HARVARD | BUSINESS | SCHOOL



8-612-093

REV: FEBRUARY 21, 2013

ANITA TUCKER

Learning About Reducing Hospital Mortality at Kaiser Permanente

In 2009, a patient presented to a Kaiser Permanente Northern California hospital Emergency Department (ED) with severe sepsis. Although she did not realize it at the time, she was extremely ill. Sepsis, a potentially deadly bloodstream infection, caused blood vessels to expand, pooling blood in the body and reducing the flow of oxygenated blood to tissue and organs. If left unchecked, sepsis can cause multiple organ failure and eventually death. Severe sepsis is the number one cause of death in U.S. hospitals², accounting for over 200,000 deaths per year. Patients with severe sepsis experience mortality rates of 35 percent³.

Fortunately, the patient survived. Her ED physician used a recently implemented bundle of clinical procedures for treating patients with severe sepsis. The Kaiser Permanente Northern California-wide initiative to reduce hospital mortality from sepsis had been spearheaded by a team of four senior leaders from the quality and physician functions. The team targeted sepsis because it was the leading cause of hospital mortality in Northern California, (with more than 1 of every 5 deaths caused by sepsis), despite being only 2.7 percent of hospital admissions.⁴ By 2013, the region's percentage of patients with sepsis who died (the "sepsis mortality rate") had dropped from 24.5 to 9.6 percent.⁵

Kaiser Permanente Northern California's initiative and results led other Kaiser Permanente regions to consider adopting sepsis programs. However, the lack of published scientific evidence on the best way to treat sepsis positioned all of Kaiser Permanente at the frontier of evidence-based medicine. Some regions implemented sepsis programs with less structure. Some decided to test programs without some components that the Kaiser Permanente Northern California team believed essential to its program's results. The other regions investigated whether a less standardized approach would be successful for those regions. At the same time, Northern California contemplated its next steps in further reducing hospital mortality in the region. Should they refine their existing protocol based on their current results, expand use of the protocol to a larger group of patients with less advanced sepsis, or focus on reducing mortality from other, better researched medical conditions, such as heart attacks?

^a This document has been developed for the purposes of business education, not for scientific or medical purposes, and the facts and statements have been simplified for purposes of a business education tool. This document is not intended to be used for any other purpose, including any medical or scientific purpose or any purpose related to a standard of care.

Professor Anita Tucker prepared this case with the assistance of Research Associates Rakeen Mabud and Rhea Ghosh. HBS cases are developed solely as the basis for class discussion. Cases are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

Copyright © 2012, 2013 President and Fellows of Harvard College. To order copies or request permission to reproduce materials, call 1-800-545-7685, write Harvard Business School Publishing, Boston, MA 02163, or go to www.hbsp.harvard.edu/educators. This publication may not be digitized, photocopied, or otherwise reproduced, posted, or transmitted, without the permission of Harvard Business School.

Kaiser Permanente's Organizational Structure

Kaiser Permanente traced its origins to the late 1930s, when Sidney Garfield, MD, opened a hospital and a prepaid health insurance plan for workers building the Los Angeles Aqueduct in southern California. Garfield went on to operate similar plans, including one for 30,000 workers at the Kaiser Shipyards in Richmond, California, during World War II. After the war ended in 1945, Garfield and the owner of the shipyards, Henry J. Kaiser, opened the health plan to the public. By 1952, it had evolved into three integrated entities in various geographic regions: the Kaiser Foundation Health Plan, a non-profit health maintenance organization, Kaiser Foundation Hospitals, a network of health care facilities; and the Permanente Medical Groups, a network of for-profit, physician-owned organizations that provided medical care to Kaiser Foundation Health Plan members. Collectively, these organizations are known as Kaiser Permanente.

Kaiser Permanente was one of a handful of health care organizations^b where physicians were salaried rather than independent agents who collected fees for each service provided to patients. By 2010, Kaiser Permanente had grown into the largest managed care organization in the United States, with \$2 billion in annual net income and 8.6 million members enrolled in its health plan. It also employed more than 15,000 physicians and more than 164,000 medical and support staff at its 454 medical offices and 35 hospitals across eight regions.^c Kaiser Permanente's two California regions—Southern California and Northern California—accounted for the majority of members, medical offices and hospitals. (See Exhibit 1 for Kaiser Permanente's statistics.)

Kaiser Permanente's regions historically had been given significant operating independence.⁷ Kaiser Permanente Northern California's hospitals and health plan were led by Gregory A. Adams. Robert Pearl, MD, served as executive director and CEO of The Permanente Medical Group, Inc., the medical group in Northern California.

The Kaiser Permanente Northern California sepsis mortality reduction team worked together across the organization to secure support for the initiative. (Exhibit 2 provides an abbreviated organizational chart for Kaiser Permanente Northern California.) Barbara Crawford, RN, Kaiser Permanente Northern California's vice president of Quality and Regulatory Services, and Philip Madvig, MD, associate executive director of the Permanente Medical Group, communicated laterally and upward in the organization to the senior leaders of Kaiser Permanente Northern California. Melinda Skeath, RN, Kaiser Permanente Northern California's executive director of Quality & Regulatory Services, and Alan Whippy, MD, medical director for Quality and Safety of the Permanente Medical Group, collaborated laterally and down the organizational chart to the physicians, clinical staff, and leadership from the region's 21 hospitals.

