

# Report of the Second Phase 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

The Rt Hon Dawn Primarolo MP  
Minister of State for Public Health

## Independent Review of NHS Pathology Services in England

I enclose the report of the second phase of our Review of NHS Pathology Services.

Pathology services are crucial to healthcare in England. The advent of genomics and molecular testing will bring a shift to more preventive medicine and more personalised care, and these developments will place ever greater reliance on pathology services.

This review is not simply about extracting the most efficiency from a mature service. It is about meeting the growing and changing demands that will be placed on pathology provision in England.

So our report focuses on three main themes:

- improving quality and patient safety
- improving efficiency
- identifying the mechanisms for delivering change.

Based on the evidence we have collected, we believe there is a strong case for consolidation of pathology to improve quality, patient safety and efficiency. Characteristics of a good consolidated service would be end-to-end management of the service (including transport and logistics, IT connectivity and efficient and effective use of resources, including people) and the concentration of non-urgent and specialist work in one or more centralised and accredited core laboratories where throughput is sufficient to ensure high-quality results. Only tests/investigations requiring a rapid turnaround on clinical grounds would be processed on site.

The key issue is how to deliver consolidation. The historical command and control model of the NHS (if it ever existed) is no more. The strongly competitive ethos of the foundation trusts (and those organisations that seek to move towards that status), together with the nascent authority of commissioners, make this a difficult time to deliver change. However, a large number of practitioners have told us that they want consolidation, and already there are excellent and commendable examples of collaborative ways of working which are delivering improved quality and patient safety and better value.

Everyone we have spoken to acknowledges that driving up standards, quality and patient safety, at the same time as reducing costs by between £250 and £500 million a year for reinvestment in the service, is a prize worth pursuing vigorously.

In this phase of the review we have worked with a wide range of people – practitioners and managers at local, regional and national levels in the NHS, the Department of Health and outside, at both operational and strategic levels. They have contributed enormously to our work and I should like to thank them all.

A handwritten signature in black ink, appearing to read 'Lord Carter of Coles', written in a cursive style.

Lord Carter of Coles  
Chair  
Independent Review of NHS Pathology Services in England

## Summary and Recommendations

In this second phase of the review we set out our vision for NHS pathology services. The main objective must be improved quality and patient safety, delivered through service consolidation. The case for consolidation is based on the activity and cost data we collected from a representative sample of NHS pathology pilot sites in England. Wide variations between pilot sites were found, and analysis of these variations confirms the main recommendations made in our first report. Modelling exercises for two strategic health authorities (SHAs) were undertaken which showed that significant savings could be achieved through the reconfiguration and consolidation of pathology services, based on certain assumptions (see paragraphs 39–41 below).

Service consolidation is necessary to transform pathology services so that they can respond swiftly to the challenges presented by innovation (particularly from the genomic revolution), system reform across the NHS and reform of the workforce. Consolidation provides the means of improving service quality, responsiveness and cost-effectiveness by enabling resources to be reinvested in pathology services. Reinvestment of savings is essential to deliver and assure service quality, and to support the rapid adoption of innovative new technology and new approaches to the delivery of pathology services.

Accordingly we recommend that:

1. objective and measurable quality standards should be developed for pathology services, from sample request to delivery of interpreted result (see paragraph 8);
2. the accreditation process should be reviewed so that it inspects against the quality standards (once developed) referred to in Recommendation 1 (paragraph 11);
3. pathology service providers – and, in future, consolidated networks – should be subject to mandatory accreditation by an organisation independent of the providers and the professions (paragraph 12);
4. all providers of pathology services (including providers of point-of-care testing) should be required to participate in clinical audit and other clinical governance activities (paragraph 14);
5. IT connectivity should be put in place for NHS pathology services as a matter of priority (paragraph 15);
6. priority should be given to ensuring that pathology services are made more responsive to users' requirements; and, in particular, that phlebotomy and sample collection services should be made more accessible and convenient (paragraph 17);

7. the Department of Health should formulate proposals for ensuring that more information is made available to service users about the quality and safety of services (paragraph 18);
8. specialist services should be consolidated through referral to specialist testing centres to assure quality and to address professional isolation (paragraphs 24–25);
9. pathology networks should be developed on the lines set out in paragraph 43;
10. each consolidated network should have a single integrated management structure, including a clinical director and commercial director, who would provide clear leadership and accountability (paragraphs 44–45);
11. a national clinical director for pathology should be appointed, working in partnership with a national commercial director for pathology (paragraph 53);
12. our proposals for the reform of NHS pathology services should be reflected in the Department of Health’s Operating Framework for the NHS in England (paragraph 54);
13. the NHS pathology workforce should be reformed as set out in paragraphs 58–59 (paragraph 60);
14. based on guidance and support from the Department of Health, each SHA should require the primary care trusts (PCTs) in its area to take the lead with providers (existing and – where known – potential) in drawing up cost-effective plans for implementation of this report’s proposals (paragraph 61);
15. further work should be undertaken by the Department of Health to develop a tariff for community-based and specialist pathology (paragraph 69);
16. the Department of Health should determine the coverage and format of benchmarking data to be collected from all pathology providers, and procure the collection of such data (paragraph 70);
17. the Department of Health should develop commissioning guidance as a matter of priority (paragraph 71);
18. the Department of Health should consider the development of model contracts for pathology (paragraph 72);
19. the Department of Health should ensure that a pathology “formulary” equivalent to that used for medicines, is introduced (paragraph 88); and
20. the Department of Health should identify ways to facilitate the adoption of innovation in pathology (paragraph 89).

## Introduction

1. In our first report, published in August 2006, we made a number of recommendations (see Annex A) aimed at improving the delivery of NHS pathology services, while noting the lack of good-quality data about the costs of providing these services.
2. When Lord Warner, then Minister for Health, published our report he asked us to “oversee a programme of pilot projects which will trial the way forward in partnership with the NHS, and provide robust evidence to guide future reforms”. He added: “I want to move forward with a change programme for pathology services that benefits patients, taxpayers and staff, and to do so on a fully consultative basis involving all interests. The objective of the pilots is to identify a new model for commissioning and organising NHS pathology services that offers increased quality and responsiveness to patients and reduces NHS costs.”

## Our vision for pathology

3. Our vision for NHS pathology services puts patients first by providing services which are:
  - a) **clinically excellent:**
    - (i) based on evidence of impact on health outcomes;
    - (ii) of high quality, underpinned by a mandatory accreditation system;
    - (iii) optimised for pathology’s contribution to the care pathway;
    - (iv) swift to adopt innovative technology and practices, where effectiveness is proven;
    - (v) operated by appropriately qualified/trained staff;
  - b) **responsive** to users:
    - (i) convenient;
    - (ii) accessible;
    - (iii) equitable;
    - (iv) personalised;
    - (v) effective;
    - (vi) safe;

- c) **cost-effective:**
    - (i) consolidated into reconfigured commissioning networks;
    - (ii) managed end to end – from request being made to delivery of an interpreted result;
    - (iii) inclusive of logistics and transportation of samples;
    - (iv) based on full IT connectivity;
    - (v) operated by appropriately and effectively deployed staff; and
  - d) **integrated** with other elements of the Government's health reform strategy, by:
    - (i) delivering choice and contestability;
    - (ii) supporting community-based services;
    - (iii) promoting world-class commissioning;
    - (iv) enhancing other clinical services (e.g. cancer services, chronic disease management) through the care pathway; and
    - (v) contributing to disease prevention through appropriate screening.
4. Our vision of the future provides a valuable framework for this phase of the review's work. But how can this vision be realised? The main objective must be improved quality and patient safety, delivered through service consolidation, as we show in this report. Consolidation enhances quality by creating critical mass and by delivering better value for money through economies of scale. It creates the scope for increasing investment in order to improve service quality and provide more responsive services. Consolidation must, however, have a solid foundation of evidence. We return to this point at paragraph 38 below.

## Quality and patient safety

- 5. Across the NHS, services are becoming increasingly responsive to users' requirements and preferences. Members of the public – patients and other users of services – are rightly becoming more aware of service quality and patient safety, and the process of providing services is becoming more transparent as a result.
- 6. Over recent years, the NHS has given increasing priority to improving service quality. Improved quality strengthens patient safety through the assessment and management of risk. The extent to which the quality of NHS pathology services can be improved has become clearer to us through this phase of our review – not only in relation to pathology services themselves but also the contribution made by pathology services to the care pathway.
- 7. In our view there are three dimensions of quality:
  - service quality: the quality of the service experienced by a member of the public;

- clinical quality: the quality of the service provided by professionally qualified staff; and
  - system quality: the quality of the management of the end-to-end service – from advice on appropriate requesting of investigations, through sample collection, to delivery of interpreted result, and the way in which that result is used.
8. In pathology, standards are at present too subjective and are applied to the clinical quality of the laboratory service rather than to the end-to-end service. Accordingly **we recommend that objective and measurable standards be developed to assure the quality of NHS pathology services, from sample request to delivery of interpreted result.** These standards may draw on existing arrangements, including those for external quality assessment and clinical audit. The Department of Health should take the lead in developing such standards, in consultation with the representative bodies in pathology.

## Accreditation

9. In our first report we noted that the accreditation of laboratories was voluntary and that point-of-care tests in pathology were not covered by the Clinical Pathology Accreditation (CPA) accreditation scheme. In our recommendations we called for both issues to be addressed.
10. During this phase of our review the Healthcare Commission published (in March 2007) its report<sup>1</sup> on hospital-based NHS pathology services, which reported that only 55 per cent of pathology laboratories were fully accredited by CPA (with a further 40 per cent either partially accredited or in the process of being assessed for accreditation purposes).
11. On further investigation it became clear to us that the present accreditation process is not satisfactory. Some of the judgements made are too subjective. **We therefore recommend that the accreditation process should be reviewed. In future it should inspect against the quality standards (once developed) referred to above.**
12. **We also recommend that all pathology service providers should be subject to mandatory accreditation by an organisation independent of the providers and the professions.** Mandatory accreditation (including of point-of-care testing) gives members of the public and other NHS staff the confidence that the quality of the service has been independently verified as meeting objective service standards. We welcome the commitment shown by the Department of Health to reforming the

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1 *Getting results; Pathology services in acute and specialist trusts. Acute hospital portfolio review.* Healthcare Commission, 2007.

process of accreditation of pathology services, and hope that the reform process will reflect our concern that the accrediting body should be fully independent.

