Early detection and intervention of sepsis
2018

Intervention Feature	Details	Explanation
0. Introduction (TH, TG)	Name of Project: Early detection and intervention of sepsis in ER	Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection(1), and is estimated to be the leading cause of worldwide mortality (2). In 2013 Sepsis was the most expensive condition treated in US hospitals, accounting for over $23 billion dollars (6% of national healthcare costs) (3). In 2016 new guidelines for the diagnosis of sepsis were published. These guidelines defined the Sequential [Sepsis-related] Organ Failure Assessment (SOFA) as a means of identifying patients with organ dysfunction and therefore meet the definition of sepsis. As our project is located in the emergency department, more relevant is the associated definition of the qSOFA (quick SOFA), a bedside clinical score, consisting of 2 of the following 3 clinical criteria: 1) respiratory rate of 22/min or greater, 2) altered mentation, or 3) systolic blood pressure of 100 mm Hg or less. (4). As part of the surviving sepsis guidelines, an Institutional recommendation was that "hospitals and hospital systems have a performance improvement program for sepsis, including sepsis screening for acutely ill, high-risk patients (BPS)" (4). Given the applicability of the qSOFA to the ED and the mandate to develop performance improvement projects for sepsis, we chose to develop an alert system for the ED triage. 1) JAMA. 2016 February 23; 315(8): 801–810 2) Am J Respir Crit Care Med. 2016 Feb 1;193(3):259-72 3) https://www.hcup-us.ahrq.gov/reports/statbriefs/sb204-Most-Expensive-Hospital-Conditions.jsp viewed May 3, 2018 4) Crit Care Med. 2017 Mar;45(3):486-552

1.Objective (TH, TG)	Minimize the mortality rate of patients from sepsis Maximize the number of patients who treated with "Sepsis bundles" Minimize the time to completion of the "Sepsis Bundle"	According to Surviving Sepsis guideline 2015, early intervention is a key to improve their survival rate. More precisely, administration of IV antibiotics within 1 hour and resuscitation from sepsis-induced hypoperfusion by giving massive IV crystalloid fluid within 3 hours (3) The Surviving Sepsis Campaign has published "bundles" of interventions that should be enacted once a patient has been diagnosed with sepsis(1). Given our projects setting of the ED, we have chosen to focus on the "3-hour bundle" being appropriately enacted. The 3-hour bundle consists of: 1. Measure lactate level 2. Obtain blood cultures prior to administration of antibiotics 3. Administer broad-spectrum antibiotics 4. Administer 30ml/kg crystalloid for hypotension or lactate ≥4mmol/L NB: these bundle will be revised mid-May 2018 Completion of these interventions in a timely manner truly is a matter of life and death as each additional hour until completion is associated with increased mortality (odds ratio, 1.04 per hour; 95% confidence interval, 1.02 to 1.05) (2) 1.http://www.survivingsepsis.org/SiteCollectionDocuments/SSC_Bundle.pdf viewed May 4, 2018) 2. N Engl J Med 2017;376:2235-44 3. *Intensive care medicine* 43.3 (2017): 304-377.
2. Context (TH, TG)	[Location (clinic, home, health managers' office, government agency office, etc.) or time (clinic visit, mornings, daily check, etc.), which is the primary focus of your intervention]	Sepsis has a mortality rate of 30-50%(1). Timely, appropriate care in sepsis has been shown to reduce mortality. The necessary care has been well defined as "Sepsis bundles.(2) The orders necessary to create these bundles are simple and straightforward and can easily be incorporated as part of an order set. Further, identification of patients at risk for sepsis has been well defined with a scoring system (SOFA), and this scoring system has a bedside corollary scoring system (qSOFA) which uses items that are already collected as part of an Emergency Department triage system(3). The triage area is very busy and

	Emergency Department	triage nursing staff must evaluate patients for multiple diagnoses while also attending to bed assignment, patient flow, and multiple other criteria, all in a state of constant task interruption. In such an environment information overload is a real possibility, and some might say a constant state of existence. In this scenario, the decision support algorithm would serve to monitor triage information and flag patients who meet criteria for sepsis according to risk factors (low, moderate, high risk). Thus patients with sepsis requiring immediate initiation of care would have that care started earlier rather than being redirected to the waiting area until a room was available and they could be further evaluated. Once the patient is flagged, pre-arranged orders could be immediately populated and with an order set then immediately pended to the patient chart for completion. The combination of automated actions would be hypothesized to shorten the time to completion of the 3-hour sepsis bundle. 1. Liu, Vincent, et al. "Hospital deaths in patients with sepsis from 2 independent cohorts." Jama 312.1 (2014): 90-92. 2..http://www.survivingsepsis.org/SiteCollectionDocuments/SSC_Bundle.pdf viewed May 4, 2018) 3. Crit Care Med. 2017 Mar;45(3):486-552
3. Target actions (TG, CM)	1) Triage nurse to place IV, Draw labs, and room patient identified as potentially septic. 2) Physician to confirm dignosis of sepsis and sign sepsis bundle orderset 3) completion of sepsis bundle as quickly as possible	In order to achieve the goals of the CDS tool, the tool must: a) identify patients at risk for sepsis b) decrease the time to appropriate care Time to sepsis bundles is defined from triage time. Therefore the decision tool begins acting at triage. Once the triage vitals and assessment are entered, if they meet criteria for sepsis, then the preliminary events of the bundle (namely labs, and placement of IV so that IVF and antibiotics can be delivered) are initiated as part of a protocol not requiring physician signature, and the patient is immediately roomed. This automates the response to a patient with a potentially life-threatening condition, and therefore hopefully shortens the time

