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# **Final Report on Options for Treatment of Severe Sepsis and Septicemia**

**As Required By S.B. 1542 and Rider 85, 83<sup>rd</sup> Legislature,  
Regular Session, 2013**

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**Health and Human Services Commission  
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## Executive Summary

S.B. 1542, 83<sup>rd</sup> Legislature, Regular Session, 2013 mandates the Texas Health and Human Services Commission (HHSC) to develop and implement a quality improvement process to receive and evaluate selected suggestions for clinical initiatives designed to improve the quality of care and the cost-effectiveness of the Medicaid program. Part of this legislation requires HHSC to conduct a full analysis and submit a final report for a clinical initiative related to requiring hospitals to implement evidence-based protocols, including early goal-directed therapy, for treatment of severe sepsis and septicemia by January 1, 2014. Similarly, Rider 85 in the *2013-2014 General Appropriations Act, S.B. 1, 83rd Legislature, Regular Session, 2013 (Article II, Health and Human Services Commission)* entitled “Study and Report on Sepsis Infections in Medicaid” requires HHSC to publish a report on findings from an analysis on this topic by September 1, 2014. This report fulfills the requirements for both legislations.

## Scope of the Report

This report:

- Outlines the relative strengths and weaknesses of early goal-directed therapy (EGDT), the most widely used evidence-based protocol for the treatment of severe sepsis, as compared to traditional therapies;
- Provides a comprehensive review and impact assessment of initiatives underway related to this topic;
- Describes a set of policy options and considerations, ranging from prescriptive (i.e., statutory and/or regulatory requirements) to market- or incentive-based (i.e., outcome-based financial incentives/disincentives); and
- Discusses whether additional information is needed in order to better evaluate impacts (i.e., perform additional studies/evaluation of initiatives already underway).

## Background on “Sepsis”

Sepsis is a general term used to describe a syndrome that occurs when the body’s immune system overreacts to a local infection, resulting in uncontrolled system-wide inflammation. Since 1991, diagnostic criteria for sepsis have evolved to characterize the disease as a continuum of progressively worsening clinical states accompanied by associated signs and symptoms. Based on the most current diagnostic criteria, “sepsis” can be further broken down into categories, as follows:

- **Systemic inflammatory response syndrome (SIRS)** is diagnosed when a patient presents with at least two of four vital signs: (1) temperature greater than 38.3°C (100.4°F) or less than 36°C (96.8°F); (2) heart rate greater than 90 beats per minute; (3) respiratory rate greater than 20 breaths per minute; and (4) white blood cell count greater than 12,000/mm<sup>3</sup> or less than 4,000/mm<sup>3</sup> or with greater than 10 percent bands.
- **Sepsis** is SIRS with a strongly suspected or confirmed infection. Sepsis can be caused by bacteria, virus, fungi, or parasites.
- **Septicemia** refers to bacterial infection in the blood.

- **Severe sepsis** is sepsis associated with hypotension or acute organ dysfunction.
- **Septic shock** is severe sepsis associated with hypotension that remains unresolved even after attempts of fluid resuscitation.

This report focuses primarily on sepsis, severe sepsis, and septicemia. These clinical states are associated with high mortality, morbidity, and health care costs. Results from an epidemiologic study of seven states using 1995 hospital discharge data showed that at a cost of \$16.7 billion per year, more than 750,000 cases of *severe sepsis* (as specified in the study) and 215,000 related deaths occur in the United States. Data from the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases (SID) sponsored by the Agency of Healthcare Research and Quality showed that in 2011 *septicemia* was the most expensive condition billed to Medicare and the second most expensive billed to Medicaid.

For healthcare utilization associated with sepsis, severe sepsis, and septicemia in Texas, an analysis of Medicaid claims and encounter data showed that in 2012, a total of 27,423 clients (fee-for-service and managed care) who had a primary diagnosis of sepsis (including severe sepsis) and septicemia received inpatient, outpatient, and professional services with estimated total costs of \$112.5 million. These data are based on diagnosis codes specific to sepsis, severe sepsis, and septicemia. Consequently, additional cases of sepsis may have been coded under another primary diagnosis, thus contributing to underestimation of the actual burden.

In terms of mortality related to sepsis, severe sepsis, and septicemia in Texas, the best available data are those published by the Texas Department of State Health Services. However, the data is limited to *septicemia* (i.e., bacterial infection in the blood). There are no known reliable estimates for sepsis or severe sepsis in Texas. The number of deaths attributed to *septicemia* increased from 2,649 deaths in 2006 to 3,166 deaths in 2010. Whether this increase in the number of deaths related to *septicemia* was associated with an increase in the total Medicaid population of the corresponding year is unclear. The increase in number of deaths could be due to better compliance with coding and reporting by the hospitals.

There are various approaches to identifying and treating “sepsis” within a hospital setting. Most studies in current literature focus on *severe sepsis* and *septic shock*. This report focuses on comparing and contrasting traditional treatment strategies with more aggressive approaches, most notably early goal-directed therapy (EGDT) protocols, for *severe sepsis* (to correspond with the scope of this report and what is available in the literature). Because there are also numerous initiatives underway to either avert or treat sepsis, severe sepsis, and septicemia, information on these was also provided to give the reader a full picture of prevention and intervention efforts.

Generally, treatment of sepsis, septicemia, or severe sepsis upon a patient’s presentation to the emergency department involves identifying the source of infection, administering appropriate antibiotic therapy, and monitoring the patient’s hemodynamic and physiologic functions (e.g., blood pressure, heart rate, and respiratory rate). Depending on which clinical state the patient is in (i.e., sepsis, septicemia, or severe sepsis), additional therapies such as drugs to increase blood pressure and the heart’s ability to contract and other support measures such as mechanical ventilation may be given.

More aggressive approaches, namely EGDT, involve screening for patients at high risk for developing sepsis, intensive monitoring of certain parameters (i.e., serum lactate level, central venous oxygenation saturation, mean arterial pressure, and central venous pressure), and administering treatment accordingly before admission to the intensive care unit (ICU). Each approach is based on a set of clinical decision-making criteria; hence for the purposes of this report, each is considered “evidenced-based.”

## **Findings**

Based on HHSC staff’s analysis of the literature, survey results, input from stakeholders, and public comments, some studies and anecdotal sources (e.g., news articles, presentations, or testimonies) the findings were split between implementation of EGDT rendering a positive impact to skepticism of any effect of EGDT on patient outcomes. EGDT has been shown to be associated with positive clinical impacts on individuals (e.g., decrease in the patient’s length of hospital stay, decrease in patient mortality) and potential for cost savings (e.g., reduced hospital payments and lower post-discharge utilization and costs). However, there are concerns about the effectiveness of monitoring certain parameters as guidelines to administer therapy and strength of evidence (i.e., use of relatively small patient cohorts and single-center studies), as well as barriers encountered in efforts to implement EGDT protocols. Further research to validate the effectiveness of EGDT is currently in the pipeline at the national and international levels, including several clinical trials to address some of the methodological concerns reported in the literature (e.g., use of relatively small patient cohorts and single-center studies).

Currently, there are a number of sepsis-related quality improvement initiatives underway in Texas. Some 20 Delivery System Reform Incentive Payment (DSRIP) projects funded through the Medicaid 1115 waiver (Texas Healthcare Transformation and Quality Improvement Program) in Texas aim to improve quality of care and reduce sepsis-related mortality through the use of sepsis management bundles. In addition, several hospitals such as the Methodist Hospital Research Institute in Houston and Baylor Regional Medical Center at Plano in Plano have realized positive outcomes as a result of their efforts and are continuing to revise their project goals to further improve sepsis care in their hospital/health systems. Texas may benefit from the study of patient, provider, and system outcomes in these projects.

## **Conclusion**

Given the current state of evidence and available data, the staff was unable to extrapolate potential impacts to Medicaid (i.e., estimates of overall improvements in morbidity, mortality, and cost savings) associated with requiring hospitals to implement evidence-based protocols, including early goal directed therapy for the treatment of severe sepsis and septicemia. Using healthcare claims and encounter data as the primary sources for analysis, staff was unable to quantify the specific types of intervention utilized by each hospital to treat sepsis and septicemia-related diagnoses (i.e., traditional vs. EGDT interventions). An accurate assessment of the impact would require a much more extensive evaluation such as provider-level medical records review (resources and timing are insufficient). Additionally, to implement this initiative as written in the bill would require additional legislative action. However, there are a number of ways to address this clinical topic in addition to a statutory/regulatory approach and staff has

provided a number of alternative strategies for consideration. These are described in Table 3 of the report.

## **Introduction**

S.B. 1542 was passed in the 83<sup>rd</sup> Texas Legislative Session in 2013. This legislation relates to clinical initiatives to improve the quality of care and cost-effectiveness of the Medicaid program. It directs the Texas Health and Human Services Commission (HHSC) to develop and implement a quality improvement process to receive and evaluate suggestions for clinical initiatives designed to potentially improve quality of care provided under and the cost-effectiveness of the Medicaid program. In addition, the bill requires HHSC to conduct a full analysis and issue a final report in accordance with the requirements of the bill for an initiative that would require hospitals to implement evidence-based protocols, including early goal-directed therapy, for treatment of severe sepsis and septicemia by January 1, 2014.

Similarly, Rider 85 in the *2013-2014 General Appropriations Act, S.B. 1, 83rd Legislature, Regular Session, 2013 (Article II, Health and Human Services Commission)* entitled “Study and Report on Sepsis Infections in Medicaid” requires HHSC to publish a report on findings from an analysis on this topic by September 1, 2014.

This report fulfills the requirements for both pieces of legislation. Sections relevant for this report are summarized below.

## **Legislation**

Section 538.0521 in Section 1 of the S.B. 1542 requires HHSC to conduct a full analysis and issue a final report for an initiative that would require hospitals to implement evidence-based protocols, including EGDT, for the treatment of severe sepsis and septicemia as specified in the following sections.

Section 538.054 specifies the key elements that must be included in the analysis for the clinical initiative related to requiring hospitals to implement evidence-based protocols for treatment of severe sepsis and septicemia. The analysis included:

- Public comments and submitted research relating to the initiative;
- Available clinical research and historical utilization information relating to the initiative;
- Published medical literature relating to the initiative;
- Adoption of the initiative by medical societies or other clinical groups;
- Whether the initiative has been implemented under the Medicare program, another state medical assistance program, or a state-operated health care program, including the child health plan program;
- Results of reports, research, pilot programs, or clinical studies relating to the initiative conducted by institutions of higher education, including related medical schools; governmental entities and agencies; and private and nonprofit think tanks and research groups;
- Any potential impact that the initiative would have on the Medicaid program if implemented in this state, including: (1) an estimate of the number of recipients under the Medicaid program that would be impacted by implementation of the initiative; (2) a description of any

potential cost savings to the state that would result from implementation of the initiative; and  
(3) any statutory barriers to implementation of the initiative.

Section 538.055 specifies the key components that must be included in the final report for this clinical initiative. Based on the requirements described in Section 538.054, the final report includes:

- A final determination of the feasibility of implementing the initiative, the likely impact implementing the initiative would have on the quality of care provided under the Medicaid program, and the anticipated cost savings to the state that would result from implementing the initiative;
- A summary of the public comments, including a description of any opposition to the initiative;
- An identification of any statutory barriers to implementation of the initiative; and
- If the initiative is not implemented, an explanation of the decision not to implement the initiative.

Finally, Section 538.057 describes action on the clinical initiative to be taken by the commission.

## Background

### *Definitions of Severe Sepsis and Septicemia*

Sepsis is a general term used to describe a syndrome that occurs when the body's immune system overreacts to a local infection, resulting in uncontrolled system-wide inflammation. Since 1991, diagnostic criteria for sepsis have evolved to characterize the disease as a continuum of progressively worsening clinical states accompanied by associated signs and symptoms. Based on the most current diagnostic criteria, "sepsis" can be further broken down into categories as follows:

- **Systemic inflammatory response syndrome (SIRS)** is diagnosed when a patient presents with at least two of four vital signs: (1) temperature greater than 38.3°C (100.4°F) or less than 36°C (96.8°F); (2) heart rate greater than 90 beats per minute; (3) respiratory rate greater than 20 breaths per minute; and (4) white blood cell count greater than 12,000/mm<sup>3</sup> or less than 4,000/mm<sup>3</sup> or with greater than 10 percent bands.
- **Sepsis** is SIRS with a strongly suspected or confirmed infection. Sepsis can be caused by bacteria, virus, fungi, or parasites.
- **Septicemia** refers to bacterial infection in the blood.
- **Severe sepsis** is sepsis associated with hypotension or acute organ dysfunction.
- **Septic shock** is severe sepsis associated with hypotension that remains unresolved even after attempts of fluid resuscitation.

While improved understanding of sepsis pathophysiology has allowed more clearly defined diagnostic criteria, the interchangeable use of terms to describe "sepsis" in addition to refinement of diagnostic criteria may have caused confusion among clinicians.<sup>1</sup> These changes may also affect estimates of sepsis burden in terms of prevalence, incidence, and costs. For example, the term *septicemia*, defined as sepsis caused by a bacterial infection, is no longer commonly used in the literature. However, estimates of sepsis occurrence and costs based on data predating the 2012 updated diagnostic criteria are based on this term (See also Epidemiology of Severe Sepsis and Septicemia). In addition, although more accurately defined diagnostic criteria are available, signs and symptoms associated with "sepsis" often lack specificity, thereby inhibiting early detection and accurate diagnosis (i.e., SIRS can be caused by trauma, stroke, and other conditions, not just sepsis).<sup>2</sup> Furthermore, the etiology of "sepsis" is complex, with a multitude of possible biomarkers but no definitive source.<sup>3</sup>

### *Epidemiology and Impact of Severe Sepsis and Septicemia*

Sepsis, severe sepsis, and septicemia are associated with high mortality, morbidity, and health care costs. Results from an epidemiologic study of seven states using 1995 hospital discharge data showed that at a cost of \$16.7 billion per year, more than 750,000 cases of severe sepsis and 215,000 related deaths occur in the United States, with a projected annual increase of 1.5 percent

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<sup>1</sup> Rivers et al. 2008, Critical Care Clinics

<sup>2</sup> Perman et al., 2012

<sup>3</sup> Faix, 2013

in the number of cases.<sup>4</sup> Healthcare costs were higher in infants diagnosed with severe sepsis, as well as in patients who did not survive severe sepsis, were admitted to the ICU because of severe sepsis, underwent surgical procedures and developed severe sepsis, or suffered from more extensive organ failure that resulted in severe sepsis. The mortality rate for severe sepsis is estimated to be between 40 and 50 percent and increases with age, ranging from 10 percent in children to 38.4 percent in adults 85 years and older.<sup>5</sup>

Data from the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases (SID) project, sponsored by the Agency of Healthcare Research and Quality (AHRQ), illustrated the burden of sepsis and septicemia in terms of hospital charges, average length of stay and average charge per hospital discharge, and in-hospital deaths in the U.S. It is important to note that *sepsis* was used to report 2008 data while *septicemia* was used to report 2011 data. These two terms were used interchangeably.<sup>6</sup>

In 2008, *sepsis* ranked as the second most expensive condition treated in U.S. hospitals by all payers.<sup>7</sup> It accounts for approximately 4.1 percent (i.e., \$48 billion) of the total national hospital bill (i.e., \$1,155 billion) and 791,000 hospital stays.<sup>8</sup> By payer category, *sepsis* was the most expensive condition billed to Medicare (\$30.5 billion, 5.7 percent of total national hospital charges for Medicare, and 535,000 hospital stays) and the third most expensive condition billed to Medicaid (\$5.7 billion, 3.6 percent of total national hospital charges for Medicaid, and 73,000 hospital stays).