Learning through Collaborative Change

Kaiser Permanente Northern California used a collaborative model for performance improvement. The collaborative model involves forming a group of cross-functional teams from multiple hospitals to design and implement improved care protocols.⁸ Meetings of the collaborative on sepsis care alternated between learning sessions in the cross functional teams from all hospitals came together

^b Other well-known healthcare organizations with salaried physicians included the Mayo Clinic and Cleveland Clinic.

^eThe eight regions are Colorado, Georgia, Hawaii, the Mid-Atlantic States, Northern California, the Northwest, Ohio and Southern California.

and discussed the topic, and action periods in which the teams returned to their hospitals to implement ideas shared during the learning sessions. During action periods, hospitals improved their processes through repeated cycles of 1) designing what process change could be made to improve performance (PLAN); 2) making the change (DO); 3) testing whether the change resulted in the desired impact (STUDY); and 4) evaluating whether to adopt the change, continue modifying the process, or abandon the change (ACT). These activities formed a Plan-Do-Study-Act (PDSA) cycle. (See Exhibit 3 for Kaiser Permanente Northern California's adaptation of the collaborative model.)

Kaiser Permanente Northern California enhanced the collaborative model by adding three components to foster spread and sustainability. They called the enhanced version their "Four-Wheel Drive" model of change. The additional components were: 1) a compelling need to change; 2) a set of elements they believed greatly enhanced the potential for success (standardized processes, leadership alignment, performance measures, and project management infrastructure); and 3) continued measurement and incorporation into work flows to ensure sustainability. (See **Exhibit 4** for the model.)

Selecting Sepsis as the Target

Although Kaiser Permanente Northern California was considered a high-performing health care provider based on both clinical and financial outcomes, Crawford recalled: "We had been struggling with variation between our region and other regions with respect to our hospital standardized mortality ratio. We really wanted to understand what was driving that variation."

In early 2008, with assistance from the region's Division of Research, the team analyzed Kaiser Permanente Northern California hospital's mortality rates by clinical condition to understand the causes of and contributors to mortality. The data had been organized using a complex diagnosis and procedure coding system (ICD-9), resulting in an overwhelming number of categories with little relevance to the teams' work in understanding the drivers of mortality. The team reorganized individual insurance codes into broader clinical buckets, which enabled calculation of the total number of deaths attributable to distinct and actionable clinical conditions. Fourteen categories accounted for approximately 80 percent of deaths, with sepsis emerging as the primary driver of mortality. To supplement this analysis, they conducted a thorough review of the last 50 deaths in all of their hospitals. The detailed investigation reinforced sepsis' disproportionate role in hospital mortality.

Successfully treating sepsis was challenging because major symptoms, such as fever, chills, and dizziness, did not seem life-threatening in the early stages and could be attributed to other illnesses. However, when left untreated for too long, sepsis became difficult to reverse and could quickly lead to death. Kaiser Permanente Northern California's Oakland Medical Center ED physician Jason Lau, MD, explained:

It can be tricky to sort out who has sepsis. Sometimes it's not immediately apparent that there's an infection and people who had major trauma, a major operation, or who are in lot of pain can have similar symptoms. To confirm the diagnosis you need to collect lab results, diagnostic imaging, and the clinical story. It can take several hours to gather this information. If information gets missed, that patient probably won't do well. If sepsis is caught early and treated aggressively, it can be reversed. However, if the patient reaches late stage sepsis and multi-organ dysfunction, it's hard to reverse the process.

Armed with the data from the mortality diagnostic, Crawford and Madvig made the business case to Kaiser Permanente Northern California's senior leaders. Crawford recalled, "We provided

evidence that showed that sepsis should be a strategic priority. We brought the findings from the mortality diagnosis to the senior leaders from both the hospital and health plan and the medical group to get their support to move forward." Adams and Pearl made sepsis mortality reduction a strategic priority, and authorized the team to move forward with a coordinated, region-wide initiative to combat the deadly disease.

In May 2008, the mortality analysis findings were shared with Kaiser Permanente Northern California physicians, nurses and administrators at a regional mortality summit. The team conveyed the message that sepsis care needed improvement, but did not dictate a sepsis program. Instead they presented data that energized physicians to embrace their proposal to explore new ways to reduce sepsis mortality. Whippy compared the 3.7 percent mortality rates of heart attack (AMI) patients, for whom there was an infrastructure for care and reliable interventions, to the 24 percent mortality rates of patients with sepsis, for whom care was designed individually. The team was successful in convincing physicians to commit to becoming more systematic and aggressive in their approach to sepsis. Now they needed to learn what to do to reduce sepsis mortality.

Assembling Experts to Develop the Sepsis Bundle& Playbook

In the summer of 2008, the team assembled a group of subject matter experts including physicians outside of Kaiser Permanente who had conducted the seminal study on treating sepsis, the Chair of all the Chief Intensivists from the Kaiser Permanente Northern California hospitals, and the Chair of the ED Chiefs. They also included ED and ICU physicians and nurses from Kaiser Permanente Northern California's San Jose and Vallejo Medical Centers, which had agreed to be pilot sites for the sepsis program. Madvig commented on their decision to engage a broad interdisciplinary team to develop the sepsis bundle.

