

# Report of the Review of NHS Pathology Services in England

Chaired by Lord Carter of Coles



*An Independent Review for the Department of Health*

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# Foreword

To: Lord Warner  
Minister of State for NHS Reform

## REVIEW OF NHS PATHOLOGY SERVICES IN ENGLAND

I have pleasure in submitting to you the report of the review of NHS pathology services in England, which you asked me to undertake.

Pathology is a large and important clinical service which touches the lives of substantial numbers of people. It employs 25,000 staff and costs the NHS in the order of £2.5 billion a year, representing nearly 4 per cent of total NHS expenditure.

In common with other sectors of the NHS, a process of modernisation of these services has begun. A degree of reform has been put in place, and the benefits are already being seen in a number of parts of the country.

Practitioners of pathology have told us that there is now an opportunity for a step change in the development of the specialty, building on the progress already made. The debate is not whether, but how and when, further beneficial change can be delivered.

In formulating conclusions we have found that one of the greatest obstacles has been the lack of good quality useable data about costs, activity and performance within NHS pathology services. Accordingly our main recommendation is that a series of pilot projects should be undertaken in order to obtain the information and to test different approaches to the future organisation and management of the specialty.

From the evidence received we are convinced that there is scope to achieve significant benefits from further reform of pathology: for those who use the service, for those who provide it and for those who fund it. We are also convinced that there is scope for pathology to make an even greater contribution to clinical care than at present. The advent of the genomic revolution is bringing new tests with potentially profound implications for the organisation and delivery of health care. Laboratories need to gear up now in order to exploit these new opportunities for personalising health care.

We have been encouraged by the positive attitude shown by all involved in pathology towards the conduct of this review. We have detected a widespread willingness to embrace further change in the quest to deliver a constantly improving, high quality service which is responsive to the people who use it.

I could not have fulfilled my remit without the tremendous support, commitment and help of the members of my panel, Professor Chris Price and Marcus Robinson. I am extremely grateful to them. I am equally grateful to the review manager Edmund Waterhouse and all those in the Department of Health, NHS and within the pathology professions who have contributed to ensuring this Review reaches a successful conclusion.

Yours sincerely,

A handwritten signature in dark ink, appearing to read 'Lord Carter of Coles', written over a horizontal line.

LORD CARTER OF COLES

# Part One: Summary and Recommendations

## Summary

### Context

1. Pathology services lie at the heart of the health care services provided to patients. They are essential to the delivery of many of the national priorities and targets for the NHS. It is estimated that 70–80 per cent of all health care decisions affecting diagnosis or treatment involve a pathology investigation, with individuals' treatment decisions – and the monitoring of their response to treatment – often dependent on a range of pathology-based tests and investigations. In England in one year over 500 million biochemistry and 130 million haematology tests are carried out, over 50 million microbiology requests are processed, over 13 million histopathology slides and 4 million cytology slides are examined. Of these requests over a third (35–45 per cent) come from primary care. Demand across virtually all disciplines of pathology has been rising at an average of 10 per cent per annum over the past 3 years (spanning an 18 per cent increase in biochemistry tests but a 2 per cent reduction in cytology slides). Average demand is predicted to grow at the same pace in future. Overall, pathology services cost the NHS an estimated £2.5 billion per annum, of which the single largest element is the workforce.
2. In keeping with other areas of the NHS, pathology services have developed in recent years. Our recommendations build on these developments, including *Modernising Pathology Services*, published in February 2004, which confirmed the direction of reform of pathology services in this country by advocating the establishment of managed pathology networks, alongside reform of the workforce.
3. We are conscious that there are differences between the different specialties within pathology, and the extent to which problems impact on each specialty can vary considerably. We have therefore sought to identify those issues which apply across pathology as a whole, rather than attempting the more complex task of formulating recommendations specific to each specialty. Further work is therefore likely to be needed in this area.
4. Through this report we intend that the pace of change already under way be accelerated, and that pathology services develop in line with the Government's wider strategy for health reform based on, for example, creating greater choice for the users of health care services, separating commissioning from the provision of services, with more

contestability and greater plurality of provision, and with a stronger emphasis on community-based services – while also improving quality. This approach incorporates the four pillars of system reform – demand, supply, transactional, and system management – and incentivises responsiveness, quality and value for money in health care.

- 5.** In this review we have studied the evidence before us and listened carefully to what we have been told. This is not another “false dawn”: we believe our proposals will enable pathology services to meet the needs and demands of health care provision for the future by strengthening the delivery of high quality, efficient, effective and responsive pathology services. Our confidence stems from the clear consensus we have found about the barriers to progress and the steps needed to overcome them.
- 6.** Over time, several different models of service delivery have evolved within pathology, from small in-house laboratories to managed networks. The scope of these services varies, from local routine testing to national specialist screening. As a result, services have become fragmented. This fragmentation is made worse because the operations and the costs of hospital-based laboratory services are generally intertwined with those of their host NHS trusts. Such shared costs can be difficult to identify separately. So while there is a plethora of data and statistics about pathology services, there is little centrally collected and standardised information about either the true end-to-end costs and quality standards associated with pathology or the key elements of the service such as capital investment strategies and the workforce. Without such information, we believe it will be difficult to assess the extent to which the efficiency and effectiveness of the service can be improved, and whether the projected increases in future demand can be accommodated safely. We also believe that without such data it will not be possible to establish a level playing field for securing plurality of pathology service provision, as envisaged in the Government’s modernisation strategy for the NHS. For similar reasons it has proved difficult to make comparisons (for benchmarking purposes) between pathology in this country and overseas.
- 7.** While pathology is seen by many as a backroom function, it has been obvious to us that the range of pathology services that are now delivered has evolved. There is now greater involvement – and greater scope for involvement – of pathology in end-to-end patient pathways (from the selection of the most appropriate test or investigation, to the interpretation and provision of clinical advice across the spectrum of clinical specialties). Furthermore, the needs of the pathology services (in relation to funding, for example) have often been diverted to meet other obligations. Many of the issues identified in this report stem from the recognition that pathology needs to be managed in future as an end-to-end clinical service in its own right – both as a provider of optimal laboratory-based services and a core contributor to the clinical aspects of the patient’s journey. We consider that pathology services should be commissioned on that basis, in accordance

with a service specification which enhances efficiency and effectiveness and improves service quality. This approach should help, in part, to raise the profile of pathology services as a key provider specialty in health care. One option – although outside our remit – would be to change the name, perhaps to laboratory medicine.

- 8.** In framing our conclusions we have been conscious of the NHS's unique structure which enables commissioning bodies and service providers to exercise a high level of autonomy, in keeping with an increasingly devolved service. So it is clear to us that our recommendations must make sense and be easy to implement at the grass roots level of the service. This local flexibility is central to the Government's vision of a patient-led NHS, and intrinsic to a commissioner-led health care system.
- 9.** We understand the principles which underpin the Government's strategy for health reform and consider that the same principles need to inform the continuing development of pathology services. We envisage a position where there is contestability and choice in respect of pathology services, where commissioners determine the level and quality of such services based on a national specification or plan, in an environment where NHS and independent sector providers of pathology services can compete fairly.
- 10.** Such a commissioning specification or plan would reflect the best configuration for integrating and rationalising pathology services so as to improve efficiency and effectiveness – and would identify the benefits achievable through economies of scale. It would form the basis of the specification on which commissioners could go out to tender; or, if commissioners chose to use an existing provider (a lead provider, acting on behalf of a managed network) without testing the market, it could be the plan on which the contract with the provider body was based. In either case there would be an important role for the Strategic Health Authority, not least because of the issue of scale. That role could include ensuring contestability in cases where, because of the size of the managed network, there was in effect a monopoly of supply. By the same token the Strategic Health Authority could ensure that the process of reconfiguring pathology services was undertaken in an open manner – and that it was not controlled by the provider organisation.
- 11.** For the reasons set out previously, however, we have concerns about the current state of the evidence on which such a commissioning specification or plan for pathology, if drawn up at this stage, would have to be based. In our report we have identified a range of improvements which we believe – but at this stage cannot prove – will cut out waste, improve efficiency and enhance service responsiveness and quality. We consider, therefore, that the first step in developing such a specification or plan needs to be supply-side reform. Without that, the potential benefits stemming from this review are unlikely to be achieved. Through a series of pilots (see below) the extent of those

potential benefits can be assessed and evaluated. In the light of such an evaluation a commissioning specification or plan could be developed on the best configuration of pathology services, so as to extend to the whole of the country the improvements in overall service efficiency, effectiveness and quality which can and should be achieved. Such an approach requires a clear national vision and strong leadership at all levels. Critically, it requires pathology services to be viewed within a broad clinical context, so that the contribution they can make to the provision of health care services generally can be maximised for the benefit of patients while also ensuring the most effective use of resources.

### Key drivers of change

12. In reaching our findings we have identified a number of important drivers of change which reflect the changing climate for health care in this country:
- the service needs to be developed to meet people's changing expectations with regard to high quality, safe and efficient health care services, delivered closer to home;
  - the service needs to be redesigned and streamlined around people and the main users' requirements for pathology-based investigations;
  - the service needs to embrace competitiveness and plurality of provision and a commissioner-led focus;
  - the service requires strong local clinical leadership and a business orientated management infrastructure;
  - the service needs to focus on productivity through matching the workforce not only to activity and workflow, but also to the roles and functions that are needed to deliver it; through improving systems and processes and realising the benefits of new technology, with faster adoption;
  - the core information required to enable the service to be run efficiently and effectively needs to be defined, and steps taken to collect, record and use such data;
  - the service needs to be recognised as a core clinical service in relation to its impact on the patient's journey and therefore should be planned, commissioned and delivered as part of an integrated health care system.

## Barriers to change

13. Pathology service managers need to be able to control the major determinants of service quality and efficiency. We have identified a number of factors which impede the delivery of an efficient and effective service. These include:
- the lack of end-to-end IT connectivity in pathology which limits the opportunity to deliver effective order communications and decision support (both of which would help to minimise inappropriate or unnecessary repeat testing) as well as to meet additional, but essential, clinical and management needs;
  - the fragmentation of sample collection services, which limits the opportunity for delivering an efficient patient focused service, as well as end-to-end pathology service management;
  - among commissioners, the lack of understanding about the tests available, leading to sub-optimal and occasionally inappropriate use;
  - for laboratory services, the questionable quality of logistical support (especially transport of samples) and the impact this has on the efficiency of the service;
  - the fact that the management of the pathology services, especially financial, is overly influenced by the priorities and financial health of the host trust;
  - the exclusion of pathology from local delivery planning processes and investment strategies, as well as the lack of consideration of pathology when formulating national plans, leading to unexpected, unplanned and unresourced demands being made on the pathology services;
  - the high degree of variability in test repertoire, investigation protocols and guidelines on the use of pathology services, as well as in the results obtained and reference ranges employed in their interpretation, increasing the risk to patients;
  - inconsistency in the application of data (whether from this country or overseas) to inform the systematic optimal configuration of pathology services, in order to achieve the highest standards of efficiency and effectiveness;
  - the current complex make-up of the pathology workforce and the absence not only of a national definition of the comprehensive functions of pathology services, but also the skills which match that functionality and the skill mix required to deliver a modern pathology service;
  - the difficulties of implementing workforce change and development at a local level, often linked to the lack of local investment (sometimes a reflection of the level of understanding of pathology and the lack of engagement of its managers and laboratory directors in planning processes);

- the fragmentation of parts of the service, particularly point-of-care services which are increasingly being undertaken by other members of the health care team, often with no reference to pathology services.

## Priorities for change

14. Accordingly we have identified six main priorities for change:

- the development of a national specification or plan as a basis for improving quality, both in relation to the delivery of the pathology service itself, and the more effective use of the service in the wider context of the patient journey. Clear performance standards for the delivery of the service should be developed, and for ensuring the effective use of the pathology service;
- the creation of stand-alone pathology service providers. This would enable commissioners to focus on what is required for the local health economy as a whole and for such care-specific pathways as for cancer and coronary heart disease. This in turn could be linked to a more fully developed nationally defined tariff;
- end-to-end IT connectivity in pathology, to enable order communications and decision support to be put in place nationally across the different health provider sectors, and to support other demands on pathology such as health protection, disease surveillance and the management of long-term conditions and chronic disease;
- the introduction of a national system for reimbursement to inform the use of a tariff, and to encourage appropriate investment in new tests and technology, reflecting the value of the contribution made by pathology to the overall delivery of effective health care;
- integrated service improvement and large scale workforce change – with improvements in systems and processes linked to workforce functions, skill sets and skill mix, so as to connect activity and work flow – including more multidisciplinary working and an infrastructure that informs workforce planning and numbers; identifies learning and development requirements, and opportunities for common approaches to delivery; and addresses training capacity as well as recruitment and retention issues;
- development of stronger clinical leadership and management skills, including skills in the management of change.

## Pilot projects

15. Because of the lack of nationally collected activity, cost and performance information, we conclude that our recommendations – set out below – should be tested through a

series of pilot projects and subsequently reappraised. The purpose of these pilot projects would be to work up the specification or plan for pathology according to the best configuration. If the benefits identified in the preliminary planning phase are demonstrated we would expect that wider implementation would follow. We would wish to see a variety of different models tested. As far as possible the pilots would operate on a common framework so that their relative performance could be evaluated.

16. Accordingly we propose that a set of common templates should be developed which would enable baseline data to be established in respect of volumes of activity, current costs and levels of service for a given geographical area. To do this we would intend to work with a number of selected sites, chosen to reflect a broad range of geographical locations, covering urban, rural and metropolitan areas, in order to determine the costs and service levels within their direct control. Those costs and service levels which are shared or are dependent on services provided by or through the host NHS trust would be separately identified. Examples of the latter would be transport, IT support, and shared premises. In terms of volumes of activity, we would aim to separate out genuine demand from unnecessary repeat testing, incomplete testing (because of sample contamination) and tests for which the patient does not receive the result. We would also need data in order to understand trends over time. In establishing costs we would seek to evaluate those savings from service consolidation which could be made from the release of assets. The output of each of the pilots would be reviewed and compared as a means of validating the recommendations in this report.
17. As part of the planning process, and to inform the national commissioning specification or plan, we would wish to see parallel initiatives started in relation to workforce, reimbursement, IT and a national quality framework. The first two and the last should inform the baselines; the third would inevitably need to run over a longer timescale, and for that reason we would wish to see a start made as soon as possible. We see much advantage in forging close links with the workforce pilot projects already planned or under way within the Department of Health.

## Recommendations

18. Our recommendations reflect the findings and conclusions which we have reached on the evidence before us so far; it is probable that they will evolve as more information and knowledge becomes available. Because we are convinced that reform of the supply of pathology must precede the move to a commissioner-led model of provision, the recommendations which follow are aimed primarily at developing the best configuration of services. These steps are essential for the development of a commissioning specification or plan which will have the best chance of delivering improved service quality and responsiveness, allied with improved value for money. As stated earlier, we suggest that our recommendations are tested in practice through a number of pilot

projects so as to develop the specification or plan and ensure that it is workable in practice and delivers the improvements which we envisage can be made to the delivery of pathology services.

## Managed pathology networks

19. Accordingly we recommend that **managed pathology networks** (whether existing or new) should be established as free standing organisations, having many of the characteristics of NHS trusts (but not as statutory bodies). The term “managed pathology network” is not intended to describe a mode of delivery, but rather an organisational framework that delivers an integrated service to a defined standard to meet the needs of all patients, and their carers, within a prescribed geographical area. The size, nature and coverage of each network would need to be determined in consultation with stakeholders, based on the outcomes of the pilot projects. For each network a clinical director and business manager should be appointed.
20. We envisage that a pathology network would be established and defined in terms of the geographical area it covers; and that the clinical director and business manager of the pathology network would have financial and managerial control over the operation of the laboratory service, including such logistical elements as the collection and transport of samples. Where service decisions are shared between different providers, there would be a transparent process for apportioning costs.
21. In addition, the network’s clinical director/business manager would:
  - (i) with service commissioners, appraise the quality and responsiveness of the service offered to patients, whether directly (for example to patients with chronic conditions) or indirectly (for example through the users of the service such as GPs or hospital clinicians). In doing so they should look at the end-to-end service, and determine through consultation with others what improvements could be achieved through for example enhanced accessibility, further investment in point-of-care testing, ever lower error rates, agreed turnaround times, elimination of unnecessarily repeated testing, more informed requesting of tests, and minimisation of fragmentation of services;
  - (ii) engage actively with pathology service commissioners in order to understand and beneficially influence the drivers of demand as well as the location and nature of the services to be provided in the future;
  - (iii) engage actively with pathology service commissioners in order to ensure that the service is incorporated and used effectively in relation to care pathways, so as to improve health outcomes;

- (iv) establish the cost base of their operations, including the appropriate proportion of overheads, and develop forward plans on different assumptions about levels of activity and therefore income. These forward financial plans would include appropriate provision for new investment, both in terms of technology and tests;
- (v) in developing such financial plans, examine critically those factors identified in this report which could contribute to greater efficiency, including for example examining whether the laboratories across the network could be used in a different way in order to benefit from economies of scale and critical mass in relation to low volume specialised testing;
- (vi) actively represent the contribution which pathology services can make to broader clinical service design and delivery;
- (vii) similarly, in the light of this report, ensure that they have optimised the efficient and effective management of processes. Factors relevant here would include the design of premises to facilitate efficient work flow, including through the deployment of appropriately skilled staff. Techniques such as “lean” and “six sigma” have proved useful to some, and the principles reflected in them could be adopted more generally;
- (viii) define a workforce for each network which directly matches service needs and functions to skill mix requirements against the cost envelope and performance outcomes, recognising learning and development needs;
- (ix) manage the network in matrix form, with strong clinical and business leadership;  
and
- (x) ensure the network is represented in some way at commissioner level in order to influence decision-making processes.

### **NHS trust providers**

**22.** In respect of **NHS trust providers** we recommend that:

- (i) for the service delivered by the laboratory to clinical departments within trusts, there would be a service level agreement specifying agreed quality standards, and (in the absence of a tariff price) the level of reimbursement payable for specified service volumes;
- (ii) mechanisms would be put in place to ensure effective operations – both clinical and managerial – between the trust and the managed pathology network, for example through the designation of a clinical lead in each specialty with regular monitoring and review of the contract;
- (iii) the contribution which pathology services can make to the overall delivery of high quality clinical services across the trust would be recognised through the

appointment of the clinical leader of the pathology network or laboratory to the trust's clinical executive board (or similar committee);

- (iv) in addition the leadership of the pathology network would have the scope (for example through inclusion in the NHS trust's executive team) to participate in and influence as appropriate certain executive decisions made by NHS trusts, for example in relation to investment decisions, service reconfigurations and delivery specifications, where increased investment in pathology or different service models would bring improved service outcomes or reduced costs for other clinical departments;
- (v) where necessary and appropriate, improvements in laboratory premises would be facilitated in order to enhance efficiency.