In 2011, excluding childbirth, *septicemia* (i.e., bacterial infection in the blood) was the most expensive condition treated in U.S. hospitals by all payers. It accounted for 5.2 percent (i.e., \$20.3 billion) of total national costs for all hospitalizations (i.e., \$387.3 billion) and more than one million hospital discharges.<sup>9</sup> *Septicemia* was the most expensive condition billed to Medicare (\$12.7 billion, 6.9 percent of total national costs for Medicare, and 722,000 hospital discharges) and the second most expensive condition billed to Medicaid (\$2.7 billion or 4.5 percent of national costs for Medicaid and 113,000 hospital discharges).

Trends in hospitalizations and readmissions associated with septicemia were also examined using HCUP SID data for seven states: Arizona, California, Florida, Nebraska, New York, Utah, and Washington. Across these states, the rate of hospitalizations related to septicemia as a primary or secondary diagnosis increased more than 32 percent from 491.8 per 100,000 in 2005 to 651.3 per 100,000 in 2010.<sup>10</sup> In 2010, more than 350,000 individuals were admitted to the hospital at least one time with a septicemia diagnosis, and 16 percent were admitted two or more times for septicemia within a one-year period compared to 11.5 percent in 2005. Of all the patients admitted with septicemia as a principal diagnosis in 2010, 46.8 percent of patients were

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<sup>4</sup> Angus et al., 2001

<sup>5</sup> Angus et al., 2001

<sup>6</sup> Sutton and Friedman, 2013

<sup>7</sup> Based on most recently published data online from the Healthcare Cost and Utilization Project (HCUP) sponsored by the Agency for Healthcare Research and Quality (AHRQ); sepsis was the ninth most expensive of all payer types in 2004 and sixth in 2006

<sup>8</sup> Wier and Andrews, 2011

<sup>9</sup> Torio and Andrews, 2011

<sup>10</sup> Sutton and Friedman, 2013

readmitted, while 24.6 percent of those who were not readmitted were discharged to a long-term care facility.<sup>11</sup>

The HCUP database also allows customized queries for obtaining state-level estimates of inpatient service use.<sup>12</sup> In 2011, Texas had 6,515 hospital discharges, with an average length of stay of 10.7 days, an average charge of \$100,795 per discharge, and 722 in-hospital deaths associated with *septicemia* (See Table 5 in Appendix B for comparisons across all types of payers for Texas).

For Texas Medicaid programs, data from healthcare claims and encounters show varying numbers of *sepsis* and *septicemia* cases and associated costs for fiscal years 2011 and 2012. In 2011, there were 25,016 clients in the FFS only program with a primary diagnosis of sepsis or septicemia that received inpatient, outpatient, and professional services at a total cost of \$93.7 million. In comparison, 27,444 clients with a primary diagnosis of sepsis or septicemia received services at a total cost of \$103.2 million. A total of 3,193 clients receiving services through managed care plans had a primary diagnosis of sepsis or septicemia and received services at a total cost of nearly \$9.5 million. Data for 2012 showed a similar distribution of the number of clients with a primary diagnosis of *sepsis* or *septicemia* with clients in managed care plans having received a noticeably larger increase in total amounts paid for related services (See Tables 6 and 7 in Appendix C). However, any comparisons between numbers for 2011 and 2012 should be made with caution because in March 2012, many clients in fee-for-service (FFS) and primary care case management (PCCM) Medicaid programs were transferred to Medicaid programs being managed by health maintenance organization (HMO) health plans.<sup>13</sup> The numbers associated with the Texas Medicaid program, as described above are based on specific diagnosis codes for *sepsis* and *septicemia*. Accordingly, this may understate the actual impact of “sepsis” in Texas.

In terms of mortality related to “sepsis” in Texas, the best available data reported were for *septicemia* (i.e., bacterial infection in the blood) by the Texas Department of State Health Services. The number of deaths attributed to *septicemia* increased from 2,649 deaths in 2006 to 3,166 deaths in 2010.<sup>14</sup> Whether this increase in the number of deaths attributed to *septicemia* was associated with an increase in the total Medicaid population of the corresponding year is unclear. The increase could be due to better compliance with reporting by the hospitals (See Table 4 in Appendix B).

*(Note: The lack of consistency of the terms used in the various data sources discussed above could be due to recent revisions in the definition and diagnostic criteria of “sepsis.” A lack of consistent definitions or diagnostic criteria used to determine sepsis burden can influence the*

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<sup>11</sup> Sutton and Friedman, 2013

<sup>12</sup> Agency of Healthcare Research and Quality. H-CUPnet – Information on stays in hospitals for participating states from the HCUP state inpatient databases (SID). <http://hcupnet.ahrq.gov/HCUInet.jsp?Id=174B078CD115D8D6&Form=SelCROSSTAB&JS=Y&Action=%3E%3ENext%3E%3E&Oneway=Yes>. Accessed October 1, 2013.

<sup>13</sup> Texas Health and Human Services Commission, Strategic Decision Support, Research Team, November 2013; \* Note: Health Plan Encounters represent totals submitted by the individual HMO Health Plans. Paid amounts are only estimates for services paid and do not represent dollars paid by HHSC as HMO Health Plans are paid on a capitated basis method.

<sup>14</sup> Texas Department of State Health Services. Table 18 – Resident Mortality from Selected Causes in Texas, 2006-2010, <http://www.dshs.state.tx.us/chs/vstat/vs10/t18.shtm>. Accessed October 14, 2013.

*accuracy of its incidence and prevalence, as well as quality metrics used to track progress being made in quality improvement efforts.)*

### *Treatment of Severe Sepsis and Septicemia*

Due to the non-specific nature of signs and symptoms used to diagnose “sepsis,” its complex etiology, and the challenge of identifying the causative infectious agent, treating “sepsis” early, before it progresses to a worse state, is challenging.<sup>15,16</sup> Furthermore, symptoms associated with “sepsis” can lead clinicians to easily misdiagnose septic patients with other conditions (e.g., stroke, flu, etc.).<sup>17</sup>

**Traditional therapy for sepsis:** This approach consists of identifying the causative infectious agent, administering the appropriate antibiotic to rid the body of the infection, and continuous monitoring of the patient’s hemodynamic and physiologic functions (e.g., blood pressure, organ function, and fluid status). In addition, depending on the patient’s vitals, drugs that increase blood pressure and the heart’s ability to contract (i.e., vasopressors and inotropes, respectively) as well as other supportive measures (e.g., mechanical ventilation, sedation, glucose control, and renal replacement) are administered.<sup>18,19,20</sup> Effective management of sepsis requires an individualized, multi-prong/multi-modality approach.<sup>21,22</sup>

Extensive research has been conducted internationally for at least the past two decades in efforts to identify the optimal therapeutic regimens that can be used as the evidence-based protocol for the treatment of sepsis. Some treatment modalities demonstrate a moderate effect while others demonstrate little or no effect (e.g., corticosteroids).<sup>23,24</sup> The most prominent therapeutic approach for sepsis treatment researched and discussed to date is EGDT.

**Early goal-directed therapy for sepsis (EGDT):** This approach involves screening patients who are at high risk for developing sepsis by monitoring certain hemodynamic and physiologic parameters intensively (i.e., blood pressure, heart rate, and respiratory rate) and administering aggressive treatment (i.e., fluids, antibiotic, or vasopressor) within the “golden hours” to maintain or restore the patient’s vitals back to optimal functioning before the syndrome progresses to a worsened state.<sup>25</sup> The “golden hours” is a time frame during which “definitive recognition and treatment provide maximal benefit in terms of outcome.”<sup>26</sup> These golden hours may elapse in the emergency department, hospital unit, or the intensive care unit and are condition-specific. For *severe sepsis*, it is six hours as specified by the care bundle protocol

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<sup>15</sup> Nguyen and Smith, 2007

<sup>16</sup> Angus and Poll, 2013

<sup>17</sup> Perman et al., 2012

<sup>18</sup> Angus and Poll, 2013

<sup>19</sup> Nguyen and Smith, 2007

<sup>20</sup> Dellinger et al. Surviving Sepsis Campaign guidelines, 2012

<sup>21</sup> Surviving Sepsis Campaign guidelines, 2012

<sup>22</sup> Faix, 2013

<sup>23</sup> Annane et al., 2009

<sup>24</sup> Skrupky et al., 2011

<sup>25</sup> Rivers et al., 2001

<sup>26</sup> Rivers et al., 2001

provided by the Surviving Sepsis Campaign (SSC) guidelines (See Appendix D for a description of sepsis management bundles).<sup>27</sup>

Key elements of EGDT include measuring serum lactate level, administering aggressive volume resuscitation (i.e., 5 liters), rapid transfer to the ICU, and continuous monitoring of central venous oxygen saturation, central venous pressure, and mean arterial pressure.<sup>28</sup> EGDT has been used to treat severe sepsis and septic shock in the ICU and involves adjusting the amount of blood flowing through the heart as well as the heart's ability to contract as a means to balance oxygen demand and oxygen delivery to organ tissue using measures such as the administration of certain drugs.<sup>29,30</sup> (See Appendix D for a flow chart of EGDT protocol and sepsis management bundles.)

A landmark study published in 2001 showed that EGDT was efficacious in reducing hospital mortality for patients who presented to the emergency department (ED) with signs and symptoms of SIRS or sepsis and received EGDT compared to similar patients who received standard therapy. Since then, a number of studies have also demonstrated that EGDT is associated with a significant reduction in hospital mortality, a decrease in the average length of stay, and potential cost savings.<sup>31,32,33</sup> One study showed that potential cost-effectiveness and cost-savings of EGDT is primarily due to a reduction in ICU length of stay.<sup>34</sup> Evidence from these research studies culminated in the SSC guidelines, which describe a comprehensive approach to sepsis management, including two sepsis management bundles to be used for quality improvement.<sup>35</sup> More recently, a number of studies have also examined the effectiveness of instituting these bundles; and, most notably, the compliance rate associated with using them. Some of these studies showed that a higher compliance rate was associated with reduced hospital mortality and average length of stay.<sup>36,37,38</sup> (Rivers and Ahrens, as well as others, have published comprehensive reviews of EGDT and quality improvement tools for its implementation.<sup>39,40</sup>)

Although a number of studies have demonstrated that EGDT is associated with some key positive clinical outcomes, the strength of evidence as determined by the SSC Steering Committee remains moderate. Some criticisms surrounding EGDT include:

- Recommendations in the SSC guidelines are not evidence-based.<sup>41</sup>
- Major components of the 6-hour bundle (based on EGDT) are based on a single-center study, which is under scrutiny for its validity.<sup>42</sup>

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<sup>27</sup> Dellinger et al. Surviving Sepsis Campaign guidelines, 2012

<sup>28</sup> Presentation by Edwards Lifesciences, November 6, 2013

<sup>29</sup> Rivers et al., 2001

<sup>30</sup> Lees et al., 2009

<sup>31</sup> Thielke and King, 2013

<sup>32</sup> Rivers et al., 2008

<sup>33</sup> Levy et al., 2010

<sup>34</sup> Huang et al., 2007

<sup>35</sup> Dellinger et al. Surviving Sepsis Campaign guidelines, 2012

<sup>36</sup> Zubrow et al., 2008

<sup>37</sup> Nguyen et al., 2007

<sup>38</sup> Sawyer et al., 2011

<sup>39</sup> Rivers and Ahrens, 2008

<sup>40</sup> Nguyen et al., 2006

<sup>41</sup> Marik, 2011

- Early trials of EGDT are based on the use of a pulmonary artery catheter (PAC), which was considered synonymous with EGDT.<sup>43</sup> When studies supporting PAC showed conflicting evidence, there was some confusion about which patients may benefit from EGDT.
- Standard parameters for EGDT have been found to be not predictive of desired outcomes or are not routinely being used to adjust treatments to improve outcomes.<sup>44</sup> Use of certain parameters are controversial (i.e., lactate blood level and venous oxygen saturation as key parameters).<sup>45</sup>
- The exact components required to optimize resuscitation (e.g., choice and amount of fluids, appropriate type and intensity of hemodynamic monitoring, and role of adjunctive vasoactive agents) remain debatable.<sup>46</sup>

Further research to validate the effectiveness of EGDT is currently in the pipeline. Other forms of evidence are more anecdotal (e.g., news articles, presentations, or testimonies). It appears there are several current clinical trials underway related to EGDT that address some of the concerns reported in the literature (e.g., use of relatively small patient cohorts and single-center studies) (See Appendix E for summaries of selected research studies). It should be noted the use of small patient cohorts in these studies may be understandable and expected in critical care research because critical care units may see only a handful of septic patients during a short timeframe in which the study takes place.

### *Challenges and Barriers of Implementing Early Goal-Directed Therapy Protocols*

In addition to the concerns surrounding the concept of EGDT, there are a number of challenges and barriers related to the implementation of this therapeutic approach. As reported in the literature and in a survey to hospitals conducted by HHSC staff, hospitals that have attempted to implement these protocols encountered some of the following challenges and barriers:

- Equipment limitations, staff shortages, and resistance from institutional administration and staff<sup>47</sup>
- Limited critical care resources<sup>48</sup>
- Many units are unable to admit high-risk patients pre-operatively to institute EGDT, and many high-risk patients do not return to a critical care environment following surgery.<sup>49</sup>
- Barriers and risks associated with placement of central venous access for monitoring of venous oxygen saturation<sup>50</sup>

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<sup>42</sup> However, a number of studies have attempted to validate findings from the 2001 landmark study, including three major clinical trials that are examining the impact of implementing resuscitation bundles based on EGDT (i.e., Protocolized Care for Early Septic Shock, ProCESS, U.S.; Protocolized Management in Sepsis, ProMISe, U.K.; and Australasian Resuscitation in Sepsis Evaluation Randomized Controlled Trial, ARISE) (See Appendix E).

