Case Report Form

"Anti-Influenza Therapy in Hospitalized patients with Community-Acquired Pneumonia"

January 2012

Principal Investigator: _____

Hospital: _____

Subject Name: _____

Medical Record Number: _____

DEMOGRAPHICS

Sex: _____

Age: _____

Weight: _____

Height: _____

Data collection form done: O Prospective O Retrospective

Date of Arrival to Hospital: _____

Time of Arrival to Hospital: _____

Was the patient admitted to an intensive care unit on admission to the hospital?

O Yes
O No

Did the patient need ventilatory support?
O Invasive mechanical ventilation
O Non-invasive mechanical ventilation (e.g. CPAP/Bilevel)
O No

Did the patient need blood pressure support?
O Fluid resuscitation
O Vasopressors
O No

Was the patient transferred to an intensive care unit during the hospitalization?

O Yes Date: _____
O No

Date of Discharge from the ICU: _____

Date of Discharge from the hospital: _____

Abstractor: _____

- If you have any questions regarding data collection please e-mail your question to Paula Peyrani, MD at p0peyr01@louisville.edu

1. DIAGNOSIS OF CAP

Chest X-ray/CT scan within 24 hours of admission (CT scan overrides CXR findings)

Date of x-ray _____ Time of x-ray _____

- New pulmonary infiltrate
  □ RUL □ RML □ RLL □ LUL □ LLL □ Unspecified location □ Cavitation
  □ Interstitial Bilateral Infiltrate □ Normal

- Pleural effusion
  O None O Right O Left O Bilateral

Date of CT scan _____ Time of CT scan _____ O Not done

- New pulmonary infiltrate
  □ RUL □ RML □ RLL □ LUL □ LLL □ Unspecified location □ Cavitation
  □ Interstitial Bilateral Infiltrate □ Normal

- Pleural effusion
  O None O Right O Left O Bilateral

Criteria for diagnosis of CAP*:

A. New pulmonary infiltrate (at time of hospitalization)	O Yes O No
B. New or increased cough with/without sputum production	O Yes O No
C. Fever >37.8^{o} C (100.0^{o} F) or hypothermia <35.6^{o} C (96.0^{o} F)	O Yes O No
D. Changes in WBC (leukocytosis, left shift, or leukopenia)	O Yes O No

*Diagnosis of CAP requires the presence of criteria A (new pulmonary infiltrate) plus at least one of criteria B, C, or D.

Diagnosis
O CAP O COPD Exacerbation O acute bronchitis

If patient doesn't meet CAP criteria, the case SHOULD NOT be entered in the study web site

Comment: _____

2. HISTORY AND PHYSICAL AT ADMISSION

2.1. Number of days with respiratory symptoms before admission _____ days
 Unknown

2.2 Past medical history

Neoplastic disease (active or within the last year)	O Yes O No
Congestive heart failure	O Yes O No
Cerebrovascular disease	O Yes O No
Renal disease	O Yes O No
Liver disease	O Yes O No
Chronic Renal Failure	O Yes O No
Neurologic Diseases/Mental Illness	O Yes O No
Diabetes	O Yes O No
Prior Admission for CAP within 1 year	O Yes O No
Suspicion of Aspiration	O Yes O No
Cirrhosis	O Yes O No
Asplenia	O Yes O No
Acute alcoholism/alcoholic withdrawal	O Yes O No
IV steroids on admission:	O Yes O No
name	_____
dose	_____
On oral steroids prior to admission	O Yes O No
COPD	O Yes O No
If available, last FEV1 within the previous year	_____
Home O_2	O Yes O No
HIV positive	O Yes O No
If available, last CD_4 within the previous year (absolute)	_____
last CD_4 within the previous year (%)	_____
last viral load within the previous year	_____
Duration of HIV seropositivity in years	_____
On HAART	O Yes O No
Current episode of CAP as initial presentation of HIV	O Yes O No
Prior AIDS defining illness	O Yes O No
Intravenous drug use	O Yes O No
Prior history of pneumonia	O Yes O No
Prior history of PCP	O Yes O No
Prior history of tuberculosis	O Yes O No
Antibiotic prophylaxis for PCP or MAC	O Yes O No

