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Regulatory Mandates for Sepsis Care — Reasons for Caution

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Sepsis, the syndrome of dysregulated inflammation that occurs with severe infection, affects millions of people worldwide each year. Multiple studies suggest that the incidence of sepsis is dramatically increasing. According to the Centers for Disease Control and Prevention (CDC), for example, sepsis rates doubled between 2000 and 2008.[1] In 2010, sepsis was the 11th leading cause of death in the United States,[2] and in 2011, it was the single most expensive condition treated in hospitals.[3]

This apparent explosion in sepsis is spurring high-profile initiatives to promote earlier recognition and better treatment. Standardized screening protocols, bundled order sets, and algorithms for early, goal-directed therapy are becoming the norm in hospitals throughout the country. These algorithms typically require clinicians to measure lactate levels, deliver a minimum amount of fluids, draw blood for culture, and initiate treatment with broad-spectrum antibiotics, all within a narrow window of time. Some also require placement of a central venous catheter, admission to an intensive care unit (ICU), or both.

Policymakers are actively encouraging these efforts. In response to the well-publicized death of a 12-year-old boy from unrecognized sepsis, New York State now requires all hospitals to adopt sepsis protocols ("Rory's Regulations"). Later this year, New York will begin requiring hospitals to report protocol-adherence rates and outcomes. Other agencies may soon follow suit. The National Quality Forum (NQF) recently ratified a metric for adherence to sepsis protocols, and the Centers for Medicare and Medicaid Services (CMS) is considering whether to adopt the NQF metric for public reporting and payment programs.

The attention and resources being dedicated to improving sepsis care are welcome. The policy response to this apparent epidemic, however, ought to be tempered by two limitations. First, the publication of the ProCESS study in the *Journal* (pages 1683–1693) reminds us that we still have much to learn about how best to organize sepsis care. Second, we do not yet have reliable tools for measuring sepsis incidence. Current methods are based on analyses of insurance-claims data using sepsis-specific codes or separate codes for infection and organ dysfunction.

Tracking sepsis incidence using claims codes is unreliable, because coding patterns are almost certainly changing over time. Awareness campaigns and influential studies are

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making clinicians more vigilant about diagnosing sepsis. Reimbursement formulas are making hospitals more diligent about coding for sepsis and acute organ dysfunction. Both trends are compounded by the subjective nature of the diagnosis. The current standard definition for sepsis includes criteria such as “suspected infection” and requires nuanced judgments about whether to attribute organ dysfunction to infection. The definition thus allows both clinicians and hospitals considerable discretion when diagnosing and coding for sepsis.

Trends in nationwide hospital-discharge diagnoses belie the accuracy of claims codes in monitoring sepsis rates (see graph). Claims data show a steady increase in the rate of hospitalizations for sepsis, but they show stable or decreasing rates of hospitalizations for the infections that most commonly cause sepsis (pneumonia, urinary tract infections, intraabdominal infections, and bacteremia). Other claims-based analyses suggest that rising sepsis rates have been accompanied by a steady decrease in sepsis-related mortality rates.[4] Although decreasing mortality rates may be due to improvements in care, it is also possible that progressively more sensitive coding is capturing a larger but less severely ill group of patients over time. These incongruities raise the possibility that the apparent surge in incidence over the past decade may be at least partly due to changes in coding practices rather than a true increase in sepsis rates.

Knowing whether sepsis rates are truly changing has important implications for both policy and practice. Sepsis care mandates are not without risk. The mandate from the Joint Commission and CMS to initiate antibiotic therapy within 4 hours after a patient with community-acquired pneumonia arrives at the hospital is informative in this regard. With hindsight, we now know that this requirement probably led to overdiagnosis of pneumonia and unwarranted antibiotic treatment for patients with undifferentiated respiratory symptoms.[5] Sepsis mandates carry similar risks, since the signs and symptoms of sepsis are also subjective and nonspecific; many noninfectious inflammatory disorders can manifest similarly. Protocols that force physician behavior risk promoting inappropriate prescribing of broad-spectrum antibiotics for noninfectious conditions, unnecessary testing, overuse of invasive catheters, diversion of scarce ICU capacity, and delayed identification of nonsepsis diagnoses.

