

An Office Model of Outpatient Parenteral Antibiotic Therapy

Alan D. Tice

*From Infections Limited, Physicians Medical Center,
Tacoma, Washington*

This office-based program for parenteral therapy began with the im administration of therapy to outpatients in 1981. Since then it has expanded in scope and staff and has provided more than 1,200 courses of iv antibiotics. The success of the program is dependent on patients' ability to provide iv medication to themselves. These patients are trained and cared for by a team consisting of a physician who specializes in infectious diseases, nurses trained in iv techniques, a pharmacist, and microbiologists who are all part of a practice of the subspecialty of infectious diseases. This office model has resulted in excellent quality of care for patients who have experienced few adverse effects or complications. The cost savings of an office program are significant compared to hospitalization for iv administration of antibiotics, but issues related to reimbursement are a constant issue.

A parenteral therapy program for outpatients began in 1981 when I undertook an investigation of ceftriaxone for the treatment of osteomyelitis. The research was coordinated by a nurse who was also an iv therapist at a neighboring hospital. Although I had not initially intended to provide ceftriaxone on an outpatient basis, the patients enrolled in the study complained about being confined to the hospital for a single daily dose of parenteral antibiotic therapy, so I finally agreed to administer the drug once daily in the office by either the im or iv route. As I gained experience and word spread among the orthopedists, it became common practice to administer ceftriaxone to patients in my office, often avoiding hospitalization altogether. A year later, my study of ceftriaxone was expanded to include treatment of soft tissue infections as well as osteomyelitis. A process that had begun in a single converted examination room has now expanded, requiring >1,500 square feet of office space for outpatient iv therapy.

In 1984, ceftriaxone was released for general use by the U.S. Food and Drug Administration and free samples for study of the drug were no longer available. By this time, my program was well recognized in the community and I was receiving an increasing number of requests for consultations with the expectation that I would be able to help patients avoid or shorten hospitalization. I had to find a way to continue to provide office-based service and to recover the costs of providing the medication.

Establishing an Outpatient Program

Because an iv therapy nurse was already on staff and because my experience with ceftriaxone had been positive but

that with the local alternatives for outpatient iv therapy had been disappointing, I decided to continue the office-based program and to include administration of antibiotics other than ceftriaxone. The model already established by Poretz et al. was quite helpful [1]. There were some interesting problems in the areas of acquisition of parenteral antibiotics, billing, and compensation for provision of outpatient parenteral therapy. These obstacles were eventually overcome and have led to a program that has been well worth the effort in terms of patient care, cost effectiveness, and satisfaction among physicians.

My iv therapy team has grown from one infectious disease physician and a part-time iv therapy nurse to four infectious disease specialists, five iv therapy nurses, a pharmacist, a pharmacy technician, three microbiologists, and additional laboratory personnel and administrative support staff. These services are available to 150,000 people in a city just south of Seattle. As this program has grown and our expertise has increased, we have found that approximately one-third of the patients we treat with iv antibiotics can be treated at home.

Introducing the Patient to the Program

Many of our patients who require iv therapy have consultations in the hospital with an infectious disease specialist from our program. Candidates for iv therapy in the home are either trained in the hospital by our iv therapist or are sent directly from the hospital to our office for training, depending on their knowledge of parenteral antibiotic therapy and the drugs to be administered. In other cases, patients are referred to our program directly from another physician's office, usually for infections such as pelvic inflammatory disease, for infected wounds, or for osteomyelitis.

When a patient is referred to our office, he or she is first seen by a physician, who obtains a thorough history and performs a physical examination. Gram stains and cultures are performed in our office laboratory. If outpatient iv therapy still seems appropriate after evaluating the patient's medical,

Please address requests for reprints to Dr. Alan D. Tice, Infections Limited, P.S., Physicians Medical Center, Suite 402, 1624 South I Street, Tacoma, Washington 98405.

social, and mental situation, the iv therapist is contacted. The iv therapist is given background information on the patient and is told what antibiotic will be administered and what the dosing schedule will be. The patient's insurance company is contacted for prior authorization and to confirm that coverage is available. This is an important part of the program as it ensures our financial survival. Once that information has been obtained and this treatment modality seems feasible, the iv therapist meets with the patient and discusses the options (including programs other than our own), the potential out-of-pocket cost, and the problems that may be experienced with therapy that is administered at home. The therapist also evaluates the patient for dexterity and possible problems related to drug abuse, the home situation, and transportation. If the therapist believes that the patient is still a suitable candidate, the program is begun.

