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COMMENTARY

From Public Health Emergency to Public Health Service: The Implications of Evolving Criteria for Newborn Screening Panels

Scott D. Grosse, PhD, Coleen A. Boyle, PhD, Aileen Kenneson, PhD, Muin J. Khoury, MD, PhD, Benjamin S. Wilfond, MD

Although newborn screening has been a public health activity for >40 years, technological advances are beginning to reshape these programs. In particular, states have begun to use tandem mass spectrometry (MS/MS), a technology that measures metabolic analytes that allow for the detection of dozens of disorders. A new report from the American College of Medical Genetics (ACMG) commissioned by the Maternal and Child Health Bureau of the Health Resources and Services Administration (HRSA) has proposed that 29 conditions be included in a uniform newborn-screening condition panel, including nonmetabolic disorders. As a result, several states have moved forward with the recommended core panel. In addition, there have been proposals by others to screen for conditions such as fragile X syndrome and Duchenne muscular dystrophy.

We suggest that such proposals to expand newborn screening represent a paradigm shift in how newborn screening is justified. The consequences of such a shift need to be considered carefully. By newborn screening we refer to a comprehensive system that begins with parent and provider education and dried-blood-spot specimen collection and includes follow-up, diagnosis, treatment, and evaluation; newborn screening is not just a laboratory test. The historical rationale for newborn screening was the prevention of devastating harm to affected infants by providing immediate treatment after birth, an urgent response to avert a potential emergency of public health importance. Although newborn screening for most disorders still prevents deaths and disability, screening for certain disorders under the new paradigm may carry less dramatic or immediate benefit, as well as benefits beyond those to the newborn.

We argue that the selection of disorders for population-based screening should follow the standards of evidence-based public health, which includes the systematic assessment of evidence of effectiveness using standardized methods. For example, the US Preventive Services Task Force and the Task Force on Community Preventive Services develop recommendations for decision-makers on the basis of systematic reviews of evaluations of interventions, which include assessments of the strength of research designs. A comparable evidence-based process should be established for newborn screening that takes into account the scarcity of randomized, controlled trials and population-based studies of long-term outcomes.

Abbreviations: MS/MS, tandem mass spectrometry; ACMG, American College of Medical Genetics; HRSA, Health Resources and Services Administration; PKU, phenylketonuria; SCD, sickle cell disease; CF, cystic fibrosis; CDC, Centers for Disease Control and Prevention

Opinions expressed in this commentary are those of the author(s) and not necessarily those of the American Academy of Pediatrics or its Committees.

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Address correspondence to Scott D. Grosse, PhD, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, 1600 Clifton Rd, Atlanta, GA 30333. E-mail: sgrosse@cdc.gov
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Newborn screening began in the early 1960s with a test for phenylketonuria (PKU) using dried blood spots collected on filter-paper cards. Newborn screening for PKU was justified by the prevention of severe disability, because even a few weeks of delay in initiation of a low-phenylalanine diet can result in irreversible neurologic damage. In 1963, Massachusetts mandated that all newborns be screened for PKU, and other states soon followed. Screening was mandated because of concern that providers and parents might be slow to adopt screening voluntarily. An economic justification for public funding of screening for PKU was that prevention of mental retardation would result in budgetary savings in institutional care.

During the 1960s and 1970s, states began to screen for other conditions for which it was believed that severe outcomes could be avoided. Screening for several metabolic diseases, including galactosemia, maple syrup urine disease, and homocystinuria, was initiated in a number of states by the late 1960s to prevent deaths during the neonatal period. Beginning in the late 1970s, screening and early treatment for congenital hypothyroidism was adopted to prevent intellectual disability and, like PKU, was found to be cost-saving. A few tests, including tests for adenosine deaminase deficiency in New York and α-1-antitrypsin deficiency in Oregon, were introduced in the 1970s but subsequently removed because clinical benefits were not apparent.