We believe that policy mandates are premature until we can develop better diagnosis and surveillance metrics. Current clinical criteria and claims codes are too subjective and too susceptible to external influences to inform or measure the effects of policy changes. The current policy environment favors more diagnoses and increased coding for sepsis, but if policies evolve to include public reporting, benchmarking, and financial penalties, the pendulum could easily swing toward fewer diagnoses and decreased coding. Sepsis diagnosis, management, and surveillance sciences need to mature before they can become a reliable basis for policies and performance measures.

Fortunately, there are specific steps that stakeholders can take now to improve sepsis care while mitigating the risk of unintended consequences. Clinicians and hospitals can continue to embrace best practices for treating patients with sepsis but be attentive to rates of overtreatment and under-treatment. Policymakers and payers can continue to encourage best

practices but avoid mandating rigid protocols or tying reimbursements to protocol-implementation rates or outcomes. We recommend focusing instead on enhancing education for clinicians and the public, providing resources for developing and testing new protocols, and increasing funding for research on sepsis pathophysiology, diagnosis, treatment, and surveillance. There is also a pressing need to evaluate the hospital-level effects of sepsis protocols on total antibiotic dispensing, antimicrobial resistance, *Clostridium difficile* infections, ICU-bed availability, and complications of central venous catheter placements. Such evaluation is particularly important if policymakers do move ahead with mandates, since forcing behavior increases the risk of unintended harms.

On the surveillance side, there may be lessons to be learned from the CDC's new paradigm for ventilator-associated events. The challenges of sepsis surveillance parallel many of those related to surveillance for ventilator-associated pneumonia; both conditions lack a clear standard definition, and their definitions contain multiple subjective elements. The CDC's paradigm for ventilator-associated events acknowledges the difficulty of accurate clinical identification of ventilator-associated pneumonia and focuses instead on identifying the syndrome of nosocomial respiratory deterioration by monitoring patients' ventilator settings for sustained increases after a period of stability or improvement. This strategy is objective and efficient and permits detection of events strongly associated with increased length of stay and hospital mortality. One analogous strategy for sepsis might be to conduct surveillance for unambiguous, clinically significant, objective events; for example, one could monitor the frequency of positive blood cultures that occur concurrently with lactic acidosis or vasopressor use. This approach would miss some patients, because only about 50% of patients with severe sepsis have bacteremia. Surveillance definitions, however, do not need to be perfectly sensitive to be useful, and they do not need to perfectly match the criteria used to guide the clinical care of patients. It is more important for surveillance definitions to be simple, objective, clinically meaningful, resistant to ascertainment bias, and ideally, suitable for automation using data routinely stored in electronic health records.

Sepsis is a major public health problem. Resources are appropriately being directed toward finding better ways to diagnose, treat, and prevent this important condition. Mandating sepsis bundles and benchmarking hospitals on their adherence rates, however, risk causing unintended harms. Furthermore, current limitations in sepsis diagnosis and surveillance sciences prevent us from being able to reliably measure the impact of sepsis campaigns and policies. Until these issues are resolved, we advise caution before prescribing more mandates.

