

Transforming Pathology

Project Initiation Document

PATH0001

March 2010

Project Initiation Document

This document defines the Transforming Pathology Project in terms of delivery timescales, scope and available resources, forming a basis for its management. The PID details the Pathology Transformation Board's (PTB) approach to managing uncertainty (risk), change, quality and communications and describes the PTB's position within the AHB Programme hierarchy.

Document Version Control			
Transforming Pathology PID			
Version	Date	Author	Change
0.1	22/03/10	Ian White	First Draft
0.2	25/03/10	Ian White	update from comments on 0.1

Document Distribution		
Distribution/Approval	Date	Version
Andrew MacPherson, Martin Peat, Hemal Desai	22/03/10	v0.1
Pathology Transformation Board	01/04/10	v0.x

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Executive Summary

1.1 Background

- 1.1.1 There have been successive reviews of the Pathology Service in England. Reviews since 1999, including the Carter Review of Pathology Services in 2008, have recommended a fundamental reconfiguration via the formation of Managed Pathology Networks as the optimum mode of delivery for Pathology Services.
- 1.1.2 The Carter Report made 20 discrete recommendations covering 8 broad topics.
- Quality – standards, accreditation, audit
 - Communication – IT connectivity
 - User responsiveness and information transparency
 - Consolidation – specialist services, networks, network management
 - Workforce reform
 - Tariffs/Benchmarking
 - Commissioning Guidance – model contract, formulary
 - Innovation
- 1.1.3 Carter noted that the principle mechanism for performance improvement lies in the consolidation of Acute Trust Pathology Services into Managed Pathology Networks. All of the Hospitals within a Network would have a Rapid Response Laboratory on site to perform the limited range of Pathology tests that are required in < 4 hours. The bulk of the testing for all of the hospitals and associated GP practices (some 80% by volume) that requires a response in a timeframe of >4 hours and <24 hours would be performed at a single, high throughput laboratory.
- 1.1.4 Following QIPP principles, the rationalisation of Pathology Services into Networks offers maximum flexibility, operational and financial efficiency through significant economies of scale, and improvements in quality.
- 1.1.5 A survey of Pathology in the East of England in 2007 estimated total Pathology expenditure to be £209m – £216m. The GP/community work accounts for 40 – 50% by volume, but mainly consists of a limited range of tests that can be performed via highly automated methods. In consequence the GP/community work only accounts for around a quarter of Pathology expenditure and is estimated to be between £50m and £60m
- 1.1.6 The Carter Report concluded that rationalisation of Pathology could reduce costs by 10%-20%, which equates to approximately £20m - £40m per annum in the East of England. Detailed modelling by the Carter Team indicated total savings of between £21m and £29m in the East of England, based on a variety of different delivery scenarios. Performing the high volume/low complexity testing required by primary care/community care in a high efficiency high throughput laboratory is estimated to offer cost reductions in the order of £10m - £12m across the region per annum. Consequently reconfiguration of remaining pathology work could yield a further £11m to £17m across the region. One aim of this project is to establish the nature and extend of savings and service improvements that can be achieved.

- 1.1.7 The recommendations of the Carter Report are in alignment with the recent review of the NHS by Lord Darzi, “High Quality Care for All”, which emphasised the importance of the principle of “localise where possible, centralise where necessary” . The principle of expanded healthcare delivery in the community, and of greater centralisation of complex services, infers that the standard “DGH” style of hospital Trust, delivering a full range of services, is likely to be increasingly unsustainable. There will be an increasing demand for blood tests carried out in primary care or even at patients’ homes, avoiding needless travel to and from hospital and with results made available more quickly. Specialist pathology will be required in centres of excellence.
- 1.1.8 The Carter review also recommended that, with the support of the Department of Health (DH), each Strategic Health Authority should require the Primary Care Trusts in its area to take the lead with providers (existing and potential) in drawing up cost effective plans for implementation of the reports’ proposals.
- 1.1.9 On behalf of NHS East of England the Strategic Projects Team has carried out a review of Pathology service delivery across the region. Discussions have been held with all of the Commissioners and Providers within the region. Additional discussions have been held with Independent Sector providers of pathology services, and with the directors of six Pathology rationalisation projects that are ongoing in other areas of the country.

