



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Heritable
Disorders in Newborns and Children
5600 Fishers Lane, Room 18A19
Rockville, Maryland 20857
www.hrsa.gov/heritabledisorderscommittee

March 9, 2012

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Sebelius:

The Secretary's Advisory Committee of Heritable Disorders in Newborns and Children (SACHDNC) held its twenty-sixth meeting in Washington, D.C. on January 26–27, 2012. During this meeting, the SACHDNC reviewed and discussed a Committee report, *Improving Data Quality and Quality Assurance in Newborn Screening by Including the Bloodspot Screening Collection Device Serial Number on Birth Certificates*, which provides information, advice and recommendations to enhance the ability of state newborn dried bloodspot screening (NDBS) programs to improve and verify universality of the screening program for quality assurance purposes using the latest information technology.

Quality assurance of the NDBS screening process needs timely comparison (matching) of screening records with birth records in order to assure universal access to early detection, follow-up and treatment of newborns born in the state for the disorders screened. The enclosed report describes examples of how to capture and harmonize relevant data fields and software requirements across state programs and offers a simplified linking mechanism that expedites the matching of birth certificates and NDBS specimens.

One method of linking the birth certificate information and the NDBS specimen is to include the NDBS serial number on the birth certificate. In fact, in a recent survey reported to SACHDNC at this meeting, it was found that 11 states have included a field on their electronic birth registration forms for the NDBS serial number and four states are currently adding the NDBS serial number field to the electronic birth registration.

The SACHDNC determined that the advice, information and recommendations detailed in the enclosed report have a high potential impact and ability to improve practices and outcomes for individual states. The Committee voted to officially support the report and issue the following formal recommendations for Secretarial consideration:

1. The Secretary should encourage state NDBS programs to utilize the unique serial number on each initial newborn screening 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.

2. The Secretary should work with the National Association for Public Health Statistics and Information Systems (NAPHSIS) toward a goal of including the NDBS serial number on the birth certificate, to facilitate confirming access of all newborns to timely newborn screening 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.
3. The Secretary should work with the National Center for Health Statistics (NCHS) toward a goal of including a field for the NDBS serial number (consistent with recommendations in CLSI LA4-A5) in the next revision of the U.S. 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 to NDBS specimen records represents the most efficient way to confirm screening universality.
4. The Secretary should encourage State birth registrars and state newborn screening program directors to consider ways in which electronic data validation of the demographic information, collected by the NDBS and EBRIS activities, can be used for cross validation and data quality improvement.

We look forward to receiving your decision on the SACHDNC recommendations. Thank you for your consideration on this important topic.

Sincerely yours,

A handwritten signature in blue ink, reading "Joseph A. Bocchini Jr.", with a stylized flourish at the end.

Joseph A. Bocchini Jr., M.D.
Chairperson

Enclosure:

Report - *Improving Data Quality and Quality Assurance in Newborn Screening by Including the Bloodspot Screening Collection Device Serial Number on Birth Certificates*

cc: Sara Copeland, M.D., Designated Federal Official

Improving Data Quality and Quality Assurance in Newborn Screening by Including the Bloodspot Screening Collection Device Serial Number on Birth Certificates

Prepared by Brad Therrell and Colleen Buechner, National Newborn Screening and Genetics Resource Center for the Subcommittee on Long Term Follow-up and Treatment of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children with input from NAPHSIS and NCHS

Executive Summary

Electronically recoding and transmitting accurate health information is currently a focus of national health improvement efforts. Birth records [more appropriately referred to as electronic birth registration (EBR) or electronic birth registration systems (EBRS)] are critical information to which significant amounts of health data must eventually be linked. All states require newborn dried bloodspot screening (NDBS), a primary goal of which is to ensure that all newborns are properly screened. Quality assurance of the screening process requires timely comparison of screening records to birth records to assure universal access to early detection and treatment of screened disorders. Various mechanisms are used by state health departments to accomplish this critical matching. Commonly used electronic matching algorithms are either probabilistic (involving parts of names, dates of birth, location, etc.) or deterministic (exact matches on name or number), or a combination of the two. In many cases, matching is reported to be time and labor intensive resulting in matches long after the critical time period in which newborn screening is optimally effective.