13. In working out the details of a new accreditation scheme it will be important to balance continued service provision against quality and safety requirements. Where provision falls below the required standards, and depending on the level of risk, sensible arrangements need to be made to enable it to make good the deficiency within a reasonable time, so that services can be maintained wherever possible. Prolonged failure to secure accreditation should result in the termination of contracts which involve the NHS.
14. **We also recommend that all providers of pathology services (including providers of point-of-care testing) should be required to participate in clinical audit and other clinical governance activities**, as a further means of underpinning quality; and that all staff involved in the delivery of pathology services, including technical and support staff, participate in relevant continuous professional development as part of maintaining their competence.

## IT connectivity

15. In our earlier report we emphasised the importance of IT connectivity. Good electronic communication – for example, between the pathology service provider on one hand and healthcare providers on the other – is an essential element of any efficient and effective service. In pathology it can help to address unnecessary and inappropriate demand and reduce the risk of errors (as identified by the Healthcare Commission report of March 2007). The collection and analysis of IT-based data can improve the way that pathology enables decisions about diagnosis and treatment to be made. **We recommend therefore that IT connectivity be put in place for NHS pathology services as a matter of priority.** We welcome the initiative taken by the Department of Health in piloting electronic order communications for primary care in two sites to complement the roll-out in secondary care, and look forward to them being rolled out across the country as soon as possible. Such IT links could be extended to cover other primary care settings such as pharmacies.

## Responsive services

16. One of the striking differences between this country and others is the extent to which services reflect the requirements of users. A survey undertaken by the Central Office of Information (COI) on behalf of the Department of Health noted that there were instances where respondents indicated that they had to take time off work to attend phlebotomy appointments, and there were significant delays in gaining these appointments. Users were rarely able to access services except via their GP; if a sample needed to be taken, an appointment might have to be made with the practice's phlebotomist or with the local hospital. In other countries, such as Canada, Australia

and the Netherlands, the public can have samples taken and/or collected at service centres, which are accessible (for example in shopping centres) and open at convenient times (before and after the working day). Because in primary care phlebotomy and other sample collection services are generally provided by GPs, the NHS pathology service has at present little influence over their accessibility and convenience.

17. The increasing use of point-of-care testing shows that pathology is moving towards more accessible community-based services. This is consistent with the current trend, set out for example in Lord Darzi's report *Healthcare for London: A Framework for Action*<sup>2</sup>, of moving services out of hospitals and into the community. Where that occurs, it is important that pathology services are co-located in polyclinics, health centres or other primary care settings (such as pharmacies) in order to facilitate diagnosis and treatment. Point-of-care testing facilities should be provided on these sites to ensure that a rapid turnaround service is available where needed, although non-urgent tests/investigations would ordinarily be referred to the network's core laboratory.

**We recommend that priority is given to ensuring that pathology services are made more responsive to users' requirements; and, in particular, that phlebotomy and, other sample collection services should be made more accessible and convenient for service users.**

18. In this country, little information is made available to members of the public to help them understand which test(s)/investigation(s) might be most relevant to the diagnosis or treatment of their condition. Help and advice in understanding the meaning or the implications of the test/investigation result are equally scarce. Outside the laboratory no evidence of the safety or quality of the clinical service is available. We wish to see more information being made available to service users about the quality and safety of services. **We recommend that the Department of Health formulates proposals to address this issue.**
19. In the COI survey, members of the public said that they might have to wait for up to two weeks for a test result, even where the turnaround time in the laboratory was a couple of hours. To obtain their results, many had to call the GP surgery; and in a number of cases their results were given to them by the receptionist, not by a clinical member of the practice.
20. Service expectations need to be realistic (in terms of cost and the implications for wider service delivery). But all these factors are consistent with a provider-led rather than customer-driven service. However good the clinical content of the laboratory process, users often find that services are provided at inconvenient times and are difficult to access. For services to become more responsive to members of the public,

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2 *Healthcare for London: A Framework for Action*. NHS London, 2007.  
See [www.healthcareforlondon.nhs.uk](http://www.healthcareforlondon.nhs.uk).

the focus has to change. Above all, the public needs information to enable them to become more discerning, discriminating and demanding.

## Integration of pathology with other clinical services

21. Pathology is a core component in 70 per cent of clinical interventions (diagnosis, choice of treatment, efficacy of treatment); so, in improving service quality, it is important to evaluate the integration of pathology within the overall care pathway. This is a major challenge for the future. The pathology practitioner of the future, as a member of the multidisciplinary team, must ensure that the investigation(s) which contribute most to the diagnosis and/or treatment of the individual are undertaken. Through this role, the practitioner can improve health outcomes as well as value for money.
22. The work of the NHS radiology and pathology service improvement teams has shown that if pathology is configured to meet the needs of clinical service users, significant savings can be made outside pathology. By improving the flow of information – pathology’s core commodity – the flow of patients through the care pathway can be improved and patients’ satisfaction increased. By supporting continuing improvements in laboratories’ efficiency, the national pathology improvement teams can help the wider NHS to become more efficient and effective, and we wish to encourage such developments.
23. Pathology provision is closely integrated with other clinical services, including cancer, infection control, blood transfusion and screening. Some of these services are managed nationally; others are not. We welcome the approach taken in the Government’s *Cancer Reform Strategy*, published in December 2007, which fits well with our proposals for service consolidation (set out below).

## Clinical quality: specialised tests/investigations and screening services

24. Consolidation of services would greatly strengthen quality in relation to specialised tests/investigations. At present, specialised tests and some screening services are undertaken in a small number of centres. These centres depend upon referrals from other laboratories, so that expertise can be concentrated on a small number of sites where clinical quality can be assured. **We support these arrangements, and recommend accordingly.**
25. We have received evidence that a minority of laboratories still perform investigations (whether specialised or not) and provide screening services where there is not a sufficient volume to underpin clinical quality. In these instances **we recommend that in future such investigations should be referred to a specialist testing centre which is appropriately accredited and which undertakes the minimum level**

**of activity to guarantee service quality.** What constitutes a sufficient level of activity to ensure high clinical quality and consistency of outcomes should be determined by the clinical director for pathology in discussion with the pathology professions; and the number of centres required nationally would reflect nationally determined quality standards.

26. Service consolidation would also help to address professional isolation. We heard evidence that small-scale pathology services may be reliant on a small number of pathologists, whose ability to maintain a high-quality service was put at risk when key staff were sick, on holiday or undertaking training. The scope for staff in such settings to meet their peers regularly might be severely limited, and consolidation would help to address this problem (for example, by facilitating the establishment of specialist IT networks).

## Gathering the data

27. In order to provide a solid basis for improving service quality and patient safety in pathology as set out above, and to obtain “robust evidence to guide future reforms” as requested by the Minister, we worked collaboratively with 12 pilot sites (selected – see Annex B – to represent a range of geographical settings across the country). Using data which they provided, we built a comprehensive database of their pathology activity and costs. A description of our methodology is at Annex C. In the minority of cases where the volume of activity was too low for reliable cost data to be produced, the results were discarded. Throughout the process we took an interactive approach with the pilot sites, enabling them to review and refine their data returns to ensure that they were as accurate as possible a reflection of each site’s activity levels and costs.
28. As a result we are confident that the database is reliable and robust. Indeed, we have been told that never before has such a comprehensive study been undertaken of the operation of NHS pathology services: the volumes of activity by pathology specialty and by degree of complexity; the functions which make up the service; and the costs attributable to each such function. Elsewhere we suggest that the data collection undertaken in respect of the pilot sites should be extended (see paragraph 70 below) and procured through a nationally determined process to ensure consistency and therefore comparability between all providers.

## Findings from the pilot sites' data

### Variations in costs

29. The resulting database showed wide variation in costs per investigation – not only in relation to high-volume, automated investigations, but also more complex manual ones.
30. For example, the direct cost<sup>3</sup> of analysing a routine high-volume laboratory test varied:
  - a) in **biochemistry**, from £0.50 per test to £2.80, with a median cost of £1.00;
  - b) in **microbiology**, from £4.00 to £9.40, with a median of £6.10; and
  - c) in **haematology**, from £1.50 to £3.70, with a median of £2.40.
31. In **histopathology**, the cost of analysing routine non-complex cases varied from £21.40 to £73.40, with a median of £48.10.
32. The costs of other tests/investigations also varied significantly.
33. We tested our findings against other data sources, notably the Healthcare Commission's report<sup>4</sup> and the Keele University benchmarking service.<sup>5</sup> Despite differences in methodology, we were reassured that the results of our data collection were broadly in line with these sources.
34. In partnership with the pilot sites, we explored the reasons for the variations in costs. The main factors were scale of operation (and the associated economies of scale) and the way in which staff were deployed (see paragraphs 58–60 below).

### Economies of scale

35. Economies of scale arise for the following reasons:
  - a) larger pathology services are able to allocate their fixed costs over a larger number of investigations;
  - b) greater purchasing power in relation to equipment and reagents: for example, a laboratory which processed 4 million investigations a year had more than twice the equipment costs, per investigation, of a laboratory processing 30 million;

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3 i.e. excluding the trust-wide overheads added to the laboratories' operating costs.

4 *Getting results; Pathology services in acute and specialist trusts*. Acute hospital portfolio review. Healthcare Commission, 2007.