Newborn screening for sickle cell disease (SCD) and other hemoglobinopathies was introduced in New York in 1975 but did not become widely adopted until after a Consensus Development Conference in 1987. The recommendation for screening was based on evidence from a randomized, clinical trial that showed that antibiotic prophylaxis begun before 6 months of age could prevent most cases of pneumococcal sepsis in children with sickle cell anemia. The timing of treatment was less urgent, but newborn screening was regarded as the only way to ensure presymptomatic identification of affected children. Coincident with screening and improvements in treatment, mortality during the first 3 years of life among children with SCD was reduced—a public health success.

Screening for SCD and other hemoglobinopathies results in the detection and reporting of multiple disorders and variants, with ~50 carriers of hemoglobin variants identified for each case of SCD detected. States do not all report the same hemoglobin variants. Certain variants are benign, whereas other disorders are associated with mild outcomes or with severe outcomes that cannot be avoided with early treatment. In most cases, confirmatory testing is required to distinguish asymptomatic variants or mild disorders from clinically important conditions. Other than SCD, however, outcomes may be no different with early detection. Thus, newborn screening for hemoglobinopathies set a precedent for the detection and reporting of multiple disorders, and only certain ones have clear evidence of benefit from early treatment.

### EVOLVING CRITERIA FOR NEWBORN SCREENING

In 1968 the World Health Organization articulated criteria for population-screening programs that focused on public health benefits. In 1975, the National Research Council issued a report that concluded that mandated screening could be justified only if there was evidence that it would prevent death or other serious harm to the affected individual. A 1994 Institute of Medicine report reaffirmed this approach to newborn-screening criteria based on the traditional public health emergency rationale.

In the United States, authority to determine which disorders are included in screening panels rests with the states, which use a variety of criteria. A few states have conducted evidence reviews. At the national level, the US Preventive Services Task Force has recommended newborn screening for 3 groups of disorders on the basis of systematic reviews of evidence of prevented deaths and disabilities: PKU, congenital hypothyroidism, and hemoglobinopathies; no other dried-blood-spot newborn-screening tests have been evaluated. No ongoing process of evidence-based reviews for newborn screening is in place in the United States, unlike the United Kingdom with its Health Technology Assessment Program.

In recent years, parents, consumer advocacy groups, and health professionals have pushed for screening of more disorders. In 2000, a National Newborn Screening Task Force convened by the American Academy of Pediatrics and HRSA called for standardizing a list of diseases to be screened by all states. The HRSA subsequently contracted with the ACMG to propose criteria and recommend a core screening panel. The ACMG convened an expert group primarily of specialists in metabolic disorders and biochemical genetic screening that developed a new set of criteria for newborn-screening panels. A survey instrument based on these criteria was distributed to available experts and advocates who were asked their opinions about the value of testing for up to 84 disorders. A draft report with a recommended core panel based primarily on the survey results, as well as condition summaries prepared by disease experts, was “accepted” by the Secretary’s Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children in September 2004, and the HRSA released the report for public comment in March 2005.

The criteria developed by the ACMG panel broaden the rationale for newborn screening beyond the need to detect children soon after birth to prevent death or disability. First, the criteria include a broader definition of benefits to the affected child. These include all “out-

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**HISTORY OF NEWBORN SCREENING**

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The criteria developed by the ACMG panel broaden the rationale for newborn screening beyond the need to detect children soon after birth to prevent death or disability. First, the criteria include a broader definition of benefits to the affected child. These include all “out-
comes” and “negative consequences” that can be optimized or prevented. Additionally, benefits to families from timely knowledge of recurrence risks and the avoidance of “diagnostic odysseys” associated with delayed diagnoses are given as much weight as the prevention of mortality. Below we offer an analysis of the implications of a shift toward greater emphasis on more moderate and parent-centered benefits and implications for policy deliberations.

NEWBORN SCREENING AS A PUBLIC HEALTH SERVICE

Newborn screening for particular disorders can be provided to all newborns under the public health authority of the state or as a clinical service at either provider discretion or consumer request.17 Currently, several commercial laboratories offer supplemental screening for disorders not included in state screening panels.6-33 A policy decision to add a disorder to a state screening panel means that the state takes responsibility for ensuring access to all components of the newborn-screening system as a public health service.

