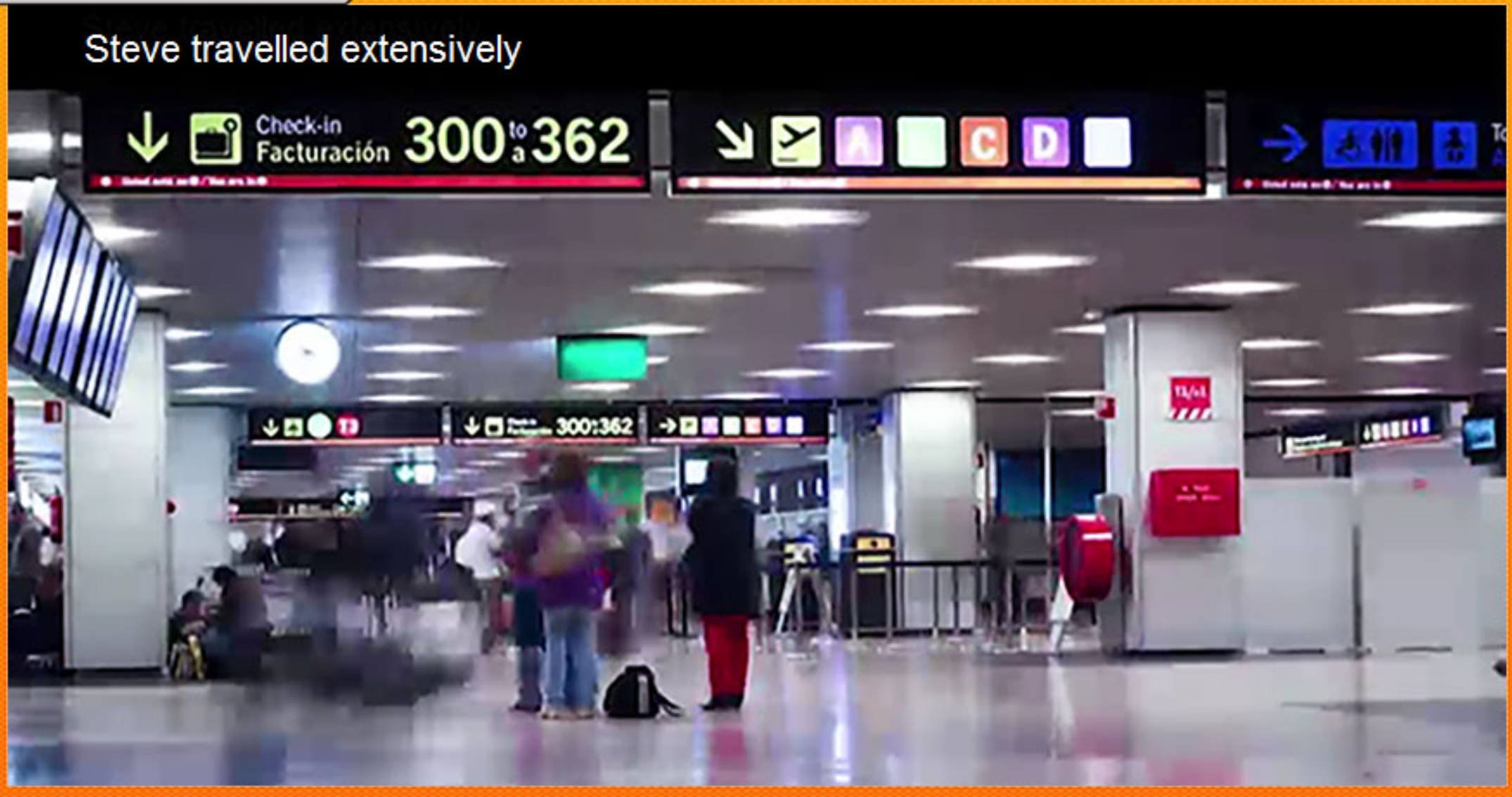
Augmentin® 875 mg Tablets

Amoxicillin as trihydrate 875 mg

Clavulanic Acid as potassium salt 125 mg



Since few days,

he was febrile and had productive cough with sputum

Steve took medications for symptomatic relief but did not have much relief.

Advised

- Routine laboratory investigations
- Chest X-ray

- Blood pressure : 120/73
- Pulse: 102 and regular
- Respiratory rate : 25 / min.
- Temperature: 100.9°F / 38.27°C
- **Lung examination revealed the presence of right lower lung crackles with decreased breath sounds in this area as well.**

KEY RECOMMENDATIONS FOR PRACTICE[1]

Clinical recommendations	*Evidence rating*	*References*
In patients with clinically suspected CAP, chest radiography should be obtained to confirm the diagnosis.	C	12
Evaluation for specific pathogens that would alter standard empiric therapy should be performed when the presence of such pathogens is suspected on the basis of clinical and epidemiologic clues; this testing usually is not required in outpatients.	C	12
Mortality and severity prediction scores should be used to determine inpatient versus outpatient care for patients with CAP.	A	22-24
All patients with CAP who are admitted to the intensive care unit should be treated with dual therapy.	A	28
Prevention of CAP should focus on universal influenza vaccination and pneumococcal vaccination for patients at high risk of pneumococcal disease.	B	12, 35-37

CAP = community-acquired pneumonia.

A = consistent, good-quality patient-oriented evidence; B = inconsistent or limited-quality patient-oriented evidence; C = consensus, disease-oriented evidence, usual practice, expert opinion, or case series. For information about the SORT evidence rating system, go to http://www.aafp.org/afpsort.xml.

In patients with clinically suspected CAP, chest radiography should be obtained to confirm the diagnosis.

