El Camino Hospital
THE HOSPITAL OF SILICON VALLEY

AGENDA

Quality, Patient Care and Patient Experience Committee Meeting of the El Camino Hospital Board

Wednesday, June 1st, 2016, 5:30 p.m.
El Camino Hospital, Conference Room A & B
2500 Grant Road, Mountain View, California

Purpose: The purpose of the Quality, Patient Care, and Patient Experience Committee ("Quality Committee") is to advise and assist the El Camino Hospital (ECH) Board of Directors ("Board") in constantly enhancing and enabling a culture of quality and safety at ECH, and to ensure delivery of effective, evidence-based care for all patients. The Quality Committee helps to assure that excellent patient care and exceptional patient experience are attained through monitoring organizational quality and safety measures, leadership development in quality and safety methods and assuring appropriate resource allocation to achieve this purpose.

AGENDA ITEM	PRESENTED BY		
1. CALL TO ORDER	David Reeder, Chair Quality Committee		5:30 – 5:31 p.m.
2. ROLL CALL	David Reeder, Chair Quality Committee		5:31 – 5:32
3. POTENTIAL CONFLICT OF INTEREST DISCLOSURES	David Reeder, Chair Quality Committee		5:32 – 5:33
4. CONSENT CALENDAR ITEMS: Any Committee Member may pull an item for discussion before a motion is made.	David Reeder, Chair Quality Committee	*public comment*	**Motion Required** 5:33 – 5:38
Approval: a. Minutes of Quality Committee Meeting - May 2, 2016 **Information:** b. Pacing Plan c. Patient Story d. Research Article			
5. REPORT ON BOARD ACTIONS	David Reeder, Chair Quality Committee		**Discussion** 5:38 – 5:43
6. BOARD DISCUSSION **ATTACHMENT 6**	David Reeder, Chair Quality Committee	*Public Comment*	**Possible Motion** 5:43 – 5:53
7. FY16 EXCEPTION REPORT **ATTACHMENT 7**	Daniel Shin, MD, Medical Director Quality Assurance and Patient Safety		**Discussion** 5:53 – 6:03
8. FY17 EXCEPTION REPORT – METRICS & TRACKING DISCUSSION **ATTACHMENT 8**	Daniel Shin, MD, Medical Director Quality Assurance and Patient Safety		**Discussion** 6:03 – 6:18

A copy of the agenda for the Regular Committee Meeting will be posted and distributed at least seventy-two (72) hours prior to the meeting. In observance of the Americans with Disabilities Act, please notify us at 650-988-7504 prior to the meeting so that we may provide the agenda in alternative formats or make disability-related modifications and accommodations.

Agenda: El Camino Hospital Quality, Patient Care, and Patient Experience Committee Meeting
June 1, 2016

	AGENDA ITEM	PRESENTED BY		
9.	**FY17 QUALITY ORGANIZATIONAL GOAL – METRICS DISCUSSION** **ATTACHMENT 9**	Daniel Shin, MD, Medical Director Quality Assurance and Patient Safety		**Discussion** 6:18 – 6:28
10.	**PATIENT AND FAMILY ADVISORY COUNCIL UPDATE** **ATTACHMENT 10**	Cheryl Reinking, Chief Nursing Officer		**Discussion** 6:28 – 6:48
11.	**PUBLIC COMMUNICATION**	David Reeder, Chair Quality Committee		**Information** 6:48 – 6:51
12.	**ADJOURN TO CLOSED SESSION**			6:51 – 6:52
13.	**POTENTIAL CONFLICT OF INTEREST DISCLOSURES**	David Reeder, Chair Quality Committee		6:52 – 6:53
14.	**CONSENT CALENDAR** Any Committee Member may pull an item for discussion before a motion is made.	David Reeder, Chair Quality Committee		**Motion Required** 6:53 – 6:56
	Approval: Meeting Minutes of the Closed Session *Gov't Code Section 54957.2.* - May 2, 2016 **Information:** Report related to the Medical Staff quality assurance matters, *Health and Safety Code Section 32155.* - Meeting Minutes of Quality Council April 6, 2016			
15.	Report related to the Medical Staff quality assurance matters, *Health and Safety Code Section 32155.* Red Alert and Orange Alert Update	Daniel Shin, MD, Medical Director Quality Assurance and Patient Safety		**Discussion** 6:56 – 7:11
16.	**RECONVENE OPEN SESSION/REPORT OUT**	David Reeder, Chair Quality Committee		7:11 – 7:14
	To report any required disclosures regarding permissible actions taken during Closed Session.			
17.	**ADJOURNMENT**	David Reeder, Chair Quality Committee		7:15p.m.

Upcoming FY 17 Quality Committee Meetings

- **August 1, 2016**
- **August 29, 2016**
- **October 3, 2016**
- **November 2, 2016**
- **December 5, 2016**

May 2, 2016

Minutes of the Open Session of the
Quality, Patient Care and Patient Experience Committee Meeting of the
El Camino Hospital Board
Monday, May 2nd, 2016
El Camino Hospital, Conference Rooms A&B
2500 Grant Road, Mountain View, California

Members Present	Members Absent	Members Excused
Dave Reeder; Peter Fung, MD; Diana Russell, RN; Jeffrey Davis, MD; Nancy Carragee, Mikele Bunce, Melora Simon, and Wendy Ron.	Katie Anderson, Lisa Freeman and Alex Tsao.	Robert Pinsker, MD

A quorum was present at the El Camino Hospital Quality, Patient Care, and Patient Experience Committee on the 2nd day, May, 2016 meeting.

Agenda Item	Comments/Discussion	Approvals/Action
1. CALL TO ORDER	The meeting of the Quality, Patient Care, and Patient Experience Committee of El Camino Hospital (the "Committee") was called to order by Committee Chair Dave Reeder at 5:35 p.m.	***None***
2. ROLL CALL	Chair Reeder asked Stephanie Iljin to take a silent roll call.	***None***
3. POTENTIAL CONFLICT OF INTEREST DISCLOSURES	Chair Reeder asked if any Committee member or anyone in the audience believes that a Committee member may have a conflict of interest on any of the items on the agenda. No conflict of interest was reported.	***None***
4. CONSENT CALENDAR ITEMS	Chair Reeder asked if any Committee member wished to remove any items from the consent calendar for discussion. None were noted. **Motion:** To approve the consent calendar (Open Minutes of the February 29, 2016, April 4, 2016 Meeting, FY17 Quality Meeting Calendar, and Environmental Policies were approved). **Movant:** Fung **Second:** Russell **Ayes:** Davis, Fung, Russell, Bunce, Reeder, Carragee, Simon, and Ron. **Noes:** None **Abstentions:** None **Absent:** Anderson, Tsao, and Freeman.	***The Open Minutes of the February 29th and April 4th meeting, FY17 Quality Meeting Calendar, and Environmental Policies were approved.***
5. REPORT ON BOARD ACTIONS	Chair Reeder reported that the Board is currently focused on the end of FY16 Budget, and asked the Committee members for confirmation of their service on	***None***

Agenda Item	Comments/Discussion	Approvals/Action
	the Committee for FY17. Chair Reeder asked for the following items to be agendized for further discussion at the next Quality Committee Meeting: • How much time to be spent on Quality at the Board Meetings? • FY17 Exception Report – Discussion of the dashboard and metrics. What to include or delete?	
6. PROPOSED FY17 COMMITTEE GOALS	Chair Reeder reviewed the Proposed FY17 Committee Goals to include #5 as requested by the Committee: 1. Review the hospital's organizational goals and scorecard and ensure that those metrics and goals are consistent with the strategic plan and set at an appropriate level as they apply to the Quality, Patient Care, and Patient Experience Committee. 2. Biannually review peer review process and medical staff credentialing process. 3. Develop a plan to review exceptions for goals that are being monitored by the management team and report those exceptions to the El Camino board of directors. 4. Review and oversee a plan to ensure the safety of the medication delivery process. The plan should include a global assessment of adverse events and it should include optimizations to the medication safety process using the new iCare tool. 5. Further investigate Patient and Family Centered Care and develop an implementation plan. Chair Reeder asked the Committee for any questions or feedback, and discussion ensued. The Committee briefly discussed the implementation of Patient and Family Centered Care (PFCC) using Planetree's baseline assessment during Q1 of FY 2017, building a roadmap by Q2 FY 2017, and aligning current efforts to increase patient-centrism. **Motion:** To approve the Proposed FY17 Committee Goals. **Movant:** Russell **Second:** Ron **Ayes:** Davis, Fung, Russell, Bunce, Reeder, Carragee, Simon, and Ron. **Noes:** None **Abstentions:** None **Absent:** Anderson, Tsao, and Freeman.	***The Proposed FY17 Committee Goals were approved.***

Agenda Item	Comments/Discussion	Approvals/Action
7. DRAFT FY17 ORGANIZATIONAL GOALS	Mick Zdeblick, Chief Operating Officer presented the Draft FY17 Organizational Goals to the Committee further detailed in the packet. He reiterated the Committee's agreement from the April 4th meeting with the addition of Option 2, Pain Management Indicator, to the Patient Safety & iCare section of the FY17 Organizational Goals. This would be in conjunction with the Length of Stay Reduction and Maintaining Current Readmissions Rates. Chair Reeder asked the Committee for feedback and discussion ensued. The Committee discussed pain reassessment as a process measure, and patient satisfaction scores of pain management as an outcome measure for a quality component of Patient Safety and iCare FY 17 Organizational Goals. The Committee generally agreed with the recommendation of Option 2, Pain Management Indicator, as an addition to the quality component of the FY 17 Organizational Goals. **Motion:** To approve for recommendation to the Board Option #2 - Pain Management Indicator as a Quality Component to the FY17 Organizational Goals. **Movant:** Simon **Second:** Fung **Ayes:** Davis, Fung, Russell, Bunce, Reeder, Carragee, Simon, and Ron. **Noes:** None **Abstentions:** None **Absent:** Anderson, Tsao, and Freeman.	***The Proposed Quality Goal # 2 was approved for recommendation to the Board.***
8. FY 16 EXCEPTION REPORT	Dr. Shin, Medical Director of Quality Assurance and Patient Safety, reviewed the exception report and noted that most metrics have remained stable or improved. He reported that Specimen labeling errors decreased to "zero" in February due to new hand-held technology and remain at a good level for the month of March. He noted that Surgical site infections also remained stable for the month of March, yet there was a spike in Patient Falls. There was no trend noticed among the Patient Falls. As a result, the departments have implemented increased staff and patient education, and awareness. Dr. Shin asked the Committee for feedback and discussion ensued.	***None***
9. PUBLIC COMMUNICATION	Chair Reeder asked for follow up information on a previous Public Communication in reference to a public guest who presented material to the Committee regarding an incident during her mother's ER visit	

Agenda Item	Comments/Discussion	Approvals/Action
	which led to urgent surgery. RJ Salus, Director of Patient Experience report that both he and Joy Pao, MD, Senior Director of Quality, Patient Safety, and Clinical Effectiveness, had reopened the case for further investigation. After further discovery, it was found that while it was an unfortunate case there was no indication of wrongdoing on the part of staff or hospital personnel.	
10. AGENDA ITEM 15 RECONVENE OPEN SESSION/ REPORT OUT	*Agenda Items 10 – 14 were reported in closed session.* Chair Reeder reported that Closed minutes of the February 29, 2016 and April 4, 2016 Quality Committee Meeting were approved. Chair Reeder also noted the upcoming Quality Committee Meeting dates	***None***
11. AGENDA ITEM 16 ADJOURNMENT	There being no further business to come before the Committee, the meeting was adjourned at 7:35p.m.	***None***

Attest as to the approval of the Foregoing minutes by the Quality Committee and by the Board of Directors of El Camino Hospital:

_____

Dave Reeder
Patient Experience Committee

Pacing Plan

QUALITY, PATIENT CARE AND PATIENT EXPERIENCE COMMITTEE
PROPOSED FY2017 PACING PLAN

FY2017: Q1		
JULY - No Meeting	**AUGUST 1, 2016**	**AUGUST 29, 2016 (*In place of Sept Meeting*)**
Routine Consent Calendar Items: ▪ Approval of Minutes ▪ FY 2017 Committee Goal Completion Status ▪ Pacing Plan ▪ Quality Council Minutes ▪ Patient Story ▪ Research Article	▪ Review and discuss quality summary with attention to risks and overall performance ▪ Corporate scorecard trending **Standing Agenda Items:** ▪ Consent Calendar ▪ Exception Report ▪ Patient Centered Care Plan ▪ Drilldown on Quality Program ▪ Red and Orange Alert as Needed **Info: Research Article & Patient Story**	▪ APPROVE FY 2017 Organizational Goals (Metrics) ▪ Approve FY 16 Organizational Goal Achievements ▪ Update on PaCT Plan ▪ Year-end review of RCA **Standing Agenda Items:** ▪ Consent Calendar ▪ Exception Report ▪ Patient Centered Care Plan ▪ Drilldown on Quality Program ▪ Red and Orange Alert as Needed **Info: Research Article & Patient Story**
FY2017: Q2		
OCTOBER 3, 2016	**NOVEMBER 2, 2016**	**DECEMBER 5, 2016**
▪ Safety Report for the Environment of Care (consent calendar) **Standing Agenda Items:** ▪ Consent Calendar ▪ Exception Report ▪ Patient Centered Care Plan ▪ Drilldown on Quality Program ▪ Red and Orange Alert as Needed **Info: Research Article & Patient Story**	▪ Committee Goals for FY17 Update ▪ ICare Update **Standing Agenda Items:** ▪ Consent Calendar ▪ Exception Report ▪ Patient Centered Care Plan ▪ Drilldown on Quality Program ▪ Red and Orange Alert as Needed **Info: Research Article & Patient Story**	▪ iCare Update **Standing Agenda Items:** ▪ Consent Calendar ▪ Exception Report ▪ Patient Centered Care Plan ▪ Drilldown on Quality Program ▪ Red and Orange Alert as Needed **Info: Research Article & Patient Story**

QUALITY, PATIENT CARE AND PATIENT EXPERIENCE COMMITTEE

PROPOSED FY2017 PACING PLAN

FY2017: Q3		
JANUARY 30, 2017	**FEBRUARY 27, 2017**	**MARCH – No Meeting**
▪ Patient and Family Centered Care ▪ Service Line Update ▪ Top Risk Case Review **Committee Members to complete on-line self-assessment tool.* **Standing Agenda Items:** ▪ Consent Calendar ▪ Exception Report ▪ Patient Centered Care Plan ▪ Drilldown on Quality Program ▪ Red and Orange Alert as Needed **Info: Research Article & Patient Story**	▪ Begin Development of FY 2018 Committee Goals (3-4 goals) ▪ Peer Review/Care Review Process ▪ Top Risk Case Review **Standing Agenda Items:** ▪ Consent Calendar ▪ Exception Report ▪ Patient Centered Care Plan ▪ Drilldown on Quality Program ▪ Red and Orange Alert as Needed **Info: Research Article & Patient Story**	
FY2017: Q4		
APRIL 3, 2017	**MAY 1, 2017**	**JUNE 5, 2017**
▪ Finalize FY 2018 Committee Goals ▪ Proposed Committee meeting dates for FY2017 ▪ Review DRAFT FY2018 Organizational Goals ▪ Annual Review of Committee Charter ▪ Top Risk Case Review **Standing Agenda Items:** ▪ Consent Calendar ▪ Exception Report ▪ Patient Centered Care Plan ▪ Drilldown on Quality Program ▪ Red and Orange Alert as Needed **Info: Research Article & Patient Story**	▪ Review DRAFT FY18 Organizational Goals (as needed) ▪ Set proposed committee meeting calendar for FY 2018 ▪ Review Committee Assessment Results ▪ Top Risk Case Review **Standing Agenda Items:** ▪ Consent Calendar ▪ Exception Report ▪ Patient Centered Care Plan ▪ Drilldown on Quality Program ▪ Red and Orange Alert as Needed **Info: Research Article & Patient Story**	▪ PFAC Update (6 months since Jan) ▪ Review and Discuss Self-Assessment Results ▪ Develop Pacing Calendar for FY18 ▪ Top Risk Case Review **Standing Agenda Items:** ▪ Consent Calendar ▪ Exception Report ▪ Patient Centered Care Plan ▪ Drilldown on Quality Program ▪ Red and Orange Alert as Needed **Info: Research Article & Patient Story**

Patient Story

El Camino Hospital
THE HOSPITAL OF SILICON VALLEY

2500 Grant Road
Mountain View, CA 94040-4378
Phone: 650-940-7000
www.elcaminohospital.org

Patient Story

This patient story had an unusual start as it begins outside the walls of El Camino Hospital… Our Interim Manager of CPWC and Hospital Supervisor, were out at a local restaurant – Los Altos Grill – for a casual dinner when a call for help came with "someone is down outside". They went outside to find a man in full cardiopulmonary arrest with bystander CPR in progress. As a seasoned CCU and ED nurse, the Manager assessed the situation and determined that the quality of the CPR was ineffective. She quickly intervened and began to implement CPR herself. The EMS unit responded and arrived quickly; they continued the resuscitative efforts and transported the gentleman to the nearest hospital – El Camino.

In the ED, the patient was first evaluated by Dr. Aaron Gladman with an immediate consult to Dr. Chad Rammohan for treatment of a STEMI. The patient became alert in the ED after restoration of spontaneous circulation and quickly proceeded to the Cath Lab for PCI. His cardiology team performed an immediate PCI which included aspiration thrombectomy and implantation of a stent to the LAD. The patient was sent to the CCU for continued management post procedure and then on to 3B Telemetry.

Of note is that the patient is visiting from France and speaks very little English. He has had his medical care and treatment plan interpreted via a close friend and via use of the ATT Language Line. His plan was to return to France post discharge and the Care Coordination Team is working diligently to make that happen safely. The patient is also being served by the Meds to Beds Program in order to ensure that all his discharge medications are available to him immediately at the time of discharge.

The patient is anxious to return to France to continue his recovery with his family. As I close this story, the patient has been on a smooth path of recovering and is being prepared for discharge possibly today!

Research Article

Original Investigation | CARING FOR THE CRITICALLY ILL PATIENT

Assessment of Clinical Criteria for Sepsis
For the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)

Christopher W. Seymour, MD, MSc; Vincent X. Liu, MD, MSc; Theodore J. Iwashyna, MD, PhD; Frank M. Brunkhorst, MD; Thomas D. Rea, MD, MPH; André Scherag, PhD; Gordon Rubenfeld, MD, MSc; Jeremy M. Kahn, MD, MSc; Manu Shankar-Hari, MD, MSc; Mervyn Singer, MD, FRCP; Clifford S. Deutschman, MD, MS; Gabriel J. Escobar, MD; Derek C. Angus, MD, MPH

IMPORTANCE The Third International Consensus Definitions Task Force defined sepsis as "life-threatening organ dysfunction due to a dysregulated host response to infection." The performance of clinical criteria for this sepsis definition is unknown.

OBJECTIVE To evaluate the validity of clinical criteria to identify patients with suspected infection who are at risk of sepsis.

DESIGN, SETTINGS, AND POPULATION Among 1.3 million electronic health record encounters from January 1, 2010, to December 31, 2012, at 12 hospitals in southwestern Pennsylvania, we identified those with suspected infection in whom to compare criteria. Confirmatory analyses were performed in 4 data sets of 706 399 out-of-hospital and hospital encounters at 165 US and non-US hospitals ranging from January 1, 2008, until December 31, 2013.

EXPOSURES Sequential [Sepsis-related] Organ Failure Assessment (SOFA) score, systemic inflammatory response syndrome (SIRS) criteria, Logistic Organ Dysfunction System (LODS) score, and a new model derived using multivariable logistic regression in a split sample, the quick Sequential [Sepsis-related] Organ Failure Assessment (qSOFA) score (range, 0-3 points, with 1 point each for systolic hypotension [≤100 mm Hg], tachypnea [≥22/min], or altered mentation).

MAIN OUTCOMES AND MEASURES For construct validity, pairwise agreement was assessed. For predictive validity, the discrimination for outcomes (primary: in-hospital mortality; secondary: in-hospital mortality or intensive care unit [ICU] length of stay ≥3 days) more common in sepsis than uncomplicated infection was determined. Results were expressed as the fold change in outcome over deciles of baseline risk of death and area under the receiver operating characteristic curve (AUROC).

RESULTS In the primary cohort, 148 907 encounters had suspected infection (n = 74 453 derivation; n = 74 454 validation), of whom 6347 (4%) died. Among ICU encounters in the validation cohort (n = 7932 with suspected infection, of whom 1289 [16%] died), the predictive validity for in-hospital mortality was lower for SIRS (AUROC = 0.64; 95% CI, 0.62-0.66) and qSOFA (AUROC = 0.66; 95% CI, 0.64-0.68) vs SOFA (AUROC = 0.74; 95% CI, 0.73-0.76; $P < .001$ for both) or LODS (AUROC = 0.75; 95% CI, 0.73-0.76; $P < .001$ for both). Among non-ICU encounters in the validation cohort (n = 66 522 with suspected infection, of whom 1886 [3%] died), qSOFA had predictive validity (AUROC = 0.81; 95% CI, 0.80-0.82) that was greater than SOFA (AUROC = 0.79; 95% CI, 0.78-0.80; $P < .001$) and SIRS (AUROC = 0.76; 95% CI, 0.75-0.77; $P < .001$). Relative to qSOFA scores lower than 2, encounters with qSOFA scores of 2 or higher had a 3- to 14-fold increase in hospital mortality across baseline risk deciles. Findings were similar in external data sets and for the secondary outcome.

CONCLUSIONS AND RELEVANCE Among ICU encounters with suspected infection, the predictive validity for in-hospital mortality of SOFA was not significantly different than the more complex LODS but was statistically greater than SIRS and qSOFA, supporting its use in clinical criteria for sepsis. Among encounters with suspected infection outside of the ICU, the predictive validity for in-hospital mortality of qSOFA was statistically greater than SOFA and SIRS, supporting its use as a prompt to consider possible sepsis.

JAMA. 2016;315(8):762-774. doi:10.1001/jama.2016.0288

Editorial page 757

Author Audio Interview at jama.com

Related articles pages 775 and 801

Supplemental content at jama.com

Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Christopher W. Seymour, MD, MSc, Departments of Critical Care Medicine and Emergency Medicine, University of Pittsburgh School of Medicine, Clinical Research, Investigation, and Systems Modeling of Acute Illness (CRISMA) Center, 3550 Terrace St, Scaife Hall, Ste 639, Pittsburgh, PA 15261 (seymourcw@upmc.edu).

Although common and associated with high morbidity and mortality,[1,2] sepsis and related terms remain difficult to define. Two international consensus conferences in 1991 and 2001 used expert opinion to generate the current definitions.[3,4] However, advances in the understanding of the pathobiology and appreciation that elements of the definitions may be outdated, inaccurate, or confusing prompted the European Society of Intensive Care Medicine and the Society of Critical Care Medicine to convene a Third International Consensus Task Force to reexamine the definitions. Like many syndromes, there is no "gold standard" diagnostic test for sepsis. Therefore, the task force chose several methods to evaluate the usefulness of candidate clinical criteria, including clarity, reliability (consistency and availability), content validity (biologic rationale and face validity), construct validity (agreement between similar measures), criterion validity (correlation with established measures and outcomes), burden, and timeliness. Unlike prior efforts, the task force used systematic literature reviews and empirical data analyses to complement expert deliberations.

EHR *electronic health record*

GCS *Glasgow Coma Scale*

ICU *intensive care unit*

LODS *Logistic Organ Dysfunction System*

qSOFA *quick Sequential [Sepsis-related] Organ Function Assessment*

SIRS *systemic inflammatory response syndrome*

SOFA *Sequential [Sepsis-related] Organ Function Assessment*

Based on clarity and content validity and after literature review and expert deliberation, the task force recommended elimination of the terms *sepsis syndrome*, *septicemia*, and *severe sepsis* and instead defined sepsis as "life-threatening organ dysfunction due to a dysregulated host response to infection."[5] Of note, the task force did not attempt to redefine infection. Rather, it next sought to generate recommendations for clinical criteria that could be used to identify sepsis among patients with suspected or confirmed infection. The purpose of this study was to inform this step by analyzing data from several large hospital databases to explore the construct validity and criterion validity of existing and novel criteria associated with sepsis.

Methods

This study was approved with waiver of informed consent by the institutional review boards of the University of Pittsburgh, Kaiser Permanente Northern California (KPNC), Veterans Administration (VA) Ann Arbor Health System, Washington State Department of Health, King County Emergency Medical Services (KCEMS), University of Washington, and Jena University Hospital.

