Reducing Invasive Care for Low-risk Febrile Infants Through Implementation of a Clinical Pathway

Kathryn E. Kasmire, MD, MS,a,b Eric C. Hoppa, MD,a,d Pooja P. Patel, BS,b Kelsey N. Boch, MD,b Tina Sacco, RN, BS, CPHQ,a Ilana Y. Waynik, MDa,d

abstract

BACKGROUND AND OBJECTIVES: Significant variation in management of febrile infants exists both nationally and within our institution. Risk stratification can be used to identify low-risk infants who can be managed as outpatients without lumbar puncture (LP) or antibiotics. Our objective was to reduce invasive interventions for febrile infants aged 29 to 60 days at low risk for serious bacterial infection (SBI) through implementation of a clinical pathway supported by quality improvement (QI).

METHODS: The evidence-based clinical pathway was developed and implemented by a multidisciplinary team with continuous-process QI to sustain use. Low-risk infants who underwent LP, received antibiotics, and were admitted to the hospital were compared pre- and postpathway implementation with SBI in low-risk infants and appropriate care for high-risk infants as balancing measures.

RESULTS: Of 350 included patients, 220 were pre- and 130 were postpathway implementation. With pathway implementation in July 2016, invasive interventions decreased significantly in low-risk infants, with LPs decreasing from 32% to 0%, antibiotic administration from 30% to 1%, and hospital admission from 17% to 2%. Postimplementation, there were 0 SBIs in low-risk infants versus 29.2% in high-risk infants. The percentage of high-risk patients receiving care per pathway remained unchanged. Improvement was sustained for 12 months through QI interventions, including order-set development and e-mail reminders.

CONCLUSIONS: Implementation of a clinical pathway by using QI methods resulted in sustained reduction in invasive interventions for low-risk febrile infants without missed SBIs. Clinical pathways and QI can be key strategies in the delivery of evidence-based care for febrile infants.
specificity, resulting in a number of infants without SBI undergoing extensive testing and treatment. Although the risks of missing SBI are significant compared with the risks of evaluation and treatment, aggressive evaluation and intervention can cause unnecessary pain to infants, stress to caregivers, adverse events, and significant cost to the health care system.\textsuperscript{9} The risks associated with evaluation and empirical treatment likely contribute to the significant variability in care provided to febrile infants, resulting in many febrile infants not receiving appropriate evaluation for SBI.\textsuperscript{10–13}

The epidemiology of SBIs in young infants has changed since the development of the most commonly used criteria with a predominance of urinary tract infection (UTI)-associated pathogens, a decrease in bacteremia, and an overall low incidence of bacterial meningitis.\textsuperscript{14,15} In keeping with this changing epidemiology, evaluation for UTI and bacteremia remain essential; however, criteria exist to identify low-risk infants in whom LP may be avoided. Growing evidence reveals that the use of stepwise evaluation by using risk stratification without initial LP in infants ages 29 to 60 days is safe, with LP and empirical antibiotic administration being reserved for high-risk infants.\textsuperscript{6,16,17} In particular, the Rochester criteria, with the use of white blood cell count, band count, and urinalysis to risk stratify infants, has been shown to have \( \geq 97\% \) negative predictive value for SBI.\textsuperscript{3,4,18–21}

Clinical pathways are a useful strategy to improve the delivery of evidence-based care, with numerous examples of successful implementation seen in the pediatric ED setting.\textsuperscript{22–25} Given the widespread variation in the management of febrile infants, the use of a clinical pathway could be a beneficial strategy to reduce variability. Byington et al\textsuperscript{17} showed that implementing a pathway based on modified Rochester criteria decreased overall cost while improving appropriate testing and treatment of high-risk infants without increasing missed SBIs. Similar pathways are in use at other institutions.\textsuperscript{17,26–28}

