Complete Summary

GUIDELINE TITLE

Practice guidelines for outpatient parenteral antimicrobial therapy.

BIBLIOGRAPHIC SOURCE(S)

Tice AD, Rehm SJ, Dalovisio JR, Bradley JS, Martinelli LP, Graham DR, Brooks Gainer R, Kunkel MJ, Yancey RW, Williams DN. Practice guidelines for outpatient parenteral antimicrobial therapy. Clin Infect Dis 2004 Jun 15;38(12):1651-72. [237 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Practice guidelines for community-based parental anti-infective therapy. Clin Infect Dis 1997 Oct;25(4):787-801.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- July 08, 2008, Fluoroquinolones (ciprofloxacin, norfloxacin, ofloxacin, levofloxacin, moxifloxacin, gemifloxacin): A BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones for systemic use.
- September 11, 2007, Rocephin (ceftriaxone sodium): Roche informed healthcare professionals about revisions made to the prescribing information for Rocephin to clarify the potential risk associated with concomitant use of Rocephin with calcium or calcium-containing solutions or products.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Infectious conditions suitable for outpatient parenteral antimicrobial therapy (OPAT) include:

- Cellulitis/soft-tissue infection/wound infection
- Osteomyelitis
- Septic arthritis/bursitis
- Prosthetic joint infections
- Pneumonia/severe lower respiratory infections
- Cystic fibrosis (infectious exacerbations)
- Sinusitis (complicated)
- Chronic otitis/mastoiditis
- Endocarditis
- Intravenous catheter-associated infection
- Vascular graft infections
- Hepatic or splenic abscess
- Peritonitis or intra-abdominal infection
- Complicated urinary tract infections
- Tubo-ovarian abscess/pelvic inflammatory disease
- Meningitis or encephalitis
- Brain or epidural abscesses
- Neutropenic fever
- Lyme disease
- Bacteremia
- Fungemia/systemic mycosis
- Cytomegalovirus infections

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To update the Infectious Diseases Society of America (IDSA) guidelines written in 1997
- To assist physicians and other health care professionals with various aspects of the administration of outpatient parenteral antimicrobial therapy (OPAT)

TARGET POPULATION

All persons who are candidates for outpatient parenteral antimicrobial therapy (OPAT)

Note: Initiation of OPAT requires that a physician determine that such therapy is needed to treat a defined infection, that hospitalization is not needed to control the infection, and that alternate routes of drug delivery are not feasible or appropriate.

INTERVENTIONS AND PRACTICES CONSIDERED

1. Patient evaluation and selection including consideration of the following factors:
    - Is parenteral antimicrobial therapy needed?
    - Do the patient´s medical care needs exceed resources available at the proposed site of care?
    - Is the home or outpatient environment safe and adequate to support care?
    - Are the patient and/or caregiver willing to participate and able to safely, effectively, and reliably deliver parenteral antimicrobial therapy?
    - Are mechanisms for rapid and reliable communications about problems and for monitoring of therapy in place between members of the OPAT team?
    - Do the patient and caregiver understand the benefits, risks, and economic considerations involved in OPAT?
    - Does informed consent need to be documented?
2. Antimicrobial selection and administration
    - Consideration of multiple factors including the probable infecting organism, the pharmacodynamic and pharmacokinetic properties of candidate drugs, and drug stability.
    - Antimicrobials frequently used for OPAT include:
        - Aminoglycosides
        - Antivirals
        - Ceftriaxone
        - Ceftazidime
        - Cefazolin

        - Cefepime
        - Cephalosporins
        - Clindamycin
        - Meropenem
        - Oxacillin/nafcillin
        - Other beta-lactams
        - Penicillins
        - Vancomycin
    - Patient/caregiver training/education
3. Clinical and laboratory monitoring
4. Follow-up on patient outcomes and safety
5. Special considerations for pediatric patients (e.g., certain competencies in physical examination, familiarity with common pediatric infections and antimicrobial toxicities specific to children)

MAJOR OUTCOMES CONSIDERED

- Overall measures of outcome (e.g., death, successful completion of the program, or number of changes in the antiinfective therapy)
- Clinical endpoints
- Complication rates
- Quality of life
- Patient satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Executive Summary

These guidelines were formulated to assist physicians and other health care professionals with various aspects of the administration of outpatient parenteral antimicrobial therapy (OPAT). Although there are many reassuring retrospective studies on the efficacy and safety of OPAT, few prospective studies have been conducted to compare the risks and outcomes for patients who receive treatment as outpatients rather than as inpatients. Because truly evidence-based studies are lacking, the present guidelines are formulated from the collective experience of the committee members and advisors from related organizations.

