

CAMPAIN Update

A global effort to improve care for patients with severe sepsis and septic shock

April 2007 Special Edition



Campaign Update is the official newsletter of the Surviving Sepsis Campaign. The Surviving Sepsis Campaign is a partnership of the European Society of Intensive Care Medicine, the International Sepsis Forum and the Society of Critical Care Medicine. This bi-monthly communiqué focuses on topics related to local, regional and national SSC activities. Feedback and content suggestions may be sent to campaignupdate@survivingsepsis.org.



Surviving Sepsis Campaign to Focus on Specific Bundle Elements

PDSA Process Key to Improvement



The chart below reflects the initial step in documenting the value of the Surviving Sepsis Campaign as an improvement tool throughout the world. Showing the overall compliance with the individual elements of the 6-hour resuscitation bundle over the 20 months the Campaign has received data, the chart clearly indicates that 2 elements require attention overall. While the survival rates have increased over time, how much better might the rates be if these 2 elements—CVP and ScvO₂, the early goal directed therapy measures—were improved? The Rivers' trial 16% reduction in mortality compared with controls suggests the rates should look substantially better.

to create change. For the first time in a major quality improvement initiative we now have enough statistical information to conclude that even hospitals engaging in a highly structured quality improvement program are still universally struggling with early goal directed therapy.

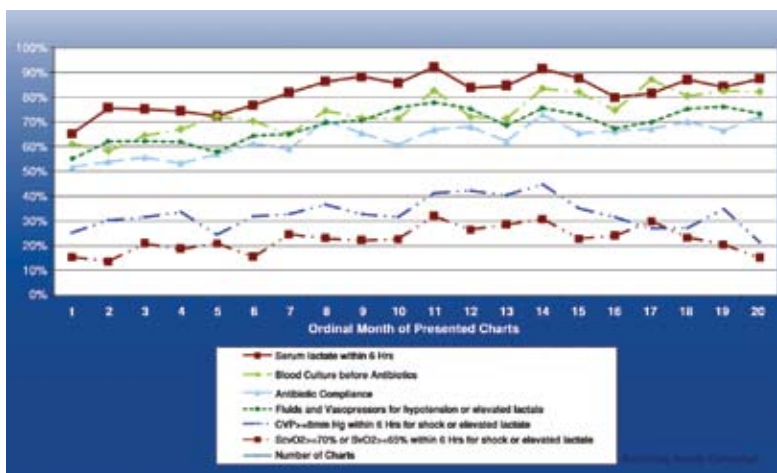
The PDSA approach—Plan-Do-Study-Act—is the linchpin of the improvement process (Shewhart, 1939). In many ways, the Campaign has already done the first *Study* component of a PDSA cycle by noting the global failure to implement effective early goal directed therapy. As such, the Campaign is now proposing a global PDSA cycle. The Campaign has identified the problem; hospitals will now tackle it. Hospitals should begin at the *Plan* level to reverse this trend. Hospitals can envision many Plan-Do-Study-Act cycles before their early goal directed therapy numbers trend upward. A log of each intervention should be made, reporting results from each cycle to guide the next. Setting an explicit aim is key: “we aim to be a center of excellence in early goal directed therapy,” for example. Next, hospitals should

By using the Campaign's data collection and reporting tools as an improvement technique, individual hospitals as well as the Campaign as a whole have powerful resources

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Resuscitation Bundle



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Photo by [unclear] **Campaign's ability to create global change in care is clear**



As the leaders of the Surviving Sepsis Campaign met in Brussels in late March to review the initial data sets derived from the aggregate database, it became clear that the Campaign will have a far-reaching, long term impact on the way clinicians manage patients with severe sepsis and septic shock. While the original goal of the Campaign was to reduce mortality from sepsis by 25% in 5 years, the evidence suggests that whether or not that metric is met, major changes are occurring in how patients are treated. We continue to be delighted with the regular increases in submissions to the global database.

