

Subcommittee (SC) on Antifungal Susceptibility Tests
The Tempe Mission Palms Hotel
Tempe, Arizona
Abbey Room

Meeting Title:	SC on Antifungal Susceptibility Tests	Contact:	mhackenbrack@clsi.org
Meeting Date:	Saturday, 14 January 2017	Secretary	camille.hamula@mountsinai.org
Start Time:	8:00 AM Eastern (US) time	End Time:	12:00 PM
Meeting Purpose:	To review and discuss SC business		
Requested Attendee(s):	Subcommittee members, advisors, reviewers		
Actual Attendee(s):			
Barbara D. Alexander, MD, MHS Chairholder		Duke University Medical Center	
Gary W. Procop, MD Vice-Chairholder		Cleveland Clinic	
Camille Hamula, PhD, D(ABMM) Secretary		Icahn School of Medicine at Mount Sinai	
Members Present			
Philippe Dufresne, PhD, (RMCCM)		Laboratoire de sante publique du Quebec	
Jeff fuller, PhD, FCCM, ABMM		London Health Sciences Center	
Mahmoud A. Ghannoum, MSc, PhD, EMBA		Case Western Reserve University	
Nicole Holliday		Thermo Fisher Scientific	
Audrey Schuetz, MD, MPH, D(ABMM)		Mayo Clinic	
Adrian M. Zelazny, PhD, D(ABMM)		NIH, Department of Lab Medicine	
Members Excused			
Kim E. Hanson, MD, MHS		University of Utah and ARUP Laboratories	
Denise Holliday, MT(ASCP)		BD Diagnostic Systems	
Luis Ostrosky-Zeichner, MD, FACP		University of Texas Medical School At Houston	
Nathan P. Wiederhold, PharmD		Univeristy of Texas Health Science Center	
Advisors Present			
Elizabeth Berkow, PhD, MLS(ASCP) ^{CM}		Centers for Disease Control and Preventino	
Mariana Castanheira, PhD		JMI Laboratories	
Jennifer Chau, PhD		Beckman Coulter	
Sharon K. Cullen, BS, RAC		Beckman Coulter – West Sacramento	
Scott B. Killian		Thermo Fisher Scientific	
Laura Kovanda		Astellas Pharma Global Development, Inc.	
Raymond Kwong, PhD, DABCC, FACB		Beckman Coulter Diagnostic, MicroScan	
Shawn R. Lockhart, PhD, D(ABMM)		Centers for Disease Control and Prevention	
Jaques F. Meis, MD, PhD		Canisius Wilhelmina Hospital	
Ribhi M. Shawar, PhD, D(ABMM)		FDA Center for Devices and Radiological Health	
Dee Shortridge, PhD		JMI Laboratories	



Maria M. Traczewski, BS, MT(ASCP)
Paul E. Verweij, MD, PhD
Nancy L. Wengenack, PhD, D(ABMM)

The Clinical Microbiology Institute
Radboud University Medical Center
Mayo Clinic

Reviewers Present

Lynette Y. Berkeley, PhD
Tanis Dingle, PhD, D(ABMM), FCCM
Bharat Gandhi, M(ASCP), S(CCM), BSc
Beth P. Goldstein, PhD
William W. Gregory, PhD
Patricia Hogan, MT(ASCP), MBA
Cynthia C. Knapp, MS
Mark J. Lee, PhD
Jonathan Schmitz, MD, PhD, D(ABMM)
S. Steve Yan, PhD

FDA Center for Drug Evaluation and Research
University of Alberta Hospital
LifeLabs
Beth Goldstein Consultant
Pfizer Inc.
Pfizer Inc.
Thermo Fisher Scientific
UCLA Department of Pathology and Lab Mewe4dicine
Vanderbilt University Medical Center
FDA Center for Veterinary Medicine

Guests

Erica Alberson
Cara Bastulli
Cassiana Bittencourt
Maryann Brandt
Benjamin Brielmaier
Darcie Carpenter
Parampal Deol
Hari Dwivedi
Kelly Engelhard
Robert Eusebio
Gina Ewald-Saldana
Karen Kryston
David Paisey
Christine Pallotta
Zachary Ratzlaff
Nilia Robles Hernandez

bioMérieux, Inc.
Thermo Fisher Scientific
UCI Medical Center
Norman Regional Health System
Astellas Pharmaceutical
Beckman Coulter – West Sacramento
bioMérieux, Inc.
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Thermo Fisher Scientific
Thermo Fisher Scientific
Norman Regional Health System
bioMérieux, Inc.

