

APHL Position Statement/Policy Statement

Parental Consent in Public Health Newborn Screening Programs

A. Statement of Position

Explicit parental consent is not necessary for mandated public health newborn screening. This statement applies only where the panel of screened for conditions is limited to those of medical consequence which when detected in the newborn period can be treated so as to limit the medical consequences of the condition. The mandated screening program must also assure that the test assays employed have been fully analytically and clinically validated to standards established by the program, and that the clinical utility of the assay is known. Parental and provider education must be an integral part of the program even where documentation of consent is not required.

To the extent that state programs elect to utilize the process of documented informed consent to encourage and assure pre-test parental education they are to be encouraged and their experiences shared with all members. Any parental consent or dissent obtained should be clearly documented and maintained as part of the infant's newborn screening program record.

Where programs elect to include new assays or conditions for which the above conditions cannot be met, explicit consent may be required under state statutes and policies and should be required in the spirit of informed participation in medical procedures of limited or unproven benefit. Any research use of newborn screening specimens must be done only with review of appropriate human research subjects' protection procedures.

B. 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. The information conveyed must include all "material information" so that an individual of reasonable mind could make an autonomous informed decision under similar circumstances. In the case of newborn screening the risk of adverse medical consequences associated with the collection of a few drops of blood by heel stick is small. The possible consequences of a false positive result are generally limited by referral for immediate follow-up and reassurance of the parents and other interested parties that no further medical consequences are anticipated. 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 may be as high as 1/500 infants as indicated by the rate of referral for presumptive positive infants (as reported by the New York program). 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."¹

¹ Genetic Testing and Screening in the Age of Genomic Medicine, the New York Task Force on Life and the Law, November 2000, pp 169.

Currently only two states (Maryland and Wyoming) have elected to operate mandated public health newborn screening programs utilizing explicit consent. Most other states allow parental dissent on at least religious grounds. The experiences of Maryland and Wyoming, and the New York experience during the brief period of statutory consent requirement for HIV screening of the newborn specimen before this condition could be added to the mandatory un-consented program by legislative and regulatory amendment, suggest formal parental consent procedures can be incorporated into newborn screening programs. The recent experience in Massachusetts utilizing pilot programs to implement expansion of newborn screening and the inclusion of documented refusal of pilot screening additions suggest this alternative may also be feasible in limited circumstances. However, the practical implications of consent procedures for program costs in large scale universal screening programs of doing so has been the subject of much debate. The potential benefit of a better informed parent population may not warrant the potential expense.

The critical components of the newborn screening program which must be in place in order to support the absence of documented informed consent include:

- The mandatory screening panel includes only tests which have been fully analytically and clinically validated by standards established by the program,.
- The screening panel includes conditions only where early detection can be followed by interventions known to alleviate the severity of the condition.²
- 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 testing, and as early in the pregnancy as possible.

C. References

Serving the Family from Birth to the Medical Home: Newborn Screening: A Blueprint for the Future, Report of the American Academy of Pediatrics Newborn Screening Task Force, 106 Pediatrics 389,409-410, 2000.

Genetic Testing and Screening in the Age of Genomic Medicine, the New York Task Force on Life and the Law, November 2000, pp 169.
(see footnotes)

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² Serving the Family from Birth to the Medical Home: Newborn Screening: A Blueprint for the Future, Report of the American Academy of Pediatrics Newborn Screening Task Force, 106 Pediatrics 389,409-410, 2000.