The Campaign's uptake throughout the world is occurring at various levels. On one hand, some networks implemented the guidelines independently before the Campaign's data collection and performance improvement tools were available. And some small hospitals are starting now to put together change teams inviting their ER and ICU staffs to participate. With some facilities having collected and submitted data on bundle elements for 20 months now, and some just beginning, the SSC leaders recognize that we need to provide a range of tools and experiences for groups at varying levels. But most of all, from looking at the 20 months of data now available that indicate changes in how care is given, we recognize the opportunity to improve bedside care further by utilizing the model we have introduced for changing clinical practice.

Rather than waiting for more patients' charts to be entered into the database, SSC wants to take bold action consistent with the nature of the Campaign. Instead of resting on the laurels of an obviously successful attempt to change clinical practice by declaring a cut-off date for contributions to the database, we plan to continue collection and regular analysis of data as we encourage more and more hospitals throughout the world to document their efforts on the individual SSC bundle elements. By focusing on those elements that show lower compliance, we intend to assist with the quality-improvement efforts integral to the Campaign that will ultimately result in better treatment of our patients. Through use of the Plan-Do-Study-Act cycle that is the basis of the improvement efforts of the Campaign, we expect to improve overall compliance with the bundles and thereby reduce mortality.

As members of the Surviving Sepsis Campaign steering committee took a cursory look at data from nearly 4500 patient charts, they recognized that performance on individual bundle elements definitely improves over time. Tentative analysis indicates that the Campaign is moving in the right direction with increasing contributions to the database weekly. Month-to-month decreases in mortality and improvements in compliance with certain bundle elements are also evident. The good news is that the Surviving Sepsis Campaign has been successful in guiding the improvement of knowledge transfer and behavior change. The bad news is that compliance with some of the bundle elements demands attention. As we all can see from the graph of compliance with the bundle elements of the 6-hour resuscitation bundle (shown on page 1 of this newsletter), overall compliance and survival rates are improving. Nevertheless, compliance with achieving central venous pressure (CVP) of ≥ 8 mm Hg and central venous oxygen saturation (ScvO₂) of $\geq 70\%$ needs improvement. Based on current knowledge, SSC recommends both the CVP indicator and the ScvO₂ indicator as important components of initial resuscitation of patients with sepsis-induced tissue hypoperfusion.

Through focusing on these 2 elements, the Campaign intends to rectify this ongoing deficit in practice and enhance the effort to improve patient care. We will deliver on our promise to provide quality-improvement and change tools to Campaign participants through educational materials, frequent data reports in this newsletter, and conference calls with network heads. In the next 12 to 18 months of Phase III of the Campaign, we hope to deliver another quantum change in compliance with these 2 bundle elements.

Doing so will further the historic nature of the Campaign's ability to create a global change in clinical practice through the application of the bundle concept. Speaking for the Campaign leadership, I encourage you to rededicate your efforts to improving care for these critically ill patients.

Mitchell M. Levy, MD, FCCM
Professor of Medicine
Brown University
Director, Medical ICU
Rhode Island Hospital
Providence, Rhode Island, USA

Member, SSC Executive Committee

Below are resources from the literature that provide additional background on the improvement process to practitioners as they implement SSC.

Amalberti, R: **Revisiting safety and human factors paradigms to meet the safety challenges of ultra complex and safe systems.**

In: Willpert B, Falhbruch B, eds. *Challenges and Pitfalls of Safety Interventions*. North Holland: Elsevier; 2001

An elegant, if not philosophical, investigation into the nature of reliable systems and how to make complex systems more reliable and safe. The essential thesis is that unconstrained human behavior (guided by personal discretion only) is characteristic of chaotic, unreliable environments. Through the acceptance of constraints, more orderly, safe systems can be developed.

Clemmer TP, Spuhler VJ, Berwick DM, Nolan TW: **Cooperation: the foundation of improvement.** *Ann Intern Med* 1998;128:1004-9

A review of the conditions required to produce clinical change and improvement arguing that "cooperation" is the essential element required when we work to change care. PDSA cycles minus collaboration are unlikely to succeed.

