

# Regulating Sepsis Care in New York Hospitals: A Statewide Quality Initiative



## **PRESENTATION TO KENTUCKY HOSPITAL ASSOCIATION**

**FOSTER GESTEN, MD  
FORMER CHIEF MEDICAL OFFICER  
OFFICE OF QUALITY AND PATIENT SAFETY  
NYS DEPARTMENT OF HEALTH**

# Financial Disclosures/Conflicts



- NONE

# Background and Context



# Sepsis Incidence and Mortality



- **Global Burden of Disease (Lancet, Jan 2020)**
  - Estimated burden in 2017 TWICE what was previously thought (~49 million cases and ~11 million deaths worldwide)
  - Higher burden among people living in areas with lower socio-demographic index
  - Need for greater prevention and treatment
- **Sepsis Among Medicare Beneficiaries: 2012-18 (CCM Mar 2020)**
  - Total costs rose from \$27.7 to \$41.5 billion
  - Mortality remains high
    - ✦ Septic shock: 60%
    - ✦ Severe sepsis: 36%
    - ✦ Inpatient admission with sepsis associated with increased risk of worsening health, mortality, use of advanced services, readmission

# New York Landscape: 2011/12



- 40,334 cases of severe sepsis
  - 15,311 deaths from sepsis
- Mortality rate: 37.96 %
- Risk Adjusted Mortality (administrative data) in NYS varies between hospitals from 15% to over 58%
- Surviving Sepsis Guidelines and Initiative (including IHI Sepsis Bundles)
- STOP Sepsis Initiative (NYC): Voluntary
- Hospital Medical Home Demonstration Waiver (Medicaid): Sepsis QI Pilot in Teaching Hospitals
- Statewide Initiatives For Time Sensitive Treatments
  - STEMI
  - Stroke
  - Trauma

# New York Times: Rory Staunton – July 11, 2012



# What We Did



# What Happened?



- Health Agency in conjunction with Governor's Office
- Initial Multi-stakeholder meeting sponsored by DOH
- Creation of Clinical Advisory Group(s)
  - Regulation development
  - Protocols: what is 'required' and what is 'flexible'
  - Data and measurement
    - ✦ Data dictionary
- Engaged External Quality Review Organization
  - Protocol review
  - Data collection and auditing



# Regulation, Not Legislation



- Amendments to existing hospital regulations
- Apply to acute care hospitals only
- Required hospitals to:
  - develop and implement a sepsis protocols (adult and pediatric)
  - train staff in its use
  - report data to the NYS DOH (adherence and RA mortality)
- Subsequent legislation protecting hospital specific data from FOIL for two (2) years to allow for audit and pilot phase to complete prior to public release (Fall/Winter 2016)

