Implementation of Goal-Directed Therapy for Children With Suspected Sepsis in the Emergency Department
Andrea T. Cruz, Andrew M. Perry, Eric A. Williams, Jeanine M. Graf, Elizabeth R. Wuestner and Binita Patel

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abstract

BACKGROUND: Suboptimal care for children with septic shock includes delayed recognition and inadequate fluid resuscitation.

OBJECTIVE: To describe the implementation of an emergency department (ED) protocol for the recognition of septic shock and facilitate adherence to national treatment guidelines.

PATIENTS AND METHODS: Root-cause analyses and morbidity and mortality conferences identified system problems with sepsis recognition and management. A group of ED and critical care physicians met to identify barriers and create solutions.

RESULTS: To facilitate sepsis recognition, a computerized triage system alarmed on abnormal vital signs, and then toxic-appearing children or children at high risk for invasive infection were placed in a resuscitation room. To facilitate timely delivery of interventions, additional nursing, respiratory therapy, and pharmacy personnel were recruited. Fluids were administered via syringe delivery; standardized laboratory studies and antibiotics were ordered and prioritized. Frequent vital-sign measurements and interventions were documented on a graphical flow sheet to facilitate interpretation of physiologic response to therapy. After protocol initiation, there were 191 encounters in 167 patients with suspected sepsis. When compared with children seen before the protocol, time from triage to first bolus decreased from a median of 56 to 22 minutes ($P < .001$) and triage to first antibiotics decreased from a median of 130 to 38 minutes ($P < .001$).

CONCLUSIONS: The protocol resulted in earlier recognition of suspected sepsis and substantial reductions in both time to receipt of time-sensitive interventions and a decrement in treatment variation. Pediatrics 2011;127: e758–e766

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KEY WORDS
goal-directed therapy, pediatric, sepsis

ABBREVIATIONS
ED—emergency department
QI—quality improvement

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Between 20,000 and 40,000 US children develop septic shock annually; chronically ill children are overrepresented in incidence and mortality rates. Despite evidence-based guidelines, a minority of children receive the standard of care. Although delays in fluid resuscitation have been associated with increased mortality rates, many barriers to timely resuscitation exist in busy emergency departments (EDs). 

We hypothesized that process barriers resulted in delays in shock recognition and management in our ED and that system changes would result in improved outcomes. We designed a quality-improvement (QI) intervention to maximize the recognition of patients at risk for septic shock and facilitate the ED implementation of preexisting national guidelines in 3 ways. First, we created an automated triage tool to recognize vital-sign abnormalities. Second, we harnessed resources for the more intensive nursing care needed to implement national guidelines. Third, we designed a physiologic flow sheet to characterize temporal changes in vital signs that could assist in patient handoffs and maintain awareness of the guideline.

METHODS

Root-cause analyses and morbidity and mortality conferences revealed areas for improvements in sepsis management. With support from hospital leadership, a multidisciplinary team (ED and ICU physicians and nurses and ancillary services) identified several obstacles including variation in experience of staff in performing initial evaluations; lack of adequate nursing staff for resource-intensive patients; difficulty obtaining frequent vital-sign measurements; lack of standardization of empiric antibiotics and diagnostic tests; lack of medication prioritization; and barriers to patient flow through the institution.

Subsequently, a prospective QI project was designed to measure the impact of early recognition and intensive nursing resources on the ability to deliver fluids and antibiotics more rapidly to children in shock; the project was termed the “shock protocol.” This project was conducted in the Texas Children’s Hospital ED, where >200 practitioners and 170 nurses care for ~85,000 children annually. All children for whom the shock protocol was implemented were included. Children were clinically diagnosed as septic; case definitions were not used as inclusion criteria. Patients included in the protocol were identified from a shock protocol order set. Patients in shock who did not receive the protocol (missed patients) were identified from several sources: records of triage tool alerts; admission/discharge diagnoses of PICU admissions; and inpatient rapid-response team calls <24 hours after admission. For patients in shock for whom the triage tool was triggered but the protocol was not used, chart review and discussion with the individual clinician(s) were performed to determine obstacles to protocol use.

