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

Reconfiguration of NHS Pathology Services

A Statement from The Royal College of Pathologists

Executive Summary and Table of Contents

Reorganisation and consolidation of medical laboratory services can offer considerable benefits, but the complexity of the task must not be underestimated. It is therefore essential that pathologists, who by their work understand such complexity and have the best interests of the patients at heart, provide leadership in this project.

This statement is written in the context of an urgent need to reform pathology services in the UK to achieve more efficient use of resources.
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In part, this document builds on the report of a Royal College of Pathologists meeting entitled '**What is quality in pathology?**', available at www.rcpath.org/resources/pdf/rcpath_quality_meeting_draft_13.pdf. It considers the application of the conclusions of that meeting in the light of Lord Carter's reports on the future of NHS pathology services, in the current setting of more limited health service finance.

Rationalisation, consolidation and contracts

NHS laboratory services must work within increasingly tightened financial constraints to maximise efficient output and quality and to cope with a steady increase in demand, including more sophisticated and expensive investigations. If such demands are to be met, service delivery must be rationalised, at least in part by improved networking of laboratories.

It will be difficult for commissioners and planners to appreciate what constitutes high quality and efficiency in pathology services because there are no agreed definitions, nor are there well-developed metrics relating to outcome. As a consequence, they might struggle to manage contracts effectively, or they might agree to contracts that unwittingly result in a lower standard of service than that currently provided by NHS laboratories. They will need sophisticated skills and knowledge to test the cost-effectiveness of those providing pathology services.

Radical reform and managerial control should improve productivity and quality in any health care system.

Reform

1. **Response to need**
   A good frontline clinical service must have a closely integrated pathology service. Pathology services should be more responsive to users' requirements. In particular, phlebotomy and sample collection services should be made more accessible and convenient.

   Clinical services stretch across whole communities. In many regions NHS pathology services have developed mainly in response to the needs of acute hospitals, not the community. Provision corresponding more closely to overall need should lead to greater productivity and quality. Laboratories which exist only because of the assumed needs of a local hospital could be reduced in number, size and scope (see 2 and 3). For example, not all hospitals require on-site microbiology or transfusion laboratories.

2. **Consolidation of laboratories**
   At present there are too many laboratories too close together, each undertaking a similar large repertoire of tests. There is the prospect of economy of scale by consolidation in such circumstances.

   Some very specialised tests are already consolidated in small numbers of centres (e.g. by central funding through the National Commissioning Group). These demonstrate that such centralisation can ensure quality and improve links with academic departments to facilitate research.

Concentration of the 'cold' analysis of large numbers of samples for a far greater range of tests could, in many situations, lead to improved efficiency and improved overall quality of service, providing there is good transport and IT support. These two items are crucial and will usually demand investment. They should be under the control of the management of the consolidated laboratory. The operational success of rationalisation of pathology services will be heavily dependent on efficient and reliable IT homogeneity and connectivity within any given network. Complete uniformity of reference ranges and units of measurement and reliable methods for identifying patients (ideally NHS number) are obvious prerequisites.

However, there is no single formula that is suitable for all tests and for all populations. A division into 'hot' tests (where urgency demands analysis in a local laboratory) and 'cold' tests (which can be delivered by a more distant laboratory serving a much larger population) is a gross oversimplification of the clinical problem. First, the urgency of different tests varies considerably, not only between different tests, but on the circumstances of the individual patient. Second, this approach ignores the fact that some 'cold' tests require very close clinical integration. This is particularly true where the laboratory output is an opinion rather than a measurement. For example, most histopathology tests are 'cold' but clinical interaction, for example at multidisciplinary team meetings, is vital. Third, if a unit needs a 'hot' blood sciences laboratory running 24/7, there are likely to be times when its staff and machines would be idle if not utilised to deliver tests that would otherwise be considered 'cold'. Similarly it will be difficult to maintain 'hot' histopathology services (frozen sections, fine needle aspirate clinics) if a core histopathology laboratory is geographically distant.

Thus the optimal configuration of laboratory services represents a complex balance, not a binary split, and will need careful design depending on local needs. Population density and geography will influence the optimal configuration. In some circumstances point of care testing (POCT) devices may satisfy local needs for 'hot' results, but compliance with MHRA guidance on POCT use is essential (MHRA DB 2010 (02).

However, it is undoubtedly the case that most current NHS service providers could achieve greater efficiency through consolidation of 'cold' testing.

The development of consolidated networks demands collaboration and cooperation between local groups of NHS Trusts.

3. Single disciplinarity

Amalgamation of automated chemistry, haematology, immunology and microbiology in single multidisciplinary laboratories has been achieved in some centres but is overdue in many. Multidisciplinary biomedical scientist work is necessary and possible.

