



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

How to Assess the Quality of a Pathology Service

Report of a meeting
held to discuss the
evaluation of medical
laboratories

in the context of
health service reform

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Table of Contents

Measuring laboratory quality: The problem we are trying to address.....	3
Background	4
What else needs to be assessed?.....	4
How should the results be reported?.....	6
Process	7
Recommendations	9
Recommendations pertaining to the current system of accreditation	9
Additional Performance Indicators	11
Additional Performance Indicator: Provision of senior staff.....	11
Additional Performance Indicator: Senior staff cover and handover.....	11
Additional Performance Indicator: Senior staff appraisal.....	11
Additional Performance Indicator: Senior staff CPD.....	11
Additional Performance Indicator: Training future laboratory staff.....	12
Additional Performance Indicator: Undergraduate, Postgraduate & Primary Care Teaching.....	12
Additional Performance Indicator: Integrity of data transmission.....	12
Additional Performance Indicator: Demand management.....	13
Additional Performance Indicator: Test repertoire.....	13
Additional Performance Indicator: Point of care testing.....	13
Additional Performance Indicator: Patient opinions.....	13
Additional Performance Indicator: Documentation of histopathology second opinions.....	14
Additional Performance Indicator: Histopathology reporting of cancer resections.....	14
Additional Performance Indicator: Monitoring histopathology delayed reports.....	14
Additional Performance Indicator: Long term stability of methods.....	14
Additional Performance Indicator: Communication of results directly to patients.....	14
Additional Performance Indicator: A&E blood sciences turn-around-times.....	15
Additional Performance Indicator: Histopathology reporting turnaround times.....	15
Additional Performance Indicator: Cross-matching of deceased donor transplantation.....	15
Additional Performance Indicator: Routine antenatal screening tests for Hepatitis B, HIV, Syphilis, and Rubella susceptibility.....	15
Additional Performance Indicator: Late presentation antenatal screening tests.....	15
Additional Performance Indicator: Turnaround times linked to patient pathways.....	15
Additional Performance Indicator: Critical results communication.....	16
Additional Performance Indicator: Clinical Advice Availability.....	16
Additional Performance Indicator: Timeliness of responding to requests for clinical advice.....	16
Additional Performance Indicator: Quantitative User Satisfaction Survey.....	17
Additional Performance Indicator: Analytical EQA schemes.....	17
Additional Performance Indicator: Interpretive EQA schemes.....	17
Additional Performance Indicator: EQA scheme results.....	17
Additional Performance Indicator: Incident and error reporting.....	17
Information for a 'Pathology quality dashboard'	18
Different reports for different purposes.....	18
Involvement of statutory regulators.....	19
List of meeting attendees	20

Measuring laboratory quality: The problem we are trying to address

The systems for the evaluation of medical laboratory quality that are currently available deliver their aims extremely well; but their aims were designed for the NHS as it used to be.

This report is the result of acceptance by medical laboratory professionals and others that the methods by which we currently evaluate the quality of medical laboratory services need to improve. It includes our recommendations on how that should be achieved.

Recent changes to the NHS have revealed two broad areas of deficiency:

1. Laboratory accreditation concentrates too much on the operation of the laboratory, on the areas where laboratory managers have control. It pays too little attention to what happens before a patient's sample reaches the laboratory or after the report leaves it; there is too much focus on how, rather than why, or on how the test is used. This is despite evidence from the National Patient Safety Agency, amongst others, that the majority of pathology-associated patient safety incidents occur not in the laboratory, but at these 'interface' zones. It also ignores demand management; the need to avoid unnecessary testing; compliance with national and international guidance/standards and the need to use laboratory tests when they can genuinely improve outcomes. Consequently, if we are concerned about improving patient outcomes, we need systems to measure the whole service, from the decision to use a laboratory test through to the interpretation and clinical implementation of the result of the test.
2. Most available quality evaluation systems have focussed on the needs of the pathology manager who wants to produce accurate results. They have not considered adequately the needs of the user; they consider neither the patient, where phlebotomy, sample delivery and report availability are likely to be important, nor (to any great extent) the clinician who requests tests. They have not considered adequately the needs of those who commission or pay for the service, because the division between purchaser and provider was not an issue when the system was designed. Consequently (and with the arguable exception of some benchmarking services which are not universally used) they do not consider efficiency. Systems to deliver appropriate demand management are neither required nor assessed.

The Royal College of Pathologists held an invited meeting of experts to discuss how to resolve these matters on 26th October 2011, with subsequent email discussion amongst members of College Council. This was followed by an internet-based consultation. Pathologists, service users, patients, managers and commissioners were invited to comment. A total of 275 responses were received, with a large majority of contributions coming from pathologists.

The College hopes that this report will be of value to UKAS, which provides the laboratory accreditation service; to users of the service; to those who commission and pay for laboratory services; and most of all, to the patients whom we all serve.

