The Royal College of Pathologists
Pathology: the science behind the cure

Key performance indicators – proposals for implementation

July 2013

Following extensive discussion within the College, the following proposals for key performance indicators (KPIs) have been developed. The College is working with the Institute of Biomedical Science (IBMS) and Clinical Pathology Accreditation (UK) (CPA) within the United Kingdom Accreditation Service (UKAS) to implement a pilot study in Autumn 2013 that will examine:

- the feasibility of data collection
- the optimum way to present the data
- the value of the KPIs to CPA/UKAS and laboratories in assessing conformity with CPA/UKAS standards
- the possibility of deriving national standards based on the KPI targets
- any unintended consequences of implementation of the indicators.

This document has been compiled by Dr Tim Helliwell and Dr Rachael Liebmann on behalf of the Professionalism and Clinical Effectiveness Department of The Royal College of Pathologists, on the basis of the deliberations of College working groups that represented the Specialty Advisory Committees and the Institute of Biomedical Science (see Appendix).

The document was placed on The Royal College of Pathologists' website for consultation from 15 to 29 April 2013. Fellows of the College were invited to comment on the clarity of expression of the KPIs and whether, for each specialty, the specific targets are realistic.

129 responses were received and have been considered in detail. The authors' comments are available from publications@rcpath.org on request.

Many respondents made specific and highly relevant points that have been incorporated into this final guidance document. Of particular note, there has been a major change and KPI 6.1 in the previous draft has been deleted and incorporated into KPI 1.2. Other KPIs have been renumbered.

55 of the 129 respondents were content with the KPIs, broken down as follows:

Number of unconditional approvals	32
Number willing to defer to the author/s	16
Number of supportive responses provided as free text	7

Contents

General introduction

Key performance indicators (KPIs) for pathology services are intended to provide:

- additional information that laboratories can provide as evidence to CPA/UKAS assessors of compliance with the Standards for Laboratory Accreditation. Laboratories will be aware that CPA now operates within the United Kingdom Accreditation Service (UKAS) and that, starting in 2013, laboratories will be accredited to the international ISO15189 standards. These indicators will help laboratories demonstrate conformity with ISO15189:2012 standard 4.14.7
- a national framework of standards through which pathology laboratories can demonstrate the clinical effectiveness of their services.

The development of key performance indicators

KPIs have been developed through a series of meetings, the outcomes of which are published on the College website (www.rcpath.org/profession/college-responses.html):

- How to Assess the Quality of a Pathology Service
- Key Performance Indicators in Pathology.

These documents should be referenced for the detailed background to the KPIs and debate on the standards.

The meetings were followed by discussions at the Specialty Advisory Committees (SACs) and the formation of a joint RCPath/CPA steering group to develop practical proposals for piloting with a view to full implementation. The Steering Group asked a working group to develop the proposals; the membership of the working group is provided in Appendix A. This document is the outcome of these deliberations and has been agreed by SACs as ready to proceed to a pilot study.

The College and CPA/UKAS are fully aware of the additional work that will be required to demonstrate compliance with the indicators and the potential limitations of current information management systems. There will clearly be overlap with data currently collected for a variety of other purposes and we would encourage laboratories to indicate during the pilot phase where existing documents might be used to demonstrate compliance.

For several KPIs, there is an indication that the College or other groups should develop methods for presenting data in a consistent way. This is work in progress, some of which will be tested during the pilot phase. Laboratories are invited to contribute to the process of finding the optimal way(s) of presenting the data.

Where possible, the KPIs are written to be applicable to most specialties. Some specialties also work to national defined specialist services guidance (dashboards), e.g. medical genetics (www.specialisedservices.nhs.uk/library/27/Medical_Genetics.pdf). Aspects of such guidance are likely to be incorporated into College KPIs in the future.

Once the pilot study has been completed and evaluated, additional KPIs may be introduced in a second phase of implementation. The KPIs will be regularly reviewed so that they reflect current practice in the profession of pathology and indicate where testing sits within a clinical laboratory service which is part of high quality healthcare provision. Throughout this document the term ‘users’ implies healthcare professionals requesting pathology services and guidance from pathologists. The term ‘patient’ also is used to include members of the public involved in screening programmes as well as those presenting to healthcare professionals with symptoms and signs of disease.

Layout of key performance indicators

The indicators are presented as:

- a note of the current CPA/UKAS standard(s) against which the indicator might provide information of compliance. For ease of reference these include CPA standards and the ISO15189:2012 standards
- statement of purpose
- evidence required from the laboratory to demonstrate compliance
- standard of performance expected of the laboratory. For most indicators, realistic standards of documentation or clinical performance have been proposed. This assumption will be tested during the pilot phase of implementation
- specialty-specific notes and interpretation, for the guidance of laboratories and assessors.

Where agreement with users is stated, this may be at organisational level (on behalf of all users) or for specific clinical teams and to meet specific clinical requirements.

1 Staffing

All laboratory staff should demonstrate evidence of training, competency and continuing professional development for the tasks that they perform.

KPI 1.1 Provision of senior staff

This informs CPA standard B2 and ISO15189:2012 standard 5.1.2.

All clinically qualified consultants and consultant-level healthcare scientists providing clinical advice, diagnostic and/or interpretive services shall have FRCPath by examination or equivalent in the relevant specialty.

