



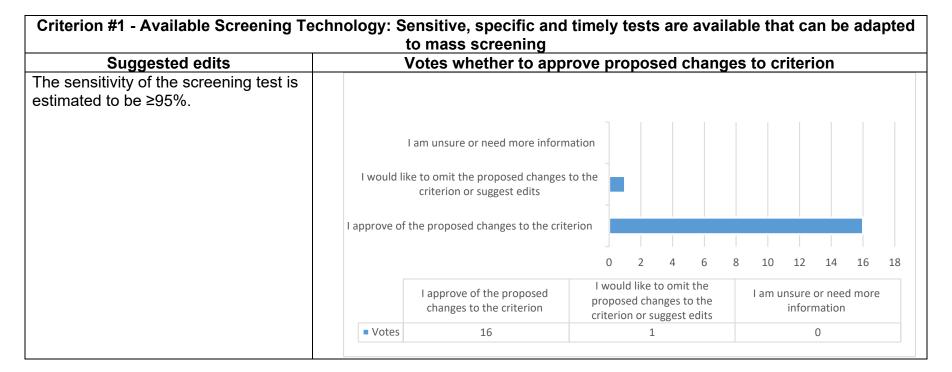


Newborn Screening Technical Advisory Committee (TAC)

Meeting to Review Criteria to Evaluate Conditions for the Newborn Screening Panel

TAC Member Voting Summaries and Comments

The following is a compilation of comments from TAC members provided when voting on each individual criteria, and an overall recommendation. Comments have been summarized and are organized by each criterion and then overall comments provided.

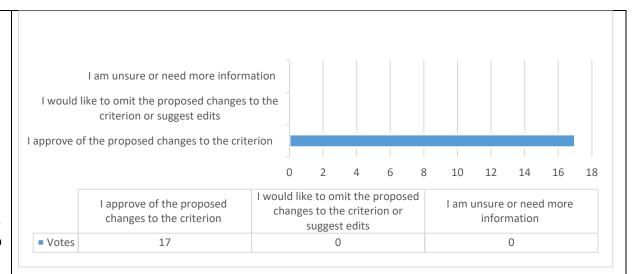


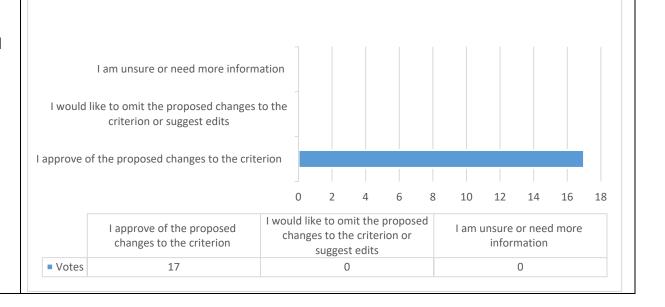
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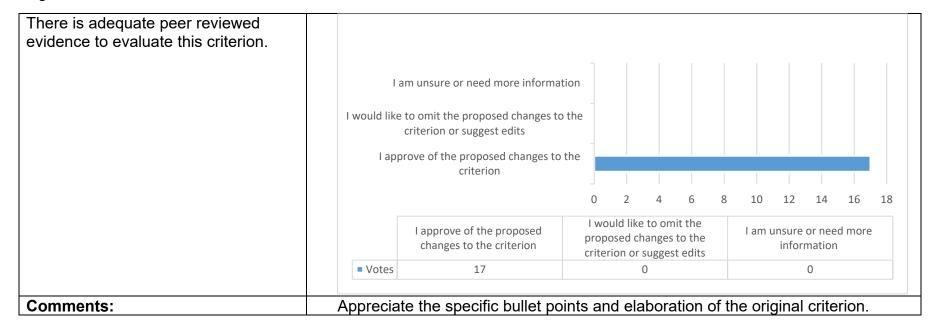
The specificity of the screening test is considered acceptable based on the estimated number of false positive results and their potential impact on families, the healthcare system, and the newborn screening program.

