# HCIA Final Performance Progress Report

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<th>Federal Agency and Organization Element to Which Report is Submitted:</th>
<th>Centers for Medicare &amp; Medicaid Services</th>
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<tr>
<td>Federal Grant or Other Identifying Number Assigned by Federal Agency:</td>
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<td>• i.e. CMS Awardee Number (1C1CMS33####)</td>
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<tr>
<td>Recipient Organization Name:</td>
<td>Trustees of Dartmouth College</td>
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<tr>
<td>Recipient Organization Address:</td>
<td>Dartmouth Medical School</td>
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<td>♦ Including zip code</td>
<td>11 Rope Ferry Rd</td>
</tr>
<tr>
<td>♦ Month, Day, Year (e.g., 12/31/2012; 3/31/2013; 6/30/2013)</td>
<td>Hanover, NH 03755-1404</td>
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<td>Reporting Period End Date:</td>
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Certification: I certify to the best of my knowledge and belief that this report is correct and complete for performance of activities for the purposes set forth in the award documents.

<table>
<thead>
<tr>
<th>Name and Title of Awardee Project Director (Certifying Official):</th>
<th>Allison Hawke, Data Manager</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone Number:</td>
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<tr>
<td>Date Report Submitted:</td>
<td>9/28/2016</td>
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Narrative Progress Report
Health Care Innovation Award (HCIA)

Title: High Value Healthcare Collaborative: Optimizing the treatment of septicemia and sepsis through implementation of bundled care

Section 1: Final Report
Award Period: July 1, 2012 – June 30, 2015

The contents of this report are solely the responsibility of the authors and do not necessarily represent the official views of the Department of Health and Human Services or any of its agencies.

This report highlights accomplishments of the three-year HVHC quality improvement project entitled “Optimizing the treatment of septicemia and sepsis through implementation of bundled care interventions.”

Goal: To significantly enhance the value of health services delivered to patients admitted for sepsis or septicemia by increasing the delivery of optimal care (perfect bundle adherence for sepsis) by five percent over three years.

Improvement Targets (from Driver Diagram)

Triple Aim targets include:

1. Reduce cost: Achieve a 5% relative rate reduction over three years in the number of patients with sepsis requiring long term acute care or sub-acute nursing care after an incident episode of severe sepsis; $12.24M savings at HVHC hospitals for Medicare beneficiaries over the 3-year award. Note: we could not include partial year 2015 in our calculations (see explanation below) so used prorated target of $9.9M for 2013-2014 analytics.

2. Improve health: Reduce the burden of chronic morbidity from sepsis-associated chronic organ dysfunction, achieving a 5% relative rate reduction over three years in the number of patients with sepsis requiring long term acute care or sub-acute nursing care after an incident episode of severe sepsis (where episode refers to events that are bracketed by the admission and discharge from an inpatient acute care facility).

3. Improve care: Improve optimal adherence to sepsis bundled care by 5% (relative rate) over three years.
Executive Summary

Severe sepsis, defined as a clinical syndrome of infection plus organ dysfunction (1) affects 1.16 million patients per year in the United States (2) and is a major public health challenge with an estimated mortality rate between 20% and 45%. (3-6) Care for patients with sepsis is costly and resource intensive with many or most patients requiring intensive care during a hospitalization. Survivors experience serious and prolonged long-term morbidities that limit function and economic productivity.

There are few proven specific therapies for sepsis and no single effective therapy. Current guidelines for care highlight the reliance on *bundled care* with rapid intravenous fluid administration, source control of infection and initial empiric antibiotic treatment. The consequence of ineffective resuscitation and initial management of sepsis is progressive multi-organ failure, severe disability and death as well as costly dependence for survivors. Increasingly, delivery of complex care for illnesses like sepsis has been evaluated and reported using composite multi-parameter measures of process and outcome. These composite measures referred to as a “bundle” – an aggregate of process interventions connected to outcomes – is commonly used to evaluate the delivery of optimal (perfect) care for certain conditions using "all or none" criteria (7). Yet a common hurdle in delivering care bundles in these complex environments (ED and ICU) is the potential for wasteful and ineffective care that detracts from the delivery of highly reliable, high value care. (8)

As part of the CMMI award, HVHC implemented this sepsis care bundle in 23 facilities (both Emergency Department (ED) and Intensive Care Unit (ICU) settings) across eight (8) member health systems as part of a two-year quality improvement project. The overall goal was to improve inpatient acute care bundle adherence for severe sepsis and/or septic shock by 5% over three years to achieve a $12.4M cost savings to Medicare (prorated to $9.9M to exclude partial year in 2015).

*Note: in the analysis against our CMMI goals, we focused specifically on the two complete calendar years for which data were available: 2013 and 2014. We excluded the 2015 partial year (Jan-Jun) from our analyses for two reasons: (1) seasonal changes (11) have been reported to impact sepsis outcomes and; (2) this partial year included a lower number of enrollees both due to the half year time period and due to enrollment dropping off in anticipation of grant funding coming to an end (the problem with "short term funding" to solve a major, life threatening, health issue). Also, the manual data entry into the study web portal for the sepsis patients turned out to be quite challenging, so our Enrolled Cohorts are much smaller than the CMS Claims-based Cohorts for those participating hospitals. Therefore, we calculate the savings against both cohorts.*

Our progress against stated goals follows:

- **Reduce costs:** The actual median 90-day episode costs for the Enrolled/CMS Cross-walked Cohort (see definitions below) was $38,049 in 2013 and $35,099 in 2014, dropping 7.7%.
  - If we apply this mean cost savings to the 2014 cohorts, we achieved $10.9M savings for the Enrolled cohort (includes non-Medicare), $2.4M savings for the Enrolled/CMS Cross-walked Cohort, $7.3M for the CMS Claims-based Sepsis Cohort, and $33.4M for the total estimated sepsis cases for the participating hospitals (includes non-Medicare).
  - The total annual cost savings are higher if we apply the 14.4% cost savings achieved by those hospitals launching in Y1 (who had more time to realize the potential savings) to these cohorts, in which case we would achieve $16.7M savings for the Enrolled cohort.
Improving Health: The percentage of sepsis patients who were Medicare-eligible requiring long-term acute care or sub-acute nursing care after an incident of severe sepsis was 47.9% in 2013 and 44.7% in 2014, dropping 7%, achieving the target of reducing sub-acute nursing care by 5%.

Improve care: Among all participating member systems, three-hour bundle adherence for sepsis patients in 2013 was 66.1% and in 2014 was 64.5%. Overall, sepsis bundle care adherence decreased by 2.5% in the comparison period, falling short of the target increase of 5%. When limiting the analysis to evaluate only those members who had not started implementing the sepsis bundle prior to the CMMI launch, we increased bundle adherence from 48.8% to 61.5%, increasing adherence by 26%, far exceeding our target 5% increase for those members.

To use another race metaphor, comparing our “sustaining” sites to our “just starting” sites is similar to improving time for a racer who runs a four-minute mile versus one who runs a ten-minute mile. Our members who already had sepsis bundles initiatives in place were already good (like the four-minute milers) and couldn’t improve by as much; but this initiative demonstrated that we could accelerate the improvements for those who were just starting their implementations and training (like the ten-minute milers).

We are proud of these accomplishments in such short period of time in a complex, large implementation. These measurable improvements in such a short window suggest we could do so much more.

The CMMI award provided an extremely rewarding opportunity to collaborate with our member institutions from across the US with a focus on better care, smarter spending, and healthier people. We faced many trials throughout this multi-site initiative in achieving the goals, but achieved significant progress in uncovering and addressing challenges and leveraging lessons learned through collaborative implementation to set us up for continued improvement and progress toward our stated goals beyond the limited CMMI timeframe.

If we, as a nation, are to improve care and lower cost, we need to work not just from policy down but from the ground up to make real change – as in this project, directly with the health systems. We must do so not in short sprints, but in marathons that continue to improve each of the hundreds of handoffs necessary to significantly improve care and lower costs; and in this project, save lives. This is not in a single race or single event but must occur continuously across thousands of events in cities, across this country, every day. We must approach the inequities that exist and capitalize on the knowledge of those who can lead and are committed to change. While we had a good start, a two-year timeframe is not enough time to fully achieve these changes.

Having access to data can drive real change and using Medicare data the way we did in this project is of particular value. Being able to organize this data into useful data sets is no simple task and despite being home to the Dartmouth Atlas for years, the efforts necessary to make use of this data are extremely
challenging. That said, we now have the foundation upon which we can make change and recommendations that can be meaningful for this country to make real change for real illness. This in and of itself is a great accomplishment. What follows is what we believe to be the first attempt to use this data linked with EMR data to measure outcomes in real clinical practice that can lead to valued-based measurement and improvement.

We feel we made real progress in overcoming barriers in setting up this foundation for sustainable change, but we need to continue working on structural barriers. Implementing an intervention across multiple disparate systems is challenging due to different cultures, infrastructure, and remote communication. Collecting consistent, standardized data (e.g., bundle adherence data) from eight different systems, (many of which have multiple IT systems within their healthcare systems, still use paper or were transitioning to new electronic medical records) also presented challenges. As a country we have failed to create integrated IT systems and despite legislation, we are now strapped with expensive IT systems that don’t talk to each other, even from the same vendor.

Cultural change and resistance to change were also significant barriers early in the implementation that we overcame through rapid improvement events (LEAN) and other workflow analysis and improvement efforts involving of all levels of the health system. Additionally, the identification of septic patients and the appropriate “time-zero” (the time sepsis was identified and the three-hour bundle time begins) required troubleshooting and midstream corrections (e.g., triage time, ICU door time). Given a fast changing field of evidence, the participating HVHC member organizations were able to adapt, rapidly change course when necessary (e.g., revised protocol with the Shock Bundle of CVP and ScvO2 measures as optional data collection points), and ultimately save lives. Despite these major barriers we have made real progress.

Section 2: Accomplishments & Lessons Learned
Major accomplishments, main improvement and most meaningful contributions over the entire project period (July 1, 2013 – June 30, 2015) are described below:

**Trained 212 staff across eight different healthcare systems in Lean Process Improvement methodology through Lean Rapid Improvement Events (RIE).** A total of 13 clinical sites convened teams of frontline clinical providers and support staff at each institution for the on-site events. These teams included physicians, nurses, respiratory therapists, pharmacists, mid-level providers, laboratory professionals, pharmacists and pharmacy professionals, management and leadership in the ED, and institution leaders and champions. The RIEs were designed to collaboratively build the bundle into the workflow and were instrumental in achieving rapid implementation of the HVHC sepsis bundle into front line clinical practice within a short period of time.

