

AMERICAN ACADEMY OF PEDIATRICS

Committee on Bioethics

Ethical Issues With Genetic Testing in Pediatrics

ABSTRACT. Advances in genetic research promise great strides in the diagnosis and treatment of many childhood diseases. However, emerging genetic technology often enables testing and screening before the development of definitive treatment or preventive measures. In these circumstances, careful consideration must be given to testing and screening of children to ensure that use of this technology promotes the best interest of the child. This statement reviews considerations for the use of genetic technology for newborn screening, carrier testing, and testing for susceptibility to late-onset conditions. Recommendations are made promoting informed participation by parents for newborn screening and limited use of carrier testing and testing for late-onset conditions in the pediatric population. Additional research and education in this developing area of medicine are encouraged.

ABBREVIATIONS. IOM, Institute of Medicine; AAP, American Academy of Pediatrics; CF, cystic fibrosis.

INTRODUCTION

The Human Genome Project formally began in 1990 with an original goal of mapping and sequencing the complete set of human genes by the year 2005. Remarkably, the sequencing of the human genome essentially was complete in early 2000. The ultimate purpose of the research is to develop more effective strategies for disease prevention and treatment. However, the first practical applications of this knowledge will be expanded possibilities for genetic testing for individual evaluation and population screening. Although pediatricians are familiar with genetic testing for specific indications and rare conditions, new generations of genetic technology will detect persons at increased risk for common conditions, such as cancer, hypertension, and Alzheimer disease.¹ Although genetic research offers great promise for improvements in child health, the use of new genetic tests in children must be considered carefully. In the absence of clearly beneficial treatments or effective preventive strategies, genetic testing of children and adolescents may not be justified. This statement reviews the potential uses of genetic testing in children and offers guidance for pediatricians on the appropriate applications of this technology. This statement draws on analyses of ethical issues in genetic testing by a number of influential bodies, including the National Academy of Sci-

ences,² the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research,³ the Institute of Medicine (IOM),⁴ and the Working Group on Genetic Testing for the National Human Genome Research Institute.⁵

Medical testing is familiar to physicians in the routine practice of medicine. A legitimate question may be raised whether genetic testing is sufficiently different from other forms of testing to justify additional scrutiny. Several aspects of genetic testing should be considered in this regard.⁶ First, genetic information is familial. Thus, the test results of one person have direct health implications for others who are genetically related. Second, the risks of genetic testing may not be obvious because the primary risks are psychological, social, and financial. The psychosocial risks include guilt, anxiety, impaired self-esteem, social stigma, and insurance and employment discrimination. Third, genetic information often has limited predictive power. Our genes interact with our environments in complex ways, often making predictions impossible about whether disease will develop or the severity of its manifestations. Finally, many genetic conditions remain difficult to treat or prevent, meaning the value of genetic information may be limited for altering the clinical care of the person. Genetic testing is not unique in any of these respects, but the cumulative complexity of these issues requires that genetic testing receive careful consideration. Given these concerns, detailed counseling, informed consent, and confidentiality should be key aspects of the genetic testing process, particularly when the benefits are uncertain. Because young children are unable to discern the value of genetic information for their own lives, particular care must be exercised by parents and pediatricians when making decisions about genetic testing for children.

The American Academy of Pediatrics (AAP) believes pediatricians can best help children and parents by working to promote child and parent understanding of relevant information, ensure privacy and confidentiality for test results to the extent permissible by law, and provide or refer children for counseling and testing only when it is in the best interest of the child or when the legitimate interests of the parents or family can be promoted without anticipated harm to the child. This statement addresses 3 potentially problematic applications of genetic testing and screening: newborn screening, carrier testing and screening, and predictive testing for late-onset disorders.

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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NEWBORN SCREENING

The purpose of newborn screening for genetic disorders is to limit the morbidity and mortality attributable to selected inherited diseases. Because newborn screening programs are organized through state governments, substantial variability in testing exists between states.⁷ As new genetic tests become available, extensive consideration will be given to the introduction of these tests into newborn screening programs. Consistent with earlier guidelines on the issue, the IOM report⁴ recommends that 3 principles govern the introduction of new tests and the maintenance of established tests: 1) identification of the genetic condition must provide a clear benefit to the child; 2) a system must be in place to confirm the diagnosis; and 3) treatment and follow-up must be available for affected newborns.

