

ENDSEPSIS

The Legacy of Rory Staunton

Dear Friend,

Thank you for joining the fight against sepsis.

In this toolkit you will find everything you need to educate lawmakers and other officials about the preventable tragedy of sepsis. The fight for protocols is not an easy one, but hundreds of thousands of lives depend on it.

While the voices and experiences of constituents are the most persuasive tool we have to advocate for change, End Sepsis is here to provide all the support you need. We are glad to discuss your efforts, advise on strategy, and leverage our connections. We can also supply you with a personalized letter of support addressed to your elected representatives and/or to officials at your state Department of Health. This letter will outline the shocking sepsis statistics and present the work already done in New York and other states as a model for change.

Following the death of our 12-year-old son from preventable, undiagnosed sepsis, we went to work in our home state of New York to enact the strongest, most impactful protocols possible so that no other families would experience our pain. The protocols that went into effect in 2013 are called Rory's Regulations in honor of our son. They remain the gold standard for sepsis protocols in the United States. The New York protocols are overseen and enforced by the New York State Department of Health. All hospitals are required to report on their sepsis cases and the data gathered are used to assess each hospital and to provide researchers and policymakers with critical information needed to better understand how sepsis can best be prevented and treated. As numerous scholarly studies published in leading medical journals—including the Journal of the American Medical Association (JAMA)—show, Rory's Regulations save thousands of lives each year and have lowered pediatric deaths from sepsis by an astounding 40%. New York is the only state to report these numbers. At End Sepsis, we firmly believe that the New York State protocols should be implemented in all 50 states.

We wish you the best of luck in your efforts and look forward to supporting you in your fight.

Warm regards,

Ciaran and Orlaith Staunton
Co-Founders, End Sepsis

ENDSEPSIS

The Legacy of Rory Staunton

Welcome to the Sepsis Protocol Toolkit!

Thank you for starting the journey towards mandatory sepsis protocols in your state. Our goal is to provide you with everything you need to understand sepsis protocols, educate public officials, and start advocating.

The information in this toolkit uses New York State sepsis protocols, known as Rory's Regulations, as the preferred model. Rory's Regulations were introduced by the Department of Health in 2013 and remain by far the strongest state-mandated protocols in the country and the only protocols that require hospitals to document and submit data for every sepsis patient to the Department of Health for review and analysis.

Included in this folder you will find:

1. A step-by-step guide for your meeting with elected and/or appointed officials
2. Several news articles that report on the impact of Rory's Regulations in New York State (important background information).
3. A copy of the Rory's Regulations legislation
4. A copy of the Parents' Bill of Rights, included with Rory's Regulations in New York State
5. An overview explaining what sepsis protocols are and how they work
6. Sample questions you may face in your meeting and appropriate responses, including a side-by-side comparison of Rory's Regulations (as the protocols are called in New York) and the CMS sepsis guidelines.
7. A graph that you can print out showing how sepsis mortality numbers compare to other leading causes of death
8. Quotes that articulate the desperate need for sepsis protocols

Thank you for taking this important first step! We are here to support you!

ENDSEPSIS

The Legacy of Rory Staunton

Meeting Guide

Sepsis protocols have been proven to save lives. Currently, three states, accounting for 42 million people, are covered by mandatory sepsis protocols. In each case, these protocols have been the result of grassroots efforts spearheaded by individuals who feel personally invested in preventing needless deaths from sepsis. With the support of End Sepsis and by following the steps outlined below, you can make your state safe from sepsis.

