Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures Implementation Guide

Implementation Guide
EP21-Ed2-IG

Introduction

This implementation guide describes the minimum procedures necessary for a medical laboratory to determine total analytical error (TAE) for quantitative measurement procedures. For additional information on evaluating TAE, see CLSI document EP21.[1]

Several terms and abbreviations used in this implementation guide—and other CLSI documents—deserve careful attention and understanding because of their similarity and the way in which they are represented in other sources. They include:

- **Total analytical error (TAE):** a measured and calculated quantity that includes errors associated with the examination (analytical) phase of testing.
- **Allowable total error (ATE):** an error goal set by the laboratory. In other publications, ATE might be abbreviated as TEa (ie, total error allowable).
- **Total error (TE):** includes errors from preexamination, examination, and postexamination sources.

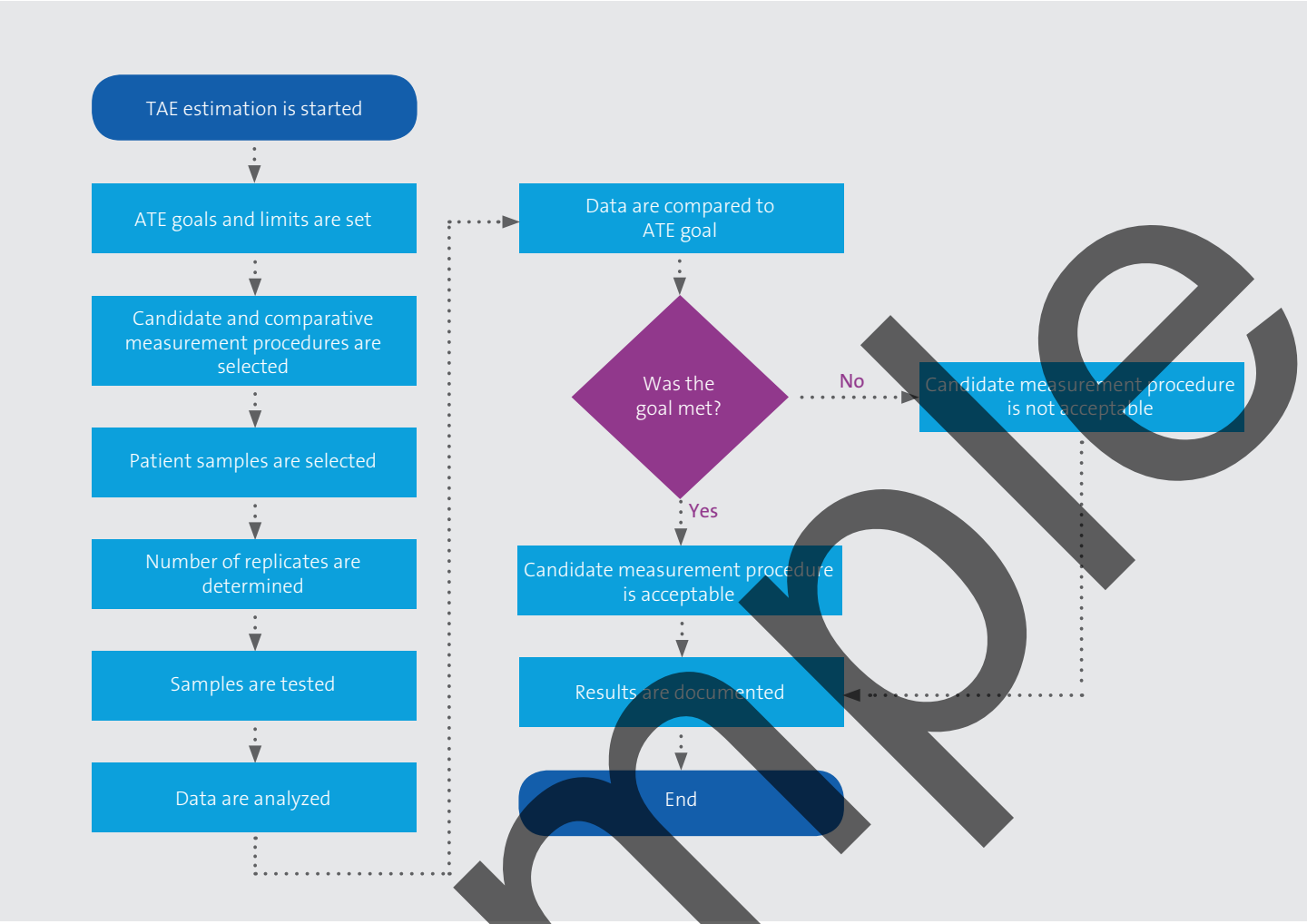
NOTE: Laboratories and commercial manufacturers are collectively referred to as "developers" in this implementation guide.

What Is Total Analytical Error?

TAE is an estimate of error in the results for patient samples, including imprecision, bias, nonlinearity, interferences, matrix differences, and other sources of analytical testing error. TAE can be measured over the entire analytical measuring interval (AMI) or at specific subintervals. The TAE calculation is compared with user-selected limits based on clinical need. Knowledge of the TAE is important when the laboratory is deciding whether differences in results for a patient are meaningful, as well as in answering the questions "How accurate are these results?" or "Does the measurement procedure meet clinical performance needs?"

Accuracy: A Combination of Precision, Bias, and Other Sources of Error

It is important that measurement procedures provide accurate results. In order to do so, they must both be precise and have low bias as shown in the figure below.



Abbreviations: ATE, allowable total error; TAE, total analytical error.

Preparing for the Study

The ATE goal and limits should be determined by asking, "What is the maximum amount of error in the test result that will not lead to patient harm, alter a medical decision, or otherwise cause an adverse outcome?" The ATE goal should include all sources of inaccuracy occurring during preexamination, examination, and postexamination processes. There are no established criteria for defining the ATE. The laboratory director should determine the ATE based on how the test results will be used. If the measurement procedure has multiple decision levels, a different ATE for each decision level might be needed. The ATE can be expressed in measurand units or in percentage units. The ATE limits should be symmetrical (eg, ± 0.4 mg/dL or ± 20%). See CLSI document EP21[1] for additional information on selecting ATE limits.

The minimum study protocol should include:

- Candidate measurement procedure (**NOTE:** The candidate measurement procedure is the measurement procedure for which the performance characteristics are being evaluated for suitability for clinical use.)
  - One reagent lot
  - One instrument system
  - One calibrator lot