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

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

A guideline for global application developed through the NCCLS consensus process.

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Serving the World's Medical Science Community Through Voluntary Consensus

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. NCCLS 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, NCCLS provides an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

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

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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 NCCLS 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 NCCLS 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 (i.e., "tentative") consensus level.

Proposed An NCCLS 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.

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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.

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VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

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

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

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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 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 of the scope of this document.

Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to "standard precautions." Standard precautions are new guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals*. Infection Control and Hospital Epidemiology. CDC. 1996;Vol 17;1:53-80), (MMWR 1987;36[suppl 2S]2S-18S), and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials and for recommendations for the management of blood-borne exposure, refer to the most current edition of NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections.*

Key Words

Antibiogram, antimicrobial agent, epidemiology, resistance

NCCLS Subcommittee on Antimicrobial Susceptibility Testing
Mission Statement

The NCCLS 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 NCCLS voluntary consensus process, the subcommittee develops standards that promote accurate antimicrobial susceptibility testing and appropriate reporting.

The mission of the NCCLS 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 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

1 Introduction

Specific recommendations are presented for the collection, analysis, and presentation of cumulative antimicrobial susceptibility test data. Among the issues addressed in this guideline are the way in which multiple isolates are handled, the species included or combined in a statistic, the frequency of data analysis, and the format for data presentation. This guideline also identifies additional data that may be useful to certain groups for specialized applications.

It is important to recognize that some of the specific recommendations (e.g., inclusion of the first isolate of a given species from an individual patient) have been made with the primary aim of guiding clinicians in the selection of empiric therapy. The cumulative antimicrobial susceptibility report generated according to recommendations presented in this guideline may not reveal some trends in emerging resistance, and thus cannot substitute for the careful analysis of all susceptibility data derived from examining and/or analyzing all antimicrobial susceptibility test results.

2 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 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 data (e.g., LIS vendors, manufacturers of diagnostic products that include epidemiology packages).

3 Definitions[a]

Antibiogram, *n* - Overall profile of antimicrobial susceptibility results of a microbial species to a battery of antimicrobial agents.

Breakpoint/Interpretive Criteria, *n* - MIC or zone diameter value used to indicate susceptible, intermediate, and resistant as defined by the interpretive criteria used in NCCLS documents M2—*Performance Standards for Antimicrobial Disk Susceptibility Tests;* M7—*Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically;* and M11—*Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria*.

[a] Some of these definitions are found in NCCLS document NRSCL8—*Terminology and Definitions for Use in NCCLS Documents.* For complete definitions and detailed source information, please refer to the most current edition of that document.

For example, for antimicrobial X with interpretive criteria (µg/mL) of:

	MIC (µg/mL)	Zone Diameter (mm)
Susceptible	≤ 4	≥ 20
Intermediate	8-16	15-19
Resistant	≥32	≤14

"Susceptible breakpoint" is 4 µg/mL or 20 mm
"Resistant breakpoint" is 32 µg/mL or 14 mm

Cascade reporting, *n* - Strategy of reporting antimicrobial susceptibility results based on organism identification, body site, and overall susceptibility profile. **NOTE:** Secondary (broader spectrum, more costly, more toxic) agents may be only reported if an organism is resistant to primary agents within a particular drug class or if the secondary drugs offer some significant clinical advantage.

Cumulative antibiogram: See **Cumulative antimicrobial susceptibility report.**

Cumulative antimicrobial susceptibility report, *n* - The report generated by analysis of isolates from a particular institution that reflects the percentage of first isolates (per patient) of a given species that is susceptible to each of the antimicrobial agents routinely tested.

Duplicate isolate, *n* – Two isolates that are the same based on defined phenotypic or genotypic characteristics.

HIS (hospital information system), *n* - The computer system used for management of data collected and generated by various services, laboratories, and facilities served by a hospital.

Line listing of antibiogram data, *n* - Listing of all individual antimicrobial susceptibility test results for individual isolates.

LIS (laboratory information system), *n* - The computer system used for the management of data collected and generated by a clinical laboratory, frequently integrated into a hospital information system (HIS).

Multiple isolates, *n* - Isolates of the same species recovered from separate cultures, regardless of body site, obtained from a given patient during a defined time period.

Resistant breakpoint, *n* - The lowest MIC or the largest zone diameter value considered resistant.

Selective reporting, *n* - Reporting of certain antimicrobial susceptibility results on an individual patient's isolate based on defined criteria, such as organism identification, body site, and overall susceptibility profile.

Suppression reporting: See **Cascade reporting.**

Surveillance isolates, *n* **-** Organisms obtained from cultures that are taken for the purpose of determining if a patient is harboring a particular organism; and are not from cultures that are taken as part of the clinical evaluation of a patient's illness. For example, rectal cultures are sometimes performed to determine if a patient is colonized with vancomycin-resistant enterococcus (VRE).

Susceptible breakpoint, *n* - The highest MIC or smallest zone diameter value considered susceptible.

4 Information System Design

Most clinical laboratories are likely to use a locally developed or commercial data management computer system to analyze their cumulative susceptibility data. This software may be an integrated component of their LIS system, an analysis utility provided with their susceptibility test instrument, or a desktop software application. The guidelines below recommend a number of desirable characteristics of the data analysis software and data elements that should be considered for inclusion in the analysis database. It is hoped that commercial vendors of software for the analysis of microbiology data will consider the guidelines proposed herein.

4.1 Data Exportation

If the data analysis software is not fully integrated into a laboratory's primary data management system (e.g., LIS or susceptibility test instrument), the data system must have the capability to periodically export results to the external analysis software.

4.2 Desirable Attributes of the Data Analysis System

The data analysis system should capture all verified, finalized antimicrobial susceptibility test results generated by the laboratory with the required data elements described below. Optionally, the system may also capture the results of specimens in which no susceptibility test results were performed (fungi, 'normal flora,' negative cultures).

The software must be versatile and flexible and have the ability to:

- analyze data for a defined time period to generate cumulative statistics and line listings as described below; and
- remove or edit incorrect data in the database.

4.3 Patient Demographic Information

4.3.1 Required

The following demographics are required:

- a unique patient identification number.
- healthcare facility (for laboratories serving multiple facilities).