<sup>43</sup> Lees et al., 2009

<sup>44</sup> Lees et al., 2009

<sup>45</sup> Jones et al., 2010

<sup>46</sup> Angus and Poll, 2013

<sup>47</sup> Rivers et al. 2008, Critical Care Clinics

<sup>48</sup> Lees et al., 2009

<sup>49</sup> Lees et al., 2009

<sup>50</sup> Perman et al., 2012

However, some hospitals and quality improvement experts focusing on sepsis care have proposed possible solutions to overcome these challenges and barriers including providing physician education and identifying a leader or group of leaders who have the knowledge, resources, and authority to remove barriers to take on the role of quality improvement champion to initiate culture change within the organization.<sup>51,52,53</sup>

In a survey administered through the Texas Hospital Association to obtain information on hospitals' experience with implementing evidence-based protocols to treat sepsis, 10 responded. These hospitals reported the following challenges and solutions with which they used to overcome them:

- Difficulty with culture of care, silos, and complexity of implementing a functioning process
- The bundle, though simplified, is still difficult to implement and adhere to
- Invasive devices for hemodynamic assessment (e.g., CVP, arterial line, and SvcO2) are frequently not obtained due to practitioner's inability to place lines or being uncomfortable with their use. Use of non-invasive devices may be helpful but require new training (e.g., handheld echo) or additional funding (e.g., NICOM).
- Physician buy-in – Some physicians do not believe that all patients who meet SIRS criteria with a source of infection are necessarily septic. There is a lot of resistance from established community-based physicians. Sometimes physicians are not receptive to a non-physician clinician instructing them on how to treat their patients.
- Physician training – Family practice and internal medicine physicians in rural and small hospital settings are, in general, uncomfortable with treating severe sepsis and septic shock and have been slow to follow evidence-based practices; traveling, interdisciplinary simulation is hard to carry out.

Some of the hospitals that responded to the survey reported they are overcoming the barriers listed above through physician education on the continuum of sepsis, rationale for starting fluids and antibiotics based on diagnostic criteria, evidence-based protocols, and other strategies for protocol implementation. One hospital reported that their primary focus is to ensure that providers in both the emergency department and the critical care unit are fully engaged in the protocol implementation process. In the context of quality improvement, an integrated healthcare delivery system that supports clinical care team collaboration, thereby eliminating silos, should be encouraged. In order to achieve this, organizational culture would need transformation.

### *National and International Quality Improvement Initiatives for Sepsis Management*

To help increase awareness of the importance of reducing mortality related to sepsis, a number of national organizations and quality improvement initiatives have been established. These organizations provide educational materials, raise funds for research, and develop toolkits to facilitate process improvement efforts related to implementing EGDT (Table 1).

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<sup>51</sup> Rivers et al., 2008, Critical Care Clinics

<sup>52</sup> Nguyen et al., 2006

<sup>53</sup> Institute for Healthcare Improvement

**Table 1 Quality Improvement Initiatives for Sepsis Management**

<u>Organization</u>	<u>Role</u>
Surviving Sepsis Campaign <sup>54</sup>	Champions quality improvement in sepsis management worldwide. Developed evidence-based practice guidelines, including EGDT, in 2004 that were later updated in 2008 and 2012.
Sepsis Alliance <sup>55</sup>	Increases awareness of sepsis to promote early detection and treatment. Provides information and educational material to the public and medical professionals and raises funds for research.
Institute for Healthcare Improvement <sup>56,57</sup>	Helped Surviving Sepsis Campaign steering committee develop the treatment guidelines for sepsis that include severe sepsis 3-hour resuscitation bundle and 6-hour septic shock bundle as well as a quality improvement program. <sup>58</sup>
High Value Healthcare Collaborative <sup>59</sup>	Is implementing sepsis bundled care measures as part of a three-year Centers for Medicare and Medicaid Services (CMS) innovation award.
Joint Commission Center for Transforming Healthcare <sup>60</sup>	In June 2012, launched a project to reduce sepsis mortality by addressing barriers that may hinder “consistent, successful implementation of early detection and rapid initiative of appropriate treatment” for sepsis management. Is working with five leading hospitals and health centers to identify root causes of barriers and find solutions.
Agency for Healthcare Research and Quality Protocol <sup>61</sup>	In October 2013, released a new protocol for implementing universal decolonization in adult ICUs to improve infection control based on materials used in the Randomized Evaluation of Decolonization vs. Universal Clearance to Eliminate Methicillin-Resistant <i>Staphylococcus aureus</i> Trial, which showed universal decolonization to be the most effective intervention to prevent ICU infection.

<sup>54</sup> Surviving Sepsis Campaign. About the surviving sepsis campaign. <http://www.survivingsepsis.org/About-SSC/Pages/default.aspx>. Accessed November 7, 2013.

<sup>55</sup> Sepsis Alliance. <http://www.sepsisalliance.org/about/>. Accessed November 7, 2013.

<sup>56</sup> Severe sepsis bundles <http://www.ihl.org/knowledge/Pages/SevereSepsisBundles.aspx>

<sup>57</sup> Using care bundles to improve health care quality <http://www.ihl.org/knowledge/Pages/IHIWhitePapers/UsingCareBundles.aspx>

<sup>58</sup> The bundles were originally 6 hours for initial resuscitation and 24 hour management; since the latest update of the SSC guidelines, the 6 hour bundle has been split into 3 hour and 6 hour and the 24 hour management bundle eliminated from the guidelines (Institute for Healthcare Improvement, Severe sepsis bundles).

<sup>59</sup> High Value Healthcare Collaborative (HVHC). Sepsis Improvement. <http://highvaluehealthcare.org/what-we-do/clinical-areas/sepsis>. Accessed October 8, 2013.

<sup>60</sup> Joint Commission Center for Transforming Healthcare. [http://www.centerfortransforminghealthcare.org/assets/4/6/CTH\\_Sepsis\\_Fact\\_Sheet.pdf](http://www.centerfortransforminghealthcare.org/assets/4/6/CTH_Sepsis_Fact_Sheet.pdf). November 7, 2013.

<sup>61</sup> Agency for Healthcare Research and Quality. Universal ICU Decolonization: An Enhanced Protocol. [http://www.ahrq.gov/professionals/systems/hospital/universal\\_icu\\_decolonization/index.html](http://www.ahrq.gov/professionals/systems/hospital/universal_icu_decolonization/index.html). Accessed October 4, 2013.

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**Organization****Role**

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*Other States' Quality Improvement Initiatives for Sepsis Management*

Some states have already taken action to address sepsis-related mortality, either through regulation, collaborative efforts, or Medicaid waiver funds (Table 2).

**Table 2 State Quality Improvement Initiatives for Sepsis Management**

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<b><u>State</u></b>	<b><u>Description</u></b>
New York State Department of Health Sepsis Regulations (2013) <sup>62,63</sup>	Requires all hospitals to adopt best practices for early identification and treatment of sepsis. These measures have been implemented through the state's Department of Health and have been estimated to save 5,000-8,000 lives per year.
Kansas Sepsis Project (2009) <sup>64,65</sup>	Aims to reduce mortality from severe sepsis in Kansas by 10% by the end of 2015. The project mission is to teach physicians, extenders, and nurses in all specialties and in hospitals of every size to recognize severe sepsis, to realize that it is an emergency, and to take rapid, organized steps to treat it aggressively and successfully.
KanCare 1115 DSRIP Project (2013) <sup>66</sup>	Statewide expansion of sepsis early-warning and escalation process – To expand on work already done in an inpatient setting around early identification and treatment of sepsis to the general public and long-term/extended care facilities (i.e., Kansas Sepsis Project).
Kaiser Permanente's Saving Lives Through Better Sepsis Care (2008) <sup>67,68</sup>	In 2008, in response to sepsis being identified as number one cause of death in U.S. hospitals, Kaiser Permanente in Northern California (KPNC) developed a program to screen and provide effective treatments to hospital patients identified at risk for sepsis. Since implementation, KPNC has reduced mortality for

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<sup>62</sup> Governor Andrew M. Cuomo. Governor Cuomo announces New York State to lead the nation in fighting sepsis. January 29, 2013 (Albany, New York). <http://governor.ny.gov/print/4975>. Accessed September 12, 2013.

<sup>63</sup> New York State Department of Health. Sepsis regulations: guidance document 405.4(a)(4). Revised July 2013. [http://www.health.ny.gov/regulations/public\\_health\\_law/section/405/index.htm](http://www.health.ny.gov/regulations/public_health_law/section/405/index.htm). Accessed October 4, 2013.

<sup>64</sup> University of Kansas Medical Center. Kansas sepsis project. <https://coa.kumc.edu/kansassepsis/>. Accessed October 4, 2013.

<sup>65</sup> Midwest Critical Care Collaborative. Kansas sepsis project. <http://www.mwcritcare.org/sepsis-project>. Accessed October 4, 2013.

<sup>66</sup> KanCare 1115 DSRIP Project. [http://kancare.ks.gov/download/Kansas\\_DSRIP\\_Protocols.pdf](http://kancare.ks.gov/download/Kansas_DSRIP_Protocols.pdf). Accessed October 4, 2013.

<sup>67</sup> Kaiser Permanente News Center. Clinical Excellence, April 14, 2011. Saving lives through better sepsis care. <http://xnet.kp.org/newscenter/clinicalexcellence/2011/041411sepsis.html>. Accessed October 29, 2013.

<sup>68</sup> Kaiser Permanente Institute for Health Policy. Kaiser Permanente policy story, V1, No. 4. Saving lives through better sepsis care. 2012. <http://www.kpihp.org/wp-content/uploads/2012/10/KPStories-v1-no4-Sepsis-FINAL-B.pdf>. Accessed October 29, 2013.

<u>State</u>	<u>Description</u>
	patients admitted to hospitals with sepsis by more than 40 percent, more than 1,400 lives saved. Based on its success, the program is introduced in all Kaiser Permanente hospitals.
The University of California, San Francisco's Integrated Nurse Leadership Program (2008) <sup>69</sup>	A 22-month collaborative involving nine San Francisco Bay area hospitals that focused on reducing deaths from sepsis. In general, participating hospitals adopted four common approaches: sepsis screening of all patients, fast-track workup to confirm diagnosis, initiatives to promote adherence to protocols that call for prompt initiation of appropriate treatment, and ongoing monitoring. During the study period, mortality among sepsis patients was reduced by 44%; one-year post-study mortality decreased 54.4% and was sustained from 2 years after the study at 49.8%.
Robert Wood Johnson University Hospital (2012) <sup>70</sup>	To decrease length of stay and standardize care for adult sepsis patients, the hospital formed a task force. The approach they undertook included detecting and alerting for signs of sepsis in adult medical and surgical patients; and developing a research-based, best practice protocol for treating these patients. The protocol consisted of two phases: first 6 hours of treatment after sepsis has been identified and treatment after first 6 hours, throughout hospitalization. Length of stay was reduced by 2.1 days (as of January 2012).

In addition, a survey developed by HHSC was sent to state Medicaid directors outside of Texas to inquire about whether their respective states require hospitals to implement evidence-based protocols for the treatment of severe sepsis and septicemia. One state responded and reported that they do not currently have regulations that require hospitals to implement evidence-based protocols for the treatment of sepsis due to other competing priorities but referred to New York's regulatory requirements (See Appendix G for more details).

*Texas: Related State and Local Quality Improvement Initiatives*

**Medicaid Reimbursement Adjustments and Quality Improvement Strategies Based on Potentially Preventable Events**

The HHSC initiatives related to potentially preventable events (PPEs) do not focus specifically on the intervention and management of sepsis, severe sepsis and septicemia, but rather avoidance of these conditions, as well as other potentially preventable events. They are based on diagnosis-related group (DRGs) that include septicemia (potentially avoidable incidence of) and risk-

<sup>69</sup> AHRQ Healthcare Innovations Exchange, 2008

<sup>70</sup> Anglin and Biddle, 2012

adjusted rates that can be used to promote quality improvement through payment models that include financial incentives/disincentives.

HHSC has begun to focus on PPEs as key healthcare outcome measures, which may encompass quality issues such as access to care, coordination of care, and quality of care. The effort related to PPEs began in January 2011, with the reporting of Potentially Preventable Readmissions (PPRs) to hospitals for FFS and managed care populations. In February 2012, HHSC began reporting rates and costs associated with Potentially Preventable Admissions (PPAs), PPRs, and Potentially Preventable Emergency Room Visit (PPVs) to managed care organizations (MCOs) that administer the STAR and STAR+PLUS programs and CHIP. This effort has expanded to include Potentially Preventable Complications (PPCs). Potentially Preventable Ancillary Services (PPSs) will likely be a future measure, but more development is needed.

**Fee-For-Service (FFS) Medicaid:** In FFS Medicaid, hospital payment adjustments based on rates of PPRs were implemented in May 2013. HHSC implemented similar hospital payment adjustments for PPCs later in November 2013.

**Managed Care Medicaid/CHIP:** MCO capitation rate adjustments are being implemented in fiscal year 2014. These adjustments are/will be based on hospital performance for PPRs and PPCs in each MCO's network.

Additionally, beginning in calendar year 2014, PPVs, PPAs, and PPRs will be utilized in the MCO incentive/disincentive (capitation at-risk) program. This program will place *four percent* of the MCO capitation at-risk amounts based on their performance on a set of quality measures, including PPVs, PPAs, and PPRs.

HHSC has started to use performance data related to PPEs coupled with financial incentives/disincentives to promote healthcare quality and efficiency within the Medicaid/CHIP programs. In particular, compared to other PPEs, PPCs and PPRs capture a relatively large proportion of cases and costs among Medicaid clients with a principle diagnosis of sepsis and septicemia. (For more details, see reports on PPCs and PPRs for Texas Medicaid populations for fiscal years 2009-2012 in Appendix D).

### **Definition of PPEs and Measurement of PPEs**

To provide context for how PPEs are useful quality indicators for monitoring progress in quality improvement related to sepsis care, each type of PPE is described below.<sup>71</sup>

- **Potentially Preventable Emergency Department Visit (PPV):** treatment of a person in a hospital emergency room or freestanding emergency medical care facility for a condition that may not require emergency medical attention because the condition could be, or could have been, treated or prevented by a physician or other health care provider in a nonemergency setting.

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71 Goldfield et al., 2012

*Designed to measure:* Outpatient provider accessibility, quality and efficacy; while sepsis, severe sepsis, and septicemia are not the exclusive focus of PPRs; the avoidance of these conditions is being measured

- **Potentially Preventable Admission (PPA):** an admission of a person to a hospital or long-term care facility that may have reasonably been prevented with adequate access to ambulatory care or health care coordination.

