

The Practice of Emergency Medicine Emergency Physicians Emergency Medicine Specialty Reports[®] included with this issue.

Emergency Medicine Reports

Volume 24, Number 22

October 20, 2003

Cephalosporins, macrolides, and fluoroquinolones currently represent foundation antimicrobials for managing common respiratory infections caused by bacterial and/or atypical pathogens. Prudent, evidence-based utilization of these agents is of paramount importance not only to ensure optimal outcomes across a broad range of patient subtypes, but also to decrease the rate of drug resistance, which continues to grow at an alarming pace.

Many factors must be entered into the therapeutic equation for antibiotic use when managing patients with acute bacterial exacerbations of chronic bronchitis (ABECB). There is general agreement that selecting among available antibiotic classes and choosing specific agents within those classes is optimized when results of clinical trials, antimicrobial

Appropriate and Outcome-Effective Antibiotic Use in Acute Bacterial Exacerbations of Chronic Bronchitis (ABECB)

The SCARTI (Selection of Cephalosporins, Macrolides, and AFQs for Respiratory Tract Infections) Clinical Consensus Panel Report[®]—Landmark Series in Antibiotic Management: Year 2003 Update: Part I

Authors: **Gregory A. Volturo, MD, FACEP**, Vice Chairman and Associate Professor, Department of Emergency Medicine, University of Massachusetts, Worcester; and **Gideon Bosker, MD**, Assistant Clinical Professor, Section of Emergency Services, Yale University School of Medicine, Associate Clinical Professor, Oregon Health Sciences University, Portland.

—On behalf of the SCARTI Clinical Consensus Panel

Peer Reviewers: **Charles Emerman, MD**, Chairman, Department of Emergency Medicine, MetroHealth Medical Center, Cleveland Clinic Foundation, Cleveland, OH; and **J. Stephan Stapeczynski, MD**, Professor and former Chair, Department of Emergency Medicine, University of Kentucky College of Medicine, Lexington.

resistance data, surveillance networks, and epidemiological trends are factored into a complex management equation designed to cure patients today and protect the community from developing drug resistance in the future.

Matching “correct spectrum” antibiotics with bacterial pathogens is a multifactorial process. As a result, the therapeutic landscape for anti-infective management continues to shift as it undergoes intense analysis.

Despite new data pointing to possible limitations of some agents within certain classes, the cephalosporins, macrolides, and advanced-generation fluoroquinolones (AFQs) continue to be the most widely used and the most consistently recommended antimicrobials for

managing patients with bacterial respiratory tract infections

EDITOR IN CHIEF

Gideon Bosker, MD
Special Clinical Projects and Medical Education Resources
Assistant Clinical Professor
Section of Emergency Services
Yale University School of Medicine
Associate Clinical Professor
Oregon Health Sciences University

EDITORIAL BOARD

Paul S. Auerbach, MD, MS, FACEP
Clinical Professor of Surgery
Division of Emergency Medicine
Department of Surgery
Stanford University School of Medicine
Stanford, California

Brooks F. Bock, MD, FACEP
Dayanandan Professor and Chairman
Department of Emergency Medicine
Detroit Receiving Hospital
Wayne State University
Detroit, Michigan

William J. Brady, MD, FACEP, FAAEM
Vice Chairman of Emergency Medicine and Associate Professor,
Department of Emergency Medicine,
Associate Professor of Internal Medicine and Program Director of Emergency Medicine Residency,
Department of Internal Medicine
University of Virginia School of Medicine
Charlottesville, Virginia

Kenneth H. Butler, DO
Associate Residency Director
University of Maryland Emergency
Medicine Residency Program
University of Maryland School
of Medicine
Baltimore, Maryland

Michael L. Coates, MD, MS
Professor and Chair
Department of Family and Community
Medicine
Wake Forest University School
of Medicine
Winston-Salem, North Carolina

Alasdair K.T. Conn, MD
Chief of Emergency Services
Massachusetts General Hospital
Boston, Massachusetts

Charles L. Emerman, MD
Chairman
Department of Emergency Medicine
MetroHealth Medical Center
Cleveland Clinic Foundation
Cleveland, Ohio

Kurt Kleinschmidt, MD, FACEP
Assistant Professor
University of Texas Southwestern Medical
Center, Dallas
Associate Director
Department of Emergency Medicine
Parkland Memorial Hospital
Dallas, Texas

David A. Kramer, MD, FACEP, FAAEM
Program Director,
York Hospital Emergency Medicine
Residency
Clinical Associate Professor
Department of Emergency Medicine
Penn State University
York, Pennsylvania

Larry B. Mellick, MD, MS, FAAP, FACEP
Vice Chairman for Academic Development
and Research
Department of Emergency Medicine
Medical College of Georgia
Augusta, Georgia

Paul E. Pepe, MD, MPH, FACEP, FCCM
Professor and Chairman
Division of Emergency Medicine
University of Texas Southwestern Medical
Center
Dallas, Texas

Charles V. Pollack, MA, MD, FACEP
Chairman, Department of Emergency
Medicine, Pennsylvania Hospital
Associate Professor of Emergency
Medicine
University of Pennsylvania School of
Medicine
Philadelphia, Pennsylvania

Robert Powers, MD, MPH, FACP
Chief and Professor, Emergency Medicine
University of Connecticut
School of Medicine
Farmington, Connecticut

David J. Robinson, MD, MS, FACEP
Assistant Professor, Vice-Chairman,
Research Director
Department of Emergency Medicine
The University of Texas – Health Science
Center at Houston
Director, Diagnostic Observation Center
Memorial Hermann Hospital
Houston, Texas

Steven G. Rothrock, MD, FACEP, FAAP
Associate Professor of Emergency Medicine
University of Florida College of Medicine,
Department of Emergency Medicine
Orlando Regional Medical Center
Orlando, Florida

Barry H. Rumack, MD
Director, Emeritus
Rocky Mountain Poison and Drug Center
Clinical Professor of Pediatrics
University of Colorado Health Sciences
Center
Denver, Colorado

Richard Salluzzo, MD, FACEP
Chief Executive Officer and Chief
Medical Officer
Conemaugh Health System
Johnstown, Pennsylvania

Sandra M. Schneider, MD
Professor and Chair
Department of Emergency Medicine
University of Rochester School
of Medicine
Rochester, New York

John A. Schriver, MD
Chief, Section of Emergency Medicine
Yale University School of Medicine
New Haven, Connecticut

David Sklar, MD, FACEP
Professor and Chair
Department of Emergency Medicine
University of New Mexico School of Medicine
Albuquerque, New Mexico

Corey M. Slovis, MD, FACP, FACEP
Professor and Chairman
Department of Emergency Medicine
Vanderbilt University School of Medicine,
Medical Director
Metro Nashville EMS
Nashville, Tennessee

J. Stephan Stapeczynski, MD
Professor and Chairman
Department of Emergency Medicine
University of Kentucky Medical Center
Lexington, Kentucky

Charles E. Stewart, MD, FACEP
Emergency Physician
Colorado Springs, Colorado

Gregory A. Volturo, MD, FACEP
Vice Chairman and Associate Professor
Department of Emergency Medicine
University of Massachusetts Medical
School
Worcester, Massachusetts

Albert C. Wehl, MD
Assistant Professor of Medicine and Surgery
Department of Surgery
Section of Emergency Medicine
Yale University School of Medicine
New Haven, Connecticut

Steven M. Winograd, MD, FACEP
Attending Physician
Department of Emergency Medicine
Jeannette District Memorial Hospital
St. Clair Memorial Hospital
Pittsburgh, Pennsylvania
University of Pittsburgh Medical Center

Allan B. Wolfson, MD, FACEP, FACP
Program Director,
Affiliated Residency in Emergency Medicine
Professor of Emergency Medicine
University of Pittsburgh
Pittsburgh, Pennsylvania

© 2003 Thomson American Health
Consultants. All rights reserved.

(RTIs). Given the plethora of guidelines and consensus statements published in the medical literature and the formidable number of anti-infectives available in the therapeutic arsenal, it is not surprising that there is a diversity of opinion about specific antibiotic choices.

Clearly, there is no substitute for fair balance and for recommendations that encourage appropriate based medicine as a guide to ensure customized therapy for the individual, risk-stratified patient. This is a prudent approach that will help clinicians complete the journey from trial-generated information to the real world of clinical application. Although the clinical effectiveness and safety profiles for the aforementioned antimicrobials are well documented, there are other clinically relevant differences among

Emergency Medicine Reports™ (ISSN 0746-2506) is published biweekly by Thomson American Health Consultants, 3525 Piedmont Road, N.E., Six Piedmont Center, Suite 400, Atlanta, GA 30305. Telephone: (800) 688-2421 or (404) 262-7436.

Vice President/Group Publisher: Brenda Mooney
Editorial Group Head: Valerie Loner
Specialty Editor: Shelly Morrow Mark
Marketing Manager: Schandale Kornegay
GST Registration No.: R128870672

Periodicals postage paid at Atlanta, GA. **POSTMASTER:** Send address changes to **Emergency Medicine Reports**, P.O. Box 740059, Atlanta, GA 30374.

Copyright © 2003 by Thomson American Health Consultants, Atlanta, GA. All rights reserved. Reproduction, distribution, or translation without express written permission is strictly prohibited.

Back issues: \$31. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue's date.

Multiple copy prices: One to nine additional copies, \$359 each; 10 to 20 additional copies, \$319 each.

Accreditation

Emergency Medicine Reports™ continuing education materials are sponsored and supervised by Thomson American Health Consultants. Thomson American Health Consultants designates this continuing education activity for up to 60 hours in Category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

This CME activity was planned and produced in accordance with the ACCME Essentials.

Emergency Medicine Reports™ also is approved by the American College of Emergency Physicians for 60 hours of ACEP Category 1 credit and has been approved for 52 Category 2B credit hours by the American Osteopathic Association. Emergency Medicine



Statement of Financial Disclosure

In order to reveal any potential bias in this publication, and in accordance with Accreditation Council for Continuing Medical Education guidelines, we disclose that Dr. Stapczynski (peer reviewer) reports no relationships with companies related to the field of study covered by this CME program. Dr. Volturo is on the speaker's bureau for Pfizer and Scios and receives research grants from Roche. Dr. Emerman (peer reviewer) is a consultant for Scios and Aventis; is on the speaker's bureau for Scios, Pfizer, Roche, and Bayer; and conducts research for Scios and Aventis. Dr. Bosker (editor and author) is on the speaker's bureau for Pfizer, Rhone-Poulenc Rorer, and Parke-Davis. Dr. Bosker also acknowledges that he receives royalties, commissions, and other compensation relating to the sale of textbooks, reprints of articles, and other written materials to the following pharmaceutical companies: Pfizer, Genentech, Aventis, Pharmacia, and Bayer.

Subscriber Information

Customer Service: 1-800-688-2421

Customer Service E-Mail: customerservice@ahcpub.com

Editorial E-Mail: shelly.mark@ahcpub.com

World Wide Web page: http://www.ahcpub.com

Subscription Prices

1 year with 60 ACEP/60 AMA/60 AAFP

Category 1/Prescribed credits

(52 AOA Category 2B credits): \$544

1 year without credit: \$399

Resident's rate \$199

All prices U.S. only.

U.S. possessions and Canada, add \$30 plus applicable GST. Other international orders, add \$30.

