

Key assurance indicators for pathology services

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Foreword

The College has undertaken a revision of its published key performance indicators (KPIs) to ensure that these remain current and are adapted, where necessary, to focus on indicators that assure service quality rather than performance efficiency. To this end, and following extensive consultation with stakeholders – including all College members – each KPI has been reframed as a key assurance indicator (KAI). This work was led by the College’s Clinical Effectiveness team.

When approving the generic change to KAIs, College Council also agreed that, where needed, each of the specialty advisory and intercollegiate committees will provide further input into creating a limited portfolio of specialty-specific KPIs. Consultation on and publication of these specialty-specific indicators will take place as a second phase of work. All members’ contributions to such specialty-specific indicators will be welcomed.

It also remains an aspiration of the College to develop, through multidisciplinary discussion and collaboration, indicators that will provide measures of the value of pathology within wider patient pathways.

The College will undertake a revision of this document if new evidence becomes available that would alter the strength of the KAIs.

Introduction

Key performance indicators (KPIs) were first published by the Royal College of Pathologists (RCPATH) in May 2011. They were subsequently developed further and reissued in 2013. The operational and political landscape for the provision of laboratory diagnostic services has changed dramatically since this time, and continues to do so as a result of diverse consolidation initiatives, greater private sector involvement, increasing use of point-of-care tests and transition of services to accreditation against ISO15189:2012. Workforce shortages, realignment of services to create more 'hub and spoke' arrangements and greater private sector provision will continue to challenge laboratories' abilities to deliver against indicators of quality and effectiveness.

These ongoing organisational and professional changes also influence the value, validity and feasibility of data collection for some of the previously published RCPATH indicators, and raise questions about their value in serving their intended purpose. In parallel, increased governance emphasis on assuring the quality of services rather than simply measuring straightforward performance metrics has meant that it is now appropriate for RCPATH to modify its approach to such indicators and recommend a suite of key assurance indicators (KAIs). This is in keeping with recommendations made in the Pathology Quality Assurance Review, published in 2014.

Difference between a KPI and a KAI

The critical difference between a performance and an assurance indicator is that the former measures whether something is being done, while the latter measures whether what is being done is of appropriate quality. 'Appropriate quality' should ideally be assessed from the patient's or clinical end-user's perspective. If a KAI is being met, service providers and commissioners can have confidence that the service is safe, even if a time- or volume-defined KPI is not being met.

There is considerable overlap between the two. However, we believe that the focus on quality of measures formulated as KAI makes these generally more compelling than efficiency-focused KPI in clinical services, where staff are highly motivated by considerations of patients' experiences. After extensive review, we believe that all the indicators presented here justify being categorised as KAI. We have renamed them accordingly.

A change of approach to measurement

In undertaking this revision, we have regularly asked stakeholders for their views on appropriate measures to inform each indicator. In particular, we have sought opinion on adopting a benchmarking approach, linked to an intent for continuous improvement over time, rather than a pass/fail assessment represented by achieving (or not achieving) a given percentage or other specified numerical value that denotes compliance.

With some reservations about how such results will be appropriately incorporated into trust board reporting systems, we have received a balance of responses favouring benchmarking. We believe that this approach is in line with the intended outcomes of the Pathology Quality Assurance Review (2014) and will act as a driver for continuous quality improvement in laboratory services. Evidence from a range of business contexts, including within the NHS, shows that rigid target-setting promotes 'gaming' and has the potential both to distort priorities and limit performance.

We have deliberately not aimed to replicate quality measures that are mandated by legislation or covered directly by requirements to comply with relevant ISO standards (e.g. ISO15189:2012, ISO22870:2016). For many indicators, we propose that evidence to demonstrate that an indicator has been met will consist of a stated policy indicating that principles of the indicator have been espoused, supported by results of regular survey/audit activities to show that the policy has been followed. Ideally, these will be linked to quality improvement initiatives confirming that the policy is being implemented appropriately.

It is important to note that the suggested evidence for each indicator, along with the notes providing further guidance on such evidence, are advisory and not mandated. We believe that staff working on the ground know best how to identify the evidence to show that each KAI is being met for their local services; there is no 'one size fits all'. In the complex and rapidly changing healthcare environment that we face for the foreseeable future, we believe that this approach will have the added benefit of fostering local ownership and responsibility for the policies developed, the evidence collected and the quality improvement activities that will arise from these.