Study Design, Setting, and Population

A retrospective cohort study was performed among adult encounters (age ≥18 years) with suspected infection. The primary cohort was all hospital encounters from 2010 to 2012 at 12 community and academic hospitals in the UPMC health care system in southwestern Pennsylvania. The cohort included all medical and surgical encounters in the emergency department, hospital ward, and intensive care unit (ICU). We created a random split sample (50/50) from the UPMC cohort, the derivation cohort for developing new criteria, and the validation cohort for assessment of new and existing criteria.

We also studied 4 external data sets: (1) all inpatient encounters at 20 KPNC hospitals from 2009 to 2013; (2) all encounters in 130 hospitals in the United States' VA system from 2008 to 2010; (3) all nontrauma, nonarrest emergency medical services records from 5 advanced life support agencies from 2009-2010 transported to 14 hospitals with community infection in King County, Washington (KCEMS)[6]; and (4) all patients from 2011-2012 at 1 German hospital enrolled with hospital-acquired infection in the ALERTS prospective cohort study.[7] These cohorts were selected because they included patient encounters from different phases of acute care (out of hospital, emergency department, hospital ward) and countries (United States and Germany) with different types of infection (community and nosocomial). The UPMC, KPNC, and VA data were obtained from the electronic health records (EHRs) of the respective health systems; KCEMS data were obtained from the administrative out-of-hospital record; and ALERTS data were collected prospectively by research coordinators.

Defining a Cohort With Suspected Infection

For EHR data (UPMC, KPNC, and VA), the first episode of suspected infection was identified as the combination of antibiotics (oral or parenteral) and body fluid cultures (blood, urine, cerebrospinal fluid, etc). We required the combination of culture and antibiotic start time to occur within a specific time epoch. If the antibiotic was given first, the culture sampling must have been obtained within 24 hours. If the culture sampling was first, the antibiotic must have been ordered within 72 hours. The "onset" of infection was defined as the time at which the first of these 2 events occurred (eAppendix in the Supplement). For non-EHR data in ALERTS, patients were included who met US Centers for Disease Control and Prevention definitions or clinical criteria for hospital-acquired infection more than 48 hours after admission as documented by prospective screening.[7] For non-EHR data in KCEMS, administrative claims identified infection present on admission (Angus implementation of infection using *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) diagnosis codes).[6]

Determining Clinical Criteria for Sepsis Using Existing Measures

In UPMC derivation and validation data, indicators were generated for each component of the systemic inflammatory response syndrome (SIRS) criteria[4]; the Sequential [Sepsis-related] Organ Failure Assessment (SOFA) score[8]; and the Logistic Organ Dysfunction System (LODS) score,[9] a weighted organ dysfunction score (**Table 1**). We used a modified version of the LODS score that did not contain urine output (because of poor accuracy in recording on hospital ward encounters), prothrombin, or urea levels. The maximum SIRS criteria, SOFA score, and modified LODS score were calculated for the time window from 48 hours before to 24 hours after the onset of infection, as well as on each calendar day. This window was used

Table 1. Variables for Candidate Sepsis Criteria Among Encounters With Suspected Infection

Systemic Inflammatory Response Syndrome (SIRS) Criteria (Range, 0-4 Criteria)	Sequential [Sepsis-related] Organ Failure Assessment (SOFA) (Range, 0-24 Points)	Logistic Organ Dysfunction System (LODS) (Range, 0-22 Points)[a]	Quick Sequential [Sepsis-related] Organ Failure Assessment (qSOFA) (Range, 0-3 Points)
Respiratory rate, breaths per minute	Pao_2/Fio_2 ratio	Pao_2/Fio_2 ratio	Respiratory rate, breaths per minute
White blood cell count, 10^9/L	Glasgow Coma Scale score	Glasgow Coma Scale score	Glasgow Coma Scale score
Bands, %	Mean arterial pressure, mm Hg	Systolic blood pressure, mm Hg	Systolic blood pressure, mm Hg
Heart rate, beats per minute	Administration of vasopressors with type/dose/rate of infusion	Heart rate, beats per minute	
Temperature, °C	Serum creatinine, mg/dL, or urine output, mL/d	Serum creatinine, mg/dL	
Arterial carbon dioxide tension, mm Hg	Bilirubin, mg/dL	Bilirubin, mg/dL	
	Platelet count, 10^9/L	Platelet count, 10^9/L	
		White blood cell count, 10^9/L	
		Urine output, L/d	
		Serum urea, mmol/L	
		Prothrombin time, % of standard	

Abbreviation: Fio_2, fraction of inspired oxygen.

[a] Measurement units for LODS variables per original description by Le Gall et al.[9]

for candidate criteria because organ dysfunction in sepsis may occur prior to, near the moment of, or after infection is recognized by clinicians or when a patient presents for care. Moreover, the clinical documentation, reporting of laboratory values in EHRs, and trajectory of organ dysfunction are heterogeneous across encounters and health systems. In a post hoc analysis requested by the task force, a change in SOFA score was calculated of 2 points or more from up to 48 hours before to up to 24 hours after the onset of infection.

Deriving Novel Clinical Criteria for Sepsis

In the derivation cohort (UPMC), new, simple criteria were developed according to the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD) recommendations.[10] This entailed 2 steps: (1) assessing candidate variable quality and frequency of missing data and (2) developing a parsimonious model and simple point score.[3,8,11] Because of the subjective nature and complexity of variables in existing criteria, we sought a simple model that could easily be used by a clinician at the bedside.

Based on the assumption that hospital mortality would be far more common in encounters with infected patients who have sepsis than in those who do not, all continuous variables were dichotomized by defining their optimal cutoffs using the minimum 0/1 distance on the area under the receiver operating characteristic curve (AUROC) for in-hospital mortality.[12] Cutoffs were rounded to the nearest integer, and standard single-value imputation was used, with normal value substitution if variables were missing. The latter approach is standard in clinical risk scores[8,13,14] and mirrors how clinicians would use the score at the bedside. Multiple logistic regression was used with robust standard errors and forward selection of candidate variables using the Bayesian information criterion to develop the "quick SOFA" (qSOFA) model. The Bayesian information criterion is a likelihood-based stepwise approach that retains variables that improve the model's overall ability to predict the outcome of interest while incorporating a penalty for including too many variables. Favoring simplicity over accuracy, a point score of 1 was assigned to each variable in the final model, irrespective of the regression coefficients. Model calibration was assessed by comparing clinically relevant differences in observed vs expected outcomes, as the Hosmer-Lemeshow test may be significant due to large sample sizes.[15]

Assessments of Candidate Clinical Criteria

The test:retest or interrater reliability of individual elements was not assessed, in part because most elements have known reliability. However, the frequency of missing data was determined for each element because more common missing data for individual elements will potentially affect the reliability of integrated scores such as the SOFA score. Construct validity was determined by examining the agreement between different measures analogous to the multitrait-multimethod matrix approach of Campbell and Fiske, using the Cronbach α to measure agreement or commonality.[16,17] Confidence intervals were generated with the bootstrap method (100 replications).

Criterion validity was assessed using the predictive validity of the candidate criteria with outcomes (primary outcome: in-hospital mortality; secondary outcome: in-hospital mortality or intensive care unit [ICU] length of stay ≥3 days). These outcomes are objective, easily measured across multiple hospitals in US/non-US cohorts, and are more likely to be present in encounters with patients with sepsis than those with uncomplicated infection. To measure predictive validity, a baseline risk model was created for in-hospital mortality based on preinfection criteria using multivariable logistic regression. The baseline model included age (as a fractional polynomial), sex, race/ethnicity (black, white, or other), and the weighted Charlson comorbidity score (as fractional polynomial) as a measure of chronic comorbidities.[18,19] Race/ethnicity was derived from UPMC registration system data using fixed categories consistent with the Centers for Medicare & Medicaid Services EHR

Table 2. Summary of Data Sets

Characteristics	UPMC[a]	KPNC	VA	ALERTS	KCEMS
Years of cohort	2010-2012	2009-2013	2008-2010	2011-2012	2009-2010
No. of hospitals	12	20	130	1	14
Total No. of encounters	1 309 025	1 847 165	1 640 543	38 098	50 727
Data source and study design	Retrospective study of EHRs	Retrospective study of EHRs	Retrospective study of EHRs	Prospective cohort study	Retrospective study of administrative records
Setting	Integrated health system in southwestern Pennsylvania	Integrated health system in northern California	All hospitals in the US VA system	Single university hospital, Jena, Germany	Out-of-hospital records from integrated emergency medical services system in King County, Washington
Definition of suspected infection	Combination of body fluid culture and nonprophylactic antibiotic administration in the EHR[b]	Combination of body fluid culture and nonprophylactic antibiotic administration in the EHR[b]	Combination of body fluid culture and nonprophylactic antibiotic administration in the EHR[b]	CDC criteria for hospital-acquired infections[c]	*ICD-9-CM* codes for infection, with present-on-admission indicators[d]
No. with suspected infection (% of total)	148 907 (11)	321 380 (17)	377 325 (23)	1186 (3)	6508 (13)
Location at onset of infection, No. (%) infected					
Intensive care unit	15 768 (11)	7031 (2)	73 264 (19)	300 (25)	0
Outside of intensive care unit	133 139 (89)	314 349 (98)	304 061 (81)	886 (75)	6508 (100)
In-hospital mortality, No. (%) infected[e]	6347 (4)	16 092 (5)	22 593 (6)	210 (18)	700 (11)

Abbreviations: KCEMS, King County Emergency Medical Services; KPNC, Kaiser Permanente Northern California; EHR, electronic health record; *ICD-9-CM*, *International Classification of Diseases, Ninth Revision, Clinical Modification*; VA, Veterans Administration.

[a] Referred to as the primary cohort, further divided into derivation (n = 74 453) and validation (n = 74 454) cohorts.

[b] See the eAppendix in the Supplement for details about time windows specified between body fluid cultures and antibiotic administration.

[c] Patients were enrolled in ALERTS if the in-hospital stay was longer than 48 hours and in-person prospective screening revealed hospital-acquired infection criteria according to Centers for Disease Control and Prevention (CDC) guidelines.[7]

[d] Required Angus implementation *ICD-9-CM* code for infection accompanied by present-on-admission indicator, as previously validated.[6]

[e] Among UPMC encounters, 28 286 (19%) had in-hospital mortality plus intensive care unit length of stay of 3 days or longer.

meaningful use data set.[20] Race/ethnicity was included in the baseline model because of its described association with the incidence and outcomes of sepsis.[21]

Encounters were then divided into deciles of baseline risk. Within each decile, the rate of in-hospital mortality ± ICU length of stay of 3 days or longer was determined comparing encounters with infection with 2 or more SIRS, SOFA, LODS, and qSOFA points vs encounters with less than 2 criteria of the same score (threshold of 2 points was determined a priori). Model discrimination was assessed with the AUROC for each outcome using the continuous score(s) alone, then added to the baseline risk model. Analyses were separately performed in ICU encounters and non-ICU encounters at the onset of infection. New, simple criteria in external data sets were assessed in both ICU and non-ICU encounters.

Because serum lactate is widely used as a screening tool in sepsis,[22] how its measurement would improve predictive validity of new criteria was assessed in post hoc analyses. Evaluation included qSOFA models that did and did not include serum lactate at thresholds of 2.0, 3.0, and 4.0 mmol/L (18, 27, and 36 mg/dL) and as a continuous variable.[23] Only KPNC data were used for these analyses because an ongoing quality improvement program promoting frequent serum lactate measurement across the health system minimized confounding by indication.[24]

Several sensitivity analyses were performed to assess robustness of the findings. These included a variety of restrictions to the cohort, more rigorous definitions of suspected or presumed infection, alternative ways to measure clinical variables (such as altered mentation in the EHR), and multiple imputation analyses for missing data. There are many possible time windows for criteria around the onset of infection. A variety of windows differing from the primary analysis were tested, including (1) 3 hours before to 3 hours after; (2) 12 hours before to 12 hours after; and (3) restricting to only the 24 hours after the onset of infection. Detailed descriptions are in the Supplement.

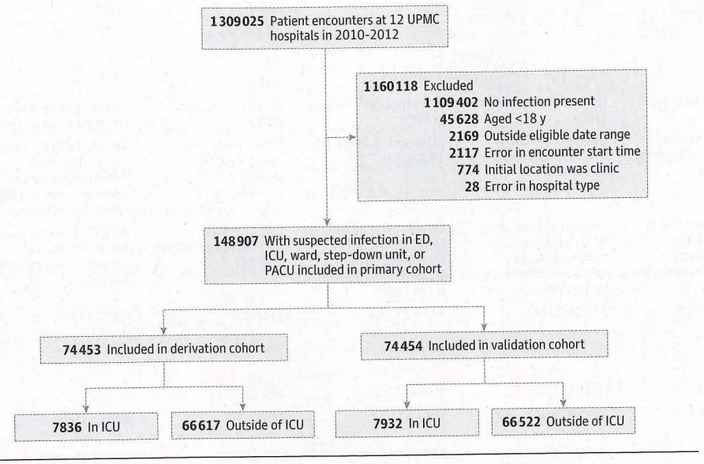
All analyses were performed with STATA software, version 11.0 (Stata Corp). All tests of significance used a 2-sided $P \le .05$. We considered AUROCs to be poor at 0.6 to 0.7, adequate at 0.7 to 0.8, good at 0.8 to 0.9, and excellent at 0.9 or higher.[25]

Results

Cohorts and Encounter Characteristics

At 177 hospitals in 5 US and non-US data sets between 2008 and 2013 (**Table 2**), 4 885 558 encounters were studied. In the primary cohort of 1 309 025 records (UPMC derivation and validation; **Figure 1**), 148 907 encounters had suspected infection, most often presenting outside of the ICU (n = 133 139 [89%]). As shown in **Table 3**, first infection was commonly suspected within 48 hours of admission (86%), most often presenting in the emergency department (44%) compared with the ward (33%) or ICU (11%), and mortality was low (4%). The

Figure 1. Accrual of Encounters for Primary Cohort



ED indicates emergency department; ICU, intensive care unit; PACU, postanesthesia care unit.

median time from the start of the encounter until the onset of suspected infection (defined as culture or antibiotics order) was 4.2 hours (interquartile range, 1.6-19.2 hours). In KPNC hospitals (eTable 1 in the Supplement), first suspected infections occurred outside the ICU (98%) with similar mortality (5%) and proportion identified within 48 hours of admission (81%). Serum lactate was measured in 57% of suspected infection encounters in KPNC hospitals compared with less than 10% in the other cohorts. In VA hospitals, encounters with suspected infection had similar mortality (6%) but were more likely to be first identified in the ICU (19%). A minority of first infection episodes occurred following surgery, and positive blood cultures were found in 5% to 19% of encounters. In the baseline risk model, using only demographics and comorbidities, there was a 10-fold variation for in-hospital mortality across deciles of baseline risk, ranging from 0.7% to 8% (eFigure 1 in the Supplement).

Frequency of Missing Data Among Clinical and Laboratory Variables

In the UPMC derivation cohort, SIRS criteria and selected laboratory tests in SOFA and LODS were variably measured in the EHR near the onset of infection (eFigure 2 in the Supplement). Tachycardia, tachypnea, and hypotension, although present in less than 50% of encounters, were the most common clinical abnormalities. Encounters in the ICU were more likely to have SIRS and SOFA variables measured and values were more likely to be abnormal. For encounters outside of the ICU, laboratory data were less available, with total bilirubin, ratio of Pao_2 to fraction of inspired oxygen, and platelet counts absent in 62%, 74%, and 15% of encounters, respectively.

Performance of Existing Criteria in the ICU in the UPMC Cohort

Among ICU encounters with suspected infection in the UPMC validation cohort (n = 7932 [11%]), most had 2 or more LODS points (88%), SOFA points (91%), or SIRS criteria (84%) near the time of suspected infection, with mortality rates of 18% for all scores at this threshold (**Figure 2** and eFigure 3 in the Supplement). SOFA and LODS had greater statistical agreement with each other (α = 0.87; 95% CI, 0.87-0.88) but lower with SIRS (α = 0.43 [95% CI, 0.41-0.46] for SOFA; α = 0.41 [95% CI, 0.38-0.43] for LODS) (**Figure 3**). Encounters in the ICU with 2 or more vs less than 2 SIRS criteria were compared within decile of baseline risk and observed a 1- to 2-fold increased rate of hospital mortality compared with a 3- to 11-fold increase in mortality comparing those with 2 or more vs less than 2 SOFA points (**Figure 4**). The fold change in the LODS score was even greater than that for SOFA.

In the ICU, the predictive validity for hospital mortality using SOFA (AUROC = 0.74; 95% CI, 0.73-0.76) and LODS (AUROC = 0.75; 95% CI, 0.73-0.76; $P = .20$) were not statistically different but were statistically greater than that of SIRS (AUROC = 0.64; 95% CI, 0.62-0.66; $P < .001$ for either LODS or SOFA vs SIRS) (Figure 3 and eFigure 4 and eTable 2 in the Supplement). Results for a change in SOFA of 2 points or more were significantly greater compared with SIRS (AUROC = 0.70; 95% CI, 0.68-0.71; $P < .001$ vs SIRS criteria). The SOFA score was 2 or more in 98% of decedents (95% CI, 97%-99%); among survivors, the SOFA score was less than 2 in 10% (95% CI, 10%-11%). These proportions were similar for a LODS threshold of 2 or 3 (eTable 3 in the Supplement). Among decedents, 2 or more SIRS criteria were present in 91% (95% CI, 89%-92%). Results were consistent for the combined outcome (eFigures 5 and 6 in the Supplement).

Performance of Existing Criteria Outside the ICU in the UPMC Cohort

For encounters with suspected infection outside of the ICU (n = 66 522 [89% of cohort]), 20 130 (30%) had no SIRS criteria, 27 560 (41%) had no SOFA points, and 29 789 (45%) had no LODS points (Figure 2). Agreement followed a pattern similar to that in the ICU encounters but with generally smaller Cronbach α statistics (Figure 3). Over deciles of baseline risk (Figure 4), encounters with 2 or more vs less than 2 SIRS criteria had a 2- to 7-fold increase in the rate of in-hospital mortality compared with up to an 80-fold change for 2 or more vs less than 2 SOFA points.

Table 3. Characteristics of Encounters With Suspected Infection in the Primary Cohort at 12 UPMC Hospitals From 2010 to 2012 (N = 148 907)[a]

Variables	All Encounters	Derivation Cohort		Validation Cohort	
		ICU Encounters	Encounters Outside of ICU	ICU Encounters	Encounters Outside of ICU
Total encounters with suspected infection, No.	148 907	7836	66 617	7932	66 522
Infection type, No. (%)[b]					
Presumed	112 850 (76)	7282 (93)	49 287 (74)	7351 (93)	48 930 (74)
Confirmed bacteremia	6875 (5)	646 (8)	2780 (4)	652 (8)	2797 (4)
Age, mean (SD), y	61 (19)	62 (17)	61 (20)	62 (17)	60 (20)
Male, No. (%)	63 311 (43)	4192 (54)	27 418 (41)	4255 (54)	27 446 (41)
Race/ethnicity, No. (%)					
White	113 029 (76)	5774 (74)	50 843 (76)	5881 (74)	50 531 (76)
Black	20 892 (14)	808 (10)	9552 (14)	777 (10)	9755 (15)
Other	14 986 (10)	1254 (16)	6222 (9)	1274 (16)	6236 (9)
Weighted Charlson comorbidity index, median (IQR)	1 (0-2)	1 (0-2)	1 (0-2)	1 (0-2)	1 (0-2)
Surgery prior to infection suspected, No. (%)	17 327 (12)	2153 (27)	6517 (10)	2171 (27)	6486 (10)
Onset of infection within 48 h of admission, No. (%)	128 358 (86)	6022 (77)	58 187 (87)	5993 (76)	58 156 (87)
Unit location at time infection suspected, No. (%)					
Emergency department	65 934 (44)		32 902 (50)		33 032 (50)
Ward	49 354 (33)		24 787 (37)		24 567 (37)
ICU	15 768 (11)	7836 (100)		7932 (100)	
Postacute care unit or procedure unit	1965 (1)		960 (1)		1005 (2)
Step-down unit	15 662 (11)		7855 (12)		7807 (12)
Other or missing data	224 (<1)		113 (<1)		111 (<1)
SIRS near onset of suspected infection[c]					
Mean (SD)	1.3 (1.1)	2.5 (1.0)	1.2 (1.1)	2.5 (1.0)	1.2 (1.0)
Median (IQR)	1 (0-2)	3 (2-3)	1 (0-2)	3 (2-3)	1 (0-2)
SOFA near onset of suspected infection[d]					
Mean (SD)	2.0 (2.7)	6.3 (4.0)	1.4 (1.9)	6.2 (3.9)	1.4 (2.0)
Median (IQR)	1 (0-3)	6 (3-9)	1 (0-2)	6 (3-9)	1 (0-2)
LODS near onset of suspected infection[e]					
Mean (SD)	2.0 (2.8)	6.3 (3.9)	1.5 (2.1)	6.3 (3.8)	1.5 (2.1)
Median (IQR)	1 (0-3)	6 (4-9)	1 (0-3)	6 (3-9)	1 (0-3)
Serum lactate measured on day of infection, No. (%)	13 492 (9)	3187 (41)	3611 (5)	3067 (39)	3627 (5)
Serum lactate ≥2.0 mmol/L, No. (%)	6177 (4)	1643 (21)	1444 (2)	1555 (20)	1535 (2)
ICU admission, No. (%)	37 528 (25)	7836 (100)	10 935 (16)	7932 (100)	10 825 (16)
Hospital length of stay, median (IQR), d	6 (3-10)	12 (7-20)	6 (3-9)	12 (7-19)	6 (3-9)
Hospital mortality, No. (%)	6347 (4)	1298 (17)	1874 (3)	1289 (16)	1886 (3)

SI conversion: To convert serum lactate to milligrams per deciliter, divide by 0.111.

Abbreviations: ICU, intensive care unit; IQR, interquartile range; LODS, Logistic Organ Dysfunction System; SIRS, systemic inflammatory response syndrome; SOFA, Sequential [Sepsis-related] Organ Function Assessment.

[a] Data derived from electronic health records.

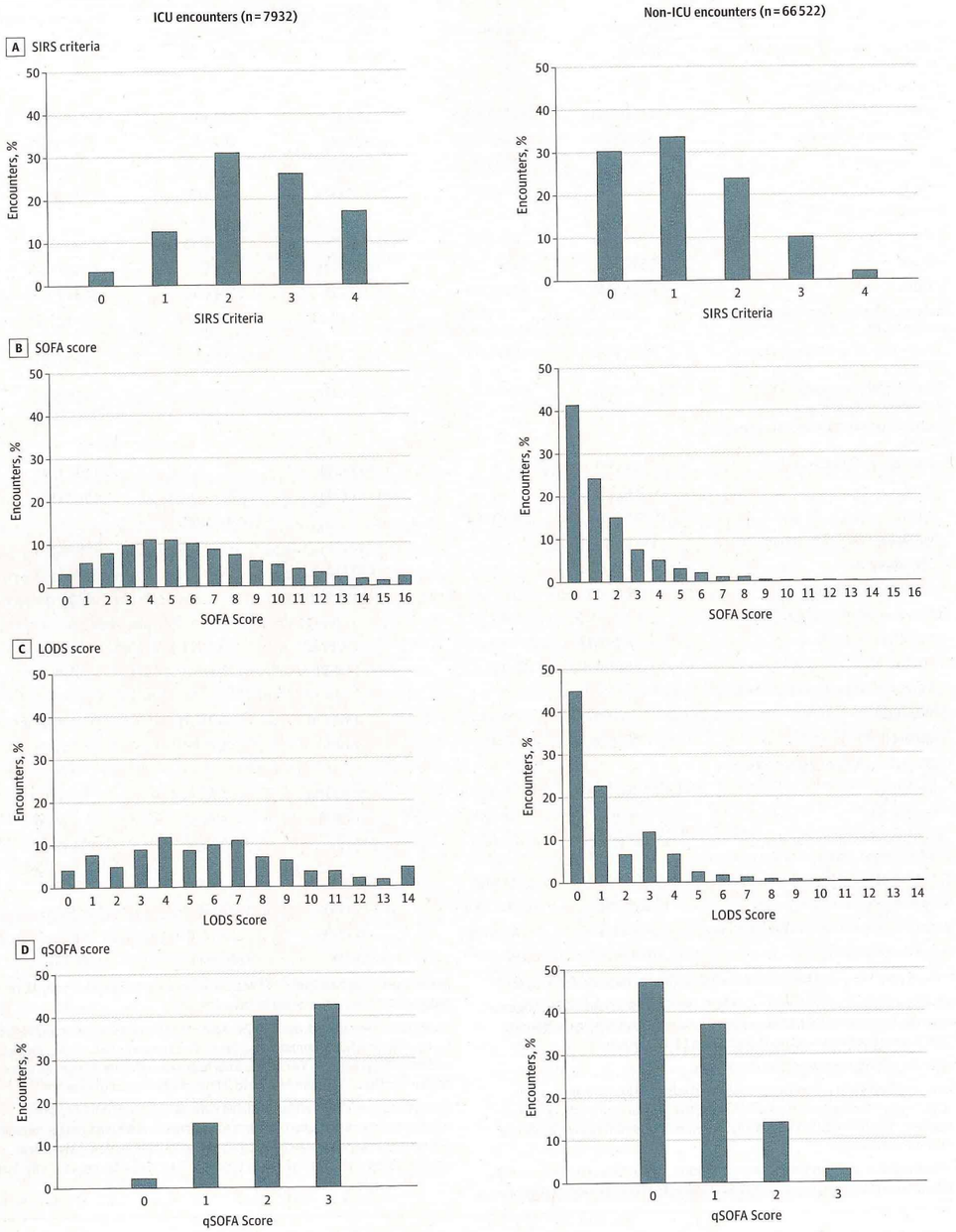
[b] Presumed infection is a subset of suspected infection in which encounters received 2 or more doses of an antibiotic within 96 hours of onset of infection. Confirmed bacteremia is a subset among which blood cultures were positive during the encounter.