2.3 Risk factors for healthcare-associated pneumonia (HCAP)

Nursing home resident	O Yes O No
Hospitalized ≥ 2 days in the prior 90 days	O Yes O No
IV antibiotic therapy in the prior 90 days	O Yes O No
Home infusion therapy (including ABT and chemotherapy)	O Yes O No
Chronic dialysis within prior 30days	O Yes O No
Home wound care	O Yes O No

2.4 Risk factors for Cardiovascular Events

Family history of Coronary Artery Disease	O Yes O No
Active Coronary Artery Disease	O Yes O No
Essential arterial hypertension	O Yes O No
Hyperlipidemia	O Yes O No
Prior myocardial infarction	O Yes O No
Prior PTCA / CABG / angioplasty	O Yes O No
Atrial fibrillation	O Yes O No

2.5 Cardiovascular medications prior hospital admission

Aspirin	O Yes O No
Beta-blockers	O Yes O No
ACE - I	O Yes O No
Warfarin	O Yes O No
Heparin	O Yes O No
Antiplatelet:	O Yes O No
Statins:	O Yes O No

2.6 Physical examination on admission

Altered mental status on admission	O Yes O No	
Heart rate	_____	
Respiratory rate	_____	
Systolic blood pressure	_____	
Diastolic blood pressure	_____	
Temperature	_____	
O_2 saturation	_____	□ Not done

2.7 Laboratory findings

Hematocrit:	_____			□ Not done
Hemoglobin:	_____			□ Not done
WBC:	_____			□ Not done
Bands:	_____			□ Not done
Platelet Count:	_____			□ Not done
Serum Sodium:	_____			□ Not done
Serum Potassium:	_____			□ Not done
Serum BUN:	_____	units _____		□ Not done
Serum Creatinine:	_____			□ Not done
Serum Bicarbonate:	_____			□ Not done
Serum Glucose:	_____			□ Not done
Albumin:	_____			□ Not done
Serum Troponin I or T	(1) _____	(2) _____	(3) _____	□ Not done
Serum CK-MB	(1) _____	(2) _____	(3) _____	□ Not done
LDL:	_____			□ Not done
HDL:	_____			□ Not done
LDH:	_____			□ Not done
Cholesterol:	_____			□ Not done
Trygliceride:	_____			□ Not done
Lactate:	_____	units _____	elevated? O Yes O No	□ Not done
BNP:	_____			□ Not done
C-Reactive protein:	_____	units _____	elevated? O Yes O No	□ Not done
Procalcitonin:	_____	units _____	elevated? O Yes O No	□ Not done

Vitamin D _ _____ units _____ elevated? O Yes O No □ Not done

2.7 Laboratory findings (continuation)

ABG: pH _____ □ Not done
$PaCO_2$ _____
PaO_2 _____
Bicarbonate _____
FiO_2 _____

**** PSI score, CURB-65, and CRB-65 will be automatically calculated once all data have been entered ****

Comment: _____

3. RISK FACTORS FOR TUBERCULOSIS

Check all that apply:

Symptoms:
□ Night sweats □ Hemoptysis □ Weight loss □ Hoarseness

Member of High Risk Group:
□ HIV/AIDS positive
□ History of positive PPD
□ Homeless
□ Alcohol/Drug abuse
□ Health care worker
□ History of TB
□ Age > 65 years
□ Community living (prison, nursing home, shelter)
□ Recent exposure to Active TB
□ From area with high risk of tuberculosis

History of Chronic Illness:
□ Silicosis
□ End-Stage Renal Disease
□ Gastrectomy
□ Cancer of Mouth or GI Tract
□ 10% or below ideal body weight
□ Diabetes Mellitus
□ Hematologic disease
□ Intestinal bypass
□ Chronic Malabsorption Syndrome
□ Long term cortisone therapy
□ Other immunosuppressive state

Number of risk factors present: _____

Was patient diagnosed with pulmonary tuberculosis?

