Practice Guidelines for Community-Based Parenteral Anti-Infective Therapy

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This is the fourth in a series of practice guidelines commissioned by the Infectious Diseases Society of America through its Practice Guidelines Committee. The purpose of this guideline is to provide assistance to clinicians when making decisions on when and how to best administer parenteral antimicrobial therapy. The targeted providers are internists, pediatricians, family practitioners, and other providers of outpatient antinfective therapy. Criteria for selecting the appropriate patients and settings to deliver therapy in the community are described. Panel members represented experts in adult and pediatric infectious diseases. The guidelines are evidence-based. A standard ranking system is used for the strength of the recommendations and the quality of the evidence cited in the literature reviewed. The document has been subjected to external review by peer reviewers as well as by the Practice Guidelines Committee and was approved by the IDSA Council. An executive summary and tables highlight the major recommendations. The guideline will be listed on the IDSA home page at http://www.idsociety.org.

-- Peter A. Gross, MD for the IDSA Practice Guidelines Committee

Executive Summary

These guidelines were formulated to provide guidance for physicians on various aspects of the administration of community-based parenteral antinfective therapy (CoPAT). Nine areas are addressed. Patient evaluation and selection criteria are discussed in detail, with an emphasis on the importance of determining the need for parenteral therapy as well as assessing the patient’s general medical condition and the infectious process.

The section on “Key Elements for a CoPAT Program” underscores the team concept (the patient, nurse, pharmacist, and physician) and the importance of assuring clear lines of communication between members of the team. A list of evaluation criteria is provided to address the dilemmas facing physicians when insurance companies or managed care organizations designate a specific home care program that the prescribing physician may be unfamiliar with.

The physician’s roles and responsibilities as a member of the CoPAT team are also addressed, emphasizing unique responsibilities such as establishing a diagnosis, authorizing treatment when the final care plan is developed, determining the appropriate site of care, and monitoring the patient’s clinical response to therapy. Many responsibilities are shared between members of the team.

Monitoring the care of patients receiving CoPAT includes attention to venous access, monitoring by means of specific laboratory tests, and emphasizing the importance of administering the first dose of an antibiotic in a supervised setting. Anti-infective selection and administration issues involving CoPAT include observations that once-daily drug administration is convenient and, in the case of aminoglycosides, has potential therapeutic advantages; vancomycin use should be limited to defined situations.

While there are many reassuring retrospective studies on the efficacy and safety of CoPAT, few prospective studies have been conducted to compare the risks and outcomes for patients treated as inpatients rather than outpatients. The outcome studies of pneumonia in cystic fibrosis patients, for which several parameters were used, showed no significant differences between inpatient and outpatient therapy. The Joint Commission on Accreditation of Healthcare Organizations has devised a number of indicators for home infusion therapy, and in this paper, a number of other parameters are recommended for possible inclusion for comparative and trend analyses.

For carefully selected patients, the benefits of CoPAT outweigh the risks; these benefits include the direct cost savings that accrue to the health care system as well as the indirect and intangible benefits that accrue to the individual. It is not always easy to calculate precisely how much less costly CoPAT is than inpatient administration of antibiotics because of differences in definitions of costs and charges in various publications. However, in most publications, the message is clear: CoPAT saves money when it is used appropriately. Provision of CoPAT for patients who are eligible for Medicare is limited by the fact
that home expenses other than skilled nursing visits are not covered.

While there are potential risks associated with CoPAT, the benefits to the patient and society are considerable. CoPAT should be embarked upon as a team approach to medical care, with structured services and outcome analyses to assure both safety and quality. The physician’s role in coordinating patient care is crucial.

Introduction

The practice of administering parenteral anti-infective therapy in the home and in other community settings has grown rapidly over the past 20 years [1–11]. In the United States, community-based parenteral anti-infective therapy (CoPAT) is a multibillion-dollar-a-year industry. It is estimated that more than 250,000 Americans are treated with CoPAT each year, and the growth rate for this practice is estimated to exceed 10% per year. The growth of CoPAT has been fueled by a variety of factors including an increased emphasis on cost containment, the availability of antibiotics that can be administered once or twice daily, technological advances in vascular access and in infusion devices, increased acceptance of such therapy by both patients and health care personnel, and the availability of structured services for CoPAT.

These guidelines were drafted in an attempt to ensure appropriate and successful implementation of parenteral anti-infective services for patients in a variety of community settings including the home, outpatient facilities (e.g., physicians’ offices and infusion centers), skilled nursing facilities, and rehabilitation centers. The guidelines have been formulated from the physician’s standpoint, emphasizing the physician’s responsibilities. However, it is appreciated that CoPAT is a multidisciplinary activity demanding close cooperation between nurses, pharmacists, and other members of the health care team [5–7, 12, 13]. Accordingly, the overlapping roles and responsibilities have to be reconciled to ensure success and reduce potential risks.

The guidelines proposed herein are general and may need modification in certain settings. We would encourage consultation with an infectious diseases physician in such circumstances. The guidelines address basic definitions, patient evaluation and selection criteria, basic prerequisites and key elements for CoPAT programs, responsibilities of team members (with an emphasis on the physician’s role), clinical aspects, including monitoring, anti-infective selection and administration, outcome measures, economic considerations, and risk-benefit analysis.

Basic Definitions

The guidelines were formulated on the basis of the collective clinical experience of the Guideline Committee. Wherever possible, the strength of the recommendation and quality of evidence available to support the recommendation were assessed with use of previously published criteria [14].

The term community-based is used to reflect the various nonpatient hospital settings (a home, an infusion center, a physician’s office, a skilled nursing facility, or a rehabilitation center) where parenteral therapy is administered. The term parenteral is favored to reflect both intravenous and intramuscular routes of administration. Anti-infective is used, as it reflects the growing use of antiviral and antifungal therapies as well as antibiotic therapies in community settings. Patient is used throughout this paper rather than client, consumer, or any other designation. Caregiver refers to any individual with the ability and willingness to administer treatment and observe and report significant events. The caregiver may be a family member, friend, or health care professional (i.e., a nurse or physician). All caregivers, particularly nonprofessionals, need to be trained and educated to perform designated tasks.

CoPAT delivery systems refers to infusion companies, hospital-based home care services, or other organizations that ensure delivery of drugs and devices.