[c] SIRS criteria range from 0 to 4, wherein 1 point is given for perturbations of the following variables: respiratory rate, white blood cell count/bands, heart rate, and temperature (see Table 1).[29] Maximum score is determined from 48 hours before to 24 hours after onset of infection.

[d] The SOFA score ranges from 0 to 24, where 0 to 4 points are assigned for 1 of 6 organ dysfunctions: hematologic, hepatic, respiratory, neurologic, cardiac, and renal.[8] A greater score corresponds to greater severity. Maximum score is determined from 48 hours before to 24 hours after onset of infection.

[e] The LODS score, modified for available data, ranges from 0 to 22 points, wherein points are assigned with increasing severity to hematologic, hepatic, pulmonary, neurologic, cardiovascular, and renal dysfunction.[9] Maximum score is determined from 48 hours before to 24 hours after onset of infection.

Figure 2. Distribution of Patient Encounters Over SIRS Criteria and SOFA, LODS, and qSOFA Scores Among ICU Patients and Non-ICU Patients With Suspected Infection in the UPMC Validation Cohort (N = 74 454)



ICU indicates intensive care unit; LODS, Logistic Organ Dysfunction System; qSOFA, quick Sequential [Sepsis-related] Organ Function Assessment; SIRS, systemic inflammatory response syndrome; SOFA, Sequential [Sepsis-related] Organ Function Assessment. The x-axis is the score range, with LODS truncated at 14 points (of 22 points) and SOFA truncated at 16 points (of 24 points) for illustration.

Figure 3. Area Under the Receiver Operating Characteristic Curve and 95% Confidence Intervals for In-Hospital Mortality of Candidate Criteria (SIRS, SOFA, LODS, and qSOFA) Among Suspected Infection Encounters in the UPMC Validation Cohort (N = 74 454)

A ICU encounters (n = 7932)

	SIRS	SOFA	LODS	qSOFA
SIRS	**0.64 (0.62-0.66)**	0.43 (0.41-0.46)	0.41 (0.38-0.43)	0.46 (0.43-0.48)
SOFA	<.001	**0.74 (0.73-0.76)**	0.87 (0.87-0.88)	0.65 (0.63-0.66)
LODS	<.001	0.20	**0.75 (0.73-0.76)**	0.76 (0.75-0.77)
qSOFA	.01	<.001	<.001	**0.66 (0.64-0.68)**

B Non-ICU encounters (n = 66 522)

	SIRS	SOFA	LODS	qSOFA
SIRS	**0.76 (0.75-0.77)**	0.52 (0.51-0.53)	0.43 (0.42-0.44)	0.61 (0.61-0.62)
SOFA	<.001	**0.79 (0.78-0.80)**	0.80 (0.80-0.81)	0.59 (0.58-0.60)
LODS	<.001	<.001	**0.81 (0.80-0.82)**	0.68 (0.68-0.69)
qSOFA	<.001	<.001	.72	**0.81 (0.80-0.82)**

ICU indicates intensive care unit; LODS, Logistic Organ Dysfunction System; qSOFA, quick Sequential [Sepsis-related] Organ Function Assessment; SIRS, systemic inflammatory response syndrome; SOFA, Sequential [Sepsis-related] Organ Function Assessment. The area under the receiver operating characteristic curve (AUROC) data in the blue-shaded diagonal cells derive from models that include baseline variables plus candidate criteria. For comparison, the AUROC of the baseline model alone is 0.58 (95% CI, 0.57-0.60) in the ICU and 0.69 (95% CI, 0.68-0.70) outside of the ICU. Below the AUROC data cells are *P* values for comparisons between criteria, while above the AUROC data cells are Cronbach α data (with bootstrap 95% confidence intervals), a measure of agreement.

The discrimination of hospital mortality using SOFA (AUROC = 0.79; 95% CI, 0.78-0.80), LODS (AUROC = 0.82; 95% CI, 0.81-0.83), or change in SOFA (AUROC = 0.79; 95% CI, 0.78-0.79) scores was significantly greater compared with SIRS criteria (AUROC = 0.76; 95% CI, 0.75-0.77; $P < .01$ for all) (Figure 3 and eFigure 4 and eTable 2 in the Supplement). Sixty-eight percent (95% CI, 66%-70%) of decedents had 2 or more SOFA points and 67% (95% CI, 66%-67%) of survivors had less than 2 SOFA points. In comparison, only 55% (95% CI, 53%-57%) of decedents had 2 or more SIRS criteria, whereas 81% of survivors had less than 2 SIRS criteria (95% CI, 81%-82%) (eTable 3 in the Supplement). Results were consistent for the combined outcome (eFigures 5 and 6 in the Supplement).

Performance of New, Simple Criteria

The final qSOFA model included Glasgow Coma Scale (GCS) score of 13 or less, systolic blood pressure of 100 mm Hg or less, and respiratory rate of 22/min or more (1 point each; score range, 0-3) **(Table 4)**. Most encounters with infection (73%-90%) had less than 2 qSOFA points, and mortality ranged from 1% to 24% over the score range (eFigure 7 in the Supplement). Calibration plots showed similar observed vs expected proportion of deaths across qSOFA scores (eFigure 8 in the Supplement). The qSOFA agreed reasonably well with both SOFA (α = 0.73; 95% CI, 0.73-0.74) and LODS (α = 0.79; 95% CI, 0.78-0.79) and, unlike SOFA and LODS, also agreed more with SIRS (α = 0.69; 95% CI, 0.68-0.69) (Figure 3). The 24% of encounters with infection with 2 or 3 qSOFA points accounted for 70% of deaths, 70% of deaths or ICU stays of 3 days or longer.

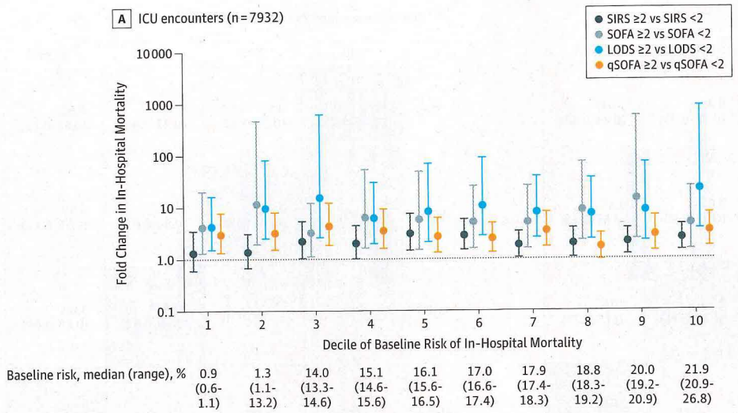
In the ICU, the predictive validity for hospital mortality of qSOFA above baseline risk (AUROC = 0.66; 95% CI, 0.64-0.68) was statistically greater than SIRS criteria ($P = .01$) but significantly less than SOFA ($P < .001$) (Figure 3 and eFigure 4 and eTable 2 in the Supplement). Outside of the ICU, there was a 3- to 14-fold increase in the rate of hospital mortality across the entire range of baseline risk comparing those with 2 or more vs less than 2 qSOFA points (Figure 4). The predictive validity of qSOFA was good for in-hospital mortality (AUROC = 0.81; 95% CI, 0.80-0.82), was not statistically different from LODS ($P = .77$) and was statistically greater than SOFA or change in SOFA score ($P < .001$ for both) (Figure 3, Figure 4, and eFigure 4 and eTable 2 in the Supplement). Seventy percent (95% CI, 69%-72%) of decedents had 2 or more qSOFA points and 78% (95% CI, 78%-79%) of survivors had less than 2 qSOFA points (eTable 3 in the Supplement). Results were consistent for the combined outcome (eFigures 5 and 6 in the Supplement).

Among encounters with 2 or more qSOFA points, 75% also had 2 or more SOFA points (eFigure 9 in the Supplement). This proportion was greater among decedents (89%) and ICU encounters (94%) and increased as the time window for evaluation was extended to 48 hours (90%) and 72 hours (92%) after the onset of infection.

External Data Sets

The qSOFA was tested in 4 external data sets comprising 706 399 patient encounters at 165 hospitals in out-of-hospital (n = 6508), non-ICU (n = 619 137), and ICU (n = 80 595)

Figure 4. Fold Change in Rate of In-Hospital Mortality (Log Scale) Comparing Encounters With ≥2 vs <2 Criteria for Each Decile of Baseline Risk in the UPMC Validation Cohort (N = 74 454)



ICU indicates intensive care unit; LODS, Logistic Organ Dysfunction System; qSOFA, quick Sequential [Sepsis-related] Organ Function Assessment; SIRS, systemic inflammatory response syndrome; SOFA, Sequential [Sepsis-related] Organ Function Assessment. Panel A shows ICU encounters comparing fold change for SIRS, SOFA, LODS, and qSOFA. Panel B shows non-ICU encounters. Medians and ranges of baseline risk of in-hospital mortality within decile shown are below the x-axis.

Interpretive example: The x-axis divides the cohort into deciles of baseline risk, determined by age, sex, comorbidities, and race/ethnicity. For a young woman with no comorbidities (panel A, decile 2) admitted to the ICU with pneumonia, her chance of dying in the hospital is 10-fold greater if she has 3 SOFA points compared with 1 SOFA point. On the other hand, she has only a small increase in the chance of dying if she has 3 SIRS criteria compared with 1 SIRS criterion. For an older woman with chronic obstructive pulmonary disease admitted to the ward with pneumonia (panel B, decile 6), her chance of dying in the hospital is 7-fold higher if she has 3 qSOFA points compared with 1 qSOFA point. On the other hand, she has only a 3-fold increase in odds of dying if she has 3 SIRS criteria compared with 1 SIRS criterion.

settings (eTable 1 in the Supplement). Among encounters with community infection (KCEMS) or hospital-acquired infection (ALERTS), qSOFA had consistent predictive validity (AUROC = 0.71 and 0.75, respectively) (**Table 5** and eFigure 4 in the Supplement). Results were similar in the VA data set (AUROC = 0.78), in which no GCS data were available.

Serum Lactate

During model building in UPMC data, serum lactate did not meet prespecified statistical thresholds for inclusion in qSOFA. In KPNC data, the post hoc addition of serum lactate levels of 2.0 mmol/L (18 mg/dL) or more to qSOFA (revised to a 4-point score with 1 added point for elevated serum lactate level) statistically changed the predictive validity of qSOFA (AUROC with lactate = 0.80; 95% CI, 0.79-0.81 vs AUROC without lactate = 0.79; 95% CI, 0.78-0.80; $P < .001$) (eFigure 10A in the Supplement). As shown in eTable 4 in the Supplement, this was consistent for higher thresholds of lactate (3.0 mmol/L [27 mg/dL], 4.0 mmol/L [36 mg/dL]) or using a continuous distribution ($P < .001$). However, the clinical relevance was small as the rates of in-hospital mortality comparing encounters with 2 or more vs less than 2 points across deciles of risk were numerically similar whether or not serum lactate was included in qSOFA (eFigure 10B in the Supplement).

Among encounters with 1 qSOFA point but also a serum lactate level of 2.0 mmol/L or more, in-hospital mortality was higher than that for encounters with serum lactate levels of less than 2.0 mmol/L across the range of baseline risk. The rate of in-hospital mortality was numerically similar to that for encounters with 2 qSOFA points using the model without serum lactate (eFigure 11 in the Supplement). Because serum lactate levels are widely used for screening at many centers, the distribution of qSOFA scores over strata of serum lactate level was investigated. The qSOFA consistently identified higher-risk encounters even at varying serum lactate levels (eFigure 12 in the Supplement).

Table 4. Odds Ratios for Baseline Model and qSOFA Variables for In-Hospital Mortality in the UPMC Derivation Cohort (N = 74 453)

	Total No. With Categorical Variable	Deaths, No. (% of Total)	In-Hospital Mortality, Adjusted Odds Ratio (95% CI)
Baseline risk model[a]			
Age, y[b]			1.03 (1.03-1.03)
Charlson comorbidity index[b]			1.13 (1.11-1.15)
Race/ethnicity			
White	56 617	2470 (4)	1 [Reference]
Black	10 360	319 (3)	0.89 (0.79-1.01)
Other	7476	383 (5)	1.37 (1.22-1.53)
Male			
No	42 843	1467 (3)	1 [Reference]
Yes	31 610	1705 (5)	1.56 (1.45-1.68)
qSOFA model[c]			
Respiratory rate, /min			
<22	45 398	676 (1)	1 [Reference]
≥22	29 055	2496 (9)	3.18 (2.89-3.50)
Systolic blood pressure, mm Hg			
>100	44 669	789 (2)	1 [Reference]
≤100	29 784	2383 (8)	2.61 (2.40-2.85)
Altered mental status, Glasgow Coma Scale score			
14-15	66 879	1677 (3)	1 [Reference]
≤13	7574	1495 (20)	4.31 (3.96-4.69)

Abbreviations: qSOFA, quick Sequential [Sepsis-related] Organ Failure Assessment; UPMC, University of Pittsburgh School of Medicine.

[a] Fully parameterized using fractional polynomials in final analyses.

[b] Odds ratios correspond to a comparison between encounters separated by 1 unit change in age or Charlson comorbidity index score.

[c] Multivariable logistic regression model of qSOFA variables illustrates their association with in-hospital mortality. The odds ratios compare groups of encounters with vs without the specified criteria.

Table 5. AUROCs for In-Hospital Mortality for qSOFA in External Data Sets

Data Set and Infection Type	No. of Patients With Suspected Infection	AUROC (95% CI)	
		Baseline Model	Baseline Model + qSOFA
KPNC (all suspected infections)	321 380	0.67 (0.67-0.67)	0.78 (0.78-0.78)
ICU patients	7031	0.64 (0.62-0.66)	0.72 (0.70-0.73)
Non-ICU patients	314 349	0.68 (0.67-0.68)	0.78 (0.78-0.79)
VA (all suspected infections)[a]	377 325	0.73 (0.73-0.74)	0.78 (0.78-0.79)
ALERTS (hospital-acquired infections)	1186	0.55 (0.51-0.60)	0.73 (0.69-0.77)
KCEMS (community-acquired infections)	6508	0.59 (0.57-0.62)	0.71 (0.69-0.73)

Abbreviations: AUROC, area under the receiver operating characteristic curve; ICU, intensive care unit; KCEMS, King County Emergency Medical Services; KPNC, Kaiser Permanente Northern California; qSOFA, quick Sequential [Sepsis-related] Organ Function Assessment; VA, Veterans Administration.

[a] The VA data did not include Glasgow Coma Scale scores; the qSOFA is a modified 2-variable model (systolic blood pressure and respiratory rate only), with a range from 0 to 2 points.

Time Windows for Measuring qSOFA Variables

When qSOFA variables were measured in the time window from 3 hours before/after or 12 hours before/after the onset of infection in KPNC data (eTable 4 in the Supplement), results were not significantly different from the original model ($P = .13$ for 3 hours and $P = .74$ for 12 hours). When qSOFA variables were restricted to only the 24-hour period after the onset of infection, the predictive validity for in-hospital mortality was significantly greater (AUROC = 0.83; 95% CI, 0.83-0.84; $P < .001$) compared with the primary model.

Additional sensitivity analyses are shown in eTable 4 in the Supplement. The predictive validity of qSOFA was not significantly different when using more simple measures, such as any altered mentation (GCS score <15 [$P = .56$] compared with the model with GCS score ≤13). The predictive validity was also not significantly different when performed after multiple imputation for missing data and in a variety of a priori subgroups.

Discussion

The Third International Consensus Definitions Task Force defined sepsis as a "life-threatening organ dysfunction due to a dysregulated host response to infection."[5] In the absence of a gold-standard test for sepsis, several domains of validity and usefulness were used to assess potential clinical criteria to operationalize this definition. Among encounters with suspected infection in the ICU (Figure 3), SOFA and LODS had statistically greater predictive validity compared with SIRS criteria. Outside of the ICU, a simple model (qSOFA) of altered menta-

tion, low systolic blood pressure, and elevated respiratory rate had statistically greater predictive validity than the SOFA score (Figure 3). The predictive validity of qSOFA was robust to evaluation under varied measurement conditions, in academic and community hospitals, in international locations of care, for community and hospital-acquired infections, and after multiple imputation for missing data. It was, however, statistically inferior compared with SOFA for encounters in the ICU and has a statistically lower content validity as a measure of multiorgan dysfunction. Thus, the task force recommended use of a SOFA score of 2 points or more in encounters with infection as criteria for sepsis and use of qSOFA in non-ICU settings to consider the possibility of sepsis.

Criteria Outside of the ICU

For infected patients outside of the ICU, there is an increasing focus on early recognition of sepsis. Potential criteria for organ dysfunction like SOFA or LODS required clinical and laboratory variables that may be missing and difficult to obtain in a timely manner. These characteristics may increase measurement burden for clinicians. In comparison, a simple model (qSOFA) uses 3 clinical variables, has no laboratory tests, and has a predictive validity outside of the ICU that is statistically greater than the SOFA score ($P < .001$). The qSOFA and SOFA scores also had acceptable agreement in the majority of encounters.

However, 3 potentially controversial issues are worth noting. First, qSOFA was derived and tested among patient encounters in which infection was already suspected. The qSOFA is not an alert that alone will differentiate patients with infection from those without infection. However, at least in many US and European hospital settings, infection is usually suspected promptly, as evidenced by rapid initiation of antibiotics.[26,27]

Second, mental status is assessed variably in different settings, which may affect the performance of the qSOFA. Although the qSOFA appeared robust in sensitivity analyses to alternative GCS cut points, further work is needed to clarify its clinical usefulness. In particular, the model evaluated only whether mental status was abnormal, not whether it had changed from baseline, which is extremely difficult to operationalize and validate, both in the EHR and as part of routine charting. An alternative to the GCS (eg, Laboratory and Acute Physiology Score, version 2, in KPNC encounters)[28] found similar results.

Third, serum lactate levels, which have been proposed as a screening tool for sepsis or septic shock, were not retained in the qSOFA during model construction. One reason may be because serum lactate levels were not measured commonly in the UPMC data set. When serum lactate levels were added to qSOFA post hoc in the KPNC health system data set, in which measurement of lactate levels was common, the predictive validity was statistically increased but with little difference in how encounters were classified. This analysis assessed only how serum lactate levels at different thresholds contributed above and beyond the qSOFA model. However, among intermediate-risk encounters (qSOFA score = 1), the addition of a serum lactate level of 2.0 mmol/L (18 mg/dL) or higher identified those with a risk profile similar to those with 2 qSOFA points. Thus, areas for further inquiry include whether serum lactate levels could be used for patients with borderline qSOFA values or as a substitute for individual qSOFA variables (particularly mental status, given the inherent problems discussed above), especially in health systems in which lactate levels are reliably measured at low cost and in a timely manner.

Criteria in the ICU

Among ICU encounters, the diagnosis of sepsis may be challenging because of preexisting organ dysfunction, treatment prior to admission, and concurrent organ support. In this study, as others have reported in a distinct geographic region and health care system,[29] traditional tools such as the SIRS criteria have poor predictive validity among patients who are infected. Yet in our study, SOFA and LODS scores had superior predictive validity in the ICU and greater agreement, perhaps because more variables were likely to be measured, abnormal, and independent of ongoing interventions. These results are consistent with prior studies of SOFA and LODS in the ICU.[30,31] On average, only 2 of 100 infected decedents in the ICU had a SOFA or LODS score of less than 2. The qSOFA score had statistically worse predictive validity in the ICU, likely related to the confounding effects of ongoing organ support (eg, mechanical ventilation, vasopressors).

Advances Using EHRs

The data from these analyses provided the Third International Consensus Task Force with evidence about clinical criteria for sepsis using EHRs from 3 large health systems with both academic and community hospitals. More than 60% of US nonfederal, acute care hospitals (and all US federal hospitals) now use advanced EHRs. Adoption of EHRs has increased 8-fold since 2009 in the United States and will continue to increase.[32] The EHR may present hospitals with an opportunity to rapidly validate criteria for patients likely to have sepsis, to test prompts or alerts among infected patients with specific EHR signatures suggestive of sepsis, and to build platforms for automated surveillance.[33] In addition, criteria such as in the qSOFA can be measured quickly and easily and assessed repeatedly over time in patients at risk of sepsis, perhaps even in developing countries without EHRs.

Limitations

This investigation has several limitations. First, we studied only patients in whom infection was already suspected or documented. We did not address how to diagnose infection among those in whom life-threatening organ dysfunction was the initial presentation. Therefore, these data alone do not mandate that hospitalized patients with SOFA or qSOFA points be evaluated for the presence of infection.

Second, we chose to develop simple criteria that clinicians could quickly use at the bedside, balancing timeliness and content validity with greater criterion validity. We acknowledge that predictive validity would be improved with more complex models that include interaction terms or serial measurements over time.[3,34,35] We tested how the change in SOFA score over time would perform, and although similar to the maximum SOFA score, the optimal time windows over which change should be measured are not known.

Third, no organ dysfunction measurements evaluated in this study distinguish between chronic and acute organ dysfunction, assess whether the organ dysfunction has an explanation other than infection, or attribute dysfunction specifically to a dysregulated host response. For example, a patient with dementia with an abnormal GCS score at baseline will always have 1 qSOFA point but may not be as likely to have sepsis as a patient with a normal baseline sensorium. As such, we illustrated the predictive validity of various criteria across a full range of underlying risk determined from comorbidity and demographics.

Fourth, we chose 2 outcomes associated more commonly with sepsis than with uncomplicated infection. These outcomes have high content validity and were generalizable across data sets, but there are certainly alternative choices.[36]

Fifth, we compared predictive validity with tests of inference that may be sensitive to sample size. We found that statistically significant differences in AUROC were often present, yet these resulted in differences in classification with debatable clinical relevance. We reconciled these data by reporting the fold change in outcome comparing encounters of different scores to provide more clinical context.

Sixth, the acute, life-threatening organ dysfunction in sepsis may also occur at different times in different patients (before, during, or after infection is recognized).[37] Results were unchanged over a variety of time windows, including both long (72-hour) and short (6-hour) windows around the onset of infection. Prospective validation in other cohorts, assessment in low- to middle-income countries, repeated measurement, and the contribution of individual qSOFA elements to predictive validity are important future directions.

Conclusions

Among ICU encounters with suspected infection, the predictive validity for in-hospital mortality of SOFA was not significantly different than the more complex LODS but was statistically greater than SIRS and qSOFA, supporting its use in clinical criteria for sepsis. Among encounters with suspected infection outside of the ICU, the predictive validity for in-hospital mortality of qSOFA was statistically greater than SOFA and SIRS, supporting its use as a prompt to consider possible sepsis.

ARTICLE INFORMATION

Author Affiliations: Department of Critical Care Medicine, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania (Seymour, Kahn, Angus); Clinical Research, Investigation, and Systems Modeling of Acute Illness (CRISMA) Center, Pittsburgh, Pennsylvania (Seymour, Kahn, Angus); Division of Research, Kaiser Permanente, Oakland, California (Liu); Department of Internal Medicine, University of Michigan, Ann Arbor (Iwashyna, Escobar); Veterans Affairs Center for Clinical Management Research, Ann Arbor, Michigan (Iwashyna, Escobar); Australia and New Zealand Intensive Care Research Centre, Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Victoria, Australia (Iwashyna, Escobar); Center for Clinical Studies, Jena University Hospital, Jena, Germany (Brunkhorst); Division of General Internal Medicine, University of Washington, Seattle (Rea); Research Group Clinical Epidemiology, Integrated Research and Treatment Center, Center for Sepsis Control and Care, Jena University Hospital, Jena, Germany (Scherag); Trauma, Emergency, and Critical Care Program, Sunnybrook Health Sciences Centre; Interdepartmental Division of Critical Care, University of Toronto, Toronto, Ontario, Canada (Rubenfeld); Critical Care Medicine, Guy's and St Thomas' NHS Foundation Trust, London, England (Shankar-Hari); Bloomsbury Institute of Intensive Care Medicine, University College London, London, England (Singer); Feinstein Institute for Medical Research, Hofstra–North Shore–Long Island Jewish School of Medicine, Steven and Alexandra Cohen Children's Medical Center, New Hyde Park, New York (Deutschman).

