Risk-Based Statistical Quality Control Planning Should Be Based More on Patient Risk

TO THE EDITOR:

The main purpose of statistical quality control (SQC)[1] is to prevent patient results with medically important errors (produced as a result of instabilities of the analytical process) from reaching healthcare providers and causing incorrect clinical decisions, thus harming patients.

The main goal of risk-based SQC planning is to select the most efficient and effective quality control (QC) procedures that can be used to limit the risk of patient harm to an acceptable residual level. As the number of erroneous patient results for a given test reported to healthcare providers is related to the harm caused to patients, the acceptable risk level can be determined using the maximum expected increase in the number of unacceptable results reported during an undetected out-of-control error condition [Max E(N_{UF})] estimated for that test. This parameter has been recently used as a measure of QC performance to guide the planning of QC processes.

Appropriate QC procedures can be easily chosen using published nomograms relating Max E(N_{UF}) with the capability of the analytical process (σ) for different QC procedures and for out-of-control conditions resulting in increased systematic (*1*, *2*) or random error (*3*).

In a study recently published in this journal, Bayat et al. (*4*) proposed the alternative use of a "run size" nomogram to determine the appropriate frequency of QC checks when planning risk-based SQC strategies. The nomogram relates the capability of the analytical process with the run size, defined as the frequency of QC necessary to achieve a goal of Max E(N_{UF}) = 1. To justify its usefulness, the authors argue that the probability of false rejection is not included as a planning parameter in previous nomograms, although this has been considered in recently published examples (*3*). Moreover, to construct this nomogram, it is necessary to assume that Max E(N_{UF}) = 1 represents a common goal for all tests, which is an important drawback not considered in the aforementioned work but is worthy of comment.

First, it must be considered that Max E(N_{UF}) is proportional to the number of patient samples analyzed between QC events (M). For example, if a laboratory wants to reduce Max E(N_{UF}) from 2 to 1, it can use the same SQC procedure but reduce M by half, which means doubling the number of controls analyzed for a given number of patient samples and thus increasing the false rejection rate. Therefore, the target for Max E(N_{UF}) has important economic consequences and should not be defined arbitrarily.

Second, Max E(N_{UF}) refers only to the results reported during the presence of an out-of-control error condition. Highly reliable analytical systems have a low rate of failure; therefore, they can analyze a greater number of patient samples between failures than less reliable ones. Defining the same goal for all systems (i.e., the extra amount of erroneous results reported in each failure) is difficult to justify.

Third, Max E(N_{UF}) depends on the type of error that increases as a result of an out-of-control error condition. Out-of-control conditions represent generally greater patient risk when they increase random error rather than systematic error (*3*) because they are more difficult to detect. For example, for a σ = 4 analytical process, the goal Max

[1] **Nonstandard abbreviations:** SQC, statistical quality control; QC, quality control; Max E(N_{UF}), maximum expected number of unreliable final patient results.

$E(N_{UF}) = 1$ can be achieved using the rule $1_{3s}/2_{2s}/R_{4s}$ and analyzing 2 controls every 40 patient samples when the out-of-control condition results in increased systematic error (*2*), but it is necessary to analyze up to 5 controls when an increase in imprecision occurs (*3*), a cost hard to accept by many laboratories for most tests.

Last and most important, Max $E(N_{UF})$ is related to the probability of patient harm, but it is only a proxy measure of patient risk. The risk of harming patients because of erroneous results reported for a given test depends not only on the number of erroneous results reported but also on the risk (i.e., the probability and severity of harm) that an erroneous result of that test represents for a patient. Cholesterol in primary care and troponin in acute care, for example, are 2 tests with clearly different risk.

Many years ago (*5*), we learned that any SQC procedure cannot be used for all tests because the tests have different clinical requirements, defined in the form of a total error goal. Reporting the same number of erroneous results for each test when an out-of-control condition occurs is unacceptable because the probability of the clinician making a wrong decision and the severity of the harm that this decision may cause in the patient depend on the clinical use of the test in question.

In conclusion, there are practical and conceptual reasons for not recommending the use of the nomogram proposed by Bayat et al. (*4*). The introduction of risk management concepts should greatly change SQC planning, shifting the focus from the probability of detecting "critical errors" to the risk of harming the patient. If we manage to move in this direction, QC will become more cost-effective, thus improving patient benefit.

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