Sepsis is unique from other clinical conditions because of the large number of different players who have a role and therefore have to be on board with the initiative. It's not as though you can just take it to one unit of the hospital, or one specialty, or one classification like nursing or physicians. This involves so many different pieces and requires things like extensive training and acquisition of equipment that it was more of a mammoth undertaking than many of the things that we've done. It needed to be sold to a lot of different parties.

The group leveraged prior research on a bundled approach to treating sepsis called Early Goal Directed Therapy (EGDT).¹¹ EGDT was a set of prescribed steps for aggressively identifying and treating severe sepsis beginning in the ED and continuing through admission to the ICU. All of the steps in the bundle were to be completed within a 6-hour window. This early treatment plan for sepsis contrasted sharply with the typical chain of events for a septic patient, whose mild condition upon arrival to the ED resulted in a lack of urgency and missed sepsis diagnosis until his condition suddenly became so dire that he had to be admitted to the ICU with multiple organ failure.

The group modified the original bundle to better fit the needs of Kaiser Permanente Northern California's medical centers. Their bundle consisted of (1) the range of vital signs and clinical conditions that triggered an order for a laboratory test; (2) three medical treatments to be initiated if the laboratory test result was higher than a specified threshold; (3) time frames for accomplishing these treatments; and (4) goals for three measures of the patient's blood system. Clinicians would use the patient's values on the three measures to adjust the patient's treatment levels with the aim of achieving the goals within a six-hour window. (See **Exhibit 5** for an overview of Kaiser Permanente Northern California's EGDT Sepsis Bundle.)

Kaiser Permanente Northern California piloted the bundle at two facilities, San Jose and Vallejo Medical Centers. Skeath explained the role of pilot testing.

The pilot sites learned how to implement the bundle elements in a standardized and simplified workflow that could be successfully implemented across 21 medical centers. For example, one of the bundle treatments was insertion of a central line within two hours. Patients historically have been in the ICU for central line insertion. However, the pilot testing confirmed that the central line had to be placed in the ED rather than in the ICU because we couldn't transfer patients to the ICU and insert the line within the two hour time limit. Similarly, we learned that we needed to have a sepsis cart with necessary supplies and train nurses to set up the procedure for physicians so it could be completed in less than 30 minutes.

The leadership team also used the pilot testing to create process metrics to evaluate the medical centers' performance. Sets of measures were developed for each anticipated phase of the project. The set of measures for the first year were to have the people and processes in place at each medical center necessary to implement the bundle elements. For example, the measures included whether the medical centers had assembled a multi-disciplinary team spanning ED, ICU and house-based staff physicians; held regular meetings; and trained physicians and nurses on central line placement. The second phase's measures focused on implementation of bundle elements.

A final role of pilot testing was to refine information created for the pilot sites' implementation to create an EGDT Playbook (Playbook). The Playbook's purpose was to provide tools to support the spread of the bundle to the remaining medical centers in Kaiser Permanente Northern California. It detailed the EGDT Sepsis Bundle, laid out the performance measures, provided information about equipment in the bundle, had copies of training materials that would be used to educate physicians and nurses about the treatments such as ultrasound-guided central line insertion, and contained articles on best-practice sepsis treatments from medical journals.

After developing the bundle, the team obtained required human and capital resources. For example, with regard to human resources, they began cultivating locally influential individuals who understood and supported the initiative ("local champions") from the ICU and ED at each medical center. Capital was also needed to implement the bundle. Hospitals had to purchase sophisticated monitoring equipment to track patients' vital signs and mannequins for training ED physicians and nurses on ultrasound-guided central line insertion, one of the most difficult treatments in the bundle. Therefore, Crawford and Madvig circled back to senior administrators to secure regional-level funding for necessary equipment for all hospitals, rather than impacting each hospital's local budget. They also lined up regional and local champions from the ICU and the ED, and made arrangements for training the staff on the bundle elements.

Spreading the Bundle

Learning Sessions

As part of the collaborative approach, each Kaiser Permanente Northern California medical center assembled a multidisciplinary team responsible for implementing the sepsis bundle. These teams of 10 to 20 people from each medical center attended an inaugural "Sepsis Summit" in November 2008, which served as the first learning session. At the day-long meeting, experts presented evidence motivating the need to improve sepsis care at Kaiser Permanente Northern California, the research behind the EGDT bundle, the elements in the bundle, how it was going to be implemented, and the performance measures for the first year. Each medical center received a copy of the Playbook.

Action Periods

After the summit, Kaiser Permanente Northern California participants began implementing the bundle. Project management staff, funded through a \$5.5 million dollar grant from the Gordon and Betty Moore Foundation, supported the medical centers' implementation efforts. Regional improvement advisors led monthly conference calls with the medical center teams, which enabled the teams to learn from other centers' experiences. For example, after hearing about other center's success with alerts, South Sacramento created "sepsis alerts" and "central line alerts" that notified ED staff to quickly assemble at the septic patient's bedside to implement the bundle. The regional improvement advisors also conducted site visits to the medical centers to observe and guide medical center teams on implementing the bundle. Additional support was provided by a regional steering committee, comprised of key physician stakeholders and regional ICU and ED clinical nursing specialists, who were available for consultation on patient-specific case review. Steering committee members also traveled to the medical centers to provide additional training and guidance for clinical aspects of bundle implementation.