## Commissioners

**23.** In respect of **Commissioners** we recommend that:

- (i) in developing strategic plans, commissioners take full account of the potential contribution which pathology services can make in improving the effectiveness and responsiveness of the wider health care system; determine the optimal size and configuration of the pathology network(s) in their area; define and promulgate their approach to the management of the performance of the local pathology network(s); particularly in relation to quality standards and costs; ensure the efficient operation of the local health care market; and enable the local network(s) to contribute effectively to nationally managed laboratory-based services such as screening for disease, the protection of health, and the maintenance of an adequate and safe supply of blood;
- (ii) a clear commissioning specification or plan of an area's requirements in terms of pathology services is drawn up, in consultation with stakeholders. It would specify the area to be covered, the nature of the service in terms (for example) of the availability and location of sample collection and point-of-care testing sites; it would incorporate expected volumes of activity and define quality standards in line with a national quality framework for pathology;
- (iii) the service specification would be reflected in the contract between the commissioning body and the service provider, with clear quality and performance criteria included as well as a defined level of reimbursement (based on the pathology tariff price, if available);
- (iv) the core information requirements essential for monitoring the quality and performance of the service would be identified and mechanisms put in place for collecting the information in a prompt and accurate manner;

- (v) the workforce requirements would be clearly defined and included within local delivery planning processes and commissioning arrangements;
- (vi) pathology would be represented within the new structures.

## Department of Health

**24.** In respect of the **Department of Health** we recommend that:

- (i) a commissioning specification or plan is drawn up for pathology service commissioners, based on the findings of this Review, previous initiatives to modernise pathology, and the outcomes from the proposed pilots; it would be based on agreed quality standards and informed by clear service specifications and would reflect the best configuration of services;
- (ii) as soon as possible, further work is undertaken to ensure that within pathology there is end-to-end IT connectivity and national availability of order communications and decision support, based on an agreed data set including a unique patient identifier (the NHS number), and other core information needs;
- (iii) a knowledge dissemination programme based on clinical best practice is developed for pathology to enhance the accurate and appropriate ordering of tests and the interpretation and use of results;
- (iv) a reimbursement mechanism is developed in tariff form which sets the price for specified tests or groups of tests. This tariff would encourage continuing investment in new tests and new technology where appropriate;
- (v) new technology is introduced, based on a benefits realisation analysis, through the inclusion of a specific pathology focus within the Technology Innovation Hubs and the Centre for Evidence-based Purchasing;
- (vi) competition between different potential providers would be based on best quality and value, not solely on cost;
- (vii) further work is put in hand to reform the workforce and to provide greater clarity with respect to roles and functions and equivalence in terms of education and training requirements. This work needs to identify and develop the skills and skill mix reflecting the functions needed for the provision of contemporary pathology services, in particular the enhancement of clinical leadership and general management skills and the specialist clinical and scientific skills; training curricula would be revised accordingly and models to provide sustainable training capacity introduced. This needs to be linked to more intelligent workforce planning arrangements to cover pathology as a whole and to encompass independent sector providers;

- (viii) wherever possible, and as soon as possible, steps would be taken to promote greater standardisation of test results and reference ranges to minimise variability, in order to enhance service quality and patient responsiveness;
- (ix) the independent accreditation process is reviewed to ensure flexibility of approach and is extended to cover all providers of pathology services (including point-of-care testing); and, where possible, future pathology accreditation requirements are embedded within the standards set by the Healthcare Commission and which apply across health care;
- (x) all pathology providers, including point-of-care testing providers, are accredited in accordance with a national independent accreditation process which is responsive to changes in the nature, scope and delivery of pathology (and the wider health care system) and which requires full participation in external quality assurance schemes;
- (xi) work undertaken as part of each national screening programme is managed as a single national network and led by a designated clinical director in accordance with a national agreement specifying quality standards and based on agreed volume levels and rates of reimbursement;
- (xii) similar arrangements would apply in respect of national specialist laboratory services;
- (xiii) for similar reasons there would be closer working between the national genetics programme and the pathology services, reflecting the close operational links between the two services, so as to develop common IT systems (where possible), and share best practice, recognising that both services contribute significantly to the patient's journey;
- (xiv) in addition, arrangements for promoting contestable services and plurality of providers would:
  - provide sufficient stability in the short term for returns on investment to be realised;
  - be delivered in ways which prevent the fragmentation of an integrated service;
  - specify how assets (including people) should be treated where there is a change of service provider;
  - establish a level playing field between the public and independent sectors.

## Pilot projects

25. We recommend that a series of pilot projects be set up to test the recommendations set out in this report and to enable a specification or plan to be developed. The first phase, lasting about six months, would be to:
- (i) establish the requirements of commissioners in terms of service quality, responsiveness and choice;
  - (ii) using the approach set out above, based on a set of agreed templates, establish a volume cost and service baseline;
  - (iii) develop and model different service approaches in order to establish the optimal configuration, taking account of the costs of any assets which could not be redeployed, defining the functions to be delivered and the skill mix of the workforce, and identifying ways of overcoming barriers and obstacles to change;
  - (iv) in consultation with stakeholders, test the optimal configuration including the necessary workforce change, with clear processes bridging from initial request to communication and interpretation of the test result; draw up costed plans for investment in new technology, and improved operations based on defined service levels and supported by appropriate management information flows;
  - (v) test the operation of a pathology-specific tariff;
  - (vi) model the workforce of the future, and establish its cost and the expected performance outputs;
  - (vii) assess the risks associated with the new models of delivery;
  - (viii) in consultation with stakeholders, pilot the commissioners' role in terms of developing a commissioning specification or plan in line with a national quality framework; determine the role of the Strategic Health Authority in relation to ensuring contestability and the openness of the reconfiguration process; and
  - (ix) provide an indication of the benefits and costs of adopting this approach.

# Part Two: Findings and Conclusions

## Introduction

26. In this section we review our findings, looking first at the data available (and the data quality) on international benchmarking, then considering the evidence under a series of headings from which we draw out some important overarching themes.
27. Pathologists and clinical scientists provide a direct clinical service through the control of infection, through ward rounds in intensive care (for example), through participation in multidisciplinary meetings and diagnostic reviews and through the provision of advice and interpretation to GPs and others. From the evidence received it is clear that pathology services in this country have many strengths. The quality of service is very good, with a highly committed workforce which has substantially increased its productivity over recent years, despite in many cases operating from premises which impede rather than facilitate the delivery of an effective service and without adequate control over the logistical elements of the service, notably phlebotomy, transport and IT.
28. We have noted the developments which have taken place in pathology in recent years, particularly following publication of *Modernising Pathology Services* in 2004. We endorse the direction confirmed by that document, above all the focus it brought to the user's perspective of the service; and the progress subsequently made, especially in establishing managed pathology networks. At PathLinks in Lincolnshire for example, we saw the substantial gains that came from consolidation and integration of laboratory testing (including histopathology and microbiology) across multiple hospitals – once the local political issues of the individual hospitals and pathology staff had been resolved; here the goals of pathology modernisation appeared to us to have been largely achieved. Our conclusions and recommendations build on those useful foundations. Our aim is to take that work forward faster and more consistently across the country.

## Productivity

29. Evidence from Keele University's Clinical Benchmarking Company shows that in clinical biochemistry (for which there is more peer reviewed data) over the five years to 1999-2000 there was a 53 per cent increase in requests to laboratories in England, while over the same period staffing levels fell by 9 per cent (consultant chemical pathologists) 8 per cent (clinical biochemists) and 1 per cent (biomedical scientists). Productivity rose over the five years by 46 per cent (an average of 8 per cent per annum) and the average

cost per test by 7 per cent (over 1 per cent per annum). These findings were borne out in more recent data presented to the review.

## International Comparisons

30. As required by our terms of reference we have sought to benchmark the performance of pathology services in England against comparable services in other countries. Little information is however available. In many countries where the laboratory services are run as businesses there is far greater information about the amount of work performed, the resources spent and the drivers of quality (though little information about the effective operation of the end-to-end pathology service, and its contribution to wider health care delivery). Those studies that do exist suggest that total spend per capita on in vitro diagnostics in the UK (a reasonable proxy for England only) is half (10.4 Euros) that of equivalent countries in Europe – Germany (21.9), France (24.2), Italy (24.8). As a proportion of total health care expenditure, spend on in vitro diagnostics in the UK is half (0.55 per cent) that of Italy (1.18 per cent), and in Europe only Denmark (0.54 per cent) is below the UK level. Data from the USA suggests that the spend on diagnostics is at least four times that of the UK.
31. In terms of productivity the improvement quoted above for England matched that of the USA. Comparisons with the USA and Australia showed that the costs of routine chemistry and haematology tests were broadly equivalent between the three countries (\$0.89 in the USA, \$0.87 in the UK and \$0.88 in Australia). There were however significant cost differences in relation to more complex tests: at \$13 the average cost in the USA was half the Australian cost (\$26) and lower still when compared with the cost in England (\$32). It is thought that the divergence in cost data is attributable to differences in the extent of automation between the three countries as well as to economies of scale deriving from variations between laboratories in terms of the size, and complexity, of the workload being handled.
32. We also looked at the international data on service quality. Studies undertaken in 2000 and 2005 compared patients' views on health care provision in a range of countries including the UK, USA, Canada, Australia and New Zealand. Although the quality factors did not include a specific section on the influence of laboratory services, the proportion of incorrect test results and delays in communicating abnormal results were addressed. These showed that the UK performed significantly better than the USA and Canada with lower laboratory error rates, shorter delays in reporting results and fewer repeat tests. In the case of the USA the observations accorded with the findings in the Institute of Medicine report *To Err is Human* published in 2000, which expressed concern about the fragmentation of services in that country. A second report pointed out the discrepancy between the high investment in new technologies and the apparent limited impact on health outcomes.

- 33.** We noted however that in England there was little evidence of a strategic programme of investment in pathology (whether in respect of new or replacement technology, and whether linked to broader developments of clinical services or reconfigurations). The fact that most laboratory services are run as separate “financial and management silos” exacerbates the problem: other than at PathLinks we saw little evidence of the service being managed across hospital department silos so as to maximise the benefits for patients.
- 34.** These findings suggest that pathology service providers in England are operating both safely and efficiently. Yet from the evidence presented to us there are specific areas where in our judgement there is scope for improvement – specifically in relation to the integration of the pathology services in, and the impact on, the patient care pathway. It is also worth noting that there have been independent reviews related to the use of technology in health care in the UK (Department of Trade and Industry, Health Select Committee, and Healthcare Industries Task Force reports) which have all come up with a broadly similar conclusion, namely that the NHS is too focused on cost rather than on benefit when making investment decisions. Yet, as previously stated, a small investment in pathology services can disproportionately improve the overall quality and lower the total cost of a health care encounter. For example, HIV viral load/mutation testing may show that a patient’s monthly drug cocktail (costing £2,000) is no longer very effective; in this case the investment in the laboratory test can drive improvement in efficiency and effectiveness while at the same time the patient gets a higher quality outcome. We believe this is applicable to pathology, from the perspective of investment in new technology, as well as in the use of established pathology investigations in any patient journey.

## Laboratory Services in England: Processes and Logistics

### The user perspective – an end-to-end service?

- 35.** From the perspective of the user – whether patient or clinician – the laboratory is critical to the patient journey (ie the interaction the patient has with the laboratory) and the care pathway (ie how the test results are used to make the right decisions). The process of requesting and analysing a laboratory test and reporting the test result is straightforward but, despite the extensive literature on process management in industry, there is little evidence of the application of best practice to pathology, or more broadly to the patient journey and care pathway. Where pathology services have taken the initiative to adopt best practice in relation to their internal process improvement projects there have been impressive results and direct improvements both in patient care and patient satisfaction. Such examples stand out all the more clearly.

- 36.** From the evidence before us it is clear that the delivery of pathology services is fragmented, with no single person having overall responsibility for the entire patient journey regarding “pathology investigations” or more than limited involvement in how pathology services are best used in the interests of the patient (integration into the care pathway). For example, in the first instance a patient may seek medical advice from a number of different health care providers, each of whom may recommend that a laboratory test is undertaken to assist with diagnosis and treatment. The patient may be referred to a separate facility for the specimen to be taken. The specimen is then transported to the laboratory. Tests are conducted and the results communicated to the originating clinician. Usually the patient is invited back for face-to-face delivery of the test results and discussion of diagnosis and treatment. Each time there is a transfer from one separately managed service element to another, risks arise.
- 37.** The case for managing the service in an end-to-end integrated manner was made by the National Pathology Service Improvement Team, funded by the Department of Health. As part of its National Framework for Service Improvement, published in September 2005, the Team produced a Modernising Pathology Toolkit which invited managers to undertake a series of challenges in order to identify local priorities and apply improvement principles and techniques. This publication is clear and practical, and we endorse the approach set out in it. More work is needed in order to maximise the contribution which pathology makes to the patient’s journey.

### **Information technology**

- 38.** At the core of any managed service is information. To run a service effectively, management has to have relevant and timely information. At present, we understand that, although virtually all laboratories have their own information systems, the coverage of these systems beyond the laboratory is limited. For example, although there is now near universal IT linkage for the transmission of test results to GPs as well as to wards, the connectivity is not reciprocal: the GP cannot electronically transmit test requests to the laboratory. In consequence, at critical stages in the pathology process, there is still reliance on paper rather than electronic communication. We consider this to have a major impact on fully realising the potential benefits from a good pathology service.
- 39.** Such a system is inefficient and susceptible to a number of risks associated with manual transfer of data, as well as repetition of requests. Accordingly we have identified as a high priority the need to put in place across a network (which should be defined from the perspective of the patients) a computer-based system for ordering laboratory tests and for communicating and interpreting test results (“order communications”), as well as for informing these processes (“decision support”). We have seen the benefits of this end-to-end connectivity working well in other countries, notably during our visit to Sweden, to Kaiser Permanente and other individual providers in the USA.

- 40. Order communications** are also important because they give management notice of workload demands, and therefore enable resources to be managed proactively and cost-effectively – both within and outside laboratory services. They create time for dialogue between the person requesting a test and the tester, so that the appropriateness and timeliness of the test can be constructively challenged before resources are committed to analysis; and they enable samples which are lost or delayed to be identified at an early stage.
- 41. Decision support** is equally important. Test results expressed in bald numerical terms are seldom helpful to the requesting clinician, who needs to know whether the result is normal for his or her patient, whether any further tests are required, and what diagnosis and treatment is indicated. Different equipment can produce slightly different readings from identical samples, and the requesting clinician may require assistance in understanding that marginally different scores may not of themselves have significance. Laboratory staff can also help by providing interpretation: for example, the outcome of a particular test might fall within the normal range for one patient, but for a different patient it could indicate the need for urgent corrective action. Some “results” can be communicated only as a diagnostic opinion for which reference ranges do not exist, as in the case of histopathological investigations as well as some investigations in other specialties.
- 42.** Richard Granger, Director General of NHS IT at the Department of Health, described to us the IT strategy being delivered by *Connecting for Health*, which he has developed in order to link together all parts of the NHS electronically. This is an exciting and ambitious programme which will have a profound and beneficial impact on the delivery of health care across England. Because of the scale and cost, it is currently envisaged that it will be rolled out over several years. A key part of the strategy is the introduction of integrated electronic care records. We understand that they will initially impact on pathology later this year (2006), with the implementation of order communications. Under *Connecting for Health* this functionality and decision support technology will not however be available to all pathology departments until 2009 at the earliest. Once all aspects of the local health community are using the care record service duplicate investigations and inappropriate requests should be minimised.
- 43.** In the meantime, we were informed, local IT systems are likely to be developed to fill the void, taking advantage of the new national network (N3) and the messaging capabilities of the NHS Information Spine service, in order to minimise problems of connectivity. For example GP systems could be upgraded to send pathology requests electronically, thus improving efficiency and record integrity, and avoiding duplicate data entry.

44. In addition, we were informed that modern pathology laboratory information systems are available from *Connecting for Health* through the contracts with Local Service Providers. This allows trusts to buy new pathology systems without the need for a full procurement.
45. Developments in point-of-care testing, where laboratory equipment can be located in a number of hospital and community settings (for example a GP's surgery or a health centre), are especially dependent on good IT links with the parent laboratory as the only means of maintaining a complete record of the patient's results.

### Unique patient identifier

46. From our visits overseas we have seen the importance for service efficiency of using a consistent and unique patient identifying number for samples. Benefits include minimal risk of mistaken identity, avoidance of the need to match different patient identifying systems at different stages in the overall process, and improved sample tracking. Curiously in this country there is currently no insistence on using a single identifier throughout the health care system, although on the face of it the NHS number would appear to be intended for precisely this purpose. In addition there appears to be only limited use of machine-readable patient recognition systems (for example barcoded wrist bands) in the hospital setting. Within a system still substantially dependent on paper requisitions there is a heightened risk of error in the identification of the patient, as well as in transcription of the identifier – another argument for hastening the national computerisation of pathology.

### Phlebotomy

47. In this country, it is generally phlebotomists who collect samples from patients in hospital, and those attending outpatient clinics. In primary care the situation is much more varied. In some cases people working within primary care collect samples from patients for analysis by the laboratory, and the service works well. However, the service can suffer from, on one hand, a lack of ownership by the parent laboratory, which sees it as a primary care responsibility; and on the other a lack of desire on the part of GPs to exert ownership of it. The consequence may be that patients are sent to the hospital in order for the sample to be collected, thereby unnecessarily inconveniencing the patient as well as overburdening the hospital service particularly where repeat blood testing is required.
48. The situation is, by contrast, very different in other countries such as the USA, Australia and Sweden, where there is increasing provision of patient service centres in locations convenient to patients, specifically for the collection of samples.

