



## Effective Health Care

### Sepsis Biomarkers and Their Utility Nomination Summary Document

#### Results of Topic Selection Process & Next Steps

- The use of procalcitonin for the diagnosis and management of sepsis will go forward for refinement as a systematic review. The scope of this topic, including populations, interventions, comparators, and outcomes, will be further developed in the refinement phase.
- When key questions have been drafted, they will be posted on the AHRQ Web site and open for public comment. To sign up for notification when this and other Effective Health Care (EHC) Program topics are posted for public comment, please go to <http://effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/>.
- The topic of biomarkers other than procalcitonin for the diagnosis and management of sepsis is not feasible for a full systematic review due to the limited data available at this time; however, it will be considered for a potential technical brief by the EHC Program.
- To see a description of a technical brief, please go to <http://effectivehealthcare.ahrq.gov/index.cfm/research-for-policymakers-researchers-and-others/>.
- If this topic is developed into a technical brief, key questions will be drafted and posted on the AHRQ Web site. To sign up for notification when this and other EHC Program topics are posted, please go to <http://effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/>.

#### Topic Description

**Nominator:** Health care professional association

**Nomination Summary:** The nominator states that several biomarkers have been proposed for diagnostic and/or prognostic uses in the management of sepsis including C-reactive protein, procalcitonin, cortisol, fibrinogen, leukocyte count, prothrombin time, partial thrombin time, interleukin 6, and tumor necrosis factor. The nominator asks whether these serum biomarkers provide evidence for the diagnosis or prognosis of sepsis for patients at risk for, or in, sepsis.

**Key Questions from Nominator:**

1. For patients at risk for, or in, sepsis, are there serum biomarkers available for the diagnosis and prognosis of sepsis?
2. For patients at risk for, or in, sepsis, does C reactive protein provide any utility in their management?
3. For patients at risk for, or in, sepsis, does procalcitonin provide any utility in their

- management?
4. For patients at risk for, or in, sepsis, does cortisol provide any utility in their management?

## Considerations

- The topic meets all EHC Program selection criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)
- Sepsis is a systemic illness caused by microbial invasion of normally sterile parts of the body. The process that underlies sepsis is highly heterogeneous, and the clinical management and prognosis are greatly variable. Patients with sepsis can differ with regards to inciting organism, focus of infection, and response to antibiotic treatments. These complexities have led to a search for a biomarker or set of biomarkers with compelling sensitivity and specificity for identifying the disease, predicting patient outcomes, and reliably guiding treatment.
- Given that procalcitonin is increasingly being used to guide treatment-related decisions regarding patients with, or at risk for, sepsis, and given that there are a number of published trials evaluating the use of procalcitonin for the diagnosis and management of sepsis, a comparative effectiveness review would be both useful and feasible.
- The literature does not appear as well developed for other biomarkers, such as C-reactive protein, cortisol, fibrinogen, leukocyte count, prothrombin time, partial thrombin time, interleukin 6, and tumor necrosis factor. Therefore, it was decided that a technical brief to identify the contextual factors and the current state of the science for other biomarkers would be of benefit to practitioners and researchers.