Both NDBS collection devices and birth records usually include different unique identification numbers assigned by individual state NDBS and vital records programs to meet the needs of their record keeping systems. A national standard for NDBS programs recommends a unique number format to facilitate harmonization of computer software requirements for a data field across state programs. A standardized data format (number/position of characters and state identifier) can provide data transfer compatibility when babies move across state jurisdictions. Capturing this NDBS serial number in the EBRS can provide a simplified linking mechanism that facilitates rapid matching of births and NDBS specimens. In addition to facilitating the early identification and follow-up of patients not screened, this process can provide an early validation opportunity for certain birth record demographic information.

State newborn screening programs were surveyed to determine the extent to which linking with EBRs currently exists and the interest level in this matching method. A subsequent survey of those with the NDBS serial number field in the EBR ascertained additional costing information for software modification. Twelve states reported the presence of a data field for the NDBS serial number in their current EBRS. Four of these reported that the NDBS data field is a 'required' field. Lower compliance with completing this data field was noted in states where it was not designated as a 'required' field. At least three other states indicated that efforts were underway to include a field for the NDBS identifier on their state's birth certificate. A separate survey showed that matching activities are a part of NDBS quality assurance efforts in 21 states and newborn hearing screening quality assurance in 26 states, although timeliness may be an

issue in some. While it was recognized that inclusion of the NDBS serial number in the EBRS involves an expense, all programs noted that the cost had been absorbed in a system update without directly impacting the NDBS program; however, this may not be the case in instances where a routine update is not possible.

A national not-for-profit, membership organization, the National Association for Public Health Statistics and Information Systems (NAPHSIS), provides a policy discussion forum for state vital records registrars and directors of vital statistics. This organization, in collaboration with the National Center for Health Statistics (NCHS), provides technical assistance to the 57 U.S. vital records jurisdictions to facilitate high quality, timely vital record data collection and reporting. While legal authority for vital registration rests with the states and territories, a 2003 U.S. Standard Certificate of Live Birth is the basis for data collection and reporting in most jurisdictions. Recommendations for revision are periodically submitted to the Secretary of Health and Human Services by the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS). The data fields on the recommended form are carefully debated before any changes are suggested, and while states are not currently required to use the 2003 birth items, their utilization will be required as of December 2013 in order to receive full NCHS funding from the NCHS funding as part of the Vital Statistics Improvement Program (VSCP). Because actions by NAPHSIS and/or NCHS often impact the way in which birth registration is implemented at the state level, both NAPHSIS and NCHS were contacted, and both agreed with the overall concept presented here. Further, both organizations agreed to explore the feasibility of this initiative.

As part of its charge to engage in a multi-step process that (1) identifies barriers to short and long-term follow-up and treatment and NBS results specific to the challenges in integration of health care system, financing of services, and information systems, (2) develops recommendations for overcoming identified barriers in order to improve short and long-term follow up results and, and (3) recommends mechanisms for establishing accountability for NBS follow-up guidelines, the Long Term Follow-up and Treatment Subcommittee recommends that the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children consider the following activities to assist in refining quality assurance practices in state health departments and state NDBS programs:

1. The SACHDNC should encourage State NDBS programs to utilize a unique serial number on each initial newborn screening specimen collection device to aid in electronic tracking and identification. To facilitate national harmonization, the format of this number should follow that recommended by the national standard for collection of dried blood on filter paper, including strong consideration of a checksum character as an aid in assuring the quality of the computerized input of the serial number.
2. The SACHDNC should work with NAPHSIS to explore the feasibility of including the NDBS serial number in state EBRs to facilitate confirming access of all newborns to timely newborn screening and to provide an external mechanism for evaluating certain demographic data recorded in the birth record. The use of

these data for improving electronic health information and service quality should be emphasized.