Reports has been reviewed by the American Academy of Family Physicians as having educational content acceptable for Prescribed credit hours. This volume has been approved for up to 60 Prescribed credit hours. Term of approval covers issues published within one year from the beginning distribution date of 1/03. Credit may be claimed for one year from the date of this issue. Thomson American Health Consultants (AHC) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

This is an educational publication designed to present scientific information and opinion to health professionals, to stimulate thought, and further investigation. It does not provide advice regarding medical diagnosis or treatment for any individual case. It is not intended for use by the layman. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

For Customer Service and CME questions,

Please call our customer service department at **(800) 688-2421**. For editorial questions or comments, please contact **Shelly Morrow Mark**, Specialty Editor, at shelly.mark@ahcpub.com or (404) 262-5514.

specific antibiotics within each class that warrant more detailed consideration. For example, resistance-induction studies, minimal inhibitory concentration (MIC) data, and surveillance data have highlighted the potential advantages of moxifloxacin compared to other AFQs for initial treatment of ABECB patients in whom AFQs are deemed appropriate. Among the advanced-generation macrolides, short-duration (i.e., 3-day) courses of azithromycin for outpatient ABECB have introduced dosing regimens with the capacity to improve medication compliance. It also has been recognized that the ability to achieve excellent outcomes with potent, broad-spectrum agents must be balanced against the pitfalls of inducing drug resistance among nosocomial pathogens, especially if used excessively and inappropriately. In addition, it should be stressed that antibiotic therapy is not always necessary, and that most patients who have acute bronchitis that is not superimposed on a history of chronic obstructive pulmonary disease (COPD) do not benefit from antimicrobial therapy.

Identifying "correct spectrum" coverage for common bacterial infections involving the respiratory tract is essential, especially for the fluoroquinolones. While this class is effective against many bacterial RTIs, some agents may have a propensity for inducing resistance at a disproportionately accelerated rate compared to other agents. Evaluating the effects on clinical outcomes of increasing in vitro resistance among respiratory pathogens (especially *S. pneumoniae*) to advanced-generation macrolides and determining the role that such resistance trends should play on inpatient and outpatient management (i.e., antibiotic selection) of ABECB are among the issues that require consideration.

The landscape shift in drug resistance and antibiotic selection has spawned the concept of "curing patients today, while protecting the community tomorrow." This means identifying pharmacotherapeutic strategies that not only optimize short-term outcomes for RTIs—in which curing patients is the preeminent goal—but also achieve this end point while reducing the likelihood of developing drug resistance. The mandate to cure patients acutely and preserve long-term antimicrobial efficacy represents one of the most important challenges primary care physicians face when developing protocols and pathways for outpatient management of ABECB.

Because the aforementioned issues are of great interest to a wide range of practitioners and investigators, it is important that clinical scholars and experts continue to evaluate the most recent data to generate clear, concise, and evidence-based recommendations for this therapeutic arena. To achieve this goal, the SCARTI (Selection of Cephalosporins, Macrolides, and AFQs for Respiratory Tract Infections) Clinical Consensus Panel and Scientific Roundtable* was convened for the purpose of publishing an evidence-based document outlining antibiotic selection strategies, treatment guidelines, and other recommendations that would provide expert guidance for use of cephalosporins, macrolides, and AFQs for patients with ABECB.

Specifically, the SCARTI Clinical Consensus Panel reviewed epidemiological trends, national association guidelines, clinical trials, and resistance databases to help establish evidence-based approaches for managing RTIs commonly encountered in the outpatient/emergency department setting. Finally, in addition to criti-

Table 1. Factors Influencing Patient Disposition in ABE/COPD

- Age of patient
- Overall respiratory status
- Respiratory rate
- O₂ saturation
- Steroid use
- Degree of hypercarbia
- Patient's status compared to baseline
- Mental status
- Home environment
- Likelihood of acceptable medication compliance
- Nighttime emergency department visit
- Previous pattern of frequent relapse
- Pulmonary function tests
- FEV₁ less than 40% of predicted normal
- Multiple ED courses of aerosolized beta-agonists

cal pathways and treatment tables, this report also incorporates risk-stratification tools that can be used to identify patients with ABECB who require more intensive, broad-spectrum therapy and that will help distinguish those patient subgroups more appropriately managed in the outpatient setting from those that should be admitted to the hospital for more intensive care.

—The Editor

Acute Bacterial Exacerbations of Chronic Bronchitis (ABECB): Introduction

During the past 10 years, clinicians and investigators have developed a more complete understanding of the pathogenesis and consequences of acute bacterial exacerbations of COPD (ABE/COPD). Several studies during that period support bacterial precipitation in about one-half of all exacerbations. Contrary to previous data, recent studies with improved techniques have demonstrated that exacerbations probably contribute to the loss of lung function in COPD. In addition, it appears that colonization by bacterial pathogens may not be innocuous, and in fact may lead to airway inflammation and contribute to the pathogenesis of COPD.

Evidence that bacteria cause exacerbations that lead to loss of lung function and that chronic bacterial colonization may be harmful has underscored the importance of appropriate antibiotic use and selection in patients with ABECB. Unfortunately, unlike the case of community-acquired pneumonia (CAP), there is a paucity of data from large, well-controlled prospective trials that provide definitive guidance regarding choice of antibiotic therapy for exacerbations of COPD. What is clear, however, is that outcome-effective antibiotic selection for ABECB means taking into account local antibiotic resistance patterns, epidemiological and infection incidence data, and patient demographic features. Then, against the background of clinical judgment, it also means determining the most appropriate agent for an individual patient. Finally, emerging data that antibiotics differ in unconventional measures of efficacy such as time to next exacerbation, improvement in health-related quality of life, and bacteriologic eradica-

tion, are additional factors that will help formulate concrete recommendations in the future.

While bacteriologic eradication, objective improvement of pulmonary function, and amelioration of symptoms are accepted end points guiding antibiotic therapy in ABECB, other factors also may play a role. In this regard, new recommendations regarding antibiotic therapy have been prompted by recent introduction of short-duration regimens that may promote greater patient compliance and acceptability. Such short-duration options include a five-day course of moxifloxacin (400 mg PO qd) and an even shorter three-day course of azithromycin (500 mg PO once-daily x 3 days) to treat acute exacerbations of COPD precipitated by *S. pneumoniae*, *H. influenzae*, and *M. catarrhalis*.

In addition, because appropriate disposition of patients with ABECB has become essential for cost-effective patient management, the SCARTI Clinical Consensus Panel recommends the use of critical pathways and treatment tables that incorporate risk stratification protocols and intensification-of-treatment trigger (IOTT) criteria that can be used to identify those patient subgroups that are suitably managed in the outpatient setting from those more appropriately admitted to the hospital for more intensive care. Identifying treatment trigger points, risk factors, and historical features that support amplifying spectrum of coverage from a "correct spectrum" macrolide to an extended spectrum fluoroquinolone are essential for outcome-effective antibiotic use.

Historically, cephalosporins, macrolides, and AFQs have been used as initial agents of choice. Patients with advanced disease and multiple risk factors may have exacerbations caused by Klebsiella species, *Pseudomonas aeruginosa*, and other gram-negative species. As will be discussed below, these patients may require intensification of therapy with agents—in particular, AFQs such as levofloxacin or gatifloxacin—that are active against gram-negative organisms. Development of advanced-generation macrolides (e.g., azithromycin and clarithromycin), as well as extended spectrum quinolones such as moxifloxacin have made it possible to treat most patients using monotherapy.

Etiology and Risk Stratification. The severity of ABE/COPD is common, costly, and, above all, complex to manage. In fact, few conditions produce such a broad range of outcomes, require such customized approaches, or present so many options for treatment.^{1,2} Although there have been important advances in patient assessment techniques and therapeutics, including pulmonary function testing, capnometry, pulse oximetry, disposition support tools, and antimicrobial therapy, ABECB continues to be a leading cause of morbidity and mortality in the United States.¹ From patient disposition to antimicrobial selection, optimizing antimicrobial management of these patients requires the clinician to integrate a number of clinical, laboratory, radiologic, and etiologic factors, and then initiate a course of action that accounts for all the risks, costs, and benefits of an individualized treatment plan.

Despite a number of guidelines and the availability of new, targeted-spectrum antibiotics, the management of ABECB in the outpatient setting remains extremely challenging. More than ever, it requires a multifactorial analysis of myriad clinical, his-

torical, and laboratory parameters that predict success or possible failure for each individual case. In this regard, clinical decision-making in ABECB can be problematic for the emergency medicine specialist and primary care physician.

Achieving optimal patient outcomes for this common and debilitating condition requires the physician to consider several features of each individual case. (See Table 1.) Factors that must be considered include the patient's age, response to medical therapy, overall pulmonary function, character and severity of previous exacerbations, bacterial colonization status of the patient, previous requirements for mechanical ventilation, previous therapy, exacerbation-free interval, steroid use, and local antimicrobial resistance patterns. With this in mind, a severity-of-exacerbation and risk factor (SERF) pathway can be employed to help guide patient disposition, empiric antibiotic selection, and whether additional diagnostic investigation is necessary. (See Table 2.)

Currently, the bacterial pathogens most often responsible for causing "uncomplicated and typical" cases of ABECB amenable to treatment in the outpatient setting include *S. pneumoniae*, *H. influenzae*, and *M. catarrhalis*. Because it may be difficult, if not impossible, to identify a specific pathogen at the time of initial patient assessment, empiric antimicrobial coverage against all the expected (aforementioned) pathogens usually is necessary to minimize treatment failures.

Although the role of bacterial infection as the precipitating process in exacerbations of COPD has been controversial, a recent study has clarified the role of bacterial pathogens in ABE/COPD.³ In older studies, the rates of isolation of bacterial pathogens from sputum were the same during acute exacerbations and during stable disease. However, these studies failed to differentiate among strains within a bacterial species; therefore, they could not detect changes in strains over time. More recent investigations have attempted to document that acquisition of a new strain of a pathogenic bacterial species is associated with exacerbation of COPD.

To clarify the role of bacterial pathogens, investigators conducted a prospective study in which clinical information and sputum samples for culture were collected monthly and during exacerbations from 81 outpatients with COPD.³ Molecular typing of sputum isolates of nonencapsulated *H. influenzae*, *M. catarrhalis*, *S. pneumoniae*, and *P. aeruginosa* was performed.

Over a period of 56 months, the 81 patients made a total of 1975 clinic visits, 374 of which were made during exacerbations (mean, 2.1 per patient per year). On the basis of molecular typing, an exacerbation was diagnosed at 33% of the clinic visits that involved isolation of a new strain of a bacterial pathogen, as compared with 15.4% of visits at which no new strain was isolated ($p < 0.001$; RR of an exacerbation, 2.15; 95% confidence interval, 1.83-2.53). Isolation of a new strain of *H. influenzae*, *M. catarrhalis*, or *S. pneumoniae* was associated with a significantly increased risk of an exacerbation.

Investigators concluded that the association between an exacerbation and the isolation of a new strain of a bacterial pathogen supports the causative role of bacteria in exacerbations of COPD.³

Acute Bacterial Exacerbations of Chronic Bronchitis (ABECB): Antibiotic Selection Strategies

Although it is possible to make evidence-based recommendations for management of patients with ABECB, the SCMArti Clinical Consensus Panel noted that the number, quality, and design of studies evaluating and comparing effectiveness of and indications for antibiotic therapy in ABECB are less than optimal and, in general, inferior to those available for CAP. In addition, upon review of multiple studies comparing advanced-generation macrolides (i.e., azithromycin or clarithromycin) and AFQs (i.e., moxifloxacin, levofloxacin, and gatifloxacin), it is difficult to identify significant differences in clinical outcomes that could be observed in outpatients managed with these antibiotic regimens.^{4,9}

More important, perhaps, than specific antibiotic choices, is the tendency to overuse antibiotics in patients with acute, self-limited bronchitis. Only patients meeting clinical criteria for bacterial exacerbations of COPD should receive antibiotic therapy for their exacerbations. The SCMArti Clinical Consensus Panel's recommendations for antibiotic-based, outpatient management of ABECB are summarized in the following sections. These guidelines are based on supportive evidence, analysis of clinical trials, and emerging resistance trends.