1. Watkins R, Lemonovich T, *et al.* Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.

Results of investigation

Routine lab investigations were suggestive of infection

Chest X-ray

- Right lower lobe infiltrate
- No evidence of pleural effusion or abscess

Diagnosis of Pneumonia

"In addition to a constellation of suggestive clinical features, a demonstrable infiltrated by chest radiograph or other imaging technique with or without supporting microbiological data, is required for the diagnosis of pneumonia."[1]

1. Mandell L, Richard G, Wunderink, *et al*. Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in adults, Clin Infect Dis. 2007; 44(2):S27-72.

CURB-65 Mortality Prediction Tool for Patients with Community-Acquired Pneumonia

Prognostic variables*[2]

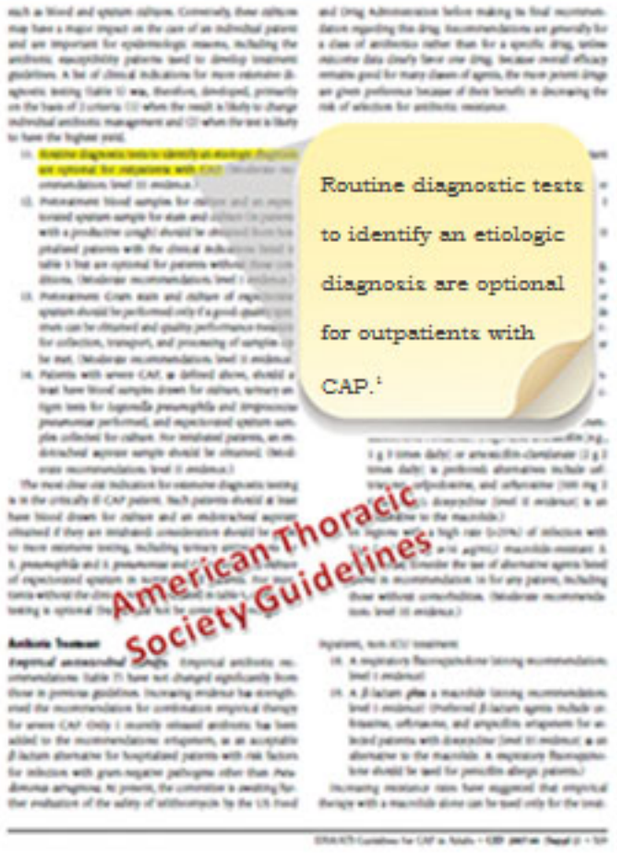
- Confusion
- Blood urea nitrogen level > 20 mg per dL (7.14 mmol per L)
- Respiratory rate ≥ 30 breaths per minute
- Blood pressure (systolic < 90 mm Hg or diastolic ≤ 60 mm Hg)
- Age ≥ 65 years

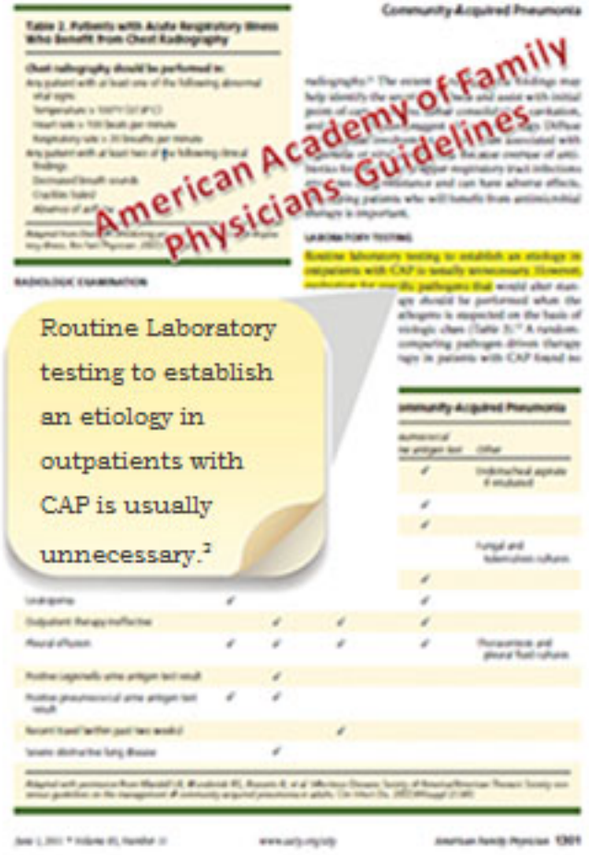
Score	Inpatient vs. outpatient	30-day mortality (%)
0 or 1 point	Treat as outpatient	0.7 to 2.1
2 points	Treat as inpatient	9.2
≥3 points	Treat in intensive care unit	15 to 40

*–Assign 1 point for each variable.

2. Watkins R, Lemonovich T, *et al*. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.

Recommendations on 'culture tests'





1. Mandell L, Richard G, Wunderink, *et al*. Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in adults, Clin Infect Dis. 2007; 44(2):S27-72.

