



Complete Summary

GUIDELINE TITLE

ASHP therapeutic guidelines on antimicrobial prophylaxis in surgery.

BIBLIOGRAPHIC SOURCE(S)

American Society of Health-System Pharmacists. ASHP therapeutic guidelines on antimicrobial prophylaxis in surgery. American Society of Health-System Pharmacists. Am J Health Syst Pharm 1999 Sep 15;56(18):1839-88. [559 references] [PubMed](#)

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Postoperative infections (i.e, initial infection following surgical procedures).

The guideline does not address secondary (reactivation of a preexisting infection) infection or bacterial colonization following surgical procedures.

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Prevention

CLINICAL SPECIALTY

Anesthesiology
Colon and Rectal Surgery
Gastroenterology
Internal Medicine
Neurological Surgery

Obstetrics and Gynecology
Ophthalmology
Orthopedic Surgery
Pediatrics
Pharmacology
Preventive Medicine
Surgery
Thoracic Surgery
Urology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Hospitals
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide practitioners with standardized effective regimens for the rational use of prophylactic antimicrobials.
- To revise the American Society of Health-System Pharmacists (ASHP) 1992 recommendations on antimicrobial prophylaxis in surgery based on new clinical evidence and additional concerns.

TARGET POPULATION

Adult and pediatric patients (1- 21 years of age), including infants (one month to 2 years of age)

Geriatric patients, newborns (premature and full-term), and patients with renal or hepatic dysfunction are not specifically addressed

INTERVENTIONS AND PRACTICES CONSIDERED

Primary antimicrobial prophylaxis (i.e., prevention of an initial infection) for surgical procedures, including antibiotic choice, dose, and dosage regimen. The antimicrobial agents considered include:

- Ampicillin
- Cefamandole
- Cefazolin
- Cefmetazole
- Cefotaxime
- Cefotetan
- Cefoxitin
- Cefuroxime
- Clindamycin

- Erythromycin
- Gentamicin
- Lomefloxacin
- Metronidazole
- Nafcillin
- Neomycin sulfate
- Neomycin-polymyxin B-gramicidin
- Oxacillin
- Piperacillin
- Sulfamethoxazole
- Tobramycin
- Trimethoprim
- Vancomycin

MAJOR OUTCOMES CONSIDERED

- Postoperative infection rates
- Postoperative morbidity and mortality rates
- Duration and cost of health care

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The primary literature from the previous American Society of Health-System Pharmacists (ASHP) Therapeutic Guidelines on Antimicrobial Prophylaxis in Surgery was reviewed together with the primary literature between the date of the previous guidelines and August 1997, identified by a MEDLINE search.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The strength of evidence represents only support for or against prophylaxis and does not apply to the antimicrobial choice, dose, or dosage regimen. Studies supporting the recommendations for the use of an antimicrobial were classified as follows:

Level I: evidence from large, well-conducted randomized, controlled clinical trials or a meta-analysis

Level II: evidence from small, well-conducted randomized, controlled clinical trials

Level III: evidence from well-conducted cohort studies

Level IV: evidence from well-conducted case-control studies

Level V: evidence from uncontrolled studies that were not well conducted

Level VI: conflicting evidence that tends to favor the recommendation

Level VII: expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Particular attention was paid to study design, with greatest credence given to randomized, controlled, double-blind studies. Established recommendations by experts in the area (Centers for Disease Control and Prevention [CDC], American College of Obstetricians and Gynecologists [ACOG]) were also considered.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

These guidelines were prepared by the Rocky Mountain Poison and Drug Center under contract to the American Society of Health-System Pharmacists (ASHP). The project was coordinated by a drug information pharmacist who worked with a multidisciplinary consortium of writers and consulted with six physicians on staff at the University of Colorado Health Sciences Center. The project coordinator worked in conjunction with an independent panel of eight clinical pharmacy specialists with expertise in either adult or pediatric infectious disease. The panel was appointed by ASHP.

Guideline development included consideration of the following characteristics: validity, reliability, clinical applicability, flexibility, clarity, and a multidisciplinary nature as consistent with ASHP's philosophy on therapeutic guidelines. Recommendations on the use of an antimicrobial are substantiated by the strength of evidence that supports the recommendation.