Resuscitation timeliness was measured by documentation of time from triage to initiation of first fluid and subsequent boluses, bolus volume/duration, and timing of vasoactive agent use. Antibiotic use and timing were measured. Both included and missed patients were evaluated for ED and hospital length of stay, and rapid-response teams called within 24 hours of admission to a non-PICU bed. These admissions were compared with PICU admissions for sepsis in 2009. Data were analyzed by using MiniTab (State College, PA). Statistical process control charts were used to compare outcome measures in time order in consecutive patients from 2009 to the study period (February to August 2010). Control limits define 3 SDs around the mean; outliers signify causes not inherent to the process. Data points within the control limits signify variability in the process that requires system changes. Retrospective anecdotal discussions helped us to document institutional protocol-related cultural changes. Institutional review board approval was obtained.

RESULTS

Our first priority was improving shock recognition, specifically easily identifying patients with abnormal vital signs. We needed to create a system that would minimize variation in ED provider experience and the fluctuations in ED patient arrivals that contributed to delayed recognition of abnormal vital signs. Information technology helped create a computerized triage tool that corrected heart rate for pyrexia. If vital signs were outside of age-appropriate norms, an electronic alert forced the triage nurse to consider the shock protocol. If the patient was at high risk (Table 1) or appeared ill, the triage nurse was empowered to call the charge nurse and activate the protocol. With activation, the transport team and PICU charge nurse were also alerted of a potential admission. The patient was immediately taken to a designated room, and an attending physician was called to evaluate the patient and initiate treatment appropriately. Although intended to be activated from triage, the shock protocol could be initiated by nurses or physicians for any patient at any point in the ED stay, and children could be taken off the protocol by an attending physician at any time.

In addition, nurses on the QI team pointed out that the existing nurse/patient ratio was impractical given the urgency and resource intensity of...
shock treatment. With protocol activation, our pediatric transport team (nurse, respiratory therapist, emergency medical technician) now served as ad hoc shock-team responders when available. They assisted in obtaining vascular access, administering medications and fluids, and documentation and transported the patient to the PICU. The additional support for the bedside ED nurse allowed patients in the protocol and their other assigned patients to continue receiving timely care. Also, trends in vital signs are essential for monitoring response to therapy but were obtained infrequently before the protocol because of the lack of resources and standardization. A graphical flow sheet (Fig 1) was created by the team to assist in ongoing assessments and facilitate handoffs across the continuum of care.

A major tenet of goal-directed therapy is the early reversal of volume depletion in the face of a compromised vascular bed.4 Accomplishing this goal required a change in nursing culture, in which isotonic fluid boluses were generally administered over an hour on a pump. All boluses for patients in the protocol were administered via rapid infuser system or using a manual syringe-delivery system. Physicians were notified if vascular access was not obtained in 5 minutes. The goal of this protocol was not to dictate therapy but, rather, to facilitate rapid fluid administration once the decision was made.

The team also identified wide variation in laboratory evaluations and antibiotic therapy. After consultation with subspecialty services, preprinted order sheets (Table 2) were created by the team to standardize therapy and laboratory evaluation. The order-set sequence reflected a stepwise approach to the treatment of shock. Before protocol implementation, ED pharmacists had no acuity-based medication prioritization and filled orders on first-come basis. The preprinted order sets served as a prioritization tool for pharmacists, who hand-delivered medications to the room. In addition, the laboratory prioritized shock protocol tests and made them available within 10 minutes via telephone calls to physicians.

Finally, variation in disposition of patients in the protocol needed to be addressed. The team decided that children who required ≥60 mL/kg of fluid resuscitation would be admitted to the PICU for continued monitoring regardless of their postresuscitation condition. This determination was made because of the lack of data regarding risk stratification of septic children and to avoid boarding ill patients for long periods in the ED until their clinical course was more evident. Well-appearing children who required fluid resuscitation <60 mL/kg were admitted to other hospital units.

After creation of the protocol, a communication strategy was developed. The month before protocol initiation, 2-hour education sessions were conducted with all ED nurses and the transport team to explain inclusion criteria and changes from existing procedures. This education was repeated 4 months later. E-mail communications were sent to ED and PICU staff, and leadership was available to answer questions. Subspecialty services were involved in protocol design to verify acceptable fluid volumes, empiric antibiotics, and pertinent laboratory evaluation. As a continuous QI project, it was recognized that modifications would be necessary and communicated. With feedback, the order set was revised to include additional medications that were commonly used in patients with shock, add laboratory measures, and change empiric antibiotics for previously healthy children. These changes and interval outcome measures were posted in the ED and e-mailed to providers and stakeholders every 2 months.

