

Introduction

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Since its inception, the hospital has been a cornerstone of medicine. In addition to providing patient care, the hospital is a center for physician education and the development of new medical treatments and technologies. Nevertheless, there are few patients who would rather be in the hospital than at home, and because of this, there always has been an interest in providing advanced medical care at home.

In recent years, a number of factors have converged to provide an extra impetus to the burgeoning field of outpatient parenteral antibiotic therapy (OPAT). First, and most apparent, is the emphasis on cost containment in health care. Although some authorities argue that intravenous antibiotic therapy should be administered only in the hospital, no matter what the cost, they are a diminishing minority. Second, the availability of antibiotics that need to be administered only once a day, along with the technical advances in intravenous access and infusion devices, have greatly reduced the barriers to treatment in the outpatient setting. Third, patients and their families increasingly prefer outpatient therapy, since it is less disruptive of both their personal life and their job.

OPAT is a fairly new form of therapy, and the medical literature contains very little information on the subject. This symposium and the publication of its proceedings are thus timely events. The cumulative experience of the symposium participants provides another significant step in defining the issues and outlining the solutions. And the issues are many. For example, what structural model or system provides the most efficient and effective OPAT? Which infectious diseases can be treated on an outpatient basis, and at what stage of the disease should therapy transfer from inside to outside the hospital? Which antibiotics are most amenable to outpatient therapy, and what equipment is best suited to their efficacious delivery? Which patients are the best candidates for OPAT, and how much can we expect them to participate in their own care? How do we assure the safety

and quality of care? When is OPAT most cost-effective? What is the role of the third-party payers? What are the legal ramifications?

These fundamental issues form the basis of this supplement. A second supplement will focus on OPAT strategies for specific infections, including endocarditis, cellulitis, meningitis, pneumonia, pelvic inflammatory disease, pyelonephritis, and osteomyelitis. It will also outline the delivery of OPAT in a variety of settings, such as the home, office, emergency department, managed care organization, and extended care facility (e.g., nursing homes).

OPAT adds another burden to the legal responsibilities facing physicians today. The physician who prescribes OPAT remains responsible for patient care but may have less control over care than is usually afforded in the hospital. The clear lines of hospital authority ensure that hospital personnel will monitor and promptly respond to therapeutic complications and equipment failures. Such assurance is not always to be had in the outpatient setting. Indeed, home care personnel often regard the outpatient setting as a way of replacing aspects of physician involvement in patient care. In reality, the need for physicians' medical expertise and involvement is even more important here than in the hospital setting. The challenges to the physician's leadership role should motivate us to familiarize ourselves with all aspects of OPAT and to keep abreast of the rapid changes taking place in this field. Our efforts in this regard will bring about safer and more effective outpatient care, greater patient satisfaction, and increased cost saving. □

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The Team Concept

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The delivery of outpatient parenteral antibiotic therapy is a team effort that, at minimum, requires a physician, a nurse, and a pharmacist. Other specialists may be added as needed. The team may be structured in several different ways, but two basic models emerge: physician-directed and nonphysician-directed. Whatever the structure, the physician should maintain a leadership role in the care of the patient.

Outpatient parenteral antibiotic therapy (OPAT), by its very nature, requires the coordinated services and expertise of physicians and nonphysician specialists. That health care should be delivered with the help of nonphysicians is nothing new; hospital physicians, for example, rely heavily on the services of nurses, laboratory technicians, social workers, and administrators to provide complex therapies and optimal care.

The recent emphasis on health care cost control—coupled with evolving medical technology and improved outpatient care—has provided the impetus to move some treatments out of the hospital.¹ The delivery of parenteral antibiotics outside the hospital is just one example of the growing trend toward home health care. Just how much medical care can be moved to the outpatient setting is not yet known; that depends a great deal on patients' willingness to participate in their own care and the ability of medical

and related professionals to provide care of quality and reduced cost. What is clear, however, is that health care teams that work outside the hospital require even better teamwork and communication than do those that work in the hospital, since team members often no longer share the same work space and do not operate under the controls inherent to the hospital setting.