# Protocol Requirements: Basics



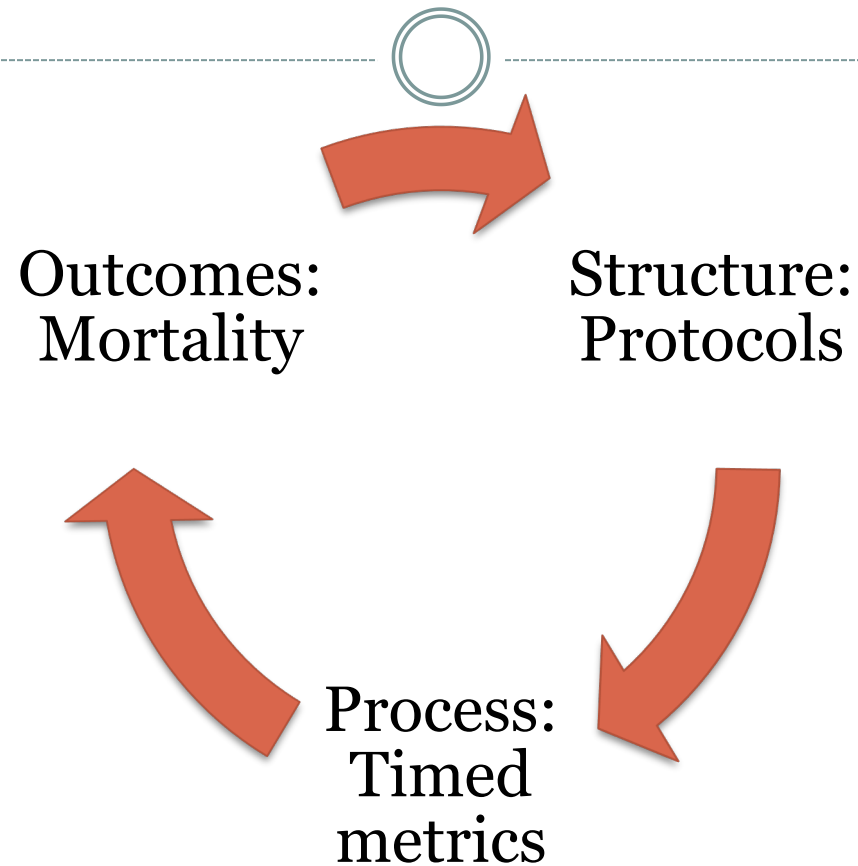
- System for screening and early recognition of patients with sepsis, severe sepsis and septic shock
- Criteria for those who are appropriate for and those who should be excluded from severe sepsis/septic shock protocols
- Guidelines for hemodynamic support, including where appropriate, vasoactive agents
- Address use of biomarkers (lactate)
- Method for invasive or non-invasive hemodynamic monitoring treatment goals
- Time-frame goals
- Update protocol for any 'significant' revisions

# What Did We Not Do?



- Require those protocols to include central line insertion and invasive monitoring
- Require all patients with possible infection, elevated temperature, to be subjected to protocols or aggressive interventions
- Require all patients, regardless of advanced directives or clinical appropriateness, to be treated with a protocol
- Suggest that use of billing data was the best way to identify cases
- Create any new definitions for severe sepsis/septic shock beyond current international definitions

# Quality Improvement Triad

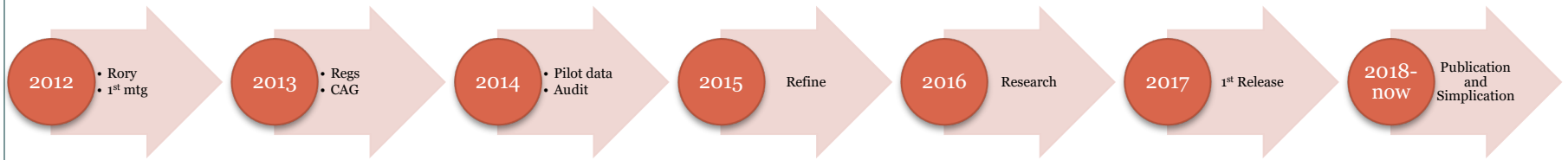


# Partnership



- Hospital Advisory Group
  - Clinicians
    - ✦ Adult and pediatric
    - ✦ ICU/ED/ID/Nursing
  - Hospital association
- Clinical Experts
  - External to NYS
- Risk Adjustment Experts
  - Internal and external

# Timeline



# Major Challenges



- Clinical Controversy
  - Invasive monitoring
  - Fluids
- On-going RCTs
- Pediatric vs Adult
- Data collection burden
- Clinical definitions for data dictionary
- Resources
  - Hospitals
  - DOH
- Public reporting
  - Accuracy
  - Fairness
  - Gaming
  - Risk adjustment
- Volume of cases and number of hospitals
- CMS and SEP-1
- Time Zero!
- Transfers and case exclusions (DNR and others)

# Results





# Clinical Data

- 70 variables
  - Demographic variables
  - Hospital Stay variables
  - Protocol variables
  - Adherence variables

# Variables Collected in Clinical Data

- **Treatment variables** (date/time)
  - Lactate result
  - Blood culture result
  - Antibiotics started
  - Fluids given
  - Vasopressors given
  - CVP/ScVO<sub>2</sub> measured (if done)
- **'Severity' variables**
  - Platelet level
  - Bandemia
  - Hypotension
  - Lower Respiratory Infection
  - Altered mental status
  - Mechanical ventilation
  - ICU stay