Author Contributions: Dr Seymour had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Seymour, Iwashyna, Rubenfeld, Kahn, Shankar-Hari, Deutschman, Escobar, Angus.
Acquisition, analysis, or interpretation of data: Liu, Iwashyna, Brunkhorst, Rea, Scherag, Kahn, Singer, Escobar, Angus.
Drafting of the manuscript: Seymour, Singer, Deutschman, Angus.
Critical revision of the manuscript for important intellectual content: Liu, Iwashyna, Brunkhorst, Rea, Scherag, Rubenfeld, Kahn, Shankar-Hari, Singer, Deutschman, Escobar, Angus.
Statistical analysis: Seymour, Liu, Iwashyna, Scherag.
Obtained funding: Escobar.
Administrative, technical, or material support: Brunkhorst, Rea, Scherag, Deutschman, Escobar, Angus.
Study supervision: Deutschman, Escobar.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Seymour reports receipt of personal fees from Beckman Coulter. Dr Singer reports board memberships with InflaRx, Bayer, Biotest, and Merck. Dr Deutschman reports holding patents on materials unrelated to this work and receipt of personal fees from the Centers for Disease Control and Prevention, the World Federation of Societies of Intensive and Critical Care, the Pennsylvania Assembly of Critical Care Medicine, the Society of Critical Care Medicine, the Northern Ireland Society of Critical Care Medicine, the International Sepsis Forum, Stanford University, the Acute Dialysis Quality Initiative, and the European Society of Intensive Care Medicine. Dr Escobar reports receipt of grants from the National Institutes of Health, the Gordon and Betty Moore Foundation, Merck, Sharpe & Dohme, and AstraZeneca-MedImmune. No other disclosures were reported.

Funding/Support: This work was supported in part by the National Institutes of Health (grants K23GM104022 and K23GM112018), the Department of Veterans Affairs (grant HSR&D 11-109), the Permanente Medical Group, and the Center of Sepsis Control and Care, funded by the German Federal Ministry of Education and Research (grant 01 EO 1002/01 EO 1502).

Role of the Funder/Sponsor: The funding sources had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: This article does not necessarily represent the view of the US government or Department of Veterans Affairs. Dr Angus, Associate Editor, *JAMA*, had no role in the evaluation of or decision to publish this article.

Additional Contributions: We acknowledge the European Society of Intensive Care Medicine and Society of Critical Care Medicine for their partial administrative support of this work. We acknowledge the contributions of the 2016 Third International Consensus Sepsis Definitions Task Force members, who were not coauthors, for their review of the manuscript: John C. Marshall, MD, University of Toronto, Toronto, Ontario, Canada; Djilalli Annane, MD, PhD, Critical Care Medicine, School of Medicine, University of Versailles, France; Greg S. Martin, MD, Emory University School of Medicine, Atlanta, Georgia; Michael Bauer, MD, Center for Sepsis Control and Care, University Hospital, Jena, Germany; Steven M. Opal, MD, Infectious Disease Section, Brown University School of Medicine, Providence, Rhode Island; Rinaldo Bellomo, MD, Australian and New Zealand Intensive Care Research Centre, School of Public Health and Preventive Medicine, Monash University, University of Melbourne, and Austin Hospital, Melbourne, Victoria, Australia; Gordon R. Bernard, MD, Vanderbilt Institute for Clinical and Translational Research, Vanderbilt University, Nashville, Tennessee; Jean-Daniel Chiche, MD, PhD, Réanimation Médicale-Hôpital Cochin, Descartes University, Cochin Institute, Paris, France; Craig M. Coopersmith, MD, Emory Critical Care Center, Emory University School of Medicine, Atlanta,

Georgia; Tom van der Poll, MD, Academisch Medisch Centrum, Amsterdam, the Netherlands; Richard S. Hotchkiss, MD, Washington University School of Medicine, St Louis, Missouri; Jean-Louis Vincent, MD, PhD, Université Libre de Bruxelles, and Department of Intensive Care, Erasme University Hospital, Brussels, Belgium; and Mitchell M. Levy, MD, Division of Pulmonary and Critical Care Medicine, Brown University School of Medicine, Providence, Rhode Island. These contributions were provided without compensation.

REFERENCES

1. Liu V, Escobar GJ, Greene JD, et al. Hospital deaths in patients with sepsis from 2 independent cohorts. *JAMA*. 2014;312(1):90-92.

2. Angus DC, Linde-Zwirble WT, Lidicker J, Clermont G, Carcillo J, Pinsky MR. Epidemiology of severe sepsis in the United States: analysis of incidence, outcome, and associated costs of care. *Crit Care Med*. 2001;29(7):1303-1310.

3. Levy MM, Fink MP, Marshall JC, et al; SCCM/ESICM/ACCP/ATS/SIS. 2001 SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference. *Crit Care Med*. 2003;31(4):1250-1256.

4. Bone RC, Balk RA, Cerra FB, et al; ACCP/SCCM Consensus Conference Committee; American College of Chest Physicians/Society of Critical Care Medicine. Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. *Chest*. 1992;101(6):1644-1655.

5. Shankar-Hari M, Phillips GS, Levy ML, et al; Sepsis Definitions Task Force. Developing a new definition and assessing new clinical criteria for septic shock: for the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA*. doi:10.1001/jama.2016.0289.

6. Seymour CW, Rea TD, Kahn JM, Walkey AJ, Yealy DM, Angus DC. Severe sepsis in pre-hospital emergency care: analysis of incidence, care, and outcome. *Am J Respir Crit Care Med*. 2012;186(12):1264-1271.

7. Hagel S, Ludewig K, Frosinski J, et al. Effectiveness of a hospital-wide educational programme for infection control to reduce the rate of health-care associated infections and related sepsis (ALERTS)—methods and interim results [in German]. *Dtsch Med Wochenschr*. 2013;138(34-35):1717-1722.

8. Vincent JL, Moreno R, Takala J, et al. The SOFA (Sepsis-Related Organ Failure Assessment) score to describe organ dysfunction/failure. *Intensive Care Med*. 1996;22(7):707-710.

9. Le Gall JR, Klar J, Lemeshow S, et al; ICU Scoring Group. The Logistic Organ Dysfunction System: a new way to assess organ dysfunction in the intensive care unit. *JAMA*. 1996;276(10):802-810.

10. Collins GS, Reitsma JB, Altman DG, Moons KG. Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD): the TRIPOD statement. *Ann Intern Med*. 2015;162(1):55-63.

11. Rangel-Frausto MS, Pittet D, Costigan M, Hwang T, Davis CS, Wenzel RP. The natural history of the systemic inflammatory response syndrome (SIRS): a prospective study. *JAMA*. 1995;273(2):117-123.

12. Perkins NJ, Schisterman EF. The inconsistency of "optimal" cutpoints obtained using two criteria based on the receiver operating characteristic curve. *Am J Epidemiol*. 2006;163(7):670-675.

13. Seymour CW, Kahn JM, Cooke CR, Watkins TR, Heckbert SR, Rea TD. Prediction of critical illness during out-of-hospital emergency care. *JAMA*. 2010;304(7):747-754.

14. Knaus WA, Zimmerman JE, Wagner DP, Draper EA, Lawrence DE. APACHE—Acute Physiology and Chronic Health Evaluation: a physiologically based classification system. *Crit Care Med*. 1981;9(8):591-597.

15. Kramer AA, Zimmerman JE. Assessing the calibration of mortality benchmarks in critical care: the Hosmer-Lemeshow test revisited. *Crit Care Med*. 2007;35(9):2052-2056.

16. Bland JM, Altman DG. Cronbach's α. *BMJ*. 1997;314(7080):572.

17. Campbell DT, Fiske DW. Convergent and discriminant validation by the multitrait-multimethod matrix. *Psychol Bull*. 1959;56(2):81-105.

18. Quan H, Sundararajan V, Halfon P, et al. Coding algorithms for defining comorbidities in *ICD-9-CM* and *ICD-10* administrative data. *Med Care*. 2005;43(11):1130-1139.

19. Royston P, Sauerbrei W. Building multivariable regression models with continuous covariates in clinical epidemiology—with an emphasis on fractional polynomials. *Methods Inf Med*. 2005;44(4):561-571.

20. Centers for Medicaid and Medicare Services. *Eligible Professional Meaningful Use Core Measures: Measure 7 of 13*. 2014. https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/7_Record_Demographics.pdf. Accessed January 1, 2016.

21. Barnato AE, Alexander SL, Linde-Zwirble WT, Angus DC. Racial variation in the incidence, care, and outcomes of severe sepsis: analysis of population, patient, and hospital characteristics. *Am J Respir Crit Care Med*. 2008;177(3):279-284.

22. Dellinger RP, Levy MM, Rhodes A, et al; Surviving Sepsis Campaign Guidelines Committee Including the Pediatric Subgroup. Surviving Sepsis campaign: international guidelines for management of severe sepsis and septic shock: 2012. *Crit Care Med*. 2013;41(2):580-637.

23. Cecconi M, De Backer D, Antonelli M, et al. Consensus on circulatory shock and hemodynamic monitoring: task force of the European Society of Intensive Care Medicine. *Intensive Care Med*. 2014;40(12):1795-1815.

24. Liu V, Morehouse JW, Soule J, Whippy A, Escobar GJ. Fluid volume, lactate values, and mortality in sepsis patients with intermediate lactate values. *Ann Am Thorac Soc*. 2013;10(5):466-473.

25. Hanley JA, McNeil BJ. The meaning and use of the area under a receiver operating characteristic (ROC) curve. *Radiology*. 1982;143(1):29-36.

26. Ferrer R, Martin-Loeches I, Phillips G, et al. Empiric antibiotic treatment reduces mortality in severe sepsis and septic shock from the first hour: results from a guideline-based performance improvement program. *Crit Care Med*. 2014;42(8):1749-1755.

27. Houck PM, Bratzler DW, Nsa W, Ma A, Bartlett JG. Timing of antibiotic administration and outcomes for Medicare patients hospitalized with community-acquired pneumonia. *Arch Intern Med*. 2004;164(6):637-644.

28. Escobar GJ, Gardner MN, Greene JD, Draper D, Kipnis P. Risk-adjusting hospital mortality using a comprehensive electronic record in an integrated health care delivery system. *Med Care*. 2013;51(5):446-453.

29. Kaukonen KM, Bailey M, Pilcher D, Cooper DJ, Bellomo R. Systemic inflammatory response syndrome criteria in defining severe sepsis. *N Engl J Med*. 2015;372(17):1629-1638.

30. Vincent JL, de Mendonça A, Cantraine F, et al. Use of the SOFA score to assess the incidence of organ dysfunction/failure in intensive care units: results of a multicenter, prospective study. *Crit Care Med*. 1998;26(11):1793-1800.

31. Ferreira FL, Bota DP, Bross A, Mélot C, Vincent JL. Serial evaluation of the SOFA score to predict outcome in critically ill patients. *JAMA*. 2001;286(14):1754-1758.

32. Charles D, Gabriel M, Furukawa MF. *Adoption of Electronic Health Record Systems among US Non-Federal Acute Care Hospitals: 2008-2013*. Washington, DC: Office of the National Coordinator for Health Information Technology; 2014. ONC Data Brief 16.

33. Rhee C, Murphy MV, Li L, Platt R, Klompas M; Centers for Disease Control and Prevention Epicenters Program. Comparison of trends in sepsis incidence and coding using administrative claims vs objective clinical data. *Clin Infect Dis*. 2015;60(1):88-95.

34. Shapiro NI, Wolfe RE, Moore RB, Smith E, Burdick E, Bates DW. Mortality in Emergency Department Sepsis (MEDS) score: a prospectively derived and validated clinical prediction rule. *Crit Care Med*. 2003;31(3):670-675.

35. Opal SM. Concept of PIRO as a new conceptual framework to understand sepsis. *Pediatr Crit Care Med*. 2005;6(3)(suppl):S55-S60.

36. Iwashyna TJ, Odden A, Rohde J, et al. Identifying patients with severe sepsis using administrative claims: patient-level validation of the Angus implementation of the International Consensus Conference definition of severe sepsis. *Med Care*. 2014;52(6):e39-e43.

37. Kellum JA, Kong L, Fink MP, et al; GenIMS Investigators. Understanding the inflammatory cytokine response in pneumonia and sepsis: results of the Genetic and Inflammatory Markers of Sepsis (GenIMS) study. *Arch Intern Med*. 2007;167(15):1655-1663.

Original Investigation | CARING FOR THE CRITICALLY ILL PATIENT

Developing a New Definition and Assessing New Clinical Criteria for Septic Shock

For the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)

Manu Shankar-Hari, MD, MSc; Gary S. Phillips, MAS; Mitchell L. Levy, MD; Christopher W. Seymour, MD, MSc; Vincent X. Liu, MD, MSc; Clifford S. Deutschman, MD; Derek C. Angus, MD, MPh; Gordon D. Rubenfeld, MD, MSc; Mervyn Singer, MD, FRCP; for the Sepsis Definitions Task Force

IMPORTANCE Septic shock currently refers to a state of acute circulatory failure associated with infection. Emerging biological insights and reported variation in epidemiology challenge the validity of this definition.

OBJECTIVE To develop a new definition and clinical criteria for identifying septic shock in adults.

DESIGN, SETTING, AND PARTICIPANTS The Society of Critical Care Medicine and the European Society of Intensive Care Medicine convened a task force (19 participants) to revise current sepsis/septic shock definitions. Three sets of studies were conducted: (1) a systematic review and meta-analysis of observational studies in adults published between January 1, 1992, and December 25, 2015, to determine clinical criteria currently reported to identify septic shock and inform the Delphi process; (2) a Delphi study among the task force comprising 3 surveys and discussions of results from the systematic review, surveys, and cohort studies to achieve consensus on a new septic shock definition and clinical criteria; and (3) cohort studies to test variables identified by the Delphi process using Surviving Sepsis Campaign (SSC) (2005-2010; n = 28 150), University of Pittsburgh Medical Center (UPMC) (2010-2012; n = 1 309 025), and Kaiser Permanente Northern California (KPNC) (2009-2013; n = 1 847 165) electronic health record (EHR) data sets.

MAIN OUTCOMES AND MEASURES Evidence for and agreement on septic shock definitions and criteria.

RESULTS The systematic review identified 44 studies reporting septic shock outcomes (total of 166 479 patients) from a total of 92 sepsis epidemiology studies reporting different cutoffs and combinations for blood pressure (BP), fluid resuscitation, vasopressors, serum lactate level, and base deficit to identify septic shock. The septic shock–associated crude mortality was 46.5% (95% CI, 42.7%-50.3%), with significant between-study statistical heterogeneity (I^2 = 99.5%; τ^2 = 182.5; P < .001). The Delphi process identified hypotension, serum lactate level, and vasopressor therapy as variables to test using cohort studies. Based on these 3 variables alone or in combination, 6 patient groups were generated. Examination of the SSC database demonstrated that the patient group requiring vasopressors to maintain mean BP 65 mm Hg or greater and having a serum lactate level greater than 2 mmol/L (18 mg/dL) after fluid resuscitation had a significantly higher mortality (42.3% [95% CI, 41.2%-43.3%]) in risk-adjusted comparisons with the other 5 groups derived using either serum lactate level greater than 2 mmol/L alone or combinations of hypotension, vasopressors, and serum lactate level 2 mmol/L or lower. These findings were validated in the UPMC and KPNC data sets.

CONCLUSIONS AND RELEVANCE Based on a consensus process using results from a systematic review, surveys, and cohort studies, septic shock is defined as a subset of sepsis in which underlying circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than sepsis alone. Adult patients with septic shock can be identified using the clinical criteria of hypotension requiring vasopressor therapy to maintain mean BP 65 mm Hg or greater and having a serum lactate level greater than 2 mmol/L after adequate fluid resuscitation.

JAMA. 2016;315(8):775-787. doi:10.1001/jama.2016.0289

Editorial page 757

Author Audio Interview at jama.com

Related articles pages 762 and 801

Supplemental content at jama.com

Author Affiliations: Author affiliations are listed at the end of this article.

Group Information: Members of the Sepsis Definitions Task Force are listed at the end of this article.

Corresponding Author: Manu Shankar-Hari, MD, MSc, Department of Critical Care Medicine, Guy's and St Thomas' NHS Foundation Trust, London SE1 7EH, United Kingdom (manu.shankar-hari@kcl.ac.uk).

Consensus definitions, generated in 1991[1] and revisited in 2001,[2] describe septic shock as a state of cardiovascular dysfunction associated with infection and unexplained by other causes. The increasing availability of large electronic health record (EHR) data sets, registries, national case mix programs, trial data sets, and claims databases using *International Classification of Diseases* codes have since generated multiple observational studies reporting septic shock epidemiology. However, variable interpretation and application of the consensus definitions[1,2] have contributed to variable estimates of both incidence and outcomes.[3-8] It is unclear to what extent these variations represent true differences or an artifact attributable to inconsistent use of definitions.[8,9] Furthermore, emerging insights into sepsis pathophysiology[10-13] warrant a review of the current septic shock definition and the criteria used to identify it clinically.

Against this background, the Society of Critical Care Medicine (SCCM) and the European Society of Intensive Care Med (ESICM) convened an international task force to review definitions of sepsis and septic shock in January 2014. To support the task force deliberations on redefining septic shock, a series of activities was performed: a systematic review and meta-analysis of criteria used in observational studies reporting sepsis epidemiology in adults; a Delphi study to achieve consensus; cohort studies using the Surviving Sepsis Campaign (SSC) registry; and subsequent testing of the applicability of the new criteria in patients with suspected infection from 2 large EHR-derived data sets. The aims of this study were to develop an updated septic shock definition and to derive clinical criteria for identifying patients with septic shock meeting this updated definition. Specifically, this updated definition and these criteria are intended to provide a standard classification to facilitate clinical care, future clinical research, and reporting.

Methods

In this article, "definition" refers to a description of septic shock and "clinical criteria" to variables used to identify adult patients with septic shock.

Task Force

The SCCM and ESICM each nominated cochairs of the task force and provided unrestricted funding support toward the work conducted. The 2 cochairs then selected 17 other task force participants based on their scientific expertise in sepsis epidemiology, clinical trials, and basic or translational research. Task force participants are listed at the end of the article. The task force retained complete autonomy for all decisions. ESICM and SCCM had no role in study design, conduct, or analysis but were consulted for peer review and endorsement of the manuscript.[14]

Systematic Review and Meta-analysis

The aims of the systematic review were to assess the different criteria used to identify adult patients with septic shock and whether these criteria were associated with differences in reported outcomes. MEDLINE was searched using search terms, MeSH headings, and combinations of *sepsis*, *septic shock*, and *epidemiology* and limits of human studies; adults 19 years or older; English-language publications; and publication dates between January 1, 1992 (1991 definitions[1]), and December 25, 2015. For full-text review, only noninterventional studies reporting sepsis epidemiology and all-cause mortality were included. Randomized clinical trials were excluded, because the additional inclusion and exclusion criteria might confound the effect of criteria on mortality (the study objective).[8] To avoid variability in outcomes related to specific pathogens, specific patient groups, and interventional before-and-after studies, studies reporting these populations were also excluded. Data were extracted on cohort recruitment period, cohort characteristics, setting, criteria used to identify septic shock, and acute mortality. Detailed methods, including search strategy, are presented in eMethods 1 and eTable 1 in the Supplement.

Delphi Study

To generate consensus on the septic shock definition and criteria, 3 face-to-face meetings, 3-round sequential pretested questionnaires, and email discussions among the task force participants were conducted. One task force member did not participate in these surveys because of lack of content expertise, and 1 did not respond to the first 2 surveys. Questionnaires were developed, refined, and administered consisting of single- and multiple-answer questions, free-text comments, and a 5-point Likert agreement scale. For consensus discussions and noting agreement, the 5-point Likert agreement scales were grouped at the tails of the scale choices (ie, "strongly disagree" grouped with "disagree"; "strongly agree" grouped with "agree"). All outputs from the systematic review, surveys, and the results of cohort studies were made available to participants throughout the Delphi study.

In the first round (August 2014), using 26 questions in 4 domains, agreement and opinions were explored on (1) components of the new septic shock definition; (2) variables and their cutoffs identified by the systematic review; (3) definitions of, and criteria for, hypotension, persistent hypotension, adequacy of resuscitation, and resuscitation end points; and (4) septic shock severity scoring. In the second round (November 2014), 4 questions were used to generate statements for key terms (persistent hypotension, adequacy of resuscitation, and septic shock) and to reach agreement on test variables and outcomes for subsequent analysis of predictive validity. The objectives of the third round (January 2015) were to establish a consensus definition of septic shock and related clinical criteria. In the third survey, the task force members were given 4 choices for the septic shock updated criteria ([1] serum lactate level alone; [2] hypotension alone; [3] vasopressor-dependent hypotension or serum lactate level; [4] vasopressor-dependent hypotension and serum lactate level) and were asked to provide their first and second choices. The cumulative first or second choices were used to agree on the reported septic shock criteria.

Questionnaire items were accepted if agreement exceeded 65%. Choices for which agreement was less than 65% were rediscussed to achieve consensus or were eliminated, as appropriate to achieve the project aims. The survey questionnaires are presented in eMethods 2 in the Supplement.

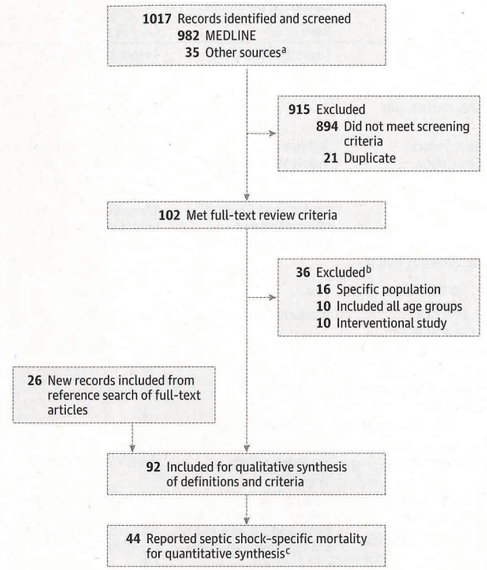
Cohort Studies

The institutional review boards of Cooper University Hospital (Camden, New Jersey),[15] University of Piitsburgh Medical Center (UPMC; a network of hospitals in western Pennsylvania), and Kaiser Permanente Northern California (KPNC)[16] provided ethics approvals for research using the SSC and EHR data sets, respectively.

The SSC registry includes data collected from 218 hospitals in 18 countries on 28 150 patients with suspected infection who, despite adequate fluid resuscitation as judged by the collecting sites, still had 2 or more systemic inflammatory response syndrome criteria and 1 or more organ dysfunction criteria (eMethods 3 in the Supplement). The SSC database setup, inclusion, and reporting items are described in detail elsewhere.[6,17] To select clinical criteria for the new septic shock definition, an analysis data set was created that included all patients with a serum lactate level measurement or a mean arterial pressure less than 65 mm Hg after fluids, or who received vasopressors.

For external validation, mortality was determined using the same clinical criteria in patients with suspected infection (cultures taken, antibiotics commenced) within 2 large EHR databases from UPMC (12 hospitals, 2010-2012, n = 1 309 025) and KPNC (20 hospitals, 2009-2013, n = 1 847 165). Three variables (hypotension, highest serum lactate level, and vasopressor therapy as a binary variable [yes/no]) were extracted from these 2 data sets during the 24-hour period after infection was suspected. Descriptive analyses, similar to those performed on the SSC data set, were then undertaken. Because of constraints on data availability, hypotension was considered present if systolic blood pressure was 100 mm Hg or less for any single measurement taken during the 24-hour period after infection was suspected. Serum lactate levels were measured in 9% of infected patients at UPMC and in 57% of those at KPNC after implementation of a sepsis quality improvement program.

Figure 1. Study Identification and Selection Process Used in the Systematic Review



[a] Nonduplicate references from other sources included review articles.[3,108-110] See eMethods 1 in the Supplement for further details of search strategy.

[b] Refers to records that were excluded after reference screening of full text articles. The screening criteria for full text inclusion were reporting of all case sepsis epidemiology in adult populations without specific assessment of interventions. The qualitative review assessed sepsis and septic shock definitions and criteria. The records included in the qualitative review (92 studies[5-7,19-107]) are presented in eTable 2 in the Supplement. The quantitative review assessed septic shock criteria and mortality.

