CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

EP27

Constructing and Interpreting an Error Grid for Quantitative Measurement Procedures

This guideline provides recommendations on constructing and using error grids to evaluate the clinical acceptability of quantitative measurement procedures, based on the potential harm that may be caused by erroneous measurements with clinical consequences.

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

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Constructing and Interpreting an Error Grid for Quantitative Measurement Procedures

Anthony Killeen, MD, PhD
Paula Ladwig, MS, MT(ASCP)
Nicholas Burn, BASc, MSc
David Alter, MD
Jeffrey R. Budd, PhD
Paula V. Caposino, MA, PhD
Janel Huang
Adil Khan, MSc, PhD
Marina V. Kondratovich, PhD
Jeffrey E. Vaks, PhD
Anca Roxana Varlan, PhD
Hubert W. Vesper, PhD
Clarke Xu, PhD

Abstract

Clinical and Laboratory Standards Institute guideline EP27—*Constructing and Interpreting an Error Grid for Quantitative Measurement Procedures* explains the function of an error grid, illustrates the concept with examples, and provides recommendations on constructing and using one. For a given measurand, error grids characterize the relationship between measurement errors and clinical management errors that may harm patients. This guideline covers the process of creating error grids with multiple error zones and describes the two primary options for doing so. After error grids have been constructed, they can be populated with data from a measurement procedure comparison experiment, as described in this guideline. A candidate measurement procedure's clinical performance is evaluated by visually comparing the experimental data points with the error grid and tabulating the number of points that fall within each error zone. This guideline includes an example experiment that demonstrates proper interpretation of an error grid plot and its tabulated results.

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Contents

Foreword

Error grids are a widely accepted tool for visualizing a measurement procedure's clinical acceptability. Most commonly, they have been used to evaluate blood glucose monitor performance, but they can also be used to evaluate other measurement procedures. As explained in this guideline, error grids illustrate the clinical consequences of measurement errors, as quantified by differences in results between a candidate measurement procedure and a comparative measurement procedure.

This guideline provides recommendations on constructing an error grid based on the likely clinical effect associated with measurement errors. It also explains how to estimate the proportions of results that are likely to fall within each error grid zone. Additionally, this guideline provides direction on using an error grid to evaluate a candidate measurement procedure and provides examples to illustrate these concepts.

Overview of Changes

This guideline replaces the previous edition of the approved guideline, EP27-A, published in 2012. Several changes were made in this edition, including:

- Adding an initial flow chart that depicts the processes of creating and using an error grid
- Aligning the guidance with CLSI document EP21[1] on allowable total error
- Updating and adding plots to more clearly demonstrate the process of error grid creation
- Adding an example plot from an error grid experiment, including the grid and its data points
- Moving error grid construction examples to appendixes to more closely follow the initial flow chart

NOTE: The content of this guideline is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

Allowable total error
Error grid
Error zones
Limits of erroneous results
Measurement procedure comparison

Constructing and Interpreting an Error Grid for Quantitative Measurement Procedures

1 Introduction

1.1 Scope

This guideline provides recommendations on constructing and using error grids to evaluate the clinical acceptability of quantitative measurement procedures, based on the potential harm that may be caused by erroneous measurements with clinical consequences. This guideline is intended for use by laboratories and manufacturers (collectively referred to as "developers") and users of quantitative measurement procedures.

1.2 Background

An error grid is a graphical tool for interpreting data from an experiment that compares a candidate measurement procedure with a comparative measurement procedure, using the same patient samples. Erroneous measurements can lead to diagnostic or therapeutic errors that harm the patient. A grid of zones is constructed, with each zone corresponding to a different level of severity of harm, and the data points from the measurement procedure comparison are plotted on the grid.

