diminishes their ability to use these data for population studies. Finally, almost half of the programs collecting LTFU data do so annually. This undermines their ability to evaluate or monitor care on a real-time basis or as close as possible to the actual patient-provider visits.

The emphasis on LTFU data collection from specialty providers and the deemphasis on data from primary care providers is also noteworthy. This indicates that LTFU activities that depend on information from primary care providers are less likely to be performed or may be less effectively performed in state NBS programs. For example, the NBS literature emphasizes the identifica-
tion and ongoing assurance of medical home access as critical in ensuring appropriate follow-up for newborns with diagnosed disorders. However, if most state programs do not have consistent data exchange with primary care providers, it is not likely that they can reliably assess the use of medical homes for children with diagnosed disorders, to the extent that those homes reside in the primary care system.

This study is limited in several ways. First, it is a cross-sectional view of the LTFU data collection practices in state NBS programs. One would expect these programs to evolve and perhaps strengthen their data-related capabilities in the LTFU area across time. A second study limitation is that the sample included only state NBS programs, just 1 part of the larger public health system. There may be other entities at the state level, such as various child health programs, which collect different types of LTFU data. A third limitation is that 16 state NBS programs did not participate in the survey. Whether their LTFU data practices are meaningfully different from those observed in the other 34 programs is an empirical question. However, there may be little reason to believe that such programs are distinct in this regard. An earlier survey of 46 state NBS programs, which included programs not participating in the present study, found consistent LTFU practices and capacity across all 46 programs.

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Author Contributions: Dr Hoff was the principal investigator of the study and had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Hoff, Ayoob, and Therrell. Acquisition of data: Hoff and Ayoob. Analysis and interpretation of data: Hoff and Ayoob. Drafting of the manuscript: Hoff, Critical revision of the manuscript for important intellectual content: Hoff, Ayoob, and Therrell. Statistical analysis: Hoff and Ayoob. Obtained funding: Hoff and Therrell. Administrative, technical, and material support: Hoff and Ayoob. Study supervision: Hoff.

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