Staff

Marcy L. Hackenbrack, MCM, M(ASCP)
Glen Fine, MS, MBA, CAE

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AGENDA				
Item #	Start	Time	Presenter	Item
Breakfast/Breaks: Courtyard East - Available 7:00 am - 12:00 pm; 12:30 - 5:00 pm				
1.	8:00 am	15 min.	B. Alexander	Opening remarks/Introductions
2.	8:15 am	15 min.	G. Fine	CLSI Update
3.	8:30 am	30 min.	B. Alexander	Annual SC Update (Presentation) <ul style="list-style-type: none"> • Vote: May 2016 meeting summary • Rotations: Members/advisors/reviewers • Appointment: Subcommittee Secretary - Camille Hamula • Update on Antifungal Documents • Review outstanding action items
4.	9:00 am	30 min.	M. Traczewski	Review and discuss data for zone breakpoints/interpretive categories for <i>C. glabrata</i> and micafungin
	9:30 am	15 min.	Break	
5.	9:45 am	60 min.	S. Lockhart	Data review and VOTE: ECVs for <i>Candida</i> spp. and azoles
6.	10:45 am	15 min.	S. Lockhart	Plan for collecting additional ECV data
7.	11:00 am	30 min.	S. Lockhart	Discussion of how to address truncated MIC data
8.	11:30 am	15 min.	A. Schuetz M. Castanheira	Overview of CLSI Web Conference (held 15 November 2016): Practical Recommendations for Antifungal Susceptibility Testing and Reporting in Clinical Laboratories: New Drugs, New Breakpoints, New Guidelines
9.	11:45 am	10 min.	B. Alexander	Review outstanding and new action items
10.	11:55 am	5 min.	B. Alexander	Plans for next meeting: Web conference - May or June, or Face-to-face - 24 June 2017 January 2018 meeting: Saturday, 27 January 2018; Dallas, Texas
11.	12:00 pm		B. Alexander	Adjourn
Luncheon: Cloister (12:00 - 1:00 pm)				

SUMMARY MINUTES	
Item	Description
1.	Dr. Alexander opened the meeting at 8:00 AM Mountain (US) time by welcoming the participants. She noted that only 6 voting members were present and would determine which votes would be accepted.
2.	Mr. Fine provided a brief CLSI organizational update. He also announced and presented the Excellence in Consensus Management award to Dr. Alexander and expressed his gratitude for all her dedication and hard work.
3.	Dr. Alexander discussed ongoing SC business and provided roster updates (see attached presentation for additional details). The items reviewed include: <ul style="list-style-type: none"> • The 2017 roster additions and rotations • The conflict of interest policy and disclosure summary • The member voting rules. It was noted that with only 6 members (of 10) present, any important votes would be administered electronically. • The email voting procedure • The summary minutes of the Web Conference held on 26 May 2017. <ul style="list-style-type: none"> – There were no additional comments on the minutes. – A motion to accept the minutes was made and seconded. Vote: 6 – 0; 4 absent. Dr. Alexander opted to accept the voting results.