At our institution, a clinical pathway for the evaluation and management of neonates \( \leq 28 \) days old with fever was implemented in 2014, but the management of febrile infants \( > 28 \) days of age was not standardized; providers at our institution varied greatly in their care of this group. In particular, care for low-risk infants had high variability, with low-risk infants undergoing LP 100\% of the time in some months versus 0\% in other months, and monthly antibiotic use ranged from 0\% to 100\% (Fig 1). To improve care for febrile infants aged 29 to 60 days, an evidence-based clinical pathway was developed and implemented at our institution, and continuous quality improvement (QI) was used to support the implementation of the pathway, including promoting use and sustainability. Our aim in implementation was to reduce LP, antibiotic administration, and hospital admission for infants at low risk for SBI to \( < 10\% \) in 12 months without missing SBIs.

\section*{METHODS}

\subsection*{Context}

This QI project was deemed exempt from full review by our institutional review board.

\subsection*{Study Population}

The study population consisted of febrile infants aged 29 to 60 days meeting inclusion criteria for the febrile-infant clinical pathway: fever \( \geq 38.0^\circ \text{C} \) (rectal; before arrival or in the ED) and gestational age \( \geq 37 \) weeks. Exclusions included evaluation initiated at an outside ED or recent previous ED visit, history of immunodeficiency, identified focal infection, underlying chronic medical disease, current antibiotic therapy, gestational age \( < 37 \) weeks, or a clinical diagnosis of bronchiolitis.

\subsection*{Planning the Intervention}

Before our QI initiative, significant variability existed in care for febrile infants aged 29 to 60 days at our institution. To standardize and improve care for febrile infants, an evidence-based clinical pathway (based on modified Rochester criteria)\textsuperscript{3,17,18} was developed over a period of 17 months (starting in February 2015) with input from key stakeholders from the divisions of emergency medicine, hospital medicine, and infectious disease. The initial development phase engaged stakeholders in the ED, including pediatric emergency medicine physicians and fellows, and pediatric hospitalists. Journal club sessions were held for hospitalists and ED physicians (in February 2015 and April 2015, respectively) to review evidence in febrile-infant management, and after discussion, consensus was reached on a pathway involving risk stratification for SBI based on modified Rochester criteria (shown in Fig 2). Collaboration between ED and hospitalist providers during the development period allowed for the creation of a multidisciplinary team and coordination of care across the hospital continuum. Final
FIGURE 1
Statistical process control chart with the percentage of low-risk infants who received an invasive intervention. A, Percentage of low-risk infants who underwent LP. B, Percentage of low-risk infants who received an antibiotic. C, Percentage of infants who were admitted to the hospital. Dotted lines represent control limits.
FIGURE 2
Clinical pathway for the evaluation and treatment of infants aged 29 to 60 days with fever. ALT, alanine aminotransferase; AST, aspartate aminotransferase; CBC, complete blood cell count; CSF, cerebrospinal fluid; hx, history; HSV, herpes simplex virus; IM, intramuscularly; IV, intravenously; PCP, primary care provider; PCR, polymerase chain reaction; PE, physical exam; q6h, every 6 hours; q8h, every 8 hours; q12h, every 12 hours; RSV, respiratory syncytial virus; sxs, symptoms; WBC, white blood cell count.

Inclusion criteria: infant 26 to 60 days of age with rectal temperature ≥38.0°C (at home, at PCP's office, or in ED), gestational age ≥37 weeks

Exclusion criteria: immunodeficiency, known focal infection, underlying chronic medical disease, current antibiotic therapy, gestational age <37 weeks, bronchiolitis (if infant has bronchiolitis, please treat on bronchiolitis clinical pathway and do not continue on this pathway)

Well Infant (by hx and appearance on PE)

Diagnostic Tests
Blood: CBC with differential, culture
Urine: (catheter) urinalysis UA, culture
Consider:
- Stool culture and stool norovirus and rotavirus studies (if diarrhea)
- Chest radiograph (if significant respiratory signs and sxs)
- Nasal RSV and influenza PCR (if symptoms and late fall and/or winter season)

