

# Protocol-Based Resuscitation Bundle to Improve Outcomes in Septic Shock Patients: Evaluation of the Michigan Health and Hospital Association Keystone Sepsis Collaborative\*

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**Objectives:** To evaluate the impact of a multi-ICU quality improvement collaborative implementing a protocol-based resuscitation bundle to treat septic shock patients.

**Design:** A difference-in-differences analysis compared patient outcomes in hospitals participating in the Michigan Health & Hospital Association Keystone Sepsis collaborative ( $n = 37$ ) with noncollaborative hospitals ( $n = 50$ ) pre- (2010–2011) and post-implementation (2012–2013). Collaborative hospitals were also stratified as high ( $n = 19$ ) and low ( $n = 18$ ) adherence based on their overall bundle adherence.

**Setting:** Eighty-seven Michigan hospitals with ICUs.

**Patients:** We compared 22,319 septic shock patients in collaborative hospitals compared to 26,055 patients in noncollaborative hospitals using the Michigan Inpatient Database.

**Interventions:** Multidisciplinary ICU teams received informational toolkits, standardized screening tools, and continuous quality improvement, aided by cultural improvement.

**Measurements and Main Results:** In-hospital mortality and hospital length of stay significantly improved between pre- and postimplementation periods for both collaborative and noncollaborative hospitals. Comparing collaborative and noncollaborative hospitals, we found no additional reductions in mortality (odds ratio, 0.94; 95% CI, 0.87–1.01;  $p = 0.106$ ) or length of stay ( $-0.3$  d; 95% CI,  $-0.7$  to  $0.1$  d;  $p = 0.174$ ). Compared to noncollaborative hospitals, high adherence hospitals had significant reductions in mortality (odds ratio, 0.84; 95% CI, 0.79–0.93;  $p < 0.001$ ) and length of stay ( $-0.7$  d; 95% CI,  $-1.1$  to  $-0.2$ ;  $p < 0.001$ ), whereas low adherence hospitals did not (odds ratio, 1.07; 95% CI, 0.97–1.19;  $p = 0.197$ ;  $0.2$  d; 95% CI,  $-0.3$  to  $0.8$ ;  $p = 0.367$ ).

**Conclusions:** Participation in the Keystone Sepsis collaborative was unable to improve patient outcomes beyond concurrent trends. High bundle adherence hospitals had significantly greater improvements in outcomes, but further work is needed to understand these findings. (*Crit Care Med* 2016; 44:2123–2130)

Basis:

Currently, most clinical guidelines are protocol-based therapies with focus on time-dependency

Debate as to whether this is effective

Problems with protocol based = increased antimicrobial use, unnecessary testing, overused invasive treatment

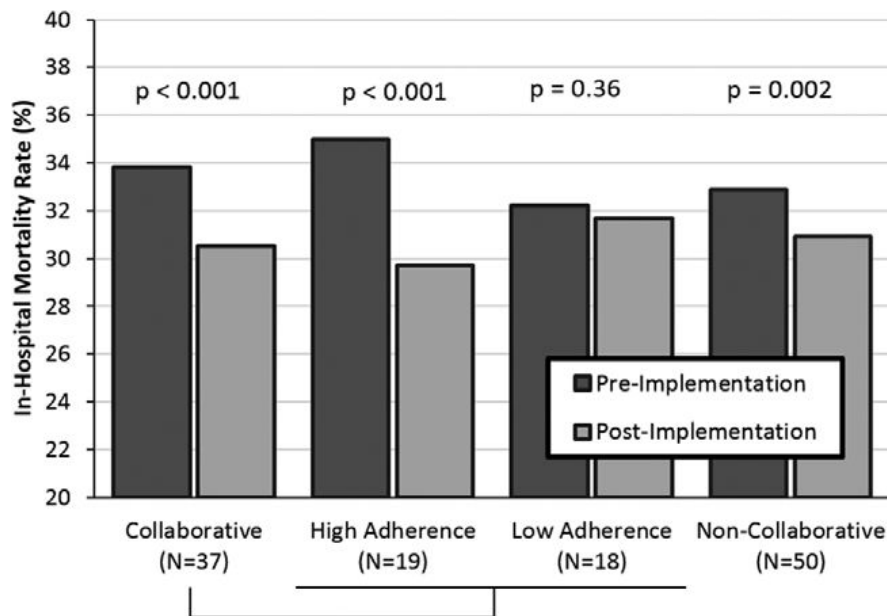
Study design: “Difference in difference” - comparing hospitals over time. Hospitals that did protocol versus hospitals that didn’t

Bundle care focused on:

The eight bundle measures reflected the 2008 SSC guidelines:

- fluid bolus administration
- lactate measurement

- antibiotic administration
- obtaining two blood cultures
- blood cultures obtained prior to antibiotic administration
- clinical achievement in:
  - central venous pressure (> 8 mmHg)
  - mean arterial pressure (> 65 mmHg), and central venous oxygen saturation (> 70%)



**Results:**

When comparing all collaborative hospitals, there was no significant difference in outcome improvement over non-collaborative

When subgroup analysis of high adherence hospitals is performed, then there is an improvement in outcomes

**Conclusions:** There is a chance that high-adherence to protocol based septic shock treatment can improve outcomes more than overall trends