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Effect of automated real-time feedback on early sepsis care

Submission date
31/10/2022

Recruitment status
No longer recruiting

Registration date
07/11/2022

Overall study status
Completed

Last Edited
29/12/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sepsis is the leading cause of death among US hospitals, accounting for 6% of all hospitalizations and 35% of all inpatient deaths. International guidelines and the Centers for Medicare and Medicaid Services (CMS) severe sepsis and septic shock management (SEP-1) bundle stress the importance of adhering to specific steps in the diagnosis and management of sepsis. This can be very difficult, especially in the setting of a busy emergency department, ward, or intensive care unit where there are multiple simultaneous demands on a provider's attention and time. Critical steps can be missed or delayed. The CMS SEP-1 bundle is a measure of compliance with sepsis care that is being tracked nationally across hospitals. The adherence rate at Massachusetts General Hospital (MGH) has been below the national average since public reporting began, with a pass rate of 47% in 2018 (compared with a national average of 55%). Unfortunately, a recent study demonstrated that every hour of delay to the completion of a sepsis bundle, including antibiotic administration, was associated with a 4% increase in risk-adjusted hospital mortality.

One strategy to improve the care and outcomes of patients with sepsis is the use of information technology to support our providers in a targeted manner. Technology has already been developed and deployed to help with the early identification of patients with sepsis using a Best Practice Advisory (BPA), which has been in place at MGH since 2017. This pop-up window alerts the team to the possibility of sepsis based on data within the medical record. However, once the BPA is accepted or declined, the BPA does not offer ongoing support to clinicians, leaving the clinician to track and execute multiple time-based and interdependent sepsis bundle measures in a busy and hectic environment. To augment this existing tool, here we propose to study the efficacy of a novel technology (Sepsis Care Tracking Platform; SCTP) to provide ongoing support at the bedside to providers, thus improving the care we deliver to patients.

SCTP is a monitoring and notification platform that aims to increase the timely delivery of key elements of evidence-based sepsis care. This platform, which was built by clinicians for clinicians, leverages the electronic medical record (EMR) to track real-time compliance with key components of the CMS SEP-1 bundle, including timely antibiotics, blood cultures prior to antibiotics, initial blood lactate level measurements, and repeated blood lactate measurements for those patients with an initially elevated level. SCTP underwent technical validation toward the end of 2019 with a pilot in the MGH emergency department. The pilot confirmed that SCTP

correctly identified missing bundle elements and paged the appropriate team members connected with the patient's care. The pilot also did not find alarm fatigue to be an issue. We hypothesize that SCTP will increase compliance with sepsis process metrics and improve patient outcomes.

By monitoring real-time data and automatically alerting bedside providers to missing elements within an actionable timeframe, SCTP has the potential to drive improvements in clinical care even in the extremely busy and complex environment of the emergency department and inpatient units.

Who can participate?
Patients at MGH who trigger a Sepsis BPA will be automatically enrolled

What does the study involve?
Patients will either receive usual care, or usual care plus a reminder page sent to their clinician if an automated monitoring system flags them as at risk of receiving delayed initial sepsis care. There will be no other changes to care or non-routine data collection for participants.

What are the possible benefits and risks of participating?
Patients enrolled in this study may have more immediate recognition of clinically significant changes in their health and recovery, such that they experience fewer adverse events and more timely care. Importantly, patients not enrolled in this study will continue to receive the current standard of care at MGH.

There is extremely minimal risk of a threat to patient safety in either arm of the study. Patients who are assigned to the intervention arm and the control arm will both receive the standard of care. Intervention arm patients will additionally have the SCTP software relaying alerts to designated providers. The software does not create new, previously non-existent data. It relays data that is already available and viewable by all providers in the medical record for the patient. There will be no additional equipment, devices, attachments, leads, etc. SCTP is only a software that filters data emanating from the medical record. The patient will perceive no difference in their care with regard to their monitoring. The patient will receive standard monitors whether they are in the control or intervention arm.
The primary risks to the patient are related to privacy and security considerations. There are two major security risks with the SCTP software:
1. Unauthorized access to SCTP- Access to the application is limited to hospital staff with existing access to patient data.
2. Unauthorized access to data- SCTP data is transported across several different channels. Only authorized individuals have access to the data in these transmissions or data stored in the SCTP databases.
Briefly, the security risks mentioned above are mitigated in the following manner:
1. Unauthorized access to SCTP- No passwords are hard-coded into the application. To access the program, SCTP checks that the entered user ID is registered in the hospital's Epic system, and the user ID/password is checked using the hospital's authentication system.
2. Unauthorized access to data- The SCTP database is only accessible if someone is able to access the internal server where the databases are hosted and have a user ID/password which allows such access. The database will be hosted on the same server that hosts the Epic data that is managed by hospital IT staff. In our study, only the providers receiving alerts from the SCTP will see data regarding the patient. SCTP prevents data interception by:
1. The web server that hosts SCTP will be owned by the hospital and internal to the hospital only, and not accessible outside the hospital network
2. Data communications and accessing happens over a wired or Wi-Fi connection that encrypts

all data. An HTTPS website is used that encrypts all data transmitted in both directions
3. data transmitted along other channels occurs on wired connections on hospital networks. The only people with direct access to these networks are hospital IT staff.

