

International CAPO Study Case Report Form

“An International, Observational Study to Evaluate Current Management of Hospitalized Patients with Community-Acquired Pneumonia”

May 2017

The data on this page are to be collected by the investigator and will not be entered into the study database. Please keep this first page of the case report form for you records in a secure place. This page is the only way to link the CAPO Case ID with the patient name for data quality queries and corrections.

Principal Investigator: _____

Hospital: _____

First Name: _____ Middle Initial: _____ Last Name: _____ Suffix: _____

Medical Record Number: _____

Arrival Date: ____/____/____ (mm/dd/yyyy) Arrival Time: ____:____ (hh:mm)

Initial Data Collected by (Name): _____

Case ID: _____

***** All dates should be collected in Month/Day/Year format. All times should be collected in 24-hour time format (e.g. 1200 for noon, 0000 for midnight). *****

*******CAPO PATIENT SCREENING FORM*******

INCLUSION CRITERIA:

NOTES: Only patients diagnosed with Community Acquired Pneumonia should be included in this study. Diagnosis of Community Acquired Pneumonia (CAP) requires the presence of all three of the following criteria.

Community-acquired pneumonia, defined as follows:	O Yes	O No
A. Chest imaging with evidence of new pulmonary infiltrate obtained within 48 hours before or 48 hours after time of arrival.		
B. ONE OF THESE:		
<input type="checkbox"/> FEVER $\geq 38^{\circ}\text{C}/100.4^{\circ}\text{F}$ OR HYPOTHERMIA $\leq 35.5^{\circ}\text{C}/95.9^{\circ}\text{F}$.		
<input type="checkbox"/> CHANGES IN WBC (leukocytosis or leukopenia by lab)		
<input type="checkbox"/> SUPPORTING SIGNS AND SYMPTOMS:		
<input type="checkbox"/> New/increased cough <input type="checkbox"/> New/increased sputum <input type="checkbox"/> Rales, wheezes or rhonci		

Frequently asked questions regarding inclusion to the CAPO study

- 1) Can a patient with the diagnosis of Healthcare-Associated Pneumonia (HCAP) be included in the study?
 - a. Yes. From the CAPO study perspective, patients with HCAP are considered patients with CAP who have risk factors for multidrug-resistant organisms.

EXCLUSION CRITERIA

***** If either exclusion criteria are marked "Yes" do not continue data collection and do not enter this case into the CAPO database. *****

1. Transferred directly after already being hospitalized for 48 hours or more AND the information from the previous hospitalization is not available.	O Yes	O No
2. Hospital acquired pneumonia.	O Yes	O No

Frequently asked questions regarding exclusion criteria in the CAPO study

- 1) Should I exclude a patient based only on the fact that it was transferred directly to our site (hospital) after already being hospitalized for 48 hours or more?
 - a) NO, you shouldn't exclude the patient right away. **If the patient met all the Inclusion and Exclusion Criteria at the beginning of the previous hospitalization, and all the clinical information since arrival time to the prior hospital is available**, you can enroll the subject. Day 0, for data collection purposes, will start at arrival date and time of the previous hospitalization. Therefore, you would collect all the initial data starting from the prior admission.
- 2) The patient was admitted with a working diagnosis of CAP, but at the time of discharge an alternative diagnosis of urinary tract infection (UTI) and congestive heart failure (CHF) explained the pulmonary infiltrate, fever and leukocytosis. Should this patient be excluded from the CAPO study?
 - a) YES, **exclude this patient after discussing the case with the PI**. The goal of the CAPO study is to enroll only patients with a diagnosis of CAP. If at the time of hospital discharge an alternative diagnosis other than CAP was reached, the patient should be excluded. **However, if the patient has CAP plus another infection, this patient should not be excluded.**

***** Principal Investigator opinion overrides any inclusion/exclusion criteria*****

DATA COLLECTION

Hospital: _____

Data were collected:

- Prospectively
- Retrospectively

DEMOGRAPHICS AND HOSPITALIZATION

Age _____

Gender Male

Female

If female, is she pregnant?

Yes

No

Puerperal State (the first 6 weeks after completion of labor)

If pregnant, what trimester?

