Addressing Challenges in Veterinary Diagnostics

The National Academies of Sciences, Engineering, and Medicine

Examining the Long-Term Health and Economic Effects of Antimicrobial Resistance in the United States

Maintain perspective

- Despite challenges, the veterinary profession does a good job of utilizing diagnostic testing
- Veterinarians want to practice high-quality medicine

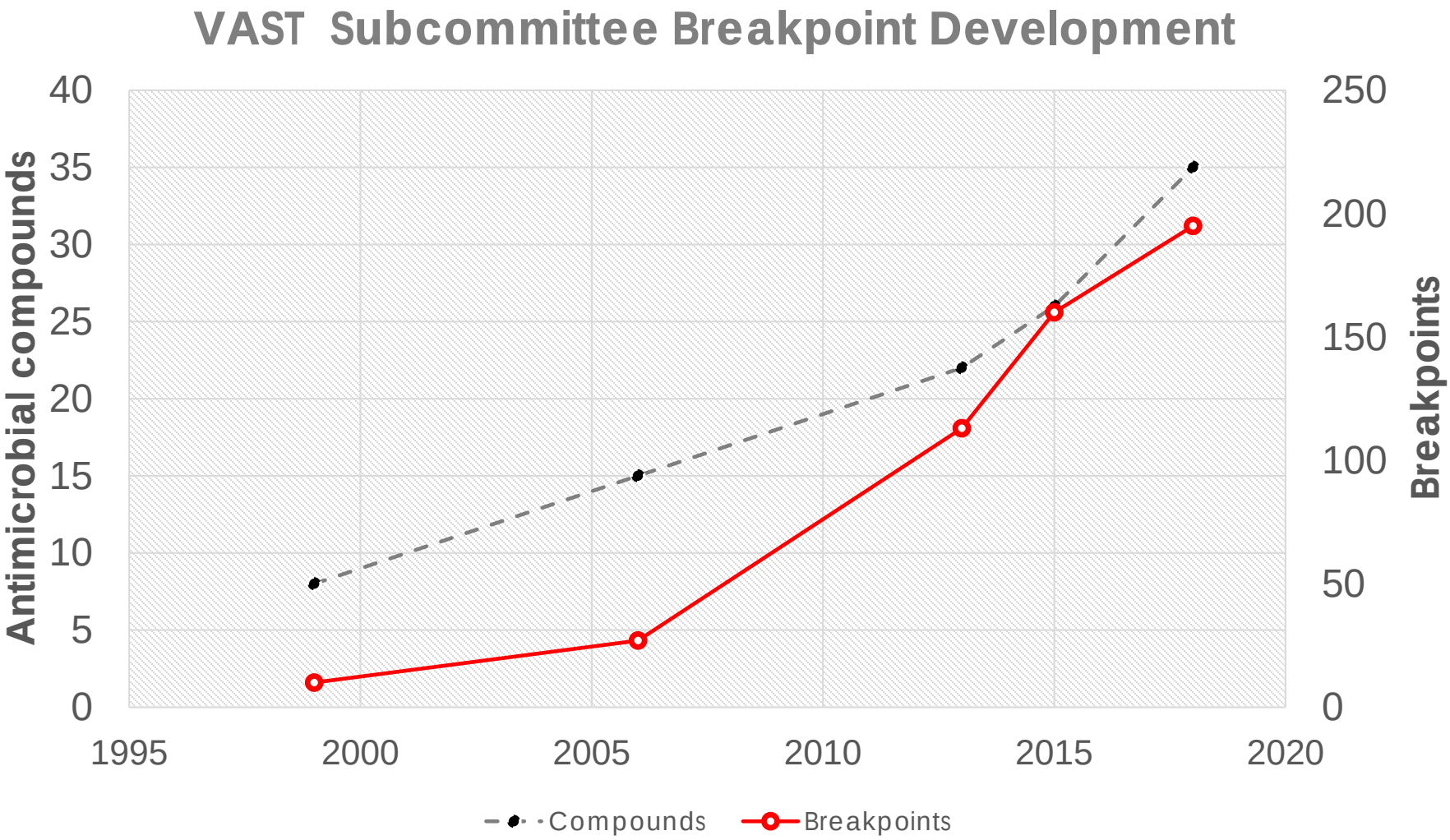
Challenges in Veterinary Diagnostics

1a. There aren't enough breakpoints

1b. There isn't a breakpoint for the specific pathogen, antimicrobial, disease, or host species I am treating