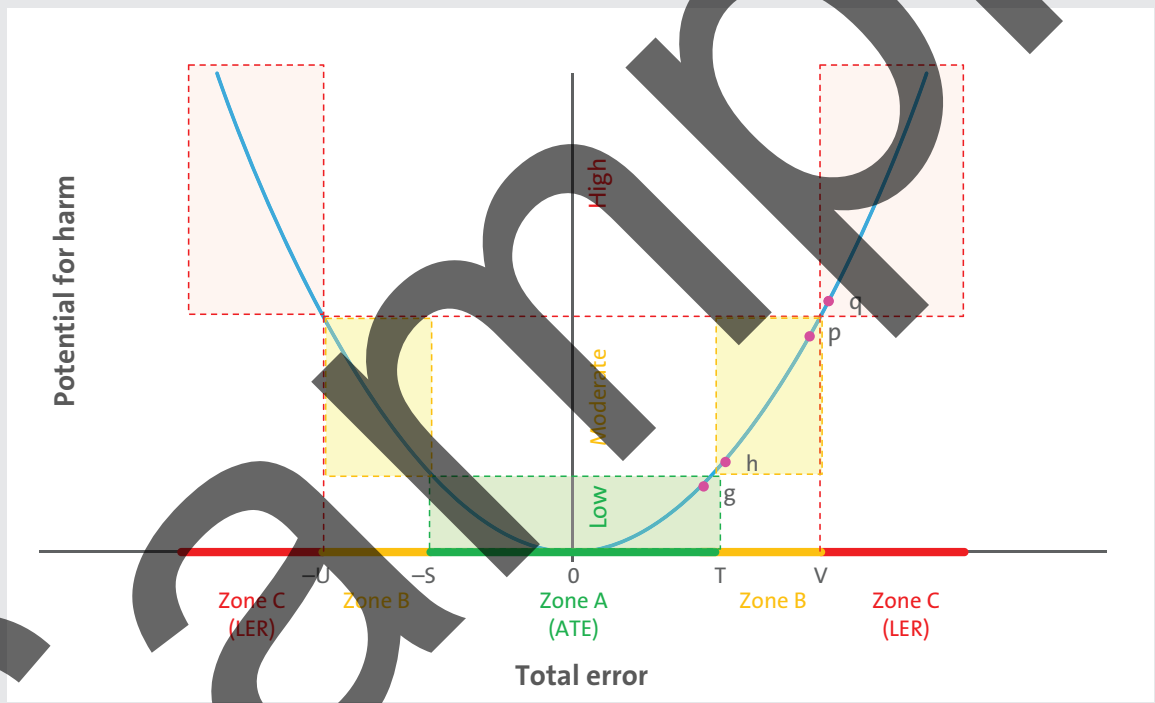
The error grid displays all data points on an X-Y plot. The x-axis represents the comparative measurement procedure, and the y-axis represents the candidate measurement procedure. The *x* values are defined as true, so any difference between a true value and a *y* value is regarded as a quantification of measurement error. The plot also includes boundary lines separating zones of observed error at different concentrations into a hierarchy based on their magnitude. Small errors may be tolerated because they pose minimal risk to the patient, whereas large errors are likely to cause patient harm. Thus, limits bound the region of allowable errors, Zone A, which ideally contains most data points (see the green area in Figure 1); another region of unacceptably large errors, Zone C, where there should be no data points (see the red area in Figure 1); and the intermediate region representing moderate errors, Zone B (see the yellow area in Figure 1), where it is acceptable to have a few data points.

The error grid can be used to evaluate the candidate measurement procedure, in terms of both the percentage of results within the desirable zones and the percentage of results with unacceptably large errors. Error grid analysis is most appropriate for measurement procedure comparison experiments that use many patient samples. Testing fewer patient samples provides less confidence in data interpretation, so using an error grid might not be appropriate.

- **Nonreported results:** This part of error grid analysis tallies the instances in which the candidate measurement procedure failed to produce a valid result. The potential for harm from nonreported results varies, depending on the application. In some cases, patient harm may be likely if a valid result cannot be obtained within a specified time. In other cases, the delay may be short enough that a repeat result can be obtained without harm. The error grid summary includes the number of nonreported results but does not evaluate the associated risk, because doing so requires consideration of additional factors.

2.6 Considerations for Zone Placement

Figure 6 is a generic representation of the probability of patient harm in relation to the magnitude of measurement error. The larger the error, the greater the probability of harm. The symmetrical, parabolic shape of the bold line, representing the probability of harm, is idealized. The actual shape varies, depending on the application. For example, the interval from –S to T represents the ATE zone, where the interval from –S to 0 could be larger or smaller than the interval from 0 to T. Similarly, the interval from –U to V represents the ATE and intermediate zones, where the interval from –U to 0 could be larger or smaller than the interval from 0 to V.