4.3.2 Desirable

The following demographics are desirable:

- age or date of birth;
- sex;
- nursing unit, clinic (e.g., surgical clinic, medical intensive care unit, emergency room, diabetes clinic);
- clinical service (e.g., medicine, surgery, obstetrics);

- admission date;
- supplemental information (e.g., patient's clinical picture or situation, other pertinent medical information);
- diagnosis;
- current antimicrobial therapy; and
- previous antimicrobial therapy.

4.4 Specimen Information

4.4.1 Required Information

The following specimen information is required:

- Specimen number (or other unique identifier for original specimen).
- Specimen type (e.g., blood, cerebrospinal fluid, urine). The system should have a mechanism for identifying specimens submitted for purposes other the patient diagnosis (e.g., quality control, proficiency testing, screening, surveillance).
- Date of specimen collection.

4.4.2 Desirable Information

The following specimen information is considered desirable:

- Body site from which original specimen was obtained.

4.5 Organism Information

4.5.1 Required Information

The following organism information is required:

- Identification (genus and species preferred).

4.5.2 Desirable Information

The following organism information is desirable:

- The data analysis software should permit the comparison of organism results over time, regardless of code or taxonomic name changes (e.g., *Pseudomonas maltophilia, Xanthomonas maltophilia,* and *Stenotrophomonas maltophilia* are different names for the same organism).
- Supplemental information from infection control or clinical services:
    - Colonization or infection.
    - Community-acquired or nosocomial.

4.6 Antimicrobial Susceptibility Test Information

4.6.1 Required

The following antimicrobial susceptibility result information is required:

- Quantitative test results (MIC or disk diffusion zone diameters) and/or qualitative test interpretations (susceptible, intermediate, or resistant). Wherever feasible and available, quantitative susceptibility test data should be used. The database should include the results of all antimicrobials tested, including those agents that may not be routinely reported to clinicians when selective suppression or cascade reporting algorithms are applied.
- Separate data fields for the MIC or zone measurement value and the interpretation (susceptible, intermediate, or resistant).
- Susceptibility test method employed in obtaining result (disk diffusion, MIC, etc.).
- Specialized testing results if they represent the primary testing method (e.g., beta-lactamase test, agar screening).

4.6.2 Desirable

The following antimicrobial susceptibility test result information is desirable:

- Specific susceptibility test system used (e.g., broth microdilution, agar diffusion, commercial system, specific MIC panel).
- The ability to store both original susceptibility test results and "expertized" results. For example, the interpretation of all cephalosporin results may be modified to "resistant" for ESBL-producing *E. coli*, regardless of MIC or zone diameter; however, the original MIC or zone diameter should also be stored.

5 Data Analysis

Certain criteria, as listed below, must be considered to produce the most meaningful and useful cumulative antimicrobial susceptibility report.

5.1 Data Verification

Only include final, verified results. It is important to verify the antimicrobial susceptibility result on every isolate prior to inclusion of these data in the data set to be analyzed. Many LIS and commercial susceptibility test instrument data management systems include software (e.g., expert systems) that automatically checks the results to ensure that they appear reasonable, that also cautions the user to verify unusual results. (See Appendix A.)

Examples include:

- Imipenem resistance in *E. coli*, which is extremely rare;
- Vancomycin resistance in *Streptococcus pneumoniae*, which (to date) has not been reported;

- Amikacin resistance coexisting with gentamicin and tobramycin susceptibility in *Klebsiella pneumoniae*. Because amikacin is typically more active than gentamicin or tobramycin *in vitro* against *K. pneumoniae*, such results are unusual.

5.2 Facility

Cumulative susceptibility test reports should represent local susceptibility data for a given institution and separate reports should be generated for each healthcare facility served by a laboratory.

5.3 Frequency

For the purpose of providing data to guide empiric therapy choices, it is recommended that data be analyzed at least yearly. More frequent analysis may be performed when large numbers of isolates have been tested or when clinically important changes are perceived. Presentation of data on a more frequent basis may be complicated by seasonal variations in resistance rates and imprecise measures due to small numbers of isolates.

5.4 Isolates

Multiple isolates of the same species are frequently recovered from successive cultures on the same patient. These isolates may or may not represent identical strains. Inclusion of all isolates in the cumulative data summaries may bias the results toward the susceptibilities of isolates from the patients who are cultured most intensively.

Therefore, for the purposes of supporting clinical decisions about empiric therapy, a single isolate should be included in the summary data. Include the first isolate of a given species per patient per analysis period (e.g., year), irrespective of body site, antimicrobial susceptibility profile, or other phenotypic characteristics (e.g., biotype). The first isolate is easily identified, and summary data prepared using the first isolate is generally comparable to summary data calculated by other methods. Further rationale supporting this view is presented in Appendix B. Include only organisms with ten or more tested isolates (see Section 8.2). Include only patient specimens taken for diagnostic purposes. Do not include data on isolates recovered from surveillance cultures (e.g., VRE, MRSA), environmental cultures, or other non-patient sources.

5.5 Antimicrobial Agents

5.5.1 Selection of Antimicrobial Agents

Include antimicrobial agents routinely tested against the population of isolates to be analyzed.

5.5.2 Selective Reporting

Many laboratories apply cascade or selective reporting rules where secondary agents are only reported if the isolate is resistant to the primary agent(s) of a specific drug class. It is important to analyze all stored data for the cumulative antimicrobial susceptibility report and not just those results that are reported to the clinician. If only isolates resistant to primary agents were analyzed, results for secondary agents would be biased towards higher levels of resistance.

5.5.3 Supplemental Drug Testing

Some laboratories maintain additional antimicrobial agents or panels of antimicrobial agents that are tested only on isolates demonstrating significant resistance or in response to a physician's request to test additional agents. Example: *Pseudomonas aeruginosa* isolates resistant to all antimicrobial agents on the

primary panel may be tested against additional or restricted agents. Additionally, agents may be selectively tested when certain results are obtained with screening tests. For example, some laboratories selectively test extended-spectrum cephalosporins and fluoroquinolones only on isolates of *Streptococcus pneumoniae* that are not susceptible to oxacillin (zones ≤ 19 mm) using the disk diffusion screen. Results of agents selectively or supplementally tested should not be included in the routine cumulative antimicrobial susceptibility test report.