Background

For many years after the foundation of the NHS, medical laboratories were funded on the basis of a perception of the local need, with little or no competition between providers. Senior laboratory staff attempted to provide the best service they could, within the constraints of the available funding. Inevitably, some achieved better results than others, but there were no truly objective methods to identify best practice - nor to identify laboratories with serious deficiencies.

In the 1960s, recognition that the technical performance of laboratories differed considerably led to the establishment of nationally-organised external quality assessment schemes. Initially these addressed only the accuracy of laboratory assays. In the 1990s these schemes were extended into the 'interpretive' aspects of laboratory medicine. Other schemes to assess specific aspects of laboratory quality were developed – such as 'benchmarking' schemes – although they were not universally used and were little understood by groups other than laboratory staff.

In the early 1990s, collaboration between the UK Government and professional organisations led to the development of a national laboratory accreditation scheme – Clinical Pathology Accreditation Ltd (CPA). Initially this was greeted by suspicion by many inside the profession. Being scrutinised and criticised by 'outsiders' was a novel and uncomfortable experience. But its value was soon recognised by all concerned. Its system of self-assessment followed by an independent on-site inspection drew together and harmonised the many and varied aspects of evaluating laboratory quality into a single process with a consistent conclusion that could be understood by all. Medical laboratory accreditation became a model for accreditation of other medical systems. The standards developed by CPA subsequently formed the basis of an international standard for medical laboratories (ISO 15189).

What else needs to be assessed?

Laboratory accreditation concentrates on the laboratory. It is generally accepted that if a CPA-accredited laboratory is given a specimen to analyse, it can be relied upon to produce an accurate result.

But good laboratory medicine needs more than that.

- **It needs systems to ensure that tests are being appropriately selected for use and to ensure that results are being appropriately interpreted.** This is increasingly important as newly qualified doctors in the UK have received much less instruction on these matters than their predecessors.
- **It needs systems to ensure patient safety** – that the right sample is actually in the right bottle, is delivered in a timely manner, and that the report is read, understood and acted upon by the appropriate clinician.
- **It needs to maximise efficiency.** This has two aspects. Money wasted in the laboratory is money that could have been spent on patient care, whether in the laboratory or elsewhere. But sometimes additional money spent in the laboratory can save money elsewhere – by reducing length of stay in hospital, by ensuring the right drug is used or by avoiding the need for other expensive investigations. A good medical laboratory service maximises its own efficiency *and* that of medical services that use it.

These issues were clearly identified by Lord Carter in his review of NHS pathology services in England and Wales.

Lord Carter's report is now mainly referred to in respect of just one of its many recommendations; that up to 20% of cost could be reclaimed by consolidation of services and improved efficiency. However, that recommendation was actually well down a long list of recommendations. The first and second recommendations listed in that report were:

- 1. Objective and measurable quality standards should be developed for pathology services, from sample request to delivery of interpreted result**
- 2. The accreditation process should be reviewed so that it inspects against the quality standards (once developed) referred to in Recommendation 1**

The use of the phrase "**from sample request to delivery of interpreted result**" is a clear reference to the importance of the 'end to end' pathology service. It means that the evaluation of quality is not confined to events within the laboratory.

In October 2009, before Lord Carter's final report was published, a meeting had been convened by the Royal College of Pathologists entitled 'What is Quality in Pathology?' The report of that meeting set out a consensus on what aspects of quality need to be considered if the whole 'end to end' process is to be evaluated.¹ It explicitly included efficiency as an important aspect of quality.

That meeting also emphasised the need for sustainability of the service. A system that does not train the staff needed to provide the service in years to come, or is unstable for any other reason, is not a high quality system.

Unfortunately it provided little guidance on how these aspects of quality should be evaluated in a consistent and reproducible manner. Nor did it indicate how the results should be reported, how overall conclusions should be drawn.

More recently, the Department of Health has put great emphasis on the measurement and promotion of quality, largely through the work of the National Institute for healthcare and Clinical Excellence (NICE). This work has focused on specific care pathways. While logical and laudable, this approach underestimates the important influence of laboratory medicine, because laboratory medicine affects *all* care pathways. Indeed, laboratory diagnostics are often most important in deciding which care pathway a patient enters. Measuring the outcome of care pathways usually ignores events before the pathway starts.

A recent RCPATH publication on the reconfiguration of pathology services² states:

The only 'real' test of the quality of a medical laboratory service is its effect on patient outcomes. Anything else is a surrogate measure. Direct measurement of effect on outcomes is rarely possible, so surrogate measures have to be used, but their limits must be understood and a suitable spread of measures is essential.

¹ http://www.rcpath.org/resources/pdf/rcpath_quality_meeting_draft_13.pdf

² http://www.rcpath.org/resources/pdf/reconfiguration_of_nhs_pathology_services.pdf

The available 'spread of measures' did not adequately evaluate the crucial pre-analytical and post-analytical aspects of 'end to end' laboratory quality. There have been several attempts to resolve this. The RCPATH recently published a set of 'Key Performance Indicators' (KPIs) that focus on these areas³ and the Association of Clinical Biochemists has published a set of Quality Indicators for the clinical laboratory⁴, which address pre-analytical aspects, post-analytical aspects and sustainability of the service.