Appropriate Use of Antibiotics. As a rule, the clinical criteria for initiating antibiotic therapy in a patient with a documented history of COPD, and who is suspected of having an acute bacterial exacerbation, include the presence of at least two of the following three symptoms: increasing purulence of sputum, increasing volume of sputum production, and increasing cough and/or dyspnea. In contrast, patients with symptoms of acute tracheobronchitis who have no history of COPD initially should not be treated with antibiotics, since antibiotics have not been shown to improve outcomes in this patient population.

However, it was recognized by the SCMArti Clinical Consensus Panel that in real world practice a significant percentage of patients fall into a clinical gray zone. In particular, those outpatients with persistent (i.e., > 10-14 days) symptoms of acute tracheobronchitis who have no history of COPD may be considered appropriate candidates for antibiotic therapy, especially if clinical assessment suggests that persistent symptoms may be due to infection with such atypical organisms as *C. pneumoniae* or *M. pneumoniae*. Pertussis also should be considered as an etiologic agent in this subgroup.

Appropriate use of antibiotics in ABECB requires clinical confirmation of the diagnosis, which usually is made on the basis of symptom exacerbation and clinical history. As a rule, chest x-ray is not recommended or encouraged for typical cases of ABECB, but should be considered in patients who present with an atypical presentation and in whom CAP is suspected.⁴

Appropriate antibiotic use and selection is designed to accomplish the following: 1) return patient's respiratory status (FEV₁, oxygenation, respiratory rate, symptoms, etc.) back to baseline; 2) reduce the number and frequency of exacerbations; and 3) prevent hospitalization.

The principal respiratory tract pathogens that must be covered on an empiric basis in individuals with moderate-to-severe

Table 2. OMBIRT (Outpatient Management of Bacterial Infections in the Lower Respiratory Tract) Panel Treatment[†] Guidelines¹⁷ Endorsed by SMARTI Clinical Consensus Panel

SERF CATEGORY A**

CONDITION • SEVERITY • SUSPECTED PATHOGENS

Acute Bacterial Exacerbation of COPD (ABE/COPD)

Mild severity based on SERF (severity of exacerbation and risk factors) pathway and IOTT (intensity of treatment triggers) criteria

— Suspected pathogens: *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*

Initial (preferred agent, any class) first-line therapy: Azithromycin 500 mg PO qd x 3 days

Initial (preferred AFQ): Moxifloxacin 400 mg PO qd x 5 days

Alternative first-line agents (macrolides): Clarithromycin 500 mg PO qd x 7 days

Alternative first-line agents (fluoroquinolones): Gatifloxacin 400 mg PO qd x 7 days; Levofloxacin 500 mg PO qd x 7 days

Alternative first-line agents (other classes, including generic formulations): Amoxicillin-clavulanate 875 mg PO q 12 hours x 10 days; Doxycycline 100 mg PO bid x 7-14 days; Trimethoprim-sulfamethoxazole 1 DS tablet PO bid x 7-14 days

SERF CATEGORY B

CONDITION • SEVERITY • SUSPECTED PATHOGENS

Moderate-to-severe bacterial exacerbation of COPD (ABE/COPD)

Severity based on SERF (severity of exacerbation and risk factors) pathway and IOTT (intensity of treatment triggers) criteria

— Suspected pathogens: *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*

Initial (preferred agent, any class) first-line therapy: Azithromycin 500 mg PO qd x 3 days

Initial (preferred AFQ): Moxifloxacin 400 mg PO qd x 5 days

Alternative first-line agents (macrolides): Clarithromycin 500mg PO qd x 7 days

Alternative first-line agents (fluoroquinolones): Gatifloxacin 400 mg PO qd x 7 days; Levofloxacin 500 mg PO qd x 7 days

Alternative first-line agents (other classes): Amoxicillin-clavulanate 875 mg PO q 12 hours x 10 days

SERF CATEGORY C

CONDITION • SEVERITY • SUSPECTED PATHOGENS

Severe and/or frequently recurrent bacterial exacerbation of COPD (ABE/COPD)

Severity based on SERF (severity of exacerbation and risk factors) pathway and IOTT (intensity of treatment triggers) criteria

— Associated risk factors and/historical features: Recent hospitalization for ABE/COPD and documented infection with gram-negative organisms such as: *Klebsiella*, *Pseudomonas*, and other enterobacteria; patients with structural lung disease (bronchiectasis); or patients who have failed first-line macrolide therapy.

— Suspected pathogens: *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*, in addition to possible infection with gram-negative organisms known to cause exacerbations in patients who are risk-stratified to a more severe category (see above)

Initial (preferred agent, any class) first-line therapy: Moxifloxacin (preferred) 400 mg PO qd x 5 days; Gatifloxacin 400 mg PO qd x 7 days; Levofloxacin 500 mg PO qd x 7 days

Alternative first-line agents (fluoroquinolones): Ciprofloxacin 500 mg PO bid x 10 days (Although effective in clinical trials and recommended for acute, documented gram-negative exacerbations of COPD, ciprofloxacin is not the agent of choice when ABE/COPD is thought to be secondary to *S. pneumoniae* infection)

Alternative agents (other classes): Amoxicillin-clavulanate 875 mg PO q 12 hours x 10 days

*** Approved Indications for recommended antimicrobial agents:**

Azithromycin: Indicated for acute bacterial exacerbations of COPD caused by susceptible species of *Streptococcus pneumoniae*, *Moraxella catarrhalis*, and *Haemophilus influenzae*.

Clarithromycin: Indicated for acute bacterial exacerbations of COPD caused by susceptible species of *Streptococcus pneumoniae*, *Moraxella catarrhalis*, *Haemophilus influenzae*, and *Haemophilus parainfluenzae*

Moxifloxacin: Indicated for acute bacterial exacerbations of COPD caused by susceptible species of *Streptococcus pneumoniae*, *Moraxella catarrhalis*, *Haemophilus influenzae*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, and *Haemophilus parainfluenzae*

Gatifloxacin: Indicated for acute bacterial exacerbations of COPD caused by susceptible species of *Streptococcus pneumoniae*, *Moraxella catarrhalis*, *Haemophilus influenzae*, *Staphylococcus aureus*, and *Haemophilus parainfluenzae*

Levofloxacin: Indicated for acute bacterial exacerbations of COPD caused by susceptible species of *Streptococcus pneumoniae*, *Moraxella catarrhalis*, *Haemophilus influenzae*, *Staphylococcus aureus*, and *Haemophilus parainfluenzae*

† OMBIRT Panel recommendations and preferences are based on a critical analysis and evaluation of published clinical trials, FDA indications, association guidelines, and pharmatectural criteria, including cost, spectrum of coverage, compliance parameters (daily dose frequency, duration of therapy, and side effects), pregnancy category, and risk of drug-drug and/or drug-disease interactions.

**** SERF** - Severity of Exacerbation and Risk Factor clinical assessment strategy.

ABE/COPD in the outpatient setting include *S. pneumoniae*, *H. influenzae*, *M. catarrhalis*, *H. parainfluenzae*, and *S. aureus*. Some patients, especially those with severe disease, a recent history of mechanical ventilation and hospitalization, and/or high-dose chronic steroid therapy, are more susceptible to infection with *Pseudomonas* species.

Antimicrobial Selection Strategies

The majority of double-blinded, prospective clinical trials comparing new-generation macrolides (i.e., azithromycin and clarithromycin) to new-generation fluoroquinolones (i.e., moxifloxacin, gatifloxacin, and levofloxacin) demonstrate comparable outcomes in terms of clinical cure and bacteriologic eradication rates at days 7, 14, and 28 in outpatients with either moderate or severe ABECB.^{5-7,10-13} Moreover, increasing resistance among *S. pneumoniae* to new generation fluoroquinolones, especially levofloxacin, has been reported in a number of geographic regions, including the United States, Hong Kong, and Canada.¹⁴⁻¹⁶

The precise clinical effects of these evolving resistance patterns is not completely understood. However, given the emergence of such strains and the presence of numerous studies demonstrating comparable effectiveness between macrolides and AFQs, the SMARTI Clinical Consensus Panel supports cautious and prudent use of fluoroquinolones, especially those agents with extended spectrum coverage, such as levofloxacin, for appropriately selected patients with ABECB.

For reasons related to short-course therapy, tolerability, and clinical outcomes, the SMARTI Panel recommends the advanced-generation macrolide azithromycin as the initial agent of choice for managing appropriately risk-stratified outpatients with ABECB. Among the AFQs, moxifloxacin is recommended as the initial agent of choice, except in patients in whom bacterial exacerbations of COPD are likely to be caused by gram-negative organisms such as *Pseudomonas* species. In this case, fluoroquinolones (i.e., levofloxacin or gatifloxacin) with activity against this pathogen should be considered as initial therapy.

The frequency of drug-resistant *S. pneumoniae* (DRSP) causing ABECB is not known, but is presumed to be less than or equal to the incidence of DRSP causing outpatient CAP. As a result, there is currently no evidence to support initial outpatient therapy directed at DRSP for patients with ABE/COPD. As it does in the management of CAP, the SMARTI Clinical Consensus Panel cautions against overuse of AFQs as initial agents in outpatients with ABECB, except in cases where coverage against *Pseudomonas* and other gram-negative organisms is warranted. The panel recommends use of AFQs as alternative agents when: 1) first-line therapy with advanced-generation macrolides such as azithromycin fails; 2) patients are allergic to first-line agents; or 3) patients have documented or suspected infection with gram-negative organisms resistant to macrolides.

Given concerns about antibiotic overuse, the potential for emerging resistance among DRSP to fluoroquinolones, the SMARTI Clinical Consensus Panel concurs with other guideline panels specifying advanced-generation macrolides and fluoroquinolones as initial therapy for outpatient ABECB. Fluoro-

quinolones are recommended in patients who fail therapy or who have risk factors predictive of gram-negative infection. Patients who do not respond to oral therapy with one class of antibiotics (relapse) may be treated with a course of antibiotics with different gaps in coverage. Reinfections should be treated with antibiotics that have been shown to be effective in previous exacerbations. Cost factors also should be considered. Agents such as TMP/SMX, tetracycline, and amoxicillin are less costly than non-generic antibiotics, and when acquisition of drug therapy is compromised by cost factors, such second-line agents are preferable.

Unfortunately, limited data exist to guide physicians in the cost-effective treatment of ABECB. One important study, however, attempted to determine the antimicrobial efficacy of various agents and compared total outcome costs for patients with ABECB.¹⁸ For the purpose of this analysis, a retrospective review was performed of 60 outpatient medical records of individuals with a diagnosis of COPD associated with acute episodes seen in the pulmonary clinic of a teaching institution. Empirical antibiotic choices were divided into first-line (amoxicillin, co-trimoxazole, tetracyclines, and erythromycin); second-line (cephradine, cefuroxime, cefaclor, and cefprozil); and third-line (azithromycin, amoxicillin-clavulanate, and ciprofloxacin) agents. In this study, patients receiving first-line agents (amoxicillin, co-trimoxazole, tetracyclines, and erythromycin) failed significantly more frequently (19% vs 7%; $p < 0.05$) than those treated with third-line agents (azithromycin, amoxicillin-clavulanate, and ciprofloxacin). Moreover, patients prescribed first-line agents were hospitalized significantly more often for ABE/COPD within two weeks of outpatient treatment as compared with patients prescribed third-line agents (18.0% vs 5.3% for third-line agents; $p < 0.02$). Time between subsequent ABE/COPD episodes requiring treatment was significantly longer for patients receiving third-line agents compared with first-line and second-line agents ($p < 0.005$).¹⁸

Two advanced-generation macrolides (azithromycin and clarithromycin) are available for treating ABECB. Based on outcome-sensitive criteria and pharmaceutic considerations such as cost, daily dose frequency, duration of therapy, side effects, and drug interactions, the SMARTI Clinical Consensus Panel recommends azithromycin as preferred initial therapy in moderate-to-severe, non-hospitalized patients, with clarithromycin or doxycycline as an alternative agent; among AFQs, moxifloxacin is preferred for initial therapy, with gatifloxacin or levofloxacin as alternative agents. Amoxicillin-clavulanate is another effective option. When historical or clinical factors in the SERF (Severity of Exacerbation and Risk Factor) pathway suggest the presence of gram-negative infection, an expanded spectrum fluoroquinolone would be considered the agent of choice. Physicians are urged to prescribe antibiotics in ABECB at the time of diagnosis and to encourage patients to fill and begin taking their prescriptions on the day of diagnosis.

