Reporting in vitro diagnostic medical devices concerns policy

Title	Reporting in vitro diagnostic medical devices concerns policy
Description	Policy for the management of risk assessment and actioning of poor performance in external quality assurance programmes arising from issues with in vitro diagnostic medical devices or equipment/method technology/digital technology.
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1. Introduction and purpose

To provide a policy and documents for the management and risk assessment of poor performance arising from issues from external quality assessment (EQA) programmes with in vitro diagnostic medical devices (IVD) or equipment/method technology/digital technology. The aim of this policy is to reduce the risk of avoidable harm to patients.

This document is concerned with IVD devices or equipment/method technology/digital technology and as such compliments, and is an adjunct to, Escalation of EQA performance concerns policy (document WS20501), which is concerned with diagnostic laboratories and testing sites. The Escalation policy (document WS20501) remains the over-arching document and this policy feeds into it.

Where a problem is considered by the EQA scheme organiser, simplistically, to be a methodological problem rather than a concern over the performance of a laboratory, there should be a process in place to engage with the IVD manufacturer/provider to record and, where necessary, escalate the non-conformance.

For the purposes of this document, a ‘method’ will be defined as an instrument/analyser/technology/series of reagents/calibrators/algorithm software, as defined in the Glossary (document WS20202).

For each discipline, the actions may change in detail, but the broad definitions and responsibilities remain.

2. Scope

This document is for EQA providers. The decision as to whether a problem is at a laboratory level or at an IVD manufacturer/provider level is a judgement call for the EQA provider.

For some schemes/analytes/procedures, there is a very strong overlap/correlation between laboratory performance and method performance. While a laboratory is responsible for the results it is producing, it can only ever be as good as the performance of the systems it is using. If the ‘method’ itself is not fit for purpose, for whatever reason,

then the IVD manufacturer/provider of that method needs to be involved in assisting with resolution of the non-conformance. This does not mean that laboratories are free to choose poor methods and they must remain accountable for the choice and verification of the methods in use.

The scope of this document is to ensure that if performance of a laboratory or testing site is not fit for purpose due to the methodology in use, a mechanism is in place to escalate and resolve in parallel with any interaction between individual laboratories or testing sites with the EQA provider or National Quality Assurance Advisory Panels (NQAAPs).

The Escalation flowchart (document WS20502) covers the escalation process, and this document is only to ensure that each EQA provider has a system in place to initiate that part of the process concerning methodological issues.

3. Tools

1. A risk matrix (see **Appendix A**) should be completed by the EQA provider. If the score is above the scheme's threshold, the incident will be escalated as being methodological in nature as well as being deemed to be of sufficient seriousness.
    a. For the purposes of quality management systems (QMS), this matrix should be compliant with the EQA provider's QMS existing format, but an example of a typical risk matrix is in this document.
    b. The detail will be unique to each centre but should incorporate likelihood and consequence both in terms of number of participants affected and the impact of the test result/results being out of consensus/incorrect in a patient's clinical management.
2. Since this is a specific part of a wider process, this risk matrix should be completed to take conscience of other documents, including:
    a. escalation flowchart (document WS20502)
    b. PPE escalation report template, for reporting persistent poor performance (PPE) to the NQAAP (document WS20503)

c. PPE escalation report template, for disclosure of identity of a laboratory to the NQAAP (document WS20503)

d. PPE escalation report template, for reporting PPE to the Quality Assurance in Pathology Committee (QAPC) (document WS20503)

e. PPE escalation report template, for reporting PPE to the Care Quality Commission (CQC) (document WS20503)

f. cross reference to policy on liaison with the Medicines and Healthcare products Regulatory Agency (MHRA) for method-related issues (document WS20901).

3. For consistency, the use of the generic Situation, Background, Assessment, Recommendation (SBAR) based reporting tool should be used when escalating this methodological problem to the NQAAP.

4. Where the concern warrants reporting to the MHRA, the procedure is described in the Reporting EQA performance concerns to MHRA policy (document WS20901).

4. Responsibilities

4.1 EQA provider

The EQA provider will contact the IVD manufacturer/provider in a timely fashion to discuss informally, in the first instance, the methodological issues that are causing concern.

If the EQA provider considers the concern to warrant formal escalation, this should be done using the SBAR approach and include the relevant NQAAP and a named contact with the IVD manufacturer/provider. The scheme organiser should sign this document.

Contact with the MHRA is at the discretion of the scheme organiser and/or the NQAAP chair, depending on the risk assessment by the EQA provider and their professional judgement of the impact of the performance concern on patient safety.

The contact details of the scheme organiser are always contained in the UKAS Schedule of Accreditation website (www.ukas.com/find-an-organisation).

4.2 IVD manufacturer/provider

The IVD manufacturer/provider should provide the EQA provider with specific contact details (not just a generic corporate contact email) for whom to contact for issues of method-related out-of-consensus performance. These contact details need to be reviewed annually or when the named contact changes. It is up to the IVD manufacturer/provider to keep the EQA provider informed of any designated contact changes.

If the IVD manufacturer/provider fails to maintain these contacts, or to provide a contact in the event of a performance concern, the EQA provider and/or NQAAP chair should consider referral to MHRA. Lack of contact details or responsiveness on the part of the IVD manufacturer/provider and any actions taken should be noted in the SBAR report.

4.3 Both parties

Both parties must agree to meet, physically or virtually, to discuss the problem within a calendar month of the formal escalation.

The outcome of this meeting should be an agreed resolution, a timely further meeting if either/both sides need to collate further data or a further escalation involving the MRHA using the processes outlined in the Escalation policy (document WS20501) and Reporting EQA performance concerns to MHRA policy (document WS20901).