1. Contact End Sepsis to see if efforts are already underway in your state and to connect with fellow advocates.
2. Request a meeting with your State Representative, State Senator or State Health Official (or someone senior on their staff). Our friends at Common Cause have developed a database to help you reach your state representatives: Find Your Elected Officials Database <https://www.commoncause.org/find-your-representative/>. Your State Health Official can be found here: <http://www.astho.org/Directory/>
3. Before your meeting: Print out copies of Rory's Regulations and the Parents' Bill of Rights to bring with you. These are the protocols in place in New York State and should act as a model for your state's protocols.
4. Familiarize yourself with the information in the Sepsis Protocols Fact Sheet and the contents of this folder. It will help you make the case for sepsis protocols clearly and persuasively.
5. During the meeting:
 - Educate your representative about sepsis and its impact. Remember, most people have never heard of sepsis and/or don't understand the extent of the problem.
 - Don't forget that the personal is powerful. Why are you concerned about sepsis? Do you have personal experience with sepsis? Are you a healthcare professional? Are you concerned constituent, alarmed by number of needless deaths from sepsis?
 - Ask when you can follow up and what the next steps will be. Make sure you have a clear understanding of the process and next steps before you leave.
6. After the meeting:
 - Be persistent and don't be discouraged! Elected officials have many competing priorities. Keep checking in regularly and schedule a follow up meeting if necessary.
 - Get in touch with us at End Sepsis at any time to receive support and guidance on how to proceed and to report in on any action being taken in your state.
7. Be creative about gaining support your campaign for sepsis protocols. Circulate a petition, start a letter-writing campaign, contact local media, hold an event, invite others with firsthand experience with sepsis to share their stories with the elected officials you meet with.

ENDSEPSIS

The Legacy of Rory Staunton

What is Sepsis?

Sepsis is a medical condition that can result from any type of infection. Instead of fighting the infection, the immune system attacks its own organs and tissues, releasing chemicals that cause widespread inflammation. If not diagnosed early, sepsis can rapidly lead to tissue damage, organ failure and death. Any kind of infection can lead to sepsis: a small wound, a urinary tract infection, pneumonia, a dental abscess. When diagnosed early, sepsis can be treated with broad spectrum antibiotics and IV fluids.

The Stats on Sepsis

- **Sepsis kills more than 270,000 Americans each year:** more than breast cancer, prostate cancer, opioid overdoses, and AIDS combined.
- There are **more than a million cases of severe sepsis diagnosed each year** in the United States.
- **Hundreds of thousands of sepsis survivors are left with life-changing disabilities**, including amputated limbs and cognitive damage.
- Sepsis is the **number one cause of death in hospitals**.
- Sepsis is the **most expensive condition treated in U.S. hospitals**, costing more than \$23 billion.

Why are protocols important?

More than a million Americans develop sepsis each year. Approximately 30% die from the condition, many of them needlessly due to fatal delays in diagnosis in treatment. Sepsis protocols ensure that hospital staff receive sepsis training and that sepsis is identified and treated rapidly, which is crucial to the survival of the patient. In fact, when a patient in septic shock becomes hypotensive (the medical term for low blood pressure), chance of survival decreased by nearly 8% each hour that antibiotics are delayed.

States and individual hospital systems that have enacted common-sense, evidence-based protocols have shown substantial reductions in mortality from sepsis, as well as reductions in the cost of care:

- In their first 30 months, sepsis protocols in New York State (Rory's Regulations), **reduced the odds of dying for adult sepsis patients by 21%, resulting in more than 5,000 lives saved.**
- **Mortality for pediatric patients was reduced by 40%** when protocols were correctly administered.

What do Rory's Regulations require?

Rory's Regulations were enacted in New York State in 2013. They require hospitals to adopt protocols that provide for:

- The training of all relevant hospital in staff in the identification and treatment of sepsis
- The screening and early recognition of patients with sepsis, severe sepsis and septic shock;
- Guidelines for treatment including for early delivery of antibiotics, essential to survival;
- A process to identify and document individuals appropriate for treatment through severe sepsis protocols;
- Guidelines for treatment including for early delivery of antibiotics.

The protocols must be submitted to the state health department for approval and periodically updated. Hospitals are required to train all relevant staff in the protocols and to collect and submit all sepsis data to the state for analysis so that challenges can be identified and protocols strengthened.

ENDSEPSIS

The Legacy of Rory Staunton

Commonly Asked Questions

Hospitals are already following CMS sepsis guidelines (SEP-1); why do we need more regulations?