[c] Refers to the records included for quantitative assessment of septic shock mortality and the heterogeneity by criteria using random-effects meta-analysis (44 studies[5-7,19-59]) (eTable 2 in the Supplement).

Statistics

Meta-analysis

A random effects meta-analysis of septic shock mortality by study-specific septic shock criteria and sepsis definitions was performed. Two meta-regression models of septic shock mortality were tested with the covariates: sepsis definition, criteria for shock, mid-cohort-year of study population, single center or multicenter, and World Health Organization member state regions.[18] These 2 models (with and without per capita intensive care unit beds) were generated to account for international cohorts and countries for which per capita intensive care unit bed data were unavailable (See eMethods 1 in the Supplement for details).

Cohort Studies

Hospital mortality was used as the primary outcome for derivation and descriptive validation analysis. Using the 3 dichotomous variables identified in round 2 of the Delphi process, the SSC cohort was divided into 6 groups and the variables tested either alone or in combination: (1) hypotension (mean arterial pressure <65 mm Hg) after fluid administration; (2) vasopressor therapy; and (3) serum lactate level greater than 2 mmol/L or 2 mmol/L or less (to convert serum lactate values to mg/dL, divide by 0.111). Hypotension was assumed when vasopressor therapy was being administered, generating 6 distinct potential septic shock patient groups using the 3 selected variables (eTable 5 in the Supplement). Analyses were performed using either the 6 groups or the 3 dichotomous variables as the risk factor. Subsequent analyses using the serum lactate level as a categorical variable were performed using a χ^2 test of trend for mortality.

Currently, there are no gold standard septic shock criteria for predictive validity comparisons.[8] Thus, these analyses aimed to identify a patient population that has the attributes of the newly proposed definition, which includes higher mortality compared with other patient populations commonly reported as having septic shock in the literature identified by the systematic review. Therefore, the independent relationship between the 3 potential criterion variables (hypotension, serum lactate level, and vasopressor therapy) agreed on the second round of the Delphi process and a future outcome (hospital mortality) was tested using

Table 1. Summary of Septic Shock Definitions and Criteria Reported in the Studies Identified by the Systematic Review[a]

Criteria	Septic Shock Case Definitions and Corresponding Variables Reported in Literature				Other Description of Criteria Variables
	Consensus Definitions		Other Definitions		
	Bone et al[1]	Levy et al[2]	SSC[111]	Trial-based[112]	
Infection	Suspected or proven	Suspected or proven	Suspected or proven	Suspected or proven	Bacteremia, culture positive; CDC definitions for infection
SIRS criteria, No.	2	One or more of 24 variables[b]	2	3	NA
Septic shock description	Sepsis-induced hypotension despite adequate resuscitation OR receiving vasopressors/Inotropes plus presence of perfusion abnormalities	State of acute circulatory failure characterized by persistent arterial hypotension after adequate resuscitation unexplained by other causes	Sepsis-induced hypotension persisting despite adequate fluid resuscitation	Cardiovascular dysfunction defined as hypotension despite adequate resuscitation or need for vasopressors	Precoded data using *ICD-9* and *ICD-10* codes[c]
Hypotension, mm Hg					
Systolic BP	<90	<90	<90	<90	<100
Decrease in systolic BP	Decrease >40	Decrease >40	Decrease >40	NA<70	>50% decrease in hypertension
MAP	No	<60	<70	Hypotension lasting >1 h after resuscitation	<65
Adequate resuscitation definition	Not defined	Not defined	Goals set as CVP 8-12 mm Hg; urine output ≥0.5 mL/kg/h; $ScvO_2$ >70%	Not defined	After resuscitation fluids (0.5 L; 1 L; 1.5 L; 20 mL/kg ideal body weight
Vasopressor use	Yes (not absolute requirement)	Yes (CVS SOFA score)	Yes (not absolute requirement)	Yes (not absolute requirement)	Vasoactive drugs required for >30 min
Hypoperfusion abnormalities	Hypoperfusion abnormality defined as lactic acidosis; oliguria; low Glasgow Coma Score	Tissue hypoperfusion defined as serum lactate >1 mmol/L or delayed capillary refill	Tissue hypoperfusion defined as infection-induced hypotension, elevated serum lactate (>4 mmol/L), or oliguria	No description	Serum lactate >2.5 mmol/L; base deficit >5 mEq/L, alkaline reserve <18 mEq/L; CVP <8; PCWP <12
Data points from included studies, No. (%)[d]	39 (75)		13 (25)		
Sample size, No.	158 354		8125		
Mortality by septic shock definition using random-effects meta analysis, % (95% CI)	47.2 (42.7-51.7)		44.2 (38.5-49.9)		
I^2, %[e]	99.6		95.9		
τ^2[f]	191.21		94.9		
P value heterogeneity	<.001		<.001		

Abbreviations: BP, blood pressure; CDC, Centers for Disease Control and Prevention; CVP, central venous pressure; CVS, cardiovascular system; *ICD, International Classification of Diseases*; MAP, mean arterial pressure; NA, not applicable; PCWP, pulmonary capillary wedge pressure; SBP, systolic blood pressure; $ScvO_2$, central venous oxygen saturation; SIRS, systemic inflammatory response syndrome; SOFA, Sequential [Sepsis-related] Organ Failure Assessment; SSC, Surviving Sepsis Campaign.

SI conversion factor: To convert serum lactate values to mg/dL, divide by 0.111.

[a] The summary table was generated from eTable 2 data from 92 studies.[5-7,19-107]

[b] Levy et al highlight an extended variable list as a replacement for SIRS criteria consisting of general (n = 7); inflammatory (n = 5); hemodynamic (n = 3); organ dysfunction (n = 7) and tissue perfusion (n = 2) variables.[2]

[c] Different *ICD-9* codes are reported to identify septic shock in the literature. These include shock without trauma code 785.50 with all subcodes (785.51, 785.52, 785.59), hypotension code 458 with subcodes (458.0, 458.8 458.9), cardiovascular failure code 427.5 and the nonspecific low blood pressure code 796.3.

[d] Studies reporting 2 or more subsets,[6,7,30,32] current study (whole population and Group 1), and GiViTI database account for 52 data points from 44 studies. See Figure 2 notes for further details.

[e] I^2 is the percentage of between-study heterogeneity that is attributable to a true variability in septic shock mortality, rather than sampling variation, implying heterogeneity.

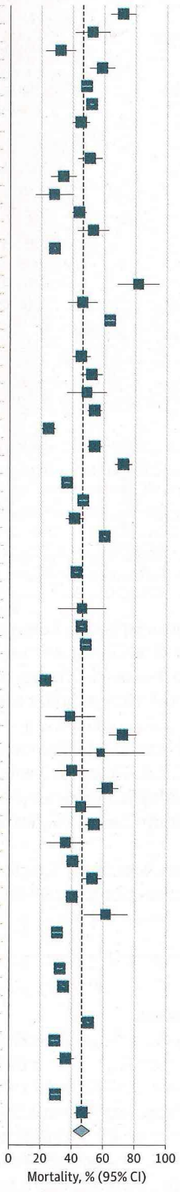
[f] τ^2 refers to the between-study variance within groups in random-effects meta-analysis.

2 generalized estimating equation population-averaged logistic regression models with exchangeable correlation structure, where hospital site was the panel variable.

The first model used the potential septic shock groups 1 to 6 derived from these variables (eTable 5 in the Supplement), with group 1 as the referent group and adjusted for other covariates to assess true mortality difference between these groups. The second model assessed the independent association of these 3 potential criterion variables on hospital mortality adjusted for other covariates. These models also included an a priori adjustment variable for covariates including region (United States and Europe), location where sepsis was suspected (emergency department, ward, or critical care unit), antibiotic administration, steroid use, organ dysfunction (pulmonary, renal, hepatic, and acutely altered mental state), infection source (pneumonia, urinary tract infection, abdominal, meningitis and other), hyperthermia (>38.3°C), hypothermia (<36°C), chills with rigor, tachypnea (>20/min), leukopenia (<4000 cells/μL), hyperglycemia (plasma glucose level >120 mg/dL [6.7 mmol/L), platelet count <100 ×10^3/μL, and coagulopathy.

Figure 2. Random-Effects Meta-analysis of Studies Identified in the Systematic Review, Reporting Septic Shock Mortality

Source	Septic Shock Deaths, No.	Patients With Septic Shock, No.	Mortality, % (95% CI)
Consensus Definition			
Degoricija et al,[46] 2006	90	125	72.0 (64.1-79.9)
Angkasekwinai et al,[38] 2007	41	78	52.6 (41.5-63.6)
Nesseler et al,[27] 2013	30	93	32.3 (22.8-41.8)
Sakr et al,[25] 2013	85	145	58.6 (50.6-66.6)
Goncalves-Pereira et al,[23] 2014	418	856	48.8 (45.5-52.2)
Leligdowicz et al,[5] 2014	4146	7974	52.0 (50.9 -53.1)
Ortiz et al,[19] 2014	144	319	45.1 (39.7-50.6)
Hypotension			
Laupland et al,[47] 2004	81	159	50.9 (43.2-58.7)
Gaspraovic et al,[45] 2006	44	129	34.1 (25.9-42.3)
Shapiro et al,[44] 2006	15	53	28.3 (16.2-40.4)
Povoa et al,[35] 2009	202	458	44.1 (39.6-48.7)
Klein Klowenberg et al,[7] 2012	52	98	53.1 (43.2-62.9)
Kaukonen et al,[22] 2014	14609	51079	28.6 (28.2-29.0)
Hypotension + Perfusion Abnormalities and/or Vasopressor Therapy			
Rangel-Frausto et al,[56] 1995	51	110	46.4 (37.0-55.7)
Salvo et al,[55] 1995	27	33	81.8 (68.7-95.0)
Alberti et al,[52] 2002	752	1180	63.8 (60.7-67.0)
Hypotension + Vasopressor Therapy			
Rodriguez et al,[31] 2001	129	283	45.6 (39.8-51.4)
Silva et al,[48] 2004	106	203	52.2 (45.3-59.1)
Laupland et al,[49] 2005	28	57	49.1 (36.5-61.8)
Vincent et al,[43] 2006	250	462	54.1 (49.6-58.7)
Karlsson et al,[40] 2007	90	363	24.8 (20.4-29.2)
Sakr et al,[39] 2007	250	462	54.1 (49.6-58.7)
Kauss et al,[34] 2010	185	255	72.5 (67.1-78.0)
Levy et al,[6] 2010	915	2494	36.7 (34.8-38.6)
Phua et al,[32] 2011	441	939	47.0 (44.3-49.7)
Ogura et al,[20] 2014	117	282	41.5 (35.7-47.2)
GiViTI database, 2015[a]	15935	26295	60.6 (60.0-61.2)
Hypotension + Vasopressor Therapy + Serum Lactate Level >2 mmol/L			
Group 1[b]	3602	8520	42.3 (41.2-43.3)
Hypotension + Perfusion Abnormalities + Vasopressor Therapy			
Lundberg et al,[54] 1998	19	41	46.3 (31.1-61.6)
Levy et al,[6] 2010	3428	7436	46.1 (45.0-47.2)
Quenot et al,[26] 2013	728	1495	48.7 (46.2-51.2)
Hypotension ± Vasopressor Therapy or Metabolic Abnormalities			
Peake et al,[36] 2009	75	324	23.1 (18.6-27.7)
Hypotension or Vasopressor Therapy			
Dahmash et al,[59] 1993	14	36	38.9 (23.0-54.8)
McLauchlan et al,[58] 1995	73	101	72.3 (63.5-81.0)
Pittet et al,[57] 1995	7	12	58.3 (30.4-86.2)
Schoenberg et al,[53] 1998	32	80	40.0 (29.3-50.7)
Engel et al,[42] 2007	119	190	62.6 (55.8-69.5)
Esteban et al,[41] 2007	27	59	45.8 (33.1-58.5)
Khwannimit and Bhuayanontachai,[37] 2009	164	303	54.1 (48.5-59.7)
Moore et al,[33] 2011	22	61	36.1 (24.0-48.1)
Zahar et al,[30] 2011 (community)	215	530	40.6 (36.3-44.8)
Zahar et al,[30] 2011 (ICU)	123	232	53.0 (47.1-59.0)
Zahar et al,[30] 2011 (nosocomial)	233	580	40.2 (36.1-44.2)
Klein Klowenberg et al,[7] 2012	29	47	61.7 (47.8-75.6)
Park et al,[28] 2012	228	740	30.8 (27.5-34.1)
Hypotension or Serum Lactate Any Value or Vasopressor Therapy			
Liu et al,[21] 2014	827	2536	32.6 (30.8-34.4)
SSC database,[16] 2016[b]	6556	18840	34.8 (34.1-35.5)
***International Classification of Diseases* Codes**			
Annane et al,[51] 2003	13269	26172	50.7 (50.1-51.3)
Flaatten,[50] 2004	457	1562	29.3 (27.1-31.6)
Whittaker et al,[24] 2013	117	321	36.4 (31.2-41.7)
Serum Lactate Level >4 mmol/L			
Levy et al,[6] 2010	242	811	29.8 (26.7-33.0)
Phua et al,[32] 2011	219	466	47.0 (42.0-52.0)
Overall (I^2 = 99.5%; *P* = .000)			46.5 (42.7-50.3)



Forty-four studies report septic shock–associated mortality[5-7,19-59] and were included in the quantitative synthesis using random-effects meta-analysis. The Surviving Sepsis Campaign (SSC) database analyses with similar data are reported in 2 studies[6,29]; therefore, only one of these was used in the meta-analysis reported.[6] Levy et al report 3 septic shock subsets,[6] Klein Klowenberg et al report 2 (restrictive and liberal),[7] Zahar et al report 3 (community-acquired, ICU-acquired, and nosocomial infection–associated septic shock),[30] and Phua et al report 2 groups,[32] which were treated as separate data points in the meta-analysis. Studies under "consensus definition" cite the Sepsis Consensus Definitions.[1,2] The categorization used to assess heterogeneity does not fully account for septic shock details in individual studies.

SI conversion factor: To convert serum lactate values to mg/dL, divide by 0.111.

[a] Data obtained from GiViTI database provided by Bertolini et al (published 2015[8]).

[b] The mortality data of Group 1 patients (new septic shock population) and the overall potential septic shock patient populations (n = 18 840) described in the manuscript from the current study using the Surviving SSC database are also included in the meta-analysis. Septic shock–specific data were obtained from Australian & New Zealand Intensive Care Society Adult Patient Database (ANZICS), from a previously published report.[22] This results in 52 data points for random-effects meta-analysis.

Table 2. Random Effects Meta-Analysis by Septic Shock Criteria Groups

Septic Shock Case Definition Criteria[a]	No.[b]	Mortality, No. of Events/ No. of Patients (%) [95% CI][c]	Heterogeneity Statistic[d]	df	*P* Value	I^2, %[e]	τ^{2f}
Consensus definitions cited (no description)	7	4954/9590 (51.6) [46.3-56.9]	53.2	6	<.001	88.7	39.9
Hypotension	6	15 003/51 976 (39.8) [30.1-49.5]	100.5	5	<.001	95.0	129.5
Hypotension + perfusion abnormalities and/or vasopressor therapy	3	830/1323 (63.3) [48.3-78.4]	20.4	2	<.001	90.2	155.8
Hypotension + vasopressor therapy	11	18 446/32 095 (48.9) [40.5-57.4]	919.8	10	<.001	98.9	195.8
Hypotension + vasopressor therapy + serum lactate level >2 mmol/L	1	3602/8520 (42.3) [41.2-43.3]		0			
Hypotension + perfusion abnormalities + vasopressor therapy	3	4175/8972 (47.0) [45.0-49.0]	3.4	2	.19	40.5	1.33
Hypotension ± vasopressor therapy or metabolic abnormalities	1	75/324 (23.1) [18.6-27.7]		0			
Hypotension or vasopressor therapy	13	1286/2971 (48.4) [41.3-55.5]	165.3	12	<.001	92.7	142.3
Hypotension or serum lactate any value or vasopressor therapy	2	7383/21 376 (33.9) [31.8-36.0]	4.9	1	.03	79.4	1.9
International Classification of Diseases codes	3	13 843/28 055 (38.9) [22.5-55.2]	343.8	2	<.001	99.4	205.6
Serum lactate level >4 mmol/L	2	461/1277 (38.3) [21.5-55.1]	32.6	1	.005	96.9	142.6
Overall	52	70 058/166 479 (46.5) [42.7-50.3]	11026.7	51	<.001	99.5	182.5

Abbreviation: df, degree of freedom.

SI conversion factor: To convert serum lactate values to mg/dL, divide by 0.111.

[a] Interpretation of the operationalization described for criteria to detect a septic shock case in individual studies reporting septic shock mortality.

[b] Number of data points from studies included in the systematic review shown in Figure 2 (see Figure 2 legend).

[c] Septic shock mortality was reported by 44 studies. Four studies report septic shock subsets[6,7,30,32]; data obtained from GiViTi database provided by Bertolini et al[8] and the current septic shock study resulting in 52 data points (further information provided in Figure 2 legend).

[d] The categorization used to assess heterogeneity does not fully account for septic shock details in individual studies.

[e] Percentage of between-study heterogeneity attributable to true variability in septic shock mortality, rather than sampling variation, implying heterogeneity.

[f] τ^2 refers to the between-study variance within groups in random-effects meta-analysis.

These models were used to estimate acute hospital mortality odds ratios (ORs) and adjusted ORs for mortality per-unit increase in the serum lactate level using continuous natural log-transformed serum lactate level. The operating characteristics (sensitivity/specificity over hospital mortality curves; positive and negative predictive values) of different serum lactate cutpoints (2, 3, and 4 mmol/L) were also tested using the logistic regression model. Multiple imputations (n = 20) were used to assess the statistical effect of missing serum lactate values.

$P < .05$ (2-sided) was considered statistically significant. All analyses were performed using Stata version 13.1 (StataCorp).

Results

Systematic Review and Meta-analysis

The systematic review identified 44 studies (166 479 patients) reporting septic shock mortality[5-7,19-59] from a total of 92 studies reporting sepsis cohorts between 1987 and 2015[5-7,19-107] (**Figure 1**; eTable 2 in the Supplement). Different shock criteria were used for systolic blood pressure (<90 mm Hg; <100 mm Hg; decrease >40 mm Hg; or decrease >50% of baseline value if hypertensive), mean arterial pressure (<70; <65; <60 mm Hg), serum lactate level (>4, >2.5, >2, >1 mmol/L) and base deficit (−5 mmol/L) (**Table 1**; eTable 2 in the Supplement). Temporal relationships between resuscitation status and end points to shock diagnosis were seldom reported. The studies differed in the description of resuscitation, persistent hypotension, and in their vasopressor definitions when using the cardiovascular Sequential [Sepsis-related] Organ Failure Assessment (SOFA) score categories.[113] Diverse infection and organ dysfunction codes were also used in the *International Classification of Diseases*-based derivations.[63,70,79,90] Variables highlighted in Table 1 and in eTable 2 in the Supplement informed the Delphi survey questions.

The random-effects meta-analysis showed significant heterogeneity in septic shock mortality (mean mortality, 46.5% [95% CI, 42.7%-50.3%], with a near 4-fold variation from 23.0% to 81.8%; $I^2 = 99.5\%$; $\tau^2 = 182.5$; and $P < .001$) (**Figure 2**). Statistically significant heterogeneity was also observed in random-effects meta-analysis by clinical criteria reported for septic shock case definition in studies (**Table 2**). The meta-regression models described could not explain this heterogeneity (eTable 3A and eTable 3B in the Supplement).

Delphi Study

In the first round, informed by the systematic review, 15 task force members (88%) voted to include persistent hypotension, vasopressor therapy, and hyperlactatemia in the updated criteria. There was no agreement on the lower cutoff for serum lactate level in this round. Eleven members (65%) voted that including fluid resuscitation would improve the

Table 3. Distribution of Septic Shock Cohorts and Crude Mortality From Surviving Sepsis Campaign Database (n = 18 840 patients)

Cohorts[a]	Lactate Category, mmol/L[b]	No. (% of total) [n = 18 840]	Acute Hospital Mortality, No. (%) [95% CI]	χ^2 Test for Trend	Mortality, Adjusted OR (95% CI)[c]	*P* Value[c]
Group 1 (hypotensive after fluids and vasopressor therapy and serum lactate levels >2 mmol/L)	>2 to ≤3	2453 (13.0)	818 (33.3) [31.5-35.3]	<.001	1 [Reference]	
	>3 to ≤4	1716 (9.1)	621 (36.2) [33.9-38.5]			
	>4	4351 (23.1)	2163 (49.7) [48.2-51.2]			
	All	8520 (45.2)	3602 (42.3) [41.2-43.3]			
Group 2 (hypotensive after fluids and vasopressor therapy and serum lactate levels ≤2 mmol/L)	≤2	3985 (21.2)	1198 (30.1) [28.6-31.5]	NA[d]	0.57 (0.52-0.62)	<.001
Group 3 (hypotensive after fluids and no vasopressors and serum lactate levels >2 mmol/L)	>2 to ≤3	69 (0.4)	15 (21.7) [12.7-33.3]	.04	0.65 (0.47-0.90)	.009
	>3 to ≤4	57 (0.3)	14 (24.6) [14.1-37.8]			
	>4	97 (0.5)	35 (36.1) [26.6-46.5]			
	All	223 (1.2)	64 (28.7) [22.9-35.1]			
Group 4 (serum lactate levels >2 mmol/L and no hypotension after fluids and no vasopressors)	>2 to ≤3	860 (4.6)	179 (20.8) [18.1-23.7]	<.001	0.71 (0.62-0.82)	<.001
	>3 to ≤4	550 (2.9)	105 (19.1) [15.9-22.6]			
	>4	1856 (9.9)	555 (29.9) [27.8-32.0]			
	All	3266 (17.3)	839 (25.7) [24.2-27.2]			
Group 5 (serum lactate levels between 2-4 mmol/L and no hypotension before fluids and no vasopressors)	>2 to ≤3	1624 (8.6)	489 (30.1) [27.9-32.4]	NA[d]	0.77 (0.66-0.90)	.001
	>3 to ≤4	1072 (5.7)	313 (29.2) [26.5-32.0]			
	>4	790[e]				
	All	2696 (14.3)	802 (29.7) [28.0-31.5]			
Group 6 (hypotensive after fluids and no vasopressors and serum lactate ≤2 mmol/L)	≤2	150 (0.8)	28 (18.7) [12.8-25.8]	NA[d]	0.32 (0.20-0.51)	<.001

Abbreviations: NA, not available; OR, odds ratio.

SI conversion factor: To convert serum lactate values to mg/dL, divide by 0.111.

[a] Mean arterial pressure less than 65 mm Hg was used to define hypotension. "After fluids" was defined using the field "crystalloids" coded as a binary term within the Surviving Sepsis Campaign database.

[b] Using χ^2 tests, trends in mortality across serum lactate categories within groups (>2 to ≤3 mmol/L; >3 to ≤4 mmol/L and >4 mmol/L) were assessed.

[c] Refers to the adjusted OR generated using generalized estimating equation regression model (eTable7 in the Supplement).

[d] χ^2 test for trend could only be performed if there were 3 or more serum lactate categories.

[e] Excluded from full case analysis.

criteria. The task force determined that neither a severity grading for septic shock nor criteria for either adequacy of fluid resuscitation or persistent hypotension should be proposed because of the nonstandardized use of hemodynamic monitoring, resuscitation protocols, and vasopressor dosing in clinical practice. (Other results are reported in eTable 4 in the Supplement.)

In Delphi round 2, the task force was provided with a preliminary descriptive analysis from the SSC database. With agreement on the description of the septic shock illness concept, 3 test variables (hypotension after fluid resuscitation, vasopressor therapy, and serum lactate level) were agreed on for predictive validity analyses. The "after fluids" field in the SSC database was used as a proxy for resuscitation. The need for vasopressors was agreed as a proxy for persistent hypotension by 95% of the task force. Twelve members (71%) voted that a minimum vasopressor dose should not be proposed in view of the variability in blood pressure targets and resuscitation protocols identified by the systematic review, and because of variable sedation use. Vasopressor therapy was therefore treated as a binary variable within the analysis. To derive an optimal cutoff for serum lactate level, 13 task force members (77%) agreed on acute hospital mortality as the outcome variable. The test variables could be present either alone or in combinations, thus identifying 6 potential groups of patients with septic shock (**Table 3**; eTable 5 in the Supplement).

