WIAAP Policy Statement

Addition and Deletion of Tests from the Wisconsin Newborn Screening Program

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Background:

Over 65,000 babies undergo newborn blood spot screening in Wisconsin each year. Around 1 in 500 of these children have a serious condition identified by the newborn screening (NBS) program that leads to beneficial early intervention. Advances in testing have made it possible to identify many additional disorders beyond those currently screened for in Wisconsin. Evolving technology will make it possible to test for thousands of disorders from blood spots, creating unprecedented challenges in deciding when, whether, and how to incorporate this information into the NBS program. Many disorders have a constituency, including: families; professional and consumer organizations; health care providers; corporations that make testing equipment and reagents; drug, formula, and food companies; researchers; and others who vigorously advocate for the early identification of their disorder. Some of these groups turn to legislators to get a condition added to a state NBS panel.

There is concern that without a well-designed framework for considering the addition and deletion of disorders, tests may be added without regard to the complex medical, ethical, legal, economic, and social issues balancing (1) benefit to the children with conditions detected by screening, (2) risks of false positives in children without these conditions, (3) cost, and (4) availability of treatment and follow-up.

In late 2012 the Wisconsin Secretary of Health Services formed a task force charged with proposing a framework for making decisions regarding the addition and deletion of tests from the state NBS panel that would allow for scientific weighing of evidence and removal of bias. This task force made reported its recommendations to the Secretary in June 2013, and these recommendations have now become policy. The Task Force made the following recommendations:

1. The Task Force recommends the formation of a new committee to advise the Secretary on additions and deletions.

    a. This body should make final recommendations to the Secretary of the Department of Health Services, who has decision-making authority.

    b. This body should be constituted of individuals whose areas of expertise and experience include medicine and science; statistics and epidemiology; ethical, legal, social, and policy analysis; laboratory medicine; and should include representation from practicing physicians, the NBS program, and individuals with target conditions or their parents.

   c. This advisory committee would hear testimony from the Umbrella Committee, subcommittees, and other individuals with relevant information or who can speak for important constituencies.

2. Mandated testing should be limited to conditions that cause serious health risks in childhood that are unlikely to be detected and prevented in the absence of newborn screening.

3. For each condition, there should be information about the incidence, morbidity and mortality, and the natural history of the disorder.

4. Conditions identified by newborn screening should be linked with interventions that have been shown in well-designed studies to be safe and effective in preventing serious health consequences.

5. The interventions should be reasonably available to affected newborns.

6. Appropriate follow-up should be available for newborns that have a false positive screen.

7. The characteristics of mandated tests in the newborn population should be known, including specificity, sensitivity, and predictive value.

8. Disorders on the testing panel should be reviewed at appropriate specified intervals. A new test might require review more frequently than a long-established test.

9. If a new sample collection system is needed to add a disorder, reliability and timeliness of sample collection must be demonstrated.

10. Before a test is added to the panel, the details of reporting, follow-up, and management must be completely delineated, including development of standard instructions, identification of consultants, and identification of appropriate referral centers throughout the state/region.

11. Adding point-of-care testing to the congenital disorders statute would allow point- of-care newborn screening to be reviewed under the criteria set forth by the administrative rule and not require legislation for each disorder. (The law allowing this was passed and signed in March 2014).

12. Recommendations and decisions should include consideration of the costs of the screening test, confirmatory testing, accompanying treatment, counseling, and the consequences of false positives. The mechanism of funding those costs should be identified. Expertise in economic factors should be available to those responsible for recommendations and decisions.

13. Reporting of test results should be subjected to the same criteria, regardless of whether it is a requested or targeted test, or an unintended or unavoidable byproduct of the testing technology.

14. Research to advance knowledge about the incidence or natural history of poorly understood disorders, or for the purpose of identifying potential subjects for clinical trials, should be conducted in compliance with existing ethical and legal guidelines, including review by an institutional review board (IRB).

15. The Task Force believes that all children should be screened. However, parents should maintain the opportunity to opt out of newborn screening, after receiving appropriate information about the testing program on the basis of personal conviction (and not just for religious reasons). Information should be presented in the prenatal period, to allow time for questions and counseling with medical advisors.

16. There should be high standards for consent of tests which are of unproven value, or tests linked to treatments of unproven value. Such tests and treatments should be instituted on a research basis, with review by an IRB, and in general, with traditional opt-in consent. Some studies might qualify for exempt status, not requiring IORB oversight, or meet criteria for waiver of informed consent.

Following the adoption of the Task Force recommendations in 2013, the Secretary of Health Services appointed an Advisory Committee for the purposes of advising the Secretary on the addition and deletion of tests to the newborn screening panel, using the above recommendations. This committee later reviewed pulse oximetry screening for cyanotic congenital heart disease, subsequently recommending that this testing be added to the panel.

Position:

The Wisconsin Chapter of the American Academy of Pediatrics (WIAAP) endorses the recommendations of the Newborn Screening Task Force as outlined in this document above.

Because the Secretary's Advisory Committee has now been created, with demonstrated success already with CCHD screening, all addition and deletion matters should be run through this committee for final recommendation to the Secretary of Health Services.

WIAAP opposes the addition and deletion of tests to the NBS panel through direct legislative action.