# Variables Collected in Clinical Data

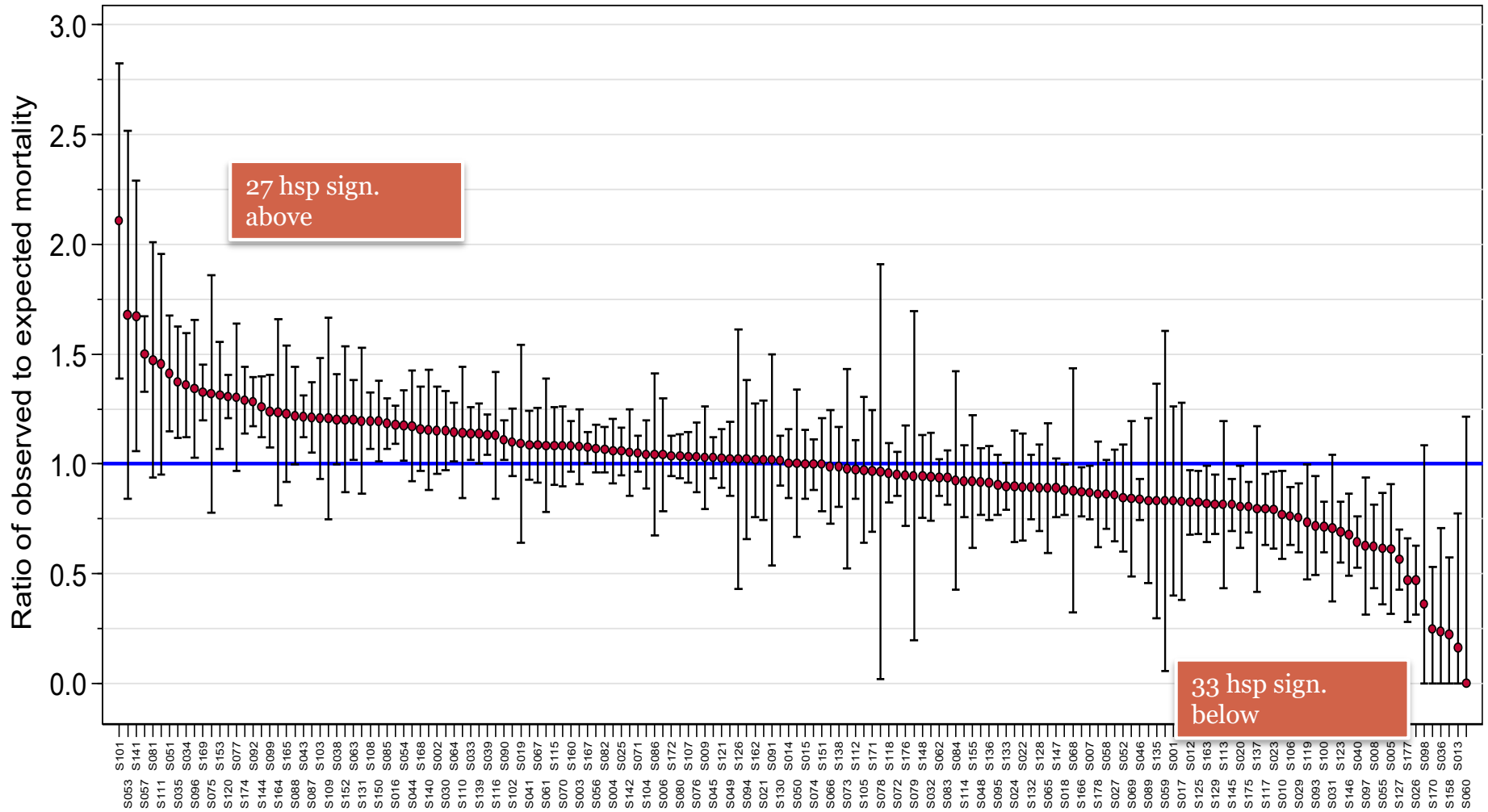
- Comorbidity variables
  - Chronic Respiratory Failure
  - AIDS/HIV
  - Cancer
  - Lymphoma/Leukemia/Multiple Myeloma
  - Immune Modifying Medications
  - CHF
  - Chronic Liver Disease
  - Chronic Renal Failure
  - Diabetes
  - Organ Transplant