The patient participates for ~2 hours in a training course that is taught by the iv therapist with the help of a basic informational booklet. During the training, the initial dose of antibiotic is prepared by the pharmacist, a heparin lock is put in place by one of our iv therapists, and the first infusion is administered. In addition to preparing medication, the pharmacist reviews the other drugs the patient is receiving and determines what potential problems may arise with administration and storage of the antibiotic solutions at home. At the end of the training session, every patient is given a list of instructions and the telephone numbers for the physician, the iv therapist, and the pharmacist in case any questions or problems arise. All of these members of the staff are available 24 hours a day, 7 days a week. The patient is then sent home with a set of instructions, the booklet, the necessary iv tubing, heparin flushes, and enough antibiotic solution to last until the next visit in 3–4 days.

We have also worked out some temporizing measures that are useful under certain circumstances. For instance, if a new patient is referred to the office in the late afternoon (which is not unusual), it may be best to administer a dose of ceftriaxone and wait for preliminary results of culture the next day before starting training. A small number of patients prefer to come to the office once a day for infusions, rather than learn to administer the drugs to themselves; thus, the office is open 7 days a week. Administration of infusions in the office is less efficient but is necessary for some patients with physical limitations. Patients who receive Medicare are only treated in the office so that we are able to meet the established criteria for payment.

Follow-up of Patients

A team approach enables us to monitor our patients closely. The iv therapists spend enough time training patients and following up on their progress that they come to know the patients well. The nurse who is on call at night and during the weekends has records of every patient for reference. The iv

therapist is very helpful in coordinating care and alerting the physicians to problems.

When we use outside agencies for iv therapy at home, there are often a number of nurses who see the patients at each visit and they are usually nurses who we do not know. This makes assessment of a patient's status and resolution of problems much more difficult and increases our liability.

Once patients are trained and sent home, they are usually in a much more pleasant and comfortable environment than that of the hospital; they may receive their infusions with their family present and while seated in their favorite chair, an advantage which is especially important for children.

As financial pressures increase for hospitals and shortages of nurses worsen, the quality of care provided in hospitals may decline. In our outpatient program we take advantage of an important and often overlooked resource—the patient. At home, patients are responsible for their own therapy, something that is not allowed in a hospital. We find that well-trained patients can provide iv antibiotics for themselves as well as or better than they are provided in the hospital. This is especially true when a nurse on duty must care for 10 other patients with ivs and cannot always flush the site of infusion in a timely manner. We suspect that the incidence of phlebitis and clotted needles is lower in the home than it is in the hospital, but we have no data to prove it. We do know that patients who have experience with administering iv antibiotics to themselves at home often complain about the poor techniques used by the nurses when these patients require hospitalization.

We usually schedule patients to return to the office twice each week—either Monday and Thursday or Tuesday and Friday. We decided to see patients twice weekly because we found that heparin locks usually remain functional for 3–4 days in the home. Furthermore, we believed that assessment by physicians and laboratory monitoring of both the medical problems (often multiple) being treated and the effects of the antibiotics would not be as beneficial at less-frequent intervals [2]. In other programs, all the maintenance of ivs is done at home, but the cost of a nurse's visit to the home to restart an iv is more than a visit to a physician's office. If a patient in our program has returned to work or school, we are usually able to see him or her before or after work (our hours are 8:30 AM to 6:00 PM) or on a day off. When patients come to the office, they are evaluated by the infectious disease team, which consists of the physician, an iv therapy nurse, the pharmacist, and a microbiologist. This team is similar to that described in the report of the Cleveland Clinic experience [3] but differs slightly in terms of the personnel that it comprises.