Important aspects of OPAT are described in the text and tables in the original guideline document and include the following:

1. The literature supports the effectiveness of OPAT for a wide variety of infections (see below).
2. A thorough assessment of the patient´s general medical condition, the infectious process, and the home situation is necessary before starting therapy (see Table 2 of the original guideline document)
3. Prescribing physicians should be aware of a number of aspects of OPAT which distinguish it from other forms of therapy. These include the required teamwork, communication, monitoring, and outcome measurements (see Tables 3 and 4 of the original guideline document).
4. The physician has a unique role on the OPAT team, which may also include nursing, pharmacy, and social services. These responsibilities include establishing a diagnosis, prescribing treatment, determining the appropriate site of care, monitoring during therapy, and assuring the overall quality of care.
5. Antimicrobial selection for OPAT is different from that for therapy in the hospital. Once-daily drug administration has many advantages. Potential for adverse effects and the stability of an antimicrobial once it is mixed must be considered (see Tables 5–7 of the original guideline document).
6. The importance of administering the first dose of an antibiotic in a supervised setting is emphasized.
7. Regular clinical and laboratory monitoring of patients receiving OPAT is essential and varies with the antimicrobial chosen (see Table 8 of the original guideline document).
8. Outcomes measures should be an integral part of any OPAT program, to assure the effectiveness and quality of care (see Table 9 of the original guideline document).
9. Children receiving OPAT must be considered differently because of their special needs. (See the section "Considerations for Pediatric Patients" in the original guideline document)

Table 1. Infections Treated with Outpatient Parenteral Antimicrobial Therapy (OPAT) and the Antibiotics Used in 4 Studies or Sites

OPAT Network (1996–2002)[a]	**Cleveland Clinic (1986–2000)[b]**	**Minneapolis area (1978–1990)[c]**	**Children´s Hospital San Diego (2000)[d]**
Type of infection, ranked by frequency (% of OPAT courses)			
Skin and soft tissue (23) Osteomyelitis (15) Septic arthritis/bursitis (5)	Musculoskeletal Infected devices Bacteremia Intra-abdominal Skin and soft tissue	Cellulitis (15) Osteomyelitis (13) Late-stage Lyme disease (10) Pyelonephritis	Bacteremia (16) Pyelonephritis (13) Meningitis (13) Intra-

OPAT Network (1996–2002)[a]	Cleveland Clinic (1986–2000)[b]	Minneapolis area (1978–1990)[c]	Children´s Hospital San Diego (2000)[d]
Type of infection, ranked by frequency (% of OPAT courses)			
Bacteremia (5) Wound (4) Pneumonia (4) Pyelonephritis (3)	... ...	and UTI (9) Septic arthritis (7) Other (46) ...	abdominal (8) Cellulitis (7) Osteomyelitis (7) Wound (7)
Antimicrobial, ranked by frequency of use (% of OPAT courses)			
Ceftriaxone (33) Vancomycin (20) Cefazolin (6) Oxacillin/nafcillin (5) Aminoglycosides (5) Clindamycin (3) Ceftazidime (3)	Vancomycin (31) Penicillins (20) Antivirals (12) Cephalosporins (9) Aminoglycosides (5) Other beta-lactams (4)	... ...	Ceftriaxone (42) Meropenem (11) Cefazolin (11) Cefepime (6) Ceftazidime (6) Vancomycin (6)

Abbreviation: UTI, urinary tract infection

[a] Data from OPAT Outcomes Registry (available at http://www.opat.com).

[b] Data from Susan Rehm, personal communication. Percentage of infections not recorded.

[c] Data from Williams DN. Home intravenous antibiotic therapy (HIVAT): Indications, patients and antimicrobial agents. Int J Antimicrobial Agents. 1995; 5:3–8.

[d] Data from John Bradley, personal communication.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

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.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

These guidelines are intended to ensure successful implementation of parenteral antimicrobial services for patients in varied community settings, including the home and outpatient facilities, such as physicians´ offices, hospital clinics, ambulatory-care centers, day hospitals, and skilled nursing facilities. They have been formulated to incorporate the perspectives of the team of physicians, nurses, pharmacists, and other health care professionals necessary for an effective and safe program.