Finally, we must emphasise that RCPATH has no current resources to oversee implementation of these indicators. We hope to collaborate with other organisations to explore the feasibility of evidence collection in relation to the KAI and we shall welcome feedback from within the profession to inform future updating.

Acknowledgements

The Clinical Effectiveness team would like to acknowledge and thank our stakeholders for their indispensable input throughout the review of this document. Their contribution and engagement is much appreciated.

Stakeholders

- Association for Clinical Biochemistry and Laboratory Medicine
- Association of Clinical Pathologists
- British Division of the International Academy of Pathology
- British In Vitro Diagnostics Association
- British Infection Association
- British Society of Haematology
- Institute of Biomedical Science
- NHS Improvement
- Pathological Society of Great Britain and Ireland
- RCPATH Cellular Pathology Specialty Advisory Committee
- RCPATH Clinical Biochemistry Specialty Advisory Committee
- RCPATH Forensic Pathology Specialty Advisory Committee
- RCPATH Genetics and Reproductive Science Specialty Advisory Committee
- RCPATH Histocompatibility and Immunogenetics Specialty Advisory Committee
- RCPATH Immunology Specialty Advisory Committee
- RCPATH Lay Governance Group
- RCPATH Quality Assurance Management Group
- RCPATH Medical Microbiology Specialty Advisory Committee
- RCPATH Neuropathology Specialty Advisory Committee
- RCPATH Pre/Perinatal/Paediatric Specialty Advisory Committee
- RCPATH Toxicology Specialty Advisory Committee
- RCPATH Transfusion Medicine Specialty Advisory Committee
- RCPATH Veterinary Pathology Specialty Advisory Committee
- Intercollegiate Committee for Haematology.



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Key assurance indicators

1. KAIs for Senior staff

KAI 1: Provision of senior staff

All medically qualified consultants and consultant-level scientists providing clinical advice, diagnostic and/or interpretative services shall have FRCPath (or other relevant equivalent pathology qualifications) and be registered with the General Medical Council (GMC), General Dental Council (GDC) or Health and Care Professions Council (HCPC), as appropriate.

Suggested evidence

- The laboratory shall maintain a list of staff who currently provide clinical advice, diagnostic and/or interpretative services, together with their qualifications and any supervisory arrangement (if appropriate).

Notes

Where recognised or comparable qualifications, training and experience are demonstrated and meet the regulatory requirements for the UK, additional education, training or qualifications are unnecessary, except in the context of keeping up to date and continuing professional development.

To demonstrate equivalence, an individual will have to provide the appropriate evidence to a regulatory authority.

Where staff grade and associate specialist doctors, advanced practitioners, locums or appropriately trained trainees are providing clinical advice, there should be oversight as needed, matched to their roles and responsibilities.

References to senior staff in subsequent KAIs relate to these groups of staff.

KAI 2: Senior staff cover

There shall be documented and named cover of the service by staff delivering clinical advice and laboratory oversight, including cover for planned leave. The laboratory should agree with users any requirement for clinical cover outside the normal working day and the level of cover required.

When acute medical advice is required, this shall be available 24 hours a day, seven days a week, 365 days a year. When initial clinical advice is provided by staff still in training, clear accountability and supervisory arrangements by senior staff must be in place.

Suggested evidence

- Published rotas identifying named individuals with appropriate skills to deliver the service, with mechanisms to allow them to be contacted.
- Records of management oversight and protocols of the appropriate staffing of clinical cover.
- Medical and scientific staff job plans indicating availability for the provision of clinical advice.
- Proof that rotas and contact arrangements are made available to service users at the point of need, with robust procedures to ensure currency and continuity of this information.
- A document (agreeing services with users) that indicates cover is not required outside the working day, when appropriate.

Notes

Where urgent, clinically appropriate advice is required, it shall be available 24 hours a day, seven days a week, 365 days a year. The appropriate level of cover and communication of cover arrangements will depend on clinical requirements; these should be agreed with users and management. Anyone providing cover for a clinical service should have an appropriate knowledge of the workings of that service.

