

# Hyperbilirubinemia: Discussion

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# Key Questions

## Key Question #1:

- Is there direct evidence that screening for the condition at birth leads to improved outcomes for the infant or child to be screened, or for the child's family?
  - No direct evidence that screening for neonatal hyperbilirubinemia prevents CBE

# Key Questions

## Key Question #2:

- Is there a case definition that can be uniformly and reliably applied? What are the clinical history and the spectrum of disease of the condition, including the impact of recognition and treatment?
  - Seems to be a clear definition of CBE: clinical manifestations
  - Incidence rates vary due to factors used to characterize ABE and CBE (levels of TSB and risk factors in the population studied; baby characteristics and time of testing)
  - Spectrum of conditions (hyperbili, ABE, CBE) is not well defined; evidence for long term outcomes other than CBE is limited and inconsistent

# Key Questions

## Key Question #3:

- Is there a screening test or screening test algorithm for the condition with sufficient analytic validity?
  - There appears to be a reliable screening tool (TcB) for detecting significant hyperbilirubinemia requiring confirmatory F/U with TSB
  - Screening methods vary and can be dependent upon institution
  - Screening has been associated with a lower incidence of hyperbilirubinemia

# Key Questions

## Key Question #4:

- Has the clinical validity of the screening test or screening algorithm, in combination with the diagnostic test or test algorithm, been determined and is that validity adequate?
  - Newborns with increased TSB levels experience an increase in acute clinical manifestations (not as tightly linked as we would like)
  - Linkage with CBE is insufficient

# Key Questions

## Key Question #5:

- What is the clinical utility of the screening test or screening algorithm?
- 5a: What are the benefits associated with use of the screening test?
- 5b: What are the harms associated with screening, diagnosis and treatment?
  - Clinical utility is unclear; earlier treatment with phototherapy decreased the likelihood of EcT, treatment lowers TSB, but limited evidence exists that treatments actually prevents CBE

# Key Questions

## Key Question #6:

- How cost effective is the screening, diagnosis and treatment for this disorder compared to usual clinical case detection and treatment?
  - Lack of data

# Decision Matrix

- If a policy of universal screening was implemented what would be the magnitude of net benefit?
- What is the level of certainty about magnitude of net benefit?



**Table 1. Decision Matrix for Advisory Committee Recommendations**

CATEGORY	RECOMMENDATION	LEVEL OF CERTAINTY	MAGNITUDE OF NET BENEFIT
1.	Recommend adding the condition to the uniform panel	Sufficient	Significant
2.	Recommend not adding the condition, but instead recommend specific additional studies	Insufficient, but the potential for net benefit is compelling enough to recommend specific additional studies to evaluate	Potentially significant, and supported by contextual considerations
3.	Recommend not adding the condition based on current knowledge	Insufficient, and substantial additional evidence is needed to make a conclusion about net benefit	Unknown
4.	Recommend not adding the condition to the uniform panel	Sufficient	Zero or net harm