Complete Summary

GUIDELINE TITLE

Best practice policy statement on urological surgery antimicrobial prophylaxis.

BIBLIOGRAPHIC SOURCE(S)

American Urological Association Education and Research, Inc. Best practice policy statement on urologic surgery antimicrobial prophylaxis. Baltimore (MD): American Urological Association Education and Research, Inc.; 2007. 45 p. [100 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse (NGC): 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.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Infections associated with urologic surgery:

- Surgical site infection
- Urinary tract infection

GUIDELINE CATEGORY

Prevention
Risk Assessment

CLINICAL SPECIALTY

Internal Medicine
Preventive Medicine
Surgery
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To assist urologists in the appropriate use of periprocedural antimicrobial prophylaxis

TARGET POPULATION

Patients undergoing urologic surgery

INTERVENTIONS AND PRACTICES CONSIDERED

Periprocedural systemic antimicrobial prophylaxis:

- First, second, or third-generation cephalosporin
- Fluoroquinolone
- Aminoglycoside
- Ampicillin
- Trimethoprim-sulfamethoxazole (TMP-SMX)
- Clindamycin
- Metronidazole
- Vancomycin
- Amoxicillin/clavulanate
- Ampicillin/sulbactam
- Neomycin plus erythromycin base
- Piperacillin/tazobactam

- Ticarcillin/clavulanate

MAJOR OUTCOMES CONSIDERED

- Rate of postoperative infection
- Cost, convenience, and safety of antimicrobial agents
- Emergence of resistant bacterial strains

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A Medline search was performed using the Medical Subject Headings (MeSH) index headings "antimicrobial prophylaxis," "postoperative complications," "surgical wound infection," "anti-bacterial agents," and the names of specific urologic procedures, from 1996 through 2006. This initial search was supplemented by scrutiny of bibliographies and additional focused searches, and 169 publications were selected for analysis by the Panel members. These included guidelines and policies from other groups, some of which were identified by Panel members outside of the Medline search; the guidelines from other groups were considered in the Panel's deliberations.

NUMBER OF SOURCE DOCUMENTS

A total of 169 publications were selected for analysis.

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

Levels of Evidence

Ia Evidence obtained from meta-analysis of randomized trials

Ib Evidence obtained from at least one randomized trial

IIa Evidence obtained from at least one well-designed controlled study without randomization

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study

III Evidence obtained from well-designed nonexperimental studies, such as comparative studies, correlation studies, and case reports

IV Evidence obtained from expert committee reports, or opinions, or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Assessment of the literature by the American Urological Association (AUA) Practice Guidelines Committee suggested that insufficient information was available to derive a guideline statement on antimicrobial prophylaxis during urologic surgery based solely on literature meta-analyses. As such, the Panel was charged with developing a Best Practice Policy Statement, which uses published data in concert with expert opinion, but does not employ formal meta-analysis of the literature.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The American Urological Association (AUA) convened the Urologic Surgery Antimicrobial Prophylaxis Best Practice Policy Panel, comprised of six urologists, to formulate recommendations for the use of antimicrobial prophylaxis during urologic surgery. The Panel formulated recommendations based on review of all material and the Panel members' expert opinions. Levels of evidence were assigned (see the "Rating Scheme for the Strength of the Evidence" field).

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Published cost analyses were reviewed.

Data regarding the costs associated with prophylactic antimicrobial use specifically for urologic surgery are not readily obtainable, but data from other surgical disciplines are enlightening. Clearly, surgical site infections (SSIs) are associated with poorer patient outcome and increased costs. A review of the outcomes of 3,864 surgical patients (general, cardiothoracic, and neurosurgical) showed an overall nosocomial infection rate of 11.3%. Even after accounting for covariates, nosocomial infection was associated with increased postoperative length of stay, hospital readmission rate, and outpatient use of antimicrobial agents - all of which significantly increased costs and utilization of medical resources. A recent large

review of data from European centers confirmed the great cost of SSIs. Moreover, it has also been demonstrated in a variety of settings that surgical antimicrobial prophylaxis, by reducing the incidence of SSIs, reduces costs. Conversely, excess and/or inappropriate antimicrobial prophylaxis increase costs, which is reversed by measures to improve compliance with evidence-based recommendations.

