

Reducing sepsis risk:

The role of public policy
in protecting patients

Introduction

Meet Rory Staunton, a bright 12-year-old boy from New York who passed away after a simple playground scrape led to a complicated journey ending with sepsis.ⁱ Rory's story began on a typical Wednesday, when, as an enthusiastic middle schooler, he dove for a loose ball during a basketball game with his friends and received two Band-Aids on what appeared to be a minor cut. By Thursday evening when Rory arrived at the emergency room, he had a 104-degree fever, severe leg pain, nausea, and a stomachache. Doctors gave him fluids, prescribed medication for his nausea, and after an initial diagnosis of stomach flu, told him he would be better in a week. Before the week was up, Rory was admitted to intensive care. By Sunday, Rory had passed away.

Rory's medical records would show that his untimely death was the direct result of rapid sepsis onset. What his records cannot show is the tangled web of medical protocol ambiguity, misaligned insurer coverage priorities, and public policy gaps that together fail patients like Rory daily. This all-too-common experience also impacts clinicians, who widely report selecting their professions because of a passion for healing. That passion is undermined when they are forced to watch as those under their care unnecessarily suffer. The resulting rise in clinician burnout and increasing exodus from medical practice creates additional challenges that must be addressed to protect healthcare access now and into the future. The following report discusses the contributing factors that lead to unnecessary sepsis risk and offers a public policy solution which would safeguard access to lifesaving care and the clinicians who provide it.

Sepsis definition

Medical science, like all scientific disciplines, is constantly evolving because of new findings in research, innovations in technology, and the advent of new ideas. Debate is an integral component of scientific development and advancement. As experts seek to align theories with practice, even the best and brightest minds must actively explore areas of disagreement, including on issues as seemingly straightforward as how a disease is defined. The evolution of how we define, diagnose, and treat sepsis is a chief example of such a debate.

At its most basic definition, sepsis is a potentially life-threatening condition which impacts the body's response to infection, causing injury to tissues and organs. However, diagnosing sepsis is anything but basic. As the Society for Critical Care Medicine states, "Understanding that sepsis exists not as a discrete entity, but rather as a constellation of signs and symptoms along a spectrum of severity suggests that the search for a 'gold standard' diagnostic definition will remain elusive." Said simply, sepsis diagnosis is as much a science as it is an art.

There is general consensus among clinicians that early detectionⁱⁱ is imperative for proper treatmentⁱⁱⁱ and avoiding patient mortality^{iv}, particularly for sepsis cases in children^v and other high-risk patients. However, some have focused on the presence of catastrophic infection and signs of organ failure to trigger sepsis care, citing concerns that treatment occurring too early could create second-order issues, such as antibiotic resistance.

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– Society for
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The balance of science and art in sepsis diagnosis and care has been debated in the medical community for more than 30 years. Following the 1991 American College of Chest Physicians (CHEST) and Society of Critical Care Medicine (SCCM) Consensus Conference, experts agreed to adopt new criteria to define sepsis^{vi} known as systemic inflammatory response syndrome (SIRS) criteria. This definition, now commonly referred to as Sepsis-1, leaned heavily on the presence of infection, or general “inflammatory excess”^{vii} and its link to organ system dysfunction.

As science evolved, practicing clinicians from SCCM, CHEST, the European Society of Intensive Care Medicine (ESICM), the American Thoracic Society (ATS), and the Surgical Infection Society (SIS) convened in 2001 to improve the definition of sepsis. The new Sepsis-2 definition they developed cast a wider net and added earlier indicators of changes in organ function, additional signs of increasing inflammation, and certain anti-inflammatory responses where there was a notable lack of otherwise expected infection due to disruption in normal body responses.^{viii} The most notable change that came from the Sepsis-2 definition was an agreement among front-line clinicians that sepsis should be considered “a continuum rather than a static state.”^{ix} This shift meant patients would receive sepsis treatment before the most dire symptoms begin.

