TAHOE FOREST HOSPITAL DISTRICT

2017-09-19 Board Quality Committee Meeting

Tuesday, September 19, 2017 at 12:00 p.m.

Foundation Conference Room - Tahoe Forest Health System Foundation

10976 Donner Pass Rd, Truckee, CA 96161

Meeting Book - 2017-09-19 Board Quality Committee Meeting

9/19/17 Quality Committee

AGENDA

ITEMS 1 - 4: See Agenda

5. APPROVAL OF MINUTES

6. ITEMS FOR COMMITTEE DISCUSSION AND/OR RECOMMENDATION

6.2. Patient & Family Centered Care (PFCC)

Oral update. No related materials.

6.4. Patient Safety

6.4.2. AHRQ Patient Safety Culture Survey

No related materials.

6.5. Medication Safety Committee
Scott Cooper, Director of Pharmacy
No related materials at this time.

ITEMS 7 - 9: See Agenda

TAHOE FOREST HEALTH SYSTEM

QUALITY COMMITTEE
AGENDA

Tuesday, September 19, 2017 at 12:00 p.m.
Foundation Conference Room, Tahoe Forest Hospital
Donner Pass Road, Truckee, CA

1. CALL TO ORDER

2. ROLL CALL
Alyce Wong, RN, Chair; Charles Zipkin, M.D., Board Member

3. CLEAR THE AGENDA/ITEMS NOT ON THE POSTED AGENDA

4. INPUT – AUDIENCE
This is an opportunity for members of the public to address the Committee on items which are not on the agenda. Please state your name for the record. Comments are limited to three minutes. Written comments should be submitted to the Board Clerk 24 hours prior to the meeting to allow for distribution. Under Government Code Section 54954.2 – Brown Act, the Committee cannot take action on any item not on the agenda. The Committee may choose to acknowledge the comment or, where appropriate, briefly answer a question, refer the matter to staff, or set the item for discussion at a future meeting.

5. APPROVAL OF MINUTES OF: 7/11/2017 ..... **ATTACHMENT**

6. ITEMS FOR COMMITTEE DISCUSSION AND/OR RECOMMENDATION

6.1. Quality Committee Charter and 2017 Focus ..... ATTACHMENT
BOD Quality Committee Focus 2017 was approved on March 14, 2017 and available for reference during the meeting.

6.2. Patient & Family Centered Care (PFCC)

6.2.1. Patient & Family Advisory Council Update
An update will be provided related to the activities of the Patient and Family Advisory Council (PFAC).

6.2.2. Patient Experience Presentation
Identify patients that may be interested in sharing their healthcare story at an upcoming TFHD Board of Directors (BOD) or BOD Quality Committee meeting.

6.3. Epic Quality Reports ..... ATTACHMENT
Discuss the quality reports that Epic is able to provide us when the system is implemented in November 2017.

6.4. Patient Safety ..... ATTACHMENT

6.4.1 Sepsis Bundle
Review the sepsis bundle quality metrics and the process improvement teams plans for improvement.

6.4.2 AHRQ Patient Safety Culture Survey

Provide a status report on the biennial survey conducted in May 2017.

6.5. Medication Safety Committee .....ATTACHMENT*
Review the Committee's functions, including medication safety monitoring, and the impact of the Bar Coding system on patient safety.

6.6. Medical Staff Quality Assurance Committee (MSQAC) .....ATTACHMENT
Discuss the 2018 meeting calendar in which the Board Quality Committee will follow the MSQAC meeting.

6.7. Board Quality Education .....ATTACHMENT
Discuss the *Third International Consensus Definitions for Sepsis and Septic Shock* (2016), JAMA, 315(8), 801-810.
The Committee will review and discuss topics for future board quality education. Identify best practice topics for review at future meetings.

7. REVIEW FOLLOW UP ITEMS / BOARD MEETING RECOMMENDATIONS

8. NEXT MEETING DATE
The date and time of the next committee meeting, Tuesday, November 14, 2017, at 12:00 p.m. will be confirmed.

9. ADJOURN

*Denotes material (or a portion thereof) may be distributed later.

Note: It is the policy of Tahoe Forest Hospital District to not discriminate in admissions, provisions of services, hiring, training and employment practices on the basis of color, national origin, sex, religion, age or disability including AIDS and related conditions.

Equal Opportunity Employer. The meeting location is accessible to people with disabilities. Every reasonable effort will be made to accommodate participation of the disabled in all of the District's public meetings. If particular accommodations for the disabled are needed (i.e., disability-related aids or other services), please contact the Executive Assistant at 582-3481 at least 24 hours in advance of the meeting.

QUALITY COMMITTEE
DRAFT MINUTES

Tuesday, July 11, 2017 at 12:00 p.m.
Human Resources Conference Room, Tahoe Forest Hospital
10024 Pine Avenue, Truckee, CA

1. CALL TO ORDER
Meeting was called to order at 12:00 p.m.

2. ROLL CALL
Board: Alyce Wong, RN, Chair; Charles Zipkin, M.D., Board Member

Staff: Harry Weis, Chief Executive Officer; Judy Newland, Chief Operating Officer; Karen Baffone, Chief Nursing Officer; Janet Van Gelder, Director of Quality and Regulations; Martina Rochefort, Clerk of the Board

3. CLEAR THE AGENDA/ITEMS NOT ON THE POSTED AGENDA
No changes were made to the agenda.

4. INPUT – AUDIENCE
No public comment was received.

5. APPROVAL OF MINUTES OF: 5/9/2017
Committee directed Clerk of the Board to change "compromise" to "comprise" and "charter" to "bylaws" under Item 6.1.

Director Zipkin moved approval of the May 9, 2017 Board Quality Committee minutes with the changes noted above, Director Wong seconded.

6. ITEMS FOR COMMITTEE DISCUSSION AND/OR RECOMMENDATION
6.1. 2017 Quality Committee Focus
Jean Steinberg, Director of Medical Staff Services, joined the meeting at 12:03 p.m.

Board Quality Committee will continue to meet as is until the board changes its bylaws.

Discussion about the Quality Assurance Performance Improvement Plan (QA/PI) and committee's focus.

The Quality Department runs the QA/PI plan which is a focus of the health system. The Quality Committee has overall oversight.

COO noted having just the QA/PI plan limits the focus of the board members.

There is overlap between the QA/PI plan and committee focus but they ultimately have different targets.

Dr. Josh Scholnick joined the meeting at 12:14 p.m.
Trish Foley, Patient Advocate, joined the meeting at 12:15 p.m.

Board bylaws will be revised but have to undergo two readings at regular board meetings before they will be final.

6.2. Patient & Family Centered Care (PFCC)

6.2.1. Patient & Family Advisory Council Update

Patient Advocate provided an update on the activities of the Patient and Family Advisory Council (PFAC).

Patient Advocate noted the PFAC received a presentation from Jason Grosdidier, Director of Respiratory Therapy and Environmental Services (EVS), at their May meeting. He highlighted the services offered by Respiratory Therapy, updated equipment the department is utilizing, and future services to be offered. Mr. Grosdidier noted how EVS is using a new cleaning solution with no odor or residue that kills bacteria. EVS is also trying out a disposable curtain in patient rooms that is more cost effective and recyclable.

PFAC suggested a bench outside of the main hospital entrance. Mr. Grosdidier followed up and a bench was approved.

PFAC discussed the Johns Hopkins article *No Room for Error* and family involvement.

Bev Schnobrich from Case Management and Kristy Blake of Women and Family presented at the June PFAC meeting.

Case Management services were reviewed with PFAC. PFAC suggested a community class or healthcare talk surrounding Medicare benefits and supplements. The suggestion was forwarded to Ted and Paige in marketing to work it into the schedule.

Kristy Blake reviewed new services for Women and Family.

Changes regarding the inpatient televisions will occur post EPIC implementation.

Director of Quality and Regulations thanked Trish for her years of service as the District's patient advocate.

Patient Advocate departed the meeting at 12:25 p.m.

6.2.2. Patient Experience Presentation

No discussion was held on this item.

6.3. BOD Quality Reporting Calendar

Board President previously requested monthly quality presentations to the Board of Directors.

Quality reports (i.e. dashboard, Service Excellence report) are presented quarterly.

Clerk suggested August topic may want to defer to another month due to the meeting location change.

Director Zipkin will put safety as an education topic for the board.
CNO noted there are lots of proactive actions being taken on the safety front.

Dr. Scholnick suggested displaying safety information on the intranet.
Safety is part of CNO's rounding.

Director Wong inquired if any information on patient safety has been added to the TFHD website.
Director of Quality and Regulations noted there is a quality specific section but she is not aware if there is something separate on patient safety.

6.4. Hospice/Palliative Care Program

CNO provided an update to hospice and palliative care program.

Hospice and palliative care generally go hand and hand. A number of readmissions at our facility are related to cancer center.

Kathy Bervid resigned her palliative care position at the cancer center.

CNO met with cancer center and Dr. Rohlen. There is a constraint on the advancement of this program as there is a build that has to be done on the financial side and it cannot be done until after the EPIC implementation.

Dr. Rohlen is working with Bev Schnobrich in case management. The District will find office space for Dr. Rohlen to see patients.

Discussion was held about the Medical Director of Hospice's involvement in palliative care program.
Dr. Koch has been extremely supportive of hospice program and has been available 24/7.

Director Wong suggested the District host a community talk about the program.

CNO noted the term "hospice" will phase out and move towards "palliative care" or "comfort care".

Dr. Scholnick commented Bev Schnobrich is incredible.

6.5. Patient Safety

6.5.1 Educational Article

Committee reviewed and discussed the *No Room for Error* article from Johns Hopkins.

Near misses at Tahoe Forest Hospital and Incline Village Community Hospital get picked up through self-reporting. Self-reporting takes place through Quantros.

Director Wong asked if employees use Quantros. Yes, employees use Quantros. CNO also noted it is part of rounding protocols.

Director of Quality and Regulations and Chief Medical Officer reviewed in detail. Group has spent a lot

of time refining the disclosure policy and care for caregiver program. Next year the District will plan to participate in the BETA heart program.

6.5.2 AHRQ Patient Safety Culture Survey

Director of Quality and Regulations provided an update on the biennial AHRQ Patient Safety Culture Survey conducted in May 2017.

358 survey responses were received.

Director of Quality and Regulations believed some staff did not complete survey because they felt it did not apply to them.

Risk and Patient Safety Manager will create a summary report that will go to board.

The benchmarking data will not be received until October.

6.6. Quality Metrics

Committee reviewed key quality and service metrics, how the data is shared throughout the organization, and how plans for improvement are developed and monitored.

Director of Quality and Regulations included a blank copy of the dashboards in the packet for comments on what information the committee and board would like to have included.

CEO would like to see a linear trend line added to show direction and tilt, above or below the trend line.

COO noted this is an opportunity to have add more robust data and update the dashboards. New Emergency Department outpatient measures can be included, along with hospital acquired conditions.

There are significant issues with data collection for home health metrics. Home health does not usually receive enough survey responses.

Director Zipkin commented that it should never be assumed the board has medical expertise.

CEO said the next step is to finalize metrics.

Discussion was held about the District's care coordination program. The growth of care coordination is exponential.