Low-risk Laboratory Results

High-risk Laboratory Results

Discharge from the hospital
- Do not give empiric antibiotics
- Call PCP to inform of workup
- PCP or ED follow-up in 24 hours
- If barriers to follow-up, consider placing in observation

If risk factors for HSV:
Skin:
- HSV PCR and culture (swab mouth, conjunctiva, rectum) if age ≤6 weeks
- For uncloved vesicles if present, send PCR only
- CSF: HSV PCR
Consider:
- Stool culture and viral stool studies (if diarrhea)
- Chest radiograph (if significant respiratory signs and sxs)
- Nasal RSV and influenza PCR (if symptoms and late fall and/or winter season)

WBC ≥5000 or ≤1500 and absolute band count <1500
Urinalysis <5 WBC, negative leukocyte esterase and nitrate radiograph: no infiltrate

WBC <5000 or >15000 or absolute band count >1500
Urinalysis >5 WBC or positive leukocyte esterase or nitrate radiograph: plus infiltrate

3 Risk Factors for HSV?
- Hx of maternal genital lesions at delivery (not risk factor if >6 weeks)
- Infant thrombocytopenia
- Ill-appearing infant
- Hx of seizures
- Vesicles on skin examination
- CSF pleocytosis, especially if CSF Gram-stain is negative

4 Low-risk Laboratory Results

5 High-risk Laboratory Results

Discharge Criteria
- Infant well appearing, improving clinically, and tolerating feeds well
- Blood, urine and CSF bacterial culture result negative after 36 hours for well-appearing infants and high-risk laboratory results
- Blood, urine and CSF bacterial culture result negative after 24 hours for well-appearing infants and low-risk laboratory results
- CSF HSV PCR results negative
- No new symptoms of concern
- Family understands discharge instructions and ongoing infant needs
- Follow-up provider identified, discharge plan and dose follow-up arranged

Further evaluation and treatment per inpatient team and consider infectious disease consultation

Improving?

Yes

Treat as indicated, consider infectious disease consultation

No

Yes

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pathway review and approval was obtained following standard hospital process through the institution’s clinical effectiveness committee. A hospital-wide grand rounds presentation in January 2016 on febrile-infant management was given, which was focused on presentation of the proposed pathway and the supporting evidence.

**Interventions**

The clinical pathway (Fig 2) was implemented in July 2016. As with all of our clinical pathways, an educational PowerPoint presentation was provided to pathway end users via e-mail and posted on the hospital intranet at time of pathway implementation. QI interventions occurred in plan-do-study-act cycles to improve and sustain pathway adherence, including implementation of a pathway order set in the electronic medical record in November 2016, monthly e-mail reminders about the pathway for residents rotating through the ED (starting in January 2017), and a ceftriaxone order panel (which was introduced in April 2017).

**Study of the Interventions**

Evaluation and management of febrile infants aged 29 to 60 days was assessed retrospectively for 2 years before implementation (from May 2014 to June 2016) and compared with the postimplementation period, which was assessed prospectively for 1 year. Data collected included completion of LP, administration of antibiotics, hospital admission, and adherence to modified Rochester criteria as presented in our institution’s pathway (Fig 2), with adherence being defined as the collection of all necessary laboratories and/or cultures, correct use of LP, the correct use of antibiotics, and hospital admission when indicated. Additional data were collected as necessary for risk stratification (white blood cell and band counts, urinalysis results, and general appearance) as well the ultimate presence of SBI and demographic information. After pathway implementation, data were collected weekly by our quality department and reviewed by a collaborative ED and hospitalist team. A clinical data coordinator designated patients as low or high risk on the basis of the treating provider’s documentation and laboratory results. If a discrepancy was found, physician consensus was used (according to the pathway definitions of low and high risk). Data were analyzed periodically to drive additional plan-do-study-act cycles and interventions.