5 The National Pathology Benchmarking Service at Keele University.

- c) better utilisation of equipment: nearly three-quarters of pathology services had utilisation rates of less than 20 per cent, whereas others achieved closer to 80 per cent. Although some spare capacity is necessary to guarantee continuity of service, it is reasonable to expect most service providers to achieve higher utilisation rates than at present;
  - d) more efficient management of workload. Pathology activity – and productivity – varied considerably during the day, reaching a peak in the afternoon, with evening surgery activity having to be absorbed by the on-call services;
  - e) better deployment of staff. Different services had different skills profiles for staff, different approaches to out-of-hours arrangements, and different retirement, recruitment and retention rates.
36. In some instances the volume of more complex and specialist pathology work undertaken on site is low, resulting in unusually high costs per test/case. A low volume of complex investigations results in expertise being spread more thinly, hindering specialisation and access to specialist expertise. Consolidation of specialist as well as routine services would therefore enhance service quality and improve cost-effectiveness.

## Conclusions from the pilot sites' data

37. Overall we consider that the data we have collected confirm the main recommendations made in our first report (see paragraphs 19–21).
38. The data provided by the pilot sites point strongly towards the consolidation of services as a means of improving service quality and cost-effectiveness. During this review we have seen some good examples of networks and have noticed a growing momentum towards consolidation. Consolidation of core laboratories took place in the USA more than 20 years ago; and it is interesting to observe that in Canada and Australia there is also a history of consolidation, in both the public and private sectors.

## Modelling future services

39. Given that consolidation is the right approach, what is the right level of consolidation? To answer this question we commissioned some modelling of pathology services based on information from two SHAs. The models assumed that consolidated, reconfigured services – networks – would have the following features, in order to benefit from the economies of scale:
- a) responsibility for the end-to-end service (i.e. from collection of sample to delivery of interpreted result, including transport and logistics);

- b) full IT connectivity to link the requester (whether in primary, secondary or tertiary care) with the laboratory. It was assumed that no reduction in demand (or demand growth) would follow, as currently unmet need would balance out inappropriate or unnecessary requests;
  - c) effective and economic management of resources (people, equipment), in line with best practice (e.g. on call, skill mix, productivity).
40. Certain additional assumptions were made, as follows.
- a) Although consolidation of pathology services should enable many NHS trusts to rationalise their sites (for example because some pathology would move off site or reduce in scale), the value of freeing space on site and any associated savings would be difficult to estimate and are therefore not included in the modelling work (such savings are additional to our estimates below of the benefits flowing from service consolidation).
  - b) Existing equipment would be fully written off, with new networks procuring all their equipment afresh in accordance with a professionally developed, standardised inventory. This would facilitate the standardisation of test repertoires and identification, analytical methodology and reference ranges; it would also ensure interchangeability across the new networks and enable providers to benefit from the latest technology.
  - c) Non-urgent and specialist investigations would be carried out at a single core laboratory for each network (exceptionally a network might have two core laboratories to serve a highly dispersed population or to serve a particular clinical need), with other laboratories located only in settings where a rapid turnaround was needed. For these purposes, based on returns from the pilot sites, around 20 per cent of activity was assumed to require a rapid turnaround.
41. Based on these models, we estimate that potential savings of between 10 and 20 per cent could be achieved. At a national level, this would imply **annual savings of between £250 and £500 million** in total, based on figures for 2005. If savings from rationalisation of the estate were included, these figures would be even larger.

## Service consolidation

42. The smaller the number of consolidated networks, the greater the level of savings. In urban areas the scope for consolidation is likely to be greater than in rural areas, where the benefits of scale may be outweighed by the higher costs of consolidation. Further modelling exercises need to be undertaken for other SHAs.
43. Several factors will determine the right approach to consolidation. In most parts of the country, for example, there are natural “networks” which reflect “patient flows” – in other words the historic pattern of referrals of people from primary to secondary and

tertiary care, and between secondary care providers in the NHS. We see these networks as the core building blocks for a reformed pathology service. The number will vary from one SHA to another, reflecting factors such as population density; and network boundaries may cross SHA boundaries. These pathology networks would include accessible and convenient locations where users of the service could provide samples (for example in polyclinics, health centres or on the High Street). They would also include facilities for urgent testing and, as appropriate, for point-of-care testing.

**We recommend that networks for commissioning pathology should be developed on these lines.**

44. As the modelling work showed for the relevant SHAs, the greater the level of consolidation, the greater the economies of scale. The benefits of scale can be maximised where commissioning networks operate under a single overarching management structure. Such an approach enables capacity to be optimised and the workforce to be planned and deployed effectively across the network. Non-urgent work would be taken to the network's core laboratory (in a geographically dispersed area, there may be more than one) and higher volumes of specialist work would be concentrated in the core laboratory (or laboratories), thereby enabling professional expertise to be built up and, with it, the quality of the clinical service.

**We recommend that for each consolidated commissioning network there is a single integrated management structure.**

45. **We recommend that each consolidated network should have a clinical director responsible for quality and clinical governance, and a commercial director with responsibility for contractual and other commercial arrangements.** They would provide clear leadership and accountability across all the networks within the consolidated service. Governance and accountability arrangements for these networks might be as follows:

- a) **a consortium arrangement**, where provider trusts agree to cede responsibility for the provision of their pathology services to the consortium, which then manages the combined service in accordance with a service level agreement with the trusts. A good example would be PathLinks;<sup>6</sup>
- b) **a commissioning arrangement**, where commissioners employ the network manager and pathology director to work with the provider trusts and other potential providers, again in accordance with a service level agreement/legally binding contract. A good example would be Kent and Medway Pathology Network. Of course, commissioners would need to ensure that a competitive market existed locally;
- c) **a contracted-out model** where service provision is outsourced to another organisation, either wholly to the independent sector or via a joint venture.

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6 PathLinks: see Annex B.

46. We believe that a range of different providers will be involved in the future provision of NHS pathology services. We can see a strong case in some parts of the country for involving the independent sector in some form of partnership arrangement, whereby it contributes its proven skills in business transformation and change management and (perhaps less importantly) its capital to reconfiguring services. The choice must always be made at local level, so long as it reflects the market framework set by the SHA.
47. It would be important for pathology networks to have good and effective working relations with other NHS networks, such as those for cancer and neonatal services, but they need not be coterminous. The factors determining the organisation of each network will differ from one to another, but all should interact and combine efficiently and effectively to ensure that people receive high-quality, responsive services which reflect the care pathway.
48. Furthermore, the implementation at local level of national strategies and policies (for example in respect of the NHS workforce), and of the priorities set out in the NHS's Operating Framework, must be taken into account.
49. We have considered whether there is an optimum number of consolidated networks. Overall, we would expect that the number would not exceed three networks per SHA; indeed, a single network might cover one or more SHAs.
50. In some areas, implementation of these new structures for pathology would be led by NHS trusts. They would benefit not only from the improved service quality which consolidation would bring but also the improved efficiency and value for money. Already we have seen this process developing, most clearly in the South East Coast SHA and in PathLinks. Providers that remain outside the consolidated services might be less able to deliver high-quality services and could face higher costs in service delivery.
51. Commissioners, however, have the main potential to drive change. Because pathology is central to the delivery of responsive and high-quality NHS services, over time we envisage commissioners becoming increasingly involved with, and expert in, the commissioning of community-based and specialist pathology services. Later in this report we identify tools which will help them to become more effective commissioners of pathology services.
52. As now, the role of SHAs would be to manage the performance of commissioners (and those NHS trusts which have yet to achieve foundation trust status) to ensure that services are provided by a range of providers – from both the public and independent sectors) – to meet the requirements of the local health economies. (In this regard we envisage a role for the proposed 'Cooperation and Competition Panel'.) This implies clarity about objectives, and it would be for commissioners to draw up plans for reform. Progress against plans could then be reported annually.

53. How, though, could an SHA determine whether such plans were reasonable? And what mechanism would ensure that the pace of reform was appropriate? In other clinical specialties (cardiac, cancer, renal) a national clinical director has been appointed to provide clinical leadership, to champion reform and to oversee implementation across the country. We see a strong case for a similar role to be created for pathology to oversee the reform process. The post holder would be located within the Department of Health and be accountable to the NHS's Chief Executive or Clinical Director, and the clinical director of each pathology network would have a line of professional accountability to the national clinical director for pathology. **We recommend that a national clinical director for pathology should be appointed.** As the roles of commissioners and providers become clearer we also see an increasingly important role for a national commercial director, who would work in partnership with the national clinical director of pathology. **We recommend accordingly.**
54. The national pathology director should ensure that pathology reform is incorporated into the NHS planning process for implementing strategic change. To initiate change, we consider that the recommendations set out in this report should be reflected in the annual Operating Framework for the NHS in England (which sets out the priorities and actions for the NHS). Specifically, we would wish to see included in the framework (for 2009–10) a requirement on SHAs to ensure that all PCTs develop plans for establishing consolidated commissioning networks; in the following year (2010–11) different priorities could be set, based on this report (for example, PCTs to clarify the quality standards to be achieved and to quantify the efficiency gains envisaged). For year three (2011–12), the framework might stipulate that consolidated networks should be fully established across the country and performing to the revised quality standards. **We recommend that our proposals for reform of NHS pathology services are reflected in the Operating Framework for the NHS in England.**
55. Our analysis – and our view on the number of consolidated networks – is of course based on the current structure of the NHS. But whatever structures are put in place, the logic for consolidation remains the same.
56. Whatever approach is taken, however, we consider that all consolidated networks should have a number of common characteristics, as set out in paragraph 39 above: responsibility for management of the end-to-end service; full IT connectivity; effective resource management; and non-urgent and specialist tests concentrated in a core laboratory (or, exceptionally, more than one), with other work located in settings where a rapid turnaround is needed (see paragraph 40 above).
57. In implementing these arrangements, it would be important to take opportunities to maximise cost-effectiveness. We recognise however that to realise these potentially significant savings from consolidation, some transitional investment and support may be required.

