TO: Physicians, Advanced Practice Nurses, Clinics, Federally Qualified Health Centers– For Action
Providers of Pharmaceutical Services, Health Maintenance Organizations – For Information Only

SUBJECT: Clinical News from the New Jersey Drug Utilization Review Board (DURB)

PURPOSE: To provide practitioners useful clinical information that may be helpful to the prescribing of prescription drugs

BACKGROUND: The DURB serves as an advisory board to the New Jersey Department of Human Services and the New Jersey Department of Health and Senior Services. The Board’s responsibilities include recommending clinical standards based, in part, on the evaluation of prescription drug use by participants in the State’s prescription drug programs. The Board is also responsible for disseminating information that the Board has determined would encourage appropriate drug utilization.

ACTION: Attached is a discussion regarding changes to the Dental Prophylaxis Guidelines. This bulletin can be viewed electronically by visiting http://www.nj.gov/humanservices/dmahs/durb.html. The Board welcomes your comments regarding this bulletin. Send comments to www.state.nj.us/humanservices/dmahs/durb.html. The Subject should read, “DURB Comments.”

RETAIN THIS NEWSLETTER FOR FUTURE REFERENCE
Dental Prophylaxis Guidelines

Background
The American Heart Association has recently revised recommendations for dental prophylaxis for infective endocarditis (IE). Although infective endocarditis is relatively rare, it can become a life-threatening disease. It primarily occurs in dental procedures when a thrombus forms on the surface of the heart and bacteria is present in the blood. This can lead to bacteria attaching to the clot and growing around the heart. In recent years, IE prophylaxis has become overly complicated and performed in patients who have no indications. Many also question the efficacy of IE prophylaxis and whether the risks outweigh the questionable benefits. The maintenance of optimal oral health and hygiene is more effective in reducing the risk of bacteremia from daily activities and is more important than antibiotic prophylaxis for a dental procedure for the same purpose.

Substantial Changes
Major changes to the guidelines target patients for whom prophylaxis is appropriate. Simple dental procedures no longer justify treatment and only patients with cardiac conditions associated with the highest risk of adverse outcomes are eligible.

Other significant changes to the guidelines include the following: new research shows that bacteremia associated with daily activities is more likely to cause IE than bacteremia secondary to dental procedures. Research suggests even if prophylaxis is 100% effective, only a small number of IE cases would be prevented. Prophylaxis is only for patients with underlying cardiac conditions associated with the highest risk of adverse events from IE (see Table 1). Prophylaxis is not recommended based solely on an increased lifetime risk of acquiring IE.

High Risk of Adverse Outcome
These conditions are associated with the highest risk of adverse outcomes; these are the patients for whom prophylaxis is reasonable:

- Prosthetic cardiac valve of prosthetic material used for cardiac valve repair
- Previous infective endocarditis
- 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 six months after the procedures
  - 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
Table 1: Current Recommended Indications

<table>
<thead>
<tr>
<th>Recommended</th>
<th>Not Recommended</th>
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<tr>
<td>• All dental procedures that involve manipulation of gingival tissue or the periapical region of teeth or perforation of the oral mucosa if they are patients at the high risk of adverse outcome (see above)</td>
<td>• Patients who solely have a high risk of acquiring IE</td>
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<td></td>
<td>• Routine anesthetic injections through noninfective tissue</td>
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<td></td>
<td>• Taking dental radiographs</td>
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<td></td>
<td>• Placement of removable prosthodontic or orthodontic appliances</td>
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<td></td>
<td>• Adjustment of orthodontic appliances</td>
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<tr>
<td></td>
<td>• Placement of orthodontic brackets</td>
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<tr>
<td></td>
<td>• Shedding of primary teeth</td>
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<td></td>
<td>• Bleeding from trauma to the lips or oral mucosa</td>
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</table>

**Treatment**

Antibiotic prophylaxis should be administered as a single dose before the procedure, if not, it can be administered up to 2 hours post procedure but this should only be considered if pre-procedural administration is not possible. If the provider suspects coincidental systemic infection, it is important to obtain blood cultures and other relevant tests to diagnose possible cases.