2. Watkins R, Lemonovich T, *et al*. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.

CAP : Decision for Admission

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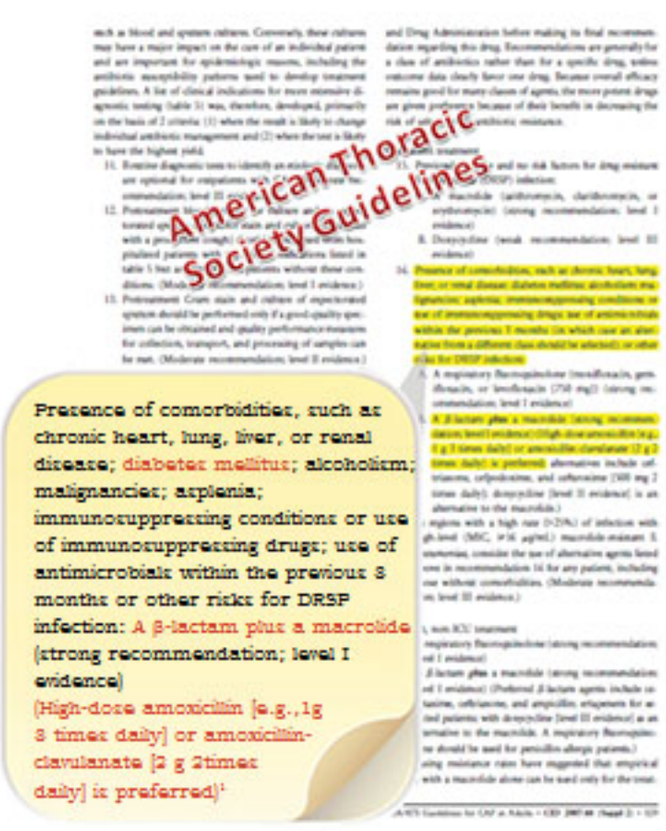
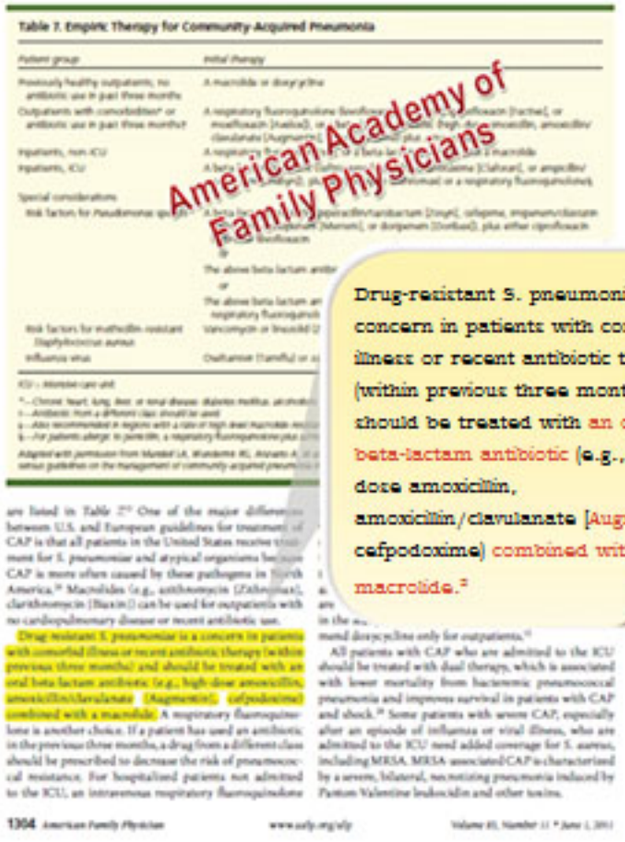
1. Watkins R, Lemonovich T, *et al*. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.

Guidelines for selection of antibiotics





1. Mandell L, Richard G, Wunderink, *et al*. Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in adults, Clin Infect Dis. 2007; 44(2):S27-72.

2. Watkins R, Lemonovich T, *et al*. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.

Follow up, reassessed

- Fever reduced
- Respiratory rate returned to normal

Criteria to judge patient's positive response

Phillipine Clinical Practice Guidelines

Temperature, respiratory rate, heart rate, blood pressure, sensorium, oxygen saturation and inspired oxygen concentration should be monitored to assess response to therapy.[1]

A patient is considered to have responded to treatment if...

- fever decreases within 72 hours
- temperature normalizes within 5 days
- respiratory signs, particularly tachypnea, return to normal[1]

1. Chua M, Villa. Ma, Alejandria M, *et al.* Philippine Clinical Practice Guidelines on the Diagnosis, Empiric Management, and Prevention of Community-acquired Pneumonia (CAP) in Immunocompetent Adults, available on www.psmid.org.ph/clinical/cap_guidelines_2010.pdf accessed on 5th Jan 2013.

Steve was back to his normal life

Augmentin® 875 mg Tablets

Amoxicillin as trihydrate 875 mg
Clavulanic Acid as potassium salt 125 mg

✓ 30 years of clinical experience

Augmentin® 875 mg Tablets

Amoxicillin as trihydrate 875 mg
Clavulanic Acid as potassium salt 125 mg

CAP treatment guidelines recommend Amoxicillin-Clavulanic acid

- Recommended empirical antimicrobial therapy for community acquired pneumonia in adults[1*]
- Preferred oral therapy against beta-lactamase producing *Haemophilus influenzae* infection[1]
- Preferred initial empirical parenteral treatment regimen for high severity community acquired pneumonia in adults[2]

1. Lionel A. Mandell *et al.*, Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults, Clinical Infectious Diseases 2007; 44(2):S27–72.
2. Lim WS, Baudouin SV, George RC, *et al.* BTS guidelines for the management of community acquired pneumonia in adults Update 2009, Thorax 2009;64(3):1-55.

* A b-lactam plus a macrolide in Presence of comorbidities, such as chronic heart, lung,liver, or renal disease; diabetes mellitus; alcoholism; malignancies;asplenia; immunosuppressing conditions or use of immunosuppressing drugs; use of antimicrobials within the previous 3 months (in which case an alternative from a different class should be selected); or other risks for DRSP infection.

Dosage

Comparative studies

Azithromycin
Clarithromycin

IDSA Adults CAP guidelines, 2007

Recommend a β-lactam plus a macrolide (high-dose amoxicillin [e.g.,1 g 3 times daily] or amoxicillin-clavulanate [2 g, 2 times daily] is preferred) as empirical antimicrobial therapy in certain conditions*[1]

1. Lionel A. Mandell *et al.*, Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults, Clinical Infectious Diseases 2007; 44(2):S27–72.