POTENTIAL HARMS

Adverse effects in patients receiving antimicrobial therapy are not unusual. Table 6 in the original guideline document displays information from the Outpatient Parenteral Antimicrobial Therapy (OPAT) Outcomes Registry, which indicates that 3–10% of antimicrobial courses are stopped prematurely because of an adverse reaction. If laboratory parameters show an adverse trend, the frequency of laboratory monitoring should be increased; in some cases, the medication may need to be changed or its use discontinued. Data suggest that some adverse reactions, such as renal or vestibular toxicity and leukopenia, become more frequent as the length of therapy increases. Even though an infection is responding, the need for regular laboratory monitoring remains.

Subgroups Most Likely to Experience Harms

A number of drugs are not approved for pediatric use—for example, fluoroquinolone and quinupristin-dalfopristin.

QUALIFYING STATEMENTS

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- In the majority of cases, the strength and quality of evidence in support of outpatient parenteral antimicrobial therapy (OPAT) is limited by a lack of prospective studies and a large number of confounding variables, therefore no ratings are given here. The information herein, however, can provide a guide for programs to develop the best practices possible in their environment.

- These guidelines are general and need to be adapted to many variables in each treatment setting. Because of the focus on OPAT, the related topics of duration of therapy, when to switch to oral anti-infective therapy, and infusion therapies other than antimicrobials are not addressed.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Dissemination of the Guidelines

The contributors to these guidelines considered what could be done to optimize their understanding and use. Timely publication of the guidelines or their abstracts in the various society journals is possible. In addition, the Internet offers the ability to disseminate information and support it through links to documents from other societies and to patient education materials.

The potential exists for continual updating and close cooperative activities among the societies represented in these guidelines. Many of these resources are available through the Web page of the Infectious Diseases Society of America (http://www.idsociety.org). Additional information about outpatient parenteral antimicrobial therapy (OPAT) can be found at the OPAT Outcomes Registry Web site (http://www.opat.com) and at the Web pages of the contributing societies listed in Table 9 in the original guideline document.

OPAT Outcomes and Patient Safety

The measurement of outcomes by an OPAT program is a part of the continuous performance improvement process through which health care providers attempt to improve and assure the quality of their care and service. Parameters are chosen to assess the safety, efficacy, and cost of the OPAT program. The best-studied OPAT outcomes indicators have been those related to cost savings and financial analyses. Results of outcomes analyses may also be useful for marketing and contracting with payors. Accrediting bodies such as the Joint Commission for the Accreditation of Health Care Organizations (JCAHO) and the National Committee for Quality Assurance require outcomes measurements as a part of their certification process but do not specify the parameters or indicators to use. The JCAHO requires reporting and root cause analysis of "sentinel events" resulting in unexpected death or permanent injury arising from therapy. As the financial pressures mount for earlier hospital discharge of sicker patients, the importance of monitoring outcomes to assure patient safety increases.

Since the 1997 OPAT guidelines were published, some progress has been made in defining the appropriate outcomes to monitor and the techniques for their measurement; however, available data are sparse and rarely prospective. The articles referenced in the Appendix of the original guideline document support the effectiveness of OPAT for many indications.

OPAT centers should have an active performance improvement program that can track clinical and program outcomes. Limited data are available to allow for comparison of a program´s performance with a national database for

benchmarking purposes. The OPAT Outcomes Registry is a national database that is accumulating data that can help compare a program´s performance with that of an aggregate of 130 centers with over 14,000 cases. An OPAT center collects data on outcomes for the patients and can monitor its own clinical performance over time. This is particularly useful in the absence of published outcomes standards for infections treated with OPAT. Parameters which are monitored in the OPAT Outcomes Registry are listed in table below.

Patient safety and health care–related infections are of particular concern with OPAT. The home environment is rarely constructed for safety; hence, application of hospital infection control polices may not be appropriate. Fortunately, the risk of infection related to home care appears to be much less than the risk of hospital-acquired infection and the chances of acquiring an antimicrobial-resistant organism from the home environment appear to be lower. Long-term care facilities are challenged with a concentrated population of debilitated but mobile patients, many of whom are recovering from hospital-acquired infections.