Evidence

The laboratory shall publish a list of the clinically qualified staff who currently provide clinical advice, diagnostic and/or interpretative services together with their qualifications.

Standard

100% compliance.

Notes and specialty-specific guidance

The laboratory should list the clinically qualified staff (consultants, associate specialist, senior trainees, clinical scientists and advanced practitioners) who are authorised to provide diagnostic reports and clinical advice. Staff grade pathologists, locum consultants and senior trainee pathologists may not have FRCPath but may report independently in accordance with College guidance and local practice. Advanced practitioners in cytology will often report a large proportion of gynaecological cytology reports; the range of specimen types that may be reported by advanced practitioners may expand and this should be recognised in the list provided by the laboratory.

In microbiology and virology, consultants in infectious diseases may provide diagnostic reports and advice.

This list should be up to date at the time of CPA/UKAS assessment.

Where more senior staff were appointed before FRCPath or equivalent was required, assessors should use judgement in assessing conformity with the KPI.

KPI 1.2 Senior staff cover and handover

This informs CPA standards A2, B2, E1, G1 and G5 and ISO15189:2012 standards 5.1.3, 5.8.3.

There shall be documented and named cover for planned leave of staff delivering clinical advice and laboratory oversight. The laboratory should agree with users the requirement (or not) for clinical cover outside the normal working day and the level of cover required. Clinical advice in biochemistry, haematology, histocompatibility and immunogenetics (for organ transplant programmes) and medical microbiology and virology shall be available 24 hours a day, 7 days a week, 365 days a year.

Evidence

1. Published rotas identifying named individual with appropriate skills to deliver the service, with mechanisms to allow them to be contacted.
2. Laboratories should undertake a random audit of availability on at least an annual basis, and publish the result.
3. Medical staff job plans should indicate availability for the provision of clinical advice.

Standard

100% compliance.

Notes and specialty-specific guidance

The appropriate level of cover may depend on the clinical needs of the subspecialty but should be agreed with users. The key point is that anyone providing cover for a clinical service should have an appropriate knowledge of the workings of that service.

Cellular pathology is rarely required to be available 24/7. For highly specialised diagnostic services, immediate cover for expert opinion may be at a lower level, although laboratories should indicate how expert opinion is maintained during periods of leave.

Public health: where appropriate, public health laboratories may also wish to use this KPI.

Cross-cover from other laboratories may be required. The details of such an agreement should be available.

KPI 1.3 Senior staff appraisal

This informs CPA standard B7 and ISO15189:2012 standards 5.1.7, 5.1.8.

It is the professional responsibility of all pathologists and healthcare scientists who provide clinical interpretation and advice to maintain their appraisal portfolio and to complete an appraisal of their clinical practice annually. 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 annual appraisal or shall have documented approval from their Responsible Officer or clinical line manager to defer.

Evidence

Published list of senior staff with dates of last two appraisals (where appropriate).

Standard

100% compliance within a period of 14 months before date of CPA/UKAS assessment.

Notes and specialty-specific guidance

A 14-month period is used to allow some flexibility for laboratories over the precise timing of appraisals. For staff on long-term sick leave, this period may not be applicable.

The five-year revalidation cycle should cover this for medical staff in part, but the fact of annual appraisal should be monitored.

Appraisal should normally be performed by a clinician who understands the work involved and can provide an appropriately supportive and challenging discussion.

KPI 1.4 Senior staff clinical professional development

This informs CPA standard B6 and ISO15189:2012 standard 5.1.8.

All senior staff providing laboratory oversight and clinical advice at consultant or consultant-equivalent level (i.e. independent practice, clinical and scientific staff) shall be registered for Continuing Professional Development (CPD) with the RCPath, The Royal College of Physicians (RCP) or equivalent, and must satisfy the requirements of the scheme.

Evidence

1. Registration with appropriate organisation.
2. Evidence of satisfactory performance – normally from a rolling five-year summary of credits accrued.

Standard

100% compliance.

Notes and specialty-specific guidance

This should be reported annually, preferable on 30 May to fit in with the annual College CPD reporting cycle.

Advanced practitioners who provide independent reporting will normally be registered for CPD with the Institute of Biomedical Science.

2 Training and education

In a high-quality, sustainable 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.

KPI 2.1 Training future laboratory staff

This informs CPA standards B6 and B9 and ISO15189:2012 standard 5.1.5.

The proportion of staff in training grades shall be sufficient to maintain the stability of the service, but not so high that the quality of training or service is compromised.

Evidence

The numbers of staff in training posts in each of the following groups:

- medically qualified staff
- clinical scientists
- biomedical scientists.

Standard

Published list of numbers of staff in training for each group. If training is not provided for any group, there should be a brief explanation.

Notes and specialty-specific guidance

Small and/or specialised laboratories may not have the resources to support a training post at all times. A commitment to training may be demonstrated by the release of staff to other laboratories or the acceptance of staff from other laboratories for training. In some specialist areas, training may be organised regionally or nationally – this can be declared by the laboratory.

Assessors need to exercise judgement as to what is the appropriate proportion of trainees in specific situations; 15–30% is a suggested range.

KPI 2.2 Undergraduate, postgraduate and primary care teaching

This informs CPA standard G5 and ISO15189:2012 standard 5.4.2.

Laboratories shall provide evidence of their involvement in undergraduate (where appropriate) and postgraduate education for both hospital and primary care users of the service.