3. The SACHDNC should work with NCHS toward a goal of including a field for the NDBS serial number (consistent with recommendations in CLSI LA4-A5) in the next revision of the U.S. Standard Certificate of Live Birth to be recommended to the Secretary of Health and Human Services. State birth registrars should be encouraged to ‘require’ completion of this field, if added to the standard birth data items, in as much as NDBS is a legally required activity in all states and comparison of birth records to NDBS specimen records represents the most efficient way to confirm screening universality.

4. State birth registrars and state newborn screening program directors should be encouraged to consider ways in which electronic data validation of the demographic information collected by the two activities can be used for cross validation and data quality improvement.

Introduction

Newborn screening (NBS) includes various tests that can occur during the first few hours or days of a newborn’s life and which, when properly timed and performed, have the potential for preventing catastrophic health outcomes. NBS has been defined as a **core** public health program by the Association of State and Territorial Health Officials (ASTHO).[1] Currently, two types of screening are commonly considered as NBS in the public health sector: newborn dried blood spot screening (NDBS), which commonly seeks to identify congenital inherited disorders through laboratory analyses of blood collected by heelstick using a special filter paper collection device; and newborn hearing screening (NHS), which seeks to identify hearing disorders using certain non-invasive audiometric screening techniques.

While national guidelines exist that define the recommended screening conditions, [2] guidance is limited with respect to implementation methods and system-wide quality assurance measures.[3] State health departments are generally responsible for implementing, overseeing and sustaining statewide NBS. Similarly, they are responsible for maintaining vital records that document births, deaths, and other vital events. Each state has laws and/or rules that require both newborn screening and birth registration. Electronic record keeping for both activities exists in most states and where it does not exist, it is in the development stage. Exchange of electronic health information between healthcare providers and systems is a rapidly expanding process, and both NBS and records of birth events comprise early entry points into an individual’s electronic health record.

Appropriate newborn screening is critical to ensuring the health and well-being of newborns and accurate birth registration is critical legal documentation that will follow an individual throughout their lifetime. In order to ensure that all newborns obtain the required NBS and to provide an external source of basic demographic information that can be used for birth registration validation, it is logical to link birth records with NBS information. Similarly, both NDBS and NHS should be linked to ensure that each newborn receives the full spectrum of

required newborn screening tests, and other linkages can provide broader assurances of public health and related services. Comparison of information identifying screened newborns in both NDBS and NHS systems to official birth records is an essential quality assurance step in the screening process.[4-7] Although not currently a part of the quality assurance procedure for assuring accurate birth data collection, demographic information collected and reported as part of NBS provides an opportunity to validate certain critical information in the birth record, particularly if it can be done electronically and seamlessly.

Each NDBS program uses special filter paper collection devices approved by the Food and Drug Administration (FDA) for specimen collection and data submission/linking. These devices are obtained from commercial sources; currently limited to two in the U.S. 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 given to each specimen at the screening laboratory to maintain sequencing in the laboratory.

A national standard developed and distributed by the Clinical and Laboratory Standards Institute (CLSI), a global, nonprofit, standards-developing organization within and for the health care community, currently describes *Blood Collection on Filter Paper*. [7] This standard was originally approved for distribution in 1988 [8] and has included a recommended format for a unique NDBS specimen identifier since its second edition in 1992. [9] The format of this identifier (state abbreviation, two digit year, seven digit sequence number, and optional one character check sum for number verification) provides a means of harmonizing both the identification mechanism and data field contained in NDBS patient records. If adopted by all NDBS programs, the initial NDBS specimen serial number provides a unique identifier that can facilitate patient tracking. Multiple records on the same patient are minimized by linking subsequent specimens on the same patient to the initial specimen. This procedure is already in place in some programs that obtain routine second NDBS specimens.