O Yes
O No

If Yes, enter the following information:
□ AFB smears positive
□ Cultures positive Source: _____
□ DNA amplification positive
□ Resistant *Mycobacterium Tuberculosis*

Comment: _____

4. MICROBIOLOGICAL WORK-UP

Was the following work-up performed?

Respiratory cultures:	O Yes	O No	Date: _____
Blood cultures:	O Yes	O No	Date: _____
Pneumococcal urinary antigen:	O Yes	O No	Date: _____
Legionella urinary antigen:	O Yes	O No	Date: _____
Rapid flu test?	O Yes	O No	Date: _____
Respiratory Viral Panel	O Yes	O No	Date: _____

Was the cause of the pneumonia identified? O Yes O No Sample collection date: _____

If yes, what organism(s) were identified as the cause?

Organism 1: _____ Relevant susceptibilities:

What source(s)? - check all that apply
- ☐ Blood
- ☐ Sputum
- ☐ Tracheal aspirate
- ☐ BAL
- ☐ Urinary antigen
- ☐ Serology
- ☐ Other: _____

_____

_____

_____

Comment: _____

Organism 2: _____ Relevant susceptibilities:

What source(s)? - check all that apply
- ☐ Blood
- ☐ Sputum
- ☐ Tracheal aspirate
- ☐ BAL
- ☐ Urinary antigen
- ☐ Serology
- ☐ Other: _____

_____

_____

_____

Comment: _____

5. ANTIBIOTIC THERAPY

- Did the patient receive oral antibiotics during the last 30 days? O Yes O No
- Was the antibiotic given for the treatment of CAP? O Yes O No Name: _____ _____
- Did the patient fail outpatient oral antibiotic therapy for CAP? O Yes O No

5.1 Antibiotics received for empiric therapy of CAP

For the purpose of this clinical trial, "empiric therapy" is defined as all antibiotics started during the first 24 hours of hospitalization. Collect only the antibiotics (IV, PO, IM) STARTED during the first 24 hours of hospitalization (use date and time when the antibiotics were given; do not use physician's orders).

- Initial antibiotic given Date: _____ Time: _____

Antimicrobial	Dose	Route	Frequency	Start Date	Start Time	Stop Date

Please classify the empiric therapy based on the antibiotics received within the first 24 hours of admission.

O Beta-lactam monotherapy only
O Beta-lactam + macrolide combination only
O Beta-lactam + quinolone combination only
O Quinolone monotherapy only
O Any other antibiotic combination

Comment: _____

5.2 Antibiotics received for the treatment of CAP after empiric therapy and before switch therapy

Use this table to enter all the antibiotics STARTED for CAP AFTER the first 24 hours BUT BEFORE switching the patient to PO antibiotics**:**

Antimicrobial	Route	Start date	Stop date

Comment: _____

5.3 Antibiotics received after switch to oral therapy (use the physician's orders)

Antimicrobial	Dose	Unit	Frequency	Start Date (day physician ordered oral antibiotics)	Stop Date

Comment: _____

6. CLINICAL COURSE

6.1 Criteria for Clinical Stability / Switch therapy during first 7 days of hospitalization

Check the box when the criterion is met. Keep checking the criterion (if met) until four criteria are met on a single day

Definitions:

- Day 0 (day of admission or diagnosis) begins at the time of admission or diagnosis and ends at midnight that evening. If the patient is afebrile on day 0 or with normal WBC count, then the criteria is fulfill on day 0 and the box should be checked. Otherwise leave the box blank. See "Guidelines for completion of Case Report Form" for further clarification.
- Day 1 begins at 00:01 and ends at midnight. 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 box until all 4 boxes are checked on one day.
- The first day that the 4 boxes are checked is the day that the patient reached clinical stability and is a candidate for switch therapy. If the patient does not meet all four criteria by day 7, the patient is not a candidate for switch therapy.
- If patient dies during first 7 days of hospitalization, check NK box for all 4 criteria.

	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day >7 or NK
Cough and shortness of breath Normal or improving?									
Afebrile for at least 8 hours? ($< 37.8^{o}$ C, $<100^{o}$ F)									
WBC Normal or improving? ($\downarrow > 10\%$)									
Oral intake and absorption are adequate									

Comment: _____

6.2 Criteria for Clinical Failure.

These criteria should be checked until patient is discharged from the hospital or up to day 14 if patients is still hospitalized.

