LifeFlow®

Potential Facility Impact of an Innovative Fluid Delivery Device on Outcomes and Costs Associated with Pediatric Septic Shock

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Key Take-Away
Early and rapid fluid resuscitation has been shown to significantly impact health and economic metrics in pediatric septic shock; however, using current techniques providers are rarely able to achieve published fluid delivery guidelines. In this model of fluid resuscitation in pediatric septic shock, use of the LifeFlow Rapid Infuser resulted in lower expected mortality compared to standard IV fluid delivery methods (8% vs. 27%). LifeFlow use also resulted in lower expected hospital costs ($12,865 vs. $45,296), a lower expected average Length of Stay (LOS; 6 days vs.10 days), and significantly greater adherence to ACCM/PALS guidelines for fluid delivery (91% vs. 37%).

Introduction
The LifeFlow Rapid Infuser is a hand-operated device that enables health care providers to rapidly and accurately deliver intravenous (IV) fluids to critically ill patients. This is particularly important in pediatric septic shock, where delays in recognition and treatment may have a profound effect on morbidity, mortality, hospital length of stay, and other health-related outcomes (Balamuth 2016, Lane 2016, Paul 2012). The American College of Critical Care Medicine/Pediatric Advance Life Support (ACCM/PALS) guidelines for septic shock specify that patients receive 20ml/kg within 5 minutes of establishing vascular access, and up to 60ml/kg in the first 15 minutes of care until perfusion improves (Brierley 2009, Davis 2017). Achieving this rate of fluid delivery is difficult, especially in pediatric septic shock; in practice, it is almost never accomplished. Therefore, a commonly accepted goal for fluid resuscitation is three 20ml/kg boluses of fluid delivered within 60 minutes (Davis 2017, Paul 2012).

Current methods of fluid resuscitation include gravity infusion, IV infusion pumps, pressure bags, and the use of manual syringes (the “push-pull” technique, or PPT). All of these techniques have drawbacks which limit the ability of providers to achieve fluid delivery goals. Infusion pumps deliver a maximum rate of 1000ml/hr and can only achieve 60ml/kg over 15 min in patients weighing less than 4kg. Gravity flow is universally too slow, and while the addition of a pressure bag inflated to 300mm/Hg may speed the infusion, this technique requires constant re-inflation to achieve adequate flow (Stoner 2007, Reddick 2011). With PPT, providers may be able to achieve the ACCM/PALS guidelines, but it is a complex and labor-intensive technique (Cole 2014, Stoner 2007, Reddick 2011).

In contrast, LifeFlow provides an intuitive method for rapid, controlled, and measured fluid bolus delivery. This technique enables healthcare professionals to provide an immediate response when a patient requires rapid fluid resuscitation. Simulation and post-market clinical analysis comparing LifeFlow to other fluid delivery alternatives, specifically pressure bags and PPT, has demonstrated that LifeFlow provides fluid volume faster than current standard of care, enabling routine achievement of ACCM/PALS guidelines (Piehl 2016). LifeFlow also improves the accuracy of fluid bolus size administered compared to standard techniques (Data on File, 410 Medical, Inc.).

Because adherence to fluid delivery guidelines is associated with improved health outcomes in pediatric septic shock, it is important for healthcare facilities to understand the clinical and economic implications associated with improved fluid delivery methods compared to current standard of care. This analysis examines expected clinical and economic consequences which may be associated with consistent achievement of fluid resuscitation guidelines through the use of LifeFlow device in pediatric septic shock.

Methods
A decision analytic model (Appendix A) was developed to compare costs and outcomes associated with the decision to utilize LifeFlow technology or the current IV fluid administration standards (infusion pump, pressure bag, or PPT) in pediatric patients presenting with septic shock. The analysis was conducted from the perspective of a facility operating within a traditional fee-for-service reimbursement environment where the facility is not accountable for reducing longer-term costs of patient care.