## Transport logistics

49. Within process management, pathology presents a number of specific challenges. Of these, one of the biggest is the logistics of transporting samples. Although transport can be an issue within a single hospital trust, for example where samples need to be moved between different sites, the main challenge arises in the transport of samples between primary care and hospital laboratories.
50. There is a clear objective: to facilitate the delivery of an efficient and high quality service which is responsive to the needs and wishes of patients, with samples collected at times and in places which are convenient for patients. So long as the test results (based on a good quality sample) are available within an appropriate time, it does not matter to the patient whether the sample is transported to a local or a distant laboratory for analysis.
51. In the USA the two largest pathology laboratory companies, Quest and LabCorp, have invested significantly in their own transport networks – aeroplanes as well as vans – in order to move samples from across the USA to one of their central laboratories. In this way they can deliver a 24-hour turnaround service for common tests by ensuring that samples reach the central laboratory where they are analysed overnight and the results communicated to the physicians before they start work the following morning.
52. This system enables the companies to manage their transport systems in a way which optimises laboratory performance. By contrast, in England transport systems are generally managed on a hospital-wide basis in order to control costs. Under this approach utilisation patterns reflect the best fit across all consumers of transport services, of which pathology is but one. The effect is that from the pathology perspective the transportation of samples does not facilitate optimal laboratory performance; trays of samples may be collected from GP surgeries (alongside, say, the dirty laundry) and delivered to the laboratory only once the particular van has completed its entire journey. Anecdotally we heard of samples arriving at the laboratory at the end of the afternoon, when staff were completing their day's work; the samples then had to be stabilised and stored overnight so that they could be analysed the following morning. Laboratories operating a shift system would process these tests in the evening. In addition because of the inflexibility of transport services there was an unnecessary dependence on the use of taxi services to transport urgent samples between sites. These practices are clearly inefficient and expensive.

## Round the clock operation

53. This touches on another important issue. Many laboratories are open 24 hours a day, 7 days a week, in order to deal promptly with urgent test requests originating within the acute wards of their parent hospital. The question of 24/7 operation is a complex one.

There is a clinical need for such a laboratory to be available to support the hospital's clinical services, but the nature and the extent of the service provided by the laboratory out of hours is less clear. We heard from witnesses that urgent demands on the laboratory fall away after a certain point in the evening but the provision of an emergency service can place undue strain on a workforce, especially in the smaller laboratories. The *Hospital at Night* project established by the Department of Health will, we believe, help bring the attention of management to this area. It is made more complex by virtue of certain workforce practices which we address in a later section of this report. On the face of it, however, there is scope for improving efficiency here, albeit within the context of the needs of the service. In primary care greater clarity is needed in respect of the target turnaround time: we were told of instances where the results were returned to the GP within a few hours of receipt, but the patient was not recalled for a week. It may not be cost-effective to deliver a faster turnaround time than is required by the GP. In addition we heard of concerns expressed by many laboratory staff about the difficulties of reporting abnormal results (including unexpected abnormalities) back to primary care "out of hours".

- 54.** There is also the question of utilisation of assets, which in this country tend not to be deployed beyond the normal working day even though the equipment now available in certain specialties within pathology can operate effectively around the clock. In our view such equipment should be worked harder wherever possible, in order to achieve better value for money. This may require more flexible staffing patterns (perhaps incorporating shift working and a different skill mix) in terms of supervision and maintenance, and remapping of processes to ensure the supply of appropriate volumes of tests. For GPs in Canada, Australia and the USA it is normal for the results of routine assays to be delivered the following morning. By contrast, in England the emphasis on same-day testing for GPs in hospital-based laboratories could be viewed as over-production – and precludes more productive use of existing instruments and infrastructure "after hours". Put another way, laboratories in England have a maximum specimen throughput for only a few hours per day. In industrial engineering and business management, the aim is for peaks in work flow to be reduced through continuous operation of the facility. With specimens arriving over 18 hours – not 8 hours – peak capacity in the laboratory can be reduced and existing equipment can be used more intensively.

### **New technology**

- 55.** Compared with other countries England makes relatively little use of automated "front end" technology such as for sample tracking and reception, although the picture is changing. In part this reflects the emphasis on "cost" within the NHS: it can be difficult for pathology professionals to argue successfully for investment in new technology when there is downward pressure across all hospital budgets. Equipment manufacturers are therefore often willing to strike creative financial deals to enable them to introduce new

equipment, for example by reducing the costs of leasing equipment but charging more for reagents. Whether these deals are in the NHS's best interests in the medium or long term is open to question. We see the opportunity for greater investment in automated processes with benefits to the internal working of the laboratories as well as downstream benefits to the users of the service. There is also a perceptible risk of duplication of equipment. Examples of automation and the consequent benefits include:

- (i) pre-analytical sample recognition and preparation in clinical biochemistry, haematology and immunology;
- (ii) similarly in histopathology with rapid tissue processing systems and block identification systems;
- (iii) greater use of automated urinalysis and molecular testing systems in microbiology;
- (iv) more automated serology testing;
- (v) integration of similar analytical systems across disciplines;
- (vi) sample aliquoting systems prior to automated storage;
- (vii) automated storage of slides and tissue blocks.

**56.** Benefits would include:

- (i) reduction in lost samples;
- (ii) reduction in sampling errors;
- (iii) reduction in use of qualified staff time;
- (iv) reduction in overall test turnaround times;
- (v) reduction in sample retrieval time.

**57.** In consequence the adoption of new technology can be slow and patchy. In addition, as there is no common, national framework for evaluation (of the kind which NICE provides in relation to new medicines) each pathology department has to decide for itself whether to adopt a particular new product. Taken with the evidence of a lack of investment in established tests, delayed deletion of old and superseded tests from the repertoire, the limited impact of measures to curb inappropriate use of tests – an overall picture emerges of avoidable inefficiencies within pathology.

**58.** Manufacturers of diagnostic equipment operate within an international market. In England, spend on instrumentation and reagents in pathology represents less than two per cent of the world market. Accordingly the NHS exerts little influence in respect of innovation in technology, or in the commitment to global research and development costs.

### Minimising variation in results through standardisation of processes

59. Different manufacturers can make their equipment and analytical methods to different specifications – often dictated by requirements or practice in other countries, as well as establishing intellectual property rights. These differences in the range and nature of the assays performed on identical samples can lead to different results being generated. In certain circumstances these variations can have clinical significance for a patient. This is clearly unsatisfactory. Pathologists themselves have argued for some time that there needs to be greater standardisation of test results, and common reference ranges set for specific tests in so far as is practicable. We strongly endorse this, especially within the context of a local network.
60. This is particularly relevant at a time when opportunities for greater access and choice may result in patients attending a range of health care facilities during their journey along the care pathway. Greater standardisation would help to reduce the fragmentation of services, repeat testing and the consequent errors that occur. In addition there is a growing demand for point-of-care testing and patients may be managed using a combination of laboratory and point-of-care testing systems. There is also a growing market in do-it-yourself testing, which from a patient safety perspective should be considered in the same way. These developments raise a number of concerns which we address elsewhere in this report. What is clear however is that these developments in near-patient testing must be safe, accurate – and foolproof.

### Premises

61. From our visits to laboratories in England we were struck by the variability of premises from which laboratory services were run. There appeared to be a tendency to relegate pathology laboratories to remote and often cramped corners of hospital sites, where there was little if any scope for adapting the building ergonomically so as to facilitate the efficient operation of the service, and the introduction of new equipment was hindered by the limitations of space. Sometimes laboratories could be split between different sites.
62. The contrast with laboratories in the USA and in Europe was striking. We saw several modern laboratories which had been constructed around the core functions of the laboratory. Reception bays led into sample preparation areas which in turn led into the analytical laboratories. In short, the building design had been developed to maximise the internal processes.

## Process management

- 63.** Some modern laboratories of this kind have been built in England. Process management techniques developed overseas such as “lean” and “six sigma” have been adopted in some pathology departments with great success. These techniques are focused on determining the essential processes and functions within the laboratory, the flows and interconnections between them, and on the activities and movement of staff. What is inessential or unnecessary is stripped away in order to maximise the productive use of staff time and energy.
- 64.** Whether these particular techniques or indeed others are adopted, it is clearly beneficial for all pathology services to analyse processes and functions in this way as a means of improving the management and operation of the laboratory, as well as improving the quality of each health care encounter and reducing the cost per episode of care. Where it is not already done routinely we consider the benefits of this approach should be explored and should be matched with the workforce skill requirements.

## Operations

- 65.** So far this section has described a broad range of specific processes and logistics where we have identified scope for improvement in laboratory performance. Those processes are managed within an overall operational environment; yet we have found a number of obstacles which inevitably impede the effective and efficient running of pathology services.

## Costs of pathology services

- 66.** First, we were struck by how little the available information – financial, operational, workforce or performance – currently tells us about pathology (an issue by no means unique to pathology). This appears to hold true at national, regional and local levels. For example it has proved surprisingly difficult to obtain a reliable estimate of the total cost of providing pathology services within this country.
- 67.** The difficulty of estimating overall costs arises chiefly because the pathology services are not currently managed in an integrated manner. Different lines of financial accountability operate in primary and secondary care, and the cost of pathology is not separately identified. For example, where phlebotomy is undertaken in primary care the cost falls on the provider (for example GP, health centre); in the hospital it may form part of the laboratory budget or it may be included within the out-patient department’s budget. The share of hospital overheads (premises, cleaning, lighting, heating, maintenance) consumed by the laboratory may be accounted for in different ways in different NHS trusts. The proportion of hospital transport costs attributable to pathology

are rarely recorded separately; and as stated earlier a variety of different financial arrangements may have been made in respect of the acquisition of laboratory equipment.

- 68.** The picture is further complicated by the extent to which the pathology services not only provide training but also invest in research and development (both internally and as a service to commissioners).
- 69.** With the help of the Department of Health’s analysts, and drawing on data from the independent pathology sector, we consider that in aggregate pathology services in England cost in the range of about £2-3 billion per annum. This is a significant sum, equivalent to 3-4 per cent of the total budget for the NHS – with higher figures in teaching hospitals, where the costs of teaching are included.
- 70.** Most pathology budgets are set without reference to changes in workload. Each department within a trust is normally allocated its own operating budget; this is sometimes referred to as “silo budgeting”. Investment decisions are made within a silo with little attention to the impact – positive or negative – on other departments within the trust, or in primary care. In pathology, for example, the introduction of a new test would increase costs and put the overall budget under pressure; yet it might produce significant savings for other departments at the same time as improving patient care. An example is the use of an intra-operative parathyroid hormone measurement, which enables a surgeon to assess whether cancerous tissue has been completely removed. There is evidence that this test, combined with imaging of the gland, has resulted in a reduction in the re-operation rate (with a consequent reduction in risk to the patient), and conversion to a day case procedure (at reduced cost to the provider).
- 71.** In the above example there is benefit to all parties; but the benefit accrues only where the extra costs for pathology are balanced by a transfer of resources met from the savings made in surgery. There are many other examples where use of pathology services can be seen to improve the efficient utilisation of health care facilities, services and resources as well as improving patient outcomes.
- 72.** Point-of-care testing raises a different financial issue. It is generally accepted that locating test equipment near to the patient produces a faster result for that patient; this could be especially valuable when a patient’s life is under threat (for example in emergency or intensive care); in the management of a long term condition, where the results can inform the consultation between the patient and his/her carer; and in situations where the patient may have heightened concern about the outcome of the test, for example screening for cancer, or infection with a sexually transmitted disease (when the patient may not return for a result – leading to the avoidable risk of infecting others, as well as

of developing complications associated with the disease). Point-of-care testing may also make triage of patients more efficient.

- 73.** Though in such circumstances the service to patients is better, it is also more expensive – unless account is taken of the potential “downstream” savings in terms of earlier detection and treatment, reduction in use of clinic visits, bedstay for example. Such investment decisions need to weigh the cost/benefits at a level beyond simply the pathology department.

### **Pathology services management**

- 74.** Pathology services are not managed in an end-to-end manner. The lack of managerial coherence which makes overall cost estimates hard to construct also impedes the efficient management of the service. For example, under their new contract GPs gain financially from increasing the number of laboratory tests they request; predictably this has led to a significant increase in laboratory activity, although there was no corresponding increase in investment in laboratory funding at a national level. Similarly, transport costs are controlled not by reference to laboratory efficiency but to overall transport activity, even where from the laboratory perspective the consequence is higher costs than necessary.
- 75.** In the independent pathology sector, as we saw during our visits overseas, the drivers of costs are controlled by the service provider. This integration enables the managers to define the optimal configuration of the overall system; phlebotomy, transport, laboratory and workforce can all be aligned to deliver a responsive, high quality, efficient and effective service. Realising these downstream benefits has no bearing on the pathology service provider; and it was not clear to us what efforts were made by customers to operate the overall system in an integrated manner. It is important to recognise that in pathology, clinical investment decisions should be evaluated by reference to their impact on overall clinical service quality and costs.
- 76.** Where the laboratory is part of the hospital there is greater scope for managing health care resources in an integrated way in order to deliver better overall health care across the patient pathway – an option which in a formal contractual relationship of the USA kind may not be identified: or, if it is, would not occur without renegotiation of the contract. The realisation of these system-wide service improvements depends crucially on active clinical leadership.
- 77.** This argues for regional consolidation and integration of pathology services and the rationalisation of resources on lines similar to those adopted in Canada and the USA in the 1990s and currently being adopted in Australia. This suggests that in England the

rationalising of resources in pathology and the better alignment of services with the wider needs of the health care system are lagging behind these other countries.

### **Demand management**

- 78.** A key inefficiency at present is the lack of management of demand. This has several aspects. First, several witnesses said that there were substantial levels of unnecessary testing (although we have found no robust studies which verify this statement). Such witnesses have stated that a proportion of tests requested in primary care are repeated unnecessarily in secondary care following the patient's admission to hospital. Overall a figure of 25 per cent – mentioned by several witnesses – for unnecessary repeat tests might be approximately right. It is easier to repeat the test (and incur the extra cost) than to look up the earlier result – which might then involve dialogue with the original requester. There is published data showing a large variation in requesting patterns in general practice – although this equally could reflect under-, as well as over-requesting. There is also published data to show that not all results are accessed and used by the requester. We were told that unnecessary, and repeat, testing was also prevalent in the USA and Australia.
- 79.** The Healthcare Commission's review of pathology, published in 2005, noted that in a quarter of trusts more than 20 per cent of written requests from GPs were only partially legible.
- 80.** It is also claimed that up to 40 per cent of tests requested within the hospital may be unnecessary; again this figure is not substantiated. The Healthcare Commission's review of pathology noted that wide variations existed in the way pathology services were used in different hospitals, with patients attending accident and emergency departments in some hospital trusts having on average one biochemistry test while patients at other hospital trusts have five tests. It also found that in a third of trusts more than 15 per cent of full blood counts were repeated three times in three days for the same patient. In a third of trusts more than 20 per cent of ward requests were missing important clinical information about the patient's history. There was limited evidence that trusts were taking action to address these issues. We were given evidence that when demand management was introduced (albeit on a limited scale) a reduction in requests was achieved, although it is clear that this activity is hampered by the poor quality of IT links between laboratory information systems, and hospital and primary care systems.
- 81.** Demand management is obviously harder to achieve where IT support is imperfect or incomplete. It would however be reasonable to suppose that some unnecessary testing could be caused by the practice of defensive medicine. It is safer for a clinician to request tests – whether necessary or not – than to have to justify the judgement not to make the request. High levels of unnecessary tests are more common at night, when the clinicians

on call are generally more junior and less experienced. Defensive medicine was given as one of the reasons for the higher level of testing in the USA.

82. The impact of the new contract for GPs has already been mentioned. It is important to acknowledge however that some increase in demand is clinically justified. The Department of Health's development programme for National Service Frameworks is a driver of increased demand for laboratory tests. In such cases, of course, there is an evidence-based requirement for additional, often regular, testing to inform the diagnosis, treatment and management of a patient.
83. Low rates of requests may also be worth investigating as they may reveal areas of practice where tests could add value to the diagnosis and treatment of a patient. Analysis of the requesting rates of different practices, and of different GPs within a practice, may therefore be helpful in improving clinical effectiveness as well as cost-effective use of the pathology services.

## Knowledge

84. We heard from several witnesses that unnecessary demand stemmed from a lack of appreciation on the part of the requesting clinician about the appropriateness of particular tests and the usefulness of the information obtained from the test result. As laboratory medicine becomes more sophisticated it is inevitable that the knowledge gap between the requester and the pathologist grows wider.
85. This knowledge gap highlights the clinical contribution which laboratory medicine can make to the treatment and care of a patient, and the desirability of dialogue between the pathologist and the clinician. This is particularly valuable when the clinician is considering making a test request and, later on, when the result of the test is interpreted – and related to the clinical condition of the patient in question.
86. In its review of pathology services published in 2005 the Healthcare Commission concluded that “the key challenge facing many pathology services – and a major theme to emerge from the review – was the need to improve the level of understanding of pathology services among doctors and other staff using these services. Improved understanding should help users ensure that they are ordering the right tests, providing the right supporting information and correctly interpreting results.”
87. Pathology is not purely a laboratory service. For certain patients, in particular those with chronic conditions who have become expert in managing their illness, there can be a direct relationship between the patient and the pathologist. Some pathologists hold regular clinics for such patients. Such individuals are not in need of the clinician's help in respect of diagnosis, albeit he/she will remain under the overall care of a clinician

(specialist and/or GP), as in the case of recognising early signs of the development of long term complications. Through regular self-testing they can monitor their condition and adjust their management of it accordingly. In such cases the key is having access to the test and to the knowledge of what the test result means for their condition.

88. It is recognised that pathology services are a powerful tool for disseminating knowledge within the NHS. The reports on individual patients routinely carry clinical guidance which is drawn from such evidence-based sources as NICE and the National Electronic Library for Health. The NHS National Knowledge Service is building this activity into the *Connecting for Health* programme in relation to the formulation of best clinical practice, the protection of patients and the economic effectiveness of diagnostic testing within patient pathways. It is essential for these developments to continue within pathology services. On any view the advantage of including them in the future configuration of NHS pathology services is clear.

### **Pathology networks: segmentation and critical mass**

89. During our visits overseas we noticed that laboratories were typically formed into networks comprising “hot” laboratories which provide the essential support for acute activity (accident and emergency, critical care), which therefore requires co-location with acute hospitals; “cold” laboratories which process high volumes of routine tests, and which have no requirement for co-location with other hospital activities; and specialised or esoteric laboratories which provide analysis of less common, more complex and usually more expensive tests.
90. By contrast, not long ago the traditional pattern in England was of a laboratory, often free standing, located at an acute or district general hospital, and (for the most part) undertaking all the laboratory work for that hospital independent of other laboratories. Laboratory staff did not differentiate hot from cold activity and carried out all but the most specialised tests on the premises.
91. This model has increasingly been questioned, from a number of perspectives, particularly whether it maximises the use of staff and equipment and whether it optimises the configuration of staff and expertise. In its publication *Modernising Pathology Services*, published in February 2004, the Department of Health advocated the establishment of managed pathology networks which would cut across individual trust boundaries. These networks were seen as mechanisms for engaging all stakeholders in pathology and for supporting – including through the sharing of resources – service planning and delivery across the network for the benefit of the whole health community. Their primary focus was on ensuring that patients received appropriate treatment at the right time and in the right setting; and that pathology services did not stand in isolation.