Team Responsibilities

When patients return to the office for their twice-weekly visits, each member of the team has an important role. The physician is the leader of the team. The physician takes an

interim history and performs a physical examination, depending on the nature of the disease and the patient's symptoms. The physician also looks for adverse effects or other problems that may be associated with the antibiotics and reviews the microbiologic and laboratory data. The physician must also review the patient's other medical and social problems and particular needs. Based on this information, a decision is made on further therapy or studies that may need to be done.

Clinical microbiologists are also important members of our team. They may participate by performing cultures and reviewing results. Their findings are regularly reported, discussed, and updated. Patients are also seen by the laboratory technologist. Blood is usually drawn at each office visit depending on the medical problems of the patients and the drugs they are receiving.

We believe that the frequency with which blood studies are performed for outpatients should at least equal the standards for hospital patients [4]. We perform a complete blood cell count at least once a week for patients who are receiving β -lactam antibiotics and perform tests of renal function at least twice weekly for patients who are receiving aminoglycosides or vancomycin. A drop in the erythrocyte sedimentation rate or the white blood cell count may reveal valuable information on the efficacy of the drugs we are administering. Because of the potential for toxicity of iv medications, it is important that the physician be made aware of any abnormalities as soon as they are discovered. Prompt reports are facilitated by the performance of most of the tests in our office. Because of the volume of patients in our program, we have purchased an automated system for producing hematologic and chemical panels that provides urgently needed results within 15 minutes.

At the time of their return visit, patients are also seen by the pharmacist for review of any problems involving drug interactions, difficulties with storage of solutions, or drug-related adverse effects. More medication is then prepared in a laminar air-flow hood for the patient. The iv therapist places a new heparin lock and discusses any problems that may have occurred since the last visit with the patient. The therapist also evaluates the patient's training and ability to self-administer medication.

At the end of the program, patients receive a certificate commending them on their performance. This positive reinforcement is one way of showing them that they have accomplished a great deal: they have learned to perform a difficult procedure; they have provided therapy to themselves; and they have contributed significantly to the reduction of medical costs related to the treatment of their infections. Our patients who have completed therapy have, in general, had a positive experience and are quite proud of their accomplishments.

Characteristics of Our Program

Since we began this office-based iv program in 1981, we have treated >1,200 patients; no serious complications have

occurred. Only 1% of the patients who began in our program had to be hospitalized because of adverse effects or inability to administer medications to themselves. We have had no legal problems, but awareness of the risks and responsibilities involved in outpatient iv therapy is important. We believe it is important to observe these patients closely since they do not have the advantage of a controlled setting with readily available medical staff and equipment, as do hospitalized patients. As with any home-care-based program, ethical and legal considerations underlie all daily activities. It is important to observe these patients closely to ensure safe and effective therapy.

About 30 patients participate in our program on an average day. The diseases that we treated during a recent 5-month period are shown in table 1. The most frequent condition for which patients were treated was osteomyelitis, followed by wound infections and pelvic inflammatory disease. It is not unusual for us to treat abscesses, septic arthritis, serious sinus infections, and septic bursitis that have failed to respond to oral medications. The last week or 2 weeks of iv antibiotic therapy for liver abscesses, abdominal abscesses, or even meningitis or endocarditis can frequently be accomplished on an outpatient basis after the patient has been stabilized in the hospital. Our experiences have been similar to those observed in other programs [5]. We are also treating an increasing number of patients with AIDS who need gancyclovir for treatment of cytomegalovirus infections or amphotericin B for treatment of fungal infections.

The parenteral antibiotics we provide vary. The antibiotics we provided during the first 5 months of 1989 are shown in table 2. Ceftriaxone was used in half the cases primarily because of its pharmacokinetic properties, which allow once-daily administration. Clindamycin was the next most frequently used antibiotic. It is usually given every 8 hours in combination with another drug for treatment of abdominal abscesses or pelvic inflammatory disease. Cefazolin was third in frequency of use and is administered every 8 hours. We

Table 1. Diseases treated by iv antibiotic therapy for outpatients, December 1988–April 1989.