A category C recommendation represents a consensus of the expert panel based on the clinical experience of individual panel members and a paucity of quality supporting literature. In cases for which opinions were markedly divided, the recommendations indicate that a substantial number of panel members supported an alternative approach.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Each recommendation was assigned a category corresponding to the strength of evidence that supports the use or nonuse of antimicrobial prophylaxis:

Category A: levels I-III

Category B: levels IV-VI

Category C: level VII

COST ANALYSIS

Although a formal cost analysis was not performed, a cost-minimization approach was employed in developing these guidelines. When antimicrobials have been shown to be equally efficacious and safe, the recommendation is based on the least expensive agent (on the basis of average wholesale price).

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines underwent multidisciplinary field review to evaluate their validity, reliability, and utility in clinical practice. The final document was approved by the American Society of Health-System Pharmacists (ASHP) Commission on Therapeutics and the ASHP Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The categories of evidence (A-C) are defined at the end of the Major Recommendations field.

The major recommendations for surgical antimicrobial prophylaxis contained within the guideline are presented below:

I. Cardiothoracic Surgery:

Recommendation

- For patients undergoing cardiothoracic procedures, the recommended regimen is cefazolin 1 g (as the sodium) intravenously at induction of anesthesia and every 8 hours for up to 72 hours. This duration is based on consensus of the expert panel because the data do not delineate the optimal duration of prophylaxis.
- Prophylaxis for 24 hours or less may be appropriate for cardiothoracic procedures. Currently there is no evidence to support continuing prophylaxis until chest and mediastinal drainage tubes are removed.
- Cefuroxime 1.5 g (as the sodium) intravenously at induction of anesthesia and every 12 hours for up to 72 hours or cefamandole 1 g (as nafate) at induction of anesthesia and every 6 hours for up to 72 hours are suitable alternatives.
- Vancomycin 1 g (as the hydrochloride) intravenously over one hour, with or without gentamicin 2 mg/kg (as the sulfate) intravenously, should be reserved as an alternative on the basis of guidelines from the Hospital Infection Control Practices Advisory Committee (HICPAC) [of the Centers for Disease Control and Prevention, CDC] and the American Heart Association (AHA).

STRENGTH OF EVIDENCE = A

Pediatric dosage

- The recommended regimen for pediatric patients undergoing cardiothoracic procedures is cefazolin 20-30 mg/kg (as the sodium) intravenously at induction of anesthesia and every 8 hours for up to 72 hours. Cefuroxime 50 mg/kg (as the sodium) intravenously at induction of anesthesia and every 8 hours for up to 72 hours is an acceptable alternative. Vancomycin 15 mg/kg (as the hydrochloride) intravenously over one hour, with or without gentamicin 2 mg/kg (as the sulfate) intravenously, should be reserved as an alternative on the basis of guidelines from HICPAC and AHA.

II. Gastroduodenal Surgery:

Recommendation

- Antimicrobial prophylaxis in gastroduodenal surgery should be considered for patients at highest risk for postoperative infections, such as patients with increased gastric pH (e.g., patients receiving histamine H₂-receptor antagonists), decreased gastric motility, gastric outlet obstruction, gastric bleeding, or cancer. Antimicrobials are not needed when the lumen of the intestinal tract is not entered.
- A single dose of cefazolin 1 g (as the sodium) given intravenously at induction of anesthesia is recommended in procedures during which the lumen of the intestinal tract is entered. A single dose of cefazolin 1 g given intravenously at induction of anesthesia is recommended for highly selective vagotomy, Nissen's fundoplication, and Whipple's procedure.

STRENGTH OF EVIDENCE for prophylaxis = A when the lumen of the intestinal tract is entered

STRENGTH OF EVIDENCE for prophylaxis = C for highly selective vagotomy, Nissen's fundoplication

Pediatric dosage

- The recommended regimen for pediatric patients undergoing gastroduodenal surgery during which the lumen of the intestinal tract is entered, highly selective vagotomy, Nissen's fundoplication, and Whipple's procedure is a single dose of cefazolin 20-30 mg/kg (as the sodium) intravenously at induction of anesthesia.

III. Biliary Tract Surgery:

Recommendation

- A single dose of cefazolin 1 g (as the sodium) administered intravenously at induction of anesthesia is recommended for open procedures in the biliary tract

STRENGTH OF EVIDENCE for prophylaxis = A

- Antimicrobial prophylaxis is not recommended in laparoscopic cholecystectomies

STRENGTH OF EVIDENCE against prophylaxis = B

Pediatric dosage

- The recommended regimen for pediatric patients undergoing open procedures in the biliary tract is a single dose of cefazolin 20-30 mg/kg (as the sodium) intravenously at induction of anesthesia.

