Reducing Hospital Length of Stay for Febrile Infants 7-60 Days: a Project REVISE Substudy
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A. Study Purpose and Rationale

Fever in infants is a common reason for presentation to the Emergency Department or admission to the hospital, but there is significant variability in the way these children are evaluated and treated.[1,2] One notable example of this inconsistency in practice is hospital length of stay. Indeed, in a recent survey of 57 pediatric hospitalists, preferred lengths of observation ranged from 24-36 hours to >48 hours.[2] Data are emerging, however, that support the safety of shorter hospital stays for the majority of these infants.[1,3] This study aims to reduce the hospital length of stay of well-appearing febrile infants 7-60 days old following the implementation of a clinical decision guide for pediatric residents and hospitalists.

B. Study Design and Statistical Analysis

Study Design

The primary aim of this study is to reduce the average length of stay (LOS) of well-appearing, febrile infants ages 7-60 days, with the target discharge timeframe based on level of risk (24 hours for low risk infants, 36 hours for high risk infants). As with previous studies[1], and consistent with the guidelines set forth in the umbrella study (Project REVISE)[4], a six hour window will be added onto the target discharge timeframe to account for other factors aside from medical decision making and the clinical status of the infant that may affect hospital LOS. Therefore, low risk infants should be discharged by 30 hours and high risk infants by 42 hours. For the purposes of this study, LOS will be defined as the length of time from the documentation of the first set of vital signs in the Emergency Department to the placement of the discharge order in the electronic medical record. Risk status will be delineated using a set of clinical, physical examination, and laboratory parameters (Table 1) most similar to the modified Rochester criteria. To ensure that decreasing the LOS does not place infants at greater risk for adverse outcomes, data on the following balancing measures will be collected during the baseline and follow up periods: (1) readmission to the Emergency Department or hospital within 7 days of the original discharge or (2) diagnosis of bacteremia, urinary tract infection, or meningitis within 7 days of the original discharge and/or initiation of antibiotics within 7 days of the original discharge.

The study will be divided into three parts: the baseline, intervention, and follow up phases. The baseline phase represents the year leading up to the intervention, while the follow up phase comprises the year following the implementation of the intervention. During the baseline period, the average length of stay will be computed separately for low risk and high risk infants. In the subsequent intervention period, the evidence-based clinical decision guide will be rolled out in educational sessions with the pediatric residents and pediatric hospitalists. Finally, in the follow up period the average length of stay again will be computed for low risk and high risk

infants; these results will be compared to the data collected during the baseline period to assess the impact of the intervention.

The overall study approach is outlined in Figure 1.

Table 1 Risk stratification criteria

Low risk	High risk
>28 days	<= 28 days
>= 37 weeks	<37 weeks
No chronic medical conditions	Chronic medical conditions
5,000<WBC<15,000	WBC >15,000 or <5000
Band count <1500	Band count >1500
UA: <5-10 WBCs	UA: >5-10 WBCs
Normal CRP (if done)	Elevated CRP (if done)

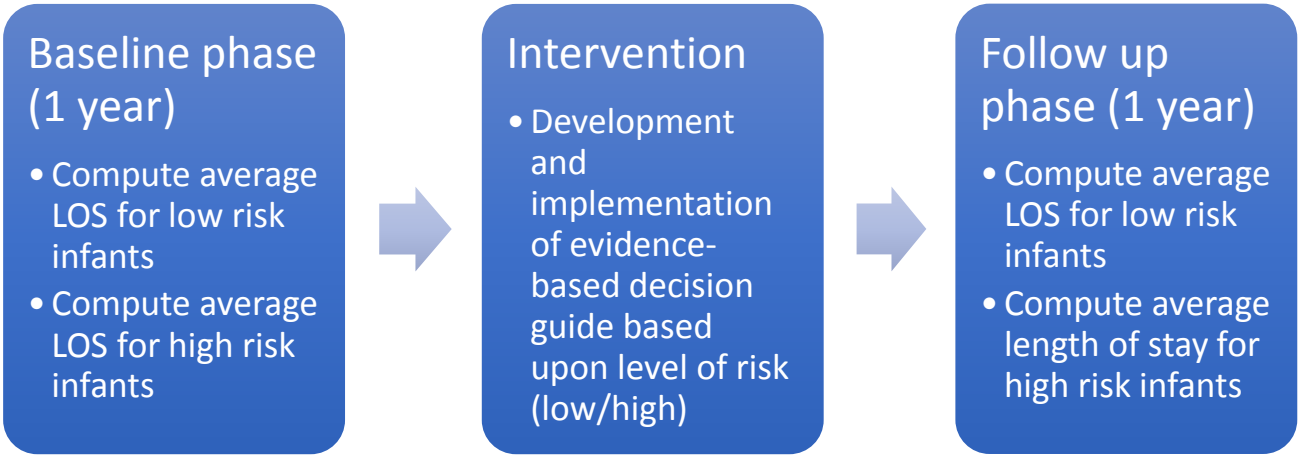

Figure 1 Outline of study phases.

