Policy #003
Iowa Department of Public Health Center for Congenital and Inherited Disorders

Management of the Iowa Newborn Screening Panel

I. Overview

The Iowa Department of Public Health (IDPH) is authorized pursuant to Iowa Code 136A and Iowa Administrative Code (IAC) 641IAC 4.3 to establish a newborn screening program, and directs that all newborns born in the state of Iowa be tested for specific congenital and inherited disorders as determined by the Center for Congenital and Inherited Disorders (CCID) and approved by the State Board of Health. Comprehensive newborn screening services including laboratory, follow-up, consultative, and educational services are provided through the Iowa Newborn Screening Program (INSP), a program of the IDPH.

INSP is a public health program under the CCID pursuant to Iowa Code chapter 136A and Iowa Administrative Code 614 IAC 4.3. The CCID provides administrative oversight to the INSP for the IDPH. The State Hygienic Laboratory (SHL) at The University of Iowa (UI) is the designated central screening laboratory pursuant to IC chapter 136A and 641 IAC 4.2. SHL tests Iowa newborns as set forth in 641 IAC 4.3 (5) and is the custodian of the residual specimens collected for newborn screening in Iowa on behalf of the INSP. Staff within the UI Departments of Internal Medicine, Pathology, and Pediatrics serves as consultants for the INSP pursuant to 641 IAC 4.3 and provide program coordination, consultation, follow-up, and education activities. IDPH and UI maintain a 28E agreement to ensure the provision of comprehensive newborn screening services for congenital and inherited disorders in the state of Iowa through the INSP.

Purpose of Managing the Iowa Newborn Screening Panel
It shall be the policy of the Iowa Department of Public Health to provide for an orderly and equitable process for decision making about which conditions shall be included on Iowa's newborn screening panel. Decisions will be made to provide the greatest benefit to the population of Iowa. As a population-based screening program, the INSP does not provide diagnostic testing, nor is it established to support clinical care; the newborn screening program allows for risk determination for the newborn regarding specific conditions on the newborn screening panel. INSP provides the risk-based information to clinicians and health care providers in order for them to develop a plan of care for the newborn.

II. Definitions

"Condition": an illness, injury, impairment, or physical or mental disorder

"*Congenital condition*": condition present at the time of birth

"Inherited condition": condition caused by a change or changes in a gene or epigenome passed from a parent or parents. Onset of the disorder may be prior to or at birth, during childhood, or in adulthood.

"Iowa newborn screening panel (IA NBS panel)": the list of conditions that are screened for and reported through the Iowa Newborn Screening Program, Early Hearing Detection and Intervention (EHDI) program, Critical Congenital Heart Disease (CCHD) screening, and other newborn screenings as required by state laws.

"Iowa Newborn Screening Program (INSP)": inclusive of systems and employees of the IDPH, State Hygienic lab, blood spot short term and long term follow up that are involved with newborn screening

"*RUSP*": U.S. Department of Health and Human Services Secretary's Recommended Uniform Screening Panel; includes core and secondary conditions.

III. NBS Panel subcommittee membership

Core committee members will be recruited and appointed with the approval of IDPH and will include individuals representing varied groups, expertise, interests and disciplines from across the state. NBS stakeholder groups represented should include advocacy groups, primary medical providers, hospitals/birthing facilities, and multiple aspects of the INSP (follow up, lab, information technology, IDPH). Members will be asked to serve for a minimum of three years with staggered terms to allow for continuity and flexibility of the subcommittee.

The subcommittee may invite subject-matter experts to participate on an ad hoc basis and/or may establish an ad hoc work group with expertise about a specific condition to assist with or conduct the review.

IV. Nomination of Conditions

When it is anticipated that there is sufficient interest to consider adding a new condition(s) to the IA NBS panel, the following policy will be utilized.

It is preferred that the condition be reviewed by ACHDNC prior to nomination for addition to Iowa's panel.