Evidence

The laboratory shall publish a description of its educational activities of laboratory staff teaching medical undergraduates, non-medical undergraduates, postgraduate medical staff and postgraduate non-medical staff. The list of activity should reflect hours allocated in job plans to teaching.

Standard

Published list of activity for each target group. If training is not provided for any group, a brief explanation should be provided.

Notes and specialty-specific guidance

Educational activity does not need to be face-to-face teaching; the provision of online resources should be included. The contribution of laboratory staff to regional, national and international education (if appropriate) should be recognised.

The list of activity should reflect hours allocated in job plans (within SPAs) to teaching.

Staff competencies and training in educational activities should be included in annual reviews/appraisals.

3 Repertoire of tests and integrity of reporting results

Laboratories should agree with users which tests should be available and should ensure that appropriate (preferably electronic) communication links are in place for the requesting and reporting of tests. The laboratories should, where appropriate, follow national guidance when advising users of the most appropriate investigations and the content of reports.
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KPI 3.1 Integrity of data transmission

This informs CPA standard D2 and ISO15189:2012 standard 5.10.3.

The laboratory shall specify and publish the standards to which its IT systems comply, in respect of pathology message content for electronic test requesting and for transmission of results.

Evidence

1. Published statement of compliance.
2. Evidence of audit against statement.

Standard

100% compliance.

Notes and specialty-specific guidance

The National Laboratory Medicine Catalogue (NLMC), when implemented, is likely to provide a standard list of tests, test codes and units of measurement. In the interim, laboratories should provide evidence of local standards.

All numerical pathology results should use the analyte name, Read code and unit of measurement as set out in the most recent version of pathology message guidance. In England and Wales this content should be configured to conform to the latest specification files downloadable from Technology Reference data Update Distribution (TRUD) and be appropriately configured no more than four weeks after the version release date.

For further guidance see www.ychi.leeds.ac.uk/pmipunits.

KPI 3.2 Messaging to primary and community care

This informs CPA standard D2 and ISO15189:2012 standard 5.10.3.

Laboratory IT systems shall send results to primary and community care using the Pathology Messaging Implementation Project (PMIP) NHS003 messaging system, except where the laboratory has transferred to HL7 messaging via the NHS Spine compliant with NLMC data standards. This criterion applies only to England and Wales as territories that have standardised their messaging.

Evidence

1. Published statement of compliance.
2. Evidence of audit against statement.

Standard

100% compliance.

Notes and specialty-specific guidance

The PMIP approach to the reporting of pathology data covers most of GP requirements for biochemistry, haematology and immunology plus some microbiology, virology and genetics. The system uses EDIFACT messages sent through the Spine Data Transfer System (DTS). The NHS003 is the required messaging system. The exception is the use of NLMC messages sent via the Spine using HL7 v3 messages.

KPI 3.3 Demand management

This informs CPA standard G5 and ISO15189:2012 standards 4.7 and 5.4.2.

The laboratory shall implement a system of demand management; this shall be designed both to reduce the number of unnecessary tests and to help to ensure that appropriate tests are used.

Evidence

1. Published statement of system of demand management.
2. Evidence of audit (by monitoring activity of testing) against agreed statement.

Standard

100% compliance.

Notes and specialty-specific guidance

Evidence may be through collective agreement with users at Trust level, or through agreement with specific clinical teams, so that patient pathways are optimised. It is important that demand management is practical; it may not be practical to implement demand management over the entire repertoire of testing.

Over time, reference should be made to the National Demand Management Toolkit (in development) and to whether the minimum retesting guidance has been implemented.

For further information, see Fryer AA, Smellie WSA. *J Clin Pathol* 2013;66:62–72.

KPI 3.4 Test repertoire

This informs CPA standard E1, E2j, G5 and ISO15189:2012 standards 4.4.1 and 5.4.2.

The published repertoire of available tests shall include all tests that are relevant to the clinical practice of the users of the service, whether by in-house analysis or outsourced (sent away). Where possible (see notes), the available tests should be listed within the NLMC.

Evidence

1. Published statement.
2. Evidence of audit against agreed statement.

Standard

100% compliance.

Notes and specialty-specific guidance

NMLC is currently only partially implemented; assessors should use judgement when assessing compliance with this indicator.

KPI 3.5 Point-of-care testing (POCT)

This informs CPA standard A3 and ISO15189:2012 standards 4.4.1 and 5.3.1.

The local community and hospital POCT machines and repertoire for which the laboratory has oversight shall be documented and published.

The published list shall provide definitions of agreed POCT use in specific patient pathways. The POCT repertoire documentation shall make explicit the areas where pathology service quality management input has been agreed. These pathways are to be signed off by appropriate clinical and scientific managers in all involved organisations.

Laboratories shall ensure that POCT services within this list have adequate QA for all users.

Evidence

1. Published statement. Laboratories should explicitly state if they do not wish to include POCT in the scope of accreditation.
2. Evidence of audit against agreed statement.

Standard

100% compliance.

Notes and specialty-specific guidance

Cellular pathology: not applicable.

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 areas that are not accredited.

KPI 3.6 Long-term stability of methods

This informs CPA standards F1, F2 and F3 and ISO15189:2012 standards 5.3.1 and 5.3.2.