KAI 3: Senior staff handover

There shall be an evidenced policy for handover between senior staff (overseeing the laboratory or giving clinical advice) undertaking standard daytime and out-of-hours working.

Suggested evidence

- The laboratory shall have a policy for the handover between senior staff that includes information on ongoing clinical decisions/discussions in progress.
- This policy should be reviewed at regular intervals using records of handover which might include items such as emails, paper handover documents, bulletin board entries and notes of telephone handover.

Notes

The policy for handover will be subject to local agreement, which shall be evidenced in a manner that is reasonable to the service. This will include local determination of the frequency of review.

KAI 4: Senior staff appraisal

All senior staff providing laboratory oversight and clinical advice at consultant or consultant-equivalent level (i.e. independent practice, clinical and scientific staff) shall have completed an annual appraisal or shall have documented approval from their responsible officer or clinical line manager to defer. The annual appraisal will include discussion of ongoing competency.

Suggested evidence

- Available list of senior staff, listing dates of last two appraisals (where appropriate), updated annually in line with the appraisal cycle.

Notes

It is the professional responsibility of all pathologists and scientists who provide clinical interpretation and advice to maintain their appraisal portfolio and complete an appraisal of their clinical practice annually.

For medical and scientific staff providing laboratory oversight and clinical advice, the organisation should expand/modify their appraisal process to include a discussion of competency.

KAI 5: Senior staff professional development

All senior medical and scientific staff providing laboratory oversight and clinical advice at consultant or consultant-equivalent level shall be compliant with regulatory requirements for continuing professional development (CPD).

Suggested evidence

- Registration for CPD with appropriate organisation (e.g. RCPATH, Institute of Biomedical Science [IBMS]).
- Record of satisfactory performance – for the RCPATH CPD scheme, this normally takes the form of a rolling five-year summary of credits accrued.
- Other evidence of appropriate CPD relevant to the whole scope of each individual's practice.
- Review of CPD at appraisal.

Notes

This indicator is intended to encompass all staff providing such advice, including associate specialists, staff-grade/specialty doctors and all clinical scientists whose roles involve laboratory oversight and/or giving clinical advice.

For medical staff, GMC guidance states the need for appropriate record-keeping; records of participation in the RCPATH scheme would be a good example.

2. KAls for training, education and innovation

In a high-quality, sustainable pathology service, laboratory staff should provide educational opportunities for current and future laboratory staff and users of the service. As laboratories provide training for the national pool of clinical and scientific staff (as well as their own needs), a commitment to training is essential.

KAI 6: Staff numbers for the training of future laboratory staff

The proportion of staff in training shall be sufficient to sustain and develop the service, but not so high that the quality of training provided or service delivered is compromised.

Suggested evidence

- The numbers of staff in training-grade posts, including:
 - medical staff
 - clinical scientists
 - biomedical scientists
 - other healthcare professionals (e.g. medical students/foundation doctors, others in healthcare science, administrative staff).
- The proportion that training-grade staff versus overall staff, and the trend of this ratio over time (there should be documented evidence that this information is reviewed regularly and used to inform service delivery plans).
- Records showing that service managers recruit according to the requirements set out in the advertised post.

Notes

Training requirements are not limited to staff holding training-grade posts. For example, undergraduate and postgraduate students from a variety of backgrounds will also require appropriate training.

Departments should review on a regular basis the ongoing/additional training needs of different individuals, and ensure that these are met without compromising the delivery of a high-quality, stable service.

Discussions should be held and plans for action should be developed if difficulties in recruiting trainees are encountered.

There should be regular departmental review of opportunities to develop advanced practice for scientists.

Appropriate numbers of trainees will need to be determined locally, depending on the nature and scope of laboratory services provided.

KAI 7: Quality of training for laboratory staff

The quality of training provided for trainees in each professional group shall meet the requirements of the relevant professional regulatory bodies (GMC, HCPC, GDC) and include relevant inter-professional learning opportunities.

Suggested evidence

- Trainee feedback, both formal (e.g. multi-source) and informal
- Records (to be reviewed at appraisal) showing that both educational supervisors and clinical supervisors have undertaken specific CPD for their supervisory roles
- Evidence of ongoing review of the content, delivery and outcomes of training programmes by the relevant regulatory and professional bodies, including universities and teaching hospitals.
- Demonstration of inter-professional learning opportunities, e.g. joint educational meetings and research involving medical and scientific laboratory staff and staff from other relevant clinical services.