1st (conception to end of week 13)

2nd (week 14 to end of week 28)

3rd (week 29 to delivery)

Date of Arrival to Hospital (Day 0): ____/____/____ (mm/dd/yyyy)

** For this study, date of arrival to the hospital is study day 0, which ends at midnight of that day.

Time of Arrival to Hospital: _____ (hh:mm)

Was the patient admitted directly to an intensive care unit from the emergency department? Yes No

If no, was the patient transferred to an intensive care unit after admission to the hospital? Yes No

If the patient was transferred to an intensive care unit after admission to the hospital, please enter the date of transfer ____/____/____ (mm/dd/yyyy)

Did the patient need ventilatory support on day 0? Yes No

If yes, type Invasive mechanical ventilation Non-invasive mechanical ventilation (e.g. CPAP/BiPAP)

Did the patient need vasopressors on day 0? Yes No

Date of discharge from the ICU: ____/____/____ (mm/dd/yyyy)

Date of discharge from the hospital: ____/____/____ (mm/dd/yyyy)

PATIENT HISTORY

Notes: Ensure all data are entered as requested. For all “yes/no” answers, if unknown, select “no”.

Is the number of days with respiratory symptoms before day 0 known?	<input type="radio"/> Yes	<input type="radio"/> No
If this is known, enter the number of days with respiratory symptoms before day 0.	_____	
<i>Past Social and Medical History</i>		
Previous hospitalization within the past 30 days?	<input type="radio"/> Yes	<input type="radio"/> No
If yes, please record the most recent D/C date.	____/____/____ (mm/dd/yyyy)	
Neoplastic disease (active or within the last year)	<input type="radio"/> Yes	<input type="radio"/> No
Congestive heart failure	<input type="radio"/> Yes	<input type="radio"/> No
Cerebrovascular disease	<input type="radio"/> Yes	<input type="radio"/> No
Renal disease	<input type="radio"/> Yes	<input type="radio"/> No
Liver disease	<input type="radio"/> Yes	<input type="radio"/> No
ESRD/Chronic Dialysis	<input type="radio"/> Yes	<input type="radio"/> No
Diabetes	<input type="radio"/> Yes	<input type="radio"/> No
If yes, insulin dependent?	<input type="radio"/> Yes	<input type="radio"/> No
If yes, do you have most recent HbA1c prior to hospitalization?	<input type="radio"/> Yes	<input type="radio"/> No
Most recent HgA1c prior to hospitalization	_____	
Suspicion of aspiration	<input type="radio"/> Yes	<input type="radio"/> No
Cirrhosis	<input type="radio"/> Yes	<input type="radio"/> No
Asplenia	<input type="radio"/> Yes	<input type="radio"/> No
Alcoholic	<input type="radio"/> Yes	<input type="radio"/> No
IV steroids on day 0?	<input type="radio"/> Yes	<input type="radio"/> No
If yes, name	_____	
Active intravenous drug use?	<input type="radio"/> Yes	<input type="radio"/> No
Cystic Fibrosis	<input type="radio"/> Yes	<input type="radio"/> No
COPD	<input type="radio"/> Yes	<input type="radio"/> No
If yes, on oral steroids prior to day 0?	<input type="radio"/> Yes	<input type="radio"/> No
If yes, do you have most recent FEV1 (%) within the past year?	<input type="radio"/> Yes	<input type="radio"/> No
If yes, most recent FEV1 (%) within the past year	_____	
If yes, is home oxygen therapy required?	<input type="radio"/> Yes	<input type="radio"/> No
HIV	<input type="radio"/> Yes	<input type="radio"/> No
If yes, please answer the following:		
Do you have the most recent CD ₄ in the past year (absolute)?	<input type="radio"/> Yes	<input type="radio"/> No
Most recent CD ₄ in the past year (absolute)	_____	
Do you have the most recent CD ₄ in the past year (percent)?	<input type="radio"/> Yes	<input type="radio"/> No
Most recent CD ₄ in the past year (percent)	_____	
Do you have the most recent viral load in the past year?	<input type="radio"/> Yes	<input type="radio"/> No
Most recent viral load in the past year	_____	
Do you have the duration of HIV seropositivity (years)?	<input type="radio"/> Yes	<input type="radio"/> No
Duration of HIV seropositivity (years)	_____	
Currently on anti-retroviral therapy?	<input type="radio"/> Yes	<input type="radio"/> No
Current episode of CAP as initial presentation of HIV	<input type="radio"/> Yes	<input type="radio"/> No
Prior AIDS defining illness	<input type="radio"/> Yes	<input type="radio"/> No
Prior history of PCP	<input type="radio"/> Yes	<input type="radio"/> No

