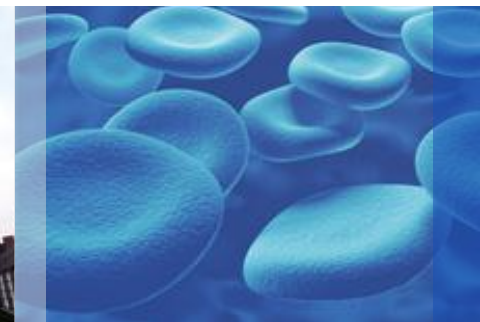
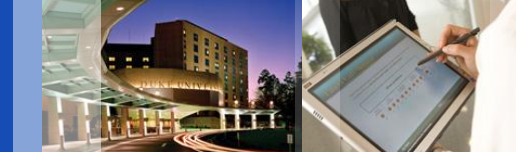


Users' Guide to the SACHDNC Decision Matrix

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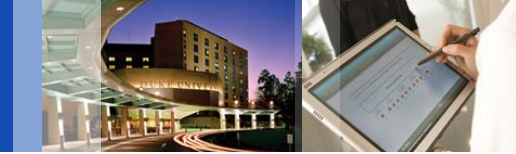
Background

- In September 2012, the SACHDNC approved the use of a decision matrix to assist with the development of recommendations regarding conditions nominated to the RUSP.
- Based on a 2-step process involving assessment of
 - *Net Benefit: Benefits - Harms*
 - *Capability of state newborn screening programs to adopt comprehensive screening*



Net Benefit

- A – high certainty of significant net benefit
- B – moderate certainty of significant net benefit
- C – high or moderate certainty of a small to zero net benefit
- D – high or moderate certainty of a negative net benefit
- L – low certainty



Assigning Net Benefit (Benefits – Harms)

- Most important consideration is to the child being screened
- Considerations
 - *The overall public health burden (birth prevalence, severity)*
 - *Benefits of early detection and treatment to affected children*
 - *Harms related to screening, diagnosis, and treatment, both to affected and unaffected children*
- False-positive screens are an important harm. However, the impact of false-positive screens can vary based on condition
- Compelling evidence needed to justify screening for late-onset disease
- The SACHDNC does not use a single defined metric for classifying net benefit



Capability to Screen

- 1 – high to moderate feasibility, most ready to begin
- 2 – high to moderate feasibility, most have developmental readiness
- 3 – high to moderate feasibility, most unprepared
- 4 – low feasibility



Assigning the Capability to Screen

- Technical and clinical feasibility is central
- Overemphasis of readiness could delay adoption.
- Assessment of readiness can
 - *help identify needs that can be addressed*
 - *guide implementation activities*



Assigning the Capability to Screen

- **Technical and Clinical Feasibility**
 - *An established screening test*
 - *A clear approach to diagnostic confirmation*
 - *Accepted treatment*
 - *Plan for long-term follow-up*
- **Readiness**
 - *Availability of resources for screening; diagnostic confirmation; long-term follow-up, including treatment*
 - *Authorization for screening*



Examples

- SCID
 - “A” net benefit, “4” → “2” ability to screen
- CCHD
 - “A” net benefit, “4” → “3” → “2” ability to screen
- Pompe disease
 - 2006 – “B” net benefit, “4” ability to screen
- Hemoglobin H Disease
 - “L” net benefit, ? ability to screen
- Hyperbilirubinemia
 - “C” net benefit, ? ability to screen
- Krabbe Disease
 - “L” net benefit, ? ability to screen



Lessons Learned

- Conditions rated as B or L should include specific guidance about what future research is needed
- A score for the ability to screen does not need to be assigned if the condition is unlikely to be recommended for screening based on net benefit
- There is overlap between readiness and feasibility. These terms are not meant to be mutually exclusive, but provide a framework to assure all issues are considered



Questions / Comments