Surgical Prophylaxis

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Special Thanks to: Mark A Kosinski, DPM, FIDSA
Speaking on surgical prophylaxis is an exercise in futility since, frankly, none of you have much choice in the matter!

Thanks to the SCIP protocols you are told what to do regardless of the evidence supporting it.
SCIP Measures pertinent to foot surgery

- INF–1: Patients who received prophylactic antibiotics within 1 hours prior to surgical intervention (2 hours if receiving vancomycin)
- INF–2: Patients who received prophylactic antibiotics *recommended for their specific surgical procedure* (emphasis added)
- INF–3: Patients whose prophylactic abx were discontinued within 24 hours after surgery end time

Stulberg, et.al JAPMA 2010
Does SCIP Work?

Adherence to Surgical Care Improvement Project Measures and the Association With Postoperative Infections

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**Context** The Surgical Care Improvement Project (SCIP) aims to reduce surgical infectious complication rates through measurement and reporting of 6 infection-prevention process-of-care measures. However, an association between SCIP performance and clinical outcomes has not been demonstrated.

**Objective** To examine the relationship between SCIP infection-prevention process-of-care measures and postoperative infection rates.

**Design, Setting, Participants** A retrospective cohort study, using Premier Inc’s
Clinical practice guidelines for antimicrobial prophylaxis in surgery

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Am J Health-Syst Pharm. 2013; 70:195-283

These guidelines were developed jointly by the American Society of Health-System Pharmacists (ASHP), the Infectious Diseases Society of America (IDSA), the Surgical Infection Society (SIS), and the Society for Healthcare Epidemiology of America (SHEA). This work rep-

Prophylaxis refers to the prevention of an infection and can be characterized as primary prophylaxis, secondary prophylaxis, or eradication. Primary prophylaxis refers to the prevention of an initial infection. Secondary prophylaxis refers to the prevention of recurrence or reactiva-

of the revised guidelines. The work of the panel was facilitated by faculty of the University of Pittsburgh School of Pharmacy and University of Pittsburgh Medical Center Drug Use and Disease State Management Program who served as contract researchers and writers for the project.
Pivotal Reference #2

ACFAS Clinical Consensus Statement

American College of Foot and Ankle Surgeons’ Clinical Consensus Statement: Perioperative Prophylactic Antibiotic Use in Clean Elective Foot Surgery

Paul Dayton, DPM, FACFAS, Jason DeVries, DPM, FACFAS, Adam Landsman, DPM, PhD, FACFAS, Andrew Meyr, DPM, FACFAS, Monica Schweinberger, DPM, FACFAS, (Chair)

Antibiotic Prophylaxis Clinical Consensus Statement Panel of the American College of Foot and Ankle Surgeons, Chicago, IL

I AM NOT GOING TO AGREE WITH EVERYTHING IN THE ACFAS CCS - THAT’S OK!

(ACFAS). It is important to appreciate that consensus statements do not represent clinical practice guidelines, formal evidence reviews, recommendations, or evidence-based guidelines. Rather, a CCS reflects information synthesized from an organized group of experts based on the best available evidence, and it also may contain opinions, uncertainties, and minority viewpoints. A CCS should open the door to discussion on a topic, as opposed to attempting to provide definitive answers. Adherence to consensus statements will not ensure suc-
Goal:

To decrease the incidence of infection (local or distant), following surgery or trauma
Prophylaxis

Prophylaxis to prevent local infection
- Surgical site infection

Prophylaxis to prevent distant site infections
- Endocarditis
- Late prosthetic joint infection
Surgical wound prophylaxis: Common Principles

An Antimicrobial for Surgical Prophylaxis Should:

- Prevent SSI
- Prevent SSI related M&M
- Reduce duration and cost of health care
- Produce no adverse events
- Have no adverse consequences for the microbial flora of the patient or hospital

Bratzler, et.al. Am J Health-Syst Pharm 2013
To Achieve Those Goals

- The antimicrobial should be:
  - Active against pathogens most likely to contaminate the surgical site
  - Given in appropriate dosage and at a time that ensures adequate serum and tissue concentrations
  - Safe
  - Administered for the shortest effective period to minimize adverse events, the development of resistance and cost.

Bratzler, et.al. Am J Health-Syst Pharm 2013
GOLDEN RULES OF PROPHYLAXIS

First Rule of Prophylaxis: The antibiotic must obtain its maximal level at the time of initial incision or injury.

Second Rule of Prophylaxis: The antibiotic should be directed against the organism most likely to cause infection.