Laboratories shall provide documentation and evidence of implementation of systems to ensure long-term stability of analytical methods and to ensure that analytical methods match national and international guidance. Where laboratories change method, there must be evidence that adequate consideration has been given to ensuring that results obtained will not differ significantly from those obtained in other UK laboratories, particularly those laboratories serving the local population. New methods should be appropriately validated and verified.

Evidence

1. Statement of principles to ensure long-term stability of results.
2. Evidence of audit or other quality assurance against that statement. This should include evidence of validation and verification of new tests or methods.

Standard

100% compliance.

Notes and specialty-specific guidance

Microbiology/virology: there is an intention to ensure that laboratories follow the UK Standards for Microbiology Investigations developed in conjunction with the Health Protection Agency (now Public Health England) wherever possible, but not need to strictly adhere to these standard methods.

www.gov.uk/government/collections/standards-for-microbiology-investigations-smi

Cellular pathology: this should include both technical and interpretative consistency:

1. published evidence of trends in NEQAS assessments over time for relevant tests
2. published evidence of repeated clinical audit of completion of cancer datasets.

The CPA/UKAS statement (2013) on validation and verification may assist laboratories in understanding the evidence needed to meet this KPI (www.cpa-uk.co.uk/support/index.htm).

KPI 3.7 Incident and error reporting

This informs CPA standards F2, F3 and H6 and ISO15189:2012 standards 4.9, 4.10, 4.14

Laboratories shall ensure there is a log for documenting laboratory-based errors and shall demonstrate evidence of measures introduced to reduce the chance of similar future errors. Errors or omissions in information provided on specimen requests and other pre-analytical errors should be recorded.

Evidence

1. Standard operating procedure stating principles of incident and error reporting.
2. Evidence of regular review of recorded incidents and errors, together with corrective actions taken.

Standard

100% compliance.

Notes and specialty-specific guidance

During 2013, the College should consider providing specialty-specific examples of incidents and errors, together with an indication of when these might be escalated to clinical incident reporting systems.

4 Engagement with patients and users

Pathology services provide important information for patient benefit. In some circumstances, results may be provided directly to patients, while for some patient-management pathways it is important for diagnostic tests to be collated with other information before a definitive diagnosis is made and management options considered.

KPI 4.1 Communication of results to patients

This informs CPA standard G1 and ISO15189:2012 standard 5.9.1.

The laboratory shall state whether or not it offers results directly to patients (in those cases where both patient and requesting clinician have requested it) or, for young children, to parents and carers. The laboratory shall publish a description of their policy on delivering results direct to patients and the percentage of results actively delivered directly to patients.

Evidence

1. Statement of principles to ensure appropriate communication of results. This should be agreed with hospital clinicians and GPs (as appropriate).
2. Evidence of audit or against that statement.

Standard

100% compliance.

Notes and specialty-specific guidance

Cellular pathology and microbiology: assessors should note that results are rarely, if ever, communicated directly to patients.

Compliance with this KPI may be influenced in the future by the development of GP portal technology.

'Delivered directly to patients' includes direct delivery by post, telephone, SMS message or email. It includes availability through a secure website only in those instances where a computer system has logged the fact that a patient downloaded the result. Merely making the result available is not sufficient; the patient must receive it.

'Percentage of results' is to be calculated using laboratory accession numbers, not individual analytes.

Results given directly to patients should be provided in accordance with published guidance: *The delivery of medical laboratory test results direct to patients* (RCPath, 2010: www.rcpath.org/profession/publications/archived-and-withdrawn-documents.html).

KPI 4.2 Patient opinions

This informs CPA standard E1 and ISO15189:2012 standard 4.14.3.

The laboratory shall conduct a survey of a random sample of patients on at least an annual basis, to assess the opinions of patients on the quality of the pathology service. The survey may be targeted to a specific group of patients, e.g. those suffering from a specific long-term condition that requires laboratory monitoring. The survey shall include a question about the

quality of sample collection services (principally phlebotomy) and questions about the speed and manner of delivery of results; it must not be limited to processes within the laboratory itself. There shall be evidence that the responses to the survey are analysed, distributed and used appropriately.

Evidence

1. Statement of principles to ensure that patients' views on the services provided by pathology laboratories inform service delivery. This should include the mechanisms for soliciting and recording these views.
2. Evidence of regular (annual) audit of activity against that statement.

Standard

100% compliance.

Notes and specialty-specific guidance

It may be difficult to obtain appropriately informed views for those aspects of the service where there is no direct patient contact. This is particularly applicable to some parts of cellular pathology and to virology. Assessors need to have a pragmatic approach.

The College should consider providing a robust and validated assessment questionnaire.

KPI 4.3 Quantitative user satisfaction survey

This informs CPA standards H1 and H2, and ISO15189:2012 standards 4.4.1 and 4.14.3.

All current users of the laboratory service shall be invited to participate in a user satisfaction survey, of a type that generates quantitative results, on an annual basis starting in 2013. The frequency of assessment may be stipulated in contracts with commissioning groups or service users.

Evidence

1. Performance of user satisfaction survey and recording of results.
2. Evidence of discussion within the laboratory to suggest that views expressed by users inform plans for service delivery.

Standard

100% compliance.

Notes and specialty-specific guidance

Historically, assessment of user satisfaction has been patchy and difficult to assess; quantitative information is now being requested.

More robust tools, e.g. RCPath survey tool and online feedback questionnaires, should be evaluated.

Cellular pathology: may be able to use minutes of multidisciplinary team (MDT) annual business meetings as one method of documenting user satisfaction.

