Law and the Public's Health

LEGAL ISSUES IN NEWBORN SCREENING: IMPLICATIONS FOR PUBLIC HEALTH PRACTICE AND POLICY

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This installment of *Law and the Public's Health* examines the legal issues surrounding state newborn screening programs. This topic raises complex questions regarding how state law might be modified to move state policy toward recommended standards, while simultaneously respecting family rights and choices. Following a brief background that reviews the evolution of newborn screening standards, the current state of the science, and current state policy, the legal issues are explored. The article concludes with a discussion of public health policy and practice implications.

BACKGROUND AND OVERVIEW

An estimated 4 million newborns are screened every year for one or more genetic and metabolic disorders. At the same time, the number of tests required under state law differs, and the standard of practice among health professionals can vary from community to community. State newborn screening laws vary in the nature of their newborn screening mandates, as well as in the number of tests covered, anywhere from four to 40 tests.[1] Some of these tests are longstanding; for example, testing for phenylketonuria (PKU) has been considered the standard of care for more 40 years, although the test was quite controversial when first introduced.[2] PKU screening ultimately gained virtually universal acceptance as the evidence grew that the test was reliable and that the condition could be readily corrected with a simple, low-cost intervention.[2]

Other tests may be more controversial, however, based on their cost, reliability, and predictive value, as well as the availability and success of treatment. This uncertainty about testing technology in a newborn context contributes to variation in both health care practice and state policy standards. Even when the correct standard is clear, it can take a long time for public policy to catch up with technology. When the standard of care itself is uncertain, variation in public policy can be even more pronounced. Furthermore, in the case of newborn testing, uncertainty in the science of predictive testing and treatment combines with issues of privacy and religious and cultural beliefs.[3,4] Public health policy tends to intervene decisively when the science is sound and the resulting balance of interests around the protection of health is clear. As the scientific questions grow fuzzier, the balance of interests begins to shift as well. This is particularly true where the issue at hand involves the rights of parents to determine the course of medical care for their children.

Under principles of federalism, it is generally states that set the standard of health care practice, unless Congress, acting under its federal powers, identifies an important national policy that merits preemption of state standards.[5] Pediatric screening standards are presumed to fall within the ambit of state authority. The Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (Advisory Committee) was established in 2003; its charge was to recommend newborn and pediatric screening improvement standards to the Secretary of Health and Human Services to help states improve their screening policies and practices. Following the 2005 release of a federally commissioned report from the American College of Medical Genetics related to newborn testing standards,[6] the Advisory Committee unanimously recommended 29 newborn tests based on their reliability, the availability of treatment, and the fact that, in its view, the tests' benefits far outweighed their risks.

Newborn screening laws have been on the books for approximately 40 years in some states. Most states have newborn screening statutes; however, some allow parents and/or guardians to refuse the screening,[7] while other statutes require a refusal to be based on a religious exemption.[8] Some statutes simply require the existence of a program and allow state public health agencies to identify required tests at their discretion.[9] Other states, however, specify required tests in statute. Thirteen states have established specific funds to finance newborn screening, while others provide discounted rates for certain services if there is no other means to pay.[10] Ten states require licensed health insurers to cover certain treatments related to newborn screening, specifically in the case of treatment for PKU and certain other deficiencies.[10] (These state laws, however, would not cover health plans offered for privately employed persons who work for self-insuring employers, whose health plans are exempt from most

state regulation under the Employee Retirement Income Security Act [ERISA].)[11] Among states that mandate fewer than all recommended tests, none require health care providers to offer tests.

With an estimated 3,000 babies born each year with a genetic or metabolic disorder,[12] advocacy groups such as the March of Dimes have also recommended that every state adopt testing requirements for the 29 disorders recommended by the Advisory Committee.[13] As of spring 2005, three states' newborn testing standards were consistent with Advisory Committee recommendations, while 25 states required less than 50% of the recommended tests. While the Advisory Committee was unanimous in its views, others have questioned these results, cautioning that for at least some of the conditions for which testing is recommended, little may be known about treatment and thus knowledge of a condition's existence may do more harm than good.[14]

LEGAL ISSUES RAISED BY NEWBORN SCREENING

Under longstanding principles of Constitutional law, states have the power to regulate the receipt of medical care to protect public health.[15–19] At the same time, compulsory newborn screening programs may raise issues, because unlike compulsory immunization statutes or quarantine and isolation laws, their nexus to population health—or even the health of the individuals tested—is more tentative. No recommended newborn screening test involves a communicable condition, although all 29 involve conditions that are thought to be hereditary. Even where a condition is hereditary, however, a different balancing of interests is Constitutionally compelled.[20–24] Many parents may wish to reject certain tests whose predictive value is limited and yet whose practical and psychological implications are strong.

The recommended tests vary in the extent to which they help identify children for whom an immediate and lifesaving intervention is warranted. The greater the problems with reliability, predictive value, or known treatments, the less basis there is for a state testing mandate.

Beyond the issue of state public health mandates, however, are other questions. For example, a pediatric provider who fails to adequately inform parents of each test may face professional liability for the foreseeable results of failing to adequately inform the family. In *Malloy v. Meier, et al.*[25] for example, a pediatrics practice was found liable for its failure to order certain tests that would have alerted parents regarding the existence of a heritable genetic disorder in subsequent children.[26] Thus, even where the Constitutional basis for compelling certain tests may be lacking, a much stronger case can be made that the recommended tests should at a minimum be offered and explained.

IMPLICATIONS FOR PUBLIC HEALTH PRACTICE

The major question confronting public health policy makers is how to address the dilemma that arises when the challenge at hand is reconciling the evolution of medical care technology with basic principles of law. On the one hand, sound public policy dictates the use of simple, reliable tests that can detect conditions at birth that can be corrected or mitigated, particularly when the intervention is low cost financially and in human terms in relation to the failure to intervene. When private health care providers fail to adhere to this principle, they can face liability for negligence as well as the failure to provide informed consent.[27]

On the other hand, there is evidence to suggest that not all recommended newborn tests squarely fall into this category of reliability and effectiveness. Thus, while public health principles suggest the value of information that the tests can provide, the case for compelling the tests is weaker.

One possible state response might be to mandate all tests but with an "opt-out clause" and to accompany the mandate with a duty to counsel about the tests, their predictive value, and their link to treatment. In this way, parents could opt out of those tests that in their view do not provide sufficiently valuable information or that identify conditions for which treatment options are limited at best. The benefit of this approach is that it promotes uniformity in testing while still honoring parental privacy considerations. Its limitation is that in the absence of a clear "no," the family might not be considered to have opted out, with subsequent unhappiness when results are received.

An alternative option would be to mandate only certain well established tests (with an opt out) but to also require that families be informed about and offered all tests and given the right to "opt in" to those tests considered valuable. The benefit of this approach is that it gives maximum flexibility to families; its limit of course is that an "opt in" provision means that the default position is no testing where the evidence is less than clear.

What is clear about the 2005 recommendations is the importance of family counseling. Public health agencies have a particular interest in promoting strong counseling programs for all families where the health of infants and children is concerned. In this regard, public health agencies may wish to consider active

initiatives with community health providers aimed at promoting the best quality newborn practice where counseling and informed consent are concerned.

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