Even with the available support, medical centers had to learn how to implement the sepsis bundle in their organizations. The bundle required different medical disciplines and departments to have a shared understanding of septic patients' care needs. Gregory Marelich, MD, physician champion, assistant physician-in-chief, and director of Critical Care at South Sacramento, explained:

The cross-functional approach helped break down informational silos that we had between departments. For example, the ED treated patients with sepsis for the first several hours, but they didn't always realize how sick those patients were because not many people die of sepsis in the ED. Similarly, the laboratory didn't understand the importance of the lactates and blood cultures until they started hearing about the data and how they could contribute to a successful outcome. Intensivists saw the complications, so they understood the urgency required in treating patients with sepsis, but previously there hadn't been data to understand the continuum of care and to devise an appropriate set of bundle elements.

They also needed to learn how to incorporate the bundle elements into their daily work. Joni Borbon, MD, ED physician champion, South Sacramento Medical Center, described how they progressively implemented the steps in the bundle.

Nurses were the first group we worked with because they had to identify which patients qualified for EGDT. We focused on education first, to build awareness. Our first goal—which was a big hurdle—was to have them to draw the required laboratory test (lactate) at the same time that they drew a blood culture. Our second goal was ensuring that septic patients were treated with urgency. In the ED, patients with potential sepsis weren't always viewed as critical as chest pain or stroke because the patients didn't look or feel that sick.

Hospitals used results from their daily work to learn how to implement the bundle more effectively. For example, Mezhgan Alamshahi, director of Patient Safety and an improvement advisor at South Sacramento, explained how they "developed a communication tool that provided information on the care of each sepsis patient within the first 24 hours so that the physicians and nurses involved in the patient's care knew the outcome. Every case provided us an opportunity to make our process better." (For a timeline of the sepsis program, see **Exhibit 6**.)

Encountering and Overcoming Resistance

Despite frontline clinician involvement in developing and implementing the sepsis bundle, hurdles existed. Aspects of Kaiser Permanente Northern California's bundle were controversial, in part because of low levels of evidence. For example, although there was moderate evidence for administering antibiotics within one hour of diagnosis of septic shock, there was only low evidence (e.g. expert opinion or a case study of a single hospital's program) supporting the insertion of a central line. ¹² This lack of evidence created resistance to the central line. Borbon elaborated: "The studies haven't been conclusive; some physicians are not convinced that all the steps in EGDT make a difference in patient mortality. Our ED doctors are critical thinkers. They don't just do what they're told, they want to know why, has it been reproduced, and will it make a difference?"

The central line also required process changes in the ED to create adequate time for busy ED physicians to apply the sepsis protocols and to appropriately tend to all patients. Borbon explained:

In the ED, they were asking us to do yet one more thing. There are a lot of conditions, such as chest pain, pneumonia, and stroke, where we have timed metrics. So we were already being pushed to do this and that by a certain time. This was one more disease that had a list of rules and guidelines. It was a lot of steps.

Sometimes the line went in easily and sometimes it didn't. To reduce the preparation time, we created a sepsis cart with kits of materials needed to put in and secure a central line, which reduced the time spent searching for equipment. We also had training sessions to teach nurses how to prepare the patient for ultrasound-guided insertion so that the doctors could just walk in and put in the line.

Furthermore, although central line insertion was part of residency training for emergency medicine, there were varying levels of skill and comfort with this procedure among ED physicians. Central lines carried the risks of puncturing a lung, internal bleeding, fluid buildup, and infection.¹³ Lau recalled: "Physicians were polarized. Half strongly supported this, and half were concerned about the time it would take and the difficulty of putting in a central line, given the lower level of evidence."

Measuring and Holding the Gains

By the third sepsis summit in May 2011, Kaiser Permanente Northern California's sepsis mortality had decreased over 50 percent, from a mortality rate of 25 percent for all sepsis admissions in May 2008 to less than 11 percent in May 2011. (See Exhibit 7 for Kaiser Permanente Northern California quarterly results.) However, part of the reduction in sepsis mortality rates was due to increased diagnosis on admission, which increased the denominator of the mortality rate. For example, by June 2010, sepsis diagnoses and admissions had risen 116 percent since the start of the intervention. At the summit, Whippy acknowledged that part of the improved mortality rate stemmed from the increase in the number of sepsis diagnoses. However, she asserted that increased diagnosis was an improvement because it implied that physicians increasingly recognized sepsis in patients.

One of our problems was that we weren't naming and documenting sepsis. The only time we documented sepsis was when somebody was dying of it. Our mortality rate was not an accurate reflection of our care, and made it look like we had a serious care delivery problem when what we had was partly a naming problem. Part of the solution was to get better at naming.

Some evidence suggested that the sepsis program was improving clinical outcomes. Even after risk adjustment for age, comorbidities, and physiology, sepsis mortality decreased. The standardized mortality rate at Kaiser Permanente Northern California's hospitals dropped from an average of 0.90 in July 2008, which was above the U.S. Medicare overall rate of 0.74, to approximately 0.65 in June 2010, below the U.S. Medicare overall rate of 0.70 in March 2010. At South Sacramento Medical Center, the mortality rate for sepsis patients dropped to 0.39 in 2011 from 1.29 in 2008. At the same time, the average length of stay for sepsis patients dropped from 7 days in 2008 to 4.6 days for January through October 2011.