## The pathology workforce

58. Service consolidation would also facilitate reform of the workforce (the age profile of the current pathology workforce cannot sustain services in their present form, so reform of some kind is inevitable). From our analysis it was also clear that the pathology workforce was not deployed to best effect. Throughout this review we have been greatly impressed by the dedication and commitment of the staff working in NHS pathology services. They have consistently provided high-quality laboratory services, in partnership with other members of the clinical team.
59. As identified earlier (see paragraph 34), reform of the pathology workforce would further enhance the provision of high-quality, efficient and effective services through:
- a) **Skill mix:** increasing automation has created a widening gap between the functions and skills of pathology staff (a point we made in our earlier report). There is scope for better alignment of skills with functions, including the grading of functions, as well as for more broadly based skills to enable staff to work more easily across and between the different disciplines. Provision to enable the future workforce to be reskilled so that they can take on new roles will help to ensure the supply of skilled staff necessary to guarantee continuity of service for the future.
  - b) **Succession planning:** provision needs to be made for maintaining specialist pathology and managerial expertise, for example through good succession-planning arrangements.
  - c) **Education and training:** education and training must be geared to the needs of the service, and reflect the appropriate skill mix. Services that are more responsive will require a different, more outward-looking approach in future. In addition, the consolidation of services will require effective management of the end-to-end service; this in turn means making available to pathologists more training in clinical leadership and for pathology managers training in business management.
  - d) **Workforce planning:** where there is a clear vision of what pathology services should look like in the future, there should also be a workforce plan (numbers, skills, grades). A migration programme could then be devised, taking account of the age profile of the existing workforce, recruitment and retention rates and skill mix. It would be important to ensure that effective arrangements for relocation and redeployment were in place. Workforce planning for consolidated pathology services should help all providers – whether from the public or independent sector – to make effective contractual arrangements for reducing reliance on costly on-call arrangements.
60. **We recommend that the NHS pathology workforce is reformed to reflect the points set out above.** We are aware that the Department of Health's Chief Scientific Officer is currently developing proposals for reform of the NHS's scientific

workforce strategy; we welcome this initiative, in the expectation that it will address the issues set out above and therefore make a significant contribution to wider reform in pathology.

## Implementation

### Barriers and the role of SHAs

61. Consolidation will drive not only improved quality and patient safety but also efficiency. The key issue however is: how to implement consolidation. The ethos of NHS foundation trusts (and those moving towards that status) is strongly competitive, and commissioners' authority is still nascent. As we have stated above, **we envisage that each SHA should require the PCTs in its area to take the lead with local providers (existing and – where known – potential) in drawing up cost-effective plans for implementation of this report, and we recommend accordingly.** In this way there should be a consensus in support of implementation of the plan. (Where one or more PCTs are unable to reach a local consensus, the SHA may need to become involved.)

### Tools to facilitate change

62. Many practitioners have told us that they want consolidation (this enthusiasm is borne out through the popularity of action learning, for example). We have also seen several excellent examples where consolidation has, over time, brought improved quality and better value for money.
63. We were particularly concerned by the reluctance of foundation trusts to consolidate their pathology services with others in areas where there was clear excess capacity. Commissioners' tools for addressing such over-provision are currently limited (but see below).
64. This is an issue where SHAs should become involved. We have been impressed by the willingness of many SHAs to become engaged in the reform of pathology services in their regions, and in the results achieved so far. With the right tools we consider that commissioners, supported by their SHAs, will drive consolidation.
65. An effective option, for example, would be for pathology services to be commissioned by a single agency on behalf of some or all of the commissioners in a particular SHA. Commissioners could also join forces to drive consolidation through the use of contracts they place for processing community pathology work (and other pathology work not included in the Health Resource Group tariff) – some 40 per cent of all pathology. Because of the impact of economies of scale, providers who lose their community or out-patient pathology would be forced to reconfigure their services.

66. More specifically, several tools could be developed to aid commissioners:
- a tariff for community-based and specialist (e.g. genetics) pathology;
  - regular publication of providers' costs (for community and specialist pathology);
  - commissioning guidance;
  - model contracts, including a service specification.

### A tariff for pathology

67. We understand that the Department of Health is considering the feasibility of a tariff for pathology.
68. Under the new arrangements, a community tariff could be set at a level that reflects the greater efficiency and lower costs achieved by larger networks following consolidation. Such a tariff should relate to the end-to-end service, which we have advocated above. Providers who did not consolidate their services would become increasingly uneconomic.
69. **We recommend that further work is undertaken by the Department of Health to develop a tariff for community-based and specialist pathology.** Such work might also explore the feasibility of a tariff for specialist investigations in pathology, and investigations associated with the provision of screening services.

### Annual publication of activity levels and costs in pathology

70. If NHS providers were required to publish details every year of the activity levels and direct costs of their community and specialist pathology services, it would serve to highlight the variations that exist. This information would help commissioners to identify best practice and to negotiate better deals for their populations. It would also enable trust managers to compare their costs relative to workload, and their efficiency relative to other providers. We would like to see the Department of Health take the lead in defining the requirements and ensuring the availability of benchmarking data (in a consistent format) covering all pathology providers, and undertake a national procurement for the provision of such a benchmarking service. **We recommend that this proposal is put in place as soon as possible.**

### Commissioning guidance

71. In our first report we recommended that a commissioning specification for pathology should be developed by the Department of Health (paragraph 24(i)<sup>7</sup>). Guidance on the development of such a specification, reflecting the quality standards referred to in paragraphs 7–8 above, would help commissioners to procure services more effectively, drive consolidation of pathology services and deliver the benefits in terms of improved

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7 See Annex A.

quality and better value for money for their populations. Such commissioning guidance is now a high priority and **we recommend that the Department of Health develops the guidance as soon as possible.**

### Model contracts

72. We note that the Department of Health has developed a model contract for NHS foundation trusts. In extending this approach to other areas, we consider that high priority should be given to the development of a model contract for community-based pathology services (including screening services). Once a preferred provider has been identified, a formal contractual relationship is set up between the two parties. If it is proposed to set up a new arrangement, the process can become complex, and the risk of naive contracting is high. The development of one or more model contracts could help both sides to cut through the complexities, and **we recommend that these are developed by the Department of Health.**

## The challenges facing pathology over the next ten years

73. We have set out the case for consolidation based on the evidence from our pilot sites and the associated modelling work; we have also described a framework for implementation across the country.
74. Looking ahead, it is clear to us that pathology faces some major challenges over the next ten years, in the following areas: demand/innovation; quality/patient safety; and resources. These cannot be addressed effectively without consolidation.

### Demand/innovation

#### Demographics

75. The demographics of this country are changing. It is projected that:
- a) the number of people in the UK aged 65 and over will rise by 63 per cent to 15.8 million over the next 25 years, representing 22 per cent of the UK population;
  - b) over the same period, the number of people aged 85 and over will more than double to 2.9 million, representing more than 4 per cent of the UK population.
76. An increasingly elderly population has a higher prevalence of chronic disease. Chronic disease accounts for around 50 per cent of all pathology activity. So there will be a greater demand for health service provision, and with it a greater demand for pathology services.

## Innovation

77. At the same time, technological advances (see paragraphs 78–79 below) are speeding up the shift towards better health outcomes delivered through personalised medicine. This trend will create demand for more molecular-based investigations, and will therefore increase pathology activity and service costs. Innovation will combine with demographic pressures to ensure that the growth in demand for pathology over the past ten years (10–20 per cent per annum) will accelerate even further over the next decade.
78. The pathology market is increasingly international. Pathologists procure their equipment (analysers and IT) from a limited range of international manufacturers. In relation to new technology, as well as in the operation and management of pathology services, knowledge and best practice are increasingly shared across and between different countries. This helps to speed up the spread of innovation.
79. Already, through more complex investigations (genomics, metabolomics, proteomics), a profile of the chemical composition of an individual's body can be produced, making it possible to identify the disease(s) to which each individual has particular susceptibility and to detect such disease(s) in pre-symptomatic form – even to predict the onset of disease. At the same time, treatment can be personalised, enabling the efficacy of the intervention to be optimised for each individual.
80. The value of these investigations will be further enhanced through planned enhancements of the electronic patient record. Using computer technology, it will become possible to identify and analyse patterns within an individual's overall health record. The identification of such patterns should help with the detection, diagnosis and treatment of disease.
81. These developments have profound implications for society, giving individuals – if they request it – the information to manage their health and enabling health services to shift their focus from the treatment of ill-health to the maintenance of good health. These emerging technologies put the individual firmly in control of his or her health status, reflecting the current emphasis in the NHS on services that are responsive to patients' needs and preferences.
82. These advances will have a major impact on pathology services. Investment will be needed to provide and undertake these complex investigations, and practitioners will require new skills to perform them. More investigations are likely to be performed outside the traditional laboratory setting. Overall, technological advances should further increase the growth in demand for pathology services.
83. Innovation in pathology may bring greater benefits for other service specialties, so it will be important to base evaluations on the impact across the individual's entire pathway through care.

## Translational and experimental research

84. In the past one of the strengths of the NHS has been the interrelationship between service provision and research. For example, the use of human biological samples, collected via the pathology laboratory, has been central to the success of much experimental medicine (itself a priority area within health). With a growing focus on service delivery, and in a more cost-conscious culture, there is evidence that the scope for researchers to gain access to such material via the pathology laboratory is becoming more difficult.
85. Such a trend is not in the long-term interests of the NHS – or of patients. We support those who wish to see research embedded into the new ways of working. We welcome the proposal to set up a working group to foster the contribution of pathology services to research. This is an issue that extends beyond pathology; but in consolidating pathology services it is essential to build in measures that facilitate translational research.