- Acute pulmonary deterioration with the need of:
  - Invasive ventilation O Yes O No Date: _____
  - Non-invasive ventilation O Yes O No Date: _____
- Acute hemodynamic deterioration with the need of:
  - Aggressive fluid resuscitation O Yes O No Date: _____
  - Vasopressors O Yes O No Date: _____
- Death during hospitalization O Yes O No Date: _____

Comment: _____

If any of the clinical failure criteria is checked, please complete the following section etiology of failure.

6.3 Etiology of clinical failure

Please first select if the failure was related to CAP (option A), not related to CAP (option B), or the cause is unable to be determined (option C). For option A and B, please select all that apply.

O **A. Failure related to CAP:** defined as failure related to the pulmonary infection and/or the inflammatory response. In this scenario, the patient usually deteriorates during the first week of hospitalization.

A1. Progression of CAP
☐ **1.** Progressive pneumonia

A2. CAP complicated with
☐ **2.** Empyema
☐ **3.** Endocarditis
☐ **4.** Meningitis
☐ **5.** Other: _____

A3. Severe sepsis due to CAP

☐ **6.** ARDS
☐ **7.** Septic shock
☐ **8.** Liver failure
☐ **9.** Renal Failure
☐ **10.** Coagulopathy
☐ **11.** Encephalopathy
☐ **12.** Other……

A4. Medical complication or deterioration of comorbidities related to the systemic inflammatory response
☐ **13.** Pulmonary embolism
☐ **14.** Myocardial infarction
☐ **15.** Cardiac arrhythmia
☐ **16.** GI bleeding
☐ **17.** Congestive heart failure
☐ **18.** COPD
☐ **19.** Diabetes
☐ **20.** Renal disease
☐ **21.** Other…….

Comment: _____

O **B. Failure not related to CAP:** defined as failure after the pulmonary infection and/or the inflammatory response. In this scenario, the patient usually improves during the first week of hospitalization and then deteriorates.

B1. Complication due to the management of CAP
☐ **1.** Hemo / Pneumothorax (iatrogenic)
☐ **2.** HAP / VAP
☐ **3.** Allergic reaction to ABT
☐ **4.** IV line infection
☐ **5.** C. diff. colitis
☐ **6.** Nosocomial UTI
☐ **7.** Other: _____

B2. Medical complication or deterioration of comorbidities not due to the pulmonary infection
☐ **1.** Pulmonary embolism
☐ **2.** Myocardial infarction
☐ 3. GI bleeding
☐ 4. Congestive heart failure
☐ 5. COPD
☐ 6. Diabetes
☐ 7. Renal disease
☐ 8. Neoplastic disease
☐ 9. Other: _____

Comment: _____

O **C. Unknown:** defined as the lack of information to classify the etiology

Comment: _____

Adult Smoking history

Pack/Year: _____
Case # _____

7. CARDIOVASCULAR EVENTS

Please the following information during hospitalization up to 30 days.

Was the patient taking antithrombotic prophylaxis during the hospitalization? O Yes O No

Was the patient taking systemic steroids during the hospitalization? O Yes O No

7.1 Development of acute myocardial infarction

- Yes O On admission O During hospitalization on Date: _____

  O STEMI O NSTEMI O Q wave O No Q wave

O No

7.2 Pulmonary edema due to congestive heart failure (acute cardiogenic pulmonary edema)

- Yes O On admission O During hospitalization on Date: _____

O No

7.3 Development of new serious arrhythmia

- Yes O On admission O During hospitalization on Date: _____

  O Flutter O Atrial Fibrillation

  O Junctional SupraVentricular O Ventricular tachycardia

  Other: _____

O No

7.4 Acute worsening of a long-term arrhythmia

- Yes O On admission O During hospitalization on Date: _____

  O Atrial fibrillation → flutter O Switch of classes in Lown classification

  O Other: _____

O No

7.5 Cerebrovascular accident

- Yes O On admission O During hospitalization on Date: _____

O No

7.6 Pulmonary embolism

- Yes O On admission O During hospitalization on Date: _____

O No

Comment: _____

8. CLINICAL OUTCOME

8.1 Outcome at hospital discharge or up to day 30 if patient still hospitalized

■ **ALIVE**

O Success

■ **DEAD**

O Death due to CAP
O Death unrelated to CAP
O Other, please comment

Comment: _____

8.2 If discharged alive, please indicate to where:

☐ **1.** Home
☐ 2. Other hospital
☐ **3.** Hospice
☐ 4. Long-term care facility
☐ 5. Other, specify_____
☐ **6.** Unknown