* in presence of comorbidities, such as chronic heart, lung, liver, or renal disease; diabetes mellitus; alcoholism; malignancies; asplenia; immunosuppressing conditions or use of immunosuppressing drugs; use of antimicrobials within the previous 3 months (in which case an alternative from a different class should be selected); or other risks for DRSP infection

IDSA Adults CAP guidelines, 2007

Recommend High-dose amoxicillin [e.g., 1 g 3 times daily] or **amoxicillin-clavulanate [2 g 2 times daily] as preferred treatment of CAP in presence of comorbidities**, such as chronic heart, lung, liver, or renal disease; diabetes mellitus; alcoholism; malignancies; asplenia; immunosuppressing conditions or use of immunosuppressing drugs[1]

1. Lionel A. Mandell *et al.*, Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults, Clinical Infectious Diseases 2007; 44(2):S27–72.

BTS guidelines 2009

Recommend parenteral amoxicillin-clavulanate as the **preferred initial empirical treatment regimen** for high severity community acquired pneumonia in adults[1]

1. Lim WS, Baudouin SV, George RC, *et al*. BTS guidelines for the management of community -acquired pneumonia in adults update 2009, Thorax 2009,Thorax 2009;64(3):1-55

Augmentin 875 mg Tablets Indication:

Augmentin is indicated for the treatment of the following infections in adults and children:

- Acute bacterial sinusitis (adequately diagnosed)
- Acute otitis media
- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- Community acquired pneumonia
- Cystitis
- Pyelonephritis
- Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis.
- Bone and joint infections, in particular osteomyelitis.

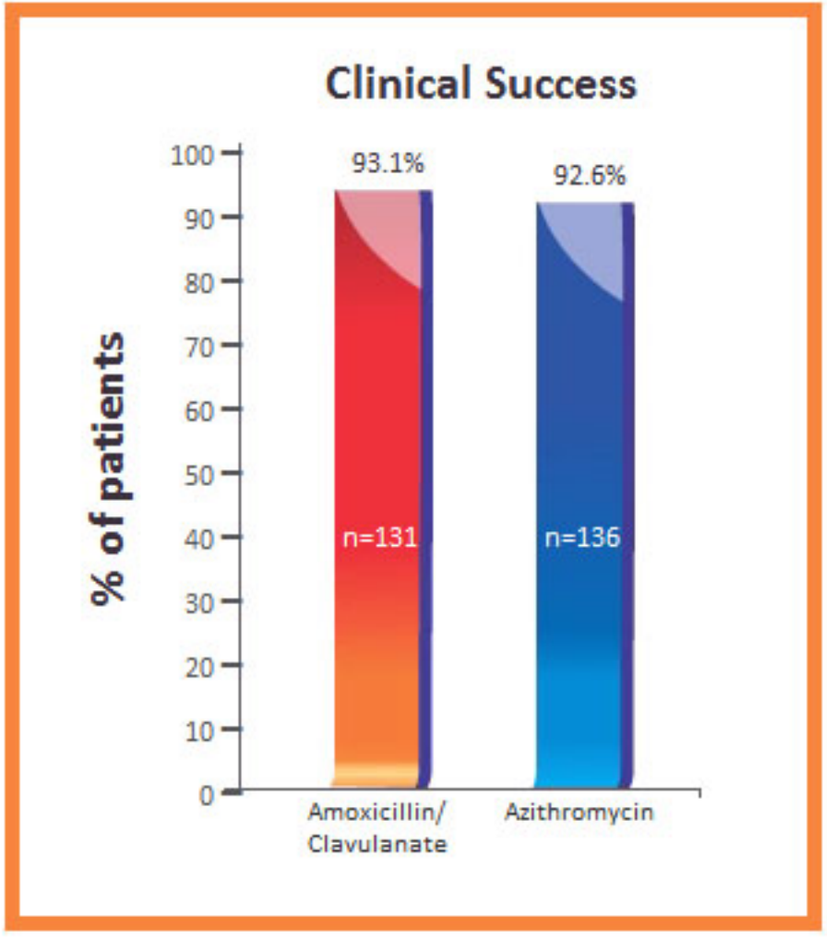
Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Dosage in adults[1]

Mild to moderate infections	875/125 mg given twice daily
Severe infections (including chronic and recurrent lower respiratory tract)	875/125 mg given 2 or 3 times daily

1.Augmentin PI MOH approved

Comparable clinical efficacy vs. azithromycin in adult CAP patients[1]