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Item	Description
	<p>The process for reviewing documents and updates on all documents administered by the SC were reviewed.</p> <ul style="list-style-type: none"> • The document categories were reviewed (Active, Archived, and Withdrawn). • The documents currently in revision are: M27, M38, M60 (replaces M27S and M44S), and M61 (replaces M38 tables and M51S). M27, M38, M60, M61 are being prepared for vote and are expected to publish in late spring or early summer 2017. • A proposal to revise M44 has been submitted to Consensus Council for review and approval. If approved, Dr. Procop and Dr. Hanson will lead the revision with an expected publication in the Fall 2018. • M59 will be revised once all ECVs have been approved.
4.	<p>The zone breakpoint data for <i>Candida glabrata</i> and micafungin was reviewed (see attached presentation).</p> <ul style="list-style-type: none"> • Due to disk diffusion's poor separation of susceptible and resistant strains as determined by broth microdilution (BMD) testing, the current M60 draft does not include zone diameter breakpoints for <i>C. glabrata</i> and micafungin. The concern was that <i>fks</i> mutations have not been captured. • Discussion and decisions from past meetings and the papers published on the subject were reviewed. Based on a review of the original data, discussion, and published journal articles, it was determined that there were 3 options to consider for setting the disk diffusion breakpoints. <ul style="list-style-type: none"> – Option 1: Keep the minimal inhibitory concentration (MIC) breakpoints (≤ 0.06, 0.12, ≥ 0.25 $\mu\text{g/ml}$) and raise the proposed disk diffusion breakpoints by 2 mm to ≥ 30, $28-29$, ≤ 27 mm (excludes very major errors). – Option 2: Keep the MIC breakpoints (≤ 0.06, 0.12, ≥ 0.25 $\mu\text{g/ml}$) and raise the proposed disk diffusion breakpoints by 2 mm but narrow the intermediate range down to 1 mm (ie, ≥ 30, 29, ≤ 28 mm)(keeps major errors). – Option 3: Raise the MIC breakpoints one dilution from ≤ 0.06, 0.12, ≥ 0.25 $\mu\text{g/ml}$ to ≤ 0.12, 0.25, ≥ 0.5 $\mu\text{g/ml}$ and keep the original proposed disk diffusion breakpoints of ≥ 28, $26-27$, ≤ 25 mm. It was noted that most of the isolates tested in 2010 have since been sequenced for <i>fks</i>. • The data's suitability was discussed. <ul style="list-style-type: none"> – It was questioned if QC data for micafungin was available and if more than one vendor was used. It was noted that M23 criteria was followed and as many vendors that were available were used. – It was agreed that since the MICs correlate well with the zone diameters, this data is suitable for predicting MIC by disk diffusion, it is good data despite the presence of outliers, and the goal of the breakpoints is not to detect <i>fks</i> mutants. – It was proposed that an alternate study be performed to generate additional data with fully characterized (sequenced) isolates. It was agreed that the cost may be an issue. Also, since breakpoints are already available, the study would only be correlative. – The consensus was that the data was sufficient and Option 1 was the best.
	<p>Action Item: Electronic Vote Since Option 1 excludes the Very Major Errors, a motion to adopt the breakpoints listed in Option 1 (≥ 30 mm [S], $28-29$ [I], ≤ 27 mm [R]) was made (Dr. Ghannoum) and seconded (Dr. Fuller). NOTE: The breakpoints were approved during an electronic vote ending 8 March 2017. VOTE: 10 – 0. Since a quorum of members was not present, the vote will be completed electronically following a</p>

SUMMARY MINUTES

Item	Description
	two-week discussion period.

5. **A report from the Epidemiological (ECV) Working Group (WG) was presented (see attached presentation for details).**
- The 2017 roster was reviewed. Dr. Lockhart has been appointed as Chairholder and Dr. Dufresne has been appointed as Vice-chairholder. Dr. Ghannoum will remain on the WG as a voting member.
 - The WG's mission, responsibilities, educational initiatives, rules for ECV determination, and meeting dates were reviewed.
- The rationale and method for normalizing ECV data was discussed. This refers to the situations when one laboratory provides > 50% of the data.**
- If the normalized data generates the same ECV as the un-normalized data, the ECV WG has approved the plan to accept the ECV.
 - When normalizing the data does not generate the same ECV, it was decided that statistical input is needed to determine if the dataset can be randomly reduced to produce a set that is below 50% of the total. The resulting data could then be normalized to generate an ECV.
 - In May 2016, an email was distributed on behalf of Dr. Alexander regarding this issue; however, no input was received.
 - It was decided to redistribute the email with some statistics included.

Action Item

Redistribute the email regarding normalized data for statistical input.