**Developed Sepsis Treatment Administration Tracker (STAT) (hereafter referred to as the "enrollment tool").** The web-based enrollment tool allowed for prospective tracking of participant counts and bundle adherence rates. Members not using the enrollment tool were required to submit the same data in accordance with a matching data specification.

**Developed Sepsis Process measures and a checklist tool.** The tool allowed for consistent application of the sepsis bundle elements (see appendix A)
Baseline Data Analysis. HVHC members submitted data to the HVHC in accordance with the provided data specification. HVHC provided data quality reports which allowed members to refine and improve the quality of their submission techniques over time.

Member-specific quarterly reports were created utilizing CMS Medicare claims data. Analysis of CMS data through 2015 Q2 has been completed. Member reports included several measures related to sepsis including 90-day episode cost and discharge disposition.

HVHC Sepsis Bundle and Learning Network. Monthly HVHC sepsis team meetings incorporated member driven presentations on progress implementing sepsis bundled care and sharing best practices. Presentations typically lasted approximately 20 minutes with additional time for Q&A and discussion.

Members identified sustainable training methods and protocols. HVHC health systems aligned ongoing education and reinforcement of improved process within local existing practices or integrated their efforts with other education tools. Some examples include: education for the identification and treatment of sepsis patients accomplished in conjunction with clinical board goals (Denver Health); on-line provider education, workforce collaboration and educational symposia incorporated into the re-training method (MaineHealth); ongoing workforce training (North Shore Long Island Jewish); and creation of a guiding team & sepsis collaborative team responsible for organizing appropriate training of staff throughout the hospital (Virginia Mason Medical Center).

Analysis of the effectiveness / success of the project

NOTE: For purposes of all analyses “cost” refers to cost to Medicare and taxpayers: the actual "reimbursement" for claims.

In the analysis against our CMMI goals, we focused specifically on the two complete calendar years for which data were available: 2013 and 2014. We excluded the 2015 partial year (Jan-Jun) from our analyses for two reasons: (1) seasonal changes have been reported to impact sepsis outcomes and; (2) this partial year included a lower number of enrollees both due to the half year time period and due to enrollment dropped off in anticipation of grant funding coming to an end, a problem with “short term funding” to solve a major, life threatening, health problem.

As described in the executive summary and in the Methods Appendix, our evaluation did not include the partial year (Jan – Jun 2015) for two reasons: (1) seasonal changes have been reported to impact outcomes and; (2) this partial year included a lower number of enrollees both due to the half year time period and due to enrollment dropping off in anticipation of grant funding coming to an end. Also, the manual data entry into the study web portal for the sepsis patients turned out to be quite challenging, so our Enrolled Cohorts are much smaller than the CMS Claims-based Cohorts for those participating hospitals. So the evaluation of this project used a range of approaches and data sources to get the most complete picture of the outcomes of interest.

To give context to the results, we are providing a brief overview of each analysis approach and data source below. More in-depth details, including formal cohort definitions, are provided in the Methods Appendix.
Data sources

- **Enrolled Cohort** included sepsis cases meeting a cohort-specific case definition (provided in Methods Appendix) that were extracted and submitted by the hospitals participating in the intervention.

- **Enrolled/CMS Cross-walked Cohort** included patients in the Enrolled Cohort (above) who matched to CMS claims data and also met a series of inclusion/exclusion criteria detailed in the Methods Appendix.

- **CMS Claims-based Cohort** included sepsis cases identified by TDI analysts in CMS claims data who presented at intervention hospitals or comparator hospitals and met a cohort-specific case definition provided in the Methods Appendix.

- **HVHC Unified Data Extract** included a broader data set provided to HVHC by members as part of HVHC’s routine surveillance program; we used this data to calculate measures that weren’t available in Enrolled Cohort data source.

Analyses

**Method 1: Year-over-year change for all participating hospitals** – We examined aggregate change in outcomes over time between calendar years 2013 and 2014 for all participating hospitals using the Enrolled/CMS Cross-walked Cohort, regardless of implementation start date. This method captures temporal patterns; however, participating hospitals started their interventions at different times and with different baseline levels of bundle adherence. Outcomes in this analysis were not adjusted for patient characteristics.

**Method 2: Year-over-year change for hospitals with at least six months of participation in 2013** – Outcomes in calendar year 2014 were again compared to calendar year 2013 outcomes using the Enrolled/CMS Cross-walked Cohort, but only among hospitals that had initiated interventions in the first six months of 2013. Outcomes in this analysis were adjusted for patient characteristics.

**Method 3: Difference-in-difference analysis** – The third analysis was a difference-in-difference analysis from the CMS Claims-based Cohortm comparing outcomes in intervention hospitals to outcomes in matched comparator hospitals over time since intervention start date of each hospital (so not a calendar year comparison). This analysis estimated difference in change in outcomes in the intervention hospital group relative to comparable non-intervention hospitals. Outcomes in this analysis were adjusted for patient characteristics.

Triple Aim Target 1: Cost Savings

**GOAL:** achieve a 5% relative rate reduction over three years in the number of patients with sepsis requiring long term acute care or sub-acute nursing care after an incident episode of severe sepsis; $12.24M savings at HVHC hospitals for Medicare beneficiaries over the 3-year program.

Our evaluation of cost savings for sepsis was limited to evaluating 90-day episode costs in the subset of sepsis cases where the patient survived the length of the 90-day episode and where the patient's record could be matched to CMS claims. The 90-day episodes started with the index admission and included all claims incurred through the 90th day post index-admission.
**90-day episode cost (Method 1)**

Applying analysis Method 1 to the Enrolled/CMS Cross-walked Cohort estimated that the average inflation-adjusted 90-day episode cost decreased by 8% and 7% in 2014 relative to 2013 for actual and standardized costs, respectively. Details are shown in Table 1.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Goal</th>
<th>Observed</th>
<th>% change 2013-2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduce 90-day episode costs</td>
<td>-$9.9M (prorated)</td>
<td>$38,049</td>
<td>$35,099</td>
</tr>
<tr>
<td>(Source = STAT data cross-walked to CMS data)</td>
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<td>$43,248</td>
<td>$40,373</td>
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<td>N=464</td>
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<td>N=807</td>
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</table>

-9.9M goal reflects to exclude two quarters from 2015

**90-day episode cost (Method 2)**

Applying Method 2 to the 2013 subset of the Enrolled/CMS Cross-walked Cohort estimated a decrease in median inflation-adjusted 90-day episode cost of -5.3% (95% CI: -16.9%, 8.0%), and -14.3% (-24.4%, -2.8%), Table 2.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Goal</th>
<th>Observed</th>
<th>Percent Change 2013 to 2014 (95% Confidence Interval)</th>
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<tr>
<td>Reduce 90-day episode costs</td>
<td>-$9.9M (prorated)</td>
<td>$30,405</td>
<td>$25,897 (-5.3% (-16.9%, 8.0%))</td>
</tr>
<tr>
<td>(Data Source = Enrolled/Cross-walked to CMS data)</td>
<td></td>
<td>$35,388</td>
<td>$30,885 (-14.3% (-24.4%, -2.8%))</td>
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<tr>
<td>N=446</td>
<td></td>
<td>N=598</td>
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</tr>
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1 - Percent change shown for 90-day episode costs and acute/sub-acute nursing care are adjusted using regression models

CMS = Centers for Medicare & Medicaid Services
Total estimated cost savings (Methods 1 and 2)

Within this subset of CMS Claims-based Cohort cases, we multiplied the difference between the average 2013 and 2014 90-day episode costs to the number of cases in 2014. For Method 1, this produced an estimated actual savings of about $2.3M. Using the Method 2, with fewer cases, but a larger difference between the 2013 and 2014 median 90-day episode costs, the estimated savings was about $2.7M for 2014 for those hospitals; if we apply that cost savings to also include the hospitals with later launch dates, the savings would be $3.6M. If we apply the Method 1 and Method 2 mean cost savings to the CMS Claims-based Cohort, we achieve $7.3M cost savings and $11.2M savings, respectively. Finally, if we apply Method 1 and Method 2 mean cost savings to an estimated sepsis cohort for all our participating hospitals (calculated by taking the ratio of the Enrolled Cohort to the Enrolled/CMS Cross-walked cohort and applying it to the CMS Claims-based Cohort), we achieve $33.4M cost savings and $51M savings, respectively (Figure 1).

### Figure 1 – Summary of Cost Savings

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2014</th>
<th>Change</th>
<th>Total cost savings estimates for participating hospitals (2013-2014) based on mean cost savings for Y1 &amp; Y2 launch sites</th>
<th>Estimated future annual total annual cost savings of bundle implementation for participating hospitals based on mean cost savings for Y1 launch sites</th>
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<td>Actual mean 90-day episode costs (all sites: Y1 &amp; Y2 launch)</td>
<td>38,049</td>
<td>$35,099</td>
<td>-$2,950</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual mean 90-day episode costs (Y1 launch sites)</td>
<td>30,405</td>
<td>$25,897</td>
<td>-$4,508</td>
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<tr>
<td>N of Enrolled Cohort (all Medicare + non-Medicare)</td>
<td>3,705</td>
<td></td>
<td></td>
<td>- $10,929,750</td>
<td>- $16,702,140</td>
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<tr>
<td>N of Enrolled/CMS Cross-walked Cohort</td>
<td>807</td>
<td></td>
<td></td>
<td>- $2,380,650</td>
<td>- $3,637,956</td>
</tr>
<tr>
<td>N of CMS Claims-based Cohort (using claims to identify)</td>
<td>2,468</td>
<td></td>
<td></td>
<td>- $7,280,600</td>
<td>- $11,125,744</td>
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<tr>
<td>Estimated N of all sepsis cases (based on Enrolled:CMS ratio)</td>
<td>11,331</td>
<td></td>
<td></td>
<td>- $33,425,803</td>
<td>- $51,079,159</td>
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</table>
90-day episode cost (Method 3)

When change in actual episode costs were estimated relative to matched comparators (method 3), the model showed episode costs in intervention facilities changed significantly more than comparators in at least one intervention quarter ($p=0.0158$) (Figure 2). In post-intervention quarters 7 and 8, intervention costs rose faster than comparators. The model for standardized episode-cost did not find a statistically significant difference in change between intervention and comparator hospitals ($p=0.0977$).