1.2 Findings of 2009 Review by NHS East of England

- 1.2.1 Consolidation of Pathology Services appears to offer significant benefits to provider Trusts through a reduction of Direct Access and Secondary/Tertiary care Pathology costs, a reduced demand for space, and through a significant reduction in financial and clinical risk.
- 1.2.2 The nascent provider networks in the East of England region have not been a success. The participating hospitals have been largely unable to take the difficult decisions and have failed to accept any closure of facilities on individual hospital sites.
- 1.2.3 The risk is that providers continue to take a “business as usual” approach, and continue to make major investments in facilities – actively avoiding consolidation and maintaining a high cost base.
- 1.2.4 The failure to consolidate exposes the providers to financial risk, and increases the potential clinical risk as individual departments undertake work outside of their specialisms to save cost or struggle to achieve the right staff mix. However, changes to the configuration of services will have a funding effect on providers, which may be destabilising, particularly where providers have long term contractual commitments.
- 1.2.5 All of the providers believe that they are providing a good community service.
- 1.2.6 All of the commissioners believe that some elements of the pathology service are unsatisfactory, and would like service improvements. Pathology is however low on the priority list.
- 1.2.7 Most Commissioners deal with one major provider, have limited expertise or experience in pathology services commissioning, and have no means of measuring local performance or costs against other providers. In consequence the risk is that the power balance lies very much with the Provider.

- 1.2.8 Some Commissioners are keen to “market test” pathology services, but others are wary of destabilising Trust services and of resultant adverse PR.
- 1.2.9 Individual Commissioners will take little action on Pathology and would welcome NHS EoE lead and support.
- 1.2.10 Visits to consolidation projects across England confirmed the benefits of consolidation in reducing costs and improving quality.

1.3 Conclusions of 2009 Review

- 1.3.1 EoE reports on pathology services indicate that rationalisation of laboratory pathology into one to three central facilities will provide significant benefits including improved quality and efficiency of service as well as better value for money across East of England. Although the detailed business cases remains to be developed.
- 1.3.2 Historically incentives for providers to reconfigure pathology services have been limited. It appears unlikely that that significant consolidation of Pathology services will occur unless the provider Trusts are faced with external pressures – either a failure of quality or serious financial pressure. Commissioners could drive reconfiguration through commissioning pathology services collectively. However, to allow providers a further opportunity to bring forward proposals for service re-design should be given.
- 1.3.3 A regionally co-ordinated project, led by a joint provider/commissioner group, is required to develop and implement plans achieve the Carter report recommendations.
- 1.3.4 There is a need to develop, articulate and communicate, through clinical engagement with the pathology community, a shared vision for the future.

1.4 Proposals

- 1.4.1 NHS EoE should work with commissioners and acute providers to prepare the ground for change. Proposed changes may include:
- Development of one or more ‘cold’ facilities providing community pathology services
 - Unbundling of tariff services
 - Provider network reconfiguration
- 1.4.2 To take forward the Carter recommendations it is proposed that NHS EoE, Providers and Commissioners should work together to establish a Pathology Transformation Board (draft Terms of Reference attached) to begin work and co-ordinate activity. The Board will be accountable to the EoE Operations Board. The project should be split into five stages:
- Stage 1 - Initiation – establishment of Pathology Transformation Board and plans
 - Stage 2 – Benchmarking, base setting and development of SOC(s) – comparison of costs and volumes of activity between Commissioners across EoE. – Development of OBC(s) for one or more community initiatives and receives OBC proposals from providers.
 - Stage 3a – Development of or more community pathology service contracts including development of model contract documents

- Stage 3b – Support to acute providers to restructure and prepare their businesses for forthcoming change
- Stage 4 - Implement change projects
- Stage 5 – Benefits tracking & review.

1.5 Pathology Transformation Board tasks:

- Review output based commissioning of community pathology services and to produce outline business case(s), specifications, proposals and implement proposals for change
- Review provider networks of pathology services and encourage providers (including networks) produce outline business case(s), specifications, proposals and implement proposals for change.
- Develop and implement effective communications strategy to involve stakeholders in the process.

1.6 Pathology Transformation Board Membership

- 1.6.1 Membership of the Board should be drawn from as wide a source of stakeholders and specialist parties as possible to ensure that any subsequent plans and initiatives are tested and approved by those most able to do so. Membership will be agreed by PTB and approved by the EoE Operations Board.

