Potential challenges when assessing organisational processes for assurance of clinical competence in labs with limited clinical staff resource

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1. Introduction

ISO 15189 is necessarily written such that it can be applied to medical laboratories of widely differing contexts. An important element in assessing a lab against ISO 15189 is judging the robustness of the organisation's processes for determining clinical competence both initially and ensuring competence is maintained. This applies not only for the Lab Director (4.1.1.4) but also other lab personnel contributing to the clinical activity of the lab including provision of Advisory Services (4.7) and Review of Results (5.7.1). Even within the UK there is a significant variation in the size and complexity of medical labs and the range of services provided both within the NHS and private sector. As a consequence, there are a wide variety of staffing models with differing balances between clinical and technical staff. In addition, there is also variation between different pathology disciplines in how the responsibility for clinical activity is divided between clinical and technical staff and even labs within the same discipline and broadly similar contexts often have different practices.

In pathology disciplines that may have relatively few clinical staff e.g. clinical biochemistry, immunology etc. or where clinical staff are based remotely from the lab, there will be increased reliance on technical staff providing the first line clinical activity with referral to clinical staff as necessary. Within the right setting and with appropriate qualifications, training and experience and with well-designed guidelines, this can be a proper and efficient use of staff resources. However, there is a risk of patient harm if technical staff are inadequately trained and are lacking the experience and clinical competence required and if there are insufficient safeguards in place for this additional clinical role. As labs respond to the increasing pressures of increasing consolidation and producing cost savings, this risk may increase further.

The technical assessor / expert therefore has the challenge of judging within the short period of an assessment visit whether the organisation is clinically competent and therefore "that laboratory services, including appropriate advisory and interpretative services, meet the needs of patients and those using the laboratory services" (4.1.2.2). Appendix 1 illustrates some real anonymous examples of medical laboratories undergoing assessment against ISO 15189 that failed to meet clauses 4.7 and/or 5.7.1.

The purpose of this paper is to provide assessors with some suggestions regarding some of the factors to consider when making these types of judgement.

2. Examples of Clinical Activity

1) **Clinical review (Review of results against available clinical information and previous results (see 5.7.1 & 5.92))**

2) **Clinical Advisory Service (see 4.7)**
   - **Within normal working hours / out of hours**
   - **Support for users**
   - **Support for technical staff**
3) **Dealing with unexpected or highly unusual results**

4) **Ambiguous requests**

3. Clinical review (authorisation)

One of the responsibilities of the laboratory director is to;

> ISO 15189 4.1.1.4 g) ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results;
>
> The laboratory director may delegate selected duties and/or responsibilities to qualified personnel; however, the laboratory director shall maintain the ultimate responsibility for the overall operation and administration of the laboratory.
>
> The laboratory director (or the designates for delegated duties) shall have the necessary competence, authority and resources in order to fulfil the requirements of this International Standard.

> 5.7.1 states "The laboratory shall have procedures to ensure that **authorized** personnel review the results of examinations before release and evaluate them **against internal quality control** and, **as appropriate**, available clinical information and previous examination results.

Within UK medical labs there are a variety of process models for reviewing results and functionally these usually divide into technical review[1] and clinical review

In some labs these two processes may be combined.

Where clinical review is combined with technical review and conducted by technical staff it can be argued that the technical staff are performing a clinical activity. The assessor should therefore assess this activity as part of the "clinical competence" of the organisation.

[1] Technical review is described in ISO15189:2012 as "against quality control" and "considering technical issues that may affect results e.g. interferences, pre-analytical factors etc."

4. Automatic selection and reporting

It is commonly accepted practice that many or even all routine hospital results should be reported automatically without clinical review to avoid delay (see 5.9.2). With the high workloads of many medical labs, real time clinical review of abnormal results is impossible without unacceptable delay. Because all results can only be released following technical review, if the staff performing the technical review process can also review previous results and have access to the clinical details and they are appropriately qualified, trained and competent then the requirements can be met.

However, if the IT system used for technical review does not allow both previous results and clinical details to be seen then this cannot be considered clinical review. If there is no other mechanism for clinical review of abnormal results then a nonconformity finding may need to be raised.

Alternatively, clinical review of selected results may be retrospective (after release) by either technical or clinical staff or there may be different selection criteria depending on the user e.g. hospital vs. primary care or routine vs. specialist tests.