Discharge to acute/sub-acute nursing care

SNF/LTAC discharge rate was listed as an outcome in both Triple Aim Target 1: Cost Savings and Triple Aim Target 2: Health Outcomes. Results for this outcome are summarized in the Health Outcomes section where we also compare it with measures of organ failure.

Length of stay (Method 3)

During the post-intervention time period, adjusted mean length of stay decreased for both intervention and comparator hospitals (Figure 3). The difference-in-difference results indicate no significant difference in the rate of decrease between intervention and comparator hospitals during this time-period ($P=0.2337$).
Triple Aim Target 2: Health Outcomes

GOAL: Reduce the burden of chronic morbidity from sepsis-associated chronic organ dysfunction, achieving a 5% relative rate reduction over three years in the number of patients with sepsis requiring long term acute care or sub-acute nursing care after an incident episode of severe sepsis (where episode refers to events that are bracketed by the admission and discharge from an inpatient acute care facility).

Discharge to acute/sub-acute nursing care (Method 1)

Decreasing discharges to acute/sub-acute nursing care (SNF/LTAC) by increased sepsis-bundle adherence is the proposed mechanism driving cost-savings in this project. Discharges to acute/sub-acute nursing care (SNF/LTAC) were 7% lower in 2014 compared to 2013 among in the Enrolled/CMS Cross-walked Cohort using Method 1 (Table 3), exceeding our target of 5%.

<table>
<thead>
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<th>Measure</th>
<th>Goal</th>
<th>Observed</th>
<th>% change 2013-2014¹</th>
</tr>
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<tr>
<td>Reduce acute/sub-acute nursing care (Source = STAT data cross-walked to CMS data)</td>
<td>-5%</td>
<td>47.9%</td>
<td>44.7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N=464</td>
<td>N=807</td>
</tr>
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Discharge to acute/sub-acute nursing care (Method 2)

When SNF/LTAC discharges were evaluated using the 2013 subset of the Enrolled/CMS Cross-walked Cohort using Method 2, the change in proportion discharged to SNF/LTAC was -1.7% (95% CI -14.8%, 11.7%) after adjustment for patient characteristics (Table 4).

<table>
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<tr>
<th>Measure</th>
<th>Goal</th>
<th>Observed</th>
</tr>
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<tbody>
<tr>
<td>Reduce acute/sub-acute nursing care (Source = STAT data cross-walked to CMS data)</td>
<td>-5%</td>
<td>47.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>N=446</td>
</tr>
</tbody>
</table>

¹ - Percent change shown for 90-day episode costs and acute/sub-acute nursing care are adjusted using regression models
Discharge to acute/sub-acute nursing care (Method 3)

When change in discharge to acute/sub-acute care in intervention hospitals was compared with matched comparators by intervention quarter in the CMS Claims-based Cohort using Method 3, a downward trend in discharge to SNF/LTAC could be seen. The model did not indicate that the proportion discharged to SNF/LTAC from intervention hospitals was decreasing faster than comparators (p=0.5231; Figure 4).

Organ dysfunction (Method 3)

Discharge to SNF/LTAC was chosen as a proxy outcome for chronic organ dysfunction. Within our CMS Claims-based Cohort, however, we were able to estimate the incidence of two classes of post-discharge chronic organ dysfunction directly, kidney failure and respiratory failure. These were measured using billing codes indicating dialysis and ventilator use, respectively, that were present after discharge, but not before the index hospitalization. For incident post-discharge dialysis, results of the difference-in-difference analysis (Method 3) found no significant difference (P=0.4765) in the rate of change in incident dialysis use (Figure 5) over the post-intervention period between the Intervention and Comparator hospitals.
Results of the difference-in-difference analysis (Method 3) for incident post-discharge ventilator use indicated a significant difference ($P=0.0263$) in the rate of change in incident ventilator use (Figure 6) between intervention and comparator hospitals during the post-intervention period. While none of the post-intervention quarters were significant individually, quarters 4 and 8 were marginally significant ($P=0.0673$ and $P=0.0537$, respectively), likely contributing to the overall significant difference-in-difference.

**Mortality (Method 3)**

We evaluate in-hospital mortality in both the CMS Claims-based Cohort and the HVHC Unified Data Extract cohort (for non-Medicare patients). In the CMS Claims-based Cohort, there was minimal or no decline over time since intervention start in in-hospital mortality (Figure 7). The difference-in-difference analysis (Method 3) did not detect statistically significant differences in-hospital mortality between intervention and comparator hospitals post-intervention ($P=0.5080$).
In the HVHC Unified Data Extract cohort, in-hospital mortality by calendar quarter of index-event data suggest a slight decline for in-hospital mortality in sepsis cases presenting in the ICU. The mortality rate shows no determinate trend in patients presenting in the Emergency Department. Mortality rates by quarter of index event for both groups are shown in Figure 8.
Triple Aim 3: Quality of Care

**GOAL:** Improve optimal adherence to sepsis bundled care by 5% (relative rate) over three years.

**Bundle Adherence (Method 1)**

Measuring bundle adherence in the Enrolled/CMS Cross-walked Cohort using Method 1, three-hour bundle adherence for all intervention sepsis patients in 2013 was 66.1%, in 2014 was 64.5%, and in 2015 (Jan through June) was 62.3%, falling short of our target to increase by 5%.

When bundle adherence was evaluated using Method 2, the analysis indicated that adherence rates were not homogeneous between all members, so we repeated the analysis by member. When bundle-adherence was evaluated by member system, the two member systems that were “just starting” sepsis interventions (UIOWA and DENVER) had substantial and statistically significant increases in bundle adherence. The members who had programs in place and were using the intervention in a “sustaining” mode had small changes around zero. These results are summarized in **Table 5. Figure 9** shows bundle adherence in systems that were starting the sepsis intervention compared to those who had a sepsis program in place prior to the start of this project and were “sustaining.” No difference-in-difference analyses (Method 3) were performed on bundle adherence since we did not have that data for comparators. When limiting the analysis to evaluate only those members who had not started implementing the sepsis bundle prior to the CMMI launch, we increased bundle adherence from 48.8% to 61.5%, increasing adherence by 26%, far exceeding our target 5% increase for those members.

**Figure 9:** Bundle adherence by quarter since intervention start and stratified by mature (sepsis intervention in place prior to start of this project) or starting (no prior intervention in place).
Table 5: Bundle adherence in 2013 compared to 2014 for members starting their sepsis interventions in the first half of 2013 (Method 2).

<table>
<thead>
<tr>
<th>Measure</th>
<th>Goal</th>
<th>Observed</th>
<th></th>
<th>Year</th>
<th></th>
<th>Percent Change 2013 to 2014¹ (95% Confidence Interval)</th>
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<td></td>
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<td></td>
<td>Member</td>
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<td></td>
<td></td>
<td></td>
<td>BAYLOR</td>
<td>2013</td>
<td>77.4%</td>
<td>-3.3% (-11.0%, 5.0%)</td>
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<td>All Members Combined²</td>
<td>2013</td>
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1 - Percent change shown for 90-day episode costs and acute/sub-acute nursing care are adjusted using regression models

2 - Breloow-Day test indicates lack of homogeneity between sites (P=0.0122), thus All Members Combined not reliable
Sepsis Bundle Components (Method 1)

Overall three-hour bundle adherence stratified by location of presentation, emergency department (ED) or intensive care unit (ICU), by calendar quarter is shown in Figure 10. The four components of the three-hour bundle Figure 11A-D include: (A) measuring initial lactate, (B) obtaining blood cultures before delivery of broad spectrum antibiotics, (C) administration of broad-spectrum antibiotics and, (D) administration of 30 ml/kg crystalloid. The figures show indeterminate bundle adherence trends for sepsis cases presenting in the ED as well as sepsis cases presenting in the ICU.
While crystalloid administration generally had the lowest adherence of any of the bundle components, the proportion of patients receiving the complete bundle was smaller than the proportion who were crystalloid compliant, suggesting that bundle adherence was not limited by only one component. Documenting Crystalloid Bolus IV fluid amounts given in the ED was identified as a significant challenge. In multiple instances, IV fluid stop times were not consistently documented in the EHR.

Results discussion – Clinical Interpretation

A total of 7,030 patients with septic shock were enrolled in the project of which 1,571 were analyzed by crosslinking to Medicare data. Using year-over-year comparisons (Method 1), the average reduction in 90-day episode cost was 8% or $2,950 comparing 2013 to 2014 data and 14.4% for mean annual savings of $4,508 when we limit our analysis to those hospitals that launched in Y1 (and had more time to realize potential savings). Discharges from the index admission to LTAC and SNF decreased by 7% from 2013 to 2014. Three-hour bundle adherence decreased from 66.1% to 64.5% across HVHC, while it increased by around 20% for institutions that had a new sepsis improvement effort. When we examined the more specific cohort for year-over-year comparisons (Method 2), results were similar.

There are several limitations that need to be considered when interpreting these results. Healthcare institutions improve the quality of their care continuously. Internal as well as external quality improvements efforts focusing on identification and treatment of sepsis patients, such as the New York state law (Rory’s law), have likely affected results It is impossible to distinguish the effects of the HVHC initiative from those confounding events. HVHC members contributing the most patients to the cohort had mature and well-established sepsis improvement efforts in place and were unlikely to improve. Indeed, the average three-hour bundle adherence rate within HVHC was already very high from the start of the project, and smaller sites with significant improvements over time were not able to impact overall change in bundle adherence. Furthermore, no baseline data on process or outcome measures were collected. Lean improvement workshops preceded any data gathering and hence we have no insight regarding before-after performance. Because of the short time span of the study, many sites that are showing promising trends toward dramatic improvements in bundle adherence and reductions in mortality, are not presented in these data. Finally, less than 25% of patients enrolled were crosslinked to Medicare data. A longer observation period would have provided valuable insight.

