Adult CAP of modest severity not requiring hospitalization

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Clinical Presentation

- 35 y.o. male resident of Boston presents with fever and cough
- Well until 3 days earlier when he suffered the onset of nasal stuffiness, mild sore throat and a cough productive of small amounts of clear secretions
- A physician office visit is motivated by a temp. of 38.3°C, now purulent secretions, and spasms of coughing

Other Pertinent History

- It is March
- Lives in city. No problems with his home.
- Wife is well; 11 y.o. child recovering from a "nagging" cough that lasted 10-14 days. All 4 children fully immunized.
- Pet parakeet of 5 yrs is well.
- No recent travel
- *Smokes 1 ppd (since age 15). Early AM purulent sputum during the winter.

More

- ♣ ROS: negative
- *PMH: none pertinent
- No prescription medications
- No allergies
- *Tobacco as above; alcohol in moderation

Physical Examination

- *Vitals: T 38.9°C, 110/min.,BP 125/75, Resp.rate 18/min. with O₂ saturation of 93% on room air.
- Nasal hyperemia, erythemia of oropharynx
- No adenopathy
- "Crackles" at the right lung base
- A spasm of coughing during the exam. produces a small plug of purulent secretion

Laboratory and X-Ray Data

- → Hg/Hct: 12.5 gm/dl / 36%
- WBC: 13,500 cell/ul with 82% polys, 11% band forms and 7% lymphocytes
- + Platelets: 180,000 per ul.
- Multichemistry screen and U/A normal
- Chest X-Ray: Bilateral lower lobe infiltrates, more pronounced on the right

Severity of the Pneumonia

- Fine Pneumonia severity risk (PSI) class: 1
- CURB-65 prognosis prediction score:

Management and Course

- No microbiologic diagnostic tests
- Empirically prescribed a "respiratory" fluoroquinolone
- Against medical advice, he continued to smoke
- Fever resolved over 3 days. Cough gradually returned to his baseline pattern over 7-10 days

Clinical Trial Design Questions

- * Is patient a candidate for a placebocontrolled, delayed treatment, or active control trial?
- Statistics: Superiority or noninferiority?
- What severity of illness is appropriate for inclusion in an outpatient treatment trial? Severity of illness determined by which scoring system?

More Trial Design Questions

- Which diagnostic tests? For viruses? For "typical" bacteria? For "atypical" bacteria?
- Most appropriate and valid clinical endpoints?
- How to "blind" treatment arms?
- How to monitor for adverse drug effects?

