

Ethics of testing and screening requirements

Most states have laws giving religious exemptions to testing and screening of children. Federal law requires doctors treating children on Medicaid or CHIP to perform several tests and screenings on the children yet federal law also allows states to offer religious exemptions. 42 U.S.C.A. §1396 ff

Governments have no evidence that the children of religious objectors will not have the diseases and disorders detected by the tests or that rituals will heal them. It is therefore in CHILD USA's view an abrogation of the state's duty toward these children to exempt them from the tests.

If a test or screening is beneficial enough that policymakers require it for most children, all children should have its benefit.

The state's right to require screening of infants over the religious objections of parents has been upheld by a federal court and a state supreme court. See *Douglas County v. Anaya*, 694 NW 2d 601 (Neb. 2005), *cert. denied*, and *Spiering v. Heineman*, 448 F. Supp. 2d 1129 (D. Neb. 2006)

There are ethical criteria that should be applied to mandates. Today there is technology to test persons for innumerable genes and not everything that technology makes possible should be required.

CHILD USA's position is that testing of newborns and children should be required only when it meets the following conditions:

1. The disease or condition (i.e. disorder) to be detected has significant mortality and morbidity among children.
2. The test is the only reliable way to identify the disorder in time for effective treatment.
3. The prevalence of the disorder in the child population is significant.
4. Medical science has an effective treatment for the child's condition.
5. The screening method is simple, minimally invasive, and carries no reasonable risk of physical harm.
6. The screening method is sensitive and specific.
7. Specimens will be collected and analyzed reliably and promptly and test results will be quickly and accurately reported to parents and the infant's physician.
8. The purpose of the screening is explained to the parents, and resources for treatment and counseling are available.
9. Test results are confidential and are used for research only with parents' consent.
10. The expected benefits to children and the public outweigh the financial costs of mandated universal screening.

These conditions are similar to those set forth by the joint report of the Association of Public Health Laboratories and Council of Regional Genetic Networks, "Recommendations and standardization of neonatal screening," March 1999.

No test should be required for purposes of research. No test should be required if medical science does not have an effective treatment for the disease or if the parents cannot access the treatment. The standard should be the potential benefit to a child.

What constitutes “significant” prevalence of disease in the child population will be debated and decided by policymakers. The metabolic disorders are not common. Phenylketonuria affects about one infant in 16,000 and galactosemia about one in 53,000.

Against those odds policymakers need to weigh the consequences of missing a case. The metabolic disorders cause death, severe mental and physical retardation, and other harms if not detected promptly by a test and treated. Furthermore, the test is very simple and so is treatment. These factors weigh heavily in favor of requiring universal screening for some metabolic disorders.

Tandem mass spectrometry tests for scores of metabolic disorders. It may test for more conditions than state law requires. Also, states often do research on test results (without identifiers).

CHILD USA believes that when parents oppose metabolic testing the infant should be tested only for the required disorders and the test results should not be used for research. This creates some inconvenience for the state but again the standard for a requirement should be the potential benefit to a child.

Like metabolic testing, tests for lead levels involve withdrawal of blood and some religious groups object to that. Several states require blood lead-level tests only in certain zip codes and only for day care or school enrollment. Such limits reflect a reasonable balancing of cost, regional prevalence of elevated lead levels, and the time for an elevated lead level to develop since it is caused by external factors. But lead poisoning does catastrophic, permanent harm to children and depriving some children of treatment and prevention purely on the basis of their parents’ religion has no ethical rationale.

Vitamin K is given to newborns to prevent spontaneous hemorrhage. Though in the standard of care for medical practice, few state laws require this life-saving preventive measure, and Oregon has a religious exemption to it.

Newborn hearing screening and pulse oximetry are completely non-invasive, painless, harmless, quick, and highly beneficial. With early detection, hearing loss can be treated so that the child will develop language skills. Pulse oximetry detects critical congenital heart defects so that the baby can receive lifesaving medical treatment. Yet most states allow religious exemptions depriving some babies of these interventions.

Some state laws have a religious exemption to all present and future testing. Thus, while a religious exemption may have been enacted because metabolic screening impacts religious beliefs about blood withdrawal, the exemption also applies when pulse oximetry is mandated. An example is Maryland Health Code §13-109.

A challenging issue with all screening and testing is enforcement. Many state laws require providers to offer tests but do not explicitly require the parents to accept them. Some states have no laws placing a requirement on either providers or parents and are content that the tests are part of the standard of care for medical practice.

Some hospitals have their own requirements to get all their newborn patients tested while others pride themselves on giving patients choices. New York State has advised providers that eye prophylaxis and Vitamin K must be given and not just offered but we have not found similar direction in other state policies. (See letter of Dennis Whalen, Exec. Deputy Commissioner New York Dept. of Health, to Colleagues Sept. 10, 1999.)

If state law and regulation require only the hospital or licensed provider to do newborn screening and preventive measures, babies born at home or attended by unlicensed midwives are deprived of those protections.

Some have suggested that parents who refuse screenings and prevention be reported to Child Protection Services. The mission of CPS, however, is usually focused on imminent harms to children rather than possible ones. Federal law requires states in its grant program to define child abuse “at a minimum” as “an act or failure to act which presents an imminent risk of serious harm.” 42 USCA 5106(g) States receiving federal grants are free to adopt a broader definition, but are not required to do so.

A better enforcement procedure is to require the person registering the birth to have screenings done. Nebraska law provides, “If a birth is not attended by a physician and the infant does not have a physician, the person registering the birth shall cause [metabolic testing] to be performed within the period and in the manner prescribed by [DHHS].” Neb. Rev. Statutes 71-519

Nebraska also provides that the district attorney may initiate a civil proceeding to have the metabolic testing performed over the objections of parents. Neb. Rev. Stat. 71-524. West Virginia requires health care providers, anyone else attending a birth, and parents to have metabolic screening done without a belief exception and provides a criminal penalty for failure to do so. WV Code 16-22-4 Montana requires metabolic testing without a belief exemption but has no enforcement mechanism. Some officials report that having a universal requirement even without a means of enforcement is helpful in that many religious objectors will obey state laws.

CHILD USA strongly recommends that states check screening records against birth certificates so that states know how many infants have not been screened. They may wish to contact parents and encourage them to get the screening. The parents may have received no information about the purpose of the screening but even if they have been given a brochure on it and even if they have religious beliefs against the procedure, they may change their minds in a followup call.

The time lag is an unfortunate aspect. Vitamin K should be given within an hour after birth. Metabolic screening should be done within 24 to 48 hours after birth. If parents are determined not to have the procedures, it might be weeks before the state becomes aware of the problem and takes action. But if the law requires the tests and preventive measures as a condition of registering a birth so religious objectors know they will have to get them, they may well decide to get the procedures within the medically appropriate time frame. State law requires registration of a child’s birth and income tax law provides a financial incentive to do so.

CHILD USA opposes all religious exemptions to health and safety laws for children. Children should not be deprived of protection on the basis of their parents' religious beliefs. Registering a child's birth can be made conditional on newborn screening and preventive measures being done. Policymakers enacting mandates for new measures should keep religious exemptions off of them.