Primary care physicians are discouraged from using antibiotics for "chronic prophylaxis" against ABE/COPD, since studies do not support the efficacy of this strategy for preventing acute exacerbations. Patients should be instructed about issues

related to the importance of medication compliance. In the case of short (3-day) courses of therapy, they should be educated that although they are only consuming medications for a three-day period, such antibiotics as azithromycin remain at the tissue site of infection for about nine days and continue to deliver therapeutic effects during that period.

Either verbal or on-site, reevaluation of patients is recommended within a three-day period following diagnosis and initiation of antibiotic therapy. Follow-up in the office or clinic within three days is recommended in certain risk-stratified patients, especially the elderly, those with co-morbid illness, significantly impaired FEV₁, and those in whom medication compliance may be compromised.¹⁹ More urgent follow-up may be required in patients with increasing symptoms, including dyspnea, fever, and other systemic signs or symptoms. Follow-up chest x-rays generally are not recommended in patients with outpatient ABE/COPD, except in certain high-risk groups.

* *The SCMARTI Clinical Consensus Panel & Scientific Roundtable was supported by an unrestricted educational grant from Pfizer Pharmaceuticals.*

References

1. Statistics VaH. Current Estimates from the National Health Interview Survey. NHS Publication. 1990:1643.
2. Cydulka R, McFadden E, Emerman C, et al. Patterns of hospitalization in elderly patients with asthma and chronic obstructive pulmonary disease. *Am J Respir Crit Care Med* 1997;156:1807-1812.
3. Sethi S, Evans N, Grant BJ, et al. New strains of bacteria and exacerbations of chronic obstructive pulmonary disease. *N Engl J Med* 2002;347:465-471.
4. Shu D, et al. A controlled randomized multicenter trial comparing 5 days of azithromycin to 10-14 days of clarithromycin for the treatment of acute bacterial exacerbations of chronic bronchitis. In: American Society for Microbiology, ed. 37th Interscience Conference on Antimicrobial Agents and Chemotherapy; Sept. 28-Oct. 1, 1997; Toronto, Ont. Washington, D.C.; 1997:372.
5. DeAbate CA, Mathew CP, Warner JH, et al. The safety and efficacy of a short course (5-day) moxifloxacin vs. azithromycin in the treatment of patients with acute exacerbation of chronic bronchitis. *Respir Med* 2000;94:1029-1037.
6. Kreis S, Herrera N, Golzar N, et al. A comparison of moxifloxacin and azithromycin in the treatment of acute exacerbations of chronic bronchitis. *JCOM* 2000;7:33-37.
7. Bauernfreund A, Jungwirth R, Eberlein E. Comparative pharmacodynamics of clarithromycin and azithromycin against respiratory pathogens. *Infection* 1995;23:316-321.
8. Guggenbichler JP, Kastner H. The influence of macrolide antibiotics on the fecal and oral flora. *Infect Medicate* 1998;15(Suppl D):17-25.
9. Adam D, Grimm H, Lode H, et al. Comparative pharmacodynamics of clarithromycin and azithromycin against respiratory pathogens. *Infection* 1996; 24:270-271.
10. Warren Whitlock on behalf of the Multicenter Chronic Obstructive Pulmonary Disease Study Group. Multicenter comparison of azithromycin and amoxicillin/clavulanate in the treatment of patients with chronic obstructive pulmonary disease. *Curr Therapeutic Res* 1995;56:10.
11. Grossman RF. The value of antibiotics and the outcomes of antibiotic therapy in exacerbations of COPD. *Chest* 1998;113:249S- 255S.
12. Chodosh S, Schreurs A, Siami G, et al. Efficacy of oral ciprofloxacin vs. clarithromycin for treatment of acute bacterial exacerbations of chronic bronchitis. The Bronchitis Study Group. *Clin Infect Dis* 1998;27:730-738.
13. Shu D, et al. A controlled randomized multicenter trial comparing 5 days of azithromycin to 10-14 days of clarithromycin for the treatment of acute bacterial exacerbations of chronic bronchitis. In: American Society for Microbiology, ed. 37th Interscience Conference on Antimicrobial Agents and Chemotherapy; 1997 Sept.-Oct. 28-1; Toronto, Ont. Washington, D.C.; 1997:372.
14. Chen D, McGeer A, de Azavedo JC, et al, and The Canadian Bacterial Surveillance Network. Decreased susceptibility of *Streptococcus pneumoniae* to fluoroquinolones in Canada. *N Engl J Med* 1999;341:233-239.
15. Linares J, De La Campa AG, Pallares R. Fluoroquinolone resistance in *Streptococcus pneumoniae* [letter]. *N Engl J Med* 1999; 341:1546-1547.
16. Ho PL, Que TL, Tsang DN, et al. Emergence of fluoroquinolone resistance among multiply resistant strains of *Streptococcus pneumoniae* in Hong Kong. *Antimicrob Agents Chemother* 1999;43: 1310-1313.
17. Bosker G, Villica B, Bonanni P, et al. Outpatient management of bacterial infections in the lower respiratory tract (OMBIRT): Diagnosis, evaluation, and antibiotic selection in the primary care setting. *Infect Dis Consensus Rep* Oct. 1, 2002.
18. Davies J. Inactivation of antibiotics and the dissemination of resistance

SCMARTI Panel Chairman: Gregory A. Volturo, MD, FACEP, Vice Chairman and Associate Professor, Department of Emergency Medicine, University of Massachusetts, Worcester, Massachusetts. **Distinguished SCMARTI Panel Members: Dave Howes, MD, FACEP**, Program Director and Chairman, Residency Program, Department of Emergency Medicine, University of Chicago Hospitals and Clinics, Associate Professor, Pritzker School of Medicine, Chicago, Illinois; **David Lang, DO, FACEP**, Operation Medical Director, Department of Emergency Medicine, Mt. Sinai Medical Center, Miami, Florida; **Sandra Schneider, MD, FACEP**, Professor and Chairman, Department of Emergency Medicine, University of Rochester/Strong Memorial Hospital, Rochester, New York; **Ethel Smith, MD**, Director, Quality Resource Unit, Case Western Reserve University, Department of Family Practice, MetroHealth Medical Center, Cleveland, Ohio; **Paul Stander, MD, FACP**, Medical Director, Department of Medicine, Banner Healthcare Systems, Author, *Quick Consult Manual for Primary Care Medicine*, Department of Internal Medicine, Arizona Health Science University; **Gideon Bosker, MD**, Section of Emergency Medicine, Yale University School of Medicine and Oregon Health Sciences University, Editor-in-Chief, *Emergency Medicine Reports*, Editor-in-Chief, *Clinical Consensus Reports*.

Statement of Financial Disclosure: In order to reveal any potential bias in this publication, and in accordance with the Accreditation Council for Continuing Medical Education guidelines, we disclose that Dr. Howes is on the speaker's bureau for Roche; Dr. Stander owns stock in Pfizer; Dr. Schneider and Dr. Smith have no financial interests related to the field of study covered by this article; for Dr. Volturo and Dr. Bosker, see the disclosure statement on page 294; Dr. Lang did not return his disclosure form.

genes. *Science* 1994;264:375-382.

19. Kanner RE, Renzetti AD, Jr., Stanish WM, et al. Predictors of survival in subjects with chronic airflow limitation. *Am J Med* 1983;74:249-255.

Physician CME Questions

211. There is a significant amount of data from large, well-controlled prospective trials to provide definitive guidance for the choice of antibiotic therapy in exacerbations of COPD.
- A. True
 - B. False
212. Which of the following factors influence patient disposition in ABE/COPD?
- A. Age of patient
 - B. O₂ saturation
 - C. Steroid use
 - D. Pulmonary function tests
 - E. All of the above
213. Factors such as local antibiotic resistance patterns, epidemiological and infection incidence data, and patient demographic features must be considered in selecting for appropriate antibiotic selection in ABECB.
- A. True
 - B. False
214. Which of the following bacterial pathogens is most often responsible for causing uncomplicated and typical cases of ABECB that are amenable to treatment in the outpatient setting?
- A. *S. pneumoniae*
 - B. *H. influenzae*
 - C. *M. catarrhalis*
 - D. All of the above
215. Which of the following statements is true regarding studies of antibiotic therapy in ABECB?
- A. The number, quality, and design of studies evaluating effectiveness of antibiotic therapy in ABECB is optimal.

CME Instructions

Physicians participate in this continuing medical education program by reading the article, using the provided references for further research, and studying the questions at the end of the article. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to evaluate their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. *After completing this activity, you must complete the evaluation form that will be provided at the end of the semester and return it in the reply envelope provided to receive a certificate of completion.* When your evaluation is received, a certificate will be mailed to you.

- B. The studies on antibiotic therapy in ABECB are superior to those for CAP.
 - C. In multiple studies comparing advanced-generation macrolides and AFQs, it is difficult to identify significant differences in clinical outcomes that could be observed in outpatients managed with these regimens.
 - D. There is a tendency to underuse antibiotics in patients with acute, self-limited bronchitis.
216. Patients with symptoms of acute tracheobronchitis who have no history of COPD initially should not be treated with antibiotics because they have not been shown to improve outcomes in this population.
- A. True
 - B. False
217. Which of the following statements is true regarding clinical confirmation of ABECB diagnosis?
- A. Clinical confirmation usually is made on the basis of symptom exacerbation and clinical history.
 - B. Chest x-rays are recommended for typical cases of ABECB.
 - C. Chest x-rays should not be considered in patients in whom CAP is suspected.
 - D. Clinical confirmation of the diagnosis of ABECB is not required to ensure appropriate use of antibiotics.
218. Appropriate antibiotic use and selection is designed to accomplish which of the following?
- A. Return the patient's respiratory status to baseline
 - B. Reduce the number of exacerbations
 - C. Reduce the frequency of exacerbations
 - D. Prevent hospitalization
 - E. All of the above
219. Which of the following respiratory tract pathogens must be covered on an empiric basis in individuals with moderate-to-severe ABE/COPD in the outpatient setting?
- A. *S. pneumoniae* and *H. influenzae* only
 - B. *S. pneumoniae*, *H. influenzae*, and *M. catarrhalis*
 - C. *S. pneumoniae*, *H. influenzae*, *M. catarrhalis*, *H. parainfluenzae*, and *S. aureus*
 - D. *M. catarrhalis*, *H. parainfluenzae*, and *S. aureus*
220. Which of the following patients are more susceptible to infection with *Pseudomonas* species?
- A. Those with severe disease only
 - B. Only patients with a history of hospitalization
 - C. Only patients on high-dose chronic steroid therapy
 - D. Patients with severe disease, a recent history of hospitalization or mechanical ventilation, and/or high-dose chronic steroid therapy