Amoxicillin (2g adults, 50mg/kg children) is the preferred antibiotic; it is well absorbed in the gastrointestinal tract (GIT) and provides high and sustained concentrations in the body. For penicillin (PCN) allergic patients, Cephelexin (2g adult, 50mg/kg children) or another first generation cephalosporin (there is no data that shows superiority of one first generation cephalosporin over another), Azithromycin/Clarithromycin (500mg adult, 15mg/kg children) or Clindamycin (600mg adult, 20mg/kg children) are the preferred choices. Patients unable to tolerate oral antibiotics, IV or IM Ampicillin (2g adult, 50mg/kg children), Ceftriaxone or Cefazolin (1g adult, 50mg/kg children) should be used. PCN allergic patients unable to tolerate oral treatment should be given Ceftriaxone, Cefazolin (1g adult, 50mg/kg children) or Clindamycin (600mg adults, 20mg/kg children) IV or IM.

Patients who are already receiving chronic antibiotic therapy that is indicated for IE prophylaxis should be given a different antibiotic rather than increasing the dose to avoid resistance issues. For example, a patient who is already receiving Amoxicillin should receive a macrolide as opposed to additional Amoxicillin. Cephalosporins should be avoided in this case due to possible cross resistance with penicillins. If possible, postpone the dental procedure until 10 days after the completion of the antibiotic course to allow normal flora to re-establish.

Patients receiving parenteral antibiotics for IE, especially those anticipating cardiac valve procedures, may require dental prophylaxis. In this case the treatment should continue and the timing adjusted so that a dose is administered 30 to 60 minutes prior to the procedure. In this case, the high dose of parenteral antibiotics will overcome any low-level resistance that may be present.

Patients receiving anticoagulation therapy should not receive intramuscular injections of antibiotics; either the oral or IV routes should be used.

Patients who are scheduled to undergo a cardiac procedure for CHD or valve replacement/repair should have a careful dental evaluation and any treatment completed prior to surgery whenever possible.
**Total Joint Replacements**

Patients who undergo total joint replacements may also need prophylaxis treatment due to possible joint infection. The prophylaxis guidelines have not changed since the last publication in 2003.

Risk factors include:
- First two years following joint replacement include
- Immuno-compromised/Immuno-suppressed Patients
- Patients with Comorbidities

**Incidence of Bacteremic Dental Procedures**

<table>
<thead>
<tr>
<th>Higher Incidence</th>
<th>Lower Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usually for more invasive procedures (dental extractions, implants, periodontal procedures)</td>
<td>Less invasive procedures (restorative dentistry, local anesthetic injections)</td>
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Prophylaxis should be considered for these patients if they have the above risk factors (see Risk factors during first two years following joint replacements) Usually prophylaxis not indicated except selected circumstances that may cause significant bleeding

**Treatment Regimens**

<table>
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<tr>
<th>Conditions</th>
<th>Recommended Drug Treatment</th>
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<tr>
<td>Not Allergic to Penicillin Can take Oral Medications</td>
<td>Cephalexin or Amoxicillin 2 grams orally 1 hour prior to procedure</td>
</tr>
<tr>
<td>Not Allergic to Penicillin Cannot take Oral Medications</td>
<td>Cefazolin or Ampicillin Cefazolin 1 g or Ampicillin 2 g IM or IV 1 hour prior to procedure</td>
</tr>
<tr>
<td>Patients Allergic to Penicillin Can Take Oral Medications</td>
<td>Clindamycin 600 mg orally 1 hour prior to procedure</td>
</tr>
<tr>
<td>Patients Allergic to Penicillin Cannot take Oral Medications</td>
<td>Clindamycin 600 mg IV 1 hour prior to procedure</td>
</tr>
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**Conclusion**

It is important to determine whether prophylaxis is appropriate in your patient. Drug choice and dosing have not changed from the previous guidelines. Proper risk vs. benefit analysis is essential in deciding whether or not a patient should receive antibiotic prophylaxis.

**References:**