## The role of the Health Innovation Council

86. There is an important role for the Health Innovation Council, recently established by the Government, in keeping abreast of the latest research and developments in pathology, and monitoring the safe and appropriate adoption of new technology across the NHS.

## A formulary for pathology

87. As new products enter the market it is harder for non-pathologists to keep up-to-date. Already the proportion of inappropriate or unnecessary investigations is high – estimated by some at up to 25 per cent of all requests – yet there is probably a similar amount of under-requesting. There is insufficient awareness of the range and capability of pathology investigations available, and of the evidence of their impact on health outcomes.
88. This leads us to the view that there should be a pathology “formulary” equivalent to that used for medicines. The purpose of the formulary would be to ensure that a single “menu” of pathology tests/investigations is available which would provide GPs, clinicians and service users with information on the range and functionality of available tests/investigations and their appropriateness for particular conditions. The inclusion of a new test/investigation, or the deletion of an existing one, would be decided through a clear and transparent mechanism under a single point of control, in a manner broadly equivalent to that currently undertaken by the National Institute for Health and Clinical Excellence (NICE). Before a test/investigation was included in the formulary, there would have to be good evidence of effectiveness (including cost-effectiveness).
- We recommend that the Department of Health should ensure that a pathology formulary equivalent to that used for medicines is introduced.**

- 89. We recommend that the Department of Health identifies ways to facilitate the adoption of innovation in pathology.**

## Conclusion

90. Change is inevitable because of the pressures of demography, the tide of new technology and the constraints imposed by the supply of a skilled workforce. Rising expectations in terms of quality and patient safety will not be met without service reform.
91. Change is also driven by the Government's strategy for health: the continued development of contestability and choice; of foundation trusts and world-class commissioning; and of more community-based services.
92. The costs of reform will be harder to meet because NHS expenditure is set to grow less rapidly than hitherto.
93. Consolidation of pathology services into reconfigured networks will improve services for patients by enhancing value for money and releasing resources for investment to improve service quality and patient safety. Accordingly we recommend that pathology services are consolidated along the lines set out above; and that SHAs draw up implementation plans for consolidating services in their regions.

# Annex A: Recommendations made in our first report

## Report of the Review of NHS Pathology Services in England, published September 2006

### 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.

## Annex B: Pathology pilot sites

- North East wide Pathology (NEwPath) Network (North East SHA)
- Barts and The London NHS Trust (London SHA)
- King's College Hospital NHS Trust (London SHA)
- Luton and Dunstable Hospital NHS Foundation Trust (East of England SHA)
- North Cumbria University Hospitals NHS Trust (North West SHA)
- Royal Devon and Exeter NHS Foundation Trust (South West SHA)
- University Hospitals Birmingham NHS Foundation Trust (West Midlands SHA)
- Leeds Teaching Hospitals NHS Trust (Yorkshire and the Humber SHA)
- PathLinks – a pathology network involving Northern Lincolnshire and Goole Hospitals NHS Foundation Trust and United Lincolnshire Hospitals NHS Trust (Yorkshire and the Humber SHA and East Midlands SHA respectively)
- Derby Hospitals NHS Foundation Trust (East Midlands SHA)
- Joint pilot between Frimley Park Hospital NHS Foundation Trust and the Royal Surrey County NHS Trust (South East Coast SHA)
- Oxford Radcliffe Hospitals NHS Trust (South Central SHA)

## ANNEX C: Our methodology

### Activity-based costing

1. At our request, a group of expert pathologists divided up the current repertoire of tests and cases into a set of broadly comparable “baskets”. They defined a set of 43 different baskets spanning all pathology disciplines: 8 baskets for biochemistry, 8 for haematology, 11 for microbiology (including 6 for virology), 4 for immunology, 10 for histopathology and 2 for cytology. The tests/cases grouped within each basket have common characteristics in terms of their complexity and their requirements (in terms of personnel, equipment and processing time).
2. Representatives of the pilot sites were asked to consider the feasibility of allocating tests/cases to these baskets, and the definitions of the baskets were then reviewed and amended where appropriate.
3. A firm of business transformational experts specialising in healthcare was engaged by the Review Team to collect data on activity and costs and to calculate a cost applicable to each basket of tests/cases. With the backing of the Review, in mid-January 2007 they issued a set of working definitions and a questionnaire (with accompanying guidance notes) to all the pilot sites. The questionnaire had the following sections:
  - details about the “respondent” pathology service;
  - organisation charts and other documentation, including details of the transportation of samples to the lab from within the hospital and from PCTs; the numbers of tests judged to be urgent, intermediate or standard; details about point-of-care testing; phlebotomy; relationship with blood banks, mortuary services, infection control; measurement of quality and performance; and regional/national screening;
  - financial data;
  - activity data split between requests, samples and tests for each discipline within pathology;
  - personnel numbers by professional group/support role, split by department and by other activity, including filled and vacant posts;
  - personnel costs by professional group/support role, split by department and by other activity, with costs divided between basic pay, supplements, overtime, out-of-hours, agency costs, pension and national insurance;

- non-pay costs by department and by other activity, split between reagents, disposables and other non-pay costs, including the volumes and costs of “send-aways” (i.e. tests not analysed on site); equipment costs (capital charges and equivalent); trust overhead costs chargeable to pathology; and other indirect costs – and any external funding – attributable to pathology;
  - fixed assets, hired equipment and leased equipment, split between departments.
4. A second questionnaire was then issued in mid-February 2007 requesting information on:
- the activity of staff split by professional group/support role, by department and other activity and by main processes and other work;
  - the number of tests performed by department, detailing their Read code, and the cost of reagents and disposables per test;
  - the amount of time spent by staff (split between medical staff, clinical scientists, biomedical scientists and medical laboratory assistants/medical technology officers) attributable to each basket of tests;
  - the type, function and use made of equipment, attributable to each basket of tests;
  - the skills and competences of staff split by professional group/support role and by main processes and other work;
  - the name, description, function and use made of the IT platform and hardware used; and
  - the volume and funding of work undertaken for the Health Protection Agency.
5. The consultants subsequently issued a final questionnaire asking pilots how the overheads of NHS trusts were apportioned to pathology departments. The intention was to understand what proportion of common services – finance and procurement, human resources and administrative support, information services and IT, clinical governance and quality, estates management – was charged to pathology.
6. The consultants worked closely with all the pilot sites to help them complete the questionnaire. Once the returns were received, the evidence was checked, analysed and collated. From this information the consultants were able to identify the drivers of activity and costs, and to calculate a cost per representative basket of tests/cases. These results were collated for each pilot site. A set of tables was produced showing, for each of the baskets, the cost per representative basket of tests/cases in each of the pilot sites. This in turn revealed the extent of the variation between pilot sites in cost per test.
7. These tables were anonymised. Each pilot was then given a pack showing how its data compared with the returns for the other sites.

8. Pilot sites were then invited to review their previous returns and amend them. The revised returns were similarly analysed, collated, anonymised and shared with the pilot sites. The process was then repeated.
9. By July, a final set of results had been presented to the pilot sites and agreed by them. It was emphasised that the information was not regarded as perfect, but represented the most accurate analysis to date in respect of pathology activity and costs. For example, in some of the baskets where levels of activity were low the results were volatile.
10. The findings showed variations in costs, activity and performance, including cost per test, workforce configuration, utilisation of equipment and process both inside and outside the laboratory. The analysis enabled workload and cost data to be allocated across each stage across the range of pathology processes, from sampling to interpretation, and including time spent on management, research, training and professional duties. The distribution of staff by professional and support grouping was analysed by pathology department, and the relationship between basic pay and supplementary costs was identified.
11. Overall, the analysis showed:
  - variation in efficiency and in the allocation of resources (cost per representative basket of tests/cases varied relative to test volumes – the greater the number of tests, the lower the unit cost);
  - that processing and interpreting tests accounted for more than half but less than two-thirds of overall costs;
  - that teaching hospitals had more medical staff and clinical scientists but fewer managers, medical laboratory assistants and medical technical officers;
  - that the average cost for medical staff in teaching hospitals was lower than for similar staff in non-teaching hospitals; and
  - that the composition of supplementary costs varied significantly by type of staff.
12. If the variation between pilot sites was addressed, for example by excluding the “lowest score” in each of the baskets and bringing all up to the level of efficiency of the fourth-best pilot, and assuming that the pilot sites were representative of pathology services across the country, it was estimated that savings of around £250 million could be achieved.

## **Modelling alternative options for reconfiguring pathology services**

13. In our first report we made the case for developing a robust economic evidence base that could be used to support the case for change in pathology. We commissioned a firm of experts in economic modelling to undertake economic analysis and modelling

work based on the cost and activity data collected from the 12 pilot sites. This section of the report sets out the methodology that was used to collect and develop evidence of the economics of pathology.

14. The methodology had four key stages:
  - **Stage one: mapping the existing pathology service** to identify the number, location and cost of existing pathology services. This forms the base against which any proposals for change are assessed.
  - **Stage two: understanding the cost differences between existing pathology services.** Data collected from the 12 pilot sites was used to assess the extent to which some pathology services are more expensive than others. Contextual data from the pilot sites was used to identify the key factors that drive the cost differences for the pilot sites.
  - **Stage three: assessing the strength of economies of scale within pathology.** The scale of operation was one factor identified as being a potentially important determinant of costs. Data from a range of sources was used to assess the strength of its impact.
  - **Stage four: undertaking an indicative “bottom-up” costing exercise.** Drawing on the evidence collected during stages one to three, this stage involved modelling options for a more efficient reconfigured pathology service.
15. The remainder of this section discusses each stage of work in turn.

