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Summary Minutes
Subcommittee on Veterinary Antimicrobial Susceptibility Testing
The Buttes Marriott Resort
Tempe, Arizona
25-26 January 2012

A meeting of the Clinical and Laboratory Standards Institute (CLSI) Subcommittee on Veterinary Antimicrobial Susceptibility Testing (VAST) was held on 25-26 January 2012 in Tempe, Arizona. The following were in attendance:

Mark G. Papich, DVM, MS
Chairholder

North Carolina State University

Shabbir Simjee, PhD
Vice Chairholder

Elanco Animal Health

Members Present

Mike Apley, DVM, PhD
Viginia R. Fajt, DVM, PhD, DACVCP
Thomas R. Fritsche, MD, PhD
Cynthia C. Knapp, MS, MT(ASCP)
Markus Rose, DVM, PhD.
Stefan Schwarz, DVM
Maria M. Traczewski, BS, MT(ASCP)
John Turnidge, MD
Jeffrey L. Watts, PhD, RM (NCRM)
Ching Ching Wu, DVM, PhD

Kansas State University
Texas A & M University
Marshfield Clinic
Thermo Fisher Scientific
Intervet Innovation GmbH
Friedrich-Loeffler-Institute (FLI)
The Clinical Microbiology Institute
Women's and Children's Hospital
Pfizer Animal Health
Purdue University School of Veterinary
Medicine

Advisors Present

Donald Bade
Steven D. Brown, PhD
Robert P. Hunter, MS, PhD
Cindy Lindeman, BS
Ron A. Miller, PhD*
Ian Morrissey
Thomas R. Shryock, PhD
Peter Silley, PhD

Microbial Research, Inc.
The Clinical Microbiology Institute
Elanco Animal Health
Pfizer Animal Health
FDA Center for Veterinary Medicine
Quotient Bioresearch Ltd.
Elanco Animal Health
MB Consult Limited

* Participated by conference call

Reviewers Present

Tara Bidgood, DVM, PhD, DACVCP
Timothy S. Frana, DVM, MS, MPH, PhD
Joshua Hayes, PhD

Pfizer Animal Health
Iowa State University
FDA Center for Veterinary Medicine

Daniel J. Keil, DVM, PhD, DACVM
Scott B. Killian
Jennifer Lorbach, BS, MBA
Brian Lubbers
Maureen Mansfield
Lori T. Moon, MT(ASCP)
Toni Poole
James Brandon Reinhold
Vijaya K. Singu
Debora Sweeney
Michael T. Sweeney
Cornelia Wilhelm, DVM

Bayer Healthcare- Animal Health
Thermo Fisher Scientific
Thermo Fisher Scientific
Kansas State Veterinary Diag Lab
Thermo Fisher Scientific
MSU Diag Ctr for Population & Animal Health
USDA/ARS
Elanco Animal Health
Central States Research Centre, Inc.
Micromyx, LLC
Pfizer Animal Health
Intervet Innovation GmbH

CLSI Staff Present

Tracy Dooley, BS, MT(ASCP)
Jenny Sarkisian, MLS(ASCP)

Opening Remarks

Dr. Papich began the meeting Wednesday, 25 January at 8:00 a.m. He stated that the purpose of Wednesday's session was to provide an opportunity for the working groups to address their agenda topics and obtain input from the subcommittee. Sponsor presentations and final working group reports would be presented to the full subcommittee during Thursday's session.

AST Liaison Report

Dr. Turnidge provided an update on the activities of CLSI and the AST subcommittee as it relates to the VAST subcommittee. The main points are listed below.

- The AST subcommittee is working on new ways to improve the process for how the current working groups function. A small group has been formed to try and organize this and make recommendations. One suggestion is to work during the interim months of the January and June meetings by conference calls or webinars so that most work can be done prior to a meeting making things more efficient, allowing decisions to be made in a more timely manner.
- A small ad-hoc group is going to be formed to look a drug that currently has FDA breakpoints but does not have interpretive criteria in M100 (tigecycline). The group will review the FDA data and any additional data/literature to determine if the FDA breakpoints can be accepted or propose alternative breakpoints.
- New breakpoints for doxycycline and revised breakpoints for tetracycline were approved for *S. pneumoniae*.
- Disk diffusion breakpoints for oxacillin for *S. aureus* were deleted since the ceftoxin disk diffusion test is more accurate for detection of *mecA*-mediated resistance.
- The Data Analysis Working Group reviewed a method developed by Dr. Bruce Craig for determining disk zone correlates.
- Levofloxacin MIC breakpoints for extraintestinal *Salmonella* spp. were approved. Will look at disk correlates next.
- The Antifungal subcommittee is currently addressing EVC's. Since this is a big topic that is being addressed by all 3 susceptibility subcommittees, a workshop on this topic is being planned for January 2013 and will be scheduled so that participants of each of the 3 committees may attend.

