Updated Guidelines for Antibiotic Prophylaxis in Surgery/SCIP Impact and the Operational Impact and Implementation

Carmen M Faulkner-Fennell, PharmD, BCPS (AQ-ID)
Clinical Pharmacy Specialist-Infectious Diseases
Greenville Health System

Disclosure

- I have no conflicts of interest to disclose

Objectives

- Discuss the 2013 ASHP clinical practice guidelines for antimicrobial prophylaxis in surgery and compare to the current surgical care improvement project (SCIP) national hospital inpatient quality measures
- Identify common operational and implementation pitfalls with the surgical antimicrobial prophylaxis recommendations
- Describe the implementation process of a surgical antimicrobial prophylaxis protocol at an academic medical center

1999 versus 2013 Guidelines

<table>
<thead>
<tr>
<th></th>
<th>1999 (48 pages)</th>
<th>2013 (89 pages)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative-dose timing</td>
<td>“At induction of anesthesia”</td>
<td>Within 60 minutes before surgical incision (vancomycin and fluoroquinolones 120 minutes)</td>
</tr>
<tr>
<td>Updates on recommended doses</td>
<td>Recommends lower doses: Cefazolin 1 gm, Vancomycin 1 gm, Clindamycin 600 mg, Gentamicin 1.7 mg/kg</td>
<td>Recommends higher doses: Cefazolin 2 gm, Vancomycin 15 mg/kg, Clindamycin 900 mg, Gentamicin 5 mg/kg</td>
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<tr>
<td>Morbidity obese</td>
<td>No comments</td>
<td>Cefazolin 3 gm for patients weighing ≥ 120 kg</td>
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<td>Redosing intervals defined</td>
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<tr>
<td>Duration of prophylaxis</td>
<td>Evidence discussed in text, however no definitive recommendations</td>
<td>Single dose or continuation for &lt; 24 hours for most procedures</td>
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Am J Health-Syst Pharm 2013;70:195-283
Am J Health-Syst Pharm 1999;56:1839-88

2013 Antimicrobial Prophylaxis Guidelines for Surgery

Updates from the 1999 Guidelines

- Vancomycin
  - Routine use of vancomycin prophylaxis is not recommended for any procedure
  - Consider:
    - Known to be colonized with MRSA
    - High risk for colonization in the absence of surveillance data
    - Clusters of MRSA or MRSE cases
  - Use of vancomycin for MRSA prophylaxis does not supplant the need for routine surgical prophylaxis

Am J Health-Syst Pharm 2013;70:195-283
SCIP Hospital Inpatient Quality Measures (Also VBP*)

- Prophylactic antibiotic (abx) received within ONE HOUR prior to surgical incision
- Prophylactic abx SELECTION for surgical patients
- Prophylactic abx DISCONTINUED within 24 HOURS after surgery end time
  - Overall rate
  - CABG (abx discontinued within 48 hours)
  - Other cardiac surgery (abx discontinued within 48 hours)
  - Hip arthroplasty
  - Knee arthroplasty
  - Colon surgery
  - Hysterectomy
  - Vascular surgery

SCIP Hospital Outpatient Quality Measures

- Prophylactic antibiotic received within one hour prior to surgical incision
- Prophylactic antibiotic selection for surgical patients
  - Cardiac (Pacemakers or AICDs) or Vascular
  - Orthopedic/Podiatry
  - Genitourinary
    - Prostate biopsy
    - Penile prosthesis insertion, removal or revision
  - Gastrointestinal
    - Gastric/Biliary-PEG placement
    - Gynecological
      - Laparoscopically assisted hysterectomy
      - Vaginal hysterectomy
      - Pubovaginal sling
    - Head and Neck
    - Neurological

Should Protocols Be Based on SCIP Criteria or Guidelines?