Increasing laboratory specialisation has also led to complaints that methods for evaluating 'routine' medical laboratory services may not be well suited to the evaluation of highly specialised or newly developing services, such as molecular pathology laboratories.

How should the results be reported?

Lord Carter's second recommendation clearly anticipates that these 'end to end' measurements of quality will be evaluated and published through the system of laboratory accreditation. But the current CPA accreditation has several problems in this respect.

- The publicised outcome of CPA's evaluation of a laboratory is a simple pass or fail; accredited or not accredited. More detailed reports are generated for laboratory managers, but these are not normally publicised. This has the great advantage of simplicity. To an external user, an accredited laboratory can be trusted to produce a reliable result. But this binary decision makes it inappropriate for CPA to measure and to demand high standards in areas that may not be controlled by the laboratory managers who seek accreditation – such as phlebotomy, specimen transport and the delivery of results.
- If a laboratory is accredited, no information is provided to those outside the laboratories (such as commissioners) on where the laboratory's performance exceeds CPA's demands. Thus, excellence is not rewarded.
- If a laboratory is not accredited, no information is provided to those outside the laboratory on where the problems lie. Historically, CPA accreditation has quite often been refused as a result of an antiquated mortuary, which is mainly of importance to the local coroner; thus a failure of accreditation might be quite irrelevant to (for example) local primary care services.
- Laboratory accreditation hinges around the biennial inspection. Significant alterations occurring before that review should be self-reported, but there is no penalty for failing to do so. Laboratory accreditation status may therefore fail to give an up to date evaluation of quality.
- Different groups can have radically different perceptions of what represents quality. This is supported by a recent report on the opinions of patients and general practitioners,⁵ which highlights many aspects of quality not covered adequately by current accreditation processes.
- Many laboratories have to satisfy statutory regulators (such as the Human Tissue Authority and the Medicines and Healthcare products Regulatory Agency). These organisations have standards that overlap to a significant extent to those of CPA, but they are not entirely

³ http://www.rcpath.org/resources/pdf/key_performance_indicators_in_pathology_3_2.pdf

⁴ Barth JH. Selecting clinical quality indicators for laboratory medicine. *Ann Clin Biochem*, in press

⁵ <http://www.strategicprojectseoe.co.uk/uploads/files/Views%20from%20patients%20and%20GPs%20FINAL.pdf>

congruent. As a result, laboratories have to satisfy overlapping assessment and inspection regimes; it is not unknown for there to be two independent inspection teams on site at the same time. This is not efficient.

If those who have to commission laboratory services demand CPA accreditation (and they have no obligation in law to do so) the process gives them no further information on how to evaluate a service. **Market forces only work if the purchaser has tools to evaluate the quality of a product. For reasons given above, purchasing decisions based only on accreditation status and price would risk being seriously flawed.**

The meeting on October 26 2011 and subsequent consultations were designed to suggest solutions to these problems.

Process

Invitations to the meeting were based initially on the list of those who attended the 2009 meeting on evaluating quality, but extended to ensure representation from key areas including patient representatives, general practice, those with responsibility for commissioning pathology services and private sector laboratories. Some invitees were unable to attend but nevertheless contributed by email, both before and after the meeting.

Before the meeting, a copy of the current version of CPA's 'Standards for the Medical Laboratory' was edited to insert the RCPATH's Key Performance Indicators and the ACB's recently published Quality Indicators. These were inserted at what appeared to be relevant points in the CPA Standards, highlighted in different colours, to suggest how the current assessment process might be modified to collect additional data.

At the meeting, the following presentations were heard.

- Professor Peter Furness (President, RCPATH) set out the nature of the problem and the aims of the meeting, including much of the material described in the opening sections of this report.
- Dr Rachael Liebmann (Assistant Registrar, RCPATH) described the development of the RCPATH's Key performance Indicators.
- Dr Julian Barth (Past President, ACB) described the development of the ACB's Quality Indicators.
- Dr Ian Watson (President, EFCC) described his experience of a recently developed Australian system to evaluate aspects of pre-analytical quality.
- Mr Paul Stennett (Chief Executive, UKAS) set out how CPA might amend its processes to satisfy the changing demands for evaluation of laboratory quality, and the constraints. Specifically, he emphasised that CPA can evaluate laboratories against defined standards, but it is not qualified to identify and define those standards; that is a task for the professional bodies, working in consultation with others.

Participants were then divided into six tables. Each table was asked to consider the problem from a different perspective:

- Patients
- Laboratory managers
- Service users – primary care
- Service users – secondary care
- Commissioners
- Statutory regulators

Each table was asked to address two questions:

- What would you like to see in a CPA report on laboratory quality that's designed to help you do your job?
- Which items should be included in a more regularly-updated 'Pathology quality dashboard'?