- 92.** Because the process of forming these networks was based on voluntary co-operation the degree and pace of change has to date been steady rather than speedy. In particular, pathology departments (or their parent trusts) have been understandably reluctant to surrender autonomy. In consequence there has been little progress in differentiating routine from specialised testing, and “hot” from “cold” work. The scope for realising economies of scale arising from such differentiation or – more particularly – from the concentration on a single site of the uncommon, highly specialised tests has therefore not been tested to any significant extent. The equation is complex however: where such changes reduce overall test volumes the average cost per test in the “hot” laboratory will rise. Interestingly in our visits in the USA we noted that there was an increasing trend away from sending cold work to “offsite” facilities towards the development of local outreach services. One of the key drivers for the change appeared to be a desire to increase the income of local hospital-based laboratories.
- 93.** It is important to understand that the fundamental objective of a managed network is not the mode of delivery (for example the use of a core laboratory for “cold” work), but rather the provision of an integrated service across a defined geographical area, which is equitable to all users and patients, and reflects the needs of all stakeholders.
- 94.** We consider that the benefits of optimising services for both quality and economies of scale should be investigated in pilot studies. These studies would determine the potential impact on patient care, the extent of the extra opportunities for greater specialisation amongst staff (where appropriate with a skills- and competence-based approach to workforce planning requirements), the level of improved value for money, and the scope for greater concentration of specialised testing to promote greater knowledge. We have already seen encouraging progress in this direction, particularly at Pathlinks in Lincolnshire.
- 95.** There is probably an optimal level of organisation – the “sweet spot” as one witness called it – at which the economies of scale are realised. In the USA we found a growing awareness among service users and service providers alike that the concentration of routine testing in one or two factory-style laboratories had probably passed the “sweet spot”; providers barely made any profit per routine test; users were concerned about error rates, and were looking for more local service providers. In relation to specialised tests however the picture was very different, with tests being referred to a number of reference laboratories (including ARUP, Quest and LabCorp) from across the country. Kaiser Permanente, which is both an insurer and a provider of health care and manages its own network of laboratories, still finds it cost-effective to refer several specialised tests to these reference laboratories. It should be recognised however that the decision to send work out was predominantly made on the grounds of cost.

96. In order to explore and resolve a number of issues we consider that pilot studies should be set up in this country which can help to identify the optimal configuration of services for both routine and specialist work. We are conscious however of the difficulties of promoting organisational change which spans primary and secondary care, and includes Foundation Trusts. We envisage the need for further discussion with stakeholders before any pilot projects begin in order to identify and address their concerns. Local commissioning based on a commissioning specification or plan is however the key to effective change.

### Performance measures

97. Laboratory performance is usually measured in turnaround time – invariably the time it takes to process a test, albeit it should be from when the request is made until the result is received. The Healthcare Commission’s review of pathology found some problems with the speed and accessibility of pathology services. In particular it found that the time taken to process tests – including urgent tests such as for troponin (used to diagnose the cause of chest pain) – varied considerably. Evidence presented to us suggests that this may reflect the absence of investment in new tests, or in new demands for a faster service. The Commission also found that around a third of ward managers reported that at least once a week late or lost pathology reports had an adverse impact on the care or discharge of patients. Nearly half of those managers thought pathology services should be improved by extending opening hours in the evening or at weekends. This conclusion needs to be reviewed in the light of the *Hospital at Night* project and the state of connectivity of IT facilities.
98. Other measures seek to relate activity to cost (for example through cost per test), activity to workforce (typically through productivity) and service quality (for example through error rates, patient safety, “patient-centredness”, timeliness). Elsewhere we describe the outcome of international studies of these performance measures. Within England pathology services can opt to join Keele University’s Clinical Benchmarking Company scheme, which enables them to benchmark their performance against other pathology service members. Unfortunately it did not prove possible for us to access this information within the time available. However we heard from several witnesses that this service provided a valuable management tool for promoting service improvement.
99. Overall there was little evidence of laboratory performance being assessed not simply within its own specialty but – more importantly – in terms of its impact on broader health outcomes. It is clear, however, that for active, efficient and effective management of pathology services there needs to be more and better performance information than at present, so that managers can understand better the performance of their services and compare it with services elsewhere in the country and overseas.

## Workforce

**100.** As outlined earlier in this report the pathology workforce of about 25,000 people currently consists of a number of different professional and/or employment groups who work in five main disciplines or specialties:

- **Medically qualified pathologists** who provide direction, interpretation of results, and direct patient care, having membership of the Royal College of Pathologists and being registered with the General Medical Council;
- **Clinical scientists** who provide direction, interpretation, and advanced scientific expertise, usually having membership of the Royal College of Pathologists and being registered with the Health Professions Council;
- **Biomedical scientists** who provide the core of the benchwork associated with pathology, and are registered with the Health Professions Council;
- **Medical technical officers** who provide higher level technical support and include, as a distinct group, anatomical pathology technologists;
- **Medical laboratory assistants** who provide technical assistance (some of which may be shared across disciplines);
- **Cervical cytology screeners** who provide technical support to the national cancer screening programme and to cervical cytology in general;
- **Phlebotomists** who undertake venepuncture and (in some areas) other haematology investigations or point-of-care testing;
- **Administrative and clerical staff** who undertake a wide range of support roles.

**101.** Pathology is a consultant-led service. The consultant role may be undertaken by either a medically qualified pathologist or a clinical scientist qualified in one of the recognised specialties such as clinical biochemistry, immunology or microbiology. There is usually a clinical director of pathology services, an increasing number being clinical scientists. Biomedical scientists have been extending their roles, for example, in relation to cytology, in conjunction with the Royal College of Pathologists.

**102.** We have observed that the composition of the pathology workforce appears to be one of the most complex and heterogeneous in the NHS. This complicates service planning, particularly in relation to workforce planning. Managers and other NHS staff have difficulty understanding the differing education and training requirements developed for each pathology discipline but sometimes relating to the same role or function. Partly as a result of this complexity neither the total size of the workforce nor its overall cost is known with any accuracy. Furthermore, there is currently a general lack of coherence in workforce planning and development. We note with approval the initiatives launched by

the Department of Health's Chief Scientific Officer with a view to providing a greater understanding of these matters.

- 103.** The complexity of the workforce – not seen in other countries – probably reflects the ad hoc and silo-based evolution of the different professional/employment groups (as, we understand, evidenced in projects such as the National Occupational Standards Project in Healthcare Science which reported the delivery of overlapping roles and functions by some of the groups) rather than active, managed change driven by the requirements of local pathology services and based on the functions that need to be delivered, and the opportunity for more effective multidisciplinary approaches to working.
- 104.** We observed that technological advances (such as laboratory automation and point-of-care testing) and other clinical and scientific advances in laboratory medicine are changing the skill set required to deliver pathology services, and this has yet to be generally reflected in the composition of the current workforce. With the greater involvement of medically qualified pathologists in multidisciplinary teams and in direct patient care, the roles of clinical and biomedical scientists are also changing, while ensuring that the pure scientific base (often provided by clinical scientists) is maintained to allow the service to develop and improve. This points up the need, however, to review the roles and structures of the workforce with a view to reducing its complexity and to ensure that, in common with the rest of the health care workforce and as outlined in the Department of Health's workforce strategy, it is equipped to deliver modernised affordable high quality pathology services for the future. We are aware that the Department's Chief Scientific Officer has initiated work nationally in this area.
- 105.** Across the NHS there is an increasing emphasis on integrated service improvement as a means of achieving associated gains in productivity. This report recognises the need for pathology to streamline its processes and service functions (including understanding the impact of new technology) and to develop its skill requirements accordingly in order to improve efficiency and effectiveness. This would imply an integrated pathology service model where inputs (such as demand; the type and range of general and specialist provision; hours of operation, and automation) could be matched to skill and knowledge requirements and thereby a workforce profile could be developed which optimised the desired service outputs. This will undoubtedly be different from the workforce which has evolved to date.
- 106.** Within the broader context pathology services should be considered within the delivery of end-to-end patient pathways, where logistics and other backroom functions will equally need to be reflected within workforce modelling and planning. The development of point-of-care testing and the use of pathology-based tests and investigations by members of the wider health care team may require a change in the role of the

pathology workforce in order to ensure that safety and quality are maintained. Indeed, based on the evidence before us, it is clear that there are opportunities for the extension of roles beyond traditional delivery boundaries, including in the community. This direction of travel will, we understand, be reflected in the Department of Health's framework on the roles of healthcare scientists in primary care, which is currently in the final stages of development.

- 107.** From the foregoing we have identified a number of workforce themes which require attention. They are:

**(a) Professional demarcations**

- 108.** With the advances in science and technology there appears to be a blurring of boundaries between some disciplines/specialties which would lend itself to the introduction of greater service and workforce flexibility which is generally not being exploited. This suggests that the pathology workforce needs to be considered as a whole, by emphasising the complementarity of skills within a common service and competence framework.
- 109.** The range and extent of internal distinctions can cause practical problems in relation to the flexible deployment of staff especially in smaller departments, and there appears to be greater scope for multidisciplinary working in biochemistry, haematology and immunology, for example, as well as in the support functions such as specimen reception.

**(b) Workforce numbers and planning**

- 110.** In order to understand the full costs of pathology services it is critically important to know the size and composition of the workforce. This information needs to be available for planning purposes both locally (at Strategic Health Authority level) and nationally (to inform policy development and strategic planning, as well as to facilitate national approaches to commissioning especially for small or specialist areas within pathology). We recognise that the Department of Health has a number of initiatives aimed at improving data collection in respect of the non-medical workforce.
- 111.** Any workforce planning model must be capable of reflecting the changing requirements of the pathology workforce and be based on skills and competences. It must not preserve the current professional silos. If clinical scientists are to take on roles equivalent to those of medical consultants in all of the specialties, then their workforce planning needs to be set in the context of the whole career pathway and the whole workforce, with provision for roles to be extended as appropriate, and put onto a footing similar to that for medical training. A similar position should be adopted for biomedical scientists, medical laboratory assistants and others. Furthermore, there needs to be greater clarity in the

expansion of non-medical roles across the pathology workforce. We understand that work is currently under way in this area within the Department of Health.

**(c) Recruitment and retention**

- 112.** We understand that the pathology workforce has been relatively stable in recent years, although there are significant recruitment and retention issues in some parts of the country, in some professional groups and in some specialties.
- 113.** A degree of turnover of staff is of course to be expected. It has been suggested to us however that a lack of resources has led to the freezing or loss of a number of posts at local level and the restricted provision of basic and higher specialist training. Some see the implementation of *Agenda for Change* as exacerbating the problem. Most recently, the financial deficits of some NHS trusts has had an impact on pathology staffing.
- 114.** There is evidence of an ageing workforce in some disciplines and some professional groupings. If the skill sets and skill mix of these groups and individuals were matched directly to the functions of the pathology services of the future, there could already be an urgent need to plan for their replacement, taking account of the costs of, and timescales for completing, training.
- 115.** This forecast shortage also provides scope for introducing into the overall workforce new staff with new skill sets aligned with the changing pathology service. In refreshing the workforce in this way it should be possible to develop attractive career pathways (supported by active recruitment campaigns and investment in training capacity) which should remove barriers to the successful recruitment and retention of the future pathology workforce.

**(d) Career pathways**

- 116.** As for other specialties, and in keeping with the UK-wide programme for modernising health care careers, career pathways in pathology need to be clearly defined, based on the skills and competences required for modernised services and transferable roles.
- 117.** As mentioned earlier in this report – and in keeping with such Government policies as *Improving Working Lives* – there are opportunities for improving the match between workload and work flow on one hand and extended hours of operation, the introduction of flexible shift patterns and condensed working days on the other. We know these practices have been successfully introduced in some trusts and operate in other countries; they can provide a better working pattern for many individuals, thus potentially enhancing recruitment and retention.

- 118.** While medical career pathways are part of the modernising medical careers initiative, career pathways for healthcare scientists are part of the modernising healthcare science career strand and linked to the Department of Health’s career framework for healthcare scientists in the NHS. This programme includes modernisation of pre-registration education and training. To avoid overlap between the medical and non-medical pathology workforce it will be critical to ensure there is coherence between these two different strands of work so that a truly competence-based workforce can be introduced.
- 119.** In particular we recognise that there is a need for the Healthcare Scientist Career framework to be fully implemented, informed by the National Occupational Standards that have been developed in the pathology disciplines. Integral to this is the need to ensure that pre-registration education and training programmes are fit for the modernised pathology service of the future; and that specialist and higher specialist training requirements are clearly identified and resourced, and common approaches to education and training are adopted. In our opinion this coherence is necessary to avoid the duplication and fragmentation that currently exists, especially with regard to the stand-alone qualifications which different professional groups are developing.

**(e) Skill mix and general requirements**

- 120.** As outlined earlier, we have noted an increasing divergence between the skill mix of the current workforce and the functions required by a modern laboratory service driven by, for example, the introduction of automation, steeply rising demand and the evolution of the service (through, for example, more involvement in direct patient care and in clinical decision-making). This is coupled with a more sharply defined need for active “business orientated” management of the service, not only to ensure effectiveness and efficiency of operation but also in terms of service responsiveness and improvement, with strong overall leadership and the development of local champions.
- 121.** This will require radical change and a clear vision for the future. Large scale workforce change is difficult to deliver and national support will be required to assist and direct the process.
- 122.** Pathology staff in some areas have already responded well to the challenges outlined. They are therefore well placed to help with the further development of the workforce, so that there is uniform coverage across the profession.
- 123.** In particular, we see a powerful case for strong clinical leadership. Such leadership would mean representing the specialty to others, so as to promote its potential for contributing beneficially to wider clinical decisions and enhanced patient responsiveness, and to make the case, where appropriate, for spending more on pathology in order to reap bigger savings elsewhere. It would also mean defining the nature, range and scope of the service

in order to meet the needs of patients and their carers; defining the standards to which they should be delivered and ensuring that these standards are met; and ensuring that the service is employed effectively – in relation to the current repertoire of investigations as well as new investigations and new technology.

**124.** In summary we see the need for:

- (i) clear definitions of functions within pathology;
- (ii) delineation of roles based on skill- and knowledge-based competences derived from functions spanning the whole career pathway, from support worker to consultant-level practitioner and clinical director;
- (iii) identification and development of common education and training pathways;
- (iv) enhanced clinical leadership skills, especially at consultant level, to represent pathology to service users and commissioners and to secure more awareness for the role of the specialty in diagnosis and treatment;
- (v) enhanced business orientated management skills;
- (vi) skills in the management of change.

**(f) Training**

**125.** This requires more detailed consideration than we have been able to give it; but we are attracted to a model which is driven by defined standards for training informed by the functions that need to be delivered and the need for equivalence in terms of the academic levels attained, with enhanced training capacity delivered through appropriate training institutions (perhaps modelled on the training schools for histopathology); and where all pathology service providers including the independent sector participate in the provision of training.

**126.** It is recognised that due consideration needs to be given by the Department of Health and Strategic Health Authorities to the provision of a level playing field for the funding of education and training, and the commissioning of supporting programmes for the complete pathology workforce, in order to ensure that the pathology workforce is fit for purpose. Currently higher specialist training and (in some disciplines) basic training is not being fully funded for the non-medical workforce; this funding is essential if the workforce is to take on more advanced roles. This needs to be linked to the introduction of designated training numbers (as outlined earlier) to support more intelligent workforce planning for the future and commissioning of supporting educational programmes.

127. In order for pathology services to be developed and based on clear evidence-based standards there is no doubt that a sustainable academic base for promoting research and development in pathology needs to be created, in keeping with the Department of Health's recent publication *Best Research for Best Health*. The functions of such an academic base would include evaluating new technology and supporting clinical trials.

**(g) The professions**

128. Finally, the number of disciplines, professional groupings and bodies within pathology serve to promote an impression of professional fragmentation, which in turn makes it more difficult to provide integrated leadership and representation.
129. Accordingly consideration needs to be given to the scope for diminishing the barriers between different disciplines and promoting a more united professional face for pathology, so as to promote closer working while not inhibiting the development of specialist skills – or the role of specialist scientific professional bodies; and we suggest that the Royal College of Pathologists and the other professional bodies work with the Department of Health to address this – and indeed our other conclusions in respect of the workforce.

## Accreditation

130. At present pathology service providers are expected to register for accreditation through Clinical Pathology Accreditation (UK) Ltd. While we welcome the concept of accreditation in pathology, we are concerned that the process should be flexible enough to accommodate changed approaches in the delivery of pathology services. It has been suggested to us that there is scope for improvement in this respect.
131. In pathology we also see the need for accreditation of point-of-care testing (irrespective of site of provision), with this preferably being integrated with that of the laboratory service because of the close synergies – from the patient's perspective – between the two modes of testing.
132. This is a specialised field, and we have insufficient evidence to do other than indicate in broad terms what we see as the core requirements of an accreditation system, namely, that all services should be required to obtain accreditation; the process by which accreditation is secured should be responsive to and reflect changes in functions and skills, based on service quality standards, including those set out above; and that the accrediting body is seen as impartial and independent, rather as the Healthcare Commission is in respect of the regulation and inspection of health care bodies.