IV. Appendectomy:

Recommendation

- For uncomplicated appendicitis, the recommended regimen is a cephalosporin with anaerobic and aerobic activity (cefoxitin, cefotetan, cefmetazole) 1-2 g intravenously at induction of anesthesia. An alternative is piperacillin 2 g (as the sodium) intravenously. For penicillin-allergic patients, an alternative is metronidazole 500 mg plus gentamicin 2 mg/kg (as the sulfate) intravenously at the induction of anesthesia.

STRENGTH OF EVIDENCE for prophylaxis = A

Pediatric dosage

- The recommended regimen for pediatric patients undergoing procedures for uncomplicated appendicitis is a single intravenous dose of cefoxitin 20-40 mg/kg (as the sodium), cefotetan 20-40 mg/kg (as the disodium), or cefotaxime or ceftizoxime 25-50 mg/kg (as the sodium) at induction of anesthesia.

- An alternative is piperacillin 50 mg/kg (as the sodium) intravenously at induction of anesthesia.
- For penicillin-allergic patients, an alternative is metronidazole 10 mg/kg plus gentamicin 2 mg/kg (as the sulfate) intravenously at induction of anesthesia.

V. Colorectal Surgery:

Recommendation

- Patients undergoing colorectal surgery should receive mechanical bowel preparation. Numerous bowel preparations are available. Lavage solutions are contraindicated in patients with obstruction.
- Oral neomycin sulfate 1 g and erythromycin base 1 g should be given after the bowel preparation is complete at 19, 18, and 9 hours before surgery.
- If the oral route is contraindicated, a single 2 g dose of an intravenous cephalosporin with both aerobic and anaerobic activity (e.g., cefoxitin, cefotetan, cefmetazole) should be given at induction of anesthesia.
- Because there is no demonstrable difference in efficacy among these cephalosporins, the choice should be based on local drug acquisition costs.
- In patients undergoing high-risk surgery, such as rectal resection, a combination of oral neomycin-erythromycin plus a cephalosporin administered intravenously is recommended.

STRENGTH OF EVIDENCE for prophylaxis = A

Pediatric dosage

- Pediatric patients undergoing colorectal surgery should undergo mechanical bowel preparation. Numerous bowel preparations are available. Lavage solutions are contraindicated in patients with obstruction. One regimen for pediatric patients is polyethylene glycol-electrolyte lavage solution given orally or by nasogastric tube at a rate of 25-40 mL/kg/hr until rectal effluent is clear.
- Oral neomycin sulfate 20 mg/kg and erythromycin base 10 mg/kg should be given after the bowel preparation is complete at 19, 18, and 9 hours before surgery.
- If the oral route is contraindicated, a single 30-40 mg/kg intravenous dose of cefoxitin or cefotetan should be given at induction of anesthesia.
- In patients undergoing high-risk surgery, such as rectal resection, a combination of oral neomycin and erythromycin plus a cephalosporin administered intravenously is recommended.

VI. Head And Neck Surgery:

A. Clean procedures

Recommendation

- Antimicrobial prophylaxis is not justified in patients undergoing clean surgical procedures of the head and neck.

- If there is prosthetic placement, cefazolin 1 g (as the sodium) intravenously at induction of anesthesia is appropriate.

STRENGTH OF EVIDENCE against prophylaxis = B

STRENGTH OF EVIDENCE for prophylaxis with prosthetic placement = C

Pediatric dosage

- Antimicrobial prophylaxis is not recommended in pediatric patients undergoing clean head and neck procedures unless there is prosthetic placement. In these cases, cefazolin 20-30 mg/kg (as the sodium) administered intravenously at induction of anesthesia is appropriate.

B. Clean-contaminated procedures

Recommendation

- Cefazolin 2 g (as the sodium) intravenously at induction of anesthesia and every 8 hours for 24 hours or clindamycin 600 mg (as the hydrochloride) intravenously at induction of anesthesia and every 8 hours for 24 hours.
- The necessity of giving gentamicin with clindamycin or metronidazole with cefazolin remains controversial.
- If these combinations are selected, the dosages are gentamicin 1.7 mg/kg (as the sulfate) intravenously and metronidazole 500 mg intravenously every eight hours. Agents should be administered at induction of anesthesia.
- Prophylaxis should not exceed 24 hours. Single-dose regimens may be preferable, particularly when cost and the possibility of resistance are considered; however, this approach remains controversial.