Disease	No. (%) of patients treated
Osteomyelitis	58 (32)
Gynecologic infections	34 (19)
Wound infections	19 (11)
Septic arthritis	17 (9)
Cellulitis	13 (7)
Abdominal abscess	11 (6)
Endocarditis	5 (3)
Sinusitis	5 (3)
Respiratory tract infections	4 (2)
Cytomegalovirus retinitis	3 (2)
Lyme disease	2 (1)
Urinary tract infections	2 (1)
Fungal infections	2 (1)
Other	5 (3)
Total	180 (100)

Table 2. Antibiotics used for iv therapy for outpatients, December 1988–April 1989.

Antibiotic	No. (%) of courses	Mean duration (d) of course
Ceftriaxone	106 (50)	15
Clindamycin	25 (12)	16
Cefazolin	16 (8)	24
Imipenem	15 (7)	16
Teicoplanin	12 (6)	16
Vancomycin	9 (4)	23
Ceftazidime	8 (4)	22
Tobramycin	6 (3)	17
Gancyclovir	3 (1)	...
Amphotericin B	2 (1)	...
Penicillin	2 (1)	...
Other	8 (4)	...
Total	212	

also use aminoglycosides, imipenem, vancomycin, ceftazidime, and investigational drugs such as teicoplanin.

While we do administer penicillins at times, their usefulness is limited by their half-life that requires them to be administered every 4–6 hours. In treatment of outpatients, there is an important difference in patient compliance and tolerance when a drug must be given every 6 as opposed to every 8 hours, as the 6-hour regimen interferes with sleep patterns. It is possible that portable, programmable infusion pumps may make this problem avoidable in the near future [6].

Our office also provides iv immune globulin for treatment of patients with hypogammaglobulinemia; and we perform blood transfusions, provide inhalation therapy with pentamidine, provide α_1 -antitrypsin replacement, and supply parenteral antibiotic prophylaxis for patients who have prosthetic heart valves and need dental work.

Our patients are a unique factor in our program. In hospitals, the patient is considered to be a passive subject and is given responsibility and credit for little more than self-feeding and excretory function, if that. However, the patient is usually capable of contributing more toward self-care. We rely on patients' intellect, experience, and abilities and find that they contribute significantly to the quality, safety, and cost effectiveness of the program.

It is also important to remember that our program is part of an infectious disease practice. The entire operation is under the direction of a specialist with specific training, knowledge, and experience in the treatment of infectious diseases with parenteral antibiotics. This physician is particularly qualified to assure the quality of the program, provide medical input, and supervise the other members of the team.

Potential Problems with an Office-based Program

There have been some problems with our outpatient program that deserve consideration. Reimbursement, for instance, is a thorny and complex issue. We experienced tremendous prob-

lems with billing for the antibiotics and services we provide. Insurance companies would not accept any billing system other than a hospital- or pharmacy-based model, but pharmacists and hospitals would not help us set up a system since they were involved in competing programs. We were finally able to gather some information that allowed us to bill as a pharmacy, charging only for the drugs and equipment that included a markup that covered the cost of nursing time and overhead. Gradually, through trial and error, we improved the system and came to recognize what constituted a reasonable charge and what did not. We were lucky enough to make the right decisions and thus have succeeded, although we know of other programs that failed, at least temporarily, because of inadequate reimbursement.

Even though multiple studies have shown the cost-effectiveness of outpatient iv antibiotic therapy [7, 8], we still have a problem with some third-party payors, including Medicare. If a patient, hospital, or third-party payor is not going to pay for the therapy, we will not accept the patient in our program. We do not think that increasing the cost for other paying patients to recoup the loss is fair. We have been able to work out an agreement with the Medicaid office in our state that covers most of our costs. When hospital administrators complain that our charges are lower than theirs because we do not accept all patients who have Medicare, our response is that hospitals receive a payment for the diagnosis-related group in which an illness is categorized and that is enough to cover not only the cost of hospitalization but also the entire course of antibiotic therapy. If a patient who has Medicare is discharged early to complete therapy as an outpatient, the hospital should be responsible for the cost of that therapy.

