Error and poor performance policy

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1. Introduction and purpose

To define error and poor performance in the context of external quality assessment (EQA), and to allow their standardised classification to be used for the purpose of reporting to the appropriate designated oversight body in a consistent manner by all reporting EQA providers.

The target audience for this document is those organisations with a responsibility for the oversight of EQA provision in healthcare laboratories, EQA providers and EQA participants.

2. Scope

This policy defines error and poor performance within a single EQA provider. The definition of multiple performance concerns by a single laboratory across multiple analytes or multiple EQA providers by oversight bodies is outside the remit of this document.

Escalation procedures and the management of performance concerns across multiple analytes or EQA providers are included in the Escalation policy (document WS20501).

The policy recognises that all patient safety events (PSEs), for example, performance that would lead to a misdiagnosis if the EQA specimen had been a patient's sample, are instances of poor performance that require escalation; however, not all instances of poor performance are PSEs.

3. Responsibilities

Scheme organisers are responsible for applying these defined terms in their scheme's EQA procedures. Scheme organisers shall have the responsibility of ensuring the terms and their definitions are clearly visible in information provided to their participants.

All members serving on oversight and stakeholder bodies have a responsibility to know and understand the definitions of these terms and applying them consistently in their procedures.

4. Error

An error is something done or stated that is not correct, not accurate or does not give the right result.

Errors may occur during:

- pre-analytical, analytical or post-analytical stages of an examination
- provision of advice and/or an interpretation of patient-related information.

4.1 Types of error

For purposes of reporting to oversight bodies a distinction is made between an escalated error and a non-escalated error.

An escalated error is an error that breaches the EQA scheme's acceptable performance criteria and must be reported to the appropriate oversight body. These are errors that may lead to misdiagnosis, missed diagnosis, inappropriate patient management and/or misinterpretation of results such that patient safety may be compromised. Any PSE is classified as an escalated error.

A non-escalated error is an error or out of consensus performance deemed to be actionable by the EQA provider but is not escalated to the relevant oversight body in isolation. Multiple or recurrent events may breach the agreed performance criteria and be escalated as persistent poor performance, as indicative of systematic failure and risk. These are errors, which do not influence diagnosis, patient management or result interpretation.

The distinction between an escalated and a non-escalated error is set by the scheme organiser in consultation with expert advisors and other stakeholders.

Escalated errors, PSEs and non-escalated errors will always be reported to EQA scheme participants.

4.2 Measurement of error

EQA providers gather differing types of data, and the types of error generated can be divided into quantitative errors and qualitative errors.

Quantitative errors are numerical results whose divergence from a target value is sufficient to be identified by the EQA scheme's measure of poor/unsatisfactory performance.

Examples may include a significantly biased random result, a series of persistently scattered or biased results.

Typical measures that identify quantitative errors may include z-scores, standard deviations, confidence intervals or trends.

Qualitative errors refer to non-numerical results whose departure from a consensus or expert opinion is such that it can be identified by the EQA scheme's measure of poor/unsatisfactory performance.

Examples may include the report of a positive instead of a negative result, misreporting of an ABO blood group, failure to demonstrate expected knowledge/skills/competence or an opinion report that is outwith that of the expert view.

Typical measures that identify qualitative errors may include non-parametric statistics, classifications and expert opinion.

5. Poor performance

Poor performance is defined as a PSE, an escalated error or multiple non-escalated errors within a given timeframe (where these may be indicative of a systematic problem) by a participant for a single EQA analyte.

Poor performance is incurred for the following reasons and applies to all laboratories:

- non-submission of results with no acceptable prior notification to the scheme
- critical analytical/genotyping error (incorrect result for the patient)
- critical interpretation error, which adversely affects patient management
- no interpretation of the results (where the EQA includes an interpretative element)

- incorrect/inappropriate advice (where these are expected).

A scheme organiser has the right to refer a participant to the designated oversight body if a PSE is identified and/or they judge the error to be sufficiently outwith accepted clinical practice, or there are multiple non-escalated errors that may be indicative of systematic failings.

6. Persistent poor performance

Persistent poor performance is defined as the occurrence of poor performance on more than one occasion within a given timeframe with a single EQA provider. These may be for a single analyte or across a range of related analytes, as defined by the EQA provider.

The number of occasions and the timeframe to be considered shall be determined by the scheme organiser and communicated to the designated oversight body at the outset of their collaborative association and shall be reviewed on a scheduled basis.

Continued non-return of data to an EQA survey by a participant will be automatically deemed as persistent poor performance, unless that non-return has been pre-agreed and authorised by the scheme organiser.

Poor performance accompanied with non-return of data will be automatically deemed as persistent poor performance, unless the non-return has been pre-agreed and authorised by the scheme organiser.

7. Reporting performance concerns

The EQA scheme organiser shall report PSEs, escalated errors and persistent poor performance to the designated oversight body in the timeframe and using the mechanism described in the Escalation policy (document WS20501).

8. Communication with stakeholders

EQA providers are required by ISO/IEC 17043 Conformity assessment – General requirements for proficiency testing (www.iso.org/standard/29366.html) to have means of communication with participants (reports), which include an assessment of performance, and to have means of communication with oversight bodies.

EQA providers are responsible for clearly publishing and making directly available to every participant, on their registration, criteria defining errors, poor performance and persistent poor performance. EQA providers will communicate with a participant on all appropriate occasions when their EQA return (or a non-return) results in an error, using a participant EQA report, root cause analysis form and/or a formal letter. Documented proof of that communication must be retained on the participant's record or form part of the report to the participant.

EQA providers will inform a participant on each occasion they fall into persistent poor performance (see below). Documented proof of that communication must be retained on the participant's record or form part of the report to the participant.

Evidence of communication(s) shall be retained by the EQA provider and the EQA participant. The minimum length of time for storage of such records will be in line with the accreditation body inspection cycle, sufficient to ensure their availability for one complete cycle.

9. Related documents

The escalation pathway and reporting templates are described in the Escalation policy (document WS20501) and associated templates.

10. Authorisation and review

Authorisation will be made by the chair of the EQA Oversight Board. The policy will be reviewed at least every 2 years and may be reviewed at any other time as need arises.