The model examined probable outcomes and costs based on existing literature on pediatric patients with septic shock, covering the time from Emergency Department (ED) presentation to hospital discharge or death (but not subsequent phases of care). Patient mortality, hospital LOS, the occurrence of "adequate" fluid delivery (60ml/kg within 60 minutes), and facility costs associated with the timeliness of septic shock diagnosis, vascular access, and IV fluid delivery were tracked. Paths 1-12 modeled patients treated with current standard of care and receiving septic shock diagnosis within and after five minutes, vascular access within and after five minutes, and IV fluids within 15 minutes, within 60 minutes, and after 60 minutes, respectively. Paths 13-24 modeled patients treated with LifeFlow in an identical manner. It was conservatively assumed that the availability of LifeFlow could not influence the timeliness of septic shock diagnosis or the timeliness of vascular access; the use of LifeFlow could only influence the speed with which fluid delivery could occur post- vascular access.

For the current standard of care (i.e., standard IV fluid [IVF] delivery), transition probabilities dictating patient movement through the model were drawn from the peer-reviewed literature (Paul 2012; Leisman 2016). For LifeFlow, transition probabilities were drawn from data gathered to obtain regulatory approval and from post-market clinical cases. Model assumptions related to patient mortality were drawn from peer-reviewed literature which demonstrated a two-fold increase in mortality for every hour delay in appropriate fluid delivery (Han 2003). Costs of care associated with septic shock management on each model pathway were obtained from prior studies evaluating the impact of fluid resuscitation on LOS (Paul 2012) and the Agency for Healthcare Research and Quality (AHRQ) Healthcare Utilization Project (HCUP) Kids' Inpatient Database from 2012. All costs were updated to 2016 US$ utilizing the Consumer Price Index for healthcare services. Costs associated with analogous standard of care and LifeFlow pathways (e.g., Path 1 and Path 13; Path 12 and Path 24) were assumed to be identical except for the additional cost of the LifeFlow technology, estimated to be $250 per unit.

Results
As shown in Appendix B, the cost of care on each analogous model pathway was similar for patients managed with standard IV fluid delivery methods vs. LifeFlow with LifeFlow patients incurring only an additional technology acquisition cost of $250. Mortality rates for standard IV fluid delivery methods vs. LifeFlow were identical across analogous model pathways; i.e., mortality depends on time-sensitive patient outcomes (i.e. sepsis diagnosis, vascular access, IV fluid receipt), but not on the means to achieve those outcomes. However, the percentage of patients traversing analogous model pathways varied markedly for patients managed with standard IV fluid delivery methods vs. those managed with LifeFlow. For example, with standard of care delivery, no patients achieved IVF fluid delivery within 15 minutes (Paths 1, 4, 7, and 10), while 60% of LifeFlow patients achieved IVF fluid delivery within 15 minutes (Paths 13, 16, 19, and 22).

Table 1. Expected Costs and Outcomes: Standard IV Fluid Delivery vs. LifeFlow

Costs & Outcomes	Standard IV Fluid Delivery	LifeFlow
Expected Mortality	27%	8%
Expected Hospital Length of Stay (LOS)	10 days	6 days
Expected Likelihood of Adequate Fluid Delivery*	37%	91%
Expected Per Patient Cost	$45,296	$12,865

^Expected mortality, LOS, adequate fluid delivery, and cost were calculated as weighted averages.
**According to ACCM/PALS Guidelines*

The decision to utilize LifeFlow had lower mortality rates as compared to the standard IV fluid delivery methods (8% vs. 27%; Table 1). Furthermore, LifeFlow had lower expected hospital costs compared to standard IV fluid delivery ($12,865 vs. $45,296) and a lower average LOS (6 days vs. 10 days). Additionally, LifeFlow had significantly increased AACM/PALS compliance regarding adequate fluid delivery (91% vs. 37%).

Lastly, to determine if modeled findings were robust to all reasonable changes in model assumptions, one-way sensitivity analyses were performed in which each model variable for LifeFlow and standard IV delivery procedures was allowed to vary up or down by 30% (per standard health economics practice). In all sensitivity analyses, LifeFlow was associated with improved outcomes and lower costs as compared to the current standard IV delivery procedures, demonstrating the stability of modeled results.

Conclusion

Early, rapid fluid resuscitation has been demonstrated to have a significant benefit in the treatment of pediatric septic shock. This analysis demonstrates that the use of LifeFlow may offer a significant mortality and cost benefit compared to standard IV fluid delivery methods for pediatric septic shock presenting in the emergency department. LifeFlow cost savings appear to be due to the shorter inpatient hospital stay and increased ACCM/PALS guideline compliance associated with early, rapid fluid delivery. This analysis adds to the knowledge base regarding the outcomes and related facilities costs of alternative fluid resuscitation treatments in septic shock. When compared to other fluid delivery methods, LifeFlow offers faster, more efficient, and more controlled fluid resuscitation resulting in better patient health and economic outcomes.