For special reports, see Section 5.8.

5.6 Calculations

The correct interpretation for certain organism/antimicrobial agent combinations is not always determined by zone diameter or MIC (e.g., oxacillin-resistant *S. aureus* isolates are correctly reported as resistant to other beta-lactam antibiotics regardless of their zone diameter or MIC). Use the corrected interpretation when calculating the percent susceptible.

5.7 Validation of Calculations

Line listings of data should be used as a quality assurance check to ensure that the analytical software is calculating data accurately and selection criteria are met. Results from manual calculations of data reported from a short but complete line listing can be compared to the computer-generated cumulative reports. This should be done the first time the program is used and subsequently if any changes are made to the analytical software.

5.7.1 Validation Suggestions

Using the computer-generated cumulative report, select a species that has a small number of isolates. Print a line listing with all isolates of this species, including multiple isolates from each patient. Compare susceptibility test results shown in the line listing to the actual results on the original verified patient reports stored in the primary data system (e.g., LIS or susceptibility test instrument) to document the accuracy and completeness of the line listing data. Verify that manual calculations using patient first isolates from the line listing agree with the software-determined values for:

- the total number of patients
- the percent susceptible for each antimicrobial agent.

An alternative approach to confirming the validity of analyses is to compare the results generated from one computer system (e.g., LIS) to another (e.g., the antimicrobial susceptibility test instrument) provided that both systems use the same calculation algorithms for the cumulative antimicrobial susceptibility report.

5.8 Supplemental Analyses and Selection Criteria

5.8.1 Suggested Supplemental Analyses

For these organism/antimicrobial agent combinations, in addition to calculating percent susceptible, perform the following supplemental analyses:

- *S. pneumoniae.* Calculate the percent intermediate to penicillin. For cefotaxime and ceftriaxone, indicate the percent susceptible using the meningitis breakpoints and also indicate the percent susceptible using the nonmeningitis breakpoints. In countries where cefepime has a meningitis and nonmeningitis clinical indication, indicate the percent susceptible using both sets of breakpoints for this agent also.

- Viridans group *Streptococcus* spp. Calculate the percent intermediate to penicillin. Include sterile body site isolates only.

- *Staphylococcus aureus.* It may be useful to perform a separate analysis on resistance rates in MRSA (e.g., use the selection criterion of oxacillin resistance). (See example in Appendix C).

5.8.2 Additional Data Stratification

Stratification of data by additional variables may be useful in answering questions that a specific institution may have related to guiding clinicians in empiric therapy decisions in specific clinical scenarios. Each institution must determine: 1) if additional data stratification is warranted (e.g. ICU); 2) if sufficient numbers of isolates have been tested; and 3) how to effectively communicate the information generated. This may be in a separate report to individual users rather than part of the annual cumulative antimicrobial susceptibility report.

When analyzing a specific subset of isolates (e.g. blood isolates), count the first isolate of a given species recovered from blood, even if the patient had a previous isolate from another body site during the analysis period. To identify emerging resistance, the entire dataset may need to be analyzed.

5.8.3 Examples of Selection Criteria

Examples of selection criteria include (but are not limited to) the following:

- patient location;

- healthcare facility (must be able to produce facility-specific report);

- specific ward, clinic, inpatient, outpatient, intensive care unit (e.g., it may be useful to calculate the prevalence of MRSA among *S. aureus* from ICU patients);

- clinical service (e.g., medical, surgical);

- specimen type (e.g., blood, urine);

- certain organism subgroups (e.g., MRSA, VRE); and

- special patient populations (e.g., cystic fibrosis).

6 Data Presentation

For the cumulative antimicrobial susceptibility report, present data in tabular form. An example of one format is given in Appendix C.

6.1 Items to Be Considered With the Title

6.1.1 Dating of the Report

The inclusive dates used to create the cumulative susceptibility report should be indicated.

6.1.2 Comments on Methodology

When the recommendations included in this guideline are used to prepare the cumulative antimicrobial susceptibility report for the first time, a notation should be made that a new analytical method has been applied to generate the data, and comparisons with previous reports must be made with caution.

It may be helpful to provide an explanation of how data were generated such as:

"Percent susceptible for each organism/antimicrobial combination was generated by including the first isolate of that organism encountered on a given patient."

6.2 Items to Be Considered With the Tables

6.2.1 Organisms

Prepare separate tables for gram-negative, gram-positive, and, if applicable, anaerobic bacteria.

List organisms alphabetically or by organism group or by prevalence. Analyze by organism group where species information is not routinely available. For example:

- Coagulase-negative *Staphylococcus* spp.
- Species recommended for inclusion when sufficient numbers of isolates are tested:

  Gram-negative:

  - *Acinetobacter baumannii*
  - *Citrobacter freundii*
  - *Citrobacter koseri*
  - *Enterobacter aerogenes*
  - *Enterobacter cloacae*
  - *Escherichia coli*
  - *Klebsiella pneumoniae*
  - *Morganella morganii*
  - *Proteus mirabilis*
  - *Providencia* spp.
  - *Pseudomonas aeruginosa*
  - *Salmonella* spp.
  - *Serratia marcescens*

- *Shigella* spp.
- *Stenotrophomonas maltophilia*

Gram-positive:

- *Enterococcus* spp. (preferable to split into *E. faecalis* and *E. faecium*)
- *Staphylococcus aureus*
- Coagulase-negative *Staphylococcus* spp.
- *Streptococcus pneumoniae*
- Viridans group *Streptococcus* spp.

Anaerobes:

- *Bacteroides fragilis*
- *Clostridium perfringens*

Others:

- If sufficient numbers of isolates are tested.

  — *Haemophilus influenzae* and *Moraxella catarrhalis* – Beta-lactamase results (e.g., percent beta-lactamase positive) may be reported as a footnote to the table.