Prior history of tuberculosis	<input type="radio"/> Yes	<input type="radio"/> No
Antibiotic prophylaxis for PCP (<i>current</i>)	<input type="radio"/> Yes	<input type="radio"/> No
Antibiotic prophylaxis for MAC (<i>current</i>)	<input type="radio"/> Yes	<input type="radio"/> No
<i>Risk factors for healthcare-associated pneumonia (HCAP)</i>		
Nursing home resident	<input type="radio"/> Yes	<input type="radio"/> No
Hospitalized ≥ 2 days in the prior 90 days	<input type="radio"/> Yes	<input type="radio"/> No
IV antibiotic therapy in the prior 30 days	<input type="radio"/> Yes	<input type="radio"/> No
Home infusion therapy (including ABT and chemotherapy) within prior 30 days	<input type="radio"/> Yes	<input type="radio"/> No
Chronic dialysis within prior 30 days	<input type="radio"/> Yes	<input type="radio"/> No
Home wound care within prior 30 days	<input type="radio"/> Yes	<input type="radio"/> No
<i>Risk factors for cardiovascular events</i>		
Family history of coronary artery disease	<input type="radio"/> Yes	<input type="radio"/> No
Coronary artery disease	<input type="radio"/> Yes	<input type="radio"/> No
Essential arterial hypertension	<input type="radio"/> Yes	<input type="radio"/> No
Hyperlipidemia	<input type="radio"/> Yes	<input type="radio"/> No
Prior myocardial infarction	<input type="radio"/> Yes	<input type="radio"/> No
Prior PTCA/CABG	<input type="radio"/> Yes	<input type="radio"/> No
Atrial fibrillation	<input type="radio"/> Yes	<input type="radio"/> No
<i>Cardiovascular medications prior to hospital admission</i>		
Aspirin	<input type="radio"/> Yes	<input type="radio"/> No
Beta-blockers	<input type="radio"/> Yes	<input type="radio"/> No
ACE inhibitors/ARBs	<input type="radio"/> Yes	<input type="radio"/> No
Anticoagulants	<input type="radio"/> Yes	<input type="radio"/> No
If yes, please specify:		
Warfarin	<input type="radio"/> Yes	<input type="radio"/> No
Heparin	<input type="radio"/> Yes	<input type="radio"/> No
Other	<input type="radio"/> Yes	<input type="radio"/> No
If other, name _____		
Antiplatelet	<input type="radio"/> Yes	<input type="radio"/> No
Statins	<input type="radio"/> Yes	<input type="radio"/> No

PHYSICAL EXAMINATION AND LABORATORY AT ADMISSION

*The period of admission includes the first 24 hours since the time that the patient arrived to the hospital. Vital signs and laboratory values should be collected during the first 24 hours only. The only exceptions to this rule are **LDL, HDL, LDH, Cholesterol, Triglycerides, HgA1c and Vitamin D**, where values from anytime in the previous **3 months** or the **current hospitalization** can be used. For **Hemoglobin A1c**, results obtained **up to 2 months after** the time of hospitalization should be considered. If more than one value per field exists, **select the worst value** for the first 24 hours.

If one of the values is out of range you MUST verify it and then you will write down the term “Verified” next to the table in the corresponding row.