5 Interpretative clinical advice and engagement with multidisciplinary teams

Across the pathology specialties, there are many situations in which laboratory staff (clinicians and scientists) provide clinical advice. These KPIs cover selected areas in which assessment against standards is likely to be possible.

KPI 5.1 Availability of clinical advice at multidisciplinary team (MDT) meetings

This informs CPA standards E1, G1 and G5 and ISO15189:2012 standard 4.7.

Pathologists are core members of cancer MDTs and important contributors to many non-cancer MDTs (including, for example, those dealing with inflammatory skin disease, clinical haematology, orthopaedic infections, endocarditis). Clinical scientists may provide MDT input in some specialties. The decision-making process of the MDT should be supported by pathological advice and interpretation of diagnostic reports.

Evidence

1. List of MDTs supported by the laboratory; if any MDT is not supported, an explanation should be provided.
2. Summaries of MDT attendance records (number and percentage of meetings where any pathologist or clinical scientist was present, and records of attendance of individual pathologists or clinical scientists.
3. For cancer MDTs, the designated lead cancer pathologist should attend at least 66% meetings (Cancer Peer review standard), unless there is prior agreement for only one pathologist from a team to attend.

Standard

90% of MDTs have pathologist present.

Designated lead cancer pathologist attends 66% of relevant MDT meetings.

Notes

The availability of consultant staff to attend MDTs is contingent on appropriate staffing levels. Deficiencies in staff that impact on this activity should be recorded.

Trainee pathologists should attend and present cases at MDTs under consultant supervision and it is appropriate for senior trainees to provide cover for consultants during periods of leave. Advanced practitioners may, with consultant guidance, provide similar cover for colposcopy correlation meetings.

Cancer standards may differ between devolved administrations within the UK; assessors should be aware of these differences and accommodate these in their assessments.

KPI 5.2 Cellular pathology reporting of cancer resections

This informs CPA standard G2 and ISO15189:2012 standard 5.8.3.

Cancer resections shall be reported using a template or proforma, including items listed in the English Cancer and Outcomes Services Dataset which are, by definition, core data items in RCPath cancer datasets (where available). English Trusts are required to implement the structured recording of core pathology data in the COSD by January 2014.

Evidence

Local audits, verified by random sampling by assessors of appropriate cancer reports.

Standard

95% reports contain structured data.

Notes

Although cancer peer review standards differ between devolved adminstrations in the United Kingdom, the KPIs are College recommendations and reflect the College view on the acceptably standard of service delivery.

Some laboratories may be limited by the laboratory information management system (LIMS); if structured reports are not available, laboratories should be able to provide evidence of liaison/communication with the LIMS provider on the subject and a plan for future implementation.

KPI 5.3 Documentation of cellular pathology second opinions

This informs CPA standard G2 and ISO15189:2012 standard 5.8.3.

The extent to which laboratories require internal or external consultation varies according to the clinical context, the experience of the pathologists and patterns of working in specialised teams. Assessors should therefore be looking for a risk assessment of the consultation process in the light of local circumstances, agreement with users that this is appropriate and evidence that the local policies are carried out, in particular that any consultations are recorded in the laboratory management system, preferably as an addendum to the diagnostic report. Although this is primarily an issue with malignant diagnoses, other reports should follow similar principles.

Evidence

1. Published laboratory policy to include as a minimum all cancer MDTs.
2. Agreement with users, for example, through minutes of MDT business meetings or annual reports.
3. Evidence of audit of compliance with user agreements.
4. Evidence that, where a second opinion has been sought, the outcome is documented in the electronic record.

Standards

100% compliance with laboratory policy.

80% of patient pathways/MDTs should have user agreements.

80% of pathways should have audit of compliance.

6 Timeliness of reports and clinical advice

Laboratories should ensure that reports on diagnostic specimens are available in a timely manner, and that additional interpretative advice is available, as agreed with users. Timeliness should be agreed with users in the context of patient pathways and the amount of work required to provide a final report (this will vary between specialties and specimen types).

KPI 6.1 Critical results communication

This informs CPA standards E1, G1 and G5 and ISO15189:2012 standard 5.9.1.

Critical results are defined as results that require clinical action as soon as possible, typically within one hour. The laboratory shall have a document defining what results shall be telephoned urgently to a responsible clinician (see CPA standard G1.1b). If that policy involves a professional decision as to whether or not to telephone a candidate result, the laboratory shall have 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 telephone a result, the reason shall be documented. This may be part of a written agreement with commissioners or local clinical governance that recognises the need for requestors of laboratory investigations to provide clear contact details. The policy should also indicate the action required in the event of the requesting clinician not being available.

Evidence

1. Statement of laboratory policy. This should include a defined list of critical results.
2. Evidence of laboratory audit against statement. This should be performed on at least an annual basis.

Standards

100% compliance.

Notes and specialty-specific guidance

Electronic delivery of critical results to an electronic post box that will trigger urgent clinical review and action is acceptable.

Threshold levels for tests may vary between clinical teams; the local policy should indicate agreed variations.

The RCPath publication, *Out-of-hours reporting of laboratory results requiring urgent clinical action to primary care: Advice to pathologists and those working in laboratory medicine* (2010), provides guidance in this area for clinical biochemistry, immunology and microbiology. The table (below) is the current guidance for haematology.