STRENGTH OF EVIDENCE for prophylaxis = A

Pediatric dosage

- The recommended regimen for pediatric patients undergoing clean-contaminated head and neck procedures is cefazolin 30-40 mg/kg (as the sodium) intravenously at induction of anesthesia and every 8 hours for 24 hours or clindamycin 15 mg/kg (as the hydrochloride) intravenously, at induction of anesthesia and every 8 hours for 24 hours. The addition of gentamicin 2.5 mg/kg (as the sulfate) intravenously to clindamycin remains controversial, as does the addition of metronidazole 10 mg/kg intravenously every eight hours to cefazolin. Agents should be administered at induction of anesthesia. Single-dose regimens may be preferable, particularly when cost and the possibility of resistance are considered; however, this approach remains controversial.

VII. Neurosurgery:

Recommendation

- A single dose of cefazolin 1 g (as the sodium) intravenously at induction of anesthesia is recommended for patients undergoing clean neurosurgical procedures or cerebrospinal fluid (CSF)-shunting procedures. Alternatively, a single intravenous dose of one of the β -lactamase-stable penicillins might be used (oxacillin 1 g [as the sodium] or nafcillin 1 g [as the hydrochloride]) intravenously over one hour should be reserved as an alternative on the basis of previously outlined guidelines from HICPAC.

STRENGTH OF EVIDENCE for prophylaxis for clean neurosurgical procedures = A

STRENGTH OF EVIDENCE for prophylaxis for CSF-shunting procedures = A

Pediatric dosage

- The recommended regimen for pediatric patients undergoing clean neurosurgical procedures or CSF-shunting procedures is a single dose of cefazolin 20-30 mg/kg (as the sodium) intravenously at induction of anesthesia. Vancomycin 15 mg/kg (as the hydrochloride) intravenously should be reserved as an alternative on the basis of previously outlined guidelines from HICPAC.

VIII. Cesarean Delivery:

Recommendation

- The recommended regimen for all women (low and high risk) undergoing cesarean delivery is a single dose of cefazolin 2 g (as the sodium) intravenously immediately after clamping of the umbilical cord.

STRENGTH OF EVIDENCE for prophylaxis for low-risk women = B

STRENGTH OF EVIDENCE for prophylaxis for high-risk women = A

Pediatric dosage

- The recommended regimen for low-and high-risk adolescents undergoing cesarean delivery is a single dose of cefazolin 2 g (as the sodium) intravenously immediately after clamping of the umbilical cord.

IX. Hysterectomy:

Recommendation

- The recommended regimen for women undergoing vaginal hysterectomy, abdominal hysterectomy, or radical hysterectomy is a single intravenous dose of cefazolin 1 g (as the sodium) or cefotetan 1 g (as the disodium) at induction of anesthesia. An alternative is cefoxitin 1 g (as the sodium) intravenously at induction of anesthesia.

STRENGTH OF EVIDENCE for prophylaxis for vaginal hysterectomy = A

STRENGTH OF EVIDENCE for prophylaxis for abdominal hysterectomy = A

STRENGTH OF EVIDENCE for prophylaxis for radical hysterectomy = A

Pediatric dosage

- The recommended regimen for adolescent women undergoing vaginal hysterectomy, abdominal hysterectomy, or radical hysterectomy is a single dose of cefazolin 1 g (as the sodium) or cefotetan 1 g (as the disodium) intravenously at induction of anesthesia. An alternative is cefoxitin 1 g (as the sodium) intravenously at induction of anesthesia.

X. Ophthalmic Surgery:

Recommendation

- The prophylactic antimicrobials used in ophthalmic procedures should provide coverage against Staphylococcus species and gram-negative organisms, in particular Pseudomonas species. The necessity of continuing topical antimicrobials postoperatively has not been established. The frequency of administration is based on usual treatment regimens.
- Antimicrobials that are appropriate include commercially available neomycin-polymyxin B-gramicidin solution one or two drops topically and tobramycin 0.3% or gentamicin 0.3% solution two drops topically before the procedure.
- Continuation of antimicrobials postoperatively is not supported by data.
- Addition of a subconjunctival antimicrobial, tobramycin 20 mg (as the sulfate) is optional.