### Stage one: pathology mapping

16. This stage provided useful contextual information on the set-up and structure of pathology and led directly into the indicative modelling work undertaken as part of Stage four. For example, information on the location of pathology services – their proximity to each other and to the hospitals and GPs they serve – was used to establish the appropriateness of a range of transport and logistics options.
17. The output from the work was a national mapping of pathology consisting of:
  - the number and location of pathology services in England;
  - the volume of tests conducted by each pathology service;
  - a breakdown of tests by specialty and source;
  - the number and grade of staff employed by the pathology service; and
  - the approximate running costs of each pathology service.
18. Detailed mapping work was also undertaken for two SHAs so that indicative cost modelling could be undertaken for them.

19. As the only available national information source on pathology, the mapping work drew heavily on the Healthcare Commission dataset for 2005. Internet searches, discussions with experts and postcode data for GPs and hospitals were used to supplement this information.
20. The Healthcare Commission dataset contains information on the cost and characteristics of pathology in all acute, multi-service and specialist NHS trusts (including NHS foundation trusts) in England.
21. The dataset is split into four main sections:
  - The main form covers services and functions, staff numbers, activities and roles, finance data, communication patterns, use of technology, auditing, point of care and general information.
  - A supplementary form collects details on the number and sources of pathology tests for the period 1 April to 30 September 2005.
  - A further supplementary form collects details on pathology sites. This includes details of turnaround times, automation, logistics and opening hours.
  - A final supplementary form collects details on pathology requests. This includes a short review of the quality of information on written requests.

### Stage two: understanding the cost differences between pilot sites

22. In our first report we made several recommendations aimed at making pathology services more efficient. The lack of good and accurate cost information was the key constraint in assessing the likely scale of the efficiencies that could be made.
23. As stated earlier, we asked the consultants to collect detailed cost and activity data from 12 pilots for the nine-month period from April to December 2006. They divided the information they collected into several categories:
  - staff costs;
  - marginal costs (e.g. reagents and disposables);
  - indirect costs (e.g. phlebotomy and transportation);
  - cost of capital; and
  - pathology, trust, SHA and Department of Health overheads.
24. Using this information, they estimated the cost per test for the 43 baskets. Analysis of this information shows large cost differences between pilot sites for similar test baskets. Observed differences could result from a range of different factors, including:

- the number of staff employed, their seniority levels and their pay;
  - the reagent and equipment deals secured with equipment manufacturers;
  - the utilisation levels of equipment; and
  - the complexity of tests being undertaken.
25. Where possible, an assessment was made of the extent to which the observed differences between pilots could be explained by each of these factors.

### Stage three: assessing the strength of the evidence of economies of scale

26. Economies of scale were identified as a key factor. Their relevance was also consistently highlighted in discussions with practitioners and private sector providers. To be able to say anything meaningful about the scale of reconfiguration that such economies would suggest, it was necessary to understand the magnitude of the economies of scale and the factors that constrain them from being realised at present.
27. This stage of work explored the evidence for economies of scale in pathology in more detail by drawing on evidence from three main sources:
- cost and volume information collected for all pathology services by the Healthcare Commission;
  - responses from a selection of the pilot sites about economies of scale within their business and their current use of capacity; and
  - information collected from equipment manufacturers about the costs of different sizes of laboratories.

### Stage four: indicative cost modelling

28. In this stage, the analysis from the previous stages was used to build a series of indicative models for reconfiguring pathology services. Different options were considered. The models aim to set out the implications of organising pathology in a way that allows it to take greater advantage of economies of scale, i.e. reconfiguring the service around a small number of core (“cold”) labs in each SHA, with “hot” labs on site in each of the acute hospitals.
29. Detailed modelling work was undertaken for two SHA areas. Each model considers the implications of three different reconfiguration scenarios. For one SHA, the three scenarios that were considered were for one, four and eight core laboratories. One, two and four core laboratories were considered for the other SHA.
30. Each model consists of three key modules:
- A staff module that estimates the cost of efficiently staffing different-sized core and hot labs, based on data derived from the 12 pilot sites.

- An equipment module that estimates the costs of running the equipment for core labs of different sizes and also a range of hot labs based on detailed cost estimates collected by an expert in pathology equipment.
  - A logistics module that estimates:
    - the cost of a transport contract to service the core labs and the hot labs, based on the geography of the area; and
    - the cost of building the IT systems required.
31. Drawing the three modules together gives estimates for the total cost of running a pathology service following reconfiguration. These costs are then compared with the current estimates of the cost of pathology to provide an indication of possible savings that could be made.

## Annex D: Cost differences across the pilot services

This annex presents a selection of the cost information collected for the review. It shows the extent of the direct laboratory cost-per-test<sup>8,9</sup> differences that currently exist between the 12 pilot sites that were selected to participate in the review. The disparities that are observed form the starting point for assessing a range of possible recommendations for changes to pathology in the future.

Information is presented in detail for the highest-volume baskets in each of the four main specialties: biochemistry, haematology, microbiology and histopathology. Tests in these baskets account for 75 per cent of pathology tests across these specialties. These baskets tend to be the most automated, and therefore also allow for the most reliable comparisons between pilot sites. The section covers each of the four main specialties in turn. Summary-level information is presented for the other baskets of tests.

### Biochemistry

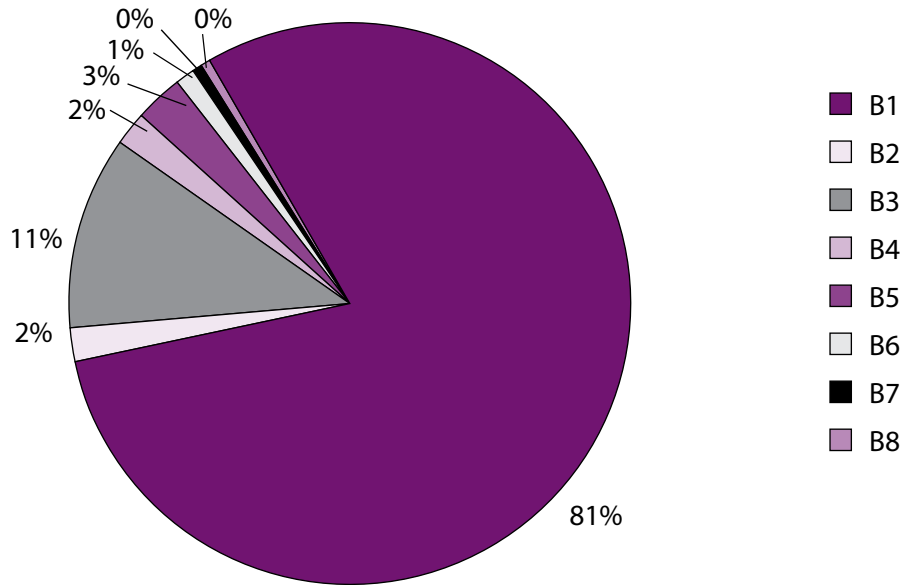
Detailed cost-per-test information is presented for the combined biochemistry baskets B1 and B2. Typical tests in this basket include liver function, renal and electrolytes, bone profile, glucose and paracetamol. Tests in baskets B1 and B2 account for just over 80 per cent of biochemistry tests across the pilot sites.

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8 Due to the difficulties associated with identifying overhead costs and with allocating them to particular test baskets, the analysis focuses on a comparison of direct laboratory costs between pilots.

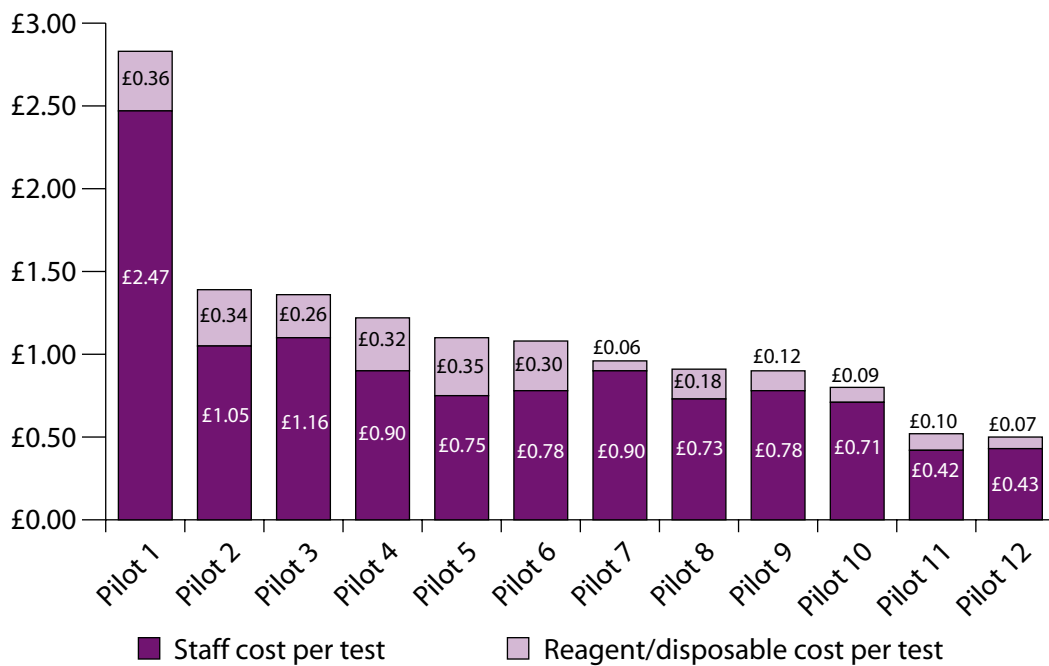
9 The direct laboratory costs compared are those related to sampling (where allocated to pathology departments), internal transportation of samples, reception, processing of tests undertaken within the pilot, interpretation and outbound costs.

Figure 1: Breakdown of biochemistry test volumes<sup>10</sup>



The figure below shows the cost differences between the 12 pilots for this combined basket. The costs range from £0.50 per test for Pilot 12 to £2.80 per test for Pilot 1. Cost differences are more material for staff costs, with costs per test ranging from around £0.40 to almost £2.50 (around a six-fold difference). However, they are also significant for reagent/disposable costs per test. These costs range from less than £0.10 for the most efficient pilot to around £0.40 for the least efficient (again, a six-fold difference).