Because NDBS specimens are collected on a special collection device (card) physically available at submitting facilities and containing a unique identifier (serial number), the initial NDBS card number represents a logical and unique electronic linking number. The inclusion of the initial specimen serial number as a data field in the birth record could allow a simple matching mechanism for confirming whether all newborns have obtained their required screening. Similarly, linkage between NDBS, NHS, and other public health programs can be simplified by cross linking with a unique patient identifier such as the initial NDBS serial number. [3-6]

In order to verify that NBS on all newborns has occurred, it is incumbent on state health departments to confirm that all newborns have received the required screening by checking testing records against births. In some NDBS and NHS programs, demographic information is electronically transferred from the specimen submitter or hearing tester to a centralized state tracking database. Other data transfer processes exist, and these include submission of information for both screening programs on the NDBS specimen collection device. Unfortunately, NBS screening records do not always contain the same name or other identifying information as that recorded on the birth certificate. Likewise, birth certification regulations do not always require final disposition of the birth certificate in a manner that ensures timely

comparison with NBS test records. Despite these challenges, a number of state health departments have procedures for attempting to match birth records and NBS screening records.

Matching newborns screened to birth records can be time and labor intensive. Some states, particularly those with smaller birth cohorts, utilize manual matching to ensure that all newborns have been screened. In cases where matching is performed electronically, a matching algorithm is required, and these vary across states. The simplest matching, deterministic matching, requires exact agreement between characters in a specific data field(s), (eg. name, identification number, etc.). More complex probabilistic matching uses statistical methods to determine the frequency of data field matches and calculates a likelihood score (eg. first and last initial, date of birth, and sex).

Deterministic matching with birth certificate information using the baby's name is problematic because names are often subject to errors in recording or spelling, and newborn's names are often not finalized by the time the specimen is submitted. Timely matching depends on the availability of completed birth certificates and may be beyond the time most useful for optimal newborn screening. This occurs primarily when naming a baby is slow or when there is a lengthy time allowed by the state for birth certificate submission. As a result, NBS programs confirming specimens received versus birth certificate information tend to use probabilistic matching algorithms. The accuracy of matching using such algorithms is directly related to the number of fields being matched, and resolution of incomplete matches often requires excessive time and labor.

Legal authority for birth registration in the U.S. rests within 57 vital record jurisdictions, and therefore there is variation in the data obtained across jurisdictions. The National Association for Public Health Statistics and Information Systems (NAPHSIS) is a national non-profit organization representing the 57 jurisdictions that provides advocacy and national leadership. NAPHSIS membership includes state registrars and directors of vital statistics and evolved from the American Association of State Registration Executives, formed in 1933 (see <http://www.naphsis.org/index.asp?bid=386>). NAPHSIS works cooperatively with the CDC National Center for Health Statistics (NCHS) to develop and promote data standards, promote data quality, improve timeliness of reporting, and provide technical assistance to improve the processing of vital records and statistics by its membership. Both NAPHSIS and NCHS have input into the content and format of the U.S. Standard Certificate of Live Birth, the national model birth certificate created by the NCHS (last updated in 2003 [10]).

Review of the *U.S. 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. While utilization of the *U.S. Standard Certificate of Live Birth* is not legally required, acceptance of most data fields by state registrars is widespread and considered critical to national vital records data collection and research. Certain birth certificate data fields are often recommended as 'required' in individual jurisdictions if their completion provides critical health information. Others less essential or informational may be considered 'optional.' 'Required' status does not ensure total compliance, but it generally increases significantly the likelihood that the requested information will be reported. The items included in the model birth certificate are carefully debated before any changes are suggested, and while states are not currently required to

use the 2003 birth items, their utilization will be required as of December 2013 in order to receive full NCHS funding from the NCHS funding as part of the Vital Statistics Improvement Program (VSCP). Both NAPHSIS and NCHS have agreed to explore the feasibility of the initiative outlined here.

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 newborn screening 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 interconnected. Additionally, we obtained baseline information enumerating 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). Because it is recognized that there is a cost associated with adding a field to the EBR, we subsequently investigated costs incurred by NBS programs in jurisdictions where the EBR includes a field for the NDBS serial number. The intent of this survey was to investigate the expense and possible methods for paying for addition of this data field.

Methods

A six-item survey was emailed to state newborn screening laboratory and follow-up personnel identified by state NDBS programs as their primary contact persons in 2009. This survey assessed the extent to which newborn screening 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).