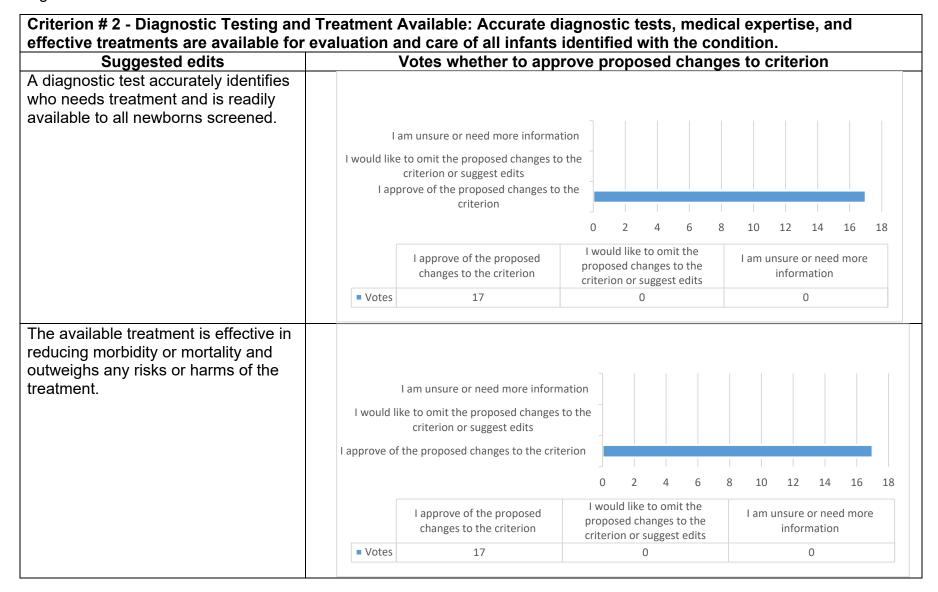
Note: original suggested update read as "...their potential impact on the healthcare system, the newborn screening program, and families." The TAC suggested the change in order to reflect importance of the impact on families.

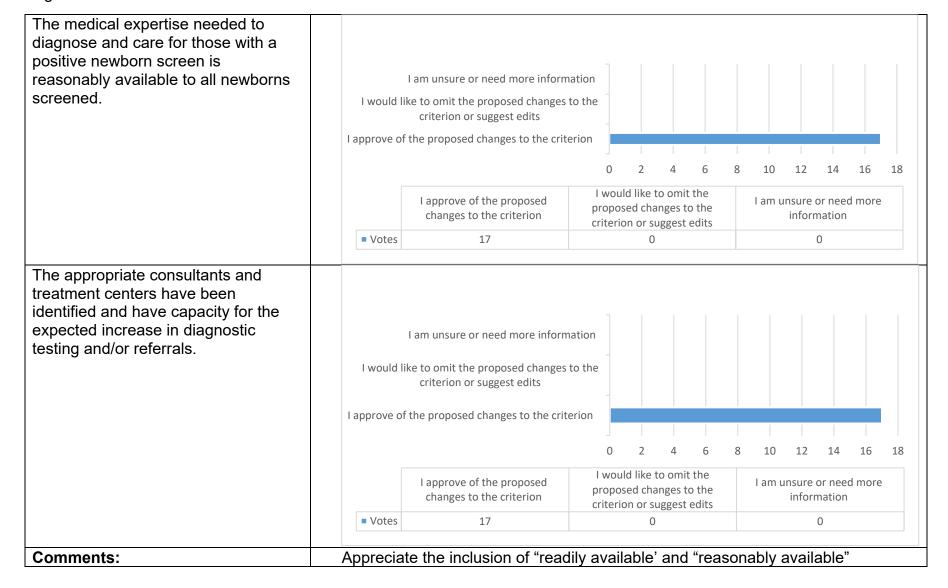
A timely test is one that enables intervention before irreversible harm develops, within the current standard timeframes for specimen collection, receipt, testing, and reporting.