A team that delivers OPAT should, at minimum, include a physician who specializes in infectious diseases or is knowledgeable in OPAT, a nurse who is trained in IV techniques, and a pharmacist.² Such a team may be more effective and efficient if it also includes a social worker, a laboratory technician, a microbiologist, and a reimbursement specialist.^{3,4}

The Three-Member Team

While the three primary team members each have separate roles, they also have overlapping functions⁵ (see Table). The physician's role is central, as he or she establishes the diagnosis, prescribes treatment, and oversees follow-up. The physician bears ultimate responsibility for the quality of patient care and

the outcome of the treatment program. By virtue of that alone, the physician should be the team leader.^{6,7}

It goes without saying that the physician's responsibilities include taking a thorough history, performing a physical examination, and reviewing appropriate Gram stains, cultures, and other laboratory test results.⁸ If outpatient therapy seems appropriate within the context of the patient's medical and physical status, other team members are called in for further assessment to help develop a treatment plan. The physician continues to take an active follow-up role, performing interim histories and examinations, monitoring for adverse effects associated with antibiotic therapy, reviewing all new microbiologic and laboratory data, reviewing the patient's other medical and social problems, and making any necessary referrals.

The physician's initial assessment, including the choice of antibiotic and its dosing schedule, is passed on to the nurse or pharmacist. The nurse meets with the patient to discuss treatment and the problems that may occur with home- or office-based IV therapy. At this time, the patient is evaluated for dex-

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terity and possible problems related to drug abuse, the home situation, or transportation.

If the nurse agrees that the patient is a suitable candidate for OPAT, patient training is begun. The initial dose of antibiotic is prepared by the pharmacist, a heparin lock is put into place, and the first infusion is administered. (If another IV-access device is used, patient preparation and training may vary.) The patient is then sent home with printed instructions, the necessary IV equipment, and enough antibiotic solution to last until the next office visit, usually three or four days later. Not all patients are candidates for self-administration at home: Those with physical or mental limitations may require nurse-administered infusions in the home, whereas others may be more appropriately treated with once-a-day infusions in an office, clinic, or infusion center.⁹

Of the three team members, the nurse maintains the most regular contact with the patient and is thus pivotal in coordinating care and alerting the physician to problems. The nurse also monitors the patient's continuing ability to self-administer medication and deal with any problems of venous access.

The pharmacist, in addition to preparing medication, may help the physician select the appropriate antibiotic. The pharmacist also reviews the patient's other drugs for possible interactions, anticipates problems that may arise with storage and administration of the IV antibiotic at home, helps choose the drug delivery system, and participates in patient training. Advising the patient about possible adverse side effects is another important function, as is monitoring laboratory values and antibiotic levels during follow-up.

Close follow-up and immediate availability of all team members is obviously essential to the success and safety of OPAT. Thus, the physician, nurse, and pharmacist must be on call 24 hours a day to deal with potential problems. In addition, at our center, patients usually are seen twice a week by all three team members. These visits correlate well with the need to change peripheral IV lines and with the shelf-life of antibiotic solutions. They also permit clinical assessment by team members to determine treatment progress, institute necessary modifications, and define the duration of therapy.

Additional Members

The work load of a three-member team can be reduced and overall efficiency increased by adding other specialists. A social worker, for example, can assess socioeconomic and insurance factors that may affect the effective delivery of OPAT and can arrange for ancillary support and services, as needed.

A laboratory technician and clinical microbiologist can perform appropriate studies and cultures for assessing the efficacy of therapy and potential toxicity. For example, we perform a complete blood count at least once a week for patients receiving β -lactam antibiotics, and we perform renal function tests twice a week for patients who are receiving aminoglycosides or vancomycin.

Because reimbursement is often a thorny and complex issue, it is helpful to have a reimbursement specialist on the administrative staff. The patient's insurance company should be contacted for prior authorization to confirm that coverage is available and to determine the patient's copayment. Other administrative personnel may be employed to facilitate communication between team members, review the legal and regulatory aspects of OPAT, and coordinate quality assurance programs.

The role of third-party payers has become so prominent that they can almost be considered members of the OPAT team. The

	<i>Physician</i>	<i>Nurse</i>	<i>Pharmacist</i>
Establish diagnosis	•		
Authorize treatment	•		
Evaluate patient	•	•	•
Develop treatment plan	•	•	•
Train patient		•	•
Coordinate care	•	•	•
Establish venous access		•	
Prepare antibiotic			•
Provide supplies		•	•
Monitor for toxicity	•	•	•
Follow infection status	•	•	
24-Hour availability	•	•	•

