CHAPTER 1

# Saving Lives by Improving Processes of Care

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## THE NEED FOR GREATER SEPSIS RECOGNITION

At 11 pm on a typical Saturday night, the waiting room of the emergency department (ED) is full. Suddenly, four patients are brought in by ambulance. The first is Martha, a 75-year-old woman with a cough and mild confusion, whose blood pressure, heart rate, respiratory rate, and temperature are mildly abnormal. Martha doesn't look that sick, so her nurse puts her in a back room of the ED where less acute patients are evaluated. Routine blood tests and a chest X-ray are ordered.

With multiple patients to evaluate, the ED physician has to prioritize those who seem to need the most attention. While the ED physician is sedating a disruptive patient and cleaning his wound, Martha is decompensating in the back room. Her blood pressure is dropping, her heart rate is climbing, and she is becoming sleepy, but no one notices. When the ED physician goes to evaluate Martha at 2 am, she is in shock. Her blood pressure is 60/30, and she is unresponsive.

Martha had severe sepsis (an overwhelming bacterial infection) due to pneumonia, and if the severity of her condition had been recognized and rapidly treated when she first arrived in the ED at 11 pm, her chance of survival would have been 80 percent. By the time she was treated at 2 am, her chance of survival had fallen to 50 percent. Meanwhile, the other three patients had predicted survivals of greater than 95 percent on arrival, and all received attention before Martha.

This scenario plays out in EDs all over the United States every day. In 2004, I asked, "Why can't we recognize and treat the sickest patients first?" In that same year, the Surviving Sepsis Campaign (SSC) was launched (Dellinger et al. 2004). The campaign focused on the early recognition and rapid treatment of patients with overwhelming bacterial infections that kill more than 200,000 people in the United States annually. For many years, despite new antibiotics and other medical advances, the mortality from these diseases had not changed. However, between 2000 and 2002, several large studies targeting different aspects of sepsis treatment demonstrated significantly lower mortality from severe sepsis and septic shock (Rivers et al. 2001; Annane et al. 2002; Van den Berghe et al. 2001; ARDSNet 2000; Bernard et al. 2001). By bundling these different treatments, investigators hoped to reduce sepsis mortality by at least 25 percent.

## THE JOURNEY

### Paradigm Shift

I realized that the implementation of the SSC at our hospital would require multidisciplinary cooperation. I became the physician champion committed to developing a sepsis protocol. I had no experience developing and implementing such a complex protocol.

My first step was to analyze the SSC guidelines in detail and compare the requirements to the realities at our hospital. Our strengths included

- a committed nursing and ancillary staff eager to improve patient quality and safety;
- a physician community with high standards of care;
- medical and surgical residency programs, which make physicians immediately available to treat sepsis patients (rather than on-call from home or other settings);
- trauma service and cardiac catheterization programs that could serve as models for interdisciplinary cooperation; and
- a not-for-profit structure and a board of directors committed to improving quality standards and clinical outcomes for the community.

The barriers to implementation of a sepsis protocol included

- a busy community ED, averaging approximately 40,000 annual visits, that needed a better system of triage to incorporate the needs of sepsis patients;
- lack of ED recognition of the problem and its urgency;
- laboratory turnaround times that were too slow for key tests, such as lactate and complete blood count (CBC) with differential;
- pharmacy delivery times that were too slow for antibiotics and other critical medications;
- slow transfers from the ED to the intensive care units (ICUs), where sepsis patients receive most of their care;
- a need for new technology, which would require both capital expenditures and physician and nurse training; and
- a need for extensive education of medical staff, residents, ED nurses, critical care nurses, respiratory therapists, pharmacy staff, and laboratory personnel.

## The Prerequisites to Change

Although multiple departments needed to collaborate, no structure existed to bring people together. Additionally, I had no support staff of my own to help with development. I decided to break down the problem into discrete parts and map out the changes we would need to make to our current practices and processes. I soon realized that a few key components needed to be put in place before the entire protocol could be implemented.

The first component included the purchase of new patient monitoring equipment—an $ScvO_2$ catheter, which measures the balance between oxygen supply and demand, a key component of sepsis monitoring. Fortunately, at the time, the catheter had recently been developed, and the company was willing to loan us the monitors if we would purchase the disposable catheters. Thus, we were able to develop this capability without any capital equipment outlay. Our ICU nursing leadership and critical care nurse educator developed a training program for the nurses. I developed an ICU rotation for our medical residents and trained them to insert the intravenous catheters, monitor oxygen supply and demand, and treat patients according to the principles of early goal-directed therapy (Rivers et al. 2001).