		to bundle completion. By creating a standard order set for such patients, this decreases the risk of errors of omission and standardizes care for potentially septic patients in the hospital. (TG) An alert to the ED physician regarding the patient triage status and pending orders for his attention would also allow the physician to check the EHR patient details to confirm the assessment and sign off any pending orders earlier than might have taken place thereby facilitating earlier initiation of treatment. (CM) Workflow: Upon the triage nurse entering triage vitals that the algorithm identifies as potential sepsis 1. Triggers automatic order (does not require physician signature) allowing nurse to: a) Place IV b) Obtain Lactate c) Obtain Blood culture x 2, aerobic and anaerobic 2. Nurse then immediately rooms patient 3. Patient is flagged with sepsis icon on the ED "board" 4. Upon entering the chart Physician/NP/PA receives pop up of sepsis alert. They then a) Acknowledge sepsis alert triggering - results in pending of orders or IVF and antibiotics OR b) dismiss alert with a selection of reason as to why the patient does not meet criteria for sepsis

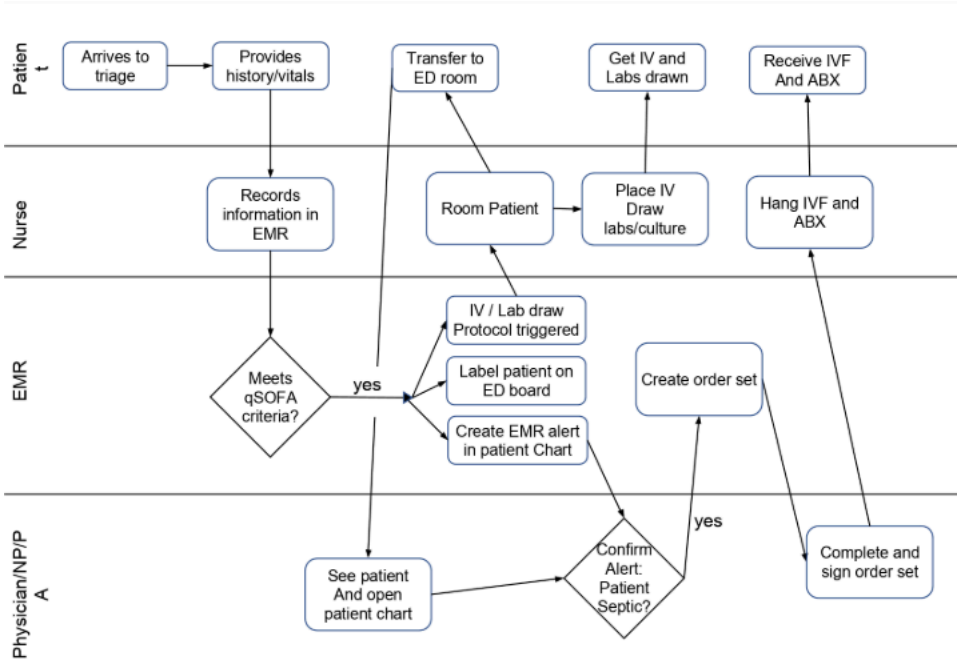
		5. Physician/NP/PA signs pended orders
4. Baseline performance: (TK, CM)	Baseline performance will be assessed by completion of a retrospective case study for patients with an ICD-10 code of sepsis either entered in the ED or within 24 hours of admission. The measurements/outcomes we will be using for our patient's baseline performance will be the following: 1. Percentage of cases with serum lactate measured in the ED 2. Percentage of cases receiving IVF in ED and time to IVF hung. 3. Percentage of cases receiving antibiotics in the ED and time to antibiotic infusion 4. Percentage of cases having blood cultures drawn before antibiotic administration 5. outcome of the patient 1. BMJ Qual Saf 2015;24:787–795	These are readily obtainable from the medical record. Our baseline measures capture the goal for our CDS intervention, which is improving the time-to-intervention (antibiotics and IV fluids) for patients identified with sepsis and mortality in this population. (TK) Other baseline measures to evaluate the performance of this intervention as related to patient outcomes may include the analysis of historic ED EHR data to assess the following: - Historic sepsis rates, seasonality trends, trends associated with shifts - Historic trends on mortality associated with sepsis - Average time (and range) to initiation of treatment for patients diagnosed with or possible sepsis in ED from the time of triage - Average time to complete administration of sepsis treatment bundle? - Average time to triage. Is this a contributing factor to the delay in treatment? - Missed ED sepsis cases referred for admission (diagnosed after transfer from ED without any indication of suspected or confirmed risk) Assessment of baseline measures can assist in developing targets for improvement. (CM)

5. ~~Threshold~~		Old criterion removed
6. Desired outcome (TG)	A greater number of patients with sepsis: 1. Are identified at triage 2. Have a lactate drawn in the ED 3. Have blood cultures drawn and drawn prior to antibiotics 4. receive IVF and time to IVF being hung is less than 3 hours 5. Receive antibiotics and the time to antibiotic delivery is less than 3 hours	These are the goals of the sepsis bundle.
7. Associated interventions focused on an objective (TK, CM)	**Triage Nurse Changes in Triage Practice:** The triage nurses had previously been getting vitals but not formally evaluating for altered mental status changes. However, this practice is changing and triage nurses are being educated to formally evaluate for altered mental status during triage. **Clinician/Nursing sepsis management changes:** The data from multiple studies that help form the current sepsis	Explain whether your intervention should work the best, the least, or intermediate, compared to decision support at these other locations in the decision making process/ecology. Several components of the decision making process/ecology already being performed (described in the left-hand column) aim at clinical decision support in sepsis management through education and availability of EBM query tools. However, changing clinical behavior is not easy. Especially surrounding clinical entities such as sepsis where the guidelines on screening and management have changed frequently since the Early-Goal Directed Therapy in Treatment of Sepsis was published by Dr. Rivers et al in NEJM, 2001. Clinical decision support such as education and providing workstations with EBM querying tools, require the clinician to remember their new training and to take the time to either use it or query a search tool like up-to-date to provide appropriate care. In the ED, where the clinical environment is busy,