A second brief survey was also submitted to state NDBS coordinators to determine baseline information for a possible objective being considered for publication as part of the national 2020 goal setting process for improving health (*Healthy People 2020* Objective HP2020--22a -- "Increase the proportion of states who verify, through linkage with vital records, that all newborns are screened shortly after birth for conditions mandated by their State-sponsored screening program.") (<http://www.healthypeople.gov/hp2020/Objectives/ViewObjective.aspx?Id=214&TopicArea=Maternal%2c+Infant+and+Child+Health&Objective=MICH+HP2020%e2%80%9322&TopicAreaId=32>; accessed July 16, 2010). This survey sought to ascertain which NDBS programs currently compare births to 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 present time and the process for doing so.

Results

Responses to the initial survey on birth certificate linkage were received from all programs for a response rate of 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 EBR was now available in their state. Eleven states (22%) initially reported that the state EBR included a field for the NDBS identifier (serial number) and an additional 4 states (8%) reported that plans were in place to add such a field. (Note: A recent update increased the number of programs with a field for the NDBS identifier in their EBR to 12.)

Of the 12 states that have a field for the serial number, 4 reported that it was a ‘required’ field. Ten of the 12 reported that the serial number is 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 reported routinely using the newborn screening serial number to link NBS 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 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 are not currently performing any matching and 4 (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 currently ensure that all newborns are 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 currently check to see that all newborns are screened, it did not explore the time period in which such matching occurs. Clearly, based on the previous survey, some matching occurs in a time frame not conducive to optimizing newborn screening outcomes.

Discussion

The majority (96%) of states in the United States currently utilize an EBR, which provides hope that public health departments and other appropriate healthcare stakeholders will soon have the ability to link to these records in a secure manner in order 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 information in the EBR becomes widely used as a vital record.

Furthermore, the national health objectives published as *Healthy People 2020* will likely contain an objective in line with the linkages noted (see Introduction).

Currently, some state NBS programs attempt to match newborns screened to birth records in order to ensure that all receive appropriate screening in order to prevent certain congenital health issues that require early diagnosis and treatment for optimal health benefit. While 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. [11] 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 more often occurs earlier than submission of the EBR.

We surveyed state NBS programs to determine the current state of affairs relative to matching screening tests to birth records. We found that at least half of U.S. NBS programs do not attempt to match newborn screens to birth certificates. These programs cannot confirm that all newborns received the state required screening. Approximately 40% of NDBS and 50% of NHS go through a matching process that often takes weeks or months to complete and minimizes its value to ensuring timely newborn screening. Only about 25% of NBS programs currently utilize a data field containing the NDBS serial number in the EBR against which to match newborn screening records in order to confirm that all newborns were screened, and at least 4 programs are working to include this process in the near future. Only 4 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 utilizing 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 4 states reporting the existence of a 'required' data field for the NDBS serial number on the birth certificate, only 2 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 since it was not a 'required' data field. In that state, the data field was recently removed from the EBR in favor of another field as a result of space limitations.

While legal authority for vital registration rests with the states and territories, the U.S. 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, while its recommendation for inclusion would be helpful and should be pursued, it is likely that other actions within NAPHSIS would be timelier. State birth certificates are often updated more frequently than the *U.S. 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 have a broader and more timely 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. [12] 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 logistics may have to be changed within these facilities to accommodate this process. 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 be embraced as a useful concept and that secure methods for creatively utilizing birth records, newborn screening records and other health information for patient benefit be considered. Whether or not the process described here solves all 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. One vital records program noted that an approximate cost of \$25,000 was part of their cost accounting estimates for adding this field. While cost specifics will be impacted differently in different states, it a plan to offset this expense should be considered. Since NDBS programs are fee funded in most states, it may be possible to increase the fee by a small amount to offset the expense. Other possibilities might exist including small grants or inclusion in a more comprehensive grant request.

