

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

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Brief Background Review

- A report on these issues was presented to the SACHDNC on January 22, 2010 on behalf of the NBS Follow-up and Treatment Subcommittee.
- Discussions included whether result information should also be included on the birth certificate
- Final recommendation was development of “a short white paper on the recommended changes to the birth certificate to ensure that all newborns are screened at birth ...”
- Subsequently the Executive Secretary of SACHDNC requested discussions with NAPHSIS and NCHS to obtain their concurrence.

Introduction

- NBS has been defined as a core public health program by the Association of State and Territorial Health Officials (ASTHO).
- The Secretary of HHS has endorsed national guidelines exist that define the recommended screening conditions.
- All states have laws and/or rules that require both newborn screening (NBS) and birth registration.
- State health departments are generally responsible for implementing, overseeing and sustaining statewide NBS and for maintaining birth registration and other documentation of other vital events (e.g. death).

Introduction

- Electronic record keeping for both activities exists in most states and where it does not exist, it is in final development.
- Newborn Dried Bloodspot Screening (NDBS) serial numbers are used for inventory control and partial patient tracking in all state NDBS programs.
- NDBS programs [and newborn hearing screening (NHS) programs] have a responsibility to monitor screening compliance as part of their quality improvement efforts.
- Compliance requires validation against birth records.

Challenges

- NDBS and/or NHS records do not always contain the same name or other identifying information as that recorded in the birth registration record.
- Birth registration regulations do not always require final completion in a manner that ensures timely comparison with NBS test records.
- NDBS and Newborn Hearing Screening (NHS) programs are sometimes not co-managed and each may have a different tracking system.
- Management of birth registration programs and newborn screening programs are usually separated within the health department infrastructure and their inter-relatedness may not be fully appreciated.

Solutions?

- Manual matching – particularly those with smaller birth cohorts.
- Electronic matching
 - Deterministic matching – Relies on exact agreement between characters in specific data field(s) (eg. name, identification number, etc.).
 - 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)

Solutions?

- Deterministic matching using the baby's name is problematic because of errors in recording or spelling, and because names may not be final by the time the specimen is submitted.
- Some states allow birth registration times that may be beyond the time most useful for optimal newborn screening validation.
- As a result, NBS programs 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.

Simplest Solution?

- Record initial NDBS serial number on birth certificate and link the two databases.
- Linkage provides multiple payoffs:
 - NDBS programs can confirm that a specimen was collected (or not) on all newborns.
 - NHS programs could also have a link if the NDBS serial number were collected as part of the NHS screen.
 - Birth registration database is provided with an external mechanism for electronically validating patient demographic data.

External Contributors

- CLSI Standard LA4-A5 - specifies a format suitable for NDBS serial numbers (includes optional checksum character for quality check)
- NAPHSIS (organization for state birth registrars) - creates a national forum to discuss and debate vital records policy issues.
- NCHS (CDC Center responsible for health statistics) - maintains the *U.S. Standard Certificate of Live Birth*, a suggested model for states to follow in collecting birth registration information.
- HHS - National efforts to improve electronic health record keeping.

CLSI = Clinical Laboratory Standards Institute; NAPHSIS = National Association for Public Health Statistics and Information Systems; NCHS = National Center for Health Statistics; HHS = Department of Health and Human Services

Current Situation

- 96 % of states with electronic birth registration.
- 11 states with field in birth registration for NDBS serial number (22%). 4 others (8%) with plans to implement soon.
- 4 states report that the serial number field is a 'required' field in the birth registration process.
- 5 report using the field for linkage to assess compliance with NDBS requirement (others reported plans to use it in this manner).
- 33 programs (66%) report some probabilistic linkage between NDBS and birth certificates; 13 (26%) report no linkage; 4 (8%) did not respond.
- Matching time varied from hours to months.

Recommendations?

1. The SACHDNC should encourage State NDDBS 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.

Recommendations?

2. The SACHDNC 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 newborn screening and to provide an external mechanism for evaluating certain demographic data recorded on the birth certificate. The use of these data for improving electronic health information and service quality should be emphasized.

Recommendations?

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. Inclusion of this field should be 'required' inasmuch as 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.

Recommendations?

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.

Discussion