Eligible patients were identified from all ED patients 29 to 60 days of age by using chief complaint of fever or a relevant International Classification of Diseases, 10th Revision code (including fever, UTI, bacteremia, meningitis, and pneumonia). Charts were reviewed for inclusion and exclusion criteria.

**Measures**

The primary outcome measure was the percentage of low-risk infants who received LP or antibiotics or were admitted to the hospital. Before pathway implementation, there was frequent use of LP and antibiotic administration for infants who could be classified as low risk (Fig 3A). The specific goal was to decrease LP, antibiotic use, and hospital admission for low-risk infants aged 29 to 60 days to <10% by increasing the percentage of febrile infants managed according to the clinical pathway.
from 60% to 90% in 12 months. ED length of stay (LOS) was assessed as a secondary outcome. Process measures included pathway adherence and order-set use. Pathway adherence was defined as having all of the following: collection of complete blood count, urinalysis, and blood and urine cultures as well as appropriate use of LP, antibiotics, and hospital admission based on risk classification.

SBI in low-risk infants was assessed pre- and postpathway implementation as a balancing measure, with SBI being defined as a true-positive blood or cerebrospinal fluid culture result or a positive urine culture result (≥100 000 colony-forming units [CFUs] per mL of a pathogenic bacteria or ≥10 000 CFUs/mL with positive urinalysis results). The lower cutoff for urine cultures was used because our laboratory does not specify counts between 10 000 and 100 000 CFUs/mL, and recent studies have revealed that true UTIs in infants commonly have counts <100 000 CFUs/mL.29,30 To detect a doubling of SBIs in low-risk infants with 80% power and 95% confidence, a sample size of ~3000 would be required, which was not feasible in our study time frame. In light of this limitation, we also tracked care for high-risk infants (LP, antibiotics, and hospital admission) as balancing measures.

**Analysis**

Demographic and clinical characteristics, LOS, process measures, and balancing measures were compared between the pre- and postimplementation groups by using t tests and $\chi^2$ tests or Fisher’s exact tests for comparisons with $n < 5$ and with statistical significance set at $\alpha = .05$. Statistical process control charts were used to assess the impact of the intervention on outcome and process measures. Control limits were set at 3 SDs from the mean. Standard rules were used to determine special cause variation, including ≥8 values above the baseline centerline.51

**RESULTS**

**Outcome Measures**

During the 3-year study period, 350 febrile infants aged 29 to 60 days were included, 220 before (62.9%) and 130 after (37.1%) pathway implementation (Table 1). We excluded 120 infants (total pre- and postpathway), most commonly because of prematurity ($n = 52$) and bronchiolitis ($n = 43$). There were no significant differences in demographic and clinical characteristics between the pre- and postimplementation groups, including in age, sex, maximum temperature, proportion of low-risk infants, or prevalence of SBI (Table 1).

Before pathway implementation, low-risk infants frequently underwent testing and treatment not indicated by modified Rochester criteria (Fig 3). Of 136 low-risk infants before pathway implementation, 44 (32%) underwent LP, 41 (30%) received antibiotics, and 23 (17%) were admitted to the hospital.

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Improvements were seen in all measures after pathway implementation, with 0 (0%) low-risk infants undergoing LP, 1 (1%) receiving antibiotics, and 2 (2%) being admitted to the hospital out of 82 low-risk infants, all of which were below the aim of 10% (Fig 1). The control charts show special cause variation at the time of pathway implementation with decreased interventions after pathway implementation for LP, antibiotics, and admission for low-risk infants (Fig 1). LPs, antibiotic use, and hospital admission remained at low rates after pathway implementation, during which time additional QI cycles were conducted, including order-set implementation, e-mail reminders, and a ceftiraxone order panel to further improve pathway adherence (Figs 1 and 4).

Average ED LOS decreased from 295 minutes before pathway implementation to 272 minutes after implementation for all patients ($P = .03$). For patients discharged from the ED, LOS decreased significantly from 279 minutes before implementation to 237 minutes after ($P < .001$). ED LOS increased for admitted patients from a mean of 320 minutes before implementation to 359 minutes after ($P = .01$).