6.2.2 Number of Organisms

- Only species for which there is a minimum of ten isolates should generally be included. When there are not ten isolates, it may be appropriate to group several species together (e.g., *Shigella* spp.).
- Include the number of observations (N) based on the highest number of organism/antimicrobial combinations tested. If a subset of isolates (e.g., urine isolates) is not tested against all drugs, the N will be smaller, but this will not likely affect clinical relevance of the cumulative antimicrobial susceptibility summary.
- Footnote (*) the drugs which are selectively tested, for example: "tested on urine isolates only" (e.g., nitrofurantoin). See Section 6.3 for other presentation options.
- The guideline suggests reporting data for species for which there are a minimum of ten isolates tested. Ten isolates was an arbitrary choice based on a desire to have a reasonable number of isolates upon which to estimate percent susceptible while allowing the reporting of clinically relevant organisms that are isolated in small numbers. The recommendation to include number of observations (N) for each organism listed on the cumulative report allows the user to estimate the relative precision of the percent susceptible value.

6.2.3 Antimicrobial Agents

Use complete antimicrobial names, abbreviations listed in Appendix F, or abbreviations used on patient reports in the institution.

6.2.4 Data

- Enter %S for each organism/antimicrobial agent in the respective box.

- Place a dash (-) in the data box if a drug is either not tested, or known to be clinically ineffective (e.g., the combination of *P. aeruginosa* and ampicillin).

6.3 Other Presentation Options

6.3.1 Variations in Drug Panels

Laboratories may use different panels of drugs for the testing of isolates from various organism groups or body sites. For example, one set of drugs may be tested for urine gram-negative isolates and another for nonurine gram-negative isolates. Options for data presentation include:

- Separate tables for gram-negative urine and nonurine isolates (if large numbers of isolates are routinely tested).

- One table for gram-negative isolates; however, qualify with a footnote the number of isolates tested.

6.3.2 Specific Locations

Laboratories may wish to present a cumulative antimicrobial susceptibility report for a critical care area or other specified unit as a separate table. Such a table allows comparison between the specified unit and total hospital susceptibility data and thereby enables customized empiric therapy. Isolates from ICU patients are often significantly more resistant.

6.3.3 Emerging Resistance Trends

A table or graph demonstrating data accumulated over several years can be used to emphasize emerging resistance in an institution (e.g., MRSA, VRE, etc.).

7 Use of Cumulative Antimicrobial Susceptibility Reports

The following represent suggestions for educational efforts to facilitate understanding and use of the cumulative antimicrobial susceptibility report.

7.1 Use of the Report

The cumulative antimicrobial susceptibility report may be used as a general guide to empiric therapy only until such time that specific antimicrobial susceptibility testing results become available on a given patient's isolates. Clinical application of the assembled antimicrobial susceptibility data in initial choice of drugs will depend on a variety of factors, including the organism, the antimicrobial agent, and the clinical context. Thus, the patient's physician will use the susceptibility data as one, but not the only, criterion for drug choice.

7.2 Distribution of the Report

7.2.1 "Pocket" Guides

It is best if the report is printed in a format that the clinician finds easily accessible. A foldout card has been shown to be useful, providing a readable font size (no smaller than 8) is used, as has a laminated page placed at the front of each new patients chart.

7.2.2 Website Application

Presentation of the report on an institution's website would likely meet the needs of some clinicians. However, a printed version should also be available in most settings.

7.2.3 Users of the Report

The report should be made available to all those prescribing antimicrobial agents and to infection control personnel, pharmacists, and microbiology personnel.

8 Limitations of Data, Data Analysis, and Data Presentation

8.1 Culturing Practices

The quality of the data relates to culturing practices. If an institution does very few cultures (and frequently treats empirically), data may not truly represent the susceptibility profiles of etiologic agents in that environment.

8.2 Influence of Small Numbers of Isolates

The number of isolates per species, which is used to generate each cumulative antimicrobial susceptibility report, should be noted. Results of small numbers (<10) of isolates may be misleading and usually should not be included in the report. However, such data should be kept on file in the laboratory for easy access.

Possible ways to provide guidance for treatment where the number of tested isolates is small include:

- combining data on the organism from several years of data;
- combining data from several institutions in a geographic area; and
- data from published summaries and guides.

8.3 Comparison of Individual Antimicrobial Agent Results

Results may be misleading when agents to be compared are tested on different groups of isolates in the data set (e.g., an antimicrobial tested only against urine isolates compared with a drug tested against organisms from all sites). (See Section 6.2.2.)

8.4 Identification of New Patterns of Resistance

When summaries are based on the first isolate per patient, changes related to the emergence of new patterns of resistance may be missed. For example, a second or later isolate of *Staphylococcus aureus* intermediate to vancomycin would not be represented in the susceptibility summary if the initial isolate of *S. aureus* was susceptible to vancomycin. Detecting and dealing with new or unusual patterns of this type is best handled as part of the day-to-day function of data verification (see Section 5.1) or thorough analysis of the complete database, not only the patient's first isolates.

Appendix A. Some Atypical Findings Suggesting Verification of Susceptibility Results and Confirmation of Organism Identification

These examples are divided into reports of resistance patterns that would be: 1) biologically implausible or infrequently found to date in any location; and 2) unusual at a given institution. In which category a given example would fit depends on global and local patterns of resistance and might well vary from institution to institution or from year to year.

A1. Biologically Implausible Resistance Patterns or Patterns Infrequently Found (to date) in Any Setting

A1.1 Verify by Repeat Testing Unless Patient Had Isolate Previously

- *Staphylococcus aureus* intermediate or resistant to vancomycin
- *Enterococcus faecalis* resistant to ampicillin or penicillin
- *Enterococcus faecium* resistant to quinupristin-dalfopristin or *Enterococcus faecalis* susceptible to quinupristin-dalfopristin
- Beta-hemolytic streptococci resistant to penicillin
- Enterobacteriaceae resistant to gentamicin + tobramycin + amikacin
- *Stenotrophomonas maltophilia* resistant to trimethoprim-sulfamethoxazole
- *Haemophilus influenzae* resistant to ampicillin and beta-lactamase negative or resistant to amoxicillin-clavulanic acid or third-generation cephalosporin.

Any isolate demonstrating intermediate or resistant results for those organism/antimicrobial combinations for which only susceptible category criteria are defined in M2—*Performance Standards for Antimicrobial Disk Susceptibility Tests,* and M7—*Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically* (e.g., *Streptococcus pneumoniae* resistant to vancomycin).

