Clinical responses to the downturn

Pathology

The following recommendations were produced by the Royal College of Pathologists to highlight where resources could be released in NHS pathology services, while maintaining or enhancing quality.

Themes

- Intelligent requesting
- Workforce profiles and training
- Efficiency and productivity
- Openness on performance
- New developments and molecular testing
- Intelligent commissioning
- Information technology and disintermediation
- Clinical leadership in pathology
- Who should do what?

Background

The Royal College of Pathologists has been helping to keep pathology professionals informed and in step with financial challenges facing the NHS. This is particularly important given the prominence given to Lord Carter’s reports on NHS pathology services in QIPP (Quality, Innovation, Productivity and Prevention), with QIPP workstreams in every SHA led by the SHA medical directors. In December 2009, the assistant registrar of the College was given the task of providing a link between the Pathology Clinical Director at the Department of Health and the College’s professional membership in addressing the financial challenges ahead for pathology in a thoughtful, clinically sound and effective way.

The need for laboratory managers to be better informed of the QIPP agenda was highlighted at a Siemens-sponsored meeting in Manchester in June 2010. The opening topic was ‘The changing NHS environment and the impact on pathology.’ An interactive quiz showed that over 50 per cent of the lab managers attending had not heard of QIPP.

The NHS Confederation contacted the College in January 2010 to suggest that the organisations work together with other healthcare partners. A focus group was held on 24 August 2010 to explore the existing areas of reforming activity, progress with implementation and identify where further work was needed.

In the interim, and in anticipation of the coalition government’s white paper, Equity and excellence: liberating the NHS, the College published its own statement on pathology service reconfiguration in July 2010.¹

Several themes emerged from the group which met on 24 August.

Intelligent requesting

“If we could stop doing unnecessary laboratory tests, we could at a stroke make efficiency savings that are probably greater than those that are currently being demanded. However, too often laboratories find it easier to do a test than to argue that it is not necessary.”³

In ‘default testing’, tick-box-style request forms nudge clinicians towards doing more tests than is necessary and encourage a habit of ticking all the boxes without thinking. Some teams even pre-prepare forms in advance with all the boxes ticked before seeing the patient.
In ‘active requesting’, clinicians must write on the request form the tests they wish the lab to do. This leads to significant reductions in demand, with no noticeable effect on quality of care.

Alternatively, ‘problem-based’ requesting models encourage clinicians to state questions that they would like answered about the patient, and the pathologist then decides what tests this justifies.

- In Salisbury, when the reason for requesting thyroid function tests was introduced rather than simply requesting thyroid function tests, the use of an algorithm enabled an appropriate response.

- One area that used this model saw a 25 per cent reduction in the number of tests needed. It also led to the reports generated by the lab being more relevant and comprehensible to the clinician as they answered the question posed.

There are also specific issues around the overuse of testing by doctors in training, for whom it is often a medical crutch with tests performed ‘just in case’ when the doctor’s knowledge of laboratory investigation is insecure. The reduction of basic science and pathology in medical education and training needs to be addressed and reversed. This problem emphasises 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 is still under development.

Duplicate requesting for the same patient is common. An effective way of reducing this is to require the use of a patient’s NHS number in the testing process, supported by IT systems that can identify and flag duplicate tests; yet 20 per cent of pathology labs do not routinely use the NHS number and there is frequently no compulsion on requestors.

One local study of an A&E department found that 10 per cent of the test results requested by junior doctors were never looked at. This is a clear area of both resource wastage and poor quality of care. In blood sciences, where urgent cases may be identified at requesting (if IT systems allow), the lab may be able to check whether a high priority result has been viewed after a reasonable period of time. If there is no record that it has been accessed within a reasonable time, the consultant should be notified.

Point of care testing (POCT) has enabled more testing to be done outside the laboratory in ways that may be more convenient for the patient. It is often not the cheapest option, however, and the quality of POCT is variable. There should be compliance with MHRA recommendations in the use of POCT, including links with a pathology laboratory to ensure proper quality assurance. The College would support the introduction of a mandatory accreditation scheme to address this patient safety issue. The evidence on the cost-effectiveness and clinical utility of POCT for some indications is unclear and warrants further investigation, particularly if it leads to duplicate testing in the central lab as clinical colleagues are reluctant to treat patients on the evidence provided by POCT alone.