<i>Physical examination on admission</i>	
Height (122-198 centimeters)	
Weight (20-182 kilograms)	
Heart rate (60-100 beats/minute)	
Respiratory rate (5-45 breath/minute)	
Systolic blood pressure (60-300 mmHg)	
Diastolic blood pressure (30-200 mmHg)	
Temperature (35-40.5 Degrees Celsius)	
O2 saturation collected?	O Yes O No
If yes, O ₂ saturation (60-100 %)	
FiO ₂ at the time of O ₂ saturation measurement (Decimal) (0.21-1)	
Altered mental status	O Yes O No
<i>Laboratory findings</i>	
Hematocrit (18-60%)	
Hemoglobin (6-19 mg/dL)	
WBC (0.9-20 x 10 ³ /μL)	
Bands (2-6 %)	
Platelet count (10-1000 x 10 ³ /μL)	
INR [International Normalized Ratio] (1.0-5.0)	
Serum Sodium (110-150 mEq/L)	
Serum Potassium (2-8 mEq/L)	
Blood Urea Nitrogen (BUN) (5-70 mg/dL)	
Serum Creatinine: (0.2-10 mg/dL)	
Serum bicarbonate or CO ₂ : (10-40 mEq/L)	
Serum Glucose: (30-600 mg/dl)	
Albumin (1-40 g/dL)	
Aspartate transaminase (AST) (0-35 units/L)	
Alanine transferase (0-35 units/L)	
Bilirubin (0.0-1.0 mg/dL)	
Serum troponin I (0.001-10 ng/mL)	
Serum troponin II (0.001-10 ng/mL)	
Serum troponin III (0.001-10 ng/mL)	
Serum CK-MB 1 (0.01-50 ng/mL)	
Serum CK-MB 2 (0.01-50 ng/mL)	
Serum CK-MB 3 (0.01-50 ng/mL)	
Low Density Lipoprotein (LDL) (10-1000 mg/dL)	
High Density Lipoprotein (HDL) (10-1000 mg/dL)	
Cholesterol (< 200 mg/dL)	
Triglycerides (10-1000 mg/dL)	
Lactate (0.5-1 mmol/L)	
HbA1c (5-9%)	
Lactate Dehydrogenase (LDH) (10-1000 units/L)	

Brain natriuretic peptide (BNP) (0-80,000 pg/mL)		
C-reactive protein (CRP) (0-1000 mg/L)		
Procalcitonin (<0.05 µg/L)		
25-hydroxy Vitamin D (20-100 pg/mL)		
Was arterial blood gas (ABG) obtained?	<input type="radio"/> Yes	<input type="radio"/> No
If yes, pH (7.3-7.5 pH units)		
If yes, PaCO2 (35-45 mmHg)		
If yes, PaO2 (75-100 mmHg)		
If yes, bicarbonate (10-40 mEq/L)		
If yes, FiO2 (Decimal) (0.21-1)		

RADIOLOGICAL FINDINGS

Notes: A pulmonary infiltrate can be diagnosed with a chest X-ray or a CT scan obtained within 48 hours before or 48 hours after time of arrival. CT findings, if present, override chest X-ray findings. Example: If an infiltrate is seen on CT but not chest x-ray, CAPO inclusion criteria are met. If an infiltrate not seen on a Chest CT but reported on chest x-ray the new pulmonary infiltrate criterion is NOT met.

1. Chest X-ray within 48 hours of arrival

Was a Chest X-ray done? Yes No

Date of X-ray done: ____/____/____ (mm/dd/yyyy) Time of x-ray _____ (hh:mm)

New pulmonary infiltrate

- Right Upper Lobe Yes No
- Right Middle Lobe Yes No
- Right Lower Lobe Yes No
- Left Upper Lobe Yes No
- Left Lower Lobe Yes No
- Diffuse Bilateral Yes No
- Diffuse unilateral Yes No

Cavitation

Cavitation Yes No

Pleural Effusion

None Right Left Bilateral

Multiple lesions (cavitary or not) compatible with CAP due to hematogenous spread. Yes No

2. CT Scan within 48 hours of arrival

Was a CT done? Yes No

Date of CT scan done: ____/____/____ (mm/dd/yyyy) Time of CT scan _____ (hh:mm)

New pulmonary infiltrate

- Right Upper Lobe Yes No
- Right Middle Lobe Yes No
- Right Lower Lobe Yes No
- Left Upper Lobe Yes No
- Left Lower Lobe Yes No
- Diffuse Bilateral Yes No
- Diffuse unilateral Yes No

Cavitation

Cavitation Yes No

Pleural Effusion

None Right Left Bilateral

Multiple lesions (cavitary or not) compatible with CAP due to hematogenous spread. Yes No

INITIAL MICROBIOLOGICAL WORKUP FOR CAP

(Obtained within 48 hours before or after arrival for the diagnosis of CAP)

Was the following workup performed?