CEO asked if frequent patients are being picked up into our care coordination program.
CNO noted there has been increased methamphetamine and alcohol use in the community. Discharge of these patients will become problematic with homelessness on the rise.

6.7. Medical Staff Quality Committee (MSQAC)

Committee discussed the option of having two Board members attend the Medical Staff Quality Assurance Committee (MSQAC) closed session to discuss case review process improvement.

CEO felt agenda planning will create a convergence between the two quality committees.

Discussion was held about board members attending MSQAC closed session. General Counsel previously advised the board members would have to be invited by the Chief of Staff in concurrence with the Medical Executive Committee (MEC).

Director of Medical Staff Services will add this as a discussion item on the next MEC agenda.

6.8. Board Quality Education

Director of Quality and Regulations remarked the Hospital Quality Institute conference is not governance specific and focuses on process improvement opportunities.

Director of Quality and Regulations recommended the Executive Director of Governance have Hospital Quality Institute on his list of possible board education opportunities.

7. REVIEW FOLLOW UP ITEMS / BOARD MEETING RECOMMENDATIONS

Director of Medical Staff Services would like to add the physician satisfaction survey to the next Quality Committee meeting agenda.

Director of Medical Staff Services also noted the Town of Truckee has asked the hospital to take a stance on marijuana.

8. NEXT MEETING DATE

The next Board Quality Committee meeting date of Tuesday, September 19, 2017, at 12:00 p.m. was confirmed.

9. ADJOURN

Meeting adjourned at 1:52 p.m.

Board Quality Committee

2017 QA/QI Plan Focus	2017 Board Quality Committee Focus
1. Top decile quality of care and patient satisfaction metric results	1. Monitor Quality, service and patient safety metrics and support processes, with a focus on outliers to achieve top decile performance and measurable improvement
2. Support Patient and Family Center Care	4. Provide appropriate resources to assist the Patient and Family Advisory Council (PFAC)
3. Sustain a Just Culture philosophy that promotes patient safety, openness and transparency	
4. Promote lean principles to improve processes, reduce waste and eliminate inefficiencies	
5. Implement the Epic electronic health record to enable integration of medical services at all levels of the organization	6. Support the Epic electronic health record implementation with a focus on quality, service and patient safety
6. Facilitate integrated continuum of care management system	
7. Ensure Patient Safety across the entire Health System	2. Monitor the Patient Safety Culture Survey plan for improvement progress
8. Achieve Public Hospital redesign and Incentives in Medi-Cal (PRIME) project initiative	
	3. Support the Quadruple Aim, including improving the experience of providing care and workforce engagement
	5. Provide direction on how to best educate the community about the TFHD quality and service metrics (ie website, public speaking, social media, quarterly magazine, newspaper articles, etc.)

6/30/2017 aw

	1	2	3	4
1	**Source**	**Template/Folder Path**	**Report/Tool Name**	**Description**
2	My Reports	2014 Find IP Patients Generic Criteria	IP Patients with Positive C-Difficile	This report searches patients admitted to user's login department and returns those with positive C-Diff results
3	My Reports	2014 Find IP Patients Generic Criteria	IP Patients with Positive Influenza Surveillance	This report searches patients admitted to user's login department and returns those with positive influenza results.
4	My Reports	2014 Find IP Patients Generic Criteria	IP Patients with Positive MRSA/MSSA Surveillance	This report searches patients admitted to user's login department and returns those with positive MRSA/MSSA results
5	My Reports	2014 Find IP Patients Generic Criteria	IP Patients with Positive VRE Surveillance	This report searches patients admitted to user's login department and returns those with positive VRE results
6	My Reports	2014 Find IP Patients Generic Criteria	IP Patients with Active Isolation Orders	This report lists patients admitted to the user's login department and returns those with active isolation orders.
7	My Reports	2014 Find IP Patients Generic Criteria	IP Patients with Foley: My Department	This report is used for Foley Monitoring Metrics. This report will show all patients on the user's login department that have either a Foley Monitoring order or documentation.
8	My Reports	Find IP Patients LDA Criteria	Patients with Active Central Lines	This report provides a list of patients that have documentation for central lines.
9	My Reports	Find IP Patients LDA Criteria	Patients with Active Peripheral Lines	This report provides a list of patients that have documentation for peripheral lines.
10	My Reports	Find IP Patients LDA Criteria	Patients with Active PICC Lines	This report provides a list of patients that have documentation for a PICC line.
11	My Reports	Find IP Patients LDA Criteria	Patients with Active Urinary Catheters	This report provides a list of patients that have documentation using urinary catheter flowsheet groups.
12	Mercy Insight	Clinical > Clinical Documentation	Admission Assessment Documentation	This report provides a list of patients who are currently in-house with the corresponding date/time when the following admission assessment activities where undertaken: height, weight, pain, skin, fall risk, allergy, nutrition and advance directives. The total time to complete all these admission assessments is calculated and the number of assessments done within 24 hours from admission is displayed.

	1	2	3	4
13	Mercy Insight	Clinical > Clinical Documentation	Blood Transfusion Audits	Blood transfusion is now based on orders rather than flowsheets. The report date range is based on the order instance and captures patients who have had a blood transfusion. It provides the patient name, MRN ID, product type, unit number, taken time, action type, and first and second user making the verification.
14	Mercy Insight	Clinical > Clinical Documentation	Central Line Days	This report provides a list of patients who have a central line for the specified date range. Removal date would be blank if patient still has the central line while in the selected department. This report gives the count of days the patient was in that department for Central Line within the chosen date range. It also gives the daily count of patients with Central Line for every department in the chosen date range.
15	Mercy Insight	Clinical > Clinical Documentation	Foley Days	This report provides a list of patients who have a Foley(Urethral Catheter) in the specific department for the specified date range. Removal date would be blank if patient still has the Foley while in the selected department. This report gives the count of days the patient was in that department for Foley within the chosen date range. It also gives the daily count of patients with Foley for every department in the chosen date range. It has both Summary and Detail view options. This report pulls in patients who had a Foley already present on Admission to the unit. The report includes Indwelling and Urethral catheters.
16	Mercy Insight	Clinical > Clinical Documentation	Isolation Patient Days	This report provides a count of patients with orders for isolation per department per day for a given date range.
17	Mercy Insight	Clinical > Clinical Documentation	MAR Barcode Compliance	A report that provides information about the number and percentage of administrations given to a patient where the patient's barcode and/or the medication barcode were not scanned over a specified time period. It is developed using the Epic Denali Clarity data model.
18	Mercy Insight	Clinical > Clinical Documentation	Medication Barcode Scanning Compliance	This report displays the total number of MAR administrations and the total number of missed medication scans per user. The report can be run for selected users or all users. This report excludes patient supplied medications.

	1	2	3	4
19	Mercy Insight	Clinical > Clinical Documentation	Medication Reconciliation	This report will extract inpatient hospital base class admissions for a given period. It will also exclude newborns, born inside the hospital. The patient's encounter must have at least one medication review instance. If reviewed, the first review instance timestamp will be displayed. The report is grouped by Location Name and displays a numerator, denominator, and percent based rate of compliance. The patient detail will be available as a toggle option via a run time parameter.
20	Mercy Insight	Clinical > Clinical Documentation	Pain Reassessment Report	This report provides details around the compliance percentage of users in performing pain reassessments within one hour and two hours from the time of pain medication administration.
21	Mercy Insight	Patient Access > ADT/Registration	Admissions - Inpatient	This report will display Inpatient Admissions by flexible grouping options. The report can be displayed at a summary or detail level by grouping.
22	Mercy Insight	Patient Access > ADT/Registration	Admissions - Observation	This report will display Observation Admissions by flexible grouping options. The report can be displayed at a summary or detail level by grouping.
23	Mercy Insight	Patient Access > ADT/Registration	Discharges - Flexible Grouping	This report displays Inpatient and optional observation discharges and is based on the HAR not the ADT discharge events. The report can be ran as a summary report or a detail report with many grouping options.
24	Mercy Insight	Patient Access > ADT/Registration	DRG Readmissions Within 31 Days - ICD10	This report displays patients who have been readmitted within 31 days of a previous discharge, sorting the patients by the final DRG on their previous visit. Information about the current and previous visits' account number, attending provider, length of stay, primary final diagnosis, and the days between prior discharge and current admission is also provided.
25	Mercy Insight	Patient Access > ADT/Registration	Patient Readmissions - ICD10	This report provides a list of patients who have a hospital admission within a user-specified range from a previous hospital discharge.

	1	2	3	4
26	Mercy Insight	Patient Access > HIM	Expired Listing - Diagnoses and Procedures	This report displays all of the diagnoses and procedures coded for patients that had a discharge disposition of Expired. It allows users the option to run it for summary or detail information. Detail displays diagnoses code and procedure description associated with expired patient. Summary excludes procedure code and description.
27	Mercy Insight	Patient Access > HIM	Mortality Rates	This report will provide a user with the Mortality Rates at their facility. In addition to the Mortality Rate, which is computed by the percentage of patients with a discharge disposition of Expired compared to the total number of patients, the following metrics are displayed at all group levels: Total Patients, Total Days, Average Length of Stay, and Number of Expired Patients.
28	Mercy Insight	Patient Access > HIM	Discharges by ICD10 Diagnosis	
29	Mercy Insight	Patient Access > HIM	Core Measures Patient List	
30	Mercy Insight	Patient Access > HIM	Heart Failure Patients by Payor	
31	Mercy Insight	Clinical > Clinical Documentation	Mercy Birth Log	
32	Mercy Insight	Clinical > Clinical Documentation	Newborn CCHD	Newborn List: List of patients born in selected service area and location between date range selected. Includes flowsheet items related to CCHD screening.
33	Mercy Insight	Clinical > Clinical Documentation My Reports	Stroke Patients List ICD 10	patients with a primary diagnosis of stroke This report provides basic account information for users to pull the charts of patients within specific ICD-10 code ranges from the Admission Diagnosis, Discharge Diagnosis or Problem List.
34	My Reports	IP Stroke Core Measures Template	IP Stroke Core Measures	
35	Mercy Insight	Clinical > Surgical	Completed Surgical Procedures	all surgical procedures
36	Mercy Insight	Patient Access > ADT/Registration	Patient Readmissions - ICD10	readmissions by financial class
37	Mercy Insight	Clinical > Surgical	Procedure Frequency Report	
38	Mercy Insight	Clinical > Emergency	Inpatient Admits from the ED	IP admitted through the ED
39	Mercy Insight	Patient Access > HIM	Mortality Rates	Mortality report / Daily Mortality
40	Mercy Insight	Patient Access > HIM	Discharges by CPT	