Clemmer TP, Spuhler VJ: **Developing and gaining acceptance for patient care protocols.** *New Horiz.* 1998;6:12-9

A primer for insight into how to use protocols in a hospital environment to improve care. The crux of the piece is to endorse that a protocol is a living entity, always changing to adapt to the needs of the users. Protocols function best when serially modified as a result of PDSA cycles.

Reason J: **Human Error.** Cambridge, England & New York: Cambridge University Press; 1990

James Reason and others have clarified why humans err. Humans are not reliable. We all forget, get distracted, become overwhelmed by complex environments, and make errors on a daily basis. The use of PDSA cycles can help to overcome the potential for error and allow us to detect where error may occur and how to prevent it.

Brock W, Nolan K, Nolan T: **Pragmatic science: Accelerating the improvement of critical care.** *New Horizons* 1998; 6:61-68

A call for rapid cycle change based on the best available evidence. PDSA cycles may be executed several times per day, depending upon scale.

Langley GL et al: **The Improvement Guide: A Practical Approach to Enhancing Organizational Performance.** San Francisco: Jossey-Bass, 1996

The essential guide to rapid cycle change and application of PDSA cycles to everyday healthcare environments. The Improvement Guide clearly spells out the rationale for the use of PDSA cycles and the key components of planning, doing, studying and acting.

Shewhart, Walter Andrew: **Statistical Method from the Viewpoint of Quality Control.** New York: Dover, 1939.

PDSA cycles as described by the principal developer and proponent of the concept. In this text, Shewart asks "What can statistical practice, and science in general, learn from the experience of industrial quality control?" The PDSA principles were originally derived from industrial quality control practices.

PDSA Process Key to Improvement

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establish a goal: eg, "we will decrease the time from which patients receive early goal directed therapy from an average of 8 hours to within 6 hours by January 2008." Then, hospitals can set about achieving their aims and goal with serial PDSA cycles, slowly improving on prior results until the goal is reached.

The plan at each hospital will be to determine what actions need to be taken to reach compliance. A key understanding is that planning is predictive. That is, the plan includes a hypothesis about what is likely to happen when the plan is hatched. The *Do* portion involves launching the proposed changes to your care patterns — eg, a new protocol, a stat pager, a rapid response team call for septic patients on the floor. *Study* means collect data and review what happened. The database is not a place to store information and forget about it. We have noticed that many hospitals appear simply to be compiling data but not using the data to inform what the next set of changes should be. The key question is: did our predicted results come true? If not, why not? If results are minimal, what will push those results to the next level? If the prediction was fully achieved, what can we do next to build on that change? In the *Act* phase, the process is revised and the process begins again.

Over the course of many PDSA cycles, the pattern of care will begin to change. The constant attention to detail and refinement of approach will effect a culture change regarding early goal directed therapy. This type of quality improvement allows institutions to achieve aims and goals — otherwise you are just storing data.

CALENDAR

2007

April 25

Arizona Regional Training Program
10:00 am – 3:00 pm
Wyndham Hotel
Phoenix, AZ

October 7-10

ESICM 20th Annual Congress
SSC Educational Session
Wednesday, October 10, 2007
11:10 am – noon
Berlin, Germany

2008

February 2-6, 2008

SCCM 37th Annual Congress
SSC Educational Session
TBD
Honolulu, Hawaii

Send us your SSC meeting information and we will include it in future issues of *Campaign Update*. Send submissions to campaignupdate@survivingsepsis.org.

Guidelines Revision Committee Moves Forward

As a result of productive face-to-face meetings of SSC guidelines revision committee members who were attending the recent critical care meetings in Orlando and Brussels, the guidelines revision is nearing closure. We anticipate joint publication in *Critical Care Medicine* and *Intensive Care Medicine* in Fall 2007.

In addition to the original 11 sponsoring and participating organizations, representatives from the two primary Japanese critical care organizations and the Canadian Critical Care Society have participated in the guidelines revision deliberations along with the German and Latin American sepsis organizations. The continued discussions of the committee have focused primarily around the numerous recent study results related to steroids, vasopressin, glucose and other topics as well as deliberation on "strength of recommendation."