Another problem to be considered by anyone involved in an office-based program for antibiotic therapy is authorization for direct payment. If a bill is submitted in the usual fashion to an insurance company for payment of iv therapy, the insurance company will send a check to the patient for the amount. It is presumed that the patient will send the check to the provider, but this is not always the case, as we have learned. When a patient receives a check for several thousand dollars made payable to the patient, he or she does not always do what he or she should; thus, we ask every patient to sign an authorization for their insurer to send payments directly to us before beginning the program.

We have recently encountered an unexpected problem: the rapidly changing standard of care in our area. Physicians, patients, and third-party payors have increasingly come to expect us to provide outpatient therapy to avoid hospitalization for iv antibiotic treatment. This has made it harder to deny our program to those who are poor candidates for therapy on an outpatient basis, such as iv drug abusers or patients who are seriously ill. Many insurance companies have come to expect that iv antibiotic therapy will be performed on an outpatient basis for the treatment of many diseases and prefer to provide reimbursement on this basis (often at 80%) instead of on the basis of hospitalization (for which they usually pay

100% of charges). Because of the success achieved with treatment on an outpatient basis, some insurance companies have developed guidelines with criteria for hospitalization that may deny reimbursement for hospital care simply because an iv antibiotic was provided.

Finally, there is concern about quality control with iv antibiotic therapy for outpatients. It is a program of treatment that functions with few checks and balances and little supervision unless it is run by a third-party payor. Any physician can begin such a program even though he or she may know little about providing antibiotic therapy on an outpatient basis. We know a number of physicians who have provided iv antibiotic therapy, through their offices or the emergency rooms of the hospitals with which they are affiliated, for patients for whom this procedure may not be indicated. The criteria for screening and acceptance of patients for iv therapy in the home may be poor, especially when there is a high margin of profit for the provider. In some instances, the charges for outpatient iv antibiotic therapy have been as much as those for hospitalization. The fees paid by home iv therapy providers to referring physicians further compound the problem. Our program is far less expensive than hospitalization, provides a quality of care comparable to that received in the hospital, and provides far greater patient comfort and satisfaction.

Conclusion

We have been able to establish a program for outpatient iv therapy as a part of our office-based practice. This pro-

gram has been successful in our community in the improvement of patient care and in limiting costs. We hope that it provides a model that will be useful for others when they incorporate this service into their practices.

References

1. Poretz DM, Eron LJ, Goldenberg RI, Gilbert AF, Rising J, Sparks S, Horn CE. Intravenous antibiotic therapy in an outpatient setting. *JAMA* 1982;248:336-9
2. Health and Public Policy Committee, American College of Physicians. Home Health Care. *Ann Intern Med* 1986;105:454-60
3. Rehm SJ, Weinstein AJ. Home intravenous antibiotic therapy: a team approach. *Ann Intern Med* 1983;99:388-92
4. Kunin CM, Efron HY. Audits of antimicrobial use: guidelines for peer review. *JAMA* 1977;237:1001-8, 1134-7, 1241-5, 1366-9, 1607-8, 1723-5, 1859-60, 1967-70
5. Eron LJ. IV antibiotic therapy in an outpatient setting: report of a joint venture program. *Hosp Formul* 1988;23:440-7
6. Williams DN, Gibson JA, Bosch D. Home intravenous antibiotic therapy using a programmable infusion pump. *Arch Intern Med* 1989;149:1157-60
7. Poretz DM, Woolard D, Eron LJ, Goldenberg RI, Rising J, Sparks S. Outpatient use of ceftriaxone: a cost-benefit analysis. *Am J Med* 1984;77(4C):77-83
8. Balinsky W, Nesbitt S. Cost-effectiveness of outpatient parenteral antibiotics: a review of the literature. *Am J Med* 1989;87:301-5