In 2016, a group of researchers from pathobiology, clinical trials, and epidemiology sought to further refine the sepsis definition.^x The group believed the underlying causes of infection should be the primary focus of treatment and thus limit when the totality of symptoms indicated the presence of sepsis. They created Sepsis-3, defining the condition as a “life-threatening organ dysfunction caused by a dysregulated host response to infection,” and relying upon the Sequential Organ Failure Assessment (SOFA) score methodology rather than SIRS criteria. In practice, this often means a patient’s symptoms need to be far more severe before their condition is labeled sepsis and sepsis-level treatments are initiated. While this research-based team was certainly well-intentioned, the majority of practicing clinicians believe Sepsis-3 creates dangerous delays in identifying and treating sepsis. For these front-line clinicians, initiating sepsis-level care based on Sepsis-3 and SOFA scores is like waiting for a hurricane to make landfall before boarding a home’s windows.

As a result, the shift to Sepsis-3 was immediately called into question by practicing clinicians. A 2018 article^{xi} in the *Canadian Medical Association Journal* urged, “**For clinicians, Sepsis-3 criteria do not guide treatment and should not be used to rule out risk of deterioration.**” The authors cited a 2018 systematic review published in the *Annals of Internal Medicine* which found, “The [Sepsis-1-and-2 definitions] had sensitivity superior to [Sepsis-3], supporting their use for screening of patients and as a prompt for treatment initiation.”^{xii} Another 2018 article in the *World Journal of Emergency Surgery* stated that by focusing more on organ dysfunction and failure, Sepsis-3 fails “in identifying patients with serious infections before organ dysfunction ensues.”^{xiii}

In a world now focused on the health and affordability benefits of preventive care, the fundamental problem with Sepsis-3 lies in the

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space between theory and practice. The theory-based definition creates protocols that potentially miss opportunities for early detection and treatment by focusing so narrowly on significant organ failure. Practicing clinicians who interface with sepsis daily understand all too well that “early recognition and timely treatment largely determine the outcome of sepsis.”^{xiv}

The front-line call for definitions which embrace early detection is not only supported by anecdotal experience. Data demonstrates the stark differences early detection and treatment can make for patient outcomes. A 2023 Sepsis Alliance fact sheet showed, “the risk of mortality from sepsis increases by 4-9% for every hour treatment is delayed.”^{xv} In pediatric patients, “3-day and 30-day sepsis-attributable mortality increased with delays in antibiotic administration 330 minutes or longer from emergency department arrival.”^{xvi} “In other words, “The Sepsis-3 definition ... is more strongly associated with adverse outcomes than the Sepsis-2 definition.”^{xvii}

The high costs of sepsis

While the definition of sepsis remains the subject of debate, it is indisputable that sepsis is costly. The severity of the condition combined with its widespread prevalence means patients, caregivers, and clinicians must bear the emotional toll sepsis carries — and that toll is not a small one. Annually, over 1.7 million U.S. adults experience sepsis and nearly 50% of sepsis survivors are readmitted to the hospital within a year of their initial diagnosis.^{xviii} In the worst cases, it costs patients their lives, with approximately 270,000 U.S. deaths attributed to sepsis annually.^{xix}

Like many other conditions, sepsis disproportionately impacts historically marginalized populations and can affect patients long after they leave the four walls of the hospital.^{xx} Patients often develop post-sepsis syndrome, with 60% reporting a decrease in cognitive or physical function up to eight years post-discharge.^{xxi} This syndrome can manifest in episodes of anxiety, loss of memory, persistent fatigue, and overall lower quality of life. Additionally, the five-year mortality rate following severe sepsis is 82%.^{xxii}

As a severe condition, sepsis care is also expensive. While estimates vary, the nationwide aggregate inpatient costs associated with sepsis and hospitalizations for septicemia are \$38 billion per year^{xxiii}, with an average cost of approximately \$28,800 per hospitalization.^{xxiv} This is double the average cost per hospitalization across all other conditions.^{xxv} For children, reports show the average cost of a readmission after a sepsis hospitalization is \$7,385, which is 27% more than a non-sepsis readmission.^{xxvi}