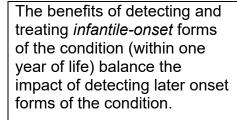


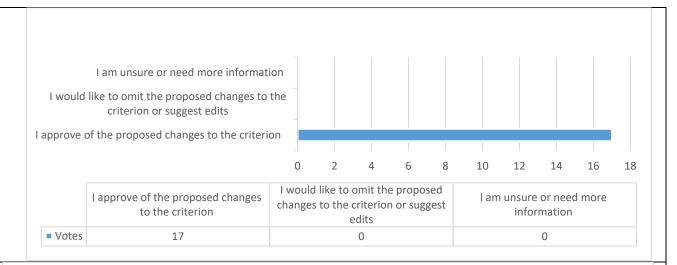






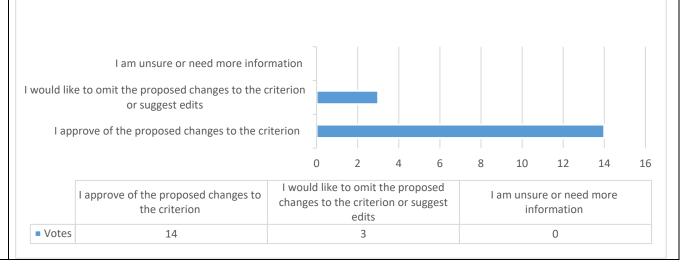
Criterion #3 - Prevention Potential and Medical Rationale: The newborn identification of the condition allows early diagnosis and intervention. Suggested edits Votes whether to approve proposed changes to criterion There is sufficient time No proposed changes. between birth and onset of irreversible harm to allow for diagnosis and intervention. The condition must have an onset form that occurs in infancy (within the first year of life); newborn screening is not I am unsure or need more information appropriate for conditions that I would like to omit the proposed changes to the only present after the first year criterion or suggest edits of life. I approve of the proposed changes to the criterion 10 12 14 I would like to omit the proposed I approve of the proposed changes I am unsure or need more changes to the criterion or suggest to the criterion information edits 17 0 0 Votes