The principal aim of this study was to improve patient outcomes and decrease cost by increasing adherence in the delivery of the sepsis bundle intervention. Multiple studies (ProMISe, ARISE) have since impacted the evidence, focusing attention on the initial intervention – the three-hour bundle (13,14). Prompt diagnosis is required for delivery of the bundle. The start time or “time zero” was required to establish and measure 3-hour bundle adherence. Since time zero needed to be consistently defined and readily available across institutions, we chose the arrival time of patients admitted via the emergency department as time zero. Internal analysis on the impact of bundle adherence on outcomes showed no association. This is likely due the fact that, in the setting chosen, we were not able to control the time of presentation or diagnosis. In other words, if the time of optimal diagnosis is delayed by 24 hours because the patient is at home, bundle adherence is less likely to have an impact on outcomes. Changing evidence impacted some measures, but also redirected the focus on early detection.

Despite these limitations, numerous important conclusions can be drawn from these results. In a group of very high performing health care institutions (as shown by high bundle adherence rates at baseline), costs can be further decreased by rigorous quality improvement using the set of strategies used by the participating hospitals. Overall cost savings of this work
are likely dramatically underreported, as less than 25% of patients enrolled have cost data available for analysis. While improvement efforts primarily targeted and are exclusively reported for patients arriving through the emergency room, simultaneous sepsis care improvement efforts outside of the emergency room are not reflected in cost saving estimates.

Results discussion – Analytic Notes

Intervention status of participating hospitals

Hospitals participating in this project included hospitals that had sepsis interventions already established and in place prior to the start of the award (“sustaining”) as well as hospitals that did not have established programs and used this award to implement the sepsis intervention (“just starting”). When we compared bundle adherence by “sustaining” versus “just starting facilities we saw little change in systems that had established bundle adherence programs, but the two “just starting” health systems showed substantial and statistically significant bundle adherence improvement from 2013 to 2014.

Organ failure and LTAC/SNF discharge

The driver diagram proposed increasing bundle adherence as a mechanism for preventing chronic organ-dysfunction and lower discharges to LTAC or SNF. Early and consistent bundle adherence, in theory, should lead to less organ dysfunction and less need for LTAC or SNF. We measured both discharge to LTAC/SNF and two measures of incident chronic organ-dysfunction, ventilator use and dialysis. While LTAC/SNF use appeared to have a downward trend, the contribution of the two measured forms of organ dysfunction appears to be a small component of the discharge to LTAC/SNF measure.

ED triage time or ICU door time

The ED triage time or ICU door time needs to be a clinically appropriate start time for the bundle. Patients where the triage time or ICU door time was not an appropriate start time for the bundle would, however, still have been impacted by the interventions of training care teams, rapid alert systems, order sets, etc. However, because the process measures need a ‘time zero’ bundle adherence is not applicable in these cases.

Example: A patient being transferred from another facility arrives at the ICU having received antibiotics 10 hours prior to arrival in the ICU (ICU door time). For this example, the patient is excluded because the ICU door time must match up with the timestamps on the process measures. Our cohort focuses on patients with rapid onset of sepsis, not transfer patients with care already administered elsewhere.

Analysis artifacts

We were limited in the amount of follow-up time available. While the project was funded for three years, interventions started in early 2013, or project 3QR. The last intervention hospitals started their interventions in the spring of 2014, or project 6QR. While the analysis was looking for homogeneous improvement throughout all intervention hospitals, some hospitals already had bundle-adherence programs in place and their performance had plateaued where substantial improvement was not likely. Other hospitals used the project as an opportunity to start an intervention and had much greater opportunities to improve. Similarly, hospitals that started their interventions late in the project were followed for fewer intervention quarters. When making year-over-year comparisons, we were limited to the complete years 2013 and 2014 since data collection ended midway through 2015. Because sepsis incidence has been shown to be seasonal (11), and half a year of data provides a smaller number of cases we did not think using half a year of data made a fair comparison and so did not include 2015 in the analysis.
Aggregate analysis of non-homogenous populations
When possible, we used the CMS cohort to compare change in outcomes in intervention hospitals against change in matched comparator hospitals. These comparisons were designed to evaluate aggregate change in a homogenous population of intervention hospitals. Those comparisons generally did not find a difference or consistent pattern between the intervention-hospital group and the comparators. Analyzing in aggregate was a design decision due to small numbers of events. We compared a combined group of hospitals that included those with established sepsis programs and those just starting with comparators that may have included the same mix. We know that there are many projects aiming to improve care of sepsis patients, so we cannot assume that comparators were not involved in some sepsis quality-improvement effort. As an example member Northwell Health (formerly North Shore – LIJ) is located in New York, where the state government mandated hospitals adopt best practices for sepsis identification and treatment in May, 2013, a time-frame similar to the HVHC intervention \(^{(12)}\).

Section 3: Challenges and Lessons Learned
All members were asked to reflect on the Sepsis Improvement efforts over the three years of the project. Each member was asked to identify which of the challenges were most difficult for their system to overcome. Results from this survey are listed below. The list is ordered by the number (in parentheses) of members who indicated the challenge as most difficult. Responses in *italics* are directly from member reports. Details describing the barrier and what each system learned are included below:

**#1 Bundle adherence tracking (e.g., time stamps, Fluid orders etc.) - (7)**

**Six-hour bundle.** Multiple members have cited changes in evidence and difficulty with physician adherence surrounding the 6-hour bundle elements. Updated evidence led us to remove the central line mandate effective July 1, 2014 \(^{(13,14)}\).

**PROVIDENCE:** Documenting IV fluid amounts given in the ED: IV fluid stop times are not consistently documented in the EHR within the ED. We did education to improve this, continue to work on this to allow automated reporting and adherence with the three-hour bundle. The blanket 30ml/kg - was found to be inappropriate in some situations (e.g., morbidly obese) making it important to have a process in place to discern the exceptional cases (e.g. use of "ideal weight" rather than actual weight).

**BETH ISRAEL DEACONESS MEDICAL CENTER:** Achieving fluid target within 3-hour time frame was challenging, particularly for delayed presentations or obese patients. Improvement was seen with modifications to POE fluid orders, elevated lactate page notification via automated paging system to senior resident in the ED in order to achieve earlier IVF administration. It is critical to define clear parameters before, identify appropriate exclusions, and give credit for ALL volume given (i.e., blood or albumin). Fluid performance did improve but the 3-hour time constraint remains challenging for certain conditions (obesity, delayed presentations). This challenge and our mitigation strategy resulted in a positive impact on sustainability – clinicians are more aware of tendency to under-resuscitate patients.

**INTERMOUNTAIN HEALTHCARE:** Data capture for the Intermountain Healthcare sepsis bundle adherence rates consists of both automated and manual functions. Our electronic health record is quite robust in automating many of the elements of data capture However it does have some holes and limitations. One of these is the volume of fluid administered and the start and stop times of fluid administration. We did use manual chart abstraction to close this gap. However, this too was difficult and consequently some estimates of the time stamps were required. This barrier is also not yet overcome but is presumed to be better under the new Cerner electronic health record. Overall this had little impact on the overall sustainability efforts. Organizations that undertake complex initiatives such as bundle adherence need to be aware of limitations of automated data capture and develop mitigating strategies beforehand.
MAINEHEALTH: Bundle adherence had challenges because there were shades of gray that made adherence difficult to assess without review, particularly in terms of the amount of fluid administered and when. Septic shock bundle implementation on the inpatient units was the most difficult to sustain due to issues with the EMR.

SCOTT & WHITE: The need to manually identify cases (defined by a number of different diagnoses) and to chart review each case resulted in relatively long delays in the time between cases and our performance reports. We worked to automate reports, but were unable to get to a trusted automated report during the project duration. We will continue to work on a reporting system that provides performance reports that are near real-time and using specifications outlined by CMS. Improvements in performance reporting will allow for continued improvement cycles and sustainment.

UNIVERSITY OF IOWA: Bundle adherence was an early issue, especially with paper tracking. Moving this to an electronic version will assist in this area.

VIRGINIA MASON MEDICAL CENTER: Accurately tracking bundle adherence and accounting for the many exceptions to care was a significant challenge. We used our data mart to identify patients based on the clinical criteria for sepsis (2 or more SIRS + lactate or systolic blood pressure <90). We also use our data mart to structure the relevant bundle data to evaluate whether or not patients received the relevant bundle elements in time. We then filter all patients who meet these criteria by diagnosis code so that we do not mistakenly include patients with alcohol withdrawal or other types of shock (e.g., hemorrhagic). Lastly, we sweep the encounters via a quick chart review to confirm the patients should not be excluded from the data. This includes patients who may be put on comfort care or are transitioned from another facility with sepsis that have been previously treated. We learned after our first iteration of our data mart that it is easier to evaluate more clinical questions by collecting the specific dates and time in which each bundle element was provided, rather than summarizing the data as the STAT data specification notes. This challenge was successfully overcome. We now have reliable monthly tracking of bundle adherence data that is used for defining improvement plans and ad hoc improvement opportunities. Overall, this barrier negatively impacted us in creating a disconnect between our clinical and data teams which had to be overcome with teamwork, leadership and exhaustive efforts to get the data accurate. The positive is, now we have reliable data that is helping to save lives through targeted clinical interventions and improvements.

#2 Cultural change / resistance (5)

NORTH SHORE LONG ISLAND JEWISH As the North Shore - LIJ Health System continues to expand, aligning new hospitals with our strategic quality objectives is a challenge. The system has developed an orientation program for hospital quality leaders to highlight key strategic initiatives. New facilities are invited to join the Sepsis Task Force.

SCOTT & WHITE: Some aspects of bundle adherence for the HVHC population defined in the data specs represented practice changes that were not necessarily supported by providers. For example, there were concerns over situations in which clinical judgment did not support administration of the full IV bolus. In addition, our project was originally introduced by teams that were not embedded in the ED. This created a natural skepticism. Our ED stakeholders willingly came on board to work through challenges and became the owners of our improvement efforts. Ownership in the ED is critical to our ongoing improvement efforts. We are seeing a good deal of progress around process changes that will likely lead to measurable improvements.

UNIVERSITY OF IOWA: There was some cultural resistance, especially regarding nurse focus and whether we could use the "I suspect sepsis" button. After speaking with other HVHC members about the issue, we were able to appropriately communicate to the team the need for it and how it could help early detection of sepsis.
BETH ISRAEL DEACONESS MEDICAL CENTER: Initially the focus on CVP and ScVO2 monitoring (prior to revision of the 6-hour bundle) was a challenge in our hospital as many clinicians had objections to those measures, particularly for normotensive patients with a single elevated lactate. We acknowledged the evolving evidence and practices early on and collected data on other measures (for example, cardiac output via NICOM), and focused our efforts primarily on the 3-hour interventions with less emphasis on the 6-hour bundle prior to the revision, which improved clinician willingness to engage with the overall work. Buy-in of clinicians is essential for successful interventions. This challenge was overcome with revision of Shock Bundle. Overall, mitigation of this barrier by revision the bundle to remove the two measures resulted in a positive impact on sustainability.

