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Introduction

Effective May 1, 2013 NYSDOH Title 10 New York Codes Rules and Regulations (NYSRR) Sections 405.2 and 405.4 were amended to require that hospitals have in place evidence-based protocols for the early recognition and treatment of patients with severe sepsis and septic shock that are based on generally accepted standards of care. Consistent with these regulations, sepsis protocols were submitted by all Article 28 hospitals with implementation by hospitals on or before December 31, 2013. In addition, subdivision 7 (i, ii) specified that “medical staff shall be responsible for the collection, use, and reporting of quality measures related to the recognition and treatment of severe sepsis for purposes of internal quality improvement and hospital reporting to the Department. Such measures shall include, but not be limited to, data sufficient to evaluate each hospital’s adherence rate to its own sepsis protocols, including adherence to timeframes and implementation of all protocol components for adults and children. (ii) Hospitals shall submit data specified by the Department to permit the Department to develop risk-adjusted severe sepsis and septic shock mortality rates in consultation with appropriate national, hospital and expert stakeholders.”

Data Submission

All NYS Article 28 hospitals are required on a quarterly basis to submit all cases of severe sepsis or septic shock to the NYS Department of Health within the following two months of the close of a quarter. For example, Quarter 2 (April, May, June discharges) are submitted by August 31. Quarter 3 (July, August, September discharges) are submitted by November 30 and so forth to capture all quarters within each year. Currently this effort is ongoing and does not have a “stop” date therefore, quarterly data submissions continue unless otherwise notified by regulation. Hospitals are also required to report all transferred cases of severe sepsis or septic shock with data collection regarding the treatment provided prior to transfer.
Data Reports

Data reports include hospital self-reported data using the specifications of the *NYS Data Dictionary for Severe Sepsis or Septic Shock*. Additional considerations for report creation included: the NYS Regulation and Guidance Documents; communication with National experts; review of relevant literature, trials, community, national, and international initiatives; suggestions of the NYS Sepsis Advisory Committee; and, consideration of the NQF #0500 measure.

Report inclusion/exclusion parameters:

- Adult cases (≥ 18 years old) with discharge dates between the quarter represented were included. Reporting for pediatric cases will be presented under separate cover, which will be released in the upcoming months.
- Cases with questionable accuracy were removed for follow-up with individual providers:
  - Cases with overlapping discharge dates;
  - Cases with data inconsistencies in medical record number, patient control number, unique personal identifier; and,
  - Cases transferred within six hours.
- Cases in which the patient expired within six hours of admission were removed from these analyses, however, these cases will be reviewed individually and may be included in future reports.
- Demographic, Treatment, and Bundle data elements were calculated for cases in which the patient(s) were not excluded from the protocol.

Data Elements:
The hospital-specific data reports contain an overview of multiple data points. These data will assist hospitals in validating the accuracy of data submitted by their hospital in addition to providing statewide comparative data. Over time, quarterly data trending will be included. All of these data may be used to foster improvements in care and outcome within your hospital. Data points include:

Protocol Excluded

The first data point presented in your report provides detail on the number and type of cases excluded from the treatment protocol. These cases and the reason for the exclusion are presented with the excluded cases removed from all analyses. An overall comparison of the number and percent of excluded cases in comparison to your patient population may assist you in determining if the percentages align with expectations within your hospital or, if further consideration of these excluded cases is warranted. It is also important to consider the percent and type of exclusion for your hospital versus the statewide averages.

Protocol Implemented

Of those cases for which the patients were NOT excluded from the protocol, the percentage of cases for which the protocol was implemented by the hospital is presented alongside the statewide implementation percentage. Importantly, excluded cases were removed from this chart, therefore protocol implementation is expected to be high. If your performance is less than robust for this data element, it is suggested that additional efforts be directed towards identifying and eradicating reasons for non-compliance with protocol implementation guidelines.

Demographics

Data points for age, gender, race, payer, source of admission, and discharge status are provided to compare the cases (and case mix) presented by your hospital in comparison to the statewide average. Disproportionate percentages in comparison to the statewide averages may suggest concerns in regards to the completeness and accuracy of the data submitted by your hospital.
Discharge status has too many codes and values in the Data Dictionary to allow graphical view, particularly for seldom used codes and values. To permit greater ease in viewing the data, discharge status has been grouped using HCUP uniform disposition (http://www.hcup-us.ahrq.gov/db/vars/siddistnote.jsp?var=dispuniform). The data element for race has also grouped instances for which multiple races were reported into the category entitled ‘multi-race’. Note that admission source is intended to capture patient location prior to arrival at your hospital. If the patient is admitted through your emergency department to your inpatient unit, the hospital should report the admission source prior to the emergency department (e.g., home, skilled nursing facility, etc).

