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EP27-A

How to Construct and Interpret an Error Grid for Quantitative Diagnostic Assays; Approved Guideline

This guideline describes what an error grid is, why it is useful, and how to construct one and interpret the information. Guidance is provided for manufacturers and for the clinical laboratory.

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

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How to Construct and Interpret an Error Grid for Quantitative Diagnostic Assays; Approved Guideline

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Abstract

Clinical and Laboratory Standards Institute document EP27-A—*How to Construct and Interpret an Error Grid for Quantitative Diagnostic Assays; Approved Guideline* describes what an error grid is, why it is useful, and how to construct it. An error grid illustrates the relationship between results obtained by one quantitative test to those obtained by a second one, while considering the diagnostic or therapeutic implications of the magnitude of the difference between the two results. Error grids inform users about the performance required to prevent potential patient harm. Once constructed, error grids can be populated with data from a measurement procedure comparison experiment. The proportion of data in each error grid zone is used to evaluate the clinical effectiveness of the measurement procedure

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Foreword

Error grids are well known for performance evaluations of blood glucose monitors, but otherwise are little used. This guideline explains the usefulness of error grids to inform users about the clinical consequences of differences in results between a candidate and a comparative measurement procedure.

Guidance is provided on how to construct an error grid, how to locate the error grid zones based on the clinical errors that may be associated with differences in results between two quantitative laboratory measurement procedures, and how to estimate the proportions of differences in results that should be assigned to each zone. The concepts are illustrated with examples.

Key Words

Allowable total error, error grid, limits of erroneous results

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1 Scope

This document explains how to construct and use error grids to evaluate the clinical acceptability of quantitative diagnostic measurement procedures based on the potential harm that may be caused by erroneous results.

This document is intended for use by developers of measurement procedures——including laboratory-developed tests—and by clinical laboratories.

2 Introduction

An error grid is a simple nonparametric graphical tool for interpreting data from an experiment comparing a candidate measurement procedure to a comparative measurement procedure when testing the same group of patient samples. An error grid interprets the data in terms of the severity of potential harm to a patient from diagnostic or therapeutic errors that may be caused by differences between the results obtained by the two measurement procedures.

The error grid displays the data on an X-Y plot, where X = comparative measurement procedure and Y = candidate measurement procedure. The plot is further divided into zones that show how much error is problematic at different concentrations. It separates the magnitude of errors into a hierarchy—small errors may be tolerated with minimal risk to the patient, whereas large errors are likely to cause patient harm. Thus, there are limits that bound a region of allowable errors, called Zone A, where it is desirable to contain most of the data (see the light gray area in Figure 1); limits that bound another region of unacceptably large errors, called Zone C, where there should be no data (see the dark gray area in Figure 1); and the intermediate region representing moderate errors, called Zone B (see the white area in Figure 1), where it is acceptable to have a small percentage of the data. The error grid evaluates the candidate measurement procedure in terms of both the percentage of results within the desirable range and the percentage of unacceptably large errors.

An error grid analysis is most appropriate for interpreting the agreement of results from two measurement procedures using many patient samples, eg, approximately 100 or more. When there are relatively fewer patient samples, eg, approximately 40 or less, there is less confidence in the interpretation of the data and error grids may not be appropriate.