DARTMOUTH-HITCHOCK: Organizationally we knew we wanted to improve our outcomes quickly. This required us to launch without consensus of all parties, which was a big culture change. We knew we would have to change things as we went to accommodate different teams. There was quite a bit of push back on the learning module and individuals felt left out. However, because this was an important initiative, we kept pushing and re-evaluating as we moved along. Having a Black Belt in process improvement helped us tremendously.

#3 Data Collection: (5)

BAYLOR: Depending on EHR, certain elements may not be available for extraction and require manual review, abstraction, and calculation. We overcame the issue with manual chart review and developing an algorithm to determine fluid stop time based off of the data available. The algorithm has mitigated the barrier.

MAINEHEALTH: Data collection through the STAT was demanding and required numerous hours of manual chart review to ensure accuracy with reporting. The tool was broken much of the time, inconsistent and difficult to use.

BETH ISRAEL DEACONESS MEDICAL CENTER: Data collection (e.g., abstracting and reporting clinical and administrative data). There is no easy method for automated data extraction for the required data elements, therefore this was manual data pull which is time consuming and labor-intensive, and requires oversight by a clinician. Mitigation involved automated screening and training research assistants to ensure complete capture, close oversight and interaction with MD PI. We overcame barrier by utilizing all available resources to ensure adequate data abstraction. Without successful mitigation, this could have a negative impact on sustainability.

DARTMOUTH-HITCHOCK: Early data collection was extremely difficult; the volume infused was often not documented. This led to the ED team feeling that the baseline performance was actually better than the data showed. Education was provided to the nursing team to assure that the volume infused was documented appropriately. Strong organizational leadership was invaluable in engaging the team to own their performance and outcomes. Also, having a weekly scorecard on bundle adherence and early detection helped the team to own their practice. The ICU was engaged and had the advantage of all the work previously done in the ED. The ICU and ED are fully engaged and active in launching to all inpatient areas.

DENVER HEALTH: The lack of electronic medical system in the ED created a significant challenge for data collection. Manual data extraction by a nurse was utilized to address the challenge. Developing methods of manual extraction and daily screening are key. Manual extraction is a good method to do more real time data extraction and reporting. Real time data reporting has shown to have a positive effect on cause analysis and case review of system improvement areas.
#4 Identifying septic patients (3)

**NORTH SHORE LONG ISLAND JEWISH:** Persuading ED physicians that existing sepsis guidelines could be revised and made relevant to the ED environment was a challenge. To overcome this hurdle, sepsis was defined as a spectrum of disease ranging from sepsis (two SIRS criteria + possible infection) to severe sepsis and septic shock. The term “super SIRS” was introduced. Multiple “time zero” allowed sepsis recognition to occur in several points on the algorithm as opposed to the arbitrary use of triage time.

**VIRGINIA MASON MEDICAL CENTER:** Identifying septic patients is challenging. We used our data mart to identify patients based on the clinical criteria for sepsis (2 or more SIRS + lactate or systolic blood pressure <90). We then decided to filter all patients who meet these criteria by diagnosis code so that we do not mistakenly include patients with alcohol withdrawal or other types of shock (e.g., hemorrhagic). Lastly, we sweep the encounters via a quick chart review to confirm the patients should not be excluded from the data. This includes patients who may be put on comfort care or are transitioned from another facility with sepsis that have been previously treated.

Designing and setting up a database is possible, but takes many resources and effort to setup. It has helped us immensely in identifying our denominator population. This challenge has been successfully overcome as we are wrapping up last minute changes to the database to perform our final reporting to HVHC. Addressing this challenge has caused us to utilize many more resources than we initially anticipated as well as required multiple iterations to improve the quality of our sepsis data. While this is a negative impact in nature, we have set up a sustainable solution to use beyond the CMMI award.

**DARTMOUTH-HITCHCOCK:** The criteria for sepsis are nebulous and can be caused by many other diagnoses such as a post op patient presenting challenges in identifying the patients. We decided to use "super SIRS" criteria to avoid the false positives. We also educated our Rapid Response Team to help filter whether the patient was septic. What we have learned is that regardless of location, when a patient meets criterion they often require some intervention regardless if it is for sepsis. House-wide education helped to identify patients earlier. We also created posters that clearly state what to look for and how to respond. We are currently working on a flagging system in the EMR.

#5 Alerts through the EMR (3)

**INTERMOUNTAIN HEALTHCARE:** We found that electronic alerts might be helpful in 2 areas. First, in helping to screen for patients who might be eligible for the bundle and second, in helping to ensure bundle adherence and correct orders for inpatients who were indeed eligible for the bundle. The second instance is rather trivial in presenting order sets. The first is more difficult as an effective screening alert must be sufficiently sensitive and specific to be meaningful to the clinical team. We worked with a number of strategies including role based and bays in operations; neither were ideal. In both cases the SIRS criteria serves as a starting point but we found temperature and respiratory rate evaluation to be unreliable. The key is in the finding some codified documentation element or order that accurately captures "suspicion for infection." As we transition to the Cerner EMR we have not yet overcome this barrier. This barrier has had a negative effect on sustainability efforts given that the rules currently in place are oversensitive and lead to alert fatigue and voluntary alert blindness.

**VIRGINIA MASON MEDICAL CENTER:** Alerts through the EMR: One of the biggest challenges we faced was setting up an electronic best practice advisory (BPA) in our EMR, Cerner. We raised this potential need to our sepsis guiding team to see if it is an appropriate intervention to take within our EMR as well as simulated several BPA options to implement. We learned that before you can move forward with such an alert, you need to gain approval from clinical stakeholders and leadership to implement such a solution. We did not overcome this barrier due in part to our position that a BPA will be more of a distraction than benefit to our clinical teams. In testing a potential BPA, we found that it would often alert the clinical team after they had already initiated treatment. Hence, it has been our
decision to not implement one. There has been little impact due to this barrier. We continue to evaluate potential options for a BPA and will implement one once we see more benefit than distraction.

#6 Reliable performance reporting (3)

Differences in how bundle adherence is measured can make the same data vary in interpretation. An example is using actual weight rather than ideal body weight for fluid administration.

**NORTH SHORE LONG ISLAND JEWISH:** Fluid resuscitation has been a challenge throughout this initiative. Many physicians are unfamiliar with the data related to the benefit of early empiric fluid administration in severe sepsis and shock. Physicians are reluctant to prescribe the defined volume of fluid to be administered as quickly as called for in evidence-based guidelines. Accurately capturing the exact amount of fluid given by bolus within 180 minutes compounds the issue.

**VIRGINIA MASON MEDICAL CENTER:** Collecting accurate information to reliably report sepsis performance is a challenge. We used our data mart to identify patients based on the clinical criteria for sepsis and treatments the patient received during their visit. We then filter all patients who meet these criteria by diagnosis code so that we do not mistakenly include patients with alcohol withdrawal or other types of shock (e.g., hemorrhagic). Lastly, we sweep the encounters via a quick chart review to confirm the patients should not be excluded from the data. This includes patients who may be put on comfort care or are transitioned from another facility with sepsis that have been previously treated. This data is used for evaluating various performance measures like sepsis mortality, bundle adherence, length of stay, discharge disposition. Designing and setting up a database is possible, but takes many resources and much effort to setup. It has helped us immensely in reducing the amount of clinical resources needed to report this data. This barrier was successfully overcome. We now have reliable monthly tracking of bundle adherence data that is used for defining improvement plans and ad hoc improvement opportunities.

**Section 4: Planned Activities**

Funded by the High Value Healthcare Collaborative, a follow-on study intends to examine the ongoing effects of health care innovations implemented through this CMMI award. The new follow-on study will allow for an extended period of evaluation and monitoring of each program utilizing CMS as well as High Value Healthcare Collaborative (HVHC) member-submitted data. This evaluation will provide the analytic evidence to help determine the long-term impact and success of sustainability of this project.

Additionally, Dartmouth has received a grant from the Laura and John Arnold Foundation to continue efforts in disseminating and implementing the sepsis care model. By sharing data and lessons learned from the original CMMI Sepsis Improvement sites, the Laura and John Arnold Foundation grant will help identify best practices for dissemination and implementation of this sepsis care model to accelerate broad-scale adoption across the HVHC health systems.

**Section 5: Stories from the Field**

Responses below are stories from members reflecting factors or characteristics of their organization that contributed to success (staffing model, local quality initiatives, organizational support, state and community initiatives etc.).
Identifying Septic Patients

INTERMOUNTAIN HEALTHCARE: Despite the limitations of our electronic health record, we have used other means including paper screening tools and order sets to help embed a certain consciousness toward potential septic patients in the ED’s, ICUs, and medical-surgical units of Intermountain Healthcare. We have engaged frontline clinicians sufficiently such that they understand the importance of sepsis screening linked to early identification and enrollment. Many facilities have built a normative peer-review process around this part of the sepsis bundle and its effect has been notable.

MAINEHEALTH: MaineHealth EDs have demonstrated success with communication and recognition of sepsis patients. The culture has shifted to having sepsis as a critical part of education and training. Also, awareness was raised about the value of early recognition of sepsis patients.

VIRGINIA MASON MEDICAL CENTER: Identifying septic patients: Sepsis identification and treatment has been an organizational goal at Virginia Mason for the last 2 years. By organizing a sepsis data mart, we are able to rely on our systems to identify sepsis patients going forward without having to add or maintain resources beyond the CMMI award.

Reliable Performance Monitoring

INTERMOUNTAIN HEALTHCARE: Our sepsis team has had dedicated statisticians and analysts for many years. They have built a robust and nearly real-time reporting system for each of the individual bundle elements as well as total bundle adherence and mortality. These metrics are reviewed on a regular basis by the clinical teams and are used to generate discussions around additional improvement strategies. We feel this is one of the key elements of a sustainable improvement effort whether it be for sepsis or any other clinical disease process.

NORTH SHORE LONG ISLAND JEWISH: The System developed a Sepsis Task Force. The Task Force meets every other month to share best practices, review KQMI metrics, motivate change and sustain results. (Attachment 5) “Collaborative calls” are held on alternating months to promote system-wide collaboration, performance review and discuss team dynamics.