## Specialist Services

- 133.** The Health Protection Agency has a network of regional laboratories across the country which work closely with microbiology/virology departments within the local pathology laboratory services. The Health Protection Agency laboratories provide the coordinating functions and specialist testing, while the local NHS microbiology/virology laboratory is expected to fulfil a public health role. The core functions expected of the local microbiology laboratory include:
- (i) contributing to surveillance of infectious diseases;
  - (ii) providing support for the investigation of local outbreaks;
  - (iii) providing specialist advice to clinicians on antimicrobial prescribing and infection control in primary care and community settings.
- 134.** The merit of the Health Protection Agency network system is clear, but the accountability of the local trust for its contribution to public health functions is less obvious.
- 135.** The NHS Blood and Transplant Authority has a network of laboratories supporting the collection and testing of blood and tissue. In relation to the collection and testing of blood for use in transfusion and the preparation of blood products there is a network of routine testing centres supported by a small number of reference centres specialising in red cell immunohaematology, histocompatibility and immunogenetics, and stem cell and immunotherapy. In addition there is also some antenatal testing. However, while there is a network of specialist services in place it does not provide complete coverage, with some trusts providing their own services. Again the merit of the networks is clear, but it should be extended to give complete coverage.
- 136.** Many of the screening services, for example, for Down syndrome and for newborn screening, are located and managed in local pathology departments. The accountability of these services to their respective national screening programmes is variable and there would appear to be merit in considering the use of a managed network to ensure proper accountability, as well as equity of coverage, while also enabling the services to take advantage of the local pathology and – importantly – the clinical infrastructure.
- 137.** There are a number of fairly loose arrangements for specialist services which derive either from earlier initiatives to establish reference services, or from the existence of local specialist expertise and initiative. While this is to be applauded, there is no systematic approach to ensuring equity of provision, or to the evaluation and implementation of new tests and technologies, although this should follow from the new work of the NHS Purchasing and Supply Agency Centre for Evidence-based Purchasing.

## The Independent Sector

- 138.** In this country the independent market in pathology is currently relatively small, but it is growing. There are several independent providers of pathology across Europe and in North America and Australia who are interested in developing their operations in this country. They are generally well managed and several have experience of working in partnership with the public health care sector, including in this country. In particular they have the ability to invest resources in the infrastructure (premises, technology, transport) in order to secure greater efficiencies, including through economies of scale, and better returns for their shareholders. However, it is also recognised that in some countries where there is a mixed economy of providers of pathology services, there is fragmentation of services with an adverse impact on patient outcomes (see earlier discussion).
- 139.** We see the potential for significant benefit from further involvement of the independent sector in the provision of pathology services in England through, for example, the sharing of best practice over logistics and business management, so long as there is a level playing field, common application of the national quality framework and avoidance of service fragmentation.

## Commissioning Pathology Services

- 140.** Within secondary care, pathology services have typically been seen as part of the overhead cost of clinical services, with no internal commissioning arrangements – though we see a case for them – and a budget set without reference to changes in activity levels or other cost variables. Test referrals between hospitals have usually been based on a specified cost per test. Requests from primary care used to be dealt with under block contracts, but there is increasing use of direct commissioning based on a fee for item of service.
- 141.** Effective commissioning is the mechanism for creating a patient-led NHS. Through Practice Based Commissioning, GP practices are increasingly commissioning the best services for their patients, choosing from a range of providers, including the independent sector. Within pathology, Primary Care Trusts provide GP practices with activity and financial information on tests and procedures, benchmarked against other NHS providers. The aim is to develop care pathways which best meet the needs of the local population while also increasing efficiency and effectiveness.
- 142.** As patients become more informed their expectations will rise. They will want:
- services that are convenient and accessible;
  - an understanding of the purpose of each test;

- tests that are timely, safe and matched to the clinical requirement;
  - accurate and reliable results;
  - the ability to understand the test results and their implications.
- 143.** Pathology providers have the opportunity, working in partnership with GP practices, to develop new care pathways and improve access, provide guidance on best practice, advise on the appropriate use of point-of-care testing and provide support on clinical governance.
- 144.** In making their commissioning decisions GP practices and Primary Care Trusts will need to satisfy themselves that the services they commission:
- are based on sound evidence;
  - are of sufficient quality;
  - are efficient and effective.
- 145.** For these reasons we see a need for a commissioning specification or plan to be produced for commissioners which should include a quality framework for pathology services.

## Conclusions

- 146.** From the evidence before us it is clear that NHS pathology service providers are currently providing an effective service. In a climate where demand is rising steeply year on year and budgets remain very tight, pathology staff have shown great professionalism and commitment despite poor logistical support. It is a testament of this dedication that the Department of Health has stated that pathology is not an impediment to the achievement of its 18-week target.
- 147.** As stated earlier, the environment within which these services are provided is changing. It is Government policy to separate health care providers from commissioners, and to make services more responsive to the needs and wishes of patients and users, with greater choice delivered through plurality of provision.
- 148.** This changing health care climate brings new challenges and new opportunities, with greater involvement of the independent sector in NHS provision, and pathology needs to adapt accordingly.
- 149.** We are aware that an increasing number of pathology services in England are entering into joint ventures with the independent sector. These arrangements can be mutually

beneficial, providing the independent sector with the scope to develop new markets, while enabling the public sector to benefit – where appropriate – from new investment and to develop new skills (particularly, perhaps, in relation to resource management). In our view it is likely that commissioners will become more discerning in terms of the quality of service they expect (it is interesting that in Australia competition is based on quality, not cost). In a more competitive market, pathology service providers will have to respond by improving quality and efficiency. Joint ventures with the independent sector represent one way of achieving this over the short term.

### **Managed Networks and Free Standing Operation**

- 150.** As the provision of clinical services becomes more complex and more specialised, with greater diversity in the way that services are delivered, the demands on pathology services (as for other specialties) become greater and more sophisticated. The concept of managed networks provides a means of addressing these challenges by ensuring there is a critical mass of resource and expertise while also enabling scarce resources to be used more efficiently.

### **Priorities for Change**

- 151.** How can pathology services improve efficiency and cost-effectiveness when at present they do not have within their control all the key determinants of activity and cost? How can commissioners ensure that the laboratory services are being used effectively in the care of patients, and are utilising resources effectively? Earlier in this report we identified a number of barriers to improved working (some of which are amenable to change at local level, though others require action to be taken centrally). We have also identified six main priorities for change, and set out why we place reliance on the development of a specification or plan.

### **A Commissioning Specification/Plan**

- 152.** Such a commissioning specification or plan would form the basis for the contractual relationship between the commissioner and the provider. We would expect the contract to cover the level of activity undertaken and the cost to be paid in return, as well as the range and nature of the services to be provided and the quality standards to be met. The contract could also require formal accreditation to be in place and could specify, if desired, levels of efficiency gains and areas for investment. In short, the contract would become the vehicle by which providers would account for the services they provide, while purchasers would be required to be explicit about their plans and requirements.

## Reimbursement/a Tariff for Pathology

- 153.** In order to drive change, as well as beginning to create a link between cost and value, we consider that a tariff should be established and applied to pathology. This would be in keeping with the tariff already put in place by the Department of Health under its policy *Payment by Results*, which currently includes pathology services within a larger bundle covering other diagnostic and imaging services. In our view this tariff should be unbundled in order to clarify the costs specifically attributable to pathology. We are aware that such tariffs form the basis of contractual relationships between pathology providers and users in the USA, Australia and Europe – in the form of reimbursement. In the USA we understand that a tariff has been developed for Medicare patients, which increasingly forms the basis for the prices set by Health Maintenance Organisations.
- 154.** Construction of such a tariff for use in England need not be too challenging if it is drawn from those tariffs already in existence in other countries. It would be a powerful mechanism for driving change because it would highlight those providers whose costs were above average. They would need to improve efficiency and/or improve income in order to avoid breaching their budget. In such cases the economies of scale achieved by rationalising the provision of pathology services across a network or a region – for example by concentrating the analysis of specialised tests, or centralising “cold” pathology work, on a single site – may become increasingly attractive. On the other hand, laboratories in the USA are, we understand, increasingly bringing in-house more of the GP work which was previously sent to offsite cold laboratories in order to bring down their costs. A balance has to be struck here.
- 155.** A tariff would also make provision for investment in new tests and technologies. We believe that there is a need for more studies into the clinical and economic benefits of such investment to be carried out. This is a trend being developed in other countries including the USA, and is also consistent with the aims and objectives of the NHS Purchasing and Supply Agency’s Centre for Evidence-based Purchasing, and the findings of the Healthcare Industries Task Force report. This would have the added advantage of identifying where the benefits from introducing new tests and technologies would be seen, as well as how clinical practice and the patient journey might change in order to achieve those benefits.

## National Screening Programmes and Specialised Services

- 156.** We are aware that a number of laboratories participate in the provision of national screening programmes which are sometimes, but not always, run independently from the rest of the laboratories’ activity; and that specialist laboratories operate within loosely managed national groupings. We see a strong case for tightening the management of these specialised national services along the lines of a dedicated managed network, albeit

with the opportunity to sit alongside managed pathology networks. How this would be achieved requires further reflection.

## Proposals for Further Work and for Pilot Projects

**157.** We have identified some important areas where, with the current state of knowledge, it would be unsafe for us to make specific detailed recommendations. In these areas we recommend that the Department of Health, working with representatives of the professions, undertakes specific further work within the next six months. Above all we see the need for more work in relation to:

- the feasibility of developing a tariff (or mechanism for reimbursement) specific to a range of pathology tests;
- the workforce, in particular the functions, skill sets, skill mix and training which future pathology services will require;
- the delivery of end-to-end IT connectivity for pathology services.

**158.** We are concerned to deliver recommendations which will provide a practical way forward. Because of the lack of nationally collected activity, cost and performance information, we conclude that our recommendations – set out above – should be tested through a series of pilot projects and subsequently reappraised.

**159.** Although the mechanisms and outcomes of the pilots would need to be centrally determined to a common standard and format (template), and there is much learning available from models already tested both in this country and overseas, we do not intend to be too prescriptive about the approach or the scale of the pilots. There would be room for local determination, taking into account the views of stakeholders and reflecting local or regional circumstances. Indeed, the broader the range of different organisational models and approaches the better, so that the relative merits of each can be evaluated against the others. It would be open to all the pilot projects to choose whether and if so how to work with the independent sector, so as to broaden further the range of approaches tested.

**160.** In our view the Department should set aside a level of investment for the pilots in order to help them overcome the barriers to effective operation identified earlier in this report – such as investment in IT, and perhaps in the workforce. In particular, we recommend that the Department explores the feasibility of a shadow tariff for pathology.

**161.** Before the pilots start, there would need to be a planning stage during which stakeholders would be invited to reach a common view on the approach and scale of them. If local GPs or Primary Care Trusts do not have a sense of commitment to the

pilots, they will not work. There must be a similar level of commitment from Strategic Health Authorities. It will take time for this planning stage to be completed: probably around six months.

- 162.** Such a planning period would also provide time for baseline data to be determined, and for agreement to be reached on the mechanism for evaluation, based on a centrally agreed template.

# Annex A: Independent Review of NHS Pathology Services in England

## Terms of Reference

“To advise Ministers, in the context of current resource constraints, on the timeliness, reliability, capacity and efficiency of current pathology services in England, benchmarked against international standards and the feasibility of and benefits arising from wide-scale service reconfiguration, innovation and modernisation and involvement of the independent sector.”

## Membership

Lord Carter of Coles – Chair

Professor Chris Price

Mr Marcus Robinson

## Secretariat

Mr Edmund Waterhouse    Review Manager

Ms Monica Acheampong    Review Assistant

# Annex B:

## Approach to the Review

1. As a first step we placed an advertisement in the national media which invited people and organisations to submit evidence to us for our consideration. We have received around 200 such submissions. A list of those who responded is incorporated in **Annex B.1** below.
2. We identified and met a wide range of individuals and organisations who are included in **Annex B.1**. We undertook a wide range of visits to laboratory sites and spoke to pathology service providers, both in this country and overseas: those we saw are also incorporated within **Annex B.1**. We accepted an invitation to attend the annual conference of Frontiers in Laboratory Medicine, held in Birmingham in February 2006.
3. In addition we asked the Department of Health to support us by establishing an Advisory Group consisting of representatives of different parts of the Department. Members of the Advisory Group would then present to us in respect of those key areas of policy which touched on our terms of reference. Membership of the Advisory Group is listed at **Annex B.2**. Through this Group we were able to invite members of the Department's analytical staff to review the pathology literature and data on our behalf so as to help us understand the extent of the information available to us.
4. At an early stage in our deliberations we decided that it would be helpful to us to view our task from five main perspectives:
  - process management;
  - operations;
  - logistics;
  - technology;
  - workforce.
5. Our findings broadly follow these divisions although our conclusions and recommendations inevitably extend into broader, more strategic issues. For each of our recommendations we have sought to identify which level of organisation – individual laboratory, NHS trust, Strategic Health Authority or Department of Health – we consider has the prime responsibility to lead implementation.

## ANNEX B.1

### List of Individuals and Organisations Providing Evidence

#### *Professional Health Bodies*

Ms Susan Allison	Clinical Pathology Accreditation (UK) Ltd
Dr Ian Bailey	Member of the British Medical Association's Pathology Committee
Dr Graham Beastall	President, Association for Clinical Biochemistry
Dr David Bullock	Director, Wolfson EQA Laboratory and Organiser, United Kingdom National External Quality Assessment Service for Clinical Chemistry
Dr Rodney Burnham	Registrar, Royal College of Physicians
Ms Gail Cartmail and Mr Dan Smith	AMICUS
Prof Marcela Contreras	National Director of Diagnostics, Development and Research, National Blood Service/NHS Blood and Transplant
Mr Gordon Cropper	Chair, Lay Advisory Committee, Royal College of Pathologists
Dr David Dance	Regional Microbiologist, Health Protection Agency (South West)
Mrs Barbara de la Salle	Vice Chairman of United Kingdom National External Quality Assessment Service
Mr J K M Duguid	Secretary, British Society for Haematology
Dr William Egner	Chair, Royal College of Pathologists Specialty Advisory Committee on Immunology
Mr Roger Evans	Health Protection Agency
Prof C S Foster	The Workforce Advisory Group of the Royal College of Pathologists and the National Steering Group for Modernising Pathology Careers
Prof Peter Furness	Vice-President, Royal College of Pathologists and Histopathology/Cytopathology Specialty Advisory Committee of the Royal College of Pathologists
Dr M J Galloway	Chairman of Council, Association of Clinical Pathologists
Sir Muir Gray	Director of Clinical Knowledge, Process and Safety, NHS Connecting for Health
Dr Graham Groom	Senior Administrator, Association for Clinical Biochemistry on behalf of the British In Vitro Diagnostics Association and the Association for Clinical Biochemistry

Dr Andrea Harmer	Chair, British Society for Histocompatibility and Immunogenetics
Ms Sue Hollinshead	Administrative Officer, Hospital Infection Society
Dr Tony Howard	President, Association of Medical Microbiologists
Mr Christopher Kibbler	Health Protection Agency Advisory Committee on Fungal Infection
Dr Susanne Ludgate	Clinical Director, Devices, The Medicines and Healthcare Products Regulatory Agency
Mr John Marshall	Project Manager, Fetal, Maternal and Child Health Subgroup of the UK National Screening Committee
Ms Sarah May	Executive Head of Strategy, Institute of Biomedical Science
Dr Gwyn McCreanor	Secretary, Association for Clinical Biochemistry
Dr Jonathan Middle	Deputy Director, United Kingdom National External Quality Assessment Service
Dr Cristina Navarrete	National Head of Histocompatibility and Immunogenetics, Platelet and Granulocyte Immunology and the British Bone Marrow Registry
Prof Adrian Newland	President, Royal College of Pathologists
Prof Sir Duncan Nichol	Chairman, Clinical Pathology Accreditation (UK) Ltd
Mr Sam Oestreicher	National Officer, UNISON Health Services
Mr Stuart Penny	Acting Director of Public and Customer Services, National Blood Service
Dr Geoff Poole	National Head of Red Cell Immunohaematology and Antenatal Screening, National Blood Service
Mr Alan Potter	Chief Executive, Institute of Biomedical Science
Mr Mark Redhead	Secretariat to the British Medical Association's Pathology Committee
Mr Richard Slack Senior	Public Health Medicine Environmental Group
Ms Janet Smith	Immediate Past Chair, Association for Clinical Biochemistry
Dr Stephen Smith	Treasurer, Association for Clinical Biochemistry
Mr Gordon Sutehall	President, Institute of Biomedical Science
Dr Anne Thorpe	Chair, British Medical Association's Pathology Committee
Dr Mathew Tomlinson	Chair, Association of Biomedical Andrologists
Dr David Tompkins	Regional Microbiologist, Health Protection Agency, Yorkshire and the Humber
Dr Michael Toop	Chair, Clinical Practice Section, The Association of Clinical Biochemists

Prof Pat Troop	Chief Executive, Health Protection Agency
Dr Jean Wardell	Trent Regional Royal College of Pathologists Council
Dr Ruth Warwick	Consultant Specialist in Tissue Services, National Blood Service
Dr Ian Watson	Chair, Association for Clinical Biochemistry
Ms Sally Watson	British Medical Association
Mr Peter White	United Kingdom National External Quality Assessment Service
Dr Helen Williams	Vice President, Royal College of Pathologists and Chair, Royal College of Pathologists Specialty Advisory Committee on Medical Microbiology
Dr David Worthington	Laboratory Adviser, National Down's Syndrome, Fetal Anomaly Ultrasound Screening Programme, UK Newborn Screening Programme Centre, NHS Sickle Cell and Thalassaemia Screening Programme

### *NHS (Clinicians and Organisations)*

Dr M A Al-Jubouri	Clinical Director of Pathology, St Helens and Knowsley NHS Trust, Prescot, Merseyside
Dr V E Andrews	Consultant Haematologist
Dr David Bareford	Consultant Haematologist
Dr Stella Barnass	Consultant Microbiologist, and Lead Clinician for Pathology, West Middlesex University Hospital
Ms Ann Barnes	Director of Operations, Stepping Hill Hospital, Stockport NHS Foundation Trust
Dr Geoffrey Bengel	Head of Service, Pathology, North Middlesex University Hospital Trust
Dr Jonathan Berg	Head of Clinical Biochemistry, Birmingham City Hospital
Dr Andrew Berrington	Microbiologist
Dr Mitzi Blennerhassett	Member, National Pathology Oversight Group
Prof Steve Bloom and Alan Howard	Clinical Director of Pathology and Managing Director, Pathology Services, Hammersmith Hospitals NHS Trust
Dr A P Boon	Consultant Cellular Pathologist, Skin Cancer Centre MDT, St James's University Hospital
Ms Lynne Bower and Mr Mike Waterson	Consultant Biochemists, Chemical Pathology Department, Torbay District General Hospital
Mr Nigel Brook	General Manager, United Kingdom Association of Cancer Registries
Mr David Burgess	Clinical Scientist, Sunderland Royal Hospital

