Highlights from 2018 USCAST

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1. EUCAST Update (Christian Giske, M.D.; EUCAST-SC Chairman)

- Breakpoint setting for oral aminopenicillin for *H. influenza* and *Strep. pneumouniae*
- Third consultation on definition of the "Intermediate" category
  - "Susceptible" with increased exposure to drug, high likelihood of therapeutic success
  - Different from the CLSI's definition of "Susceptible, dose-dependent" group
  - Purpose of this definition is to avoid clinicians likely refraining from use of a drug in the group or category
- EUCAST development labs function in the following areas:
  - Contribute to the data of Bpt tables
  - Method comparisons
  - Colistin testing
  - Validation trials
  - Rapid testing directly from blood
- Paper discussion: MIC is a range of concentrations, not a single value
- Carbapenem consultation against *Enterobacteriaceae*
  - S ≤2, I = 4, and R ≥8
- Upcoming aminoglycoside consultation
  - Will base on USCAST
  - Not fully active in monotherapy for systemic infections
  - UTI only breakpoints?

2. USCAST Update (Ronald N. Jones, M.D., USCAST Scientific Secretary)

- 2013 – informal meeting with the idea formed to establish USCAST
- 2014 – achieved a "not-for-profit" status from state of NY (for tax exempt), securing donors, family foundation, drafted 1st "drug-class Bpts on FQ report
- 2015 – first full year in operation, passing of Bill Craig, first Website publication, initiated a new Bpt project for aminoglycosides
- 2016 – Web V2.0, and 2.1; comparison tables, FQ report, first open meeting, and 2nd round of donation
- 2017 – became "financially stable for several years to come"
- 2018 – guidance development of surrogate testing, polymixin testing, 'open meeting'
- New website may come out sometime November 2018, will include newly approved USCAST Bpts on a couple of drugs (ceftaroline, dalovancin, oritavancin); "rationale for USCAST clinical BPTs", "Guidance of surrogate agent testing"

3. FDA (CDER) Update (Sumathi Nambiar, M.D.)

- Focused on "21st Century Cure Act" that was passed in Congress on December 12, 2016

- Briefly described the challenges by Section 511A that updating susceptibility testing interpretive criteria (STIC) is a complicated process and dependent on each drug sponsor's update of individual drug labeling
- The Cure Act recognizes the importance of improving the process of updating STIC
- Mentioned that FDA-CDER has established a website on STIC (December 13, 2017): www.fda.gov/STIC

4. Breakpoints proposed at the meeting

- **Meropenem-Vaborbactam:**

	MIC 9 mcg/mL)			Disk Diffusion (mm)		
	S	**I**	**R**	**S**	**I**	**R**
Enterobacteriaceae	≤8/8	-	≥16/8	≥17	-	≤16
P. aeruginosa	≤8/8	-	≥16/8	≥14	-	≤13

- **Plazomicin (a new aminoglycoside):**

MIC (mcg/mL)			Disk Diffusion (mm)		
S	**I**	**R**	**S**	**I**	**R**
S ≤ 2	I = 4	R ≥8	≥16 mm	14-15	≤13

(Note: Plazomicin is indicated for UTI caused by *E. coli*, *K. pneumoniae*, and *Enterobacter cloacea* and *Proteus mirabilis*)