The ECVs for drug and yeast combinations that are still needed were reviewed.

Drug	Organism	Issue
Itraconazole	<i>C. albicans</i> <i>C. parapsilosis</i>	• Modes were spread across a wide range; several laboratories truncated at lower end; need more data
Flucytosine	<i>Candida</i> species	• Majority of labs had truncated data for all species resulting in only 2 to 3 labs contributing data for <i>C. albicans</i> , <i>C. glabrata</i> , and <i>C. parapsilosis</i> and with 1 lab contributing >50% of data. • <i>C. tropicalis</i> & <i>C. krusei</i> weighted analyses resulted in ECVs one dilution higher than unweighted; need more data
Voriconazole	<i>Candida</i> species	• No ECVs for any <i>Candida</i> species; data available
Posaconazole	<i>Candida</i> species	• No ECVs for any <i>Candida</i> species; data available
Isavuconazole	<i>Candida</i> species	• No ECVs for any <i>Candida</i> species; data from one lab only
Fluconazole	<i>Candida</i> species	• No ECVs for any <i>Candida</i> species; data available
Posaconazole	<i>Cryptococcus gattii</i> (VGI & VGII)	• Not enough data available

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Item	Description		
	The ECVs for drug and mould combinations that are still needed were reviewed.		
	Drug	Organism	Issue
	Posaconazole	<i>Aspergillus fumigatus</i>	<ul style="list-style-type: none"> Proposed ECV (0.5) may be too high based on data presented by Dr. Meis. Drs. Meis & Dufresne to provide data (for isolates with and without mutations) for re-analysis. Dr. Perlin agreed to sequence if needed
	All drugs	<i>Aspergillus nidulans</i>	<ul style="list-style-type: none"> Tri-modal MIC distribution suggesting need for molecular identification of isolates; need more data; data request via Clin Micro Net
	All drugs	Mucorales	<ul style="list-style-type: none"> Data available for <i>L. corymbifera</i>, <i>M. circinelloides</i>, <i>R. arrhizus</i>, <i>R. microsporus</i> and ampho, itra, posa
	All drugs	<i>Fusarium</i> spp.	<ul style="list-style-type: none"> Data available for <i>F. verticillioides</i>, <i>F. oxysporum</i>, <i>F. solani</i> and ampho, itra, posa, vori
	Dr. Lockhart reviewed new rules used to generate azole ECVs that will be added to the next edition of M57.		
	<ul style="list-style-type: none"> New Rules <ul style="list-style-type: none"> When one laboratory submits data for more than 50% of the total isolates, it is weighted down to 50% rather than weighting all of the laboratories to the same percentage. When data from a laboratory looks truncated, if another species from the same laboratory with values below the truncation can be found, the laboratory data can be used. When a laboratory has a mode that falls outside of the range of the other laboratories then that laboratory is eliminated. Data may be used from laboratories that provided less than 5 isolates (It was noted that this may become essential as ECVs are developed for the more rare species). 		
	<p>Action Item: Electronic Vote</p> <p>A motion to accept the new rules was made and seconded. Since a quorum of members was not present, the vote will be completed electronically following a two-week discussion period.</p> <p>NOTE: The new rules were approved during an electronic vote ending 8 March 2017. VOTE: 10 – 0.</p>		
	<ul style="list-style-type: none"> Discussion <ul style="list-style-type: none"> Rare species must be identified with MALDI-TOF MS or using molecular methods. Although there are commercial methods that are used by most clinical laboratories, the BMD method is the reference method and must be used to generate ECV data for M59. Laboratories using the commercial methods could perform their own validation to show that they are comparable to BMD. It was emphasized that ECVs are not equivalent to breakpoints. ECVs only indicate that an isolate is a wild-type isolate or a non-wild-type isolate (one with possible resistance factors). Since the cutoff is 97.5% of wild-type distribution, there are 2.5% of wild-type isolates that will be outside the distribution. It was suggested that language could be added to M57 regarding issues to consider if the laboratory is not using BMD. It was re-affirmed that the acceptable standard error for Essential Agreement (EA) with CLSI 		