# Variables in RA Model (plus interactions)



- Gender
- Race/Ethnicity
- Payer
- Site of Infection
- Admission Source
- Altered Mental Status
- Mechanical Ventilation
- Bacteremia
- Platelet Count
- Septic Shock
- Age
- Serum Lactate
- Metastatic Cancer
- Lymphoma/Leukemia/  
Multiple Myeloma
- Comorbidity Count

# Distribution of risk adjusted ratio of observed to expected mortality along with the 95% CI



Comparison was restricted to hospitals with  $\geq 10$  sepsis discharges in 2014 4<sup>th</sup> quarter to 2015 3<sup>rd</sup> quarter (N = 162). Overall state ratio is 1.0 (blue line)

# Adult measures and bundles



- Three hour measures and bundle:
  - Antibiotics
  - Lactate
  - Culture Before Antibiotic
- Six hour measures and bundle:
  - Fluids
    - Elevated lactate ( $\geq 4$  mmol/L) or hypotension
  - Vasopressors
    - Hypotension not responsive to fluids
  - Reordered Lactate
    - If elevated (or never measured)

# Pediatric measures and bundle



- One hour measures and bundle:
  - ✦ Blood Culture Before Antibiotic
  - Antibiotics
  - Fluids

ORIGINAL ARTICLE

Mortality Changes Associated with Mandated Public Reporting for Sepsis

The Results of the New York State Initiative

Mitchell M. Levy<sup>1</sup>, Foster C. Gesten<sup>2\*</sup>, Gary S. Phillips<sup>3\*</sup>, Kathleen M. Terry<sup>4</sup>, Christopher W. Seymour<sup>5</sup>, Halle C. Prescott<sup>6,7</sup>, Marcus Friedrich<sup>8</sup>, Theodore J. Iwashyna<sup>9,7</sup>, Tiffany Osborn<sup>9,10</sup>, and Stanley Lemeshow<sup>11</sup>

<sup>1</sup>Division of Pulmonary, Critical Care and Sleep Medicine, Department of Medicine, Brown University School of Medicine, Providence, Rhode Island; <sup>2</sup>New York State Department of Health, Albany, New York; <sup>3</sup>Center for Biostatistics, Department of Biomedical Informatics, The Ohio State University, Columbus, Ohio; <sup>4</sup>IPRO, Lake Success, New York; <sup>5</sup>Department of Critical Care Medicine, The Ohio State University, Columbus, Ohio; <sup>6</sup>Department of Biostatistics, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania; <sup>7</sup>Investigation and Systems Modeling of Acute Illness Center, University of Michigan, Ann Arbor, Michigan; <sup>8</sup>University of Michigan, VA Center for Clinical Research, Ann Arbor, Michigan; <sup>9</sup>New York State Department of Health, Albany, New York; <sup>10</sup>Department of Biostatistics, University of Michigan, Ann Arbor, Michigan; <sup>11</sup>Department of Biostatistics, Ohio State University, Columbus, Ohio

Measurements and Main Results: Compliance with the sepsis bundles and risk-adjusted mortality

Among these individuals, 3-hour bundle compliance increased from 23.9% to 53.4% to 64.7% during the study period (P < .001). 6-hour bundle compliance increased from 28.8% to 33.9% to 40.1% during the study period (P < .001). 3-hour and 6-hour bundle compliance were associated with lower risk and reduced mortality.

Conclusions: New York State's mandated public reporting initiative improved compliance with sepsis bundles and reduced mortality among patients with sepsis.