A1.2 Verify by Re-Examination of Test or Repeat Testing

- *Enterobacter* spp., *Citrobacter freundii*, *Serratia marcescens, Acinetobacter baumannii*, or *P. aeruginosa* susceptible to ampicillin, cefazolin, or cephalothin
- *Klebsiella* spp., *Providencia* spp., indole-positive *Proteus* spp. susceptible to ampicillin
- Enterobacteriaceae resistant or intermediate to imipenem

A2. Resistance Patterns That Would be Unusual at a Given Institution

If resistance at a specific institution is common, repeat testing may not be necessary to verify individual patient results as those listed below:

A2.1 Verify by Repeat Testing Unless Patient Had Isolate Previously

- *Staphylococcus aureus* resistant to oxacillin

Appendix A. (Continued)

- *Enterococcus* spp. with high-level resistance to gentamicin from sterile body site
- *Streptococcus pneumoniae* resistant to penicillin or third-generation cephalosporins
- Viridans group *Streptococcus* spp. resistant or intermediate to penicillin
- *Klebsiella* spp. or *Escherichia coli* with extended-spectrum β-lactamase
- Enterobacteriaceae resistant to ciprofloxacin
- Isolate resistant to all relevant drugs; obtain guidance for testing additional agents.

Appendix B. Rationale Behind the 'First Isolate* Per Patient' Analysis Recommendation

There is no single "correct" way to estimate susceptibility and resistance rates. A variety of calculation approaches and variations exist, and each may be more or less appropriate for certain data applications. For example, each of the following percent susceptible (%S) values is equally correct for the database represented in the table below, and provide somewhat different but complementary views of the data.

Oxacillin vs. *Staphylococcus aureus*

Calculation Method	N	%S
Isolate-based estimate		
All isolates	1,544	67
Patient-based estimates		
First isolate*	931	79
Average result	931	79
Most resistant	931	78
Most susceptible	931	80
Episode-based estimates		
First isolate, 30 days	1,000	77
First isolate, 7 days	1,100	73

The following definitions have been used:

1. "All isolates." Calculations include all isolates of a given species equally, even those of patients with multiple isolates.

* 2. "First isolate" per patient. Calculations include the results of only the first isolate of a given species recovered from each patient during the investigated time interval, regardless of susceptibility profile, body source, or specimen type.

3. "Most resistant" interpretation per patient. Calculations include only the most resistant interpretation observed for each separate antimicrobial agent tested among all isolates of a given species from an individual patient. This estimate gives the 'worst-case' scenario for patient-based %S.

4. "Most susceptible" interpretation per patient. Calculations include only the most susceptible interpretation observed for each separate antimicrobial agent tested among all isolates of a given species from each patient. This estimate gives the 'best-case' scenario for patient-based %S.

5. "Average result." Calculations include all isolates from each patient. An 'average' susceptibility result for each drug is calculated for each patient. These patient averages are then used to calculate the overall average %S.

Appendix B. (Continued)

6. "First isolate per episode (7-day interval)," "First isolate per episode (30-day interval)." Calculations include the first isolate of a given species recovered from each episode of infection. An episode is defined as the set of all isolates from a patient in which the interval between consecutive isolates is less than or equal to 7 days/30 days.

7. The "All isolates" %S is lower than the corresponding patient- and episode-based estimates, as patients with multiple isolations frequently exhibit higher rates of resistance than patients with only single isolates. Thus, for empiric therapy decisions, this statistic frequently underestimates the %S for the patient population.

8. The various patient- and episode-based %S are very similar. Differences between these analysis options should generally not have a significant impact on empiric therapy decisions or for following underlying trends in resistance.

Appendix C. Cumulative Antimicrobial Susceptibility Report Example

Memorial Medical Center
January 1 – December 31, 2001 Cumulative Antimicrobial Susceptibility Summary

		Percent Susceptible											
Gram-Negative Organisms	**N**	**Amk**	**Amp**	**Cefaz**	**Cftax**	**Cftaz**	**Cip**	**Fm[a]**	**Gm**	**Imip**	**Pip**	**T/S**	**Tob**
Acinetobacter baumannii	28	100	13	0	69	63	97	-	75	100	50	75	75
Citrobacter freundii	49	100	-	-	72	67	99	78	100	100	67	67	100
Enterobacter aerogenes	31	100	-	-	83	76	100	85	91	100	81	95	91
Enterobacter cloacae	76	99	-	-	71	83	99	81	90	100	83	90	90
Escherichia coli	1,433	99	46	74	96	94	97	98	91	100	51	65	92
Klebsiella pneumoniae	543	100	-	72	91	92	98	74	94	100	86	92	94
Morganella morganii	44	100	-	-	85	81	99	-	100	99	64	75	100
Proteus mirabilis	88	100	63	80	100	100	99	-	90	100	70	73	93
Providencia spp.	30	100	-	-	77	69	98	-	98	99	82	85	98
Pseudomonas aeruginosa	397	97	-	-	-	76	75	-	80	80	85	-	83
Salmonella spp.	32	-	88	-	100	100	100	-	-	100	91	86	-
Serratia marcescens	50	100	-	-	82	94	99	91	94	100	94	100	89
Shigella spp.	29	-	64	-	100	100	95	-	-	100	84	52	-
Stenotrophomonas maltophilia	72	-	-	-	-	63	6	-	-	-	-	100	-

N = Number of isolates
(-) Drug not tested or drug not indicated
%S for each organism/antimicrobial combination was generated by including the first isolate of that organism encountered on a given patient.

[a] Tested on urine isolates only.