TFHS Quality Dashboard DB	Hand entered quarterly
Restraints usage percentage	
Medication Error Rate	
Pressure Ulcer Percentage	
IP Falls with mod to sev injury per 1000 pt days	
Sepsis early management bundler, severe sepsis/septic	
Influenza Vaccine	
VTE Prophylaxis	
ICU VTE Prophylaxis	
VTE Patients w/ Anticoagulation Overlap Therapy	
VTE Patients Receiving UFH w/ dosages/platelet count monitoring	
VTE Discharge Instructions	
Incident of Potentitally preventable VTE	
Median time from ED Arrival to Ed Dept for DC'd ED Pts - overall rate	
Median Time from ED Arrival to ED Departure for DC'd ED Pts - reporting measure	
Median Time from ED Arrival to ED Departure for DC'd ED Patients - Transfer Pts	
Door to Diagnositic Evaluation by a Qualified Medical Personnel in minutes	
Median Time to Pain Mgmt for Long Bone Fracture	
Inpatient Mortality percentage	
Primary C section percentage	
Medicare average LOS	
Pts returning to the ED within 72 hrs with same complaint requiring IP admission	
Class 1 surgical site infection rate	
ICU CLR-BSI	
VAP (Vent Associated Pneumonia)	
ICU Catheter Associated UTI	
Healthcare Acquired MRSA (per 1000 pt days)	
Foreign Object Retained after Surgery	
Air Embolism	
Blood Incompatibility	
DVT And PE Post Surgery	
HCAHPS "Recommend this hospital" Percentile Rank	
HCAHPS "Rate this Hospital 9 or 10" Rank	
OutPT Percentile Rank	
TFH ED Overall Percentile Rank	
IVCH ED Overall Percentile Rank	
ASD Overall Percentile Rank	
MSC Overall Percentile Rank	
Class 1 surgical site infection rate	
Influenza vaccine administration percentage	
ALOS	
Pressure ulcer percentage	
Inpatient falls per 1000 pt days rate	
Restraint usage per 100 pt days	
STAT CBC Turn around time <60 minutes	
Medication Error Site	
IP Mortality Number	
Median time from ED Arrival to Ed Dept for DC'd ED Pts - overall rate	
Median Time from ED Arrival to ED Departure for DC'd ED Pts - reporting measure	
Medican Time from ED Arrival to ED Departure for DC'd ED Pts - Psych patients	
Median Time from ED Arrival to ED Departure for DC'd ED Patients - Transfer Pts	
Door to Diagnositic Evaluation by a Qualified Medical Personnel in minutes	
Median Time to Pain Mgmt for Long Bone Fracture	
Percent of Pts who develop pressure ulcers	
Residents with a UTI percentage	
Percent of residents who experience unplanned weight loss	
Percentage of Falls	
	Not doing HH or hospice
Admit Decision time to ED Departure Time for Admitted Patients - Overall Rate	
Admit decision time to ED departure time for admitted patients - reporting measure	
admit decision time to ED departure time for admitted patients - psychiatric/mental health patients	
CMS 4 star rating for patient satisfaction	
Improvement in Pain	
Improved Bathing	
Improved Transferring	
Improved Ambulation	
Management of oral medications	
Improve in Surgical Wounds	
Patients with emergency care needs percentage	
HHCAHPS - Rate this agency 9 or 10	
HHCAHPS - Recommend this agency	
Match MAR vs Physician Orders	
Follow through on assessed pt needs	
Patients Pain goals are met within 48 hrs	
Hospice Patient UTI Rate	
Hospice Patient Vascular Device Infection Rate (TPD)	
Heart Attack Care	

Sepsis early management bundler, severe sepsis/septic	
TFH Medication Errors	
TFH Hospital Acquired Surgical Infections	
TFH Hospital Acquired non Surgical Infections	
TFH Hospital Acquired Conditions	
TFH Falls Rate with Moderate/Severe Injury	
TFH Pressure Ulcers Rate	
SNF 5 Star Quality Rating	
HH % Improvement in Pain	
HH % Improvement in Bathing	
HH % Improvement in Amb/Locomotion	
HH % Improvement in Surgical Wounds	
TFH Immunizations	Sort of measured in Line 7
TFH VTE Care	
TFH Stroke Care	
IVCH Hospital acquired surgical infections	
IVCH Medication errors	
Death Register	
TFHS 2017 QA/PI Reporting Measures	Authopsy/Coroner
Number of Admissions per Provider	
Ongoing Professional Practice Evaluation Report (OPPE)	

NQF-ENDORSED VOLUNTARY CONSENSUS STANDARDS FOR HOSPITAL CARE

Measure Information Form
Collected For: CMS Only

Measure Set: Sepsis

Set Measure ID #: SEP-1

Performance Measure Name: Early Management Bundle, Severe Sepsis/Septic Shock

Description: This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, it assesses measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. As reflected in the data elements and their definitions, the first three interventions should occur within 3 hours of presentation of severe sepsis, while the remaining interventions are expected to occur within 6 hours of presentation of septic shock.

Rationale: The evidence cited for all components of this measure is directly related to decreases in organ failure, overall reductions in hospital mortality, length of stay, and costs of care.

A principle of sepsis care is that clinicians must rapidly treat patients with an unknown causative organism and unknown antibiotic susceptibility. Since patients with severe sepsis have little margin for error regarding antimicrobial therapy, initial treatment should be broad spectrum to cover all likely pathogens. As soon as the causative organism is identified, based on subsequent culture and susceptibility testing, de-escalation is encouraged by selecting the most appropriate antimicrobial therapy to cover the identified pathogen, safely and cost effectively (Dellinger, 2012).

Multicenter efforts to promote bundles of care for severe sepsis and septic shock were associated with improved guideline compliance and lower hospital mortality (Ferrer, 2008 and Rhodes, 2015). Even with compliance rates of less than 30%, absolute reductions in mortality of 4-6% have been noted (Levy, 2010 and Ferrer, 2008). Absolute reductions in mortality of over 20% have been seen with compliance rates of 52% (Levy, 2010). Coba et al. has shown that when all bundle elements are completed and compared to patients who do not have bundle completion, the mortality difference is 14% (2011). Thus, there is a direct association between bundle compliance and improved mortality. Without a continuous quality initiative (CQI), even these compliance rates will not improve and will decrease over time (Ferrer, 2008). Multiple studies have shown that, for patients with severe sepsis, standardized order sets, enhanced bedside monitor display, telemedicine, and comprehensive CQI feedback is feasible, modifies

clinician behavior, and is associated with decreased hospital mortality (Thiel, 2009; Micek, 2006; Winterbottom, 2011; Schramm, 2011; Nguyen, 2007; Loyola, 2011).

Type of Measure: Process

Improvement Noted As: An increase in the rate

Numerator Statement: Patients who received ALL of the following:
Received within three hours of presentation of severe sepsis:

- Initial lactate level measurement
- Broad spectrum or other antibiotics administered
- Blood cultures drawn prior to antibiotics
  AND received within six hours of presentation of severe sepsis:
- Repeat lactate level measurement only if initial lactate level is elevated

AND ONLY if Septic Shock present:
Received within three hours of presentation of septic shock:

- Resuscitation with 30 ml/kg crystalloid fluids

AND ONLY IF hypotension persists after fluid administration, received within six hours of presentation of septic shock:

- Vasopressors

AND ONLY if hypotension persists after fluid administration or initial lactate >= 4 mmol/L, received within six hours of presentation of septic shock:

- Repeat volume status and tissue perfusion assessment consisting of either
  - A focused exam including:
    - Vital signs, AND
    - Cardiopulmonary exam, AND
    - Capillary refill evaluation, AND
    - Peripheral pulse evaluation, AND
    - Skin examination

      OR
  - Any two of the following four:
    - Central venous pressure measurement
    - Central venous oxygen measurement
    - Bedside Cardiovascular Ultrasound
    - Passive Leg Raise or Fluid Challenge

Included Populations: As described above

Excluded Populations:
None

Data Elements:

- *Bedside Cardiovascular Ultrasound Date*
- *Bedside Cardiovascular Ultrasound Performed*
- *Bedside Cardiovascular Ultrasound Time*
- *Blood Culture Collection*
- *Blood Culture Collection Acceptable Delay*

SEP-1: Early Management Bundle, Severe Sepsis/Septic Shock

Numerator: Patients who received ALL of the following:

Received within three hours of presentation of severe sepsis:

- Initial lactate level measurement
- Broad spectrum or other antibiotics administered
- Blood cultures drawn prior to antibiotics

AND received within six hours of presentation of severe sepsis:

- Repeat lactate level measurement only if initial lactate level is elevated

AND ONLY if Septic Shock present:

Received within three hours of presentation of septic shock:

- Resuscitation with 30 ml/kg crystalloid fluids

AND ONLY if hypotension persists after fluid administration, received within six hours of presentation of septic shock:

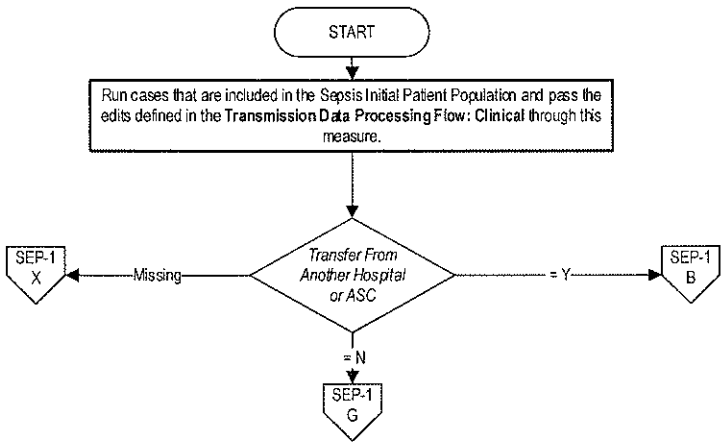
- Vasopressors

AND ONLY if hypotension persists after fluid administration or initial lactate >= 4 mmol/L, received within six hours of presentation of septic shock:

- Repeat volume status and tissue perfusion assessment consisting of either:
  - A focused exam including:
    - Vital signs, AND
    - Cardiopulmonary exam, AND
    - Capillary refill evaluation, AND
    - Peripheral pulse evaluation, AND
    - Skin examination

      OR
  - Any two of the following four:
    - Central venous pressure measurement
    - Central venous oxygen measurement
    - Bedside cardiovascular ultrasound
    - Passive leg raise or fluid challenge

Denominator: Inpatients age 18 and over with an ICD-10-CM Principal or Other Diagnosis Code of Sepsis, Severe Sepsis or Septic Shock as defined in Appendix A, Table 4.01



Variable Key:
Sepsis Discharge Time
Shock Discharge Time
Shock Six Hour Counter
Shock Physical Assessment Six Hour Counter
Initial Lactate Time
Broad Spectrum Antibiotic Time
Blood Culture Time
Blood Culture Antibiotic Time
Repeat Lactate Time
Shock Presentation Time
Crystalloid Fluid Admin Time
Vasopressor Time
Vital Signs Time
Vital Signs Fluid Time
Cardiopulmonary Eval Time
Cardiopulmonary Evaluation Fluid Time
Capillary Refill Time
Capillary Refill Fluid Time
Peripheral Pulse Time
Peripheral Pulse Fluid Time
Skin Exam Time
Skin Exam Fluid Time
Central Venous Pressure Time
Central Venous Pressure Fluid Time
Central Venous Oxygen Time
Central Venous Oxygen Fluid Time
Bedside Ultrasound Time
Bedside Ultrasound Fluid Time
Passive Leg Raise Time
Passive Leg Raise Fluid Time
Fluid Shock Time
Fluid Challenge Fluid Time