Time to Treatment and Mortality during Mandated Emergency Care for Sepsis

Christopher W. Seymour, M.D., Foster Gesten, M.D., Halle C. Prescott, M.D., Marcus E. Friedrich, M.D., Theodore J. Iwashyna, M.D., Ph.D., Gary S. Phillips, M.A.S., Stanley Lemeshow, Ph.D., Tiffany Osborn, M.D., M.P.H., Kathleen M. Terry, Ph.D., and Mitchell M. Levy, M.D.

**BACKGROUND** In 2013, New York began requiring hospitals to follow a protocol for the identification and treatment of sepsis. However, the impact of this rapid treatment of sepsis improves outcomes.

**METHODS**

We studied data from the New York State Sepsis Registry to determine the impact of the mandated protocol on time to treatment and mortality.

The New York Sepsis Severity Score: Development of a Risk-Adjusted Severity Model for Sepsis

Gary S. Phillips, MAS<sup>1</sup>; Tiffany M. Osborn, MD, MPH<sup>2</sup>; Kathleen M. Terry, PhD, BCC<sup>3</sup>; Foster Gesten, MD<sup>4</sup>; Mitchell M. Levy, MD<sup>5</sup>; Stanley Lemeshow, PhD<sup>6</sup>

In accordance with Rory's Regulations, hospitals developed and implemented protocols for sepsis to reduce variations in evidence-based care and reduce mortality. The New York Department of Health developed a risk assessment model for sepsis to allow for standardized hospital mortality comparisons of adult patients in various institutions using case-mix adjustment.

**Measurement and Main Results:** Maximum likelihood regression was used to estimate model coefficients for the New York State risk model. The model was estimated using a logistic regression model. Variables included in the model were determined through a building process. Interactions were tested if they made clinical sense. Model R-squared was 0.05.

JAMA | Original Investigation  
Association Between the New York Sepsis Care Mandate and In-Hospital Mortality for Pediatric Sepsis

Michelle V. E. Evans, MD, MSc, Gary S. Phillips, MSc, Elizabeth Alperin, MD, BCC, Derek C. Angus, MD, MPH, Margaret M. Ross, MD, William M. Tierney, PhD, Gary S. Phillips, MD, MPH, Scott L. Weiss, MD, LECC, and Jennifer Zimmerman, MD, PhD

**IMPORTANCE** The death of a pediatric patient with sepsis motivated New York to mandate statewide sepsis treatment in 2013. The mandate included a 1-hour bundle of laboratory, vital signs, and imaging elements within 1 hour improves outcomes to sepsis.

**OBJECTIVES** Statewide cohort study conducted from 2013 to 2015 to determine the risk-adjusted association between compliance with the 1-hour bundle and individual and hospital mortality.

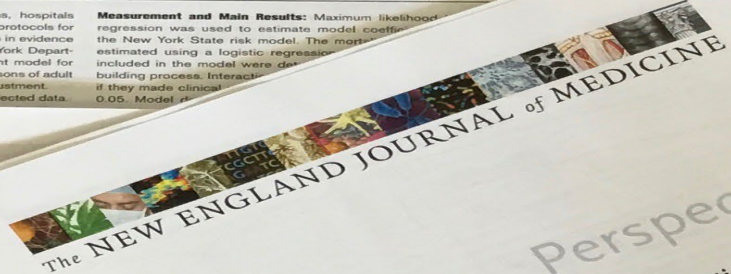
DISPARITIES

By Keith Corl, Mitchell Levy, Gary Phillips, Kathleen Terry, Marcus Friedrich, and Amal N. Trivedi

Racial And Ethnic Disparities In Care Following The New York State Sepsis Initiative

**ABSTRACT** After 2013, when New York State mandated that hospitals follow protocols to treat sepsis, completion of the protocols increased and mortality declined. Whether these encouraging trends have equitably benefited racial/ethnic minority populations is unknown. Although there were no significant racial/ethnic differences in rates of protocol completion at the onset of New York's Sepsis Initiative, over time white patients experienced a greater increase in protocol completion rates (14.0 percentage points) compared to black patients (5.3 percentage points). The emergence of this disparity was due to smaller performance improvements among hospitals with higher proportions of black patients, though white and black patients showed similar improvements when treated within the same hospital. Our study suggests an urgent need to understand why improvements in sepsis care lagged in hospitals in New York that care for higher proportions of minority patients. Policy makers should anticipate and monitor the effects of quality improvement initiatives on disparities to ensure that all racial/ethnic groups realize their benefits equitably.