Recording a 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, which already use serially numbered NDBS collection devices. The only national standard or national dimension of this number is its formatting and inclusion in official birth records. A standard format is essential to assure 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 that are placed in that data field are generated by the state, primarily as inventory control numbers to maintain quality control of specimen collection devices ordered and used by individual specimen submitters. While every infant who has a NDBS specimen collected and submitted to a state-designated screening laboratory and the numbers assigned to individual submitting facilities are recorded, any data that can be linked to a serial number is controlled by the state that assigned that number. Knowledge of the NDBS serial number and associated data, within and outside of the state in which it was assigned, is controlled by the state and is subject to state and federal privacy constraints.

As part of its charge to engage in a multi-step process that (1) identifies barriers to short and long-term follow-up and treatment and NBS results specific to the challenges of integration of health care systems, financing of services, and information systems, (2) develops recommendations for overcoming identified barriers in order to improve short and long-term follow up results and, and (3) recommends mechanisms for establishing accountability for NBS follow-up guidelines, the Long Term Follow-up and Treatment Subcommittee recommends that the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children consider the following activities to assist in refining quality assurance practices in state health departments and state NDBS programs:

1. The SACHDNC should encourage State NDBS programs to utilize a unique serial number on each initial newborn screening specimen collection device to aid in electronic tracking and identification. To facilitate national harmonization, the format of this number should follow that recommended by the national standard for collection of dried blood on filter paper, including strong consideration of a checksum character as an aid in assuring the quality of the computerized input of the serial number.
2. The SACHDNC should work with NAPHSIS toward a goal of including the NDBS serial number in the EBR to facilitate confirming access of all newborns to timely newborn screening and to provide an external mechanism for evaluating certain demographic data recorded in the birth record. The use of these data for improving electronic health information and service quality should be emphasized.
3. The SACHDNC should work with NCHS toward a goal of including a field for the NDBS serial number (consistent with recommendations in CLSI LA4-A5) in the next revision of the U.S. Standard Certificate of Live Birth to be recommended to the Secretary of Health and Human Services. State birth registrars should be encouraged to 'require' completion of this field inasmuch as NDBS is a legally required activity in all states and comparison of birth records to NDBS specimen records represents the most efficient way to confirm screening universality.

4. State birth registrars and state newborn screening program directors should be encouraged to consider ways in which electronic data validation of the demographic information collected by the two activities can be used for cross validation and data quality improvement.

References

1. Association of State and Territorial Public Health Officials. Newborn Screening Position Statement. 2009. Available: <http://www.astho.org/Advocacy/Policy-and-Position-Statements/2009-Newborn-Screening/> (accessed November 8, 2010).
2. American College of Medical Genetics, Newborn Screening Expert Group. Newborn screening: toward a uniform screening panel and system. *Genetics in Medicine* 2006;8 (suppl 1):1S-252S.
3. Therrell BL, Schwartz M, Southard C, Williams D, Hannon WH, Mann MY et al. Newborn Screening Performance Evaluation Assessment Scheme (PEAS). *Sem Perinatol.* 2010; 34(2):105-20.
4. Therrell B. Data integration and warehousing: coordination between Newborn Screening and related public health programs. *Southeast Asian J Trop Med Public Health* 2003;34 (Suppl 3): 63-8.
5. Hinman AR, Atkinson D, Diehn TN, Eichwald J, Heberer J, Hoyle T, King P, Kossack RE, Williams DC, Zimmerman A. Principles and core functions of integrated child health information systems. *J Public Health Management Practice.* 2004;Nov(suppl):s52-s56.
6. Hinman AR, Eichwald J, Linzer D, Saarlans KN. Integrating child health information systems. *Am J Pub Health.* 2005;95(11):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. Wayne, PA: CLSI, 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. Villanova, PA: NCCLS, 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. Villanova, PA: NCCLS, 1992.
10. National Center for Health Statistics. Specifications for collecting and editing the US Standard certificated of birth and death—2003 revision [CDC Web site]. Available: http://www.cdc.gov/nchs/nvss/vital_certificate_revisions.htm (accessed November 8, 2010).
11. 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):32-6.
12. Downing GJ, Zuckerman AE, Coon C, Lloyd-Puryear MA. Enhancing the quality and overall efficiency of newborn screening programs through the use of health information technology. *Sem Perinatol.* 2010; 34(2):156-62.