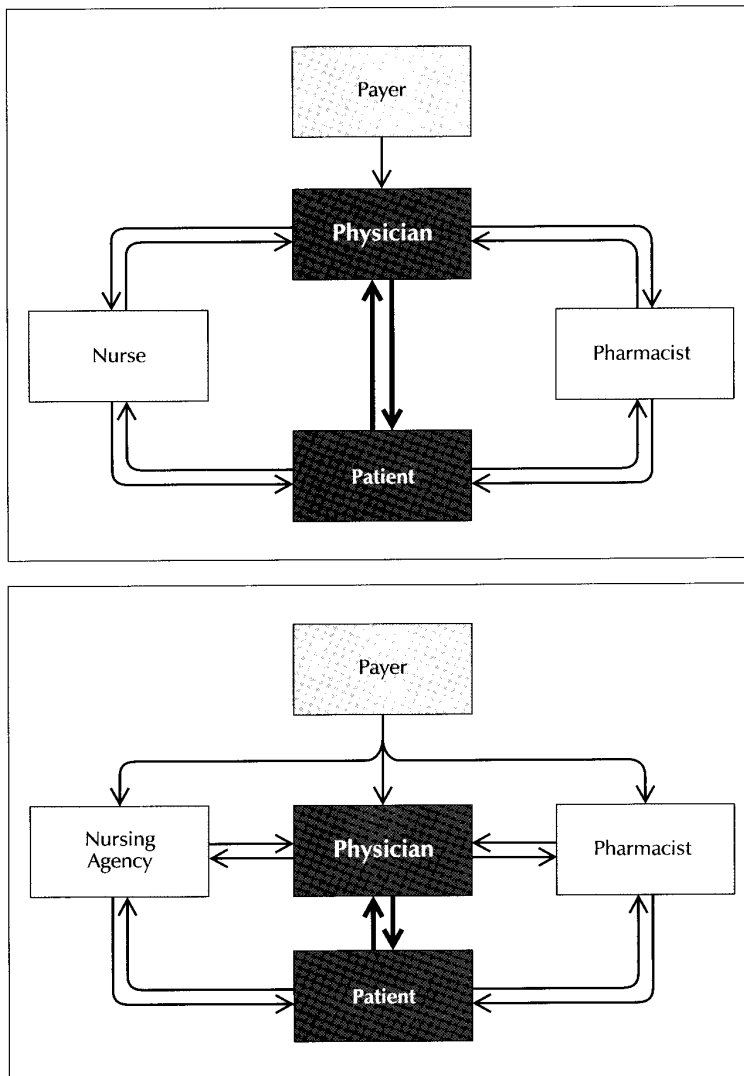


Figure 1. As the name implies, physician-directed OPAT places the physician in direct communication with all the team members and, most important, with the patient. Various permutations are possible within this model. When OPAT is based in a physician's office or clinic (top), the third-party payer usually reimburses for all services through a single channel. At times, however, the payer will establish separate contractual and financial liaisons with individual team members who work in different locations (bottom).

payer's regulations for coverage and reimbursement often determine how OPAT is provided—or if indeed it is even feasible. Medicare, for example, will not always provide reimbursement for OPAT delivered in the home without the direct supervision of a physician.

Finally, the patient's role as an OPAT team member should not be underestimated. Those patients who are willing and physically able to participate in their own treatment will be asked to assume a degree of responsibility that is vital to the quality, safety, and outcome of treatment.

OPAT Models

What has been described thus far is essentially a physician-directed model for the delivery of OPAT (see Figure 1). Within this model, various permutations are possible. For example, in addition to the home and office, infusions may be administered in hospital clinics, emergency departments, nursing homes, prisons, places of employment, schools, or freestanding infusion centers. The infusion may be administered by the patient, a properly trained friend or relative, a nurse or IV therapist, or a physician. But whatever the variation, the role of the physician remains constant: He or she sees the patient on a regular basis and takes an active role in decision making. In short, the physician should remain in control of patient care.

OPAT based in the physician's office or in a clinic is arguably the most ideal delivery model. Here the physician is always in attendance and works closely with the nurse, pharmacist, and other support personnel, who are all located in the same office. (In some states, pharmacy services must remain independent of the physician's office.) The advantage to patients is efficient, coordinated care in a single setting, with rapid and direct communication between team members.¹⁰ Patients can be seen daily and given infusions in the office, or they can be seen intermittently if they are trained to self-administer between visits. Home visits are seldom necessary, which can significantly reduce costs.¹¹

The clinic model is almost identical to the office model but offers some advantages. Since the clinic is usually set up under the auspices of a larger institution such as an HMO or a hospi-

tal, the team is consolidated under one administrative authority and automatically benefits from established procedures such as coordinated payments and cost controls.^{12,13} An infectious disease physician is usually in charge of the clinic and serves as a consultant to referring physicians.