First, only 50% of hospitals comply with CMS sepsis guidelines. In addition, the CMS guidelines differ from Rory's Regulations in a number of critical ways. This table breaks down some of the key differences:

Rory's Regulations	CMS Guidelines
Rory Regulations cover pediatric patients	CMS guidelines do not
Rory's Regulations require that all relevant hospital staff be trained in sepsis diagnosis and treatment	CMS guidelines do not
Rory's Regulations require that each hospital develop a set of written protocols, overseen by the Chief Medical Officer	CMS guidelines do not
Rory's Regulations include every sepsis case in the data submitted to the state Department of Health for measurement and review	CMS guidelines only require a sample of sepsis cases to be submitted to CMS for review
Rory's Regulations require that every patient suspected of having sepsis is treated using the hospital's sepsis protocols	CMS guidelines exclude many groups of patients, including patients that have been transferred from other facilities, from being subject to the guidelines
Rory's Regulations require data to be collection on sepsis patient outcomes and mortality rates	CMS guidelines gather data on whether the SEP-1 process is being implemented—not on whether patients live or die
Rory's Regulations require that ALL hospitals in the state adopt evidence-based protocols and submit data for patients to the state Department of Health	A 2018 study showed that only 50% of hospitals currently follow CMS guidelines

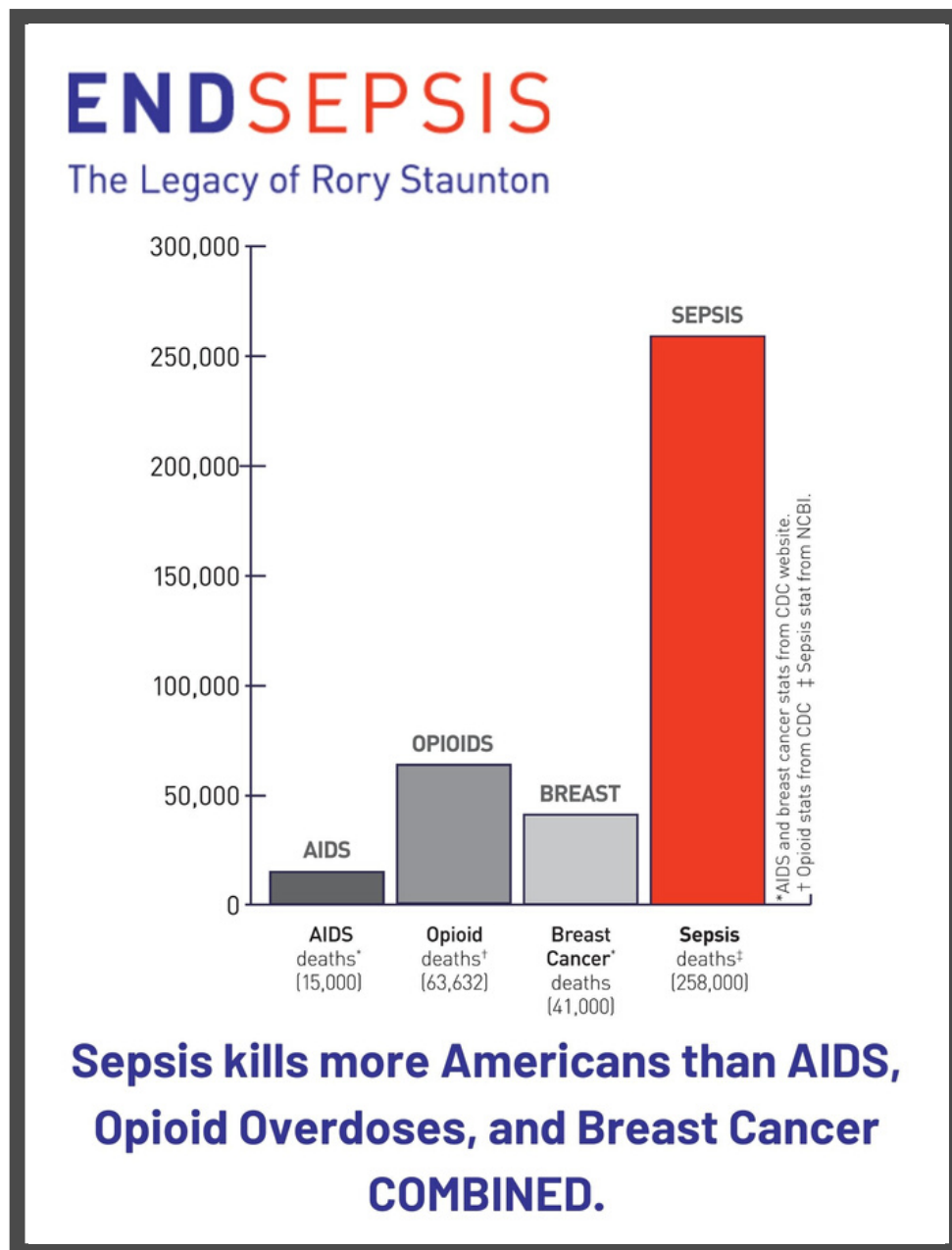
ENDSEPSIS

The Legacy of Rory Staunton

Putting protocols in place and measuring outcomes is expensive; we can't afford to do it.

Sepsis is the more expensive condition treated in U.S. hospitals, according to the CDC, and the most expensive condition billed to Medicare and Medicaid. In multiple studies, sepsis protocols have been shown to reduce the cost of care for sepsis patients. For example:

- A 2016 study of 5,918 sepsis patients in New York, published in the *Journal of the Society of Critical Care Medicine*, found that hospitals pursuing aggressive, protocolized sepsis treatment achieved substantial cost savings (and lower mortality rates).
- InterMountain Healthcare in Utah slashed its sepsis costs by \$38 million annually (and reduced mortality from 25% to 9%) after adopting sepsis protocols.



ENDSEPSIS

The Legacy of Rory Staunton

Why we need protocols, in the words of our supporters.