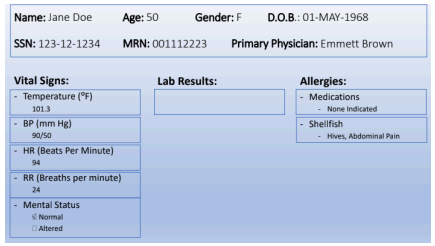
	guidelines, continues to suggest a faster time to antibiotics and IV fluids to improve mortality. Thus, clinicians are being trained/educated to identify patients with sepsis and get IV antibiotics and IV fluids started as soon as possible. **Clinical Workstations with Access to Evidence-Based Clinical Decision Support Query Based tools such as Up-to-Date**	and time is crucial, this clinical decision support is inferior to our method of 1) helping identify patients at risk of sepsis quickly and 2) initiating early action and suggesting evidence-based medicine interventions through a sepsis order set. (TK) Other interventions that may assist to reduce the occurrence of ED sepsis cases, especially for patients susceptible or considered to be at risk of infections and therefore sepsis include: 1) Primary care physician promotion of preventive measures such as flu-vaccines, smoking cessation etc. for at-risk patients 2) Patient-friendly discharge instructions to susceptible or high-risk patients within information on the signs and symptoms of sepsis, when to seek medical advice and who to contact 3) Home-based care visits or telephonic intervention post-discharge to patients at risk of developing sepsis to prevent new cases (CM)
8. Primary stakeholders (DS)	List roles 1) Nurses 2) Physicians 3) Pharmacists 4) Laboratory staff 5) Hospital Quality/Safety team 6) Hospital Management 7) Patients	How would you motivate them? (1 & 2) Septic patients have a high mortality rate if sepsis is not identified and treated rapidly. In addition, patients may present atypically, without clear Systemic Inflammatory Response Syndrome (SIRS), and in the absence of a confirmed infection. (3) Multidisciplinary sepsis response teams including pharmacists have demonstrated decreased antibiotic administration times, increased selection of appropriate, decreased mortality. (4) Due to culture technique limitations, confirmation of bacterial infection may take longer than the first 24 hours following a patient's presentation (to the ER). However, other lab tests such as white blood cell (WBC) and band counts can be obtained relatively quickly by the lab.

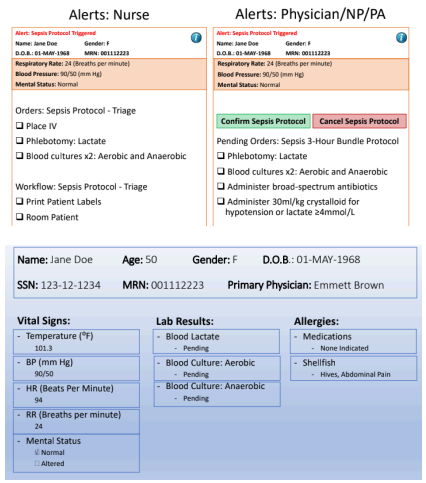
		(5 & 6) Rapid identification and treatment of sepsis can minimize related mortality and health care costs. (7) Patients at risk for developing sepsis should be aware of warning signs and actions to take given that sepsis has high mortality if not treated immediately. Combined with the speed of declining clinical conditions, early detection is critical.
9. Champion (DS)	Emergency Department Medical Director	In addition to the patient presentation, diagnosis/lab orders, and treatment, there are several critical communication streams including department handoff from ED/ER (typically where sepsis cases present) and ICU. In addition to inter-department handoff, due to the critical time component, intra-department communication between the nursing staff and physicians is key to provide coordinated timely care.
10. User (DS)	Clinician/Care Provider (Physician, Nurse, PA) assessing patient.	How would you motivate them? (1) Education on the initiative, as well as ways to identify and treat sepsis. (2) Feedback regarding: (2)(a) Temporal performance for sepsis identification and treatment initiation. (2)(b) Patient outcome (2)(c) Individual feedback in comparison to one's functional group (ER, ICU, etc.) and the hospital as a whole.
11. Jobs to be affected	**ED Nurse** **ED Triage Nurse** **Clinician (NPPA/MD)** **Phlebotomist**	**ED Floor Nurse:** The ED floor nurse will now be flagged when a patient's qSOFA screens positive and will be expected to make sure the patient has been bedded in an ED room, had an IV placed, and labs/cultures drawn. They will also need to be ready to administer IV fluids and antibiotics if the clinician signs the sepsis bundle order set.