The second component involved tight control of blood glucose. At the time, the SSC recommendations included intensive intravenous insulin therapy and hourly monitoring of glucose levels. This labor-intensive treatment requires about 120 minutes of nursing time per patient per day. This insulin protocol was developed on the basis of the protocols detailed on multiple hospitals' websites and modified to conform to our practices. The protocol was then tested for several weeks, modified, and implemented before the official "Slay Sepsis" rollout.

The third component measured blood lactate, which alerts physicians that a patient's oxygen delivery is inadequate, a condition often found in patients with severe sepsis or in septic shock. Arterial blood was considered the gold standard for this test, but

the phlebotomists could draw only venous blood. Thus, a respiratory therapist, trained in drawing arterial blood, had to obtain the sample. In discussing the problem with our respiratory care manager, I learned that our arterial blood gas (ABG) machines could be fitted with modules that measure lactate in arterial blood gas samples. The process was no more difficult or time consuming than measuring arterial blood gas alone, though the cost was a bit higher. The beauty of this solution was that the respiratory therapists could draw the arterial blood sample and then run the specimen themselves in our blood gas lab. This solution reduced the turnaround time from approximately four hours in the main clinical lab to about ten minutes using our ABG machines. We purchased the new modules and trained respiratory therapists to measure arterial lactate levels.

## Processes That Needed to Change

### *The Sepsis CBC*

First, we needed to have manual differentials performed on CBCs. This labor-intensive test, requiring a skilled clinical laboratory scientist to manually count certain cell types in a blood smear, is a key screen for sepsis. The turnaround time for this test is about four hours. When I met with the lab manager and supervisors and explained that the turnaround time for this test needed to be less than one hour, they resisted until I described how it could save as many as 30 lives per year at our hospital. I also pointed out that we would order this test only for patients we suspected to be suffering from sepsis. I estimated that about three to five tests per day would need to be performed.

Most of my previous interactions with the lab were faceless phone conversations in which I usually expressed frustration about poor service, slow turnaround time, or inability to obtain a test I needed. By meeting with the lab technologists, I realized that they cared. They were proud of their work and provided a crucial

service to patients. I gained a new respect and appreciation for the lab personnel through these face-to-face discussions.

To be able to meet the turnaround time I had specified, the lab needed to obtain the specimens from the ED more quickly. To this end, we developed a new "Sepsis CBC" that included the manual differential. It would be placed in a special bag, hand-carried to the lab by ED personnel, and personally delivered to a lab technologist. The specimen would then be processed immediately rather than batched with other lab tests.

### *ED Screening and Treatment*

We needed to develop a screening process at initial triage so that patients who had signs and symptoms of sepsis could be identified rapidly and put in a sepsis pathway specifying a set of orders and tests by which we would determine which patients needed to be treated immediately. I spoke with the nurse manager and the medical director of the ED and asked for their help. We modified a sepsis screening tool (the Institute for Healthcare Improvement's Evaluation for Severe Sepsis Screening Tool [2005]) for this purpose.

Another key component included rapid administration of appropriate antibiotics. When a patient with a severe infection presents to the ED, we usually do not know what organism is causing the infection. Depending on the site of infection, we can tell which organisms are likely to be the cause and choose an antibiotic that treats those organisms. With the help of an infectious disease specialist, we developed a one-page guide of recommended antibiotics for various types of infections, which we laminated and placed in the ED for physicians to reference.

Another problem with antibiotics was the time it took to obtain them from the pharmacy, delaying life-saving therapy by at least one to two hours. We decided that we could greatly reduce antibiotic administration time by storing initial doses of antibiotics in the ED and ICUs. Such an arrangement would enable the nursing staff to administer the antibiotics within minutes of the physician's order.