Figure 2: Cost per test comparison for biochemistry baskets B1 and B2



<sup>10</sup> The source for all figures and tables is data collected for Lord Carter's Review of Pathology.

The table below provides summary information on the range, quartile and median costs per test for the other baskets. As can be seen below, there are substantial differences in the range of costs per test across the baskets. However, analysis of the data suggests that this is driven in part by composition effects, where the test mix in the relevant basket varies substantially across the pilots. It is also driven by the small numbers of tests in the relevant basket carried out in some trusts. For example, across all pilots, only 77,000 tests were carried out in basket B8, compared to in excess of 18 million tests for baskets B1 and B2. Within the 77,000 tests, a number of the pilots had extremely low volumes, making meaningful price comparisons across the full spectrum of pilot sites more difficult.

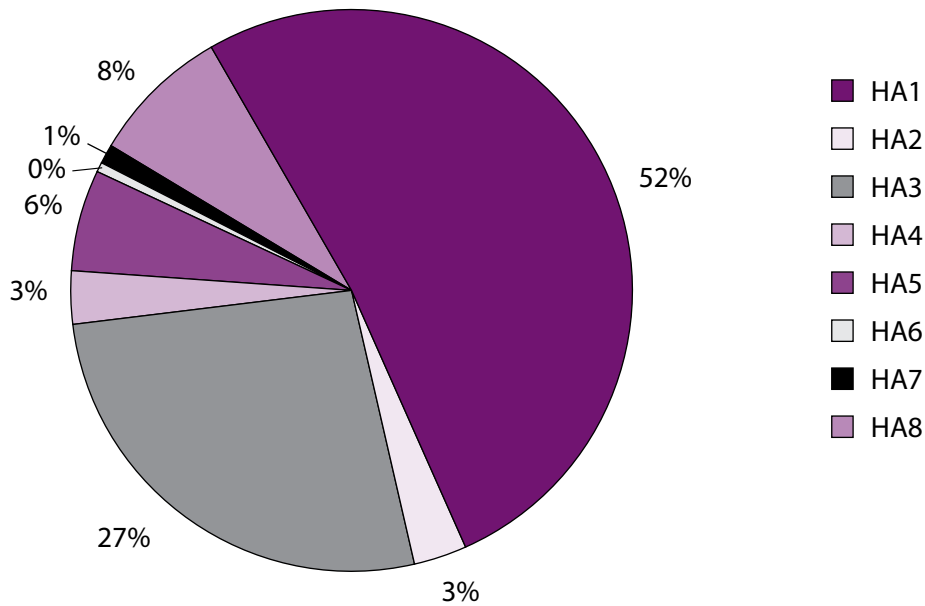
Table 1: Biochemistry costs and volumes

Basket	Minimum cost per test (£)	Lower quartile cost per test (£)	Median cost per test (£)	Upper quartile cost per test (£)	Maximum cost per test (£)	Volume of tests
B3	1.40	2.10	2.70	3.20	5.30	2,314,000
B4	2.60	3.70	5.50	6.80	10.70	470,000
B5	1.60	2.90	3.40	4.20	6.50	683,000
B6	1.60	3.20	4.80	10.00	17.50	173,000
B7	1.40	3.80	12.60	20.10	80.50	84,000
B8	4.20	8.70	12.50	21.90	24.30	77,000

## Haematology

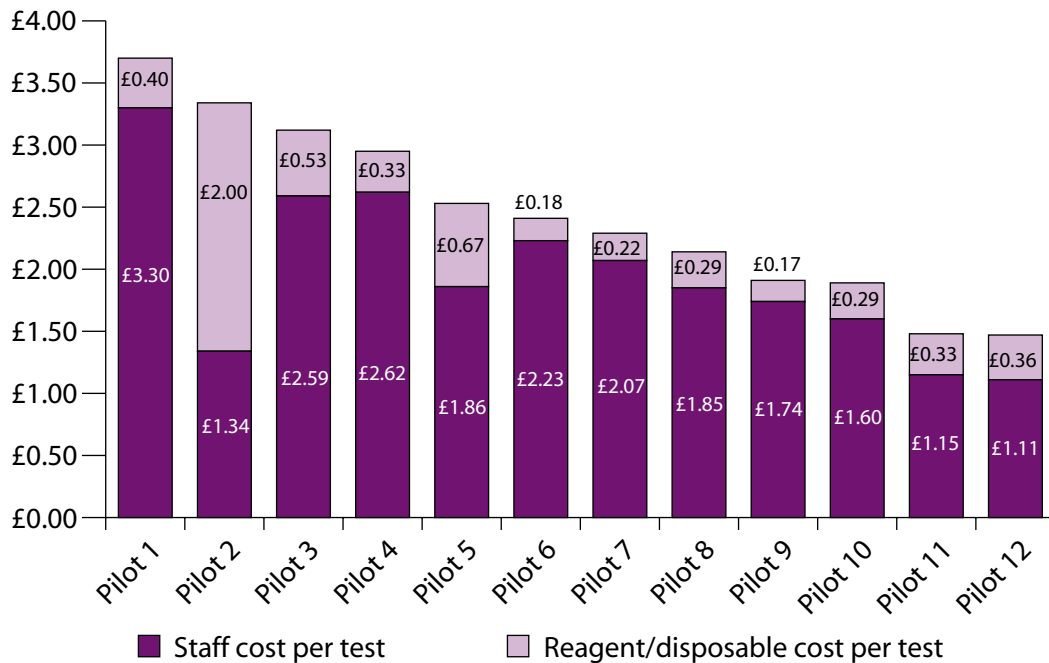
The pattern for biochemistry shown in the section above is also repeated for the haematology test baskets. Detailed cost-per-test information is presented for the combined haematology baskets Ha1 and Ha2, while summary information is presented for the other baskets. Typical tests in Ha1 and Ha2 include full blood count, reticulocytes, erythrocyte sedimentation rate and blood films. Tests in baskets Ha1 and Ha2 account for 55 per cent of haematology tests across the pilot sites.

Figure 3: Breakdown of haematology test volumes



Costs range from £1.50 per test for Pilot 12 to up to £3.70 per test for Pilot 1. Staff costs range from around £1.10 to almost £3.30 (a three-fold difference) and reagent/disposable costs range from £0.20 for the most efficient pilot to around £0.70 for the least efficient<sup>11</sup> (a three to four-fold difference).

Figure 4: Cost-per-test comparison for haematology baskets Ha1 and Ha2



11 There appears to be an anomaly in the reagent costs reported by Pilot 2, so this has been excluded from further analysis.

The table below provides summary information on the range, quartiles and median cost per test for the other baskets. As can be seen below, there are substantial differences in the range of costs per test across the baskets. Again, analysis of the data suggests that this is driven in part by test composition effects, where the test mix in the relevant basket varies substantially across the pilots. It is also driven by the small numbers of tests in the relevant basket carried out in some trusts. For example, across all pilots, only 40,000 tests were carried out in basket Ha6.

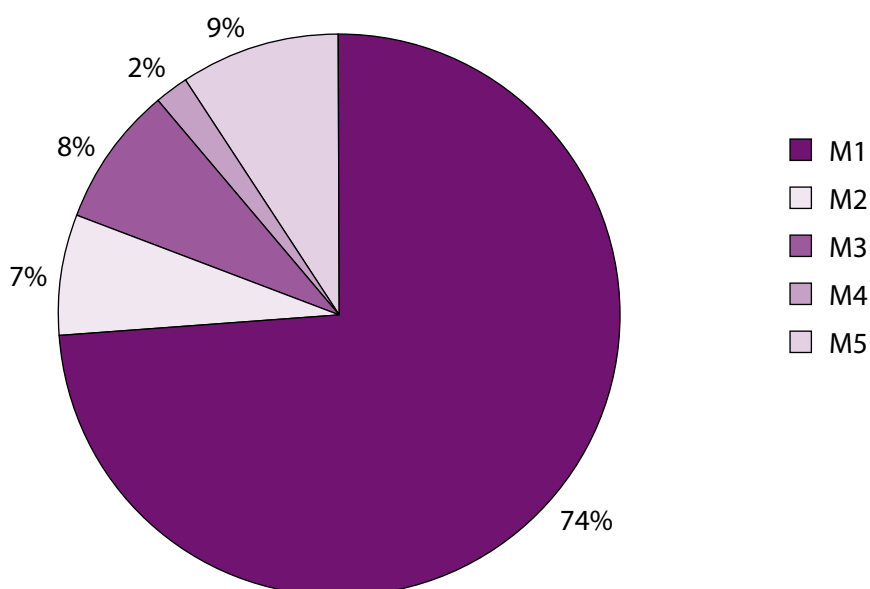
Table 2: Haematology costs and volumes

Basket	Minimum cost per test (£)	Lower quartile cost per test (£)	Median cost per test (£)	Upper quartile cost per test (£)	Maximum cost per test (£)	Volume of tests
HA3	1.40	1.90	2.10	2.70	3.10	2,701,000
HA4	1.60	4.10	11.20	14.00	20.20	300,000
HA5	2.00	2.40	3.80	5.30	6.40	575,000
HA6	4.70	21.50	29.80	43.10	74.50	40,000
HA7	3.30	6.70	10.90	26.90	165.00	148,000
HA8	2.20	2.70	5.00	6.20	24.10	790,000