- 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.
• 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.¹

It was once common practice for local labs to produce occasional reports to GPs on their requesting rates benchmarked against others in the locality. Benchmark reports were an effective and low-cost way of rapidly changing high requesting GPs’ rates. There is a programme in development to introduce this nationally, and the progress of this workstream needs to be clarified and its roll-out fully funded. The study of the profile of pathology services by NHS London revealed a strikingly disproportionate rise in requests from GPs when compared to the rise in the acute hospital setting. The reasons for this are unclear as yet but worth further investigation.

A number of pathology tests not universally available in all parts of the country can be used in place of more expensive imaging tests and are examples of evidence-based clinical practice. The improved quality of care resulting from many of these tests includes a reduced need for outpatient appointments. NHS trust managers may be reluctant to accept this reduction because fewer new outpatient appointments mean a lower income from that source. Their argument fails on two counts: the overall cost of the service rises if patients are referred for unnecessary consultation and procedures without reasoned selection; and people are converted to dependent patients inappropriately. Examples include BNP for possible cardiac failure (obviates the need for an echocardiogram in many cases) and faecal calprotectin for inflammatory bowel disease (can avoid the need for colonoscopy and expensive imaging). Fifty per cent of labs do not offer BNP and very few labs offer faecal calprotectin, despite a NICE guideline. Labs that have introduced such tests have made very significant savings for their health economies. However, as the savings are not made in pathology it is difficult for pathologists to build business cases for implementation unilaterally, especially where the savings rely on a reduction in activity in another department.

Where local pathologists are in regular and close contact with their colleagues in the acute hospital and in the community (GPs in particular) they are effective in spreading this kind of best clinical practice. This is relatively less difficult in non-metropolitan areas than in our inner cities where the challenge is greater. In any given area of the NHS, however, it does require the participation of more specialties than pathology and the attention and interest of NHS managers. The NHS Confederation and the College will push messages actively, through this project and using appropriate media outlets, such as the Health Service Journal.² There is a clear need to work closely with other medical Royal Colleges and specialty societies in order to agree maximum or rational requesting for common conditions and clinical presentations. Such guidelines do exist but their implementation is patchy and inadequate.

Workforce profiles and training

“A laboratory that has inadequately skilled staff cannot deliver a good service. However, a laboratory that has an excess of skilled staff cannot deliver an efficient service, and efficiency is an important aspect of quality.

“Maintaining staff skills includes training new staff. Organisations that choose not to employ and support trainees must not be allowed to apply this policy to gain a competitive advantage, or the long-term stability of the service will suffer.”¹
Some labs have been creative in their approach to workforce changes while others have been more resistant. There is a need for traditional roles to change, manual repetitive tasks to be taken on by staff at lower grades, and innovation in laboratory ways of working to release cost savings.

Changes must be approached systematically. One approach that has been used to good effect is the performance of a ‘per test audit’. This involves producing a breakdown of the tasks required for each common test, working out which staff capabilities and staff grades are required to do each of these tasks, calculating the cost per hour of this and therefore arriving at the optimum staff mix for a particular lab. The focus of changes should generally be on the functionality required, not on specific staff groups which can be a distraction and lead to inappropriate skill mix.

Laboratories should not be too readily criticised for being risk averse as the time (and often technological) investment required to appraise, train, support and certificate changes in workforce should not be underestimated. Workforce development plans should be for five to ten-year time horizons and the support of pathology and senior trust management must be sustained.

Major changes cannot be implemented in the short term, however. They will need careful planning as extended roles generally require training and appropriate backfill. More immediate changes may be possible outside of the lab. Some areas have successfully trained healthcare assistants (HCAs) in clinics and on wards in phlebotomy and POCT. This development requires HCA capacity to support it, but can significantly reduce the burden on more expensive clinicians. The creation of multifunctional HCA roles enhances motivation and flexibility. Nurse-led anti-coagulant clinics make better use of resources than consultant-led but are not yet universal. There are also patient self-testing schemes which have potential for national roll-out.