*Designed to measure:* Outpatient provider accessibility, quality and efficacy; while sepsis, severe sepsis, and septicemia are not the exclusive focus of PPRs; the avoidance of these conditions is being measured

- **Potentially Preventable Readmission (PPR):** a return hospitalization of a person within a period specified by HHSC that may have resulted from deficiencies in the care or treatment provided to the person during a previous hospital stay or from deficiencies in post-hospital discharge follow-up. The term does not include a hospital readmission necessitated by the occurrence of unrelated events after the discharge. The term includes the readmission of a person to a hospital for: (A) the same condition or procedure for which the person was previously admitted; (B) an infection or other complication resulting from care previously provided; or (C) a condition or procedure that indicates that a surgical intervention performed during a previous admission was unsuccessful in achieving the anticipated outcome.

*Designed to measure:* Hospital discharge process, MCO coordination of discharge and linkages to outpatient provider(s), outpatient provider coordination with discharging hospital, and accessibility, quality and efficacy; while sepsis, severe sepsis, and septicemia are not the exclusive focus of PPRs; the avoidance of these conditions is being measured

- **Potentially Preventable Complication (PPC):** a harmful event or negative outcome with respect to a person, including an infection or surgical complication, that: (A) occurs after the person's admission to a hospital or long-term care facility; and (B) may have resulted from the care, lack of care, or treatment provided during the hospital or long-term care facility stay rather than from the natural progression of an underlying disease.

*Designed to measure:* Quality and efficacy of care provided within a hospital setting; while sepsis, severe sepsis, and septicemia are not the exclusive focus of PPCs; the avoidance of these conditions is being measured

- **Potentially Preventable Ancillary Service (PPS):** a health care service provided or ordered by a physician or other health care provider to supplement or support the evaluation or treatment of a patient, including a diagnostic test, laboratory test, therapy service, or radiology service, that may not be reasonably necessary for the provision of quality health care or treatment.

*Designed to measure:* Potential over-provision of unnecessary ancillary services (procedures, treatments and other inventions)

## **Department of State Health Services (DSHS) Strategies**

The Texas Department of State Health Services received funding from CMS to establish a website to report healthcare-associated infection statistics.<sup>72</sup> The agency is also monitoring potentially preventable hospitalizations.<sup>73</sup> Even though these two initiatives do not explicitly track septicemia or sepsis, the conditions they do track (i.e., bacterial pneumonia and blood-borne infections) will help to reduce or minimize the incidence of sepsis in Texas.

In addition, future DSHS data collection and public reporting efforts will focus on potentially preventable complications (PPCs) and potentially preventable re-admissions (PPRs) for select provider types (hospitals and ambulatory surgical centers) across all payers. These initiatives by DSHS offer another strategy for helping to reduce the incidence of sepsis and costs associated with healthcare utilization attributed to sepsis in Texas.

### **1115 Medicaid Transformation Waiver's Delivery System Reform Incentive Payments (DSRIP) Projects**

At the local level, there are numerous quality improvement initiatives occurring in individual hospitals or health systems. In particular, through the 1115 Medicaid Transformation Waiver's Delivery System Reform Incentive Payments (DSRIP) projects, 21 of some 1,200 approved projects submitted by the 20 Regional Healthcare Partnerships (RHP) in Texas are evaluating the use of sepsis resuscitation and sepsis management bundles to reduce PPCs (See Table 14 in Appendix F).<sup>74</sup> Although the approved total amount for these projects is more than \$160 million, the actual valuations of the projects are based on each RHP's calculation and HHSC/CMS approval. The funding amounts to be distributed to the hospitals responsible for these DSRIP projects will depend on actual reported outcomes of the projects.

### **MCO Performance Improvement Projects**

Currently, there are not any MCO plans conducting performance improvement projects related to improving sepsis care because the condition is not explicitly tracked by the quality measures that the MCOs are required to report.

### **Other Projects or Initiatives**

In addition to the DSRIP projects, some hospitals in Texas have received federal funding to continue existing projects that focus on improving sepsis care. For example, Methodist Hospital Research Institute in Houston received a three-year grant totaling nearly \$14.4 million from the Centers for Medicare and Medicaid Services (CMS) Health Care Innovation Awards Program to

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<sup>72</sup> Texas Department of State Health Services. Health care-associated infections. [http://www.dshs.state.tx.us/idcu/health/infection\\_control/hai/](http://www.dshs.state.tx.us/idcu/health/infection_control/hai/). Accessed November 18, 2013.

<sup>73</sup> Texas Department of State Health Services. Potentially preventable hospitalizations. <http://www.dshs.state.tx.us/ph/default.shtm>. Accessed November 5, 2013.

<sup>74</sup> Texas Health and Human Services Commission (HHSC). Summaries of proposed delivery system reform incentive payment (DSRIP) projects – based on regional healthcare partnership plan submissions for federal review. <http://www.hhsc.state.tx.us/1115-Waiver-Guideline.shtml>. Accessed October 1, 2013.

continue their work on the Sepsis Early Recognition and Response Initiative (SERRI).<sup>75</sup> This initiative aimed to prevent inpatient sepsis and reduce mortality by identifying and treating sepsis early before it progresses. From 2008 to 2011, SERRI reported having saved 465 lives and potential costs of \$13.5 million. Over a three-year period, the Methodist Hospital's program will train an estimated 950 bedside nurses in sepsis screening and early recognition of the often subtle signs and symptoms of early sepsis. Additionally, an estimated 50 nurse practitioners will be trained in screening, recognition and EGDT for sepsis.

Baylor Regional Medical Center at Plano in Plano is working on reducing mortality associated with severe sepsis through a multidisciplinary approach to identify and treat severe sepsis early.<sup>76</sup> This project has resulted in a reduction of sepsis-related mortality from 31.7 percent in 2008 to 10 percent in 2009, improvements to the compliance rate with the 6-hour bundle from 79.4 to 86.0 percent in 2010 and 2011 respectively, a decrease in average length of stay per case from 15.3 in 2008 to 9.4 in 2011, and a reduction in average cost per case from \$122,839 in 2008 to \$72,517 in 2011. The project goal has been updated to reduce the severe sepsis mortality rate to less than ten percent with a ten percent reduction in length-of-stay and cost index by the end of 2011.

## **Policy Options for Texas Medicaid System**

### **Description of the Medicaid Service Delivery System**

Whether hospitals should be required to implement evidence-based protocols, including EGDT, for the treatment of severe sepsis and septicemia under the Medicaid program in Texas depends on a number of factors, particularly: the structure of the Texas Medicaid system, what the Medicaid program aims to accomplish through this clinical initiative, available resources, and current quality improvement efforts. There are also a number of alternatives to requiring hospitals to implement these protocols for treatment of severe sepsis and septicemia.

A key factor to consider for any of the options outlined below is the current structure of the Texas Medicaid system. The Medicaid system in Texas has been undergoing a process of transformation since the late 1990s. With this process, Texas Medicaid is now administered predominantly through a managed care model, in which the State competitively procures full-risk MCO contracts as opposed to the FFS model, in which the State's claims administrator pays provider claims on a unit-rate basis. Through more comprehensive managed care contracts, the MCOs develop provider networks, manage enrollee care through innovative approaches (such as alternative provider payment models, or other incentives/disincentives), adjudicate provider claims, maintain customer service centers, and provide other administrative services.

The transition of more populations and services to a managed care model will continue to occur as directed by S.B. 7, S.B. 58 and S.B. 8, 83rd Legislature, 2013. These populations and services include Nursing Facilities and Populations, Community Based Long Term Services and Supports, Children with Disabilities (S.B. 7), Mental Health Rehabilitation and Mental Health

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<sup>75</sup> Bricker D. News & Publications – Methodist granted \$26.2 million to protect Texas patients. June 15, 2012, Houston, TX. <http://www.houstonmethodist.org/body.cfm?id=495&action=detail&ref=926>. Accessed October 22, 2013.

<sup>76</sup> Texas Hospital Association, 2012

Targeted Case Management Services (S.B. 58) and Nonemergency Medicaid Medical Transportation Services (S.B. 8).

As a result of the shrinking FFS Medicaid program, approaches to quality improvement must consider the dynamics and expectations inherent within a comprehensive and risk-based managed care contracting structure. This includes delineation of contractual requirements vis-à-vis state and federal requirements and priorities and assumption of risk by the contractors, but also the mutual alignment of State, MCO and provider incentives, whenever possible.

### **Summary of Potential Options and Considerations**

There are a variety of options available to the Medicaid program to maximize quality improvements and achieve cost savings/efficiencies related to the identification and treatment of sepsis and sepsis-related conditions. As with many efforts aimed at improving healthcare quality, a single option may not be sufficient in addressing the need. Often, combinations of options are needed. These options and considerations are described in Table 3. Several of the options described may help to achieve buy-in from clinicians (i.e., engaging physicians and nurses as well as their respective advocacy organizations).

**Table 3 Options and Considerations for Texas (not exhaustive)**

Option	Description of Option	Considerations
Implement Statutory and Regulatory Requirements	Require that hospitals implement specific evidence based protocols through legislation and/or changes to DSHS hospital licensing requirements.	<ul style="list-style-type: none"> <li>• This is prescriptive. This may result in higher initial costs, but may be reduced over time. This may result in fewer sepsis-related inpatient deaths.</li> <li>• A regulatory approach is not without precedent. Example: New York has passed this type of legislation. Results not yet available (as of the date this report was completed).</li> <li>• This will likely increase operating costs to hospitals, and may result in reduced hospital revenue due to potential reductions in length of stay and reduced ICU admissions.</li> <li>• This requirement would impact all payers besides Medicaid.</li> </ul>
Implement Quality Based Payments:  Financial Incentives or Disincentives	<ul style="list-style-type: none"> <li>• Continue with existing quality-based payment policies - hospital reimbursement and MCO capitation reductions based on high rates of PPRs and PPCs, reimbursement policy for preventable adverse events (PAEs).</li> <li>• This is not limited to sepsis and sepsis related conditions, but rather a broader range of conditions.</li> <li>• Hospitals determine the most efficacious interventions based on clinicians' clinical judgment.</li> </ul>	<ul style="list-style-type: none"> <li>• Focus is on <i>avoidance</i> of potentially preventable events.</li> <li>• Disincentivizes undesirable outcomes, but does not prescribe processes at provider level.</li> <li>• An incentive pool, is chosen as an option, provides incentives, in addition to well as disincentives.</li> <li>• Reimbursement reductions for PPR and PPC are currently in place in both FFS and managed care models.</li> </ul>

Option	Description of Option	Considerations
	<ul style="list-style-type: none"> <li data-bbox="680 256 1241 467">Incentive pool: Use funds retained from reimbursement reductions due to high rates of PPCs, and use some or all of those funds for financial incentives (bonuses) for hospitals with low rates of PPCs.</li> </ul>	
Add-on payment for EGDT sepsis management bundle	Institute new billable sepsis management bundles	<ul style="list-style-type: none"> <li data-bbox="1268 532 1908 602">This would result in higher initial costs, but may be reduced over time.</li> <li data-bbox="1268 610 1908 680">This may result in fewer sepsis-related deaths in the hospital setting.</li> <li data-bbox="1268 688 1908 760">This may help offset increased hospital costs if EGDT is required</li> </ul>
Include Sepsis Related Metrics in MCO Pay for Quality Program (capitation at-risk)	Use PPCs or a subset of PPCs (e.g., sepsis) as a quality measure for MCO Pay-for-Quality.	May have a compounding effect on quality improvement if used with other approaches. It is unclear whether the MCO model can influence this type of hospital metric.
Evaluate and Determine Most Desirable Approach Based on Evaluation of Current Clinical Trials	There are three large clinical trials examining the impact of implementing resuscitation bundles based on EGDT: ProCESS (Protocolized Care for Early Septic Shock, U.S.), ProMISe (Protocolized Management in Sepsis, U.K.), and ARISE (Australasian Resuscitation in Sepsis Evaluation Randomized Controlled Trial).	Results from these studies may further support use of EGDT.

<b>Option</b>	<b>Description of Option</b>	<b>Considerations</b>
Adopt a More Narrow Focus on Select PPC and/or PPRs	<ul style="list-style-type: none"> <li>• Similar to current approach used with PPC, but create a more narrow PPC list (currently 64 PPCs), to focus on highest cost and/or severity PPCs (including sepsis)</li> <li>• Depending on the prevalence of sepsis and sepsis-related conditions in PPCs, this same approach can be adopted for PPRs.</li> </ul>	<ul style="list-style-type: none"> <li>• Not all PPCs/PPRs have the same level of cost or severity so focusing on the most prominent ones may be useful.</li> <li>• If the list is narrowed (eliminate low-priority items), more time can be spent focusing on the high-priority items. That will increase the probability of realizing savings and improve performance.</li> </ul>
Evaluate DSRIP Projects to Assess Impact	These projects are being conducted at the local level, and therefore evidence that is applicable to hospitals in Texas could be evaluated.	Results from these projects can help inform policy decisions regarding which approach may be optimal for Texas.
Increase State and Hospital Association Collaborations Related to Sepsis Campaigns	This approach will help to increase awareness of this clinical issue among hospitals in Texas and achieve buy-in from hospitals and advocacy organizations.	Instead of requiring hospitals to implement evidence-based protocols straightaway, increasing awareness and understanding of this clinical issue may help to improve buy-in.
Require Inclusion of Sepsis Quality Improvement Project in MCO Collaborative Performance Improvement Projects (PIPs)	HHSC may prescribe MCOs to work with hospitals and collaborate on Performance Improvement Projects (PIPs) in targeted areas.	This would have to be weighed against other HHSC priorities.
Evaluate Other State’s Experience where Regulatory Requirement was Implemented (e.g. New York)	Information related to impacts of such requirements is still pending.	There may be unintended consequences that HHSC/Texas can avoid by evaluating results from these other state's experiences.