My daughter died of sepsis on 4/22/14 in the ICU. She had gone to two separate ERs to be sent home with a diagnosis of ear infection and then kidney infection when she in fact had full blown sepsis. No one even diagnosed her. She was my only child and she did not need to die. I am so heartbroken. I just don't see how it could be. The emergency rooms and all the educated professionals should never let this happen. She could have been saved if someone had seen the signs. *–Susie*

I had never heard of sepsis before October 19, 2013, when my 40 year old husband went to a local ER with uncontrollable shaking. He had fever of 103.9. I could not find initial blood pressure readings in his medical records. They started IV fluids and pretty much ignored him for 7 hours, even almost discharging him with a diagnosis of the flu. No one caught on to the sepsis until his blood pressure plummeted and he was in septic shock. He died within 24 hours of having the first symptom of uncontrollable shaking. He left behind me, 35 years old, and our babies, 3 years and 9 months at the time of death. I will help in anyway I can to raise sepsis awareness. *–Lisa*

My grandson Keith was 14. On August 3, 2007, he died. He was on the football field in preparation for summer training with a “blister” from poorly fitting new cleats. He never really had a chance. After obtaining all of the medical notes and records following his death the complete chaos surrounding his care was apparent. He left a brother and a family that will never be the same. His Aunt an ICU nurse upon arrival called family to say, Mom he's going to die. Get here now. The doctor is clueless. *–Coral*

I lost my daughter, Sierra, one day after her second birthday. The pediatrician said it was a bug going around, give baby Tylenol and she be fine. She wasn't and I took her back; four days later and she was gone. I never imagined something like this would happen. Nobody could tell me why she was so sick or help her. That was my worst day ever in my life but her birth was the best day ever. *–Beverly*

I'm a paramedic and in the last couple of years sepsis awareness and education has increased dramatically in emergency medical service..now we have sepsis protocols. We are now trained to recognize and treat sepsis in the pre-hospital environment, and something as simple as establishing IV access and running fluids immediately can drastically improve patient outcomes. *–Steven*

...my husband, an extremely healthy 42 year old triathlete is now a quadruple amputee thanks to all of his physicians missing clear symptoms of severe sepsis, and later septic shock *–Anonymous*