

# Including the initial newborn screening bloodspot collection device serial number on birth certificates: basis and recommendations from the Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children

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**Purpose:** We provide background information/education for national recommendations to include initial newborn screening dried bloodspot serial numbers in electronic birth registrations. Mutual data linking would provide quality checks for each data source, determinations of percentages of newborns screened, and identification of locations where screening is lacking.

**Methods:** State newborn screening dried bloodspot programs were surveyed to determine the extent of newborn screening dried bloodspot and electronic birth registration linking and the states' level of interest in such linkages. These data were reviewed with federal and state policy makers and presented to the Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children for national policy recommendations.

**Results:** Only 40% of state newborn screening dried bloodspot programs reported comparing births with screens. All states use serially numbered newborn screening dried bloodspot collection cards,

and electronic birth registrations exist in almost all states. Newborn screening dried bloodspot serial number data fields currently exist in only 24% of state electronic birth registrations.

**Conclusion:** The Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children recommends the universal use of the newborn screening dried bloodspot serial number in a standardized format as part of state birth registration; consideration of including the initial newborn screening dried bloodspot serial number as a required data field; and, once established, using these data linkages to monitor completeness of newborn screening and to validate demographic information in both systems.

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**Key Words:** birth certificate; electronic health records; national recommendations; newborn screening; policy; quality assurance

## INTRODUCTION

Newborn screening (NBS) includes tests that are performed during the first few hours or days of a newborn's life. These tests have the potential to prevent catastrophic health outcomes. NBS has been defined as a core public health program by the Association of State and Territorial Health Officials,<sup>1</sup> and its oversight is generally recognized as a responsibility of state public health departments. Currently, NBS includes two types of screening: newborn dried blood spot screening (NDBS), which seeks to identify certain congenital inherited disorders through blood collected on special filter paper collection devices, and noninvasive point-of-care testing, which currently includes both newborn hearing screening (NHS) and critical congenital heart disease screening. Although national guidelines recommend a set of conditions for inclusion in each state-required screening panel,<sup>2</sup> national guidance on implementation and quality assurance is limited.<sup>3</sup>

In addition to NBS, state health departments are also responsible for maintaining vital records. Because both NBS and birth

registration are legal mandates, and for increased efficiency, electronic record keeping for both activities exists in almost all states and where it does not exist, it is in final development. Nationally, exchange of electronic health information between health-care providers and health support systems is a rapidly expanding process, and both NBS and electronic birth registration (EBR) constitute early entry points into an individual's electronic health record.

NBS is critical to the health and well-being of each newborn and accurate birth registration establishes critical legal documentation of a birth. To assess whether all newborns obtain the required NBS and to provide external validation of basic demographic information in the birth registration record, it is logical to link EBR with NBS information. Similarly, NDBS, NHS, and critical congenital heart disease screening data should be linked to each other to assure the full spectrum of NBS tests, and linkages to other public health programs can provide broader assurances of access to related services.

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Comparing information on screened newborns with official birth records is an essential quality assurance step in the screening process.<sup>4-7</sup> Likewise, comparing demographic NBS information provides an opportunity to validate certain critical information in the EBR, particularly if it can be performed electronically and seamlessly.

NDBS programs use special filter paper collection devices for specimen collection and data submission/linking. An identifying serial number on each collection card is commonly used as an inventory control device and/or as a specimen identifier. A separate laboratory identification number is usually assigned to each incoming specimen at the screening laboratory for laboratory sequencing/tracking. In addition, the national standard describing the specimen collection process for NDBS,<sup>7</sup> originally approved in 1988,<sup>8</sup> has included a recommended format for a unique NDBS specimen identifier (serial number) since 1992.<sup>9</sup> Using this format (state abbreviation, two-digit year, seven-digit sequence number, and an optional one-character checksum for number verification) provides a means for national data harmonization.