Patient Evaluation and Selection Criteria

Initiation of CoPAT requires that a qualified physician determines that such therapy is needed to treat a defined infection, that there is a reasonable expectation of control of the infection, and that alternate routes of drug delivery are not feasible or indicated.

Determination of need for parenteral anti-infective therapy. There is potential for both overuse and underuse of CoPAT. A careful analysis of patients referred for home therapy will demonstrate that a subset of referrals are inappropriate. Some patients require hospitalization; for others, oral antibiotic therapy is adequate, and for some, it is reasonable to discontinue antibiotic therapy altogether. Because of their experience and expertise in this area, infectious diseases specialists or physicians who are interested and experienced in CoPAT should be involved in the evaluation of patients who are candidates for therapy. The infectious diseases specialist should analyze the need for anti-infective therapy, recommend the anti-infective agent, provide orders for therapy, monitor the patient during the course of treatment, and comprehensively evaluate the patient’s clinical response.

Guidelines for patient selection. The following guidelines should be observed in determining which patients should receive CoPAT.

1. The patient’s medical care needs do not require hospitalization and do not exceed resources available at the proposed site of care.

2. The patient or caregiver is capable of safely and effectively delivering parenteral anti-infectives and is compliant with recommended treatment and, after discussion of the benefits, risks (including informed consent when appropriate), and...
economic considerations (e.g., insurance issues), willing and able to participate in the proposed therapy.

(3) Lines of communication between the patient, caregiver, physician, and other health care personnel are sufficient for monitoring therapy.

(4) The home/outpatient environment is safe and adequate to support care.

The primary goal of community-based therapy programs is to allow patients to safely and effectively complete treatment in the comfort of the home or another site, thereby avoiding the inconveniences, complications, and expense of prolonged hospitalization. This goal must not be overlooked in the midst of efforts to reduce hospital use.

Medical assessment and resource needs. Determination of the status of a patient's underlying medical condition(s) is a critical component of the assessment process. A patient's overall condition must be stable, and the risk of sudden, life-threatening changes in health should be low. The risk assessment includes determining the status of the infectious process as well as concomitant conditions that might influence the safety of continuing care outside the hospital. Patients with terminal conditions are appropriate recipients of CoPAT if the proposed therapy contributes to their quality of life and comfort. CoPAT often enables the completion of a course of therapy started in the hospital, but CoPAT may be initiated in an emergency department, outpatient clinic, or office setting if the patient's condition does not otherwise warrant care as an inpatient.

A wide range of infections have been successfully treated through CoPAT programs (table 1) [15-63]. The patient's participation is usually more dependent on the stability of medical and psychosocial factors than on the type of infection present. For most of the conditions listed, the strength of each recommendation was categorized as indicating good (A) or moderate (B) evidence in support of the use of CoPAT [14]. For the most part, the quality of the evidence on which recommendations were based was assigned a Grade III (evidence based on clinical experience or descriptive studies). There were very few Grade I recommendations (evidence from at least one properly randomized control trial) and few Grade II recommendations (e.g., evidence from at least one well-designed clinical trial without randomization) [14].

In general, patients with sepsis or focal infections such as meningitis, endocarditis, septic arthritis, or severe pneumonia should be hospitalized for initiation of parenteral antibiotic therapy [12, 15-17] because of the need for intensive medical care or the risks that such patients' medical conditions may suddenly change. For example, patients with endocarditis and persistently positive blood cultures, poorly controlled congestive heart failure, large (>10 mm) vegetations, recurrent embolic events, or conduction abnormalities are at risk for complications of endocarditis; their eligibility for completion of therapy with CoPAT must be carefully assessed. Some patients with left-sided native valve endocarditis due to Staphylococcus aureus may develop sudden complications despite clinical stability [52]. There is significant experience in treating non-Enterococcal streptococcal endocarditis on an outpatient basis with once-daily dosing of ceftriaxone [53-54].

In all situations, the patient must be able to tolerate the selected antimicrobial agent before CoPAT is initiated. Patients who are treated at home typically receive two to three skilled-nurse visits per week, although in selected situations, daily nurse visits may be appropriate. Physicians may visit once or twice a week or as deemed necessary. Most patients or their caregivers must be able to assume responsibility for the infusion and for the care of the catheter site. Daily treatments in a physician's office or infusion center may be an option if the patient's physical condition and resources, including transportation, are adequate. If the patient requires rehabilitation or extra assistance with daily care, supervised anti-infective therapy in a subacute care facility, nursing home, or rehabilitation center is preferred.

Capability and compliance. The capabilities of patients who receive parenteral anti-infectives at home need to be carefully evaluated before such patients are accepted in the program. Participation in CoPAT by selected patients with physical disabilities may be facilitated through the use of various devices such as iv pumps and elastomer-regulated infusion devices. If self-administration of anti-infectives is impossible despite exploration of these options, a caregiver or home care nurse may assume responsibility for this aspect of care. Home care of children requires the participation of parents or guardians as caregivers: the standards for evaluation of competence, compliance, and willingness to participate that apply to adults also apply to children.

The appropriateness of CoPAT for drug- or alcohol-using patients should be carefully evaluated before therapy is initiated. Patients who are likely to abuse an iv system are not desirable candidates for CoPAT [12, 64], although the use of computerized iv pump technologies reduces the likelihood of tampering. Patients' safety, as well as ability to comply with the prescribed regimen, will determine whether therapy outside the hospital setting is advisable. If a patient was actively abusing parenteral drugs immediately before the acute presentation, administration of iv antibiotics in a supervised setting is advised. The presence of other drug-using family members in the home may also lead to a recommendation that therapy be completed in a hospital, subacute care facility, or nursing home.

Patients should be aware of the economic aspects as well as the medical aspects of CoPAT before the initiation of therapy. Patients should be counseled regarding insurance coverage and anticipated out-of-pocket costs to allow an informed decision about participation in a CoPAT program.

Communication. Ongoing communication between the patient, caregiver and/or nurse, vendor-supplier, and physician is critical to the success of CoPAT. If the patient has no telephone, alternate means of communication through neighbors or friends must be established before CoPAT is initiated. Patients must have access to transportation for physician appointments and access to emergency services.
Table 1. Infectious conditions suitable for treatment with community-based parenteral anti-infective therapy.

