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# 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.

CLINICAL AND LABORATORY STANDARDS INSTITUTE ™

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# Clinical and Laboratory Standards Institute

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The Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. Our process is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, we provide an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

**PUBLICATIONS**

A document is published as a standard, guideline, or committee report.

**Standard** A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

**Guideline** A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

**Report** A document that has not been subjected to consensus review and is released by the Board of Directors.

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The CLSI voluntary consensus process is a protocol establishing formal criteria for:

- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate consensus level.

**Proposed** A consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

**Approved** An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

Our standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following CLSI's established consensus procedures. Provisions in CLSI standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

**COMMENTS**

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any document. Address comments to the Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

**VOLUNTEER PARTICIPATION**

Healthcare professionals in all specialties are urged to volunteer for participation in CLSI projects. Please contact us at customerservice@clsi.org or +610.688.0100 for additional information on committee participation.

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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.

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## Contents

## Contents (Continued)

## 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