FIRST RULE

One of the most frequent med errors in hosp

“Failure to administer the first dose of antimicrobial prophylaxis within the 2-hour window of time before incision is associated with 2– to 6– fold increases in rates of SSI”

Post-operative administration means NOTHING!

Burke JP, Clin Inf Dis, Supp 2, 2001
What, when, for how long?

- Drug
- Timing
- Duration
- Dose
INDICATIONS ???

- Prolonged surgery (> 2 hours ?)
- High risk surgery
- Immunocompromised patients
- Trauma surgery
- Implant surgery
- “Devastating consequences”

What do the ASHP Guidelines say about foot surgery?

**Recommendations.** Antimicrobial prophylaxis is not recommended for patients undergoing clean orthopedic procedures, including knee, hand, and foot procedures, arthroscopy, and other procedures without instrumentation or implantation of foreign materials. (Strength of evidence against prophylaxis = C.) If the potential for implantation of foreign materials is unknown, the procedure should be treated as with implantation.
What does the ACFAS Consensus say about foot surgery?

Consensus statement: The panel reached consensus that it is appropriate for antibiotic prophylaxis to be routinely utilized in surgeries involving bone, hardware, and prosthetic joints. With regard to soft tissue surgery, the panel reached consensus that it was uncertain whether antibiotic prophylaxis should be utilized and would be considered procedure dependent.
How can the differences in opinion be explained?

- “…this is an intervention without significant risk”
- “The 6 studies specific to elective foot and ankle surgery that the panel identified as meeting our including criteria did not demonstrate significant benefit in terms of infection prophylaxis, but at the same time they did not result in a single adverse event or complication…in more than 1000 patients studied”

WHAT ABOUT BASIC STEWARDSHIP?!

Dayton, et al. JFAS 2015
Prophylaxis is NOT benign

Alteration of Cutaneous Staphylococcal Flora as a Consequence of Antimicrobial Prophylaxis

Gordon L. Archer

From the Department of Medicine, Division of Infectious Diseases; and the Department of Microbiology/Immunology, Medical College of Virginia, Virginia Commonwealth University, Richmond, Virginia

Antimicrobial agents given as prophylaxis have profound effects on the microbial flora of the skin. Coagulase-negative staphylococci cultured from the skin of patients after cardiac surgery have been found to be more resistant to antimicrobial drugs than organisms cultured from the same skin sites preoperatively. Evidence exists both for the selection of resistant organisms from the preoperative flora and for the postoperative acquisition of such organisms from the nosocomial environment. Staphylococci causing postoperative infections have the same antimicrobial resistance phenotypes as do colonizing isolates; this observation suggests that colonized patients and hospital staff make up a nosocomial reservoir for resistant organisms.

Rev Infect Dis 1991
Prophylaxis is NOT benign

Fulminant Clostridium difficile colitis: a complication of perioperative antibiotic prophylaxis.

What does the ACFAS Consensus say about who’s at risk?

Consensus statement: The panel reached consensus that antibiotic prophylaxis is appropriate in patients who may be at increased risk for infection including those with diabetes, those who are immunocompromised, and those at risk for endocarditis. The panel noted that patient factors may more strongly drive the decision to use antibiotic prophylaxis than type of procedure performed.
Drug

Spectrum
- Active against pathogen most commonly associated with wound infection or body system being operated upon

Half-life
- Short half-life given too early = low serum levels at time of first incision
WHICH DRUGS?

GOOD
- Cefazolin
- Orals?? (i.e. cephalexin)
- Vancomycin
- Clindamycin

NOT SO GOOD
- Ciprofloxacin
- Ceftriaxone
- Aminoglycoside
Organisms

What organisms are found it:

- “Normal” post operative infection
- Post prosthetic joint implantation surgery
- Puncture Wounds
- Bite Wounds
“Routine use of vancomycin prophylaxis is not recommended for any procedure”
A cluster of MRSA cases have been detected at the institution
Patients with known colonization of MRSA
Patients at high risk for colonization (recent hospital stay, nursing home resident, hemodialysis)
Consensus statement: *The panel reached consensus that narrow spectrum antibiotics covering *Staphylococcus aureus* should be utilized for prophylaxis in patients without a history of resistant infection.*
What about Decolonization?