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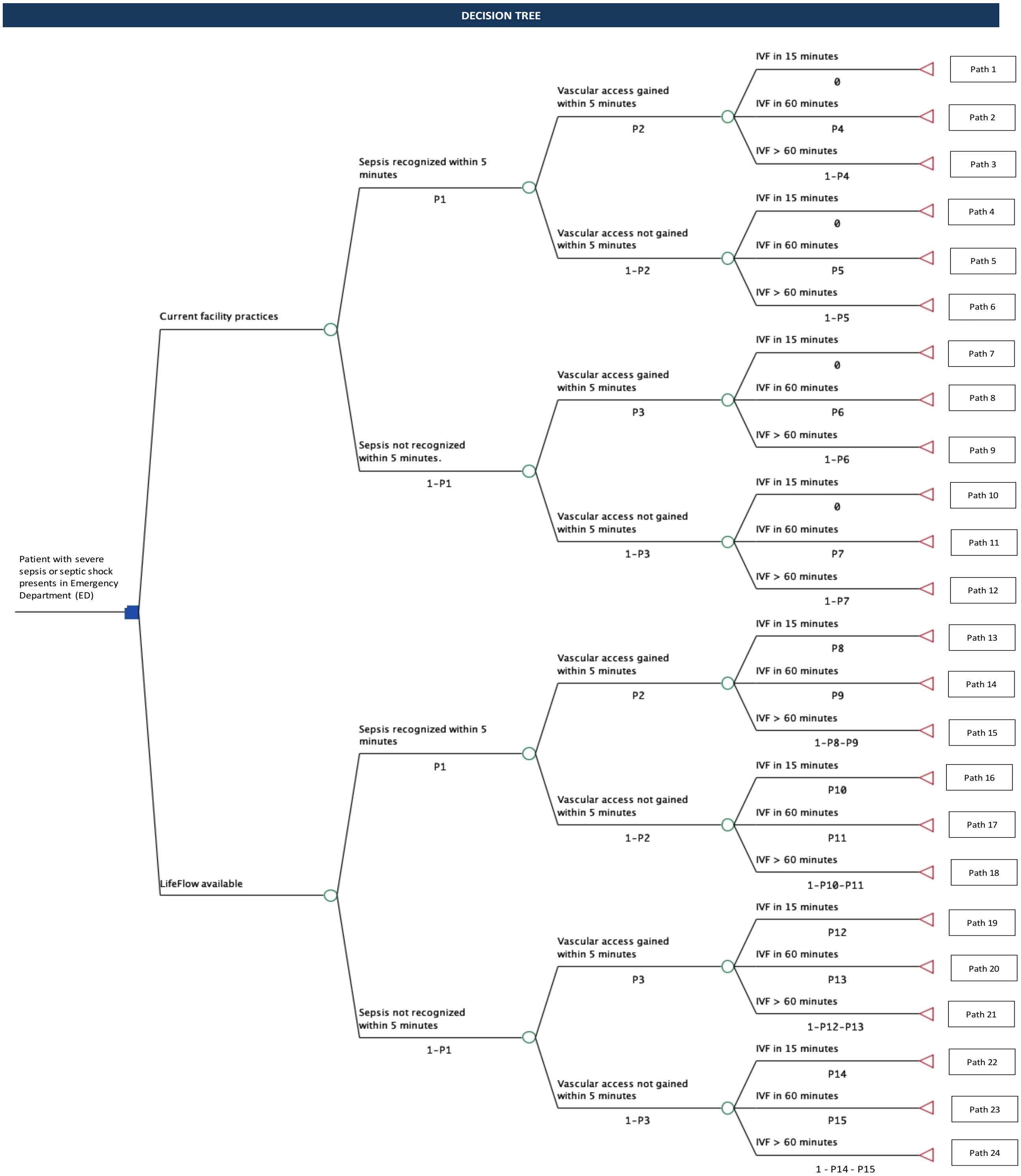
Appendix A: Decision Tree Model Structure