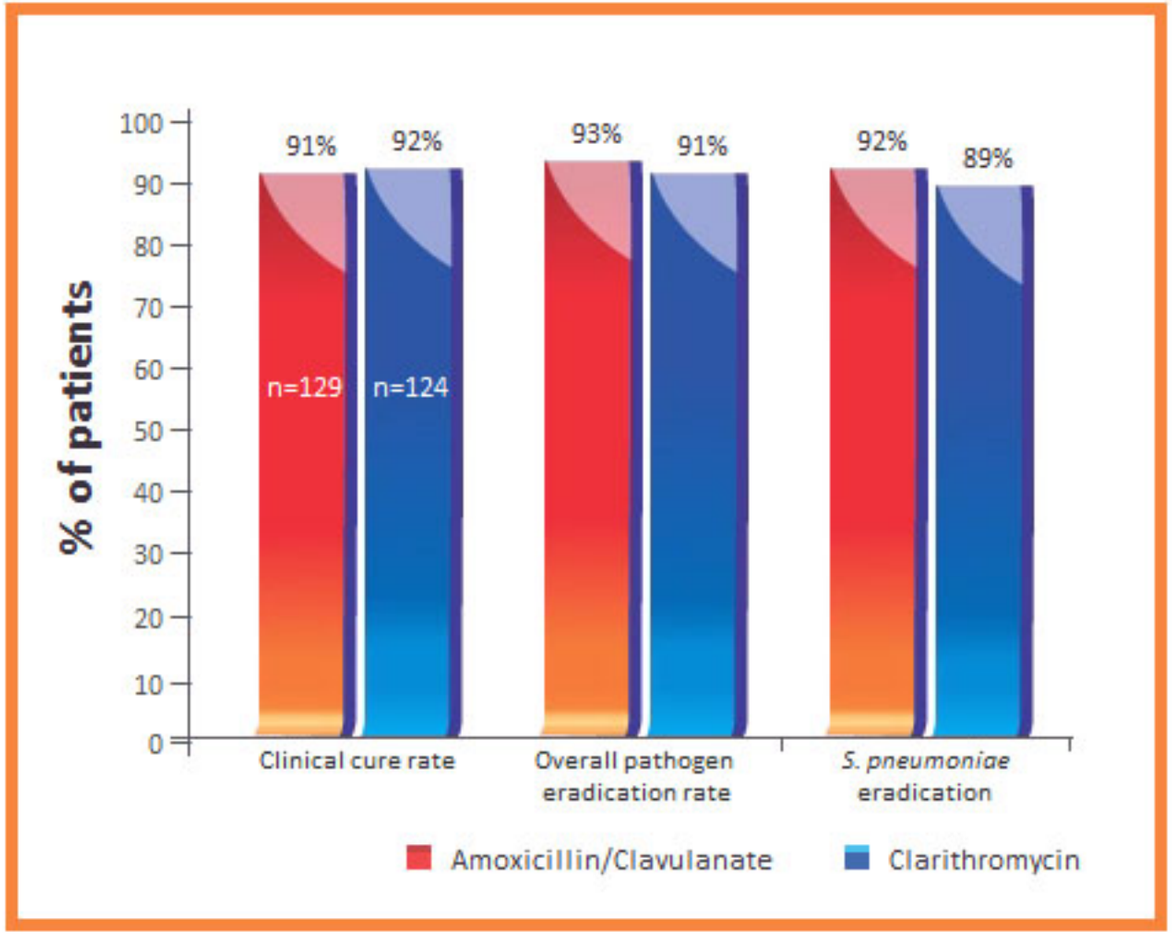
Abstract

An open-label randomised comparison of efficacy and safety of amoxicillin-clavulanate 875/125 mg twice daily for 7 days with azithromycin 1 g once daily for 3 days in the treatment of adult patients with community-acquired pneumonia showed the clinical success rate of azithromycin to be 92.6% whereas that of amoxicillin-clavulanate to be 93.1%.

- Clinical success rates were 92.6% for azithromycin and 93.1% for amoxicillin-clavulanate

1. Paris R, Confalonieri M, Mos L, *et al*. Efficacy and safety of azithromycin 1g once daily for 3 days in the treatment of community -acquired pneumonia:an open-label randomised comparison with amoxicillin-clavulanate 875/125 mg twice daily for 7 days. J Chemother. 2008 Feb; 20(1):77-86.

Comparable clinical efficacy vs. clarithromycin in CAP[1]



Abstract

A comparative study of the safety and efficacy of clarithromycin and amoxicillin/clavulanic acid in patients with community-acquired pneumonia due to penicillin-resistant and/or macrolide-resistant *Streptococcus pneumoniae*, showed the overall eradication rate for pathogens to be 91% for clarithromycin and 93% for amoxicillin/clavulanic acid, and 89% and 92%, respectively, for *S.pneumoniae* strains.

1. Bonvehi P, Weber K, Busman T, *et al*. Comparison of Clarithromycin and Amoxicillin/Clavulanic acid for Community- Acquired Pneumonia in an Era of Drug-Resistant *Streptococus pneumoniae*. Clin Drug Investig. 2003; 23(8): 491-501.

Augmentin® 875 mg Tablets

Amoxicillin as trihydrate 875 mg
Clavulanic Acid as potassium salt 125 mg

- Achieves adequate concentration in lungs[1, 2]
- Proven clinical and bacteriological efficacy in CAP[3, 4]
- Recommended by leading guidelines[5, 6]
- Available in > 100 countries[7]
- 3 decades of sustained clinical and bacteriological success rates[8, 9, 10]
- Enhanced formulation available[11, 12, 13, 14]

1. Gould IM, Harvey G, Golder D, *et al*. Penetration of amoxycillin/clavulanic acid into bronchial mucosa with different dosing regimens. Thorax. 1994 Oct;49(10):999-1001.
2. Cox AL, Meewis JM, Horton R , *et al*. Penetration into lung tissue after intravenous administration ofamoxycillin/clavulanate. J. Antimicrob. Chemother. (1989) 24 (suppl B): 87-91.
3. Paris R, Confalonieri M, Dal Negro R, *et al*. Efficacy and safety of azithromycin 1 g once daily for 3 days in the treatment of community-acquired pneumonia: an open-label randomised comparison with amoxicillin-clavulanate 875/125 mg twice daily for 7 days. J Chemother. 2008 Feb;20(1):77-86.
4. Bonvehi P, Weber K, Busman T, Shortridge D, Notario G. Comparison of Clarithromycin and Amoxicillin/Clavulanic Acid for Community-Acquired Pneumonia in an Era of Drug-Resistant Streptococcus pneumoniae. Clin Drug Investig. 2003;23(8):491-501.