If automated selection and reporting is practiced then;

ISO 15189 5.9.2 states the lab should have a documented procedure to ensure;

a) the criteria for automated selection and reporting are defined, approved, readily available and understood by the staff;

NOTE Items for consideration when implementing automated selection and reporting include changes from previous patient values that require review and values that require intervention by laboratory personnel, such as absurd, unlikely or critical values"

If automatic selection is practised, consider;

- Are there clear guidelines / protocols for staff to follow?
- Is there evidence policies are periodically reviewed and updated e.g. in light of IT/ equipment changes, changes to staffing structure or following national guidance
- Are staff familiar with the protocols – (can be confirmed via witness audit).
- Do protocols clearly define when results should be referred to clinical staff?
- Do staff understand which abnormal results are sufficiently critical to need urgent action?

During an assessment visit, it can be useful to use part of a witness audit of the post-analytical phase to assess the above. For example, witnessing a BMS validating, reporting and phoning of abnormal results. During the audit, questions can be directed to the staff being witnessed to determine their knowledge and understanding of the protocols and when they would refer more complex cases to the clinical staff. Training and competency records can also be assessed.

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When is clinical review "appropriate"?

Who should be "authorised" to review results?

The assessor needs to use their experience (or seek advice) based on the degree of complexity of the clinical activity and who are the likely recipients of the results when judging the depth of clinical review required and who is competent to perform it.

Any results that fail automated selection criteria should be reviewed by appropriately qualified, trained, competent staff.

Some factors to consider are included in appendix 2.

"Authorised personnel"

Consider

- Is the responsibility of those reviewing the results defined in their job descriptions? (5.1.3)
- Do staff performing clinical review have the appropriate qualifications, training and experience needed? (5.1.6)

Again, the context needs to be considered.

"Authorised" implies staff who have been appropriately trained and assessed competent against defined criteria, all of which must be documented and authorised following the determination of competence.

For all staff performing clinical activity, check that the training and competency documentation explicitly includes clinical activity in sufficient detail to assure you of their competence for this task.

Consider the appropriateness of the designated person judging / signing off the clinical competencies. Is this person appropriately qualified and experienced to do so?

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Clinical Advisory Services

ISO 15189 4.7 states;

The laboratory shall establish arrangements for communicating with users on the following:

a) advising on choice of examinations and use of the services, including required type of sample

(see also 5.4), clinical indications and limitations of examination procedures and the frequency of requesting the examination

b) advising on individual clinical cases

c) professional judgments on the interpretation of the results of examinations (see 5.1.2 and 5.1.6)

d) promoting the effective utilization of laboratory services

e) consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria

How many parts of this clause can be met without dedicated clinical staff support will depend on a variety of factors including size and complexity of workload and the general level of clinical competence of the users (see appendix 2). At a minimum, except for the most straightforward cases, at least telephone / email support by appropriately qualified clinical staff is required to meet 4.7 b) and c).

Out of hours clinical advisory service

Again, a variety of practices exist regarding the level of qualifications and experience required to participate in the out of hours clinical advisory service. This is the responsibility of the laboratory director to define (4.1.1.4 g). At a minimum this should be HCPC registered clinical scientists or GMC registered medical staff.

Advisory support is not solely for users. Depending on the size of the laboratory and experience of the technical staff, a significant amount of advice both within working hours but especially out of hours is required by laboratory staff.

Clinical support of technical staff both within and out of normal working hours (examples)

- Highly unusual / extreme results
- Difficulty determining the clinical significance of unusual results
- Difficulty in phoning potentially critical results
- Clinical users requiring urgent tests difficult / impossible to provide out of hours
- Unusual urgent referral tests e.g. toxicology.
- Sudden Unexplained Infant Deaths
- Requests from out of hours providers for additional clinical information
- Large scale service failures e.g. multiple POCT failures, IT, water, power etc.

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Consider

- Is clinical staff support readily available during working hours if not available on-site? (this can be assessed through Q&A with lab staff and users if available)
- Are there sufficient clinical staff available to provide a robust advisory service within normal working hours and out of hours?
- If not on-site, do users have ready access to the contact details of staff participating in the clinical advisory service?
- What cover arrangements are in place for covering sickness and leave?
- Are the qualifications and experience appropriate for the level of clinical advice required?
- In the event of a major adverse incident where cover is unavailable, do emergency contingency plans cover access to cover from elsewhere in and out of hours?
- Have the qualifications and competency of clinical staff from other supporting organisations been assessed?

Lack of Trust support for out of hours cover

The requirement for and therefore funding of an out of hours clinical advisory service is not recognised by all hospital employers (see Lab B appendix 1). Where there is no funded out of hours advisory service, the assessor needs to make a balanced judgement considering whether the need is justified based on evidence. This will include the size and complexity of the workload, the size of the hospital and the number of acute services on site, especially full A&E departments. In addition to providing clinical advice to users, it is also important to consider clinical and scientific support of the technical staff working alone. This will be more important if there is a significant number of less experienced BMS staff working out of hours, particularly if there are a high number of recently qualified trainees or locums or a high staff turnover. Evidence from user surveys or user group minutes can also be used to determine whether users have expressed the need for the service.