	Bed board (administrator)/Transport	**ED Triage Nurse:** The ED Triage Nurse is the first of the hospital staff to take a history, perform a physical exam and get vitals from the patient. Their job is essential in accurately inputting the data into the EHR so the qSOFA can be calculated by our CDS tool and if positive the proper steps taken. **Clinician:** The clinicians will be expected to quickly decide on the appropriate course of action for patient's who screened positive for sepsis and have a pended sepsis bundle order set. **Phlebotomist:** For patients who screen positive for sepsis, the phlebotomist will receive orders to draw labs/cultures from the EHR. These orders will be placed automatically, and the phlebotomist will need to be aware of this new workflow so they can properly contact the necessary staff if issues such as difficulty drawing labs occur. They will also need to prioritize these patients appropriately. **Bed Board/Transport:** When patients trigger a positive qSOFA score the patient should be bedded immediately. Bed board needs to be aware of these patients, so they can communicate with transport and prioritize these patients if needed.

12. Workflow (TG)	Provide SIMPLE cross-functional flowchart or activity diagram	
13. Workflow step (of focus) (TG)	Referring to the nurse receiving information from the patient at triage. After she enters triage evaluation she receives a notification if the patient meets sepsis criteria.	Right information: That the patient meets sepsis criteria, that they should be roomed immediately, and that they should have labs drawn and IV placed Right person: triage nurse Right format: alert Right channel: in the EMR Right time: upon completion of collection of triage data

14. Information system (TG)	ED EMR	This is where triage information is recorded and where orders are generated
16. Target population (CM)	All patients visiting the Emergency Department with known or suspected infection and clinical symptoms of concern on triage.	"Anyone can get an infection, and almost any infection can lead to sepsis."(1) Certain population groups are at increased risk of developing infections and sepsis. (discussed in further detail under "17. Selection criteria") The incidence of affected patients is expected to rise due to an aging population, a higher proportion of patients with compromised immune systems and more patients undergoing high-risk surgery. (2) Approximately 1 in 3 people who die in hospital have sepsis. Sepsis is a medical emergency and should be suspected in patients with known or suspected infection presenting to the Emergency Department.(1) 1. Basic Information | Sepsis | CDC. Cdcgov. 2018. Available at: https://www.cdc.gov/sepsis/basic/index.html. Accessed May 4, 2018. 2. Parrillo J. Septic Shock — Vasopressin, Norepinephrine, and Urgency. New England Journal of Medicine. 2008;358(9):954-956. doi:10.1056/nejme0800245. (CM)
17. Selection criteria (CM)	All patients visiting the Emergency Department with known or suspected infection should be assessed to identify: 1) A possible source of infection 2) Factors that increase the risk of sepsis 3) Any indications of clinical concern such as new onset of	Once a patient is triaged then they can be evaluated by the rule. 1) Four type of infections are often linked with sepsis (1): • lungs (e.g. pneumonia) • urinary tract (e.g. kidney) • skin • gut 2) Certain population groups are at increased risk of developing infections and sepsis. These include children under 1, adults over 65 or people who are frail, people with weakened immune systems due to illness (e.g. cancer, HIV) or drugs (e.g. immunosuppressants, long-term steroids) people with chronic

	abnormal behavior, circulation or respiration.	medical conditions such as diabetes, lung disease and kidney disease, people who have had surgery or other invasive procedure in the past 6 weeks, people who misuse drugs intravenously, people with indwelling lines or catheters and people who have a breach of skin integrity.(1,2) 3) Indications of clinical concern may include (1): • confusion or disorientation • shortness of breath • high heart rate • fever or shivering or feeling very cold • extreme pain or discomfort • clammy or sweaty skin 1. Basic Information | Sepsis | CDC. Cdcgov. 2018. Available at: https://www.cdc.gov/sepsis/basic/index.html. Accessed May 4, 2018. 2. Sepsis: recognition, diagnosis and early management | Guidance and guidelines | NICE. Niceorguk. 2018. Available at: https://www.nice.org.uk/guidance/ng51/chapter/recommendations#risk-factors-for-sepsis. Accessed May 4, 2018. (CM)
19. User interface/Widget (DS)		Critique in terms of the 10 Commandments Ten Commandments for Effective Clinical Decision Support **1. Speed Is Everything.** Primary benefit of the CDS tool for sepsis is ability to present real-time EHR review at the point of care (triage), presentation at the Emergency Department (ED)



Existing workflow (w/o CDS) requires: (1) Triage mindset manually attuned to Sepsis, and (2) Individual knowledge on intervention bundles and differing guidelines (SOFA vs. qSOFA)

Presentation of Evidence-based information, also at the point of care

Initiate time sensitive workflows for:

- Sepsis Risk Identification: qSOFA Bedside Score
- Care Interventions: 3-Hour Bundle
- Notifications: ED Physician, ED Floor Nurse, Lab Staff/Phlebotomist and Patient Transport

2. Anticipate Needs and Deliver in Real Time.

When the triage nurse captures and records the vital signs, the EHR recognizes the clinical criteria and initiates the order bundle for sepsis in real time as actions for the for nurse and as an alert for the physician/NP/PA.

3. Fit into the User's Workflow.

The guided choices are part of the ordering process

Direct to the nurse (right person) at the point of contact with the patient (right time), to the right person, with the right info at the right time.

To the Physician as an alert to confirm or deny the sepsis bundle order set.

The alert only fires when 2 of 3 criteria are met.