CME Answer Key

211. B; 212. E; 213. A; 214. D; 215. C; 216. A; 217. A; 218. E; 219. C; 220. D

OMBIRT (Outpatient Management of Bacterial Infections in the Lower Respiratory Tract) Panel Treatment[†] Guidelines Endorsed by SCARTI Clinical Consensus Panel

SERF** CATEGORY A

CONDITION • SEVERITY • SUSPECTED PATHOGENS

Acute Bacterial Exacerbation of COPD (ABE/COPD)

Mild severity based on SERF (severity of exacerbation and risk factors) pathway and IOTT (intensity of treatment triggers) criteria
— Suspected pathogens: *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*

Initial (preferred agent, any class) first-line therapy: Azithromycin 500 mg PO qd x 3 days

Initial (preferred AFQ): Moxifloxacin 400 mg PO qd x 5 days

Alternative first-line agents (macrolides): Clarithromycin 500 mg PO qd x 7 days

Alternative first-line agents (fluoroquinolones): Gatifloxacin 400 mg PO qd x 7 days; Levofloxacin 500 mg PO qd x 7 days

Alternative first-line agents (other classes, including generic formulations): Amoxicillin-clavulanate 875 mg PO q 12 hours x 10 days; Doxycycline 100 mg PO bid x 7-14 days; Trimethoprim-sulfamethoxazole 1 DS tablet PO bid x 7-14 days

SERF CATEGORY B

CONDITION • SEVERITY • SUSPECTED PATHOGENS

Moderate-to-severe bacterial exacerbation of COPD (ABE/COPD)

Severity based on SERF (severity of exacerbation and risk factors) pathway and IOTT (intensity of treatment triggers) criteria
— Suspected pathogens: *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*

Initial (preferred agent, any class) first-line therapy: Azithromycin 500 mg PO qd x 3 days

Initial (preferred AFQ): Moxifloxacin 400 mg PO qd x 5 days

Alternative first-line agents (macrolides): Clarithromycin 500mg PO qd x 7 days

Alternative first-line agents (fluoroquinolones): Gatifloxacin 400 mg PO qd x 7 days; Levofloxacin 500 mg PO qd x 7 days

Alternative first-line agents (other classes): Amoxicillin-clavulanate 875 mg PO q 12 hours x 10 days

SERF CATEGORY C

CONDITION • SEVERITY • SUSPECTED PATHOGENS

Severe and/or frequently recurrent bacterial exacerbation of COPD (ABE/COPD)

Severity based on SERF (severity of exacerbation and risk factors) pathway and IOTT (intensity of treatment triggers) criteria

— Associated risk factors and/historical features: Recent hospitalization for ABE/COPD and documented infection with gram-negative organisms such as: *Klebsiella*, *Pseudomonas*, and other enterobacteria; patients with structural lung disease (bronchiectasis); or patients who have failed first-line macrolide therapy.

— Suspected pathogens: *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis*, in addition to possible infection with gram-negative organisms known to cause exacerbations in patients who are risk-stratified to a more severe category (see above)

Initial (preferred agent, any class) first-line therapy: Moxifloxacin (preferred) 400 mg PO qd x 5 days; Gatifloxacin 400 mg PO qd x 7 days; Levofloxacin 500 mg PO qd x 7 days

Alternative first-line agents (fluoroquinolones): Ciprofloxacin 500 mg PO bid x 10 days (Although effective in clinical trials and recommended for acute, documented gram-negative exacerbations of COPD, ciprofloxacin is not the agent of choice when ABE/COPD is thought to be secondary to *S. pneumoniae* infection)

Alternative agents (other classes): Amoxicillin-clavulanate 875 mg PO q 12 hours x 10 days

* Approved Indications for recommended antimicrobial agents:

Azithromycin: Indicated for acute bacterial exacerbations of COPD caused by susceptible species of *Streptococcus pneumoniae*, *Moraxella catarrhalis*, and *Haemophilus influenzae*.

Clarithromycin: Indicated for acute bacterial exacerbations of COPD caused by susceptible species of *Streptococcus pneumoniae*, *Moraxella catarrhalis*, *Haemophilus influenzae*, and *Haemophilus parainfluenzae*

Moxifloxacin: Indicated for acute bacterial exacerbations of COPD caused by susceptible species of *Streptococcus pneumoniae*, *Moraxella catarrhalis*, *Haemophilus influenzae*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, and *Haemophilus parainfluenzae*

Gatifloxacin: Indicated for acute bacterial exacerbations of COPD caused by susceptible species of *Streptococcus pneumoniae*, *Moraxella catarrhalis*, *Haemophilus influenzae*, *Staphylococcus aureus*, and *Haemophilus parainfluenzae*

Levofloxacin: Indicated for acute bacterial exacerbations of COPD caused by susceptible species of *Streptococcus pneumoniae*, *Moraxella catarrhalis*, *Haemophilus influenzae*, *Staphylococcus aureus*, and *Haemophilus parainfluenzae*

† OMBIRT Panel recommendations and preferences are based on a critical analysis and evaluation of published clinical trials, FDA indications, association guidelines, and pharmatectural criteria, including cost, spectrum of coverage, compliance parameters (daily dose frequency, duration of therapy, and side effects), pregnancy category, and risk of drug-drug and/or drug-disease interactions.

** SERF - Severity of Exacerbation and Risk Factor clinical assessment strategy.

Factors Influencing Patient Disposition in ABE/COPD

- Age of patient
- Overall respiratory status
- Respiratory rate
- O₂ saturation
- Steroid use
- Degree of hypercarbia
- Patient's status compared to baseline
- Mental status
- Home environment
- Likelihood of acceptable medication compliance
- Nighttime emergency department visit
- Previous pattern of frequent relapse
- Pulmonary function tests
- FEV₁ less than 40% of predicted normal
- Multiple ED courses of aerosolized beta-agonists

Emergency Medicine Specialty Reports

S03180

October 2003

Emergency physicians (EPs), and physicians in general, have faced enormous tests of their core professionalism and ethical values in recent years. The unionization of resident physicians, the financial pressures of a managed care environment, and the thorny role of the pharmaceutical industry have presented new and difficult challenges for medicine. EPs and their actions are being examined ever more critically by the government, third-party payers, and by individual employers. We are being asked to do more for less in an increasingly hostile medicolegal environment. Additionally, much of the public trust that was once synonymous with medicine has been lost.

As a direct result of these difficult situations, a resurgence and redefinition of medical professionalism recently has occurred. Much of the current crisis in medical professionalism directly affects individual physicians in emergency departments (EDs). EPs practice medicine daily in an extreme environment and care for patients in their most vulnerable state. In addition to the often difficult rapid medical choices an EP is required to make, further challenges exist with documentation-based remuneration as well as a managed care environment. Professionalism is the core value that defines physicians as healers rather than market-based "health care providers" providing a service for a fee.

This article will discuss the history of medical professionalism in the Western world as well as explore some perceptions and controversies of professionalism as it applies to the emergency physician.

—The Editor

Introduction

Professionalism is a topic that has become increasingly important during the last several years.¹⁻³ It is now one of six core

competencies used to judge all post-graduate training programs, including emergency medicine.⁴ Several authors have expressed concern about how professionalism is incorporated in EP training programs.^{2,3,5} This concern comes, in part, due to a widespread feeling that medical professionalism is endangered.^{3,6,7}

Medical professionals who graduated prior to the past few years probably have received little formal training regarding professionalism. However, professionalism is hardly a cutting edge

theme or modern skill. Physicians in the past have used role models to learn professionalism without a formal curriculum. Some of these mentors likely left an indelible impression (good or bad) during a physician's training.⁸ While learning by modeling is often effective, it also lacks reliability and reproducibility, and the present and future of medicine demand more formal training.

Professionalism and Ethics in the ED

Author: **Richard Frederick, MD, FACEP**, Clinical Associate Professor of Surgery, Division of Emergency Medicine, University of Illinois College of Medicine, Attending Physician Department of Emergency Medicine, OSF Saint Francis Medical Center, Peoria, IL.

Peer Reviewer: **Andrew D. Perron, MD, FACEP**, Associate Residency Director, Department of Emergency Medicine, Maine Medical Center, Portland.

Definition

Professionalism as a concept can be difficult to define.³ Even though professionalism may not have been taught didactically in medical schools as recently as 20 years ago, the subject matter certainly was presented. Medical ethics and professionalism are inseparable, and often identical, disciplines. However, professionalism also focuses on the provider's clinical competency, and this often is not stressed in the more traditional teaching of medical ethics.

There are numerous definitions and categorizations of professionalism in the literature.^{3,5,9} The simplest and most encompassing definition is putting the patients' interests above those of self.^{1,6,10,11} This definition is quite easy to espouse but more difficult to follow in daily practice. It requires a focus and dedication that is not implicit in human nature. It is inherently human to demand primacy for one's own self-interests. The definition pro-

EDITOR IN CHIEF

John W. Hafner, Jr., MD, FACEP
Clinical Assistant Professor of Surgery
Department of Emergency Medicine
University of Illinois College of Medicine
at Peoria
Director of Research, Emergency Medicine
Residency
Attending Physician, OSF Saint Francis Hospital
Peoria

EDITORIAL BOARD

Theodore C. Chan, MD, FACEP
Associate Clinical Professor of Medicine
Department of Emergency Medicine
University of California
San Diego

Chris A. Ghaemmaghami, MD
Assistant Professor of Emergency
and Internal Medicine
Director, Chest Pain Center
Director, Undergraduate Medical Education
Department of Emergency Medicine
University of Virginia Medical School
Charlottesville

Richard A. Harrigan, MD, FAAEM
Associate Professor of Emergency Medicine
Temple University School of Medicine
Associate Research Director
Department of Emergency Medicine
Temple University Hospital
Philadelphia, PA

J. Stephen Huff, MD
Associate Professor of Emergency
Medicine and Neurology
Department of Emergency Medicine
University of Virginia Medical School
Charlottesville

Marcus L. Martin, MD, FACEP
Professor and Chair
Department of Emergency Medicine
University of Virginia Medical School
Charlottesville

Andrew D. Perron, MD, FACEP
Associate Residency Director
Department of Emergency Medicine
Maine Medical Center
Portland

Ralph Riviello, MD, FACEP
Assistant Professor
Department of Emergency Medicine
Thomas Jefferson University
Philadelphia, PA

Stephen W. Smith, MD
Faculty Emergency Physician
Hennepin County Medical Center
Minneapolis, MN

William A. Woods, MD
Assistant Professor of Emergency
Medicine and Pediatrics
Department of Emergency Medicine
University of Virginia Medical School
Charlottesville

© 2003 Thomson American Health Consultants
All rights reserved

vided by the American Board of Internal Medicine (ABIM) is perhaps more realistic. ABIM defines professionalism as “aspiring toward altruism, accountability, excellence, duty, service, honor, integrity and respect for others.”³ This definition very appropriately sets these virtues as goals to aspire toward, allowing for the inevitable human frailty and failure. The acknowledgment of that frailty is important to provide encouragement and keep individuals from abandoning the goal of altruism altogether.