**S**epsis is a life-threatening infection that afflicts over 1.5 million Americans, results in 250,000 deaths, and accounts for \$24 billion in health care spending each year.<sup>1,2</sup> The World Health Organization has identified sepsis as a major public health priority and has called for global efforts to reduce its burden. Sepsis is a leading cause of death in the United States, affecting more than 1.5 million Americans each year at an annual cost of over \$20 billion. To improve outcomes of sepsis, policymakers are increasingly using regulatory mechanisms to incentivize clinicians and hospitals to improve the quality of sepsis care. One such initiative is an unprecedented set of New York State regulations implemented in 2013 and collectively known as "Rory's Regulations." Named after Rory's Regulations, a young boy who died of sepsis, the regulations require that all hospitals follow a protocol for the identification and treatment of sepsis. The protocol includes a 1-hour bundle of laboratory, vital signs, and imaging elements within 1 hour improves outcomes to sepsis. The mandate included a 1-hour bundle of laboratory, vital signs, and imaging elements within 1 hour improves outcomes to sepsis. The mandate included a 1-hour bundle of laboratory, vital signs, and imaging elements within 1 hour improves outcomes to sepsis.



State Sepsis Mandates — A New Era for Regulation of Hospital Quality

Tina B. Hershey, J.D., M.P.H., and Jeremy M. Kahn, M.D.

**S**epsis is a major cause of illness and death in the United States, affecting more than 1.5 million Americans each year at an annual cost of over \$20 billion. To improve outcomes of sepsis, policymakers are increasingly using regulatory mechanisms to incentivize clinicians and hospitals to improve the quality of sepsis care. One such initiative is an unprecedented set of New York State regulations implemented in 2013 and collectively known as "Rory's Regulations." Named after Rory's Regulations, a young boy who died of sepsis, the regulations require that all hospitals follow a protocol for the identification and treatment of sepsis. The protocol includes a 1-hour bundle of laboratory, vital signs, and imaging elements within 1 hour improves outcomes to sepsis. The mandate included a 1-hour bundle of laboratory, vital signs, and imaging elements within 1 hour improves outcomes to sepsis.



# Time to Treatment and Mortality during Mandated Emergency Care for Sepsis



**SEYMOUR ET AL**

**NEJM**

**MAY 21, 2017**

# Seymour et al (NEJM)



## Analyzed

- NY patients with sepsis 2014-16
- Models to assess association between time until completion of 3-hour bundle and RA mortality

## Concluded

- More rapid completion of 3-hour bundle and administration of antibiotics (but not initial fluid bolus) associated with lower risk adjusted mortality

# Association Between the New York Sepsis Care Mandate and In-Hospital Mortality for Pediatric Sepsis



**EVANS ET AL**  
**JAMA**  
**JULY 24/31, 2018**

# Evans et al (JAMA)



## Analyzed

- NY patients aged 18 and younger with sepsis who had protocol initiated
- Risk adjusted mortality

## Concluded

- Completion of protocol within one hour associated with lower risk adjusted mortality

# Mortality Changes Associated with Mandated Public Reporting for Sepsis: Results of NYS Initiative



**LEVY ET AL**  
**AMERICAN JOURNAL OF RESPIRATORY AND  
CRITICAL CARE MEDICINE**  
**DECEMBER 1, 2018**

# Levy et al (AJRCCM)



## Analyzed

- NY adult sepsis patients- 2014-16
- Protocol initiation, 3- and 6-hour bundle completion, and RA mortality

## Concluded

- Greater bundle compliance associated with shorter LOS and lower risk of mortality
- NY initiative increased compliance with measures and lowered mortality