Prophylactic antimicrobial use is associated with financial, personal-health and public-health costs. Included in the consideration of the financial impact are the expense of the agent, route of administration, associated administration supplies, and labor. Costs vary widely with the antimicrobial agent selected and also according to the setting in which the administration occurs. Another important factor is variation in the duration of antimicrobial prophylaxis. A single preoperative administration has less total associated cost than a cycle of three administrations during the 24-hour perioperative period. Finally, the ultimate financial cost of antimicrobial prophylaxis incorporates both the costs associated with the agent and the costs associated with patient outcomes (SSIs, adverse reactions, etc.). Comprehensive cost differences between different regimens can be demonstrated.

The personal-health risks of prophylactic antimicrobial administration include allergic reactions, which vary from minor rashes to anaphylaxis, and suppression of normal bacterial flora, which can lead to *Clostridium difficile* colitis, colonization and infection with resistant organisms, and other adverse effects. Although the frequency of adverse events for any specific antimicrobial agent is calculable for population exposures, it is difficult to assess the gravity of each adverse event, as well as the need for specific interventions to treat consequences of the adverse events. Nevertheless, all of these factors are components of the financial impact of prophylactic antimicrobial use. In general, the financial costs of prophylaxis are controlled by using the least expensive and safest efficacious agent for the shortest duration that is consistent with good clinical practice.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This document was submitted for peer review, and comments from all 20 responding physicians and researchers were considered by the Panel in making revisions. The final document was submitted to the American Urological Association (AUA) Practice Guidelines Committee and Board of Directors for approval.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the strength of the evidence (Ia – IV) are defined at the end of the "Major Recommendations" field.

Principles of Surgical Antimicrobial Prophylaxis

1. Surgical antimicrobial prophylaxis is the periprocedural systemic administration of an antimicrobial agent intended to reduce the risk of postprocedural local and systemic infections.
2. The potential benefit of surgical antimicrobial prophylaxis is determined by three considerations: patient-related factors (ability of the host to respond to bacterial invasion), procedural factors (likelihood of bacterial invasion at the operative site), and the potential morbidity of infection.
3. Surgical antimicrobial prophylaxis is recommended only when the potential benefit exceeds the risks and anticipated costs.
4. The antimicrobial agent used for prophylaxis should be effective against the disease-relevant bacterial flora characteristic of the operative site. Cost, convenience, and safety of the agent also should be considered.
5. The duration of surgical antimicrobial prophylaxis should extend throughout the period in which bacterial invasion is facilitated and/or is likely to establish an infection.

Table. Recommended Antimicrobial Prophylaxis for Urologic Procedures

Procedure	Organisms	Prophylaxis Indicated	Antimicrobial(s) of Choice	Alternative Antimic
Lower Tract Instrumentation				
Removal of external urinary catheter **(Level of evidence: Ib, III, IV)**	GU tract[2]	If risk factors[3,4]	• Fluoroquinolone[5] • TMP-SMX[5]	• Aminoglycoside Ampicillin[5] • 1st/2nd gen. Cephalosporin[5] • Amoxicillin/Clavu
Cystography, urodynamic study, or simple cystourethroscopy **(Level of evidence: Ib, III, IV)**	GU tract	If risk factors[4]	• Fluoroquinolone • TMP-SMX	• Aminoglycoside Ampicillin • 1st/2nd gen. Cep • Amoxicillin/Clavu
Cystourethroscopy with manipulation[6] **(Level of evidence: Ia/b, IV)**	GU tract	All	• Fluoroquinolone • TMP-SMX	• Aminoglycoside Ampicillin • 1st/2nd gen. Cep • Amoxicillin/Clavu
Prostate brachytherapy or cryotherapy	Skin	Uncertain	• 1st gen. Cephalosporin	• Clindamycin[7]