CLSI Document Status Update

X08-R, *Generation, Presentation and Application of AST Data for Bacteria of Animal Origin*; A Report – Published September 2011

M43-A, *Methods for Antimicrobial Susceptibility Testing for Human Mycoplasma* – Published October 2011

Published January 2012:

M02-A11, *Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard-Eleventh Edition*

M07-A9, *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard-Ninth Edition*

M100-S22, *Supplemental Tables*

Upcoming Publications

M11-A8, *Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard – Eighth Edition* – estimated to publish February 2012.

Working Group Reports

Generic Working Group

Working Group Participants – Chairholder Ching Ching Wu; Recording Secretary Stefan Schwarz; Members – Mark Papich, Shabbir Simjee, Cindy Lindeman, Virginia Fajt, John Turnidge, Marilyn Martinez, Tara Bidgood, Rob Hunter, Vijay Singu, Tim Frana.

Dr. Papich noted that since he has rotated to subcommittee chairholder, Dr. Wu will now chair the Generic working group with Dr. Schwarz acting as recording secretary.

In reviewing drugs that the working group should review and address in the future to try and establish veterinary-specific breakpoints the below were suggested:

- Dogs – Gentamicin/Staph
- Amikacin/Staph
- Elephants – Streptomycin
- Trimethoprim-sulfa – possibly can get some data for horses
- Doxycycline – used in dogs, cats and horses
- Penicillin G in swine – data will be provided by Dr. Apley

Anyone having data for the any of the above please let Ching Ching know.

Clindamycin – Dr. Papich reviewed data he has currently gathered to see what other information is needed to determine the interpretive criteria for clindamycin against bacteria isolates from cats and bacteria other than *Staphylococcus* in dogs. Currently there is no breakpoint available for cats, and only one organism (*Staphylococcus*) listed for dogs, even though Table 1 lists both dogs and cats.

He plans to come back in June to present Monte Carlo simulations, PK/PD data, as well as look at protein binding. He is looking to possibly propose interpretive criteria for cats for *Staphylococcus* spp., *Streptococcus* spp., and *Pasteurella* spp.

Penicillin G - Dr. Papich reviewed data he currently has to try and determine the interpretive criteria for penicillin G against bacteria isolates from pigs. He plans to come back in June with additional data (eg, additional MIC data, cidal vs static T>MIC, and PD activity) and propose interpretive criteria for penicillin G for Swine Respiratory Disease with the below pathogens:

- *Pasteurella multocida*
- *Bordetella bronchiseptica*
- *Actinobacillus pleuropneumoniae*
- *Streptococcus suis*

Editorial Working Group

Working Group Participants – Chairholder Mike Sweeney; Members – Steve Yan, Jeff Watts, Mark Papich, Henry Heine, Markus Rose, Stefan Schwarz, Maria Traczewski, Lori Moon, Ching Ching Wu.

NOTE: A recording secretary still needs to be appointed.

The M31 text and tables had been circulated to the subcommittee for review and comment in October and remaining issues/changes that needed to be discussed at the meeting were reviewed. The subcommittee finalized and approved the M31 text and tables except for Table 1 and the corresponding text in Section 5 (**Approved 10-0**). Table 1 will be reviewed by the editorial working group to make sure the drugs are listed in the appropriate groups noting that any drugs listed in Group C must have QC data. They will also review the notes and footnotes to make sure they are appropriate and clarify if needed. The corresponding text in Section 5 will also be reviewed to make sure consistent with Table 1. Table 1 and Section 5 will then be circulated to the subcommittee for review and vote. Once approved, the M31 text and tables will be prepared for the next stage of voting (Draft 2, 45-day vote of the CLSI Delegates and review and comment of the Consensus Committee on Microbiology and CLSI Board).

Aquaculture Working Group

Working Group Participants – Chairholder Ron Miller; Members – Jeremy Carson, Inger Dalsgaard, Pat Gaunt, Charles Gieseke, John Hawke, Renate Reimschuessel, Peter Smith, Temdoung Somsiri, Ching Ching Wu,

Dr. Miller provided an update on the activities of the aquaculture working group and the recent teleconference held to discuss some reservations a member had regarding the historical data used to set the clinical breakpoints currently in the M42/M49 supplement. To address the concern the working group agreed as M49 is revised to include details and sources of data used to set clinical breakpoints with information such as species, water temperature and salinity, test conditions, and dose and regimen to help the user decide whether the clinical breakpoint is applicable to their drug/bacteria combination and clinical situation.

X08 Update

Dr. Simjee, chairholder of the X08 Report published in September 2011 gave an overview of proposed next steps for X08. X08 currently addresses the need for ECVs and describes how ECVs are established, as well as the usage of ECVs vs. clinical breakpoints. In moving forward to expand X08, he proposed that the document be moved under the VAST subcommittee to a small working group and potentially update it to be a guideline. The intent of the new guideline would be to include ECVs for difficult indications (e.g. mastitis), for those antibiotics that do not currently have clinical breakpoints, as well as antibiotics that do have clinical breakpoints and are routinely used in veterinary resistance monitoring programs.