After about 45 minutes each table was invited to summarise its conclusions and discussion was invited.

An initial draft of this report was written and was circulated amongst those present for email discussion and refinement.

A modified version was discussed by RCPATH Council on 10th November 2011.

The draft report and the suggestions for new standards were subjected to online consultation with pathologists, service users, patients and commissioners using 'SurveyMonkey' (www.surveymonkey.org). 275 responses to the survey were received.

The draft was modified in the light of that consultation, with the benefit of further input from the lead authors of the RCPATH's 'Key Performance Indicators' (Dr Liebmann) and the ACB's 'Quality Indicators' (Dr Barth).

This final version has been provided to pathologists to invite their participation and submitted to CPA to recommend alterations in the accreditation process.

Recommendations

Recommendations pertaining to the current system of accreditation

The current approach to laboratory accreditation needs to be maintained. It may not be sufficient for all circumstances, but it is necessary for many. Laboratories that achieve accreditation against CPA standards (or the closely related ISO15189) are widely recognised as being competent to undertake medical laboratory work. Many laboratories that undertake commercial work, especially for overseas clients, find that having ISO 15189 accreditation is essential. Consequently this service must be maintained. The ISO standards are the result of an international consensus so they cannot be modified by CPA; but CPA's work to make demonstrating compliance with those standards quicker and simpler is commended.

Laboratories should be permitted to declare the scope of activity that is accredited. The obvious problem that needs to be corrected is the situation where a laboratory cannot achieve accreditation because of a problem that affects only one specific part of the service (such as the mortuary) and the rest of the service is unaffected. The other consequence of this change is that laboratories may wish to seek (and publicise) accreditation of highly specialised services, such as molecular pathology.

At present we believe that the definition of 'scope' should be broad, i.e. by laboratory discipline, rather than specific tests being accredited. CPA should develop a list of headings against which the scope of a laboratory can be defined (e.g. cellular pathology, microbiology, virology, blood sciences, immunology). CPA should establish or consult specialist working groups to consider how the current standards should be interpreted in more specialist areas and whether any additional standards are needed for specialist areas. Such specialist areas might include molecular pathology, genetics, embryology and others.

The process of assessment should be explicitly applied to the whole laboratory service, as delivered to the patient. It should not just assess the laboratory. It must cover the 'end to end' service, including aspects that are partly or wholly outside the control of the laboratory, such as phlebotomy, transport, results delivery, demand management. It should include education and training, not just of laboratory staff but of laboratory users. The consequence of this is that the report of the evaluation must identify these aspects separately, so that it is immediately obvious where any problem lies and who has the responsibility to correct them. When evaluating an 'end to end' service, a simple 'pass/fail' result is inadequate.

Each time a laboratory service is inspected, CPA should compile a report of areas where the CPA assessors regarded the performance of the service to be particularly commendable and, if accreditation was not achieved, a list of reasons why the service failed. (It is of course perfectly possible that a laboratory which does not achieve accreditation may nevertheless have areas of outstanding performance). **These reports should be published on the CPA website against the name of the laboratory.** In that way, the strengths and weaknesses of each service can be made known to all. The attention of commissioners and regulators can be drawn to any problems, facilitating an evaluation of their seriousness.

The following 'Additional Performance Indicators' are proposed. These are **not** intended to form part of the accreditation process because they go beyond the requirements of ISO15189. They reflect areas of quality that are very important, but some of them may not be in the direct control of the laboratory.

They are called 'indicators' rather than 'standards' because the word 'standard' implies the existence of a specific level, below which performance is unacceptable and above which performance is all that could reasonably be asked for. This risks suggesting that further effort to improve is not required. Many of the indicators are quantitative measurements and it is counter-productive to impose this binary division. However, the corollary is that it should be possible to compare the results of a quantitative measurement of one service against the result of the same measurement of another service. This demands considerable transparency in the publication of externally verified results.

The results of assessment against these Additional Performance Indicators should be reported and published by CPA after each CPA inspection, whether or not CPA/ISO15189 accreditation is achieved. If the laboratory service has not collected the information needed to assess against a performance indicator, or if an indicator is not relevant due to the laboratory's scope, that should be stated. Some of them should be self-reported at least every 3 months (see the section on a 'Pathology Quality Dashboard' below). For these items, the CPA inspection process should include a check that the results of each published 'dashboard item' are being collected and published accurately. If not, the nature of the problem should be published on the CPA website.

Additional Performance Indicators

In these indicators, when the word ‘publish’ or ‘published’ is used it means, as a minimum, publication on a website that is accessible and searchable from the open Internet, in a form that is understandable by an intelligent lay reader.

It will be perfectly acceptable, indeed helpful, for laboratories to provide explanations as part of such publication, both to highlight excellent performance and to explain justifiable reasons for poor figures. However, such text should be brief and must not hide the messages from the figures. Its accuracy and acceptability should be evaluated as part of each CPA site visit.