SUMMARY MINUTES

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	<p>fungal BMD methods is ± 2 dilutions (as opposed to ± 1 for bacteria).</p> <ul style="list-style-type: none"> – It was noted that commercial, regulatory organization approved methods cannot be used to generate the data used to set ECVs. In order for laboratories using such methods to report an MIC as an ECV for a given isolate, the laboratory would be required to validate their testing method using the CLSI broth microdilution (BMD) method as the comparator. Essential agreement (not just categorical agreement) with CLSI BMD method would be required. 																												
	<p>Action Item</p> <p>A footnote will be drafted to add to the ECV tables in M59 (when revised, M57) specifying that validated alternate test methods should have solid essential agreement (EA) and should not be based on categorical agreement (CA) alone. The ECV working group will work on the exact wording of this footnote and bring it to the May meeting.</p>																												
	<p>Dr. Lockhart reviewed the data used to generate the <i>Candida</i>/azole ECVs and the ECV WG vote.</p> <ul style="list-style-type: none"> • Missing ECVs include: <table border="1" data-bbox="315 779 1490 1129"> <thead> <tr> <th data-bbox="315 779 618 831">Missing</th> <th data-bbox="618 779 1490 831">Why</th> </tr> </thead> <tbody> <tr> <td data-bbox="315 831 618 898"><i>Candida parapsilosis</i></td> <td data-bbox="618 831 1490 898">For most of the data, <i>C. orthopsilosis</i> and <i>C. metapsilosis</i> were not ruled out</td> </tr> <tr> <td data-bbox="315 898 618 1052">Voriconazole against <i>C. dubliniensis</i>, <i>C. guilliermondii</i>, <i>C. lusitaniae</i></td> <td data-bbox="618 898 1490 1052">Data is truncated or there is simply not enough data</td> </tr> <tr> <td data-bbox="315 1052 618 1129">Posaconazole against <i>C. dubliniensis</i></td> <td data-bbox="618 1052 1490 1129">Not enough data if truncated distribution is discarded</td> </tr> </tbody> </table>	Missing	Why	<i>Candida parapsilosis</i>	For most of the data, <i>C. orthopsilosis</i> and <i>C. metapsilosis</i> were not ruled out	Voriconazole against <i>C. dubliniensis</i> , <i>C. guilliermondii</i> , <i>C. lusitaniae</i>	Data is truncated or there is simply not enough data	Posaconazole against <i>C. dubliniensis</i>	Not enough data if truncated distribution is discarded																				
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	<ul style="list-style-type: none"> • WG approved ECVs for SC approval (VOTE) include: <table border="1" data-bbox="597 1209 1243 1896"> <thead> <tr> <th data-bbox="597 1209 781 1297">Antifungal</th> <th data-bbox="781 1209 1065 1297">Species</th> <th data-bbox="1065 1209 1243 1297">ECV ($\mu\text{g}/\text{mL}$)</th> </tr> </thead> <tbody> <tr> <td data-bbox="597 1297 781 1629" rowspan="6">Fluconazole</td> <td data-bbox="781 1297 1065 1350"><i>C. albicans</i></td> <td data-bbox="1065 1297 1243 1350">0.5</td> </tr> <tr> <td data-bbox="781 1350 1065 1402"><i>C. dubliniensis</i></td> <td data-bbox="1065 1350 1243 1402">0.5</td> </tr> <tr> <td data-bbox="781 1402 1065 1455"><i>C. glabrata</i></td> <td data-bbox="1065 1402 1243 1455">8</td> </tr> <tr> <td data-bbox="781 1455 1065 1507"><i>C. guilliermondii</i></td> <td data-bbox="1065 1455 1243 1507">8</td> </tr> <tr> <td data-bbox="781 1507 1065 1560"><i>C. lusitaniae</i></td> <td data-bbox="1065 1507 1243 1560">1</td> </tr> <tr> <td data-bbox="781 1560 1065 1629"><i>C. tropicalis</i></td> <td data-bbox="1065 1560 1243 1629">1</td> </tr> <tr> <td data-bbox="597 1629 781 1850" rowspan="4">Voriconazole</td> <td data-bbox="781 1629 1065 1682"><i>C. albicans</i></td> <td data-bbox="1065 1629 1243 1682">0.03</td> </tr> <tr> <td data-bbox="781 1682 1065 1734"><i>C. glabrata</i></td> <td data-bbox="1065 1682 1243 1734">0.25</td> </tr> <tr> <td data-bbox="781 1734 1065 1787"><i>C. krusei</i></td> <td data-bbox="1065 1734 1243 1787">0.5</td> </tr> <tr> <td data-bbox="781 1787 1065 1850"><i>C. tropicalis</i></td> <td data-bbox="1065 1787 1243 1850">0.12</td> </tr> <tr> <td data-bbox="597 1850 781 1896">Posaconazole</td> <td data-bbox="781 1850 1065 1896"><i>C. albicans</i></td> <td data-bbox="1065 1850 1243 1896">0.06</td> </tr> </tbody> </table>	Antifungal	Species	ECV ($\mu\text{g}/\text{mL}$)	Fluconazole	<i>C. albicans</i>	0.5	<i>C. dubliniensis</i>	0.5	<i>C. glabrata</i>	8	<i>C. guilliermondii</i>	8	<i>C. lusitaniae</i>	1	<i>C. tropicalis</i>	1	Voriconazole	<i>C. albicans</i>	0.03	<i>C. glabrata</i>	0.25	<i>C. krusei</i>	0.5	<i>C. tropicalis</i>	0.12	Posaconazole	<i>C. albicans</i>	0.06
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SUMMARY MINUTES