A decision to provide a public health service to the entire population should be made on the basis of evidence of benefit, risk, and cost and with full consideration of public resources and priorities.34 Regardless of whether universal newborn screening is publicly funded or the cost is passed through to third-party payers or parents, implications for resource allocation and the opportunity cost of foregone alternatives need to be considered. Prioritization is also important when public health agencies offer other clinical services, such as immunizations and cancer screening, to people who cannot otherwise afford them.

Providing screening as a public health service can potentially be justified on grounds of equity or efficiency.35 One equity argument is reduction of health disparities with uniform access to screening tests, presuming that early identification results in reduced death and disability. This argument is particularly powerful for children, who cannot take responsibility for their own health care. Efficiency arguments for population-based screening include lower average cost because of economies of scale in specimen collection and testing. Also, public health authorities can ensure follow-up of abnormal test results and diagnoses and collect outcome data to monitor and evaluate screening, for which private laboratories lack authority.35

Neither the equity nor the efficiency argument set a boundary for what tests should be offered as a public health service. The balance between costs borne by taxpayers and contributors to insurance programs and the benefits received by individuals and families should be considered relative to other services. In the past, on the basis of evidence for PKU and congenital hypothyroidism, it was argued that each dollar spent on newborn screening would save multiple dollars in averted health care costs, but with the expansion of screening panels, that cost-saving argument may no longer be valid.36 Resources could potentially come at the expense of access to other health care services of demonstrated benefit. Although spending on state newborn-screening programs, including laboratory testing and follow-up, in the United States is relatively modest, totaling $120 million in fiscal year 2001,27 this does not include most costs incurred by the health care system or the increase in spending from expanded screening panels.

Informed policy decisions about which newborn-screening tests are provided as a public health service require objective, multidisciplinary assessments of evidence. An example is newborn screening for cystic fibrosis (CF), which had not been widely adopted because it was not clear that early detection could prevent irreversible and devastating harm.37,38 In November 2003, the Centers for Disease Control and Prevention (CDC) and the Cystic Fibrosis Foundation convened a workshop at which evidence was presented for a broader range of outcomes, including nutritional benefits, cognitive benefits for children at nutritional risk, and reduction in diagnostic delays.39-41 A subsequent evidence review used a framework that emphasized patient-centered outcomes such as the avoidance of hospitalizations.42 The report concluded, “on the basis of evidence of moderate benefit and low risk of harm, the CDC believes that newborn screening for CF is justified.”34 The report also noted that policy decisions must balance those benefits with scarce resources and other public priorities.

The CF newborn-screening report also called attention to the value of minimizing the numbers of carriers detected. In the PKU newborn-screening model, cutoffs are set to maximize sensitivity to avoid missed cases and devastating harm. In the new paradigm, programs must balance the numbers of affected infants who might not be detected and infants who would have false-positive or ambiguous test results as well as the magnitude of harm, if any, occurring to those children and their families.43

Potential harms from newborn screening include parental anxiety resulting from the labeling of children with mild or benign conditions, misunderstanding of carrier status, and unnecessary or even harmful therapies administered to children who are incorrectly identified with a disease or to children with mild or asymptomatic disease.26 A research priority under the new paradigm should be evaluation of the balance of risks and benefits for such disorders. For example, the implications of the identification of children with hemoglobin variants that are clinically benign or mild or that are severe but are either untreatable or do not benefit from earlier treatment have not been studied thoroughly. Careful assessments must also be made for other screening technologies such as MS/MS or DNA-based screen-
ing that can reveal disorders or variants, the clinical implications of which may be poorly understood.

Referral, diagnostic, and treatment systems as well as state health departments must be prepared to handle the numbers of children referred by screening. Referrals include unaffected children with positive screening results, some of whom will be identified as carriers of genetic diseases, and children with ambiguous clinical results. Large numbers of such children could overwhelm specialists and complicate addressing the needs of the families of affected children. Although some states ensure that children identified through newborn screening have equitable access to needed services, including dietary therapies, not all do. States should not mandate screening before a comprehensive program is in place to assure appropriate follow-up and treatment.