Abbreviations: ATE, allowable total error; LER, limits of erroneous results.

Figure 6. Relationship Between Total Error and Potential for Harm

Appendix B. (Continued)

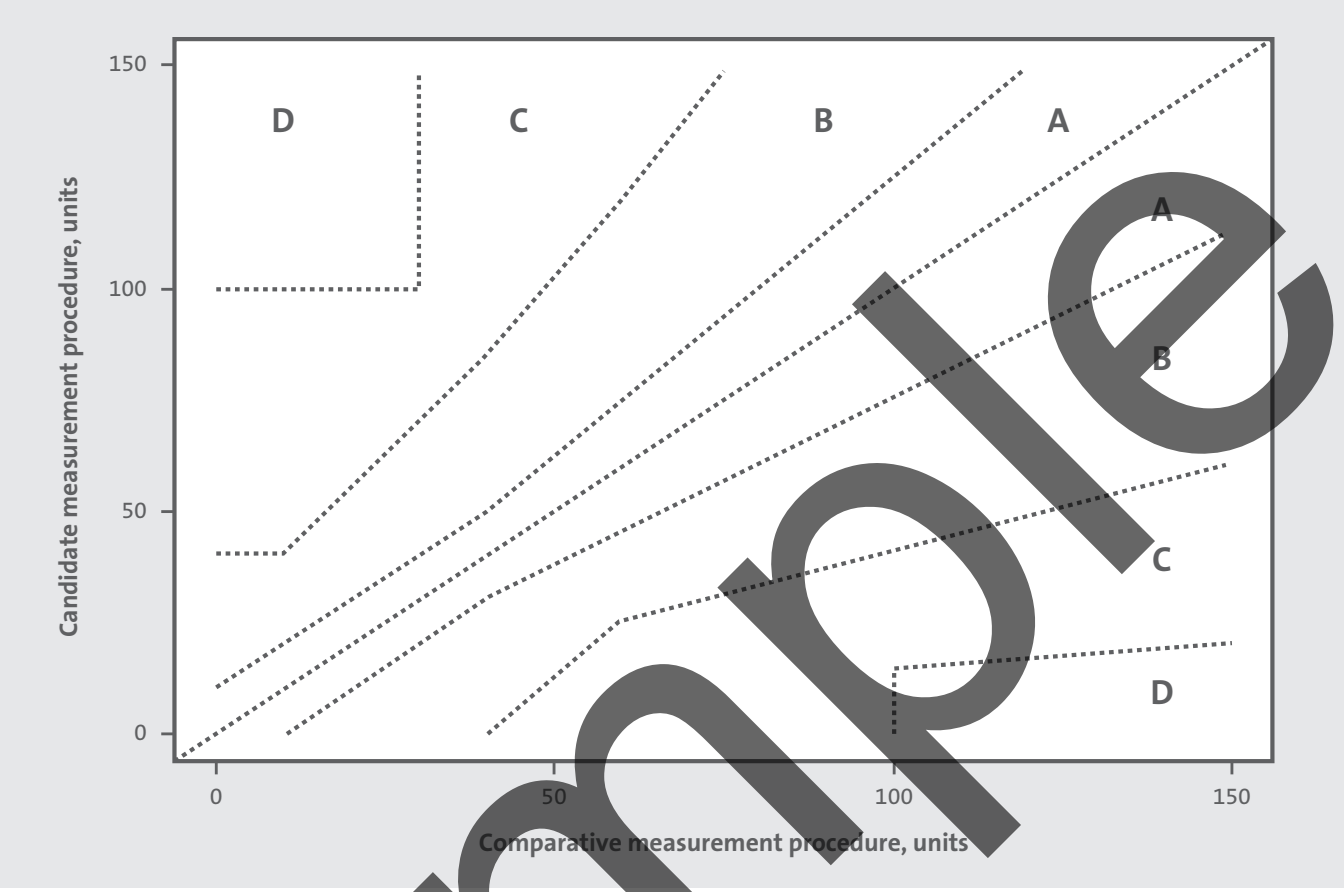


Figure B1. Error Grid for a Literature-based Approach Example

Reference for Appendix B

1 Statland BE. *Clinical Decision Levels for Lab Tests*. 2nd ed. Medical Economics Books; 1987.

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