<table>
<thead>
<tr>
<th>References</th>
<th>Site of infection or condition</th>
<th>Strength of recommendation*</th>
<th>Quality of evidence*</th>
</tr>
</thead>
<tbody>
<tr>
<td>[2, 18]</td>
<td>Cellulitis/</td>
<td>B</td>
<td>II</td>
</tr>
<tr>
<td>[4, 6, 8, 10, 13, 16, 19–33]</td>
<td>Soft-tissue infection</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[4, 6, 23, 25, 27, 28, 33]</td>
<td>Osteomyelitis</td>
<td>A</td>
<td>II</td>
</tr>
<tr>
<td>[2, 5, 18]</td>
<td>Septic arthritis/bursectis</td>
<td>A</td>
<td>II</td>
</tr>
<tr>
<td>[3, 4, 6, 11, 13, 19, 20, 22–32, 36]</td>
<td>Prosthetic joint infections</td>
<td>A–B</td>
<td>III</td>
</tr>
<tr>
<td>[11, 20, 27, 33]</td>
<td>Pneumonia/severe lower respiratory infections</td>
<td>B</td>
<td>II</td>
</tr>
<tr>
<td>[2]</td>
<td>Cystic fibrosis (infections exacerbations)</td>
<td>A</td>
<td>I</td>
</tr>
<tr>
<td>[4, 6, 8, 13, 16, 19, 20, 22–26, 29–32, 39]</td>
<td>Sinusitis (complicated)</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[40]</td>
<td>Chronic otitis/mastoiditis</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[9, 41]</td>
<td>Endocarditis</td>
<td>B</td>
<td>II</td>
</tr>
<tr>
<td>[11, 20]</td>
<td>Intravenous access-associated</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[4, 6, 13, 16, 23, 25, 27, 29, 31, 32]</td>
<td>Vascular graft infections</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[2, 5, 52, 53, 54]</td>
<td>Hepatic abscess</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[1, 3, 4, 6, 10, 11, 13, 16, 20–29, 34, 55–58]</td>
<td>Peritonitis</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[4, 8, 16, 25, 26]</td>
<td>Intra-abdominal abscess</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[10, 11]</td>
<td>Complicated urinary tract infections</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[20, 21, 25]</td>
<td>Tubo-ovarian abscess/pelvic inflammatory disease</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[31]</td>
<td>Meningitis</td>
<td>B</td>
<td>II</td>
</tr>
<tr>
<td>[6, 8, 13, 16, 21, 23, 24, 26, 29, 31]</td>
<td>Brain and epidural abscesses</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[18]</td>
<td>Splenic abscess</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[2, 4, 6, 8, 13, 16, 19, 22, 25]</td>
<td>Neutropenic fever</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[4, 6, 8, 13, 16, 19, 22, 25]</td>
<td>Lyme disease</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[18]</td>
<td>Bacteremia</td>
<td>B</td>
<td>II</td>
</tr>
<tr>
<td>[1, 2, 16, 19, 20, 23–26, 29, 32, 34]</td>
<td>Fungemia/systemic mycoses</td>
<td>B</td>
<td>III</td>
</tr>
<tr>
<td>[6, 11, 21–23, 26, 29]</td>
<td>Cytomegalovirus infections</td>
<td>B</td>
<td>III</td>
</tr>
</tbody>
</table>

* Letters represent strength of evidence in support of the use of community-based parenteral anti-infective therapy. A = good; B = moderate [14].

Numbers represent quality of evidence on which recommendations were based: I = randomized controlled trial; II = well-designed clinical trial; III = clinical experience [14].

**Environment.** The place where anti-infectives are administered must be clean. Space should be available for the storage of supplies. In most cases, a refrigerator and running water in the home are required. In addition, a defined mechanism for needle disposal (this may vary with local or state regulations) is necessary. Other criteria for determining the most suitable setting for CoPAT are more difficult to define; for example, family dynamics may significantly influence the patient’s ability to safely and successfully complete therapy outside the hospital.

**Key Elements of a CoPAT Program**

The key elements of a CoPAT program are as outlined (table 2). While any physician can legally order CoPAT, not all physicians are experienced in doing so. There has been enormous nationwide growth in all home care services; however, paradoxically, direct physician involvement has not kept pace, partly because of limited reimbursement for management of care in this setting [65, 66]. The responsible physician should be knowledgeable in infectious diseases and CoPAT so that problems such as therapeutic failure, drug toxicity, and iv access issues are avoided or appropriately and promptly addressed. In some clinical settings, an infectious diseases consultation is required before a patient is sent home to receive CoPAT [5, 67]. Recent discussions have focused on accreditation requirements to establish minimum standards for physician supervision and management of home care agencies [68]. Intravenous therapy nurses and pharmacists in the CoPAT program...
Table 2. Key elements of a community-based parenteral anti-infective program.

| Health care team | • Physician knowledgeable about infectious diseases and CoPAT  
|                  | • Primary care physician motivated to participate actively in CoPAT  
|                  | • Nurse knowledgeable about intravenous therapies and CoPAT  
|                  | • Pharmacist knowledgeable about CoPAT  
|                  | • Access to other health care professionals including physical therapist, dietitian, 
|                  | occupational therapist, and social worker  
| Communications   | • Availability of physician, nurse, and pharmacist on a 24-hour basis  
|                  | • System for rapid communication with patient and among team members  
| Written policies and procedures | • Outline of responsibilities of team members  
|                  | • Patient admission information  
|                  | • Patient selection criteria  
|                  | • Patient education  

NOTE: CoPAT = community-based parenteral anti-infective therapy

should be knowledgeable and experienced, as should other members of the health care team (e.g., social workers, physical therapists, dietitians, and occupational therapists). The American Society for Hospital Pharmacists has developed specific guidelines on the pharmacist’s role in home care [69, 70].

CoPAT programs must have systems for rapid communication between nurses, pharmacists, physicians, and patients. Such systems are required both for initial treatment planning and for the monitoring of ongoing care. Communication via pagers, cellular phones, facsimile machines, and electronic mail has become increasingly important. Programs should have written policies and procedures that outline the responsibilities of the team members and address issues such as patient selection criteria, antibiotic preparation, vascular access, laboratory monitoring guidelines, and waste and needle disposal. Patient education materials should provide specific information about the program, a list of emergency-access telephone numbers, and a statement regarding precautions and risks as well as specific information about the disease process and the anti-infectives used.

Plans for quality assurance and outcomes monitoring (see below) should be incorporated into CoPAT programs. Policies and procedures may be developed for an individual program or accessed via one of several commercial sources.