<b>Option</b>	<b>Description of Option</b>	<b>Considerations</b>
Texas Hospital Association to establish an association-led advisory committee to establish a direction and/or to make recommendations to HHSC	As with other high priority initiatives or activities, subject matter experts from the field may provide meaningful input on the problem and the solution.	This requires dedication of resources and collaboration by participants.
Improve Medicaid Public Reporting	Institute a more transparent and accessible public reporting process for MCOs and hospitals.	S.B. 7, 83rd legislative session, 2013 public reporting requirements related to hospitals.
Use Experience Rebate Funds or other funds to create a recognition/award program for sepsis quality improvement	A targeted recognition/award program for MCOs, regions, or hospitals to publicly recognize best practices/outcomes.	<ul style="list-style-type: none"> <li>• Ensuring that the data analysis that leads to the recognition is sound (i.e., risk adjustment, proper coding) can be challenging.</li> <li>• Because there are already numerous recognition programs of different types, the addition of such a program may be underappreciated by hospitals and not sufficiently “incentivizing.”</li> </ul>
Comparison study of hospitals that have implemented EGDT compared to those that have not implemented EGDT	A more in-depth study that compares outcomes and costs for hospitals that have implemented EGDT to hospitals that have not. This study could yield valuable information and help inform policy.	This is resource intensive; however, the DSRIP projects may be leveraged for this effort and could yield valuable information.
Addition of coding modifier to identify hospitals that have implemented sepsis bundles	To better ascertain impact of sepsis bundles and outcomes (e.g., mortality).	<ul style="list-style-type: none"> <li>• Cost and feasibility issues</li> <li>• Determine methods on linking death data to claims and encounter data and to look at</li> </ul>

<b>Option</b>	<b>Description of Option</b>	<b>Considerations</b>
Implement programs that will facilitate organizational culture change.	By eliminating silos and encouraging integrated and collaborative clinical care team functions.	<p>association with length of stay and other clinical/financial outcomes.</p> <p>A consideration would be that culture change takes a long time to achieve, and the associated benefits are not immediately realized. The State could provide resources (i.e. funds, consultants, etc.) to help hospitals that are having difficulties in identifying issues and executing process improvement.</p>
Combination of Approaches	Implementation of a combination of approaches listed above.	Multi-pronged approaches can often produce desired results.

## **Estimations of Quality and Fiscal Impacts, and Statutory Barriers**

Per S.B. 1542, HHSC shall assess the potential impact that requiring hospitals to implement evidence-based protocols, including EGDT may have, with:

- An estimate of the number of recipients under the Medicaid program that would be impacted by implementation of the initiative; and
- A description of any potential cost savings to the State that would result from implementation of the initiative, and
- Any statutory barriers to implementation of the initiative.

### *Number of Medicaid Recipients Impacted and Potential Cost Savings*

Based on an analysis of the current literature and anecdotal evidence (e.g., data collected from surveys on EGDT implementation in Texas and other states), the staff is unable to extrapolate potential impacts (i.e., estimates of overall morbidity, mortality, and cost savings) of requiring hospitals to implement evidence-based protocols, including EGDT, for the treatment of severe sepsis and septicemia, to the larger Texas Medicaid program at this time. The primary reason for this is the inability to detect the specific type of intervention utilized by a specific hospital for sepsis and septicemia-related diagnoses (i.e., traditional vs. EGDT interventions). An accurate assessment of the impact would require a much more extensive evaluation such as medical records review (for which there was not sufficient time or resources).

### *Statutory Barriers*

For Texas to require hospitals to implement evidence-based protocols, including EGDT, legislation would have to be passed and subsequent regulatory changes for DSHS hospital licensing made. Although not without precedent, this approach would have to consider the impact on Texas hospitals and should be executed in a thoroughly planned and coordinated manner.

## **Conclusion**

Sepsis, severe sepsis, and septicemia are associated with high mortality, morbidity, and healthcare costs. While there is an abundance of research showing that EGDT has the potential to result in improved patient outcomes and reduced healthcare costs compared to standard interventions, existing evidence appears inconclusive. However, there are several national and international organizations advocating for increased use of evidence-based protocols, particularly EGDT, and providing ample resources to promote the use of sepsis resuscitation bundle to treat severe sepsis and septicemia. Several states have already implemented quality improvement initiatives related to enhancing sepsis care with the goal of reducing mortality associated with sepsis. There are also a number of projects funded through federal grants and Medicaid waiver funds in Texas. Given these resources, especially the number of Texas-specific projects targeted towards sepsis interventions (i.e., DSRIP projects), along with current clinical trials, other states' experiences (particularly New York and California), and projects being conducted in Texas

hospitals, Texas may benefit from waiting for results from the aforementioned initiatives. In addition, implementing this clinical initiative would require additional legislative action.

For the aforementioned reasons, HHSC may choose to explore alternative strategies or further study a variety of options as described in Table 3 of the report. Some major factors such as the structure of the Texas Medicaid program, consideration of the most effective approach to achieve desired clinical and financial outcomes should also be considered (i.e., through the legislative and regulatory process, or through a package of MCO and/or provider incentives and disincentives). Furthermore, regardless of which option is selected, a more in-depth examination of the actual sepsis burden specific to the Texas Medicaid population is warranted in order to track the effectiveness of the proposed interventions.

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## Appendix A Public Comments

An announcement of S.B. 1542, 83<sup>rd</sup> Texas Legislature, 2013 soliciting public comments regarding this required clinical initiative was published in the Texas Register on September 20, 2013. The public had 30 days to provide comments. These public comments are separate from the public comments related to the rules of this bill.

### **Dr. Charles G. Macias, Baylor College of Medicine/Texas Children's Hospital, Chair of Pediatric Septic Shock of the American Academy of Pediatrics, October 29, 2013, Email**

*In regards to SB 1542, specifically for sepsis and septic shock, I am submitting the following critical points of interest:*

- *The importance of quality of care and cost effectiveness of clinical care delivery in the state of Texas is of paramount importance to improving outcomes of care for children. Particularly for sepsis and suspected sepsis, there is a gap between known outcomes of care in children and published recommendations for care (goal directed therapy). Mortality and morbidity remain problematic. As the chairman of a national Quality Improvement Collaborative under the umbrella of the American Academy of Pediatrics for Pediatric Septic Shock, we have been engaged in strategies to improve the recognition and escalation of care for children with suspected sepsis for over two years in children's hospitals across the country. We have developed metrics and intervention strategies that should inform best practices to drive those outcomes. Unfortunately, as with other pediatric diseases, the science is imperfect and much of the challenge with improving the outcomes for septic shock and suspected sepsis, is a paucity of evidence (published research) in the pediatric literature. Thus, the importance of evidence based guidelines, which can minimize variations in practice and improve outcomes by improving diagnostic accuracy and therapeutic effectiveness has surfaced as a critical element of implementing quality improvement strategies for addressing these needs. In the absence of best evidence, agreement for shared baselines is critical to improve the efficiency and effectiveness of care delivery within any health care infrastructure. As such, we believe that the adoption of shared baselines (whether as evidence based guidelines, care pathways or clinical pathways) will enhance the outcomes of care. We have demonstrated this to be the case in published work here at Texas Children's Hospital (Cruz A, et al. Pediatrics) as have others at Primary Children's Hospital in Salt Lake City. Similarly, reductions in mortality have been seen in observational studies in children when goal directed therapy is known to have been utilized (Han Y, et al).*
- *We would endorse a requirement for evidence based approaches to diagnosing and treating children with septic shock or suspected septic shock in the state of Texas. We believe that in order for such activity to be meaningful and effective at producing outcomes intended, both process and outcomes metrics also need to be clinically relevant and instituted across the state for meaningful transformation of local and aggregated data. This is particularly important with this condition as evidence has demonstrated that infrastructure changes (and not individual provider changes) are necessary to deliver rapid recognition and treatment to these children. Such metrics would define mortality as important, but would also have to*

*include more sensitive metrics of time to first IV fluid bolus, and time to antibiotics as critical process metrics to help drive rapid cycle process improvement in institutions.*

- *Unlike the adult population, there is limited data on the identification of children most at risk. SIRS criteria have not been validated in the pediatric population, thus QI strategies to define at risk populations are key (particularly from the standardization of a definition within an institution).*
- *Cost savings models are poorly delineated in pediatrics, but efforts that reduce morbidity and length of stay have clear potential in driving cost savings to the Medicaid program.*

## Appendix B Hospital Discharges and Deaths Related to Septicemia

**Table 4 Deaths associated with Septicemia in FY 2006 through 2010**

	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
All Causes	156,525	160,166	164,135	162,792	166,059
Septicemia	2,649	2,848	2,964	3,085	3,166
Percent	1.69%	1.78%	1.81%	1.90%	1.91%

**Notes:** Texas Department of State Health Services. Table 18 – Resident Mortality from Selected Causes in Texas, 2006-2010, <http://www.dshs.state.tx.us/chs/vstat/vs10/t18.shtm>. Accessed October 14, 2013.

**Table 5 Total Discharges, Length of Stay, Charges, and In-Hospital Deaths Associated with Septicemia as Principal Diagnosis by Payer in 2011 for Texas**

	<u>Total number of discharges</u>	<u>Rate of discharges per 100,000 persons</u>	<u>Length of stay in days (mean)</u>	<u>Charges, \$ (mean)</u>	<u>In-hospital deaths</u>
All discharges	72,598 (100.0%)	283.2	9.1	80,753	10,333 (14.2%)
Medicare	42,474 (58.5%)	---	9.0	76,609	6,410 (15.1%)
Medicaid	6,151 (8.5%)	---	10.7	100,795	722 (11.7%)
Private insurance	16,506 (22.7%)	---	8.9	86,010	2,168 (13.1%)
Uninsured	5,949 (8.2%)	---	8.4	75,177	790 (13.3%)
Other	1,447 (2.0%)	---	8.7	78,342	224 (15.5%)
Missing	71 (0.1%)	---	21.4	119,469	19 (26.8%)

**Notes:** Agency for Healthcare Research and Quality (AHRQ). State Statistics from HCUP State Inpatient Database 2011; based on data collected by the Texas Health Care Information Council and provided to AHRQ.

## Appendix C Sepsis Burden in Texas Medicaid Population

The numbers of cases by client and claims for, as well as amounts paid for healthcare service utilization associated with, sepsis and septicemia have been determined using administrative claim and encounter data for fiscal years 2011 and 2012. Healthcare services are categorized as inpatient, outpatient, and professional. The estimates were based on *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* codes as defined by technical specifications developed by 3M to calculate rates of PPCs, including sepsis, severe sepsis, and septicemia.<sup>77</sup>

### Texas Medicaid Payments for Sepsis and Septicemia in FY 2011 & 2012

Data for major service categories (i.e., inpatient, outpatient, and professional services) for sepsis and septicemia in fiscal years 2011 and 2012 are presented in this appendix. *Data were provided by the Research Team of the Strategic Decision Support unit in Texas Health and Human Services Commission. The data are current as of November 2013.*

**Table 6 Texas Medicaid Payments for Sepsis and Septicemia (All Services) – FY 2011**

<u>Description</u>	<u>No. of Clients</u>	<u>No. of Claims</u>	<u>Total Paid</u>
STAR, STAR Plus, STAR Health	3,193	10,000	\$9,498,748
FFS Only	25,016	91,406	\$93,727,421
Other Medicaid (PCCM)	27,444	101,406	\$103,226,169

**Notes:** FY = Fiscal Year, September 1 through December 31 of each respective year; no. = number; managed care includes STAR, STAR+PLUS, and STAR Health programs; FFS = fee-for-services; PCCM = primary care case management; source: Texas Health and Human Services Commission, Strategic Decision Support, Research Team, November 2013

**Table 7 Texas Medicaid Payments for Sepsis and Septicemia (All Services) – FY 2012**

<u>Description</u>	<u>No. of Clients</u>	<u>No. of Claims</u>	<u>Total Paid</u>
STAR, STAR Plus, STAR Health	5,483	16,561	\$37,776,431
FFS Only	22,676	78,583	\$74,648,632
Other Medicaid (PCCM)	27,423	95,144	\$112,425,064

**Notes:** FY = Fiscal Year, September 1 through December 31 of each respective year; no. = number; managed care includes STAR, STAR+PLUS, and STAR Health programs; FFS = fee-for-services; PCCM = primary care case management; source: Texas

<sup>77</sup> Source: 3M Health Information Systems. Potentially preventable complications (PPCs), definition manual, version 30.0 (effective 10/01/2012).

**Table 8 Fee-for-Service by Service Categories and Program Type – FY 2011**

<u><b>FFS &amp; PCCM</b></u>	<u><b>Number of Clients</b></u>	<u><b>Number of Claims</b></u>	<u><b>Total Paid</b></u>
Inpatient	15,019	17,508	\$87,465,333
Outpatient	1,241	1,801	\$593,305
Professional	18,625	72,097	\$5,668,783
<b>Total</b>	<b>25,016</b>	<b>91,406</b>	<b>\$93,727,421</b>

<u><b>FFS only</b></u>	<u><b>Number of Clients</b></u>	<u><b>Number of Claims</b></u>	<u><b>Total Paid</b></u>
Inpatient	11,390	13,315	\$58,256,848
Outpatient	951	1,343	\$388,273
Professional	14,563	56,103	\$3,894,779
<b>Total</b>	<b>18,963</b>	<b>70,761</b>	<b>\$62,539,900</b>

<u><b>PCCM only</b></u>	<u><b>Number of Clients</b></u>	<u><b>Number of Claims</b></u>	<u><b>Total Paid</b></u>
Inpatient	3,691	4,193	\$29,208,485
Outpatient	299	458	\$205,032
Professional	4,273	15,994	\$1,774,004
<b>Total</b>	<b>6,342</b>	<b>20,645</b>	<b>\$31,187,521</b>

**Notes:** FFS = fee-for-service; PCCM = primary care case management; \*Note: PCCM only until March 2012

**Table 9 Fee-for-Service by Service Categories and Program Type – FY 2012**

<u><b>FFS &amp; PCCM</b></u>	<u><b>Number of Clients</b></u>	<u><b>Number of Claims</b></u>	<u><b>Total Paid</b></u>
Inpatient	14,582	17,084	\$71,423,317
Outpatient	1,098	1,612	\$285,730
Professional	16,024	59,887	\$2,939,585
<b>Total</b>	<b>22,676</b>	<b>78,583</b>	<b>\$74,648,632</b>

<u>FFS only</u>	<u>Number of Clients</u>	<u>Number of Claims</u>	<u>Total Paid</u>
Inpatient	10,350	12,111	\$53,397,488
Outpatient	847	1,238	\$233,453
Professional	11,713	43,257	\$2,202,892
<b>Total</b>	<b>16,327</b>	<b>56,606</b>	<b>\$55,833,833</b>

<u>PCCM only*</u>	<u>Number of Clients</u>	<u>Number of Claims</u>	<u>Total Paid</u>
Inpatient	4,346	4,973	\$18,025,829
Outpatient	265	374	\$52,277
Professional	4,613	16,630	\$736,693
<b>Total</b>	<b>6,789</b>	<b>21,977</b>	<b>\$18,814,799</b>

**Notes:** FFS = fee-for-service; PCCM = primary care case management; \*Note: PCCM only until March 2012

**Table 10 STAR, STAR+PLUS, & STAR Health by Service Categories – FY 2011**

<b><u>STAR, STAR+PLUS, STAR Health</u></b>	<b><u>Number of Clients</u></b>	<b><u>Number of Claims</u></b>	<b><u>Total Paid</u></b>
Inpatient	317	355	\$7,867,882
Outpatient	162	188	\$169,997
Professional	3,005	9,457	\$1,460,869
<b>Total</b>	<b>3,193</b>	<b>10,000</b>	<b>\$9,498,748</b>

