

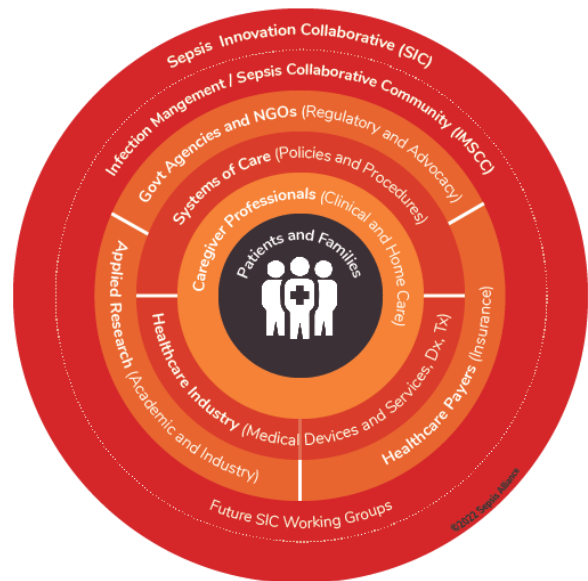


## Overview

### About the Sepsis Innovation Collaborative

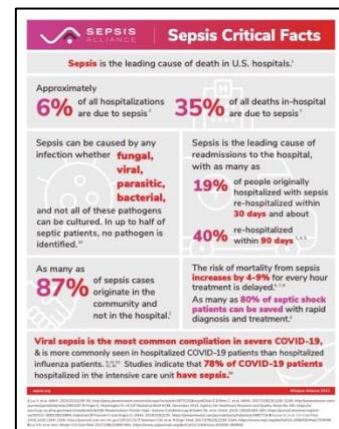
Sepsis Innovation Collaborative (SIC) is a multi-stakeholder public/private collaborative launched by Sepsis Alliance. SIC brings academic, clinical, industry, patient advocacy, reimbursement, research, and government stakeholders together with the common mission to save lives by better managing infections, solving sepsis, and improving emergency care delivery to strengthen the nation's healthcare and public health preparedness, response, and recovery. SIC members are dedicated to accelerating innovation in infection prevention and management; sepsis diagnosis and treatment; and survivor care, support, and services.

SIC Ecosystem | Users • Stakeholders



SIC's work will include the analysis of gaps in prevention, diagnosis, and treatment of infections and sepsis, and the development of tangible work streams and program initiatives across the continuum of infection management and sepsis including:

- Devices, including point of care and home diagnostic tools,
- Reimbursement challenges and opportunities,
- Therapeutics including host-response innovation,
- Equity in infection prevention and care, and
- Challenges and opportunities related to antimicrobial resistance.



## Impact on Patients and Healthcare System

Sepsis is the body's overwhelming and life-threatening response to infection which can lead to tissue damage, organ failure, and death. One in three patients who die in a hospital have sepsis, making it the leading cause of death, and the most expensive condition, in U.S. hospitals.<sup>iii</sup> Each year at least 1.7 million adults in the U.S. develop sepsis—one every 20 seconds—and more than 350,000 Americans die from sepsis—one every 90 seconds.<sup>iii</sup> That is more deaths than from stroke, prostate cancer, breast cancer, and opioid overdose combined.<sup>iv,v, vi,vii,viii,ix</sup>



Anyone affected by an infection, injury, or non-communicable disease can develop sepsis, but adults 65 or older; infants under the age of one; people with chronic medical conditions such as diabetes, lung disease, cancer, and kidney disease; people with weakened immune systems; and people with recent severe illness or hospitalization are at higher risk for sepsis.<sup>x,xi</sup> Pregnant and recently pregnant people are especially at risk for sepsis, which is responsible for 12.7% of pregnancy-related deaths, the second-leading cause of maternal death in the United States each year.<sup>xii</sup> Even for those who survive sepsis, there may be post-sepsis sequelae such as fatigue, depression, or complications from sepsis resulting in amputations. In addition to the human costs, the financial costs are staggering, with more than \$62 billion spent on sepsis annually in the U.S. for inpatient and skilled nursing care.<sup>xiii</sup>