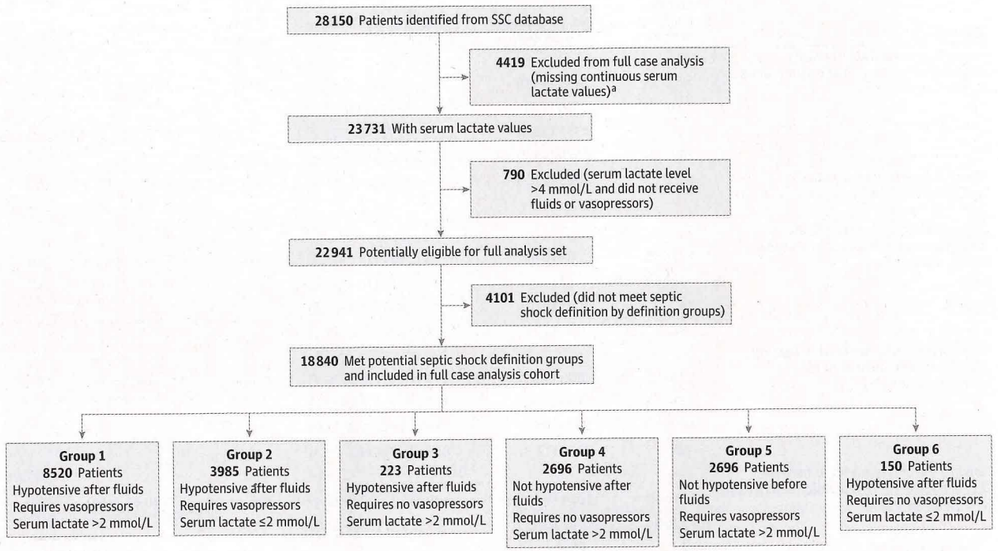
Prior to the final round of the Delphi process, all analyses from the SSC data set and the EHR data sets were provided. These findings generated the new definition—"septic shock is defined as a subset of sepsis in which underlying circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than sepsis alone"—and the clinical criteria described below.

Cohort Studies

SSC Database

Patients with serum lactate levels greater than 4 mmol/L who did not receive fluids as recommended by the SSC guidelines[111] (n = 790 [2.8%]) were excluded. Patients without any serum lactate values measured were excluded initially for full case analysis (n = 4419 [15.7%]) but were reassessed in the missing data analysis. Of the 22 941 remaining patients, 4101 coded as having severe sepsis were excluded from this analysis, generating the analysis set of 18 840 patients who were either hy-

Figure 3. Selection of Surviving Sepsis Campaign Database Cohort



Hypotension was defined as mean arterial pressure less than 65 mm Hg. Vasopressor therapy to maintain mean arterial pressure of 65 mm Hg or higher is treated as a binary variable. Serum lactate level greater than 2 mmol/L (18 mg/dL) is considered abnormal. The "after fluids" field in the Surviving Sepsis Campaign (SSC) database was considered equivalent to adequate fluid resuscitation. "Before fluids" refers to patients who did not receive fluid resuscitation. Serum lactate level greater than 2 mmol/L after fluid resuscitation but without hypotension or need for vasopressor therapy (group 4) is defined as "cryptic shock." Missing serum lactate level measurements (n = 4419 [15.7%]) and patients with serum lactate levels greater than 4 mmol/L (36 mg/dL) who did not receive fluids as per SSC guidelines (n = 790 [2.8%]) were excluded from full case analysis. Of the 22 941 patients, 4101 who were coded as having severe sepsis were excluded. Thus, the remaining 18 840 patients were categorized within septic shock groups 1 to 6.

[a]Patients with screening serum lactate levels coded as greater than 2 mmol/L (n=3342) were included in the missing-data analysis.

potensive after fluids or required vasopressors or had a serum lactate level measurement (**Figure 3** and Table 3). Hypotension was reported in 83.1%, serum lactate level greater than 2 mmol/L in 78.1%, and receipt of vasopressors in 66.4%. Overall, crude hospital mortality was 34.7%. Cohort characteristics by setting are shown in eTable 6 in the Supplement.

Predictive Validity of Potential Septic Shock Groups

Of the 6 groups of potential patients with septic shock (Table 3), the most prevalent was group 1 (hypotension + vasopressor therapy + serum lactate level >2 mmol/L) (n = 8520); followed by groups 2 (n = 3985) and 4 (n = 3266). Crude hospital mortality rates in these 3 groups were 42.3%, 30.1%, and 25.7%, respectively. Statistically significant increasing trends in crude mortality were observed over increasing serum lactate level categories within groups (χ^2 test of trend: $P < .001$ for groups 1 and 4, $P = .04$ for group 3). The adjusted OR for hospital mortality using group 1 for reference was significantly lower in all other groups ($P < .01$ for groups 2 to 6), suggesting that group 1 represents a distinct subpopulation with a significantly greater risk of death (eTable 7 in the Supplement). By a majority (cumulative first choice, 72.2%; second choice, 55.6%) (eTable 4 in the Supplement), the task force agreed that group 1 was most consistent with the proposed septic shock definition, thus generating the new septic shock criteria.

Derivation of Serum Lactate Cutoff Value and Missing Data Analysis

In the generalized estimating equation model (shown in eTable 8 in the Supplement), serum lactate level was associated with mortality, and the adjusted OR for hospital mortality increased linearly with increasing serum lactate level. An increase in serum lactate level from 2 to 10 mmol/L increased the adjusted OR for hospital mortality from 1.4 (95% CI, 1.35-1.45) to 3.03 (95% CI, 2.68-3.45) (referent lactate = 1; **Figure 4**). A serum lactate level greater than 2 mmol/L was chosen as the preferred cutoff value for the new septic shock criteria, the rationale being the trade-off between highest sensitivity (82.5% when using the n = 18 840 subset, and 74.9% when using patients in groups 1 and 2 combined [n = 12 475]), and the decision from the Delphi process to identify the lowest serum lactate level independently associated with a greater risk of death (OR of 1.4 at a lactate value of 2 mmol/L) (**Table 4**; eTable 9, eFigure 1, and eFigure 2 in the Supplement).

Predicated on this understanding of the SSC database structure and the regression analyses completed (eTable 6, eTable 7, and eTable 8 in the Supplement), we assumed that data were missing at random; ie, any difference between observed values and missing values did not depend on unobserved data. Complete case analysis was therefore performed, followed by multiple imputation analysis to support the missing-at-random assumption.[114] The ORs for mortality per unit increase in serum lactate level using complete case analysis (n = 18 840) and imputed analyses (n = 22 182) were similar (1.09 [95% CI, 1.08-1.10]; $P < .001$ vs 1.09 [95% CI, 1.08-1.09]; $P < .001$, respectively). The imputed and complete case analysis probabilities of hospital mortality were also similar (36.4% and 35.5%, respectively).

EHR Data Sets

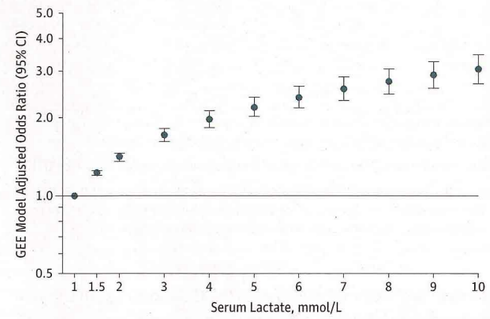
The UPMC and KPNC EHRs included 148 907 and 321 380 adult patients with suspected infection, respectively (eTable 10 in the Supplement). Forty-six percent (n = 5984) of UPMC patients and 39% (n = 54 135) of KPNC patients with 1 or more SOFA score points and suspected infection fulfilled criteria for 1 of the 6 potential septic shock groups described. Patients meeting group 1 criteria (hypotension + vasopressor therapy + serum lactate level >2 mmol/L) comprised 5.3% (UPMC) and 14.9% (KPNC) of the EHR population of patients with suspected infection and had a mortality of 54% and 35%, respectively. Similar to the SSC database, crude mortality rates within each group were higher among those with higher serum lactate levels (**Table 5**).

Discussion

The systematic review illustrated the variability in criteria currently used to identify septic shock, whereas the meta-analysis demonstrated the heterogeneity in mortality. Informed by this systematic review, a Delphi process was used to reach a consensus definition of septic shock and related clinical criteria. Three large data sets were then used to determine the predictive validity of these criteria. Septic shock was defined as a subset of sepsis in which circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than sepsis alone. The clinical criteria representing this definition were the need for vasopressor therapy to maintain a MAP of 65 mm Hg or greater and having a serum lactate level greater than 2 mmol/L persisting after fluid resuscitation.

The proposed definition and criteria of septic shock differ from prior definitions[1,2,111] in 2 respects: (1) the need for both a serum lactate level and vasopressor-dependent hypotension (ie, cardiovascular SOFA score ≥2) instead of either alone and (2) a lower serum lactate level cutoff of 2 mmol/L vs

Figure 4. Serum Lactate Level Analysis



Adjusted odds ratio for actual serum lactate levels for the entire septic shock cohort (N = 18 840). The covariates used in the regression model include region (United States and Europe), location where sepsis was suspected (emergency department, ward, or critical care unit), antibiotic administration, steroid use, organ failures (pulmonary, renal, hepatic, and acutely altered mental state), infection source (pneumonia, urinary tract infection, abdominal, meningitis, and other), hyperthermia (>38.3°C), hypothermia (<36°C), chills with rigor, tachypnea (>20/min), leukopenia (<4000 cells/μL), hyperglycemia (plasma glucose >120 mg/dL [6.7 mmol/L]), platelet count <100 ×10^3/μL, and coagulopathy (eMethods 3 in the Supplement). The adjusted odds ratio (OR) for the 6 groups presented in eTable 7 in the Supplement and the adjusted OR for the individual variables (lactate, vasopressor therapy, and fluids) are reported in eTable 8 in the Supplement. To convert serum lactate values to mg/dL, divide by 0.111.

Table 4. Characteristics of Serum Lactate Level Cutoff Values for Complete Case Analysis and Imputation Analysis Using Surviving Sepsis Campaign Database

	Serum Lactate Level, mmol/L					
	>2		>3		>4	
Characteristic	Died/Total	% (95% CI)	Died/Total	% (95% CI)	Died/Total	% (95% CI)
Complete Case Analysis (n = 18 795)						
Hospital mortality, %	5757/18 795	30.6 (29.9-31.4)	6101/18 795	32.5 (31.8-33.2)	6456/18 975	34.3 (33.7-35.0)
Sensitivity, %	5372/6509	82.5 (81.6-83.4)	3779/6509	58.1 (56.8-59.3)	2811/6509	43.2 (42.0-44.4)
Specificity, %	2748/12 286	22.4 (21.6-23.1)	6418/12 286	52.2 (51.4-53.1)	8564/12 286	69.7 (68.9-70.5)
PPV, %	5372/14 910	36.0 (35.3-36.8)	3779/9647	39.2 (38.2-40.2)	2811/6533	43.0 (41.8-44.2)
NPV, %	2748/3885	70.7 (69.3-72.2)	6418/9148	70.1 (69.2-71.1)	8564/12 286	69.8 (69.0-70.7)
Imputed Missing Serum Lactate Level (n = 22 182)						
Hospital mortality, %	6965/22 182	31.4 (30.8-32.0)	7363/22 182	33.2 (32.6-33.8)	7772/22 182	35.0 (34.4-35.7)
Sensitivity, %	6457/7748	83.3 (82.5-84.2)	4461/7748	57.6 (56.5-58.7)	2931/7748	37.8 (36.7-38.9)
Specificity, %	3341/14 434	23.1 (22.5-23.8)	7833/14 434	54.3 (53.5-55.1)	10 801/14 434	74.8 (74.1-75.5)
PPV, %	6457/17 550	36.8 (36.1-37.5)	4461/11 062	40.3 (39.4-41.2)	2931/6564	44.6 (43.4-45.8)
NPV, %	3341/4634	72.1 (70.8-73.4)	7833/11 120	70.4 (69.6-71.3)	10 801/15 618	69.2 (68.4-69.9)

Abbreviations: NPV, negative predictive value; PPV, positive predictive value.

SI conversion factor: To convert serum lactate values to mg/dL, divide by 0.111.

Table 5. Crude Mortality in Septic Shock Groups From UPMC and KPNC Data sets

Variable[a]	Highest Serum Lactate Levels 24 h After Infection Identified, mmol/L	UPMC			KPNC		
		No. (%) (n = 5984)	Acute Hospital Mortality		No. (%) (n = 54 135)	Acute Hospital Mortality	
			No.	% (95% CI)		No.	% (95% CI)
Group 1	>2 (all)	315 (5.3)	171	54.3 (48.6-59.9)	8051 (14.9)	2835	35.2 (34.2-36.3)
	>3	246 (4.1)	147	59.8 (53.3-65.9)	6006 (11.1)	2355	39.2 (38.0-40.5
	>4	189 (3.2)	120	63.5 (56.2-70.4)	4438 (8.2)	1939	43.7 (42.2-45.2)
Group 2	≤2	147 (2.5)	37	25.2 (18.4-33.0)	3094 (5.7)	582	18.8 (17.4-20.2)
Group 3	>2 (all)	3544 (59.2)	1278	36.1 (34.5-37.7)	12 781 (23.6)	2120	16.6 (15.9-17.2)
	>3	2492 (41.6)	1058	42.5 (40.5-44.4)	6417 (11.9)	1381	21.5 (20.5-22.5)
	>4	1765 (29.5)	858	48.6 (46.3-51.0)	3316 (6.1)	914	27.6 (26.0-29.1)
Groups 4 and 5	>2 (all)	1978 (33.1)	355	17.9 (16.3-19.7)	30 209 (55.8)	2061	6.8 (6.5-7.1)
	>3	1033 (17.3)	224	21.7 (19.2-24.3)	12 450 (23.0)	1138	9.1 (8.6-9.7)
	>4	566 (9.4)	146	25.8 (22.2-29.6)	5394 (9.9)	637	11.8 (11.0-12.7)

Abbreviations: KPNC, Kaiser Permanente Northern California; SSC, Surviving Sepsis Campaign; UPMC, University of Pittsburgh Medical Center.

SI conversion factor: To convert serum lactate values to mg/dL, divide by 0.111.

[a] Group 1 refers to patients with hypotension + vasopressors + serum lactate levels greater than 2 mmol/L. Group 2 refers to patients with hypotension + vasopressors + serum lactate levels less than 2 mmol/L. Group 3 refers to patients with hypotension and serum lactate levels greater than 2 mmol/L. Groups 4 and 5 refer to isolated serum lactate level greater than 2 mmol/L. Counts within a group are not mutually exclusive, as those with serum lactate levels greater than 2 mmol/L will include those in the higher serum lactate cutoffs.

4 mmol/L as currently used in the SSC definitions. In the new septic shock definition, an increase in serum lactate level is positioned as a proxy for a cellular metabolic abnormality, and as a variable independently associated with acute mortality (predictive validity), which is consistent with the published literature.[115-118] An elevated serum lactate level is not specific for cellular dysfunction in sepsis[118,119] but has face validity given the lack of a superior yet readily available alternative. This present study identifies a lower serum lactate level cutoff as an independent prognostic variable when compared with a recent analysis of the entire SSC database. This disparity is explained by using a data set of 18 840 patients in the analysis in this study rather than the total 28 150-patient SSC data set used by Casserly et al.[17] From this subpopulation 6 groups were identified and analyzed as risk strata within the generalized estimating equation model and performance-tested for various serum lactate level cutoffs. The group with a significantly greater risk of death was then selected. In contrast, Casserly et al[17] reported the independent relationship of hypotension and serum lactate levels with mortality in severe sepsis.

The 6 potential septic shock patient groups analyzed in this study also provide an explanation for the heterogeneity in septic shock mortality highlighted by the meta-analysis. Depending on the group selected, septic shock mortality ranged from 12.8% to 51.2% within the SSC data set and from 7.0% to 64.0% in the EHR data sets. The KPNC EHR data set corroborated the consistent trends of higher mortality associated with a higher serum lactate level, even in a population with a wider range of illness severity captured by more prevalent measurement of serum lactate levels.

The key strengths of the present study are in the methodology used to arrive at the new definition and clinical criteria for septic shock, a clinical syndrome with a range of signs, symptoms, and biochemical abnormalities that are not pathognomonic. Furthermore, the supporting studies (systematic review, Delphi process, and analyses of the SSC and EHR cohorts) were iterative and concurrent with the consensus process, a significant step forward from previous definitions.

This study also has several limitations. First, the systematic review did not formally assess study quality and was restricted to MEDLINE publications, adult populations, and observational studies reporting epidemiology. Second, only the Delphi-derived variables were tested in multiple data sets to generate the proposed septic shock criteria. Other variables, including tissue perfusion markers (eg, base deficit, oliguria, acute alteration in mentation), blood pressure characteristics (eg, diastolic pressure), resuscitation end points (eg, central venous saturation, lactate clearance), and numerous biomarkers reported in the literature,[17] could potentially improve on the proposed septic shock criteria but were not included. However, operationalizing the definition of septic shock with 3 commonly measured variables should increase both generalizability and clinical utility. Third, the lack of a gold standard diagnostic criteria for septic shock[8] precludes comparative assessment of these proposed criteria. Fourth, all data sets had missing data that could potentially introduce a form of selection bias.[120] In the primary data set (SSC database) this issue was addressed by demonstrating that full case analysis is an appropriate method (see "Derivation of Serum Lactate Cutoff Value and Missing Data Analysis"). Fifth, serum lactate measurements are not universally available, especially outside of a critical care setting or in resource-limited environments. Although feasibility is a quality indicator for a definition,[8] identification of a critically ill patient would generally trigger obtaining a serum lactate measurement, both to stratify risk and to monitor the response to treatment.[17] Sixth, although the proposed new definition and clinical criteria for sepsis are arbitrary, these do have predictive validity for mortality, alongside face and content validity.[8]

This study represents one step in an ongoing iterative process and provides a resourceful structure and a predictive validity standard for future investigations in this area. Prospective validation of the clinical criteria may improve on the variables and cutoffs proposed herein, and identification and validation of novel markers of organ dysfunction and shock may replace lactate level.[8]

Conclusions

Based on a consensus process using results from a systematic review, surveys, and cohort studies, septic shock is defined as a subset of sepsis in which underlying circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than sepsis alone. Adult patients with septic shock can be identified using the clinical criteria of hypotension requiring use of vasopressors to maintain mean blood pressure of 65 mm Hg or greater and having a serum lactate level greater than 2 mmol/L persisting after adequate fluid resuscitation.

ARTICLE INFORMATION

Author Affiliations: Division of Asthma, Allergy, and Lung Biology, King's College London, London, United Kingdom (Shankar-Hari); Department of Critical Care Medicine, Guy's and St Thomas' NHS Foundation Trust, London SE17EH, United Kingdom (Shankar-Hari); The Ohio State University College of Medicine, Department of Biomedical Informatics, Center for Biostatistics, Columbus (Phillips); Rhode Island Hospital, Brown University School of Medicine, Providence, Rhode Island (Levy); Clinical Research, Investigation, and Systems Modeling of Acute Illness Center, Department of Critical Care and Emergency Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania (Seymour, Angus); Division of Research, Kaiser Permanente, Oakland, California (Liu); Department of Pediatrics, Hofstra-North Shore-Long Island Jewish-Hofstra School of Medicine, Steven and Alexandra Cohen Children's Medical Center, New Hyde Park, New York (Deutschman); Department of Molecular Medicine, Hofstra-North Shore-Long Island Jewish-Hofstra School of Medicine, Steven and Alexandra Cohen Children's Medical Center, New Hyde Park, New York (Deutschman); Feinstein Institute for Medical Research, Manhasset, New York (Deutschman); Associate Editor, *JAMA* (Angus); Interdepartmental Division of Critical Care Medicine, University of Toronto, Toronto, Ontario, Canada (Rubenfeld); Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada (Rubenfeld); Bloomsbury Institute of Intensive Care Medicine, University College London, London, United Kingdom (Singer).

Author Contributions: Dr Shankar-Hari had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Shankar-Hari, Levy, Deutschman, Angus, Rubenfeld, Singer.
Acquisition, analysis, or interpretation of data: Shankar-Hari, Phillips, Levy, Seymour, Liu, Singer.
Drafting of the manuscript: Shankar-Hari, Phillips, Levy, Deutschman, Angus, Singer.
Critical revision of the manuscript for important intellectual content: All authors.
Statistical analysis: Shankar-Hari, Phillips, Seymour, Liu.
Obtained funding: Levy.
Administrative, technical, or material support: Shankar-Hari, Levy, Deutschman, Angus.
Study supervision: Seymour, Deutschman, Singer.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Drs Shankar-Hari and Singer reported receiving support from the UK NIHR Biomedical Research Centre schemes. Dr Levy reported receiving a grant from ImmuneExpress. Dr Seymour reported receiving personal fees from Beckman Coulter. Dr Liu reported receiving K grant support from the National Institutes of Health (K23GM112018). Dr Deutschman reported holding patents on materials not related to this work and receiving travel/accommodations and related expenses for participation in meetings paid by the Centers for Disease Control and Prevention, World Federation of Societies of Intensive and Critical Care, Pennsylvania Assembly of Critical Care Medicine/PA Chapter, Society of Critical Care Medicine (SCCM)/Penn State–Hershey Medical Center, Society of Critical Care Medicine, Northern Ireland Society of Critical Care Medicine, International Sepsis Forum, Department of Anesthesiology, Stanford University, Acute Dialysis Quality Initiative, and European Society of Intensive Care Medicine (ESICM). Dr Singer reported serving on advisory boards for Bayer and Biotest and that he is a recipient of a UK NIHR Senior Investigator Fellowship (2009-2017). No other disclosures were reported.

Members of the Sepsis Definitions Task Force and Delphi Study: Derek Angus, Djilalli Annane, Michael Bauer, Rinaldo Bellomo, Gordon Bernard, Jean-Daniel Chiche, Craig Coopersmith, Cliff Deutschman (cochair), Richard Hotchkiss, Mitchell Levy, John Marshall, Greg Martin, Steve Opal, Gordon Rubenfeld, Christopher Seymour (co-opted), Manu Shankar-Hari (co-opted), Mervyn Singer (cochair), Tom van der Poll, Jean-Louis Vincent.

Funding/Support: The Sepsis Definitions Task Force received unrestricted funding support from the European Society of Intensive Care Medicine and the Society of Critical Care Medicine (sponsors).

Role of the Funders/Sponsors: The funders/sponsors had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Disclaimer: Dr Angus, *JAMA* Associate Editor, had no role in the evaluation of or decision to publish this article.

REFERENCES

1. Bone RC, Balk RA, Cerra FB, et al. Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. *Chest*. 1992;101(6):1644-1655.

2. Levy MM, Fink MP, Marshall JC, et al. 2001 SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference. *Crit Care Med*. 2003;31(4):1250-1256.

3. Rhee C, Gohil S, Klompas M. Regulatory mandates for sepsis care—reasons for caution. *N Engl J Med*. 2014;370(18):1673-1676.

4. Iwashyna TJ, Angus DC. Declining case fatality rates for severe sepsis. *JAMA*. 2014;311(13):1295-1297.

5. Leligdowicz A, Dodek PM, Norena M, et al. Association between source of infection and hospital mortality in patients who have septic shock. *Am J Respir Crit Care Med*. 2014;189(10):1204-1213.

6. Levy MM, Dellinger RP, Townsend SR, et al. The Surviving Sepsis Campaign: results of an international guideline-based performance improvement program targeting severe sepsis. *Intensive Care Med*. 2010;36(2):222-231.

7. Klein Klouwenberg PM, Ong DS, Bonten MJ, Cremer OL. Classification of sepsis, severe sepsis and septic shock: the impact of minor variations in data capture and definition of SIRS criteria. *Intensive Care Med*. 2012;38(5):811-819.

8. Shankar-Hari M, Bertolini G, Brunkhorst FM, et al. Judging quality of current septic shock definitions and criteria. *Crit Care*. 2015;19(1):445.

9. Iwashyna TJ, Govindan S. Did they just prove that a diagnosis of "septic shock" is meaningless? *Am J Respir Crit Care Med*. 2014;189(10):1156-1157.

10. Singer M. The role of mitochondrial dysfunction in sepsis-induced multi-organ failure. *Virulence*. 2014;5(1):66-72.

11. Hotchkiss RS, Monneret G, Payen D. Sepsis-induced immunosuppression. *Nat Rev Immunol*. 2013;13(12):862-874.

12. Takasu O, Gaut JP, Watanabe E, et al. Mechanisms of cardiac and renal dysfunction in patients dying of sepsis. *Am J Respir Crit Care Med*. 2013;187(5):509-517.

13. Rudiger A, Dyson A, Felsmann K, et al. Early functional and transcriptomic changes in the myocardium predict outcome in a long-term rat model of sepsis. *Clin Sci (Lond)*. 2013;124(6):391-401.

