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Project:

Derivation of a novel clinical prediction rule for febrile young infants incorporating procalcitonin testing: A multi-center feasibility study

Summary:

Fever among infants ≤ 90 days old remains one of the most commonly encountered clinical problems in all of pediatric healthcare. Nearly 2% of all term infants will be evaluated for fever in an Emergency Department (ED) within their first 3 months of life. Although the majority of febrile young infants have viral illnesses, approximately 10% harbour potentially life-threatening serious bacterial infections (SBIs). Published SBI risk-stratification criteria developed over 30 years ago provide conflicting recommendations and predate the availability of newer diagnostic tests such as procalcitonin and viral testing. There exists no clinical prediction rule incorporating these modern diagnostic tests to identify infants at low-risk of SBI. Objective: To demonstrate the feasibility of operationalizing multi-center procalcitonin testing within an existing Febrile Young Infant Research Platform. The primary outcome will be the proportion of eligible infants enrolled with bio-samples successfully collected and analyzed. Methods: We will conduct a 1-year, multi-center prospective pilot study of infants ≤ 90 days old evaluated for fever at 2 urban tertiary pediatric centers (Phase 1). We will implement a comprehensive process to obtain consent, then collect, store and process virus panel PCR testing and small quantity blood samples for procalcitonin assays. Enrollment will occur at 2 urban Pediatric Emergency Departments in equal allocation ratios during daytime, evening and overnight hours. Blood samples will be frozen and analyzed in batch by enzyme-linked fluorescence assay. We aim to enroll 300 infants (10% sample for prediction rule derivation), aiming to achieve $>80\%$ recruitment and $>90\%$ viable sample analysis of all eligible infants, and post-discharge follow-up of all infants without CSF testing. Impact: This study is an essential first step to identify potential barriers and enhance our ability to enroll infants for the derivation of a novel clinical prediction rule to identify infants at low-risk of SBI for whom invasive testing can be safely avoided (Phase 2). A prediction rule incorporating newer diagnostic tests could reduce unnecessary invasive testing, hospitalizations and wide-spectrum antibiotic exposure, as well as inform shared decision-making and improve system-wide resource utilization.