APHL Position Statement

Newborn Screening Residual Dried Blood Spot Specimens

A. Statement of Position

APHL supports the position that public health newborn screening (NBS) programs should be able to store and use residual dried blood spot (DBS) specimens and test results for program activities without requiring parental consent. APHL recommends that NBS programs have policies on the retention and use of residual DBS specimens and test results that are transparent, protect patient privacy, address parental concerns, and promote education and informed public participation.[1]

B. Implementation

1. APHL will share this position statement with key state and federal policy makers.

2. APHL will collect and maintain information on the uses of residual DBS specimens and test results for NBS program activities to inform NBS program policymakers.

3. APHL will collaborate with CDC, newborn screening programs, and partners to collect, evaluate and share best practices, model policies, and parent/provider educational materials in order to develop guidance for public health laboratories regarding secure storage and use of residual DBS specimens and newborn screening results for program activities.

4. APHL will encourage state newborn screening programs to develop policies on retaining, storing, and using residual DBS specimens and test results that are compliant with the recommended Clinical and Laboratory Standards Institute (CLSI) storage conditions and accentuate their compliance with federal and state research privacy rules and regulations.[2]

C. Background/Data Supporting Position

Newborn screening is a state-mandated program that screens newborns at birth for a select number of serious conditions, known as a newborn screening panel. Specimens submitted undergo initial testing for heritable and congenital disorders and the results are used for the provision of follow-up services for the infant.

The Association of Public Health Laboratories (APHL) endorses the Committee Report:

Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening, 2011, put forth by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC).[1] This report states that every state newborn screening program should have a retention and use policy in place that has been reviewed by a state attorney general or other legal authority. This policy should specify who is responsible for storage, access, use, and secure destruction of residual DBS specimens after testing is completed.[1]

Once newborn screening is complete, state programs retain residual DBS specimens for various lengths of time, from several weeks to greater than 18 years.[1] Residual DBS specimens are used to support essential program functions such as program evaluation, quality assurance, result verification, test refinement, and quality improvement initiatives.[1,2,3,4] Use and analysis of residual DBS specimens is essential for some NBS program activities, which include the following:

(1) Laboratory quality control, quality assurance and improvement;

(2) To verify calibration of equipment

(3) Evaluation of equipment, reagents, and methods of newborn screening tests for conditions approved for screening by the program;

(4) Validation of equipment and screening methods;

(5) Development, testing, and maintenance of a continuity of operations plan to ensure testing can continue in the event of an emergency;

(6) Assure competency of testing personnel.

Because newborn screening programs are state-mandated and involve regulated clinical laboratories, program activities related to ensuring the accuracy, quality, and improvement of tests for conditions on the newborn screening panel are considered public health practice, not research.

Newborn screening activities may include studies for the development of new laboratory tests, which are essential for expanding public health's ability to protect newborns from congenital conditions where early detection is key. These studies may or may not be research, and opt-in or opt-out consent may be indicated, depending on the nature and details of the study, the funding source, and applicable State laws.

D. References

1. Therrell BL, Hannon WH, Bailey DB, Goldman EB, Monaco J, Norgaard-Pedersen B, Terry SF, Harris A, Vasquez LM, Johnson A, Lloyd-Puryear MA, Howell RR. Committee report: Considerations and recommendations for national guidance regarding the retention and use of residual dried blood spot specimens after newborn screening. Genet Med. 2011 Jul; 13 Available at: https://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/reportsrecommendations/reports/residualdriedbloodspots.pdf. Accessed May 17, 2017.

2. Hannon WH, Whitley RJ, Davin B, Fernhoff P, Halonen T, Lavochkin M, Miller J, Ojodu J, and Therrell

BL Jr. Clinical Laboratory Standards Institute. Blood collection on filter paper for newborn screening programs - Fifth Edition; Approved Standard. CLSI document LA4-A5. Wayne, PA: CLSI, 2007.

3. American College of Medical Genetics. Position statement on the importance of residual newborn screening dried blood spots. Available at: https://www.acmg.net/staticcontent/newsreleases/blood_spot_position_statement2009.pdf. Accessed May 17, 2017.

4. Therrell BL, Hannon WH, Pass KA, et al. Guidelines for the retention, storage, and use of residual dried blood spot specimen after newborn screening analysis: statement of the Council of Regional Networks for Genetic Services, Biochem Molec Med 57: 116-124, 1996.

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