Cellular pathology: this indicator only relates to results on specimen types that will predictably need to be reported rapidly, for example, urgent cytology, frozen sections, transplant biopsies. The unexpected result (impossible to define) on other specimen types is excluded from consideration (see College document on Alert systems, www.rcpath.org/resourceLibrary/communication-of-unexpected-findings--urgent-reports--delayed-reports-and-the-use-of-alert-systems-in-diagnostic-cellular-pathology.html).

Haematology: critical results should normally be telephoned or actively communicated to a responsible clinician with 60 minutes of the result becoming available. The following table

provides indicative critical results for haematology that should form part of a laboratory's policy.

Parameter	Unit	Level	Comment
Haemoglobin	g/L	<50	Microcytic or macrocytic
	g/L	<70	Normochromic, normocytic with no other reason as this may suggest blood loss or bone marrow failure
Neutrophils	$x10^9$/L	<0.5	
	$x10^9$/L	>50	If there has been no previous result and the history indicates that there is no obvious reactive cause such as trauma or post-operative
Platelets	$x10^9$/L	<30	
Blood film			Shows new diagnosis of acute leukaemia
Malaria			Positive
Coagulation			
INR		>8.0	For patients on Warfarin

KPI 6.2 Communication of isolates of potential significance for infection prevention and control

This informs CPA standards C5.1f and H6.4 and ISO15189:2012 standard 5.9.1.

Microbiology and virology laboratories should have systems in place to ensure timely communication of results of potential infection prevention and control significance to all relevant infection-control teams. Such results will include 'alert organism' communication, multi-drug resistant isolates and other results, based on local agreement. Laboratories will require clear standard operating procedures, the use of automatic downloading of results into electronic infection-control surveillance systems, or the use of email and/or mobile text messaging, and satisfactory feedback from infection prevention and control teams.

Evidence

1. Standard operating procedures following local agreement between the laboratory and infection control team.
2. Audit of compliance with standard operating procedure.

Standard

100% compliance.

KPI 6.3 Timeliness of responding to requests for clinical advice

This informs CPA standards E1, G1 and G5 and ISO15189:2012 standards 4.7 and 5.9.1.

All calls to the laboratory shall be promptly and professionally answered, with referral to a member of the laboratory or clinical team when appropriate. Where a call requires a clinical response and cannot be dealt with immediately (e.g. clinical staff are in an outpatient clinic, ward round or teaching activity), the degree of urgency shall be ascertained and the caller given an indication of a likely response time. It is recognised that it is often safer, and preferable from a clinical governance perspective, to defer a response until the most appropriate member of the clinical team is available. Where appropriate, laboratories should distinguish between requests for urgent clinical advice, and requests for advice on interpretation of reports.

Evidence

1. Statement of laboratory policy that should include risk stratification for the urgency of response to requests and list which members of staff are able to deal with different levels of request.
2. Evidence that designated staff are appropriately trained to deal with requests.
3. Audit by laboratory against statement.

Standards

100% compliance.

Notes and specialty-specific guidance

Cellular pathology: only applicable if there is specific local agreement for specialist advice 24/7.

Haematology and biochemistry: urgent clinical advice should be available within 60 minutes.

Microbiology: urgent clinical advice should be available within 60 minutes.

Histocompatibility and immunogenetics: urgent clinical advice should be available within 30 minutes.

KPI 6.4 Cellular pathology reporting turnaround times

This informs CPA standard G1 and ISO15189:2012 standards 4.4.1 and 4.14.1.

The proportion of all final reports on diagnostic cytology and histopathology cases that are reported, confirmed and authorised within seven and ten calendar days of the procedure shall be published and recorded. Cases requiring prolonged decalcification (not bone marrow trephines) are excluded, as are cases requiring molecular tests.

Evidence

1. Published monthly audit report on seven-day turnaround.
2. Published monthly audit report on ten-day turnaround.

Standards

100% compliance with publication.

Provisional expectations are that 80% of cases would be reported within seven calendar days and 90% of all cases are reported within ten calendar days.

Notes and specialty-specific guidance

Turnaround time relates to the **final** local report. This would exclude cases sent for external opinion.

Monthly data are suggested as analysis of trends is valuable for management and users.

The draft KPI suggested different standards for biopsy and resection specimens; the revised KPI covers all specimen types. Laboratories are encouraged to provide more detailed information on specific types of specimen that will be valuable for users, but this detail is not currently required as a KPI.

KPI 6.5 Monitoring cellular pathology delayed reports

This informs CPA standard G1 and ISO15189:2012 standards 4.4.1 and 4.14.1.

Each cellular pathology service shall have a documented system to identify cases remaining unreported longer than is anticipated, and shall have a documented system to manage and report these cases. Exception reporting shall be undertaken of all cases (including decalcified cases) remaining unreported after 20 calendar days.

Evidence

Published report on number and percentage cases reported after 20 days.

Standards

100% compliance with publication.

Notes and specialty-specific guidance

Where particular types of specimen usually take longer than 20 days, the laboratory should explain why this is the case.

KPI 6.6 Turnaround times linked to patient pathways

This informs CPA standard G1 and ISO15189:2012 standards 4.4.1 and 4.14.1.

Timeliness does not equate with speed. Some tests may require different turnaround times for different users. Consequently, agreed local patient pathways shall include turnaround times for all laboratory tests. Turnaround times need to be defined from the time of collection from the patient to completion and confirmation of the test result so that it is available to the requestor and should specify the turnaround times of any interim reports pending reflex tests or second opinions. Audits of performance against the agreed turnaround times for each such patient pathway shall be undertaken at least yearly and the results published.