There is uncertainty about the place of trainee medical staff as workforce in the provision of pathology services when funding streams are being cut or at least modified, specialty training numbers are being cut or frozen, the commissioning and provision of training programmes is being reformed in the most radical way in the history of the NHS, and the future positioning, structure and function of postgraduate deaneries is unclear. Similarly, the impact of the proposed changes implicit in the Modernising Scientific Careers programme on the availability and utility of biomedical scientists and clinical scientists as they progress through their career pathway is also unclear. This lack of clarity needs to be addressed urgently.

**Efficiency and productivity**

“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.

“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.”

On an individual basis there is variation in the rate at which consultant pathologists work in...
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terms of test volume. Some of the lower rates are due to pathologists 'over-processing' by spending longer on individual cases than is clinically required or even justifiable.

Historically it has been difficult for local managers to effectively challenge this behaviour because there is no consensus about what a reasonable case rate is. The 'new' consultant contract also makes addressing productivity difficult since it stipulates time spent at work, not productivity or measurement of outcomes.

The Royal College of Pathologists produced guidance on Histopathology of Limited Clinical Value, with recommendations to stop some 'routine' examinations, however, it is not clear what effect this publication has had in practice, because laboratories tend to comply with clinical requests for testing even if the clinical need for the test is not explained or justified.

When process management and sub-specialisation is introduced in histopathology, productivity may be improved along with quality.

The Royal College is engaged in a re-analysis of the College workload units it has published for histopathology and this should assist in the consideration of adequate case-rate parameters. It is acknowledged that some College guidelines have resulted in an increase in workload within histopathology laboratories in an attempt to improve quality and that productivity and efficiency may have been secondary considerations.

In all pathology disciplines efficiency and productivity are not just about what happens in the lab, or even pre-selection and post-result interpretation. Much pathology clinical consultation concerns discussion with non-laboratory professionals about patient management as a direct consequence of the interpretation of a result. The essential nature of this consultation is most obvious in the work of the histopathologist and the joint working of the Calman Cancer MDT. It is only slightly more subtle in other specialties but it is difficult to see how other doctors can work as safely, effectively and efficiently without the guiding opinions and advice of their local chemical pathologist, haematologist or microbiologist. Taken for granted, and never objectively studied or measured, this is an invaluable expert resource to the NHS.

Openness on performance

"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 an 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

The College welcomes moves to devise laboratory key performance indicators and make these publicly available. Transparency can be a useful tool in improving various aspects of the quality and efficiency of care, and publication of laboratory external quality assurance scheme results is one example of such transparency.

Where laboratory External Quality Assessment (EQA) data are made public, the College will work to support this and to make sure that information is released in a form that is as meaningful and comprehensible as possible, allowing commissioners to make better comparisons of laboratory performance. However, it is wasteful to demand analytical
accuracy that is far in excess of the accuracy that is needed in clinical practice, so the College has established a project to attempt to define Minimum Analytical Performance Standards (MAPS).

Some external quality assurance schemes, especially in histopathology, assess individual pathologist performance rather than overall laboratory performance. This is relevant to medical revalidation, but may not be a meaningful measure of overall laboratory quality because difficult cases would normally be subjected to internal consultation between pathologists. Care is therefore needed in the interpretation of EQA data.

The College is supporting on-going work to develop standardised outcomes-focused metrics. The College and Department of Health are supporting a number of work strands on standardisation – Minimum Analytical Performance Standards for tests, Harmonisation of Reference Ranges and development of the National Laboratory Medicine Catalogue (standardisation of names of analytes, coding, units of measurement and suitability for combination from different sources). The catalogue will ultimately deliver the ‘national formulary for laboratory testing’ recommended by Lord Carter. Its associated guidance on test use will facilitate the development of expert decision support systems that should make the use of laboratory tests more efficient. These workstreams deserve continuing central support to achieve laboratory outputs that are comparable for commissioners.