Just as professionalism is difficult to accurately define, different individuals may also perceive it different ways. Brownell et al looked at senior resident physicians’ views on the meaning of professionalism.⁹ The authors surveyed 533 residents with a response rate of 48.4% (258 residents). Competence (50%), respect for others (48%), and empathy (39%) were the most commonly named attributes. Altruism, which is at the core of the definition of professionalism, was only named by a small minority (2.3%) of respondents.⁹

Other important attributes of professionalism that were listed by a minority of the 258 respondents included: responsibility (24%), confidentiality (19%), ethical behavior (17%), devotion (7.3%), justice (6.2%), and humility (3.9%).⁹ The majority of medical ethics and professionalism’s core values were not identified by the respondents in this study, and this underlines the need for renewed efforts in the teaching of professionalism. Negative

role model clinical educators were felt to be less important in learning the tenets of professionalism (44%).⁹ This same group felt that informal discussions were the dominant vehicle for teaching (76% of the time), while course work (28%) and teaching rounds (26%) were judged to be less important.⁷

The need for more emphasis on the teaching of professionalism is highlighted by the importance assigned to professionalism by the American College of Graduate Medical Education (ACGME).⁴ Other authors have proposed innovative ways to approach both the teaching and evaluation of professionalism to medical students and residents.^{12,13} Most of the qualities that define professionalism are virtues that are universal and inherent in the human condition. It is generally unknown how difficult or successful formal teaching of these virtues will be, especially to adult learners. Educators have struggled with the didactic presentation of virtue and ethics for centuries, which is illustrated as early as the first Greek philosophers:

“Can you tell me, Socrates, is virtue something that can be taught? Or does it come by practice? Or is it neither teaching nor practice that gives it to a man, but natural aptitude or something else?”¹⁴

Pelligrino and Thomasma believe that medical virtues can and must be taught to medical professionals.¹⁵ Admittedly, medical students arrive with their own value systems and faiths that are unlikely to be altered. However, medical faculties still have a responsibility to teach those virtues inherent in becoming a physician. Even as early as the medical school admissions process, faculty members should focus on obtaining students with values concurrent with the practice of medicine. Teaching ethics and virtue as a discipline is a vital first step, but teaching by example also is essential. To quote Pelligrino and Thomasma, “The power of a faculty model to shape behavior for good or evil is enormous. It far exceeds the power of a lecture or course on ethics.”¹⁵ Those involved in the medical education process are responsible, in at least some part, for both the virtuous and abusive physicians they have trained.

History

The three traditional professions have been defined as law, clergy, and medicine. A profession has been called “a way of life with a moral value,” a definition that distinguishes a profession as being a calling rather than just an occupation. In Studs Terkel’s book *Working*, which reviewed multiple occupations, medicine was not listed.¹⁶ The author’s reasoning was that physicians work for more than just a salary. This is more than just an academic distinction. Physicians’ voices on medical and social issues often are well received by the public, especially when they speak for patient advocacy. To quote Steven Brint: “Without a strong sense of the public and social purposes served by professional knowledge, professionals tend to lose their distinctive voice in public debate.”¹⁷ When physicians declare concern about rising malpractice rates and lack of tort reform because of exorbitant overhead costs, the public has little empathy. However, when these same alarms are sounded over a possible loss of physicians in certain states or specialties, affecting the public’s access to quality med-

Emergency Medicine Specialty Reports is published by Thomson American Health Consultants, 3525 Piedmont Road, N.E., Six Piedmont Center, Suite 400, Atlanta, GA 30305. Telephone: (800) 688-2421 or (404) 262-7436.

Vice President/Group Publisher: Brenda Mooney
Editorial Group Head: Valerie Loner
Managing Editor: Allison Mechem
Marketing Manager: Schandale Kornegay
GST Registration No.: R128870672

Periodical postage paid at Atlanta, GA. **POSTMASTER:** Send address changes to **Emergency Medicine Specialty Reports**, P.O. Box 740059, Atlanta, GA 30374.

Copyright © 2003 by Thomson American Health Consultants, Atlanta, GA. All rights reserved. Reproduction, distribution, or translation without express written permission is strictly prohibited.

Accreditation

Emergency Medicine Specialty Reports’ continuing education materials are sponsored and supervised by Thomson American Health Consultants. Thomson American Health Consultants designates this continuing education activity for up to 2 hours in Category 1 credit toward the AMA Physician’s Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.



Statement of Financial Disclosure

In order to reveal any potential bias in this publication, and in accordance with Accreditation Council for Continuing Medical Education guidelines, we disclose that Drs. Frederick (author), Perron (peer reviewer), Hafner (editor), Chan, Harrigan, Huff, Martin, Perron, Riviello, and Woods (editorial board members) report no relationships with companies related to the field of study covered by this CME program. Dr. Ghaemmaghami (board member) discloses that he receives grant support for research from Bayer Diagnostics. Dr. Smith (board member) discloses that he is a stockholder in Amgen and Merck.

Subscriber Information

Customer Service: 1-800-688-2421

Customer Service E-Mail: customerservice@ahcpub.com
Editorial E-Mail: allison.mechem@ahcpub.com

World Wide Web page: <http://www.ahcpub.com>

Thomson American Health Consultants (AHC) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. This CME activity was planned and produced in accordance with the ACCME Essentials.

This is an educational publication designed to present scientific information and opinion to health professionals, to stimulate thought, and further investigation. It does not provide advice regarding medical diagnosis or treatment for any individual case. It is not intended for use by the layman. Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

For Customer Service and CME questions,

Please call our customer service department at **(800) 688-2421**. For editorial questions or comments, please contact **Allison Mechem**, Managing Editor, at allison.mechem@ahcpub.com or (404) 262-5589.

ical care, the public is much more sympathetic.

To understand current medical ethics, it is necessary to briefly review the history of professionalism in medicine. The obligations of medicine as a profession go back to ancient times, and are embodied in the Hippocratic Oath. The statements “I will keep them from harm and injustice,” “I will come for the benefit of the sick,” and “In purity and holiness I will guard my life and my art,” certainly were at the core of professionalism remain so then and now. The struggle between self-interest and patient interest is as old as medicine itself.¹⁸

From the Middle Ages to the 1700s, medicine was perceived more as a trade than a profession in the Western world. During the 1700s, the practice of medicine was competitive and market-based. Training was obtained through unregulated apprenticeships. It was during this time that the modern beginnings of professionalism were articulated by Dr. John Gregory of Scotland, who argued that the physician should be the fiduciary of the patient.^{19,20} Dr. Thomas Percival, who in 1805 wrote a seminal code of medical ethics, felt that there are three primary obligations in the fiduciary relationship. The first is an adherence to clinical competence, the second an elevation of the patients’ interests above that of the physician, and the third to maintain a “confidence that a life of service to patients will result in adequate remuneration.”²¹

In the 1800s, the advent of formal training and medical schools advanced the cause of professionalism greatly. There was significant resistance to the idea of regulation of medical training and degrees by the status quo. At that time, Yale and Harvard universities had a great deal of political influence and were successful in promoting formal training through medical schools. The American Medical Association formally published its first code of ethics in 1847. Society, in turn, recognized medicine as a profession, allowing physicians to regulate themselves, which is an important distinction between a profession and a trade.

In the early 1900s, professionalism continued to advance. In 1914, the New York Supreme Court gave a landmark ruling regarding patient autonomy. From 1940 to the 1960s, the Nuremberg and Helsinki declarations expanded that autonomy in the area of human research. This expansion of patient’s rights was affirmed in 1948 as the World Medical Association echoed much of the tenets of the Hippocratic Oath in their Declaration of Geneva Physician’s Oath. The oath was also born in response to atrocities committed by doctors in Nazi Germany and adopted near the same time as the United Nations Universal Declaration of Human Rights in 1948. The oath is applicable to all medical professionals and states that the adoptee “will practice [their] profession with conscience and dignity; the health of [their] patient will be [their] first consideration.” The oath further states: “I will maintain the utmost respect for human life from the time of conception, even under threat. I will not use my medical knowledge contrary to the laws of humanity.”²²

At this same time, unprecedented scientific and technological breakthroughs expanded the scope, as well as the cost, of medicine. This increase in medical costs also increased physician remuneration. This, together with concurrent sweeping social changes in America, caused professionalism to be questioned in the 1960s.

As medical costs continued to escalate during the next several decades, business joined government in an attempt to regulate costs. The managed care environment that subsequently emerged posed its own set of dangers to professionalism, felt by many to be more profound than that of the fee-for-service era.^{7,23,24} The challenge to remain primarily a patient advocate in a cost limiting environment seemed to threaten the very core of physician professionalism. Physicians by definition and tradition were formerly charged with placing a patient’s interests ahead of their own. In a managed care atmosphere physicians also are forced to place patients’ interests ahead of the payer’s interests, who might then hold providers economically accountable. This choice becomes even more ethically difficult when the physician is a direct employee of the managed care organization.

Alternatively, managed care also may be regarded as a steward for finite health care resources. Physicians should have a societal duty in the management of dwindling health care resources and in containing medical costs. It has been argued that clinical fidelity and societal responsibilities are not mutually exclusive, and each must be mediated in a case-by-case method.²⁵ Furthermore, there is an ethical value to clinical work occurring on behalf of socially desirable ends, but for the medical professional the privileged position of clinical fidelity must first be acknowledged.²⁵

Dr. Bulger, in his book, *Quest for Mercy*, points out the dangers of a health care system that uses a core principle of financial incentives for limiting expenditures for medical care. In addition, there are potential concomitant dangers to restrictions placed on a physician’s time. He writes, “Those caregivers whose time is excessively restricted may well lose altogether the time it takes to develop the trust that in turn empowers patients to enter into their own healing.”²⁶ On the other hand, Dr. Puma, in a series of essays entitled “Managed Care Ethics,” challenges physicians and managed care organizations to practice cooperatively in an ethical, patient-centered environment. These essays highlight many of the dilemmas facing the managed care physician, the patient, and the managed care institutions. It is felt that unless all, or at least the majority, of physicians act in concert on the vital issues surrounding patient advocacy it will become difficult to make a substantive difference.²⁷

It should not be assumed that the present crisis in professionalism is solely due to the advent of managed care. The concern regarding the decline of professionalism also is shared in the United Kingdom and Europe, where government-based, single-payer systems are the rule. “Medical Professionalism in the New Millennium: A Physician Charter” was a joint effort of the ABIM and the European Federation of Internal Medicine (EFIM) to illuminate a variety of professional issues.³ The recent concern regarding the decline in medical professionalism appears to be largely universal and multifactorial, and cannot be specifically linked to a single medical or insurance system.

Components of Professionalism

The role of medical professionalism in patient care has been expanded and adapted over the past century and also served in

Table 1. Nine Behaviors of Medical Professionalism

1. Physicians subordinate their own interest to the interests of others.
2. Physicians adhere to high ethical and moral standards.
3. Physicians respond to societal needs, and their behaviors reflect the social contract with the communities served.
4. Physicians advance core humanistic values including honesty, integrity, caring and compassion, altruism and empathy, respect for others, and trustworthiness.
5. Physicians exercise accountability for themselves and for their colleagues.
6. Physicians demonstrate a continuing commitment to excellence.
7. Physicians exhibit a commitment to scholarship and to advancing their field.
8. Physicians deal with high levels of complexity and uncertainty.
9. Physicians reflect upon their actions and decisions.

developing the modern version of professionalism. However, despite the many changes in medicine, the principles of patient advocacy and altruism remain at the core of modern day professionalism. As previously discussed, medical professionalism has been difficult concept to accurately define. However, the qualities and behaviors closely associated with professionalism often are much easier to describe. These components are helpful in eliciting a more complete picture of what professionalism means in the twenty-first century.