VIRGINIA MASON MEDICAL CENTER: We have several performance and quality measures associated with our sepsis organizational goal. This includes sepsis mortality, bundle adherence and discharge disposition. We are also tracking length of stay. By setting up the data systems to report these automatically, we have been able to sustain these efforts through the CMMI award.

PROVIDENCE: The principal strategy to sustain success with performance monitoring included data feedback. An existing chart reviewer has now been tasked with doing the "HVHC" chart reviews for bundle adherence - in as close to real time as possible.

Communication

VIRGINIA MASON MEDICAL CENTER: We have several strategies for communication that have been successful in sustaining the sepsis improvement work. First, our sepsis guiding team is responsible for determining the direction needed with the work as well as communicating interventions, improvements and progress on the existing organizational goal through monthly reporting through the board. Secondly, we have a sepsis collaborative that brings together representatives throughout the hospital on the work and provides a venue for successful strategies and barriers to be addressed.

INTERMOUNTAIN HEALTHCARE: Quarterly learning sessions incorporate collaborative rounds where sites present in poster format their current PDSA cycles and metrics. Planetary sessions by subject
matter experts address current challenges and updates on evidence-based practice. (e.g., documentation of the start/stop of a fluid bolus). These sessions conducted every 4 to 5 months enhance knowledge, enable teams to gather new skills, accelerate improvement, connect colleagues, develop action plans, and promote the spread of best practice. An active listserv was established to promote thoughtful discussion on challenging issues.

PROVIDENCE: The CMMI grant has promoted continued collaboration to reduce sepsis mortality. There has been increased communication across hospital ICUs and EDs regarding both treatment standards and strategies to achieve them. We have sustained improvement in interdisciplinary problem solving, particularly between nurses and physicians.

Sepsis Training & Education
VIRGINIA MASON MEDICAL CENTER: We assign clinical champions to each area to oversee training and education in our care processes for sepsis. We also hold huddles with each section and sepsis leadership to help disseminate new processes so that everyone across the organization is aligned in our sepsis care.

Bundle Adherence Tracking
VIRGINIA MASON MEDICAL CENTER: Bundle adherence is one of our core A3 measures that is required to be reported to our board of directors every month. With our data systems in place, we are able to sustain this tracking robustly throughout the organization and use this going forward to sustain our sepsis data collection.

BAYLOR: By hardwiring the bundle into the processes, weekly rounding, accountability & monthly reporting we have ensured sustainability.

BETH ISRAEL DEACONESS MEDICAL CENTER: We have a strong QA infrastructure in place, tightly linked with the ED Dashboard, to ensure that we sustain progress and can identify lapses in adherence.

Data Collection
INTERMOUNTAIN HEALTHCARE: This is closely linked to performance reporting. Intermountain Healthcare does understand the need for reliable data and hence for many clinical processes has augmented automated data capture with manual chart abstraction and data verification and validation. The data that populates our "Sepsis DataMart" is therefore trusted by both clinical and administrative teams and thus can be used to generate meaningful discussion, understanding, and improvement strategies. Many processes that require management and healthcare are wickedly complex. These complex processes most often require a combination of automated and manual data acquisition. By investing the extra time and money to ensure the reliability of data, it can be used more aggressively and accurately by the clinical teams.

VIRGINIA MASON MEDICAL CENTER: We set up a sepsis data mart to automatically collect clinical and administrative data.

Clinical setting ED vs. ICU
PROVIDENCE: We have successfully increased communication across hospital ICUs and EDs regarding both treatment standards and strategies to achieve them.

VIRGINIA MASON MEDICAL CENTER: We have sepsis order sets that are being used by each team in the ED and ICU. Because sepsis is an organizational goal, we have internal quality measures.
associated with our team's performance that are pushing improvement in treatment of these as well as sustain the efforts we have put in place over the last 2 years.

Electronic Medical Record System and Alerts

**VIRGINIA MASON MEDICAL CENTER:** We have designed multiple order sets to assist the treatment process, ordering and administration of the sepsis bundle within our EMR. Our data mart also leverages the data entered in the EMR so we will continue to train staff on how to use our EMR so that the data represents what occurs from a clinical standpoint.

**UNIVERSITY OF IOWA:** The alerts in the EMR will assist in identifying septic patients and assist in bundle adherence. This will also increase communication about possible septic patients to the team. We will continue to work on the Sepsis project, how we can improve electronic bundle implementation, and how we can disseminate our work to HVHC members and affiliated hospitals.

Cultural Change / Resistance

**VIRGINIA MASON MEDICAL CENTER:** We use our Virginia Mason Production System, which is our lean management method to lead cultural change and overcome resistance to change.

**NORTH SHORE LONG ISLAND JEWISH:** Implementing new processes across a system take time and resiliency. One of our keys to success has been setting aggressive internal stretch goals that in many cases exceeded the evidence-based thresholds. Our willingness to define measures that are meaningful to the front line has also proven beneficial. Initially the system focused on each of the three-hour bundle elements as an individual process. After achieving success with each of the bundle elements the System is currently moving towards achieving high reliability in all bundle elements for all patients as measured by an all-or-none-score. In 2013 New York became the first state to mandate that hospitals adopt a series of evidence-based protocols to diagnose and treat sepsis. The regulation named “Rory’s Law” requires all NY hospitals to proactively aim for early recognition and treatment of sepsis. NYSDOH requires data submission from individual hospitals on a quarterly basis. In 2015, the System focus is on fluid administration. Having all sites in addition to both the ED and inpatient teams focusing on the same issue has enabled the teams to tackle the clinical resistance associated with a fluid bolus. Other- Translation - The System has utilized this format to tackle other key initiatives like Advanced Illness and Anticoagulation.

General Sustainability Comments

**DENVER HEALTH:** Denver Health has made the care of a septic patient an organization priority. Identifying septic patients, measuring, communicating and reporting bundle adherence and performance, utilizing EMR alert systems, Sepsis training and education with documentation will all be continued past grant funding with internal funding. Denver Health is switching to a new EMR in April 2015 so a sepsis order set and BPA are being built now in anticipation.

**SCOTT & WHITE:** We are working on early identification and treatment of sepsis on our hospital floors. The HVHC project was instrumental in opening discussions about data definitions and in establishing the infrastructure for improvement.

**DARTMOUTH-HITCHCOCK:** We have a dedicated team looking at and re-evaluating the current process. We examine our patients where delays in recognition occurred and provide real time feedback. We have created monthly reports for the ICU and ED so they can review with the team their accomplishments. We are working on an inpatient report as well. Having our Rapid Response team
available has been instrumental in assuring patient recognition and appropriate interventions. Data helps the team realize where they need to improve.

ANONYMOUS “Senior leadership has expressed their appreciation of substantial progress in system wide sepsis care over the past 2 years. The CMMI/HVHC project has been recognized as a specific driver of improvement.”

“Our work with the HVHC and the sepsis initiative has re-energized our staff and clinical partners with respect to research and improvement. We have built a core research team that is conducting important research in new resuscitation strategies and the long-term cognitive and psychological impacts of septic shock including the complex interplay of proteo-genomics toward "post-ICU" syndrome. Our clinicians have loved the relationship with the HVHC in this regard.”

Section 6: Pulse Check
No additional information

Section 7: Final Report Close-out

Note: categories below required by CMMI for final report close-out.

- **Major activities that occurred during the three-year award period.**

  *Trained 212 staff across 8 different healthcare systems in Lean Process Improvement methodology through Lean Rapid Improvement Events (RIE).* A total of 13 clinical sites convened teams of frontline clinical providers and support staff at each institution for the on-site events. These teams included physicians, nurses, respiratory therapists, pharmacists, mid-level providers, laboratory professionals, pharmacists and pharmacy professionals, management and leadership in the ED, and institution leaders and champions. The RIEs were designed to collaboratively build the bundle into the workflow and were instrumental in achieving rapid implementation of the HVHC sepsis bundle into front line clinical practice within a short period of time.

  *Developed Sepsis Treatment Administration Tracker (STAT) (hear after referred to as the "enrollment tool").* The web-based enrollment tool allowed for prospective tracking of participant counts and bundle completion/adherence rates. Members not the enrollment tool were required to submit the same data in accordance with a matching data specification.

  *Developed Sepsis Process measures and a checklist tool.* The tool allowed for consistent application of the sepsis bundle elements (see appendix A)

  *Baseline Data Analysis.* HVHC members submitted data to the HVHC in accordance with the provided data specification. HVHC provided data quality reports which allowed members to refine and improve the quality of their data submission techniques over time.

  *Member-specific quarterly reports were created utilizing CMS Medicare claims data.* Analysis of CMS data through 2015 Q2 has been completed. Member reports included several measures related to sepsis including 90-day episode cost and discharge disposition.
HVHC Sepsis Bundle and Learning Network. Monthly HVHC sepsis team meetings incorporated member driven presentations on the HVHC Sepsis Bundle and sharing best practices. Presentations typically lasted approximately 20 minutes with additional time for Q&A and discussion.

Members identified sustainable training methods and protocols. HVHC health systems aligned ongoing education and reinforcement of improved process within local existing practices or integrated their efforts with other education tools. Some examples include: education for the identification and treatment of sepsis patients accomplished in conjunction with the clinical board goals (Denver Health); on-line provider education, workforce collaboration and educational symposia incorporated into the re-training method (MaineHealth); ongoing workforce training (North Shore Long Island Jewish); and a guiding team & sepsis collaborative team responsible for organizing appropriate training of staff throughout the hospital (Virginia Mason Medical Center).

- **Omissions and changes in major project activities.**
  - **Removal of the mandate for CVP and ScvO2 measures from the bundle.** Based on new evidence regarding central line placement with no improvement in outcomes (and no harm), the sepsis project team reviewed the CVP and ScvO2 measures in the 6-hr bundle and agreed to remove the CVP and ScvO2 mandate. Changes in clinical practice at member institutions have made these measures difficult to track. Although controversial, this course correction also allows for greater emphasis on the three-hour bundled care, reaching sepsis patients earlier. The ProCESS study as well as the National Quality Forum (NQF) decision, which overturned NQF’s previous endorsement of guidelines calling for central venous catheterization in some patients with severe sepsis and septic shock, was the impetus for review (13,14).