Once a policy decision is made to screen, the public health system should obtain data on short- and long-term outcomes to evaluate the effectiveness of screening and interventions. Research in Wisconsin detected an unexpected harm from exposure of young children with CF lung infections, apparently as a result of exposure of asymptomatic infants to older children in a crowded waiting room. Other research on newborn screening for CF allayed concerns about psychosocial harms. Lessons learned from these pilot studies need to be applied to ensure that “more good than harm” results from newborn screening. Monitoring outcomes is particularly crucial for disorders for which the expected magnitude of benefit is modest.

Finally, expansion of state newborn-screening panels should reopen the question of parental decision-making. Allowing for parental choices includes a spectrum of approaches, ranging from providing information about the opportunity to decline testing to requiring documentation of permission. The 2000 National Newborn Screening Task Force recommended that parents be informed and be able to refuse testing, but it concluded that documentation of permission is not warranted. A 2001 report from the American Academy of Pediatrics Committee on Bioethics recommended that states reconsider consent processes for newborn-screening tests. In addition to screening, parental permission may be required for inclusion of children in databases to track long-term outcomes or for the retention of dried-blood-spot specimens for use in research.

At present, 48 states mandate newborn screening under the public health emergency rationale to minimize the chance of missed cases and prevent death and disability. In states with voluntary screening programs (Wyoming, Maryland, and the District of Columbia), the vast majority of parents choose to have their infants screened. Although the majority of states (33 of 51) allow parents to opt out for religious reasons and some (13 of 51) allow parents to opt out for any reason, many do not inform parents of their right to opt out.

When the balance between benefits and risks is not as dramatic as it is for congenital hypothyroidism and PKU, the argument for consent becomes more compelling. Different consent processes may be set up for such disorders. For example, Massachusetts allows parents to decide on optional screening for CF and fatty acid oxidation disorders (other than medium-chain acyl-coenzyme A dehydrogenase [MCAD] deficiency) after a discussion of the risks and benefits.

**EVIDENCE-BASED ASSESSMENTS AND EXPANDED NEWBORN SCREENING**

Current proposals for a core newborn-screening panel encompass certain disorders that may not meet traditional criteria for mandated screening. Although detection of a number of fatty acid oxidation and other disorders screened through MS/MS may prevent mortality or disability, evidence is limited. Although screening decisions are often made on the basis of incomplete information, it is essential to conduct systematic evidence-based assessments before screening decisions and to collect additional evidence after screening is implemented. A systematic review of the epidemiologic and other scientific literature, such as Human Genome Epidemiology (HuGE) reviews, should be conducted to inform screening decisions and research priorities.

Other disorders that experts have proposed as candidates for newborn screening include severe combined immunodeficiency (SCID), fragile X syndrome, congenital cytomegalovirus infection, lysosomal storage disorders, and type 1 diabetes. Research to develop and assess reliable dried-blood-spot screening tests for these disorders is under way. Pilot studies to evaluate health, developmental, and other outcomes also need to be conducted. Screening for some of these disorders, notably SCID, is likely to meet the traditional criteria for mandated screening of preventing death during infancy on the basis of existing treatments. For other disorders such as Duchenne muscular dystrophy, fragile X syndrome, and type 1 diabetes, improved outcomes in early childhood may depend on the development of new therapies. Also, alternatives to universal newborn screening such as providing screening as a clinical service later in infancy have advantages for parental decision-making and should be considered.

Evidence-based reviews are needed to inform newborn-screening policy decisions, including assessment of benefits of screening and interventions, risks and costs, policy development, and program evaluation. Reviews should be conducted at the national level and include experts from a range of disciplines. The CF evidence review sponsored by the CDC was conducted by a group of 7 experts, including clinicians with expertise in CF, epidemiologists, ethicists, a screening program director, and an economist. Although both evidence-based reviews and expert opinion are valuable for informing
screening decisions, expert opinion should not substitute for independent, objective assessments of scientific evidence conducted using standardized methods. In particular, although it is important to consult experts who are advocates of expanded screening, it is essential that an evaluative process be independent of conflicts of interest. Credible evidence-based reviews can be invaluable in obtaining support from stakeholders for implementation of interventions of demonstrated effectiveness.