The challenges of introducing new tests have been brought into focus by discussions about the appropriateness of newborn screening for cystic fibrosis (CF). In 1983, the Task Force on Neonatal Screening of the AAP advised against the introduction of state programs until the validity of screening tests and the relative benefits and risks of newborn screening for CF had been evaluated.⁸ A key question has been whether detection of CF in the neonatal period improves the long-term pulmonary or nutritional status of affected children. The effects of false-positive results on parental anxiety also are a serious concern.^{9–13} In addition, a small percentage of parents may have a persistent misunderstanding of their child's risk for developing CF after a false-positive newborn screen, and false-positive results may influence parental reproductive decisions.¹⁴ Thus, the justification for newborn screening for CF has been a subject for debate, although several states, including Wyoming and Colorado, have initiated programs. A long-term study in Wisconsin demonstrated nutritional benefits to early detection of CF, and reports on the effects of screening for pulmonary function are anticipated.¹⁵ Similarly, 19 states have introduced newborn screening for congenital adrenal hyperplasia, and a number of studies are under way to evaluate the sensitivity and specificity of different approaches used by these programs^{16,17} and their impact on the health of affected children.

The AAP recommends that new newborn screening tests be introduced in a carefully designed manner that facilitates evaluation of the risks and benefits of screening, including the efficacy of follow-up and treatment protocols. The Wisconsin program for evaluating CF screening was a model in this regard. Furthermore, the AAP concurs with the IOM recommendation that established programs be reviewed periodically to consider the addition, elimination, or modification of current screening modalities.⁴

A persistent ethical issue in newborn screening is whether screening should be voluntary or mandatory. Whether programs are voluntary or mandatory has significant implications for informed responses to test results and for the integration of new tests into established programs. A *voluntary* approach in this context entails an informed decision by parents

about newborn screening. Wyoming and Maryland are the only 2 states that require informed consent for newborn screening, although 13 other states require that parents be informed about newborn screening before testing.¹⁸ A *mandatory* approach in this context requires an explicit refusal of screening by parents who object to this intervention. All states except South Dakota permit parental refusal of newborn screening for religious or personal reasons.¹⁸

The principal ethical justification offered for mandatory screening is the claim that society's obligation to promote child welfare through early detection and treatment of selected conditions supersedes parental prerogatives to refuse this simple medical intervention.¹⁹ An opposing argument maintains that parents traditionally have broad discretion for making health care decisions for their children. Although parents do not have the prerogative to forgo effective treatments for life-threatening conditions, they generally have the prerogative to pursue a variety of options in less threatening circumstances, including options that some medical professionals would consider unwise. Furthermore, it is argued that the great majority of parents will continue to be supportive of newborn screening when they are informed adequately of the risks and benefits.²⁰ With continued broad public support, approaches involving informed consent (that is, parental permission²¹) may fulfill the important goals of the programs and enhance program quality while respecting traditional parental prerogatives to be informed participants in health care decisions for their children. In a study of newborn screening in Maryland involving informed consent, the majority of women preferred that permission be asked before screening, and the informed refusal rate was only 5 per 1000 infants.²² In the Maryland study, the consent process typically took 5 minutes or less of staff time. Additional research to develop and evaluate models of parental education and consent will be valuable.

Two potential advantages of obtaining informed consent for newborn screening include more prompt and efficient responses to positive results and an ability to incorporate experimental tests into established screening programs. Under current programs, the information provided to parents about newborn screening is often minimal. A significant source of problems in newborn screening programs is slow or uninformed responses to test results by parents and physicians.²³ If an informed consent process promotes more thorough understanding of the implications of the tests, slow or inappropriate responses to positive results may decrease. Second, advances in genetic research will offer many additional tests for consideration by newborn screening programs.²⁴ The relative risks and benefits of new tests will be uncertain until adequate clinical research has been conducted. In these circumstances, experimental tests should be offered on a voluntary basis with informed consent. Experimental tests could be integrated more easily in screening programs that routinely sought informed consent for newborn screening tests.