Item	Description											
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<i>C. glabrata</i>	1											
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<i>C. krusei</i>	0.5											
<i>C. lusitaniae</i>	0.06											
<i>C. tropicalis</i>	0.12											
<p>Action Item: Electronic Vote A motion to approve the ECVs listed above was made and seconded. Since a quorum of members was not present, the vote will be completed electronically following a two-week discussion period. NOTE: The ECVs were approved during an electronic vote ending 8 March 2017. VOTE: 10 – 0.</p>												
<p>Dr. Lockhart reviewed the next items for the ECV WG to complete.</p> <ul style="list-style-type: none"> • Need verified <i>Candida</i> data to continue creating ECVs for new species and updating numbers and values for others • Isavuconazole ECVs. This data is available but needs to be organized. • ECVs for <i>Fusarium</i> spp. and Mucorales. Data need to be obtained for both and all isolated need molecular analysis. • It was also suggested that data be collected for setting ECVs for <i>Trichosporon asahii</i>. 												
<p>Action Item The ECV WG will meet to discuss and analyze the isavuconazole data that is already collected with the goal to present the data in June 2017 or January 2018.</p>												
<p>Issues regarding <i>Candida parapsilosis</i> complex were discussed.</p> <ul style="list-style-type: none"> • Current <i>C. parapsilosis</i> ECVs include: <table border="1" data-bbox="724 1276 1117 1549"> <thead> <tr> <th data-bbox="724 1276 927 1346">Antifungal</th> <th data-bbox="927 1276 1117 1346">ECV (µg/mL)</th> </tr> </thead> <tbody> <tr> <td data-bbox="724 1346 927 1415">Fluconazole</td> <td data-bbox="927 1346 1117 1415">1</td> </tr> <tr> <td data-bbox="724 1415 927 1484">Voriconazole</td> <td data-bbox="927 1415 1117 1484">0.03</td> </tr> <tr> <td data-bbox="724 1484 927 1549">Posaconazole</td> <td data-bbox="927 1484 1117 1549">0.25</td> </tr> </tbody> </table> • It was questioned as to whether species within the complex should be distinguished before setting ECVs. <ul style="list-style-type: none"> – MALDI-TOF MS does distinguish between species within the complex and ECVs may be significantly different for the three subspecies. – Breakpoints are currently set for the complex, not the subspecies. It was suggested that collecting additional subspecies data should be coordinated to investigate future subspecies breakpoints. – In the interim, the consensus was to set an ECV for the complex and label it as such in M59. Data will continue to be collected for the separate subspecies and will be based on subspecies 			Antifungal	ECV (µg/mL)	Fluconazole	1	Voriconazole	0.03	Posaconazole	0.25		
Antifungal	ECV (µg/mL)											
Fluconazole	1											
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SUMMARY MINUTES	
Item	Description
	<p>identification by MALDI-TOF MS.</p> <p>Action Item: Electronic Vote A motion was made and seconded to accept the approved ECVs for <i>C. parapsilosis</i> spp. complex. A footnote will be added to M59 stating that the ECVs are for <i>C. parapsilosis</i> complex. NOTE: The ECVs were approved during an electronic vote ending 8 March 2017. VOTE: 10 – 0.</p>
6.	<p>The plan for collecting additional ECV data was discussed.</p> <ul style="list-style-type: none"> • A call for additional data was included in the Foreword of M57 and M59 and is posted on the CLSI Website. In addition, an email was distributed through ClinMicroNet with no responses. • Other options discussed included: <ul style="list-style-type: none"> – Since many laboratories do not perform the BMD reference method, isolates from those laboratories need to be distributed to laboratories that do perform BMD testing. This will help increase the number of laboratories testing as well as the total number of isolates tested. Dr. Lockhart and Dr. Procop both run laboratories to which isolates could be sent for testing. Criteria have been established when publishing to give credit to those that provide isolates. – It was suggested that the College of American Pathologists be consulted regarding which laboratories perform BMD testing so that testing laboratories can be matched with laboratories that can provide isolates. <p>Action Item Two emails will be drafted and distributed by the ECV WG.</p> <ul style="list-style-type: none"> • Ask laboratories if they do BMD testing or know a laboratory that does and refer them to the ECV WG. • Assemble a network of laboratories that can provide isolates to BMD laboratories.
7.	<p>Options for addressing truncated data were discussed.</p> <ul style="list-style-type: none"> • It was questioned if the SC should ask vendors to shift the ranges on their panels for species that produce truncated data (ie, the MIC data does not represent the true MIC). This may be feasible for common species but not for rare ones. Establishing erroneously high ECVs for wild-type populations should be avoided. • Rather than retesting some species with lower and higher MIC ranges (at concentrations which are likely not medically relevant) It may be more useful to report in the M59 document if the ECV falls outside the recommended CLSI MIC testing range (ex. for species X the ECV was found to be ≥ 8 mg/L). • It was suggested that a footnote be added to the appropriate table in M59. • If the recommended CLSI M38 or M27 MIC testing range is inadequate for a given species and antifungal agent combination, it should be brought to the attention of the subcommittee and changed if needed. <p>Action Item The ECV WG will draft a footnote stating an ECV cannot be established for a given species because the vast majority of isolates had an MIC value that fell below or above the proposed CLSI testing range for a given antifungal agent. If the ECV is clinically relevant for a given organism-drug combination, the value will need to be revised by the WG which will decide if it should be incorporated in M59 ECV tables.</p>
8.	<p>Dr. Schuetz and Dr. Castanheira provided an overview of the CLSI Webinar titled "Practical Recommendations for Antifungal Susceptibility Testing and Reporting in Clinical Laboratories: New Drugs, New Breakpoints, New Guidelines". These webinars are prepared and presented by the</p>