Because NDBS collection devices (cards) are physically available at birthing facilities and each contains a unique serial number (within that state program), the initial NDBS card serial number represents a logical electronic identifier. Using the initial NDBS serial number for patient identification and linking subsequent specimens to it can facilitate patient tracking and avoid unnecessarily accessing (or counting) the same patient multiple times. Including the initial NDBS specimen number in the EBR provides a simple mechanism for confirming whether all newborns have obtained their required blood screening. Likewise, this identifier could be used for linkages among NDBS, NHS, critical congenital heart disease screening, and/or other public health programs to facilitate their quality assurance efforts.<sup>3-6</sup>

Currently, matching newborns screened to birth records can be time and labor intensive, particularly in states with smaller birth cohorts and manual matching. In states where electronic matching exists, the matching algorithms and timing vary. Simple deterministic matching requires exact agreement between characters in a specific data field(s) (e.g., name, identification number). More complex probabilistic matching uses statistical methods to determine the frequency of data field matches and calculates likelihood scores (e.g., first and last initial, date of birth, and sex). State public health departments tend to use probabilistic matching algorithms, often several weeks or months after birth.

Birth registration is a state activity with nationwide variability as a result. A national not-for-profit, membership organization (the National Association for Public Health Statistics and Information Systems (NAPHSIS)) composed of registrars and directors of state vital statistics programs, provides a mechanism for states to interact with the National Center for Health Statistics (NCHS) (a part of the Centers for Disease Control and Prevention) to improve US health statistics and vital record keeping. Actions by NAPHSIS and NCHS often impact the

way in which birth registration/certificates and their related information are implemented at the state level. Both organizations have input into infrequent reviews and updates of the US Standard Certificate of Live Birth, the national model birth certificate created by the NCHS (last updated in 2003).<sup>10</sup> Review of the US Standard Certificate of Live Birth occurs at the discretion of the NCHS, and revisions are recommended to the Secretary of Health and Human Services for approval as a national model. State use of the US Standard Certificate of Live Birth is not legally required, however, acceptance of most data fields by state registrars is widespread and considered critical to data collection and research of national vital records. Certain birth certificate data fields are often recommended as “required” in individual jurisdictions when their completion provides critical health information, thus increasing the likelihood that the information will be reported. Other fields that are less essential or informational are “optional.”

Because there is increasing emphasis on electronic health records and assurance that each newborn has received the required newborn screens, and because the NDBS provides a logical linking point between NBS activities and birth records (among other possible linkages), we undertook a brief study to determine the extent to which birth certificates and initial NDBS collection device serial numbers are currently linked. In addition, we obtained baseline information concerning the number of state NDBS programs that evaluate program coverage through any linking process. These data were used to inform the Subcommittee on Long Term Follow-up and Treatment in order to make recommendations to the Secretary of Health and Human Services’ Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC). To determine costs associated with the addition of a NDBS data field to the EBR, we subsequently investigated charges to NBS programs in jurisdictions where a field for the NDBS serial number has already been added to the EBR.

## MATERIALS AND METHODS

In 2009 a six-item survey was e-mailed to state NBS laboratory and follow-up personnel identified by state NDBS programs as their primary contact persons. This survey assessed the extent to which NBS programs link to birth certificates. After an initial 2-week response period, telephone contact was made with programs that had not responded. Responses were obtained from all 51 state programs (including the District of Columbia). The survey was updated by e-mail in 2010 with only one change (discussed later).

A second brief survey was also submitted to state NDBS coordinators to determine baseline information for one objective then being considered for inclusion as part of Healthy People 2020 – Objective MICH-32.1: Increase the proportion of states that verify, through linkage with vital records, that all newborns are screened shortly after birth for conditions mandated by their state-sponsored screening program (<http://healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=26>). This survey sought to ascertain which NDBS programs

compared births with screening records as part of their quality assurance process. In this case, programs were simply asked whether or not they had the capability to perform linkages at the time of the survey and the process for doing so.

## RESULTS

The response rate to the 2009 survey on birth certificate linkage was 100%. One state was unable to adequately answer the survey questions and was not included in the final analysis, leaving 50 responders. Forty-eight of these (96%) reported that an EBR was now available in their state. Eleven states (22%) initially reported that the state EBR included a field for the NDBS serial number (CO, IA, MI, NM, NY, OH, OK, OR, SD, TN, and UT), and an additional four states (8%) (KS, NJ, SC, and WI) reported that plans were in place to add such a field. (Note: A 2011 survey update increased the number of programs with a field for the NDBS identifier in their EBR to 12 (added WI) with other data remaining unchanged.)