TAHOE FOREST HOSPITAL DISTRICT MEDICAL STAFF

DATE: August 24, 2017

TO: QUALITY ASSESSMENT COMMITTEE

FROM: Jean Steinberg, CPMSM, CPCS, Director, Medical Staff Services

RE: **2018 Meeting Schedule**

The **QA Committee** meeting schedule for 2018 is listed below:

2nd Thursday (Bimonthly)
7:30 a.m. – 9:00 a.m.
Eskridge Conference Room

February 1, 2018

April 12, 2018

June 14, 2018

August 9, 2018

October 11, 2018

December 13, 2018

PLEASE MARK YOUR CALENDARS

ALL MEDICAL STAFF CALENDARS CAN BE FOUND:
G:Public/Medical Staff/2018 Meeting Calendars
TFHD Intranet – Department Pages – Medical Staff

Special Communication | CARING FOR THE CRITICALLY ILL PATIENT

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

Mervyn Singer, MD, FRCP; Clifford S. Deutschman, MD, MS; Christopher Warren Seymour, MD, MSc; Manu Shankar-Hari, MSc, MD, FFICM; Djillali Annane, MD, PhD; Michael Bauer, MD; Rinaldo Bellomo, MD; Gordon R. Bernard, MD; Jean-Daniel Chiche, MD, PhD; Craig M. Coopersmith, MD; Richard S. Hotchkiss, MD; Mitchell M. Levy, MD; John C. Marshall, MD; Greg S. Martin, MD, MSc; Steven M. Opal, MD; Gordon D. Rubenfeld, MD, MS; Tom van der Poll, MD, PhD; Jean-Louis Vincent, MD, PhD; Derek C. Angus, MD, MPH

IMPORTANCE Definitions of sepsis and septic shock were last revised in 2001. Considerable advances have since been made into the pathobiology (changes in organ function, morphology, cell biology, biochemistry, immunology, and circulation), management, and epidemiology of sepsis, suggesting the need for reexamination.

OBJECTIVE To evaluate and, as needed, update definitions for sepsis and septic shock.

PROCESS A task force (n = 19) with expertise in sepsis pathobiology, clinical trials, and epidemiology was convened by the Society of Critical Care Medicine and the European Society of Intensive Care Medicine. Definitions and clinical criteria were generated through meetings, Delphi processes, analysis of electronic health record databases, and voting, followed by circulation to international professional societies, requesting peer review and endorsement (by 31 societies listed in the Acknowledgment).

KEY FINDINGS FROM EVIDENCE SYNTHESIS Limitations of previous definitions included an excessive focus on inflammation, the misleading model that sepsis follows a continuum through severe sepsis to shock, and inadequate specificity and sensitivity of the systemic inflammatory response syndrome (SIRS) criteria. Multiple definitions and terminologies are currently in use for sepsis, septic shock, and organ dysfunction, leading to discrepancies in reported incidence and observed mortality. The task force concluded the term *severe sepsis* was redundant.

RECOMMENDATIONS Sepsis should be defined as life-threatening organ dysfunction caused by a dysregulated host response to infection. For clinical operationalization, organ dysfunction can be represented by an increase in the Sequential [Sepsis-related] Organ Failure Assessment (SOFA) score of 2 points or more, which is associated with an in-hospital mortality greater than 10%. Septic shock should be defined as a subset of sepsis in which particularly profound circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than with sepsis alone. Patients with septic shock can be clinically identified by a vasopressor requirement to maintain a mean arterial pressure of 65 mm Hg or greater and serum lactate level greater than 2 mmol/L (>18 mg/dL) in the absence of hypovolemia. This combination is associated with hospital mortality rates greater than 40%. In out-of-hospital, emergency department, or general hospital ward settings, adult patients with suspected infection can be rapidly identified as being more likely to have poor outcomes typical of sepsis if they have at least 2 of the following clinical criteria that together constitute a new bedside clinical score termed quickSOFA (qSOFA): respiratory rate of 22/min or greater, altered mentation, or systolic blood pressure of 100 mm Hg or less.

CONCLUSIONS AND RELEVANCE These updated definitions and clinical criteria should replace previous definitions, offer greater consistency for epidemiologic studies and clinical trials, and facilitate earlier recognition and more timely management of patients with sepsis or at risk of developing sepsis.

JAMA. 2016;315(8):801-810. doi:10.1001/jama.2016.0287

Editorial page 757

Author Video Interview, Author Audio Interview, and JAMA Report Video at jama.com

Related articles pages 762 and 775

CME Quiz at jamanetworkcme.com and CME Questions page 816

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

Group Information: The Sepsis Definitions Task Force members are the authors listed above.

Corresponding Author: Clifford S. Deutschman, MD, MS, Departments of Pediatrics and Molecular Medicine, Hofstra–Northwell School of Medicine, Feinstein Institute for Medical Research, 269-01 76th Ave, New Hyde Park, NY 11040 (cdeutschman@nshs.edu).

Sepsis, a syndrome of physiologic, pathologic, and biochemical abnormalities induced by infection, is a major public health concern, accounting for more than $20 billion (5.2%) of total US hospital costs in 2011.[1] The reported incidence of sepsis is increasing,[2,3] likely reflecting aging populations with more comorbidities, greater recognition,[4] and, in some countries, reimbursement-favorable coding.[5] Although the true incidence is unknown, conservative estimates indicate that sepsis is a leading cause of mortality and critical illness worldwide.[6,7] Furthermore, there is increasing awareness that patients who survive sepsis often have long-term physical, psychological, and cognitive disabilities with significant health care and social implications.[8]

A 1991 consensus conference[9] developed initial definitions that focused on the then-prevailing view that sepsis resulted from a host's systemic inflammatory response syndrome (SIRS) to infection (**Box 1**). Sepsis complicated by organ dysfunction was termed *severe sepsis*, which could progress to septic shock, defined as "sepsis-induced hypotension persisting despite adequate fluid resuscitation." A 2001 task force, recognizing limitations with these definitions, expanded the list of diagnostic criteria but did not offer alternatives because of the lack of supporting evidence.[10] In effect, the definitions of sepsis, septic shock, and organ dysfunction have remained largely unchanged for more than 2 decades.

Box 1. SIRS (Systemic Inflammatory Response Syndrome)

Two or more of:
- Temperature >38°C or <36°C
- Heart rate >90/min
- Respiratory rate >20/min or $Paco_2$ <32 mm Hg (4.3 kPa)
- White blood cell count >12 000/mm^3 or <4000/mm^3 or >10% immature bands

From Bone et al.[9]

The Process of Developing New Definitions

Recognizing the need to reexamine the current definitions,[11] the European Society of Intensive Care Medicine and the Society of Critical Care Medicine convened a task force of 19 critical care, infectious disease, surgical, and pulmonary specialists in January 2014. Unrestricted funding support was provided by the societies, and the task force retained complete autonomy. The societies each nominated cochairs (Drs Deutschman and Singer), who selected members according to their scientific expertise in sepsis epidemiology, clinical trials, and basic or translational research.

The group engaged in iterative discussions via 4 face-to-face meetings between January 2014 and January 2015, email correspondence, and voting. Existing definitions were revisited in light of an enhanced appreciation of the pathobiology and the availability of large electronic health record databases and patient cohorts.

An expert consensus process, based on a current understanding of sepsis-induced changes in organ function, morphology, cell biology, biochemistry, immunology, and circulation (collectively referred to as pathobiology), forged agreement on updated definition(s) and the criteria to be tested in the clinical arena (content validity). The distinction between definitions and clinical criteria is discussed below. The agreement between potential clinical criteria (construct validity) and the ability of the criteria to predict outcomes typical of sepsis, such as need for intensive care unit (ICU) admission or death (predictive validity, a form of criterion validity), were then tested. These explorations were performed in multiple large electronic health record databases that also addressed the absence (missingness) of individual elements of different organ dysfunction scores and the question of generalizability (ecologic validity).[12] A systematic literature review and Delphi consensus methods were also used for the definition and clinical criteria describing septic shock.[13]

When compiled, the task force recommendations with supporting evidence, including original research, were circulated to major international societies and other relevant bodies for peer review and endorsement (31 endorsing societies are listed at the end of this article).

Issues Addressed by the Task Force

The task force sought to differentiate sepsis from uncomplicated infection and to update definitions of sepsis and septic shock to be consistent with improved understanding of the pathobiology. A definition is the description of an illness concept; thus, a definition of sepsis should describe what sepsis "is." This chosen approach allowed discussion of biological concepts that are currently incompletely understood, such as genetic influences and cellular abnormalities. The sepsis illness concept is predicated on infection as its trigger, acknowledging the current challenges in the microbiological identification of infection. It was not, however, within the task force brief to examine definitions of infection.

The task force recognized that sepsis is a syndrome without, at present, a validated criterion standard diagnostic test. There is currently no process to operationalize the definitions of sepsis and septic shock, a key deficit that has led to major variations in reported incidence and mortality rates (see later discussion). The task force determined that there was an important need for features that can be identified and measured in individual patients and sought to provide such criteria to offer uniformity. Ideally, these clinical criteria should identify all the elements of sepsis (infection, host response, and organ dysfunction), be simple to obtain, and be available promptly and at a reasonable cost or burden. Furthermore, it should be possible to test the validity of these criteria with available large clinical data sets and, ultimately, prospectively. In addition, clinical criteria should be available to provide practitioners in out-of-hospital, emergency department, and hospital ward settings with the capacity to better identify patients with suspected infection likely to progress to a life-threatening state. Such early recognition is particularly important because prompt management of septic patients may improve outcomes.[4]

In addition, to provide a more consistent and reproducible picture of sepsis incidence and outcomes, the task force sought to integrate the biology and clinical identification of sepsis with its epidemiology and coding.

Identified Challenges and Opportunities

Assessing the Validity of Definitions When There Is No Gold Standard

Sepsis is not a specific illness but rather a syndrome encompassing a still-uncertain pathobiology. At present, it can be identified by a constellation of clinical signs and symptoms in a patient with suspected infection. Because no gold standard diagnostic test exists, the task force sought definitions and supporting clinical criteria that were clear and fulfilled multiple domains of usefulness and validity.

Improved Understanding of Sepsis Pathobiology

Sepsis is a multifaceted host response to an infecting pathogen that may be significantly amplified by endogenous factors.[14,15] The original conceptualization of sepsis as infection with at least 2 of the 4 SIRS criteria focused solely on inflammatory excess. However, the validity of SIRS as a descriptor of sepsis pathobiology has been challenged. Sepsis is now recognized to involve early activation of both pro- and anti-inflammatory responses,[16] along with major modifications in nonimmunologic pathways such as cardiovascular, neuronal, autonomic, hormonal, bioenergetic, metabolic, and coagulation,[14,17,18] all of which have prognostic significance. Organ dysfunction, even when severe, is not associated with substantial cell death.[19]

The broader perspective also emphasizes the significant biological and clinical heterogeneity in affected individuals,[20] with age, underlying comorbidities, concurrent injuries (including surgery) and medications, and source of infection adding further complexity.[21] This diversity cannot be appropriately recapitulated in either animal models or computer simulations.[14] With further validation, multichannel molecular signatures (eg, transcriptomic, metabolomic, proteomic) will likely lead to better characterization of specific population subsets.[22,23] Such signatures may also help to differentiate sepsis from noninfectious insults such as trauma or pancreatitis, in which a similar biological and clinical host response may be triggered by endogenous factors.[24] Key concepts of sepsis describing its protean nature are highlighted in **Box 2**.