5. Procedures

5.1 Internal systems analysis

The EQA provider should implement an analysis to establish whether the out-of-consensus performance is the result of the laboratory or the method/kit/manufacturer. This may not be straightforward and will require an understanding of the aim of the EQA programme, the survey material, the statistical procedures, the impact of different software algorithms, the mode of analysis and the historical performance of the analyser/method.

For each analyte/measurand/examination, the boundary will lie somewhere on the spectrum of ‘most users get the right result, so if you are out of consensus then the likelihood is that it is with you that the problem lies’ through to the ‘everyone who uses this

system is out of consensus and so the likelihood is that the problem lies with the method, not with the laboratories who use it'.

For some disciplines, the manufacturer level might only be the analyser itself. For other disciplines, the manufacturer level might only be the reagents themselves. In clinical chemistry, the manufacturer level is often a combination of instrument/reagent/calibrator and indeed these can be further split into lots/batches/software version and so on.

This policy does not seek to limit and prescribe the elements relevant for every situation. Rather it is to ensure that, if a given risk level has been passed, an escalation process is progressed.

The risk matrix (see **Appendix A**) should assist with this.

5.2 Formal discussions between EQA providers and IVD manufacturer/provider

Many EQA providers are already regularly in conversations with their laboratory participants and the IVD manufacturer/provider providing the systems and methods. This document is concerned with formalising discussions where the problem is wholly or largely outside the control of the laboratory and manifests itself as non-conforming work that affects most, if not all, users of that method.

Where necessary, a formal meeting should be convened between the EQA provider and the IVD manufacturer/provider to scope the extent of the issue and to discuss possible remedies and timescales.

The EQA provider should initiate this meeting, but the IVD manufacturer/provider must agree to have the meeting within a reasonable timeframe and have sufficient supporting data, perhaps from the manufacturer or from head office to make the meeting as beneficial as possible.

5.3 Confounding factors

Problems with IVD devices or equipment/method technology/digital technology can be long-running and are very technical in nature. Both the laboratory and the IVD manufacturer/provider will be examining the method in the context of state-of-the-art performance, whether reference methods or international standards exist, and how the method performs compared to those. The commutability of EQA material and data from other EQA providers, both in the UK and internationally, will be of use. The EQA provider should be aware that satisfactory performance in another EQA programme may not mean that the performance they observe will not be a concern.

Although both parties will be pushing for an agreed resolution, it's likely that there will be an 'agree to disagree' endpoint. Often, there will not be a universal 'truth' and, if an IVD manufacturer/provider provides compelling evidence that they are within specification and fit for purpose, then even if they are at odds with results coming from all other methods, they will not change their position.

There is often disagreement on what constitutes 'clinically significant' and there is a case to be made that methods should be of an acceptable standard compared to other methods in use, even where patient harm may not be likely. This contrasts with the situation where very small differences in methodological output exist and which would be difficult to eradicate using current technology but nevertheless give rise to a large impact on the journey/diagnosis/monitoring of the patient.

The use of the risk matrix (see **Appendix A**) is advisable to assess the degree of risk to patient safety and management. The assessment of risk should also be used to inform laboratories of the limitations of the method in use, allowing them to take appropriate action to ensure patient safety, for example, around clinical decision-making points or undertaking a lookback exercise.

5.4 Further escalation

The issue will be escalated if it cannot be resolved between the IVD manufacturer/provider and the EQA provider. The relevant NQAAP must be notified if this has not already been done.

The escalation process is outlined in the Escalation policy (document WS20501). The detail of the escalation process will vary depending on the risk assessment of the impact on patient safety. It is essential that all parties (the EQA provider, the IVD manufacturer/provider, the MHRA and the NQAAP) are involved in discussions. The EQA provider will usually have feedback from participant laboratories on the impact that the performance of the method is having on their service provision.

Where a clinically significant risk to patient safety is recognised, the QAPC should advise on further action to be taken.

6. 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.

7. Glossary of terms

See Glossary (document WS20202).

Appendix A

Risk matrix for method

No method or laboratory is above scrutiny and all errors are fed back to participants through their regular reports.

		Scale of Problem and/or Clinical Consequence for Scale of Problem				
Number of Participants affected		Insignificant	Minor	Moderate	Severe	Catastrophic
		1	2	3	4	5
Majority method	5	5	10	15	20	25
Major method	4	4	8	12	16	20
Common method	3	3	6	9	12	15
Small number	2	2	4	6	8	10
One or two users	1	1	2	3	4	5

This risk matrix tries to prioritise the route and urgency of method-related problems.

- This can be ‘calibrated’ by each centre to suit the analyte/investigation.
- This can be adjusted on whether the method is growing or waning in popularly.
- This can be adjusted based on the degree of bias/inconsistency/misclassifications and so on.
- An example of classifying a problem as a method problem is when more than X% of users are out of consensus, for example, they lie in the ‘poor performer’ category.
- An example of classifying a problem as a ‘severe problem’ is when results obtained would give a wrong diagnosis or treatment path.
- An example of classifying a method as a 'common method’ might be when there are Y% of users in the scheme using that method but, depending on it being on the rise or on the wane in popularity, this will influence the approach from the EQA provider.
- All red category incidents should be escalated to the IVD manufacturer/provider as per this policy.

Note: Even methods with small numbers of users will be under scrutiny from the EQA provider, notwithstanding it is difficult to apportion a root cause when datasets are small. The laboratory user(s) will be contacted by the EQA provider under the laboratory escalation process so no laboratory or method will be exempt from surveillance.