Ms Lynda Burt	Clinical Lead for Nurse Practitioners, Bradford City Primary Care Trust
Mr Stuart Carlton	Pathology Services Manager, Queen's Medical Centre, Nottingham
Mr Colin Carr	Pathology Services Manager, Cambridge University Hospitals NHS Foundation Trust
Dr C P Chan Seem	Consultant Chemical Pathologist, The Queen Elizabeth Hospital, King's Lynn
Ms Phillipa Cheshire	Haematology Department, Rotherham District General Hospital
Dr H R Cochrane	Consultant Histopathologist, Sunderland Royal Hospital
Dr Paul Conn	Consultant Histopathologist and Cytopathologist, Colchester General Hospital
Ms Cathryn Corns	Consultant Biochemist, Clinical Director of Pathology, Southend Hospital NHS Trust
Dr Ceridwen Coulson	Consultant Chemical Pathologist, Frenchay Hospital, North Bristol
Dr Ranjit Dasgupta	Consultant Haematologist, University Hospital, Aintree
Dr Miles Denton	Consultant Microbiologist, Leeds Teaching Hospitals NHS Trust
Dr Stefan Dillon	Chemical Pathologist, City Hospitals Sunderland NHS Foundation Trust
Dr Alan Evans	Consultant Pathologist, Tayside University Hospitals NHS Trust
Mr Andrew Fisher	Wessex Regional Genetics Laboratory, Salisbury District Hospital
Dr Danielle B Freedman	Consultant Chemical Pathologist and Medical Director, Luton and Dunstable Hospital NHS Trust
Dr Ian Fry	Director of Pathology, Partnership Pathology Services, Joint venture between Frimley Park Hospital NHS Foundation Trust and Royal Surrey County Hospital NHS Trust
Mr Charles Green	Area Laboratory Manager, NHS Ayrshire and Arran Crosshouse Hospital, Kilmarnock
Mr Stephen Halloran	Consultant Clinical Biochemist, The Royal Surrey County Hospital
Dr Robert Hangartner	Clinical Director of Pathology, Guys and St Thomas' NHS Foundation Trust
Prof David Harrison	Professor of Pathology and Director, Edinburgh Cancer Research Centre, University of Edinburgh
Dr Richard Hobson	Consultant Microbiologist, Leeds General Infirmary

Dr Paul Holloway	The North West London Chemical Pathology Modernisation Forum
Mr Chris Holwill	Pathology IT Manager, Derriford Hospital
Dr Janet Horner	Consultant in Clinical Biochemistry and Metabolic Medicine, St James's University Hospital, Leeds
Mr Nick Hurlock	Operational Director, Division of Laboratory Medicine, Southampton University Hospitals NHS Trust
Dr Keith Hyde	Consultant Clinical Scientist and Clinical Director of Laboratory Medicine, Central Manchester and Manchester Children's University Hospitals
Dr David James	Consultant Chemical Pathologist, Department of Pathology, Taunton and Somerset NHS Trust
Mr Tony Johnston	Project Manager, Pathology Redevelopment, Kings College Hospital NHS Trust
Dr Rick Jones	Clinical Biochemistry and Immunology, Leeds Teaching Hospitals NHS Trust
Prof Noor Kalsheker	Co-Director of the Institute of Genetics, University Hospital, Queens Medical Centre, Nottingham
Mr Edward M Kearney	Consultant Clinical Biochemist, Queen Elizabeth the Queen Mother Hospital, East Kent Hospitals NHS Trust
Mr M J Kelly	Consultant Colorectal Surgeon, National Lead Clinician for Colorectal Cancer, University Hospitals of Leicester
Ms Julie King	Microbiology Manager, Royal Devon and Exeter NHS Foundation Trust, South West Peninsula Pathology Learning Set
Dr Simon Knowles	Pathologist, Somerset Pathology Service
Mrs Ruth Lapworth	Clinical Director, Pathology, East Kent Hospitals NHS Trust
Dr J C Macartney	Consultant Histopathologist, Department of Pathology, University Hospitals Coventry and Warwickshire NHS Trust
Dr Gautam Majumdar	Consultant Haematologist, Doncaster and Bassetlaw Hospitals NHS Foundation Trust
Dr Marian Malone	Lead Clinician, Histopathology, and Service Unit Chair, Pathology, Department of Pathology at Great Ormond Street Hospital for Children
Prof Jo Martin	Clinical Director for Pathology, Barts and The London NHS Trust
Dr Albert J Mifsud	Director, Infection Prevention and Control and Consultant Microbiologist, Whipps Cross University Hospital, Leytonstone

Dr Debra Milne	Head of Department, Department of Histo- and Cytopathology, City Hospitals, Sunderland
Prof Gemmell Morgan	Medical Consultant, Clinical Biochemist, Glasgow
Prof Ghulam Mufti	Director of Pathology, Kings College Hospital NHS Trust
Dr David Muir	Consultant Virologist, St Mary's Hospital, London
Dr M A Myers	Clinical Director, Pathology, Lancashire Teaching Hospitals NHS Foundation Trust and Lead Pathologist, Cumbria and Lancashire Pathology Network
Ms Lorraine Norden	Pathology Directorate, University College Hospitals NHS Foundation Trust
Dr Norman Parker	Consultant Haematologist, Whittington Hospital
Ms Helen Plumb	Laboratory Manager, Microbiology, Torbay Hospital
Dr Essam A Raweily	Head, Department of Histopathology, Epsom General Hospital
Dr Norman L Reeve	Clinical Director, Stockport NHS Foundation Trust
Prof Tim Reynolds	Queens Hospital, Burton-on-Trent
Mr David Ricketts	Laboratory Manager, North Middlesex University Hospital NHS Trust, Edmonton
Dr M C Ruddy	Consultant Microbiologist, NPHS Microbiology, Carmarthen GICC NHS
Dr Rosemary Scott	Consultant Histopathologist and Honorary Senior Lecturer, Department of Histopathology, University College, London
Mr Jeff Seneviratne	Consultant Biochemist, Department of Clinical Biochemistry, Stepping Hill Hospital
Mr Andrew Shand	Business Manager, Severn Institute, Severn and Wessex Deanery
Dr Michael Sheaff	Consultant in Histopathology/Cytology, Barts and The London NHS Trust
Mr Stephen Shiel	Pathology Services Manager, Ashford and St Peter's Hospitals NHS Trust
Mr Roland Sinker	Director of Strategy, Kings College Hospital NHS Trust
Dr John Sloss	Consultant Microbiologist, County Durham and Darlington Acute Hospitals NHS Trust
Dr David I Slovic	Consultant Physician, Ealing and Claypods Hospitals
Dr Irene A Stables	Divisional Director, Clinical Support 2/Head of Strategy and Service Development, City Hospitals Sunderland NHS Foundation Hospital
Dr T J Stephenson	Consultant Histopathologist and Clinical Director of Laboratory Medicine, Sheffield Teaching Hospitals NHS Trust

Ms Jan Teahon	Head of Pathology Development and Strategy, Kings College Hospital NHS Trust
Dr J H Tripp & Dr C O Holme	Chairmen, Exeter Confidential Review of Perinatal and Early Childhood Deaths, Department of Child Health, Royal Devon and Exeter Hospital (Wonford)
Ms Judith Tye	Departmental Manager, Clinical Biochemistry Department, Sandwell Hospital
Mr John Watson	General Manager for Clinical, Scientific and Diagnostics, Kings College Hospital
Dr Eric Watts	Clinical Director and Clinical Lead for the Essex Pathology Network and Consultant Haematologist, Basildon Hospital
Prof Ian Wells	Consultant Computer Scientist, Department of Medical Physics, Royal Surrey County Hospital
Prof Mark H Wilcox	Consultant/Clinical Director of Microbiology, Director of Infection Prevention and Control, Leeds Teaching Hospitals NHS Trust
Ms Shelley Wilson	Departmental Manager, Virology Department, Barts and The London NHS Trust
Ms Fiona Wise	Chair, North West London Pathology Review Steering Group and Chief Executive, Ealing Hospital NHS Trust
Dr Tim Wreghitt	Regional Microbiologist, East of England

### *Pathology and Specialist Networks*

Dr Jacqui Calvin	Chairman, UK Newborn Screening Laboratory Network
Prof Anne Green	The National Metabolic Biochemistry (biochemical genetics) Network
Dr Tim Helliwell	Merseyside and Cheshire Cancer Network Group
Mr Peter Huntley	Director, Kent and Medway Pathology Network
Ms Jaki Meekings	Director of Specialist Commissioning (South) South Specialist Commissioning Group – Genetics Subgroup
Dr Linda Morgan	Molecular Genetics Group of the Nottinghamshire Clinical Pathology Network
Dr Terry Riordan	South West Peninsula Pathology Network
Prof Colin Self	Chairman, The Supra Regional Assay Service
Mr Paul Skingley	Essex Pathology Network
Dr Jim Smallwood	Medical Director, Cancer Network Medical Directors
Dr Jenny Taylor	Oxford Genetics Knowledge Park and the National Translational Cancer Research Network

Mr Mike Vogler	Network Manager, Nottinghamshire Clinical Pathology Network
Ms Karen Ward	Network Manager, North East London Pathology Network

### *Strategic Health Authorities and Primary Care Trusts*

Dr Mike Burrows	Chief Executive, Salford Primary Care Trust, Greater Manchester Pathology Network
Mr Tony Gibson	Pathology Modernisation Project Manager, Northumberland, Tyne and Wear Strategic Health Authority
Dr Neil Goodwin	Chief Executive, Greater Manchester Strategic Health Authority
Mr Ian Johnson	Health Strategy Consultant, South West London Strategic Health Authority
Ms Maggie Morgan Cooke	Head of Improvement, West Midlands South Strategic Health Authority
Mr Joe Rafferty	Director of Performance and Improvement, The Diagnostics Futures Team, Cumbria and Lancashire Strategic Health Authority
Ms Sandra Tribe	South East London Specialised Commissioning Team, Bexley Care Trust
Mr Steve Webster	Bristol Pathology Project Board (comprising Avon, Gloucestershire and Wiltshire Strategic Health Authority, North Bristol NHS Trust and United Bristol Healthcare NHS Trust)

### *Independent Sector*

Mr Mark Adams	Chief Executive Officer, Netcare Healthcare (UK) Ltd
Mr Steve Adkin	Principal, Private Equity Group, Mizuho International plc
Mr Anil Asnani, Mr Paul Billings, Mr Kevin DeAngelo & Mr Andrew Ginsberg	Laboratory Corporation of America
Mr John Bagshaw	Sales and Marketing Manager, Immunoassay and Molecular Diagnostics, bioMerieux
Ms Jacqui Balchin	Sales Director, Dade Behring
Mr Rayner Brammall	Director, Market Development, Independent Integrated Services, QinetiQ
Mr Christopher Brocklebank-Fowler & Lord Foster of Bishop Auckland	Pathuser (Caithness Multi Media)

Mr Andy Buffon	Director, External and Regulatory Affairs, Abbott Laboratories Diagnostic Division
Mr Robert Cooke	Symbian Healthcare, Australia
Mr Kevin Bilson	Kernodle Clinic, Burlington, North Carolina, USA
Ms Judy Davis and Ms Suzanne Phillips	Compliance Manager, Laboratory and Imaging and Administrative Director, respectively, Baptist Hospital, Nashville, Tennessee, USA
Mr Richard Down	Adviser to Clinical Intelligence Ltd
Dr Colin G Fink	Medical Director, Consultant Virologist and GP, Micropathology Ltd Research and Diagnosis
Mr Kevin Finnegan, Mr Peter Chou, Mr Nathan Sherman and others	Quest Diagnostics, USA
Dr Colin Goldschmidt	Sonic Healthcare, Australia
Mr Andrew Goodsall	Healthcare and Biotech Research, Sonic Healthcare Ltd, Citigroup, Smith Barney, Australia
Ms Peggy Hardcastle	Laboratory Manager, River Park Hospital, McMinnville, Tennessee, USA
Mr Brian Jackson & Mr Mark Nash	Argent, USA
Mr Orde Levinson	Managing Director, JBOL Ltd
Mr Robert Michel	The Dark Group, USA
Ms Martha Miers & Mr George McCulloch Jr	Department of Pathology, Vanderbilt University Medical Center, Nashville, Tennessee, USA
Mr Dan Olsson & Dr Lars Lundgren	Capio Diagnostics, Sweden
Ms Ruth Powell	Director of Marketing for UK and Ireland, Bayer Healthcare, Diagnostics Division
Ms Jane Price-Lewis	Laboratory Operations Manager, Kaiser Permanente, Springfield, Virginia, USA
Dr R. Prudo	Executive Chairman, The Doctors Laboratory Limited (Sonic Healthcare Ltd)
SRL Ranbaxy	Confederation of Indian Industry
Prof Sir Gareth Roberts	Medical Solutions plc
Dr Rabelo Rogerio	Fluerry Laboratory
Dr Sushil Shah	Managing Director, Chairman Metropolis Health Services (I) Pvt Ltd

Mr Roger Steer	Executive Director, Pathology Audit Consultants
Ms Sue Sterling	Roche Diagnostics Ltd
Mr John Steward	Welsh Cancer Intelligence and Surveillance Unit
Mr James Stewart	Partnerships UK
Dr Fred Swaine	Calgary Laboratory Services, Canada
Dr Jenny Taylor	Programme Director, Oxford Genetics Knowledge Park, Wellcome Trust Centre for Human Genetics
Dr Murray Treloar	Chief and Medical Director, Laboratory and Genetic Services, Lakeridge Health Corporation, Oshawa, Canada
Dr John Wain	Genome Campus, Wellcome Trust and Sanger Institute
Dr Paul Weinberger	Chairman, British In Vitro Diagnostics Association and Director of Business Development, Roche Diagnostics
Ms Doris-Ann Williams	Director General, British In Vitro Diagnostics Association
Mr Matthew Young	Adam Smith Institute

***Other comments received by email with no organisational details supplied  
and/or provided on a personal basis***

Dr J Aparna  
 Dr Martin Auger  
 Mr Anubha Bajaj  
 Mr Graham Danks  
 Mr Steve Fell  
 Mr James J Going  
 Mr Brian Gostelow  
 Mr Mustafa Haqqani  
 Dr Andrew Iversen  
 Ms Mary Kennedy  
 Mr Ian Lancaster  
 Mr John Looney  
 Mr Les Martin  
 Dr W G Phillips  
 Mr David Robertshaw  
 Mr James Walk

*Department of Health*

Mr Ken Anderson	Commercial Director
Mr Gary Belfield	Head of Primary Care
Mr Harry Cayton	Director for Patient and Public Involvement
Mr Rajesh Chauhan	Analyst, Payment by Results Team
Prof Brian Duerden	Inspector of Microbiology and Infection
Ms Liz Eccles	Deputy Director, Policy and Strategy Directorate
Mr Richard Granger	Director General of NHS IT
Ms Dianne Kennard	Team Leader, NHS Genetics and White Paper Implementation
Prof Martin Marshall	Deputy Chief Medical Officer
Mr Bill McCarthy	Acting Director General, Policy and Strategy
Prof Mike Richards	National Director for Cancer

*Please note that in the case of individual submissions, names, titles and positions are as supplied.*

## ANNEX B.2

### Membership of the Pathology Review Advisory Group

Lord Carter of Coles	Chair – Pathology Review
Prof Chris Price	Member – Pathology Review
Mr Marcus Robinson	Member – Pathology Review
Mr Edmund Waterhouse	Review Manager
Dr Ian Barnes	National Clinical Lead for Pathology
Dr Gillian Chapman	Head of Programmes, National Service Frameworks and Service Reviews
Ms Deirdre Feehan	Project Lead, Modernising Pathology Team
Mr Paul Macnaught (from February 06)	Head of Elective Care and Diagnostics
Mr Martyn Forrest	Regional Director NE Cluster, National Programme for IT
Dr Robert Alexander	Head of RDI, Commercial Directorate
Dr Neil Goodwin	Chief Executive, Greater Manchester Strategic Health Authority
Mr Martin Campbell	Head of Efficiency and Income Generation
Mr Peter Grummitt	Account Manager, Diagnostic Workforce
Prof Sue Hill	Chief Scientific Officer
Mr Gary Belfield	Head of Primary Care

Mr Matthew Coats until January 2006

Mr Mathew Kershaw until January 2006

# Annex C:

## What are Pathology Services?

1. Pathology (also commonly referred to as laboratory medicine) comprises those services which provide knowledge and diagnostic information for the care of individual patients through the scientific analysis of specimens of blood, fluids, tissue and other samples. Pathology services constitute an essential element of clinical services through the contribution they make to the effective prevention, detection, diagnosis, treatment and management of disease, especially chronic disease. The pathology services work closely with the Health Protection Agency in the surveillance of infectious diseases, as well as in the provision of specialist diagnostic services. Pathologists also provide autopsy and mortuary services. In this country (unlike some other countries) the pathology services are **not** responsible for the provision of blood (which in England is provided by NHS Blood and Transplant) – although they cross-match and issue blood and use blood products.
2. The pathology services have three key elements: the **pre-analytical** (for example phlebotomy, logistics, advice on appropriate tests, production of clinical guidelines), the **analytical** and the **post-analytical** (for example interpretation and dissemination of results to requesters, provision of further appropriate investigations and advice on the diagnosis and treatment of patients). In all of these areas they play a key role in delivering clinical governance (through for example clinical audit). They also participate in training, teaching and research, including with other health care professionals, and provide a support service for the conduct of clinical trials. A fuller description is provided at the end of this section.
3. The pathology services therefore support other clinicians and care givers, whether elsewhere within the hospital, in primary care or in the wider community. Some pathologists also provide direct clinical care to some cancer patients, people with haemophilia, people with immune system problems, and people with metabolic disorders, for example diabetes. The pathology services also include elements of antenatal, neonatal, metabolic and other screening services. Above all, they provide guidance on appropriate choice of tests and on clinical interpretation of laboratory test results. Pathology therefore plays an important role in maintaining high standards of clinical practice and a health care-wide contribution to clinical governance. It is estimated that 70-80 per cent of all health care decisions affecting diagnosis or treatment involve a pathology investigation.