Comment: _____

OUTCOME AT DAY 30

this outcome should be evaluated at day 30 from the day of enrollment (clinic visit, telephone call) if the information is available

O Alive, no record of re-hospitalization
O Alive, with record of re-hospitalization due to CAP. Date (mm/dd/yyyy) _____
O Alive, with record of re-hospitalization due to other reasons. Date (mm/dd/yyyy) _____
O Dead, Date (mm/dd/yyyy) _____
O Information not available

1. Where do you live currently?

O Home by myself
O Home with family
O Long-term care facility
O Homeless
O Other, specify _____
O Refuse to tell

Comment: _____

2. If in group B, did you finish taking Tamiflu at home after leaving the hospital?

O Yes
O No

3. While you were finishing the Tamiflu or in the week after, did you have any side effects from the drug that you remember?

O Yes
O No

4. Do you have any of the following symptoms?

Cough	O Y	O N	O DK
Shortness of breath	O Y	O N	O DK
Wheezing	O Y	O N	O DK
Fever	O Y	O N	O DK
Chills	O Y	O N	O DK

5. At this time, would you say your health is

O Excellent
O Very Good
O Good
O Fair
O Poor
O Don't know/Refuse to tell

6. At this time, can you walk a quarter a mile-or 2 or 3 blocks without problems?

O No, I don't have difficulty
O Yes, I have difficulty but can manage
O Yes, I'm unable to do this activity
O Don't know/Refuse to tell

7. At this time, do you have difficulty doing the following activities without special equipment or help from another person?

	No, I do not have difficulty	Yes, I have difficulty but can manage	Yes, I'm not able to do it	DK	RTT
Bathing…….	☐	☐	☐	☐	☐
Dressing……...	☐	☐	☐	☐	☐
Eating……...	☐	☐	☐	☐	☐
Getting in or out of chairs……	☐	☐	☐	☐	☐
Walking……...	☐	☐	☐	☐	☐
Using the toilet…….	☐	☐	☐	☐	☐

Comment: _____

OUTCOME AT 6 MONTHS

this outcome should be evaluated at 6 months from the day of enrollment (clinic visit, telephone call) if the information is available

O Alive, no record of re-hospitalization
O Alive, with record of re-hospitalization due to CAP. Date (mm/dd/yyyy) _____
O Alive, with record of re-hospitalization due to other reasons. Date (mm/dd/yyyy) _____
O Dead, Date (mm/dd/yyyy) _____
O Information not available

1. Where do you live currently?

O Home by myself
O Home with family
O Long-term care facility
O Homeless
O Other, specify _____
O Refuse to tell

2. At this time, would you say your health is
O Excellent
O Very Good
O Good
O Fair
O Poor
O Don't know/Refuse to tell

3. At this time, can you walk a quarter a mile-or 2 or 3 blocks without problems?
O No, I don't have difficulty
O Yes, I have difficulty but can manage
O Yes, I'm unable to do this activity
O Don't know/Refuse to tell

4. At this time, do you have difficulty doing the following activities without special equipment or help from another person?