Of the 12 states that have a field for the serial number, four reported that it was a “required” field. Ten of the 12 reported that the serial number was routinely recorded in at least some EBRs; however, some noted that recording was inconsistent due to the lack of designation of this field as a “required” field. Five of the 12 states reported routinely using the NBS serial number to link NDBS forms to birth certificates as a quality measure to assure that all newborns received screening, and several others indicated plans to routinely use this number for linkage in the future.

For programs that might use other procedures to link various NBS records with birth records, an open-ended question requested descriptions of other linking experiences. Thirty-three NDBS programs (66%) responded to this question noting their use of various probabilistic matching protocols. Thirteen programs (26%) stated that they were not currently performing any matching and four (8%) did not respond. A few states reported using manual matching. The amount of time taken in accomplishing the matching process ranged from hours to months, with most programs reporting >90% accuracy using their local protocol.

A second survey sought to clarify which state NBS programs ensured that all newborns were screened using any type of birth matching process. Of the 51 state programs responding, 21 (41%) reported matching all newborns in their NDBS program and 26 (51%) reported matching all newborns in their NHS program. Because the questionnaire was aimed at determining baseline information on the extent to which NBS programs checked to see that all newborns were screened, it did not explore the time period over which such matching occurs. Clearly, based on the previous survey, some matching occurs in a time frame not conducive to optimizing NBS outcomes. Nonetheless, there is value in knowing whether all newborns were screened, so that facilities not screening all newborns can be contacted to learn the reason(s) for such noncompliance and to provide targeted education for quality improvement.

## DISCUSSION

Almost all states in the United States currently use an EBR,<sup>11</sup> which provides hope that public health departments and other appropriate health-care stakeholders will soon have the ability to link to these records in a secure manner to validate critical demographic information and to ensure appropriate service delivery. As one step in the information utilization process, NBS programs are considering ways in which to increase the efficiency of their processes for ensuring that all newborns are appropriately screened. Likewise, birth registrars are continuously assessing ways in which to better assure accurate birth record information. Electronic matching between birth records and other critical health program information provides a mechanism for improving both processes, particularly if it can be simply performed within a short time period following birth. This can allow newborns who missed screening to be tracked and provided with appropriate screening tests, diagnosis, and treatment/management in time to prevent catastrophic health outcomes if screened conditions exist. It can also provide validation of critical demographic information in the birth record as an early quality check before the EBR becomes widely used as a vital record. Furthermore, the national health objectives published as Healthy People 2020 contains an objective in line with the linkages noted (see Introduction section).

Currently, some state NBS programs attempt to match newborns screened to birth records to ensure that all receive appropriate screening to prevent certain congenital health issues that require early diagnosis and treatment for optimal health benefit. Although many NBS programs match screening information and birth records weeks or months after birth, primarily for Medicaid or other reimbursement, few match the information within a time period that allows for optimum screening outcomes. Limited matching with hospital birth records occurs, but a universally accepted linking process or record numbering system does not currently exist. Likewise, unique program identifiers allow electronic matching in both NDBS and NHS programs through custom software in at least one state.<sup>12</sup> There appears to be growing recognition that inclusion of unique NBS patient identifiers on the birth certificate, or inclusion of the birth certificate number in the screening information transferred to the NBS program, provides a simple means of matching records between these programs. The latter method is more problematic because screening often occurs before submission of the EBR.

We surveyed state NBS programs to determine the state of affairs relative to matching screening tests to birth records. We found that at least half of the US NBS programs do not attempt to match newborn screens to birth certificates. These programs cannot confirm whether or not all newborns received the state-required screening. Approximately 40% of NDBSs and 50% of NHSs go through a matching process that often takes weeks or months to complete and minimizes its value toward ensuring timely NBS. Only about 25% of NBS programs currently use a data field containing the NDBS serial number in the EBR against which to match NBS records to confirm that all newborns were screened, and at least four programs are working

to include this process in the near future. Only four programs reported that the serial number data field is a “required” field on the birth certificate, but many noted that requiring its reporting would likely aid in their matching efforts.