Your hospital’s overall raw mortality percentage is provided in comparison to the statewide raw mortality percentage. It is anticipated that a risk-adjusted mortality rate will be provided in the future.

**Treatment**
Timely treatment of severe sepsis and septic shock is crucial for preventing mortality and reducing costly comorbidities and complications of care. It is imperative that we work together to quickly identify and treat severe sepsis and septic shock. The following data elements are provided as independent elements of care. It is expected that hospitals will strive towards and see evidenced, improvements within their hospital across subsequent data reports.

Each data point is calculated regardless of response to the initiation of your protocol (e.g., protocol initiated equals “not initiated” however you reported timely administration of an antibiotic. In this example, the hospital would receive a “met” for administering the antibiotic).

1. **Timely lactate level**
   - **Numerator**: The number of severe sepsis or septic shock patients for whom a lactate level was obtained within 3 hours of presentation.
   - **Denominator**: The total number of severe sepsis or septic shock patients.
   - **Inclusion/Exclusions**: As detailed in the inclusion/exclusion parameters section.

2. **Timely blood cultures prior to antibiotics**
   - **Numerator**: The number of severe sepsis or septic shock patients for whom blood cultures were obtained prior to antibiotic administration and within 3 hours of presentation.
   - **Denominator**: The total number of severe sepsis or septic shock patients.
   - **Inclusion/Exclusions**: As detailed in the inclusion/exclusion parameters section.

3. **Timely administration of broad spectrum antibiotics**
   - **Numerator1**: The number of severe sepsis or septic shock patients who received broad spectrum antibiotics within one hour of presentation.
   - **Numerator2**: The number of severe sepsis or septic shock patients who received broad spectrum antibiotics within three hours of presentation.
   - **Denominator**: The total number of severe sepsis or septic shock patients.
   - **Inclusion/Exclusions**: As detailed in the inclusion/exclusion parameters section.

4. **Timely crystalloid administration**
   - **Numerator**: The number of adult hypotensive or elevated lactate, severe sepsis or septic shock patients who were administered 30 ml/kg of crystalloid within 6 hours of time of presentation.
   - **Denominator**: The total number of severe sepsis or septic shock adult patients with elevated lactate or hypotension.
   - **Inclusion/Exclusions**: As detailed in the inclusion/exclusion parameters section.

5. **Timely vasopressor administration**
   - **Numerator**: The number of severe sepsis or septic shock patients with hypotension unresponsive to fluid resuscitation for whom vasopressors were administered within 6 hours of presentation.
   - **Denominator**: The total number of severe sepsis or septic shock, unresponsive, hypotensive patients.
   - **Inclusion/Exclusions**: As detailed in the inclusion/exclusion parameters section.

6. **Timely remeasurement of lactate**
Numerator: The number of severe or septic shock patients with baseline elevated lactate levels who were remeasured for lactate within 6 hours of presentation.
Denominator: The total number of severe or septic shock patients with baseline elevated lactate levels.
Inclusion/Exclusions: As detailed in the inclusion/exclusion parameters section.

**Treatment Bundles**
Treatment bundles refer to select grouped data elements of care provided within windowed timeframes. The report provides a three hour bundle and a six hour bundle.

**Three hour bundle**
1. Timely lactate measurement;
2. Timely blood culture prior to antibiotic; and,
3. Timely administration of a broad spectrum antibiotic.

To achieve a designation of “met” for the three hour bundle, each of the above listed data elements must have been provided within three hours.

**Six hour bundle**
1. The complete 3-hour bundle=”met”;
2. Timely crystalloid administration (IF hypotensive or elevated lactate);
3. Timely vasopressor administration (IF hypotensive and unresponsive to fluids); and,
4. Timely remeasurement of lactate (IF elevated lactate).

To achieve a designation of “met” for the six hour bundle, the three hour bundle must have achieved a “met” in addition to providing timely administration of each element of the six hour bundle.

**Next Steps**
One important component of the data report is a determination of data accuracy and completeness. As such, the NYSDOH requests that you review your hospital report to determine if the report accurately portrays the volume and type of data you provided in the NYS Data Collection Portal. If you find inaccuracies in volume and type of cases, please contact the Sepsis Help Desk to discuss your concerns at sepsis-ny@support.ipro.us. Please remember that volume may not align exactly with submitted data due to exclusions described within the Inclusion/Exclusion Parameters.

It is the intention of the Department to follow-up with providers for problematic cases as described in the excluded claims. Should your hospital have cases requiring discussion, you will be contacted under separate cover within the next couple of months. Further, if your hospital has been identified for a data audit, you will be contacted under separate cover.

We greatly appreciate the efforts put forth by the entire community as we work towards reducing mortality and improving care. We look forward to seeing the improvements in individual data elements, the bundles, and reduced mortality.