WHONET
Software for surveillance of microbial populations and antimicrobial resistance

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The Vision of WHONET

Clinical microbiology laboratories generate routine data daily that could be utilized to provide a detailed view of evolving microbial populations in real-time. Yet this resource remains largely untapped and underutilized.

The use of a common software supports local, national, regional, and global collaboration and analyses to support:

- recognition, tracking, and containment of emerging threats
- cost-effective care and treatment guidelines
- public health policy, interventions, advocacy, and research
- laboratory capacity-building
WHONET Objectives

• Improve the use of local data for local purposes
• Promote national and international collaborations

WHONET Users

• Human, animal, food, environmental sectors
• Microbiologists, pharmacists, infection control practitioners, infectious disease specialists, clinicians, IT staff, epidemiologists
Types of data collection

• Surveillance for advocacy
• Surveillance of policy and treatment guidelines
• Surveillance for resistance containment
• Surveys for public health research
• Data collection for improving diagnostic laboratory capacity
Table 1
Estimate of WHONET software use by WHO region. 2010 Estimates

| WHO region                                           | Number of countries | Number of laboratories
|------------------------------------------------------|---------------------|------------------------
| AFRO = WHO Regional Office for Africa                | 13                  | 69                     |
| EMRO = WHO Regional Office for the Eastern Mediterranean | 15                  | 64                     |
| EURO = WHO Regional Office for Europe                | 39                  | 505                    |
| AMRO/PAHO = WHO Regional Office for the Americas/Pan American Health Organization | 25                  | 466                    |
| SEARO = WHO Regional Office for South-East Asia      | 6                   | 105                    |
| WPRO = WHO Regional Office for the Western Pacific   | 13                  | 568                    |
| Total                                               | 111                 | 1777                   |

*a In some countries, figures reflect the estimated number of laboratories which use the WHONET software, while in others figures reflect the estimated number of laboratories managed with WHONET at the national level.
WHONET Installation – www.whonet.org

The microbiology laboratory database software.

- **WHONET 2018**
  - This is our NEW version of WHONET. It is a modernized version of WHONET 5.6. In addition to the standard WHONET 5.6.

- **WHONET WEB In development**
  - This version of WHONET is still in development. In addition to the standard features of the desktop softwares, For U.S.

- **WHONET 5.6 Old version**
  - This is the version of WHONET used in over 120 countries and 2,300 laboratories around the world. WHONET 5.6 is a...
WHONET Data entry

Patient/Animal/Food
Location
Specimen
Organism
Antibiotics
Disk, MIC, Etest
Other
Data analysis
Isolate listing
List of patients with MRSA

Resultados del Análisis

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## %RIS and histograms

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### Gentamicin

- Resistant
- Intermediate
- Susceptible
- Unknown
- Number tested

### Test measurements

- Ciprofloxacin
- Colistin
- Gentamicin
- Imipenem
- Levofloxacin
- Meropenem
- Piperacillin
- Tobramycin

### Zone of inhibition (mm)

- % 0 - 4
- % 5 - 9
- % 10 - 14
- % 15 - 19
- % 20 - 24
- % 25 - 29
- % 30 - 34
- % 35 - 39
- % 40 - 44
- % 45 - 49
- % 50 - 54
- % 55 - 59
- % 60 - 64
Multi-resistance profiles
Multiple facilities in a U.S. state - isolates resistant to cefotaxime and ciprofloxacin, but susceptible to ceftazidime.

Hospital B
Hospital C
Nursing homes
Hospital F
Shigellosis in Argentina
Cluster detection by automated algorithms

Reported to MOH

Suggested by SaTScan

S. sonnei non-susceptible to SXT
Conclusions

• WHONET is for the surveillance of evolving microbial populations
  – One focus is on annual surveillance of priority resistance trends
  – But there are many other applications needed in real-time to support the recognition and containment of emerging threats at local, national, regional, and global levels
Interpretation of AST results in food, animal, and environmental sectors

Comparison of CLSI and EUCAST
**EUCAST vs. CLSI - Timeline**

**EUCAST**
- 1960s-1990s – Establishment of national AST committees (UK, FR, NL, SE, NO, DE, EE, CH)
- 1997 – Establishment of EUCAST and beginning of process to harmonize
- ~2002 – EUCAST MIC breakpoints
- ~2006 – EUCAST Disk breakpoints
- 2019 – Veterinary breakpoints in development

**CLSI**
- 1968 – Established as the National Committee for Clinical Laboratory Standards
- 1975 – Accredited by ANSI
- ~2003 – Veterinary breakpoints
- 2005 – renamed to Clinical and Laboratory Standards Institute
- 2010 – formal accord with FDA
EUCAST vs. CLSI - Scope

EUCAST
- Antimicrobial susceptibility testing
  - Human (now)
  - Veterinary (in development)

CLSI
- Automation and informatics
- Clinical chemistry and toxicology
- General laboratory
- Hematology
- Immunology and ligand assay
- Method evaluation
- Microbiology (including AST)
  - Human, veterinary
- Molecular methods
- Newborn screening
- Point-of-care testing
- Quality management systems
- Miscellaneous
EUCAST and VetCAST – www.eucast.org

Veterinary Susceptibility Testing

VetCAST is a EUCAST subcommittee dealing with all aspects of antimicrobial susceptibility testing of bacterial pathogens of animal origin and animal bacteria with zoonotic potential. The subcommittee will operate within the format and structure of EUCAST (The European Committee on Antimicrobial Susceptibility Testing).

