

Breakpoint Working Group

June 2014

Membership

- Bush, Karen
- Eliopoulos, George*
- Lewis, James*
- Galas, Marcelo
- Mathers, Amy
- Nicolau, David
- Powell, Mair
- Satlin, Michael
- Schreckenberger, Paul
- Shurland, Simone
- Thrupp, Lauri
- Schuetz, Audrey
- Wang, Hui
- Weinstein, Melvin
- Wikler, Matthew
- Zimmer, Barbara

Breakpoint WG Charter

- Identify which breakpoint investigations are needed
 - For revisions, identify the M23 basis for revision
- Prioritize breakpoint investigations
- Recommend members of an ad hoc WG to investigate BP issues in a balanced manner
- Serve as consultative experts to the ad hoc WG:
 - Recommend data sources
 - Review data package before comment period or Subcommittee presentation

Agenda June 2014

San Diego

- Consider recommendations from SDD WG
 - Jorgensen, Weinstein
- Consider recommendations from FQ WG re disk diffusion test for *Salmonella*
 - Sader
- Consider recommendations for azithromycin breakpoints for *Salmonella*
 - Turnidge

Summary of Recommendations From Three WG Presentations

- Salmonella Typhi (John Turnidge)
 - Azithromycin breakpoint: rationale document
 - Working group vote: recommend to Subcommittee
- Salmonella spp. (Romney Humphries)
 - Pefloxacin disk test
 - WG: recommend to Subcommittee
- SDD (Mel Weinstein)
 - Other cephalosporins for SDD
 - Survey cefepime breakpoint users
 - Pseudomonas cefepime breakpoint harmonization

Azithromycin

- Voted to recommend to Subcommittee
- For *Salmonella Typhi* only
 - Susceptible $\leq 16 \mu\text{g/mL}$ ($\geq 13 \text{ mm}$)
 - Resistant $\geq 32\mu\text{g/mL}$ ($\leq 12 \text{ mm}$)

Pefloxacin Disk

- No formal vote, but unanimous sentiment of WG was to recommend to Subcommittee
- For *Salmonella* spp, add pefloxacin 5 µg disk test to replace nalidixic acid disk for detection of fluoroquinolone non-susceptibility
 - Zone \leq 24 mm = non-susceptible

SDD (1)

- FDA 5/1/14:
- Cefepime breakpoints ($\mu\text{g/mL}$) against Enterobacteriaceae:

$S \leq 2$

I 4-8*

$R \geq 16$

* For isolates of Enterobacteriaceae with intermediate susceptibility, use a dose of 2 g every 8 hours in patients with normal renal function

SDD Discussions (2)

- Expanding SDD to other β -lactams
 - Reviewed possible changes
 - No action now
- Survey of SDD adopters
 - No action now
- Pseudomonas breakpoints
 - Harmonize with FDA for cefepime
 - $S \leq 8 \mu\text{g/mL}$ $R \geq 16 \mu\text{g/mL}$
 - Dose 2 gm every 8 hours with normal renal function
 - Review ceftazidime and aztreonam

Cefepime PI

FDA 5/1/14

- Cefepime breakpoints ($\mu\text{g/mL}$) against Enterobacteriaceae:

$S \leq 2$

I 4-8*

$R \geq 16$

* For isolates of Enterobacteriaceae with intermediate susceptibility, use a dose of 2 g every 8 hours in patients with normal renal function