STRENGTH OF EVIDENCE for prophylaxis = C

Pediatric dosage

- The recommendations for the use of topical antimicrobials in pediatric patients undergoing ophthalmic procedures are the same as for adults. Subconjunctival tobramycin cannot be recommended because there is a lack of pediatric data and dosages cannot be extrapolated from the insufficient adult data.

XI. Orthopedics:

Clean orthopedic procedures not involving implantation of foreign materials

Recommendation

- Antimicrobial prophylaxis is not recommended for patients undergoing clean orthopedic procedures not involving implantation of foreign materials.

STRENGTH OF EVIDENCE against prophylaxis = C

Pediatric dosage

- Antimicrobial prophylaxis is not recommended for pediatric patients undergoing clean orthopedic procedures not involving implantation of foreign materials.

A. Hip fracture repair and other orthopedic procedures involving the implantation of internal fixation devices

Recommendation

- Despite the lack of substantial data, the use of antimicrobial prophylaxis in hip fracture repair and in other orthopedic procedures involving the implantation of internal fixation devices may be substantiated by the morbidity (possible removal of an infected internal fixation device) and costs associated with infectious events.
- The recommended regimen is cefazolin 1 g (as the sodium) intravenously at induction of anesthesia and continued every 8 hours for 24 hours. Vancomycin 1 g (as the hydrochloride) intravenously over one hour should be reserved as an alternative agent on the basis of previously outlined guidelines from HICPAC.

STRENGTH OF EVIDENCE for prophylaxis for hip fracture = A

STRENGTH OF EVIDENCE for prophylaxis for implantation procedures = C

Pediatric dosage

- Despite the lack of substantial data, the use of antimicrobial prophylaxis in hip fracture repair and in other orthopedic procedures involving the implantation of internal fixation devices may be substantiated by the morbidity (possible removal of an infected internal fixation device) and costs associated with infectious events. The recommended regimen for pediatric patients is cefazolin 20-30 mg/kg (as the sodium) intravenously at the induction of anesthesia and every 8 hours for 24 hours. Vancomycin 15 mg/kg (as the hydrochloride)

intravenously should be reserved as an alternative on the basis of previously outlined guidelines from HICPAC.

XII. Total Joint Replacement:

Recommendation

- The recommended regimen for patients undergoing total hip, elbow, knee, or shoulder replacement is cefazolin 1 g (as the sodium) intravenously at induction of anesthesia and every 8 hours for 24 hours.
- Although continuing prophylaxis until drainage tubes are removed may be warranted, there is currently no evidence to support this practice.
- Vancomycin 1 g (as the hydrochloride) intravenously over one hour should be reserved as an alternative agent on the basis of previously outlined guidelines from HICPAC.

STRENGTH OF EVIDENCE for prophylaxis = A

Pediatric dosage

- The recommended regimen for pediatric patients undergoing total hip, elbow, knee, or shoulder replacement is cefazolin 20-30 mg/kg (as the sodium) intravenously at induction of anesthesia and every 8 hours for 24 hours. Vancomycin 15 mg/kg (as the hydrochloride) intravenously should be reserved as an alternative on the basis of previously outlined guidelines from HICPAC.

XIII. Urologic Surgery:

Recommendation

- Considering the low risk of serious infection after urologic surgery, antimicrobial prophylaxis should be considered only in patients at high risk of postoperative bacteriuria (patients likely to require prolonged postoperative catheterization and patients with a positive urine culture) or in hospitals with infection rates of greater than 20%. Low-risk patients do not appear to benefit from the use of perioperative antimicrobials.
- If oral antimicrobials are used, a single dose of trimethoprim 160 mg with sulfamethoxazole 800 mg or lomefloxacin 400 mg (as the hydrochloride) should be administered two hours before surgery. If an injectable agent is preferred, cefazolin 1g (as the sodium) intravenously at induction of anesthesia is recommended.
- Continuation of antimicrobial prophylaxis postoperatively is not recommended.