## Microbiology

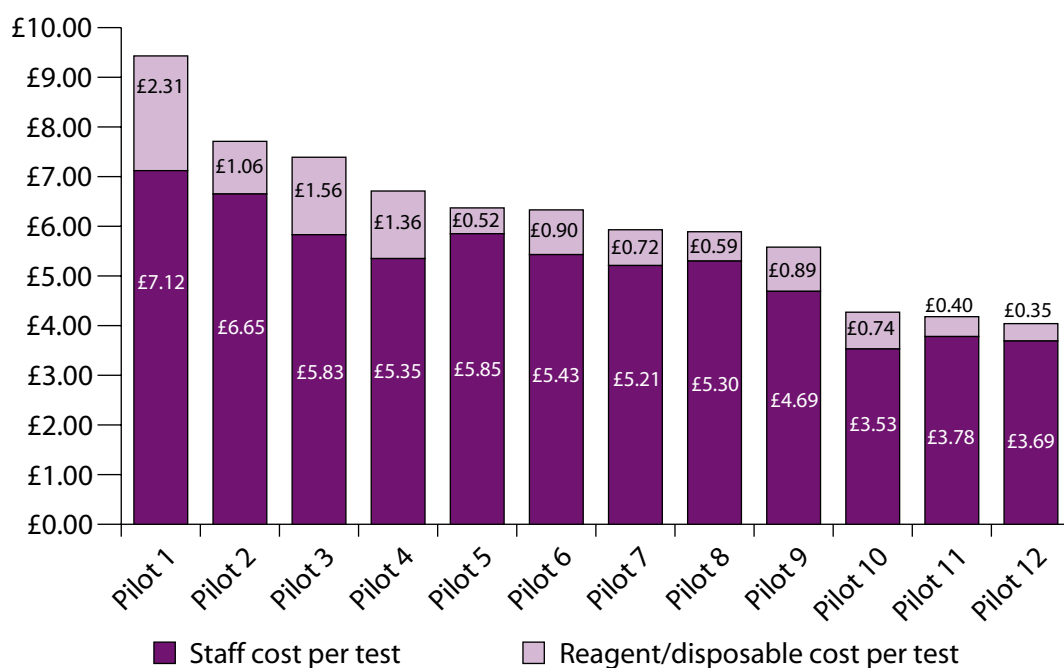
For microbiology, cost-per-test information is presented below for basket M1. Summary information is presented for the other baskets. Typical tests in this basket include urine tests and faeces cultures. Tests in this basket account for 74 per cent of microbiology tests across the pilot sites.

Figure 5: Breakdown of microbiology test volumes



Unit costs for basket M1 range from around £4.00 to £9.40. Staff costs range from around £3.50 to £7.10 (a two-fold difference) and reagent/disposable costs range from £0.40 for the most efficient pilot to around £2.30 for the least efficient (more than a six-fold difference).

Figure 6: Cost-per-test comparison for microbiology basket M1



The table below provides summary information on the range, quartile and median costs per test for the other baskets. As can be seen below, there are substantial differences in the range of costs per test across the baskets.

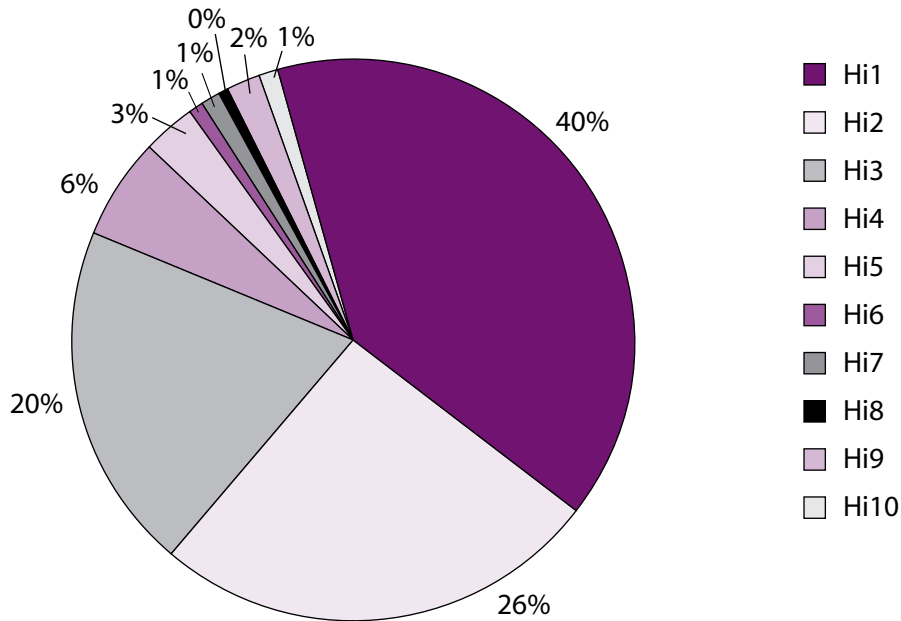
Table 3: Microbiology costs and volumes

Basket	Minimum cost per test (£)	Lower quartile cost per test (£)	Median cost per test (£)	Upper quartile cost per test (£)	Maximum cost per test (£)	Volume of tests
M2	3.70	6.60	8.60	10.00	10.70	239,000
M3	5.20	8.50	10.00	10.90	13.70	284,000
M4	6.50	7.20	7.60	9.80	23.80	81,000
M5	6.00	8.00	9.90	12.30	14.50	322,000

## Histopathology

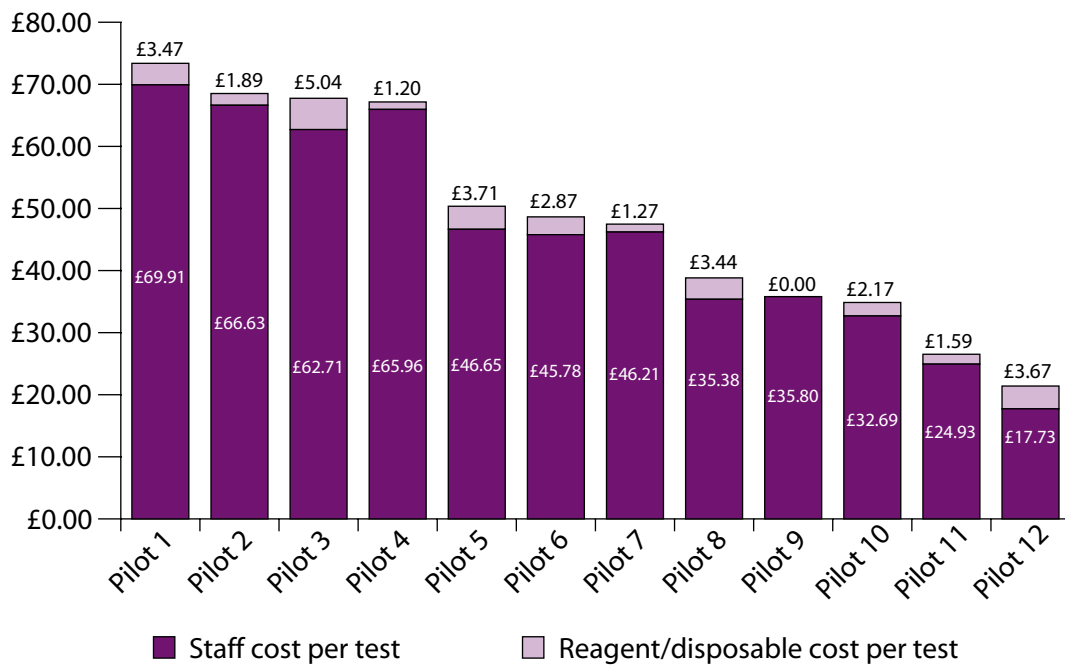
For histopathology, cost per test information is presented for the combined baskets Hi1 and Hi2. Typical tests in this combined basket include skin nevus, appendix and large lipoma. Hi1 and Hi2 tests account for 66 per cent of histopathology tests across the pilot sites. Summary information is presented for the other baskets.

Figure 7: Breakdown of histopathology test volumes



Unit costs for tests in this combined basket range from £21.40 to £73.40. Staff costs, which account for over 90 per cent of test costs, range from around £17.70 to almost £69.90 (a four-fold difference).

Figure 8: Cost-per-test comparison for combined baskets Hi1 and Hi2



The table below provides summary information on the range, quartile and median costs per test for the other baskets. For histopathology the variation in costs across sites is extremely large. We suggest that this reflects both the diversity of tests that are carried out across the pilots but reported in the same basket, and the extremely low volume of tests being considered. For example, Hi8 only had 2,000 tests across all of the pilots, so substantial differences in the reported costs are to be expected.

*Table 4: Histopathology costs and volumes*

Basket	Minimum cost per test (£)	Lower quartile cost per test (£)	Median cost per test (£)	Upper quartile cost per test (£)	Maximum cost per test (£)	Volume of tests
Hi3	27.60	58.80	83.70	108.40	128.10	69,000
Hi4	33.20	92.90	111.40	165.70	198.00	22,000
Hi5	72.60	111.70	162.50	189.10	242.40	11,000
Hi6	164.00	180.90	238.70	292.60	419.00	3,000
Hi7	74.00	224.20	280.00	329.10	409.60	4,000
Hi8	141.90	202.10	306.50	423.90	585.70	2,000
Hi9	74.10	275.00	356.60	442.10	716.80	6,000
Hi10	100.10	265.60	419.90	619.90	773.70	4,000

## Annex E: Membership of the Project Board

Lord Carter of Coles	Chair
Edmund Waterhouse	Review Manager
Daniel Gosling	Assistant Review Manager
Robert Alexander	Department of Health
Malcolm Argent	Lay member
Ian Barnes	Department of Health
John Bromley	Department of Health
Jon Crockett	Wolverhampton City PCT
Deirdre Feehan	Department of Health
Margaret Edwards	Yorkshire and the Humber SHA
Martyn Forrest	NHS Connecting for Health
Sue Hill	Department of Health
Adrian Newland	Royal College of Pathologists
Sam Oestreicher	UNISON
Mark Otway	Alsbridge
Chris Price	Consultant
Marcus Robinson	Consultant
Dan Smith	Amicus