Of the 191 discrete encounters in 167 unique patients with suspected sepsis, 158 were enrolled at triage and 33 were enrolled after triage (Table 3). Of the encounters enrolled after triage, 21% should have been enrolled at triage. The remainder of the patients were enrolled after physician evaluation; 64% were previously healthy, and 15% had underlying medical problems but did not trigger the screening alert. In addition, through review of all PICU admissions, a diagnosis consistent with systemic inflammatory response syndrome/sepsis was identified in 25

### TABLE 1 Triage Algorithm

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature abnormality</td>
<td>≥100.4°F/38°C&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>High-risk patient (any of the conditions listed)</td>
<td>Malignancy Bone marrow transplant Asplenia</td>
</tr>
<tr>
<td>and Abnormal pulse beyond temperature correction&lt;sup&gt;b&lt;/sup&gt;</td>
<td>—</td>
</tr>
<tr>
<td>and/or Abnormal mental status or capillary refill time of &gt;3 s</td>
<td>—</td>
</tr>
<tr>
<td>or Patient in shock without meeting criteria listed above</td>
<td>—</td>
</tr>
</tbody>
</table>

<sup>a</sup> Fever or hypothermia may have been documented at home or in the ED.
<sup>b</sup> Five beats/1°F above 100°F.
<sup>c</sup> This category requires no vital-sign or risk-factor criterion.
FIGURE 1
Shock flow sheet.
patients for whom the protocol was not used. Of these children, 12% had high-risk conditions; however, none was tachycardic at triage. The nonenrolled patients were more acutely ill and required immediate interventions and initial airway management (Table 4). Statistical process control charts that presented time to interventions in chronological order showed that children on the shock protocol received interventions more rapidly and with less variation than the patients with sepsis in 2009 (Fig 2). There were no rapid-response teams called for patients admitted to non-PICU settings after the shock protocol.

Several changes occurred at a systems level. First, the triage tool was developed with information technology as electronic medical records were introduced. Second, project success led to the protocol being prioritized for integration into electronic algorithms. Third, the protocol was integrated into hospital evidence-based guidelines for shock. Fourth, the decision of where to admit potentially septic children was critically evaluated.

Changes also occurred at the nursing level. The most significant change was that nurses were empowered to initiate the protocol from triage, and the team encouraged physicians to communicate with nurses when the decision was made to stop the protocol. The nurses became protocol advocates. Within 1 month, nurses were asking if fluid boluses for children who were not in shock could be given more rapidly. The nurses were instrumental in redesigning order sets and the flow sheet. There was concern that there would be territorial issues or blurring of responsibilities between the ED nurses and transport team. The ED nurses appreciated the skills and workforce provided by the transport team.

Before project roll-out, we recognized that frequent measurement of vital signs was of minimal utility without creating a documentation system that was easy to complete and read. Multi-tasking ED physicians were given instantly readable graphical vital-sign

<table>
<thead>
<tr>
<th>Table 2 Preprinted Order Set for Shock Protocol</th>
<th>Expected Time Frame From Protocol Initiation</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nursing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vital-sign measurement</td>
<td>Supplemental oxygen; pulse oximetry; cardiopulmonary monitoring</td>
<td>5 min</td>
</tr>
<tr>
<td>Vascular access</td>
<td>No anesthetic creams used; freezing sprays can be used</td>
<td>5–10 min</td>
</tr>
<tr>
<td>Strict monitoring of UOP, fluids administered</td>
<td>Foley catheter if not neutropenic</td>
<td>From onset</td>
</tr>
<tr>
<td>Blood pressure support</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fluid resuscitation</td>
<td>20 mL/kg (maximum: 1 L) IV up to 3 boluses; all boluses were given push-pull or via rapid infuser</td>
<td>15 min (to start of first bolus)</td>
</tr>
<tr>
<td>Vasoactive agents</td>
<td>Warm shock: norepinephrine; cold shock: dopamine ≥ epinephrine</td>
<td>Order with completion of third bolus</td>
</tr>
<tr>
<td>Antibiotic therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High risk (except asplenia)</td>
<td>Piperacillin-tazobactam, aminoglycoside, vancomycin</td>
<td>30 min</td>
</tr>
<tr>
<td>Asplenia and immunologically normal hosts</td>
<td>Ceftriaxone, vancomycin, nafcillin</td>
<td>30 min</td>
</tr>
<tr>
<td>Other medications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stress-dose steroids</td>
<td>Hydrocortisone 100 mg/m²</td>
<td>30 min</td>
</tr>
<tr>
<td>Laboratory, radiographic evaluation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screening laboratory tests</td>
<td>CBC, chemistries; liver panel; DIC panel; CRP, VBG with lactate; consider type and screen</td>
<td>10 min after received by laboratory</td>
</tr>
<tr>
<td>Microbiology</td>
<td>Blood culture: peripheral and central (if applicable); urine culture, rapid RSV and influenza assays</td>
<td>—</td>
</tr>
<tr>
<td>Radiology</td>
<td>Portable chest radiograph</td>
<td>—</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Page primary services; page ICU</td>
<td>—</td>
<td>At time of protocol initiation; with completion of third bolus</td>
</tr>
</tbody>
</table>