Rapid and aggressive administration of intravenous (IV) fluids required a cultural shift. Nurses and physicians may be reluctant to administer fluid aggressively for fear that they might administer too much and cause patients to develop fluid overload in the lungs and subsequently experience respiratory failure. Education of the nursing and physician staffs about the importance of fluids in resuscitating sepsis patients was essential. Part of this education included emphasizing the importance of using a pressure bag instead of electronic IV pumps to administer fluid rapidly. A pressure bag is a device similar to a blood pressure cuff that is placed around an IV bag and pumped by hand, pushing fluid rapidly into the patient. Only after repeated demonstrations was the nursing staff convinced that cheap, old-fashioned manual pressure bags could deliver fluid four to five times faster than our new, expensive, electronic IV pumps.

We needed a system to move patients more rapidly from the ED to the ICUs, where they could have special catheters placed and receive the majority of their treatment. We developed rules regarding the rapid transfer of patients to the ICUs to reduce the time patients spent in the ED and improve patient throughput. We also developed a sepsis team to respond rapidly to the ED call. The sepsis team would accelerate diagnosis and therapy for critically ill patients and free up understaffed ED personnel so they could devote attention to their other patients at peak times. This team would consist of medical or surgical residents supported by an intensive care attending physician. Once in the ICU, rapid treatment of sepsis patients was facilitated by sepsis carts, which contained all of the supplies necessary to treat them, enabling the care team to stay at the patients' bedsides.

Finally, we needed to develop a system to measure what we were doing, including compliance with elements of the care protocol and clinical outcomes. Metrics are critical to determining what is working, even though gathering and analyzing them are labor intensive. *Labor intensive* equates to *expensive* and *time consuming*. For the first two years we followed this protocol, I, along with a few dedicated medical residents and medical students, personally

collected these data. After two years, I secured the services of two critical care nurses working in our quality services department, who agreed to screen patients, collect data, and maintain the database.

## Initial Clinical Outcomes

After education and implementation of process changes, the Slay Sepsis Protocol went live September 1, 2005. The results have been remarkable. Six months prior to initiating this protocol, mortality from septic shock at our hospital was 44 percent of sepsis patients, consistent with the published mortality rates in the United States and Europe of 40 to 55 percent (Friedman, Silva, and Vincent 1998; Annane et al. 2003; Vincent et al. 2006; Blanco et al. 2008; Po'voa et al. 2009; Russell et al. 2008). In the first two years after initiating this protocol, our mortality rate dropped to 24 percent, nearly half the pre-protocol rate.

## Our Gains Start Slipping

After two more years of collecting data, we noted that our annual mortality rates were creeping up to 27 percent. When we looked at our process measures, we noticed that we were not performing as well as we had initially. Some of the reason might have been protocol fatigue (Devlin and Nasraway 2008; Nasraway 2004). When a protocol is new, enthusiastic practitioners put forth effort to make it work, but as time goes on, enthusiasm and effort wane.

Additionally, the turnover of nurses in the ED and ICUs during this period was significant, and new nurses did not receive as much education about the protocol as their colleagues received when we first launched it. Disturbed by this trend, one of our administrators suggested that we perform a Lean analysis. For two days, a group including myself; all managers from the ED, ICUs, lab, and respiratory care; and representatives from the ED physician staff, medical residents,

and quality improvement nurses responsible for tracking our sepsis outcomes met with this administrator and mapped out every step of the protocol, from the ED through the ICU stay.

## Process Changes

Among the most significant changes was redevelopment of a screening tool. Although we had implemented a tool initially, the ED nursing staff, averse to using paper, refused to use it. Once they realized how critical it was to the triage process, they redesigned the tool and made it their own. They now use it regularly.

The ED nursing staff also suggested that we assign a level of severity to sepsis patients at triage. A patient designated with "Level 1 sepsis" would be immediately triaged to one of the rooms reserved for the sickest patients and assigned two RNs, an ED patient care technician, and an ED physician who would evaluate the patient immediately. We initiated automated order sets on these patients so that necessary tests would be ordered and sent immediately. We developed guidelines for placing central lines in the ED instead of waiting until transfer to the ICU to do so and created rules for rapid transfer to the ICUs.

The best part of the Lean process was having all the stakeholders together in one room at the same time. When I developed the initial protocol, I had broken down the process into parts and dealt with the appropriate manager and personnel individually; rarely, if ever, did we all meet together. Although more difficult, bringing everyone together was advantageous in the following ways:

- Everyone had an idea of the whole process, not just his or her part in the process, and that understanding enabled a free exchange of ideas on the impact each department's performance had on everyone else's performance.
- Peer pressure fostered change. If a department was asked to modify its usual practice, it couldn't say "no" to the group as easily as it could say "no" to just me.