4. **Little Things Can Make a Big Difference.**

Triggering Criteria built directly into triage workflow

Separate and specific role-based alerts for Nurse and Physician

Use of color:

- Alerts are Orange along with triggering criteria to indicate "caution"

		- For the physician, use of (1) green to confirm sepsis protocol, and use of (2) red to cancel sepsis protocol (also why red not used for alert) Infobutton in blue: as is common, blue Infobutton denotes a link. **5. Recognize that Physicians Will Strongly Resist Stopping.** Alternatives to Stopping Workflows: Automated ordering for nurse to begin lab draws and prep patient for IVF and antibiotics Physicians can stop the sepsis protocol or confirm the protocol. The condition is emergent, so the choice is not to delay patient care, but rather to confirm/deny the next steps, downgrade the response. **6. Changing Direction Is Easier than Stopping.** The default is continuation of the sepsis protocol, so a "stop" by the physician is a self-selected change of direction. Presumably this type of direction change is less emergent, empowering the physician to determine his/her own workflow response. **7. Simple Interventions Work Best.** We have chosen a simple intervention based on expedited guidelines to integrate into an already existing workflow for ED triage which initiates a response, alerts and provides guided choices. The underlying rule logic for the alert is quite simple: if two of the three qSOFA criteria are met upon presentation and triage in the ED, then the sepsis 3-hour bundle response is initiated We have designed the response to align with the guideline, ad provided information linked to the guideline, as needed. User testing the interface/usability is planned prior to roll-out. **8. Ask for Additional Information Only When You Really Need It.**

		The only information we ask for are a subset of those required already for triage: BP, Mental Status and RR. If the trigger fires, then the only other question is physician confirmation of the existing response. 9. **Monitor Impact, Get Feedback, and Respond**. The sepsis risk monitoring and treatment initiation CDS program is designed to respond to potentially life-threatening, front-line patient – nurse interactions. Monitoring assessments include baseline sepsis identification and response times (based on existing EHR information) compared to post-CDS times. In addition to response, outcomes (mortality as a percentage of cases) will be compared. Survey responses, usability testing and override percentages are all mechanisms for feedback. If alert fatigue is identified as an issue, there is opportunity to adjust the identification system as the updated 2018 guidelines are released. 10. **Manage and Maintain Your Knowledge-based Systems.** We have resources (qSOFA) identified, staff/stakeholders and timelines for the critical CDS tool. There will be a review committee to determine appropriateness of selected recommendations and to identify knowledge update requirements as new information becomes available.
20. What information presented to the user in #19 (and other screens implied in your solution) (DS)	List data elements, along with data/vocabulary standards qSOFA Assessment:(triggering) and response (3-hour bundle) as an Infobutton Patient Information & Entry: Name, MRN (medical record number), DOB (date of birth) and age, sex/gender, allergies, pending orders.	Justification for the qSOFA and 3-hour bundle are as above. The use of the Infobutton to access this information in real-time can serve as an adjunct to (a) the sepsis protocol triggering and response, and (b) the physician's exisiting knowledge and expereince. The alert information is restricted to the data related to the cause for the alert triggering for (1) clinical decision making and (2) patient identification Alergies are necessary for example if someone allergic to penicilin presents with becteremia Diagnosis confirmation (from blood cultures) will come later, but confirmation of test order status ("pending") is highly important.

21. Rule logic (DS)	Provide pseudocode for LHS IF... Then rule logic IF [CRITERIA1] AND [CRITERIA2] THEN alert AND COMPLETE ORDERS Sepsis_Pseudocode	Source/citation, if available Pseudocode adapted from Arden syntax as described in Module 4, Part 2 "The Language of Knowledge" Additionally, sepsis-prediction models have recieved a lot of attention given: (A) meaningfull use applications[1], (B) variable outcomes observed[2], (C) different HIT/CDS approaches to early sepsis detection[2,3], and (D) financial costs to the US care system[2]. While some systems have focused on machine learining[2] with an objective of diagnosis support, others have been rule-based systems. Recognizing these complexities, our CDS tool for use upon triage in the ED setting focuses on intervention speed for suspected (vs. confirmed) spesis cases, and puts the diagnosis in the hands of the ED physician following entry into initial treatment and diagnostic-support protocols. [1]Sepsis Core Measure [2]HealthIT.Gov [3]Sepsis Sniffer
22. Knowledge representation (CM)	List your choice: How will the knowledge contained in the Workflow and/or the Rule Logic be represented within your computer system. (Rule, ontology, order set...). DOES NOT have to follow the "You SHOULDT" scheme.	Justify choice Explain why you didn't use any 2 other possibilities Knowledge representation will include: 1) rules in the form of Arden Syntax triggering an alert (to the user and EHR) of suspected or confirmed sepsis with an indication of the risk factors triggering the alert and an indication of (low, moderate or high-risk patient). The alert will need to be accepted or declined with a reason for the decline. 2)an automatically generated order set in response to the alert will be created based on evidence-based treatment guidelines to ensure consistency and quality of care. The order set will be set up to enable the treating physician to opt-out (de-select) standard components or order additional items. (Perhaps a reason for the amendment should be requested to facilitate future analysis of additional requirements for improvement on the CDS intervention.