4. Maximum ordering systems (MOS)

Uncontrolled over-requesting is rife and acceptable limited requesting for common conditions can reduce requests by up to 40%. Mechanisms to achieve this are discussed below. The development of a national test formulary with authoritative guidance on appropriate test use will facilitate this development. All providers of pathology services (including providers of point-of-care testing) should be required to participate in activities which drive adherence to the MOS.

5. Rebasing

If NHS pathology laboratory services are reconfigured on a hub and spoke basis, hubs should be able to meet both "routine" demand and that of other centralised acute services such as trauma centres, cardiothoracic surgery, cancer MDTs, intensive care units etc. Confounding drivers in 1 and 5 will need careful study, option appraisal and planning.

This new formatting of services will require that objective and measurable quality standards are developed for pathology services, from sample request to delivery of the interpreted result. The evaluation of quality is discussed below.

Managerial control

1. **Multiple purchasers**
   The UK Departments of Health should consider the development of model contracts for pathology, including an agreed national tariff and test formulary. Multiple purchasers need clear guidance on how to manage contracts with multiple providers. These should indicate how to ensure productivity and quality from both provider and purchaser. A national NHS body should monitor purchasers' and providers' conduct of these contracts, encouraging rather than inhibiting productivity and quality through competition. The UK Departments of Health should develop commissioning guidance as a matter of priority.

2. **Multiple providers**
   Commissioners and planners must have the necessary skills to evaluate quality in pathology services in a way that relates to patient outcomes, not merely relying on mechanistic measures such as turnaround time and cost.

   Provided that the conditions for all competitors and providers are equal and performance is properly scrutinised, particularly with regard to Quality Assurance, training, interpretation of results and clinical liaison, competitive contracts with a private provider could encourage rather than inhibit productivity and quality. The contracts should include mandatory accreditation against minimum acceptable standards that are sufficiently sophisticated to reflect the impact on patient outcomes, as discussed below. They should include the quality of the 'end to end' pathology service and factors that ensure the long term sustainability of the service, such as appropriate provision for modernisation, introduction of new tests and training.

3. **Networking of competitors and providers**
   This aspect of the Carter Reports and the Government's response has not been discussed openly. NHS SHAs or regional bodies should have some control over how independent competitors and providers collaborate in networking of centralised laboratories, otherwise potential gains from competition could be lost. IT connectivity must ensure that results are available to doctors in primary and secondary care even if a different provider delivers different parts of the service. This also brings up the question of the comparability of results from different providers, which can require expert review and has been addressed by the 'Harmony' project.

4. **Workforce**
   The laboratory workforce needs to be continuously aligned to the changing needs of the service. Major metropolitan centres that choose to train staff (medical and non-medical) more for their own local needs rather than for those of the whole country, have the potential to reduce trainee numbers. Therefore, knowledge of the necessary contribution that trainees make to the service is essential to ensure productivity and quality. This is hidden currently but will not remain so if funding of trainees is cut. There are no easy answers but there is risk in ignoring this issue.

What is quality?

Impact on patient outcomes

The quality of a pathology service can only be properly evaluated by considering its impact on patients; anything else is a surrogate measurement. Unfortunately, to measure the impact of laboratory services on the huge number and variety of patients that laboratories serve is extremely difficult, so surrogate measurements are unavoidable; but they remain surrogates, so their relevance and power must always be considered.

For example, 'laboratory turnaround time', self-evidently measures only one small part of the process that contributes to patient benefit. Thus, to measure the quality of a laboratory exclusively on cost and turnaround time demonstrates a failure to understand how a laboratory generates benefit for patients. It is analogous to choosing to buy a car simply on the basis of its maximum speed and price, ignoring all other features (such as reliability, ease of use, future maintenance costs and safety).

A proper evaluation of the quality of a laboratory service must include a balanced assessment of the entire, end-to-end service to patients, including:

- **The provision of readily available, high quality clinical advice** on appropriate test use (discussed below) combined with audit of test use, ongoing clinician education on test use and effective demand management (discussed below).

- **The availability, speed and reliability of phlebotomy and specimen transport services.** These services are often not in the control of laboratory managers, but NPSA data suggests that they are the single largest source of patient safety incidents in laboratory medicine so it is essential that they are included in the quality evaluation. This is emphasised by the observation that delivery of the specimen to the laboratory often takes far longer than the intra-laboratory turnaround time.