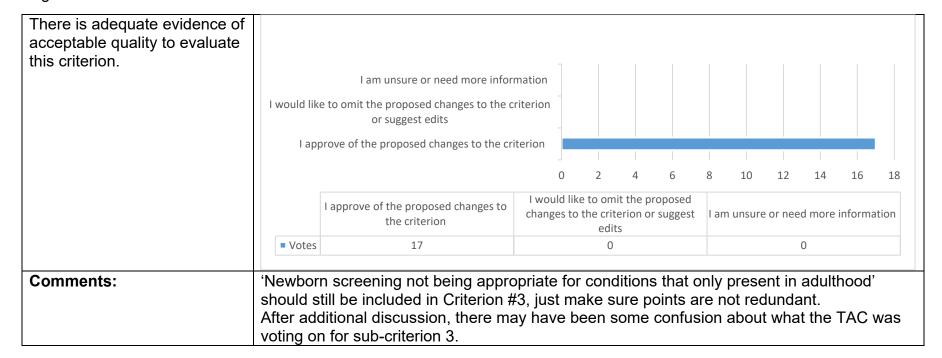


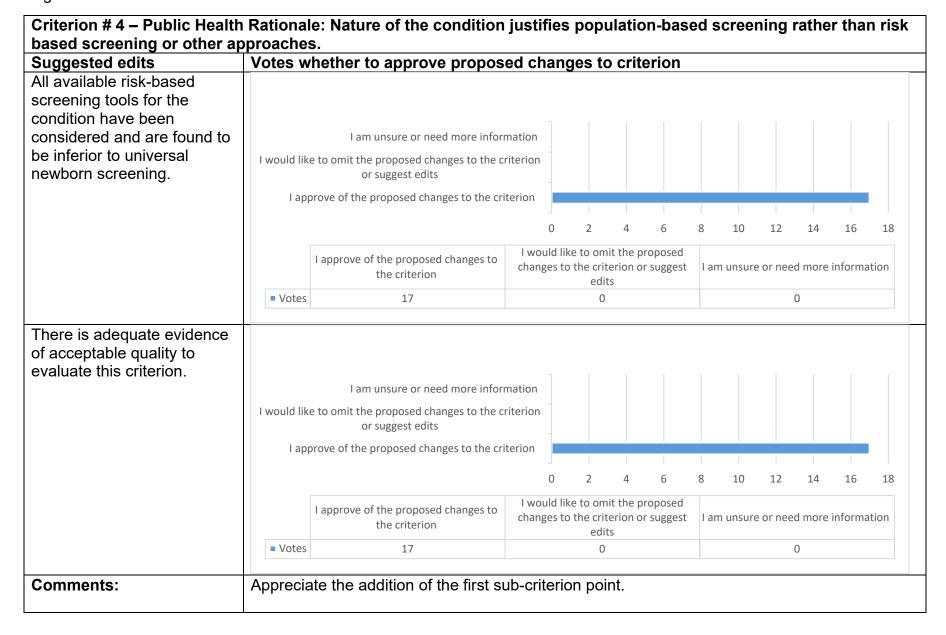


Newborn screening is not appropriate for conditions that only present in adulthood. (*Strike sub-criteria*)