		Other representation possibilities would be a table as tables could be useful to check whether the rules are working and to check for contradictions in the classification of patients at risk. However, due to the complexity of the rules with multiple risk factors and different thresholds of risk (low, moderate, high), it would have been difficult to capture all the rules in a table. An ontology defining the concepts of sepsis, immunocompromised etc. could be useful as part of building the final representation but Arden syntax rules would be most appropriate in this situation since there are multiple sources of information, a number of risk factors on the LHS as well as thresholds which Arden syntax rules would be able to easily deal with. (CM)
23. Alerting (TG)	The alerts exist in two stages, both are synchronous 1. The triage nurse has an alert upon completion of the triage data collection that uses that information to tigger the alert. This automatically creates a new workflow based. It is "hard" in that it does not allow an override. It does not stop workflow but rather changes it's direction. 2. The alert for the physician/NP/PA is a soft stop in that it can be overridden and dismissed by the clinician, but it must be dealt with.	We have attempted to minimize alert fatigue by limiting the firing of this to the first time the clinician interacts with the patients chart only. The more effective way however to deal with alert fatigue would be to more exactly target the patients that are identified as potentially septic. The firing of the alert is based entirely on the qSOFA score, that consists of 1) respiratory rate of 22/min or greater, 2) altered mentation, or 3) systolic blood pressure of 100 mm Hg or less. As currently written, this will fire for any patient meeting this criteria. On the one hand, this score exists because it has been validated as a predictive bedside score applicable to places like a busy emergency room. Given that mortality from sepsis increases for every hour in delay of enactment of the sepsis bundle, one would a priori assume that deviation from this as a notification of the risk of sepsis has attendant risks. However, the utility as a screening tool depends on the prevalence of sepsis in our particular emergency room. Given that the data exists in the EMR the historically we can 1) identify patients for whom the alert would fire, and 2) identify patients for whom sepsis was diagnosed, we can calculate the number of patients per shift that would fire the alert as well as PPV and NPV for the alert. This would allow a priori modeling to determine if the thresholds would be appropriate. If the

		predictions are not appropriate, then additional criteria could be included to, for example: exclude patients with conditions that cause tachypnea that have a low risk of sepsis. For example a) if RR>22 AND NOT (History of Asthma with Chief complaint of Asthma Exacerbation) b) if altered mentation and NOT (chief complaint of closed head trauma) C) if SBP < 100 and NOT (massive blood loss) Other sepsis alert systems have had improved sensitivity and specificity by creating extensive and complex algorithms that take multiple comorbid conditions into account in evaluating the triggering rules (1) 1. Journal of the American Medical Informatics Association, 24(1), 2017, 88–95
24. Action items	The RHS. Should be consistent with #3.	Justify
25. Knowledge acquisition (CM)	List steps for obtaining the knowledge for #21 and #22 to do this for real. Include how you will gain knowledge of user behavior. Steps to obtain knowledge include defining the sources of and owners for the information required for this CDS intervention. (Where is the knowledge and who signs it off)	The following steps could be used to acquire the specific data knowledge required: 1) Evidence-based guidelines on which the sepsis trigger is based and any thresholds that need to be established will need to be acquired from the hospital clinical committee or relevant responsible stakeholders. A formal process to address any changes in future is needed to ensure timely communication to the CDS team so any rules can be updated. 2) Patient-specific data for the (data-driven) rules will need to be acquired from the various sources within the EHR for use by the rules or first acquired via rules as well before being used by the rule. This will help to compile the

	Determining the format in which the data is required for the rules Developing rules or code that may be required to extract the data required, as required Bringing the data into the system for use by the rules Ensuring knowledge is up to date Storing new data acquired or created by the CDS intervention (CM)	risk factors required to assess the sepsis risk for each patient which can be present with binary variables (1=present; 0= not present). Examples of how the data required for the rule could be acquired include: a) age can be calculated from date-of-birth in EHR and compared against a threshold (eg less than 1yr or over 65yrs) b) a list procedures having occurred in the past 6 weeks can be acquired from the EHR at triage (by searching for specified events within a specified time period from the time of ED triage) to indicate a recent event that may have been the cause of infection, c) patient diagnoses for infections within a specified time-frame (another piece of information to be agreed on by the clinical committee) starting with the most recent can be determined from EHR to check for any confirmation of recent infection, d) specific diagnoses e.g. diabetes (from a predetermined list) can be determined from a history of diagnoses associated with the patient to indicate relevant risk factors, e) specific drug classes associated with immunosuppression can be used to identify immunosuppressant drugs to indicate the presence of this risk factor f) the presence of confusion or disorientation could be indicated by a tick box at triage and used by the algorithm g) Shortness of breath and heart rate would be determined by evaluating the respiratory and heart rates above certain thresholds h) Symptoms such as fever or shivering, extreme pain etc. which ordinarily may be difficult to detect from text notes could be determined by symptom checkboxes which could be completed (opt-in) at triage from the patient or family members 3) Based on the above risk factors an algorithm could be developed to classify patients according to the risk of possible sepsis using various thresholds. For e.g. patients could be classified as low risk of having sepsis if none of the key risk factors are present or high-risk for example if all of the key risk-factors are present.

		4) It would be helpful if the patient-specific information required at triage could be populated into the triage form where available or applicable to ensure a more efficient, quicker triage process Knowledge of user behavior could be acquired using the following methods: 1) Data on whether the user took action or not following the alert could be stored (e.g. alerts accepted, standard orders approved, reasons for declining the alert) 2) Surveys, observing users as well as screen recording software to track users maneuvering through the process can also be used to gain knowledge on user behavior (CM)
26. Monitoring (CM)	List variables to be collected to monitor use and activity of the CDS. Variable List: 1.Number of sepsis alerts of all triage cases 2. Number of alerts correctly fired of all eligible (i.e. did the alert take place for all cases identified as high-risk) 3.Number of alerts accepted (% of total alerts) 4.Number of overrides(declines) (% of total alerts) 5. Number of missed sepsis cases referred for admission (later diagnosed) 6.Counts of overrides per reason or reason category 7. Number of standard bundles ordered of total alerts accepted	Define the decision(s) for which these data will be used for managing the decision-support process/content. Variables 1 (sepsis rate) and 2 (correctly fired alert, PPV) will assist with deciding whether the alerts are working properly. Variables 3,4,5: will assist with monitoring the true positives (preferably high), false positives and alert fatigue (preferably low) Variable 6: May indicate the thresholds are too sensitive and should be revised Variables 7, 8: is the automatically generated order set appropriate for the majority of cases? Revise existing order set or add another order set(s). Variables 9,10: Does the CDS intervention reduce the time from triage to treatment? (desired outcome) Does it increase or reduce triage time per case? (possible trade-off between the increase in time (within reason) for (significant) reduction in missed cases?) Variable 11: Mortality rate in hospital due to sepsis - Is use of the CDS intervention reducing associated mortality? Variable 12: User experience ratings - How can the CDS intervention be improved from a user experience perspective, but also efficiency and patient outcome perspective (based on survey questions) (CM)