- **The quality of the laboratory** processes. This is currently subject to evaluation by a number of mechanisms, such as internal audit, laboratory accreditation and benchmarking systems. However, it is important to recognise that the measurement of process quality is merely a surrogate for the measurement of laboratory output quality, which is in turn a surrogate for the measurement of patient outcome quality.

- **The quality of laboratory output**. This is currently subject to evaluation by a variety of processes, including a broad range of external quality assessment schemes; though the results of these schemes are too rarely made public. Users of a laboratory should have access to measurements of the confidence limits (or error rates) of key tests, with national averages and professionally recommended maximum acceptable limits, to permit meaningful interpretation.

- **The speed and reliability of results delivery.** Although often outside the control of laboratory management, this is the second commonest source of patient safety incidents reported to the NPSA, so it is essential that it is included in the quality evaluation. A high quality laboratory service will have effective fail-safe mechanisms to ensure that a defined range of 'critical results' are received, understood and acted upon.

These aspects of evaluation of quality apply equally to point of care testing devices and to 'conventional' laboratory services. It is illogical to have different standards depending on the mode of delivery of a test.

Efficiency

A high quality laboratory service must be efficient; otherwise, in a resource-limited service, it is using resources that could benefit patients in other ways. Although the argument is self-evident, this factor has too often been omitted from measurements of quality in the NHS.

This applies to all areas of laboratory practice. The need for demand management, and the need for appropriate training programmes and skillmix, are discussed below. Guidance and protocols that have been developed in the past exclusively on the basis of 'best practice', without explicitly considering efficiency or resource use, should be reviewed with cost-benefit analysis in mind.

Sustainability

A high quality laboratory service must be relied upon to produce high quality for the foreseeable future. This means:

- Appropriate financial resources, stable management and governance

- A programme for replacement and updating of equipment

- A programme for the introduction of new tests and the elimination of obsolete tests (discussed below)

- A training and education programme that not only keeps current staff up to date, but also trains new staff at an appropriate rate to replace those who retire. A system that relies on other units to train its staff, without contributing to the cost of that training, is fundamentally parasitic. This is not a sustainable model when viewed from a national perspective.

Pre-analytical and post-analytical advice

Medical laboratories have always provided guidance on the appropriate use of tests (pre-analytical advice) and on the appropriate interpretation of test results (post-analytical advice). Such advice usually represents a high-level professional consultation and therefore has to be delivered by, or at least under the supervision of, Consultant grade staff. To provide such a service therefore appears to be relatively expensive. However, the cost of ***not*** providing this service will not only result in an inferior service to patients (see the discussion of quality above), it will, in the long term, be far more expensive; not only because of inappropriate and wasteful use of tests (see Demand Management below) but also because it will result in the inefficient use of other health services resources.

Non-medical staff, including senior non-medical managers, sometimes assume that doctors are trained to use and interpret laboratory investigations. This has led to at least one suggestion (thankfully not implemented) that a laboratory could provide a 'results only' service, without the benefit of clinical advice. The fallacy of this belief is obvious to anyone who works in a medical laboratory and is asked to provide advice to frontline clinical staff.

Newly qualified doctors have spent less time than ever before learning how to use a medical laboratory. The new version of 'Tomorrow's Doctors', the GMC publication setting out how medical students should be trained, has 174 paragraphs but only one (No. 8) relates to laboratory investigation. It merely states that a newly qualified doctor should be able to:

(c) Justify the selection of appropriate investigations for common clinical cases.
(d) Explain the fundamental principles underlying such investigative techniques.

Note the requirement only in relation to 'common' cases; note also the requirement only to '*justify the selection*' of investigations, not appropriately to 'select*, use, interpret and act upon*' laboratory investigations.

With experience, doctors do become familiar with the small range of tests that they use frequently. But familiarity does not necessarily mean optimal use and interpretation and the total range of laboratory investigations is huge. So the availability of assistance with pre-and post-analytical advice remains essential, both in relation to the use of less commonly used tests (or the use of common tests in unusual clinical situations) and in keeping senior medical staff up to date with new developments in laboratory medicine. Furthermore, the availability of senior clinical staff within laboratories is vital for the maintenance and future development of the service.

Demand management

The ability to control laboratory workload by eliminating tests that do not add clinical value is crucial to the delivery of an efficient service, but it is difficult to achieve. Laboratory test utilisation has been increasing in the UK for many years. This uncontrolled burden on stagnant laboratory budgets leaves little reserve for service development, thus impeding implementation of new (and existing) technologies, new diagnostic methods and staff development.