- ASHP 2013 Guidelines
  - Best practices
- SCIP/VBP/JACHO
  - Reportable hospital compare data
  - Reimbursement

- Overall goal
  - Provide optimal patient care while meeting quality measures in the best way possible for your institution

Advice Regarding Quality Measures-from the Guidelines

- "Quality-improvement initiatives and mandated performance reporting are subject to change,...consult ...local or institutional quality improvement departments for new developments in requirements for measures and data reporting that apply to...practice"

***2013 Clinical practice guidelines for antimicrobial prophylaxis in surgery***

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

Compare the Guidelines to SCIP Measures

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SCP National Hospital Inpatient Quality Measures. Version 4.2b

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Determine Procedures Performed at Your Institution

• Start with SCIP procedures first
• Add any subsequent surgical procedures performed
• Group surgeries by specialty and list specifics underneath
• Ask the surgery specialties for input

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Principles of Antibiotic Prophylaxis in Surgery

• Ideal agent for prophylaxis
  – Prevent skin and soft tissue infections (SSI)
  – Prevent SSI-related morbidity and mortality
  – Reduce duration and cost of healthcare
  – Produce no adverse effects
  – No adverse consequences for microbial flora of patient or hospital

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Antimicrobial Selection

• Review SCIP recommendations and choose from available selections
  – Review data in guidelines
• Try to select antimicrobials that can be used multiple times in the protocol
• Utilize microbiology data
• Preferential agents in guidelines and SCIP
  – 1st generation cephalosporins
    • Cefazolin
  – 2nd generation cephalosporins
    • Cefotaxim or ceftriaxone

Vancomycin Issue

The SCIP Perspective

• Inpatient or outpatient cardiac, vascular and orthopedic surgeries
• Outpatient head and neck, neurological surgeries
  – Acceptable 1st line if there is documentation why
    • Physician/APN/PA/pharmacist
  – Acceptable 2nd line for beta-lactam allergic patients
    • Vancomycin alone
    • Clindamycin alone
Vancomycin Issue
Things to Consider

- Gather data
  - Review rates of SSIs by organism and surgery types
    - MRSA, MRSE, MSSA, gram negatives
      - Cefazolin more effective than vancomycin for preventing SSIs caused by MSSA
      - Cefazolin offers some coverage for enteric gram negatives (depending on resistance patterns)
  - Review MRSA colonization surveillance program with infection control/prevention
- Review logistics of use
  - Longer infusion times
  - Dose calculations

Antimicrobial Selection in Beta-Lactam Allergic Patients

- Other SCIP surgery types
  - Clindamycin PLUS
    - Quinolone
    - Aminoglycoside
  - Metronidazole PLUS
    - Aminoglycoside
    - Quinolone
- Consider
  - Metronidazole does not provide gram positive or negative aerobic coverage
  - Potential resistance issues
  - Historical shortages
  - Ease of administration within 60 minute of incision

Compare the Guidelines to SCIP Measures

Antimicrobial Timing
Guideline Data

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SCIP National Hospital Inpatient Quality Measures. Version 4.2b
Antimicrobial Timing

- Anesthesia administers antimicrobial prophylaxis medications at GHS
- Procedures requiring vancomycin or fluoroquinolones
  - Floor nurse or MD notifies pharmacy or order-set for procedure used with time of anticipated surgery
  - Dose sent to floor, RN to administer dose when OR calls for patient
  - Procedure for STAT situations

Dosing Recommendations

- SCIP does not currently review antimicrobial dosing
- Guidelines provide some data utilizing
  - Cefazolin 1 gm in patients < 80 kg
  - Cefazolin 2 gm in patients > 80 kg
  - Cefazolin 3 gm in patients > 120 kg
  - Gentamicin 4.5-5 mg/kg versus 1.5 mg/kg

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Antimicrobial Dosing in Obese Patients

Guideline Data

- Little data available for antimicrobial dosing in obese patients
- Cefazolin 3 gm recommendation
  - Study 1 gm vs 2 gm in gastric bypass patients
  - Suggested that 1 gm doses did not achieve adequate tissue levels to exceed MIC of common pathogens
- BMI vs body fat percentage
  - Data suggests body fat percentage (> 25% in men and > 31% in women) has greater risk of developing SSI versus using BMI > 30 kg/m²

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Antimicrobial Dosing Guideline Data

