**ABSTRACT**

**Introduction:** The FDA recommends that hospitalized patients with CAP should be evaluated for early outcomes because early outcomes are defined as clinical response or critical failure within 72 hours after initiation of treatment. Criteria for clinical stability can be used to define early clinical response (≤3 days) and late clinical response (4–7 days). Data evaluating the number of CAP patients that will reach early clinical stability using the recommended FDA outcome timing are limited.

The objective of this study was to define the percentage of hospitalized patients with CAP who reach FDA endpoints of clinical response at different time periods.

**KIM:** this can be cut if space is needed.

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**MATERIALS AND METHODS**

This was a secondary data analysis of the Community-Acquired Pneumonia Organization (CAPO) International Cohort Study database. Data was collected between 2001 and 2015. In each participating center, non-consecutive medical records of hospitalized patients with the diagnosis of CAP were reviewed. A sample of the data collection form is available at the study website (www.caposite.com). Validation of data quality was performed at the study center before the case was entered into the CAPO database. Institutional Review Board approval was obtained by each participating center.

**STUDY DEFINITIONS—Community Acquired Pneumonia:**

Diagnosis of CAP required the presence of criteria A, B, and C:

- A. New pulmonary infiltrate on imaging (CT scan or chest x-ray) at the time of admission to the hospital.
- B. Signs and Symptoms of CAP (at least one of the following)
  - New or increased cough (per the patient).
  - Fever >37.8°C (100.0°F) or hypothermia <35.6°C (96.0°F).
  - Changes in WBC (leukocytosis >11,000 cells/mm³, left shift >10% band forms, or leukopenia <4,000 cells/mm³).
- C. Working diagnosis of CAP at the time of hospital admission with antimicrobial therapy given within 24 hours of admission.

**RESULTS**

**Pneumonia:**

- A total of 2,724 patients were included in the analysis.
- Patient characteristics are depicted in Table 1.
- The clinical response for all the population is depicted in Figure 1.

**Table 1—Patients’ characteristics are shown in the following table:**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>31,285</td>
</tr>
<tr>
<td>Age (years)</td>
<td>80.8 ± 10.9</td>
</tr>
<tr>
<td>Sex</td>
<td>Male 58% (n=1,582), Female 42% (n=1,142)</td>
</tr>
<tr>
<td>Race</td>
<td>White 34% (n=1,054), Black 25% (n=743), Other 41% (n=1,151)</td>
</tr>
<tr>
<td>Clinical stability</td>
<td>Early 60% (n=1,634), Late 40% (n=1,090)</td>
</tr>
<tr>
<td>Mortality</td>
<td>2% (n=55)</td>
</tr>
</tbody>
</table>

**CONCLUSIONS**

- This study indicates that clinical response occurs in approximately 2/3 of hospitalized patients with CAP, with the majority of patients reaching FDA timing for early clinical improvement.
- These data suggest that the FDA recommendation of evaluating clinical response to therapy within the first 72 hours of hospitalization is applicable to a significant number of patients.
- Patients who reached clinical improvement and are able to tolerate oral medications can be switched to oral antibiotics, thus decreasing the number of days that intravenous access may be needed.
- Clinical failures can be seen in the patients with inappropriate antimicrobial therapy, misdiagnoses of community acquired pneumonia, superimposed nosocomial infections, medical complications or metastatic cancer.
- The challenge for future research is to:
  1. Define the substantial causes of non-resolving pneumonia
  2. To improve patient outcomes.
  3. To define most effective antimicrobial therapy.

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**REFERENCES**