Box 2. Key Concepts of Sepsis

- Sepsis is the primary cause of death from infection, especially if not recognized and treated promptly. Its recognition mandates urgent attention.
- Sepsis is a syndrome shaped by pathogen factors and host factors (eg, sex, race and other genetic determinants, age, comorbidities, environment) with characteristics that evolve over time. What differentiates sepsis from infection is an aberrant or dysregulated host response and the presence of organ dysfunction.
- Sepsis-induced organ dysfunction may be occult; therefore, its presence should be considered in any patient presenting with infection. Conversely, unrecognized infection may be the cause of new-onset organ dysfunction. Any unexplained organ dysfunction should thus raise the possibility of underlying infection.
- The clinical and biological phenotype of sepsis can be modified by preexisting acute illness, long-standing comorbidities, medication, and interventions.
- Specific infections may result in local organ dysfunction without generating a dysregulated systemic host response.

Variable Definitions

A better understanding of the underlying pathobiology has been accompanied by the recognition that many existing terms (eg, *sepsis*, *severe sepsis*) are used interchangeably, whereas others are redundant (eg, *sepsis syndrome*) or overly narrow (eg, *septicemia*). Inconsistent strategies in selecting *International Classification of Diseases, Ninth Revision* (*ICD-9*), and *ICD-10* codes have compounded the problem.

Sepsis

The current use of 2 or more SIRS criteria (Box 1) to identify sepsis was unanimously considered by the task force to be unhelpful. Changes in white blood cell count, temperature, and heart rate reflect inflammation, the host response to "danger" in the form of infection or other insults. The SIRS criteria do not necessarily indicate a dysregulated, life-threatening response. SIRS criteria are present in many hospitalized patients, including those who never develop infection and never incur adverse outcomes (poor discriminant validity).[25] In addition, 1 in 8 patients admitted to critical care units in Australia and New Zealand with infection and new organ failure did not have the requisite minimum of 2 SIRS criteria to fulfill the definition of sepsis (poor concurrent validity) yet had protracted courses with significant morbidity and mortality.[26] Discriminant validity and convergent validity constitute the 2 domains of construct validity; the SIRS criteria thus perform poorly on both counts.

Organ Dysfunction or Failure

Severity of organ dysfunction has been assessed with various scoring systems that quantify abnormalities according to clinical findings, laboratory data, or therapeutic interventions. Differences in these scoring systems have also led to inconsistency in reporting. The predominant score in current use is the Sequential Organ Failure Assessment (SOFA) (originally the Sepsis-related Organ Failure Assessment[27]) (**Table 1**).[28] A higher SOFA score is associated with an increased probability of mortality.[28] The score grades abnormality by organ system and accounts for clinical interventions. However, laboratory variables, namely, Pao_2, platelet count, creatinine level, and bilirubin level, are needed for full computation. Furthermore, selection of variables and cutoff values were developed by consensus, and SOFA is not well known outside the critical care community. Other organ failure scoring systems exist, including systems built from statistical models, but none are in common use.

Septic Shock

Multiple definitions for septic shock are currently in use. Further details are provided in an accompanying article by Shankar-Hari et al.[13] A systematic review of the operationalization of current definitions highlights significant heterogeneity in reported mortality. This heterogeneity resulted from differences in the clinical variables chosen (varying cutoffs for systolic or mean blood pressure ± diverse levels of hyperlactatemia ± vasopressor use ± concurrent new organ dysfunction ± defined fluid resuscitation volume/targets), the data source and coding methods, and enrollment dates.

Table 1. Sequential [Sepsis-Related] Organ Failure Assessment Score[a]

	Score				
System	0	1	2	3	4
Respiration					
Pao_2/Fio_2, mm Hg (kPa)	≥400 (53.3)	<400 (53.3)	<300 (40)	<200 (26.7) with respiratory support	<100 (13.3) with respiratory support
Coagulation					
Platelets, $\times 10^3/\mu L$	≥150	<150	<100	<50	<20
Liver					
Bilirubin, mg/dL (μmol/L)	<1.2 (20)	1.2-1.9 (20-32)	2.0-5.9 (33-101)	6.0-11.9 (102-204)	>12.0 (204)
Cardiovascular	MAP ≥70 mm Hg	MAP <70 mm Hg	Dopamine <5 or dobutamine (any dose)[b]	Dopamine 5.1-15 or epinephrine ≤0.1 or norepinephrine ≤0.1[b]	Dopamine >15 or epinephrine >0.1 or norepinephrine >0.1[b]
Central nervous system					
Glasgow Coma Scale score[c]	15	13-14	10-12	6-9	<6
Renal					
Creatinine, mg/dL (μmol/L)	<1.2 (110)	1.2-1.9 (110-170)	2.0-3.4 (171-299)	3.5-4.9 (300-440)	>5.0 (440)
Urine output, mL/d				<500	<200

Abbreviations: Fio_2, fraction of inspired oxygen; MAP, mean arterial pressure; Pao_2, partial pressure of oxygen.

[a] Adapted from Vincent et al.[27]

[b] Catecholamine doses are given as μg/kg/min for at least 1 hour.

[c] Glasgow Coma Scale scores range from 3-15; higher score indicates better neurological function.

A Need for Sepsis Definitions for the Public and for Health Care Practitioners

Despite its worldwide importance,[6,7] public awareness of sepsis is poor.[29] Furthermore, the various manifestations of sepsis make diagnosis difficult, even for experienced clinicians. Thus, the public needs an understandable definition of sepsis, whereas health care practitioners require improved clinical prompts and diagnostic approaches to facilitate earlier identification and an accurate quantification of the burden of sepsis.

Results/Recommendations

Definition of Sepsis

Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection (**Box 3**). This new definition emphasizes the primacy of the nonhomeostatic host response to infection, the potential lethality that is considerably in excess of a straightforward infection, and the need for urgent recognition. As described later, even a modest degree of organ dysfunction when infection is first suspected is associated with an in-hospital mortality in excess of 10%. Recognition of this condition thus merits a prompt and appropriate response.

Nonspecific SIRS criteria such as pyrexia or neutrophilia will continue to aid in the general diagnosis of infection. These findings complement features of specific infections (eg, rash, lung consolidation, dysuria, peritonitis) that focus attention toward the likely anatomical source and infecting organism. However, SIRS may simply reflect an appropriate host response that is frequently adaptive. Sepsis involves organ dysfunction, indicating a pathobiology more complex than infection plus an accompanying inflammatory response alone. The task force emphasis on life-threatening organ dysfunction is consistent with the view that cellular defects underlie physiologic and biochemical abnormalities within specific organ systems. Under this terminology, "severe sepsis" becomes superfluous. Sepsis should generally warrant greater levels of monitoring and intervention, including possible admission to critical care or high-dependency facilities.

Clinical Criteria to Identify Patients With Sepsis

The task force recognized that no current clinical measures reflect the concept of a dysregulated host response. However, as noted by the 2001 task force, many bedside examination findings and routine laboratory test results are indicative of inflammation or organ dysfunction.[10] The task force therefore evaluated which clinical criteria best identified infected patients most likely to have sepsis. This objective was achieved by interrogating large data sets of hospitalized patients with presumed infection, assessing agreement among existing scores of inflammation (SIRS)[9] or organ dysfunction (eg, SOFA,[27,28] Logistic Organ Dysfunction System[30]) (construct validity), and delineating their correlation with subsequent outcomes (predictive validity). In addition, multivariable regression was used to explore the performance of 21 bedside and laboratory criteria proposed by the 2001 task force.[10]

Full details are found in the accompanying article by Seymour et al.[12] In brief, electronic health record data of 1.3 million encounters at 12 community and academic hospitals within the University of Pittsburgh Medical Center health system in southwestern Pennsylvania were studied. There were 148 907 patients with suspected infection, identified as those who had body fluids sampled for culture and received antibiotics. Two outcomes—hospital mortality and mortality, ICU stay of 3 days or longer, or both—were used to assess predictive validity both overall and across deciles of baseline risk as determined by age, sex, and comorbidity. For infected patients both inside and outside of the

Box 3. New Terms and Definitions

- Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection.
- Organ dysfunction can be identified as an acute change in total SOFA score ≥2 points consequent to the infection.
  - The baseline SOFA score can be assumed to be zero in patients not known to have preexisting organ dysfunction.
  - A SOFA score ≥2 reflects an overall mortality risk of approximately 10% in a general hospital population with suspected infection. Even patients presenting with modest dysfunction can deteriorate further, emphasizing the seriousness of this condition and the need for prompt and appropriate intervention, if not already being instituted.
- In lay terms, sepsis is a life-threatening condition that arises when the body's response to an infection injures its own tissues and organs.
- Patients with suspected infection who are likely to have a prolonged ICU stay or to die in the hospital can be promptly identified at the bedside with qSOFA, ie, alteration in mental status, systolic blood pressure ≤100 mm Hg, or respiratory rate ≥22/min.
- Septic shock is a subset of sepsis in which underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality.
- Patients with septic shock can be identified with a clinical construct of sepsis with persisting hypotension requiring vasopressors to maintain MAP ≥65 mm Hg and having a serum lactate level >2 mmol/L (18 mg/dL) despite adequate volume resuscitation. With these criteria, hospital mortality is in excess of 40%.

Abbreviations: MAP, mean arterial pressure; qSOFA, quick SOFA; SOFA: Sequential [Sepsis-related] Organ Failure Assessment.

ICU, predictive validity was determined with 2 metrics for each criterion: the area under the receiver operating characteristic curve (AUROC) and the change in outcomes comparing patients with a score of either 2 points or more or fewer than 2 points in the different scoring systems[9,27,30] across deciles of baseline risk. These criteria were also analyzed in 4 external US and non-US data sets containing data from more than 700 000 patients (cared for in both community and tertiary care facilities) with both community- and hospital-acquired infection.

In ICU patients with suspected infection in the University of Pittsburgh Medical Center data set, discrimination for hospital mortality with SOFA (AUROC = 0.74; 95% CI, 0.73-0.76) and the Logistic Organ Dysfunction System (AUROC = 0.75; 95% CI, 0.72-0.76) was superior to that with SIRS (AUROC = 0.64; 95% CI, 0.62-0.66). The predictive validity of a change in SOFA score of 2 or greater was similar (AUROC = 0.72; 95% CI, 0.70-0.73). For patients outside the ICU and with suspected infection, discrimination of hospital mortality with SOFA (AUROC = 0.79; 95% CI, 0.78-0.80) or change in SOFA score (AUROC = 0.79; 95% CI, 0.78-0.79) was similar to that with SIRS (AUROC = 0.76; 95% CI, 0.75-0.77).