The process conformance measures were another key indicator of improvement. The percentage of ED patients who had their lactate levels tested along with standard blood tests rose from 55 percent in January 2009 to 95 percent by August 2009.¹⁷ They also found that the percentage of sepsis patients whose clinical scores fell within the targeted guidelines 6-hours after initiating the sepsis bundle had increased. At the end of 2009, Skeath observed that at most hospitals the percentage of patients with clinical scores within target guidelines 6 hours after initiating the sepsis bundle was between 2 to 5 percent. By September 2011, across Kaiser Permanente Northern California region that percentage was at 59 percent. Given that some patients came to the hospital in a stage of septic shock that was irreversible, it was unlikely that any hospital could achieve 100 percent. Instead, 55 percent was viewed as a realistic target.

Whippy felt that continuing to generate and present data was critical to the sustainability of the program. She explained, "On a recent sepsis collaborative call, we had the bundle elements mapped out to show that there is a 13 percent sepsis mortality when all bundle elements are met, compared with a 21 percent mortality when they are not. This gives doctors hard evidence for why they should pursue success over the entire bundle." (See **Exhibit 8** for Kaiser Permanente Northern California medical center compliance with the EGDT Sepsis Bundle.)

Moving Forward

In the summer of 2010, some other regions had introduced sepsis interventions that leveraged Kaiser Permanente Northern California's program. All modified certain elements of care and measurement.

Kaiser Permanente Northwest

Kaiser Permanente Northwest implemented a modified sepsis bundle after David Schmidt, MD, physician leader and director of critical care at Kaiser Permanente Northwest's Sunnyside Medical Center, attended Kaiser Permanente Northern California's first sepsis summit. Schmidt believed Kaiser Permanente Northwest's sepsis care could be improved, but he had not rigorously analyzed the data prior to hearing about Northern California's work. After Schmidt learned from fellow critical care physicians at Kaiser Permanente Northern California about the region's sepsis initiative, he collected baseline data about sepsis identification and mortality in the Northwest. Kaiser Permanente physicians then looked at the playbook and recognized the opportunities created by the many hours of work of Kaiser Permanente Northern California.

Kaiser Permanente Northwest implemented a modified version of Kaiser Permanente Northern California's bundle, which provided slightly different guidelines for how to manage sepsis patients and when to deliver the bundle elements. Kaiser Permanente Northwest sepsis algorithms were a bit less rigid than in California. Schmidt's team modified the bundle elements to meet their best

understanding of good care which led to improved acceptance by the Northwest's physicians. Schmidt explained:

Regarding measuring the delivery of the bundle elements, one of the common criticisms was that people felt they were being graded, but some of the bundle elements reflect the extent of the patient's disease, not the diligence of the care. What could they do if the patient was too sick for all the therapy in the world to make a difference? We gather data and report it, but we all continue to learn about the actual science behind the elements. My view is that these bundle elements are simply the current lines that we measure ourselves against. What we don't want to do is to go back to chaotic, unmeasured, unevaluated care. We might change where our lines in the sand is as we learn more, and that is okay. No one's saying this is the final word on the very best way to manage sepsis.

Overall, Schmidt saw the intervention as having aided in a change of culture. He estimated that their ability to deliver the bundle of care reliably placed their performance within the center of the range of Kaiser Permanente Northern California's hospitals. Overall sepsis mortality in Kaiser Permanente Northwest had been lower than Kaiser Permanente Northern California's prior to implementation. It improved moderately after implementation, and by 2010 was similar to the improved Kaiser Permanente Northern California mortality rates.

Kaiser Permanente Northern California

The Kaiser Permanente Northern California team was committed to further reducing hospital mortality. One way that they believed could accomplish this goal was to expand the use of the sepsis bundle from patients with high lactate values of 4.0 or higher to patients with intermediate lactate values of 2.0 to 4.0. This was a promising extension because more patients had intermediate than high values and intermediate lactate value patients accounted for more deaths. But the evidence for best practice intermediate lactate treatment was sparse. They also could continue to refine their existing sepsis bundle to further test which treatments were associated with improved outcomes. Madvig acknowledged the challenge of improving performance on conditions, such as sepsis, which had a limited evidence base:

There is little published evidence on what to do with regard to managing sepsis. There are some medical conditions that are clear-cut about what to do, such as heart attacks. However, this is not the case for sepsis. We have to ask ourselves, 'Can we move forward on this despite the limited body of evidence?' I think we can, but we have to pay close attention to our results. We have tried to create a learning model by putting out a standardized practice and learning from it.

Crawford elaborated on their ability to use a standardized process as a learning platform:

We looked at process, outcome, and balancing measures as part of this work. A balancing measure is one that looks at unintended consequences of the processes that have been implemented, and one concern expressed by some clinicians was that requiring central line insertion as part of the Early Goal Directed Therapy bundle would increase complications from central lines. As the volume of patients treated with the bundle grew, we discovered that when there was 100 percent adherence to the bundle, the risk of mortality was significantly lower than when partial bundle implementation occurred. At the same time we could demonstrate

that the number of complications from central line insertion was not significantly worse than prior to the start of the program.

As they pondered their approach moving forward, Skeath remained convinced of the importance of standardization:

Performance improvement experts say that when you reduce variability and improve standardization, you are more likely to get the results you want. Our experience matches this assertion. If we allow process variation, we might not get to where we want to be as quickly as we could with standardization. We strongly believe that if we have reviewed the evidence with the help of experts, decided what process measures are the right ones for us, and collected process and outcome measures, we will accelerate improvement by standardizing our practice.