Dr. Turnidge noted that both the Antifungal and the AST subcommittees are also starting to deal with ECVs and with some of the unresolved issues and questions it will be important that each of the committees is doing it correctly including:

- Only using results from a reference method
- All results being on-scale
- Results need to be from multiple labs since no 2 labs get the same answer
- Should be pooling only by species
- Need to determine how do you choose the data points
- Determine what to call the results (can't call S, I, R)

Dr. Turnidge mentioned the educational workshop that he will be organizing for the January 2013 meeting on ECVs that may help each of the committees address this as they move forward. The workshop will be scheduled to allow for each of the committees to attend. In the meantime, Dr. Simjee will get a small group together to try and look at some of the unresolved issues.

Education Working Group

Working Group Participants – Chairholder Virginia Fajt; Recording Secretary Mike Apley; Members – Bob Badel, Rob Hunter, Jennifer Lorbach, Mark Papich, Tom Shryock, Ching Ching Wu.

Dr. Fajt outlined some educational initiatives that can be considered as M31 gets close to publication including:

- Possibly have Table 2 as a stand-alone product. Would need to work with CLSI marketing staff to determine best way to do this.
- Have an educational teleconference on the updates in M31 and using the document. This could potentially be scheduled through CLSI/APHL.
- Hold an education session at AAVLD, ASM or AAVM.
- Once M31 is published, send a letter to the editor making them aware of the recent changes in the document.

Dr. Fajt asked for anyone having any additional suggestions to let her know.

Mycoplasma Working Group Update

Working Group Participants: Chairholder, Ching Ching Wu: Members- Donald Bade, Maureen Davidson

This working group will fall under the new M45-like document for infrequently isolated veterinary pathogens once this project is formally approved. Currently Dr. Davidson from FDA and Mr. Bade are working to standardize testing media and will then proceed to initiate testing 1 organism at a time.

M45-Like Document Update

Working Group Participants: Chairholder, Maria Traczewski, Co- Chairholder, Michael Sweeney: Members- Donald Bade, Tom Fritsche, Brian Lubbers, Patrick McDonough

Based on their review of the background material put together by the working group including a the list of organisms that have current AST methods as well those that have methods in the literature, the Consensus Committee on Microbiology approved the proposal to develop an M45-like document for veterinary pathogens. They also provided some input for consideration as the working group develops the document including:

- If less than 50 results (the number is subject to discussion) are available for an organism/drug combination and no PK/PD data are available, a histogram of MIC results could be displayed rather than setting breakpoints.
- Come up with rules or basic criteria that would be used for allowing information from the literature and laboratories to be used for establishing interpretive criteria and QC parameters for the document.
- The process should move slowly in order to gather enough data and to validate the information.
- The working group should set a threshold for the number of published results for each method for acceptance of the data.

The next step is for the project proposal and background materials to be presented to the CLSI Chairholders Council for approval as a new project at their March meeting.

M37 Update

Updates and necessary revisions for **M37 will be discussed at the January 2013 meeting.**

Presentations

QC Ranges for Disk Diffusion Susceptibility Testing for Tildipirosin

Dr. Brown presented quality control study data for disk diffusion testing of Tildipirosin against *S. aureus* ATCC® 25923 on plain MHA and on MH with sheep blood, *A. pleuropneumoniae*, ATCC® 27090, and *H. somni* ATCC® 700025. Based on the data presented, the following QC ranges were proposed:

Organism	Proposed QC range (mm)	Vote
<i>S. aureus</i> ATCC® 25923 on plain MHA	20-26 (98.2%)	Approved 8-0; 2 abstain
<i>S. aureus</i> ATCC® 25923 on MHA with sheep blood	20-26 (99.2%)	Approved 8-0; 2 abstain
<i>A. pleuropneumoniae</i> , ATCC® 27090	15-23 (99.5%)	Approved 8-0; 2 abstain
<i>H. somni</i> ATCC® 700025	15-24 (99.2%)	Approved 8-0; 2 abstain

Plans for Next Meeting

The next meeting of the Subcommittee on Veterinary Antimicrobial Susceptibility Testing will be scheduled as a two-day meeting on Friday, 8 June and Saturday, 9 June 2012 in Atlanta, Georgia.

The submission deadline for the June meeting will be **Thursday, 3 May 2012**. Materials for the June meeting will be distributed to the subcommittee on a CD prior to the meeting. The meeting rooms will be equipped with power strips for those who prefer to view the material on their computer instead of printing the material. Please note the meeting rooms will not have wireless access.

POST MEETING CHANGE: Due to insufficient agenda items for the 8-9 June 2012 meeting the VAST subcommittee meeting was canceled. The next meeting of the Subcommittee on Veterinary Antimicrobial Susceptibility Testing will be scheduled as a two-day meeting on 10-11 January 2013 in Tampa, Florida. Additional meeting details and agenda deadline information will be forthcoming.

Also note that an Educational Workshop on ECVs is being planned for the morning of Saturday, 12 January 2013 so that participants of the VAST Subcommittee can attend if they like. Additional details for this workshop will be circulated when available.

Adjournment - Dr. Papich thanked the participants for their attendance and input. The meeting was adjourned at 9:40 a.m.

Respectfully submitted,

Tracy Dooley, BS, MT (ASCP)
Senior Project Manager