Note: see comments

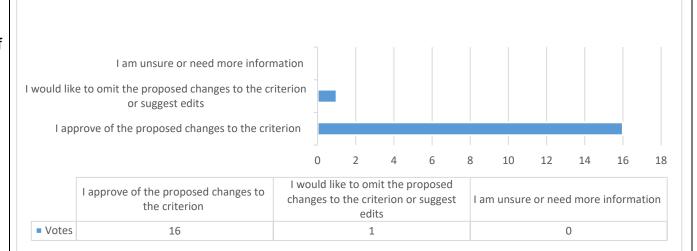




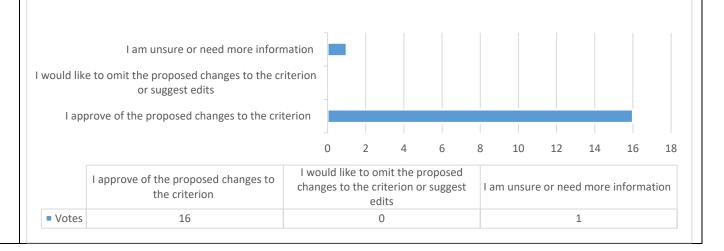


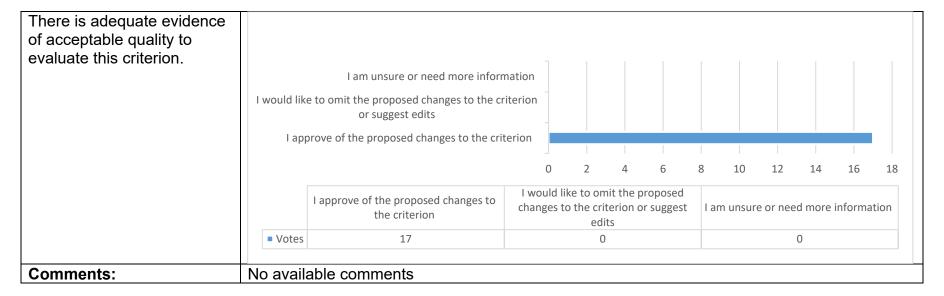
positive and negative, need			d chan	ane ta	o crite	rion						
The economic analysis considers: The prevalence of the condition among newborns. The positive and negative predictive values of the screening and diagnostic tests. Variability of clinical presentation by those who have the condition.		hether to approve propose osed changes.	d chan	ges to	o crite	erion						
Dollar values for costs and benefits of screening vs. no screening.		I am unsure or need more informe to omit the proposed changes to the cror suggest edits prove of the proposed changes to the crit I approve of the proposed changes to the criterion	terion 0	to the cr		6 proposed or suggest	8 I aı	10 m unsur	12	14	16	18
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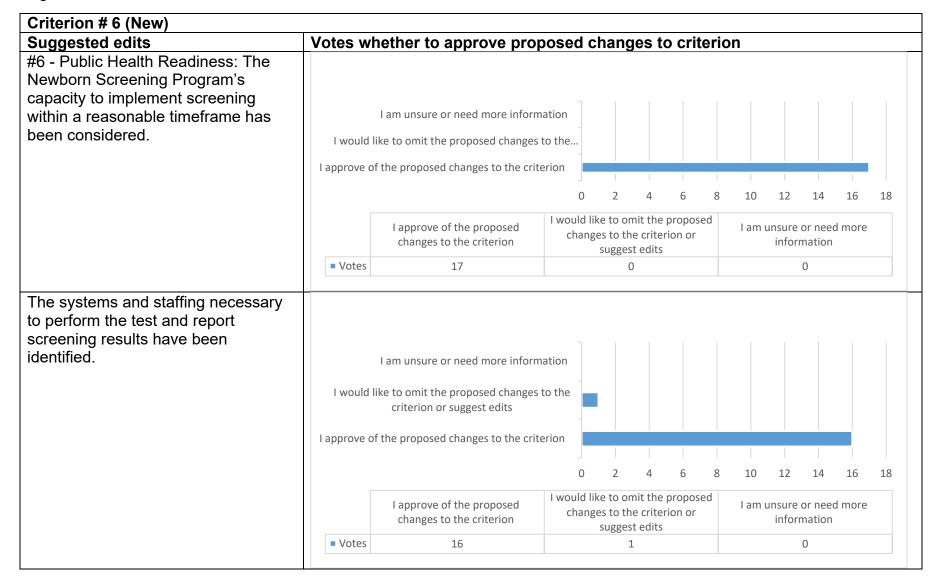
The impact of ambiguous results, adverse effects, or unintended consequences of screening, such as psychosocial or economic impacts on the family and medical system, must also be considered.

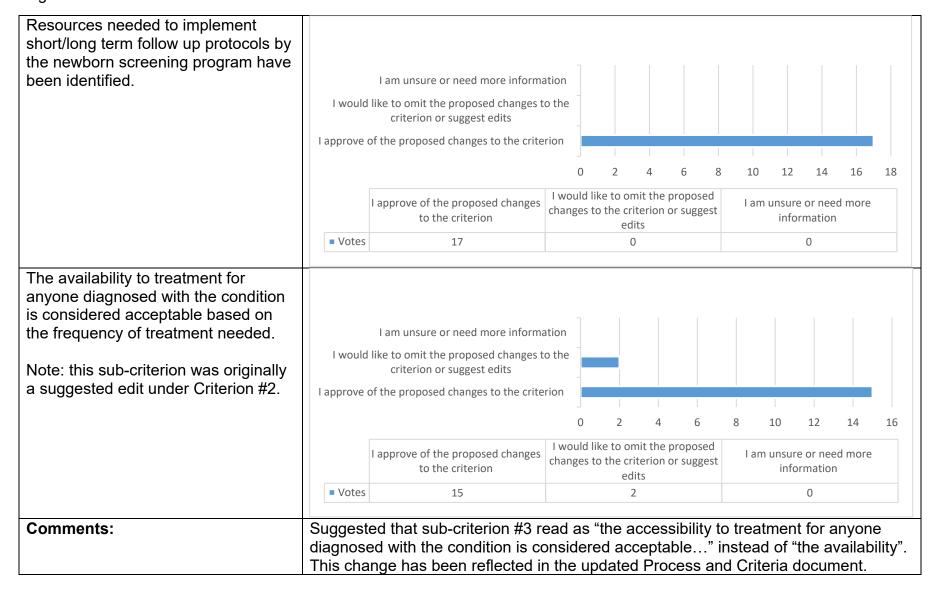


The results of the economic analysis shows that the outcomes, financial or otherwise, outweigh the costs of screening.









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