SHEA Newsletter

Edited by Robert A. Weinstein, MD

The Society of Hospital Epidemiologists of America

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President's Message

As we approach midyear for the Society's councilors and officers, a number of milestones have been passed and several initiatives implemented. An extremely successful first national meeting was held in Baltimore March 10-12, with over 300 attendees and three days of presentations and discussions devoted to AIDS, new initiatives in hospital epidemiology and, on the final clay, leading-edge topics in infection control. Discussion at the question-and-answer sessions was spirited and detailed. Responses from presenters and attendees have been highly complimentary. Drs. Garibaldi and Hamory are reviewing the financial outcome of the meeting with our co-sponsor, *Infection Control and Hospital Epidemiology*. Dr. Dennis Schaberg is chairing a National Meeting Evaluation Committee for the SHEA Board. This committee is charged with critiquing the Baltimore meeting and making recommendations concerning the best options for timing, place and content for future national meetings of the Society

The second SHEA/CDC training program for H os pi tal E pide - miologists was in Atlanta March ?!I-31. Over 60 people applied for the 30 available positions, and as a result of the demand, attendance limit was stretched to 36. Over 28 applications were received for the five Merck Sharp & Dohme scholarships, and all participants and faculty were treated by Merck, Inc. to cocktails and dinner on the second night of the program. As a result of hard work by course coordinators Drs. Allen Kaiser, Bill Martone and Donald Goldmann, an excellent curriculum has been established and tested. Plans include some further fine tuning of the curriculum and investigation of the potential for offering a second session each year on the west coast. The Education Committee, chaired by Dr. Goldmann, has received and is reviewing several additiottal requests for educational consultation or services, and in the future may be seeking individuals to serve as program coordinators and lecturers. Individuals interested in assisting the committee should write to Dr. Goldmann, Division of Infectious Diseases, The Children's Hospital, 300 Longwood Avenue, Boston, MA 02115.

Two new committees have begun activities for the board. The first is the Position Analysis Committee, chaired by Dr. Glen Mayhall. This committee is charged with the identification and review of topics of national interest relevant to Hospital Epidemiology and preparation of statements by the Society where appropriate. The committee has been funded by the board to allow

Please send me an application form and Information about membership in The Society of Hospital Epidemiologists of America (SHEA). (Eligibility for membership requires a doctoral degree and either activity in hospital epidemiology or current participation in a training program in this field)

My address is: (Please print) _____

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Mall this request to Timothy R. Townsend, MD, SHEA Secretary Brady 119. Johns Hopkins Hospital, 600 N. Wolfe St., Baltimore, MD 21205.

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the formation and support of several "expert" groups. The Joint SHEA/APIC Task Force(s) will continue to operate under this new umbrella. Membership on the committee will always include the president-elect and the vice president, who will serve as the Chair. According to Dr. Mayhall, topics under consideration or review include medical waste handling, the HIV-infected health care worker and national health objectives for the year 2000. Individuals wishing to contribute to such discussions or to suggest topics of interest should contact Dr. Mayhall, Division of Infectious Diseases, Medical College of Virginia, MCV Station Box 19, Richmond, VA 23298.

A second committee, under the leadership of Past President, Dick Garibaldi, is the Resource Development Committee. This committee is charged with the task of stabilizing SHEA's financial base by identifying new and continuing sources of revenue, in addition to the various ad hoc sources identified for past projects. Dr. Garibaldi said in last year's messages that increasing membership is an important feature in adding to the resources of the Society, and members are urged to encourage their younger (and older) colleagues to become active members of SHEA.

The SHEA luncheon at ICAAC this year will be held on Monday, September 18, at the Four Seasons Hotel Ballroom. This year's speaker will be Dr. W. Paul Glezen of the Influenza Research Center in Houston. Dr. Glezen is professor of microbiology and pediatrics at Baylor and an expert on the epidemiology of influenza. He will discuss recent advances for dealing with influenza, residual problems in control and his thoughts on the potential for great pandemic(s) to come.

Prior to the fall meeting:. members will be receiving the ballot for new councilors and officers and a notification of a request by the board to modify the bylaws of the corporation to improve the Society's posture to protect its board and officers from liability. This latter change is recommended by legal counsel and the board as a necessary modification in lieu of major increases in liability insurance that might otherwise be requited.

I look forward to meeting you all in Houston and to a continuing successful and productive year for SHEA.

Walter J. Hierholzer, Jr., MD
President, Society of Hospital Epidemiologists of America

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A history of hypersensitivity **to** ciprofloxacin is a contraindication to its use. A history of hypersensitivity to other quinolones may **also** contraindicate the use of ciprofloxacin.