2 Historical Background

2.1 Overview

- 2.1.1 Pathology is a highly complex and highly technical service, covering a range of disciplines, a range of response times, and a variety of delivery locations. Pathology is single name covering a complex range of activities performed in a variety of different settings and via a number of different delivery methods. There follows a brief outline of the basics of Pathology to serve as a reference to facilitate a full understanding of the issues covered in the main body of the report.

2.2 Pathology Services

- 2.2.1 The complexity of Pathology is reflected in the number of different ways that the discipline as a whole can be segmented including:
- Sub disciplines
 - Volume/automation
 - Response times
 - Source of Request

2.3 Sub Disciplines

- 2.3.1 Pathology has four main (high volume) sub disciplines – these are Bio or Clinical Chemistry, Haematology, Histology and Microbiology. These four main disciplines will usually be covered by all Acute Trusts. There are a number of smaller volume specialist disciplines which are not necessarily covered in all Trusts – these include Virology, Cell Cytology, Genetics and Immunology. Confusingly the nomenclature of

the various disciplines can vary from Trust to Trust, and some tests, especially in Clinical Chemistry and Histology are performed via Immunochemical Methods. Blood typing for transfusion is also carried out in Pathology.

- 2.3.2 In the case of Haematology and Histology, Pathologists are intimately involved in the management of cancer patients via Multi Disciplinary Teams (MDT's). As cancer treatment develops there is an increasing need for Pathology Sub Specialization. This is putting significant staffing pressure on smaller hospitals as they find it difficult to maintain the requisite Sub Specialist cover from a limited pool of staff and yet do not have the overall workload to justify increasing Pathologist staffing, Also, especially for the smaller hospitals, there is considerable difficulty in recruiting suitably qualified pathologists and laboratory staff with an ageing and reducing pool of potential candidates.
- 2.3.3 Microbiology staff are heavily involved in infection control, including providing services directly for the Health Protection Agency.
- 2.3.4 Some services are part laboratory and part clinical service, for example management of leukaemia/ haematological malignancies.

2.4 Volume/degree of automation

- 2.4.1 There are a relatively small number of tests that are performed in very high volumes, and that can be subject to a high degree of automation, especially in Clinical Chemistry, Haematology and Microbiology. Of the four main disciplines Histology is relatively low volume and is only amenable to limited automation in specimen preparation. The assessment of slides and interpretation of results is highly dependent on the availability of qualified staff (see the discussion above on the issue of Sub-Specialisation).
- 2.4.2 There is also a “long tail” of tests across all disciplines that are performed in much lower volumes, and which may be contracted out to specialist laboratories.

2.5 Response Time

- 2.5.1 A small proportion of tests (approx 20%) are performed with a very short turn around time, usually 1 hour or less and certainly less than 4 hours. In the Acute Sector these reflect the need to provide a rapid diagnosis in support of A&E, ITU/HDU and Maternity services. A rapid response can also be required to support patient discharge so that patient turnaround can be facilitated.
- 2.5.2 In the Community a Rapid Response is required in order to minimize patient appointments, and to give data on patient status immediately prior to an appointment with the Clinician/Nurse managing the patient. This is especially relevant to the monitoring of patients with Long Term Conditions.
- 2.5.3 Much of the Rapid Response testing is/can be performed on simplified analyzers, designed to measure a very limited range of parameters (often only one). This is known as Point of Care Testing (POCT). In the Hospital setting these machines are usually in the care of the staff from the main laboratory, though they can be operated by clinical staff or nurses. In the community there is an issue with the Quality Assurance and Maintenance of POCT equipment, and with training of the operatives.

- 2.5.4 The bulk of Pathology testing for hospital inpatients, outpatients and GP/Community patients is performed on highly automated equipment, and expected to be turned around within 24hrs.

2.6 Source of Request

- 2.6.1 For Clinical Chemistry, Haematology and Microbiology between 30% and 50% of test requests originate in the Community. Around 20% of Histology testing originates in the community. These tests are paid for via direct access contracts with commissioners.
- 2.6.2 All of the remaining test requests originate from Secondary or Tertiary care clinicians, and cover inpatients and outpatients and are included in the HRG costs under PbR. Virtually all of the Esoteric Testing originates from Secondary and Tertiary care.