Where is the study run from?
The Massachusetts General Hospital (USA)

When is the study starting and how long is it expected to run for?
February 2019 to December 2021

Who is funding the study?
CRICO program (USA)

Who is the main contact?
Kyan Safavi, MD, MBA
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2020P002676

Study information

Scientific Title
Effect of automated real-time feedback on early sepsis care

Study objectives
Automated paging reminders will improve 3-hour sepsis bundle order compliance, care delivery, and outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/09/2020, Mass General Brigham Institutional Review Board, (399 Revolution Drive, Suite 710, Sommerville, MA, 02145, USA; +1 857 282 1900; irb@partners.org), ref: none available

Study design
Single-center semi-concealed assessor-blinded interventional cluster-randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Early treatment of patients with probable sepsis

Interventions
Real-time automated monitoring of the electronic medical record to identify suspected sepsis patients without completion of sepsis bundle measures within 1-hour of the completion deadline and generated reminder pages. Clinicians responsible for patients randomized to the intervention receive reminder pages whereas no pages are sent for control arm patients.

Intervention Type
Other

Primary outcome measure
Overall 3-hour bundle ordering compliance, defined as orders for all 3-hour bundle measures monitored by the study platform completed within the bundle time limits - i.e., orders for antibiotics, blood cultures, and lactate measurement measured from the electronic medical record at the end of the study period

Secondary outcome measures
The following secondary outcomes were measured from the electronic medical record at the end of the study follow-up period (T0 + 28 days):
1. Antibiotic ordering compliance, defined as orders for antibiotics placed within 3 hours of time-zero
2. Blood culture ordering compliance, defined as orders for blood cultures placed within 3 hours of time-zero
3. Initial blood lactate level ordering compliance, defined as orders for initial blood lactate level within 3 hours of time-zero
4. Repeat blood lactate level ordering compliance, defined as orders for repeat blood lactate level placed within 6 hours of time-zero and within 3 hours of initial lactate measurement, among patients with initial lactate > 2.0mmol/L
5. Overall 3-hour bundle care delivery compliance, defined as the implementation of all 3-hour bundle measures monitored by the study platform completed within the bundle time limits - i.e., administration of antibiotics, collection of blood cultures prior to antibiotic administration, and lactate measurement.
6. Antibiotic delivery compliance, defined as administration of antibiotics within 3 hours of time-zero
7. Blood cultures delivery compliance, defined collection of blood cultures within 3 hours of time-zero and prior to antibiotic administration
8. Initial lactate delivery compliance, defined measurement of initial lactate within 3 hours of time-zero
9. Repeat lactate delivery compliance, defined as the measurement of a repeat lactate within 6 hours of time-zero and within 3 hours of initial lactate measurement, among patients with an initial lactate > 2.0mmol/L
10. Mortality by Day 28
11. Early mechanical ventilation, defined as the receipt of mechanical ventilation or death within 72 hours of time-zero
12. Early intensive care unit (ICU) admission, defined as ICU admission or death within 72 hours of time-zero
13. Mechanical ventilation during hospitalization, defined as receipt of mechanical ventilation or death within 28 days of time-zero
14. ICU admission during hospitalization, defined as ICU admission or death within 28 days of time-zero
15. Early antibiotic discontinuation, defined as discontinuation of all antibiotics for at least 24

hours by 48 hours post-time-zero
16. Hospital length of stay, defined as hospital days from time-zero through day 28
17. Blood culture positivity, defined as bacterial growth recovered from any blood culture collected 24 hours before or 7 days after time zero
18. Non-blood culture positivity, defined as bacterial pathogen recovery from any urine, respiratory, peritoneal, pleural, joint, or cerebrospinal fluid culture collected 24 hours before or 7 days after time zero
19. Any culture positivity, defined as a composite of positive results from either the blood or non-blood culture positivity outcome

Overall study start date
05/02/2019

Completion date
28/12/2021

Eligibility

Key inclusion criteria
1. Adult patients aged 18 years old and over
2. Who triggered a sepsis best practice advisory that was subsequently acknowledged by a treating clinician as "yes, sepsis possible"

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12 months (52 clusters) with an anticipated total enrollment of 3000 patients

Total final enrolment
3269

Key exclusion criteria
1. Transfer from an outside hospital
2. Sepsis best practice advisory triggered while the patient is in an intensive care unit
3. Sepsis best practice advisory triggered while the patient is in a perioperative care area

Date of first enrolment
12/01/2020

Date of final enrolment

30/11/2021

Locations

Countries of recruitment
United States of America

Study participating centre
Massachusetts General Hospital
55 Fruit Street
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Sponsor information

Organisation
CRICO

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Sponsor type
Research organisation

Website
https://www.rmf.harvard.edu/About-CRICO

Funder(s)

Funder type
Research organisation

Funder Name
CRICO

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Kyan Safavi, ksafavi@partners.org as fully de-identified data derived from the final analysis dataset with all potentially identifying data fields removed. These date with be available from 6 months after publication in a peer-reviewed journal. This study received a waiver of informed consent from the IRB.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan		24/03/2021	02/11/2022	No	No
Results article		13/12/2023	29/12/2023	Yes	No