KAI 8: Commitment to innovation and continuous quality improvement

Laboratories shall demonstrate commitment to sustained innovation of their services through continuous quality improvement (CQI), which may include the conduct of formal academic research and the evaluation of novel approaches aimed at improving the health of patients and the wellbeing of the wider population.

Suggested evidence

- A documented approach to pursuing CQI using a systematic and rigorous methodology, with examples demonstrating the application of this in practice.
- Evidence that audit is being used to inform CQI rather than as a 'standalone' activity, mapping services against pre-existing standards.
- Research outputs relevant to improving patient experiences or outcomes.
- Records of systematic approaches to identifying, validating and adopting new technologies.

Notes

We recognise the value of high-quality audit and believe the greatest value of such data collection lies in its capacity to support CQI. Historically, audits have been used to demonstrate whether a predetermined standard has been reached and/or maintained over time.

If an audit highlights that a standard has not been met, pursuit of CQI offers the best option for reaching it. If the standard is easily met, the system should be challenged to seek further improvement for patient benefit.

Clinical research is a desirable activity within laboratories; indeed, it is sometimes essential, providing appropriate evidence to inform this indicator for some organisations. However, the current reality is that such research is not a formally planned or funded activity within many organisations providing pathology services. While the need to plan and fund research activity should be encouraged, it cannot be expected, and evidence of research output may only be offered by some departments.

3. KAIs for repertoire of tests and reporting of errors

Laboratories should agree with users which tests should be available and should ensure that appropriate (preferably electronic) communication links are in place for requesting tests and reporting test results. Laboratories should, where appropriate, follow national guidance when advising users of the most appropriate investigations and the content of reports.

KAI 9: Point-of-care testing (POCT)

Local community and hospital POCT equipment and repertoire, for which the laboratory has oversight, shall be documented, with itemisation and description, and published.

Suggested evidence

- Published statement of POCT services provided, for which laboratory has oversight (laboratories should explicitly state if they do not include POCT in the scope of their repertoire).

Notes

There should be a robust POCT governance framework at Board level (or equivalent in primary care) as this is a patient safety risk for the organisation.

The published statement shall include definitions of agreed POCT use in specified patient pathways.

Documentation of the POCT repertoire shall make explicit the equipment, assays and uses for which there is pathology service quality management, agreed by appropriate clinical and scientific managers in all organisations. It shall be evident at the point of use that equipment and assays are governed by the laboratory, including conditions of use, with information available for users to access laboratory support as needed.

Laboratories shall ensure that POCT services within their governed repertoire have adequate and documented programmes of quality assurance, including competency-based training for all users. We would anticipate that all such services would fall under the remit of the laboratory Quality Management System.

If a laboratory is not responsible for POCT in part or all of its host organisation, appropriate clinical and scientific managers should be aware of the clinical areas that are not laboratory accredited for POCT testing.

KAI 10: Demand optimisation

The laboratory shall actively engage in demand optimisation, designed both to reduce the number of unnecessary tests and to help ensure that appropriate tests are used.

Suggested evidence

- Published policy of engagement with demand optimisation.
- Documentation of audit (by monitoring activity of testing) against policy
- Records of engagement with stakeholders, e.g. education for other clinical groups.

Notes

Please refer to the College's *National minimum retesting intervals in pathology: A final report detailing consensus recommendations for minimum retesting intervals for use in pathology* (2016), available from: <https://www.rcpath.org/profession/guidelines/cross-specialty-publications.html>

KAI 11: Incident and error reporting

Laboratories shall ensure that errors, from specimen collection through laboratory processes to receipt of report, including errors of interpretation and clinical advice, are logged and reviewed systematically, with evidence of effective learning. Laboratories shall be able to demonstrate measures introduced to reduce the likelihood of similar future errors, and that these measures are evaluated for effectiveness.

Suggested evidence

- Standard operating procedure stating principles of incident and error reporting.
- Evidence of regular, documented review of recorded incidents and errors, together with corrective actions taken.
- Reports submitted to relevant external organisations where there is a regulatory requirement to do so, e.g. Medicines and Healthcare Products Regulatory Authority, Human Tissue Authority.