Published data are lacking regarding the efficiency of matching NBS records to birth records by any procedure. However, because of the need for rapid matching to identify missed screens, it seems particularly important to consider using electronic matches between birth records and other health program records like NBS. Simplification of the matching process by using a unique serial number for NDBS and recording it in the EBR appears to be a useful quality improvement procedure that potentially benefits both the birth certification process and NBS. Of four states reporting the existence of a “required” data field for the NDBS serial number on the birth certificate, only two reported sufficient experience to comment on the usefulness of this requirement. Both reported positive experiences, particularly after some education had been given to birth certificate registrars at birthing facilities. Five other programs reported occasional use of the data field that would potentially be increased if its completion were required. One state reported that the data field had been included in the EBR for many years but was not routinely completed because it was not a “required” data field. In that state, the data field was recently removed from the EBR in favor of another legal field as a result of space limitations.

Although legal authority for vital registration rests with the states and territories, the US Standard Certificate of Live Birth exists as a model for state use and provision of a data field within this model would emphasize its importance to state birth registrars. However, there is currently no plan to revise the standard certificate and so, although its recommendation for inclusion would be helpful and should be pursued, it is likely that other actions within NAPHSIS would be more timely. State birth certificates are often updated more frequently than the US Standard Certificate of Live Birth, and acceptance of a national recommendation from the SACHDNC and/or the Secretary of Health and Human Services to NAPHSIS would likely have a broader and more rapid impact.

## Conclusion

As exchange of health information grows as a national priority, it is increasingly evident that NBS records, birth records, and other public health records will be an integral part of an individual’s electronic health record.<sup>13</sup> It seems clear that inclusion of a unique NDBS identifier, such as the initial NDBS collection kit serial number, can provide a readily available electronic means of accurately linking births to screening. There will undoubtedly be challenges in educating birth facility personnel on the need for recording the NDBS serial number in the EBR, and internal program or birthing facility logistics may have to be modified to accomplish this goal. To be sure, there are other means of linking, some of which are rapid and accurate, but none are as simple and clean.

It is critical that health information exchange is embraced as a useful concept and that secure methods for creatively using

birth records, NBS records, and other health information for patient benefit are considered. Whether or not the process described here solves all of the problems related to validating birth records and NBS screens remains to be seen, but at this time, it appears to be both logical and prudent to include a unique NDBS serial number in state EBRs. There is, of course, a cost associated with inclusion of a new data field in vital records software and this needs consideration. To date, systems that have incorporated this change have done so as a part of other system modifications such that no itemized “extra” cost was incurred. However, for inclusion in some state software systems, a cost will no doubt be realized. Although costs will be different in the different states, a plan to offset this expense should be considered. Because NDBS programs are fee funded in most states, it may be possible to increase the fee by a small amount to offset the expense. Where fees do not exist, state appropriations may need to be slightly increased to cover the conversion expense, at least initially. Other funding possibilities might include small grants or additional support funding as part of a larger grant request.

Recording an NDBS serial number in a nationally standardized format may be argued by some as creating a national patient identifier. Hence, it is important to reaffirm that this number is not intended to serve that purpose and does not pose any new privacy risks that do not already exist in state public health systems that already use serially numbered NDBS collection devices. The only national standard or national dimension of this number is its suggested format and its inclusion in official birth records. A standardized format is essential for assuring that identifiers generated within states can be exchanged electronically as part of a national health information exchange system, which will include birth information. The numbers recorded in that particular data field would be generated by the state, primarily as inventory control numbers for specimen collection devices ordered and used by individual specimen submitters. Although a unique identifier would be recorded for every newborn in a particular state for whom a NDBS specimen was submitted, any data linked to that newborn would be controlled by the state and subject to state and federal privacy laws.

## Recommendations

The SACHDNC reviewed the information collected and presented here on behalf of the Long Term Follow-up and Treatment Subcommittee and voted agreement to make the following recommendations to the Secretary of Health and Human Services:

- The Secretary of Health and Human Services should encourage state NDBS programs to use the unique serial number on each initial NBS specimen collection device to aid in electronic tracking and identification. To facilitate national harmonization, the format of this number should be in a standard format that includes a checksum character to assure quality control of the computerized input of the serial number.