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5. Watkins R, Lemonovich T, *et al*. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.
6. Mandell LA, Wunderlink RG, Anzueto A, *et al*. Infectious Diseases Society of America/American Thoracic Society consensus guidelines on the management of community-acquired pneumonia in adults. Clin Infect Dis. 2007 Mar 1;44 Suppl 2:S27-72.
7. GSK data on file
8. Karachalios GN. Treatment of respiratory tract infections with a combination of amoxycillin and clavulanic acid. Int J Clin Pharmacol Ther Toxicol. 1985 Dec;23(12):647-9.
9. Higuera F, Hidalgo H, Feris J, *et al*.Comparison of oral cefuroxime axetil and oral amoxycillin/clavulanate in the treatment of community-acquired pneumonia. J Antimicrob Chemother. 1996 Mar;37(3):555-64.

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11. Benninger MS. Amoxicillin/clavulanate potassium extended release tablets: a new antimicrobial for the treatment of acute bacterial sinusitis and community-acquired pneumonia. Expert Opin Pharmacother. 2003 Oct;4(10):1839-46.
12. Augmentin 875 PI MOH approved
13. Petitpretz P, Chidiac C, Soriano F, *et al*. The efficacy and safety of oral pharmacokinetically enhanced amoxycillin-clavulanate 2000/125 mg, twice daily, versus oral amoxycillin-clavulanate 1000/125 mg, three times daily, for the treatment of bacterial community-acquired pneumonia in adults. Int J Antimicrob Agents. 2002 Aug;20(2):119-29.

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community-acquired pneumonia. Expert Opin Pharmacother. 2003 Oct;4(10):1839-46.
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14. File TM Jr. The development of pharmacokinetically enhanced amoxicillin/clavulanate for the management of respiratory tract infections in adults. Int Antimicrob Agents. 2007 Dec;30 Suppl 2:S131-4.

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Adequate concentration in lungs[1]

- Achieves concentrations well above the MIC_{90} for the common bacterial respiratory pathogens including *H. influenzae, M. catarrhalis and S. penumoniae*[1]
- Mean mucosal levels were 200% and 118% of the corresponding serum levels for amoxicillin and clavulanic acid respectively[1]

Dose of amoxicillin (co-amoxiclav)[1]	Serum levels (mg/l)	Bronchial mucosa levels (mg/l)
250 mg	2.6	4.1
500 mg	5.6	10.1

Dose of clavulanic acid (co-amoxiclav)[1]	Serum levels (mg/l)	Bronchial mucosa levels (mg/l)
125 mg	1.4	1.9
250 mg	2.3	2.4

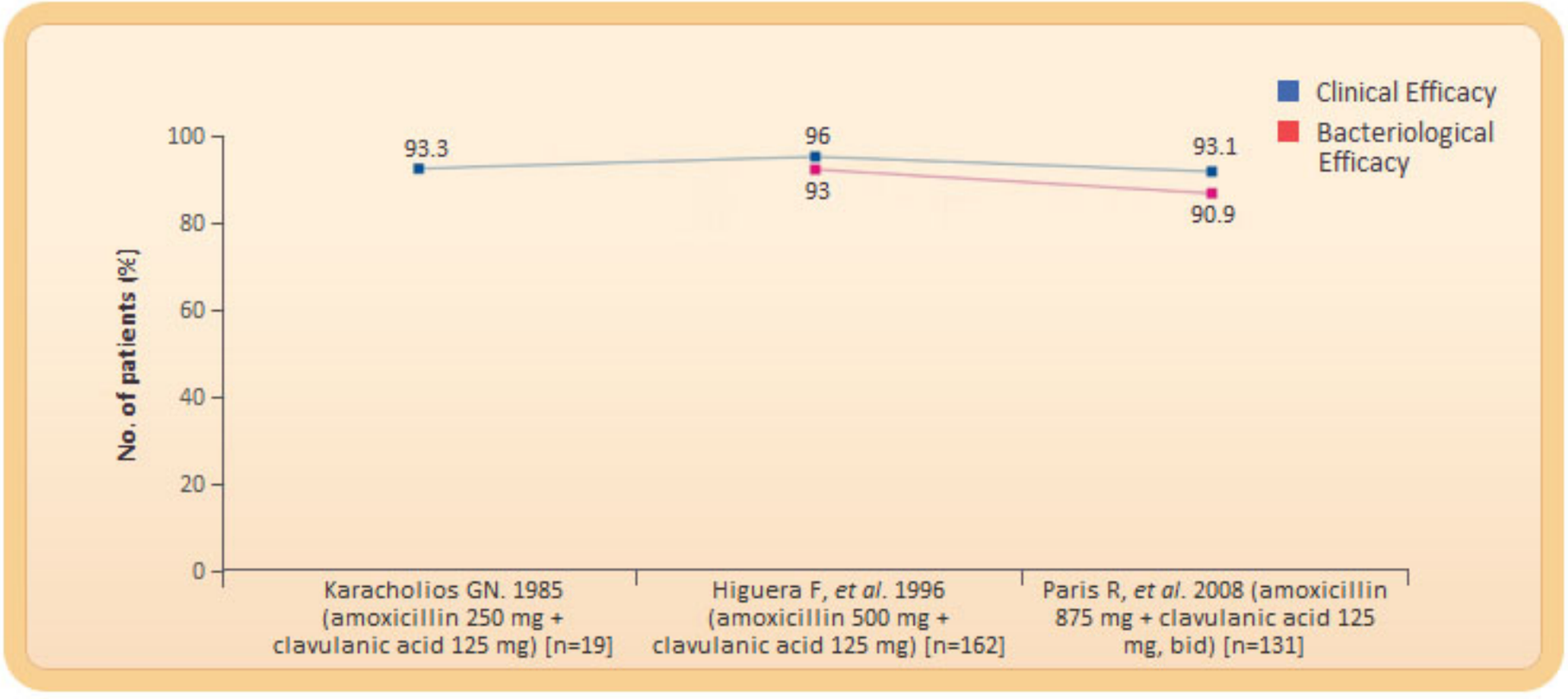
1. Gould IM, *et al*. Penetration of amoxycillin/clavulanic acid into bronchial mucosa with different dosing regimens.,Thorax,1994 Oct;49(10):999-1001.

