Antibiotic Dosing

To the Editor:

Recently, a 76-year-old man was diagnosed with aspiration pneumonia secondary to nasogastric tube feeding. On transfer from his hospital to a long-term care facility, his intravenous antibiotic therapy was changed to oral therapy. The dosage as prescribed by the attending physician (750 mg every eight hours) exceeded both the package inserts of the manufacturer and the 1991 *Physicians' Desk Reference (500* mg every 12 hours).

When an antibiotic dosage is exceeded by 2.25 times per day for ten days (with resolution of the pneumonia) how are medical directors or therapeutic committee members to evaluate this possible controversy? How binding is the maximum dose per day, for both the attending physician and any reviewing committee?

Harry J. Silver, MD
Los Angeles, California

This letter was forwarded to Michael D. Decker, MD, MPH, for a reply.

Dr. Silver's inquiry presents several issues of interest.

The Joint Commission on the Accreditation of Healthcare Organizations standards (and in most jurisdictions, applicable law) make it clear that the organized medical staff of an institution is responsible for "development or approval of policies and procedures relating to the selection, distribution, handling, use, and administration of drugs and diagnostic testing materials," including the setting of drug-use criteria and the evaluation of drug use by members of the medical staff.' Thus, there is no doubt that the questions raised may properly be referred to an appropriate medical staff committee for resolution.

How should they be resolved? Although the *Physicians' Desk Reference* and the package inserts provide important guides to the appropriate use of a drug, it must be remembered that they describe the uses for which the manufacturer has requested, and the government has granted, permission to market the drug. They do not provide an exclusive definition of the appropriate uses of the drug. The evaluating medical staff committee must consider (as should have the prescribing physician) the current state of the art as reflected in the medical literature, other available research data, and prevailing practice.

What do those sources tell us about the specific question raised here? Although Dr. Silver does not name the drug in question, the facts stated suggest strongly that it was ciprofloxacin. Recommended doses for ciprofloxacin in the 1991 *Physicians' Desk Reference* are 500 mg every 12 hours "for more severe or complicated infections, 750 mg every 12 hours."[2] In response to my telephone call, a representative of Miles Inc., the manufacturer of ciprofloxacin, informed me that dose-ranging studies of ciprofloxacin showed no remarkable findings at a dose of 1000 mg once daily, that studies were in progress evaluating a dose of 400 mg infused intravenously twice daily (equivalent to 750 mg taken orally twice daily), and that Miles was not aware of any evidence of a disproportionate increase in toxicity with an increase of this magnitude in dose (personal communication, 1991).

In conclusion, medical directors or therapeutic committee members have the authority and responsibility to address such questions. They do so by considering the specifics of the case, in light of the medical literature and the prevailing standards. If the drug involved was ciprofloxacin, the dose used was not so unreasonable as to force a presumption of inappropriate prescribing. If Dr. Silver's investigation suggests that the prescribing physician was responding to a specific perceived need of this patient, rather than manifesting a pattern of routine overprescribing, it would be reasonable to conclude that no further action was necessary.

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REFERENCES

1. *1990 Accreditation Manual for Hospitals.* Oakbrook Terrace, Ill: Joint Commission on the Accreditation of Healthcare Organizations; 1989.
2. *1991 Physicians' Desk Reference.* Oradell, NJ: Medical Economics Co; 1991.

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