There are of course many reasons for the rising demand on laboratory services. They include an expanding repertoire of available tests; increased expectations (of both doctors and patients); financial incentives; government policy; new clinical guidelines; changing population demographics; shifting patient pathways; fear of litigation; and the simple fact that laboratory testing has become easier for doctors, with the introduction of phlebotomy services and improved access to laboratories. Some of this represents a justifiable increase in testing. But there has also been a parallel increase in inappropriate requesting. Such unnecessary testing wastes valuable laboratory resources; but it may also have a further adverse financial impact by stimulating

cascade testing, additional investigation and prolonged unnecessary use of other services. There would therefore be substantial benefits to the whole NHS, not just to laboratory budgets, if test ordering could be rationalised.

Inefficient use of NHS resources is of course generated not only by over-utilisation of laboratory services but also by under-utilisation of tests that could promote cost-effectiveness in other parts of the NHS. The importance of good pre-analytical advice on test use is discussed above.

Modifying test ordering behaviour
How can more appropriate use of tests be encouraged or enforced? A variety of mechanisms have been described to help achieve this.

Financial regulatory controls can be used to limit inappropriate testing for distinct clinical conditions and, if sufficiently sophisticated, financial controls can also be used to reward users for the more appropriate use of under-utilised tests. Returning financial responsibility for diagnostic budgets to the users may itself help reduce inappropriate reflex testing. However, financial controls tend to be relatively crude and cannot fully drive the use of appropriate tests, tailored to individual patient needs.

The user-provider interface provides many opportunities to modify requesting behaviour:

- Explicit justification: a test is only sanctioned following discussion with the laboratory – useful for low volume/high cost tests.

- Request form changes: good design can help promote/avoid particular requesting patterns.

- Disease specific order sets: can guide evidence-based requesting for particular diagnostic presentations.

- Test profile minimisation: ensuring that established test profiles (U&Es, LFTs) only provide the minimum relevant tests, while other related tests are left to discretionary requesting. Consistency of test repertoires, profiles and advice across all laboratories should also be a goal. Benchmarking data and the eventual development of the National Laboratory Medicine Catalogue may help facilitate this.

- Test rationing: introducing rules so that particular tests can only be requested at certain times or frequencies for individual patients or by individual doctors or locations.

Feedback of performance information to requesting clinicians, whether it be audit information about their requesting rates or information about the appropriateness of their test ordering, has been shown to lead to more rational requesting.

The Supply End, when requests have consequences for provision of products or services, e.g. in blood transfusion, can be better controlled using clear, consistent mechanisms such as electronic selection and issue.

Clinician Education can be labour intensive, but if targeted in the form of guidelines or associated with performance feedback, can lead to more appropriate test requesting.

Information Technology Solutions are increasingly being developed, with electronic protocols, algorithms and expert decision support systems guiding evidence-based requesting (or imposing test rationing) according to the clinical circumstances. The use of such sophisticated order entry systems is likely to be an important route to improved efficiency and quality of patient care in the future.

However, the delivery of all these demand management solutions depends, at least to some extent, on the availability of good advice on appropriate test use. Such advice has to be of high

quality and it must have adequate authority if it is to counter the tendency to undertake testing 'just in case', to counter a fear of criticism or even litigation for failing to order a test when the doctor's knowledge of laboratory investigation is insecure. This underlines the need for a national 'formulary' of laboratory tests, giving authoritative guidance in a manner analogous to the service provided by the British National Formulary for drugs. This was recommended by Lord Carter but has not yet been delivered.

Training, staff development and skillmix

It is self-evident that a laboratory needs to have a sufficient number of adequately trained members of staff. However, bearing in mind that a high quality laboratory must deliver an efficient use of resources, a good laboratory will not have highly trained members of staff regularly undertaking work that could be undertaken by less skilled members of staff. It is not enough to have sufficiently skilled staff; staff should not be over-skilled for the jobs they perform. In addition to the waste of resources, over-skilled staff are likely to become disillusioned with undertaking unskilled work and low morale will result.

A suitable programme of training must be available to maintain staff skills. However, it must also be recognised that staff retire and move to other posts. A high quality service must be a service that can guarantee a stable long-term service. Consequently new staff must be trained.

Historically there have always been some centres that have trained more staff than they needed and others that have relied on recruiting such trained staff. That situation is acceptable if there is a source of funding for the service that takes account of the additional cost of training new staff. It is not acceptable if organisations that train staff are placed in direct competition for contracts with organisations that do not. In that situation, organisations that rely on recruiting staff that have been trained by others will be at a financial advantage. The subsequent disadvantage to training units will ultimately destabilise the service.