VetCAST Newsletter, December 2017.

VetCAST vision, strategy, remits, Steering committee and members.
VetCAST Guidance on how to collect and handle PK data (April 2018)
CLSI – www.clsi.org

Or... Google “CLSI Free” to find M100, M60, and VET08
EUCAST and CLSI are different

EUCAST

- Committee of representatives of national breakpoint committees and the medical profession in European countries.
- In dialogue with regulatory authorities (ECDC, EMEA)
- In consultation with industry.
- Consensus decisions, no vote

CLSI

- Committee of representatives from the medical profession, science, industry and regulatory authorities.
- Decisions by vote

Slide from Olga Perovic – “CLSI vs. EUCAST”, NICD, South Africa, 2014 presentation
EUCAST vs. CLSI

EUCAST

• Funded by ESCMID, ECDC and nationals breakpoint committees
• Industry consultative role
• Five meetings per year
• EUCAST functions as the breakpoint committee of EMEA
• Rationale documents published on EUCAST website for free
• Clinical breakpoints and epidemiological cut-offs

CLSI

• Funded by member-national (industry, government institutions, societies, laboratories) and sale of documents
• Industry part of decision process
• Two meetings per year
• FDA determines breakpoints
• CLSI was recognized by FDA from 2010
• Breakpoints determined by FDA may be amended by CLSI after 2 yrs
• Rationale for decisions not published in an organized fashion and for sale
• Clinical breakpoints

Slide from Olga Perovic – “CLSI vs. EUCAST”, NICD, South Africa, 2014 presentation
Disc tests from EUCAST and CLSI

**EUCAST**
- Mueller Hinton Inoculum 0.5 McF
- Incubation 18 +/- 2 h (24h for some organisms)
- MH+5% Horse Blood and 20 mg β-NAD for streptococci, pneumococci & H. influenzae
- Disk strengths
- QC strains and reference ranges

**CLSI**
- Mueller Hinton Inoculum 0.5 McF
- Incubation 18 +/- 2 h (24h for some organisms)
- Two different plates for fastidious organisms
- Disk strengths
- QC strains and reference ranges
Breakpoint documents

- EUCAST
  - Human clinical breakpoints
  - Animal clinical breakpoints – in development
  - Epidemiological Cut-off Values (ECOFF) - many

- CLSI
  - Human:  M100 (routine), M45 (rare and fastidious), M60 (yeast), M61 (mold), M62 (Nocardia, etc.),
  - Animal:  VET08 (routine), VET06 (rare and fastidious), VET03/04 (aquatic)
  - Epidemiological Cut-off Values (ECV) – few

Over time, EUCAST and CLSI clinical breakpoints have become closer
A common misperception

• The purpose of routine antimicrobial susceptibility testing is NOT to find “resistant” bacteria.

• The purpose of CLSI and EUCAST clinical breakpoints is to predict treatment outcome in a sick human or animal patient
  – Is the antibiotic a reasonable choice for treating a sick patient?

• The purpose of Epidemiological Cut-off values (ECOFF or ECV) is to recognize microbes with some degree of resistance irrespective of treatment outcome. Until 2007, usually referred to as “Microbiological Breakpoints”
Interpretation categories

• CLSI clinical breakpoints
  – Usual: Resistant (R), Intermediate (I), Susceptible (S)
  – Others: Non-susceptible (NS), Susceptible-Dose Dependent (SDD)
  – Historical: Indeterminate, Moderately Susceptible

• EUCAST clinical breakpoints
  – Usual: Resistant (R), Susceptible with Increased Exposure (I) since 2019, Susceptible (S)
  – Other: Area of Technical Uncertainty (ATU)
  – Historical: Intermediate (prior to 2019)

• Epidemiological Cut-off Values (ECOFF/ECV)
  – Wild Type (WT), Non-Wild Type (NWT)
Ciprofloxacin / Escherichia coli

Antimicrobial wild type distributions of microorganisms – reference database EUCAST

EUCAST determines epidemiological cut-off values for early detection of resistance

ECOFF: WT ≤ 0.032 mg/L

8011 observations (14 data sources)
Clinical breakpoints: S ≤ 0.5 mg/L, R > 1 mg/L

Epidemiological cut-off: WT ≤ 0.032 mg/L

MIC

Slide from Olga Perovic – “CLSI vs. EUCAST”, NICD, South Africa, 2014 presentation
So what “breakpoints” should we use for non-human microbial isolates? It depends on your objective.

• Treatment of sick animals
  – CLSI veterinary breakpoints
  – EUCAST human breakpoints until VetCAST progresses

• Exploring the impact of resistance on human populations
  – Human clinical breakpoints
    • Especially zoonotic pathogens to predict clinical outcome
    • Comparisons with AMR surveillance results from human programs
  – Epidemiological cut-off values, especially to recognize the presence and transfer of resistance genes
Please record your zone diameter and MIC measurements!!

- To provide the clinician with the correct results. No more “eyenometer”, “oculometer”, “eyeball”
- Breakpoints may change over time and you need the measurements to compare the old and new results. The method hasn’t changed! Only our understanding of patient outcomes.
- Flexible selection of breakpoints depending on the objective
- Assessing data quality (disks, media, inoculum, etc.)
- Epidemiological recognition and tracking of distinct microbial populations