4. In the UK pathology is a consultant-led clinical service. Consultants may be qualified in medicine or in a clinical science such as clinical biochemistry, immunology or microbiology. A wide range of occupational groups are employed in pathology: in addition to medical pathologists there are clinical scientists, biomedical scientists, medical technical officers, medical laboratory assistants, phlebotomists and administrative and clerical staff. The pathology workforce – estimated at around 25,000 people (whole time equivalents) – is covered in more detail elsewhere in this report.
5. Pathology itself is made up of a number of different clinical specialties of which the main ones are:
  - clinical biochemistry;
  - haematology;
  - histopathology and cytology (also referred to as cellular pathology);
  - immunology;
  - microbiology and virology.
6. Phlebotomy – the collection of blood samples from patients – and specimen collection is a key component of the pathology service. In the community, phlebotomists are likely to be employed by GPs or other providers of primary care services. In hospitals, blood may be collected on the ward by nurses or other clinical staff. The transport of specimens is, similarly, not part of the pathology services. The fragmented nature of these arrangements builds unnecessary inefficiency into the service, by serving to inhibit patients' access and creating extra logistical barriers for laboratory professionals.
7. Providers of pathology services mostly work in the NHS but there is a small private/independent sector presence. The independent health care sector (BUPA, Nuffield, etc) has its own laboratory network but may also use NHS laboratories for specialised work. Over the past decade there has been limited involvement of the independent sector in the provision of NHS pathology services (the experience has had mixed results). Independent providers are showing increasing interest in working with the NHS to provide pathology services for the future.
8. Within the NHS, pathology services are overwhelmingly provided from acute hospital sites, with the provision of more specialised pathology services often being associated with teaching hospitals. From the visits we have undertaken it is clear that the quality of sites varies considerably across the country: some laboratories are currently located in poor accommodation, sometimes split between two or more buildings, which can only hinder the provision of an efficient service; others operate from new, purpose-built facilities. Some services are situated in peripheral laboratories, others are located near to

clinical services. Currently, the only pathology service facilities in primary care are a few discrete point-of-care testing services.

9. The patient's contacts with the service might typically consist of the following:
- the patient sees the GP;
  - the GP requests a blood sample;
  - either the patient goes to a different part of the GP surgery, or to a health centre or hospital out-patient department where a phlebotomist takes a blood sample (for an in-patient the sample would normally be taken in the hospital ward);
  - where the request is for haematological or biochemical analysis, the result is known within 8 hours for the majority of tests and will be communicated to the GP (for in-patients and out-patients, the results are available on the same day, perhaps even within the hour);
  - for microbiological analyses the result is typically available within 1–3 days;
  - for histopathology the result could take a week (though some hospital-based investigations are completed more quickly);
  - tests referred to a reference laboratory could take longer depending on the nature of the test requested;
  - GP arranges to see the patient (possibly several days later) in order to report on the outcome of the test and discuss diagnosis and treatment. Alternatively, in the case of repeat tests, the patient may be asked to telephone for the results.
10. In line with the Government's policy of providing services which are focused on the needs and wishes of patients, there is a growing trend towards point-of-care testing in pathology. Point-of-care testing may be located elsewhere within the hospital setting – in accident and emergency departments, critical care wards or outpatient departments, for example – or outside the hospital in, say, community pharmacies, GPs' surgeries, in ambulances or elsewhere in primary care (as in the case of anticoagulation services). The Medicines and Healthcare Devices Regulatory Agency (MHRA) recommends that formal arrangements are made for the local laboratory to manage and regulate point-of-care testing but to date such arrangements have not been universally adopted across England. There is little scope for the results from point-of-care testing to be entered into the patient record. In other countries point-of-care testing is highly regulated, in a fashion similar to laboratory-based services.
11. Most individual laboratories are themselves computerised, but pathology services are not connected to the NHS-wide computer network *Connecting for Health* – and are not

scheduled to become connected for another few years. This means that there is at present no “end-to-end” IT connectivity in pathology. When therefore a GP (for example) requests a test, the laboratory does not receive electronic notification automatically; similarly the test results cannot be communicated to the GP electronically (unless separate arrangements have been made to enable electronic communications). This is a major limitation in the light of the fact that a high proportion of the content of the electronic patient record comprises laboratory-based information. At **Annex C.2** we have set out a model for the IT requirements of pathology services in a network.

- 12.** Pathology services are becoming increasingly mechanised and automated, though laboratories vary in the extent to which they deploy new technology, mainly because of a record of poor capital investment. Laboratory equipment is generally specific to a discipline. It is developed and manufactured by a variety of companies which compete within an international market. Typically each laboratory determines its own needs and negotiates for the purchase or lease of equipment in accordance with what it can afford. A variety of creative financial arrangements are made in this manner. Because machines can differ in the range and nature of the assays they perform, the results they produce are sometimes different from those which another machine would produce using an identical sample. This lack of standardisation can create difficulties in the interpretation of the results. Expenditure on pathology instrumentation and reagents in England represents less than two percent of the world market and consequently does not have a major influence on the innovation agenda, but also does not contribute greatly to the research and development costs.
- 13.** Demand for pathology services is high. In England over 160 acute hospital trusts have pathology departments. Data collected by the Healthcare Commission for 2005 showed that over 500 million biochemistry and 130 million haematology tests were carried out, over 50 million microbiology tests were processed over 13 million histopathology and 4 million cytology slides were examined.
- 14.** Over the past few years the level of demand has been rising consistently – and steeply – without corresponding uplifts in pathology budgets. Studies suggest that, after a period of relative stability, growth in pathology requests is now averaging around ten per cent per annum. In part this growth properly reflects the role which pathology can and should play in the monitoring and treatment of disease: new National Service Frameworks have highlighted the importance of using laboratory tests for this purpose.
- 15.** The recent introduction of the new contract for GPs has had a major impact on the growth in requests. Patients with long term medical conditions can use pathology tests to monitor and manage their own health without the need to consult their GP every time. But there is also evidence (albeit mainly anecdotal) that tests are repeated unnecessarily;

for example when a patient is admitted to hospital for treatment the evidence of tests requested by the GP is often set aside and new tests are requested.

- 16.** It is important to emphasise that pathology services can disproportionately improve the quality of care of an individual's health care encounter. Undertaking the right test at the right time allows treatment or care to be initiated before the individual has an acute or episodic event. This is linked to the ability of pathology to reduce the overall cost of such health care encounters, when used in a timely and appropriate manner. For example, in accident and emergency and intensive care units "close glucose monitoring" (where glucose tests are performed every 1-2 hours) may raise the cost of pathology services in relation to the particular patient, but if the patient is transferred out of critical care a day or two sooner (and with faster recovery) significant intensive care costs may be saved.
- 17.** The points made above illustrate some of the fragmentation that exists in pathology services (though it is not as great as that seen in some other countries).
- 18.** Total costs of providing pathology services in England are not known exactly. Work undertaken by the Healthcare Commission in 2005 estimated operating costs – excluding shared overhead costs – at £1.8 billion; applying a standard uplift for overheads (based on research data) suggests that total costs – ie comprising all service costs, including logistics, phlebotomy, premises and overheads – would be in the region of £2.5 billion. This figure would therefore be comparable with aggregate costs of equivalent services in other countries. These estimates are difficult to obtain because different elements of the overall pathology service are accounted for in different budgets. For example, the cost of collection of samples may be included within the GP surgery budget or, within a hospital, included as an overhead of the ward where the patient is being treated. The costs of transporting samples may not be separately identified within a hospital's transport budget; and the cost of premises and equipment may be accounted for in different ways.
- 19.** The Government's policy of separating commissioners from providers of services has led to the development of a tariff system (*Payment by Results*) in order to clarify the costs of specific transactions and promote efficiency. At present pathology costs are not separately identified within the tariff, but are bundled together with other diagnostic and imaging services commissioned from acute hospital trusts. There is however a cost for referral to specialist centres for testing, and for some separate commissioning of direct access tests undertaken at the request of GPs.

## **ANNEX C.1**

### **Features of a Pathology Service within a Network**

#### **Functions involved in service operation and delivery**

- To provide guidance on the selection of appropriate investigations including protocols, patient preparation and sampling, and to indicate any additional tests that may assist the requesting health care professional
- To base such guidance on the highest quality of evidence available and to disseminate it through the most appropriate means available
- Where appropriate, to provide clinical diagnostic and treatment services directly to patients and/or members of the public
- To provide a phlebotomy service, together with a specimen collection and transport service
- To provide a high quality laboratory service, on a 24-hour basis, where appropriate, and delivered from the most appropriate site to meet the needs of patients
- To provide turnaround times for components of the service that are consistent with clinical requirements and which support local and national targets for patient management
- To provide appropriate interpretation of results, clinical liaison and advice on further investigations and choice of therapy in a variety of settings including the community, primary care and the hospital sector
- To participate in multidisciplinary clinical team meetings to maximise the effectiveness of the service
- To define the quality requirements for all of the services required and thereby to be able to select the most appropriate supplier taking account of what can be supplied locally, and what may be required from other providers such as specialist services
- To monitor the quality and cost of all services provided
- To ensure that the quality of the service provided meets the needs of individual patients and that the service is used effectively by all clients of the service.

#### **Functions required to support service operation and delivery**

- To provide training and continuing education for all staff involved in the provision of the pathology services
- To provide training and continuing education for all commissioners and users of the pathology services

- To operate a knowledge management system that provides up-to-date information and evidence on the scope and fitness for purpose of the service
- To provide continuous assurance of quality through use of internal quality control and external quality assurance schemes
- To provide a quality management system for all aspects of the service, including document control and regular internal vertical, horizontal and examination audits
- To provide support for the quality management of point-of-care testing services within the network including training, maintenance, quality control and trouble shooting
- To contribute to clinical governance activities through service-wide clinical audit, annual management review and service improvement programmes.

### **Direction, clinical leadership and management of the service**

- To identify and maintain a complete repertoire of services based on the needs of patients and commensurate with the requirements of commissioners, including quality specifications and costs
- To negotiate the contract with the purchasers of the service, taking account of clinical needs and operational requirements
- To monitor compliance with the terms of the contract, with the emphasis on meeting quality, workload and cost targets
- To monitor effectiveness of use of the service and associated outcome measures
- To engage in any change management dialogue with users of the service to ensure clinical and economic effectiveness are maximised
- To identify unmet needs and prepare business cases for satisfying these needs
- To support the development activities of the health care provider organisation
- To identify the workforce (including skill mix) required to provide the service required
- To ensure the competence of the workforce is demonstrated to be fit for purpose and is maintained
- To communicate on a regular basis with the workforce, including annual performance management
- To ensure that accreditation of the service is achieved and maintained.

**Specialist functions as required**

- To work closely with other pathology related services and agencies in meeting their objectives including the Health Protection Agency and NHS Blood and Transplant
- Specifically to contribute to surveillance for infectious diseases and support for the investigation of local outbreaks
- To provide support for disease registries through provision of relevant data
- To provide an infection control service
- To provide a blood product service
- To provide an appropriate autopsy and mortuary service.

## ANNEX C.2

### The Need for a National Pathology IT Programme and its Relation to *Connecting for Health*

The scope of IT needs in pathology extends beyond the individual patient's request-reporting cycle. Though automated order communications and improved knowledge-driven reporting are essential, other areas of investment are needed.

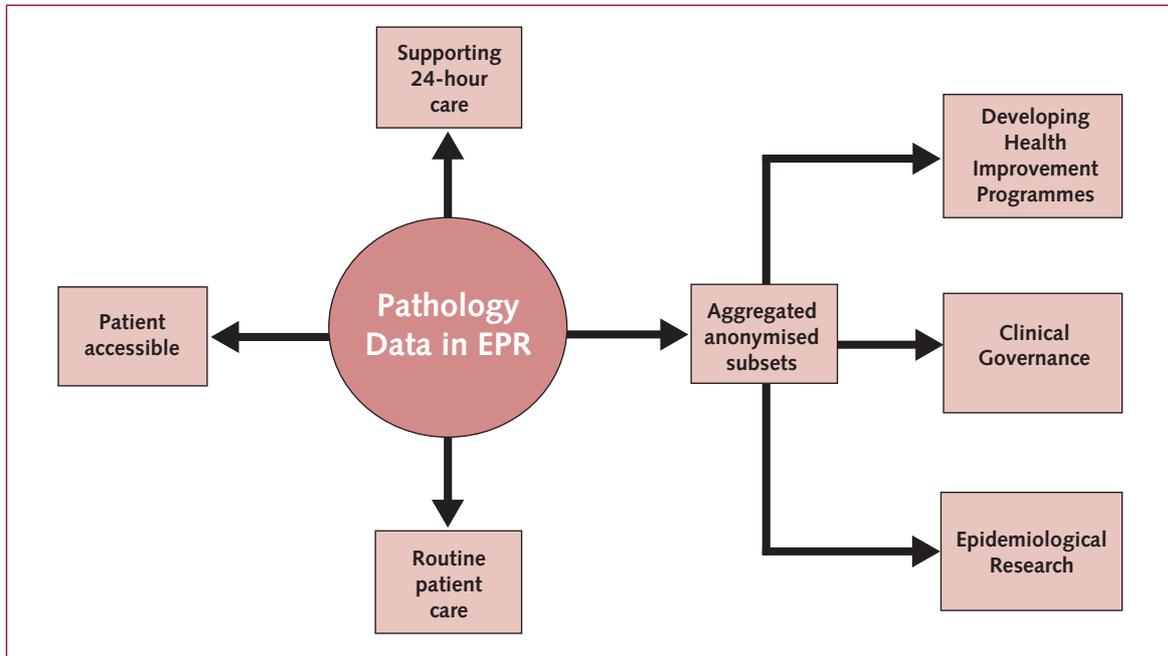
Specifically these need to cover:

- clinical functionality
  - epidemiological surveillance – especially in microbiology;
  - image exchange – for remote reporting in histopathology;
  - data exchange (requests/reports) for tertiary referrals between laboratories;
  - chronic disease management systems – for example warfarin monitoring;
  - support for registry functions, for example cancer, diabetes and coronary heart disease registers;
  - connectivity for point-of-care systems running within primary and secondary care and extending outside into the wider community including pharmacies and other non-NHS providers;
  - laboratory knowledge support for clinical rules in clinical systems;
- business support
  - business support for workload analysis and forecasting;
  - benchmarking of usage based on NICE guidelines and population norms;
  - support for health and performance management at a national level;
  - development of an IT/bioinformatics workforce within the pathology services to support the above functions.

There is a need for a Pathology IT Programme within *Connecting for Health* which addresses the requirements of pathology services and the integration of data into the Clinical Records Service.

This programme should not only consider IT systems but should also pay attention to the skills requirements for IT support and strategic development of pathology services.

**Figure 1: The core role of pathology data in clinical service delivery.**



# Annex D:

## Context

1. It is over a decade since the Department of Health conducted a strategic review of pathology services. It was prompted partly by the development of the internal market within the NHS; partly by the Audit Commission's report *Critical Path*, published in 1993; and partly by other factors such as the introduction of new technology, the increasing emphasis on clinical care outside hospitals and the impact on pathology of changes to clinical practice.
2. In *Critical Path* the Audit Commission had concluded that communication and organisation needed to be improved at three levels: between laboratories and users; within laboratories; and between laboratories and general managers. It recommended that laboratories should be given greater control over arrangements for transporting specimens; and levels of demand should be managed, using improved information to inform pathologists of patterns of requests and to inform users of how their requesting patterns compared with those of their peers. The report also reported on "much conflict between laboratory management and general managers who often have only a hazy knowledge of pathology, but who see steadily rising costs against a background of constrained NHS budgets. They have responded by tightly controlling inputs while laboratory staff for their part face steadily increasing demand."
3. The report *Strategic Review of Pathology Services*, published in 1995, concluded that "the present arrangements gave the NHS the flexibility to explore different ways of providing pathology without the need to superimpose further mechanisms"; it endorsed the principle that service development was a matter for local decision; and took the view that the pathology service should be professionally directed by a consultant pathologist or by a clinical scientist of equivalent standing. It "did not feel that any particular model of service provision was so self-evidently better than others as to justify special promotion from the centre". Any changes in patterns of service provision needed to take account of "the potential impact on teaching arrangements, academic responsibilities and commitment to research arising from changes in the pathology staffing structure and the sessional commitments of pathologists".
4. Following the change of Government in 1997 and the publication of *The NHS Plan*, the Department of Health launched a Pathology Modernisation Programme in 1999 with the key goals of improving the quality and efficiency of NHS pathology services and encouraging the introduction of new technologies and practices to deliver high quality care for patients.

5. *Modernising Pathology Services*, published in February 2004, proposed a number of steps intended to build capacity in pathology by:
- setting up managed pathology networks;
  - reviewing local pathology services and promulgating implementation arrangements to achieve change;
  - participating in audit of delivery and continuous quality improvement;
  - undertaking a workforce review and skill mix profile of the staff required to deliver improved services, linked to a training needs analysis.
6. Managed pathology networks would modernise services by:
- integrating pathology into wider service developments;
  - redesigning systems;
  - decreasing inappropriate variation;
  - making effective use of IT and new technologies;
  - improving information management.
7. Just over a year later, in September 2005, the Department of Health published *Modernising Pathology: Building a Service Responsive to Patients*. In the foreword the Minister, Lord Warner, noted that much progress had been achieved through the hard work and engagement of people working in pathology services; but there was a lot more to do following the changes seen in the previous 12 months. He said “The White Paper on health care outside of hospitals will set the framework for new and innovative approaches to delivering health care services. This and other key initiatives such as *Creating a Patient-Led NHS* and the new Healthcare Industry Task Force Report mean that pathology is at the forefront of new challenges to develop and deliver services that patients want, where and when they want them.”
16. The publication highlighted the key elements of the Government’s strategy for the NHS and their implications for pathology services:
- *The NHS Improvement Plan* outlined a vision in which choice and responsiveness to individual needs would be a reality for all and waiting for treatment would no longer be a major issue for patients and the public;
  - *Building on the Best: Choice, Responsiveness and Equity in the NHS* noted that members of the public wanted a modern health service which responded to modern expectations by offering flexible access to services shaped around individuals’ needs and preferences, rather than an expectation that people will fit the system; greater

choice and shared decision-making between patient and clinical team over treatment and care; and better access to the information and support that people need to exercise choice;

- the Healthcare Industries Task Force report *Better health through partnership: a programme for action* identified as priorities the need for improving device evaluation, greater support for innovation and improving procurement processes through regional focus and clinician involvement.
17. The report *Modernising Pathology: Building a Service Responsive to Patients* concluded by announcing the establishment of this review and setting out our terms of reference – see Annex A. At our first meeting we endorsed these terms of reference subject to the inclusion of service effectiveness.
  18. At the same time – September 2005 – *Pathology: A National Framework for Service Improvement* was published by the National Pathology Service Improvement Team (funded by the Department of Health). This document set out key success factors for delivering sustainable change and a framework for pathology service improvement.
  19. Also in September 2005 the National Pathology Service Improvement Team published the *Modernising Pathology Services Toolkit – A Practical Guide to Service Improvement*. The toolkit provides a basis for service improvement and redesign at department and network level within pathology by putting the patient and the user at the core of the service, and by viewing pathology services from the perspective of the patient’s journey. It outlines the tools and techniques that have led to successful and sustained change in pathology departments across the country. To help implement change locally, the Department of Health funded six pilot sites to implement these tools and techniques. The pilots were completed by Easter this year (2006) and a report on them was in preparation at the time we were completing this report.
  20. Since September last year the Department of Health has published several major policy documents, including:
    - *Health Reform in England: update and next steps* (December 2005), which set out in clear terms a vision of the NHS and the strategic drivers of change which will deliver it, including through the rationalisation of Primary Care Trusts and Strategic Health Authorities. It also set out the basic framework for commissioning, key components of which are:
      - the move towards free choice for patients;
      - universal coverage of practice based commissioning (see below);

- standard template contracts for use across the service, with clear national standards and scope for local conditions;
- the essential role of Primary Care Trusts in reflecting local patient needs in contracts, and in ensuring the effective operation of practice based commissioning to deliver service improvements;
- *Practice based commissioning: achieving universal coverage* (January 2006) which envisages that by the end of 2006 there will be universal coverage of practice based commissioning. This policy will make a crucial contribution to the delivery of a patient-led NHS by ensuring that the NHS delivers a high quality service for patients, achieves a balance in the range of services available and in relation to those services delivers value for money for the taxpayer. Practice based commissioning gives practices and professionals – working in partnership with their Primary Care Trusts – the freedom to develop innovative high quality services for patients through a range of mechanisms;
- *The NHS in England: the operating framework for 2006/7* (January 2006), which sets out the priorities for the NHS for 2006/7. They are:
  - achieving robust financial health;
  - pushing forward the implementation of reform;
  - achieving six specific service priorities derived from the Planning and Priorities Framework;
- *Our health, our care, our say: a new direction for community services* (January 2006) which sets a new direction for the whole health and social care system, with a “radical and sustained shift in the way in which services are delivered – ensuring that they are more personalised and that they fit into people’s busy lives”. The White Paper’s four goals are:
  - better prevention services with earlier intervention;
  - more choice and a louder voice for people;
  - more on tackling inequalities and improving access to community services;
  - more support for people with long-term needs.