Because SOFA is better known and simpler than the Logistic Organ Dysfunction System, the task force recommends using a change in baseline of the total SOFA score of 2 points or more to represent organ dysfunction (Box 3). The baseline SOFA score should be assumed to be zero unless the patient is known to have preexisting (acute or chronic) organ dysfunction before the onset of infection. Patients with a SOFA score of 2 or more had an overall mortality risk of approximately 10% in a general hospital population with presumed infection.[12] This is greater than the overall mortality rate of 8.1% for ST-segment elevation myocardial infarction,[31] a condition widely held to be life threatening by the community and by clinicians. Depending on a patient's baseline level of risk, a SOFA score of 2 or greater identified a 2- to 25-fold increased risk of dying compared with patients with a SOFA score less than 2.[12]

Box 4. qSOFA (Quick SOFA) Criteria

Respiratory rate ≥22/min

Altered mentation

Systolic blood pressure ≤100 mm Hg

As discussed later, the SOFA score is not intended to be used as a tool for patient management but as a means to clinically characterize a septic patient. Components of SOFA (such as creatinine or bilirubin level) require laboratory testing and thus may not promptly capture dysfunction in individual organ systems. Other elements, such as the cardiovascular score, can be affected by iatrogenic interventions. However, SOFA has widespread familiarity within the critical care community and a well-validated relationship to mortality risk. It can be scored retrospectively, either manually or by automated systems, from clinical and laboratory measures often performed routinely as part of acute patient management. The task force noted that there are a number of novel biomarkers that can identify renal and hepatic dysfunction or coagulopathy earlier than the elements used in SOFA, but these require broader validation before they can be incorporated into the clinical criteria describing sepsis. Future iterations of the sepsis definitions should include an updated SOFA score with more optimal variable selection, cutoff values, and weighting, or a superior scoring system.

Screening for Patients Likely to Have Sepsis

A parsimonious clinical model developed with multivariable logistic regression identified that any 2 of 3 clinical variables—Glasgow Coma Scale score of 13 or less, systolic blood pressure of 100 mm Hg or less, and respiratory rate 22/min or greater—offered predictive validity (AUROC = 0.81; 95% CI, 0.80-0.82) similar to that of the full SOFA score outside the ICU.[12] This model was robust to multiple sensitivity analyses including a more simple assessment of altered mentation (Glasgow Coma Scale score <15) and in the out-of-hospital, emergency department, and ward settings within the external US and non-US data sets.

For patients with suspected infection within the ICU, the SOFA score had predictive validity (AUROC = 0.74; 95% CI, 0.73-0.76) superior to that of this model (AUROC = 0.66; 95% CI, 0.64-0.68), likely reflecting the modifying effects of interventions (eg, vasopressors, sedative agents, mechanical ventilation). Addition of lactate measurement did not meaningfully improve predictive validity but may help identify patients at intermediate risk.

This new measure, termed *qSOFA* (for quick SOFA) and incorporating altered mentation, systolic blood pressure of 100 mm Hg or less, and respiratory rate of 22/min or greater, provides simple bedside criteria to identify adult patients with suspected infection who are likely to have poor outcomes (**Box 4**). Because predictive validity was unchanged (P = .55), the task force chose to emphasize altered mentation because it represents any Glasgow Coma

Scale score less than 15 and will reduce the measurement burden. Although qSOFA is less robust than a SOFA score of 2 or greater in the ICU, it does not require laboratory tests and can be assessed quickly and repeatedly. The task force suggests that qSOFA criteria be used to prompt clinicians to further investigate for organ dysfunction, to initiate or escalate therapy as appropriate, and to consider referral to critical care or increase the frequency of monitoring, if such actions have not already been undertaken. The task force considered that positive qSOFA criteria should also prompt consideration of possible infection in patients not previously recognized as infected.

Definition of Septic Shock

Septic shock is defined as a subset of sepsis in which underlying circulatory and cellular metabolism abnormalities are profound enough to substantially increase mortality (Box 3). The 2001 task force definitions described septic shock as "a state of acute circulatory failure."[10] The task force favored a broader view to differentiate septic shock from cardiovascular dysfunction alone and to recognize the importance of cellular abnormalities (Box 3). There was unanimous agreement that septic shock should reflect a more severe illness with a much higher likelihood of death than sepsis alone.

Clinical Criteria to Identify Septic Shock

Further details are provided in the accompanying article by Shankar-Hari et al.[13] First, a systematic review assessed how current definitions were operationalized. This informed a Delphi process conducted among the task force members to determine the updated septic shock definition and clinical criteria. This process was iterative and informed by interrogation of databases, as summarized below.

The Delphi process assessed agreements on descriptions of terms such as "hypotension," "need for vasopressor therapy," "raised lactate," and "adequate fluid resuscitation" for inclusion within the new clinical criteria. The majority (n = 14/17; 82.4%) of task force members voting on this agreed that hypotension should be denoted as a mean arterial pressure less than 65 mm Hg according to the pragmatic decision that this was most often recorded in data sets derived from patients with sepsis. Systolic blood pressure was used as a qSOFA criterion because it was most widely recorded in the electronic health record data sets.

A majority (11/17; 64.7%) of the task force agreed, whereas 2 (11.8%) disagreed, that an elevated lactate level is reflective of cellular dysfunction in sepsis, albeit recognizing that multiple factors, such as insufficient tissue oxygen delivery, impaired aerobic respiration, accelerated aerobic glycolysis, and reduced hepatic clearance, also contribute.[32] Hyperlactatemia is, however, a reasonable marker of illness severity, with higher levels predictive of higher mortality.[33] Criteria for "adequate fluid resuscitation" or "need for vasopressor therapy" could not be explicitly specified because these are highly user dependent, relying on variable monitoring modalities and hemodynamic targets for treatment.[34] Other aspects of management, such as sedation and volume status assessment, are also potential confounders in the hypotension-vasopressor relationship.

By Delphi consensus process, 3 variables were identified (hypotension, elevated lactate level, and a sustained need for vasopressor therapy) to test in cohort studies, exploring alternative combinations and different lactate thresholds. The first database interrogated was the Surviving Sepsis Campaign's international multicenter registry of 28 150 infected patients with at least 2 SIRS criteria and at least 1 organ dysfunction criterion. Hypotension was defined as a mean arterial pressure less than 65 mm Hg, the only available cutoff. A total of 18 840 patients with vasopressor therapy, hypotension, or hyperlactatemia (>2 mmol/L [18 mg/dL]) after volume resuscitation were identified. Patients with fluid-resistant hypotension requiring vasopressors and with hyperlactatemia were used as the referent group for comparing between-group differences in the risk-adjusted odds ratio for mortality. Risk adjustment was performed with a generalized estimating equation population-averaged logistic regression model with exchangeable correlation structure.

Risk-adjusted hospital mortality was significantly higher ($P < .001$ compared with the referent group) in patients with fluid-resistant hypotension requiring vasopressors and hyperlactatemia (42.3% and 49.7% at thresholds for serum lactate level of >2 mmol/L [18 mg/dL] or >4 mmol/L [36 mg/dL], respectively) compared with either hyperlactatemia alone (25.7% and 29.9% mortality for those with serum lactate level of >2 mmol/L [18 mg/dL] and >4 mmol/L [36 mg/dL], respectively) or with fluid-resistant hypotension requiring vasopressors but with lactate level of 2 mmol/L (18 mg/dL) or less (30.1%).

With the same 3 variables and similar categorization, the unadjusted mortality in infected patients within 2 unrelated large electronic health record data sets (University of Pittsburgh Medical Center [12 hospitals; 2010-2012; n = 5984] and Kaiser Permanente Northern California [20 hospitals; 2009-2013; n = 54 135]) showed reproducible results. The combination of hypotension, vasopressor use, and lactate level greater than 2 mmol/L (18 mg/dL) identified patients with mortality rates of 54% at University of Pittsburgh Medical Center (n = 315) and 35% at Kaiser Permanente Northern California (n = 8051). These rates were higher than the mortality rates of 25.2% (n = 147) and 18.8% (n = 3094) in patients with hypotension alone, 17.9% (n = 1978) and 6.8% (n = 30 209) in patients with lactate level greater than 2 mmol/L (18 mg/dL) alone, and 20% (n = 5984) and 8% (n = 54 135) in patients with sepsis at University of Pittsburgh Medical Center and Kaiser Permanente Northern California, respectively.

The task force recognized that serum lactate measurements are commonly, but not universally, available, especially in developing countries. Nonetheless, clinical criteria for septic shock were developed with hypotension and hyperlactatemia rather than either alone because the combination encompasses both cellular dysfunction and cardiovascular compromise and is associated with a significantly higher risk-adjusted mortality. This proposal was approved by a majority (13/18; 72.2%) of voting members[13] but warrants revisiting. The Controversies and Limitations section below provides further discussion about the inclusion of both parameters and options for when lactate level cannot be measured.

Recommendations for *ICD* Coding and for Lay Definitions

In accordance with the importance of accurately applying diagnostic codes, **Table 2** details how the new sepsis and septic shock clini-

cal criteria correlate with *ICD-9-CM* and *ICD-10* codes. The task force also endorsed the recently published lay definition that "sepsis is a life-threatening condition that arises when the body's response to infection injures its own tissues," which is consistent with the newly proposed definitions described above.[35] To transmit the importance of sepsis to the public at large, the task force emphasizes that sepsis may portend death, especially if not recognized early and treated promptly. Indeed, despite advances that include vaccines, antibiotics, and acute care, sepsis remains the primary cause of death from infection. Widespread educational campaigns are recommended to better inform the public about this lethal condition.

Controversies and Limitations

There are inherent challenges in defining sepsis and septic shock. First and foremost, *sepsis* is a broad term applied to an incompletely understood process. There are, as yet, no simple and unambiguous clinical criteria or biological, imaging, or laboratory features that uniquely identify a septic patient. The task force recognized the impossibility of trying to achieve total consensus on all points. Pragmatic compromises were necessary, so emphasis was placed on generalizability and the use of readily measurable identifiers that could best capture the current conceptualization of underlying mechanisms. The detailed, data-guided deliberations of the task force during an 18-month period and the peer review provided by bodies approached for endorsement highlighted multiple areas for discussion. It is useful to identify these issues and provide justifications for the final positions adopted.

The new definition of sepsis reflects an up-to-date view of pathobiology, particularly in regard to what distinguishes sepsis from uncomplicated infection. The task force also offers easily measurable clinical criteria that capture the essence of sepsis yet can be translated and recorded objectively (**Figure**). Although these criteria cannot be all-encompassing, they are simple to use and offer consistency of terminology to clinical practitioners, researchers, administrators, and funders. The physiologic and biochemical tests required to score SOFA are often included in routine patient care, and scoring can be performed retrospectively.

The initial, retrospective analysis indicated that qSOFA could be a useful clinical tool, especially to physicians and other practitioners working outside the ICU (and perhaps even outside the hospital, given that qSOFA relies only on clinical examination findings), to promptly identify infected patients likely to fare poorly. However, because most of the data were extracted from extracted US databases, the task force strongly encourages prospective validation in multiple US and non-US health care settings to confirm its robustness and potential for incorporation into future iterations of the definitions. This simple bedside score may be particularly relevant in resource-poor settings in which laboratory data are not readily available, and when the literature about sepsis epidemiology is sparse.

Neither qSOFA nor SOFA is intended to be a stand-alone definition of sepsis. It is crucial, however, that failure to meet 2 or more qSOFA or SOFA criteria should not lead to a deferral of investigation or treatment of infection or to a delay in any other aspect of care deemed necessary by the practitioners. qSOFA can be rapidly scored at the bedside without the need for blood tests, and it is hoped that it will facilitate prompt identification of an infection that poses a greater threat to life. If appropriate laboratory tests have not already been undertaken, this may prompt testing to identify biochemical organ dysfunction. These data will primarily aid patient management but will also enable subsequent SOFA scoring. The task force wishes to stress that SIRS criteria may still remain useful for the identification of infection.