- Cefazolin 1 gm discussed in text
  - Determine cost benefit of 1 gm vs 2 gm doses
  - Some hospitals utilize 2 gm doses only
  - Ease of supplying doses
  - Assess need for 3 gm doses
- Clindamycin dose
  - 900 mg vs 600 mg
- Gentamicin dose
  - 5 mg/kg vs 1.7 mg/kg
Redosing Intervals

• SCIP does not currently review antimicrobial redosing
• Intraoperative redosing
  – Ensures adequate serum and tissue concentrations
  – Should be given if
    • Procedure exceeds 2 half-lives of antimicrobial
    • Excessive blood loss (>1500 mL)
  – Redosing should be measured from time of preoperative dose given, not incision time
  – Redosing may not be needed when half-life of antimicrobial is extended
    • Renal failure

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Redosing Intervals

• At GHS
  – Redosing information available on protocol
  – IV rates and IV push information included
  – In process of reviewing for revisions

<table>
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<tr>
<th>Antimicrobial</th>
<th>Dose</th>
<th>IV Rate</th>
<th>IV Push</th>
<th>Redosing Interval</th>
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<tr>
<td>Cefazolin</td>
<td>1 g</td>
<td>500 mL/</td>
<td>1 hour</td>
<td>1 hour</td>
</tr>
<tr>
<td></td>
<td></td>
<td>minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cefotetan</td>
<td>1 g</td>
<td>1000 mL</td>
<td>1 hour</td>
<td>1 hour</td>
</tr>
<tr>
<td></td>
<td></td>
<td>minutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gentamicin</td>
<td>120 mg</td>
<td>15 minutes</td>
<td>Not recommended</td>
<td>1 hour</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Piperacillin/</td>
<td>4 g</td>
<td>60 mL/</td>
<td>Not recommended</td>
<td>3 hours</td>
</tr>
<tr>
<td>Tazobactam</td>
<td></td>
<td>minute</td>
<td></td>
<td></td>
</tr>
<tr>
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<td>1 g</td>
<td>60 mL/</td>
<td>Not recommended</td>
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Discontinuation of Antimicrobial Prophylaxis

• SCIP measure
  – Antimicrobial prophylaxis stopped less than 24 hours (less than 48 hours for cardiac surgery)
• Guidelines state
  – Duration of antimicrobial prophylaxis should be less than 24 hours for most procedures
  – 48 hour duration for cardiac procedures has been accepted without evidence
    • Expert opinion: less than 24 hours is appropriate
    • No data to support continuation of prophylaxis until indwelling drains and intravascular catheters removed

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Discontinuation of Antimicrobial Prophylaxis

• All surgical procedures at GHS limit post-op prophylaxis to < 24 hours
  – Cefazolin, cefotetan, clindamycin
    • 2 doses post-op
  – Vancomycin
    • 1 dose post-op
  – Gentamicin
  – No post-op doses
• Common pitfall
  – Post-op prophylaxis stopped, but prescriber starts antimicrobial for “possible infection”
    • Must provide documentation of infection
      – Educate prescribers on importance of documentation
      – Could require all antimicrobials have an indication listed prior to being profiled

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SCIP National Hospital Inpatient Quality Measures. Version 4.2b
Pre- and Post-Surgery Possible Infection Issue

- Evidence of infection prior to surgery
  - Must be documented
  - Not counted in SCIP antimicrobial measures
- Antibiotics prior to surgery
  - Not counted in SCIP antimicrobial measures if receiving for >24 hours prior to surgery
- Guidelines recommend
  - Appropriate surgical prophylaxis for procedure type should be given even if patient already receiving antibiotics
- Antimicrobial use for “possible infections” post-surgery MUST be documented appropriately in the chart

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Pediatric Data

- Pediatric antimicrobial prophylaxis in surgery is currently not reviewed by SCIP
- Current guidelines include pediatric recommendations
  - Most recommendations extrapolated from adult data
- Recommend to have a pediatric procedure similar to adults if your institution performs pediatric surgeries

At GHS

- Pediatric sub-group added to SCIP committee
- Protocol developed to mirror adult protocol as much as possible
- In process of being updated with new dosing and redosing recommendations