<b><u>STAR exclude STAR Health</u></b>	<b><u>Number of Clients</u></b>	<b><u>Number of Claims</u></b>	<b><u>Total Paid</u></b>
Inpatient	293	325	\$6,961,503
Outpatient	124	138	\$106,193
Professional	1,400	2,513	\$440,886
<b>Total</b>	<b>1,574</b>	<b>2,976</b>	<b>\$7,508,582</b>

<b><u>STAR Health</u></b>	<b><u>Number of Clients</u></b>	<b><u>Number of Claims</u></b>	<b><u>Total Paid</u></b>
Inpatient	23	29	\$906,379
Outpatient	5	6	\$2,997
Professional	54	135	\$33,374
<b>Total</b>	<b>62</b>	<b>170</b>	<b>\$942,751</b>

<b><u>STAR+PLUS</u></b>	<b><u>Number of Clients</u></b>	<b><u>Number of Claims</u></b>	<b><u>Total Paid</u></b>
Inpatient	1	1	\$0
Outpatient	33	44	\$60,807
Professional	1,552	6,809	\$986,608
<b>Total</b>	<b>1,559</b>	<b>6,854</b>	<b>\$1,047,415</b>

**Notes:** STAR = State of Texas Access Reform; STAR, STAR+PLUS, and STAR Health programs are administered through MCOs

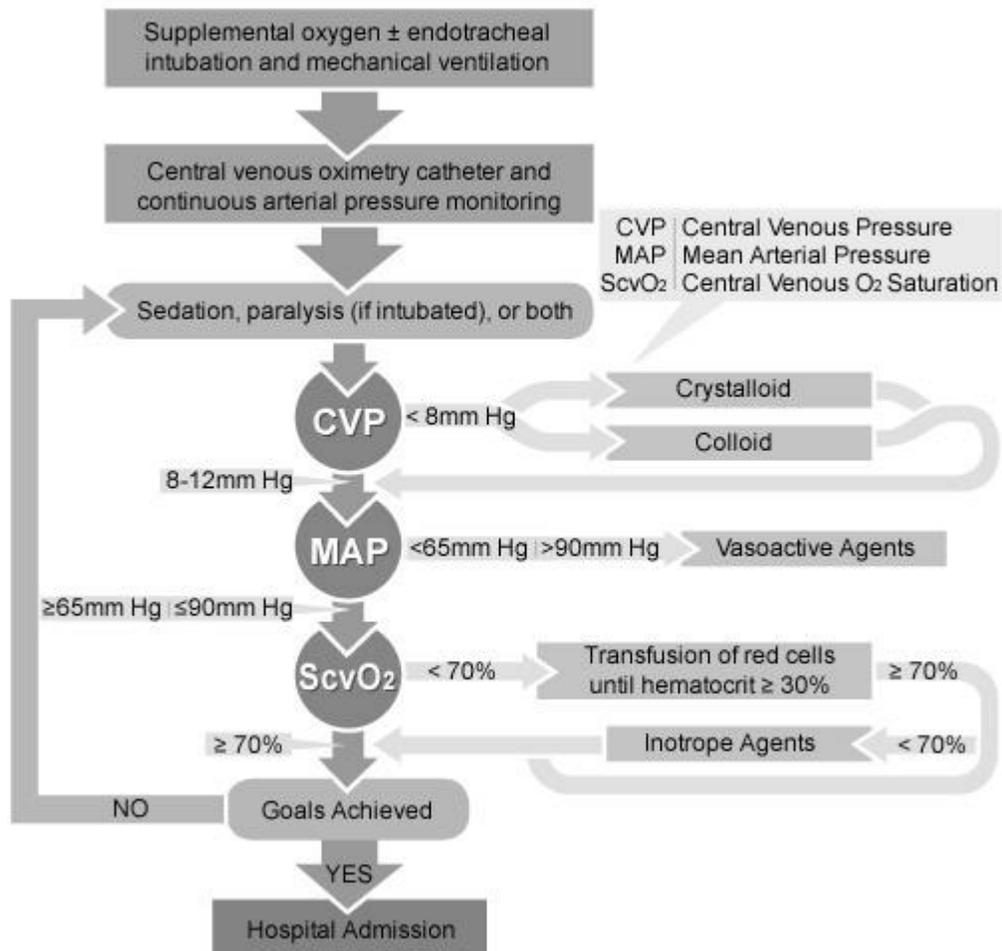
**Table 11 STAR, STAR+PLUS, & STAR Health by Service Categories – FY 2012**

<b><u>STAR, STAR+PLUS, STAR Health</u></b>	<b><u>Number of Clients</u></b>	<b><u>Number of Claims</u></b>	<b><u>Total Paid</u></b>
Inpatient	1,855	2,079	\$35,239,130
Outpatient	275	326	\$241,469
Professional	4,653	14,156	\$2,295,832
<b>Total</b>	<b>5,483</b>	<b>16,561</b>	<b>\$37,776,431</b>
<b><u>STAR exclude STAR Health</u></b>	<b><u>Number of Clients</u></b>	<b><u>Number of Claims</u></b>	<b><u>Total Paid</u></b>
Inpatient	785	872	\$14,767,373
Outpatient	182	201	\$128,317
Professional	2,216	4,586	\$931,502
<b>Total</b>	<b>2,655</b>	<b>5,659</b>	<b>\$15,827,192</b>
<b><u>STAR Health</u></b>	<b><u>Number of Clients</u></b>	<b><u>Number of Claims</u></b>	<b><u>Total Paid</u></b>
Inpatient	11	11	\$509,529
Outpatient	7	11	\$4,655
Professional	53	115	\$39,213
<b>Total</b>	<b>61</b>	<b>137</b>	<b>\$553,397</b>
<b><u>STAR+PLUS</u></b>	<b><u>Number of Clients</u></b>	<b><u>Number of Claims</u></b>	<b><u>Total Paid</u></b>
Inpatient	1,060	1,196	\$19,962,229
Outpatient	86	114	\$108,498
Professional	2,387	9,455	\$1,325,117
<b>Total</b>	<b>2,771</b>	<b>10,765</b>	<b>\$21,395,843</b>

**Notes:** STAR = State of Texas Access Reform; STAR, STAR+PLUS, and STAR Health programs are administered through MCOs

## Appendix D Early Goal-Directed Therapy and Sepsis Management Bundles

Early goal-directed therapy treatment protocol consists of the following steps:



**Source:** Edwards Lifesciences. Advanced hemodynamic monitoring – early goal-directed therapy treatment protocol.

<http://www.edwards.com/Products/mininvasive/Pages/egdtprotocol.aspx>. Accessed December 9, 2013.

## Sepsis Management Bundles

A bundle is a set of elements of care selected from evidence-based practice guidelines that when implemented as a group can have larger positive impact on patient outcomes compared to using the elements of care singly.<sup>78</sup>

For sepsis management, there are two care bundles:

### To be completed within 3 hours:

1. Measure lactate level
2. Obtain blood cultures prior to administration of antibiotics
3. Administer broad spectrum antibiotics
4. Administer 30mk/kg crystalloid for hypotension or lactate  $\geq 4\text{mmol/L}$

### To be completed within 6 hours:

5. Apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP)  $\geq 65\text{mmHg}$
6. In case of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate  $\geq 4\text{mmol/L}$  (36mg/dL):
  - a. Measure central venous pressure (CVP) (target at  $\geq 8\text{mmHg}$  and normalization of lactate)
  - b. Measure central venous oxygen saturation (ScvO<sub>2</sub>) (target at  $\geq 70\%$  and normalization of lactate)
7. Remeasure lactate if initial lactate was elevated

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<sup>78</sup> Surviving Sepsis Campaign. Bundles. <http://www.survivingsepsis.org/BUNDLES/Pages/default.aspx>. Accessed December 9, 2013.

## Appendix E Summary of Select Studies and Initiatives

Studies focusing on early goal-directed therapy for sepsis have utilized various healthcare settings from single centers to multiple institutions within the same health system, in addition to multiple healthcare systems nationwide and internationally. These research studies include varying sizes of patient cohorts, incorporate prospective and retrospective research designs, and utilize both observation and intervention methods. Furthermore, studies have included process and outcome measures such as compliance rate, hospital mortality, average length of stay, and costs saved.

**Table 12 Summary of Recent Clinical Trials for Severe Sepsis and Septic Shock**

<u>Title</u>	<u>Description</u>
<b>ProCESS</b> (Protocolized Care for Early Septic Shock) <sup>79</sup> (U.S.)	<p><b>Design:</b> a large, 5-year, multicenter study of alternative resuscitation strategies for septic shock.</p> <p><b>Purpose:</b> to show that there are “golden hours” in the initial management of septic shock where prompt, rigorous, standardized care can improve clinical outcomes.”</p> <p><b>Outcome measures:</b> hospital mortality (prior to discharge or 60 days, whichever is first); and changes in markers of inflammation, oxidative stress, cellular hypoxia and coagulation/thrombosis (study hour 0, 6, 24, and 72) and resource use and costs of alternative resuscitation strategies (at discharge or 60 days, whichever is first).</p> <p><b>Sample size:</b> 1,351 participants</p> <p><b>Study period:</b> March 2008 and estimated end December 2013</p>
<b>ProMISe</b> (Protocolized Management in Sepsis) <sup>80</sup> (U.K.)	<p><b>Design:</b> a multicenter, randomized controlled trial of the clinical and cost-effectiveness of EGD protocolized resuscitation for emerging septic shock</p> <p><b>Purpose:</b> to validate results from the 2001 single center study conducted by Rivers et al. comparing the effectiveness of 6-hour, EGD, protocolized resuscitation versus usual resuscitation in patients presenting at the emergency department with emerging septic shock</p> <p><b>Population:</b> 48 hospitals and 1,260 patients in the United Kingdom</p>
<b>ARISE</b> (Australasian Resuscitation in Sepsis Evaluation)	<p><b>Design:</b> a multicenter, unblinded, randomized, controlled trial of EGDT versus standard care in patients with severe sepsis presenting to the emergency department of hospitals in Australia, new Zealand, Finland, and Hong Kong.</p>

<sup>79</sup> ClinicalTrials.gov. Protocolized care for early septic shock (ProCESS). <http://clinicaltrials.gov/ct2/show/NCT00510835>. Accessed September 30, 2013.

<sup>80</sup> Mouncey P. Intensive Care National Audit & Research Centre. ProMISe (Protocolized management in sepsis) Information Sheet, V9, June 20, 2012.

<u>Title</u>	<u>Description</u>
Randomized Controlled Trial) <sup>81</sup> (Australia)	<b>Purpose:</b> to test the hypothesis that EGDT compared to standard care reduces 90-day mortality in patients presenting to the ED with severe sepsis. <b>Population:</b> as of December 2011, the trial is enrolling patients at 45 ICUs internationally and over 800 patients have been recruited. The target enrollment is 1,600 patients

**Table 13 Summary of State-Based Quality Initiatives Related to Sepsis**

<u>Organization</u>	<u>Year</u>	<u>State</u>	<u>Purpose</u>	<u>Results</u>
Intermountain Healthcare <sup>82</sup>	2013	Utah	To assess the effect of compliance with a severe sepsis and septic shock management bundle on mortality	Among 4,329 patients with severe sepsis or septic shock admitted to ICUs from emergency department in the study, between January 2004 and December 2010, hospital mortality was 12.1%, reduced from 21.2% in 2004 to 8.7% in 2010. All or none total bundle compliance increased from 4.9 to 73.4% (increase of 68.5%). Among patients who did not receive one or more bundle element, mortality declined from 21.7% in 2004 to 9.7% in 2010. Compliance was significantly associated with a 59% relative reduction in hospital mortality after adjustment for age, severity of illness, and comorbidities. Compliance with early resuscitation elements (within 3 hours) predicted ineligibility for inotropes and red cell transfusions, glucocorticoids, and lung-protective ventilation.
Newark Beth Israel Medical Center <sup>83</sup>	2012	New Jersey	To evaluate use of a screening tool and an early alert system to improve compliance with sepsis bundles and	A total of 58 patients were divided into two groups: 34 for whom their physician activated the early alert system known as Code SMART (Sepsis Management Alert Response team) and 24 for whom their physician did not (non-Code SMART group). The Code SMART group achieved greater compliance with timely antibiotic administration (P<0.001), lactate draw (P<0.001), and steroid use

<sup>81</sup> Bellomo Rinaldo. Monash University. ARISE-RCT: Australasian resuscitation in sepsis evaluation randomized controlled trial. Last updated: January 24, 2013. <http://www.anzicrc.monash.org/arise-rct.html>. Accessed September 30, 2013.