An experienced physician director or advisor for the CoPAT delivery organization is important for the success of the program. This position is analogous to that of the medical directors for hospice programs. Such persons provide clinical input into policies and procedures and oversee quality-of-care activities.

Physicians who prescribe CoPAT may face dilemmas when insurance companies or managed care organizations designate referrals to specific home care programs. In some cases, the prescribing physician may be unfamiliar with a program; in other cases, he or she may be aware of quality issues as a result of previous encounters with the program. The characteristics of CoPAT programs listed in table 2 should be useful in assessing the capabilities of the delivery system (see "CoPAT delivery systems" on page 788). In addition, specific administrative elements, as listed in table 3, should be in place. Since prescribing physicians remain responsible for clinical care decisions, it is important for them to assess the quality of care provided by the CoPAT delivery organization. In general, physicians are considered legally responsible for deciding when it is appropriate to discharge patients from hospitals [71]. It is incumbent upon consultants to clarify their postdischarge role with other doctors involved in a patient’s care [72].

Role of the Team Members in CoPAT

As in the hospital setting, an effective CoPAT program requires a team of professionals, each with his or her area of

Table 3. Criteria for evaluating a community-based parenteral anti-infective therapy program.

- Medical director or advisor knowledgeable about infectious diseases and CoPAT  
- Defined role for prescribing physician in relation to case management, medical director, nurse, and pharmacist  
- Standards for nurse, pharmacist, physician, and other patient care personnel in regard to training, experience, and licensure  
- Accreditation or certification (e.g., JCAHO or other)  
- Experience in providing CoPAT  
- Policies regarding:
  a. frequency of physician's and nurse's clinical assessments of the patient  
  b. staffing and on-call policies  
  c. frequency of clinical status reports to physicians  
  d. reporting of laboratory results to physicians within 24 hours  
  e. rapid reporting of patient problems and critical laboratory values  
- Willingness to share quality and outcomes information (see table 9)  
- Willingness to share charge information regarding individual patients as well as data on:
  a. Anti-infective preparation and dispensing  
  b. Vascular access systems and care  
  c. Infusion device care  
  d. Monitoring guidelines for physician visits, nurse evaluations, and laboratory studies  
- Waste disposal  
- Patient education and resource materials:
  a. Instructions for emergency situations  
  b. Information about anti-infective use and possible adverse effects  
  c. Understanding of potential risks and problems and patient responsibilities in regard to CoPAT  
- System for ongoing quality assurance and outcome monitoring:
  a. JCAHO home infusion therapy indicators (see table 9)  
  b. See section on outcome measures

NOTE: CoPAT = community-based parenteral anti-infective therapy; JCAHO = Joint Commission on Accreditation of Healthcare Organizations.
Table 4. Roles of physicians, nurses, pharmacists, and patients in a community-based parenteral anti-infective therapy program.

<table>
<thead>
<tr>
<th>Function</th>
<th>Physician</th>
<th>Nurse</th>
<th>Pharmacist</th>
<th>Patient and/or parent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Establish diagnosis</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Authorize treatment</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Evaluate for suitability for CoPAT</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Develop treatment plan</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Provide education and training</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Coordinate care</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Establish vascular access</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Monitor vascular access</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Prepare anti-infective agent</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Provide supplies</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Monitor for drug toxicity</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Follow infection status</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Availability on a 24-hour basis</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Outcome assessment</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

NOTE. Data are from [6]. CoPAT = community-based parenteral anti-infective therapy.

expertise, as well as a willingness and interest in working together for optimal patient care [5, 7]. The outpatient team differs from the in-hospital team particularly with regard to challenges in communication. Reports of laboratory values, patient assessments, and problem-solving are often handled by phone or facsimile instead of through face-to-face contact. The basic CoPAT team consists of a physician, an iv therapy nurse, and a pharmacist. The patient should also be considered a member of the team, since outside the hospital setting he or she usually plays a much more active role and may be responsible for reporting clinical problems and monitoring vital signs (table 4) [6]. There are many areas of overlapping responsibilities, and all team members should be constantly available for handling problems that may arise.

The physician’s role in CoPAT has several unique aspects, including the establishment of a diagnosis, the authorization of treatment when the final plan of care is developed, and the determination of the appropriate site for care. Both the physician and nurse should participate in determining appropriate vascular access. The physician is responsible for monitoring the patient’s clinical response to therapy, evaluating for evidence of drug toxicity, continually assessing for other medical problems that may arise, and coordinating the efforts of other members of the team. Physicians who serve as the medical directors of outpatient therapy programs have additional responsibilities including some of the administrative aspects of the program, communication with other physicians, utilization review, quality assurance, and resolution of problems regarding the medical issues of service and treatment.

The choice of a model for administering CoPAT varies on the basis of individual patients’ needs, the program resources available, and the payer. It is possible to change the type of delivery model depending on the anti-infective used, the patient’s ability for self-care, and the need for other medical services. The delivery models can be roughly classified on the basis of whether therapy is self-administered, administered by a visiting nurse, administered at an infusion center, or administered at a skilled nursing facility. The advantages and disadvantages of these delivery models are shown in table 5 [19].

The self-administration model can be provided by the patient, a family member, or another responsible person. This model may be combined with other models and has the advantage of autonomy for the patient, as well as reduced expense. Methods by which therapy can be self-administered include gravity bags and a variety of infusion devices that can be adapted to the needs of the patient, the vascular access device, and the drug used. Physicians may allow patients some flexibility in iv dosing requirements so as to reduce family and work conflicts and to ensure that patients get adequate rest.

If a visiting nurse service has staff who are experienced in home infusion and iv line maintenance, medications can be provided in the home under the direct supervision of a nurse. This model is relatively safe and convenient for the patient, but medication scheduling conflicts may arise. While most medications are given as 30-minute infusions, there has been a tendency towards rapid infusion (or iv push) therapy [73]. Because of its expense (due in particular to frequently dosed medications), nurses’ travel schedules, and the occasional concerns about patient privacy and caregiver safety, this model may not be appropriate in some situations.

The infusion center model may be established in a variety of locations including a clinic or physician’s office, a freestanding infusion center, a hospital outpatient clinic, or, less frequently, an emergency department or extended care facility. These centers offer the advantage of ready access to medical equipment and personnel but require travel to the facility for treatment. Skilled nursing facilities may be used to provide parenteral antibiotic therapy and have replaced prolonged hospitalization.
in situations where patients are incapable of self-care, do not have satisfactory caregivers, have multiple medical problems, are undergoing rehabilitation, or have problems with compliance.