- The Secretary of Health and Human Services should work with NAPHSIS toward a goal of including the NDBS serial number on the birth certificate to facilitate confirming access of all newborns to timely NBS and to provide an external mechanism for evaluating specific demographic data recorded on the birth certificate. The use of these data for improving electronic health information and service quality should be emphasized.
- The Secretary of Health and Human Services should work with NCHS toward a goal of including a field for the NDBS serial number (consistent with recommendations in Clinical Laboratory Standards Institute Standard LA4-A5) in the next revision of the US Standard Certificate of Live Birth. Inclusion of this field should be “required” because NDBS is a required activity in all states, and comparison of birth certificates with NDBS specimen records represents the most efficient way to confirm universality of screening.
- The Secretary of Health and Human Services should encourage state birth registrars and state NBS program directors to consider ways in which electronic data validation of the demographic information collected by NDBS and EBR activities can be used for cross-validation and data quality improvement.

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#### DISCLOSURE

The authors declare no conflict of interest.

#### REFERENCES

1. Association of State and Territorial Public Health Officials. Newborn Screening Position Statement. 2009. <http://www.astho.org/Display/AssetDisplay.aspx?id=2867>. Accessed 1 August 2012.
2. American College of Medical Genetics, Newborn Screening Expert Group. Newborn screening: toward a uniform screening panel and system. *Genet Med* 2006;8(suppl 1):15–252S.
3. Therrell BL Jr, Schwartz M, Southard C, Williams D, Hannon WH, Mann MY; PEAS Organizing and Working Groups. Newborn screening system performance evaluation assessment scheme (PEAS). *Semin Perinatol* 2010;34:105–120.
4. Therrell BL Jr. Data integration and warehousing: coordination between newborn screening and related public health programs. *Southeast Asian J Trop Med Public Health* 2003;34(suppl 3):63–68.
5. Hinman AR, Atkinson D, Diehn TN, et al. Principles and core functions of integrated child health information systems. *J Public Health Manag Pract* 2004;2004(suppl):S52–S56.
6. Hinman AR, Eichwald J, Linzer D, Saarlans KN. Integrating child health information systems. *Am J Public Health* 2005;95:1923–1927.
7. Clinical and Laboratory Standards Institute. Blood Collection on Filter Paper for Newborn Screening Programs – Fifth Edition; Approved Standard. CLSI document LA4-A5. CLSI: Wayne, PA, 2007.
8. National Committee for Clinical Laboratory Standards. Blood Collection on Filter Paper for Neonatal Screening Programs – First Edition; Approved Standard. NCCLS document LA4-A. NCCLS: Villanova, PA, 1988.
9. National Committee for Clinical Laboratory Standards. Blood Collection on Filter Paper for Neonatal Screening Programs – Second Edition; Approved Standard. NCCLS document LA4-A2. NCCLS: Villanova, PA, 1992.
10. National Center for Health Statistics. Specifications for Collecting and Editing the US Standard Certificate of Birth and Death—2003 revision [CDC Web site]. [http://www.cdc.gov/nchs/nvss/vital\\_certificate\\_revisions.htm](http://www.cdc.gov/nchs/nvss/vital_certificate_revisions.htm). Accessed 1 August 2011.
11. National Association for Public Health Statistics and Information Systems. Electronic Birth Registration System Development Map – January 2012 revision. <http://www.naphsis.org/naphsis/files/cclibraryFiles/Filename/000000001569/January%202012%20EBRS%20Implementation%20Map.pdf>. Accessed 1 August 2012.
12. Hall K, Zimmerman A, Samos J, Simon PR, Hollinshead WH. Coordinating care for children’s health: a public health integrated information systems approach. *Am J Prev Med* 1997;13(suppl 1):32–36.
13. Downing GJ, Zuckerman AE, Coon C, Lloyd-Puryear MA. Enhancing the quality and efficiency of newborn screening programs through the use of health information technology. *Semin Perinatol* 2010;34:156–162.