	8. Number of custom bundles ordered of total alerts accepted 9.Average time taken (including range) from sepsis alert to initiation of treatment 10.Average time required to complete triage per ED case 11. Mortality rates due to sepsis 12. User satisfaction survey (CM)	
27. Feedback channel and plans (TH)	List steps for getting monitoring data collected 1. Plan to a one-month pilot test before launching. 2. Gather the feedback by the focus group interview from ten test users including ED Nurse, ED triage Nurse, clinician Phlebotomist and physician/PA/NP and asking following questions. • Is the CDS effective? • Is the CDS user friendly? • What can be the barriers? • Does the CDS interfere your workflow and how? • Do you agree with the introduction of this CDS?	End-User feedback is very important and will be instrumental in guiding the design of the alert. Those feedbacks should be utilized to inform the decision about final design. Individual interview might be good, however, in the CDS, which many types of workers will use, group interview may be more helpful to gather the team opinion. The timely feedback is very important when deploying a new decision support tool. Direct user feedback is required and valuable even after launching. These feedbacks should be gathered both at the outset of the project, and during any pilot phase.

	3. Summarize the feedbacks and modify the system as final design if need. 4. After launching, plan to regular feedbacks from users for 6 months.	
28. Knowledge management (CM)	Knowledge that will need to be maintained: 1.Sepsis guidelines and treatment protocols (e.g. qSOFA criteria; 3-hour sepsis bundle targets) 2.Patient EHR data 3.Thresholds used in the rules 4.Inclusion and exclusion lists (e.g. diagnoses and drug lists) 5.The logic of the rules themselves (rules management) (CM)	How will it be maintained: 1.Hospital clinical committee ownership to ensure CDS intervention for sepsis is evidence-based (physician champion will need to provide updates to the EMR team as new guidelines are published) 2.By the EHR Data Management team 3.By periodic review by the hospital clinical committee 4.By periodic review by the hospital clinical committee 5.By the respective part of the Data Management team skilled to update the rules which may include coders/software developers etc. Knowledge management also involves staying up-to-date with latest technology/methods in addition to the content. (CM)
29. Evaluation	collect: number of patients triaged time of triage patients triggering Alert patients for whom the physician did not agree with the alert patients with an ICD10 code for sepsis in the ED or within 24 hours after admission	To evaluate the alert properly, we will need to know the percent of patients that triggered the alert had a physician agree they had a diagnosis of sepsis (True Positive). We will also need to know all patients who were diagnosed with sepsis to find any patients who were diagnosed who did not trigger the alert (False negative). Patient outcomes are needed to calculate any change in mortality (primary outcome) between prior to the use of the alert and after. Outcomes for patients who triggered the alert but for whom the provider did not say they had sepsis also need to be evaluated to determine the effect of the (inappropriate) intervention on the patient and the cost to the hospital and resulting effect on workflow. Lastly, the secondary outcomes (Percentage of cases with serum lactate measured in the ED, Percentage of cases receiving IVF in ED and time to IVF hung, Percentage of cases receiving antibiotics in

	patients who died patients who had serum lactate and time from triage patients receiving IVF in ED and time to IVF hung,Â patients receiving antibiotics in the ED and time to antibiotic infusion patients having blood cultures drawn before antibiotic administration	the ED and time to antibiotic infusion, Percentage of cases having blood cultures drawn before antibiotic administration) will also be needed.
30. Urgency/delivery time horizon (TH)	Specify a high-level project management plan, to jibe with #7, above. Timeline and Phases of Implementation: • Gather the baseline data (3 months) • Gather the opinion from end users (1 week) • Design the CDS (3 months) • Integration of CDS with EHR system (3 months) • Pilot testing of the system (1 month) • Evaluation of Overall System (6 months)	This CDS involves many types of workers. Therefore, we need to show them persuasive evidences and current situation. In that sense, baseline data is crucial. After they understand its importance and need to change current situation, we gather their opinion first. By doing so, we may avoid unnecessary conflict. Since they have many suspected patients with sepsis, we think one-month pilot testing is enough. As above, after 6 months of launching, we plan to hold regular meeting abbot this system with this CDS.