**Clinical Aspects, Including Monitoring**

As emphasized earlier, CoPAT is used for a wide variety of infections. In some geographic areas, patients with infectious complications of HIV infection and AIDS become the major users of CoPAT programs; these patients require careful clinical monitoring because of the complexity of their care. Likewise, patients with endocarditis and meningitis require carefully directed and structured monitoring because of the potential for life-threatening sequelae. The duration of IV anti-infective therapy is not specifically addressed in the present guidelines except to underscore the concern that some patients receive inappropriately prolonged therapy for Lyme disease [74–76].

**Clinical monitoring.** A plan of care needs to be established prospectively and will vary with the acuity of a patient’s illness, the clinical stability of a patient’s condition, and the drug(s) used. For example, a patient with an acute infection who is admitted directly to a CoPAT program without antecedent hospitalization may need to be seen by a physician daily during the first several days of care. Clinical monitoring needs to be coordinated between physicians and nurse specialists, and the treatment plan should clearly identify the physician responsible for the care of a given patient. The degree, complexity, and frequency of nurses’ visits will vary with the clinical situation. A nurse’s visit should include assessments of compliance with the treatment program, the status and potency of the venous access device, and the patient’s overall status; a directed physical examination tailored to the diagnosis; and a review of side effects (e.g., rash or gastrointestinal symptoms) associated with the prescribed anti-infective.

A variety of factors should prompt consideration of a change in the type and route of administration of parenteral anti-infective therapy; these factors include clinical evidence that a patient’s condition has not improved, unwanted side effects, and complications of drug administration. The reason(s) for any change of therapy should be recorded as part of programmatic outcome measures.

**Venous access.** Venous access routes include a variety of short peripheral IV catheters, mid-line peripheral IV catheters, peripherally inserted central venous catheters (PICCs), centrally inserted central venous catheters (CVCs), and subcutaneously implanted infusion port devices. In the United States, im antibiotic therapy is infrequently used; however, in some parts of the world, im drugs are used extensively, in part because of their low cost. Data on the efficacy of the im route exist for a few selected drugs including ceftriaxone [28], ceftazidime [30, 34, 36], the aminoglycosides [77], and teicoplanin [78, 79].

Peripheral vascular access is simple and is associated with few complications. The IV therapy nurse’s role is critical for peripheral line access and maintenance. Peripheral lines are used primarily for anti-infectives that are well tolerated and are given at infrequent intervals and in situations where there is a low likelihood that phlebitis will develop. Typically, the course of therapy is relatively short (usually <2 weeks, or <1 week for children), and venous access is easy. In infants and young children, short peripheral IV catheters usually do not
remain patent for more than a few days, and reininsertion is often required when therapy extends beyond 3–5 days.

Mid-line catheters are longer (length, 3–8 inches) than peripheral iv catheters and may be used for longer courses of therapy. They are inserted via the antecubital fossa into the proximal basilic or cephalic veins. Overall, mid-line catheters appear to be associated with low rates of phlebitis and infection and are less expensive than CVCs. Anaphylactoid reactions and other severe reactions have recently been reported in association with one type of mid-line catheter made of an elastomeric hydrogel [80]. PICCs of various types are now increasingly used because they appear to be associated with fewer mechanical complications and cost less than CVCs. PICCs are inserted into the antecubital fossa and threaded into the distal superior vena cava. PICC lines may be used in a number of specific situations—e.g., when venous access is difficult, when a longer course of therapy (usually >2 weeks) is anticipated, when potentially irritant or vesicant drugs are administered, and when the use of infusion devices is contemplated.

While CVC-associated infection rates vary as a result of a number of factors, including use of single vs. multiple-lumen catheters or a subclavian vs. internal jugular access site, duration of insertion, or the presence of neutropenia, most infectious diseases consultants favor tunneled catheters for administering CoPAT. In general, the rates of infection associated with the use of tunneled CVCs have been significantly lower than those reported with the use of nontunneled CVCs [81]. However, a recent prospective randomized study involving 212 CVCs in 169 immunocompromised patients at one center showed no difference in infection rates between subcutaneous tunneled CVCs and nontunneled subclavian CVCs [82]. Implanted infusion ports are rarely used solely for anti-infective therapy. Dressing changes and examination of the venous access site are usually performed by the iv nurse. Protocols for the frequency of dressing changes will vary with the type of venous access.

The venous access site and device generally need to be carefully examined every 3–4 days by a nurse or physician for evidence of local tenderness, phlebitis, infiltration, erythema, or other signs of local infection. Investigators for the Centers for Disease Control and Prevention have recently drafted general guidelines for prevention of intravascular device-related infections [81].

Traditionally, patients or their caregivers have infused anti-infective drugs by the gravity-infusion method. A variety of alternative methods including elastomeric infusion devices, syringe pumps, programmable infusion devices, or direct iv bolus injection techniques have been used increasingly to circumvent several potential barriers to the use of CoPAT [83]. Circumstances when infusion pumps may be used are as shown (table 6) [20]. A descriptive listing of infusion devices has recently been published [84].

**Laboratory monitoring.** Laboratory monitoring should be tailored to the likely or known side-effect profile of the anti-infective agent used. The recommendations contained herein are tailored to safety and toxicity concerns rather than the response to therapy. There are no firm data or guidelines indicating the frequency of laboratory testing [85]; this lack of guidance was demonstrated in a recent report on monitoring iv pentamidine therapy in the home [39]. Therefore, many infusion companies have developed their own criteria. A schedule of laboratory testing for patients with normal or stable renal function is shown (table 7). Most of the laboratory tests have been assigned a BI designation (indicating that the strength of the recommendations has moderate supportive evidence, and the quality of the evidence was based on at least one well-designed nonrandomized clinical trial [14]).

For children receiving β-lactam antibiotics, the required complete blood count and serum creatinine level determination may be done less frequently (e.g., every 2 weeks) than for adults. Blood levels of aminoglycosides may be determined at the outset to ensure adequacy of therapy; however, there are no recommendations for routine rechecking of these blood levels unless there is a change in renal function (e.g., an increase in the serum creatinine level of ≥0.5 mg/mL over baseline).