Appendix B: Costs and Outcomes of Standard IV Fluid Delivery vs LifeFlow

Standard IV Fluid Delivery Costs & Outcomes (Paths 1-12)

Path	**Percentage of Patients**	**Mortality**	**Cost of Care**
Path 1 (Sepsis dx ≤5min, vascular access gained ≤5min, IVF ≤15min)	0.0%	4%	$5,037
Path 2 (Sepsis dx ≤5min, vascular access gained ≤5min, IVF ≤60min)	28.6%	8%	$13,599
Path 3 (Sepsis dx ≤5min, vascular access gained ≤5min, IVF >60min)	29.8%	38%	$63,679
Path 4 (Sepsis dx ≤5min, vascular access gained >5min, IVF ≤15min)	0.0%	4%	$5,037
Path 5 (Sepsis dx ≤5min, vascular access gained >5min, IVF ≤60min)	5.8%	8%	$13,599
Path 6 (Sepsis dx ≤5min, vascular access gained >5min, IVF >60min)	14.8%	38%	$63,679
Path 7 (Sepsis dx >5min, vascular access gained ≤5min, IVF ≤15min)	0.0%	4%	$5,037
Path 8 (Sepsis dx >5min, vascular access gained ≤5min, IVF ≤60min)	2.3%	8%	$13,599
Path 9 (Sepsis dx >5min, vascular access gained ≤5min, IVF >60min)	6.9%	38%	$63,679
Path 10 (Sepsis dx >5min, vascular access gained >5min, IVF ≤15min)	0.0%	4%	$5,037
Path 11 (Sepsis dx >5min, vascular access gained >5min, IVF ≤60min)	0.0%	8%	$13,599
Path 12 (Sepsis dx >5min, vascular access gained >5min, IVF >60min)	11.8%	38%	$63,679
Expected Mortality: 27% **Expected Hospital Length of Stay (LOS): 10 days** **Expected Likelihood of Adequate Fluid Delivery according to PALS Guidelines: 37%** **Expected Cost of Standard IV Delivery: $45,296**			

Expected mortality, LOS, adequate fluid delivery, and cost were calculated as weighted averages.

LifeFlow Costs & Outcomes (Paths 13-24)

Path	**Percentage of Patients**	**Mortality**	**Cost of Care**
Path 13 (Sepsis dx ≤5min, vascular access gained ≤5min, IVF ≤15min)	52.7%	4%	$5,287
Path 14 (Sepsis dx ≤5min, vascular access gained ≤5min, IVF ≤60min)	2.9%	8%	$13,849
Path 15 (Sepsis dx ≤5min, vascular access gained ≤5min, IVF >60min)	2.9%	38%	$63,929
Path 16 (Sepsis dx ≤5min, vascular access gained >5min, IVF ≤15min)	5.1%	4%	$5,287
Path 17 (Sepsis dx ≤5min, vascular access gained >5min, IVF ≤60min)	15.4%	8%	$13,849
Path 18 (Sepsis dx ≤5min, vascular access gained >5min, IVF >60min)	0.0%	38%	$63,929
Path 19 (Sepsis dx >5min, vascular access gained ≤5min, IVF ≤15min)	2.3%	4%	$5,287
Path 20 (Sepsis dx >5min, vascular access gained ≤5min, IVF ≤60min)	6.9%	8%	$13,849
Path 21 (Sepsis dx >5min, vascular access gained ≤5min, IVF >60min)	0.0%	38%	$63,929
Path 22 (Sepsis dx >5min, vascular access gained >5min, IVF ≤15min)	0.0%	4%	$5,287
Path 23 (Sepsis dx >5min, vascular access gained >5min, IVF ≤60min)	5.9%	8%	$13,849
Path 24 (Sepsis dx >5min, vascular access gained >5min, IVF >60min)	5.9%	38%	$63,929
Expected Mortality: 8% **Expected Hospital Length of Stay (LOS): 6 days** **Expected Likelihood of Adequate Fluid Delivery according to PALS Guidelines: 91%** **Expected Cost of LifeFlow: $12,865**			

Expected mortality, LOS, adequate fluid delivery, and cost were calculated as weighted averages.