Evidence

1. Statement of agreement between users and laboratory of turnaround times for specific patient pathways. The laboratory also needs to provide evidence that the needs of different users are balanced.
2. Audit of performance against agreed times. Audit to be performed as a minimum annually and, if resources permit, monthly (see notes).
3. The results of audits of turnaround times shall be published.

Standards

100% compliance.

Notes and specialty-specific guidance

Most laboratories current measure ‘in laboratory’ turnaround times. It is currently unclear how quickly systems can be developed to monitor end-to-end times from specimen collection to report completion; this is more important for some samples (some blood tests) than for others (some microbiology tests) and assessors should initially use judgement in interpretation of this indicator.

Assessors should use judgement in determining how this information is recorded. Some patients may only enter a clinical pathway after the diagnostic test has been reported.

This KPI would be particularly important for situations where specific patient pathways relied crucially on diagnostic test turnaround time, for example, troponin in acute coronary syndrome, BNP in A&E breathless patients.

In some specialties, and where prompt reporting is clinically critical, audits should be quarterly. If audits can be automated, then monthly reporting can be considered.

KPI 6.7 Policy for the provision of results and blood products for patients with massive haemorrhage

This informs CPA standard G1 and ISO15189:2012 standards 4.4.1 and 4.14.1.

NPSA RRR017 stipulates that all hospitals in England must have policies in place for massive haemorrhages wherein the role of each agency is clear. This document had a deadline for action of April 2011. This KPI addresses the compliance of the laboratory with turnaround time for this group of patients. Target turnaround times have not been defined. The Hospital Transfusion Committee (HTC) is the deemed agency to agree this for their institution.

Evidence

The laboratory shall have a document ratified by the HTC defining the role of the haematology, haemostasis and transfusion laboratories in massive haemorrhage protocols.

The document shall publish an agreed list of standards including:

a. haematology blood tests and turn-around-time for these tests, from collection of sample

b. blood product requirement and turn-around-times for these from the time of request.

Standards

Publication of approved policy.

The proportion of compliance with turnaround times for tests and products shall be recorded and published and updated on at least a monthly basis. The target KPI is 100% for both measurements.

Notes and specialty-specific guidance

Hospitals will need to simultaneously audit performance against other standards of a massive haemorrhage policy including clinical decisions, porterage, etc. However, this is outside the remit of the CPA/UKAS. Although the NPSA standard is specifically for England, this may be a useful aspirational standard for laboratories elsewhere.

KPI 6.8 A&E blood sciences turnaround times

This informs CPA standard G1 and ISO15189:2012 standards 4.4.1 and 4.14.1.

Reports of certain blood tests from patients in accident and emergency department should be available to guide immediate patient management. The specified indicator tests are:

- renal function tests
- U&E
- troponin
- liver function tests
- full blood counts.

Evidence

The percentage of specified investigations from A&E completed within one hour of sample collection (see notes) should be recorded and published.

Standard

90% completed within one hour by April 2014.

Notes and specialty-specific guidance

Laboratories may initially only be able to report on time from specimen receipt. The standard will move to one hour from sample collection by April 2015.

The standard is challenging. Experience from the pilot sites will indicate whether or not it is achievable.

In the paediatric context, it may not be clinically appropriate for tests such as troponin-T to be reported urgently.

KPI 6.9 HLA typing of deceased donors for solid organ transplantation

This informs CPA standard G1 and ISO15189:2012 standards 4.4.1 and 4.14.1.

HLA offer typing of deceased organ donors for transplantation must meet the requirements of the NHSBT ODT Specification for the Provision of Deceased Donor HLA Offer Typing.

Evidence

1. The proportion of deceased donor offer types meeting the requirements of the NHSBT ODT Specification for the Provision of Deceased Donor HLA Offer Typing shall be recorded and published. Exception reports shall be completed and reported for all requests where the resolution of typing does not meet the specification.

2. The time between the sample being taken and the result of a deceased donor HLA offer type being reported to NHSBT ODT shall be recorded and published. Exception reports shall be completed and reported for all requests where the reporting time exceeds eight hours.

Standards

1. 100% of donor types should comply with the minimum resolution required.
2. Deceased donor HLA offer typing results should be available within eight hours of the sample being taken in 80% of cases.

KPI 6.10 HLA typing for haematopoietic stem cell transplantation

This informs CPA standard G2 and ISO15189:2012 standards 4.4.1 and 4.14.1.

1. For 100% of those HSC-related transplants where HLA identity by descent has not been proven, HLA typing for recipients and intra-familial donors must include high resolution Class I and/or Class II typing by DNA methods as documented in the transplant protocol.

2. For 100% of HSC unrelated transplantation, HLA typing for recipients and unrelated donors must include as a minimum requirement low resolution HLA-A/B/C typing and high-resolution DRB1 typing by DNA methods.

Evidence

1. The proportion of related recipient/donor pairs (with the exception of transplants from related donors where identity by descent is proven) proceeding to transplantation where high resolution typing of HLA Class I and Class II has been completed shall be recorded and published. Exception reports shall be completed and reported for all transplants where the degree of HLA matching at high resolution is not determined.