If aminoglycosides are going to be administered for more-prolonged periods (>2 weeks), baseline audiograms should be obtained as close to the initiation of therapy as possible, and repeated audiograms should be obtained every 2 weeks. This recommendation was assigned a CIII designation, indicating both poor evidence in support of a recommendation for or against use and that the quality of the evidence was based on opinions of respected authorities [14]. Patients who should be routinely evaluated with audiograms include those who have preexisting renal failure, those who are aged ≥65 years, those who have a family history of hearing problems related to aminoglycosides, or those who are being treated with prolonged courses of aminoglycosides.

There are no reliable, universally agreed-upon standards for the definition of drug-induced otoxicity. In most studies, otoxicity is considered to have occurred if there is an increase in the auditory threshold of ≥15 decibels over baseline at any two frequencies or 20 decibels over baseline at one or more frequencies [86]. Such changes should prompt discontinuation.

**Table 6. Indications for infusion pump therapy.**

<table>
<thead>
<tr>
<th><strong>Indication</strong></th>
<th><strong>Definition</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient requires frequent (every 4–6 h) or continuous iv drug administration</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Patient is unwilling or unable to learn the necessary techniques for injection of anti-infectives or has a caregiver who is unable or unwilling to learn these techniques</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Patient lacks a support person at home</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Patient has impaired manual dexterity or cognitive function</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Patient has an aversion to needles</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Patient is immunologically compromised (reduces the number of times the iv cannula has to be manipulated)</strong></td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** Data are from [20].

*New “needleless” systems may help.*
### Table 7. Laboratory parameters that should be monitored on a weekly basis during community-based parenteral anti-infective therapy.

<table>
<thead>
<tr>
<th>Anti-infective agent</th>
<th>Complete blood count</th>
<th>Creatinine level</th>
<th>Potassium level</th>
<th>Magnesium level</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>β-Lactams</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aztreonam</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cefadroxil and Cefadroxzol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cephalosporins*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbapenems (imipenem/meropenem)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Anti-pseudomonal pencidines</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ticarcillin</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mezlocillin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Piperacillin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aminoglycosides</td>
<td>1</td>
<td>2</td>
<td></td>
<td></td>
<td>Blood levels as clinically indicated; consider audingram(^1)</td>
</tr>
<tr>
<td><strong>Miscellaneous</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clindamycin</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycopeptides (vancomycin/ teicoplanin)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trimethoprim-sulfamethoxazole</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pentamidine</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>Daily blood sugar (finger stick); chemistry profile(^2) (2 × w)</td>
</tr>
<tr>
<td><strong>Antifungals</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amphotericin B</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Fluconazole</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Antivirals</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ganciclovir</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acyclovir</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Forskarnet</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>Chemistry profile(^2) (1 × w); include calcium level</td>
</tr>
<tr>
<td>Cidofovir</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td>Urinalysis, chemistry profile(^2) (1 × w)</td>
</tr>
</tbody>
</table>

**NOTE.** Data are number of times per week that test should be done and represent minimal criteria for patients with normal or stable renal function (different criteria may apply for children; see text).

* For patients receiving ampicillin, oxacillin, or ceftriaxone, monitoring of liver function tests may be indicated.

\(^1\) See text for details.

\(^2\) Chemistry profile = liver function tests and electrolyte level determinations.

Of therapy. There is evidence that once daily dosing of aminoglycosides is associated with a lower degree of hearing loss than is traditional dosing [87]. There are no good laboratory indicators of vestibular toxicity. For this reason, patients should be aware of this potentially disabling side effect and should be told to report suggestive symptoms such as dizziness, unexplained nausea (e.g., while watching television or traveling in a car), or a sense of imbalance to their physicians. Patients' understanding of the risks associated with aminoglycoside therapy should be clearly documented in their medical records.

As part of the care plan, physicians should establish parameters for the notification of abnormal laboratory values, for follow-up visits, and for anticipated therapy stop dates. Physicians should be notified immediately in the event of significant laboratory abnormalities.

**First-dose policies.** As a rule, the first dose of an anti-infective should be administered in a supervised setting where a physician is readily available (e.g., a physician's office or an outpatient clinic) and where medication, equipment for resuscitation, and trained personnel are readily available. The complexities of this issue have been addressed elsewhere [88].

### Anti-infective Selection and Administration

Several factors, including the likely infecting organism, pharmacodynamic and pharmacokinetic factors, and drug stability, must be taken into account in selecting anti-infectives. While almost any anti-infective can be used for CoPAT, drugs with long half-lives continue to be extensively prescribed. Use of agents that can be administered once or twice daily results in minimal disruption of daily activities and limits the number of IV line manipulations and, thus, the potential for IV catheter-associated complications. In most published series on outpatient antibiotic therapy, ceftriaxone and other cephalosporins have been the most commonly prescribed drugs. The choice of anti-infectives for CoPAT needs to be monitored because of increasing concerns regarding the development of resistance, even in community settings.

Recent research on pharmacodynamic factors has influenced the dosing of drugs (Table 8) [21]. Thus, aminoglycosides, which show concentration-dependent killing, should be dosed once a day. Such a regimen may offer therapeutic advantages and may also reduce the incidence of nephrotoxicity and ot-
Table 8. Correlation of pharmacodynamic factors and efficacy of various agents used for community-based parenteral anti-infective therapy.

<table>
<thead>
<tr>
<th>Anti-infective agent</th>
<th>Pharmacodynamic characteristics</th>
<th>Goal of dosage regimen</th>
<th>Parameter correlating with in vivo efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aminoglycosides, fluoroquinolones, metronidazole</td>
<td>Concentration-dependent killing, prolonged persistent effects</td>
<td>Maximization of concentrations</td>
<td>Peak level, MIC*</td>
</tr>
<tr>
<td>Pencillins, cephalosporins, aztreonam</td>
<td>Time-dependent killing, short or no persistent effects</td>
<td>Maximization of exposure time</td>
<td>24-Hour AUC, MIC'</td>
</tr>
<tr>
<td>Carbapenems, vancomycin, clindamycin, macrolides</td>
<td>Time-dependent killing, prolonged persistent effects</td>
<td>Maximization of exposure time (serum levels can fall below MIC)</td>
<td>Time serum levels exceed MIC/MBC</td>
</tr>
</tbody>
</table>

NOTE: Data are from [21]. AUC = area under the curve.
* Applies only to aminoglycosides.
' Applies only to fluoroquinolones and metronidazole.

toxicity [89, 90]. However, the use of once-daily aminoglycoside therapy in pregnant women, children, the elderly, and critically ill patients has not been fully evaluated. This applies to patients with renal dysfunction, neutropenia, burns, liver disease, or endocarditis as well [91].