The revision has been accomplished in collaboration with the GRADE evidence based medicine (EBM) group. At the time the original guidelines were being developed, the Society of Critical Care Medicine and the American College of Chest Physicians used the Sackett EBM system for guidelines. A limitation of this system was that it used quality of evidence as the sole criteria for grading recommendations. Many clinicians considered this problematic since those recommendations that are not amenable to clinical trials will, by definition, have low levels of quality of evidence. For example, in the first guidelines process, early administration of antibiotics received a Grade E (expert opinion) rating while interventions such as early goal-directed therapy received a Grade B rating based on one large randomized clinical trial. In the revision, we have added a strength of recommendation grading that is characterized by 1 (strong) or 2 (weak).

Variables used for determining the strength of recommendation include not only quality of evidence but, in addition, risk of intervention, cost of intervention, consistency of literature support, and ability to conduct clinical trials in the presence of general acceptance of the intervention being graded. In the revised guidelines, use of early antibiotics becomes a 1C recommendation with the 1(strong) designation, given the fact that there will never be clinical trials that randomize subjects to receive immediate versus delayed antibiotics in the presence of severe sepsis and with the knowledge that the intervention is both safe and relatively inexpensive. The "C" is related to the change in the level of evidence grades for the revision from "A to E" to "A to D" and the recently published retrospective database study which supports the beneficial effect of early antibiotic administration in patients with septic shock.

The much-anticipated revision is on track to live up to the Campaign goals to cement a worldwide best practice for the management of severe sepsis. Through implementation of the guidelines and participation in the global performance improvement database, facilities will be able to document improved patient care both in their own institution and around the world.

Plan now to attend SSC session at ESICM

The Surviving Sepsis Campaign Session is scheduled for Wednesday, October 10 from 11:10 am until noon during the European Society of Intensive Care Medicine's 21st Annual Conference in Berlin. The session will be introduced by Jean-Louis Vincent and will include a presentation on the revised guidelines by R. Phillip Dellinger. Julian Bion will explain the GRADE system of rating evidence including the GRADE Grid that was used by the Campaign to ensure

that all participants' points of view were considered equally. An interim analysis of the results of the global data collection will be presented by Mitchell Levy. How the Campaign's 6-hour and 24-hour bundle data collection and analysis are being used as a performance improvement tool to effect change in various clinical settings will be highlighted in the presentations. Make your plans now to hear this information firsthand at the ESICM meeting.

CAMPAIGN at-a-Glance

Asia

China

Europe

Denmark—*Lone Poulsen*

England—*Jane Eddleston*

Germany—*Konrad Reinhart*

Ireland—*Jeanne Moriarty,*

Brian McCloskey

Italy—*Massimo Antonelli,*

Roberto Fumigalli

Netherlands—*Arthur Van Zanten,*

Dave Tjan

Poland—*Andrzej Kubler*

Portugal—*Antonio Cameiro*

Scotland—*Simon Mackenzie,*

Louie Plenderleith

Spain—*Antonio Artigas*

Sweden—*Hans Hjelmqvist*

Wales—*Mark Smithies*

Latin America

Brazil—*Eliezer Silva*

Chile

North America

Alabama—*Moustafa Hassan*

California (Southern)—

Herbert Rogove

California (Sutter)—*John Mesic*

Colorado—*Ron Rains*

Connecticut—*Dawn Martin*

Florida—*Edgar Jimenez*

Georgia—*Kenneth Kalassian*

Illinois—*Nathan Lidsky, John Butler,*

Michael Ries, Jay Cowen

Iowa—*James Boddicker, Jill Morgan*

Kansas—*Steve Simpson*

Maryland/Washington, DC—

Gabriel Hauser

Michigan—*Joseph Bander*

Minnesota—*Henry Mann*

New Jersey—*R. Phillip Dellinger*

New York (NYHHC)—

Karen Scott Collins

North Carolina—*C. Diane Byrum*

Puerto Rico—*Gloria Rodriguez*

Texas (Memorial-Hermann)—

James Heisler

Virginia—*William Brock*