**Key Concepts 1.1: Eleven Steps to a Successful Surviving Sepsis Campaign**

1. Identify a physician champion who will be committed to spending time on this process.
2. Familiarize yourself with the revised SSC guidelines (Dellinger et al. 2008) and map out the time and intervention goals that must be achieved to comply with them.
3. Secure the support of your administrators and their commitment to provide the resources you need to create the protocol and, most important, to track the process and outcomes. Determine your current mortality rates for sepsis by current or retrospective chart review. Convince the medical staff to endorse the development of a sepsis protocol.
4. Examine the current process for treating sepsis patients at your hospital, and determine which areas will need to change to accommodate the time and process goals mapped in #2.
5. Meet with the managers of the various departments and physician leaders who will be involved in the process improvement, and enlist their support.
6. Bring the entire group together as a sepsis improvement task force and map out a stepwise process of all interventions that need to be performed, from ED triage through ICU, to achieve the goals from #2.
7. Identify obstacles that prevent or delay necessary care. Appropriate screening at triage is critical; otherwise, all downstream efforts will be delayed. Encourage participants to create solutions to identified problems.
8. Develop a process for tracking performance of the various components of the protocol and outcomes (e.g., mortality). Components should include the "bundle" goals of the SSC guidelines as well as identified choke points in the process.

9. Develop an education plan for participating departments and medical staff that focuses not only on their specific roles in the protocol but also on the overall goals of the campaign.
10. The sepsis task force should meet regularly to review performance and revise components that are not working. Weekly meetings may be needed initially.
11. Trumpet your successes to all participants, the hospital, and the medical staff; they need to know that all the extra effort is saving lives.

- All problem areas were identified and addressed at once rather than in isolation.
- We incorporated new performance measurements into the process so we could determine whether the changes we made were working. Having tracked outcomes for four years, I was already aware of most of the problems, yet I could never obtain enough buy-in from the appropriate parties to make the necessary changes. Working as a group, everyone bought into the process, and each stakeholder took ownership of his or her part of the process as well as the success of the entire protocol.

## CASE ANALYSIS

The capital outlay required to implement this protocol was approximately $10,000. Virtually all of the improvement in outcomes resulted from improving processes of care. The greatest expenditure was the cost of collecting data to validate the protocol and measure outcomes.

Although we implemented the revised sepsis improvement project only recently, we are already seeing dramatic improvements in our process measure compliance times, which have significantly reduced our septic shock annual mortality to less than 20 percent. On the basis of the number of patients we have admitted with a

diagnosis of severe sepsis and septic shock over the past five years, we estimate that more than 200 lives have been saved as a result of the Slay Sepsis Protocol. These lives were not saved by the addition of new expensive drugs or treatments to our armamentarium but by the collaborative efforts of a healthcare team committed to improving the **process** of how we take care of our patients.

## LESSONS LEARNED

- A physician champion is essential. Without the involvement of a person who has earned the respect of his or her colleagues, most clinical process changes are unsustainable.
- Know your institution's strengths and weaknesses.
- Learn everything you can about what you are trying to accomplish, and determine which departments and resources you will need help from in your endeavor.
- Having the backing of senior administrators is helpful, but middle managers make things happen at the clinical level.
- People need to have a reason to implement change. Most people who work in the hospital are genuinely concerned about patients. If you can convince them that the change will benefit patients, they will work with you to effect it.
- Measuring what you do on an ongoing basis is critical to quality improvement. It also seems to be the most difficult part of the process to maintain and requires a long-term commitment of resources.
- Have everyone at the table from the beginning. You can work with individual departments and managers on specifics, but have all parties meet frequently from the start to obtain everyone's buy-in and to help everyone understand how his or her part relates to the whole.
- Encourage reluctant stakeholders to customize protocols to fit with their experience and become process owners.

- To achieve significant improvement, you do not always need the latest, greatest, and most expensive drug or technology. Enormous gains can be made by improving processes of care at little cost.

## SUGGESTED READING

www.ihi.org/IHI/Topics/CriticalCare/Sepsis

www.survivingsepsis.com

## REFERENCES

References appear at the end of the book on pages 243–245.