Procedure	Organisms	Prophylaxis Indicated	Antimicrobial(s) of Choice	Alternative Antimic
(Level of evidence: III, IV)				
Transrectal prostate biopsy **(Level of evidence: Ib)**	Intestine[8]	All	• Fluoroquinolone	• Aminoglycoside + Metronidazole or Clindamycin[7]
Upper Tract Instrumentation				
Shock-wave lithotripsy **(Level of evidence: Ia)**	GU tract	All	• Fluoroquinolone • TMP-SMX	• Aminoglycoside + Ampicillin • 1st/2nd gen. Cep • Amoxicillin/Clavu
Percutaneous renal surgery **(Level of evidence: IIb, III)**	GU tract and skin[9]	All	• 1st/2nd gen. Cephalosporin • Aminoglycoside + Metronidazole or Clindamycin	• Ampicillin/Sulbac • Fluoroquinolone
Ureteroscopy **(Level of evidence: Ib)**	GU tract	All	• Fluoroquinolone • TMP-SMX	• Aminoglycoside + Ampicillin • 1st/2nd gen. Cep • Amoxicillin/Clavu
Open or Laparoscopic Surgery				
Vaginal surgery **(Level of evidence: Ia/b, IIb)**	GU tract, skin, and Group B *Strep.*	All	• 1st/2nd gen. Cephalosporin • Aminoglycoside + Metronidazole or Clindamycin	• Ampicillin/Sulbac • Fluoroquinolone
Without entering urinary tract **(Level of evidence: Ib, III, IV)**	Skin	If risk factors	• 1st gen.Cephalosporin	• Clindamycin
Involving entry into urinary tract **(Level of**	GU tract and skin	All	• 1st/2nd gen. Cephalosporin • Aminoglycoside +	• Ampicillin/Sulbac • Fluoroquinolone

Procedure	Organisms	Prophylaxis Indicated	Antimicrobial(s) of Choice	Alternative Antimic
evidence: Ib, III, IV)			Metronidazole or Clindamycin	
Involving intestine[10] **(Level of evidence: Ia, IV)**	GU tract, skin, and intestine	All	• 2nd/3rd gen. Cephalosporin • Aminoglycoside + Metronidazole or Clindamycin	• Ampicillin/Sulbac • Ticarcillin/Clavul • Piperacillin/Tazol • Fluoroquinolone
Involving implanted prosthesis **(Level of evidence: Ia, IV)**	GU tract and skin	All	• Aminoglycoside + 1st/2nd gen. Cephalosporin or Vancomycin	• Ampicillin/Sulbac • Ticarcillin/Clavul • Piperacillin/Tazol

Order of agents in each column is not indicative of preference. The absence of an agent does not preclude its appropriate use depending on specific situations.

[1]Additional antimicrobial therapy may be recommended at the time of removal of an externalized urinary catheter.

[2]GU tract: Common urinary tract organisms are *Escherichia coli*, *Proteus species (sp.)*, *Klebsiella sp.*, *Enterococcus*.

[3]See Table 1 in the original guideline document "Patient-related factors affecting host response to surgical infections."

[4]If urine culture shows no growth prior to the procedure, antimicrobial prophylaxis is not necessary.

[5]Or full course of culture-directed antimicrobials for documented infection (which is treatment, not prophylaxis).

[6]Includes transurethral resection of bladder tumor and prostate, and any biopsy, resection, fulguration, foreign body removal, urethral dilation or urethrotomy, or ureteral instrumentation including catheterization or stent placement/removal.

[7]Clindamycin, or aminoglycoside + metronidazole or clindamycin, are general alternatives to penicillins and cephalosporins in patients with penicillin allergy, even when not specifically listed.

[8]Intestine: Common intestinal organisms are *E. coli, Klebsiella sp.*, *Enterobacter*, *Serratia sp.*, *Proteus sp.*, *Enterococcus*, and Anaerobes.

[9]Skin: Common skin organisms are *Staph. aureus*, coagulase negative *Staph. sp.*, Group A *Strep. sp*.

[10]For surgery involving the colon, bowel preparation with oral neomycin plus either erythromycin base or metronidazole can be added to or substituted for systemic agents.

Abbreviations: gen, generation; GU, genitourinary; sp, *species; Staph*., *Staphylococcus; Strep*., *Streptococcus;* TMP-SMX, trimethoprim-sulfamethoxazole.

Refer to Table 3b in the original guideline document for information on recommended dosages of prophylactic antimicrobial agents.

Table. Antimicrobial Prophylaxis for Patients with Orthopedic Conditions

- Antimicrobial prophylaxis is not indicated for urologic patients on the basis of orthopedic pins, plates, and screws, nor is it routinely indicated for most urologic patients with total joint replacements on that basis alone.
- Antimicrobial prophylaxis intended to reduce the risk of hematogenous total joint infection is recommended in patients who meet BOTH sets of criteria in the table below. The recommended antimicrobial regimen in these patients include:
    - A single systemic level dose of a quinolone (e.g., ciprofloxacin, 500 mg; levofloxacin, 500 mg; ofloxacin, 400 mg) orally one to two hours preoperatively.
    - Ampicillin 2 g intravenous (IV) (or vancomycin 1 g IV over one to two hours in patients allergic to ampicillin) plus gentamicin 1.5 mg/kg IV 30 to 60 minutes preoperatively.
    - For some procedures, additional or alternative agents may be considered for prophylaxis against specific organisms and/or other infections.
- For patients NOT meeting BOTH of these criteria, antimicrobial prophylaxis still may be indicated to reduce the risk of other infections.