  - **Removal of PSP, FS-ICU and EBPAs surveys.** The sepsis core team has proposed removing the PSP, FS-ICU and EBPAs from the measurement plan as part of mid-course corrections. These surveys have not been collected yet and it is not feasible to collect them now given our better understanding of the sepsis cohort and the challenges and complexities of this project.

- **Describe changes in key personnel for the project.**
  There were no changes in key personnel for the project

- **For projects involving computer applications, describe any changes that were made in the method of data entry, the specific data to be encoded, software, hardware, file systems or search strategies.**
  Not applicable

- **Briefly describe any efforts that were made to publicize the results of the program.**
  The HVHC standard model for public reporting includes communication strategies that cross all levels of the health system, ensuring intra- and inter-organizational sharing. The following efforts were made to publicize progress of the program:

  1) HVHC reporting portal – web-based access for members to view cost, quality, and process outcomes for the HVHC member organizations; these include longitudinal reports of measures and populations associated with best practice interventions implemented at those organizations (including cost of care, utilization of services, survival, functional outcomes, etc.);
2) Local, Regional and National meetings – training workshops, presentations and posters will be submitted for inclusion at local (e.g., HVHC shared learning events, health system symposia), regional (e.g., Center for Rural Emergency Services and Trauma conference, New England region), and national meetings of healthcare leaders (e.g., annual meeting of the American College of Health Executives and World Congresses) and clinician-researchers (such as Academy Health’s Annual Research Meeting and the semi-annual meetings of the American Association of Health Economists and the International Health Economics Association);

3) Peer-reviewed Journals – findings from our implementations are submitted to a wide array of peer-reviewed journals including specialty, implementation science, online journals, etc.

- **Plans there are to complete the project after the award period, how project activities will be funded, and when they are likely to be completed.**

As described in Section 4 Planned Activities above: HVHC has the unique ability to integrate complex, disparate information from CMS and member EMR health system data (including patient reported outcomes) across multiple organizations. HVHC health systems represent a large portion of the Medicare population. HVHC will obtain continued access to CMS data through a re-use agreement to allow us to better inform the public, health systems and their providers on how best to deliver population and value-based care in quantifiable dashboard reports for public consumption. Continuing to receive the CMS Medicare files to support ongoing evaluation and monitoring of the programs is important because it allows HVHC to:

- extend the length of time necessary to see sustained changed in health care improvements;
- leverage CMMI federal investments;
- continue cross-walking member-submitted data with CMS data critical for feedback reporting;
- leverage critical infrastructure developed to process the CMS and member-submitted data files to report process, outcomes and benchmarking data to our members via web-based portal; and
- maintain the focus and engagement of our member systems in sustainability efforts through feedback reporting so they can continue to identify improvement opportunities and monitor progress toward program goals.

Funded by HVHC Members, a follow-on study intends to examine the ongoing effects of health care innovations implemented through a CMMI award focusing on two major efforts, Patient Engagement and Sepsis Improvement. The original projects were implemented from 7/1/2012 – 6/30/2015 with initial evaluation continuing under a no-cost extension through 6/30/2016. The new follow-on study will allow for an extended period of evaluation and monitoring of each program utilizing CMS as well as High Value Healthcare Collaborative (HVHC) member-submitted data. The evaluation model will continue utilizing approved monitoring measures for each project. This evaluation will provide the analytic evidence to help determine the long-term impact and success of sustainability for both efforts.

Additionally, the HVHC has received a substantial grant from the Laura and John Arnold Foundation to continue efforts in implementing the sepsis care model. By sharing data and lessons learned from the original CMMI Sepsis Improvement sites, the Laura and John Arnold Foundation grant will help identify best practices for implementation and dissemination of this sepsis care model to drive broad-scale adoption across the HVHC health systems.

- **Describe the audiences for the project. Indicate the nature, size, geographic reach, sex and age of the audience and assess the impact that the project had on this audience.**

The project focused on health care systems utilizing a multidisciplinary approach to ensure inclusion of
physicians, nurses, physical therapists, informatics specialists, pharmacists, leadership, staff etc. This team was focused on successfully implementing sepsis bundled care to enhance the value of health services delivered to patients admitted for sepsis or septicemia. By increasing the delivery of optimal care (perfect bundle adherence for sepsis) by five percent over three years, the ultimate goal is to save lives.

- **What, if any, is the long term impact of your project for improving health care?**
  The long term impact is being assessed through a new study funded by the HVHC which will allow for an extended period of evaluation and monitoring of each program utilizing CMS as well as High Value Healthcare Collaborative (HVHC) member-submitted data. The evaluation model will continue utilizing approved monitoring measures for each project. This evaluation will provide the analytic evidence to help determine the long-term impact and success of sustainability for both efforts. Additional dissemination of the sepsis bundle is also underway supported by a grant focused disseminating the care model for sepsis.

- **Publications associated with this project over the award period.**
  Specific publications for this project are included below/ include:

  "**Qualitative Analysis of Sepsis Bundle Implementation in the High Value Healthcare Collaborative: Common Barriers and Applied Solutions**"
  Andrew L. Masica, MD, MSCI; Ashley W. Collinsworth, MPH, ScD; Todd L. Allen MD; Nancy Riebling; Michael N. Cocchi, MD; Candice D. Berryman, MBA; Adam Schlichting MD, MPH; Andreas H. Taenzer, MS, MD; Ivor S. Douglas, MD

  "**Accelerating Improvement in Sepsis Bundle Adherence across the High Value Healthcare Collaborative**"
  Andrew L. Masica, Baylor Scott & White Health, Dallas, TX, Ashley W. Collinsworth, Baylor Scott & White Health, Dallas, TX, Todd L. Allen, Intermountain Healthcare, Salt Lake City, UT, Martin E. Doerfler, North Shore-LIJ Health System, Lake Success, NY, Michael N. Cocchi, Beth Israel Deaconess Medical Center, Boston, MA, Adam B. Schlichting, University of Iowa Carver College of Medicine, Iowa City, IA, Mabel L. Balduf, Dartmouth College, Hanover, NH, Ivor S. Douglas, Denver Health, Denver, CO, Andreas H. Taenzer, Dartmouth-Hitchcock Medical Center, Hanover, NH selected for an oral presentation at the 2015 Academy for Healthcare Improvement’s conference on Teaching and Disseminating Methods to Improve Healthcare Quality and Affordability

- **Supporting materials associated with this project over the award period.**
  - Sepsis Improvement Implementation Guide
  - Sepsis Check List
  - Lean Training Curriculum
  - As part of an IHI presentation North Shore LIJ presented a video from the staff speaking about their experience. This was submitted the PMO with NSLIJ’s 10QR progress narrative. [https://www.dropbox.com/l/1iiPdVRQa6QiEOKIm3m16p](https://www.dropbox.com/l/1iiPdVRQa6QiEOKIm3m16p)
  - The attached link details in an interview with Vermont Public Radio in December of 2014 the work Dartmouth-Hitchcock and physician lead Andreas Taenzer have accomplished: [http://digital.vpr.net/post/hospitals-take-aim-deadly-sepsis](http://digital.vpr.net/post/hospitals-take-aim-deadly-sepsis)

- **Indicate whether or not any subject inventions were made.**
  No inventions were made through the award.
Section 8: References


10. Andrew L. Masica, MD, MSCI; Ashley W. Collinsworth, MPH, ScD; Todd L. Allen MD; Nancy Riebling; Michael N. Cocchi, MD; Candice D. Berryman, MBA; Adam Schlichting MD, MPH; Andreas H. Taenzer, MS, MD; Ivor S. Douglas, MD. Qualitative Analysis of Sepsis Bundle Implementation in the High Value Healthcare Collaborative: Common Barriers and Applied Solutions. 2015 (under review).


**Appendix A: Sepsis Bundle Checklist**

### Sepsis Inclusion and Bundle Checklist

**Patient Identification**
- Unique ID

**Bundle Start Time (“Time Zero”)**
- ED Triage Time OR Time ________ HH:MM (24 HR)
- ICU Door Time OR Date ________ MM/DD/YY

**Sepsis with hypotension (SBP <90mmHg) OR lactate ≥ 4 mmol/L**

**Bundle Non Adherence?**
- Advanced directive for comfort care
- Condition precluding completion
- Central line contraindicated
- Central line placement unsuccessful
- Patient decline therapy or central line
- Transfer from other facility where time window lapses
- Missed time window
- Unable to determine
- Death
- Other

**Patients suspected of sepsis per institution screening procedures**

**Bundle Inclusion Criteria**

- **Clinically Suspected Infection**
  - SIRS Criteria Positive
  - Two or more of:
    1. Temp <36°C OR >38°C
    2. Heart Rate > 90/min
    3. Respiratory Rate >20/min OR PaCO2<32 mmHg
    4. WBC <4k OR >12k OR >10% bands

- **Hypotension**
  - SBP <90 mmHg OR decrease ≥ 40 mmHg from baseline
    - mmHg
    - Time ________ hh:mm (24 hr)
    - Date ________ mm/dd/yy

- **Elevated Serum Lactate**
  - (≥ 4 mmol/L)
    - mmol/L
    - Time ________ hh:mm (24 hr)
    - Date ________ mm/dd/yy

**Severe Sepsis 3 Hour Bundle**

- **1 Measure Lactate Level**
  - (if not previously measured)
    - mmol/L
    - Time ________ hh:mm (24 hr)
    - Date ________ mm/dd/yy

- **2 Blood Cultures Before Antibiotics**
  - Time ________ hh:mm (24 hr)
  - Date ________ mm/dd/yy

- **3 Broad Spectrum Antibiotics**
  - record start time of antibiotics
    - Time ________ hh:mm (24 hr)
    - Date ________ mm/dd/yy

- **4 Crystalloid Bolus (30mL/kg)**
  - record start time of IV fluids
    - Time ________ hh:mm (24 hr)
    - Date ________ mm/dd/yy
    - Volume ________ mL at 3 Hours

**Septic Shock 6 Hour Bundle (Shock Bundle)**

- **Eligible for Shock Bundle**
  - □ No

- **For hypotension not responding to initial fluid resuscitation to maintain MAP ≥ 65mmHg**
  - □ Initiate Vasopressors
  - □ N/A
  - Time ________ hh:mm (24 hr)
  - Date ________ mm/dd/yy

- **Remeasure Lactate**
  - □ N/A
  - Time ________ hh:mm (24 hr)
  - Date ________ mm/dd/yy

**Optional Data Collection**

- In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate ≥4 mmol/L:
  - □ Measure Central Venous Pressure (CVP)
    - □ N/A
    - mmHg
    - Time ________ hh:mm (24 hr)
    - Date ________ mm/dd/yy

- □ Measure Central Venous O₂ Saturation (ScvO₂)
  - □ N/A
  - %
  - Time ________ hh:mm (24 hr)
  - Date ________ mm/dd/yy

- □ Measure Guided Ultrasound
  - □ N/A

- □ Measure NICOM
  - □ N/A

**Resuscitation Detail & Response Upon Completion of 3 Hour Bundle**

- Height ________ cm
- Age ________
- Weight ________ kg
- Gender □ Male □ Female
- Volume Crystalloid ________ mL
- Volume Colloid ________ mL
- or Blood Product

- SBP ________ mmHg
- MAP ________ mmHg
- Time ________ hh:mm (24 hr)
- Date ________ mm/dd/yy

- If SBP < 90 mmHg, MAP < 65mmHg or
  Initial lactate elevated, PROCEED to 6 hr Bundle
**Goal/Aims**

**Improve care:** Improve optimal adherence to sepsis bundled care by 5% (relative rate) over three years.

**Improve health:** Reduce the burden of chronic morbidity from sepsis-associated chronic organ dysfunction, achieving a 5% relative rate reduction over three years in the number of patients with sepsis requiring long term acute care or sub-acute nursing care after an incident episode of severe sepsis.