**Process Measures**

Modified Rochester criteria were followed more often after pathway implementation, increasing from 55.4% at baseline to 76.2% after pathway implementation ($P < .001$; Fig 4). The most common deviations from the pathway after implementation were in the care of high-risk infants, including incorrect antibiotic dosing and a lack of hospital admission when indicated (Fig 3B). The statistical process

**TABLE 1 Demographic and Clinical Characteristics**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Prepathway ($N = 220$)</th>
<th>Postpathway ($N = 130$)</th>
<th>$P$</th>
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</thead>
<tbody>
<tr>
<td>Age, d, mean (IQR)</td>
<td>45.3 (38–53)</td>
<td>45.4 (38–52)</td>
<td>.92</td>
</tr>
<tr>
<td>Male sex, n (%)</td>
<td>122 (55.5)</td>
<td>74 (36.9)</td>
<td>.88</td>
</tr>
<tr>
<td>Tmax, °C, mean</td>
<td>38.5</td>
<td>38.5</td>
<td>.82</td>
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<tr>
<td>Low risk, n (%)</td>
<td>136 (61.8)</td>
<td>82 (63.1)</td>
<td>.90</td>
</tr>
<tr>
<td>SBI, n (%)</td>
<td>19 (8.6)</td>
<td>14 (10.8)</td>
<td>.64</td>
</tr>
<tr>
<td>SBI in high-risk infants, n (%)</td>
<td>18 (21.4)</td>
<td>14 (29.2)</td>
<td>.62</td>
</tr>
</tbody>
</table>

Tmax is measured either in the ED or before arrival. IQR, interquartile range; Tmax, maximum temperature.
control chart for pathway adherence reveals an upward shift in mean adherence in November 2015 before pathway implementation (which could be attributable to educational interventions occurring before pathway implementation) and again after implementation in November 2016, indicating special cause variation (Fig 4). An order set became available in the electronic medical record in November 2016 and was used for 32% of patients postpathway implementation.

Balancing Measures

After pathway implementation, there were no missed SBIs. There was 1 missed SBI before pathway implementation: an infant classified as low risk on the basis of well appearance and low-risk laboratory results then diagnosed with Citrobacter bacteremia, which was subsequently treated successfully. In the postimplementation period, 1 questionable case was ultimately considered a contaminant (urine culture with 10 000 CFUs/mL Enterococcus faecalis with trace leukocyte esterase on urinalysis) because the infant recovered quickly without antibiotics.

Appropriate care for high-risk infants remained consistent despite our effort to reduce invasive interventions for low-risk infants. For infants classified as high risk by using our pathway, rates of all recommended interventions were not significantly different after pathway implementation: LP performed in 73% vs 83%, appropriate antibiotic administered in 77% vs 85%, and hospital admission for 70% vs 77% pre- and postimplementation, respectively ($P > .05$ for all comparisons).

**DISCUSSION**

By using continuous-process QI to support the implementation of an evidence-based clinical pathway, we successfully achieved our goal of reducing LPs, antibiotic use, and hospital admission for febrile infants who are at low risk for SBI on the basis of modified Rochester criteria. This was achieved without detriment to the identification of SBIs or care for high-risk infants. Multiple QI interventions contributed to sustained improvement during the 1-year postimplementation period.

This QI initiative had a number of strengths that contributed to achieving our goal. Most importantly, engagement of ED stakeholders (including pediatric emergency medicine physicians and fellows) and pediatric hospitalists occurred throughout the pathway development period. The plan for pathway
development was initiated by a multidisciplinary team, education on the evidence and rationale was presented at several stages of development, and input from both pediatric emergency medicine physicians and pediatric hospitalists was sought and incorporated. When the pathway was implemented, the standardized hospital process for pathway use was followed, allowing for dissemination throughout the hospital. In addition, prospective weekly tracking of outcomes after implementation allowed for continuous process improvement and further interventions aimed at sustaining improvement.