These goals will be achieved by:

- practice based commissioning;
- shifting resources into prevention;
- more care undertaken outside hospitals and in the home;

- better joining up of services at local level;
  - encouraging innovation;
  - allowing different providers to compete for services.
- 21.** There are profound implications for pathology in these publications. The focus on services responsive to patients, with greater choice, implies a pathology service which increasingly looks and operates beyond the laboratory; which recognises and responds to the central emphasis on local commissioning by practices, supported by Primary Care Trusts; and which needs to compete with other pathology service providers, whether within the NHS or from the independent sector. The extent to which pathology services have been subjected to study and review reinforce the view that a new financing and management structure for pathology is timely and absolutely essential – and probably the only approach that will break through a decade of inertia in order to implement the changes that are repeatedly recognized but not implemented.
- 22.** To rise to these fresh challenges pathology services must develop a stronger, better information base; critically appraise service functions, service quality and responsiveness; look to invest and modernise, including through the judicious adoption of new technology (above all, IT), and examine carefully the skills base of its workforce so that it is equipped to meet these challenges.

# Annex E:

## International Comparisons

1. To inform their work, members of the Review Team undertook visits to providers of pathology services in other countries, including the USA, Canada, Sweden and Australia.

### Sweden

2. In Sweden, health care provision is the responsibility of the counties. We visited two sites – Stockholm, and Nyköping in the County of Sörmland – where pathology services are provided under joint venture arrangements between the public and independent sectors. The independent sector represents about 10 per cent of the overall health care market in Sweden.
3. An independent provider of pathology services holds contracts – won through an open tender process – with the city of Stockholm and with the County of Sörmland for the provision of a range of health care services including pathology services. Under the terms of the contract for pathology, premises and equipment are leased from the public sector, and the employment contracts of those staff working within the contracted-out service are transferred. There is a detailed service level agreement covering volume, quality and performance standards. Payment is partly in the form of capitation, partly per test performed. Expenditure on some elements is capped, on others uncapped. There is a published price list for a range of procedures. Management operates in a matrix style under shared clinical and business leadership.
4. Nyköping hospital has a large central laboratory run by the independent sector provider. It has the capacity to undertake some specialised, as well as routine, tests. It is linked to a small point-of-care laboratory situated in the hospital's emergency care unit. Across the city from the hospital there is a primary care centre which contains a "mini-lab". All these facilities are connected electronically so that tests undertaken on one site can be accessed from another. A blood sample taken in the primary care laboratory could be analysed and, using the IT connectivity for decision support, the results could be returned in a matter of minutes. A core feature was a national patient ID number and an electronic patient record.
5. In Stockholm we saw a diagnostic and treatment centre provided by the independent sector, one of 20 in the city, and visited the core laboratory at St Goran's hospital which receives and analyses samples from across the city. The centre is located next to a rail station in order to provide easy access for commuters. It provides emergency care,

primary care and long term (chronic) disease management and has its own laboratory. People can make appointments to be seen, but booking is not necessary. Volumes therefore fluctuate greatly from day to day.

6. Overall we were impressed by the high quality of the pathology facilities. They had been well designed to facilitate patient access and seemed to reflect high levels of capital investment. Staffing ratios also appeared high. In discussion representatives of the independent provider stated that productivity was heavily dependent on detailed process management; because individuals – including clinician customers of the laboratory – were often slow to respond to new ways of working, the key was to have effective change management, which in their experience was dependent on demonstrating improvement across the whole system and incentivising compliance with the requirements of the optimal organisational model.

## The United States

7. We visited a number of sites in the Eastern USA including laboratories in Springfield, Virginia; Teterboro, New Jersey; Chantilly, Virginia; Burlington, North Carolina; Vanderbilt University Medical Center and the Baptist Hospital in Nashville, Tennessee; River Park Hospital at McMinnville, Tennessee; and the Kernodle Clinic in Burlington. These sites reflected both hospital and independent sector providers.
8. The USA health care system is fragmented, with health care providers separated from purchasers. In private health insurance arrangements, the individual is typically covered by an insurance plan organised on the basis of an indemnity (fee-for-service), as a preferred provider organization (PPO) or a health maintenance organization (HMO). In these private health insurance plans, there is generally a fixed monthly premium regardless of utilisation of health care services. The private insurance plan pays for the medical treatment; a small co-payment, deductible or out-of-pocket payment is usually required from the individual. These private health insurance plans provide health care services for a given geographical area and employ or contract with a network of doctors and hospitals. Some HMOs have “capitated” contracts in place, whereby they pay a prospective fixed “per member per month (PMPM)” fee to providers for offering a range of services to HMO members regardless of the quantity of services or treatments required. (The providers take on the full risk for utilisation.) Others reimburse physicians according to a discounted fee-for-service schedule. Pathology costs within these provider networks are usually covered by longer term contracts that generally have terms of two to five years.
9. For vulnerable people there are federal health insurance programmes: Medicare covers 35 million older people and 6 million younger people with disabilities – without regard to income or medical history. Medicaid is the major public health insurance programme for

low-income Americans, financing health and long term care services for over 52 million including children. It is financed jointly by federal and state governments and administered by states within broad federal guidelines. The Veterans' Administration provides a similar service for ex-service personnel. One organisation (Kaiser Permanente) is distinctive by virtue of being both an insurer and provider of health care.

10. The clinical laboratory industry in the USA generated revenues of \$40 billion in 2004 and is growing at about 5 per cent per annum. It is however highly fragmented, although there has been significant consolidation of providers in recent years. Currently there are:
  - 8,500 hospital-based laboratories;
  - 5,000 independent laboratories;
  - 11,000 physician office laboratories;
  - 58,000 other laboratories.
  
11. The independent sector constitutes 40 per cent of the USA market in pathology. It is further fragmented. National consolidators represent 59 per cent of the sector; mid-sized laboratories (generating revenues of \$10-15 million per annum) represent 17 per cent; the remainder is made up of smaller and other independent laboratories.
  
12. Pathology services are available at most main hospitals in the USA and would generally process "hot" laboratory tests. Office physicians (equivalent to GPs in this country) and local laboratories can choose to refer routine "cold" and specialised ("esoteric") tests for processing by a regional laboratory or to one of the large reference laboratories provided by the independent sector. These reference laboratories handle very large volumes of tests which they receive from across the country via their own dedicated transport systems. We were told that logistics represented about half of all expenditure by those companies. For the most specialised tests, the regional and hospital laboratories may find it more cost-effective to use them. But there are signs of a growing trend towards using local laboratories and point-of-care testing for routine tests because of the more personal service available and the reduction in errors, as well as the opportunity to generate income for the local hospital or service provider.
  
13. Reimbursement tariffs exist for most laboratory tests. Medicare now produces a tariff covering about 800 of the most commonly used tests; HMOs, we were told, increasingly set their own tariffs by reference to that tariff, both above and below. Health care providers therefore need to ensure that they provide a test which is covered by the tariff and charge the rate appropriate for the paying agency. (Where a new test is developed, before inclusion in the tariff it must complete a rigorous appraisal process set by the FDA.) Competition is based on cost and turnaround time.

14. Laboratories perform the tests requested: they do not carry out additional tests which are not requested, however worthwhile, as they would not be reimbursed for them (because for legal, ethical and cultural reasons, the ordering physician is recognized as having the primary responsibility to order the correct pathology tests). Nor do laboratories query the appropriateness of the particular test requested. Overall, the health care system in the USA provides neither financial incentive nor “scope of medical practice” guidelines which specifically define this role for pathologists. Thus pathologists in the USA recognise their potential for improving the health care system in this way, but because they lack incentives and a defined role in this regard they do not proactively offer referring clinicians the benefit of this knowledge and experience.
15. Overall we concluded that pathology facilities in the USA demonstrated high levels of investment in terms of premises, equipment (including IT and transport) and staff. The purpose-built large-scale laboratories operated by the independent sector contained state-of-the-art equipment and handled very high volumes of tests on a daily basis in a highly efficient and effective way. A high proportion of the work was processed at night. For such large-scale operations to function effectively it is essential to have outstanding processes and excellent management. Both were evident to us during our visits.
16. At Vanderbilt we were greatly impressed by the real-time integrated IT system covering physician order entry and decision support, both linked to the electronic patient record. These IT systems provide clinicians with access to contemporary research-based evidence of best practice as soon as it is published; and, based on the patient’s personal medical history, generate proposals regarding the most appropriate tests to order. The decision support system provides a wide range of information about the test result and suggests possible diagnoses and treatment for the clinician to consider, including considerable research data about outcomes for different patient groups – all designed to help the decision-making process.

## Canada: Calgary

17. We visited two sites in Canada: an independent pathology services provider in Alberta, and a public sector pathology service based at Oshawa Hospital, Ontario.
18. In Calgary, following a change of Government in the Province in the 1990s, all funding for laboratories – whether in hospitals or the community – was formed into a single budget and cut by one third. Within the Province, laboratory service providers – public and independent working in partnership – were obliged to find ways of maintaining an adequate clinical service within the substantially reduced budget.
19. This brutal approach forced rapid and significant change, leading to a 10 per cent overall reduction in laboratory staffing (56 per cent of management, 20 per cent of

medical/scientific staff), rationalisation of the testing platforms and physical facilities, consolidation of contracts and integration of all phases of the testing cycle (pre-analytical, analytical and post-analytical). Disparate cultures were integrated, based on a new laboratory information system and a common approach to best practice; a new “change order process” was introduced covering the introduction of new tests, new technology and major enhancements of programmes; testing was standardised, and services improved (common test menu, target turnaround times). Over the eight years to 2005 test volumes increased by two thirds and the average cost per test fell by 40 per cent. This demonstrated the significant scope that existed for better utilising the pathology budget.

20. This change process allowed inadequate time to develop a clear and flexible overall strategy linking the laboratory to other clinical departments, and allowed insufficient time for the selection, through benchmarking, of appropriate rational targets. The staffing reductions could not be achieved entirely through voluntary means; negotiations with staffing representative bodies took time, and understandably there was a consequent lack of involvement of the medical and scientific workforce and a loss of operational knowledge. Overall the costs of transition were high. In the event, and against a backdrop of rapidly increasing population, the cost reduction originally set was not achieved. We understand that earlier this year (2006) the private sector company withdrew from the joint venture for commercial reasons.

### Canada: Oshawa

21. Across Canada provision of laboratory services is split about 50:50 between the public and independent sectors, with different proportions in different Provinces. Quebec for example, one of the poorest Provinces, has little independent sector provision.
22. In Canada the range and cost of laboratory tests are tightly controlled. Under Canadian legislation there is an agreed menu of tests which is set by a tripartite group comprising representatives of the public and private sectors and the professions. Tests which are of diminishing clinical value but which earn income for the private sector are difficult to remove from the menu. Similarly it is difficult to introduce new tests such as BNP. Clinical guidelines also restrict the use of certain tests, for example PSA.
23. In 1990 the private sector providers came together to negotiate a global sum for their facilities. In return for this the Government introduced a national cap on private sector spend. Private sector providers therefore can determine which of the approved tests they perform within the overall expenditure cap, but cannot increase the size of the global sum. That sum has remained static in cash terms since, with the result that the private sector is now having to close some facilities which are unprofitable. About half of private sector laboratory costs are in specimen collection and management.

- 24.** Within Oshawa Hospital (a 500-bed acute hospital spread across four sites, serving a local population of 500,000) the laboratory has an annual budget of \$13 million, about 5 per cent of the overall hospital budget. Because of the budgetary constraints the laboratory has no incentive to undertake tests from outside the hospital; there is therefore no outreach service and virtually no out-patient testing (though out-patient imaging is funded on a fee-for-service basis) – and therefore no transport of samples. Phlebotomists are fully under the control of the laboratory, and ordering is fully electronic. The laboratory Director can decide not to perform tests which he judges to be unjustified or unhelpful and can do reflex testing. For esoteric tests he uses couriers to send samples to a reference laboratory. The hospital's IT system does not support the provision of test utilisation information and demand management in pathology.
- 25.** In theory resources can be switched between different departments within the hospital. In reality the departments operate in management silos. This makes it difficult to secure approval for extra investment in the laboratory even where savings would accrue in another department, although there have been successes, for example troponin for patients admitted with chest pain. For new capital spend there are two funding routes: one is through the hospital itself, in competition with all other hospital capital bids; the other is via a national Government body set up for the purpose of reviewing capital decisions for laboratories.
- 26.** The Canadian Government is increasingly looking to shift activity from hospitals into primary care, but some time ago it made the decision to limit health care costs by restricting supply. As a result, and with the rapid growth in population across the country, it can be difficult to find a GP with whom to register.
- 27.** A laboratory test request typically would originate within the primary care sector (specialists are not paid without a referral from primary care). There is no IT connectivity between the primary and secondary care sectors, so patients are referred with a paper test requisition. Test requests initiated in primary care are mostly repeated, if the patient is admitted to hospital, by the hospital laboratory because it is easier and the extra cost is small.
- 28.** Health care is highly unionised in Canada, and the salaries of medical laboratory staff are outside the control of the laboratory Director. We heard that the skills base is not keeping pace with new developments in the laboratory.
- 29.** Every three to five years the laboratory is subjected to hospital-based peer review as part of a national accreditation process which covers private as well as public laboratories.

30. The laboratory is managed on a matrix basis. There is a Clinical Director but also a laboratory manager/administrator. Pathologists in Canada tend to be located in teaching hospitals where they can divide their time between clinical activity and research. Microbiologists similarly divide their time between clinical work and infection control.
31. Canada now has clinical trials under way to evaluate two new approaches to anatomical pathology. “Sakura Finetek” and “Ntuitive” have introduced automated instrument systems that have the potential to change the discipline fundamentally by providing a faster means of fixing samples, thus dramatically reducing the time taken to create the glass slides required by anatomic pathologists to diagnose cases. This could, in turn, bring significant benefits to patients by enabling breast cancer clinics, for example, which previously depended on an overnight service to provide a same-day service, to allow the patient to remain on site while the tests were completed and the outcome communicated to her. (In the USA, the pathology department at the University of Miami/Jackson Memorial Hospital in Miami, Florida has pioneered use of the Sakura Finetek system. It now delivers 80 per cent of its anatomic pathology results on the same day.)
32. Although voice-activated computer technology is being considered to speed up the reporting process in histopathology, it has not been implemented to date. The next most likely innovation to be implemented is the opportunity to choose from a preset menu of paragraphs describing diagnostic findings, as an alternative to free-flowing prose. Computerised diagnostic imaging of sample slides is currently possible but needs further development. This again would bring substantial benefits for histopathologists.

## Australia

33. In Australia health care provision is split between the public and private health care sectors. Funding of private provision and community services is by the commonwealth (all states acting in concert) via Medicare; funding of public hospitals comes chiefly from the individual states (from the commonwealth via Australian Health Care Agreements). Funding is conditional on holding certified accreditation. In the public sector, pathology services are mainly hospital-based. In the private sector they are more commonly community-based, or in private hospitals.
34. Following concerns about the rising level of reimbursement of pathology across Australia, which culminated in a Public Accounts Committee investigation into fraud and over-servicing in pathology, in 1988 the Australian Government “slashed” the rate of reimbursement of pathology. This led to a successful legal challenge by the profession. After a period of turmoil, the Government and the profession reached agreement on a new system based on a new accreditation framework and a new approach to

reimbursement under which total spend at national level would be capped at a specified level.

- 35.** Under the new accreditation framework, minimum standards are set by the National Pathology Accreditation Advisory Council; and the National Association of Testing Authorities accredits in accordance with those standards, using an assessment process based on peer review. Pathology service providers can opt not to be accredited, but without accreditation cannot receive reimbursement.
- 36.** Under the new capped reimbursement scheme, there is a five-year pathology agreement between the Government and the profession on the size of the cap; at the end of the period the cap can be renegotiated for the next five years. Under this agreement utilisation has been rising steadily: total spend on pathology has increased at a rate of 0.1 per cent over five years: an increase of \$3 million on a total spend of \$3.5 billion, less than half that for general practice or Medicare generally.
- 37.** Overall the new approach to pathology has led to proven improvements in quality as well as reductions in costs. Competition between the public and private sectors is based not on cost but on quality.

# Annex F:

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