2. Breakpoints aren't "valuable"

NOT ENOUGH BREAKPOINTS

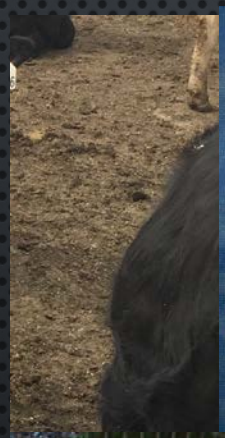


Not enough breakpoints

- Bovine
  - Respiratory disease, Mastitis, metritis
- Swine
  - Respiratory disease
- Aquaculture
  - *Aeromonas salmonicida & Aeromonas hydrophila*
  - *Flavobacterium columnare & Flavobacterium psychrophilum*
- Canine
  - Skin / soft tissue infections, wounds / abscesses, respiratory disease, UTIs
- Equine
  - Respiratory disease, skin / soft tissue infections
- Feline
  - Skin / soft tissue infections, respiratory disease, UTIs
- Poultry – *E.coli* (Drug approval withdrawn in US)

BREAKPOINT CHALLENGES

- BREAKPOINTS ARE SPECIFIC TO A PATHOGEN, ANTIMICROBIAL, DRUG REGIMEN, DISEASE PROCESS AND HOST SPECIES

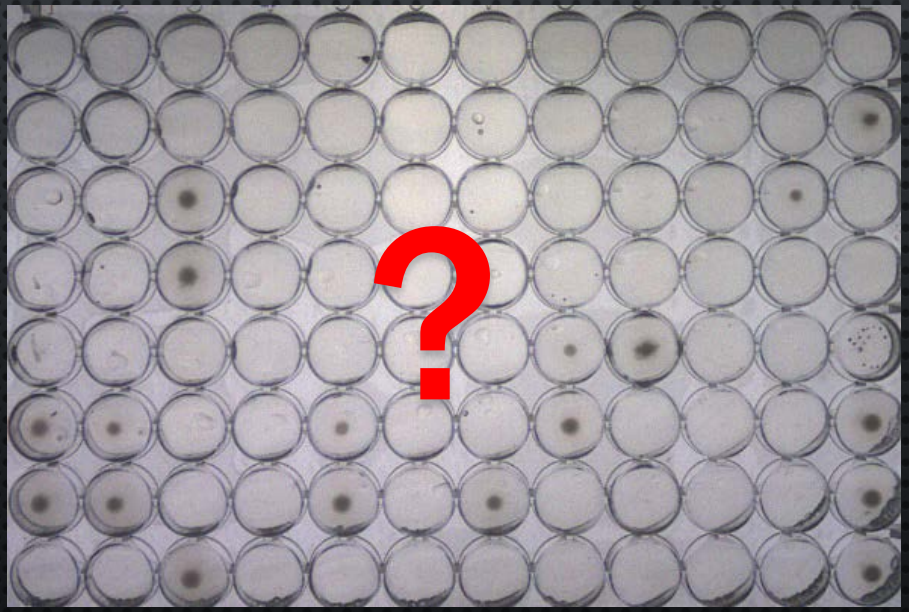


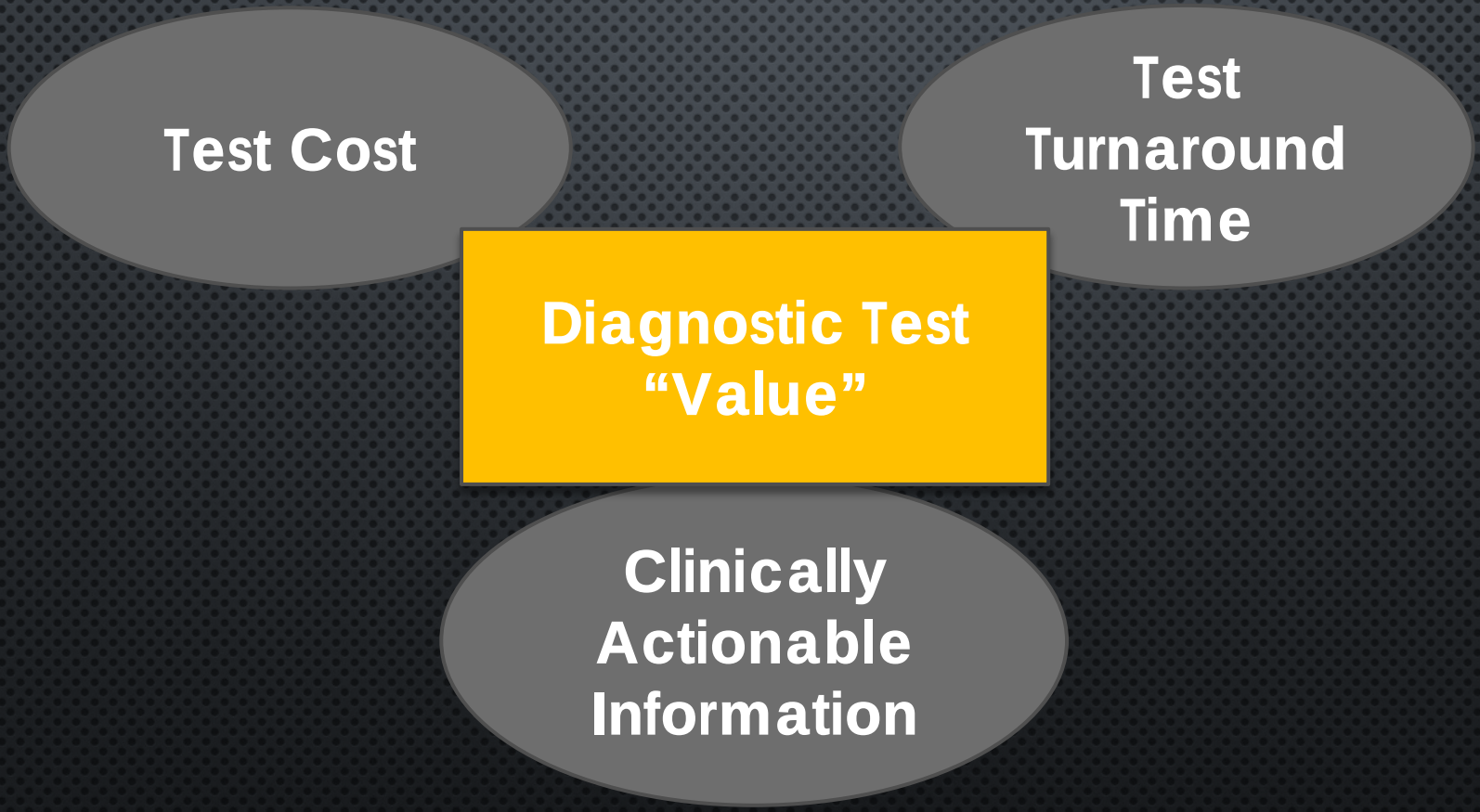



Breakpoint Challenges

- Regulatory / Ethical reasons
- Lack of standardized test method / QC
- Lack of bacterial MIC distribution data
- Lack of Pharmacodynamic data
- Lack of Pharmacokinetic data
- Lack of Disk Diffusion vs. MIC comparison data
- Lack of volunteer time / expertise

DIAGNOSTIC CHALLENGE #2
BREAKPOINTS AREN'T "VALUABLE"




Test Cost
Test Turnaround Time
Diagnostic Test "Value"
Clinically Actionable Information

Realities of Testing Costs

- In veterinary medicine, the full cost of diagnostic testing falls to the animal owner
  - What is the cost of the test?
  - What is the cost of the treatment?
  - What is the "cost" of misdiagnosis?
    - What level of uncertainty is there in the suspected diagnosis?
    - What is the value of the animal?
    - How large is the at-risk population?
    - What is the owner's tolerance for risk?
  - What are the subsides, incentives, penalties for testing?