Exhibit 1 Kaiser Permanente's Membership and Medical Facilities

Region	Members	Medical Offices	Medical Centers ^a
Colorado	480,000	20	0
Georgia	270,000	17	0
Hawaii	220,000	18	1
Mid-Atlantic States (Maryland, Virginia, Washington D.C.)	500,000		0
Northern California	3,200,000	160	21
Northwest (Oregon and Washington)	480,000	27	1
Ohio	140,000	30	0
Southern California	3,300,000	145	13

Source: Kaiser Permanente, "Kaiser Permanente Careers, Who We Are, Our Business Structure,"http://www.kaiserpermanentejobs.org/our-business-structure.aspx, accessed September 2010.

^aNumbers are hospitals owned and operated by Kaiser Foundation Hospitals. In those regions where the number is 0, Kaiser Foundation Hospitals contracts for use of hospitals owned by other parties.

for educator review use only by Julia Adler-milstein, University of Michigan - Ann Arbor until January 2017. Copying or posting is an infringement of copyright.

Permissions@hbsp.harvard.edu or 617.783.7860

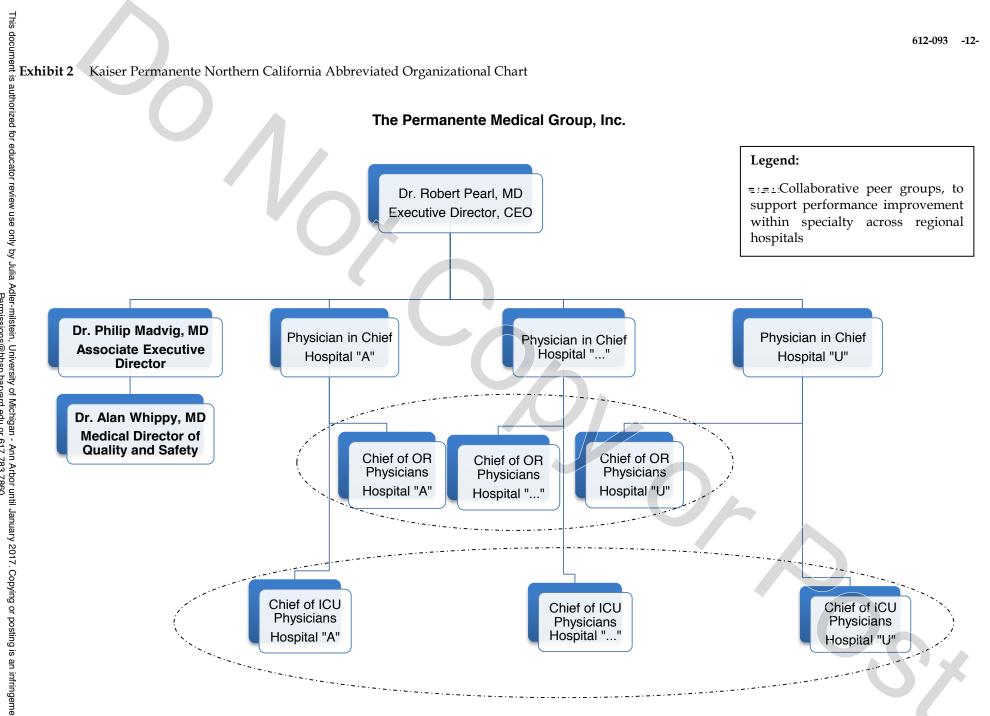
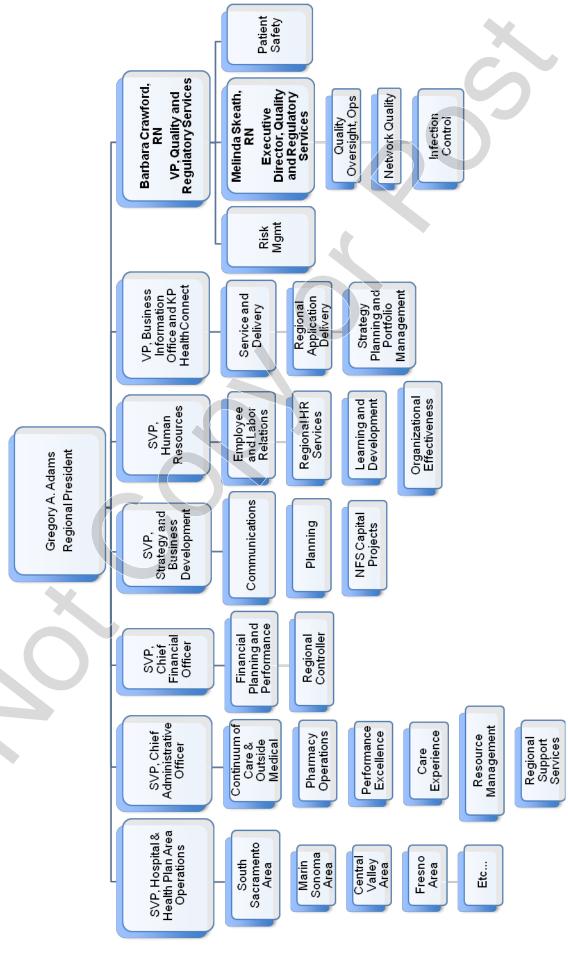