Notes

Reporting should also include incidents where clinical advice was unavailable in a timely manner, for whatever reason. This indicator is intended to include 'near miss' incidents and regularly recorded minor process errors within a laboratory that might not warrant triggering a formal report under the organisation's wider governance procedures.

4. KAIs for engagement with patients and users

KAI 12: Communication of results to patients

The laboratory shall state whether it offers results directly to patients or, for young children and others deemed to lack capacity, to parents or appropriate carers. Those laboratories offering results directly to patients shall publish a description of their policy on this; the policy shall explain how results are safely and appropriately communicated to patients.

Suggested evidence

- Published statement, accessible by service users, indicating whether the laboratory does or does not offer results directly to patients.
- A clear and understandable rationale in cases where a laboratory has opted not to communicate results directly to patients.
- If a laboratory does offer results directly to patients, a published policy that states how laboratory staff ensure the safe and appropriate communication of results to patients, including procedures to ensure correct identification, exceptions and the minimum training and qualifications of staff.
- If a laboratory does offer results directly to patients, a published statement to explain the mechanism and/or procedure they use to communicate with patients.

Notes

There is a growing demand for laboratory results to be communicated directly to patients. The College wishes to encourage laboratories to develop policies to enable such direct communication where it can be achieved safely and with appropriate interpretation and support.

Policies for the communication of results to patients should be agreed with hospital clinicians and general practitioners, as appropriate for the scope of services provided by the laboratory.

KAI 13: Patient experience

The laboratory shall conduct a survey on at least a two-yearly basis, to assess the opinions of a sample of patients on the quality of the pathology service as they have experienced it. Evidence will be available to show that responses to the survey are analysed, communicated and used to improve the quality of the service.

Suggested evidence

- Statement of principles to ensure that patients' views on the services provided by pathology laboratories inform service delivery; this should set out the processes for soliciting and recording these views.
- Documentation of survey activity in accordance with the biennial commitment to seek patients' views, which includes a list of types of patient groups who have been included in the survey.

Notes

It is recommended that the survey includes specific groups of patients, e.g. those suffering from a specific long-term condition requiring regular laboratory monitoring, who are most likely to be aware of pathology results impacting on their experience of clinical care. It is also recommended that the survey includes patient groups in primary and secondary care.

It is recognised that not all aspects of the processes involved are under laboratory control. Patients may attribute problems – such as delays – to the laboratory, when they are actually the result of limitations elsewhere in the wider system delivering their care. The College recommends that pathology staff engage with other colleagues involved in delivering care to attempt to address such issues.

It is not the intention to suggest that less formal ways and contexts in which individual patient feedback is obtained are not useful.

KAI 14: Clinical user satisfaction survey

All current clinical users of the laboratory service shall be invited to participate in a user satisfaction survey, of a type that generates quantitative and qualitative results, on a two-yearly basis. There shall be evidence that the survey responses are analysed, distributed and used appropriately to inform processes aimed at optimising service delivery.

Suggested evidence

- Performance of user satisfaction survey and recording of results.
- Records of discussions at regular clinical liaison meetings demonstrating that views expressed by clinical users are sought to inform plans for service delivery.
- Records of discussions within the laboratory demonstrating that views expressed by clinical users do inform plans for service delivery.
- Documentation of informal feedback collected between surveys.

Notes

The frequency of assessment and mechanisms for dissemination of survey findings should be stipulated in contracts with commissioners or clinical service users. The College has developed a questionnaire that can be used as a standard instrument for clinical user satisfaction surveys; contact usersurvey@rcpath.org for details.

5. KAIs for interpretative clinical advice and engagement with multidisciplinary teams

KAI 15: Availability of clinical advice at multidisciplinary team (MDT) meetings

The clinical review and decision-making processes of the MDT shall be supported, where appropriate, by advice and interpretation of diagnostic reports provided by pathologists and other appropriately qualified life science professionals who attend the MDT meetings.

Suggested evidence

- List of MDT meetings supported by the laboratory.
- Explanation of any absence of laboratory support at an MDT meeting, where clinical decision-making would be expected to benefit from pathology input
- Summaries of MDT meeting attendance records (number and percentage of meetings where any pathologist or life science professional was present, and records of attendance of individual pathologists or life science professional).
- For cancer MDT meetings, demonstration of MDT attendance by laboratory staff in accordance with cancer peer review standards.