• Gram Stain (respiratory culture)	O Yes	O No
If yes, date of Gram Stain	____/____/____ (mm/dd/yyyy)	
If yes, was the specimen acceptable?	O Yes	O No
If yes, predominant organism:		
Gram positives		
cocci unspecified	O Yes	O No
cocci in pairs	O Yes	O No
cocci in chains	O Yes	O No
cocci in clusters	O Yes	O No
bacilli/rods	O Yes	O No
Gram negatives		
cocci	O Yes	O No
cocco-bacilli	O Yes	O No
bacilli/rods	O Yes	O No
No predominant organism	O Yes	O No
No organisms seen	O Yes	O No
• Was a Respiratory Culture performed?	O Yes	O No
If yes, date of respiratory culture	____/____/____ (mm/dd/yyyy)	
If yes, site	O Sputum	O T. aspirate
	O BAL	O Other: _____

- Blood Culture O Yes O No
If yes, date of blood culture ____/____/____
(mm/dd/yyyy)

- Urinary Antigen to detect *Streptococcus pneumoniae* O Yes O No
If yes, date of urinary antigen ____/____/____
(mm/dd/yyyy)

- Urinary Antigen to detect *Legionella* O Yes O No
If yes, date of urinary antigen ____/____/____
(mm/dd/yyyy)

- Rapid Influenza Test O Yes O No
If yes, date of rapid influenza test ____/____/____
(mm/dd/yyyy)

- Viral PCR O Yes O No
If yes, date of viral PCR ____/____/____
(mm/dd/yyyy)

- Atypical Pathogens PCR O Yes O No
If yes, date of atypical pathogens PCR ____/____/____
(mm/dd/yyyy)

Did the patient have persistent bacteremia?

Yes No

(Defined as at least two positive blood cultures obtained on different calendar days or on the same calendar day but separated for at least 30 min, during the same infectious episode.)

Did the patient have Endocarditis confirmed by an Echocardiogram?
(Vegetation seen)

Yes No

Was the cause of pneumonia identified?

Yes No

If yes, what was the first organism? _____

If yes, specimen type for organism 1:

Blood (culture only)	<input type="radio"/> Yes	<input type="radio"/> No
Sputum/Tracheal Aspirate	<input type="radio"/> Yes	<input type="radio"/> No
Bronchoalveolar Lavage (BAL)	<input type="radio"/> Yes	<input type="radio"/> No
Urinary Antigen	<input type="radio"/> Yes	<input type="radio"/> No
Nasopharyngeal (NP) Swab	<input type="radio"/> Yes	<input type="radio"/> No
Oropharyngeal (OP) Swab	<input type="radio"/> Yes	<input type="radio"/> No
Serology	<input type="radio"/> Yes	<input type="radio"/> No
Other	<input type="radio"/> Yes	<input type="radio"/> No

If other, please list _____

If the organism was *Streptococcus pneumoniae* what is the MIC for Penicillin? _____ Not done

If the organism was MRSA what is the MIC for Vancomycin? _____ Not done

If there was a first organism, was there a second organism?

Yes No

If yes, what was the second organism? _____

Specimen type for organism 2:

Blood	<input type="radio"/> Yes	<input type="radio"/> No
Sputum/Tracheal Aspirate	<input type="radio"/> Yes	<input type="radio"/> No
Bronchoalveolar Lavage (BAL)	<input type="radio"/> Yes	<input type="radio"/> No
Urinary Antigen	<input type="radio"/> Yes	<input type="radio"/> No
Nasopharyngeal (NP) Swab	<input type="radio"/> Yes	<input type="radio"/> No
Oropharyngeal (OP) Swab	<input type="radio"/> Yes	<input type="radio"/> No
Serology	<input type="radio"/> Yes	<input type="radio"/> No
Other	<input type="radio"/> Yes	<input type="radio"/> No

If other, please list _____

If the organism was *Streptococcus pneumoniae* what is the MIC for Penicillin? _____ Not done

If the organism was MRSA what is the MIC for Vancomycin? _____ Not done

CLINICAL COURSE – TIME TO CLINICAL STABILITY

Criteria for clinical stability

Definitions:

- Day 0 (day of admission) begins at the time of hospital admission and ends at midnight that evening. The worst value on day 0 should be used as baseline. In the event that the patient is afebrile throughout the entire day 0 or with normal WBC count, then those criteria are fulfilled on day 0 and the box should be checked. Otherwise leave blank. By definition, cough and shortness of breath cannot be fulfilled on day 0 if the patient is afebrile and the WBC count is normal, as they are part of the inclusion criteria for the CAPO study.
- Day 1 begins at 00:01 on the day after hospital admission and ends at midnight of that day. On days 1 through 7, answer “Cough and shortness of breath normal or improving” and “WBC normal or improving” in comparison to the day before. **Check the box if the patient is improving or is back to baseline** (before this illness). Continue checking the boxes until all 4 boxes are checked on the same day.
- The first day that all 4 boxes are checked is the day that the patient reached clinical stability and is a candidate for switch from intravenous to oral antibiotics. **The remaining days should not be checked.**

	<i>SYMPTOMS</i>	<i>TEMPERATURE</i>	<i>WBC</i>	<i>ORAL INTAKE</i>	
	<i>Cough and shortness of breath improving?</i>	<i>Afebrile for at least 8 hours? (< 37.8 C, <100 F)</i>	<i>WBC Normal or improving? (Drop > 10% from the prior day)</i>	<i>Oral intake?</i>	
D A Y O F H O S P I T A L I Z A T I O N	Day 0	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Day 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Day 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Day 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Day 4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Day 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Day 6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Day 7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Day > 7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If Day > 7 is checked, please classify the case as:

O Evaluator: *One of the following scenarios occurred before the end of Day 7.*

- O The subject didn’t reach clinical stability.
- O Subject died before reaching clinical stability.

O Unevaluable: *One of the following scenarios occurred before the end of Day 7 and before reaching clinical stability.*

- O Transfer to hospice.
- O Transfer to palliative care service. (When the antimicrobial treatment is discontinued)
- O Transfer to a hospital that is not a study site.
- O Left the hospital Against Medical Advice (AMA).

CLINICAL COURSE – CRITERIA FOR CLINICAL FAILURE

This section should be completed regardless of patient meeting criteria for clinical stability or not in the prior section.

Was the patient evaluable for Clinical Failure? (From day 1 to day 14 or D/C date, whichever comes first) O Yes O No

If yes, please complete the rest of the section.

If no, please specify the reason:

- O Transfer to hospice.
- O Transfer to palliative care service. (When the antimicrobial treatment is discontinued)
- O Transfer to a hospital that is not a study site.
- O Left the hospital Against Medical Advice (AMA).

Definitions: During day 0 (day of arrival), the worst value for pulmonary function and hemodynamic status are considered to be baseline values. **Due to this, a patient cannot fail on day 0.**

For a patient to develop clinical failure, the pulmonary function and hemodynamic status are to be compared to the baseline values (worst values collected on day 0).

The following criteria should be evaluated daily from day 1 until the patient is discharged from the hospital, or up to day 14 if the patient is still hospitalized.

Criteria 1: Acute pulmonary deterioration with the need of invasive ventilation O Yes O No
If yes, date of invasive ventilation ____/____/____ (mm/dd/yyyy)

Criteria 2: Acute pulmonary deterioration with the need of non-invasive ventilation O Yes O No
If yes, date of non-invasive ventilation ____/____/____ (mm/dd/yyyy)

Criteria 3: Acute hemodynamic deterioration with the need of vasopressors O Yes O No
If yes, date of vasopressors ____/____/____ (mm/dd/yyyy)

Criteria 4: Death O Yes O No
If yes, date of death ____/____/____ (mm/dd/yyyy)

If any of the clinical failure criteria are checked “yes”, please discuss the following section of the etiology of clinical failure with the PI.

If ALL of the clinical failure criteria are checked “no”, DO NOT discuss the following section of the etiology of clinical failure with the PI, since it’s not supposed to be completed.

Etiology of clinical failure: *This section may be completed upon discussion with the PI.*