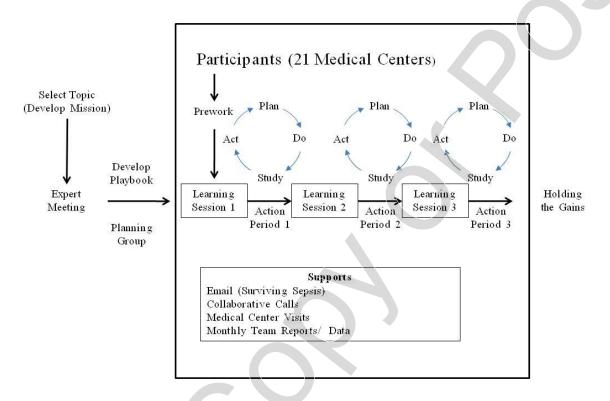
Exhibit 2 (continued)

Kaiser Foundation Hospital and Kaiser Foundation Health Plan, Inc., Northern California



Source: Casewriter adapted from company documents.

Exhibit 3 Kaiser Permanente Northern California's Adaptation of the IHI Collaborative Model



Source: Company documents.

Exhibit 4 The Four-Wheel-Drive Model



Source: Company documents.

Exhibit 5 Kaiser Permanente Northern California Sepsis Bundle Elements [INDICATE YEAR]

EARLY RECOGNITION

- 1. Test serum lactate level of all patients with suspected infection and two or more of the following:
 - Temperature (°F) < 96.8 or > 100.4
 - Heart Rate > 90
 - Respiratory Rate > 20
 - White Blood Cell Count > 12K or < 4K or > 10% bands
- If serum lactate level ≥ 4.0 mmol/L, begin EGDT

EARLY INTERVENTION: EGDT GOALS FROM TIME ZERO

- 1. WITHIN 1 HOUR: Initiate antibiotics and IV fluids
- 2. **WITHIN 2 HOURS:** Central Line Placement to monitor central venous pressure(CVP) and central venous oxygen saturation (ScvO₂)
- 3. **WITHIN 6 HOURS:** Achievement of three hemodynamic goals: CVP= 8-12; ScvO₂≥70; Mean Arterial Pressure (MAP)≥65
- 4. WITHIN 12 HOURS: Repeat lactate is lower than initial lactate

Source: Casewriters' diagram based on company documents.

Exhibit 6 Timeline of Kaiser Permanente's Sepsis Program

May 2008: Mortality Summit for Kaiser Permanente Northern California: Mortality rate for sepsis was 25 percent in 2007.

June 2008: Piloted the Sepsis Bundle at Kaiser Permanente Northern California's San Jose and Vallejo Medical Centers.

November 2008: Inaugural Sepsis Summit. Sepsis program implemented at all Kaiser Permanente Northern California hospitals. Kaiser Permanente Northwest attended summit and began modified sepsis program in its hospital.

June 2009: Began collecting bundle implementation data (antibiotics within 1 hour, CVP within 2 hours, etc.).

November 2009: Second Sepsis Summit. Kaiser Permanente Northern California's sepsis mortality was 15 percent.

June 2010: Sepsis diagnoses increased 116 percent in Kaiser Permanente Northern California from May 2008. Eleven percent reduction in all-cause mortality.

March 2011: Kaiser Permanente Northern California's sepsis program won a Kaiser Permanente Vohs Award for Quality.

April 2011: Third Sepsis Summit. Kaiser Permanente Northern California's sepsis mortality was 11 percent.

February 2013: Fourth Sepsis Summit. Kaiser Permanent Northern California's sepsis mortality was 9.6 percent.

Source: Company documents.

Phase 3 = Mar 2009 Train the Trainer for Sepsis & Sepsis web-based tool launch.