Proven clinical and bacteriological efficacy[1,2]

Year/Author	Augmentin dose	Comparator dose	Clinical efficacy	Bacteriological efficacy
Paris R, *et al.* 2008 (CAP)	7-day course of oral amoxicillin-clavulanate 875/125 mg twice daily	3-day course of oral azithromycin 1g once daily	Clinical success rates were 92.6% for azithromycin and 93.1% for amoxicillin clavulanate	Bacteriological efficacy
Bonvehi P, *et al.* 2003 (CAP)	875mg/125mg twice daily	Clarithromycin 500mg immediate-release	• Clarithromycin=92% • Amoxicillin-clavulanic acid=91%	• Clarithromycin=91 % • Amoxicillin/clavulanic acid=93%
Mouton Y, *et al.* 1991 (CAP)	Not specified	Ciprofloxacin (750mg b.i.d.)	Clinical recovery was achieved in of patients in; • Clarithromycin=73.3% • Amoxicillin + clavulanic acid=81.8%	

1. Paris R, Confalonieri M, Dal Negro R, *et al.* Efficacy and safety of azithromycin 1 g once daily for 3 days in the treatment of community-acquired pneumonia: an open-label randomised comparison with amoxicillin-clavulanate 875/125 mg twice daily for 7 days. J Chemother. 2008 Feb;20(1):77-86.
2. Bonvehi P, Weber K, Busman T, *et al.* Comparison of Clarithromycin and Amoxicillin/Clavulanic Acid for Community-Acquired Pneumonia in an Era of Drug-Resistant Streptococcus pneumoniae. Clin Drug Invest. 2003;23(8) :491-501.

Sustained clinical and bacteriological success rates[1,2,3]



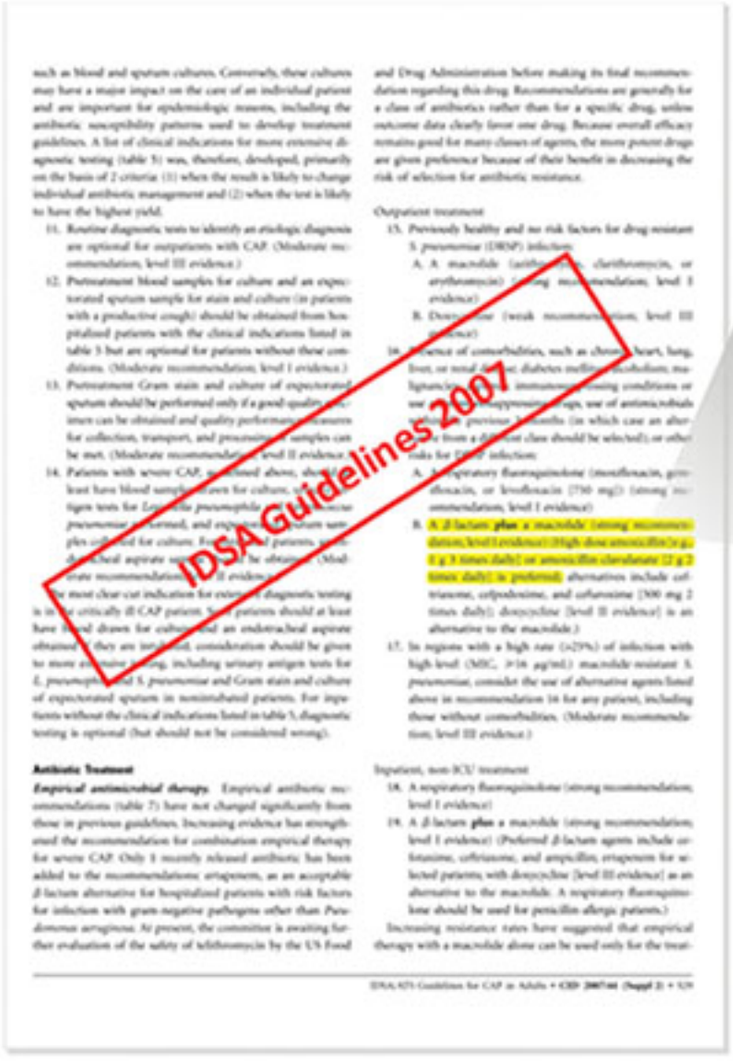
Disclaimer: Data taken from separate studies with differing dosage forms

1. Karachalios GN. Treatment of respiratory tract infections with a combination of amoxycillin and clavulanic acid. Int J Clin Pharmacol Ther Toxicol. 1985 Dec;23(12):647-9.
2. Higuera F, Hidalgo H, Feris J, *et al.*Comparison of oral cefuroxime axetil and oral amoxycillin/clavulanate in the treatment of community-acquired pneumonia. J Antimicrob Chemother. 1996 Mar;37(3):555-64.
3. Paris R, Confalonieri M, Dal Negro R, *et al.* Efficacy and safety of azithromycin 1 g once daily for 3 days in the treatment of community-acquired pneumonia: an open-label randomised comparison with amoxicillin-clavulanate 875/125 mg twice daily for 7 days. J Chemother. 2008 Feb;20(1):77-86.