**Reducing costs:** Decrease days of therapy per 1000 patient days by 10%, achieving 25% reduction (relative rates) in antibiotic acquisition; $12.25M savings at HVHC hospitals for Medicare beneficiaries over the three years of the study.

1/1/2013 - we will complete project setup activities and launch pilots for co-lead members.
6/30/2013 - we will complete the co-lead member pilots, evaluate results, adjust the protocol, codify and disseminate to new members, and prepare for new member implementation.
6/30/2015 - we will achieve the improvement targets outlined above in aggregate across all HVHC members.

**Primary Drivers**

- Clinicians and staff fully support sepsis project (>50% clinicians/staff satisfied)
- Sepsis processes and care tools are evidence-based and impactful (5% relative rate increase in patients receive sepsis bundled care)
- Transparent, frequent analyses of Sepsis process measures informs improvement (Analysis completed and posted internally quarterly)
- Codification/dissemination of best practice models, methods, and measures (drafted by Dec’13; finalized Mar’14)
- Strong network of Lean or equivalent methodology within participating sites (>50% clinicians/staff familiarity with Lean or equivalent)

**Secondary Drivers**

- Strong leadership directive and support of sepsis program
- Incentives aligned to encourage strong support of sepsis program
- Sepsis improvement process minimizes burden on physicians
- Institutional improvement culture developed and maintained
- Agreement on measures to be included in sepsis bundled care
- Infrastructure developed to measure and report processes that do not interfere with patient care
- Process and outcome measures are properly aligned with goals of sepsis program by using sepsis management bundles
- Data collected directly from patient records
- Data analyzed monthly and displayed in easy-to-use dashboard portal
- Rapid adjustment based on what’s working and what’s not
- Codification of best practice models, methods, and measures based on pilots
- Dissemination and spread demonstrates applicability to other environments and contexts
- Identify staff with expertise and training in Lean or equivalent methodology
- Conduct “train the trainer” sessions so as to disseminate knowledge within and across health systems
- Institute Lean Methodology Sepsis Learning Network enabled by online collaborative tools and regular meetings to share learnings
- Rapid Improvement Events (RIEs) to begin implementation
Appendix C: Methods

Data Sources
Data on sepsis cases included in the analysis were provided by participating hospital systems using a data-collection application and data-set definition called STAT (Sepsis Treatment Administration Tool), we refer to these cases and the Enrolled Cohort. The Enrolled Cohort refers to all cases meeting the Enrolled Cohort case definition and the Enrolled/CMS Cross-walked Cohort refers to the subset of Enrolled Cohort cases who could be cross-walked to CMS claims data and met a further set of inclusion criteria. A third, less specific, cohort containing sepsis cases found in CMS claims of participating hospitals and matched comparator facilities was constituted from HVHC’s CMS claims database. An HVHC member submitted source of outcome data on mortality, length of stay and discharge disposition came from the HVHC Unified Data Extract Specification, which is an extract of medical and billing records for patients with a selected list of conditions, including sepsis.

Case definitions
Sepsis cases included in the **Enrolled Cohort** had the following inclusion criteria:

1. Clinically suspected infection
2. Two or more Systemic Inflammatory Response Syndrome (SIRS) criteria present:
   a. Temperature <36°C or >38°C
   b. Heart rate >90/minute
   c. Respiratory rate >20/minute or PaCO₂ <32 mm Hg
   d. White blood cell count <4,000 or >12,000 or >10% bands
3. Hypotension (systolic blood pressure <90 mm Hg or drop in ≥40 mm Hg from baseline reading) OR elevated lactate (≥4 mmol/L)

Sepsis cases in the **Enrolled/CMS Cross-walked Cohort** were the subset of patients in the enrolled cohort who met the following criteria:

1. It was the patient’s first sepsis event in the timeframe of interest
2. Patient is Medicare eligible with the following coverage met:
   a. Patient had Medicare coverage for the entire episode (i.e., patient had Medicare at time of sepsis event through 90 days past sepsis event or until death date)
   b. Patient was not HMO eligible during the episode
3. Patient did not have zero costs
4. Patient did not come directly from a long term acute care hospital (LTAC), skilled nursing facility (SNF) or hospice immediately before the sepsis event

Inclusion criteria for the **CMS Claims-based Cohort** were:

1. Diagnosis and MS-DRG codes:
   o One of the ICD-9 diagnosis codes:
     995.92 - Severe sepsis
     785.52 - Septic shock
   AND
   o One of the MS-DRG Codes:
     870 - Septicemia or severe sepsis with mechanical ventilation 96+ hours
2. Admission through Emergency department
3. Medicare AB and no HMO for entire 90-day episode (Admission Date + 90 days)

Exclusion criteria for the CMS Claims-based Cohort were:
1. Transfer to hospital from hospice
2. Transfer from another hospital
3. Patients with stay in cardiac or pediatric ICU
4. Patients with hospice stay within one day prior to admission

HVHC Unified Data Extract Cohort – Sepsis Definition
All patients with an inpatient admission for any of the following ICD-9 Diagnosis codes 995.91 OR 995.92 OR 785.52 in any position, regardless of whether it is present on admission or hospital acquired or any patients presenting any of the above ICD-9 diagnosis codes and who died in the ED.

90-Day episode cost definition
The 90-day episode for episode-cost analyses began on the date of the patients’ admission for sepsis and continued for 90 days after the index admission, or until the patient’s death, whichever comes first.

Other definitions
- Incident organ dysfunction measures were defined using physician reviewed list of relevant ICD-9, ICD-10, and HCPC procedure codes for the condition being measured (respirator use or dialysis).
  
  Numerator: Count of eligible sepsis cases with presence of one or more of the relevant codes during 14-days post discharge without presence of one or more relevant codes 120-days pre admission.
  Denominator: Count of sepsis cases for patients with the following: Medicare AB and no HMO for 90-day episode; discharged alive; index admission after April 30, 2012 to allow 120-day pre-period.
- Actual episode cost was calculated using Medicare paid amount for the episode period
- Standardized costs used the HVHC modification of the Health Partners Total Care Relative Resource Value methodology https://www.healthpartners.com/ucm/groups/public/@hp/@public/documents/documents/dev_057426.pdf

  Bundle and bundle adherence. The 3-hour sepsis bundle consists of the following four elements:
  o Measure lactate
  o Obtain blood culture prior to antibiotic administration
  o Administer broad spectrum antibiotics
  o Administer 30 ml/kg crystalloid for hypotension or lactate >=4mmol/L
Analysis

Relative change
To estimate change in outcomes since intervention start relative to matched comparator hospitals, we used a difference-in-difference design. Intervention hospitals were matched to between 1 and 5 comparator hospitals based on geographic proximity; number of beds; number of sepsis cases in 2013; teaching status (medical school affiliation, residency, and membership in the Council of Teaching Hospitals); urban or rural location (based on Census Department RUCA classification) and Joint Commission accreditation and critical-access status. The population of candidate comparator hospitals consisted of all hospitals in Health Referral Regions containing at least one HVHC member hospital. The “optimal” algorithm in the %match SAS macro published by Mayo Clinic (http://www.mayo.edu/research/documents/biostat-56pdf/doc-10026923) was used to match intervention hospitals to comparators and results were reviewed by HVHC analysts to ensure that the program provided valid matches. The change in outcomes associated with participating hospitals was estimated using a mixed model with random intercepts for each hospital or hospital and intervention-comparator cluster depending on the data set. Fixed effects were included in the models to adjust for patient attributes, including age, sex, race, comorbid conditions (Charlson score) and poverty (proportion population in patient’s Zip code below poverty). All continuous variables were broken into sets of discrete categories. Cost data were log transformed to better approximate a normal distribution and appropriate distribution and link functions were used for non-normal outcomes. Time was discretized in 3-month quarter-years to minimize variance-bias trade-off and quarters were assumed to be independent. The 4 quarters prior to the start of the intervention for each intervention hospital were used as a “pre” period to test the parallel-slopes assumption of the difference-in-difference design. Participating hospitals started the intervention at different times with concomitantly different numbers of intervention quarters. All costs were inflation adjusted 2013 dollars prior to analysis.

Temporal change
Bundle adherence and its components were plotted by calendar quarter to display temporal trends. Comparisons between calendar years 2013 and 2014 were made to evaluate change within participating hospitals over the intervention period. Comparisons between calendar years 2014 and 2015 were not included since we had data for only the first 6 months of 2015. The decision was based on the decreased sample size and the documented seasonal pattern of sepsis. Bundle adherence was assessed both in aggregate and within participating hospitals. Aggregate outcomes did not distinguish individual hospital start dates, so hospitals starting the intervention in 2014 contributed to 2014, but not 2013. Within-member comparisons for outcomes except bundle adherence were adjusted using an appropriate regression model and adjusted for patient age, sex, race, HCC score and dual-eligibility. Bundle adherence was estimated using categorical relative-risk and reported at the member level due to heterogeneity in the outcome.