Appendix D. Glossary I (Part 1). β-lactams: Class and Subclass Designation and Generic Name

Antimicrobial Class	Antimicrobial Subclass	Agents Included; Generic Names
penicillins	penicillin[a]	penicillin
	aminopenicillin[a]	amoxicillin ampicillin
	ureidopenicillin[a]	azlocillin mezlocillin piperacillin
	carboxypenicillin[a]	carbenicillin ticarcillin
	penicillinase stable penicillins[b]	cloxacillin dicloxacillin methicillin nafcillin oxacillin
	amidinopenicillin	mecillinam
β-lactam/β-lactamase inhibitor combinations		amoxicillin-clavulanic acid ampicillin-sulbactam piperacillin-tazobactam ticarcillin-clavulanic acid
cephems (parenteral)	cephalosporin I[c]	cefazolin cephalothin cephapirin cephradine
	cephalosporin II[c]	cefamandole cefonicid cefuroxime (sodium)
	Cephamycin[d]	cefmetazole cefotetan cefoxitin
	cephalosporin III[c]	cefoperazone cefotaxime ceftazidime ceftizoxime ceftriaxone
	oxacephem (cephalosporin III)[c]	moxalactam
	cephalosporin IV[c]	cefepime
cephems (oral)	cephalosporin	cefaclor cefadroxil cefdinir cefditoren cefetamet cefixime cefpodoxime cefprozil cefuroxime (axetil) cephalexin cephradine ceftibuten
	carbacephem	loracarbef
monobactams		aztreonam
carbapenems		ertapenem imipenem meropenem

Appendix D. (Continued)

[a] Penicillinase-labile; hydrolyzed by staphylococcal penicillinase

[b] Not hydrolyzed by staphylococcal penicillinase

[c] Cephalosporin I, II, III, **and IV** are sometimes referred to as 1st-, 2nd-, 3rd, and **4th-**generation cephalosporins, respectively. Cephalosporin III and IV are also referred to as "**extended**-spectrum cephalosporins." This does not imply activity against ESBL-producing gram-negative bacteria.

[d] Although often referred to as a 2nd-generation cephalosporin, cephamycins are not included with the other cephalosporins with regard to reporting of ESBL-producing strains.

Appendix E. Glossary I (Part 2). Non-β-lactams: Class and Subclass Designation and Generic Name

Antimicrobial Class	Antimicrobial Subclass	Agents Included; Generic Names
aminocyclitols		spectinomycin trospectinomycin
aminoglycosides		amikacin gentamicin kanamycin netilmicin streptomycin tobramycin
ansamycins		rifampin
quinolones		cinoxacin nalidixic acid
fluoroquinolones		ciprofloxacin clinafloxacin enoxacin fleroxacin gatifloxacin gemifloxacin grepafloxacin levofloxacin lomefloxacin moxifloxacin norfloxacin ofloxacin sparfloxacin trovafloxacin
folate pathway inhibitors		sulfonamides trimethoprim trimethoprim-sulfamethoxazole
fosfomycins		fosfomycin
ketolides		telithromycin
lincosamides		clindamycin
lipopeptides		daptomycin
macrolides		azithromycin clarithromycin dirithromycin erythromycin
nitrofurans		nitrofurantoin
nitroimidazoles		metronidazole
oxazolidinones		linezolid
glycopeptides	glycopeptide	vancomycin
	lipoglycopeptide	teicoplanin
phenicols		chloramphenicol
streptogramins		quinupristin-dalfopristin
tetracyclines		doxycycline minocycline tetracycline

Appendix F. Glossary II. Abbreviations/Routes of Administration/Drug Class for Antimicrobial Agents Listed in M100

Antimicrobial Agent	Agent Abbreviation[a]	Routes of Administration[b]			Drug Class
		PO	IM	IV	
Amikacin	AN, AK, Ak, AMI, AMK		X	X	aminoglycoside
Amoxicillin	AMX, Amx, AMOX, AC	X			penicillin
Amoxicillin-clavulanic acid	AMC, Amc, A/C, AUG, Aug, XL, AML	X			β-lactam/β-lactamase inhibitor
Ampicillin	AM, Am, AMP	X	X	X	penicillin
Ampicillin-sulbactam	SAM, A/S, AMS, AB			X	β-lactam/β-lactamase inhibitor
Azithromycin	AZM, Azi, AZI, AZ	X		X	macrolide
Azlocillin	AZ, Az, AZL		X	X	penicillin
Aztreonam	ATM, AZT, Azt, AT, AZM			X	monobactam
Carbenicillin (indanyl salt) Carbenicillin	CB, Cb, BAR	X	 X	 X	penicillin
Cefaclor	CEC, CCL, Crf, FAC, CF	X			cephem
Cefadroxil	CFR, FAD	X			cephem
Cefamandole	MA, CM, Cfm, FAM		X	X	cephem
Cefazolin	CZ, CFZ, Cfz, FAZ, KZ		X	X	cephem
Cefdinir	CDR, Cdn, DIN, CD, CFD	X			cephem
Cefditoren	CDN	X			cephem
Cefepime	FEP, Cpe, PM, CPM		X	X	cephem
Cefetamet	CAT, FET	X			cephem
Cefixime	CFM, FIX, Cfe, IX	X			cephem
Cefmetazole	CMZ, CMZS, CMT		X	X	cephem
Cefonicid	CID, Cfc, FON, CPO		X	X	cephem
Cefoperazone	CFP, Cfp, CPZ, PER, FOP, CP		X	X	cephem
Cefotaxime	CTX, TAX, Cft, FOT, CT		X	X	cephem
Cefotetan	CTT, CTN, Ctn, CTE, TANS, CN		X	X	cephem
Cefoxitin	FOX, CX, Cfx, FX		X	X	cephem
Cefpodoxime	CPD, Cpd, POD, PX	X			cephem
Cefprozil	CPR, CPZ, FP	X			cephem

[a] Abbreviations assigned to one or more diagnostic products in the U.S.
[b] As available in the U.S.