30a. Deployment (CM)	Specify high-level strategies for communicating, education, and marketing related to this CDS (separate from actual training). High-level strategies for deployment of this CDS may include: 1. Stakeholder agreement and alignment of goals and incentives 2. The framing of the need for the CDS system 3. Inclusion and consultation in the development process 4. Communicate with and educate users regarding how the system can assist in achieving clinical and departmental goals 5. Ensure the CDS system is practical and works before deployment! 6. Ensure technical support is available (especially initially) to encourage early adoption. 7. Develop an internal monitoring system to track improvements and demonstrate the impact in a more tangible way	Justify. How would you motivate the primary user (from #10) Clinical Decision Support (CDS) systems have been shown to improve the performance of clinicians yet many CDS systems are rarely adopted voluntarily.(1) The following high-level strategies may help to motivate the primary user of our CDS, the clinician or care provider at the ED assessing the patient: 1. Stakeholder agreement and alignment of goals and incentives: goals of the CDS system should be aligned with the goals of the department and organization but also with that of stakeholders that may be impacted by the implementation (e.g. pharmacy department, the path lab, ICU etc.) to ensure widespread support and adoption.(1) 2. The framing of the need for the CDS system: focus on illustrating how current statistics can be improved with the new system, how adoption can make things easier and more efficient by identifying patients that may need urgent attention. Avoid associating a lack of use of the new CDS system with penalties. Rewarding uptake and integration and then improved outcomes can be more effective at generating wider interest and adoption. 3. Inclusion and consultation in the development process: including the users or representatives of the user groups and stakeholders that may be impacted to create an environment of co-development to ensure the solution is practical, meets the outcomes and workflow needs of the units concerned is recommended. This serves to cultivate a sense of shared ownership and a greater willingness of the intervention to succeed having participated in its design. 4. Communicate with and educate users regarding how the system can assist in achieving clinical and departmental goals. Enlist a primary user (perhaps someone with considerable influence in the team) to learn the system and Champion the deployment; speaking from a point of having used the system and advocating for its use by a peer can be compelling.

	8. Ensure a process of continuous improvement and knowledge sharing (CM)	5. Ensure the CDS system is practical and works before deployment! First impressions count. Ensure the best knowledge is available at the time when needed facilitating the delivery of emergency care. 6. Ensure technical support is available (especially initially) to encourage early adoption. Cheat sheets if applicable or appropriate can be developed to assist users; even if only a list of the contact details for user support. Users are more likely to attempt to use the system if support is available to quickly guide them to how to do what needs to be done and that issues can be resolved quickly. 7. Develop an internal monitoring system with key metrics that can be viewed by the department and higher management so that progress towards targets can be tracked making the impact of the system towards achieving objectives more tangible. 8. Ensure a process of continuous improvement and knowledge regarding both clinical medicine and the CDS implementation is facilitated.(1) 1. Jenders RA, Osheroff JA, Sittig DF, Pifer EA, Teich JM. Recommendations for Clinical Decision Support Deployment: Synthesis of a Roundtable of Medical Directors of Information Systems. AMIA Annual Symposium Proceedings. 2007;2007:359-363. (CM)
31. Expected adverse consequences	False positive screenings for sepsis with our CDS tool may result in these patient getting unessary labs and an IV. There may be an overreliance on qSOFA screening. In false negative cases patients who have sepsis may be overlooked because of a qSOFA score. Added alerts and changes in workflow for the nurses and	qSOFA has shown to be more specific than SIRS and other sepsis screening tools used in the past. However, qSOFA has an area under the ROC curve of .81. Although this classifies it as a good diagnostic tool, it is not excellent and will miss cases of sepsis as well as incorrectly screen individuals postivie for sepsis.. In cases where a patient is a false positive, it is often reasonable for them to get a sepsis work up with labs. However, there will be cases where it is clearly not appropiate; and in these case they may unnecessarily get labs and an IV given the autmation of this step in our CDS tool. Compared to previous screening mechanisms for sepsis, qSOFA is less sensitive. The result is an increase in false negative screenings for sepsis. For those providers who understand this feature of the test, they are less likely

	physicians will result in some negative feelings towards the CDS tool.	to prematurely close on patients who have a negative qSOFA and who they are worried may have sepsis. However, there will be providers who over rely on the test result. In this situation cases of sespsis may get missed. Our CDS tool could possilby encourage relying more heavily on the results of the qSOFA screening because of its increased use in the ED workflow and result in missed cases.
Summary	Our intervention describes the implementation of a screening tool to identify patients at risk for sepsis by extracting the qSOFA score from information already obtained from the triage nurse's assessment. It then streamlines workflow to enact the sepsis bundle in to meet current guidelines within the designated time. Overall this is a relatively straight forward implementation of computer decision support. It creates an order set for the nurse that does not require physician sign-off, but this is common for pathways in the emergency department. It does modify workflow in that a patient is to be roomed immediately, but a patient who is septic should be roomed immediately. By providing the physician with pre-populated order set is seeks to minimize errors of omission for septic patients. One concern, is that based on the prevalence of sepsis in your emergency department, there may be a unacceptably low positive predictive value and there may be an unacceptably high level of inappropriate labs being drawn. Of the labs being drawn, the blood cultures would be the most concerning that would need the highest level of post-implementation scrutiny. These labs are expensive and labor intensive, and if drawn inappropriately on a large number of patients increase the number of false positive blood cultures (cultures that grow an organism, but are actually a contaminant (usually from skin). There will need to be analysis of costs and care outcomes examining truly septic patients getting care faster and better and avoiding complications versus falsely labeled septic patients getting inappropriate care and potential complications from this. Additionally, there would need to be analysis of the effect of additional patients being immediately roomed have on departmental workflow, staffing, space, and if there was an increase in complications to other patients in the ED because time was diverted to potentially septic patients. Overall, this structured exercise provided a framework to walk through the intervention to make sure no particular step is overlooked. In general this appears to be a theme in informatics. Each step by itself is obvious that is should be considered, but the enumeration of the (in this case) thirty steps creates a implementation algorithm that is greater than the sum of its parts. This is necessary as informatics interventions have the potential to impact the care of 1000's of patients, and can be quite labor intensive and costly to be implemented on a institution or departmental wide scale. (TG)	