Developing the Protocol

- Determine who/what group owns the process
- At GHS
  - Steering committee: Anesthesia, Quality, Infection Control, Pharmacy, Infectious Diseases, Nursing, Pre-OP staff, Surgical Chairs, Information Technology
  - Anesthesia in charge of administering and selecting appropriate agent based on protocol
  - Pharmacy and Infectious Diseases in charge of maintaining antimicrobial selection protocol
At GHS

- SCIP steering committee born 2006
  - Head of anesthesia committee chair
  - SCIP reimbursement tied to key members evaluations
  - Each group assigned ownership of various surgical measures
    - Normothermia in colon surgery
    - Cardiac glucose control
    - Proper hair removal
    - VTE prevention
    - Removal of urinary catheters
    - Perioperative and post-op beta-blockers

GHS SCIP Committee

- Meets monthly
- Groups report project/initiative updates
- Quality data reviewed—all missed cases reviewed prior to and at each SCIP meeting
  - Determine patterns
  - Identify system “opportunities”
- Missed cases are reported back to person responsible and individuals involved in miss are counseled (if needed)

Common Issues for Misses

- Antimicrobial Prophylaxis
  - Antimicrobial selection in outpatient procedures
  - Discontinuation within 24 hours
    - Currently all surgical procedure post-op order-sets have orders for post-op antimicrobials
    - Surgical sticker scanned to pharmacy for antimicrobial timing
      - Anesthesia on a separate computer system than pharmacy
    - Heads of department provide feedback to physicians who start new antimicrobials or continue prophylaxis beyond 24 hours

Pharmacy Role in Surgical Prophylaxis

- Protocol development
  - Decide what antimicrobials will be included for each surgery type
    - Work with anesthesia and surgery prior to determine the surgeries performed at your institution
    - Include inpatient and outpatient procedures if applicable at your institution
    - Meet with surgery groups prospectively to discuss potential issues with agents chosen
      - Vancomycin
      - Ertapenem

Remember: Principles of Antibiotic Prophylaxis in Surgery

- Ideal agent for prophylaxis
  - Prevent skin and soft tissue infections (SSI)
  - Prevent SSI-related morbidity and mortality
  - Reduce duration and cost of healthcare
  - Produce no adverse effects
  - No adverse consequences for microbial flora of patient or hospital

- Antimicrobial agent
  - Active against pathogens likely to contaminate surgical site
  - Given at an appropriate dose and time that ensures adequate tissue and serum concentrations
  - Safe
  - Administered for shortest effective period to minimize adverse effects
  - Development of resistance
  - Cost

Other Things to Consider When Selecting Antimicrobials

- Determine how products will be supplied
  - Automated dispensing cabinets
  - OR/Anesthesia Kits
  - Pharmacy
  - Are you a system versus a single institution?
- Determine availability of dosage forms
  - Premixes, vials, medications requiring mixing
  - Storage criteria
  -Expiration dating
- Ease of use
  - IV push
  - Historical shortage issues
Information Technology (IT) Resources

- Determine availability and ability of information systems to assist with protocol
  - Work with IT upfront
    - GHS has several systems
      - Paper and computer mix
  - Work on SCIP measures first
    - Reimbursement and reportable hospital data

At GHS

- SCIP Wins
  - Anesthesia support
    - SCIP performance tied to evaluations
  - Heads of departments provide one on one feedback to individuals regarding “misses”
  - Prospective meetings with surgeons regarding “wants”
  - Pharmacy/Infectious Disease own the protocol
    - Selection
    - Dosing
- SCIP Opportunities
  - Information technology
    - Paper sheet faxed to pharmacy antimicrobial post-op timing
  - Major issue with non-antibiotic SCIP measures
  - Required indications for antibiotics
    - Assist with post-op “possible infection” documentation

Summary

- Incorporate the all the SCIP measures into the protocol
- Utilize the new antimicrobial surgical prophylaxis guidelines as a best practices resource
- Provide optimal patient care while meeting quality measures in the best way possible for your institution

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