As the human and monetary costs add up, insurers have also added to the tally: The ongoing debate between sepsis theory and experience-based practice has allowed many health plans to embrace Sepsis-3 as the basis for their coverage standards. Insurers state that by doing so, they drive down healthcare costs by removing what they consider unnecessary care from the equation. In practice, this approach opens the door to detection *only after* sepsis has reached a greater level of

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severity, resulting in more intensive treatments, expensive medications, and longer hospital stays. It is difficult to deny that for insurance companies, basing their denials and delays on Sepsis-3 has benefits for their bottom line. As the Healthcare Compliance Association noted, “Sepsis is a magnet for denials because there are a lot more dollars associated with it.”^{xxvii} Like many health systems, Novant Health has seen this delay and deny approach firsthand. At the time of this report’s publication in September 2024, Novant Health clinicians experienced a denial rate of approximately 20% for sepsis cases. As with other claims denials and delays, this forces clinicians and billing navigators to spend significant time and resources to secure coverage that aligns with necessary medical care. Clinicians and navigators must also respond to hundreds of additional sepsis-related coding and documentation queries from insurers.

As insurance companies utilize definitions that align with internal goals, the options for patients and clinicians are murkier. Clinicians, for example, are forced to weigh their medical training and expertise against the consequences of providing higher levels of care which the patient’s insurance may not ultimately cover. For clinicians, who widely report entering practice because of their core value to help people^{xxviii}, such considerations are more than disheartening and are contributing to record numbers reporting burnout — or leaving practice all together.

Burnout is further exacerbated by documentation challenges stemming from the high degree of variability in insurance coverage for the same condition. For sepsis, even when insurers choose coverage based on Sepsis-3-aligned criteria, coverage plan specifics are widely inconsistent across insurers. Some payors, most notably Medicare Advantage (MA) plans, go so far as to elect not to publish their selected sepsis definition whatsoever. The variability creates a moving target for clinicians who are required to fully document their justification for a sepsis diagnosis. In its 2022 Industry Overview Survey, the Association of Clinical Documentation Integrity Specialists (ACDIS) stated this challenge succinctly: “With payors utilizing different definitions, it makes it increasingly challenging to ensure that your documentation meets the requirements for all of the various sepsis criteria.”^{xxix}

Despite such headwinds, some healthcare systems and hospitals have heeded front-line clinician expertise and adopted Sepsis-2 as the prevailing basis for sepsis care. Novant Health is one such system. In 2023, the health system’s clinical experts adopted a systemwide policy stating sepsis is determined to be present when a patient has a suspected or known infection and several of the listed dysregulated responses consistent with Sepsis-2 SIRS criteria. **While such hospital and health system policies are a start to addressing the perils of inconsistent sepsis definitions, the resulting patchwork leaves patients at risk for both their physical and financial health if payors decline to adopt consistent sepsis criteria.**



Sepsis in the Novant Health footprint

North Carolina

11.4 deaths per 100,000 individuals

South Carolina

13.2 deaths per 100,000 individuals

North Carolina and South Carolina were among the 15 states with the highest septicemia mortality rates based on 2022 data collected by the CDC.

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– Healthcare Compliance Association

Policy solutions

A role of public policy is to minimize patchwork approaches to critical services for citizens. The Novant Health Center for Public Policy Solutions believes sepsis care is ripe for public policy engagement to solve care inconsistencies across geographies. **To that end, the Center recommends that states set statutory and regulatory standards for sepsis care.**

As data has shown, these public policies should be based on the sepsis definition and clinical criteria which is endorsed by practicing medical experts and has the greatest potential to save the most lives. That definition aligns with the Sepsis-2 criteria. Several states have already taken such action and the impacts cannot go unnoticed.

New York

After Rory Staunton's death, his home state of New York became the first state to require "all hospitals in the state adopt sepsis protocols, provide sepsis education to hospital staff, and report protocol adherence and patient outcomes to the state government."^{xxx} Known as Rory's Regulations^{xxxi}, the Sepsis-2-based policies require hospitals to adhere to a single, evidence-based definition of sepsis to reduce confusion for clinicians and create greater consistency in patient care. Requirements include:

1. Screening and early recognition of patients with sepsis, severe sepsis, and septic shock,
2. A process to identify and document individuals appropriate for treatment through severe sepsis protocols,
3. Guidelines for treatment, including the early delivery of antibiotics,
4. Suitable training, resources, and equipment for healthcare providers for quickly recognizing and treating sepsis in adults and children; and
5. The reporting of all sepsis-related data to the New York State Department of Health for use in monitoring compliance and updating best practices.