2.7 The Role of Pathologists

- 2.7.1 The clinical role of Pathologists should not be underestimated. At the minimum, clinical expertise is a necessary pre-requisite for the accurate interpretation of Pathology test results; and for the generation of, and the dissemination of, an understanding of the implications of the test results for patient care. As described above, Histologists and Haematologists in particular have become increasingly involved in the Multi-Disciplinary Teams that care for Cancer patients, and in consequence are an increasingly significant contributor to patient care. Microbiologists also have a significant role in terms of antimicrobial prescribing advice at ward level and infection prevention and control advice and support to clinical teams on particular patients and more widely.
- 2.7.2 There is also a significant role for the Pathologist in liaising with Primary Care Physicians to assist with the interpretation of Pathology Test results, and to discuss the consequent implications for patient care. However the role of the Pathologist in producing the test results (except in Histology) is increasingly tenuous, and it could be argued that a greater separation of the Pathologists from the laboratory would increase their availability as a Clinical resource.
- 2.7.3 Pathology services have been subject to a succession of reviews over the past 17 years.

2.8 Past Reviews

- 2.8.1 Performance reviews by the Audit Commission in 1991 and 1993 reported a lack of investment in Pathology, against a background of increasing test volumes, increasing automation and increasing technical sophistication. The cumulative under-investment reflected the position of Pathology in the hospital/health service as a little understood “back room” function continually failing to secure investment in the face of the competing financial needs of other services perceived to be more “front-line”. Investment across the East of England has been very variable hence stock take need to understand investment in various locations
- 2.8.2 There was a Strategic Review of Pathology Services by the NHS Executive in 1995, followed by the initiation of the Pathology Modernisation Programme in 1999. The first three years of the programme, from 1999/00 to 2001/2, concentrated on capital investment to support service modernisation. A total of £28m in capital funding was awarded to 39 demonstration projects for smaller-scale service reconfigurations;

technology and IT upgrades; rationalisation of specialist services; and larger-scale reconfiguration projects to support the development of managed pathology networks.

- 2.8.3 In 2002 the DH published a consultation document “Pathology—the Essential Service; Draft Guidance on Modernising Pathology Services”. There was an increasing recognition of the key role of Pathology in diagnosis and patient management; but also recognition that the maintenance of a full range of Pathology services at each Acute Trust would not be sustainable. The traditional DGH was no longer the optimum model for delivery of hospital services; and the Pathology Department of a traditional DGH no longer had the critical mass to support the inexorable growth in the range of Pathology Tests, nor the financial resources to sustain the necessary investment in developing technology. The Consultation Document continued to support the formation of Managed Pathology Networks as the optimum model for modernising Pathology services to meet the requirements of the evolving health service.
- 2.8.4 “Modernising Pathology Services”, published by the DH in February 2004, reflected the feedback from the consultation exercise. A central theme of the Modernisation Programme was that Pathology Networks should be established in order to make the most efficient use of capital investment, to make the best use of trained staff in increasingly poor supply, to improve communications, and to improve overall quality. A further £9.1m of revenue funding, and £54m of capital funding was to be made available in the period 2003/4 – 2005/6 to support the modernisation programme. The Royal College of Pathologists was in agreement that the development of Managed Networks represented the optimum way forward (Pathology Modernisation – the College View, Feb 2006).
- 2.8.5 In March 2007 the Health Care Commission published its latest review of the Pathology Service – “Getting Results”. The review forms a part of the Acute Hospitals Portfolio series, and builds on the survey carried out by the HCC in 2003. These reviews were the most recent in the series begun in 1991 by the Audit Commission, and focus on the performance of the service rather than on the fabric and design of the service.
- 2.8.6 Though the 2007 review noted improvements in turnaround times and increased laboratory opening hours to meet increasing demand. The review also noted a continuing inconsistency between Trusts in the number of tests performed per request, and a wide variation in costs and productivity. The report also noted the need for greater involvement in Point of Care Testing (POCT), variable quality assurance, slow adoption of new technology, and slow development of Pathology Networks.