Statistical Analysis

The average length of stay in the baseline and follow up periods will be compared separately in the low risk and high risk groups using unpaired t-tests or Wilcoxon rank-sum tests, as appropriate. Alternatively, the proportion of infants with appropriate lengths of stay based on

level of risk can be compared between the baseline and follow up periods using chi-square tests.

The proportion of patients readmitted, diagnosed with a serious bacterial infection, or started on antibiotics after discharge will be compared in the baseline and follow up periods using chi-square tests.

Sample Size Determination and Power Analysis

Based on previous reviews of our institutional data, our hospital sees ~300 qualifying febrile infants each year; assuming approximately half of these will get admitted and half the infants are low risk, we will be able to detect a difference in LOS of 3 hours with a type 1 error of 5% and a power of 80%.

If the proportions approach is utilized, assuming 50% of patients in each group have an appropriate LOS at baseline, we are powered to detect a difference of 23% (73% or greater with appropriate LOS) with a type 1 error of 5% and a power of 80%.

C. Study Procedure

The sole study "procedure" is the introduction of the residents and hospitalists to our clinical decision guide. For residents, this introduction will take place during an educational conference, while for the hospitalists the guide will be unveiled during one of the hospitalist group meetings. For both of these groups, the sessions should last about an hour. This approach has been utilized before for other pediatric quality improvement initiatives.

LOS information will be abstracted from the electronic medical record during the baseline and follow up periods; the data will not be associated with any one provider. Hospital providers will be performing their usual clinical duties during these periods and will not be involved in any dedicated study procedures.

D. Study Drugs

No study drugs, approved or investigational, will be used.

E. Medical Device

No medical devices are being employed in this study.

F. Study Questionnaires

No questionnaires will be utilized in this study.

G. Study Subjects

All Morgan Stanley-Children's Hospital of New York (MS-CHONY) pediatric residents and pediatric hospitalists will be encouraged to participate in the study.

H. Recruitment of Subjects

No resident or hospitalist will be actively recruited. For the residents, the didactic session introducing the clinical decision guide will take place during one of the daily resident education conferences. Because these conferences are scheduled during protected time, we hope to share our decision guide with as many residents as possible. However, residents will not be required to attend the conference discussing the decision guide should they not wish to do so. Likewise, hospitalist participation in the group meeting discussing the decision guide is encouraged, but not mandated.

The decision guide also will be distributed by email to reach residents and hospitalists who may not have been able to attend the in person educational sessions.

I. Confidentiality of Study Data

Study data (infant risk and LOS information) will be stored in a secure database located on NYP/CUMC hospital computers. Data will be accessed only by study investigators who have completed the appropriate HIPPA and clinical research training. Any unneeded identifying information (such as hospital MRN, birth date) will be removed from the database once data collection is complete.

No specific data will be collected from the pediatric residents and hospitalists.

J. Potential Conflict of Interest

None of the investigators have any conflicts of interest to report.

K. Location of the Study

The study will take place at Morgan Stanley Children's Hospital.

L. Potential Risks

No significant risks are anticipated for the residents and hospitalists. For the infants, there is the possibility of loss of confidentiality. However, this risk will be minimized by limiting access to the database to qualified study personnel; maintaining the data on secure hospital workstations; limiting the identifying data abstracted from the medical record; and removing any unnecessary identifying information from the database as soon as possible.

M. Potential Benefits

Aside from an increased understanding of the evidence supporting a shorter LOS, there may be no direct benefit to the residents or hospitalists. From a quality of life standpoint, Infants and their families may benefit from a shorter LOS by being able to return home more quickly. The hospital may benefit financially from decreased costs associated with shorter lengths of stay and increased bed availability for other patients.

N. Alternative Therapies

There will be no experimental therapies employed in this study.

O. Compensation to Subjects

No compensation will be provided to the pediatric residents or hospitalists. (The data on infants will be collected retrospectively; the families of these infants will not be compensated).

P. Costs to Subjects

We do not anticipate that the residents or hospitalists will incur any additional costs as a result of participating in the study. (We will follow the balancing measures closely to ensure we are not placing infants at increased risk for an adverse outcome by decreasing LOS).

Q. Minors as Research Subjects

The primary subjects of this study are residents and hospitalists, all of whom are adults. However, data will be collected retrospectively from the electronic medical record on infants; a waiver of consent will be sought, and numerous precautions will be taken to protect the data, as detailed above.

R. Radiation or Radioactive Substances

This study will not employ radiation or radioactive substances.

References

1. Byington CL, et al. Costs and infant outcomes after implementation of a care process model for febrile infants. Pediatrics. 2012; 130(1): e16-e24.
2. Biondi E, et al. Fever and bacteremia. Pediatrics in Review. 2013; 34(3): 134-136.
3. Biondi EA, et al. Blood culture time to positivity in febrile infants with bacteremia. JAMA Pediatrics. 2014; 168(9): 844-849.
4. Value in Inpatient Pediatrics (VIP) Network. Project REVISE Change Package. Accessed on August 3, 2017.