<sup>82</sup> Miller et al. 2013, American Journal of Respiratory and Critical Care Medicine

<sup>83</sup> LaRosa et al. 2012, Critical Care Research and Practice

<u>Organization</u>	<u>Year</u>	<u>State</u>	<u>Purpose</u>	<u>Results</u>
Memorial Hospital of Rhode Island <sup>84</sup>	2011	Rhode Island	<p>impact on mortality</p> <p>To evaluate the effect of implementing a collaborative protocol in a sepsis intervention program on standard processes of patient care (6 month pre- and post-implementation)</p>	<p>(P=0.02). Raw survival and survival adjusted for age, leucopenia, and severity of illness scores were greater in the Code SMART group (P&lt;0.05, P=0.03, and P=0.01).</p> <p>A total of 106 patients were admitted to the emergency department with severe sepsis and septic shock. Sepsis intervention protocol (6-hour bundle) was attempted in 76% of 87 patients who met inclusion criteria. Only 48% of eligible patients completed the EGDT protocol. In-hospital mortality rate was 30.5% for 87 septic shock patients with a mean APACHE II score of 29. Time to fluid administration, central venous access insertion, antibiotic administration, vasopressor administration, and time to Medical ICU transfer from ED arrival improved. There was no improvement in total length of stay, medical ICU days, and mortality.</p>
International <sup>85</sup>	2010	United States, South American, Europe	To evaluate compliance with bundles based on key Surviving Sepsis Campaign guidelines and association with hospital mortality	<p>Data from 15,022 patients at 165 sites were analyzed to determine compliance with bundle targets (6-hour and 24-hour bundles) and association with hospital mortality. Over two years, compliance with resuscitation bundle increased from 10.9% in first site quarter to 31.3% (P&lt;0.0001), and with management bundle increased from 18.4% in first quarter to 36.1% (P=0.008); unadjusted hospital mortality decreased from 37% to 30.8% over two years (P=0.001). Compliance with all bundle elements increased significantly, except for inspiratory plateau pressure. Unadjusted hospital mortality decreased from 37% to 30.8% over 2 years (P=0.001). Unadjusted odds ratio for mortality improved the longer a site was in the Campaign and resulted in an adjusted drop of 0.8% per quarter and 5.4% over 2 years (95% CI, 2.5-8.4%).</p>
Christiana Healthcare <sup>86</sup>	2008	Delaware, Maryland,	To evaluate the effectiveness of its	Introduction of sepsis resuscitation and critical care management standards is associated with a 49.4% reduction in mortality rates

<sup>84</sup> Casserly et al. 2011, Lung

<sup>85</sup> Levy et al. 2010, Intensive Care Medicine

<sup>86</sup> Zubrow et al. 2008, Joint Commission Journal on Quality and Patient Safety

<u>Organization</u>	<u>Year</u>	<u>State</u>	<u>Purpose</u>	<u>Results</u>
		New Jersey, Pennsylvania	Sepsis Alert Program	(p<0.0001), a 34.0% decrease in average length of stay (p<0.0002), and a 188.2% increase in the proportion of patients discharge to home (p<0.0001).
Loma Linda University <sup>87</sup>	2007	California	To examine outcomes of implementing a severe sepsis bundle in an emergency department as a quality indicator set (STOP Sepsis)	A total of 330 patients in the study had a mean age of 63.8±18.5 years, APACHE II score of 29.6±10.6, ED length of stay 8.5±4.4 hours, hospital length of stay 11.3±12.9 days, and in-hospital mortality 35.2%. Bundle compliance increased from 0 to 51.2% at the end of two years. Patients with bundle completed received more CVP/SCVO2 monitoring, more antibiotics, and more corticosteroid compared with patients with bundle not completed. Completion of EGDT was significantly associated with decreased mortality (odds ratio, 0.36, 95% ci, 0.17-0.79, p=0.01). In-hospital mortality was less in patients with bundle completed compared with patients with bundles not completed (20.8% versus 39.5%, p<0.01). There were 116 patients received treatment via protocol; mortality rate was 18% (11-25%) of which 79 patients had septic shock.
Beth Israel Deaconess Medical Center <sup>88</sup>	2006	Massachusetts	To examine effectiveness of a comprehensive interdisciplinary sepsis treatment protocol (MUST protocol)	Protocol patients received more fluid, earlier antibiotics, more appropriate empirical coverage, more vasopressors in the first 6 hours, tighter glucose control, and more frequent assessment of adrenal function. Protocol patients with septic shock showed a 28-day in-hospital mortality of 20.3% compared with 29.4% for historical control (p=0.3), because this trial was not sufficiently powered to assess mortality benefits.
Barnes-Jewish Hospital <sup>89</sup>	2011	Missouri	To evaluate whether the implementation of an automated sepsis screening and alert system facilitated early	There were 181 patients in the non-intervention group and 89 in the intervention group (intervention was a real-time sepsis alert that notified the charge nurse on the patient's hospital ward by text page). Within 12 hours of sepsis alert, 70.8% of patients in the intervention group received ≥1 intervention versus 55.8% in the non-intervention group (p=0.018). Antibiotic escalation,

<sup>87</sup> Nguyen et al. 2007, Critical Care Medicine

<sup>88</sup> Shapiro et al. 2006, Critical Care Medicine

<sup>89</sup> Sawyer et al. 2011, Critical Care Medicine

<u>Organization</u>	<u>Year</u>	<u>State</u>	<u>Purpose</u>	<u>Results</u>
Ochsner Medical Center	2011	Louisiana	appropriate interventions  To measure outcomes of implementing standardized (sepsis bundle) order sets for managing patients with severe sepsis/septic shock	intravenous fluid administration, oxygen therapy, and diagnostic tests were all increased in the intervention group. Adult patients (N=674) were admitted to the emergency department (ED) or critical care unit (CCU) with severe sepsis or septic shock from May 2008 to October 2010. ED order sets included elements of 6-hour bundle and CCU order sets included elements of both 6-hour and 24-hour bundles. A total of 622 met inclusion criteria, with 449 via ED and 213 via CCU. Comparing patients admitted through the ED and those through CCU, use of order sets was significantly associated with meeting “6-hour goals” successfully for patients who received ED orders (P<0.001). ED order set was initiated in 300 of 449 patients (67%); ED and CCU order sets in 230 of 449 patients. Order set usage explained 24% of the variation in meeting goals (P<0.0001). This study consists of two components: prospective before and after observational comparison of historical controls to patients receiving resuscitation bundle (RB) after implementation of GENESIS and the second was a concurrent comparison of patients not achieving all components of the RB to those achieving all components of the RB. Comparison between 1,554 patients who did not receive resuscitation bundle and 4,801 who did showed that those who received the bundle had a 14% reduction in mortality (42.8%-28.8%, P<0.001) and a 5.1 day decrease in hospital length of stay (20.7 vs. 15.6, P<0.001). Subgroup comparisons based on whether RB was achieved showed similar reduction in mortality.
GENESIS Project (GENERALized Early Sepsis Intervention Strategies)	2012	Multicenter	To examine in-hospital mortality effect of GENESIS (6-hour sepsis resuscitation bundle)	A total of 216 patients were treated with modified EGDT protocol, with 32.9% mortality (95% CI, 26.6%-39.2%; 183 patients (84.7%) had septic shock and mortality for this group was 34.4% (95% CI, 28%-41%). The control group consisted of 205 patients and had 27.3% mortality (95% CI, 21.2%-33.5%); 123 had septic shock
Advocate Christ Medical Center <sup>90</sup>	2010	Illinois	To determine mortality in septic patients 2 years after introduction of a modified EGDT	

<sup>90</sup> Crowe et al., 2010

<u>Organization</u>	<u>Year</u>	<u>State</u>	<u>Purpose</u>	<u>Results</u>
			protocol and measure compliance with protocol	with a mortality of 43.1% (95% CI, 34%-52%). Compliance rates were 99% received adequate intravenous fluids, 99% had central line, 98% had antibiotics in the first 6 hours, 28% had central oxygen saturation measures, 3.7% received dobutamine, and 19% received blood transfusion. Decrease in mortality among patients septic shock with absolute difference of 8.7% was not statistically significant. Compliance with individual protocol elements was variable.

## Appendix F Summary of DSRIP Projects Related to Sepsis

**Table 14 Summary of DSRIP Projects Related to Sepsis**

<u>Project Description</u>	<u>RHP*</u>	<u># Projects</u>	<u>Amounts</u>
• Part of a large high risk group – those Medicaid, uninsured, underserved or indigent that have been diagnosed with HF, pneumonia, AMI, COPD, sepsis or renal failure; use case managers/workers, CHW, and other health professionals as patient navigators	RHP 2	1	\$5,086,725
• Implement sepsis resuscitation and sepsis management bundles	RHP 4	5	\$16,192,983
	RHP 14	2	\$7,180,529
• Improve process methodology for sepsis mortality	RHP 6	1	\$12,087,560
	RHP 9	4	\$48,013,327
• Implement process improvement, sepsis resuscitation bundle, early intervention and treatment of sepsis patient entering through the emergency department	RHP10	7	\$59,971,852
• Implement sepsis resuscitation and management bundle through staff training and writing order sets	RHP 12	1	\$15,675,855
<b>Total for Sepsis</b>	<b>7 RHPs</b>	<b>21</b>	<b>\$164,208,831</b>

**Notes:** DSRIP = Delivery System Reform Incentive Payments; RHP = Regional Healthcare Partnerships; HF = Health Failure; AMI = Acute Myocardial Infarction; COPD = Chronic Obstructive Pulmonary Disorder; CHW = Community Health Workers; \* See also RHP Map. <http://www.hhsc.state.tx.us/1115-docs/Regions-Map-Aug12.pdf>. Accessed November 25, 2013.

## Appendix G Quality Improvement in Texas Hospitals

The Texas Hospital Association (THA) administered a survey to their 537 members in addition to 13 members on the Policy Committee on Quality and Patient Safety. The survey was included in the association’s weekly updates for two consecutive weeks. It included nine items that queried member hospitals about their experience with implementing evidence-based protocols for sepsis treatment. The members were given 10 days to respond. Of these hospitals, 12 responded (4 incomplete and 8 complete, see table below).

**Table 15 Summary of Survey Results from Texas Hospitals**

<u>Item</u>	<u>Questions</u>	<u>Yes</u>	<u>No</u>	<u>Skipped</u>
2	Does your hospital currently implement protocols for the treatment of severe sepsis and septicemia?	10	1	1
3	Are the protocols evidence-based?	8	--	4
4	Do they include early goal-directed therapy (EGDT)?	8	--	4
5	What outcomes or quality measures does your hospital utilize to evaluate compliance or success?	8	--	4
6	In your experience, has early goal-directed therapy (EGDT) been shown to be a more efficacious approach to lowering the incidences of sepsis? If yes, please elaborate.	7	1	4
7	In your experience, has early goal-directed therapy (EGDT) been shown to be a more cost effective approach to lowering the incidence of sepsis? If yes, please elaborate.	4	4	4
8	Is there anything that prevents your hospital from implementing early goal-directed therapy (EGDT) for the treatment of severe sepsis and septicemia? Please explain.	5	3	4
9	Please feel free to provide any additional information or comments.	4	--	8

Based on the results received, 10 of 11 hospitals currently implement protocols for the treatment of severe sepsis and septicemia, with eight hospitals having evidence-based protocols that include EGDT. The following process and outcome measures were used:

- Adherence to the sepsis management bundle, used for the purpose of treatment rather than as prophylaxis
- Time to antibiotics, measure of lactate, placements of invasive measurement devices
- Screen for patients by reviewing every chart that falls into “SIRS” category for severe sepsis and appropriate treatment
- Utilization of the 6-hour bundle, mortality reduction, and appropriate capture rate
- Use of standard order sets, measurement of serum lactate, sepsis diagnosis, and sepsis morality

In addition, seven of the eight hospitals reported that EGDT has been shown to be a more efficacious approach to lowering the incidence of sepsis but only four of the eight reported that it

has been shown to be a more cost effective approach. Five of the eight hospitals reported having encountered some barriers that prevented their hospital from implementing EGDТ.

Those who responded also reported the following potential benefits:

- *“Adherence to initial sepsis bundle reduced mortality significantly with number needed to treat (NNT) 1 of 7, which is better than other interventions, best available too for treating sepsis”*
- *“Completion of 6 hour bundle is associated with 33 percent relative risk reduction in mortality (1 out of 10 NNT); reporting timely administration of appropriate antibiotics and attainment of specific hemodynamic goals would help improve the adherence to this evidence-based practice.”*

These hospitals encountered several barriers associated with adopting evidence-based protocols for treating severe sepsis and septic shock:

- Difficulty with culture of care, silos, and complexity of implementing a functioning process
- The bundle, though simplified, is still difficult to implement and adhere to
- Physician training - family practice and internal medicine physicians in rural and small hospital settings are generally not comfortable with treating severe sepsis and septic shock and have been slow to follow evidence-based practices;
- Traveling, interdisciplinary simulation is hard to carry out; and
- Invasive devices for hemodynamic assessment (e.g., CVP, arterial line, and SvcO<sub>2</sub>) are frequently not obtained due to practitioners’ inability to place lines or being uncomfortable with their use. Use of non-invasive devices may be helpful but require new training (e.g., handheld echo) or additional funding (e.g., NICOM).
- Sometimes physicians are not receptive to a non-physician instructing them on how to treat their patients.
- Some physicians do not agree with operating under the assumption that all patients who meet SIRS criteria with a source of infection should be considered septic and cared for accordingly. There is a lot of resistance from established community-based physicians.
- Physician buy-in – Some physicians do not believe that all patients who meet SIRS criteria with a source of infection are septic. There is a lot of resistance among established community-based physicians.

Some of the hospitals that have responded to the survey are overcoming the aforementioned barriers through physician education on the continuum of sepsis, rationale for starting fluids and antibiotics based on diagnostic criteria, evidence based protocols, and strategies for protocol implementation. One hospital reported that their primary focus is to ensure that providers in both the emergency department and critical care unit are fully engaged in the protocol implementation process.

In response to what outcomes or quality measures are being used to evaluate compliance or success:

*“We are in the middle of a robust Lean based process improvement project collaborating with multiple centers nationwide to close the gaps between our policy and our actions. We are currently pulling retrospective data on 3 and 6 hour bundle compliance as a starting point for a complete redesign of our sepsis management implementation with near real time compliance dashboard tracking.”*

*“Time to antibiotics, measure of lactate, placements of invasive measurement devices (though we'd like more)”*

*“We review every chart that falls into the "SIRS" category for severe sepsis and appropriate treatment if so...”*

*“3 hour sepsis bundle for severe sepsis and septic shock, early recognition sepsis tool embedded in our EMR for our med/surg beds with a process in place "sepsis alert" for "positive" sepsis screenings. We monitor these screening results.”*

*“Utilization of the 6-hour bundle, mortality reduction, appropriate capture rate”*

*“Use of standard order sets, serum lactate measured, dx of sepsis, sepsis mortality”*

In response to whether EGDT was more efficacious than standard therapy:

*“I believe the question is misworded. EGDT does not lower the incidence of sepsis but it does improve outcomes, as shown in the literature and in the setting of local successes, though past adherence to the bundle (both locally and nationwide) has been abysmal...It is a treatment for sepsis, not a prevention tool. When implemented, it is much more cost effective in terms of reduced organ dysfunction, length of stay, mortality, and disposition.”*

*“Adequacy of resuscitation has increased, secondary organ damage (renal) has decreased, and timing of antibiotics has decreased. This is a nurse-driven protocol after the physician signs-off on the protocol. It allows them to administer reasonable amounts of fluids and vasopressor support, and if the hemodynamic targets have not been met, they call the physician with prompts for further care (e.g., additional fluids, addition of a third (specific) vasopressor, with low SvO2 giving PRBC's or dobutamine). It makes the process a lot easier up front and keeps physicians and nurses on the right track.”*

*“It doesn't lower the incidence of Sepsis, as the patient is septic (presumed or confirmed infection present) when they present. EGDT is instituted only when Sepsis is diagnosed. I believe EGDT lowers the incidence of the patient progressing to severe sepsis and septic shock.”*

*“We typically start the EDGT in our ER with fluid resuscitation, antibiotics, blood and urine cultures, CBC, lactic acid, Comp Met and anything else the physician deems necessary to determine a possible source of infection for those patients who meet SIRS criteria while in the ER.”*

*“Higher awareness and EGDT has improved our catchment of septic patients - which has not only resulted in appropriate care but a reduction in mortality.”*

*“We have seen a reduction in sepsis mortality with better/earlier recognition and goal-directed therapy.”*

In response to whether EGDT is more cost effective than standard therapy:

*“Again, it is a treatment for sepsis, not a prevention tool. When implemented, it is much more cost effective in terms of reduced organ dysfunction, length of stay, mortality, and disposition.”*

