Newborn screening panel management: the Iowa experience

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I report no conflicts of interest through the contents of this presentation.
Policy #003 – management of 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. The Iowa Newborn Screening Program provides the risk-based information to clinicians and health care providers in order for them to develop a plan of care for the newborn.”
Breakin’ it down

• ...orderly and equitable process for decision-making
• ...decisions will be made to provide the greatest benefit to the population of Iowa
• ...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
The People

The Congenital and Inherited Disorders Advisory Committee (CIDAC) will convene the NBS Panel Subcommittee when it is anticipated that there is sufficient interest to consider adding a new condition(s) to the IA NBS panel.

• Core committee members are recruited and appointed with the approval of IDPH and 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 INSPI (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.

(The NBS Panel Subcommittee also conducts an annual review of the Iowa panel to reaffirm the list of conditions screened.)
The Process: Nominations

Internal

- **INSP nomination**
  - Recommends CIDAC review conditions felt to be “on the horizon” by program staff

- **CIDAC-initiated**
  - CIDAC will typically automatically review conditions recommended by or pending for recommendation by the US secretary for Health and Human Services

External

- **Individual nominations or advocacy group nominations**
  - contact the Executive Officer for the Center for Congenital and Inherited disorders
  - Provide preliminary information
  - Schedule presentation to the CIDAC Iowa Newborn Screening Panel Management Subcommittee
The Process: Subcommittee review

- Information including, but not limited to:
  - Wilson and Jungner classic screening criteria
  - Iowa’s capacity to develop a suitable test
  - Local/regional availability of medical follow up
    - Facilities for diagnosis and treatment
    - Medical expertise for diagnosis and treatment
  - Impact on the existing screening program
  - Financial feasibility
  - Position statements from appropriate national and local organizations
  - Public forum, if needed/wanted
    - Exploring adding an ongoing constituent advisory council
The Process: Pre-implementation Assessment

After hearing the report from the NBS Panel Subcommittee, CIDAC members vote whether to commission a full pre-implementation assessment. This assessment provides detailed information about “what it would take” to conduct a screening pilot and universal newborn screening for the condition.

This assessment includes:

- Physical capacity of SHL to accommodate equipment, staff, and infrastructure needs
- Staffing: laboratory scientists, laboratory testing, laboratory administration, follow-up staffing, medical consultants, medical geneticists, sub-specialty providers
- Other options if staffing or physical capacity are not available, e.g., other labs, other staffing
- Proposed budget for screening for the condition, including expenses and projected fee increase
- Information management capacity to amend LIMS and follow-up data systems as needed
- Research requirements, including consent to screen during pilot screening
- Projected timelines – pilot screening and universal screening
- Current policy versus amendments needed to policy (administrative rules)
The Process: CIDAC

After review and deliberation of the pre-implementation assessment, CIDAC members vote on recommendation to add the condition to the Iowa NBS panel.

CIDAC sends a letter of recommendation to add the condition - pending a successful pilot - to IDPH for consideration and presentation to the State Board of Health, which has the legislative authority to add conditions to the Iowa NBS Panel.
In real time

• This policy has been revised in real-time as reviews are underway and the process is improved, and also as the “political climate” warrants changes to the process

• SMA is the most recent condition to undergo review – pre-implementation assessment report goes to CIDAC April 19

• Challenges - communicate to advocates and clinicians the nature of NBS as public health activity, and not disease detection activity

• An established policy and procedure has helped us “ward off” legislation with condition-focused mandatory screening policy
Thank you!