REALITIES OF TESTING COSTS

- COST OF SAMPLE COLLECTION

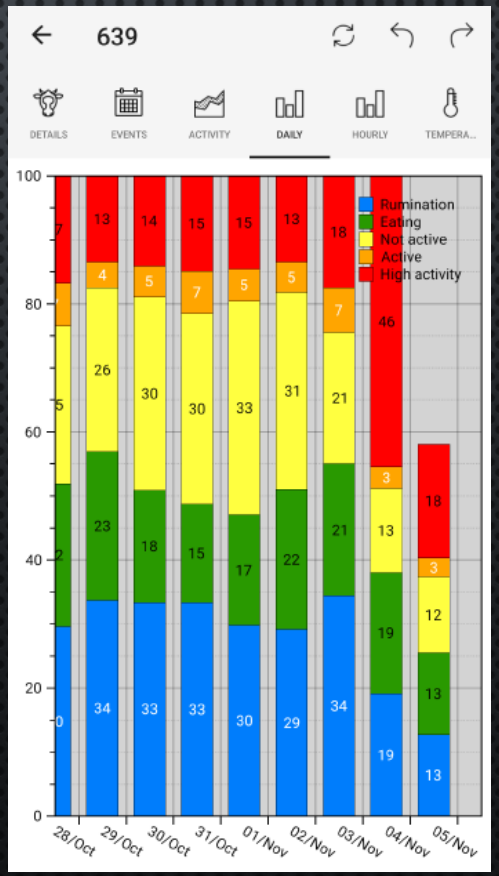
Realities of Turnaround Time

- The majority of clinical microbiology testing in veterinary medicine is done in referral laboratories
  - → specimen collection
  - → transport
  - → primary isolation
  - → secondary isolation
  - → AST reporting

30 – 72 hrs

REALITIES OF TURNAROUND TIME

- "RAPID" DIAGNOSTIC TESTS FOR CLINICAL CASES IS AN IMPROVEMENT
  - BEDSIDE / CHUTESIDE
- DIAGNOSTIC TESTS THAT DETECT SUBCLINICAL DISEASE ARE EVEN BETTER



Realities of Actionable Results

- Will the diagnostic result impact my clinical decision?
- What is my (clinician) confidence in the correlation between in vitro result and in vivo outcome?
- Am I (clinician) comfortable interpreting / Applying the diagnostic result? Or are there resources to help me do so?
- Are there clinical breakpoints to guide my decision-making?
- How will the results be applied?
  - Companion Animal – ante-mortem sample – result applied to that animal
  - Production animal – post-mortem sample – result applied to others in the group

How do we address these challenges?

- Prioritized breakpoint development effort
  - Clinicians, diagnostic laboratories, scientists, standards development organizations
- Education
  - Veterinary education with regard to AST / diagnostic testing (antibiotics, in general) in the US is quite variable
  - Even more so, globally
- Expertise development
  - Experts to continue breakpoint development, veterinary education and clinician support are desperately needed

THANK YOU!

DISCUSSION?

Clinical & Laboratory Standards Institute

- International, not-for-profit, member-volunteer organization dedicated to fostering excellence in laboratory medicine
  - Anyone is eligible (encouraged) for membership
- Representation from three constituencies
  - Professions
  - Industry
  - Government
- Consensus-driven process
  - One member, one vote

CLSI – VETERINARY ANTIMICROBIAL SUSCEPTIBILITY TESTING

- VAST Subcommittee structure (2020)
  - Chairholder, Vice-Chairholder, Secretary
  - 12 Voting Members
  - ~ 50 Advisors and Reviewers
  - Representatives from United States, Australia, Canada, France, Germany, Switzerland, Taiwan, United Kingdom

CLSI – VAST

- Working Groups
  - VAST Methods Standard (VET01)
  - Editorial/VAST Breakpoint Tables (VET08)
  - Generic Drugs
  - Veterinary Fastidious Medium
  - Education
  - Veterinary Breakpoint-Setting Requirements (VET02)
  - Pharmacokinetics/Pharmacodynamics (PK/PD)
  - Bovine Mastitis Interpretive Criteria (BMIC)
  - Aquatic Animals and Aquaculture AST methods
  - Antimicrobial Resistance/Epidemiological Cutoff Value/ Resistance Monitoring
  - Veterinary Fastidious Bacteria (VET06)

CLSI – VAST

- Role of the VAST Subcommittee
  - Approve testing methods
  - Determine quality control (QC)
  - Establish veterinary-specific breakpoints
    - Tripartite Data Approach
      - Microbiological
      - Pharmacokinetic/Pharmacodynamic
      - Clinical
    - Clinical Breakpoints apply only to the specific Pathogen-antimicrobial-dosing regimen-host species-disease process for which they were developed