In a third variation of physician-directed OPAT, the third-party payer and the physician select the nursing agency and pharmacy. Each of the team members works out of a different location and establishes different reimbursement arrangements with the payer. This system is more difficult to coordinate, but because the physician is recognized as the team leader, it does avoid questions of control and conflicts of interest. Unfortunately, physicians who work under this model rarely receive compensation for any work that does not specifically involve a patient visit in the home or office.¹⁴

The second basic model of OPAT delivery takes shape when patient care is initiated and directed by a home infusion company or a nursing agency (see Figure 2). Coordination by an infusion company is more common; in fact, most OPAT administered in the United States is done this way. The company, which usually incorporates its own pharmacy services, hires nurses or a nursing agency and bills the third-party payer for all services. The patient is generally treated at home by the nurse or may be trained to self-infuse the antibiotic. In the nurse model, the infusion company is replaced by a nursing agency, which hires its own pharmacy staff or contracts out for pharmacy services.¹⁵

When the delivery of OPAT is controlled by an infusion com-

pany or a nursing agency, the physician plays a less active role and often sees the patient less frequently than in the physician-directed model. Nevertheless, the physician remains responsible for initiating and monitoring treatment and for authorizing the charges of the company or agency. Although physicians often have received

compensation from the company or agency for "care management," these payments are viewed increasingly as "kickbacks" and incentives for physicians to refer patients to specific OPAT providers. The third-party payers should be providing compensation for management but usually reimburse the physician only for patient visits.

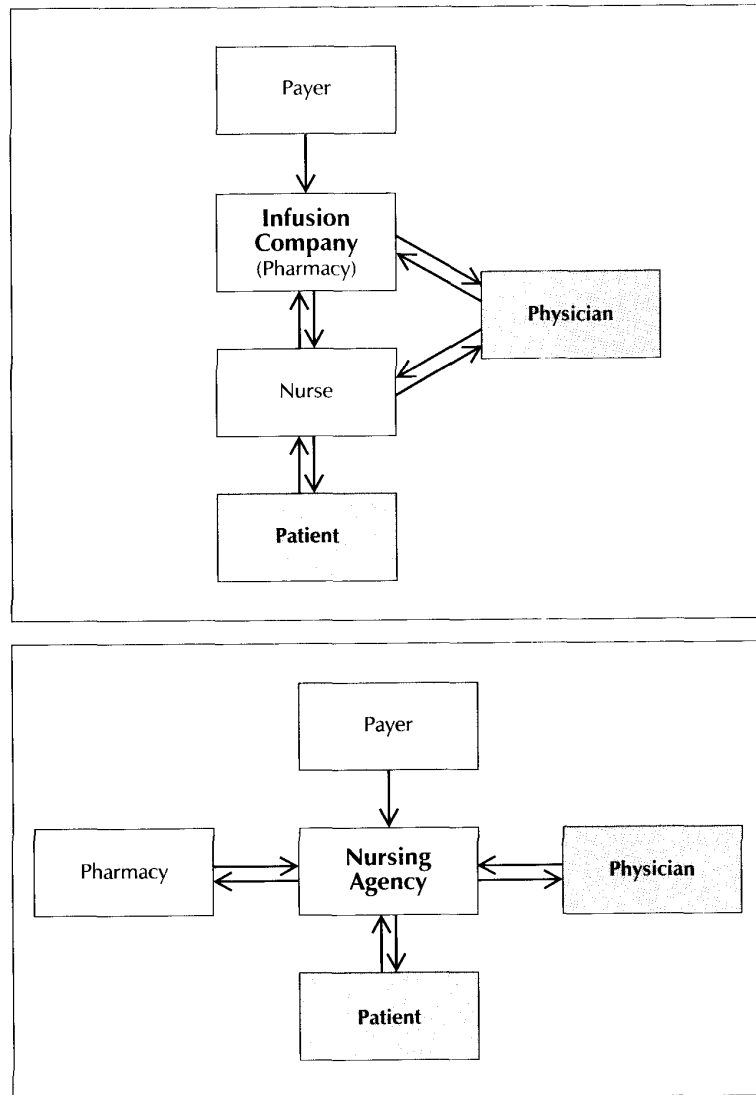


Figure 2. In the United States, outpatient parenteral antibiotic therapy is most often directed by a home infusion company (top) or, less frequently, by a nursing agency (bottom). A significant danger inherent to these two models is that the physician, despite his or her legal responsibility, may lose contact with the patient and is only peripherally involved in the patient's care.

At times, the referring physician may not see the patient at all after the initial assessment and authorization of treatment. Information about the patient's progress is provided by the nurse or infusion company. This makes assessment of the patient's status and resolution of

problems more difficult and sharply increases the physician's liability.

In summary, the delivery of OPAT requires a core team of specialists that can be expanded as needed. Various models for the coordination of care are

available. The choice of model depends on patient needs, geographic location, third-party payers, and state and federal regulations. Whatever model is selected, it is essential that the physician maintain direct contact with the patient and remain in control of care. □

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