Certain cephalosporins and penicillins with half-lives of ≤60 minutes might be best used by continuous infusion because these drugs exhibit time-dependent killing and limited postantibiotic effects [92]. On the other hand, drugs such as ceftriaxone and vancomycin have sufficiently long half-lives to provide serum concentrations above the MICs for susceptible organisms for 12–24 hours and thus can be given once daily. Vancomycin has been used extensively in outpatient settings because of its attractive dosing characteristics and the appearance of methicillin-resistant S. aureus. The increasing concern regarding vancomycin-resistant enterococci has necessitated limiting the use of vancomycin to defined situations [93].

The stabilities of imipenem/cilastatin and ampicillin in solution are of concern. These drugs are stable at room temperature for only 4 and 8 hours, respectively, so they cannot be administered via continuous infusion therapy unless the solutions are prepared freshly and changed frequently. Side effects are a concern with all anti-infective therapy and should be specifically monitored on the basis of clinical and laboratory criteria (table 7).

Outcome Measures

While there are many reassuring retrospective studies on the efficacy and safety of CoPAT, few prospective studies comparing the risks and outcomes for patients treated as inpatients rather than outpatients have been performed [40, 94]. Donati et al. [40] prospectively studied the outcome of pneumonia in cystic fibrosis patients treated at home or in the hospital. These investigators used several parameters and did not note any significant differences in outcome, with the exception of improved vital capacity in the hospitalized patients. Wilhams et al. [94] undertook a prospective randomized study of outpatient iv ceftriaxone therapy for selected febrile children with sickle-cell disease. These investigators concluded that with the use of conservative eligibility criteria, at least half of febrile episodes in children with sickle-cell disease could be safely treated with ceftriaxone as outpatients.

Members of the Joint Commission on Accreditation of Healthcare Organizations have devised a number of indicators for home infusion therapy (table 9) that emphasize processes and outcomes of home-infusion plans [95]. Process refers to the rendering of care and includes patient-selection criteria, patient education, implementation and coordination of therapy, and the monitoring of care with particular emphasis on identification of complications and other untoward events [85]. Outcome measures the effects of care on the overall health status of a patient and includes clinical endpoints, complications, quality of life, and patient satisfaction. The parameters outlined in table 9 enable a CoPAT provider to calculate the overall incidence of a particular indicator. These and other parameters should be monitored over time within a CoPAT program, and the findings should be compared with those for other programs. Examples include (1) resource utilization (i.e., equipment and nurse visits); (2) frequency of equipment malfunction (e.g., infusion pumps); (3) care-coordination events (e.g., prompt reporting, by the nurse or other care provider, of a change in a patient’s clinical condition, and reporting of critical clinical laboratory results); (4) interruption of care (e.g., noncompliance, nondelivery of anti-infectives, or drug errors); (5) quality of life and patient satisfaction (e.g., the number of complaints); (6) overall measures of outcome (e.g., death, successful completion of the program, or number of changes in the anti-infective therapy); (7) the reason for a change in the anti-infective therapy; (8) a change in the route of drug administration; and (9) a change in the type of venous access (e.g., peripheral to central).

Limited data suggest that the risk of iv catheter-associated phlebitis and infection in adults is reduced when they are treated in home iv therapy programs [23].
Table 9. Joint Commission on Accreditation of Healthcare Organizations home infusion therapy indicators.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unscheduled inpatient admission</td>
<td>Patients who have an unscheduled inpatient admission, subcategorized by reason for admission</td>
</tr>
<tr>
<td>Early discontinuation of infusion therapy</td>
<td>Courses of infusion therapy discontinued before prescribed completion, subcategorized by reason for discontinuation</td>
</tr>
<tr>
<td>Interruption in infusion therapy</td>
<td>Total number of interruptions in infusion therapy, subcategorized by reason for interruption</td>
</tr>
<tr>
<td>Prevention and surveillance of infection</td>
<td>Patients with central venous lines whose catheters are removed or who are receiving anti-infective therapy for suspected or confirmed catheter-related infections, subcategorized by type of central-line catheter and number of lumens</td>
</tr>
<tr>
<td>Adverse drug reaction</td>
<td>Total number of suspected or confirmed adverse drug reactions, subcategorized by type and severity of reaction and by drug class</td>
</tr>
</tbody>
</table>

NOTE: Data are from [95].

Economic Considerations

The risks, benefits, and outcome of CoPAT must be carefully evaluated, and this form of treatment should not be overused or underused. For carefully selected patients, the benefits outweigh the risks: this includes the direct economic benefits that accrue to the health care system as well as the indirect and intangible benefits that accrue to the patient. The occupation of a hospital bed is one of the most expensive aspects of medical care. Because of soaring costs, alternatives to in-hospital treatment must be considered when patients no longer require careful observation and daily nursing care. Intravenous anti-infective therapy that is given on an outpatient basis costs significantly less per patient per day than the same treatment administered in the hospital [16, 22, 96], primarily because savings result when a patient no longer occupies a hospital bed. Most publications ascribe the same costs for drugs and laboratory monitoring whether the patient receives care in an inpatient or an outpatient program. There are costs intrinsic to most CoPAT programs that would not normally be incurred during an inpatient hospital stay. These costs include those associated with patient education, drug delivery, home nurse visits, and, in selected situations, iv drug delivery devices.

It is not always easy to calculate precisely how much less CoPAT costs than inpatient antibiotic administration because investigators often do not clearly differentiate between cost and charge, and they do not provide exactly comparable data. However, data from a recent review [97] on this subject reveal surprisingly uniform results (table 10) [98 - 100]. In most studies, the message is clear: CoPAT saves money when it is used appropriately.

Provision of CoPAT for Medicare-eligible patients is limited by the fact that home expenses other than skilled-nurse visits are not covered. Patients covered by Medicare can be treated with iv anti-infectives under physician supervision in an outpatient center. Furthermore, hospital administrators can use CoPAT as a means of minimizing their costs for Medicare patients receiving prolonged treatment with iv anti-infectives through diagnosis-related-group payment mechanisms. This requires the hospital to partner with a CoPAT provider [24]. There is less information on the economics of CoPAT with respect to the Medicare population compared with other populations, and direct comparisons are difficult to make because methods of calculation differ. It has been estimated that by using CoPAT, savings of $288 per day occur during periods when hospital-bed occupancy is high and $125 per day during periods when hospital-bed occupancy is low [24].