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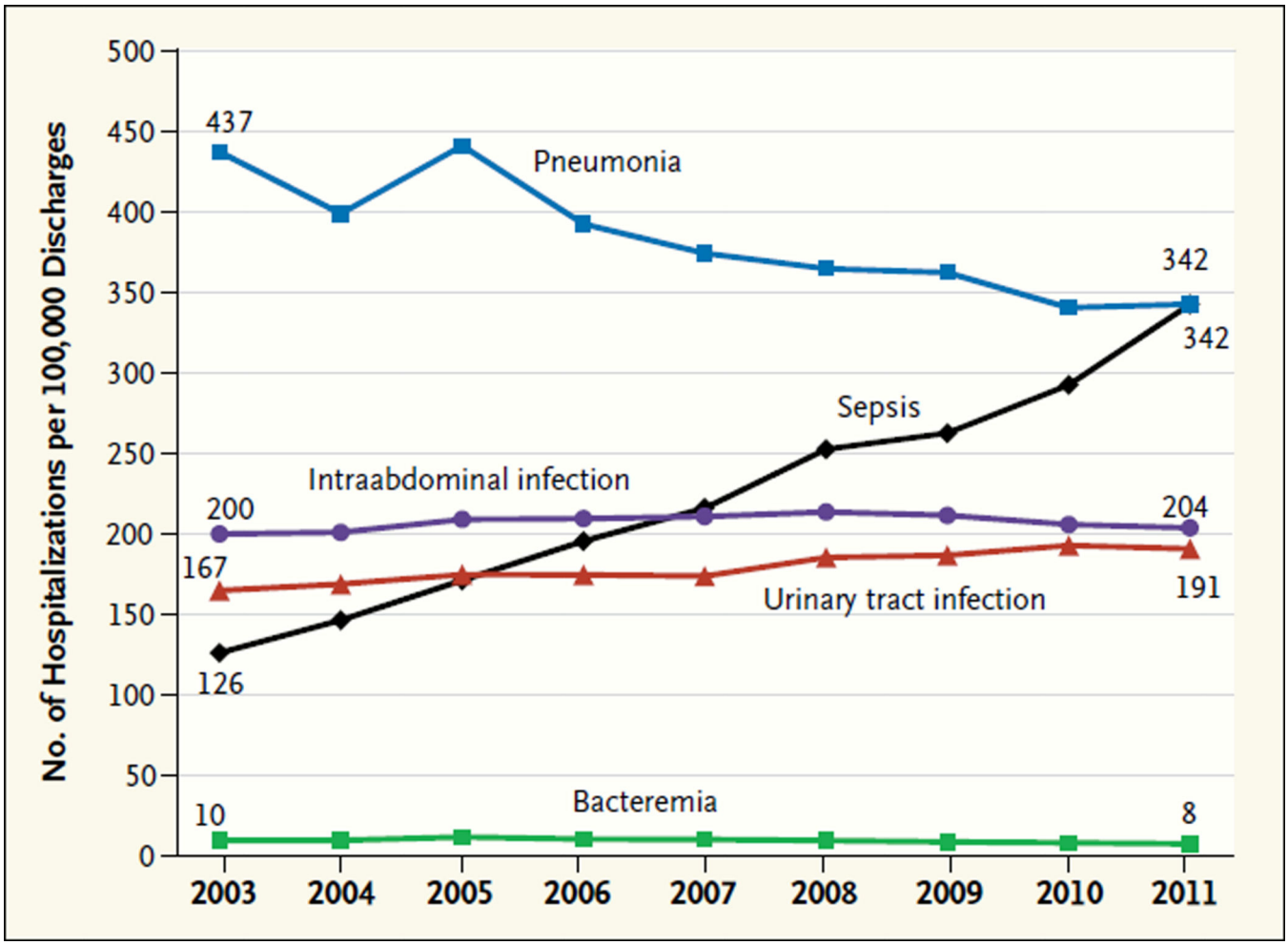

Hospitalizations for Which Certain Infection Codes Were Listed as a Primary Diagnosis, 2003–2011

Data are from weighted national estimates from the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS), Agency for Healthcare Research and Quality (AHRQ), based on data collected by individual states and provided to the AHRQ by the states. Codes used: Sepsis/Septicemia (038.0–038.9, 785.52, 995.91–995.92), Pneumonia (480.0–480.9, 481, 482.0–482.9, 483.0–483.8, 484.1–484.8, 485, 486), Intra-abdominal Infection (008.45, 009.0–009.3, 540.0–540.9, 541, 542, 543.9, 562.01, 562.03, 562.11, 562.13, 567.0–567.9, 569.5, 569.61, 569.71, 569.83, 572.0–572.8, 574.00–574.91, 575.0–575.9, 576.0–576.9, 614.0–614.9), Urinary Tract Infection (590.00, 590.01, 590.10, 590.11, 590.2, 590.3, 590.80, 590.81, 590.9, 595.0, 595.2, 595.3, 595.4, 595.89, 595.9, 597.0, 597.80, 597.89, 598.00, 598.01, 599.0), and Bacteremia (790.7).