Infectious Diseases Society of America

American Academy of Family Physicians

Infectious Diseases Society of America



IDSA Guidelines 2007

A β-lactam plus a macrolide (strong recommendation; level I evidence) (High-dose amoxicilin [e.g,1 g 3 times daily] or amoxicillin-clavulanate [2 g 2 times daily] is preferred[1]

1. Lionel A. Mandell *et al.*, Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults, Clinical Infectious Diseases 2007; 44(2):S27–72.

American Academy of Family Physicians

Community-Acquired Pneumonia

Table 7. Empiric Therapy for Community-Acquired Pneumonia

Patient group	Initial therapy
Previously healthy outpatients; no antibiotic use in past three months	A macrolide or doxycycline
Outpatients with comorbidities* or antibiotic use in past three months†	A respiratory fluoroquinolone (levofloxacin [Levaquin], gemifloxacin [Factive], or moxifloxacin [Avelox]), or a beta-lactam antibiotic (high-dose amoxicillin, amoxicillin/clavulanate [Augmentin], or cefpodoxime) plus a macrolide‡
Inpatients, non-ICU	A respiratory fluoroquinolone, or a beta-lactam antibiotic plus a macrolide‡
Inpatients, ICU	A beta-lactam antibiotic (ceftriaxone [Rocephin], cefotaxime [Claforan], or ampicillin/sulbactam [Unasyn]), plus azithromycin (Zithromax) or a respiratory fluoroquinolone§
Special considerations	
Risk factors for Pseudomonas species	A beta-lactam antibiotic (piperacillin/tazobactam [Zosyn], ceftazidime, cefepime, imipenem/cilastatin [Primaxin], meropenem [Merrem], or aztreonam [Cloribid]) plus either ciprofloxacin (Cipro) or levofloxacin or The above beta-lactam antibiotic plus an aminoglycoside and azithromycin or The above beta-lactam antibiotic plus an aminoglycoside and an antipneumococcal respiratory fluoroquinolone
Risk factors for methicillin-resistant Staphylococcus aureus	Vancomycin or linezolid (Zyvox)
Influenza virus	Oseltamivir (Tamiflu) or zanamivir (Relenza)

ICU = intensive care unit.

*—Chronic heart, lung, liver, or renal disease; diabetes mellitus; alcoholism; malignancy; asplenia.

†—Antibiotic from a different class should be used.

‡—Also recommended in regions with a rate of high-level macrolide-resistant Streptococcus pneumoniae of greater than 25 percent.

§—For patients allergic to penicillins, a respiratory fluoroquinolone plus azithromycin (Azactam) are recommended.

Adapted with permission from Mandell LA, Wunderink RG, Anzueto A, et al. Infectious Disease Society of America/American Thoracic Society consensus guidelines on the management of community-acquired pneumonia in adults. Clin Infect Dis. 2007;44(Suppl 2):S27.

are listed in *Table 7*.[1] One of the major differences between U.S. and European guidelines for treatment of CAP is that all patients in the United States receive treatment for *S. pneumoniae* and atypical organisms because CAP is more often caused by these pathogens in North America.[1] Macrolides (e.g., azithromycin [Zithromax], clarithromycin [Biaxin]) can be used for outpatients with no cardiopulmonary disease or recent antibiotic use.

Drug-resistant *S. pneumoniae* is a concern in patients with comorbid illness or recent antibiotic therapy (within previous three months) and should be treated with an oral beta-lactam antibiotic (e.g., high-dose amoxicillin, amoxicillin/clavulanate [Augmentin], cefpodoxime) combined with a macrolide. A respiratory fluoroquinolone is another choice. If a patient has used an antibiotic in the previous three months, a drug from a different class should be prescribed to decrease the risk of pneumococcal resistance. For hospitalized patients not admitted to the ICU, an intravenous respiratory fluoroquinolone alone or an intravenous beta-lactam antibiotic combined with a macrolide or doxycycline should be given. A study showed doxycycline to be comparable to levofloxacin (Levaquin) in effectiveness, length of hospital stay, and failure rate for empiric treatment of CAP; doxycycline is also a less expensive option for hospitalized patients who are not admitted to the ICU.[7] However, the sample size in the study was small and IDSA/ATS guidelines recommend doxycycline only for outpatients.[1]

All patients with CAP who are admitted to the ICU should be treated with dual therapy, which is associated with lower mortality from bacteremic pneumococcal pneumonia and improves survival in patients with CAP and shock.[7] Some patients with severe CAP, especially after an episode of influenza or viral illness, who are admitted to the ICU need added coverage for *S. aureus*, including MRSA. MRSA-associated CAP is characterized by a severe, bilateral, necrotizing pneumonia induced by Panton-Valentine leukocidin and other toxins.

1304 American Family Physician www.aafp.org/afp Volume 83, Number 11 ◆ June 1, 2011

AAFP Guidelines 2011

Drug-resistant S. *pneumoniae* is a concern in patients with comorbid illness or recent antibiotic therapy (within previous three months) and should be treated with an oral beta-lactam antibiotic (e.g., high-dose amoxicillin, amoxicillin/clavulanate [Augmentin], cefpodoxime) combined with a macrolide[1]

1. Watkins R, Lemonovich T, *et al*. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.

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Clavulanic Acid as potassium salt 125 mg

MAIN SAFETY DATA[1]

- The most common adverse effects are diarrhoea, nausea, vomiting and mucocutaneous candidiasis[1]
- Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking Augmentin at the start of a meal[1]
- Careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens, before initiating therapy with Augmentin[1]
- Should be used with caution in patients with evidence of hepatic dysfunction[1]

Reference 1: Augmentin 875 PI MOH approved

GlaxoSmithKline. 25 Basel street, P.O. Box 10283, Petach-Tikva 4900202 Israel, Tel: 03-9297100.
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