Additional Performance Indicator: Provision of senior staff.

All medically-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.

Measurement: Compliance or non-compliance.

The laboratory service shall calculate (in terms of whole-time equivalent staff) and publish the proportion of staff employed to deliver the laboratory service who actively provide laboratory oversight and clinical advice at consultant or consultant-equivalent level.

Measurement: Percentage of staff, broken down by specialty.

NOTE: See also Additional Performance Indicators on appraisal and CPD

Additional Performance Indicator: Senior staff cover and handover.

There shall be documented and named cover for planned leave of staff delivering clinical advice and laboratory oversight. The evidence shall be in the form of rotas with identified staff names with appropriate skills to deliver the out of hours service. Where such cover is less than 24/7, such exceptions shall be published and justified with reference to the need of service users. (It is recognised that 24/7 cover is not necessary in some disciplines)

There should be no reduction in the quality of clinical advice given or turnaround times when cover is provided. Any requirement for changes to patient pathways during cover or handover shall be made clear in the user information.

Measurement: Compliance or non-compliance.

Additional Performance Indicator: Senior staff appraisal.

All senior staff providing laboratory oversight and clinical advice at consultant or consultant-equivalent level (i.e. independent practice, medical and scientific staff) shall have completed annual appraisal or shall have documented approval from their Responsible Officer or clinical line manager to defer.

(It is recognised that after compulsory medical revalidation has been implemented this may become superfluous for medical staff, but it will remain important for non-medical staff with equivalent status)

Measurement: The proportion of such staff who, have a completed appraisal within the preceding twelve months or have documented approval from their Responsible Officer or clinical line manager to defer.

Additional Performance Indicator: Senior staff CPD.

All senior staff providing laboratory oversight and clinical advice at consultant or consultant-equivalent level (i.e. independent practice, medical and scientific staff) shall be registered for

Continuing Professional Development with the Royal College of Pathologists or the Royal College of Physicians, or equivalent, and must satisfy the requirements of the scheme.

(It is recognised that after compulsory medical revalidation has been implemented this may become superfluous for medical staff, but it will remain important for non-medical staff with equivalent status)

Measurement: Percentage of such staff who are so registered.

Additional Performance Indicator: Training future laboratory staff.

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.

NOTE this does NOT relate to CPD of staff in non-training posts

Measurement: Proportion of the aggregate of staff in training in BMS, clinical scientist and medical staff groups, measured separately and published at least annually.

If the stability of the service is to be maintained, it is expected that the result will be between 15 and 30% of the aggregate of fully-qualified BMS, clinical scientist and medical staff respectively. If not, an appropriate explanation shall be published along with the figure, setting out why a high figure does not compromise service quality or why a low figure is unavoidable and does not produce a commercial advantage against similar laboratories which do train new staff..

NOTE that the Government has discussed imposing a levy on service providers that do not undertake training of new staff.

Additional Performance Indicator: Undergraduate, Postgraduate & Primary Care Teaching.

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

The laboratory shall publish a brief description of its educational activity and shall provide an estimate of the total number of contact hours spent by laboratory staff teaching medical undergraduates, non-medical undergraduates, postgraduate medical staff and postgraduate non-medical staff EXCLUDING teaching provided to laboratory staff. The accuracy of this description shall be reviewed by CPA assessors during each site visit and modifications may be demanded.

Measurement: Compliance or non-compliance.

Additional Performance Indicator: Integrity of data transmission.

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. These shall include the use of the designated analyte name, appropriate test code (Read or SNOMED-CT) and units of measurement, as defined in the National Laboratory Medicine Catalogue (or, prior to implementation of the NLMC, the Pathology Bounded Code List)

There shall be regular audits of compliance (at least annually, more often if an audit identifies any non-compliance), with results available for evaluation by CPA assessors.

Measurement: Compliance or non-compliance.

NOTE: The Pathology Messaging and Interoperability Board (DH England) has produced proposed standards.

Additional Performance Indicator: Demand management.

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.

The nature of the demand management system is not specified, but a description shall be published by each laboratory for the benefit of users and commissioners. The accuracy of this description shall be reviewed by CPA assessors during each site visit and modifications may be demanded.

Measurement: Compliance or non-compliance.

Additional Performance Indicator: Test repertoire.

The published repertoire of available tests (see CPA standard E1,2j) shall include all tests from the National Laboratory Medicine Catalogue (NLMC) that are relevant to the clinical practice of the users of the service, whether by in-house analysis or outsourced (sent away).

The published list of available tests shall make explicit the proportion and types of tests which are outsourced to other providers and shall specify and document the CPA status of these provider laboratories to allow the CPA visitors to make comments on the CPA status and/or any concerns they may have regarding these other provider laboratories.

The repertoire shall be regularly reviewed (in conjunction with clinical specialist users) and the frequency of review shall be stated.

The laboratory shall not offer out of date tests or tests with no clinical utility.

The laboratory shall ensure that current national recommendations for use of tests are implemented.