Mupirocin decolonization protocols as an adjunct to i.v. cephalosporin prophylaxis in orthopedic patients resulted in significant decreases in nasal MRSA carriage\textsuperscript{150,751} and overall SSIs.\textsuperscript{157,750-752} Preoperative decolonization with intranasal mupirocin may have utility in patients undergoing elective orthopedic procedures who are known to be colonized or infected with either MRSA or MSSA.\textsuperscript{150,151,157,741,749-755}

Bratzler, et.al. Am J Health-Syst Pharm 2013
What does the ACFAS Consensus say about decolonization?

The panel reached consensus that it was not appropriate to routinely perform preoperative nasal swabs to check for methicillin-resistant Staphylococcus aureus (MRSA) colonization.
Timing

Goal

- To achieve serum/tissue concentrations in excess of MIC$_{90}$ of targeted organisms
- Administer 30–60 minutes before incision
“An eminent surgeon named Burke, thought drugs prior to surgery may work. If given on call, one dose, that’s all. He who uses them longer’s a jerk” Pierce Gardner, MD

- Pre-op dose is most important
- Post-op dose for prolonged surgery
- 24 h probably not necessary
Additional doses

- Reduced rate of effectiveness during lengthy procedures

- Additional intra-operative doses be given equal to 1–2 times the drug half life to maintain adequate levels during a long procedure.
What does the ACFAS Consensus say about timing & additional doses?

Consensus statement: The panel reached consensus that in cases where prophylaxis is used it is appropriate for the antibiotics to be administered within 60 minutes prior to surgery, discontinued within 24 hours after surgery, given prior to tourniquet inflation, and utilized routinely in prolonged foot and ankle surgery cases. The panel reached consensus that it is uncertain whether prophylaxis should be performed more than once in prolonged foot and ankle surgery cases.
Implanted materials

- No definitive studies to support the use of prophylactic abx for surgical hardware (pins, screws, plates, frames)

- Joint replacement may fall under “devastating consequences of infection”
Devastating consequence of infection

- Joint replacement
- Cardiac procedures
- Aortic vascular grafting
- Craniotomy
- Prosthetic hardware placement
  - Joint replacement = yes
  - Pins, plates, screws, frames = gray area
Devastating consequence of infection

- Infection of screws, plates, pins and frames may not be considered as “devastating”

- But as all foreign bodies, they cause local immunocompromise and may hold a statistically higher chance of infection
What foot and ankle procedures warrant prophylaxis?

Are there evidence based studies?
The efficacy of Prophylactic Intravenous Abx in Elective Foot and Ankle Surgery – Zgonis et.al.

555 Elective Foot/Ankle Sx Patients

249 (Abx: YES)

8 (1.4%) (post-op infection)

306 (Abx: NO)

9 (1.6%) (post-op infection)

Zgonis T, Jolly G. et al.
J Foot and Ankle Surgery. Vol 43 No 2  2004
The efficacy of Prophylactic Intravenous Abx in Elective Foot and Ankle Surgery – Zgonis et.al.

**FIGURE 1** The percentage of patients acquiring a wound infection by preoperative antibiotic use. Note the percentage of patients acquiring a wound infection was similar between the preoperative (1.62%) and nonpreoperative antibiotic-use (1.44%) groups.

The efficacy of Prophylactic Intravenous Abx in Elective Foot and Ankle Surgery – Zgonis et.al.

### TABLE 1
The percentage of patients with internal/external fixation (N = 555), according to preoperative antibiotic use

<table>
<thead>
<tr>
<th>Internal/External Fixation</th>
<th>Preoperative Antibiotic Use</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Yes (%)</td>
</tr>
<tr>
<td>Yes</td>
<td>33.5</td>
</tr>
<tr>
<td>No</td>
<td>21.6</td>
</tr>
</tbody>
</table>

Internal/external fixation use was significantly greater (P < .001) in patients who received an antibiotic (n = 306) than in those patients who did not receive an antibiotic (n = 249).

\(^\text{a}P < .001.\)
The efficacy of Prophylactic Intravenous Abx in Elective Foot and Ankle Surgery – Zgonis et al.

- The results suggest that prophylactic IV abxs in routine elective foot and ankle surgery are not warranted

- Pre-op abx use, PMH, internal fixation use, tourniquet use, age, gender, sx time, and sx category were not predictive of post-operative wound infection
What about Gustilo III Open Fractures?