<i>Etiology 1: Progression of CAP</i>		
Progressive Pneumonia	O Yes	O No
<i>Etiology 2: CAP complicated with:</i>		
Empyema	O Yes	O No
Endocarditis	O Yes	O No
Meningitis	O Yes	O No
Other	O Yes	O No
If other, please list	_____	
<i>Etiology 3: Severe Sepsis due to CAP</i>		
ARDS	O Yes	O No
Septic Shock	O Yes	O No
Liver Failure	O Yes	O No
Renal Failure	O Yes	O No
Coagulopathy	O Yes	O No
Encephalopathy	O Yes	O No
Other	O Yes	O No
If other, please list	_____	
<i>Etiology 4: Medical complications or deterioration of comorbidities</i>		
Pulmonary Embolism	O Yes	O No
Myocardial Infarction	O Yes	O No
Cardiac Arrhythmia	O Yes	O No
Gastrointestinal Bleeding	O Yes	O No
Congestive Heart Failure	O Yes	O No
Chronic Obstructive Pulmonary Disease (COPD)	O Yes	O No
Diabetes	O Yes	O No
Renal Disease	O Yes	O No
Other	O Yes	O No
If other, please list	_____	
<i>Etiology 5: Complication due to management of CAP</i>		
Hemo/Pneumothorax (Iatrogenic)	O Yes	O No
Allergic Reaction to Antibiotics	O Yes	O No
Hospital/Ventilator-Associated Pneumonia (HAP/VAP)	O Yes	O No
Intravenous Line Infection (CLABSI)	O Yes	O No
<i>Clostridium difficile</i> Infection	O Yes	O No
Healthcare-Associated Urinary Tract Infection	O Yes	O No
Other	O Yes	O No
If other, please list	_____	
<i>Etiology 6: Unknown</i> (Defined as lack of information to classify the etiology.)	O Yes	O No

CARDIOVASCULAR EVENTS (This section refers to events occurred from arrival to discharge. Therefore it doesn't include past medical history.)

<i>Was the patient taking anti-thrombotic prophylaxis during hospitalization?</i>	<input type="radio"/> Yes	<input type="radio"/> No
<i>Was the patient taking systemic steroids during hospitalization?</i>	<input type="radio"/> Yes	<input type="radio"/> No
Development of acute myocardial infarction?		
Development of acute myocardial infarction?	<input type="radio"/> Yes	<input type="radio"/> No
If yes, select type:	<input type="radio"/> STEMI <input type="radio"/> NSTEMI <input type="radio"/> Q Wave <input type="radio"/> No Q Wave	
If yes, when did the acute myocardial infarction occur?		
Date of first episode:	___/___/___ (mm/dd/yyyy)	
Date of second episode:	___/___/___ (mm/dd/yyyy)	
Pulmonary edema due to congestive heart failure (acute cardiogenic pulmonary edema)?		
Pulmonary edema due to congestive heart failure (acute cardiogenic pulmonary edema)?	<input type="radio"/> Yes	<input type="radio"/> No
If yes, when did the pulmonary edema occur?		
Date of first episode:	___/___/___ (mm/dd/yyyy)	
Date of second episode:	___/___/___ (mm/dd/yyyy)	
Development of new, serious arrhythmia?		
Development of new, serious arrhythmia?	<input type="radio"/> Yes	<input type="radio"/> No
If yes, select type:	<input type="radio"/> Flutter <input type="radio"/> Atrial fibrillation <input type="radio"/> Junctional supraventricular <input type="radio"/> Ventricular tachycardia <input type="radio"/> Other	
If yes, when did the new, serious arrhythmia occur?		
Date of first episode:	___/___/___ (mm/dd/yyyy)	
Date of second episode:	___/___/___ (mm/dd/yyyy)	
Development of acute worsening of long-term arrhythmia?		
Development of acute worsening of long-term arrhythmia?	<input type="radio"/> Yes	<input type="radio"/> No
If yes, select type:	<input type="radio"/> Atrial fibrillation/Flutter <input type="radio"/> Switch of classes in Lown Classification <input type="radio"/> Other	
If yes, when did the acute worsening of long-term arrhythmia occur?		
Date of first episode:	___/___/___ (mm/dd/yyyy)	
Date of second episode:	___/___/___ (mm/dd/yyyy)	
Cerebrovascular accident?		
Cerebrovascular accident?	<input type="radio"/> Yes	<input type="radio"/> No
If yes, when did cerebrovascular accident occur?		
Date of first episode:	___/___/___ (mm/dd/yyyy)	
Date of second episode:	___/___/___ (mm/dd/yyyy)	
Pulmonary embolism?		
Pulmonary embolism?	<input type="radio"/> Yes	<input type="radio"/> No
If yes, when did the pulmonary embolism occur?		
Date of first episode:	___/___/___ (mm/dd/yyyy)	
Date of second episode:	___/___/___ (mm/dd/yyyy)	

CLINICAL OUTCOMES

Notes: Mortality and re-hospitalization should be evaluated on the day indicated after the diagnosis of CAP was made (clinic visit, telephone call). For example, mortality at 1 year should be evaluated at 1 year after the initial diagnosis of CAP.

