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proposed selected method

# A Multi-Rule Shewhart Chart for Quality Control in Clinical Chemistry

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## Introduction

A statistical control procedure is an important element in a total system of quality control. The purpose of this discussion is to outline a simple statistical procedure that is widely applicable and practical in clinical laboratories. The control procedure recommended here is for applications where stable control materials are available and are analyzed repeatedly over long periods of time. This kind of control procedure was initially described by Shewhart (*1*) and later introduced in clinical chemistry by Levey and Jennings (*2*). Control data are displayed on control charts, which are sometimes referred to as "Shewhart charts" and other times as "Levey–Jennings charts."

Control charts of this kind are now in use in most clinical laboratories. The applications from laboratory to laboratory differ primarily with (*a*) the use of single measurements or replicate measurements and (*b*) the criteria used in deciding whether the data indicate the analytical run is in or out of control. In our experience, most laboratories use control procedures based on single measurements rather than replicate measurements; thus the "single-value" type of control chart is more frequently used than charts for the mean and range of replicate measurements. Because of this, we focus on single-value charts and decision criteria appropriate for such charts. The selection of these criteria is based on some studies of their statistical properties (*3–5*), with attention being given to the interpretation of the few control observations occurring in individual analytical runs, rather than the interpretation of monthly control charts containing 20 or more observations. Thus, we focus on the immediate decisions leading to data reporting, rather than the retrospective review of large amounts of charted data.

In recommending the multi-rule Shewhart procedure, the objectives have been to provide (*a*) simple data analysis and display via control charts, such that computerized data handling is not necessary; (*b*) easy adaptation and integration into the existing control practices in clinical laboratories; (*c*) a low level of false rejections or false alarms; (*d*) an improved capability for detecting analytical errors; and (*e*) some indication of the type of analytical error occurring when a run is rejected, to aid in problem solving.

## Principles

The analytical method to be controlled is first studied, to characterize its analytical performance. Measurements are made on control materials, which are assumed to be stable and to vary little in concentration from aliquot to aliquot, or vial to vial. Repeated measurements, therefore, characterize the imprecision or random errors of the analytical method. It is assumed that the distribution of these errors is gaussian and can be described by its mean ($\bar{x}$) and standard deviation ($s$).[1] These statistics are calculated from a replication study, generally over a 20-day period, with one measurement on each control material per analytical run and one analytical run per day.

A control chart is prepared for each control material. The chart displays concentration on the $y$-axis vs time on the $x$-axis. Horizontal lines are drawn for the mean, and for upper and lower control limits, which are calculated from the standard deviation. Several sets of control limits are included on the control chart recommended here, to permit the use of several different decision criteria or control rules.

We use the term "control rule" to indicate a criterion for judging whether the observed control measurements (or observations) represent typical or atypical (stable or unstable) performance of the analytical method. Many different control rules could be used, but they all attempt to signal when the control measurements no longer represent the expected or previously observed error distribution. Simultaneous use of several control rules—i.e., a combination of control rules—can improve the performance of a control procedure. Individual rules have different capabilities for detecting different types of analytical errors. At least two control rules need to be selected, one that detects random analytical error and another that detects systematic analytical error. When the control procedure signals that an analytical run should be rejected, the particular control rule providing the signal gives some indication of the type of analytical error that is occurring. This in turn may suggest certain sources of the error, and so aid in problem solving. In short, the rule violated gives some indi-

[1] Abbreviations used: $\bar{x}$, mean; $s$, standard deviation; N, number of control observations per analytical run; n, total number of control observations collected in a given time period, over many analytical runs; $1_{3s}$, $2_{2s}$, $R_{4s}$, $1_{2s}$, $4_{1s}$, $10_{\bar{x}}$, see "Control rules" in *Materials and Methods* section.

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