Notes

The availability of laboratory staff to attend MDT meetings is contingent on appropriate staffing levels. Deficiencies in staffing that impact on attendance should be recorded.

6. KAIs for timeliness of reports and clinical advice

KAI 16: Critical and unexpected results communication

The laboratory shall have a regularly audited process to define which results shall be called 'critical' and ensure that these are communicated urgently to a responsible clinician.

Suggested evidence

- A laboratory policy incorporating a defined list of critical results, the context for each and timelines for reporting, including processes for assuring (and recording?) receipt by the appropriate clinician(s).
- Records of laboratory audit of performance against this policy. Audit should be undertaken on at least an annual basis.

Notes

'Critical results' are those that have, or potentially have, critical impact for patient outcomes. They are likely to overlap extensively with other results deemed 'urgent' or 'significant' but they are not synonymous. Hence the importance of considering the patient's clinical context in defining processes for ensuring that critical results are communicated.

If the policy involves a professional decision as to whether or not to communicate a result, there shall be a clear statement of who does this, how it is done and who holds records of decisions taken.

If a clinical decision is made not to communicate a critical result, the reason shall be documented.

For further guidance, please refer to the College's *The communication of critical and unexpected results* (2017), available from: <https://www.rcpath.org/profession/guidelines/cross-specialty-publications.html>

KAI 17: Response to requests for clinical advice

All enquiries to the laboratory shall be answered in a professional and timely manner, with referral to a member of the laboratory scientific or clinical team when appropriate.

Suggested evidence

- A laboratory policy that describes risk stratification for determining the urgency of response to requests
- Lists of members of staff who are authorised to deal with different levels of request.
- Documentation confirming that authorised staff are appropriately trained to deal with requests.
- Audit by laboratory of performance against policy.
- Feedback in the form of any documented compliments and/or complaints.

Notes

If an enquiry requires a clinical response, such as a test result interpretation to support patient management, and cannot be dealt with immediately (e.g. if clinical staff are engaged in duties outside the laboratory), the degree of urgency shall be ascertained and the enquirer given an indication of the expected waiting time and mode of response.

'Laboratory scientific or clinical team' refers to the staff group addressed in KAI 1; others authorised by this team may initially receive enquiries as long as they refer them appropriately when necessary.

For further guidance, please refer to the College's *The communication of critical and unexpected results* (2017), available from: www.rcpath.org/resourceLibrary/the-communication-of-critical-and-unexpected-pathology-results-pdf.html

KAI 18: Turnaround times linked to patient pathways

Local patient pathways, agreed with requesters, shall include anticipated turnaround times for all relevant laboratory investigations.

Suggested evidence

- Statement of agreement between the laboratory and users of the laboratory services regarding turnaround times for specific patient pathways. The laboratory also needs to provide evidence that the needs of different users are balanced.
- Audit of performance against agreed turnaround times (audit to be performed at least annually).
- Published results of audits of turnaround times.

Notes

The fundamental concept here is that each laboratory result will be available at the point when it is needed for clinical decision-making. Ideally, in agreeing local targets, ongoing efforts will be made through collaboration between laboratory staff and other clinical colleagues to shorten patients' waiting times for such decisions.

Turnaround times are defined as starting from the time of specimen collection from the patient to availability of the confirmed test result to the requester of the test.

Turnaround times for interim reports (pending reflex tests and/or second opinion) shall also be specified.

Tests that are added retrospectively, after processing has begun, are excluded, or their turnaround times should be measured separately.

7. KAI for external quality assurance

KAI 19: Analytical EQA schemes – participation

Pathology services shall participate in accredited technical EQA schemes, if available, covering all analytical and technical areas of the service repertoire.

Suggested evidence

- Available, up-to-date EQA registration and performance records for all accredited technical schemes in which the laboratory participates.

Notes

Please refer to the *Joint Working Group on Quality Assessment Conditions of EQA scheme participation* (2015), available from: www.rcpath.org/resourceLibrary/joint-working-group-on-quality-assurance-conditions-of-ega-scheme-participation.html

This applies to technical schemes only, and **not** to interpretive schemes that relate to the performance of individual pathologists.