For some years College curricula have demanded training in the appropriate use of resources. Recently approved and published curricula have reinforced the need for trainees to learn to weigh the cost of all investigations against the clinical gain. In addition, the need for consideration of the resources required for audit and research projects are an integral part of specialist training in these areas. Leadership and management competencies expected from trainees include an understanding of managing resources, i.e. business planning, finance, financial control, costing, pricing, contracting, purchasing and resource management. These are vital skills for providing laboratory leadership and accomplishing the reconfiguration of pathology services needed for pathology modernisation.

Maintaining the repertoire of laboratory tests

Delivering a full repertoire

A laboratory service must be able to deliver all of the investigations that the clinicians it serves may legitimately request. Some tests, probably the more esoteric ones, may be outsourced to other organisations, as long as appropriate quality assurance procedures are in place. But a pathology service provider must offer, by whatever means, the whole repertoire of tests that could legitimately be requested. A provider should not be allowed only to offer a restricted range of commonly used tests, with the expectation that a different contract with a different provider will cover more esoteric needs. Lord Carter recognised that the 'cherry-picking' of high-volume tests could destabilise the providers of esoteric tests, to the ultimate detriment of patients.

New investigations

New investigations should be evaluated on the basis not only of their analytical validity and clinical validity, but also on their clinical utility. Clinical utility includes a cost-benefit analysis, where costs and benefits should be evaluated by the impact of the new test on the whole patient pathway, not merely the impact within the laboratory. This is difficult work; relevant evidence is often in short supply and is difficult to generate. Consequently there is a need for a national body or bodies which evaluate the usefulness of new tests so that these can be introduced as soon and as widely

as possible, if found to be cost effective and have sufficient clinical utility. The National Institute for Healthcare and Clinical Excellence has been charged with this task, but has only been able to consider a small proportion of the new developments in laboratory medicine. It is hoped that the new National Laboratory Medicine Catalogue will also address this problem, but resource is likely to be a problem.

In the interim, there is often no alternative but for local laboratory leads to assess the available evidence and decide whether to introduce a new test. In doing so it is essential that the cost must not be evaluated only within the financial 'silo' of the pathology budget. Introducing a new laboratory test often influences the duration or nature of patient care and the use of other modes of investigation and treatment. For example, introduction of a BNP assay for the evaluation of heart failure should reduce bed occupancy and the use of echochardiography. Consequently it is meaningless to evaluate the cost-benefit ratio of a new test only in respect of its impact within the laboratory. We need to find ways of collaborating across the health economy to understand the influence of tests on the whole patient pathway and to transfer the appropriate investment to pathology where new tests provide overall savings. The converse must also apply and tests of no value should cease.

Any laboratory that makes a decision to implement a new investigation has a duty to monitor its efficacy and impact. This is not only for the benefit of local patients and the local organisation; the results must be published so that others can benefit from the experience gained.

Appropriate mechanisms for quality control must always be implemented before introducing a new test. To establish such mechanisms normally demands coordination and cooperation at a national or international level.

Getting rid of the old

It is self-evident that tests which have ceased to have clinical usefulness or have been superseded by improved assays must be discontinued; but this often causes resentment amongst users who are accustomed to the interpretation of the 'old' tests. It is therefore important to provide appropriate information and training for users. In some cases it may be necessary to run old and new tests in parallel for a period, but this should be minimised in the interests of efficiency.

Introducing new tests and discontinuing obsolete tests represent difficult decisions, but these decisions have to be made. The usefulness of all tests should be audited in order to inform these decisions and the results should be published.

Leadership

To reconfigure NHS pathology services successfully, strong and effective clinical leadership is paramount. As argued by Mountford and Webb (McKinsey) and Darzi in 2008, the key factors for effective clinical leadership include identity and accountability, team working to a common goal, delivering excellent care efficiently, working with managers, administrators and, most importantly, having a patient-centred approach.

Indeed, the Department of Health in 2007 stated that the "*essence of clinical leadership is to motivate, to inspire and to promote the values of the NHS to empower and create consistent focus on the needs of patients being served. Leadership is necessary not just to maintain high standards of care, but also to transform services to achieve even higher levels of excellence*."

The Clinical Leadership Competency Framework (NHS Institute for Innovation and Improvement, May 2008) is crucial to the reconfiguration of the delivery of pathology services. It means having specific personal qualities, ability to work with others, managing services, improving services and setting direction.

The complexity of laboratory medicine, including the factors outlined above, mean that appropriate leadership in laboratory reform can only be delivered by staff who understand the delivery of a

medical laboratory service in its clinical context. Pathologists in the UK have a keen desire and ability to deliver leadership. If reconfiguration is to be effective, pathologists have to take the lead.

The reconfiguration of pathology services is a challenge; but every challenge is a leadership opportunity.

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On behalf of Executive and Council of The Royal College of Pathologists

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