1. Clinical Outcomes at 15 Days or Discharge, whichever comes first

O Alive	O Dead, all causes	/ /	(mm/dd/yyyy)
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2. Clinical Outcomes at 30 Days after Hospital Admission

O Alive	O Dead, all causes	/ /	(mm/dd/yyyy)	O Unknown
Was this patient re-hospitalized?				
O Yes O No O Unknown				
• If re-hospitalized, date of first re-hospitalization ___/___/___ (mm/dd/yyyy)				
- Reason of first re-hospitalization:	O Due to CAP	O Not due to CAP	O Unknown	
• If re-hospitalized, date of second re-hospitalization ___/___/___ (mm/dd/yyyy)				
- Reason of second re-hospitalization:	O Due to CAP	O Not due to CAP	O Unknown	

3. Clinical Outcomes at 6 months after Hospital Admission

O Alive	O Dead, all causes	/ /	(mm/dd/yyyy)	O Unknown
Was this patient re-hospitalized?				
O Yes O No O Unknown				
• If re-hospitalized, date of first re-hospitalization ___/___/___ (mm/dd/yyyy)				
- Reason of first re-hospitalization:	O Due to CAP	O Not due to CAP	O Unknown	
• If re-hospitalized, date of second re-hospitalization ___/___/___ (mm/dd/yyyy)				
- Reason of second re-hospitalization:	O Due to CAP	O Not due to CAP	O Unknown	
• If re-hospitalized, date of third re-hospitalization ___/___/___ (mm/dd/yyyy)				
- Reason of third re-hospitalization:	O Due to CAP	O Not due to CAP	O Unknown	

4. Clinical Outcomes at 1 year after Hospital Admission

O Alive	O Dead, all causes	/ /	(mm/dd/yyyy)	O Unknown
Was this patient re-hospitalized?				
O Yes O No O Unknown				
• If re-hospitalized, date of first re-hospitalization ___/___/___ (mm/dd/yyyy)				
- Reason of first re-hospitalization:	O Due to CAP	O Not due to CAP	O Unknown	
• If re-hospitalized, date of second re-hospitalization ___/___/___ (mm/dd/yyyy)				
- Reason of second re-hospitalization:	O Due to CAP	O Not due to CAP	O Unknown	
• If re-hospitalized, date of third re-hospitalization ___/___/___ (mm/dd/yyyy)				
- Reason of third re-hospitalization:	O Due to CAP	O Not due to CAP	O Unknown	

Case ID _____

Coordinator Initials at Discharge: _____ Date: _____
 Coordinator Initials at 30 days: _____ Date: _____
 Coordinator Initials at 6 months: _____ Date: _____
 Coordinator Initials at 1 year: _____ Date: _____

PREVENTION OF CAP

Was the patient given pneumococcal vaccination during the current hospitalization?

- Yes
- No, because the patient already received the vaccine
- No, because the patient refused (it includes contraindications)
- No, because the patient died
- No, no reason found

If patient already received the vaccine before the current hospitalization, approximate year of receipt:

_____ (yyyy)

If yes or patient already received the vaccine, which vaccine did they receive?

- Polysaccharide pneumococcal vaccine
- Conjugated pneumococcal vaccine
- Unknown

Is the current admission considered to be within the Flu season (it differs from one country to another)?

- Yes
- No

If yes, was the patient given influenza vaccination during the current hospitalization?

- Yes
- No, because the patient already received the vaccine
- No, because the patient refused (it includes contraindications)
- No, because the patient died
- No, no reason found

If yes or patient already received the vaccine, which vaccine did they receive?

- Intramuscular (normal dose)
- Intramuscular (high dose)
- Intranasal
- Intradermal
- Unknown

Adult smoking history

- Current smoker
- History of smoking
- Non-smoking history
- Unknown history

If a current smoker, was smoking cessation offered during the current hospitalization?

- Yes
- No, because the patient was unable to understand
- No, because the patient died
- Not applicable, unknown history/no reason found