The laboratory shall establish the utility of new tests prior to introduction.

*The laboratory shall publish the number of NLMC tests that are **not** available (and in the interest of transparency may wish to publish a full list, to demonstrate that the exclusions are reasonable). The laboratory shall be able to justify each test on this list.*

Measurement: Compliance or non-compliance.

Additional Performance Indicator: Point of care testing.

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. As these are often contentious, the POCT repertoire documentation shall make explicit the areas where pathology service quality management input has been agreed. These pathways to be signed off by appropriate clinical and scientific managers in all involved organisations.

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

Laboratories shall ensure that accreditation is in place for POCT within this list.

Measurement: Compliance or non-compliance.

Additional Performance Indicator: Patient opinions.

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.

It is recognised that this will be a new activity for many pathology laboratories. It is therefore anticipated that further guidance on what represents acceptable and good practice will be produced by the RCPATH as experience accumulates. A draft questionnaire has been developed by the Lay Advisory Committee of the RCPATH.

Measurement: Compliance or non-compliance.

Additional Performance Indicator: Documentation of histopathology second opinions.

- a) There shall be documentation of MDM or other histopathological review and discussion in a way that allows the number of cases so discussed to be identified. Cases discussed at meetings where a pathologist does not actively participate in person or by teleconference shall not be regarded as having been reviewed.*
- b) Where this quality assurance process results in any alterations to the report, there shall be a method to identify the number of amended reports so issued.*
- c) The laboratory shall calculate the number of specimens that justify MDM review, and state how that number is derived (e.g. by virtue of SNOMED coding as 'malignant').*

The laboratory shall calculate and publish the ratios a:c and b:c, as defined above, in the form of percentages, updated at least annually..

Additional Performance Indicator: Histopathology reporting of cancer resections.

Cancer resections reported shall be reported using a template or proforma including RCPATH cancer data set information (where available).

Measurement: The percentage of such cases reported using a proforma shall be recorded and published.

Additional Performance Indicator: Monitoring histopathology delayed reports.

Each histopathology 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.

Measurement: The percentage of histopathology cases that are not reported (i.e. final report) within 20 calendar days shall be reported and published. It is recognised that some areas of histopathology reporting can take longer for good reason, e.g. post-mortem neuropathology. If a laboratory manager feels that this is adversely affecting their overall result, the published result may be broken down into broad categories of specimen to provide a more detailed explanation.

Additional Performance Indicator: Long term stability of methods.

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.

Measurement: Compliance or non-compliance.

Additional Performance Indicator: Communication of results directly to patients.

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).

Measurement: 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.

NOTE: '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 guidance published by RCPATH and RCGP at

http://www.rcpath.org/resources/pdf/rcpath_results_direct_statement_v12.pdf)

Additional Performance Indicator: A&E blood sciences turn-around-times.

Measurement: The proportion of blood sciences investigations from A&E completed and reported within 1 hour of receipt by the laboratory (including out of hours) shall be recorded and published. (The indicator will move to 1 hour from sample collection by April 2015). The result shall be published and updated on at least a monthly basis.

Additional Performance Indicator: Histopathology reporting turnaround times.

Measurement: The proportion of all histopathology and diagnostic cytology final reports that are reported, confirmed and authorised within 7 calendar days of the procedure and within 10 calendar days of procedure shall be recorded and published. This includes specimens that require further investigation e.g. immunohistochemistry.

It is recognised that some specimen types may legitimately take longer than others so some laboratories, notably highly specialised laboratories such as neuropathology or ophthalmic pathology, may have justifiable difficulty with this indicator. Laboratories who believe they are so affected may also publish equivalent figures pertaining to specific specimen types (e.g. diagnostic biopsies) to provide an explanation of what might otherwise appear to be a poor result.

Additional Performance Indicator: Cross-matching of deceased donor transplantation.

Measurement: The proportion of deceased donor solid organ transplant HLA antibody test results communicated within 12 hours and 8 hours of the sample being taken shall be recorded and published. . Exception reports shall be completed and reported for all deceased donor transplantation cross-matching requests which are not reported within 12 hours of the sample being taken

(It is self-evident that this indicator only applies to transplant laboratories)

Additional Performance Indicator: Routine antenatal screening tests for Hepatitis B, HIV, Syphilis, and Rubella susceptibility.

Measurement: The proportion of routine antenatal screening tests for Hepatitis B, HIV, Syphilis, and Rubella susceptibility reported, authorised and electronically available to requestor within 6 calendar days from sample being taken shall be recorded and published.

Additional Performance Indicator: Late presentation antenatal screening tests.

Measurement: The proportion of antenatal screening tests performed on women presenting late (as defined in standard obstetric practice) or in labour reported and actively communicated to requestor within 24 hours from sample being taken shall be recorded and published.

Additional Performance Indicator: Turnaround times linked to patient pathways.

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 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.

Measurement: Compliance or non-compliance.

Additional Performance Indicator: Critical results communication.

