

M39-A2
Vol. 25 No. 28
Replaces M39-A
Vol. 22 No. 8

Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline—Second Edition

This document describes methods for recording and analysis of antimicrobial susceptibility test data, consisting of cumulative and ongoing summaries of susceptibility patterns of clinically significant microorganisms.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.



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ISO/TC 212 standards, and ISO/TC 76 standards*

Clinical and Laboratory Standards Institute

Providing NCCLS standards and guidelines, ISO/TC 212 standards, and ISO/TC 76 standards

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M39-A2
ISBN 1-56238-585-2
ISSN 0273-3099

Volume 25 Number 28

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Abstract

Susceptibility statistical data, consisting of the cumulative and ongoing summary of the patterns of antimicrobial susceptibility of clinically important microorganisms, are important to the practice of medicine on several levels.

If the methods used to create, record, and analyze the data are not reliable and consistent, however, many of the most important applications and benefits of the data will not be realized. This consensus document is an attempt: 1) to develop guidelines for clinical laboratories and their data analysis software providers for the routine generation and storage of susceptibility data and for the compilation of susceptibility statistics, and 2) to provide suggestions to clinical laboratories for effective use of their cumulative susceptibility statistics.

Clinical and Laboratory Standards Institute (CLSI). *Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline—Second Edition*. CLSI document M39-A2 (ISBN 1-56238-585-2). Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.

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Suggested Citation

(Clinical and Laboratory Standards Institute. *Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline—Second Edition*. CLSI document M39-A2 [ISBN 1-56238-585-2]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2005.)

Proposed Guideline

December 2000

Approved Guideline

May 2002

Approved Guideline—Second Edition

November 2005

ISBN 1-56238-585-2

ISSN 0273-3099

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Foreword

The antimicrobial susceptibility data generated from testing individual patients' microbial isolates can be helpful if cumulative data from such tests are assembled and appropriately reported at regular intervals. For the cumulative reports to be useful and comparable with those of other institutions, data must be presented in a clear and consistent manner.

The primary aim of this document is to assist the preparation of cumulative antimicrobial susceptibility reports that will prove useful to clinicians in the selection of the most appropriate agents for initial empiric antimicrobial therapy. Additional analyses of antimicrobial susceptibility test data may also be of significant value to clinicians, infection control personnel, pharmacists, and others but lie outside the scope of this document.

Key Words

Antibiogram, antimicrobial agent, epidemiology, resistance

Updated Information in This Edition

Definitions (Section 3)

Deleted definitions

- antibiogram
- duplicate isolate

Modified definitions

- cascade reporting
- cumulative antibiogram
- cumulative antimicrobial susceptibility test data summary

Added definitions

- first isolate
- patient location

Antimicrobial susceptibility test results

Expanded description of antimicrobial susceptibility test information required and desired (Sections 4.6.1 and 4.6.2)

Expanded suggestions for selecting antimicrobial agents for analysis (Section 5.5.1)

Data inclusion/exclusion

Expanded explanation of rationale behind including only the “First isolate per patient” in analyzing data (Sections 1, 5.4, and Appendix B)

Expanded suggestions for data export or transmission (Section 4.1)

Modified the minimum number of isolates for which misleading %S data may be generated from <10 to <30. (Section 8.2)

Calculations

Expanded recommendations for calculating %S (Section 5.6)

Added suggestions for handling certain MICs (e.g., decimal MIC values, off-scale MIC values) (Section 5.6.1)

Added explanation of why total number of observations obtained from analysis of a large dataset may not reflect the sum of the numbers of observations from the subsets within the larger dataset (Section 5.8.1)

Reports

Streptococcus pneumoniae - added option for presenting penicillin data to include %S and %I; added example for cumulative antibiogram report (Section 5.8.1)

Staphylococcus aureus - added examples for cumulative antibiogram report using selection criteria: 1) MRSA vs. MSSA vs. all (Section 5.8.1); and 2) inpatients vs. outpatients, vs. ICU patients (Section 5.8.3.1)

Updated Information in This Edition (Continued)

Enterococcus spp. - added example for cumulative antibiogram report listing all enterococci and *E. faecalis* and *E. faecium* (Section 5.8.1)

Expanded recommendations and added examples for presenting data generated when not all antimicrobial agents are tested on each isolate (Section 6.3.1)

Added suggestions for information that might be highlighted when presenting cumulative antibiogram reports to healthcare professionals (Section 7.2.4 and Appendix F).