STRENGTH OF EVIDENCE for prophylaxis = A

Pediatric dosage

- Prophylaxis for urologic surgery in pediatric patients should be considered only in patients at high risk of postoperative bacteriuria

(e.g., patients likely to require prolonged postoperative catheterization and patients with a positive urine culture) or in hospitals with infection rates of greater than 20%. If oral antimicrobials are used, a single dose of trimethoprim 6-10 mg/kg with sulfamethoxazole 30-50 mg/kg two hours before surgery is recommended. If an injectable agent is preferred, a single dose of cefazolin 20-30 mg/kg (as the sodium) intravenously at induction of anesthesia is recommended. Fluoroquinolones are not recommended in pediatric patients.

XIV. Vascular Surgery:

Recommendation

- The recommendation for patients undergoing vascular surgery is cefazolin 1 g (as the sulfate) intravenously at induction of anesthesia and every 8 hours for 24 hours. Vancomycin 1 g (as the hydrochloride) intravenously over one hour, with or without gentamicin 2 mg/kg (as the sulfate) intravenously, should be reserved as an alternative on the basis of previously outlined guidelines from HICPAC.
- Although there are no data, patients undergoing brachiocephalic procedures involving vascular prosthesis or patch implantation (e.g., carotid endarterectomy) may benefit from prophylaxis.

STRENGTH OF EVIDENCE for prophylaxis = A

Pediatric dosage

- The recommended regimen for pediatric patients undergoing vascular surgery is cefazolin 20-30 mg/kg (as the sodium) intravenously at induction of anesthesia and every 8 hours for 24 hours. Vancomycin 15 mg/kg (as the hydrochloride) intravenously over one hour, with or without gentamicin 2 mg/kg (as the sulfate) intravenously, should be reserved as an alternative on the basis of previously outlined guidelines from HICPAC. Although there are no data, patients undergoing brachiocephalic procedures involving vascular prosthesis or patch implantation (e.g., carotid endarterectomy) may benefit from prophylaxis.

XV. Heart Transplantation:

Recommendation

- On the basis of data for other types of cardiothoracic surgery, antimicrobial prophylaxis is indicated for all patients undergoing heart transplantation.
- The recommended regimen is cefazolin 1 g (as the sodium) intravenously at induction of anesthesia and every 8 hours for 48 to 72 hours.
- Currently there is no evidence to support continuing prophylaxis until chest and mediastinal drainage tubes are removed.
- Cefuroxime 1.5 g (as the sodium) intravenously at induction of anesthesia and every 12 hours for 48 to 72 hours and cefamandole 1 g (as the nafate) intravenously at induction of anesthesia and every 6 hours for 48 to 72 hours are acceptable alternatives. Further studies

are needed to demonstrate the efficacy of single-dose prophylaxis. Vancomycin 1 g (as the hydrochloride) intravenously with or without gentamicin 2 mg/kg (as the sulfate) should be reserved as an alternative agent on the basis of previously outlined guidelines from HICPAC and AHA.

STRENGTH OF EVIDENCE for prophylaxis = A

Pediatric dosage

- The recommended regimen for pediatric patients undergoing heart transplantation is cefazolin 20-30 mg/kg (as the sodium) intravenously at induction of anesthesia and every 8 hours for 48 to 72 hours. Cefuroxime 50 mg/kg (as the sodium) at induction of anesthesia and every 8 hours for 48 to 72 hours is an acceptable alternative. Vancomycin 15 mg/kg (as the hydrochloride) intravenously with or without gentamicin 2 mg/kg (as the sulfate) should be reserved as an alternative on the basis of previously outlined guidelines from HICPAC and AHA.

XVI. Lung and Heart-Lung Transplantation:

Recommendation

- On the basis of data from other types of cardiothoracic surgery, all patients undergoing lung transplantation should receive antimicrobial prophylaxis because of the high risk of infection. Patients with negative pretransplant cultures should receive antimicrobial prophylaxis as appropriate for other types of cardiothoracic surgeries.
- The recommended regimen is cefazolin 1 g (as the sodium) intravenously at induction of anesthesia and every 8 hours for 48 to 72 hours.
- There is no evidence to support continuing prophylaxis until chest and mediastinal drainage tubes are removed.
- Cefuroxime 1.5 g (as the sodium) intravenously at induction of anesthesia and every 12 hours for 48 to 72 hours and cefamandole 1g (as the nafate) intravenously at induction of anesthesia and every 6 hours for 48 to 72 hours are acceptable alternatives. Further studies are needed to demonstrate the efficacy of single-dose prophylaxis. Vancomycin 1 g (as the hydrochloride) intravenously should be reserved as an alternative on the basis of previously outlined guidelines from HICPAC.
- The prophylactic regimen should be modified to provide coverage against any potential pathogens (e.g., *P. aeruginosa*) isolated from the donor lung or the recipient. Prophylactic regimens directed against *P. aeruginosa* may include one or two drugs with activity against this pathogen, although two-drug therapy is recommended for prophylaxis and is mandatory should prophylaxis fail and an actual infection develop. The regimen may also include antifungal agents such as fluconazole if donor lung cultures are positive for *Candida* and itraconazole if cultures are positive for *Aspergillus*. The following doses would be appropriate: fluconazole 200-400 mg intravenously or orally, or itraconazole 200 mg orally as tablet or suspension. If the use of

