Clinical Laboratory Communication

Notification Date: July 16, 2019 **Effective Date:** July 16, 2019

Primary Antimicrobial Reporting

Explanation: To comply with CDC and FDA recommendations for antimicrobial stewardship, in consultation with UnityPoint Health - Des Moines Infectious Disease, Iowa Methodist Antimicrobial Subcommittee, and Pharmacy and Therapeutics Committee, the UnityPoint Health - Des Moines Pathology Laboratory, has made changes to the primary antimicrobials reported by culture type.

The changes and reasoning are summarized below.

Please note that the full battery of antimicrobials is still performed on Gram negative and Gram positive organisms and if additional drugs are necessary for patient care, providers can contact the Microbiology Laboratory and ask for additional drugs to be reported.

1. Because of several FDA black box warnings regarding the fluoroquinolones, Levofloxacin and Ciprofloxacin will only be reported when the cephalosporins are resistant (for non-urine sources), and when the cephalosporins AND nitrofurantoin OR Trimethoprim-Sulfamethoxazole are resistant for urine isolates. The FDA specifically states: "Health care professionals should not prescribe fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (uUTI) because the risks outweigh the benefits in these patients." These risks include mental health side effects, risk of C. difficile associated disease (CDAD), significant lowering or increase in blood sugar levels in some patients, risk of peripheral neuropathy, and risk of tendonitis and tendon rupture. Please see attached table outlining therapeutic options.

Table 1. Therapeutic alternatives to fluoroquinolones

Reducing Fluoroquinolone Usage

Why SHOULD we reduce fluoroquinolone (FQ) usage???

- FDA continues to issue safety warnings regarding FQs
 - 2008 Increased risk of tendinitis/tendon rupture
 - 2011 Exacerbation of myasthenia gravis
 - 2013 Potential for irreversible peripheral neuropathy
 - 2016 FDA warning that risks of FQs outweigh benefits when treating: uncomplicated UTI, acute exacerbation of COPD, or acute bacterial sinusitis
 - 2018 Increased risk of serious mental health/CNS side effects
 - 2018 Increased risk of aortic dissection
- FQs are strongly linked with development of Clostridium difficile infection
- FQs can prolong the QTc interval, potentially leading to dangerous arrhythmias
- FQs have unreliable activity against many gram negative bacteria, specifically Escherichia coli and Pseudomonas aeruginosa

So, what's a GOOD ALTERNATIVE to fluoroquinolones???	
Uncomplicated UTI	Nitrofurantoin, TMP-SMX, or fosfomycin (cystitis)
	Ceftriaxone (pyelonephritis)
Community-acquired	Amoxicillin/clavulanate or cefuroxime
pneumonia (CAP)	Ceftriaxone plus azithromycin OR doxycycline
Acute exacerbation of COPD	Amoxicillin/clavulanate, azithromycin, doxycycline or cefuroxime





Clinical Laboratory Communication

Notification Date: July 16, 2019 **Effective Date:** July 16, 2019

- 2. Due to their broad spectrum of activity and rising resistance rates as well as risk of CDAD and other potential negative side effects, aztreonam and gentamicin will not be reported except by request for the Enterobacteriaceae.
- 3. For Staphylococcus species, the Clinical Laboratory and Standards Institute Standard M52 states: "For agents with established clinical efficacy and considering site of infection and appropriate dosing, oxacillin-susceptible staphylococci can be considered susceptible to: beta-lactam combination agents (amoxicillin-clavulanate, ampicillin-sulbactam, piperacillin-tazobactam), oral cephems (cefaclor, cefdinir, cephalexin, cefpodoxime, cefprozil, cefuroxime, loracarbef), parenteral cephems including cephalosporins I, II, III and IV (cefamandole, cefazolin, cefepime, cefotaxime, ceftizoxime, ceftriaxone, cefuroxime, ceftaroline), and carbapenems (doripenem, ertapenem, meropenem, imipenem)". This statement entails all methicillin (oxacillin) susceptible Staphylococcus species. There are no breakpoint MIC's available for these agents, so they will not be individually reported. We will continue appending a comment regarding cefazolin for use for oxacillin (methicillin) susceptible Staphylococci as has been our practice.
- 4. For methicillin (oxacillin) resistant staphylococci, CLSI document M52 also states: "Oxacillin resistant staphylococci are resistant to all currently available β -lactam antimicrobial agents with the exception of ceftaroline."

If you would like more information about these changes, or to further discuss these changes, please contact:

Kathie Rogers, PhD; Microbiology Manager at 515-963-1573 or <u>Kathie.Rogers@unitypoint.org</u> Dr. Rossana Rosa Espinoza at <u>Rossana.RosaEspinoza@unitypoint.org</u>