Dr. Herbert Swick published a normative definition of medical professionalism, which he divided into the nine behaviors listed in Table 1.⁵ Dr. Swick proposes that this definition encompasses both the nature of the profession as well as the nature of the physicians' work.⁵ Dr. Cruess published a list of the characteristics defining professions and professionals. (See Table 2.) This list addresses the professions as a whole, but its tenets remain in the context of medical professionalism.²

ABIM commissioned a medical professionalism project involving ABIM, the American College of Physicians (ACP), American Society of Internal Medicine (ASIM) Foundation, and the European Federation of Internal Medicine. The preamble states that, "Professionalism is the basis of medicine's contract with society, and demands placing the interests of patients above those of physicians, setting and maintaining standards of competence and integrity in providing expert advice to society in matters of health."³

The fundamental principles on which ABIM's charter was based are the principles of primacy of patient welfare, patient autonomy, and social justice.³ The ABIM charter then follows these principles with a set of professional responsibilities. These responsibilities are defined as commitments to the responsibilities listed in Table 3.

Although a list of responsibilities like the one in Table 3 may seem straightforward, in practice professionalism can be thought of as more of an art than a science. After sufficient contact, it is possible to recognize specific actions and demeanors that embody the highest level of professionalism. Attempting to

Table 2. Characteristics of Professions and Professionals

- A profession possesses a discrete body of knowledge and skills over which its members have exclusive control.
- The work based on this knowledge is controlled and organized by professional associations that are independent of both state and capital (i.e., the marketplace).
- The mandate of these associations is formalized by a variety of written documents, including laws covering licensure and regulations granting authority.
- Professional associations are the ultimate authorities on the personal, social, economic, cultural, and political affairs relating to their domains, and they are expected to influence public policy and inform the public within their areas of expertise.
- Admission to professions requires prolonged educations and training; the professions are responsible for determining the qualifications and (usually) the numbers to be admitted, the substance of training, and the requirements of its completion.
- Within the constraints of the law, the professions control admission to practice and the terms, conditions, and goals of the practice.
- The professions are responsible for the ethical and technical criteria by which their members are evaluated, and have the exclusive right and duty to discipline unprofessional conduct.
- Individual members remain autonomous in their workplaces within the limits of rules and standards laid down by the associations and relevant laws.
- Professionals are expected to gain their livelihoods by providing service to the public in the areas of their expertise.
- Members are expected to value performance above reward.
- Professions and professionals must be moral and are held to higher standards of behavior than are non-professionals.
- Professionalism is an ideal to be pursued.

Sources: 1) Cruess R, Cruess S. Teaching medicine as a profession in the service of healing. *Acad Med* 1997;72:941-952.; 2) *Oxford English Dictionary*, 2nd ed. Oxford, U.K.: Clarendon Press; 1989; 3) Cruess S, Cruess R. Teaching professionalism. *BMJ* 1997;314:1674-1677.

measure or evaluate professionalism often is based on subjective qualitative reports. One example of an attempt to measure professionalism is a scale developed by Arnold et al.²⁹ The scale is based on physician responses to a questionnaire measuring the perceived overall environment of professionalism at their institution. Barry et al developed a physician survey instrument using six clinical scenarios designed to assess physician satisfaction with their training in professionalism.⁶ An investigator panel judged the most appropriate response for the clinical scenarios noted a range of acceptable answers in 12-86% of scenarios. Most (73%) of the respondents reported having 10 or fewer hours of formal training in professionalism.

As eluded to earlier, much of the decline in professionalism has occurred due to an overemphasis of business and economic culture in medicine. The covenantal relationship that has been at the core of the physician-patient relationship is clearly in danger.⁷ Pellegrino has accurately described the physician-patient relationship as a

Table 3. Professional Responsibilities

1. Professional competence
2. Honesty with patients
3. Patient confidentiality
4. Maintaining appropriate relations with patients
5. Improving quality of care
6. Improving access to care
7. Just distribution of finite resources
8. Scientific knowledge
9. Maintaining trust by managing conflict of interest
10. Professional responsibilities

covenant.¹⁵ A covenant implies an overall aura of fidelity and trust. These qualities stand in sharp contradistinction to the business contract, for which the adages “Look out for No. 1” and “Let the buyer beware” have been applied. Yet, even current common medical terminology reflects the influence of the business culture. Physicians are commonly referred to as “health care providers” and patients as “clients” or “customers.” Use of this language demeans the patient-physician relationship to the level of that of a business selling a product or service to a customer. Ruth Malone writes, “The product-market metaphor for [health care] policy implies that our moral capacity toward others is something up for sale.”³⁰ Physicians are the most qualified to advocate for patients, and this must supercede whatever responsibilities they have to payers.

Another factor in the decline of professionalism is physicians who become victims of their own technology. Physicians now are able to make diagnoses and affect cures that were unheard of in the 1940s and 1950s. Dr. Bulger refers to physicians as “scientific healers,” and feels that modern physicians have embraced too much the role of scientist and largely neglected the role of healer.²⁷ Bulger also points out the devotion to the reductionist, biomolecular orientation in medicine, which leaves little room for the “healer” role. If a scientific cure for a disease cannot be offered, physicians may either be reluctant or unable to offer their advice, presence, counsel, and empathy.

Bulger defines illness as disease plus suffering. Many diseases, such as diabetes, are chronic, but diabetics are only considered to be ill when their disease causes suffering. Suffering goes beyond physical pain and includes a fear of death, a loss of control, the dread of abandonment, and the loss of self-esteem. He points out that our society tends to shun suffering, and many physicians do the same.²⁶ Perhaps many of the physicians in older eras were perceived as being more professional because they effectively addressed suffering. What these physicians lacked in scientific armamentarium of modern medicine may have been replaced by increased patient communication and compassion.

Professionalism in Organized Medicine

Professionalism is a responsibility that goes beyond the individual physician and is transferred to the medical profession as a whole. This is particularly true of professional associations. The first level of professionalism must be individual. The second should be collective. These associations historically have led the

Table 4. Guidelines for Professional Organizations

1. The mission of a professional association ought to be consistent with that of the medical profession itself.
2. Medical associations should not embrace unions or try to become unions.
3. The financial support of professional medical associations ought to come from members' dues or charitable grants, not from business endorsements.
4. Journals owned by the associations must be guaranteed editorial independence.
5. Financial support for meetings should not be elicited by outside manufacturers.
6. Governance must be democratic reflecting the input of the membership with full accountability to that same membership.

professional field in developing codes of ethics, that guide conduct. There always has been a tension between self and ethical obligations.¹⁸ In an era when economic reimbursements are an enormous concern, this becomes a much larger issue. Peligrino and Railman call upon medical professional organizations to “reaffirm the ethical commitment to ground physician authenticity” and set forth six guidelines to help professional associations retain their professionalism.¹⁸ (See Table 4.)

Physician Arrogance

Many of the attributes of professionalism have been discussed and at times individuals may demonstrate behaviors that are the very opposite of professionalism. Chief among these is arrogance. Arrogance among physicians may be felt to be so commonplace as to scarcely seem worthy of mention. However, this is likely another factor that has also contributed to the decline of professionalism. In the past, physicians assumed a paternalistic role, being held in great esteem by the public and rarely having their authority or knowledge questioned.³¹ Today patients represent a more involved and educated population, often requiring autonomous control of their decisions. In addition to physicians' propensity to be impressed with their own knowledge and skills, the increasing impersonalization of medicine is epitomized in the managed care environment.³¹ As pointed out earlier, many physicians are more comfortable with their role as scientists than as healers. To truly relate to suffering, however, one cannot be arrogant or detached. Most physicians who themselves become patients experiencing significant suffering gain great insights into the true patient-physician relationship.³¹

The Abusive Physician

Much of the discussion thus far has centered on the relationship of the physician to the patient, which is at the core of a physician's identity. It also is vitally important to explore how physicians relate to each other and to other health care workers. The abusive physician is the extreme offshoot of the arrogant physician, and is the antithesis of the professional. This type of physician behavior, unfortunately, is addressed primarily in the nursing

literature with very little or no mention found in the medical literature.^{32,33} This is regrettable, but understandable, as nurses probably are the most common victims of the abusive physicians' behavior. They are not, however, the only recipients. Rare is the emergency physician who has not had to endure an abusive tirade from a primary care or specialist colleague. Residents and medical students in all fields are particularly vulnerable, as they may be dependent on an abusive physician for an evaluation of their competence and performance. Allied health care personnel also are frequent victims of inappropriate physician behavior.

The immediate problem may appear to be between the abusive physician and his/her victim, but in reality, it is a problem for all physicians. As there are ethical obligations of professional organizations, there are similar obligations for medical staff members within institutions. Professionalism not only includes physician monitoring of peers' clinical competence, but their behavior as well. Physicians should be at the forefront of implementing institutional policies to address the abusive physician. There are many policies already in existence that are easily accessible through the literature (primarily nursing or hospital literature).^{33,34} The AMA Code of Medical Ethics recommends instituting such a policy for each medical staff and includes guidelines for such a policy.³⁵

Relationships with the Pharmaceutical Industry

The role of professionalism in the relationship with the pharmaceutical industry also deserves discussion. The full breadth of this topic is beyond the scope of this article, but the way in which a physician interacts with the biomedical industry has far-reaching implications for patients, peers, and any physicians in training he/she may be in contact with. Honesty, integrity, altruism, and trustworthiness are virtues inherent in professionalism, and all must be considered carefully in a physician's dealings with the pharmaceutical industry

The biomedical industry is involved in three major categories of interaction: 1) Company-funded clinical trials; 2) Company-sponsored CME; and 3) Gifts and information on products.³⁶ Guidelines dealing with the first category can be found in the AMA Code of Medical Ethics.³⁵

The AMA guidelines on gifts from industry represent a good reference for an often nebulous topic. Gifts accepted should entail a benefit to patients and should not be of substantial value. Textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash is never appropriate. Individual gifts of minimal value are permissible as long as the gifts are related to the physicians' work (i.e., pens or note pads).³⁵

Additional guidelines for physician relationships with pharmaceutical companies concern themselves with conferences, meetings, and CME. The AMA defines a legitimate conference as having "objective scientific and educational activities and discourse" as well as the "main incentive for bringing attendees together is to further their knowledge on the topic." Subsidies from industry for CME are allowable as long as the monies go to the sponsoring organization and not to the individual physician. Subsidies for travel, lodging, or personal expenses of participat-

ing physicians are prohibited. Funds may be given for medical students to attend conferences as long as the funds are administered by the academic institution and used only for meetings of merit. No gifts should be accepted if there are strings attached.³⁵

In general these guidelines are well thought out and provide a good starting point for individual decisions. However, the influence that drug companies prevail on prescribing patterns is well documented. Forty-six percent of physicians report that drug representatives are moderately to very important in influencing their prescribing habits,³⁷ and one-third of medical residents report that they change their practice based on information provided by drug representatives.³⁸ Drug companies spent an estimated \$15.7 billion on promotion and distributed \$7.2 billion worth of free samples in 2000.³⁹ Pharmaceutical industries remain the most profitable businesses in America, posting median profits of 18% of revenue in 2001. For the remainder of Fortune 500 companies, median profits were 3.5%.⁴⁰

Case Discussions

Case No. 1. A recalcitrant 51-year-old male is coerced by his wife to come to the ED for an evaluation of chest pain that is now resolved. He is initially very resistant to answering any questions or agreeing to have any tests performed. The emergency physician spends a lengthy time establishing a rapport with the man and his wife to convince the patient of the need for further testing. He is refusing hospitalization because of economic issues unless it is definitive that "he is having a heart attack." After a negative ECG is performed, the EP suspects the patient's pain is probably secondary to reflux esophagitis and discharges him with an order for an outpatient stress test later that week. Upon discharge, the patient and his wife thank the EP for his care. The patient states, "I really trust you, Doc, and generally I don't like doctors." Several hours later and 15 minutes before the physician's shift ends, the patient returns specifically asking for the EP to evaluate him again as his chest pain has returned.