amphotericin B is desired, doses of 0.1-0.25 mg/kg intravenously may be used. Patients undergoing lung transplantation for cystic fibrosis should receive 7 to 14 days of prophylaxis with antimicrobials selected according to pretransplant culture and susceptibility results.

STRENGTH OF EVIDENCE for prophylaxis = B

Pediatric dosage

- As used for other cardiothoracic procedures, the recommended regimen for pediatric patients undergoing lung or heart-lung transplantation is cefazolin 20-30 mg/kg (as the sodium) intravenously at induction of anesthesia and every 8 hours for 48 to 72 hours. Cefuroxime 50 mg/kg (as the sodium) intravenously at induction of anesthesia and every 8 hours for 48 to 72 hours is an acceptable alternative. Vancomycin 15 mg/kg (as the hydrochloride) intravenously should be reserved as an alternative on the basis of previously outlined guidelines from HICPAC. If these regimens require modification for potential pathogens isolated from the donor or the recipient, the dosages are as appropriate for the specific agent(s) chosen. Patients undergoing lung transplantation for cystic fibrosis should receive 7 to 14 days of prophylaxis with antimicrobials selected according to pretransplant isolates and susceptibilities. These antimicrobials may be antibacterial or antifungal agents.

XVII. Liver Transplantation:

Recommendation

- All patients undergoing liver transplantation should receive antimicrobial prophylaxis because of the high risk of infectious morbidity and mortality associated with these procedures.
- Cefotaxime 1 g (as the sodium) plus ampicillin 1 g (as the sodium) should be administered intravenously at induction of anesthesia, repeated every 6 hours during the procedure, and given every 6 hours for 48 hours beyond final surgical closure.
- Other antimicrobial regimens that provide adequate coverage against gram-negative aerobic bacilli, staphylococci, and enterococci may be appropriate, but no randomized, comparative clinical trials have been conducted.

STRENGTH OF EVIDENCE for prophylaxis = B

Pediatric dosage

- The recommended regimen for pediatric patients undergoing liver transplantation is cefotaxime 50 mg/kg (as the sodium) plus ampicillin 50 mg/kg (as the sodium) intravenously at induction of anesthesia and repeated every 6 hours for 48 hours beyond final surgical closure. Other antimicrobial regimens that provide adequate coverage against gram-negative aerobic bacilli, staphylococci, and enterococci may be appropriate, but no randomized, comparative clinical trials have been conducted.

XVIII. Pancreas and Pancreas-Kidney Transplantation:

Recommendation

- The recommended regimen for patients undergoing pancreas or pancreas-kidney transplantation is cefazolin 1 g (as the sodium) intravenously at induction of anesthesia.

STRENGTH OF EVIDENCE for prophylaxis = B

Pediatric dosage

- The recommended regimen for pediatric patients undergoing pancreas or pancreas-kidney transplantation is cefazolin 20 mg/kg (as the sodium) intravenously administered at induction of anesthesia.

XIX. Kidney Transplantation:

Recommendation

- The recommended regimen for patients undergoing kidney transplantation is cefazolin 1 g (as the sodium) intravenously at induction of anesthesia.

STRENGTH OF EVIDENCE for prophylaxis = A

Pediatric dosage

- The recommended regimen for pediatric patients undergoing kidney transplantation is cefazolin 20 mg/kg (as the sodium) intravenously at induction of anesthesia.