Since policy implementation, New York saw a decrease^{xxxii} in the likelihood of sepsis-related deaths for adults by 21% and reduced sepsis-related deaths for children by 40%.^{xxxiii} The New York State Department of Health estimates the standardized protocols saved more than 16,000 lives from sepsis-related mortality between 2015 and 2019.^{xxxiv}

Rory's Regulations had the second order effect of correcting for insurance policy inconsistencies in New York. With uniform standards for hospitals and health systems in statute, state insurance coverage standards had to follow suit. For example, despite having a nationwide policy of utilizing the Sepsis-3 definitions for coverage, UnitedHealthcare created a state-specific exception for New York plans.^{xxxv}

How Medicare Got Sepsis Coverage Right

In 2015, the Centers for Medicare and Medicaid Services (CMS) created the Severe Sepsis and Septic Shock Early Management Bundle (SEP-1) performance measure which utilizes the Sepsis-2 definition. While this measure has its critics and challengers, it is supported by the Sepsis Alliance and has been found to be associated with improved outcomes for septic shock and lower 30-day mortality.

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Kentucky

In 2024, the Kentucky legislature unanimously passed a bill^{xxxvi} which required that the state's managed Medicaid program cover sepsis care based on the Sepsis-2 definition.

Specifically, Medicaid coverage for a sepsis diagnosis now must only require:

1. A provider's diagnosis of sepsis and that a suspected or confirmed source of infection is present; and
2. The presence of two or more symptoms indicating inflammatory response syndrome which may include elevated values of the patient's body temperature, heart rate, white blood count, or respiratory rate.

The bill was signed into law in June 2024. While the law went into effect immediately, it has not been in place long enough to create state-specific outcomes. However, as previously cited data indicates, the state's statutory approach to sepsis care rightfully emphasizes early detection and clinician expertise.

Other states

In Illinois, the state passed legislation requiring statewide hospital protocols to improve the identification and early treatment of sepsis and septic shock.^{xxxvii} The law was passed in 2016 after 5-year-old Gabby Galbo died of an untreated septic infection following a tick bite. Her parents worked with the Illinois legislature to draft the law which was later passed unanimously and signed into law in their daughter's honor.^{xxxviii}

Other states, notably New Jersey and Rhode Island, similarly mandate statewide sepsis protocols.^{xxxix} In Rhode Island, lawmakers went so far as to clearly and explicitly define sepsis based on SIRS criteria rather than SOFA criteria utilized in Sepsis-3.^{xl}

While several additional states have voluntary sepsis programs, the Novant Health footprint states of North Carolina and South Carolina have not yet adopted statutes or regulations to standardize sepsis care.^{xli}

Summary

Clinicians take seriously their pledge to "first, do no harm," and those at the Novant Health Center for Public Policy Solutions extend that pledge to ensuring public policies are not a barrier to this fundamental principle. For sepsis, the data and experiences of actively practicing clinicians are clear: Harm is best prevented when states enact public policies that ensure consistent clinical standards and protocols based on the Sepsis-2 definition. Thus, the Novant Health Center for Public Policy Solutions urges states, including North Carolina and South Carolina, to join those that have already adopted such statutes.

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About the authors

Rebekah DeCamillis, PA-C | Rebekah serves as APP medical director with the Novant Health Institute of Safety & Quality and co-chairs the system's acute care antimicrobial stewardship program. She additionally practices inpatient infectious disease with a background in laboratory medicine. She received her undergraduate degrees in Clinical Laboratory Science and Latin from UNC-Chapel Hill and holds a master's in physician assistant studies from Duke University.

