Committee Internal Evidence Review Process

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SACHDNC Meeting

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Issues and Concerns

- Assessment of the readiness of State Public Health Programs to incorporate new technologies
- Assessment of the readiness of the Health Care Delivery and Public Health systems to implement point of care screening in a collaborative fashion

Issues and Concerns

- Clearly linear and “duplicative” methodology for Committee decision, especially for rare disorders
- Structure to encourage thorough discussion of evidence and science

Process issues for consideration

- Standardize process for summarizing and reviewing evidence prior to a vote
- Executive session for discussion of evidence
- Use of modeling approaches for very rare disorders

Reviewing evidence

- The Committee should use an explicit, standardized process for reviewing the summarized evidence prior to voting on a condition
- Proposal:
  - The evidence review will include a summary table of conclusions from External Evidence Review Workgroup regarding the body of evidence for each key question
  - The Committee will discuss and use this table to guide the deliberations prior to voting

Executive Session

- Federal Advisory Committees often use executive sessions to support frank and open discussions among members, free from potential non-scientific influences
- Transparency and consideration of public input is maintained by allowing public comment during the meeting and making public all materials used in deliberations as well as the outcomes of the Committee's work
- Proposal: following relevant public comment and presentation of the systematic evidence review, the Committee will convene an executive session for deliberations

Very rare disorders and modeling

- There are lingering concerns that our recommendation process may still hamper decision-making around disorders so rare that published evidence of benefits and harms of screening is absent or scarce
- Modeling the bounds of potential benefits and potential harms should provide the Committee with information useful in considering screening for these rare conditions

Potential modeling approach

1. Use the estimated incidence of disease to determine the upper bound of the number of children who, if identified by screening, could potentially have an improved health outcome
   - Assumes a valid screening test with known sensitivity
   - Assumes a treatment and/or management strategy that has the potential to improve health outcomes
   - Use an estimate of the efficacy of treatment/ management to estimate the upper bounds of potential benefit

Potential modeling approach

2. Use the specificity of the screening test to determine the upper bound of potential harms associated with false positive screening tests (additional testing, potential for unnecessary treatment, anxiety and ELSI issues)

Potential modeling approach

- The Committee could then assess the balance between potential benefits and harms in decision-making regarding the condition
- This evaluation could also assist reseachers and public health professionals regarding evidence gaps

Potential modeling approach

- If directed by the Committee, the specifics of such an approach should be developed by a separate expert working group and presented to the Committee for consideration