In addition, so that there can be assurance that the quality of care given by each laboratory is maintained during the period of NHS reorganisation and afterwards, the College will assist where possible in the production of quality indicators for pathology.

The College has already made available an example of a service specification for commissioners of pathology services to inform the creation of regional and local specifications.5

**New developments and molecular testing**

“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.”1

The Royal College of Pathologists is developing advice on a stratified approach to the development of molecular testing, crucial for quality in highly specialised diagnostic services.6

There is a strong push from their manufacturers for the use of more molecular tests, yet many are not necessary or are unproven. Given this conflict of interest, and that knowledge about these tests amongst pathologists is variable, purchasing of these tests should be part of specialist commissioning with a clear evidence base for implementation.

The potential of molecular tests to focus clinical resources and improve both quality and efficiency of healthcare in the future is an important reason for protecting the skilled workforce and academic resources of pathology.

**Intelligent commissioning**

“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.”

As a profession, pathologists – including the Royal College – are keen to work with GP colleagues in the run up to GP-led commissioning. Partnership working will be important if the transition is to be smooth, quality of care protected, and improvements in their knowledge of the specialty made. Pathway mapping will be a critical tool in service development and pathologists will take an active role in this.

Certain specialist pathology services in the UK are provided by a small number of laboratories and specialists and have poor or under-prioritised succession planning. If these services are to remain in the UK, there needs to be more local support for these smaller services.

To ensure optimal patient care, it is essential that contracts for laboratory services allow laboratory staff to initiate ‘reflex testing’, where an unexpected laboratory result immediately justifies further testing of any residual sample. To insist on going back to the clinician and the patient before undertaking the further investigation can cause delay, confusion and harm. The ethics of reflex testing must always be considered, but it is usually justified by the observation that patients normally request investigation of their illness, not limiting consent to measurement of a specific analyte.

In a recent article in The Times, Chris Ham, the CEO of the King’s Fund, raised concerns about the effects of the commissioning plans laid out in the coalition government’s white paper: “Ministers should recognise the need to support collaboration in some areas while promoting competition in others. Improving results for patients with cancer or stroke victims requires forming networks of hospitals willing to concentrate services in fewer centres. Rules making it difficult for specialist networks to develop because they are anti-competitive would work against the Government’s aims.”

**Information technology and disintermediation**

“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.”

Developments in information technology continue to allow improvements in the quality and efficiency of care.

There are of course implementation costs, but electronic requesting and reporting systems can decrease transcription errors and enable sample tracking. Decision support systems embedded in the ordering system can be linked to care pathways and can introduce ‘rules’ on frequency of testing. As noted above, this has the potential to generate considerable cash savings as well as improvements in care. Using IT for reporting across laboratory and clinical networks and specialist laboratories will speed receipt of results and generate cash savings.

Such developments require the consistent use of the NHS number as the unique patient identifier and the completion and uptake of the National Laboratory Medicine Catalogue.
Clinical pathology professionals can use pathology test results to trigger appropriate actions, for example detection of acute kidney injury and early detection of liver disease.

Standardisation of pathology data enables its use within clinical networks, within disease registries and for secondary uses, including research. The Pathology Futures Group has identified many areas where the care pathway could be clarified and speeded up if the laboratory was encouraged to interact directly with the patient.8

The Royal College of Pathologists and the Royal College of GPs have issued statements on the delivery of laboratory results directly to patients.9 This is not appropriate in all circumstances, but it is anticipated that such ‘disintermediation’ would free-up the time of other clinicians, particularly GPs, enable patient empowerment in their long-term conditions and hence gain higher patient satisfaction.

Leicester’s model of direct patient contact for thyroid replacement therapy is a good example of this working in practice. Direct referral by histopathologists to colposcopy clinics based on cervical cytology findings (direct referral) is another.

One regular complaint from trainees on rotation between different hospitals, even within the same region, is the inefficient waste of their time coming to grips with the heterogeneity of the IT systems without which they cannot work and learn.