Appendix F. (Continued)

Antimicrobial Agent	Agent Abbreviation[a]	Routes of Administration[b]			Drug Class
		PO	IM	IV	
Ceftazidime	CAZ, Caz, TAZ, TZ		X	X	cephem
Ceftibuten	CTB, TIB, CB	X			cephem
Ceftizoxime	ZOX, CZX, CZ, Cz, CTZ, TIZ		X	X	cephem
Ceftriaxone	CRO, CTR, FRX, Cax, AXO, TX		X	X	cephem
Cefuroxime (axetil) Cefuroxime (sodium)	CXM, CFX, ROX, Crm, FUR, XM	X	 X	 X	cephem
Cephalexin	CN, LEX, CFL	X			cephem
Cephalothin	CF, Cf, CR, CL, CEP, CE, KF			X	cephem
Cephapirin	CP, HAP		X	X	cephem
Cephradine	RAD, CH	X			cephem
Chloramphenicol	C, CHL, CL	X		X	phenicol
Cinoxacin	CIN, Cn	X			quinolone
Ciprofloxacin	CIP, Cp, CI	X		X	fluoroquinolone
Clarithromycin	CLR, CLM, CLA, Cla, CH	X			macrolide
Clinafloxacin	CFN, CLX, LF	X		X	fluoroquinolone
Clindamycin	CC, CM, CD, Cd, CLI, DA	X	X	X	lincosamide
Daptomycin	DAP			X	lipopeptide
Dicloxacillin	DX, DIC	X			penicillin
Dirithromycin	DTM, DT	X			macrolide
Ertapenem	ETP		X	X	carbapenem
Erythromycin	E, ERY, EM	X		X	macrolide
Fleroxacin	FLE, Fle, FLX, FO	X		X	fluoroquinolone
Fosfomycin	FOS, FF, FO, FM	X			fosfomycin
Gatifloxacin	GAT	X		X	fluoroquinolone
Gemifloxacin	GEM	X			fluoroquinolone
Gentamicin Gentamicin synergy	GM, Gm, CN, GEN GM500, HLG, Gms		X	X	aminoglycoside
Grepafloxacin	GRX, Grx, GRE, GP	X			fluoroquinolone
Imipenem	IPM, IMI, Imp, IP			X	carbapenem
Kanamycin	K, KAN, HLK, KM		X	X	aminoglycoside
Levofloxacin	LVX, Lvx, LEV, LEVO, LE	X		X	fluoroquinolone
Linezolid	LNZ, LZ, LZD	X		X	oxazolidinone
Lomefloxacin	LOM, Lmf	X			fluoroquinolone
Loracarbef	LOR, Lor, LO	X			cephem
Mecillinam	MEC	X			penicillin
Meropenem	MEM, Mer, MERO, MRP, MP			X	carbapenem
Methicillin	DP, MET, ME, SC		X	X	penicillin
Mezlocillin	MZ, Mz, MEZ		X	X	penicillin

[a] Abbreviations assigned to one or more diagnostic products in the U.S.
[b] As available in the U.S.

Appendix F. (Continued)

Antimicrobial Agent	Agent Abbreviation[a]	Routes of Administration[b]			Drug Class
		PO	IM	IV	
Minocycline	MI, MIN, Min, MN, MNO, MC, MH	X		X	tetracycline
Moxalactam	MOX		X	X	cephem
Moxifloxacin	MXF	X			fluoroquinolone
Nafcillin	NF, NAF, Naf		X	X	penicillin
Nalidixic Acid	NA, NAL	X			quinolone
Netilmicin	NET, Nt, NC		X	X	aminoglycoside
Nitrofurantoin	F/M, FD, Fd, FT, NIT, NI, F	X			nitrofurantoin
Norfloxacin	NOR, Nxn, NX	X			fluoroquinolone
Ofloxacin	OFX, OFL, Ofl, OF	X	X	X	fluoroquinolone
Oxacillin	OX, Ox, OXS, OXA	X	X	X	penicillin
Penicillin	P, PEN, PV	X	X	X	penicillin
Piperacillin	PIP, PI, PP, **Pi**		X	X	penicillin
Piperacillin-tazobactam	TZP, PTZ, P/T, PTc			X	β-lactam/β-lactamase inhibitor combination
Quinupristin-dalfopristin	SYN, Syn, QDA, RP			X	streptogramin
Rifampin	RA, RIF, Rif, RI, RD	X		X	ansamycin
Sparfloxacin	SPX, Sfx, SPA, SO	X			fluoroquinolone
Spectinomycin	SPT, SPE, SC		X	X	aminocyclitol
Streptomycin Streptomycin synergy	S, STR, StS, SM, ST2000, HLS		X	X	aminoglycoside
Sulfonamides	SSS, S3	X		X	folate pathway antagonist (some PO only)
Teicoplanin	TEC, TPN, Tei, TEI, TP, TPL		X	X	glycopeptide
Telithromycin	TEL	X			ketolide
Tetracycline	TE, Te, TET, TC	X		X	tetracycline
Ticarcillin	TIC, TC, TI, Ti		X	X	penicillin
Ticarcillin-clavulanic acid	TIM, Tim, T/C, TCC, TLc			X	β-lactam/β-lactamase inhibitor
Tobramycin	NN, TM, TO, To, TOB		X	X	aminoglycoside
Trimethoprim	TMP, T, TR, W	X			folate pathway inhibitor
Trimethoprim-sulfamethoxazole	SXT, SxT, T/S, TS, COT	X		X	folate pathway inhibitor
Trospectinomycin			X	X	aminocyclitol
Trovafloxacin	TVA, Tva, TRV, TV	X		X	fluoroquinolone
Vancomycin	VA, Va, VAN	X		X	glycopeptide

[a] Abbreviations assigned to one or more diagnostic products in the U.S.
[b] As available in the U.S.

PO per OS (oral)
IM intramuscular
IV intravenous

Appendix G. List of Identical Abbreviations Used for More Than One Antimicrobial Agent in U.S. Diagnostic Products

Agent Abbreviation	Antimicrobial Agents for Which Respective Abbreviation is Used
AZM	Azithromycin, Aztreonam
AZ	Azithromycin, Azlocillin
CB, Cb	Ceftibuten, Carbenicillin
CFR, Cfr	Cefaclor, Cefadroxil
CF, Cf	Cefaclor, Cephalothin
CM	Clindamycin, Cefamandole
CFM, Cfm	Cefixime, Cefamandole
CZ, Cz	Ceftizoxime, Cefazolin
CD, Cd	Clindamycin, Cefdinir
CPZ	Cefprozil, Cefoperazone
CP, Cp	Cephapirin, Cefoperazone, Ciprofloxacin
CN, Cn	Cephalexin, Cefotetan, Cinoxacin, Gentamicin
CFX, Cfx	Cefoxitin, Cefuroxime
CL	Cephalothin, Chloramphenicol
CH	Clarithromycin, Cephradine
DX	Doxycycline, Dicloxacillin
FO	Fleroxacin, Fosfomycin
SC	Spectinomycin, Methicillin
SO	Sparfloxacin, Oxacillin
TC	Tetracycline, Ticarcillin

NCCLS consensus procedures include an appeals process that is described in detail in Section 9 of the Administrative Procedures. For further information, contact the Executive Offices or visit our website at www.nccls.org.