## Challenges in Predicting and Treating Sepsis

Any infection can lead to sepsis, but it is difficult to predict or identify risk of infection, infection status, infection severity risk, and which patients are most at risk for sepsis or long-term complications. Sepsis is also difficult to treat because it can damage organ systems throughout the entire body, beyond the site of the original infection. In addition, to further complicate diagnosis and patient management, there is great heterogeneity amongst patients due to the pathogen involved, concomitant comorbidities, and individual responses to disease. As the host responds to an

infection and becomes dysregulated, traditional pathogen-targeted approaches may not be sufficient.

The clinical complexity of infection management including early recognition of severe complications, such as sepsis, require interventions to identify and mitigate severe outcomes, including products that could aid in the prevention, detection, prediction, treatment, and management of infection and its complications. This situation is compounded by the regulatory complexity associated with infection management and sepsis-relevant products, especially those based on the host response to infection and not the pathogen. Collaboration of diverse stakeholders involved at each stage of a patient's journey through survivorship is critical to identify and pursue opportunities to address these unmet needs and improve innovation and equity in infection management and sepsis care.

### **Gaps and Opportunities in Sepsis**

While there are organizations working to improve sepsis education and awareness, there is a void when it comes to the acceleration of technology, innovation, and messaging through public-private coalitions. The limited existing collaborative efforts across the country are narrow in their scope, typically focusing on bedside process changes and healthcare quality improvements to address sepsis. While this is important work, what is missing is coordination amongst biotechnology companies interested in having an impact, the clinical professionals and research communities most familiar with how sepsis presents in and affects people, academic and professional healthcare organizations that understand bedside clinical issues, the patient advocacy organizations and patients who can speak personally and directly to the gaps in awareness and care, and the government agencies that are charged with improving care for the nation.

SIC will convene these stakeholders to identify priority areas of innovation for prevention, detection, treatment, and care for sepsis patients. SIC will spur the development and adoption of the most needed new diagnostics, therapeutics, and other tools for the fight against sepsis and severe infection such as those needed to identify infection early, gauge infection severity, and prevent and treat post-sepsis complications. Such tools will allow physicians and other caregivers to rapidly identify sepsis and administer appropriate treatment, which in turn will reduce costs and save lives and limbs.

Specifically, our goals include:

- Enhancing early diagnosis and intervention;
- Improving diagnostic speed and accuracy;
- Developing a common sepsis lexicon to promote standardized data collection, analysis, and dissemination;
- Developing better antimicrobial therapies and host modifying agents;
- Addressing the long-term healthcare challenges and heightened sepsis risks of sepsis survivors; and
- Facilitating public-private communication with U.S. government agencies on activities to strengthen health security in the area of sepsis.

### **About the Infection Management/Sepsis Collaborative Community**

SIC is organized into several community groups, each focused on a specific priority issue area. In the medical device ecosystem, collaborative communities bring together stakeholders to achieve common outcomes, solve shared challenges, and leverage collective opportunities. As one example, the Infection Management/Sepsis Collaborative Community (IMSCC) provides a venue to enhance the understanding of SIC members' perspectives by fostering communication and knowledge sharing, to better align on regulatory requirements and science in the medical device ecosystem. The development of the IMSCC was guided by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) [Collaborative Communities Toolkit](#). The IMSCC is in the process of engaging with CDRH for the collaborative community.

Sepsis Alliance is funded to convene stakeholders as part of a five-year cooperative agreement between Sepsis Alliance and the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response with support from the Biomedical Advanced Research and Development Authority.

*Disclaimer: The content is solely the responsibility of the authors and does not necessarily represent the official views of the Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response.*

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