

Proposed Changes to Advisory Committee Processes

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Secretary's Advisory Committee on Heritable Disorders in Newborns
and Children

Department of Health and Human Services
Health Resources and Services Administration

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Rationale for changes

1. AC renewal in 2013
 - Must meet legislative requirements
2. Stature and visibility of AC is growing
 - Assure our processes are well planned and thought out
3. Time to review current legislation and ensure requirements are met



Topics of Discussion

1. Incorporating Public Health Impact into the Evidence Review Process
2. Voting on Conditions
3. Reports and Products – Levels of Support
4. Term Limits for Nonvoting Members
5. Bylaws and Policies & Procedures



1. Condition Review – Current Process

1. Does screening improve outcomes?
2. Is there a case definition and what is known about the disorder?
 - Prevalence, spectrum of disease, natural history?
3. Is there a test for the disorder?
4. Has the test been validated?
5. What is the clinical utility of the test?
6. How cost effective is the screening, diagnosis, and treatment for this disorder compared with usual clinical case detection and treatment?



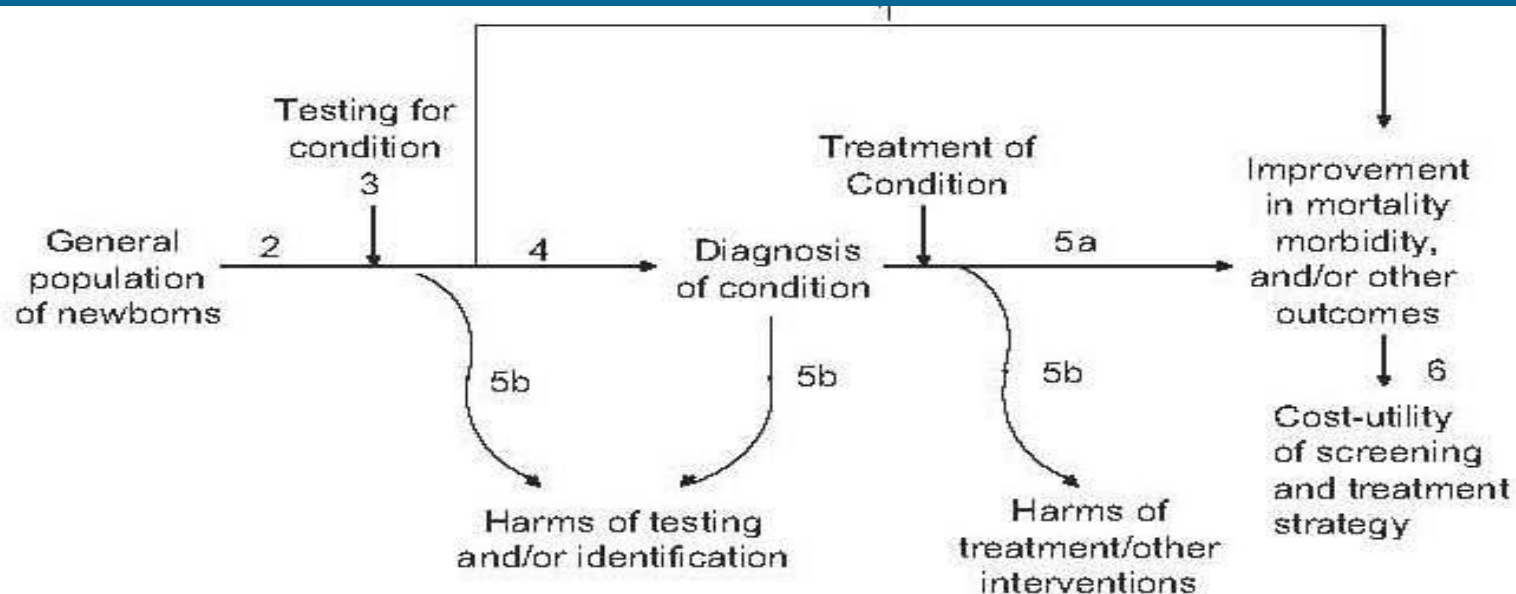


Fig. 1. The analytic framework depicts the considerations of evidence for population-based screening of newborns for a specific important health condition (or set of conditions). Each number corresponds to a key question which, in total, describes the structured analysis for considering the existing data (Adapted from U.S. Preventive Services Task Force Procedure Manual, <http://www.ahrq.gov/clinic/uspstf08/methods/procmanual.pdf>.)