*“EGDT is only for managing those with severe sepsis or septic shock, it must be present.”*

*“These patients are caught early in the disease process, thus preventing the extended and costly ICU admission for a patient experiencing severe sepsis and septic shock.”*

*“I don't have the figures in front of me but fluids and antibiotic therapy started as early as possible are certainly more cost effective than sending a patient to the critical care unit once the sepsis progresses to severe/septic shock.”*

*“Yes - providing the right care at the right time is always more efficient.”*

*“Hypothetically, this makes sense, but I can't substantiate the claim with data.”*

### **Other Comments**

*“In the baseline study, adherence to the initial sepsis bundle reduced mortality significantly with number needed to treat to save one life of 7. This is far better than many much more ‘glamorous’ interventions. The problem with the bundle, though currently more simplified, is the difficulty of implementation and adherence due to complexity. Again, it does not prevent sepsis, but it is the best tool currently available for treatment.”*

*“Similar to AMI and stroke, there is a golden hour in sepsis. Completion of the 6-hr bundle is associated with a 33 percent relative risk reduction in mortality (saving 1 life out of 10 people treated in my area). Reporting timely administration of appropriate antibiotics and attainment of specific hemodynamic goals would help improve the adherence to this evidence based practice.”*

*“We are part of the SERRI grant funded by CMS through the Methodist hospital system in Houston, Texas. Our goal is to monitor med/surg patients for signs and symptoms of sepsis through an early warning tool embedded in our nursing documentation which alerts the bedside nurse if a patient is at risk for developing sepsis. We have a process in place to follow-up with those patients.”*

## Appendix H Quality Improvement Initiatives in Other States

A short survey that includes four major questions asking state Medicaid directors about whether their respective states require hospitals to implement evidence-based protocols for the treatment of severe sepsis and septicemia was sent via a distribution list by the Office of the Medical Director at the Texas Health and Human Services Commission to all state Medicaid directors through the Agency for Healthcare Research and Quality (AHRQ) and the National Association of Medical Directors (NAMDM). The members were given two weeks to respond. The questions were as follows:

1. Are hospitals in your state required to implement evidence-based protocols, including EGDT, for treatment of severe sepsis and septicemia?
  - a. If you selected "Yes" what results has your state achieved with these requirements (i.e., improved quality of care, reduced costs, reduced in-hospital mortality, etc.)?
  - b. If you selected "No" what are the reasons for why your state has not required hospitals to implement evidence-based protocols for treatment of severe sepsis and septicemia?
2. Does your state include any financial incentives and/or disincentives as part of your reimbursement or payment methodology for requiring hospitals to implement evidence-based protocols for treatment of severe sepsis and septicemia?
  - a. If you selected "Yes" what results has your state achieved with these incentives and/or disincentives?
  - b. If you selected "No" what are the reasons for why your state does not provide financial incentives and/or disincentives for hospitals that implement evidence-based protocols for treatment of severe sepsis and septicemia?
3. Approximately what percentage of your Medicaid beneficiaries are served by managed care organizations? (This will help us understand under what service delivery and payment model this topic is being addressed.)
4. Please provide any additional comments/information related to this clinical initiative you would like to share.

One response was received. Hospitals in the responding state are not required to implement evidence-based protocols. The reason given for why the state has not required hospitals to do so was “not high enough priority with other competing demands, still gaps in evidence.” Approximately 15 percent of this state’s Medicaid beneficiaries are served by managed care organizations.

## **Appendix I Potentially Preventable Readmission and Complications Reports**

Public reports on PPRs and PPCs for the Texas Medicaid population are published annually. Below is a list of these reports.

- Texas Health and Human Services Commission. Potentially Preventable Readmissions in the Texas Medicaid Population, FY 2012. <http://www.hhsc.state.tx.us/reports/2013/PPR-Report.pdf>.
- Texas Health and Human Services Commission. Potentially Preventable Complications in the Texas Medicaid Population, FY 2012. <http://www.hhsc.state.tx.us/reports/2013/PPC-Report.pdf>.
- Texas Health and Human Services Commission. Potentially Preventable Complications in the Texas Medicaid Population, FY 2011. <http://www.hhsc.state.tx.us/reports/2012/PPC-Complications-FY-2011.pdf>.
- Texas Health and Human Services Commission. Potentially Preventable Readmissions in the Texas Medicaid Population, FY 2011. <http://www.hhsc.state.tx.us/reports/2012/PPR-Readmissions-FY2011.pdf>.
- Texas Health and Human Services Commission. Potentially Preventable Readmissions in the Texas Medicaid Population, FY 2010. <http://www.hhsc.state.tx.us/reports/2012/potentially-preventable-readmissions.pdf>.
- Texas Health and Human Services Commission. Potentially Preventable Readmissions in the Texas Medicaid Population, FY 2009. <http://www.hhsc.state.tx.us/reports/2011/PPR-Report-011811.pdf>.

## Appendix J Methodology for Analysis

Based on the scope defined by S.B. 1542, the analysis for this clinical initiative consisted of the sources of data and published evidence summarized in table below.

**Table 16 Summary of Data Sources Used**

<u>Description</u>	<u>Source(s)</u>
Background, empirical studies, reviews, case examples, etc.	<ul style="list-style-type: none"> <li>• Texas Department of State Health Services Medical Library Services</li> <li>• Texas Health and Human Services Commission Health Policy and Clinical Services staff</li> <li>• Center for Evidence-based Policy at Oregon Health and Science University that supports the Medicaid Evidence-based Decision (MED) Project</li> <li>• Subject matter experts for external stakeholders (e.g., Edward Life Sciences)</li> </ul>
Data on sepsis burden (i.e., healthcare associated infections and PPEs, including complications, for septicemia)	<ul style="list-style-type: none"> <li>• Data on healthcare associated infections were obtained from Texas Department of State Health Services (DSHS) Center for Health Statistics website.</li> <li>• Data for PPCs were obtained from Texas Medicaid Healthcare Partnership (TMHP), Texas Medicaid’s vendor that processes claims and manages data.</li> <li>• Data for PPVs, PPAs, and PPRs in calendar years 2011 and 2012 were obtained from the Institute for Child Health Policy at the University of Florida, Texas’ External Quality Review Organization.</li> <li>• Data on sepsis burden in Texas was obtained from HHSC Strategic Decision Support Research Team for FY 2011 and FY 2012.</li> <li>• Agency for Healthcare Research and Quality’s Healthcare Cost and Utilization Project website</li> </ul>
Service utilization for severe sepsis and septicemia for Texas Medicaid beneficiaries	<ul style="list-style-type: none"> <li>• Data on sepsis burden in Texas was obtained from HHSC Strategic Decision Support Research Team for FY 2011 and FY 2012.</li> <li>• Agency of Healthcare Research and Quality, Healthcare Utilization Project</li> </ul>
Survey of Texas hospitals and other state Medicaid programs regarding	<ul style="list-style-type: none"> <li>• Survey was distributed to Texas hospitals through the Texas Hospital Association</li> <li>• Survey was distributed to other state Medicaid programs through Medicaid Medical Director Network via HHSC Office</li> </ul>

<u>Description</u>	<u>Source(s)</u>
implementation of evidence-based protocols for sepsis treatment	of the Medical Directors.
National, international, state, and local quality improvement initiatives and projects	<ul style="list-style-type: none"> <li>• Information on DSRIP projects related to sepsis management was obtained from the Medicaid 1115 Transformation Waiver website</li> <li>• CMS Healthcare Innovation Award website</li> <li>• Institute for Healthcare Improvement</li> <li>• University of Kansas Medical Center</li> <li>• Joint Commission</li> <li>• Texas Hospital Association</li> </ul>
Public comments	<ul style="list-style-type: none"> <li>• Texas Register, September 20, 2013 issue</li> <li>• In person meeting with Edward Life Sciences</li> </ul>

## Appendix K Glossary – Select Terms Used in Sepsis Literature

The list below includes certain terms used in the research literature related to sepsis management that may be unfamiliar for the reader.

<u>Term</u>	<u>Definition</u>
Adjunctive vasoactive agents	Another treatment used together with the primary treatment to increase the chance of long-term survival <sup>91</sup>
Bands	Young or immature neutrophils; neutrophils are the “soldiers” that fight against infection, consume foreign particles in the body, and make up the largest percent of white blood cells <sup>92</sup>
Biomarkers	“A characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmaceutical responses to a therapeutic intervention” <sup>93</sup>
Central venous oxygen saturation	<i>Central venous</i> refers to a large vein in the neck, chest, or groin. <i>Oxygen saturation</i> is a measure of amount of oxygen dissolved or carried in a given medium; when oxygen molecules enter body tissues (e.g., blood is oxygenated in the lungs where oxygen molecules travel from the air into the blood) <sup>94</sup>
Central venous pressure	Pressure of blood in the chest area; the amount of blood returning to the heart and ability of the heart to pump blood into the arteries. <sup>95</sup>
Effectiveness versus efficacious	A treatment or intervention is considered to be <i>efficacious</i> when it produces expected results under ideal circumstances; a treatment or intervention is considered <i>effective</i> when it produces beneficial effects in “real world” clinical settings. <sup>96</sup>
Epidemiology	A branch of medicine that examines factors related to presence or absence of disease and disorders; provides understanding of how many people have a disease or

<sup>91</sup> National Cancer Institute. Adjunct therapy. <http://www.cancer.gov/dictionary?cdrid=467826>. December 11, 2013.

<sup>92</sup> National Institutes of Health Clinical Center. Understanding your complete blood count – patient education. [http://www.cc.nih.gov/ccc/patient\\_education/pepubs/cbc97.pdf](http://www.cc.nih.gov/ccc/patient_education/pepubs/cbc97.pdf). Accessed December 11, 2013.

<sup>93</sup> Strimbu K and Tavel JA. What are biomarkers? *Current Opinions in HIV/AIDS* 2010;5(6):463-466.

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078627/pdf/nihms259967.pdf>. Accessed December 11, 2013.

<sup>94</sup> Wikipedia.org. Oxygen saturation. [http://en.wikipedia.org/wiki/Central\\_venous\\_oxygen\\_saturation](http://en.wikipedia.org/wiki/Central_venous_oxygen_saturation). Also central venous catheter [http://en.wikipedia.org/wiki/Central\\_venous\\_catheter](http://en.wikipedia.org/wiki/Central_venous_catheter). Accessed December 11, 2013.

<sup>95</sup> Wikipedia.org. Central venous pressure. [http://en.wikipedia.org/wiki/Central\\_venous\\_pressure](http://en.wikipedia.org/wiki/Central_venous_pressure). December 11, 2013.

<sup>96</sup> Gartlehner G, Hansen RA, Nissman D, et al. Criteria for distinguishing effectiveness from efficacy trials in systematic reviews - technical review 12 (Prepared by the RTI-International–University of North Carolina Evidence-based Practice Center under Contract No. 290-02-0016.) AHRQ Publication No. 06-0046. Rockville, MD: Agency for Healthcare Research and Quality. April 2006. <http://www.ncbi.nlm.nih.gov/books/NBK44029/pdf/TOC.pdf>. Accessed December 11, 2013.

<b><u>Term</u></b>	<b><u>Definition</u></b>
	disorder <sup>97</sup>
Fluid/volume resuscitation	Medical practice of replacing bodily fluid lost through sweating, bleeding, diseases or disorders <sup>98</sup>
Hemodynamic functions	Functions related to blood flow or circulation <sup>99</sup>
Hypotension	Abnormally low blood pressure (force of blood against walls of arteries when the heart pumps out blood) <sup>100</sup>
Mean arterial pressure	Average level of blood pressure over several heart beats <sup>101</sup>
Pathophysiology	Study of abnormal or undesired condition related to processes or mechanisms occurring in an organism <sup>102</sup>
Pulmonary artery catheter	Insertion of a catheter into a pulmonary artery (through which deoxygenated blood is carried from the heart to the lungs); it is used for diagnostic purposes; often used to detect heart failure or sepsis, monitor therapy, and evaluate effects of drugs <sup>103</sup>
Sepsis management bundle	A bundle is a structured way of improving processes of care and patient outcomes; a set of interventions that are evidence-based best practices (usually 3 to 5); and when performed together and reliably can result in improved patient outcomes. <sup>104</sup>
Serum lactate	The amount of lactic acid in the blood; high levels of serum lactate may indicate presence of severe infections, liver disease, or alcohol abuse <sup>105</sup>
Specificity	A statistical method used to evaluate a clinical test; it represents the proportion of negatives that are correctly identified by a diagnostic test. <sup>106</sup>

<sup>97</sup> National Institute of deafness and other communication disorders (NIDCD). What is epidemiology?

<https://www.nidcd.nih.gov/health/statistics/Pages/epidemiology.aspx>. Accessed December 11, 2013.

<sup>98</sup> Wikipedia.org. Fluid resuscitation. [http://en.wikipedia.org/wiki/Fluid\\_resuscitation](http://en.wikipedia.org/wiki/Fluid_resuscitation). Accessed December 11, 2013.

<sup>99</sup> Wikipedia.org. Hemodynamics. <http://en.wikipedia.org/wiki/Hemodynamics>. Accessed December 11, 2013.

<sup>100</sup> National Heart, Lung, and Blood Institute. What is hypotension. <http://www.nhlbi.nih.gov/health/health-topics/topics/hyp/>. Accessed December 11, 2013.

<sup>101</sup> University of Washington. Mean arterial pressure and pulse pressure.

<http://courses.washington.edu/conj/circulation/reflectedPulse.htm>. Accessed December 11, 2013.

<sup>102</sup> Wikipedia.org. Pathophysiology. <http://en.wikipedia.org/wiki/Pathophysiology>. December 11, 2013.

<sup>103</sup> Wikipedia.org. Pulmonary artery catheter. [http://en.wikipedia.org/wiki/Pulmonary\\_artery\\_catheter](http://en.wikipedia.org/wiki/Pulmonary_artery_catheter). Accessed December 11, 2013.

<sup>104</sup> Institute for healthcare improvement. What is a bundle?

<http://www.ihl.org/knowledge/Pages/ImprovementStories/WhatIsaBundle.aspx>. Accessed December 11, 2013.

<sup>105</sup> Antinone R and Kress T. Measuring serum lactate. *Nursing Critical Care* 2009;4(5):55-56.

[http://www.nursingcenter.com/lnc/journalarticle?Article\\_ID=933028](http://www.nursingcenter.com/lnc/journalarticle?Article_ID=933028). Accessed December 11, 2013.

<sup>106</sup> Lalkhen AG and McCluskey A. Clinical tests: sensitivity and specificity. *Continuing Education in Anaesthesia, Critical Care & Pain* 2008;8(6):221-223. <http://ceaccp.oxfordjournals.org/content/8/6/221.full.pdf+html>. Accessed December 11, 2013.