Should the EP: A) Stay over to care for him as he already has established rapport with this difficult patient; B) Instruct the nurse to relay to the patient that he is off shift and on his way home; C) Go into the patient's room with the relieving physician and help take the initial history while introducing his partner.

The first alternative is the most altruistic and meets the highest standards of professionalism. The second option is clearly suboptimal. The third choice might be a reasonable compromise to meet fiduciary obligations to the patient without compromising physician wellness.

Case No. 2. A physician is invited to a golf outing with dinner at an exclusive local country club. All expenses are paid by a pharmaceutical company, as there is a presentation during dinner regarding a new antibiotic. The physician participates and enjoys a cordial evening with other local physicians.

The physician is also a member of her hospital's Pharmacy and Therapeutics Committee. A few weeks later she receives a visit from the same pharmaceutical representative asking that she consider approving this antibiotic for use on the hospital's formulary. The representative asks if she enjoyed the golf outing,

thanks her for coming, and then makes his pitch.

Should the physician A) Tell him, remembering his largesse, she will do her best to get the drug on the hospital's formulary; B) Tell him the golf outing has nothing to do with the hospital's formulary and then terminate the conversation; C) Listen to what the representative has to say, remaining non-committal.

Choice A is obviously a clear violation of medical ethics and professionalism. Alternatives B and C are more acceptable, but any choice in this scenario contains the taint of influence. It is exceedingly difficult to deny the pharmaceutical representative had any persuasion upon the physician from the evening of CME and entertainment. Even if the physician does not feel personally compromised, the appearance of influence is undeniable.

Case No. 3. An EP is working in the ED when a patient with abdominal pain highly suspicious for appendicitis presents. After making a tentative diagnosis, the EP calls the attending surgeon who agrees to come to the ED to evaluate the patient. After he arrives, the nurse comes to the EP and says she smells alcohol on the surgeon's breath. The emergency physician observes him from afar and notes the surgeon's gait and mannerisms appear normal.

The EP should: A) Tell the nurse it is not his problem, the surgeon is here to assume care of the patient; B) Take the surgeon aside and ask him if he has been drinking alcohol; C) Investigate further by making small talk with the surgeon to observe any smell of alcohol.

Option A obviously abrogates the physician's responsibility to the patient. Choice C, while appearing to be a reasonable step, is equivocating, as a brief conversation cannot guarantee sobriety. Option B is the correct professionalism choice, but it is considerably more intimidating in real life.

Case No. 4. An EP working at a teaching hospital supervising resident physicians is caring for a complicated patient that requires the presence of the consultant. The resident calls the consultant, who arrives in ill humor and subsequently degrades the resident liberally with verbally abusive and profane language. The EP overhears this, but none of the comments are directed at her.

The EP's options are A) Tell the resident he needs to develop a "thick skin" and not to let it bother him; B) Intervene and take the consultant aside and tell him this is inappropriate behavior and ask for an apology to the resident; C) Make herself busy charting and pretend not to hear the conversation.

Both choices A and C tolerate and even encourage disruptive behavior and give the impression that it is acceptable. These choices also damage a teacher/student relationship between the attending and resident physician, and neglects the attending physician's responsibility to the resident physician. Option B is the hard but correct choice.

Case No. 5. The administration of a hospital does a retrospective chart review of their ED. They are interested in physician productivity, as well as the frequency of tests ordered for several diagnoses. The EPs are told that their reimbursement will reflect both their productivity (patients per hour) as well as their cost per diagnosis. One physician is subsequently told he is in the bottom 20% of productivity category and the top 20% of the cost category. What should be his response?

This is a more difficult scenario than the two prior cases, as there may be unnecessary tests that the physician is ordering as well as decreased patient care efficiency. However, the physician also might feel he is being asked to lower his standard of care simply for economic reasons. It may be necessary for the physician to spend more time with the patient than other emergency physicians in the group because he feels it is important to establish trust in the physician/patient relationship. Unfortunately there is no right answer to this scenario. However, it is a breach of professionalism to order fewer tests and care for more patients per hour if the physician feels it compromises his standard of care.

Conclusion

Professionalism is at the core of physician identity. The threat of economic and sociological pressures transforming the profession into simply another trade is very real and possible. Professionalism not only defines physicians, it also defines the physician-patient relationship. If physicians recommit themselves as medical professionals and act as patient advocates they can continue to count on the public's trust and confidence in their ability to regulate themselves. If physicians travel further on the path of service merchants (health care providers), they will lose public trust and the right to self-regulation. If this occurs, both the physicians as well as their patients will be the losers.

References

1. Adams J. An argument for professionalism. Society for Academic Emergency Medicine web site. Available at <http://www.saem.org/inform/adams.htm>. Accessed May 2003.
2. Cruess RL, Cruess SR, Johnston SE. Renewing professionalism: An opportunity for medicine. *Academic Medicine* 1999;74:878-884.
3. Medical Professionalism Project. Medical professionalism in the new millennium. *Ann Intern Med* 2002;136:243-246.
4. ACGME Outcome Project, General Competencies accessed at www.acgme.org/outcomes/comp/compfull.asp. Accessed Aug. 2003.
5. Swick HM. Toward a normative definition of medical professionalism. *Academic Medicine* 2000;75:612-616.
6. Barry D, Cyran E, Anderson RJ. Common issues in medical professionalism. *Am J Med* 2000;108:136-140.
7. Sullivan WM. What is left of professionalism after managed care? *Hastings Center Report*, March-April 1999:7-13.
8. Hensel WA., Dickey NW. Teaching professionalism: Passing the torch. *Academic Medicine* 1998;73:865-870.
9. Brownell AK, Côté L. Senior residents' views on the meaning of professionalism and how they learn about it. *Academic Medicine* 2001;75:734-737.
10. Finkel MA, James G. Ethical issues in emergency medicine. *Emerg Med Clin North Am* 1999;17:1-8
11. Ludmerer KM. Instilling professionalism in medical education. *JAMA* 1999;282:881-882.
12. Wear D, Castellani B. The development of professionalism: Curriculum matters. *Academic Medicine* 2000;75:602-611.
13. Larkin GL. Evaluating professionalism in emergency medicine: Clinical ethical competence. *Acad Emerg Med* 1999;6:302-311.
14. Plato. *Meno* 70a, p1-5
15. Pellegrino ED, Thomasma DC. *The Virtues in Medical Practice*. New York: Oxford University Press; 1993.

16. Turkel S. *Working*. New York: Random House; 1974.
17. Brint S. *In an Age of Experts: The Changing Role of Professionals in Politics and Public Life*. Princeton: Princeton University Press; 1994.
18. Pellegrino ED, Relman AS. Professional medical associations ethical and practical guidelines. *JAMA* 1999;282:984-986.
19. Chervenak FA, McCullough LB. Professionalism and justice: Ethical management guidelines for leaders of academic medical centers. *Academic Medicine* 2002;77:45-47.
20. McCullough LB. *John Gregory and the Invention of Professional Medical Ethics and the Profession of Medicine*. Dordrecht, The Netherlands: Kluwer Academic Publishers; 1998.
21. Pellegrino ED. "Foreword: Thomas Percival, The Ethics beneath the Etiquette" Medical Ethics, or a Code of Institutions and Precepts Adapted to the Conduct of Physicians and Surgeons, Thomas Percival, MD {Reprinted from the 1805 version} Birmingham, AL: Classics of Medicine Library; 1985:1-65.
22. Declaration of Geneva (1948). Adopted by the General Assembly of World Medical Association at Geneva Switzerland, September 1948.
23. Kuttner R. Managed care and medical education. *N Eng J Med* 1999;341:1092-1096.
24. Larkin GL. Evaluating professionalism in emergency medicine: Clinical ethical competence. *Acad Emerg Med* 1999;6:302-311.
25. Bloche MG. Clinical loyalties and the social purposes of medicine. *JAMA* 1999; 281:268-274.
26. Bulger RJ. The quest for mercy: The forgotten ingredient in health care reform. Part I. *West J Med* 1997;167:361-373.
27. Puma JL. *Managed Care Ethics: Essays on the Impact of Managed Care on Traditional Medical Ethics*. New York: Hatherleigh Press; 1998.
28. Irvine D. The performance of doctors: The new professionalism. *Lancet* 1999;353: 1174-1177.
29. Arnold EL, Blank LL, Race K et al. Can professionalism be measured? The development of a scale for use in the medical environment. *Academic Medicine* 1998;73: 119-1121.
30. Malone RE. Policy as product: Morality and metaphor in health policy discourse. *Hastings Cent Rep* 1999;29:16-22.
31. Berger AS. Arrogance among physicians. *Academic Medicine* 2002;77:145-147.
32. Rosenstein AH. Nurse physician relationships: Impact on nurse satisfaction and retention. *AJN* 2002;102:26-34.
33. Barnsteiner JH, Madigan C, Spray T. Instituting a disruptive conduct policy for medical staff. *AACN* 2001;12:378-382.
34. Neff K. Understanding and managing physicians with disruptive behavior. In: Ransom SB, et al., ed. *Enhancing Physician Performance: Advanced Principles of Medical Management*. Tampa (FL), American College of Physician Executives: 2000;45-72.
35. American Medical Association. *AMA Code of Medical Ethics: Current Opinions with Annotations*. Chicago; AMA Press: 2002-2003 Edition.
36. Lechin J. Interactions between physicians and the pharmaceutical industry: What does the literature say? *Can Med Assoc* 1993;149:1401-1406.
37. Avorn J, Chen M, Hartley R. Scientific versus commercial sources of influence on the prescribing behavior of physicians. *Am J Med* 1982;73:4-8.
38. Lurie N, Rich EC, Simpson DE, et al. Pharmaceutical representatives in academic medical centers: Interaction with faculty and housestaff. *J Gen Int Med* 1990;5:240-243.
39. IMS HEALTH Global Services; www.ims-global.com/index.html. Accessed Sept 2003.
40. Profiting from Pain: Where Prescription Drug Dollars Go. Families USA Publication No. 02-105 Families USA, Washington, DC 2002.

Physician CME Questions

Please read the text, answer the following questions, check your answers against the key, and then review the materials

again regarding any questions answered incorrectly. **To receive credit for this activity, you must return the enclosed CME evaluation by fax to 1-800-850-1232.**

1. Professionalism is defined simply as:
 - A. medical competence and professional demeanor.
 - B. board certification in a medical specialty.
 - C. placing the patient's interest ahead of physician's interest.
 - D. adherence to the Hippocratic Oath.
2. In his survey of senior residents, Brownel found which attribute of professionalism was listed the most frequently?
 - A. Altruism
 - B. Ethical behavior
 - C. Confidentiality
 - D. Competence
 - E. Empathy
3. Which of the following terms is *not* synonymous with a business culture?
 - A. Customer
 - B. Health care provider
 - C. Product
 - D. Covenant
4. According to the AMA guidelines, which of the following gifts from the pharmaceutical industry is *not* acceptable?
 - A. Modest meals
 - B. Cash for the physician's time
 - C. Textbooks
 - D. Contributions to a general scholarship fund
5. Which of the following statements about professionalism is *false*?
 - A. Professionalism is presently under attack.
 - B. Professionalism and medical ethics are inseparable.
 - C. There are no real conflicts with professionalism and managed care.
 - D. Professionalism is one of six key competencies in residency training.

Answer Key

1. C; 2. D; 3. D; 4. B; 5. C

In Future Issues:

End of Life Issues in the ED

CME Objectives

- After completing the program, participants will be able to:
- Define medical professionalism and describe its historical development;
 - Illustrate behaviors of professionals and characteristics of medical professionalism;
 - Understand the responsibilities of the medical professional; and
 - Delineate modern threats to medical professionalism.