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New test could help catch serious infections in babies

Blood test may spare infants invasive diagnostic tests and antibiotics

Boston, MA--A simple blood test may help detect serious bacterial infections (SBIs) like urinary tract infections and blood stream infections in young infants who come to the emergency department (ED) with fevers that have no clear cause. Researchers at Children's Hospital Boston, collaborating with investigators at George Washington University, show that a new diagnostic marker called procalcitonin can help identify infants at high risk for SBIs while potentially reducing unnecessary and aggressive testing, medication and hospitalization in low risk infants. The study, published in the October *Pediatrics*, is the first to examine procalcitonin as a tool for evaluating infant fever in an emergency situation.

The researchers used a novel procalcitonin test, recently approved by the FDA, in 234 feverish babies under 3 months of age, of whom 18 percent had definite or possible SBIs confirmed by independent clinical criteria. The results showed that procalcitonin not only detected all cases of SBIs in feverous infants but proved sensitive enough to establish a threshold value that would identify infants at low risk for serious infections. Indeed, its overall performance as a single clinical marker of infection approached that of current strategies that involve a variety of laboratory tests and clinical evaluations.

In the United States, infant fever accounts for a vast majority of pediatric visits to the ED, of which up to 20 percent of cases have no identifiable cause of infection. While most turn out to be minor and self-limiting illnesses, a proportion of infants have SBIs such as bacteremia, meningitis, pneumonia or urinary tract infections. The risk is most significant in infants under 3 months of age.

"About 12 percent of those whom we consider 'well appearing' end up having serious infections when we do an evaluation," said Richard Bachur, MD, acting chief of emergency medicine at Children's.

Because clinicians cannot reliably determine which children with fever have more serious infections, many babies end up undergoing extensive evaluations. Routine evaluation of infants less than 3 months of age includes blood tests, urine tests, and often a lumbar puncture for spinal fluid, followed by treatment in the hospital with antibiotics.

Prompted by the inefficiency of current fever management in young infants, Bachur and colleagues have sought a rapid diagnostic test that will determine which children have serious infections at the first visit to the ED. "We hope to identify those infants that are at very low risk of serious infection and tailor their evaluation so as to minimize invasive testing and exposure to unnecessary antibiotics," said Bachur.

The high sensitivity of the new procalcitonin test has allowed Bachur and colleagues to establish realistic cut-off values to help guide clinicians in identifying children who are at low risk for SBIs.

The researchers are now looking to do a multi-center study to evaluate the use of procalcitonin on a larger scale. If it proves to be valuable, Bachur hopes it will become a standard tool for the evaluation of young infants with fever.

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The study was supported by the Frederick H. Lovejoy, Jr, MD Resident Research Fund and the American Academy of Pediatrics Resident Research Grant. The biomarker assay, procalcitonin (PCT), is available to clinicians and manufactured by Brahms Diagnostica.

Children's Hospital Boston is home to the world's largest research enterprise based at a pediatric medical center, where its discoveries have benefited both children and adults since 1869. More than 500 scientists, including eight members of the National Academy of Sciences, 11 members of the Institute of Medicine and 12 members of the Howard Hughes Medical Institute comprise Children's research community. Founded as a 20-bed hospital for children, Children's Hospital Boston today is a 397-bed comprehensive center for pediatric and adolescent health care grounded in the values of excellence in patient care and sensitivity to the complex needs and diversity of children and families. Children's also is the primary pediatric teaching affiliate of Harvard Medical School. For more information about the hospital and its research visit:www.childrenshospital.org/newsroom.