Some have argued that lactate measurement should be mandated as an important biochemical identifier of sepsis in an infected patient. Because lactate measurement offered no meaningful change in the predictive validity beyond 2 or more qSOFA criteria in the identification of patients likely to be septic, the task force could not justify the added complexity and cost of lactate measurement alongside these simple bedside criteria. The task force recommendations should not, however, constrain the monitoring of lactate as a guide to therapeutic response or as an indicator of illness severity.

Table 2. Terminology and *International Classification of Diseases* Coding

Current Guidelines and Terminology	Sepsis	Septic Shock
1991 and 2001 consensus terminology[9,10]	Severe sepsis Sepsis-induced hypoperfusion	Septic shock[13]
2015 Definition	Sepsis is life-threatening organ dysfunction caused by a dysregulated host response to infection	Septic shock is a subset of sepsis in which underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality
2015 Clinical criteria	Suspected or documented infection and an acute increase of ≥2 SOFA points (a proxy for organ dysfunction)	Sepsis[a] and vasopressor therapy needed to elevate MAP ≥65 mm Hg and lactate >2 mmol/L (18 mg/dL) despite adequate fluid resuscitation[13]
Recommended primary *ICD* codes[a]		
ICD-9	995.92	785.52
ICD-10[a]	R65.20	R65.21
Framework for implementation for coding and research	Identify suspected infection by using concomitant orders for blood cultures and antibiotics (oral or parenteral) in a specified period[b] Within specified period around suspected infection[c]: 1. Identify sepsis by using a clinical criterion for life-threatening organ dysfunction 2. Assess for shock criteria, using administration of vasopressors, MAP <65 mm Hg, and lactate >2 mmol/L (18 mg/dL)[d]	

Abbreviations: *ICD*, *International Classification of Diseases*; MAP, mean arterial pressure; SOFA, Sequential [Sepsis-related] Organ Failure Assessment.[27]

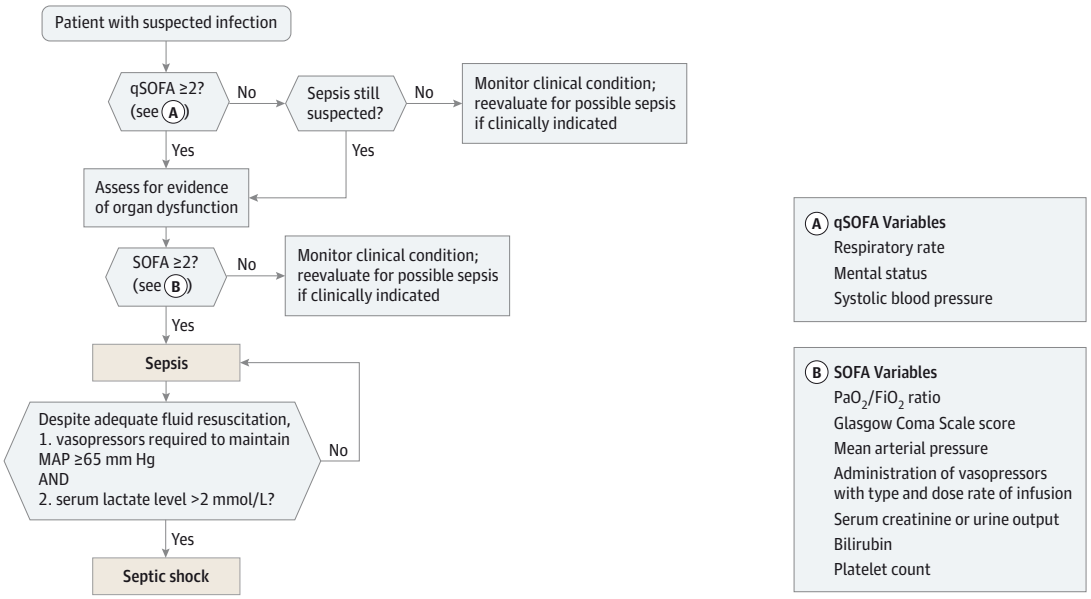
[a] Included training codes.

[b] Suspected infection could be defined as the concomitant administration of oral or parenteral antibiotics and sampling of body fluid cultures (blood, urine, cerebrospinal fluid, peritoneal, etc). For example, if the culture is obtained, the antibiotic is required to be administered within 72 hours, whereas if the antibiotic is first, the culture is required within 24 hours.[12]

[c] Considers a period as great as 48 hours before and up to 24 hours after onset of infection, although sensitivity analyses have tested windows as short as 3 hours before and 3 hours after onset of infection.[12]

[d] With the specified period around suspected infection, assess for shock criteria, using any vasopressor initiation (eg, dopamine, norepinephrine, epinephrine, vasopressin, phenylephrine), any lactate level >2 mmol/L (18 mg/dL), and mean arterial pressure <65 mm Hg. These criteria require adequate fluid resuscitation as defined by the Surviving Sepsis Campaign guidelines.[4]

Figure. Operationalization of Clinical Criteria Identifying Patients With Sepsis and Septic Shock



The baseline Sequential [Sepsis-related] Organ Failure Assessment (SOFA) score should be assumed to be zero unless the patient is known to have preexisting (acute or chronic) organ dysfunction before the onset of infection. qSOFA indicates quick SOFA; MAP, mean arterial pressure.

Our approach to hyperlactatemia within the clinical criteria for septic shock also generated conflicting views. Some task force members suggested that elevated lactate levels represent an important marker of "cryptic shock" in the absence of hypotension. Others voiced concern about its specificity and that the nonavailability of lactate measurement in resource-poor settings would preclude a diagnosis of septic shock. No solution can satisfy all concerns. Lactate level is a sensitive, albeit nonspecific, stand-alone indicator of cellular or metabolic stress rather than "shock."[32] However, the combination of hyperlactatemia with fluid-resistant hypotension identifies a group with particularly high mortality and thus offers a more robust identifier of the physiologic and epidemiologic concept of septic shock than either criterion alone. Identification of septic shock as a distinct entity is of epidemiologic rather than clinical importance. Although hyperlactatemia and hypotension are clinically concerning as separate entities, and although the proposed criteria differ from those of other recent consensus statements,[34] clinical management should not be affected. The greater precision offered by data-driven analysis will improve reporting of both the incidence of septic shock and the associated mortality, in which current figures vary 4-fold.[3] The criteria may also enhance insight into the pathobiology of sepsis and septic shock. In settings in which lactate measurement is not available, the use of a working diagnosis of septic shock using hypotension and other criteria consistent with tissue hypoperfusion (eg, delayed capillary refill[36]) may be necessary.

The task force focused on adult patients yet recognizes the need to develop similar updated definitions for pediatric populations and the use of clinical criteria that take into account their age-dependent variation in normal physiologic ranges and in pathophysiologic responses.

Implications

The task force has generated new definitions that incorporate an up-to-date understanding of sepsis biology, including organ dysfunction (Box 3). However, the lack of a criterion standard, similar to its absence in many other syndromic conditions, precludes unambiguous validation and instead requires approximate estimations of performance across a variety of validity domains, as outlined above. To assist the bedside clinician, and perhaps prompt an escalation of care if not already instituted, simple clinical criteria (qSOFA) that identify patients with suspected infection who are likely to have poor outcomes, that is, a prolonged ICU course and death, have been developed and validated.

This approach has important epidemiologic and investigative implications. The proposed criteria should aid diagnostic categorization once initial assessment and immediate management are completed. qSOFA or SOFA may at some point be used as entry criteria for clinical trials. There is potential conflict with current organ dysfunction scoring systems, early warning scores, ongoing research studies, and pathway developments. Many of these scores and pathways have been developed by consensus, whereas an important aspect of the current work is the interrogation of data, albeit retrospectively, from large patient populations. The task force maintains that standardization of definitions and clinical criteria is crucial in ensuring clear communication and a more accurate appreciation of the scale of the problem of sepsis. An added challenge is that infection is seldom confirmed microbiologically when treatment is started; even when microbiological tests are completed, culture-positive "sepsis" is observed in only 30% to 40% of cases. Thus, when sepsis epide-

miology is assessed and reported, operationalization will necessarily involve proxies such as antibiotic commencement or a clinically determined probability of infection. Future epidemiology studies should consider reporting the proportion of microbiology-positive sepsis.

Greater clarity and consistency will also facilitate research and more accurate coding. Changes to *ICD* coding may take several years to enact, so the recommendations provided in Table 2 demonstrate how the new definitions can be applied in the interim within the current *ICD* system.

The debate and discussion that this work will inevitably generate are encouraged. Aspects of the new definitions do indeed rely on expert opinion; further understanding of the biology of sepsis, the availability of new diagnostic approaches, and enhanced collection of data will fuel their continued reevaluation and revision.

Conclusions

These updated definitions and clinical criteria should clarify long-used descriptors and facilitate earlier recognition and more timely management of patients with sepsis or at risk of developing it. This process, however, remains a work in progress. As is done with software and other coding updates, the task force recommends that the new definition be designated Sepsis-3, with the 1991 and 2001 iterations being recognized as Sepsis-1 and Sepsis-2, respectively, to emphasize the need for future iterations.

ARTICLE INFORMATION

Author Affiliations: Bloomsbury Institute of Intensive Care Medicine, University College London, London, United Kingdom (Singer); Hofstra-Northwell School of Medicine, Feinstein Institute for Medical Research, New Hyde Park, New York (Deutschman); Department of Critical Care and Emergency Medicine, University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania (Seymour); Department of Critical Care Medicine, Guy's and St Thomas' NHS Foundation Trust, London, United Kingdom (Shankar-Hari); Department of Critical Care Medicine, University of Versailles, France (Annane); Center for Sepsis Control and Care, University Hospital, Jena, Germany (Bauer); Australian and New Zealand Intensive Care Research Centre, School of Public Health and Preventive Medicine, Monash University, Melbourne, and Austin Hospital, Melbourne, Victoria, Australia (Bellomo); Vanderbilt Institute for Clinical and Translational Research, Vanderbilt University, Nashville, Tennessee (Bernard); Réanimation Médicale-Hôpital Cochin, Descartes University, Cochin Institute, Paris, France (Chiche); Critical Care Center, Emory University School of Medicine, Atlanta, Georgia (Coopersmith); Washington University School of Medicine, St Louis, Missouri (Hotchkiss); Infectious Disease Section, Division of Pulmonary and Critical Care Medicine, Brown University School of Medicine, Providence, Rhode Island (Levy, Opal); Department of Surgery, University of Toronto, Toronto, Ontario, Canada (Marshall); Emory University School of Medicine and Grady Memorial Hospital, Atlanta, Georgia (Martin); Trauma, Emergency & Critical Care Program, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada (Rubenfeld); Interdepartmental Division of Critical Care, University of Toronto (Rubenfeld); Department of Infectious Diseases, Academisch Medisch Centrum, Amsterdam, the Netherlands (van der Poll); Department of Intensive Care, Erasme University Hospital, Brussels, Belgium (Vincent); Department of Critical Care Medicine, University of Pittsburgh and UPMC Health System, Pittsburgh, Pennsylvania (Angus); Associate Editor, *JAMA* (Angus).