14. Singer M, Deutschman C, Seymour CW, et al. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA*. doi:10.1001/jama.2016.0287.

15. US Department of Health and Human Services (DHHS). Frequently Asked Questions About Human Research. DHHS website. http://www.hhs.gov/ohrp/policy/faq/index.html. May 10, 2010. Accessed Feburary 1, 2016.

16. Seymour CW, Liu V, Iwashyna TJ et al. Assessment of clinical criteria for sepsis: for the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA*. doi:10.1001/jama.2016.0288.

17. Casserly B, Phillips GS, Schorr C, et al. Lactate measurements in sepsis-induced tissue hypoperfusion. *Crit Care Med*. 2015;43(3):567-573.

18. World Health Organisation (WHO). Health Statistics and Information Systems: Definition of Region Groupings. WHO website. http://www.who.int/healthinfo/global_burden_disease/definition_regions/en/. July 5, 2015.

ATTACHMENT 6

COMMITTEE MEETING AGENDA ITEM COVER SHEET

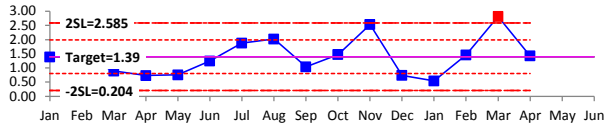
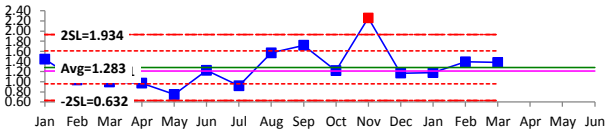
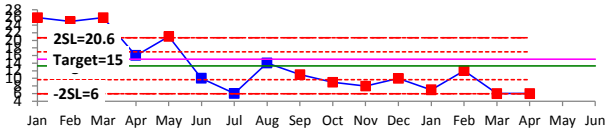
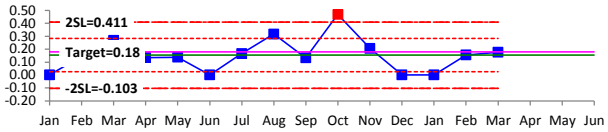
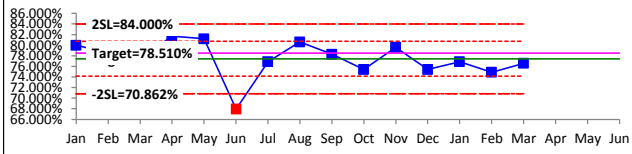
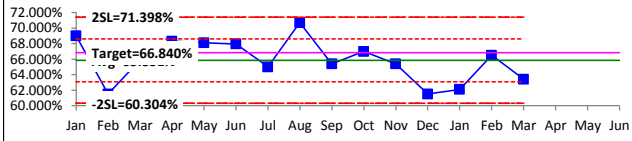
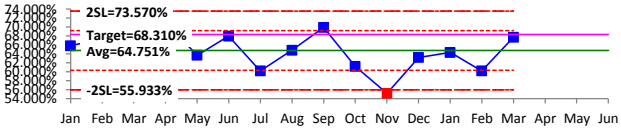
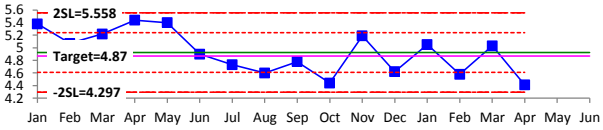
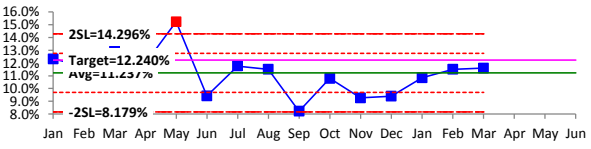
	Item:	Quality Committee - Board Discussion
	Responsibility party:	Dave Reeder, Quality Committee Chairman
	Action requested:	For Discussion
	Background: Last year, the Board engaged Via Healthcare Consulting to make recommendations about certain of our processes. Via recommended that the Board spend additional time and focus on quality related topics at each meeting. Via further recommended that the Quality Committee consider and recommend how much time the Board should spend and what specific quality related topics the Board should focus on. The Board adopted Via's recommendations and we are now seeking the Committee's input.	
	Committees that reviewed the issue and recommendation, if any: Quality, Patient Care and Patient Experience Committee on June 1, 2016	
	Summary and session objectives : Please see questions below in order to facilitate dialogue addressing the quantity and content of Quality items presented at the monthly Board meetings.	
	Suggested discussion questions: 1. How much of the Board agenda should be devoted to Quality? What percent of the Board meeting? 2. What should the Quality Committee be presenting to the Board? What specific content?	
	Proposed committee motion, if any: The Quality Committee recommends that the Board should devote (*XXX amount of time*) to discussion related to the following quality topics at each meeting: (_____,_____,_____,)	
	LIST OF ATTACHMENTS: N/A	

ATTACHMENT 7

El Camino Hospital
THE HOSPITAL OF SILICON VALLEY

Quality and Safety Dashboard (Monthly)

Date Reports Run: 4/18/2016

		Performance		Baseline	FY16 Goal	Trend
SAFETY EVENTS				FY2015	FY2016	
1	**Patient Falls** *Med / Surg / CC Falls / 1,000 CALNOC Pt Days* *Date Period: April 2016*	7/4917	1.42	1.39	1.39	
2	**Medication Errors** *Errors / 1000 Adj Total Patient Days* *Date Period: March 2016*	20/14473	1.38	1.21	1.21	
3	**Specimen Labeling Errors** *# Specimen Labeling Errors / Month* *Date Period: April 2016*	6	0	23	15	
COMPLICATIONS		**Performance**		**FY2015**	**FY2016**	
4	**Surgical Site Infection (SSI)** *SSI per 100 Surgical Procedures* *Date Period: March 2016*	1	0.18	0.19	0.18	
SERVICE		**Performance**		**FY2015**	**FY2016**	
5	**Communication with Nurses** *(HCAHPS Score)* *Date Period: March 2016*	164/214	76.6%	78.5%	78.5%	
6	**Responsiveness of Hospital Staff** *(HCAHPS Score)* *Date Period: March 2016*	124/196	63.4%	66.8%	66.8%	
7	**Communication About Medicines** *(HCAHPS Score)* *Date Period: March 2016*	90/133	67.7%	68.3%	68.3%	
EFFICIENCY		**Performance**		**Jan-Jun 2015**	**Jan-Jun 2016**	
8	★Organizational Goal **Average Length of Stay (days)** *(Medicare definition, MS-CC, ≥ 65, inpatient)* *Date Period: April 2016*	**FYTD 4000 01-06/16 1682**	**FYTD 4.74 01-06/16 4.76**	5.17	5.07 (Min) 4.97 (Target) 4.87 (Max)	
9	★Organizational Goal **30-Day Readmission (Rate, LOS-Focused)** *(ALOS-Linked, All-Cause, Unplanned)* *Date Period: March 2016*	**FYTD 369/3522 01-06/16 136/1233**	**FYTD 10.48 01-06/16 11.03**	12.24	At or below 12.24	

J Pao, Sr. Director, Clinical Quality and Patient Safety, Clinical Effectiveness
P Griesbach, Mgr, Cln Variation, Clinical Effectiveness

Definitions and Additional Information

Measure Name	Definition Owner	Work Group	FY 2015 Definition	FY 2016 Definition	Source
Patient Falls	Joy Pao; Cheryl Reinking	Falls Committee	All Med/Surg/CC falls reported to CALNOC per 1,000 CALNOC (Med/Surg/CC) patient days CALNOC Fall Definition: The rate per 1,000 patient days at which patients experience an unplanned descent to the floor (or extension of the floor, e.g., trash can or other equipment, including bedside mat). All falls are reported and described by level of injury or no injury, and circumstances (observed, assisted, restrained at the time of the fall). Include Assisted Falls (when staff attempts to minimize the impact of the fall, it is still a fall). *Excludes Intentional Falls: When a patient (age 5 or older) falls on purpose or falsely claims to have fallen, it is considered an Intentional Fall and is NOT included. It is NOT considered a fall according to the CALNOC definition.*		**QRR Reporting and Staff Validation**
Medication Errors	Joy Pao; Cheryl Reinking	Medication Safety Committee; P&T Committee	5 Rights MEdication Errors: [# of Med Errors (includes: Duplicate Dose, Omitted Dose, Incorrect Patient, Incorrect Medication, and Incorrect Route.) divided by Adjusted Total Patient Days (includes L&D & Nursery)]* 1,000 *Excludes: Wrong Time, ADR, Contrast Reaction, Incorrect Dose, "Not Yet Rated" Med errors, No risk identified and near miss*		**QRR Reporting and Staff Validation**
Mislabeled Specimens	Edwina Sequeira; Cheryl Reinking	QIPSC	Number of blood and nonblood Laboratory specimens collected by non-Lab staff that are unlabeled or contain incomplete or incorrect information for patient ID, specimen source/site, date/time, collector initials. Soft ID GoLive in May 2015 for select units, MCH full GoLive date after iCare implementation in Nov 2015.		**Staff Manual Tracking (Thara Trieu, Laboratory)**
Surgical Site Infection	Catherine Nalesnik; Joy Pao; Carol Kemper, MD	Infection Control Committee	(Number of Deep Organ Space infections divided by the # of all sugery cases)*100 counted by the month procedure under which infection was attributed to and not by the month it was discovered. All Surgery Cases in the 29 Surgical Procedural Categories required by the California Department of Public Health.		**IC Surveillance and NHSN Data Reporting**
Communication with Nurses	RJ Salus; Meena Ramchandani; Cheryl Reinking	Patient Experience Committee	Percent of inpatients responding "Always" to the following 3 questions [% Top Box]: 1. *During hospital stay, how often did the nurses treat you with courtesy and respect?* 2. *During hospital stay, how often did nurses listen carefully to you?* 3. *During hospital stay, how often did nurses explain things in a way you can understand?* CMS Qualified values are pulled from the Avatar website.Note: A complete month's data is available on the first Monday following 45 days after the end of the month.		**Press Ganey Tool**
Responsiveness of Hospital Staff	RJ Salus; Eric Pifer	Patient Experience Committee	Percent of inpatients responding "Always" to the following 2 questions [% Top Box]: 1. *During hospital stay, after you pressed the call button, how often did you get help as soon as you wanted it?* 2. *How often did you get help in getting to the bathroom or in using a bedpan as soon as you wanted (for patients who needed a bedpan)?* CMS Qualified values are pulled from the Avatar website.Note: A complete month's data is available on the first Monday following 45 days after the end of the month.		**Press Ganey Tool**
Communication About Medicines	RJ Salus; Cheryl Reinking; Bob Blair	Patient Experience Committee	Percent of inpatients (who received meds) responding "Always" to the following 2 questions [% Top Box]: 1. Before giving you any new medicine, how often did hospital staff tell you what the medicine was for? 2. Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand? CMS Qualified values are pulled from the Avatar website. Note: A complete month's data is available on the first Monday following 45 days after the end of the month.		**Press Ganey Tool**
Average Length of Stay	Eric Pifer, MD; Mick Zdeblick; Joy Pao; Petrina Griesbach	LOS Steering Committee	Average LOS of Medicare FFS, Paitents discharged from an Acute Care or Intensive Care unit. Excludes expired patients. Includes final coded patients aged 65 an older at the time of the encounter. The baseline period is from Jan-June 2015 and the performance period is from Jan-June 2016.		**EDW Data Pull, Department of Clinical Effectiveness**
30-Day Readmission (LOS-Focused)	Eric Pifer, MD; Margaret Wilmer; Joy Pao; Petrina Griesbach	Readmission Committee	Percent of Medicare inpatient discharges return for an unplanned IP stay for any reason within 30 days, aged ≥65. Excludes patients who die, leave AMA or are transferred to another acute care facility; excludes admits to ECH Rehab and Psych admissions and for medical treatment of cancer.		**EDW Data Pull, Department of Clinical Effectiveness**

ATTACHMENT 8

SAMPLE OF MAJOR QUALITY, SAFETY AND RISK MEASURES AT EL CAMINO HOSPITAL (INTERNAL AND EXTERNAL)

General Clinical Area	Name of Report Programs or Registries	Categories	Metrics	Owner
General CMS Related Inpatient and Outpatient Reporting	**CMS IQR, OQR, VBP, HAC, HACRP, HRRP Programs**		▪ AMI1 ▪ HF2 ▪ PN3 ▪ Imm ▪ SCIP4 ▪ STK5 ▪ VTE6 ▪ ED7 ▪ Sepsis ▪ PC8 ▪ EHDI9 ▪ SUB ▪ TOB ▪ HBIPS10 ▪ OP11 ▪ PSI **Infection Related:** ▪ CLABSI ▪ SSI ▪ CAUTI ▪ MRSA ▪ CDI ▪ HP Flu **Readmission:** ▪ AMI ▪ HF ▪ PN ▪ Hip/Knee ▪ HWR12 ▪ COPD ▪ STK ▪ CABG **Mortality:** ▪ AMI ▪ HF ▪ PN ▪ COPD ▪ STK **Cost and Efficiency:** ▪ MSPB-1 ▪ AMI ▪ THA/TKA ▪ Kidney/UTI ▪ Spine F/RF ▪ Cellulitis ▪ GI Hemorrhage ▪ Excess AMI ▪ Excess HF	Joy P Dept. of Clinical Effectiveness
Infection Control	**CDC NHSN Reporting/CMS**	SSI Surveillance on 29 ICD9/10 Procedural Categories Facility wide/IRF Surveillance	SSI MDRO's: CDIF; MRSA; CRE; VRE Device Associated Surveillance: CLABSI, CAUTI, CLIP Compliance Bundle	Joy P/Catherine N Dept. of Clinical Effectiveness (IC)
Surgical Quality Reporting	**National Surgical Quality Improvement Program (NSQIP)**	General, Vascular and Sub-Specialty	▪ Mortality ▪ Morbidity ▪ Cardiac ▪ Pneumonia ▪ Unplanned Intubation ▪ Ventilator > 48 Hours ▪ Renal Failure ▪ UTI ▪ SSI ▪ Sepsis ▪ ROR ▪ Readmission	Sherri W/Joy P Dept. of Clinical Effectiveness

[1] *AMI-1 Aspirin at arrival [Voluntary]* *AMI-2 Aspirin prescribed at discharge [Removed]* *AMI-3 ACEI/ARB for left ventricular systolic dysfunction [Voluntary]*
AMI-5 Beta-blocker prescribed at discharge [Voluntary] *AMI-7a Fibrinolytic (thrombolytic) agent received within 30 min of hospital arrival*
AMI-8a Timing of receipt of Primary Percutaneous Coronary Intervention (PCI) *AMI-10 Statin Prescribed at Discharge [Removed]*
[2] *HF-1 Discharge instructions [Removed]* *HF-2 Evaluation of left ventricular systolic function* *HF-3 ACE-I or ARB for left ventricular systolic dysfunction*
[3] *PN -3a Blood cultures performed within 24 hours prior to or 24 hours after hospital arrival for patients who were transferred or admitted to ICU within 24 hours of hospital arrival*
PN-3b Blood culture performed in the emergency department prior to first antibiotic received in hospital [Removed]
PN-6 Initial antibiotic selection for community-acquired pneumonia (CAP) in immuno-competent patient
[4] *SCIP INF-1 Prophylactic antibiotic received within one hour prior to surgical incision* *SCIP INF-2 Prophylactic antibiotic selection for surgical patients* *SCIP INF-3 Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery)*
SCIP INF-4 Cardiac surgery patients with controlled postoperative blood glucose *SCIP INF-6 Appropriate Hair Removal [Suspended]* *SCIP INF-9 Postoperative urinary catheter removal on postoperative day one or two with day of surgery being day zero*
SCIP INF-10 Surgery patients with perioperative temperature management [Removed] *SCIP Card-2 Surgery patients on a beta blocker prior to arrival who received a Beta Blocker during the perioperative period*
SCIP INF VTE-2 Surgery patients who received appropriate VTE prophylaxis within 24 hours pre/post surgery
[5] *STK-1 Venous thromboembolism (VTE) prophylaxis* *STK-2 Discharged on antithrombotic Therapy* *STK-3 Anticoagulation therapy for Atrial Fibrillation/Flutter* *STK-4 Thrombolytic therapy*
STK-5 Antithrombotic therapy by the end of hospital day two *STK-6 Discharged on statin medication* *STK-8 Stroke education* *STK-10 Assessed for Rehab*
[6] *VTE-1 Venous thromboembolism prophylaxis* *VTE-2 Intensive Care Unit VTE prophylaxis* *VTE-3 VTE patients with anticoagulation overlap therapy* *VTE-5 VTE Warfarin therapy discharge instructions*
VTE-4 VTE patients receiving un-fractionated heparin with dosages/platelet count monitoring by protocol or nomogram *VTE-6 Hospital acquired incidence of potentially preventable VTE*
[7] *ED-1 Median time from emergency department arrival to time of departure from the emergency room for patients admitted to the hospital*
ED-2 Median time from admit decision to time of departure from the emergency department for emergency department patients admitted to the inpatient status
[8] *PCM-01 Elective Delivery Prior to 39 completed weeks gestation: Percentage of babies electively delivered prior to 39 weeks gestation [Elective Delivery (patients w/ elective deliveries or C/S @ >37 weeks & <39 weeks gestation completed)*
PCM-02 Cesarean Section (Nulliparous women w/ term (37 weeks completed or > than this) with a term, singleton baby in vertex presentation delivered by C/S)
[9] *Early Hearing Detection and Intervention (EHDI) Goal is to ensure that all newborns are screened and assessed for hearing loss & receive appropriate intervention*
[10] *HBIPS required for free standing psychiatric hospitals; available for selection for general hospitalswith psychiatric units.*
[11] *OP-1: Median Time to Fibrinolysis* *OP-2: Fibrinolytic Therapy Received Within 30 Minutes* *OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention*
OP-4: Aspirin at Arrival *OP-5: Median Time to ECG* *OP-6: Timing of Antibiotic Prophylaxis* *OP-7: Prophylactic Antibiotic Selection for Surgical Patients*
Beginning with January 1, 2015 encounters, OP-6 and OP-7 have been removed from the Hospital OQR Program. The data will still be collected until May 1, 2015 and publicly reported until October 2015.
OP-8: MRI Lumbar Spine for Low Back Pain *OP-9: Mammography Follow-up Rates* *OP-10: Abdomen CT – Use of Contrast Material* *OP-11: Thorax CT – Use of Contrast Material*
OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non Cardiac Low Risk Surgery *OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT* *OP-15: Use of Brain CT in the Emergency Department (ED) for Atraumatic Headache†*
OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients *OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional* *OP-22: ED- Patient Left Without Being Seen*
OP-17: Tracking Clinical Results between Visits *OP-27: Influenza Vaccination Coverage among Healthcare Personnel* *OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients*
OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use *OP-31: Cataracts – Improvements in Patient's Visual Function within 90 Days Following Cataract Surgery†† OP-21 Hospital Outpatient Pain Management Population. Pain Management*
[12] *OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (Outcome Claims-Based) - Hospitals may voluntarily submit data for CY 2015 but will not be subject to a payment reduction with respect to this measure during the voluntary reporting period.*
Hospital-Wide All Cause Unplanned Readmission

SAMPLE OF MAJOR QUALITY, SAFETY AND RISK MEASURES AT EL CAMINO HOSPITAL (INTERNAL AND EXTERNAL)

General Clinical Area	Name of Report Programs or Registries	Categories	Metrics	Owner
			▪ VTE	
	Metabolic Bariatric Accreditation Quality Improvement Program (MBSAQIP)	Bariatric Surgery	200+ Data Points: ▪ Risk Standardized 30-Day Postoperative Complication Rate ▪ Risk Standardized 30-Day Readmission Rate ▪ Risk Standardized 30-Day Reoperation Rate ▪ Risk Standardized 30-Day Anastomotic/Staple Line Leak Rate ▪ Risk Standardized 30-Day Perioperative Bleeding Rate ▪ Risk Standardized 30-Day Postoperative Surgical Site Infection Rate ▪ Risk Standardized 30-Day Postoperative Nausea, Vomiting or Fluid/Electrolyte/Nutritional Depletion Rate ▪ Risk Standardized Extended Length of Stay (> 7 days) ▪ 30-Day Postoperative Follow-Up Rate	Joy P/Denise R Dept. of Clinical Effectiveness
The Joint Commission	**The Joint Commission - Disease Specific**	Ortho: Hip, Knee & Joint	▪ Ortho: Hip, Knee & Joint ▪ LOS, Readmission, Process	Debbie S/Pamela C Ortho Institute
Neurosciences	**Get with the Guidelines and TJC Disease Specific**	Stroke	▪ 8 Stroke Core Measures (STK 1 – 10) 8 Quality Measures	Sherrill H Neurology Service Line
Resuscitation	**Get with the Guidelines Resuscitation**	Resuscitation	▪ 4 CPA (Cardiopulmonary Arrest) Measures: Rapid Responses, Code Blues, Cardiac Alerts, Sepsis Alerts, Stroke Alerts, etc.	Mary C
Pediatric			▪ Newborn Volume (Live Births) ▪ NICU Discharges ▪ NICU Average Length of Stay ▪ Neonatal Deaths ▪ Newborn Tranfers Out ▪ Readmission for Hyperbilirubinemia ▪ Late Preterm Volume ▪ Late Pre-Term Infants Readmit Rate to NICU	
Acute Rehab	**General Reporting**		▪ CMI (acuity) ▪ Average Age ▪ Patients Transferred ▪ Interrupted Stay ▪ Community DC ▪ SNF DC ▪ Avg Onset Days ▪ LOS ▪ FIM Change ▪ FIM Change/Day ▪ Rehab *Unassisted* Falls/1000 Patient Days ▪ Rehab Falls Resulting in ≥Moderate Injury	Justin L (MD)
Pathology	**General Reporting**	ANATOMIC PATHOLOGY QUATLITY DASHBOARD	▪ FS-Final Dx Discrepancies Running % (<3%) ▪ Interdep. Consultation Discrepancies Running % (<3%) ▪ Autopsy PAD ,<48h Running % (100%) Action level 90% ▪ Autopsy FAD ,<60 d Running % (100%) ▪ HER2 + Breast Cancer Running %(12-20%) ▪ ER + Breast Cancer Running % (73-89%) ▪ PR + Breast Cancer Running % (70-90%) ▪ SP report TAT (1d/2d) (70/80%; 24h/48h) ▪ Amended reports (<0.23%) ▪ Non GYN cytology TAT 70%/90% <48h ▪ ASCUS:SIL ratio ▪ FS TAT <20 min (>90%) ▪ Staging on SP reports (>90%) ▪ Synoptic reporting (>90%)	Charles L (MD)
		Clinical Laboratory Dashboard	▪ Mislabeled/Unlabeled Specimens ▪ Outpatient Ordering Errors ▪ ED – "Chest pain" Troponin TAT (Order to collect in 10 minutes) ▪ ED – "Chest pain" Troponin TAT (Collect to Receive in 10 minutes) ▪ ED – "Chest pain" Troponin TAT (Receive to Verify in 30 minutes) ▪ Stroke Alert Protimes TAT (Order to Verify in 45min) ▪ Stroke Alert ProtimesTAT (Result to Call in 3 min) ▪ Redraw Rate for Specimens (Phlebs.) ▪ Redraw Rate for Specimens (Nurses) ▪ Corrected Reports –General Lab ▪ Critical Value Reporting (% called within 10min) ▪ Blood Usage (CT ratio)	

SAMPLE OF MAJOR QUALITY, SAFETY AND RISK MEASURES AT EL CAMINO HOSPITAL (INTERNAL AND EXTERNAL)