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Dosage guidelines

Mild/Moderate Infections*: 500 mg q12h

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CIPRO® TABLETS
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BRIEF SUMMARY
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INDICATIONS **AND** USAGE

Cipro® is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed below

Lower Respiratory Infections caused by *Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Proteus mirabilis, Pseudomonas aeruginosa, Haemophilus influenzae. Haemophilus parainfluenzae,* and Streptococcus *pneumoniae*

Skin and Skin Structure **Infections** caused by *Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Morganella morganii, Citrobacter freundii, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis,* and Streptococcus *pyogenes*

Bone and Joint Infections caused by *Enterobacter cloacae, Serratia marcescens,* and Pseudomonas *aeruginosa*

Urinary Tract **Infections** caused by *Escherichia colt, Klebsiella pneumoniae Enterobacter cloacae, Serratia marcescens* Proteus *mirabilis, Providencia rettgeri, Morganella morganii, Citrobacter diversus, Citrobacter freundii,* Pseudomonas *aeruginosa. Staphylococcus epidermidis,* and *Streptococcus faecalis.*

Infectious Diarrhea caused by *Escherichia coli* (enterotoxigenic strains) *Campylobacter jejuni, Shigella flexneri ,* and *Shigella sonnei** when antibacterial therapy is Indicated

*Eff cacy for this organism in this organ system was studied in fewer than 10 infections

CONTRAINDICATIONS

A history of hypersensitivity t" ciprofloxacin is a contraindication to its use A history of hypersensitivity to other quinolones may also contraindicate the "se of ciprofloxacin.

WARNINGS

CIPROFLOXACIN SHOULD NOT BE USED IN CHILDREN, ADOLESCENTS OR PREGNANT WOMEN The oral administration of ciprofloxacin caused lameness in immature dogs Histopathological examination of the weight-bearing joints of these dogs revealed permanent lesions of the cartilage Related drugs such as nalidixic acid, cinoxacin, and norfloxacin also produced erosions of cartilage of weight-bearing joints and other signs of arthropathy in immature animals of various species (SEE ANIMAL PHARMACOLOGY SECTION IN FULL PRESCRIBING INFORMATION)

PRECAUTIONS

General: As with other quinolones, ciprofloxacin may cause central nervous system (CNS) stimulation which may lead to tremor, restlessness. lightheadedness. confusion, and rarely t" hallucinations or convulsive seizures Therefore, ciprofloxacin should be used with caution i" patients with known or suspected CNS disorders, such as severe cerebral arteriosclerosis or epilepsy, or other factors which predispose to seizures (SEE ADVERSE REACTIONS)

Anaphylactic reactions following the first dose have been reported in patients receiving therapy with quinolones. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, tingling, pharyngeal or facial edema, dyspnea urticaria, and itching Only a few patents had a history of hypersensitivity reaction. Anaphylactic reactions may require epinephrine and "the, emergency measures Ciprofloxacin should be discontinued at the first sign of hypersensitivity or allergy

Severe hypersensitivity reactions characterized by rash, fever eosinophilia, jaundice and hepatic necrosis with **fatal** outcome have been reported rarely (less than one per million prescriptions) in patients receiving ciprofloxacin along with other drugs The possibility that these reactions we," related to ciprofloxacin cannot be excluded Ciprofloxacin should be discontinued at the first appearance of a skin rash or any sign "I "the, hypersensitivity reaction

Crystals at ciprofloxacin have been observed rarely in the urine of human subjects but more frequently in the urine at laboratory animals, (SEE ANIMAL PHARMACOLOGY SECTION IN FULL PRESCRIBING INFORMATION) Crystalluria related to ciprofloxacin has been reported only rarely in man. because human urine is usually acidic Patients receiving ciprofloxacin should be well hydrated. and alkalinity of the urine should be avoided The recommended daily dose should not be exceeded

Alteration of the dosage regimen is necessary for patients with impairment of renal function (SEE DOSAGE AND ADMINISTRATION)

As with any potent drug periodic assessment of organ system functions, including renal, hepatic, and hematopoietic function, is advisable during prolonged therapy

Drug **Interactions:** As with other quinolones, """current administration of ciprofloxacin with theophylline may lead to elevated plasma concentrations of theophylline and prolongation of its elimination half-life This may result in increased risk of theophyllme-related adverse reactions If concomitant use cannot be avoided, plasma levels of theophylline should be monitored and dosage adjustments made as appropriate.