UOP indicates urine output; IV, intravenous; BMT, bone marrow transplant; ACTH, adrenocorticotropic hormone; CBC, complete blood count; DIC, disseminated intravascular coagulation; CRP, C-reactive protein; VBG, venous blood gas; RSV, respiratory syncytial virus.
Trends with specific times and quantities of fluid and medications given; thus, flow-sheet results could help guide therapy. A graphical, imminently useful handoff tool for the receiving PICU or other admitting physician was created. It should be noted that although the triage alert did require an electronic medical record (EMR), use of the flow sheet, although it could be incorporated into an EMR, was not contingent on it.

**DISCUSSION**

The Surviving Sepsis Campaign has made great inroads in delivery of timely care for septic adults, and “shock” teams exist in many adult EDs. These teams have led to decreased mortality rates, a decreased need for invasive monitoring in the ICU, and an increased proportion of patients who receive goal-directed therapy per national guidelines. The few published pediatric series have focused on the logistic difficulties with meeting Pediatric Advanced Life Support/American College of Critical Care Medicine (PALS/ACCCM) guidelines. These barri-
ers primarily fall into 2 categories: delays in recognition and delays in implementation of resuscitative measures.\textsuperscript{7,8,17} Our protocol was constructed with these barriers in mind. In our ED, the problem was a delay in recognition of the child in compensated, not decompensated, shock. The triage tool identified vital-sign abnormalities and enabled more timely recognition of patients at risk. The protocol then harnessed additional resources to allow for more timely and ongoing interventions.

The protocol followed Institute of Medicine domains.\textsuperscript{18} It was safe: preprinted order sets offered correct dosage parameters and empiric medications. It was effective: the protocol enabled the ED to implement evidence-based recommendations. It was equitable: all children who met the physiologic criteria could be enrolled. It was patient-centered: parent and patient concerns were addressed at the time of protocol initiation. It was efficient: energy was expended in improving the process rather than reinventing the process with each patient, and there was decreased time in the ED and decreased PICU length of stay. And, it was timely: time to resuscitation was reduced.

We think our approach was successful because of the recognition of a need for improvement by all stakeholders, collaboration, flexibility in responding to feedback, and a culture receptive to change. Care of septic patients was recognized by hospital administration and staff as an improvement opportunity. With leadership support, frontline workers were given the opportunity to make the necessary changes to facilitate flow and dismantle barriers. There was a common vested interest that crossed service lines. Collaboration between the ED and the ICU, and between subspecialty services, was established in the nascent stages. Practitioners provided content expertise and enabled identification and removal of barriers. In turn, the smooth operation of the protocol garnered support from staff. Feedback was elicited from participants and given back to participants individually. The protocol underwent serial reviews and revisions to incorporate suggested modifications, which increased efficiency and empowered staff. Results were shared with the group via posting of interim results in work areas and collaborative conferences. Sharing our successes reinforced interest and belief in protocol efficacy. We evaluated balance measures to make sure that resources for patients who received the shock protocol did not divert care from other children. During the study period, we did not notice weakening in observed gains; delays for our pediatric transport team were not observed. We feel that this was because of nursing co-ownership of the program, repeated educational interventions, and a strong collaborative relationship established between the ED and PICU. Finally, this project came at a time when our hospital had both a culture amenable to change and an ability to analyze processes.