General Clinical Area	Name of Report Programs or Registries	Categories	Metrics	Owner
			▪ ED – "Chest pain" Troponin TAT (Order to Verify in 50 minutes) ▪ Test Orders Resulted by 0800 (received by 0600) ▪ Total Blood Component Wastage ▪ Blood Culture Contamination	
		Blood Use Report	▪ Platelets ▪ Cryoprecipitate ▪ FFP ▪ RBC's	
Women's Health	**California Perinatal Quality Care Collaborative (CPQCC)- and Vermont Oxford Network (VON)**		▪ PN-010-07 Cesarean Rate for Low-Risk First Birth Women ▪ PN022-07 Infants Under 1500g Delivered at Appropriate Site ▪ PN-021-07 Exclusive Breastfeeding at Hospital Discharge ▪ Hospital Births and NICU Admissions by Birth Weight ▪ NICU Deaths for Infants born in 2015 by birth weight ▪ NICU Transports Out by Birth Weight ▪ Hospital Births and NICU Admissions by Gestational Age ▪ Inborn Admission % ▪ Data Quality Assessment ▪ NICU Activity Overview ▪ CPQCC-CCS Linked HRIF Referral Summary for Infants Discharged Home ▪ Growth Trajectories for Infants 2-29 wks admitted to NICU ▪ % of infants 401 to 1500 grams or 22 to 29 wks with Interventions Associated with Improved or Compromised Outcomes ▪ % of infants 401 to 1500 grams or 22 to 29 Wks Gestation with Selected Morbidities ▪ Observed to Expected Ratios for Major Morbidities of infants 401 to 1500 grams or 22 to 29 weeks Gestation ▪ Central line-Associated Bloodstream Infections (CLABSI), 2013 Rates by Birth Weight and NICU Best Practices ▪ Inventory of Active Perinatal Quality Improvement Projects ▪ NICU Comments ▪ NICU Attestation and Confirmation ▪ Volume Metrics (total deliveries, total c sections, operative vaginal deliveries, Episiotomies, operative vaginal deliveries to total deliveries… etc.) ▪ Complications: 3rd/4th degree lacerations rates	Jody C
Nursing Care	**Cal NOC/Magnet**		▪ Fall ▪ Fall with injury ▪ HAPU stage 2 and above ▪ CAUTI ▪ CLABSI ▪ Restraint Prevalence	Chris T
Emergency Department	**General Policy**	Process Reporting	▪ Radiology Discrepancies – wet reads and discrepancy f/u ▪ Positive Culture Follow-Up ▪ Unassigned patient referrals – adult and peds ▪ Telepsychology: LG transfers to MV for psych ▪ ED volume adjustments ▪ C2C to Admit Order ▪ Lead time (minutes) - ED Arrival to Provider or Door to Diagnostic Eval by Qualified Med Professional ▪ Waiting for Care' Section Avatar	Laura C (MD), Michael W (MD), Karen P (MD)
		CMS PQRS	▪ EKG for Non-Traumatic Chest Pain ▪ Prevention of Catheter-Related Bloodstream Infections (CRBSI): Venous Catheter (CVC) Insertion Protocol ▪ Acute Otitis Externa (AOE): Topical Therapy ▪ Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy– Avoidance of Inappropriate Use ▪ Stroke & Stroke Rehabilitation: Thrombolytic Therapy for Ischemic CVA ▪ Ultrasound Determination of Pregnancy Location for Pregnancy Patients with Abdominal Pain	

SAMPLE OF MAJOR QUALITY, SAFETY AND RISK MEASURES AT EL CAMINO HOSPITAL (INTERNAL AND EXTERNAL)

General Clinical Area	Name of Report Programs or Registries	Categories	Metrics	Owner
			▪ Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin Prescribed for Patients with Acute Bacterial Sinusitis	
Sleep Medicine	**General Reporting**		▪ Sleep studies scored with 48 hour turnaround time. First quarter 100% compliant and Second Quarter 84% compliant due to holidays. ▪ 95% CPAP filters cleaned every 2 weeks and replaced every 6 months. First Quarter 100% compliant for cleaning and one month late on replacement. 2nd Quarter 100% compliant. ▪ 80% inter-scoring reliability using medical director as gold standard. First quarter averaged 87% and second quarter averaged 93%.	Tony M (MD)
Heart and Vascular	**HVI Registries**	▪ Cath PCI (Percutaneous Coronary Intervention) ▪ ICD (Implantable Cardioverter Defibrillators and Leads) ▪ STS (Society of Thoracic Surgeons – CABG/Valve) ▪ CCORP - California Cabbage Outcomes (CMS) CABG ▪ Carotid Stent (CMS) ▪ Santa Clara County – STEMI ▪ TAVR (new!) – Transcatheter Aortic Valve Replacement ▪ MitraClip (new!) – Transcatheter Mitral Valve Repair[13] ▪ VQI (new!) – Vascular Quality Improvement o Carotid Endarterectomy o Carotid Stent o Peripheral Vascular Interventions o Abdominal Aortic Aneurism ▪ LAAO (WATCHMAN - LEFT ATRIAL APPENDAGE OCCLUSION)	▪ Complications ▪ Mortality ▪ Length of Stay ▪ Blood utilization ▪ Process metrics	Vincent G (MD) Amy M/Rich K HVI Service line
Cancer Center	**American College of Surgeons Commission on Cancer (ASC CoC)**	**Eligibility Requirements/Standards**	**Specification**	Markettea B Cancer Service Line
		E1 Facility Accreditation	The facility is accredited by a recognized federal, state, or local authority (TJC).	
		E2 Cancer Committee Authority	Bylaws, policy or procedure define the cancer committee's authority and responsibility for the program.	
		E3 Cancer Conference Policy	Policy or procedure establishes the cancer conference activity and addresses the frequency, format, multidisciplinary attendance, attendance rate, number of total and prospective case presentations, discussion of stage and treatment planning, clinical trial options, and methods to address areas that fall below established levels.	
		E4 Oncology Nurse Leadership	A nurse(s) provides leadership across the continuum of care (including inpatient and outpatient areas).	
		E5 Cancer Registry Policy and Procedure	The cancer registry policy and procedure manual addresses the use of CoC data elements and codes along with all other cancer registry activities.	
		E6 Diagnostic Imaging	Diagnostic imaging services (following safe procedures) are available either on-site or by referral.	

[13] TVT (TRANSCATHETER VALVE THERAPIES): MITRACLIP & COREVALVE; ACTION: AMI (ACUTE MYOCARDIAL INFARCTION

SAMPLE OF MAJOR QUALITY, SAFETY AND RISK MEASURES AT EL CAMINO HOSPITAL (INTERNAL AND EXTERNAL)

General Clinical Area	Name of Report Programs or Registries	Categories	Metrics	Owner
		E7 Radiation Oncology Services	Radiation treatment services that are available on-site or at locations that are facility-owned or by referral follow standard quality assurance practices. Copies of certificates of accreditation, letters of attestation or other documentation are available.	
		E8 Systemic Services	Policies or procedures are in place to guide the safe administration of systemic therapy provided either on-site or at locations that are facility owned or at locations that contract with the facility or are supervised by members of facility's medical staff (physician offices).	
		E9 Clinical Trial Information	A policy or procedure is used to provide cancer-related clinical trial information to patients.	
		E10 Psychosocial Services	A policy or procedure is in place to ensure patient access to psychosocial services either on-site or by referral; a process is in place to make patients aware of services and to monitor use. (Facility-wide or cancer program policy or procedure can be used.)	
		E11 Rehabilitation Services	A policy or procedure is used to access rehabilitation services either on-site or by referral. (Facility-wide or cancer program policy or procedure can be used.)	
		E12 Nutrition Services	A policy or procedure is used to access nutrition services either on-site or by referral. (Facility-wide or cancer program policy or procedure can be used.)	
		Standard 1.1 Physician Credentials	All physicians who provide cancer care are currently board certified or are in the process of becoming board certified.	
		Standard 1.2 Cancer Committee Membership	The cancer committee is multidisciplinary including required members specific to category.	
		Standard 1.3 Cancer Committee Attendance	Each required member or designated alternate attends at least 75% of meetings annually.	
		Standard 1.4 Cancer Committee Meetings	The cancer committee meets at least once each calendar quarter.	
		Standard 1.5 Goals	The cancer committee establishes, implements, and monitors at least 1 programmatic and 1 clinical goal each year. Each goal is evaluated at least twice in the same calendar year.	
		Standard 1.6 Cancer Registry Quality Control Plan	The cancer committee establishes and implements a cancer registry quality control plan each year. The plan addresses all required criteria.	
		Standard 1.7 Monitoring Cancer Conference Activity	The cancer conference coordinator monitors the cancer conference activities and reports findings to the cancer committee at least annually.	
		Standard 1.8 Monitoring Community Outreach	The community outreach coordinator monitors the effectiveness of the community outreach program annually, prepares the community outreach activity summary, and presents the summary to the cancer committee annually.	
		Standard 1.9 Clinical Trials Accrual	***2015 phase in*** The required percentage of patients is accrued to clinical trials each year. The clinical trial	
		Standard 1.10 Clinical Educational Activity	The cancer committee offers 1 cancer-related educational activity to physicians, nurses, and other allied health professionals each year. The activity focuses on the use of stage, prognostic indicators, and evidence-based treatment guidelines in treatment planning.	
		Standard 1.11 Cancer Registrar Education	All registry staff participates in an annual educational activity. *Commendation: all CTRs attend a national or regional educational activity once during the 3-year survey cycle.	
		Standard 1.12 Public Reporting of Outcomes	The cancer committee develops and disseminates a report of patient or program outcomes to the public annually. *For Commendation only, not required.	
		Standard 2.1 CAP Protocols	The required data elements from the CAP protocols are included in 90% of the eligible cancer pathology reports each year. *Commendation: 90% of the path reports include the required data elements AND 95% follow a synoptic format.	
		Standard 2.2 Nursing Care	Care is provided by nurses with specialized knowledge and skills; competency is evaluated annually. *Commendation: 25% of chemotherapy-trained nurses hold a current oncology nursing certification.	
		Standard 2.3 Risk Assessment and Genetic Testing	Risk assessment and genetic counseling and testing services are provided either on-site or by referral by a qualified genetics professional.	
		Standard 2.4 Palliative Care Services	Palliative care services are available either on-site or by referral.	
		Standard 3.1 Patient Navigation	2015 phase in A patient navigation process is established to address health care disparities and barriers to care, driven by a community needs assessment. The navigation process is evaluated, documented, and reported to the cancer committee annually and then modified and enhanced each year to address additional barriers identified.	
		Standard 3.2 Psychosocial Distress	"2015 phase in	

SAMPLE OF MAJOR QUALITY, SAFETY AND RISK MEASURES AT EL CAMINO HOSPITAL (INTERNAL AND EXTERNAL)

General Clinical Area	Name of Report Programs or Registries	Categories	Metrics	Owner
		Screening		
		Standard 3.3 Survivorship Care Plan	2015 phase in The cancer committee develops and implements a process to provide a comprehensive care summary and follow-up plan to cancer patients who are completing treatment; the process is monitored, evaluated, and presented to the cancer committee at least annually.	
		Standard 4.1 Prevention Program	Each year, 1 prevention program is provided targeted to meet the needs of the community and to reduce the incidence of a specified cancer type (based on identified needs of the community).	
		Standard 4.2 Screening Program	Each year, 1 screening program is provided targeted to decreasing the number of patients with late-stage disease (based on community needs). A process is developed to follow up on all positive findings.	
		Standard 4.3 Cancer Liaison Physician (CLP) Responsibilities	The CLP evaluates, interprets, and reports the program's performance using NCDB data at least 4 times a year.	
		Standard 4.4 Accountability Measures	Each year, performance levels defined by the CoC are met for each accountability measure. (Breast - BCS, MAC, HT and Colon - ACT)	
		Standard 4.5 Quality Improvement Measures	Each year, performance levels defined by the CoC are met for each quality improvement measure. (Colon - 12RLN and Rectal - AdjRT)	
		Standard 4.6 Assessment of Evaluation and Treatment Planning	Each year, a physician member of the cancer committee performs a study to assess whether patients are evaluated and treated according to evidence-based national treatment guidelines. Results are presented to the cancer committee and documented in the minutes.	
		Standard 4.7 Studies of Quality	Each year, the quality improvement coordinator and cancer committee develop, analyze, and document 2 studies that measure quality of care and outcomes for patients with cancer.	
		Standard 4.8 Quality Improvements	Each year, the quality improvement coordinator and cancer committee implement 2 patient care improvements. One improvement is based on the results of a completed study.	
		Standard 5.1 Cancer Registrar Credentials	Case abstracting is performed by a Certified Tumor Registrar (CTR).	
		Standard 5.2 Rapid Quality Reporting System (RQRS) Participation	*For Commendation only, not required. Enrollment and participation in RQRS.	
		Standard 5.3 Follow-up of All Patients	80% follow-up rate is maintained for all eligible analytic cases from the registry reference date.	
		Standard 5.4 Follow-up of Recent Patients	90% follow-up rate is maintained for all eligible analytic cases diagnosed in the last 5 years or from the registry reference date, whichever is shorter.	
		Standard 5.5 Data Submission	Each year, complete data for all requested analytic cases are submitted to the NCDB in accordance with the annual Call for Data.	
		Standard 5.6 Accuracy of Data	Each year, the cases submitted to the NCDB meet the quality criteria and resubmission deadline specified in the Call for Data. * Commendation: Annually, the cases submitted meet the quality criteria for the annual Call for Data on initial submission.	
		Standard 5.7 Commission on Cancer Special Studies	The program participates in special studies as selected by the CoC.	

ATTACHMENT 9

El Camino Hospital
THE HOSPITAL OF SILICON VALLEY

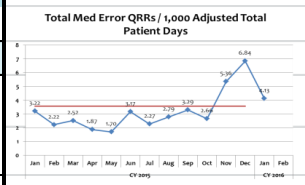
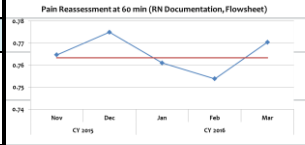
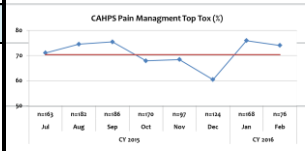
Performance Measurement

Organizational Goals FY17: Draft	Benchmark	2016 ECH Baseline	Minimum	Target	Maximum	Weight	Evaluation Timeframe
Threshold Goals							
Joint Commission Accreditation	Standard Threshhold	Full Accreditation	Full Accreditation			Threshold	FY 17
Budgeted Operating Margin	90% threshold recommended by Exec Comp Consultant (FY16)	TBD	90% of Budgeted			Threshold	FY 17
Patient Safety & iCare							
Exploring one goal from the following: Pain Management, Med Rec at Admission, Medication Safety (Quality Committee will finalize in April)						34%	FY17
Achieve Medicare Length of Stay Reduction while Maintaining Current Readmission Rates for Same Population	Internal Improvement	TBD	.05 Day Reduction from FY16 Target, Readmission at or below FY16 Target	.10 Day Reduction from FY16 Target, Readmission at or below FY16 Target	.20 Day Reduction from FY16 Target, Readmission at or below FY16 Target	33%	FY17
Smart Growth							
Targeted Growth, &/or Geographic Expansion (3/14-15 Strategic Retreat to address potential goals)						33%	FY 17
					TOTAL:	100%	

El Camino Hospital
THE HOSPITAL OF SILICON VALLEY

DRAFT – For Board Quality Discussion

Note the baselines may change, and or the targets

Organizational Goals FY17: Draft	Benchmark	2016 ECH Baseline	Minimum	Target	Maximum	Weight	Evaluation Timeframe	Baseline Trend
Patient Safety and iCare Goal Options								
Option 1: Medication Safety Indicator		*CY 2016*						
Med Errors (Total Medication Error QRRs / 1,000 Adjusted Total Patient Days)	Internal Improvement	3.56	3.49 2% decrease	3.42 4% decrease	3.35 6% decrease	34%	FY 17	
Option 2: Pain Management Indicator		*Post Go-Live*						
Pain Reassessment (% Pain Reassessment Documented within 60 min on RN Flowsheet)	Internal Improvement	76.3%	80.2% 5% increase	82.4% 8% increase	84.0% 10% increase	34%	FY 17	
		FY 2016 Q1-2						
Patient Satisfaction Pain Management Score (% Scored Top Box for CMS CAHPS - Pain Management)	Internal Improvement	70.3%	71.7% 2% increase	74.5% 6% increase	75.9% 8% increase	34%	Jul 2016 - May 2017	

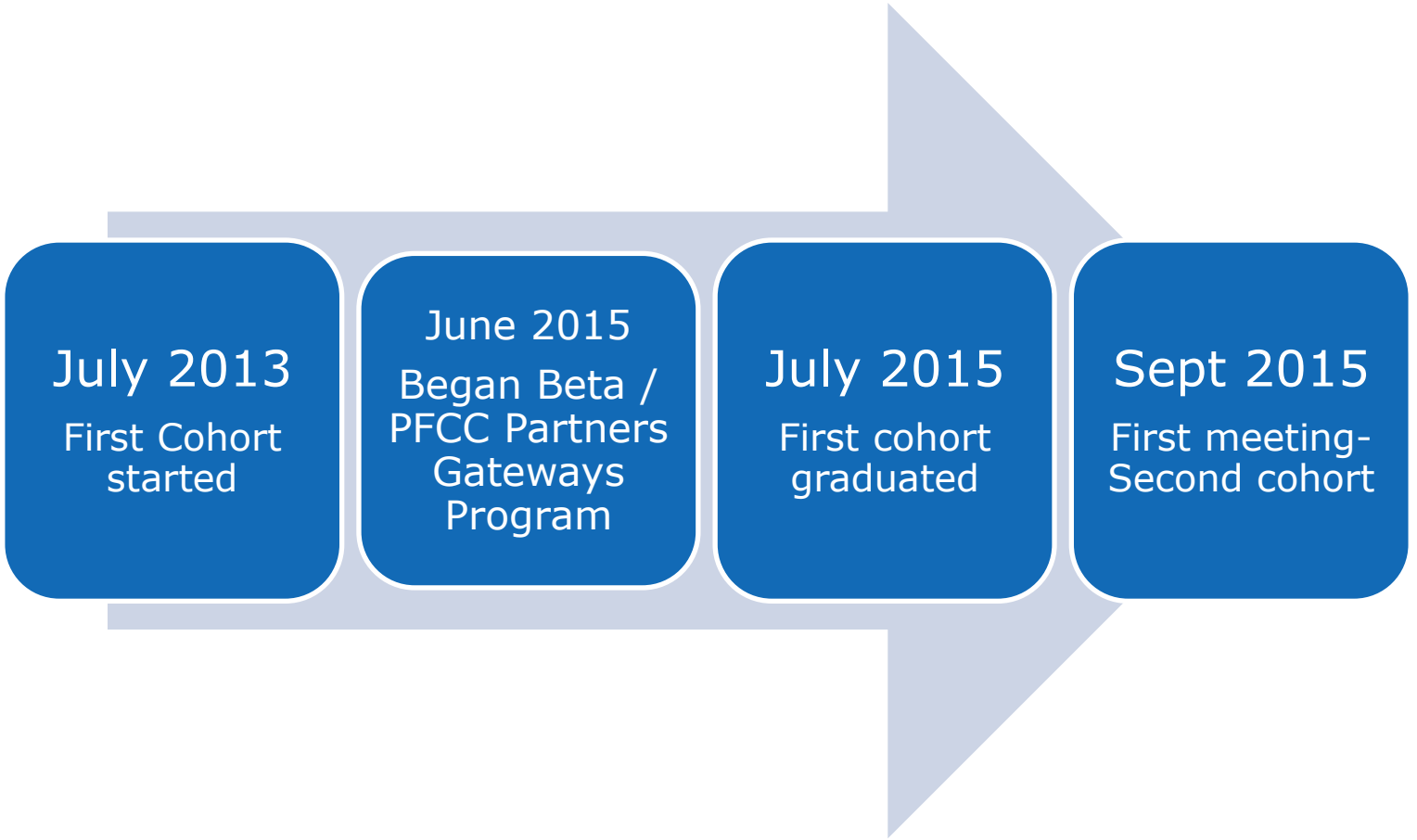
ATTACHMENT 10

El Camino Hospital
THE HOSPITAL OF SILICON VALLEY

Patient and Family Advisory Council Update

June 1, 2016

PFAC Timeline at El Camino



Recruitment

Referrals from:

- Hospital Staff
- Patient Complaints
- ECH Foundation
- Patient Satisfaction Surveys

Vision and Charter

The Patient and Family Advisory Council for El Camino Hospital provides insight and advice to the strategies and initiatives of the organization. Engaging and partnering with patients and families in meaningful ways to provide their firsthand perspectives and experience enables El Camino Hospital to reflect the voice of the diverse services and community we serve in continuous performance improvement. The knowledge of what is important to both those receiving care and those who support the patient is incorporated into the structure, processes, and culture of care provided within the hospital and in community partnerships. Patient and Family Advisors inspire and co-design an enhanced patient and family centered eco-system

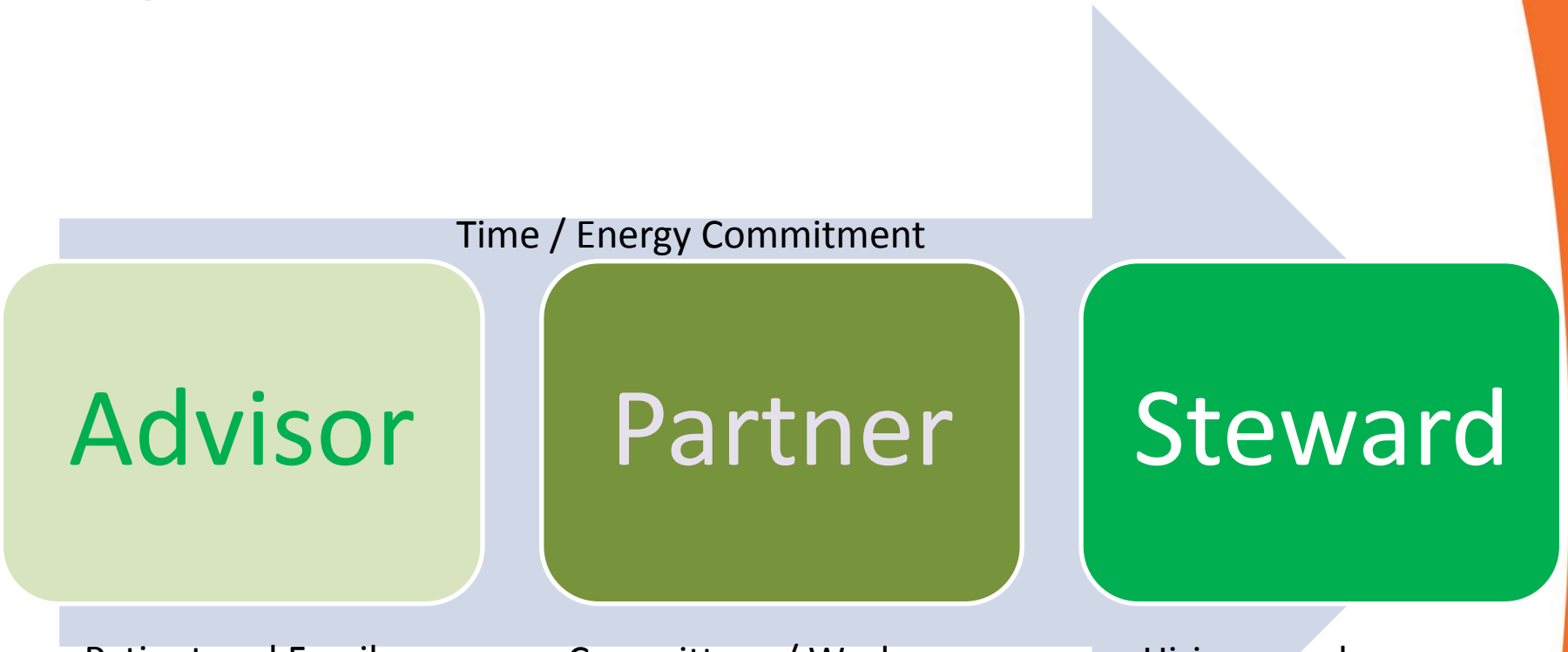
Orientation Snapshot

- Welcome Letter
- Hospital overview - CNE
- Getting to know you exercise
- Charter
- Confidentiality agreement
- Literature
  - Patient and Family Engagement Roadmap (Moore Foundation)
  - Partnering with Patients and Families to Design a Patient a Patient and Family Centered Health Care System (Institute for Patient and Family Centered Care)

Current PFAC snapshot

- Four meetings held: September 2015, December 2015, Feb 2016, and April 2016
- 8 current members after 1 relocation
  - Cardiac, Oncology, General Medical , Emergency Care, Orthopedic care experiences represented
  - Only 1 member had an experience in Los Gatos
- Our topics so far:
    - Orientation and EPIC EMR implementation
    - Patient portal - myCare
    - Health Information transparency
    - Discharge process
    - Emergency Care
    - Special projects to lend patient and family voice to

Increasing Patient and Family Involvement



- Patient and Family Advisory Council
- Board Quality Committee

- Committees / Workgroups
  - Patient Experience
  - PFCC Steering
  - Quality / Patient Safety
- Performance Improvement Activities
- Surveyor / Observer

- Hiring panels
- Patient Experience Rounds
- Morning Huddles
- Department Advisor
- Auxiliary
- Training / Simulation

Increasing the Patient Voice

- Added two patients to Board Quality Meeting
- New survey vendor in July, 2015
  - Large increase in qualitative data
- Planetree engagement
- Potential partnership focused on family housing
- Campus redevelopment – Women's Hospital
- Service line interest (NICU, Cancer)
  - NICU launched a Family Advisory in May, 2016