Clinical leadership in pathology

“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.”1

The Royal College of Pathologists has been providing guidance and setting standards for the profession since 1962 and a national pathology clinical adviser was appointed by the Department of Health in 2004.

The desire for improved clinical leadership in pathology was stated by Lord Carter of Coles in his first Report of the review of NHS pathology services in England, published in 200610 and reiterated more recently in his second report, published late in 2008.11 Also in 2008 the then Health Minister, Lord Darzi, put clinical leadership at the centre of his Next Stage Review.12

In addition to drivers which are external to pathology, in the profession there is an appetite for increased visibility. The development of National Pathology Week and the College’s public engagement programme reflect the perception within the College that the profile of pathology needs to be improved.

A small leadership group has been set up in the College, led by its vice-presidents Danielle Freedman and Tim Wreghitt, and including Ian Frayling, Rachael Liebmann and Richard Herriot.

In November 2009, an email was circulated to all those affiliated to the Royal College of Pathologists in the UK asking them to participate in an electronic survey. Almost 600 responses were received, of which almost 100 per cent felt that clinical leadership can ‘make or break pathology services’.
Again, almost all respondents felt that the College has a role in the development of clinical leadership, but half the respondents felt that the College did not currently give adequate support to clinical leadership.

There was a very strong feeling that the College has a role in developing and promulgating the concept of leadership in its fellows, both current and future. This is something that the College, with the guidance of the leadership group, is committed to providing.13

A pilot programme of pathology leadership development set up by the Department of Health in 2009 was initially taken up by two SHAs – West Midlands and South East Coast. The programme recruited scientists, managers and medics in pathology and involved a series of intense coaching sessions with education in both theory and practical strategies for leadership. Feedback from the participants was universally positive, and the pilot culminated in presentations in July 2010 at presentation and awards ceremonies held in Kent and at Warwick to mark the achievements of all participants. The programme is being rolled out to a further three SHAs, with discussions on-going about leadership development coverage more widely.

“The reconfiguration of pathology services is a challenge, but every challenge is a leadership opportunity.”1

**Who should do what?**

The areas discussed at this meeting were wide-ranging, and implementing the changes discussed will demand the involvement of many groups. This complexity could lead to paralysis if the need for shared action is not recognised. We therefore suggest the following analysis.

**Group A. Activity largely within the practice of pathology**

Work that pathologists can (and should) do within the compass of our own specialties or workplace. This may be of little interest to anyone else save to the extent that it improves the quality, safety and cost-effectiveness of the service. Activities include:

- productivity
- disintermediation and harmonisation of tests
- workforce re-profiling
- information technology (some aspects).

**Group B. Activity at the interface with clinical care**

Some of this can be achieved within pathology departments, but much will require major changes in clinical behaviour, without which there are few practical benefits; so agreements with staff outside pathology departments are essential. Behaviour modification requires resources. Activities include:

- demand management in primary care
- demand management in secondary care
- use of results
- information technology (some aspects)
- open data
- marker tests
- POCT.
Group C. Activity that integrates into the clinical QIPP pathways

A more complex area touched on in the discussion but not explicit in the discussion. This includes the use of pathology (tests and expertise) to reduce hospital admissions, expedite early discharge (cutting length of stay) and facilitate the patient pathway in the management of long-term conditions and in the elective care pathway (admissions, length of stay and outpatient appointments can all be reduced with a shift in the location of care towards the community).

Group D. Activity that requires political/commissioning input from pathologists locally and from the Royal College nationally

Merely addressing the short-term quality and productivity challenges of the downturn will fail both the NHS and the public in the long term unless attention is paid to future-proofing the service. This can be challenged by short-term commercial interests. A good example is the international commissioning of reporting of cervical smears in the Republic of Ireland, which almost caused irreversible de-skilling of the entire country.

Actions include ensuring that the commissioning process includes consideration of (and allocation of funding to support):

- specialist (regional or national) pathology, including molecular testing
- teaching and training (of clinical as well as lab staff)
- research and development.

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