	No, I do not have difficulty	Yes, I have difficulty but can manage	Yes, I'm not able to do it	DK	RTT
Bathing…….	☐	☐	☐	☐	☐
Dressing……...	☐	☐	☐	☐	☐
Eating……...	☐	☐	☐	☐	☐
Getting in or out of chairs……	☐	☐	☐	☐	☐
Walking……...	☐	☐	☐	☐	☐
Using the toilet…….	☐	☐	☐	☐	☐

Comment: _____

OUTCOME AT 1 Year

this outcome should be evaluated at one year from the day of enrollment (clinic visit, telephone call) if the information is available

O Alive, no record of re-hospitalization
O Alive, with record of re-hospitalization due to CAP. Date (mm/dd/yyyy) _____
O Alive, with record of re-hospitalization due to other reasons. Date (mm/dd/yyyy) _____
O Dead, Date (mm/dd/yyyy) _____
O Information not available

1. Where do you live currently?

O Home by myself
O Home with family
O Long-term care facility
O Homeless
O Other, specify _____
O Refuse to tell

2. At this time, would you say your health is
O Excellent
O Very Good
O Good
O Fair
O Poor
O Don't know/Refuse to tell

3. At this time, can you walk a quarter a mile-or 2 or 3 blocks without problems?
O No, I don't have difficulty
O Yes, I have difficulty but can manage
O Yes, I'm unable to do this activity
O Don't know/Refuse to tell

4. At this time, do you have difficulty doing the following activities without special equipment or help from another person?

	No, I do not have difficulty	Yes, I have difficulty but can manage	Yes, I'm not able to do it	DK	RTT
Bathing…….	☐	☐	☐	☐	☐
Dressing……...	☐	☐	☐	☐	☐
Eating……...	☐	☐	☐	☐	☐
Getting in or out of chairs……	☐	☐	☐	☐	☐
Walking……...	☐	☐	☐	☐	☐
Using the toilet…….	☐	☐	☐	☐	☐

Comment: _____

9. PREVENTION OF CAP

9A. Indicator: Was the patient given pneumococcal vaccination?

O Yes
O No, variance justified, patient already received the vaccine
O No, variance justified, patient refused
O No, variance justified, patient died
O No, variance unjustified

Comment: _____

9B. Indicator: Was the patient given influenza vaccination?

O Yes
O No, variance justified, patient already received the vaccine
O No, variance justified, patient refused
O No, variance justified, patient died
O No, variance justified, out of season
O No, variance unjustified

Comment: _____

Adult smoking history
O Current smoker
O History of smoking
O Non-smoking history
O Not document or not assessed

9C. Indicator: In patients who smoke, was smoking cessation offered?

O Yes
O No, variance justified, patient unable to understand
O No, variance justified, patient died
O Not applicable, patient does not smoke
O Not applicable, unknown history
O No

Comment: _____

10. INFLUENZA A and B VIRUS SPECIFIC DATA

1. Demographics

If patient is a woman, was she pregnant? O Yes O No

O 1st trimester O 2nd trimester O 3rd trimester

If patient is a woman, was she in the puerperal state? O Yes O No

2. Criteria for diagnosis of Influenza A or B virus infection

O Definitive: positive RT-PCR or Luminex Influenza A or B virus Date sample obtained: _____

O Presumptive: if positive test (any test) for Influenza A or B

O Suspected: if clinical presentation is compatible with Influenza

3. History and physical on admission

Sudden onset of symptoms	O Yes	O No	Myalgia	O Yes	O No
Rhinorrhea	O Yes	O No	Arthralgia	O Yes	O No
Wheezing	O Yes	O No	Dyspnea	O Yes	O No
Headaches	O Yes	O No	Sputum production	O Yes	O No
Sore throat	O Yes	O No	Diarrhea	O Yes	O No

4. Labs

Lymphocyte count _____ ALT: _____

Serum CK _____ AST: _____

5. Treatment

Oseltamivir O Yes O No

If yes dose _____ mg every _____ hours

start date _____

stop date _____

Zanamivir O Yes O No

If yes dose _____ mg every _____ hours

start date _____

stop date _____

Steroids O Yes O No

If yes name _____

dose _____ mg every _____ hours

start date _____

stop date _____

ECMO O Yes O No

Comment: _____

COMMENTS

Please provide comments for any significant information that needs clarification.

For cases of Swine influenza pneumonia, please write a summary of the case.

_____

_____

_____

_____

_____

_____

_____

- After the case is entered, please click on the submit button
- You will be contacted by the study center at the University of Louisville hospital if any data entry needs further clarifications.