Our experience may not be generalizable for several reasons. First, diagnoses were clinically based; case definitions were not used. Second, given our barriers, we wanted to take a stepwise approach to optimize adoption. Specifically, our target was implementation of the international guidelines. At present, our protocol time frames fall short of this target, but we have a system in place to continuously improve to achieve our goal. This protocol has been an important milestone for our institution. We do not view this as successful completion of a single QI project but, rather, continuous refinement of our QI process as we evolve into a learning organization. From that perspective, we will continue to attempt to reach our target. Third, it was not possible to query physicians regarding clinical decision-making; the purpose of the protocol was not to change decision-making but to make the interventions on the basis of those decisions occur more rapidly and their effects measured more consistently with data presented in more useful ways. Fourth, external validity may be decreased in centers that see lower proportions of high-risk patients and for centers in which existing infrastructure does not allow for increasing caregiver resources. Although this study addressed the obstacles found in our center, each hospital has to address its own obstacles and culture to design a protocol suitable to its individual needs.

We have plans to continue improving. First, the triage tool can be modified to increase sensitivity (eg, modify temperature correction for tachycardia). Increased sensitivity will result in

### TABLE 4 Comparison of Interventions in Children Used at Triage and not Used in the Shock Protocol

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Protocol Used at Triage (n = 158 Encounters)</th>
<th>Protocol not Used (n = 25 Encounters)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triage to first bolus, min\textsuperscript{a}</td>
<td>22</td>
<td>72</td>
</tr>
<tr>
<td>Triage to third bolus, min\textsuperscript{a}</td>
<td>61</td>
<td>279.9</td>
</tr>
<tr>
<td>Total volume of fluid given, mL/kg</td>
<td>38.9</td>
<td>58.8</td>
</tr>
<tr>
<td>Triage to first antibiotic, min\textsuperscript{a}</td>
<td>38</td>
<td>143</td>
</tr>
<tr>
<td>Intubated in ED, %</td>
<td>3.2</td>
<td>20</td>
</tr>
<tr>
<td>Vasectomy medications given in ED, %</td>
<td>10.1</td>
<td>16</td>
</tr>
<tr>
<td>Death during that admission, %</td>
<td>1.9 (PICU)</td>
<td>4 (PICU)</td>
</tr>
<tr>
<td></td>
<td>0.6 (ED)</td>
<td>—</td>
</tr>
</tbody>
</table>

Patients for whom the protocol was used after triage were not included in these analyses.

\textsuperscript{a} The time to intervention had a nonnormal distribution, and the result is presented as a medians.
overtreatment of a minority of children. However, given the risk of missing a child in compensated shock, some false-positives are acceptable. Second, criteria for ICU admission can be modified. If children receive 60 mL/kg of fluid but are then appear well in the ED, they may be candidates to go to non-ICU beds. This protocol change will require frequent vital-sign monitoring, which may be beyond the capacity of acute-care floors and may require change. Third, the use of the protocol can be extended to outpatient clinics and initiated before ED arrival and on transport. The protocol has been adopted already by the outpatient oncology clinic. In addition, efforts to use the protocol for decompensated, acutely ill patients, with and without high risk factors, need to be made. Tables 3 and 4 highlight differences between patients enrolled in the protocol and those who were not. The protocol was not used for many of these acutely ill patients because of the rapid need for airway management, not initially recognized because of the lack of risk factors, or because additional staff were already at the bedside. However, a structured, standardized method may improve their care. Finally, sonographic measurement of hemodynamic parameters may be incorporated. Differentiating between warm and cold shock is not always straightforward, but it does affect selection of vasoactive agents; 1 pediatric study revealed that warm shock was more common in children with central venous catheter infections and cold shock in those with community-acquired sepsis. Bedside ultrasonography may provide real-time quantitative measurements of vascular resistance and cardiac index, which would provide more objective data to optimize therapy. This protocol allowed earlier recognition of children in shock, identified barriers to effective management, and instituted mechanisms to harness additional resources to improve care. Standardization of fluids, antibiotics, laboratory studies, and patient disposition was emphasized, which led to substantial reductions in both time to receipt of time-sensitive interventions and a reduction in variation in how children in shock were treated.

FIGURE 2
A, Statistical process control charts of time to first bolus for children identified at triage. B, Statistical process control charts of time to third bolus for children identified at triage. C, Statistical process control charts of time to first antibiotic for children identified at triage.
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We thank Joan Shook, MD, MBA, Paul Sirbaugh, DO, Charles Macias, MD, MPH, Trung Nguyen, MD, Elizabeth Fredeboelling, RN, Gail Parazynski, RN, and Carol Miller, RN, for their support. Finally, we thank the clinicians and staffs of the ED and PICU for making this project a success.

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