APHL Position Statement
Parental Consent for Newborn Screening

A. Statement of Position

The Association of Public Health Laboratories (APHL) supports the position that state-mandated newborn screening (NBS) should not require parental consent. If state programs elect to utilize the process of informed consent or dissent for screening, such parental consent or dissent should be clearly documented and maintained as part of the infant's NBS record. Inherent to any informed consent or dissent is the implication that a discussion is involved, which results in an explicit understanding of the pros and cons of screening and the consequences of the decision to consent or dissent. To facilitate these discussions and ensure parents receive appropriate, timely and culturally-sensitive information about NBS, prenatal parental and provider education must be an integral part of the NBS program.

B. Implementation

The APHL membership must convey this position of the public health laboratory community to state health agencies and health policy makers to assure that state NBS programs will be able to continue to operate under allowed dissent rather than mandated consent. APHL, and specifically the NBS and Genetics in Public Health Committee, should continue to represent the position of the organization to other groups such as ASTHO, AMCP, NNSGRC, ACHDNC, ACMG, MOD, Hastings Center, CDC, CLIAC, etc. APHL should collect and maintain program educational materials and consent and dissent forms from all member state NBS programs and track any changes in program designs.

C. Background/Data Supporting Position

The primary purpose of execution and documentation of a formal informed consent process in the conduct of medical procedures is to assure that the patient (or in the case of minors without the capacity to consent, the parent or legal guardian) has been informed of the relevant benefit and risk associated with the medical procedure. When, where and how the education can be most efficiently and effectively delivered to expectant parents is an issue that programs have been grappling with for some time. The information provided to the patient, parent or guardian should include all pertinent facts and must be presented at an appropriate level so that an individual of reasonable mind could make an autonomous informed decision. In the case of NBS, the risk of adverse medical consequences associated with the collection of a few drops of blood by heel stick is minimal. Negative consequences of a false positive result should be reduced by the physician informing the parents, in person, about the results and the need for additional testing as well as thoroughly explaining the meaning of the initial and follow-up tests.[1] In addition, parental anxiety regarding false positive results may be directly related to how well

the parent was educated about the NBS process.

Where no specimen is submitted due to parental refusal to consent or elective dissent, the possibility of missing the diagnosis of one or more of the conditions screened for by the program is estimated to be one in 643 infants nationwide.[2] This figure depends on the state specific screening panel and population demographics. It has been suggested that this balancing of minimal risk of the test procedure and the significant medical consequences of a missed case could suggest "that the autonomy of the parent to make health care decisions for their minor children must give way to the state's role in protecting children from harm."[3]

Most states allow parental dissent for screening, at least on religious grounds. In certain states, parents and guardians can refuse the additional testing through documented dissent on the NBS collection form. This alternative method for collecting dissent could be feasible in limited circumstances. Although informed consent can be beneficial for educating parents on NBS, the practical implications including additional resources and costs to programs of implementing informed consent or dissent can be a deterrent. If a program has a dissent procedure in place, measures should be taken to ensure that parents understand the distinction between dissenting from potentially lifesaving testing of the blood spots for their newborn versus dissenting from the storage and use of the residual blood spots for research, where allowed. Documentation of consent and dissent should involve statements of the implications of consent as well as statements of the implications of dissent and parental signatures that they understand both.

The critical components of the NBS program which must be in place in order to support the position that state-mandated NBS should not require parental consent include:

- The screening panel includes legislatively-mandated and/or recommended conditions on the uniform panel endorsed by the Secretary of Health and Human Services where early detection can be followed by interventions recognized as alleviating the severity of the condition.[4]
- The overall program includes mechanisms for appropriate health care provider education so that they are available to answer parental questions and concerns.
- The overall program includes mechanisms for parental education prior to collecting the specimen and as early in the pregnancy as possible.

D. References

1. Waibren S. Expanded NBS: Information and resources for the family physician. American Family Physician. April 2008; 77; 987-994.
2. Impact of Expanded NBS – United States, 2006. Morbidity and Mortality Weekly. 2008;57:1012-1051
3. Genetic Testing and Screening in the Age of Genomic Medicine, the New York Task Force on Life and the Law, November 2000, pp 169.
4. Calonge N, Green N, Rinaldo P, Lloyd-Puryear M, Dougherty D, Boyle C, Watson M, Trotter T, Terry S, Howell RR. Committee report: Method for evaluating conditions nominated for population-based screening of newborns and children. Genetics in Medicine. January 2010.

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