Many patients who would have been hospitalized in the past never enter the hospital and receive their entire courses of anti-infective therapy as outpatients. Some insurers are concerned that CoPAT is so convenient that it may be overused in situations where cheaper oral anti-infective therapy would be as effective, while physicians express the concern that patients may be discharged into nonhospital settings prematurely because of cost issues. Interactions between physicians and insurance payers that involve CoPAT are not always harmonious. Even though the use of CoPAT is associated with greater cost savings than is inpatient therapy, insurers occasionally ask physicians to further reduce costs by decreasing the number of approved visits to the home, downgrading the level of training required of the personnel making the visits, or reducing patient monitoring requirements in other ways. Other examples include the refusal of an insurer to pay for the number of home visits by a skilled nurse that are deemed adequate for a patient with endocarditis who is in relatively unstable condition or for a patient with meningitis in whom complications of infection could lead to considerable morbidity or to death.

It is essential that knowledgeable physicians be able to ensure the provision of all necessary care for patients receiving
Table 10. Comparison of inpatient and outpatient costs per day for selected groups of patients.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Infection, condition</th>
<th>Inpatient cost per d ($)</th>
<th>Outpatient cost per d ($)</th>
<th>Percentage cost of outpatient care vs. inpatient care</th>
</tr>
</thead>
<tbody>
<tr>
<td>[98]</td>
<td>Osteomyelitis, septic arthritis, brain abscess</td>
<td>247</td>
<td>108</td>
<td>31</td>
</tr>
<tr>
<td>[99]</td>
<td>Infectious complications of cancer in children</td>
<td>618</td>
<td>214</td>
<td>35</td>
</tr>
<tr>
<td>[100]</td>
<td>Cellulitis, osteomyelitis, pneumonia</td>
<td>417</td>
<td>155</td>
<td>37</td>
</tr>
</tbody>
</table>

NOTE: Data are from [97].

CoPAT in the same way they ensure such care for hospitalized patients. Utilization review of CoPAT resources is often undertaken by nonmedical or nursing personnel. It is important that the ordering physician have easy access to the insurance plan’s medical director to facilitate appropriate medical care decisions for patients receiving CoPAT.

Methods of administration. The method of administering an anti-infective influences the cost of CoPAT. CVCs, including those inserted peripherally, are convenient for patients and nurses, are expensive to insert (there are professional fees, material costs, and operating room expenses), and are associated with increased risk of infection when compared with short peripheral iv catheters. Although CVCs are needed in patients who will be receiving long-term iv therapy or in whom venous access is inadequate, these catheters are usually not warranted for patients whose anticipated durations of treatment are < 2 weeks. Newer methods of administration based on more rapid iv injection of certain antibiotics (e.g., syringe infusion) result in avoidance of the greater cost of iv “mini bags” and tubing as well as time savings for patients and caregivers.

Average duration of therapy. The average duration of CoPAT for adults is 12–14 days, and that for children is 5–7 days. While some patients with infections require close follow-up by physicians, most patients need to see their physicians only once or twice weekly. The ongoing monitoring is conducted by a nurse skilled in CoPAT. Although patients with HIV infection and its associated infectious complications are often seen less frequently because of their prolonged treatment course, physicians should see such patients once or twice a month. Having patients return to an infusion center or other dedicated outpatient location for follow-up, rather than being visited by a nurse, is even less costly.

Laboratory monitoring. It is necessary to periodically monitor defined laboratory parameters for all patients receiving CoPAT. Excessive laboratory testing can increase the costs of CoPAT significantly. Specific suggestions for laboratory monitoring have already been outlined herein (table 7). If these recommendations are followed, treatment costs and complications should be minimized.

Physician reimbursement. In general, physicians’ professional fees are reduced by the use of CoPAT because patients are usually seen only once or twice weekly rather than daily in the hospital.

Advantages and benefits. Direct costs are easier to calculate than is the substantial indirect benefit to patients that results from the ability to stay home, return to work, or attend school. Although difficult to measure, these advantages are real and important. Other indirect savings of CoPAT include lower transportation and child care costs. The psychological benefits to infants and children are also difficult to measure but are substantial. CoPAT is safe, effective, usually preferred by patients, and cost-effective.

Table 11. Potential benefits and risks associated with community-based parenteral anti-infective therapy.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Benefits</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual or personal factors</td>
<td>At home with family; return to school or work; reduction in infectious risk; fewer iv cannula–associated infections and phlebitis</td>
<td>Disruption of family routine; increased stress; noncompliance with therapy; misuse of iv access; interruption of iv therapy; increased out-of-pocket expenses</td>
</tr>
<tr>
<td>Economic and societal factors</td>
<td>Less costly; hospital beds and hospital resources used for other patients</td>
<td>Nonavailability for insurance coverage (e.g., for the elderly)</td>
</tr>
</tbody>
</table>

NOTE: Data are from [101].
Risks and Benefits

There are several potential benefits and risks related to CoPAT (table 11) [101]. Both the benefits and risks can be defined from individual or personal perspectives as well as from more-global economic and societal perspectives. Individual benefits include the receipt of care at home with the family, the ability to return to school or work, and a potential reduction in infectious risks. Risks include treatment failure due to non-compliance or caregiver withdrawal, disruption of the family routine, and the potential for patients' misuse of IV access devices. With appropriate safeguards in patient selection and monitoring, IV-related problems and interruption of therapy can be circumvented or reduced. However, CoPAT may involve increased out-of-pocket expenses for some patients.

As noted earlier, a number of cost-benefit analyses have shown benefit when both direct and indirect benefits are analyzed. However, a true assessment of the cost differential between CoPAT and in-hospital treatment is a complex task requiring acknowledgement of the model of care and a more global vision of the health care delivery system. The greatest savings are due to the facts that a patient no longer occupies a hospital bed, and fewer hospital resources are used. Theoretically, the use of CoPAT enables the use of hospital beds and other resources for other admissions. Finally, most CoPAT programs have been associated with low overall morbidity and low levels of risk for mortality and serious IV cannula-related problems [23].

References