Patient safety issues with OPAT are similar to the hospital with potential medication errors, adverse drug effects, and complications from infusion devices. Patients and staff should be educated with regard to these risks and be immediately available if they occur. OSHA standards for health care worker safety and needle stick prevention are to be incorporated into the patient´s plan of care in the outpatient setting.

Outcome Measures for Outpatient Parenteral Antimicrobial Therapy (OPAT)

1. Clinical status (as reported by the responsible physician)
    A. Improved
    B. Clinical failure
    C. No change
2. Bacterial infection status (if a pathogen was identified and repeat culture was done)
    A. Culture negative for pathogen
    B. Persistent pathogen
    C. New pathogen
3. Program outcome (i.e., end of therapy)
    A. Therapy completed as planned
    B. Therapy not completed because of patient´s death, noncompliance with therapy, complication, patient´s preference, hospitalization (give reason), or other
4. Antibiotic use (i.e., end of treatment course)
    A. Course completed as planned
    B. Course not completed because of adverse drug reaction (note type), resistant organism, persistent organism, patient´s preference, clinical failure
5. Vascular access complications, such as phlebitis, infection, thrombosis, infiltration, or becoming dislodged
6. Additional outcome measurements
    A. Patient returned to work or school during OPAT (if applicable)
    B. Did outcome meet physician expectations?

C. Survival status (patient alive, died of infection, died of other causes, lost to follow-up, or status unknown)

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Tice AD, Rehm SJ, Dalovisio JR, Bradley JS, Martinelli LP, Graham DR, Brooks Gainer R, Kunkel MJ, Yancey RW, Williams DN. Practice guidelines for outpatient parenteral antimicrobial therapy. Clin Infect Dis 2004 Jun 15;38(12):1651-72. [237 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2004 Jun 15)

GUIDELINE DEVELOPER(S)

Infectious Diseases Society of America - Medical Specialty Society

SOURCE(S) OF FUNDING

Infectious Diseases Society of America (IDSA)

GUIDELINE COMMITTEE

IDSA Practice Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Names of Committee Members: Alan D. Tice, John A. Burns School of Medicine, University of Hawaii, Honolulu; Susan J. Rehm, Department of Infectious Diseases, Cleveland Clinic Foundation, Cleveland, Ohio; Joseph R. Dalovisio,

Ochsner Clinic, Department of Infectious Diseases, New Orleans, Louisiana; John S. Bradley, Division of Infectious Diseases, Children´s Hospital of San Diego, San Diego, California; Lawrence P. Martinelli, Consultants in Infectious Diseases, Lubbock, Texas; Donald R. Graham, Springfield Clinic, Springfield, Illinois; R. Brooks Gainer, Morgantown Internal Medicine Group, Morgantown, West Virginia; Mark J. Kunkel, Pfizer, Inc.; Robert W. Yancey, Florida Infection Physicians, Gainesville; David N. Williams, Hennepin County Medical Center, Minneapolis, Minnesota

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

John S. Bradley has received research funding from Roche, AstraZeneca, Bristol-Myers Squibb, Johnson and Johnson, and Pfizer; he has consulted for AstraZeneca, Bristol-Myers Squibb, Johnson and Johnson, and Bayer. R. Brooks Gainer belongs to the speakers´ bureaus of Roche, Merck, Pfizer, Glaxo-SmithKline, and Wyeth-Ayerst. Mark J. Kunkel is employed by Pfizer.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Practice guidelines for community-based parental anti-infective therapy. Clin Infect Dis 1997 Oct;25(4):787-801.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Infectious Diseases Society (IDSA) Web site.

Print copies: Available from Infectious Diseases Society of America, 1300 Wilson Boulevard, Suite 300, Arlington, VA 22209.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Kish MA. Guide to development of practice guidelines. Clin Infect Dis 2001 Mar 15;32(6):851-4.

Electronic copies: Available from the Clinical Infectious Diseases Journal Web site.

Print copies: Available from Infectious Diseases Society of America, 1300 Wilson Boulevard, Suite 300, Arlington, VA 22209.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on January 15, 1999. The information was verified by the guideline developer as of March 22, 1999. This summary was updated by ECRI on August 11, 2004. This summary was updated by ECRI Institute on October 3, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Rocephin (ceftriaxone sodium). This summary was updated by ECRI Institute on July 28, 2008 following the U.S. Food and Drug Administration advisory on fluoroquinolone antimicrobial drugs.

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