Our results emphasize the utility of the implementation of a clinical pathway supported by QI efforts to achieve improvement in providing evidence-based care. Although we did note improvements in care for low-risk febrile infants before the study initiation and during the pathway development period, improvement in reductions in invasive care for low-risk infants reached a consistent level only with pathway implementation, which was sustained through additional QI cycles (Figs 1 and 4). Some of the discussion and education for providers (including journal clubs and grand rounds) may have led to the adoption of modified Rochester criteria before pathway implementation.

Previous studies have also revealed benefit in the use of clinical pathways for the reduction of unnecessary testing or interventions in pediatrics, including reducing broad-spectrum antibiotic use for pneumonia, computed tomography scans for appendicitis and head injury, catheterization to test for UTIs, and decreased use of antibiotics for low-risk febrile infants.22,25,32–34

The implementation of the clinical pathway reduced ED LOS for patients who were discharged from the ED. Factors that may have contributed to this include earlier initiation of workup by residents due to comfort with pathways and order sets, reduced time spent on LPs and antibiotic administration, and earlier disposition due to the standardization of risk-stratification and admission criteria. Although we did not track this during the study period, standing nursing triage orders aligned with the pathway allowed for nurses to obtain blood and urine testing before provider evaluation. Evaluation of nursing triage order use could provide further opportunity for improvement in LOS. However, ED LOS remained high for admitted patients, and although outside factors unrelated to the pathway (such as inpatient bed availability) may have contributed, the improvement for discharged patients may have come at the expense of longer stays for admitted patients, possibly due to waiting for laboratory results to be risk stratified before performing LP rather than completing all tests on initial evaluation.

Care for low-risk infants was positively impacted by our QI initiative. However, room for improvement remains for high-risk infants, with persistent variability in antibiotic dosing and administration, use of LP, and hospital admission being observed. In addressing these differences in management, further discussion with providers regarding reasons for not following the pathway will help to plan further interventions. The low specificity of Rochester and other risk-stratification criteria may encourage providers to make exceptions for high-risk infants given the still relatively low likelihood of SBI. Newer risk-stratification tests, such as procalcitonin, hold promise,20 and once available, modification of our pathway to incorporate advances could help further standardize care.

For antibiotic dosing variability, additional plan-do-study-act cycles with interventions aimed at antibiotic dosing standardization were initiated, including the development of an order panel for ceftriaxone to aid in appropriate dose selection. Pathway order-set use remained low at the end of our tracking period, presenting another area for improvement.

This study does have several important limitations. Although we did show significant improvements with our QI interventions, including pathway implementation, outside factors (such as national trends toward fewer interventions for infants >28 days old with fever) may have contributed to this improvement given the trend in reduced interventions for low-risk infants before the study’s conception. The pathway was successfully implemented with no missed SBIs after implementation; however, the study is not powered to detect a difference in missed SBIs. In tracking the results after pathway implementation, bias could have been present in classifying patients as high-risk on the basis of appearance, although data collection by our quality department may have helped to minimize this bias, and the proportion of low- and high-risk patients was similar pre- and postpathway implementation. Because this project was conducted at an academic children’s hospital, the results may not be generalizable to other institutions or community EDs.

CONCLUSIONS

The implementation of an evidence-based clinical pathway supported by continuous-process QI resulted in a sustained reduction in invasive interventions (LP, antibiotic administration, and hospital admission) for febrile infants aged 29 to 60 days who were at low risk for SBI while reducing ED LOS and without missed SBIs. Our study reveals that using QI processes to
support clinical pathway implementation can be a key strategy in the delivery of evidence-based care for febrile infants.

**ABBREVIATIONS**

CFU: colony-forming unit  
ED: emergency department  
LOS: length of stay  
LP: lumbar puncture  
QI: quality improvement  
SBI: serious bacterial infection  
UTI: urinary tract infection

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