Published in final edited form as:

JAMA. 2014 October 8; 312(14): 1397–1398. doi:10.1001/jama.2014.11350.

Sepsis Mandates: Improving Inpatient Care while Advancing Quality Improvement

Colin R. Cooke, MD, MSc, MS[1,2,3,4] and **Theodore J. Iwashyna, MD, PhD**[1,2,4,5]

[1]Division of Pulmonary & Critical Care Medicine, University of Michigan, Ann Arbor, MI, USA

[2]Institute of Healthcare Innovation and Policy, University of Michigan, Ann Arbor, MI, USA

[3]Center for Healthcare Outcomes & Policy, University of Michigan, Ann Arbor, MI, USA

[4]Michigan Center for Integrative Research in Critical Care, University of Michigan, Ann Arbor, MI, USA

[5]Center for Clinical Management Research, VA Ann Arbor Health System, Ann Arbor, MI, USA

The last decade has witnessed significant improvements in the care of acutely ill hospitalized patients. Elderly patients with an acute myocardial infarction (AMI) are now nearly twice as likely to receive evidence-based care and one-third less likely to die during their hospital stay compared to just ten years ago[1,2]. Similar trends exist for congestive heart failure (CHF) and pneumonia[2]. National public reporting and pay for performance (P4P) efforts, such as those implemented by the Centers for Medicare and Medicaid services (CMS), have contributed to improvements in care for these conditions[1].

Since those CMS programs were developed, however, the epidemiology of hospital care has changed in the United States. Improvements in outpatient care have substantially reduced the incidence of hospitalization for the conditions on which CMS currently focuses, specifically AMI, CHF, and pneumonia. Moreover, fewer than 10% of patients with these three conditions now die during their hospital stay. Meanwhile, among inpatients, sepsis has become the most prevalent and most costly disease, and is associated with high in-hospital mortality rate[3,4]. The time has come for CMS to explicitly develop new quality mandates focused on sepsis.

By adding a specific focus on sepsis, CMS might achieve greater improvements in patient outcomes and advance the quality of hospital-based care. Sepsis is now the most common non-pregnancy related primary discharge diagnosis for Medicare and Medicaid, and in the top five for private payers[2,3]. These numbers underestimate the total burden of sepsis, as many patients admitted with other common diagnoses also have sepsis or develop sepsis during the hospital stay. With an increasing incidence and high case-fatality rate, sepsis now

Corresponding author: Colin R. Cooke, MD, MSc, MS, University of Michigan, Center for Healthcare Outcomes and Policy, 2800 Plymouth Rd., Bldg. 16, Rm. 127W, Ann Arbor, MI 48109. cookecr@umich.edu. Phone: (734) 615-9681..

Conflict of interest disclosures: Drs. Cooke and Iwashyna have no conflicts of interest to report.

Disclaimer: The opinions presented here are the authors' own and not necessarily those of the U.S. Government or the Department of Veterans Affairs.

accounts for nearly half of all hospital deaths[4]. Yet, hospitals vary widely in their adherence to sepsis guidelines[5]. In marked contrast to adherence to treatment guidelines for AMI, CHF and pneumonia process measures, published reports routinely cite less than 35% compliance with current best practice for sepsis care[5].

Some may suggest that the rollout of national accountability measures for sepsis is premature[6]. These concerns, however, are largely not empirically based. Some contend that claims-based definitions of sepsis lack adequate validity, but in fact the specificity for the most widely used claims-based definition for severe sepsis is greater than 96% and is comparable to that of other CMS conditions[7]. There are concerns that the increase in sepsis diagnoses may reflect “upcoding” (selection of billing codes intended to increase reimbursement) rather than a true change in incidence; mandates could improve the identification and appropriate care of true sepsis cases, and as an additional effect could allow more accurate epidemiology and policy monitoring. While there are concerns about whether outcomes for patients with sepsis can be improved, RCTs and observational studies have identified early recognition, timely antibiotic administration, and aggressive fluid resuscitation as effective in reducing sepsis-related mortality[8]. Moreover, sizeable improvements in mortality in sepsis can be achieved through quality initiatives that integrate these therapies[9], in part because too few patients currently receive optimal care.

A next-generation quality improvement target like sepsis will require implementation of next-generation performance measures that build on what has been learned since public reporting and P4P began. Simply mandating reporting of 30-day risk-adjusted mortality, or even CMS’ recent decision to require hospitals to report adherence to the NQF’s severe sepsis and septic shock management bundle,[10] may help, but will not be sufficient. In this, sepsis is not unique; other patients could benefit from more innovative approaches too. However, for CMS to maximally drive performance improvement, these changes are particularly important for sepsis.

First, new mandates to improve sepsis must address the reality that sepsis is frequently under-diagnosed[7]. Existing quality metrics for AMI, CHF and pneumonia capitalized on previous decades’ work to make accurate recognition of those conditions nearly universal. But quality improvement cannot be limited to only those conditions for which the diagnosis is already accurate. Quality improvement mandates could improve not only the completeness, but also the precision of sepsis diagnosis. A quality improvement focus on diagnostic accuracy could provide spillover benefits for non-sepsis patients as well. New sepsis mandates have the potential to advance the science and practice of quality improvement to face the common reality of diagnostic ambiguity or inadequacy.

Second, sepsis mandates should focus on catalyzing and aggregating local efforts for quality improvement. Increasing evidence suggests that current public reporting and P4P methods are insufficient tools to fully improve care[11]. Instead, CMS could scale up collaborative quality improvement using methods that incentivize gains in the culture of care, foster professionalism and sharing of best practices, and improve workflow of care processes—that is, work to target learning rather than only judging[11]. In doing so, CMS could promote sharing across hospital boundaries of how to better care for patients. This is particularly

important for sepsis given the need to assess timely recognition[10]—whereas traditional mandates involving financial penalties would create perverse incentives to hide delayed diagnosis of sepsis, rather than to fix the problem.

