## The burden of sepsis

Sepsis is defined as "life-threatening organ dysfunction caused by a dysregulated host response to infection."1 While sepsis is often attributed to bacterial infections, sepsis may result from infections of any etiology, including viral infections such as COVID-19. Sepsis is a leading cause of hospitalization and hospital mortality2 contributing to over a third of all hospital deaths.3,4 In the United States (U.S.), there are an estimated 1.7 million adult sepsis hospitalizations annually, of which 350,000 result in hospital death or discharge to

hospice.5 Beyond being a major driver of hospital mortality, sepsis also contributes to incident disability.6 Patients who survive hospitalization for sepsis are at increased risk for negative health outcomes, including the development of new morbidity, inability to return to work, hospital readmission, and death.7-9 Due to the burden of morbidity and mortality from sepsis, the World Health Organization recognized sepsis as a global health priority in 2017.10 Despite the burden of sepsis and importance of early treatment, community knowledge of sepsis remains low.

Efforts to improve sepsis identification, management, and outcomes There have been many initiatives to improve the identification, management, and outcomes of sepsis over the past two decades. The Surviving Sepsis Campaign first published international guidelines for the management of sepsis in 2004,12 and has issued updates to these guidelines every four years.13 Dedicated pediatric guidelines were added in 2020.14,15 More recent updates to the guidelines have used the GRADE approach to assess the

quality of the evidence and formulate recommendations using an "evidence-to-decision framework" that takes into account not only the magnitude of effect and quality of evidence, but also patient values, resources and cost, equity, acceptability, and feasibility.16-19 Large-scale quality improvement and state-based regulatory initiatives (e.g., New York State Department of Health's "Rory's Regulations") focused on recognition and early management of sepsis have been associated with reductions in in-hospital

mortality.20-24 The Centers for Medicare & Medicaid Services (CMS) Severe Sepsis and Septic Shock: Management Bundle (SEP-1) has further emphasized the importance of early sepsis management in U.S hospitals. Recently, there has been growing interest in and use of clinical decision support to facilitate sepsis recognition and treatment,25,26 although more work is needed to improve the accuracy, usability, and clinical impact of clinical decision support for sepsis.

The challenges of implementing sepsis care Despite the availability of evidence-based guidelines for sepsis, success of several large scale quality improvement initiatives, and growing interest in clinical decision support, much work remains to ensure optimal sepsis

care in hospitals. Sepsis is a complex condition that requires care to be coordinated across multiple clinical care locations and disciplines, and to be tailored to specific infections and

clinical presentations. Ethnographic studies demonstrate that the implementation of seemingly simple sepsis bundles "involve[s] a complex trajectory comprising multiple interdependent tasks that require prioritization and scheduling, and which are prone to problems of coordination and operational failures."32 Five factors were identified as critical for improving the delivery of recommended sepsis practices: (1) healthcare staff knowing what to do and why, (2) healthcare staff understanding risks and benefits of

treatments, (3) healthcare staff having strong team collaboration, (4) healthcare staff feeling empowered and supported, and (5) hospitals having adequate staffing.33 Beyond the challenges of coordinating multi-disciplinary care, the best practices for sepsis treatment continue to evolve. Many guideline statements are based on weak evidence, such that guidance may change as more evidence is accrued.16 Given this landscape, hospitals must have processes in place to implement recommended sepsis practices and also evolve practice over time in response to accruing evidence.

The purpose of the hospital sepsis program core elements This document summarizes Core Elements of hospital sepsis programs, which are intended to monitor and optimize hospital management and outcomes of sepsis. It complements existing sepsis guidelines14,18,19,34,35 and helps facilitate implementation of guideline-recommended care practices that apply to a broad range of persons with sepsis, including adults,

children, and women who are pregnant or postpartum. There is no single template for a hospital sepsis program. Rather, the complexity of medical decision-making in identification and management of sepsis, and the variability of sepsis epidemiology and patient populations served by hospitals in the U.S. require flexibility in the structure of hospital sepsis programs and the implementation of sepsis care. However, sepsis programs can be implemented effectively in a wide variety of hospitals and healthcare

systems, and this guidance lays out key features of effective programs.36 The guidance is informed by expert knowledge, examination of peer reviewed literature, and extrapolation from the features of effective quality improvement programs addressing sepsis and other conditions

Summary of the Hospital Sepsis Program Core Elements

The development of a multi-disciplinary hospital sepsis program is critical to monitoring and improving the management and outcomes of patients with sepsis. Hospital quality improvement programs focused on sepsis have been associated with reductions in hospital mortality, length of stay, and healthcare costs.37-39

The structure of hospital sepsis programs may be specific to a single hospital or span an entire healthcare system. Likewise, programs may focus on sepsis specifically or may be part of a broader initiative that addresses multiple areas of quality improvement.

Regardless of the structure of the hospital sepsis program, it should help healthcare staff improve outcomes from sepsis by aiding in the recognition of sepsis, facilitating the implementation of evidence based management of sepsis, supporting the recovery of patients after sepsis, and monitoring the impact of hospital-based interventions to improve care and outcomes of sepsis.

For each Core Element, "Priority Examples" are provided as the top priorities for hospital sepsis programs, and "Additional Examples" are additional important recommendations that can further enhance these programs. For programs that are new or are reorganizing, the "Getting Started" box may be helpful for prioritizing initial activities

Who is the Hospital Sepsis Program Core Elements guidance for?
Clinicians, hospitals, and health systems leading efforts to improve the hospital management and outcomes of sepsis. Effective leadership is required to engage the multidisciplinary expertise required to support the care of patients with sepsis, as detailed later in this document.

Hospital Sepsis Program Core Elements Hospital Leadership Commitment Accountability Action Tracking Reporting Dedicating the necessary human, financial, and information technology resources. Engaging key partners throughout the hospital and healthcare system. Appointing a leader or co-leaders responsible for program goals and outcomes. Multi-Professional Expertise Education Implementing structures and processes to improve the identification of, management of, and recovery from sepsis. Measuring sepsis epidemiology, management, and outcomes to assess the impact of sepsis initiatives and progress toward program goals. Providing information on sepsis management and outcomes to relevant partners. Providing sepsis education to healthcare professionals, patients, and family/caregivers

Getting Started For hospitals or healthcare systems just starting a sepsis program or those with limited resources, it may be most efficient to address the following steps first: • Identify the sepsis program leader or co-leaders. • Secure support from hospital or healthcare system leadership. • Conduct a needs analysis to identify applicable regulatory or reporting requirements (e.g., Centers for Medicare & Medicaid Services [CMS] Severe Sepsis and Septic Shock: Management Bundle [SEP-1]), existing sepsis screening

processes, treatment guidelines, and order sets. Obtain summary data on regulatory performance and use of sepsis screening tools and order sets to identify areas in need of improvement. • Establish initial goals for sepsis program based on needs analysis