The laboratory shall have a document defining what results shall be phoned urgently to a responsible clinician (see CPA Standard G1.1b). If that policy involves a professional decision whether or not to phone a candidate result the then laboratory shall have a clear statement of who does this, how it is done and hold records of decisions taken. If a clinical decision is made not to phone a result, the reason shall be documented. Communication of out of hours critical results shall be in keeping with RCPATH and RCGP guidance unless local agreements over-ride.

Measurement: The proportion of critical results phoned/actively communicated by laboratory to a responsible clinician within 2 hours of result being available to the laboratory shall be recorded and published, broken down by discipline (this includes out of hours, which may be reported as separate figures).

Note: The definition of results that shall be phoned urgently to a responsible clinician must be reviewed by CPA assessors to assess its suitability. The professional bodies should collaborate to produce a recommended definition. It is recognised that comparisons between laboratories will be of little value until such a definition is available and is in use.

Additional Performance Indicator: Clinical Advice Availability.

Biochemistry, Haematology and Medical Microbiology and Virology clinical advice shall be available 24 hours a day 7 days a week 365 days a year.

This shall be demonstrated by the existence of appropriate rotas identifying named individual with appropriate skills to deliver the service, with mechanisms to allow them to be contacted. Laboratories should undertake a random audit of availability on at least an annual basis and publish the result. The accreditation body (CPA) shall have the right to attempt to contact the individual providing such advice at any time, without prior warning. Failure to make contact will result in more detailed scrutiny, potentially including an externally supervised audit.

Measurement: Compliance or non-compliance.

Additional Performance Indicator: Timeliness of responding to requests for clinical advice.

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 in out-patient clinic, ward round or teaching activity), then 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. However, for genuinely urgent calls, all departments shall have a system whereby clinical advice can be accessed within 30 minutes.

Response times longer than 30 minutes to be self-reported by pathology services.

Measurement: Number of days each year when the standard is not achieved.

Note: This is self-reported, but the accreditation body (CPA) shall have the right to attempt to contact the individual providing such advice at any time, without prior warning. Failure to make contact within 30 minutes will result in more detailed scrutiny, potentially including an externally supervised audit.

Additional Performance Indicator: Quantitative User Satisfaction Survey.

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 commencing in 2012. The survey shall include questions about the availability and quality of clinical advice.

Measurement: The results of the survey shall be published annually, with documentation of trends from previous years.

NOTE: The RCPATH offers such a survey; it generates numeric scores and potentially allows benchmarking against the levels of user satisfaction produced by other laboratories in addition to changes over time. More information is available at <http://www.rcpath.org/index.asp?PageID=1669>.

Additional Performance Indicator: Analytical EQA schemes.

Pathology services shall participate in CPA accredited EQA schemes, if available, covering all analytical areas of the service repertoire. In the absence of a CPA accredited EQA scheme covering the area, the pathology service shall participate in an alternative EQA scheme covering this aspect of the service repertoire. The pathology service shall make alternative arrangements for quality assurance if no EQA scheme exists. The registration and laboratory performance records for all analytical schemes relating to tests and profiles in the repertoire shall be available for CPA visits.

Performance records for all analytical EQA schemes related to the service repertoire to be available for piloting in 2012 CPA visits.

Measurement: Compliance or non-compliance.

Additional Performance Indicator: Interpretive EQA schemes.

Interpretive EQA scheme participation shall be undertaken as a minimum by the lead / MDM lead in each area covered by the service repertoire.

Participation records (i.e. individual performance scores) for all lead / MDM lead histopathologists in relevant interpretive EQA schemes related to the service repertoire to be available for inspection during CPA visits on a confidential basis.

Measurement: Compliance or non-compliance.

Additional Performance Indicator: EQA scheme results.

A report of performance in all quantitative EQA schemes shall be published using a standard format.

NOTE: UKNEQAS should be invited to design such a report for analytical schemes. This does not apply to interpretive schemes that relate to the performance of individual pathologists.

Measurement: Compliance or non-compliance.

Additional Performance Indicator: Incident and error reporting.

Laboratories shall ensure there is a log for documenting laboratory based errors and shall demonstrate evidence of measures introduced to reduce chance of similar future errors

NOTE: This will include adequate responses and appropriate actions taken in response to poor performance letters from EQA and to laboratory errors.

There is a need for a clear definition of the types of incident that should be recorded. A potential model is available in the 'Key Incident Monitoring and Management System' developed by the Royal College of Pathologists of Australasia – see <http://www.rcpaqap.com.au/kimms/objectives.cfm>. This scheme includes an element of "benchmarking" with other comparable laboratories, but such results have to be interpreted with care because they can be heavily influenced by under-reporting

Measurement: Compliance or non-compliance.

Information for a 'Pathology quality dashboard'

The 'Additional quality indicators' include numerous items where detailed information shall be published by the laboratory, but the frequency of updating the information is in some cases not defined other than by the frequency of CPA inspections.