- The addition of gram negative coverage consisting of an aminoglycoside was first suggested by Gustilo in 1984:
  “However, as Gustilo did not study whether the addition of an aminoglycoside actually decreases the rate of infection in Type III fractures, his recommendation to add gram-negative coverage is not valid.” Ryan & Pugliano, Scand Journal of Surgery 2014

- No robust evidence exists to support either:
  ◦ The need for gram negative coverage
  ◦ The use of aminoglycosides specifically

Gustilo RB, Mendoza RM, J Trauma 1984
Hauser et al, Surg Infect, 2006
Prophylaxis to prevent distant site infections

Late prosthetic joint infections and Endocarditis
Seeding of bacteria to distal sites

Question: Does skin surgery pose a risk of bacteremia?
2.8% Incidence of bacteremia after skin surgery
Does clean orthopedic surgery pose a risk of bacteremia?
Intraoperative bacteremia during foot surgery – Trepal et al

- Blood cultures were taken peri-operatively from 42 subjects
- Swabs of the incision were made during the surgery
- No bacteremias occurred

Patients at Potential Increased Risk of Hematogenous Total Joint Infection

- All patients during the first two (2) years after prosthetic joint replacement.

- Patients with co-morbidities
  - Previous prosthetic joint infections
  - Malnourishment
  - Hemophilia
  - HIV infection
  - Diabetes
  - Malignancy

- Immunocompromised / immunosuppressed patients
You may need preventive antibiotics before all high-risk dental procedures if…

- you had a joint replacement less than two years ago.
- you’ve had previous infections in your artificial joint.
- you have an inflammatory type of arthritis, type 1 diabetes or hemophilia.
- you have a suppressed immune system or are malnourished.
- you have a history of prior or present malignancy.
Antibiotic Prophylaxis for Bacteremia in Patients with Joint Replacements

Consider antibiotic prophylaxis for all total joint replacement patients prior to any invasive procedure that may cause bacteremia.
Antibiotic Prophylaxis for Bacteremia in Patients with Joint Replacements

Patients with pins, plates or other orthopedic hardware that is not within a synovial joint are not at increased risk for hematogenous seeding
Endocarditis Prophylaxis
Endocarditis Prophylaxis

For endocarditis to develop, two independent events are normally required

1. An area of endothelium must be damaged
2. Bacteremia caused by adherent organisms must occur
Endocarditis Prophylaxis

- If endothelium is damaged but a bacteremia does not occur, bacterial endocarditis will not develop.

- Conversely, if a bacteremia occurs, normal undamaged heart endothelium is not conducive to bacterial colonization.
ENDOCARDITIS PROPHY

- Purpose is to prevent bacteremia that may seed heart valve
- 1997 recommendations:
  - Procedure through “surgically prepared” skin does not require prophy
  - Manipulation of an infection DOES require prophy
- Use antibiotic to cover suspected organisms

*Dejani AS, et.al. Circulation 1997*
Antibiotic prophylaxis is recommended for procedures on respiratory tract or infected skin, skin structures, or musculoskeletal tissue only for patients with underlying cardiac conditions associated with the highest risk of adverse outcome from IE (Table 3).

*Wilson W, et.al. Circulation 2007*
2007 Guidelines “Table 3”

- Prosthetic cardiac valve
- Previous IE
- Congenital heart disease (CHD)*
- Unrepaired cyanotic CHD, including palliative shunts and conduits
- Completely repaired congenital heart defect with prosthetic material or device, whether placed by surgery or by catheter intervention, during the first 6 months after the procedure†
- Repaired CHD with residual defects at the site or adjacent to the site of a prosthetic patch or prosthetic device (which inhibit endothelialization)
- Cardiac transplantation recipients who develop cardiac valvulopathy
# Endocarditis prophylaxis regimen

## Oral

1. Cephalexin  
   2g PO 1 hour pre-op  
2. Clindamycin  
   600mg PO 1 hour pre-op

## Parenteral

1. Cefazolin  
   1g IV 30 minutes pre-op  
2. Clindamycin  
   600mg IV 30 minutes pre-op  
3. Vancomycin  
   1.0 g IV 30 minutes pre-op

Recommendations of the American Heart Association (JAMA 1997;277:1794-1801)
DENTAL & PROSTHETIC JOINT PATIENTS

- Very few late prosthetic joint infections have been found following dental work.
- ADA and AAOS Guidelines do *NOT* recommend routine prophylaxis.
- If a patient has a PJ elsewhere in the body and they are undergoing podiatric work, do they need prophy?
Conclusions

- There is little high level evidence to inform decisions on the use of prophylaxis in foot and ankle surgery despite SCIP protocols
  - In which procedures
  - For which patients
- There are CPG and CCS from different organizations, including the new ACFAS document, that may be helpful
- There is no evidence to support the use of aminoglycosides in Grade III open fractures
- There is little need for endocarditis prophylaxis except in rare patient populations