Elizabeth Dunbar, MD, MBA, FACEP, CHCQM-PHYADV | A board-certified emergency medicine physician and fellow of the American College of Emergency Physicians (ACEP), Dr. Dunbar serves as the lead physician advisor for utilization review with Novant Health. Dr. Dunbar received her medical degree from the University of Missouri-Kansas City and holds a master's of business administration from the Fuqua School of Business at Duke University. She also earned a certification in health care quality and management from the American Board of Quality Assurance and Utilization Review Physicians (ABQAURP).

Daniel Feinstein, MD, MS, FACP, ACRP | Dr. Feinstein is a board-certified physician in internal medicine and critical care. He serves as a clinical physician executive and director of pulmonary and critical care in Novant Health Winston-Salem region and is the systemwide director of tele-ICU services. He also serves as Novant Health's systemwide co-director of sepsis care. He has published nearly 30 peer reviewed journal articles and research on sepsis, septic shock management, and antibiotic stewardship. Dr. Feinstein completed his internal medicine training at Saint Agnes Medical Center and fellowship training at Rush Medical Center.

Natalie George, MBA, RHIA, CCS, CDIP | Natalie serves as the senior director of corporate coding and utilization review for Novant Health where she oversees the acute coding, utilization review, revenue recovery, and utilization management physician advisory teams. Natalie received a master's of business administration from Fayetteville State University and is credentialed by the American Health Information Management Association as a Registered Health Information Administrator (RHIA), Certified Coding Specialist (CCS), and Certified Documentation Integrity Professional (CDIP).

Samara Llewellyn, MD, MBA | A board-certified internal medicine physician, Dr. Llewellyn serves as the senior physician executive for Safety and Quality at Novant Health and practices at the Novant Health Surgical Wellness Clinic and Novant Health Forsyth Medical Center. She received her medical degree from East Carolina University School of Medicine and completed residency at Wake Forest University School of Medicine.

Dipti Patel, MD | Dr. Patel is a board-certified internal medicine physician and serves as the medical director of the inpatient care physician team at Novant Health Mint Hill Medical Center, which was named a 5-Star Vizient facility for Quality and Safety. Dr. Patel trained at the Medical University of Lublin and Bon Secours Mary Immaculate Hospital.

Gautam Patel, MD | A board-certified family medicine physician and hospitalist, Dr. Patel serves as the hospitalist medical director for Novant Health Surgical Wellness - Matthews at Novant Health Matthews Medical Center. He received his medical degree from Government Medical College, Surat, before completing his internship and residency in family medicine at Trover Clinic Foundation.

Morgan Calhoun, PhD | Morgan serves as Novant Health's policy analyst, where she focuses on state and federal regulations and their impacts on the health system, its clinicians, and its patients. Morgan received her undergraduate degree from Covenant College and her doctoral degree in political science from the University of Georgia.

David Tyson | David serves as the lead researcher at the Novant Health Center for Public Policy Solutions and is the director of policy and regulatory affairs for Novant Health. A nationally recognized expert in healthcare regulation, David regularly advises health system leaders, elected officials, and agency staff on the public policy solutions that enable industry-leading care for health systems, clinicians, and patients. David received his undergraduate degree from North Carolina State University and a master's degree from Appalachian State University.

About Novant Health

Novant Health is united by a shared cause to create a healthier future and bring remarkable experiences to life. As an integrated network of hospitals, physician clinics, and outpatient facilities, the not-for-profit health system delivers a seamless healthcare experience to communities across North Carolina and South Carolina. The Novant Health network includes more than 1,900 physicians and nearly 40,000 team members who provide care at more than 800 locations, including 19 hospitals and hundreds of outpatient facilities and physician clinics. In 2023, Novant Health provided more than \$1.6 billion in community benefit, including financial assistance and other healthcare and community support services.

About the Novant Health Center for Public Policy Solutions

The Novant Health Center for Public Policy Solutions shapes and advances public policies to address the issues that matter most to clinicians and patients. We move beyond theory and drive action on public policies that combat clinician burnout, address access and affordability challenges, and enable innovation. Our approach utilizes the latest research, direct expertise from frontline clinicians, and our collective experience as a leading not-for-profit health system to enable human-centric solutions at all levels of government.

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