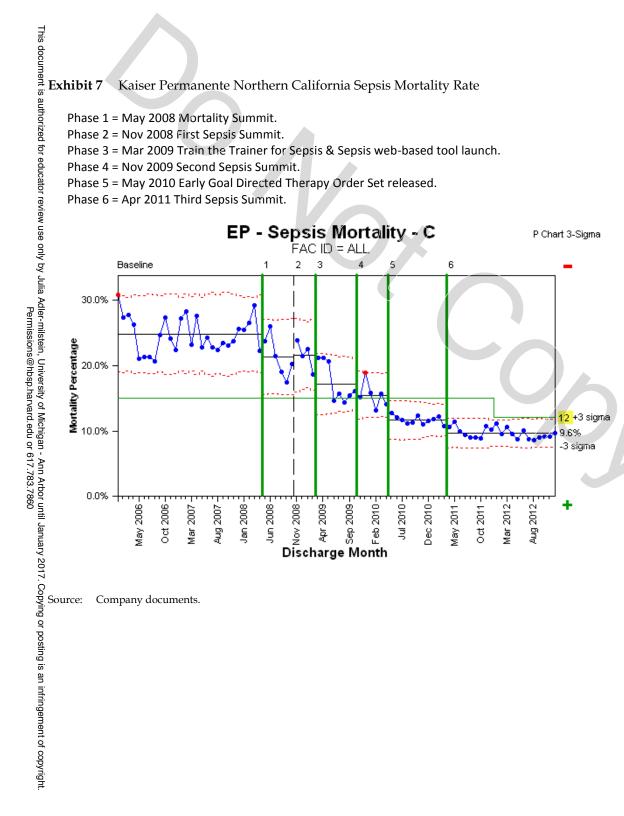


Exhibit 8 Kaiser Permanente Northern California's EGDT Sepsis Bundle Compliance

	EGDT Cases in Sept. 2011	% of patients who received Antibiotics within 1 hr. Sept 2011	% of patients who had CVP or ScvO ₂ measured within 2 hrs.	% of patients whose clinical measures met targets within 6-hours Sept 2011	Sepsis mortality rate Oct '10-Sept '11 (Nov '11 -Dec '12)
2011 Target		>=90%	>=70%	>=50%	<=15% (13%)
Medical Center "A"	5	100%	100%	80%	9% (11.1%)
Medical Center "B"	7	71%	83%	29%	15% (10.9%)
Medical Center "C"	7	100%	83%	86%	10% (9.2%)
Medical Center "D"	3	100%	100%	67%	12% (7.4%)
Medical Center "E"	5	100%	75%	60%	9% (9.7%)
Medical Center "F"	5	100%	60%	60%	11% (9.0%)
Medical Center "G"	5	100%	60%	40%	9% (8.0%)
Medical Center "H"	5	100%	100%	100%	11% (7.4%)
Medical Center "I"	5	100%	100%	80%	11% (10.4%)
Medical Center "J"	4	100%	50%	25%	8% (6.9%)
Medical Center "K"	12	100%	75%	42%	11% (9.1%)
Medical Center "L"	6	83%	50%	50%	10% (9.5%)
Medical Center "M"	4	100%	50%	50%	9% (9.2%)
Medical Center "N"	0	N/A	N/A	N/A	14% (11.9%)
Medical Center "O"	15	100%	100%	80%	10% (11.7%)
Medical Center "P"	5	100%	60%	40%	14% (8.7%)
Medical Center "Q"	8	63%	63%	50%	11% (9.1%)
Medical Center "R"	2	100%	100%	50%	10% (7.5%)
Medical Center "S"	6	100%	83%	50%	10% (9.5%)
Medical Center "T"	4	100%	75%	25%	11% (11.2%)
Medical Center "U"	7	86%	100%	86%	9% (9.6%)
Regional Average	120	94%	79%	59%	11% (9.6%)
% Meeting Target		81%	67%	71%	100%

Source: Company documents.

Endnotes

- ¹"Sepsis," *Complete Human Diseases and Conditions*, 2008, http://www.encyclopedia.com/doc/1G2-3497700347.html, accessed December 2011.
- ² Alan Whippy, Barbara Crawford, Melinda Skeath, and Carmen Adams, "Mortality Reduction through Widespread Redesign of Sepsis Care," December 2009, p. 7.
 - ³ Ibid.
- ⁴Alan Whippy, "The Sepsis Journey 2009," *Sepsis Playbook* 2010 *NCAL Sepsis Summit*, Oakland, CA: Kaiser Permanente, 2010, p. 2.
- ⁵ Alan Whippy, Melinda Skeath, Carmen Adams, and Barbara Crawford, 2011 Vohs Award Application: Sepsis Mortality Reduction Initiative.
- ⁶ Kaiser Permanente, "Kaiser Permanente More than 60 Years of Quality," http://xnet.kp.org/newscenter/aboutkp/historyofkp.html, accessed September 2010.
- ⁷ CC Cutting and MF Collen, "A historical review of the Kaiser Permanente Medical Care Program," *Journal of the Society for Health Systems*, 3(4): 25-30.
- ⁸Institute for Healthcare Improvement, "Innovation Series 2003: The Breakthrough Series, IHI's Collaborative Model for Achieving Breakthrough Improvement," Cambridge, MA: Institute for Healthcare Improvement, 2003, p. 3.
 - ⁹Ibid, p. 2.
- ¹⁰ MayoClinic.com, "Sepsis, Tests and Diagnosis," http://www.mayoclinic.com/health/sepsis/DS01004/DSECTION=tests-and-diagnosis, accessed September 2010.
- ¹¹ Rivers, E., Nguyen, B., Havstad, S., Ressler, J., Muzzin, A., Knoblich, B., Peterson, E., Tomlanovich, M., "Early goal-directed therapy in the treatment of severe sepsis and septic shock," *New England Journal of Medicine*, 2001, 345(19)1368-1377.
- ¹² RP Dellinger, MM Levy, et al, "Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2008," *Crit Care Med*, 2008, 36:296-327.
- ¹³ MedicineNet.com, "Definition of Central Line," September 8, 2003, http://www.medterms.com/script/main/art.asp?articlekey=14394, accessed September 2010.
- ¹⁴ Kaiser Permanente, "Kaiser Permanente Northern California's Journey to Becoming World-Class Hospitals, Strategic Initiatives," p. 9.
 - ¹⁵ Alan Whippy, Barbara Crawford, "The Hospital Quality and Safety Journey," June 2010, p. 5.
- Kaiser Permanente, "Kaiser Permanente Northern California's Journey to Becoming World-Class Hospitals, Strategic Initiatives," p. 9.
- ¹⁷ Kaiser Permanente, "Kaiser Permanente Northern California, Preventing Harm and Promoting Healing Sepsis Collaborative 2009-2010 Sepsis Change Package/Playbook," Presented at the NCAL Sepsis Summit, November 12, 2009.