Quinolones including ciprofloxacin, have also been show" to interfere with the metabolism of caffeine This may lead to reduced clearance of caffeine and a prolongation of its plasma half-life

Antacids containing magnesium hydroxide or aluminum hydroxide may interfere with the absorption of ciprofloxacin resulting in serum and urine levels lower than desired; concurrent administration of these agents with ciprofloxacin should be avoided

Concomitant administration of the nonsteroidal anti-inflammatory drug fenbufen with a quinolone has been reported to increase the risk of CNS stimulation and convulsive seizures

Probenecid interferes with the renal tubular secret,"" of ciprofloxacin and produces an increase in the level of ciprofloxacin in the serum This should be considered if patients are receiving both drugs concomitantly

As with other broad-spectrum antibiotics, prolonged use at ciprofloxacin may result in overgrowth of nonsusceptible organisms. Repeated evaluation of the patient's condition and microbial susceptibility testing is essential If superinfection occurs during therapy appropriate measures should be taken

Information **for Patients:** Patients should be advised that ciprofloxacin may be taken with or without meals The preferred time of dosing is tw" hours after a meal Patients should also be advised to drink fluids liberally and not take antacids containing magnesium or aluminum Patients should be advised that ciprofloxacin may be associated with hypersensitivity reactions even following a single dose and to discontinue the drug at the first sign of a skin rash or other allergic reaction

Ciprofloxacin may cause dizziness or kghtheadedness therefore patients should know how they react to this drug before they operate a" automobile or machinery or engage in activities requiring mental alertness or coordination

Patients should be advised that ciprofloxacin may increase the effects of theophylline and caffeine

Carcinogenesis, Mutagenesis. Impairment of Fertility: Eight *in vitro* mutagenicity tests have been conducted with ciprofloxacin and the test results are listed below

- Salmonella/Microsome Test (Negative)
- *E cob* DNA Repair Assay (Negative)
- Mouse Lymphoma Cell Forward Mutation Assay (Positive)
- Chinese Hamster V_{79} Cell HGPRT Test (Negative)
- Syrian Hamster Embryo Cell Transformation Assay (Negative)
- *Saccharomyces cerevisiae* Point Mutation Assay (Negative)
- *Saccharomyces cerevisiae* Mitotic Crossover and Gene Conversion Assay (Negative)
- Rat Hepatocyte DNA Repair Assay (Positive)

Thus, two of the eight tests were positive, but the results of the following three a *vivo* test systems gave negative results:

- Rat Hepatocyte DNA Repair Assay
- Micronucleus Test (Mice)
- Dominant Lethal Test (Mice)

Long-term carcinogenicity studies i" rats and mice have been completed After daily oral dosing for up to 2 years. there is no evidence that ciprofloxacin had any carcinogenic or tumorigenic effects in these species

Pregnancy—Pregnancy Category C: Reproduction studies have bee" performed in rats and mice at doses up to 6 times the usual daily human dose and have revealed no evidence of impaired fertility or harm to the fetus due to ciprofloxacin In rabbits, as with most antimicrobial agents, ciprofloxacin (30 and 100 mg/kg orally) produced gastrointestinal disturbances resulting in maternal weight loss and an increased incidence of abortion No teratogenicity was observed at either dose. After intravenous administration, at doses up to 20 mg/kg, no maternal toxicity was produced. and no embryotoxicity or teratogenicity was observed There are, however, no adequate and well-controlled studies in pregnant women SINCE CIPROFLOXACIN, LIKE OTHER DRUGS IN ITS CLASS. CAUSES ARTHROPATHY IN IMMATURE ANIMALS, IT SHOULD NOT BE USED IN PREGNANT WOMEN (SEE WARNINGS).

Nursing Mothers: It is not known whether ciprofloxacin is excreted i" human milk. however, it is known that ciprofloxacin is excreted in the milk of lactating rats and that other drugs of this class a," excreted i" human milk Because of this and because of the potential for serious adverse reactions fro," ciprofloxacin in nursing infants, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the Importance at the drug t" the mother

Pediatric Use: Patients under the age of 18 were not included in the clinical trials of ciprofloxacin because ciprofloxacin as well as other quinolones causes arthropathy in immature animals Ciprofloxacin should not be used i" children or adolescents (SEE WARNINGS)

ADVERSE REACTIONS

Ciprofloxacin is generally well tolerated. During clinical investigation 2 799 patients received 2,868 courses of the drug Adverse events that were considered likely to be drug related occurred i" 7 3% of courses, possibly related in 9 2% and remotely related in 3 0% Ciprofloxacin was discontinued because of an adverse event in 3 5% of courses, primarily involving the gastrointestinal system (1 5%). skin (0 6%). and central nervous system (0 4%) Those events typical of quinolones are italicized

The most frequently reported events, drug related or not, were *nausea (5.2%). diarrhea (2* 3%), *vomiting (2* 0%), *abdominal pain/discomfort* (17%), *headache* (1 2%). *restlessness* (1 1%). and *rash* (1 1%).

Additional events that occurred in less than 1% of ciprofloxacin courses are listed below

GASTROINTESTINAL (See *above),* painful oral mucosa, oral candidiasis, dysphagia, intestinal perforation, gastrointestinal bleeding.