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Proposed Revision

1. Does screening improve outcomes?
2. Is there a case definition and what is known about the disorder?
 - Prevalence, spectrum of disease, natural history?
3. Is there a test for the disorder?
4. Has the test been validated?
5. What is the clinical utility of the test?
6. How cost effective is the screening, diagnosis, and treatment for this disorder compared with usual clinical case detection and treatment?
- 7. What is the impact on public health for screening this disorder?**
 - **Impact on the health of the public?**
 - **Impact on the public health system?**



Rationale

- US Code 42 § 300b–10.— Advisory Committee on Heritable Disorders in Newborns and Children
 - The Advisory Committee shall—
 - (4) develop a model decision-matrix for newborn screening expansion, including an evaluation of the potential public health impact of such expansion, and periodically update the recommended uniform screening panel, as appropriate, based on such decision-matrix;
- Action:
 - Revamp review process to include public health impact and align more closely with USPSTF and Community Guide for more cross referrals as appropriate
 - Steering WG – will review and present to the AC
 - *If the public health impact has not been assessed, then it does not fulfill the model decision matrix provisions for newborn screening expansion and updates to the RUSP*



2. Vote on Conditions – Current Process

- Evidence review group (ERG) presents their data to the AC
 - Several different points in time
- AC discusses and votes
 - May include recommendations in addition to including the condition on the RUSP



Proposed Revision

- Workgroup meets prior to presentation – including 2 AC members
- Evidence is discussed
- AC members frame their perspective recommendations for the AC
- ERG presents data
- AC member presents their recommendations
- AC discusses and votes



Rationale

- Not enough time for full discussion of pros/cons during AC meetings
- Similar to process for Nomination and Prioritization group regarding sending to evidence review
- Allows a framework and reference point for more informed discussion by AC
- More participation by AC members



4. Formal process for Reports and Products

- Current process:
 - Reports presented to the AC
 - Recommendations are decided
 - Sent to the Secretary



Proposed Revision

- Each report or product is reviewed by the appropriate subcommittee
- If deemed appropriate for further processing, will be presented to AC for official support (see table)



Levels of Support for Reports & Products

Level of Support	Actions
1. Official SACHDNC Support (High)	Important to the field of NBS <u>and</u> under purview of the AC <u>and</u> authority of the Secretary. Forwarded to Secretary for consideration/action.
2. SACHDNC Affirmation of Value to the Newborn Screening Community (Moderate)	Important but neither in purview of the AC nor under authority of the Secretary to make recommendations. Forwarded to Secretary for information only.
3. SACHDNC Acknowledgment (Moderate)	Important but not actionable; not in purview of AC or Secretary; not sent to the Secretary; acknowledgement cited on website
4. No Support	Incomplete information; not original or in line with AC priorities; no further actions taken

Rationale

- SACHDNC's value is built on the reputation it has gained through its expertise, achievements and objectivity.
- Must advance newborn screening by appropriately supporting (at different levels) materials that will benefit the newborn screening community
- Not all reports require Secretarial action or review – this allows for direct support by AC



5. Term Limits for Nonvoting Members

Current Process:

- Up to 12 positions – Appointments based upon written requests from organizations
- Nominations sent to DFO; Associate Administrator, Maternal and Child Health Bureau, HRSA; Committee; Secretary - for final review and approval
- Once nominated, no limit to time despite rapidly changing landscape



Proposed Revision

- Categories of liaisons will be determined with set number of representatives
 - Developed by HRSA and ex-officio members
- Every 4 years, each liaison will roll off or be selected for another 4 year term



Rationale

- Voting members have term limits
 - Purpose - rolling influx of new ideas
- NBS and heritable disorders encompass a broad catchment and there are important stakeholders than 12 positions can fulfill
- Allows for an equitable distribution of influence with the AC



6. Separate Bylaws from Policies & Procedures

- Current process
 - Policies & Procedures include details that are considered bylaws
- **Proposed revision**
 - Separate bylaws from Policies & Procedures
 - Bylaws require formal vote by AC
- **Rationale**
 - Align with FACA legislation



Votes for the AC

- Approval of the by-laws
 - Aye vote would result in immediate implementation of new processes that do not require change to charter.



Contact Information

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