The IOM report suggests that it is appropriate for states to mandate the *offering* of "established tests

(eg, phenylketonuria, hypothyroidism) where early diagnosis leads to improved treatable outcomes.¹⁴ The AAP Committee on Genetics concurred that state governments should mandate the offering of tests (although some members of the Committee expressed the opinion that testing should be mandated).¹⁶ Consistent with the recent report of the Newborn Screening Task Force,²⁵ the AAP recommends that states evaluate an informed consent process for newborn screening tests to foster parental education and promote informed responses to test results. Given the established efficacy of newborn screening programs, it will be essential to demonstrate that expanded education and consent function to enhance the quality of these programs. Carefully conducted pilot programs to document benefits and costs of newborn screening and the frequency and consequences of informed refusal of newborn screening tests will be important. In addition, research to develop an efficient and effective informed consent process for newborn screening is necessary. Attention should be given to the education of women and couples about newborn screening before the immediate postpartum period. Publication and peer review of this research will be appropriate before substantial changes in state health policy on this issue to ensure that efficacy of screening programs is not impaired. Informed consent in this context need not involve a signed consent form for tests of established value, but must include basic information on the purpose of screening and the importance of prompt responses to abnormal results.

CARRIER SCREENING

Medical technology permits the identification of persons who are carriers for mutations in genes responsible for a variety of conditions, including Tay-Sachs disease, muscular dystrophy, sickle cell anemia, CF, and thalassemia major. Carrier testing and counseling of prospective parents can permit informed reproductive choices. A significant concern raised by carrier screening programs is the possibility for individual and community misunderstanding of the carrier state. Confusion about the difference between being an asymptomatic carrier for a genetic condition and being affected with the condition may lead to stigma and discrimination, as well as to adverse psychological reactions in those being screened.²⁶⁻²⁸ An historical example is provided by the carrier screening programs for sickle cell disease in the 1970s in the United States that were not preceded by adequate broad-based education. The subsequent misunderstanding of the benign nature of being a sickle cell carrier by employers, insurance companies, government agencies, and the community being screened led to many cases of discrimination and stigmatization.³

To date, carrier testing or screening has not been applied extensively to children or adolescents in the United States. Theoretically, carrier testing or screening before the initiation of sexual activity would increase the reproductive choices of those found to be carriers in comparison with carrier testing during pregnancy. However, children and adolescents may

be more psychologically vulnerable than adults to knowledge of carrier status, and it remains uncertain whether testing at younger ages would result in changes in future reproductive behavior. Of note, however, a report of 2 decades of carrier screening in high school students in Montreal, Quebec, suggests that many persons can effectively use the genetic information in later reproductive decisions.²⁹ Additional research is necessary to thoroughly evaluate these issues in the US health care system and in a variety of different cultures and ethnic communities.³⁰ The AAP does not support the broad use of carrier testing or screening in children or adolescents. Carrier testing for the pregnant adolescent or for the adolescent who is planning a pregnancy and who has been fully informed of the benefits and risks of carrier testing may be appropriate.

In some circumstances, carriers will be identified through newborn screening programs. For example, newborn screening for sickle cell disease will identify infants who are carriers (in addition to those who are homozygous for the disease). Reporting the infant's carrier status to parents has the theoretical advantages of informing parents that they may be at risk for bearing an affected child (if both parents are carriers) and of enabling the family to be aware of the child's future reproductive risk. However, identification of infants as carriers may lead to misinterpretation by parents and others, resulting in changes in the parent-child relationship and social discrimination. Furthermore, parents should have the opportunity to obtain or refuse their own testing for carrier status (newborn screening should not be used as a surrogate for parental testing). Finally, it remains to be determined whether newborn screening results can be used effectively years later when the person is making reproductive decisions. The AAP concurs with the IOM recommendations that newborns not be screened for the purpose of determining carrier status.⁴ Carrier status results that are obtained incidentally should be conveyed to parents who have undergone previous counseling and have given consent. Newborn screening tests should be conducted with adequate parental education, including information about implications for genetically related persons.