Summary of Comments and Working Group Responses

M39-P: *Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Proposed Guideline*

General

1. Please note that the ESBL Working Group approved a change in terminology from "expanded spectrum" beta lactamase to "extended spectrum" during the last Subcommittee on Antimicrobial Susceptibility Testing in Florida (January 2001). This wording must be changed.

- **The term "expanded-spectrum cephalosporins" has been changed to "extended-spectrum cephalosporins."**

Section 3

2. The definition of "resistant breakpoint' should be listed separately from "susceptible breakpoint" and listed in bold. The way the definition of susceptible breakpoint is written there is no punctuation at the end of the sentence and it appears to be one continuous sentence into the resistant breakpoint definition — very confusing.

- **This revision has been incorporated as suggested.**

Section 5.1

3. Data Verification and Appendix A contain valuable information, but the information is most relevant to quality assurance of individual patient results prior to release of those results. Therefore, part of Section 5.1 and all of Appendix A should be moved to documents M2, M7, and/or M100.

- **Verification of antimicrobial susceptibility test results is important when reporting individual patient results and when generating cumulative antimicrobial susceptibility test data reports. The subcommittee believes that it is useful to keep this information in M39.**

Section 5.4

4. It would be most easy for hospitals to use the first isolate per hospitalization rather than first isolate per year since many patients are admitted several times per year.

- **Depending on the laboratory information system (LIS) and hospital information system (HIS), the ease with which an institution could use the first isolate per hospitalization versus first isolate per year may vary. M39 recommends use of first isolate per year.**

Section 5.5

5. Add additional subsection entitled, "Selective Testing," to be placed between "Selective Reporting" and " Supplemental Drug Testing."

- **Section 5.5.3 has been expanded to include "selective testing" of individual antimicrobial agents.**

Section 5.5.3

6. Some laboratories perform a MIC or disk diffusion test for selected antimicrobial agents only on isolates that initially demonstrate resistance to a screening agent. For example, *Streptococcus pneumoniae* isolates may be initially screened by an oxacillin disk to predict penicillin susceptibility, and only a small subset (oxacillin zone ≤ 19 mm) is then tested by a MIC or disk diffusion method to other agents. A calculation of percent susceptible based on a selected subset of isolates would bias the results towards higher levels of resistance. Therefore, for an antimicrobial agent to be included in a cumulative antimicrobial susceptibility test report, all nonduplicate isolates for a specific pathogen (e.g., *S. pneumoniae)* should be tested against that antimicrobial agent.

- **Please see response to Comment 5.**

Section 5.6

7. Please clarify the following: The correct interpretation for certain organism/antibiotic combinations is not always determined by zone diameter or MIC (e.g., oxacillin resistant *S. aureus* isolates are correctly reported as resistant to other beta-lactam antibiotics regardless of their zone diameter or MIC). It is important to use the corrected interpretation when calculating the percent susceptible.

- **This section has been clarified.**

Section 5.7

8. Add "analytical" to the last sentence of the paragraph: "This should be done the first time the program is used and subsequently if any changes are made to the **analytical** software."

- **The suggested revision has been incorporated.**

Section 5.7.1

9. The third bullet refers to an example in Appendix C. The example is missing from Appendix C.

- **The cross reference has been deleted.**

Section 6.2.2

10. New proposed wording: Only species for which there is a minimum of 25 isolates should generally be included. When there are not 25 isolates, it may be appropriate to group several species together (e.g., *Shigella* spp.). Justifications for a minimum of 25 isolates include:

    1) The inclusion of only ten isolates would bias the results towards higher levels of resistance. For example, the impact of 2 nonsusceptible isolates in a given report would result in a calculation of 80% (8/10) susceptible for a minimum of 10 isolates, compared to 92% (23/25) susceptible for a minimum of 25 isolates. Thus, the perception of the nonsusceptible rate would increase from 8% to 20% based on the smaller denominator.

    2) The inclusion of only ten isolates would encourage the inclusion of small numbers of isolates and analysis of quarterly reports instead of annual reports. This document recommends that data be

analyzed yearly since "presentation of data on a more frequent basis may be complicated by seasonal variations in resistance rates" (Section 5.3).

3) Marked variations in susceptibility rates could occur with a small denominator of ten isolates, reducing the accuracy of year-to-year comparisons in cumulative susceptibility reports.

- **The subcommittee has decided to maintain a recommendation of a minimum of ten isolates. The rationale behind the decision has been incorporated as the fourth bullet in Section 6.2.2.**

Section 6.2.3

11. Add to the sentence, "or list abbreviations used by the laboratory's AST system."

- **This sentence has been revised.**

Related NCCLS Publications*

M2-A7 **Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard—Seventh Edition (2000).** This standard contains revised recommended techniques, interpretive criteria, and quality control parameters for disk-susceptibility testing.

M7-A5 **Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard—Fifth Edition (2000*).*** This standard provides revised reference methods for the determination of minimal inhibitory concentrations (MICs) for aerobic bacteria by broth macrodilution, broth microdilution, and agar dilution.

M11-A5 **Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard—Fifth Edition (2001).** Provides reference methods for the determination of minimal inhibitory concentrations (MICs) of anaerobic bacteria by broth macrodilution, broth microdilution, and agar dilution.

M23-A2 **Development of *In Vitro* Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline—Second Edition (2001).** Addresses the required and recommended data needed for the selection of appropriate interpretative standards and quality control guidelines for new antimicrobial agents.

M100-S12 **Performance Standards for Antimicrobial Susceptibility Testing; Twelfth Informational Supplement. (2002).** This document provides updated tables for the NCCLS antimicrobial susceptibility testing standards M2-A7 and M7-A5.

NRSCL8-A **Terminology and Definitions For Use in NCCLS Documents; Approved Standard (1998).** This document provides standard definitions for use in NCCLS standards and guidelines, and for submitting candidate reference methods and materials to the National Reference System for the Clinical Laboratory.

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

NOTES

NOTES

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