Expanded recommendations for presenting data to reflect emerging resistance trends and added example graph to illustrate trends in %S to oxacillin in *S. aureus* over five years (Appendix E)

Data review/quality assurance

Added suggestions for reviewing completed cumulative antibiogram prior to distribution (Section 5.7.2)

Replaced Appendix A with Table 4 (M2) or Table 8 (M7) from M100-S16 for verification of antimicrobial susceptibility test results and confirmation of organism identification as found in M100 (Appendix A)

Added example of a line listing to verify accuracy of %S rates determined by analysis software (Appendix C)

Statistical significance of changes in %S

Added suggestions for evaluating statistical significance of changes in %S observed when comparing data (Section 9 and Appendix G)

Subcommittee on Antimicrobial Susceptibility Testing Mission Statement

The Subcommittee on Antimicrobial Susceptibility Testing is composed of representatives from the professions, government, and industry, including microbiology laboratories, government agencies, healthcare providers and educators, and pharmaceutical and diagnostic microbiology industries. Using the CLSI voluntary consensus process, the subcommittee develops standards that promote accurate antimicrobial susceptibility testing and appropriate reporting.

The mission of the Subcommittee on Antimicrobial Susceptibility Testing is to:

- Develop standard reference methods for antimicrobial susceptibility tests.
- Provide quality control parameters for standard test methods.
- Establish interpretive criteria for the results of standard antimicrobial susceptibility tests.
- Provide suggestions for testing and reporting strategies that are clinically relevant and cost-effective.
- Continually refine standards and optimize the detection of emerging resistance mechanisms through the development of new or revised methods, interpretive criteria, and quality control parameters.
- Educate users through multimedia communication of standards and guidelines.
- Foster a dialogue with users of these methods and those who apply them.

The ultimate purpose of the subcommittee's mission is to provide useful information to enable laboratories to assist the clinician in the selection of appropriate antimicrobial therapy for patient care. The standards and guidelines are meant to be comprehensive and to include all antimicrobial agents for which the data meet established CLSI/NCCLS guidelines. The values that guide this mission are quality, accuracy, fairness, timeliness, teamwork, consensus, and trust.

Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline—Second Edition

1 Scope

The recommendations set forth in this document are intended to be used by individuals involved in the following:

- analyzing and presenting antimicrobial susceptibility test data (e.g., clinical microbiologists);
- utilizing cumulative antimicrobial test susceptibility data (e.g., clinical microbiologists, infectious diseases specialists and other clinicians, infection control practitioners, pharmacists, other healthcare personnel, and public health officials); and
- designing information systems for the storage and analysis of antimicrobial susceptibility test data (e.g., laboratory information system [LIS] vendors, manufacturers of diagnostic products that include epidemiology software packages).

The primary recommendations for analysis and presentation of the data include:

- Prepare report at least annually (see Section 5.3).
- Report %S and do not include %I in the statistic (see Section 5.6) except possibly for the unique situation with penicillin and *Streptococcus pneumoniae* (see Section 5.8.1). For *S. pneumoniae* and viridans group *Streptococcus* spp., list both the % susceptible to penicillin and separately list the % intermediate to penicillin (see Section 5.8.1).
- For reports intended to guide empiric antimicrobial therapy of initial infections, include only results from the first isolate of a given species encountered for a patient. Ignore multiple isolates of the same species irrespective of their source or overall susceptibility profile. If analyzing a subset of data (e.g., data from ICU patients or urine isolates to guide empiric therapy of initial infections), include only results from the first isolate in the subset. For reports intended for other purposes (e.g., emergence of resistance during therapy, empiric therapy of later infections), other inclusion criteria and analysis approaches may be appropriate (see Sections 5.4 and 5.8).
- It is best to report bacteria for which 30 or more isolates of a given species are available (see Section 6.2.2).
- Exclude surveillance isolates (see Section 5.4).
- Report results for all antimicrobial agents tested that are appropriate for the species and do not report supplemental antimicrobial agents that are selectively tested on resistant isolates only (see Section 5.5).

2 Introduction

This guideline presents specific recommendations for the collection, analysis, and presentation of cumulative antimicrobial susceptibility test data. Among the issues addressed are the way in which multiple isolates are handled, the species included or combined in a statistic, the frequency of data