Increased Risk of Hematogenous Total Joint Infection	Increased Risk of Bacteremia Associated with Urologic Procedures

• Patients during the first two years after prosthetic joint replacement
• Immunocompromised patients with prosthetic joint replacements
  • Inflammatory arthropathies (e.g., rheumatoid arthritis, systemic lupus erythematosus)
  • Drug-induced immunosuppression
  • Radiation-induced immunosuppression
• Patients with prosthetic joint replacements and comorbidities
  • Previous prosthetic joint infections
  • Malnourishment
  • Hemophilia
  • Human immunodeficiency virus (HIV) infection
  • Diabetes
	• Any stone manipulation (includes shock-wave lithotripsy)
	• Any procedure with transmural incision into urinary tract (does not include simple ligation with excision or percutaneous drainage procedure)
	• Any endoscopic procedures of upper tract (ureter and kidney)
	• Any procedure that includes bowel segments
	• Transrectal prostate biopsy
	• Any procedure with entry into the urinary tract (except for urethral catheterization) in individuals with higher risk of bacterial colonization:
	  • Indwelling catheter or intermittent catheterization
	  • Indwelling ureteral stent
	  • Urinary retention

Increased Risk of Hematogenous Total Joint Infection	Increased Risk of Bacteremia Associated with Urologic Procedures
• Malignancy	• History of recent/recurrent urinary tract infection or prostatitis • Urinary diversion

Adapted from American Urological Association; American Academy of Orthopaedic Surgeons: Antimicrobial prophylaxis for urological patients with total joint replacements. J Urol 2003; 169:1796.

Definitions:

Levels of Evidence

Ia Evidence obtained from meta-analysis of randomized trials

Ib Evidence obtained from at least one randomized trial

IIa Evidence obtained from at least one well-designed controlled study without randomization

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study

III Evidence obtained from well-designed nonexperimental studies, such as comparative studies, correlation studies, and case reports

IV Evidence obtained from expert committee reports, or opinions, or clinical experience of respected authorities

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each antimicrobial prophylaxis recommendation (see Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Reduction of the risk of and improved prevention of postprocedural local or systemic infections following urologic surgery
- Appropriate use of periprocedural antimicrobial prophylaxis

POTENTIAL HARMS

- The personal-health risks of prophylactic antimicrobial administration include allergic reactions, which vary from minor rashes to anaphylaxis, and suppression of normal bacterial flora, which can lead to *Clostridium difficile* colitis, colonization and infection with resistant organisms, and other adverse effects.
- The public-health risk of antimicrobial prophylaxis relates to the induction of bacterial resistance in the patient and in the community microbial reservoir. Antimicrobial usage has had a clear impact on the emergence of resistant bacterial strains.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The decision to use antimicrobial prophylaxis in urological surgery and the selection of agent and dosing can start with guidelines such as the ones presented in this document. The appropriate use of antimicrobial prophylaxis in an individual patient, however, requires consideration of not only these guidelines but also a comprehensive evaluation of the patient's specific circumstances.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Urological Association Education and Research, Inc. Best practice policy statement on urologic surgery antimicrobial prophylaxis. Baltimore (MD): American Urological Association Education and Research, Inc.; 2007. 45 p. [100 references]

ADAPTATION

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

DATE RELEASED

2007 Jan

GUIDELINE DEVELOPER(S)

American Urological Association Education and Research, Inc. - Medical Specialty Society

SOURCE(S) OF FUNDING

American Urological Association Education and Research, Inc. (AUA)

GUIDELINE COMMITTEE

AUA Antimicrobial Prophylaxis Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Members received no remuneration for their work. Each Panel member provided a conflict of interest disclosure to the American Urological Association (AUA).

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Urological Association, Inc. (AUA) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on March 21, 2008. The information was verified by the guideline developer on April 1, 2008. 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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