PREDICTIVE TESTING FOR LATE-ONSET DISORDERS

Genetic technology provides the means to diagnose disorders that develop beyond infancy, including some that become manifest only in adulthood. Examples of late-onset diseases with a high degree of predictability based on genetic tests include myotonic dystrophy, hemochromatosis, polycystic kidney disease, Huntington disease, and some cancers. Furthermore, it soon may be possible to identify genetic factors that increase the probability that common disorders, such as coronary artery disease, diabetes, stroke, hypertension, Alzheimer disease, forms of colon and breast cancer, several psychiatric conditions, and some rheumatoid diseases, will develop.

For some of these conditions, knowledge of risk status may help persons reduce morbidity or risk of

mortality. In addition, members of at-risk families may benefit psychologically from learning that they are not mutation carriers or from a reduction in uncertainty if they are found to be mutation carriers. However, a reduction in morbidity or mortality as a result of genetic testing has not been demonstrated for many conditions for which predispositional testing is available.^{31,32} Whether current recommendations for prevention or early detection will be effective in this high-risk population remains unclear. Furthermore, the knowledge of increased risk status may trigger adverse psychological responses and, potentially, discrimination by insurers, employers, or others. For these reasons, the rapid introduction of BRCA1/BRCA2 (which confer increased risk for breast and ovarian cancer) and HNPCC (or hereditary nonpolyposis colon cancer, which confers increased risk for colon cancer) mutation testing into clinical medicine for adults has been discouraged.^{33,34} The complexities of genetic testing and the uncertain risks and benefits of the results support the use of detailed genetic counseling for predictive testing for late-onset disorders. Many adults choose not to be tested for late-onset conditions, indicating that we cannot presume that children would want or will benefit from such testing.^{35,36} Further, testing in childhood inappropriately eliminates the possibility of future autonomous choice by the person and risks stigma and discrimination. Unless there is anticipated benefit to the child, pediatricians should decline requests from parents or guardians to obtain predispositional genetic testing until the child has the capacity to make the choice.^{37,38}

GENETIC SERVICES

The Human Genome Project will foster the development and rapid introduction of genetic tests into clinical practice. The number of genetic counselors and geneticists is insufficient for these professionals to take primary responsibility for managing this technology.³⁹ As a result, primary care physicians will need to expand their knowledge of genetics and the benefits and risks of genetic testing.⁴⁰

RECOMMENDATIONS

1. Established newborn screening tests should be reviewed and evaluated periodically to permit modification of the program or elimination of ineffective components. The introduction of new newborn screening tests should be conducted through carefully monitored research protocols.
2. Genetic tests, like most diagnostic or therapeutic endeavors for children, require a process of informed parental consent and the older child's assent. Newborn screening programs are encouraged to evaluate protocols in which informed consent from parents is obtained. The frequency of informed refusals should be monitored. Research to improve the efficiency and effectiveness of informed consent for newborn screening is warranted.
3. The AAP does not support the broad use of carrier testing or screening in children or adolescents. Additional research needs to be conducted on

carrier screening in children and adolescents. The risks and benefits of carrier screening in the pediatric population should be evaluated in carefully monitored clinical trials before it is offered on a broad scale. Carrier screening for pregnant adolescents or for some adolescents considering pregnancy may be appropriate.

4. Genetic testing for adult-onset conditions generally should be deferred until adulthood or until an adolescent interested in testing has developed mature decision-making capacities. The AAP believes that genetic testing of children and adolescents to predict late-onset disorders is inappropriate when the genetic information has not been shown to reduce morbidity and mortality through interventions initiated in childhood.
5. Because genetic screening and testing may not be well understood, pediatricians need to provide parents the necessary information and counseling about the limits of genetic knowledge and treatment capabilities, the potential harm that may be done by gaining certain genetic information, including the possibilities for psychological harm, stigmatization, and discrimination, and medical conditions and disability and potential treatments and services for children with genetic conditions. Pediatricians can be assisted in managing many of the complex issues involved in genetic testing by collaboration with geneticists, genetic counselors, and prenatal care providers.
6. The AAP supports the expansion of educational opportunities in human genetics for medical students, residents, and practicing physicians and the expansion of training programs for genetic professionals.⁴

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