However, the following items are suggested as ones that should be self-reported and published, with the information being updated on a more frequent basis – perhaps every three months? The veracity of the self-reporting should be checked as part of a CPA inspection every two years.

- The proportion of investigations from A&E completed and reported within 1 hour of receipt by the laboratory (including out of hours)
- The proportion of biochemistry, haematology, medical microbiology and virology critical requests phoned/actively communicated by laboratory to a responsible clinician within 2 hours of result being available to the laboratory
- The proportion of all histopathology and diagnostic cytology final reports that are reported, confirmed and authorised within 10 calendar days of procedure
- the number of days in which the laboratory fails to respond within 30 minutes to one or more requests for clinical advice (including out of hours).
- the percentage of results actively delivered directly to patients (if none, state 'none')

Different reports for different purposes

It is self-evident that several different groups have an interest in reports on the quality of medical laboratories, but their needs and priorities are different.

The meeting on October 26th 2011 was not sufficient to define the needs and preferences of different user groups, but some preferences were recorded. For example:

- **Patients** probably assume that laboratory results are correct; to ensure that this assumption is justified they should be warned if they are using a laboratory that does not have accreditation to ISO15189. More detailed information about the quality of 'their' laboratory should be available online for those who want to know. Some of this should be published by the laboratory (e.g. in a quality dashboard) but CPA should also publish more information about individual laboratories than it does at present (including verification of the laboratory's self-reporting processes).
Patients wish to have access to clear information about laboratory tests (pre-requirements such as fasting etc as well as explanations of the meaning of results) and to know when results will be ready. They wish to be reassured that if a result justifies action, then action will be taken in a timely manner. Patients with long-term conditions are often keen to have direct access to laboratory results, or at least to be informed when their results are available.
- **Commissioners** probably do not want the detail underlying ISO15189 accreditation if it has been achieved, but if a laboratory does not have such accreditation they should be informed and will want to know why. Information about the implementation of demand management

systems is likely to be relevant, as is a quantitative assessment of user satisfaction. A report in two parts would probably be welcome; one on the internal workings of the laboratory (largely based on current CPA data) and one on the 'external' aspects, provided largely by the 'Additional Performance Indicators'. In addition to cost, commissioners are particularly likely to be interested in IT (order communications and report delivery), turnaround times, availability of clinical advice, sample logistics and demand management.

- **Primary and secondary care physicians and surgeons** value a clear definition of the available test repertoire and ready access to high quality advice on the selection and interpretation of tests. They are concerned that results should be reported swiftly, or at least that they can rely on the result being available within a defined period of time. They wish to be able to rely on critical results being communicated to them in a timely and meaningful way. Support for POCT is valued in primary care. The accuracy of the result tends to be assumed, so they would wish to be actively informed about any reasons for failure to achieve accreditation or anything that might bring the accuracy of results into question (such as poor EQA results).
- **Laboratory managers** want detailed information on all aspects of the service they provide. They also want to know if user satisfaction is being decreased by aspects of the end-to-end service that they do not control directly.

It is recommended that CPA should consult with relevant groups and jointly design reports, based on the data collected in a CPA inspection, that best satisfy the needs of each group.

Involvement of statutory regulators

As is noted above, there are at present systems of assessment and inspection that are imposed by statutory regulators that overlap to a greater or lesser extent with the CPA system. This is inefficient.

Unfortunately the only statutory regulator represented at the meeting was the Human Tissue Authority, which has interests in relatively specific and restricted aspects of laboratory work.

It was nevertheless suggested that the statutory regulators involved should review the CPA Standards (as extended by the Additional Performance Indicators). They should then identify which of the standards satisfy their requirements and request a tailored report from CPA that covers the area they need. If this approach necessitates modification of CPA standards or the introduction of additional indicators, this should be negotiated. If such an approach is not possible, the regulators should consider which of their needs can be satisfied by a compliant report from CPA; their own assessment and inspection processes should then concentrate on areas that CPA does not adequately address, thereby avoiding wasteful duplication of inspection.

List of meeting attendees

Dr Ian Barnes
Dr Julian Barth
Dr Gifford Batstone
Ms Jane Beaumont
Ms Cheryl Blair
Caroline Browne
Dr David Bullock
Dr David Cassidy
Dr Bernie Croal
Ms Sylvia Debreczeny
Ms Barbara De La Salle
Dr Hemal Desai
Dr Danielle Freedman
Dr Bill Fuggle
Professor Peter Furness (Chair)
Dr John Goepel
Dr Andrea Harmer
Mr Phil Hudson
Professor James Ironside
Dr Rachael Liebmann
Dr Suzy Lishman
Mr Tom Moloney
Professor Sir Duncan Nichol
Mr Joe O'Meara
Professor William Roche
Mr Dan Smith
Mr Paul Stennett
Ms Jan Stewart
Dr Michael Thomas
Dr Anne Thorpe
Dr Ian Watson
Professor Mike Wells
Ms Doris Ann Williams