# Association Between State-Mandated Protocolized Sepsis Care and In-hospital Mortality Among Adults with Sepsis



**KAHN ET AL**  
**JAMA**  
**JULY 16, 2019**

# Kahn et al (JAMA)



## Analyzed

- NY vs 4 Control states (FL, MA, MD, NJ) using retrospective 'administrative' data (HCRIS) for over 1 million patients
- Difference in difference (DID) design

## Concluded

- In NY mandated protocolized sepsis care associated with greater decrease in sepsis mortality vs control states
- Significant relative decrease in LOS, CDiff



# Evolution



# Changes (2017-now)



- **Regulations**
  - Clarified definitions
  - Removed mention of invasive monitoring
  - No longer have to submit protocols
- **Mortality model**
  - Updated yearly
  - 30 day mortality (vs inpatient)
  - Discharge to hospice = mortality
  - Pediatric model developed
- **Metrics**
  - Process measures for adults replaced by SEP-1

# Changes (cont.)



- **Data collection**
  - Sampling for high volume hospitals
  - EHR abstracted variables
- **Research**
  - Clinical sepsis data available to access (de-identified) for research on application
  - Maternal Sepsis
- **Feedback**
  - Quarterly reports to hospitals using Tableau (interactive vs static)
- **COVID**
  - Temporary suspension
  - Inclusion of COVID cases on resumption

# Insurer Reimbursement for Sepsis Care in New York



**KATHLEEN SHURE**

FORMER SENIOR VICE PRESIDENT GREATER NEW  
YORK HOSPITAL ASSOCIATION

FORMER DIRECTOR, OFFICE OF MANAGED CARE, NEW  
YORK STATE DEPARTMENT OF HEALTH

# United Healthcare Sepsis 3 Policy



October 2018 UHC issues provider bulletin announcing adoption of sepsis 3 definition and advising that if definition is not met, it will conclude:

***‘...sepsis was not present and sepsis treatment services should not have been included as part of the member’s claim’***

# Hospital concerns



Issue came to GNYHA  
attention from quality staff at  
member hospitals

Concern that failure to reimburse hospitals for resources necessary to treat patients in accordance with NY policy would undermine statewide initiative to decrease mortality associated with sepsis.

# New York Bifurcated Regulatory Framework



## Department of Financial Services

- Banking and Insurance
- Health plans:
  - Indemnity, PPOs
  - Shared HMO oversight (solvency, prompt pay)

## Department of Health

- Public health, providers, quality & patient safety
- Health plans:
  - Medicaid Plans
  - Shared HMO oversight (certification, network adequacy, quality, provider contracting)
  - Health exchange

# Previous down-coding experience



Enactment of state law requiring health plans to accept coding that is accurate and consistent with national coding guidelines

Aetna down-coding complaint to DFS

- In violation of State law
- Inappropriate methodologically when viewed in context of DRG weight development

DFS sympathetic but had no resources with knowledge of coding and DRG development/reimbursement

Initial outreach on sepsis issue would be to DOH



# GNYHA strategy



Enlist support from  
DOH Office of Quality  
and Patient Safety

Request DOH Office of  
Health Insurance  
Plans to direct  
HMOs/Medicaid plans  
to mandate plans  
accept coding  
consistent with sepsis  
2 for payment  
purposes

Seek DOH support in  
seeking similar  
direction from DFS  
with respect to all  
insurers.

# GNYHA Advocacy on Sepsis 3



12/18/18 letter to  
UHC CEO  
protesting policy

1/3/19 UHC  
advises DFS it  
will not  
implement  
Sepsis 3 policy in  
NY

7/15/19 DOH  
issues guidance  
to Health Plans  
requiring use of  
Sepsis 2  
definition. DFS  
subsequently  
adopts DOH  
guidance

12/18/19 letter to  
DOH seeking  
confirmation on  
Sepsis 2 coding

1/10/19 DOH  
confirms Sepsis 2  
requirement and  
expresses  
concerns  
regarding Sepsis  
3 criteria