Definitions:

The strength of evidence represents only support for or against prophylaxis and does not apply to the antimicrobial choice, dose, or dosage regimen. Studies supporting the recommendations for the use of an antimicrobial were classified as follows:

Level I: evidence from large, well-conducted randomized, controlled clinical trials or a meta-analysis

Level II: evidence from small, well-conducted randomized, controlled clinical trials

Level III: evidence from well-conducted cohort studies

Level IV: evidence from well-conducted case-control studies

Level V: evidence from uncontrolled studies that were not well conducted

Level VI: conflicting evidence that tends to favor the recommendation

Level VII: expert opinion

Each recommendation was assigned a category corresponding to the strength of evidence that supports the use or nonuse of antimicrobial prophylaxis:

Category A: levels I-III

Category B: levels IV-VI

Category C: level VII

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

This guideline contains a detailed discussion of the evidence supporting each recommendation. The type of supporting evidence is identified and graded for adult recommendations (see "Major Recommendations").

The authors note there are few data on the use of surgical antimicrobial prophylaxis in the pediatric population. Pediatric dosage recommendations are based on data derived primarily from adult patients and from tertiary references.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Effective use of antimicrobials for surgical prophylaxis may:

- Reduce the rates of postoperative wound infection of surgical sites
- Prevent postoperative infectious morbidity and mortality
- Decrease the duration and cost of health care

POTENTIAL HARMS

- The use of antimicrobials for prophylaxis is associated with the risk of contributing to the development of antimicrobial resistance.
- The adverse-effect profiles of specific antimicrobials were beyond the scope of the guideline.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The recommendations in this document may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on the professional judgment of the clinician and consideration of individual patient circumstances and available resources.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

RELATED NQMC MEASURES

- [Surgical infection prevention: percent of patients who received prophylactic antibiotics within 1 hour prior to surgical incision.](#)
- [Surgical infection prevention: percent of patients who received prophylactic antibiotics consistent with current guidelines.](#)
- [Surgical infection prevention: percent of patients whose prophylactic antibiotics were discontinued within 24 hours after surgery end time.](#)

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Society of Health-System Pharmacists. ASHP therapeutic guidelines on antimicrobial prophylaxis in surgery. American Society of Health-System Pharmacists. Am J Health Syst Pharm 1999 Sep 15;56(18):1839-88. [559 references] [PubMed](#)

ADAPTATION

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

DATE RELEASED

1999 Sep 15

GUIDELINE DEVELOPER(S)

American Society of Health-System Pharmacists - Professional Association

SOURCE(S) OF FUNDING

American Society of Health-System Pharmacists (ASHP)

GUIDELINE COMMITTEE

- American Society of Health-System Pharmacists (ASHP) Commission on Therapeutics
- Rocky Mountain Poison and Drug Center under contract to ASHP

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Project Coordinator: Debbie Denzel, PharmD.

Expert Panel: John A. Bosso, PharmD, BCPS; Steven C. Ebert, PharmD, FCCP; John F. Flaherty, Jr, PharmD, FCCP; B. Joseph Guglielmo, Jr, PharmD; David P. Nicolau, PharmD; Karen Plaisance, PharmD, BCPS; Joseph T. DiPiro, PharmD; Larry H. Danziger, PharmD.

Major Contributor: Doug Fish, PharmD.

Contributors: Richard Dart, MD, PhD; Lada Kokan, MD; Edwin Kuffner, MD; Jodi Schonbok; Luke Yip, MD; Bret Fulton.

ASHP Staff Liaison: Leslie Dotson Jagers, PharmD, BCPS.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Panel members and contractors were required to disclose any possible conflicts of interest before their appointment.

GUIDELINE STATUS

This is the current release of the guideline.

These guidelines reflect current knowledge (at the time of publication) on antimicrobial prophylaxis in surgery. Given the dynamic nature of scientific information and technology, periodic review, updating, and revision are to be expected.

American Society of Health-System Pharmacists (ASHP) guidelines are reviewed and revised as needed, generally every three to five years.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Society of Health-System Pharmacists \(ASHP\) Web site](#).

Print copies: Available from the American Society of Health-System Pharmacists, 7272 Wisconsin Avenue, Bethesda, MD 20814.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 10, 2000. It was verified by the guideline developer on August 4, 2000.

COPYRIGHT STATEMENT

This summary is based on content contained in the original guideline, which is subject to terms as specified by the guideline developer. Please refer to the guideline developer's disclaimer, available at: www.ashp.org/legal.html.

© 1998-2004 National Guideline Clearinghouse

Date Modified: 11/8/2004