SUMMARY MINUTES	
Item	Description
	<p>Antimicrobial Susceptibility Testing Outreach WG.</p> <ul style="list-style-type: none"> • The webinar provided: <ul style="list-style-type: none"> – An overview of ECVs, how they can be used, and how they differ from breakpoints. – Activity and clinical role of isavuconazole. – The new fungal antimicrobial susceptibility CAP checklist questions • Dr. Schuetz identified an educational area that the Outreach WG should target regarding antifungal agents to test/report specific for organism and body site (CAP checklist item). It was suggested that a volunteer from the Antifungal SC join act as a liaison to the Outreach Working to provide input for education on antifungal susceptibility testing. The Outreach WG contacts are Janet Hindler and Audrey Schuetz.
	<p>Action Item</p> <p>A representative from the Antifungal SC will be added to the Outreach WG to act as a formal liaison between the Outreach WG and the Antifungal Subcommittee.</p>
9.	<p>Dr. Alexander reviewed the outstanding action items (see table below for new items, responsible persons, and due dates) from past meetings.</p> <ul style="list-style-type: none"> • Revisit data for <i>C. glabrata</i> with voriconazole (no breakpoints). • Collect additional data for <i>A. nidulans</i> for all antifungal agents. • Reanalyze posaconazole data for <i>A. fumigatus</i> (including data from Dr. Meis). Dr. Perlin agreed to sequence, if needed. Draft a note for footnote if can't separate. • Review data for <i>Candida</i> spp. and isavuconazole. • Revise M44 (pending approval by the Consensus Council). • Revise M59 to include <i>Candida/azole</i> and <i>Cryptococcus</i> ECVs.
10.	<p>The plans for the next meeting were discussed.</p> <ul style="list-style-type: none"> • The tentative agenda includes: <ul style="list-style-type: none"> – Vote on ECVs for <i>Fusarium</i> – Vote on ECVs for Mucorales – Vote on ECVs for Isavuconazole & <i>Candida</i> – Review Revision of M44 – Review ECVs for Posaconazole and <i>Aspergillus fumigatus</i> • Options include: <ul style="list-style-type: none"> – Web conference in May or June 2017 – Face-to-face meeting on 24 June 2017 in Philadelphia, PA.
	<p>Action Item</p> <p>Distribute a poll to determine if voting members would be available for a face-to-face meeting in June.</p>
11.	<p>There was no additional business to discuss. Dr. Alexander thanked the participants for their input and hard work. The meeting was adjourned at 12:00 PM.</p>
<p>Next Annual Meeting: Saturday, 27 January 2018 in Dallas, Texas.</p>	