We call for a process to be established at the national level that would provide ongoing objective assessments of both existing and proposed newborn-screening tests based on scientific evidence. This requires the development of a research agenda to identify methods and study questions that would provide relevant evidence. An example of a program that provides objective systematic reviews is the Evidence-Based Practice Centers program established by the Agency for Healthcare Research and Quality. Existing methods and criteria may be modified for the evaluation of screening and treatment for rare disorders, because randomized, controlled trials are rarely available. Such assessments must be interdisciplinary and explicitly address considerations of epidemiology, economics, and ethics. In addition, it is essential that organizations, whether public or private, that fund pilot screening studies should incorporate the same considerations in their study designs to provide relevant evidence for decision-makers. It is not sufficient to demonstrate the technical feasibility and validity of a screening test.

CURRENT AND FUTURE CHALLENGES

Deliberations to expand screening panels provide an opportunity to modify the model developed 4 decades ago for PKU. In particular, questions of voluntary screening and informed decision-making need to be re-opened. Much greater change would be required if disorders that manifest later in childhood were selected on the basis of a parent’s “right to know.” Surveys and focus groups suggest that many parents are supportive of screening infants for such disorders. On the other hand, there is a long-standing professional consensus to not test children for late-onset disorders. The ethical concerns are less serious for pediatric genetic disorders than for adult-onset diseases such as hereditary hemochromatosis. Nonetheless, assessment of the benefits to parents of reduction in diagnostic delays and knowledge of recurrence risks will need to be balanced against ethical concerns, resources, and priorities, and alternatives to state-sponsored newborn screening need to be considered.

Newborn screening as a public health service needs to be supported by a broad social consensus. Stakeholders, including state-level policy makers, health care payers, hospitals, clinicians, parent groups, and the public, need to weigh in on the question of which disorders should be included in newborn-screening panels as well as the criteria used to decide on screening panels. Such a consensus development process should be informed by objective evidence assessments and inclusive of ethical concerns.

Expansion of newborn screening, if it is considered to provide good value for the money (which is the meaning of cost-effectiveness), must be accompanied by the provision of adequate resources to ensure that good outcomes result. Sources of funding need to be identified for each system component, including follow-up, diagnosis, treatment, and information systems for monitoring outcomes. Education of parents and providers and adequate reimbursement for genetic counseling and case management services are also needed if newborn screening is to live up to its promise. If newborn screening is worth doing, it is certainly worth doing well.

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OSELTAMIVIR RESISTANCE: DISABLING OUR INFLUENZA DEFENSES

“As the potential for an influenza pandemic has galvanized the medical community and the public into action, physicians and patients alike have been heartened by the availability of effective antiviral drugs. The neuraminidase inhibitors provide valuable defenses against pandemic and seasonal influenza, and physicians have been flooded with requests from patients for personal supplies of oseltamivir (Tamiflu). A benefit of having oseltamivir at home is that the sooner the drug is taken after the onset of symptoms, the better its clinical efficacy. And certainly, enabling ill people to stay home and out of waiting rooms and pharmacies should limit the spread of influenza. So it is not surprising that many believe there should be a supply of oseltamivir in every medicine cabinet. This scenario, however, is potentially dangerous. . . [P]ersonal stockpiling of oseltamivir is likely to lead to the use of insufficient doses or inadequate courses of therapy. Shortages during a pandemic would inspire sharing of personal supplies, resulting in inadequate treatment. Such undertreatment is of particular concern in children—the main source for the dissemination of influenza within the community, since they usually have higher viral loads than adults and excrete infectious virus for longer periods. The habit of stopping treatment prematurely when symptoms resolve (a well-established tendency with antibiotic therapy) could also lead to suboptimal treatment of influenza and promote the development of drug resistance. . . Improper use of personal stockpiles of oseltamivir may promote resistance, thereby lessening the usefulness of our frontline defense against influenza, and should be strongly discouraged.”

Noted by JFL, MD
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