2. The proportion of unrelated recipient/donor pairs proceeding to transplantation where low resolution HLA-A/B/C typing and high resolution DRB1* typing has been completed shall be recorded and published. Exception reports shall be completed and reported for all transplants where this level of HLA typing has not been achieved.

Standard

100% compliance.

KPI 6.11 Routine antenatal screening tests for Hepatitis B, HIV, syphilis and rubella

This informs CPA standard G1 and ISO15189:2012 standards 4.4.1 and 4.14.1.

Laboratories should comply with appropriate national guidance on the timeliness of reporting of routine antenatal screening tests (excluding reports on patients presenting in labour or with late presentation) for Hepatitis B, HIV, syphilis and rubella. Reports should be confirmed, authorised and electronically available to requestor within the timescale defined in the guidance, e.g. in England five working days from the sample being submitted to the laboratory (eight days if samples have to be sent to another laboratory for confirmatory testing).

Evidence

To report, as at the 30 May and 30 November, the percentage of routine antenatal screening tests for Hepatitis B, HIV, syphilis and rubella electronically available to the requestor within five working days.

Standard

90% by April 2014, increasing to 97% by April 2015.

KPI 6.12 Late presentation antenatal screening tests

This informs CPA standard G1 and ISO15189:2012 standards 4.4.1 and 4.14.1.

Laboratories should follow appropriate national guidance in providing timely reports on antenatal screening tests for HBV, HIV and syphilis performed on women presenting late or in labour, with provisional reports available and actively communicated to requestor within 24 hours from sample being taken. Rubella also needs to be screened, with initial results available within 5 days of the sample being taken.

Evidence

Percentage of HBV, HIV and syphilis antenatal screening tests performed on women presenting late (as defined by locally agreed protocols) or in labour reported with provisional reports available and actively communicated to requestor within 24 hours from sample being taken. Rubella results should be available within 5 days of the sample being taken.

Standard

97% by April 2014, increasing to 99% by April 2015.

Notes

Local protocols will need to be established to enable the laboratories to identify the patients in this category so that relevant audit data can be produced. It is suggested that, for laboratories in England, this indicator would apply to patients after 24 weeks' gestation. This will need to be done at the frequency required by the local antenatal services.

7 External quality assurance

To ensure that laboratories perform specific tests to nationally acceptable standards, external quality assurance (EQA) schemes are available. These assess local performance against national standards, usually involving an element of peer review. Analytical and quantitative EQA schemes typically assess the performance of one area of the laboratory service. Interpretative schemes assess the performance of individual healthcare professionals. The outcome of the national review of EQA schemes during 2013 may impact on these standards. We recommend that laboratories collect the stated evidence during the pilot phase.

KPI 7.1 Analytical EQA schemes

This informs CPA standards H1 and H5 and ISO15189:2012 standard 5.6.3.

Pathology services shall participate in UKAS-accredited EQA schemes, if available, covering all analytical areas of the service repertoire. In the absence of an accredited EQA scheme covering the area, the pathology service shall participate in an alternative EQA scheme covering this aspect of the service repertoire or use inter-laboratory comparisons to ensure that results a similar in different laboratories.

Evidence

1. Statement of principles of technical EQA, covering accredited schemes and other programmes.

2. The EQA registration and laboratory performance records for all analytical schemes should be available.

Standard

100% compliance.

Notes and specialty-specific guidance

Accredited laboratories should already comply with this KPI for accredited schemes. The College needs to provide guidance during 2013 on appropriate QA for tests where there is no external QA programme.

Not all accredited schemes are UKAS (ISO17043) accredited, some are still CPA accredited.

KPI 7.2 Interpretive EQA schemes

This informs CPA standards H1 and H5 and ISO15189:2012 standard 5.6.3.

Interpretive EQA scheme participation, where available, shall be undertaken as a minimum by the lead and deputy in each area covered by the service repertoire.

Evidence

Participation records for all pathologists in relevant interpretive EQA schemes related to the service repertoire to be available for inspection during CPA/UKAS visits on a confidential basis.

Standard

100% compliance.

Notes and specialty-specific guidance

Interpretive schemes should either be accredited to the standards of CPA/UKAS or should be overseen by the National Quality Assurance Advisory Panel in Cellular Pathology, incorporating the RCPath EQA Steering Committee.

Despite the use of the term EQA, it is understood that participation in these schemes differs significantly from clinical interpretive practice. The schemes have no link to patient outcomes and currently function as fora for addressing clinical and diagnostic issues in an educational and reflective manner. While not necessarily providing assurance of clinical competence, regular involvement in this activity provides a record of professional special interest in an area of clinical interpretive practice and enables professional development.

This currently applies to interpretative EQA schemes for histopathology and cytopathology, and the UKNEQAS scheme for clinical biochemistry. Schemes in other specialties are not sufficiently developed to formally assess in this KPI.

KPI 7.3 EQA scheme results

This informs CPA standards H1 and H5 and ISO15189:2012 standards 4.14 and 5.6.3.

A report of performance in all quantitative EQA schemes shall be published using a standard format, and available to service users and patients.

Evidence

Publication of the trends of results of quantitative EQA schemes relevant to the service repertoire.

Standards

100% compliance with the publication of a report.

Notes and specialty-specific guidance

This does not apply to interpretive schemes that relate to the performance of individual pathologists (see 7.2 above).

Appendix Members of the KPI Steering Group and Working Group

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