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ACTION ITEMS			
No.	Description	Responsibility	Due Date
1.	Distribute information for electronic votes (see Items 4 and 5 [3]).	M. Hackenbrack	15 February 2017
2.	Draft a footnote to be added to the ECV tables in M59 regarding reporting ECVs when using a validated commercial method.	ECV WG	May 2017
3.	Draft emails for distribution: <ul style="list-style-type: none"> • Ask laboratories if they do BMD testing or know a laboratory that does and to refer them to the ECV WG. • Asking for isolates to assemble a network of laboratories that can provide isolates to BMD laboratories. 	ECV WG	March 2017
4.	Revisit data for <i>C. glabrata</i> with voriconazole (no breakpoints).	Dr. Alexander and Dr. Fuller	June 2017
5.	Draft a footnote regarding the lack of established ECV due to MIC values falling below the value of X (the MIC range tested).	ECV WG	June 2017
6.	Add liaison from Antifungal SC to the Outreach WG. NOTE: Mariana Castanheira has been appointed.	Dr. Alexander	Completed
7.	Collect additional data for <i>A. nidulans</i> for all antifungal agents.	ECV WG	June 2017
8.	Reanalyze posaconazole data for <i>A. fumigatus</i> (including data from Dr. Meis).	P. Dufresne D. Perlin	June 2017
9.	Submit raw <i>Fusarium</i> data to ECV Working Group / Data Repository.	A. Espinel- Ingroff	February 2017
10.	Re-analyze <i>Fusarium</i> ECV data for amphotericin B, itraconazole, posaconazole, voriconazole for SC review.	ECV WG	June 2017
11.	Submit raw Mucorales data to ECV Working Group / Data Repository.	A. Espinel- Ingroff	March 2017
12.	Re-analyze Mucorales data for amphotericin B, posaconazole & itraconazole.	ECV WG	June 2017
13.	Review data for <i>Candida</i> spp. and isavuconazole.	L. Kovanda	June 2017
14.	Analyze the isavuconazole data that is already collected with the goal to present the data in June 2017 or January 2018.	ECV WG	June 2017
15.	Revise M59 to include <i>Candida</i> /azole and <i>Cryptococcus</i> ECVs.	ECV WG	September 2017
16.	Poll subcommittee members for availability for a June 2017 face-to-face meeting.	M. Hackenbrack	Completed