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

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Singer reports serving on the advisory boards of InflaRx, Bayer, Biotest, and Merck and that his institution has received grants from the European Commission, UK National Institute of Health Research, Immunexpress, DSTL, and Wellcome Trust. Dr Deutschman reports 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 Seymour reports receiving personal fees from Beckman Coulter and a National Institutes of Health (NIH) grant awarded to his institution. Dr Bauer reports support for travel to meetings for the study from ESICM, payment for speaking from CSL Behring, grants to his institution from Jena University Hospital, and patents held by Jena University Hospital. Dr Bernard reports grants from AstraZeneca for activities outside the submitted work. Dr Chiche reports consulting for Nestlé and Abbott and honoraria for speaking from GE Healthcare and Nestlé. Dr Coopersmith reports receiving grants from the NIH for work not related to this article. Dr Coopersmith also reports bring president-elect and president of SCCM when the task force was meeting and the article was being drafted. A stipend was paid to Emory University for his time spent in these roles. Dr Hotchkiss reports consulting on sepsis for GlaxoSmithKline, Merck, and Bristol-Meyers Squibb and reports that his institution received grant support from Bristol-Meyers Squibb and GlaxoSmithKline, as well as the NIH, for research on sepsis. Dr Marshall reports serving on the data and safety monitoring board (DSMB) of AKPA Pharma and Spectral Medical Steering Committee and receiving payment for speaking from Toray Ltd and Uni-Labs. Dr Martin reports serving on the board for SCCM and Project Help, serving on the DSMB for Cumberland Pharmaceuticals and Vanderbilt University, serving on the medical advisory board for Grifols and Pulsion Medical Systems, and grants to his institution from NIH, the Food and Drug Administration, Abbott, and Baxter. Dr Opal reports grants from GlaxoSmithKline, Atoxbio, Asahi-Kasei, Ferring, Cardeas, and Arsanis outside the submitted work; personal fees from Arsanis, Aridis, Bioaegis, Cyon, and Battelle; and serving on the DSMB for Achaogen, Spectral Diagnostics, and Paratek. No other disclosures were reported.

Funding/Support: This work was supported in part by a grant from the Society of Critical Care Medicine (SCCM) and the European Society of Intensive Care Medicine (ESICM).

Role of the Funder/Sponsor: These funding bodies appointed cochairs but otherwise had no role in the design and conduct of the work; the collection, management, analysis, and interpretation of the data; preparation of the manuscript; or decision to submit the manuscript for publication. As other national and international societies, they were asked for comment and endorsement.

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

Endorsing Societies: Academy of Medical Royal Colleges (UK); American Association of Critical Care Nurses; American Thoracic Society (endorsed August 25, 2015); Australian-New Zealand Intensive Care Society (ANZICS); Asia Pacific Association of Critical Care Medicine; Brasilian Society of Critical Care; Central American and Caribbean Intensive Therapy Consortium; Chinese Society of Critical Care Medicine; Chinese Society of Critical Care Medicine-China Medical Association; Critical Care Society of South Africa; Emirates Intensive Care Society; European Respiratory Society; European Resuscitation Council; European Society of Clinical Microbiology and Infectious

Diseases and its Study Group of Bloodstream Infections and Sepsis; European Society of Emergency Medicine; European Society of Intensive Care Medicine; European Society of Paediatric and Neonatal Intensive Care; German Sepsis Society; Indian Society of Critical Care Medicine; International Pan Arabian Critical Care Medicine Society; Japanese Association for Acute Medicine; Japanese Society of Intensive Care Medicine; Pan American/Pan Iberian Congress of Intensive Care; Red Intensiva (Sociedad Chilena de Medicina Crítica y Urgencias); Sociedad Peruana de Medicina Critica; Shock Society; Sociedad Argentina de Terapia Intensiva; Society of Critical Care Medicine; Surgical Infection Society; World Federation of Pediatric Intensive and Critical Care Societies; World Federation of Critical Care Nurses; World Federation of Societies of Intensive and Critical Care Medicine.

Additional Contributions: The task force would like to thank Frank Brunkhorst, MD, University Hospital Jena, Germany; Theodore J. Iwashyna, MD, PhD, University of Michigan; Vincent Liu, MD, MSc, Kaiser Permanente Northern California; Thomas Rea, MD, MPH, University of Washington; and Gary Phillips, MAS, Ohio State University; for their invaluable assistance, and the administrations and leadership of SCCM and ESICM for facilitating its work. Payment was provided to the Center for Biostatistics, Ohio State University, to support the work of Mr Phillips.

REFERENCES

1. Torio CM, Andrews RM. National inpatient hospital costs: the most expensive conditions by payer, 2011. Statistical Brief #160. Healthcare Cost and Utilization Project (HCUP) Statistical Briefs. August 2013. http://www.ncbi.nlm.nih.gov/books/NBK169005/. Accessed October 31, 2015.

2. Iwashyna TJ, Cooke CR, Wunsch H, Kahn JM. Population burden of long-term survivorship after severe sepsis in older Americans. *J Am Geriatr Soc*. 2012;60(6):1070-1077.

3. Gaieski DF, Edwards JM, Kallan MJ, Carr BG. Benchmarking the incidence and mortality of severe sepsis in the United States. *Crit Care Med*. 2013;41(5):1167-1174.

4. 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.

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

6. Vincent J-L, Marshall JC, Namendys-Silva SA, et al; ICON Investigators. Assessment of the worldwide burden of critical illness: the Intensive Care Over Nations (ICON) audit. *Lancet Respir Med*. 2014;2(5):380-386.

7. Fleischmann C, Scherag A, Adhikari NK, et al; International Forum of Acute Care Trialists. Assessment of global incidence and mortality of hospital-treated sepsis: current estimates and limitations. *Am J Respir Crit Care Med*. 2015.

8. Iwashyna TJ, Ely EW, Smith DM, Langa KM. Long-term cognitive impairment and functional disability among survivors of severe sepsis. *JAMA*. 2010;304(16):1787-1794.

9. Bone RC, Balk RA, Cerra FB, et al. American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference: definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. *Crit Care Med*. 1992;20(6):864-874.

10. Levy MM, Fink MP, Marshall JC, et al; International Sepsis Definitions Conference. 2001 SCCM/ESICM/ACCP/ATS/SIS International Sepsis Definitions Conference. *Intensive Care Med*. 2003;29(4):530-538.

11. Vincent J-L, Opal SM, Marshall JC, Tracey KJ. Sepsis definitions: time for change. *Lancet*. 2013;381(9868):774-775.

12. Seymour CW, Liu V, Iwashyna TJ, et al Assessment of clinical criteria for sepsis. *JAMA*. doi:10.1001/jama.2016.0288.

13. Shankar-Hari M, Phillips G, Levy ML, et al Assessment of definition and clinical criteria for septic shock. *JAMA*.doi:10.1001/jama.2016.0289

14. Angus DC, van der Poll T. Severe sepsis and septic shock. *N Engl J Med*. 2013;369(9):840-851.

15. Wiersinga WJ, Leopold SJ, Cranendonk DR, van der Poll T. Host innate immune responses to sepsis. *Virulence*. 2014;5(1):36-44.

16. Hotchkiss RS, Monneret G, Payen D. Sepsis-induced immunosuppression: from cellular dysfunctions to immunotherapy. *Nat Rev Immunol*. 2013;13(12):862-874.

17. Deutschman CS, Tracey KJ. Sepsis: current dogma and new perspectives. *Immunity*. 2014;40(4):463-475.

18. Singer M, De Santis V, Vitale D, Jeffcoate W. Multiorgan failure is an adaptive, endocrine-mediated, metabolic response to overwhelming systemic inflammation. *Lancet*. 2004;364(9433):545-548.

19. Hotchkiss RS, Swanson PE, Freeman BD, et al. Apoptotic cell death in patients with sepsis, shock, and multiple organ dysfunction. *Crit Care Med*. 1999;27(7):1230-1251.

20. Kwan A, Hubank M, Rashid A, Klein N, Peters MJ. Transcriptional instability during evolving sepsis may limit biomarker based risk stratification. *PLoS One*. 2013;8(3):e60501.

21. Iskander KN, Osuchowski MF, Stearns-Kurosawa DJ, et al. Sepsis: multiple abnormalities, heterogeneous responses, and evolving understanding. *Physiol Rev*. 2013;93(3):1247-1288.

22. Wong HR, Cvijanovich NZ, Anas N, et al. Developing a clinically feasible personalized medicine approach to pediatric septic shock. *Am J Respir Crit Care Med*. 2015;191(3):309-315.

23. Langley RJ, Tsalik EL, van Velkinburgh JC, et al. An integrated clinico-metabolomic model improves prediction of death in sepsis. *Sci Transl Med*. 2013;5(195):195ra95.

24. Chan JK, Roth J, Oppenheim JJ, et al. Alarmins: awaiting a clinical response. *J Clin Invest*. 2012;122(8):2711-2719.

25. Churpek MM, Zadravecz FJ, Winslow C, Howell MD, Edelson DP. Incidence and prognostic value of the systemic inflammatory response syndrome and organ dysfunctions in ward patients. *Am J Respir Crit Care Med*. 2015;192(8):958-964.

26. Kaukonen K-M, 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.

27. Vincent JL, Moreno R, Takala J, et al; Working Group on Sepsis-Related Problems of the European Society of Intensive Care Medicine. The SOFA (Sepsis-related Organ Failure Assessment) score to describe organ dysfunction/failure. *Intensive Care Med*. 1996;22(7):707-710.

28. Vincent JL, de Mendonça A, Cantraine F, et al; Working Group on "Sepsis-Related Problems" of the European Society of Intensive Care Medicine. 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.

29. Rubulotta FM, Ramsay G, Parker MM, Dellinger RP, Levy MM, Poeze M; Surviving Sepsis Campaign Steering Committee; European Society of Intensive Care Medicine; Society of Critical Care Medicine. An international survey: public awareness and perception of sepsis. *Crit Care Med*. 2009;37(1):167-170.

30. Le Gall J-R, 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.

31. Shah RU, Henry TD, Rutten-Ramos S, Garberich RF, Tighiouart M, Bairey Merz CN. Increasing percutaneous coronary interventions for ST-segment elevation myocardial infarction in the United States: progress and opportunity. *JACC Cardiovasc Interv*. 2015;8(1 pt B):139-146.

32. Kraut JA, Madias NE. Lactic acidosis. *N Engl J Med*. 2014;371(24):2309-2319.

33. Casserly B, Phillips GS, Schorr C, et al. Lactate measurements in sepsis-induced tissue hypoperfusion: results from the Surviving Sepsis Campaign database. *Crit Care Med*. 2015;43(3):567-573.

34. 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.

35. Czura CJ. "Merinoff symposium 2010: sepsis"—speaking with one voice. *Mol Med*. 2011;17(1-2):2-3.

36. Ait-Oufella H, Bige N, Boelle PY, et al. Capillary refill time exploration during septic shock. *Intensive Care Med*. 2014;40(7):958-964.