CENTRAL NERVOUS SYSTEM (See *above). dizziness, lightheadedness, insomnia, nightmares, hallucinations, manic reaction, irritability, tremor, ataxia, convulsive seizures. lethargy, drowsiness, weakness, malaise, anorexia, phobia, depersonalization depression, paresthesia.*

SKIN/HYPERSENSITIVITY *(See above), pruritus, urticaria, photosensitivity, flushing, fever. chills, angioedema, edema of the* lace. neck. *lips, conjunctivae or hands.* cutaneous candidiasis, hyperpigmentation, erythema nodosum

Allergic reactions ranging from urticaria to anaphylactic reactions have been reported (SEE PRECAUTIONS)

SPECIAL SENSES *blurred vision, disturbed vision (change in color perception, overbrightness of lights), decreased visual acuity, diplopia, eye pain, tinnitus, hearing loss. bad taste*

MUSCULOSKELETAL *joint or back pain, joint stiffness,* achiness, neck or chest pain, flare-up of gout.

RENAL/UROGENITAL *interstitial nephritis, nephritis, renal failure,* polyuria, urinary retention, urethral bleeding, vaginitis, acidosis

CARDIOVASCULAR palpitations, atrial flutter, ventricular ectopy, syncope, hypertension angina pectoris, myocardial infarction cardiopulmonary arrest, cerebral thrombosis

RESPIRATORY epistaxis, laryngeal or pulmonary edema hiccough, hemoptysis, dyspnea, bronchospasm, pulmonary embolism

Most of the adverse events reported were described as only mild or moderate in severity, abated soon after the drug was discontinued and required no treatment

In several instances, nausea, vomiting, tremor restlessness. agitation, or palpitations were judged by investigators to be related to elevated plasma levels Of theophylline possibly as a result of a drug interaction with ciprofloxacin

Other adverse events reported in the postmarketing phase Include anaphylactoid reactions, Stevens-Johnson syndrome. exfoliative dermatitis, toxic epidermal necrolysis, hepatic necrosis, postural hypotension, possible exacerbation of myasthenia gravis. confusion dysphasia, nystagmus. pseudomembranous colitis, dyspepsia, flatulence. and constipation Also &ported were agranulocytosis; elevation of serum triglycerides serum cholesterol, blood glucose, serum potassium; prolongation of prothrombin time, albuminuria; candiduria, vaginal candidiasis, and renal calculi (SEE PRECAUTIONS)

Adverse Laboratory **Changes:** Changes in laboratory parameters listed as adverse events without regard to drug relationship

Hepatic -- Elevations of ALT (SGPT) (1 9%). AST (SGOT) (1.7%). alkaline phosphatase (0 8%). LDH (0 4%) serum bilirubin (0 3%)

Cholestatic jaundice has been reported

Hematologic—eosinophilia (0 6%). leukopenia (0 4%). decreased blood platelets (0 1%). elevated blood platelets (0.1%), pancytopenia (0.1%)

Renal—Elevations of Serum creatinine (1 1%). BUN (0 9%)

CRYSTALLURIA, CYLINDRURIA, AND HEMATURIA HAVE BEEN REPORTED.

Other changes occurring in less than 0.1% of courses were. Elevation of serum gammaglutamyl transferase, elevation of serum amylase reduction in blood glucose, elevated uric acid, decrease in hemoglobin, anemia, bleeding diathesis, increase in blood monocytes, and leukocytosis

OVERDOSAGE

Information on overdosage i" humans is not available In the event of acute overdosage, the stomach should be emptied by inducing vomiting or by gastric lavage The patient should be carefully observed and given support,"" treatment Adequate hydration must be maintained Only a small amount of ciprofloxacin (< 10%) is removed from the body after hemodialysis or peritoneal dialysis

DOSAGE AND **ADMINISTRATION**

The usual adult dosage for patients with urinary tract infections is 250 mg every 12 hours. For patients with complicated infections caused by organisms not highly susceptible, 500 mg may be administered every 12 hours

Lower respiratory tract infections, skin and skin structure infections, and bone and joint infections may be treated with 500 mg every 12 hours For more severe or complicated Infections a dosage of 750 mg may be given every 12 hours

The recommended dosage for infectious diarrhea is 500 mg every 12 hours

In patients with renal impairment, some modification of dosage is recommended (SEE DOSAGE AND ADMINISTRATION SECTION IN FULL PRESCRIBING INFORMATION)

HOW SUPPLIED

Cipro® (ciprofloxacin HCl/Miles) is available as tablets of 250 mg, 500 mg. and 750 mg in bottles of 50 and in Unit-Dose packages of 100 (SEE FULL PRESCRIBING INFORMATION FOR COMPLETE DESCRIPTION)

*Due to susceptible **strains of** indicated pathogens. **See indicated** organisms in **Prescribing Information.**

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