Third, sepsis mandates should plan for phased implementation, improving the measures in select sites prior to national rollout. CMS has developed an Innovation Center as an infrastructure for the development and testing of healthcare payment and service delivery models. Alternatively, regional quality collaboratives, such as state wide multi-hospital networks, could be contracted by CMS to examine benefits and harms of specific sepsis mandates. Early adopters serve as laboratories for refining measurement and averting unintended consequences. Such early adopters can include those just beginning quality improvement, as well as longstanding leaders such as Kaiser Permanente and Intermountain Healthcare. Careful assessment of the challenges of implementing policy mandates in these settings brings to light the potential for harms when mandates are widely implemented, but does so in a way that helps develop solutions rather than simply documenting barriers.

Fourth, sepsis mandates must plan to be highly responsive to new evidence. Quality measurement seeks to ensure that every patient receives the currently recognized best possible care; therefore, when best care improves, quality measurement should improve in tandem. One NQF sepsis measure provides an optimistic example of such responsiveness: the ProCESS trial demonstrated that focus on recognition, early antibiotics, and fluid resuscitation may achieve equivalent sepsis outcomes to more complicated protocols that mandate central line placement[8]. NQF promptly revised its measure to remove the need for central venous catheterization. A new sepsis mandate must be equally responsive to new, yet-to-be-published evidence. Pragmatically this means planning for regular review of measures, having a system for putting some measures “on hiatus” pending a review of new data, and admitting that a single promulgation will not forever capture the state-of-the-art of a dynamic science.

Sepsis is a major public health problem and has become a dominant diagnosis and cause of death in US hospitals. Implementation of national programs that track and mandate improvements in care and outcomes of sepsis could improve the prognosis for patients with sepsis. National programs for sepsis are needed that improve imperfect diagnosis, that focus on learning rather than judging, that use phased implementation, and that have planned growth in response to new scientific evidence rather than static rules. Current practices mean that only one third of patients with sepsis will receive the excellent care. Clinicians--as well as the health care system--can do better if properly led, and now is the time to start to do so.

Acknowledgments

The authors thank Justin B. Dimick, MD, MPH, of the University of Michigan and Jeremy M. Kahn, MD, MSc, of the University of Pittsburgh for graciously providing feedback on an earlier version of this manuscript.

Funding/ Support: Dr. Cooke receives grant funding from the Agency for Healthcare research and Quality (K08 HS020672), and Dr. Iwashyna receives grant funding from the Department of Veterans Affairs (HSR&D IIR 11-109) and the NIH (R21 AG044752)

Role of the sponsors: The sponsors had no role in the design and conduct of the study, in the collection, analysis, and interpretation of the data, and in the preparation, review, or approval of the manuscript

References

1. Chassin MR, Loeb JM, Schmaltz SP, Wachter RM. Accountability measures--using measurement to promote quality improvement. N Engl J Med. Aug 12; 2010 363(7):683–688. [PubMed: 20573915]
2. HCUPnet, Healthcare Cost and Utilization Project. Agency for Healthcare Research and Quality; Rockville, MD: http://hcupnet.ahrq.gov/
3. Torio, CM.; Andrews, RM. National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011. Agency for Healthcare Research and Quality; Rockville, MD: Aug. 2013 AHRQAHRQHCUP Statistical Brief #160http://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.pdf
4. Liu V, Escobar GJ, Greene JD, et al. Hospital deaths in patients with sepsis from 2 independent cohorts. JAMA. Jul 2; 2014 312(1):90–92. [PubMed: 24838355]
5. Levy MM, Dellinger RP, Townsend SR, et al. The Surviving Sepsis Campaign: results of an international guideline-based performance improvement program targeting severe sepsis. Crit Care Med. Feb; 2010 38(2):367–374. [PubMed: 20035219]
6. Rhee C, Gohil S, Klompas M. Regulatory mandates for sepsis care--reasons for caution. N Engl J Med. May 1; 2014 370(18):1673–1676. [PubMed: 24738642]
7. Iwashyna TJ, Odden A, Rohde J, et al. Identifying patients with severe sepsis using administrative claims: patient-level validation of the angus implementation of the international consensus conference definition of severe sepsis. Med Care. Jun; 2014 52(6):e39–43. [PubMed: 23001437]
8. The ProCESS Investigators. Yealy DM, Kellum JA, et al. A randomized trial of protocol-based care for early septic shock. N Engl J Med. May 1; 2014 370(18):1683–1693. [PubMed: 24635773]
9. Miller RR 3rd, Dong L, Nelson NC, et al. Multicenter implementation of a severe sepsis and septic shock treatment bundle. Am J Respir Crit Care Med. Jul 1; 2013 188(1):77–82. [PubMed: 23631750]
10. Centers for M, Medicaid Services HHS. Medicare program; hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system and fiscal year 2015 rates; quality reporting requirements for specific providers; reasonable compensation equivalents for physician services in excluded hospitals and certain teaching hospitals; provider administrative appeals and judicial review; enforcement provisions for organ transplant centers; and electronic health record (EHR) incentive program. Final rule. Fed Regist. Aug 22; 2014 79(163):49853–50536. [PubMed: 25167590]
11. Berenson, R.; Pronovost, P.; Krumholz, H. Achieving the Potential of Health Care Performance Measures. Robert Wood Johnson Foundation and The Urban Institute; May. 2013 http://www.rwjf.org/en/research-publications/find-rwjf-research/2013/05/achieving-the-potential-of-health-care-performance-measures.html and http://www.urban.org/publications/412823.html