If the lab considers provision of the service is required but it is not funded, it should be on the risk register.

If taking all the factors into account, the need for out of hours clinical support is considered necessary a nonconformity finding should be raised.

If the out of hours services is provided voluntarily, the assessor should confirm that all participants have professional indemnity cover outside of the NHS to cover this work.

Training and Competency Assessment (5.1.5 & 5.1.6)

Whether clinical activity (clinical review or advisory services) are performed by clinical staff, technical staff or both, the standards require the same evidence of documented training and competency assessments.

Consider

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- Are training and competency records available?
- Does the documentation contain sufficient detail to provide assurance of competence in clinical activity?
- Is there objective evidence of competency assessment?
- Is there evidence of a process for ensuring ongoing competency?
- If technical staff contribute significantly to clinical activity, is there sufficient evidence of departmental CPD and self-directed study (e.g. JBL) on clinically relevant topics?

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Appendix 1

Some real examples of labs with limited clinical staff resource failing to comply with ISO15189 5.7.1 and/or 4.7

Laboratory A

A single site DGH laboratory within a medium sized acute NHS hospital providing a 24/7 service to both hospital users and GPs. A wide repertoire of general chemistry tests including endocrine tests are analysed on site.

At assessment the clinical staff consisted of a single band 7 clinical scientist with no qualifications beyond those required for HCPC registration. There were no formal arrangements for providing cover for sickness or leave. A part time (0.4 WTE) consultant clinical scientist had been appointed a few weeks prior to the assessment but was due to start 3 months later.

Results are auto released but the selection criteria were not documented. There was retrospective clinical review of results failing auto-release criteria performed by technical staff. Technical staff performed combined technical and clinical review although there was no documented evidence they had been trained or had their competency assessed for this role. There were no documented protocols for technical staff to follow and no defined criteria for contacting clinical staff.

Laboratory B

A single site DGH laboratory with a 24/7 service serving both hospital users and GPs. A fairly wide repertoire of general chemistry tests are analysed in house although endocrine tests were analysed at a local referral laboratory.

The lab director role is performed by a single handed medical consultant who provided clinic sessions for 2.5 days per week. There were no other qualified clinical staff. The Trust has refused to fund an out of hours advisory service although this is still performed by the consultant on a voluntary basis.

Results are auto released but the criteria are not documented. There is no retrospective review of results failing auto-release criteria by clinical staff. Technical staff (including newly qualified band 5 staff) performed combined technical and clinical review although there was no documented evidence they had been trained or had their competency assessed. There were no documented protocols for technical staff to follow and no defined criteria for contacting clinical staff.

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Appendix 2

Factors to consider and suggested sources of evidence when judging the appropriate level of on-site clinical support required to meet 5.7.1 and 4.7

- **Size and complexity of the workload.** Labs with higher workloads are more likely to produce erroneous or rare and unusual patterns of results that require clinical experience to interpret and act upon. A wider repertoire will also tend to increase requirements for both clinical review and advice, particularly endocrine tests. GPs tend to be more reliant on advisory services during the working week as do other health professionals within the community. Clearly labs providing specialist tests will have greater demand for advisory services particularly if the test is offered as a referral service.

Sources of evidence: total workload figures, % GP work vs hospital work, in-house repertoire on AC6, specialist hospital services on intranet/internet, specialist service SLAs

- **Size and type of hospital**. Larger hospitals will tend to require more clinical advisory support, and generally higher demand for clinical advice out of hours. The presence of certain specialties and services e.g. endocrinology, paediatrics, renal units, transplant teams etc.

Sources of evidence: hospital intranet/internet sites, latest CQC report, out of hours rota.

- **Level of clinical understanding of users.** Users may be patients, nurses, midwives and other health professionals, junior doctors or consultants. For example, results generated by small labs within private hospitals are likely to be reported directly to experienced consultants. Large NHS labs offering a wide repertoire of tests including community services will generate results for a wide variety of different users, who are more likely to rely on clinical advisory services.

Sources of evidence: interview with HOD (number and type of calls), hospital intranet/internet sites, % GP work vs hospital work.

- **Experience of technical and support staff.** Departments with a high proportion of newly qualified (band 5) BMS staff will require more advisory support particularly if working alone out of hours. Large workloads typically also increase demand for advisory support from reception staff, particularly for blood sciences and these queries are often time critical.

Sources of evidence: BMS staff list (ratio of band 5: band 6), departmental structure, list of recent trainees, training and competency records, induction records, witness audits.