A. Conditions Nominated by US Secretary for Health and Human Services

When a condition is recommended by or pending with the US Secretary for Health and Human Services, this CIDAC subcommittee may conduct a review of all pertinent and available evidence including but not necessarily limited to ACHDNC evidence and findings

B. Conditions Nominated by an Individual or Advocacy Organization in Absence of ACHDNC/HHS Secretary Recommendation

In order to nominate a condition for addition to the IA NBS panel, an individual or advocacy organization must make advance notice to the IDPH by contacting the Executive Officer (EO) for the Center for Congenital and Inherited Disorders (CCID) at 1-800-383-3826 to provide preliminary information and to arrange for scheduling a presentation to the CIDAC Iowa

Newborn Screening Panel Management Subcommittee. Information about the rationale for adding the condition must include, but is not limited to:

- General information of the condition, including pertinent literature review, natural history of the condition, availability of evidence-based treatment, and incidence rate
- How newborn screening will make a difference in the outcome for the newborn;
- How screening for this disorder would fit into the existing screening program;
- General information about the technical feasibility of conducting such screening;
- General information about the current screening status in other states/programs;
- Review of position statements from all appropriate national and regional organizations

V. Process To Review Nominated Conditions

A. The CIDAC Iowa Newborn Screening Panel Subcommittee review.

1. The CIDAC Iowa Newborn Screening Panel Subcommittee (subcommittee) will evaluate all presented and other available information about a nominated condition using the following criteria:
    a. Wilson and Jungner classic screening criteria [Wilson JM, Jungner JF. Principles and practice of screening for disease. Geneva (Switzerland): World Health Organization Public Health Papers, no 34; 1968. p. 26–7.]
        i. The condition sought should be an important health problem.
        ii. There should be an accepted treatment for patients with recognized disease.
        iii. Facilities for diagnosis and treatment should be available.
        iv. There should be a recognizable latent or early symptomatic stage.
        v. There should be a suitable test or examination.
        vi. The test should be acceptable to the population.
        vii. The natural history of the condition, including development from latent to declared disease, should be understood adequately.
        viii. There should be an agreed policy on whom to treat as patients.
        ix. The cost of case finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.
        x. Case finding should be a continuing process and not a “once and for all” project.
    b. Iowa’s capacity to develop and provide a suitable, evidence-based test for the condition.
    c. Availability of facilities and expertise for diagnosis and treatment in state and/or region.
    d. Potential impact of integrating the test on existing NBS protocols, programs, systems, and the public health department.
    e. Financial feasibility.
    f. Position statements from appropriate local and national organizations.

2. A public forum or discussion may be held to determine the level of community interest or concern.
3. After adequate review and discussion, a subcommittee member can call to vote to submit recommendations to CIDAC. The subcommittee chair (and/or designee) will report the results of the vote to and answer questions from the CIDAC at the next full meeting.

B. After hearing the recommendations from the subcommittee, CIDAC members will vote to commission a full pre-implementation assessment.
    1. Full assessment will include:
        a. Physical capacity of SHL to accommodate equipment, staff, and infrastructure needs
        b. Staffing: laboratory scientists, laboratory testing, laboratory administration, follow-up staffing, medical consultants, medical geneticists, sub-specialty providers
        c. Other options if staffing or physical capacity are not available, e.g., other labs, other staffing
        d. Proposed budget for screening for the condition, including expenses and projected fee increase
        e. Information management capacity to amend LIMS and follow-up data systems as needed
        f. Research requirements, including consent to screen during pilot screening
        g. Projected timelines – pilot screening and universal screening
        h. Current policy versus amendments needed to policy (administrative rules)
        i. Other relevant information
C. After review and deliberation of the pre-implementation assessment, CIDAC members vote on recommendation to add condition to NBS panel.
D. CIDAC letter of recommendation to add condition pending a successful pilot sent to IDPH/State Board of Health.

VI. Annual Review of the IA NBS Panel

This subcommittee will review the IA NBS Panel on a yearly basis using the criteria listed above. The subcommittee will make recommendations to the CIDAC for consideration of removing a condition(s) from the IA NBS panel, changing screening methodology, or other concerns as appropriate. Review will include an invitation to current medical consultants to provide up to date information about the including conditions including natural history, screening methodologies, treatments, and other pertinent data.