3 The Carter Report 2006

3.1 Introduction

- 3.1.1 The most recent review of Pathology (Phase 1, Aug 2006 and Phase 2, Dec 2008) by Lord Carter and his team considered the current performance of the Pathology Service, the constraints on the service, and the factors governing the future development of the service. The review also compared the UK Pathology Service to various international service delivery models.
- 3.1.2 The Carter Review recognized the quality of the current Pathology service, but noted a degree of unresponsiveness to change. The Review found that the service was over equipped, but that an increasing level of technical complexity would generate a need to invest in even more equipment, and that costs per test would increase as tests

become more specialized and sophisticated. Staffing shortages were becoming an increasing problem. The demand on Pathology services continued to increase as test volumes rose significantly year on year. The demand for Point of Care Testing is also expected to increase as more services are re-located into the community away from the Acute Hospitals

3.1.3 The Carter Report made 20 discrete recommendations which cover 8 broad topics.

- Quality – standards, accreditation, audit
- Communication – IT connectivity
- User responsiveness and information transparency
- Consolidation – specialist services, networks, network management
- Workforce reform
- Tariffs/Benchmarking
- Commissioning Guidance – model contract, formulary
- Innovation

3.1.4 A further recommendation was that,

“with the support of the DH, each Strategic Health Authority should require the Primary Care Trusts in its area to take the lead with providers (existing and potential) in drawing up cost effective plans for implementation of the reports’ proposals”.

3.1.5 With respect to implementation, the Carter Report recommended that the proposals for reform should be represented in the DH’s Operating Framework for the NHS.

3.2 Quality – standards, accreditation, audit

3.2.1 The Review recognised that quality measures were limited to the analytical process, and did not reflect the quality of the end to end service. It was recommended that more suitable quality standards be developed and incorporated into a revised Accreditation Standard. All NHS Pathology Service Providers should be required to be fully accredited, and to participate in audit processes (including POCT).

3.3 Communication – IT connectivity

3.3.1 Limited IT connectivity was found to contribute to wasteful duplicate testing, and to contribute to the risk of errors (relevant clinicians not having immediate access to relevant diagnostic information). The review recommended that IT links should be developed as a matter of priority.

3.4 User responsiveness and information transparency

3.4.1 Pathology Services should be more responsive to the requirements of patients, especially with respect to phlebotomy and sample collection.

3.5 Consolidation – specialist services, networks, network management

3.5.1 The Carter Review re-iterated that Managed Pathology Networks offered the optimum model for service delivery. Each Acute Hospital site would have a Rapid Response Laboratory to meet the need for fast turnaround of results for A&E, ITU, Maternity etc. All of the “cold” work (turnaround >4hrs) would be centralised into a large site providing

services for several Acute Trusts. This model takes full advantage of the economies of scale inherent in the processing of large volumes of highly automatable tests. The establishment of Networks also makes optimum use of scarce staff resources, and allows for Clinical Sub-specialization. The flexibility of the Managed Network model also allows for full support to community services. It should be noted however that not all Networks will be the same since the local environment and demographics will place differing demands on local healthcare delivery.

3.6 Workforce reform

3.6.1 The review recognised a requirement to reform the Pathology workforce to meet the challenges arising from new methods of working, and to manage the impending shortfall in skills and experience inherent in the demographic of the current staffing of the service.

3.7 Tariffs/Benchmarking

3.7.1 The review identified a clear need for a tariff and for benchmarking data to aid commissioners.

3.8 Commissioning Guidance – model contract, formulary

3.8.1 Commissioners in Primary Care Trusts would benefit greatly from the development of clear commissioning guidance in the form of a Commissioning Specification. A formulary, defining the utility and applicability of each Pathology test would be very useful in the avoidance of waste, and in the improvement of service quality for patients.

3.9 Innovation

3.9.1 Innovation is a key driver in the development of responsive high quality Pathology services. The DH should seek ways to facilitate the adoption of innovation across the service.

3.10 Benefits

3.10.1 The Carter Report indicated that up to £500m annually could be saved nationally (England) by consolidation of the Pathology service into Managed Networks, whereby large scale capital investment was limited to a smaller number of sites. There would be consequent procurement gains, and consequent quality gains through the establishment of a greater critical mass both in operational processing and in Clinical expertise. There would remain an on-site service for Rapid Response Testing to cover the fast turnaround testing needs of the Acute Trust.

4 QIPP

4.1 QIPP Overview

4.1.1 Pathology is one of the thirteen work stream identified nationally under the Quality Innovation Productivity and Prevention (QIPP) initiative. QIPP seeks to improve efficiency within the NHS through its' four key themes. Modernising pathology seeks to address all four elements of QIPP:

- Quality – seeking to improve quality of results and services

- Innovation – improve efficiency through innovation of service delivery and use of new technologies.
- Productivity – Improve efficiency and throughput at every stage of the process
- Prevention – remove unnecessary or repetitive testing that does not contribute to diagnosis or treatment.

4.2 QIPP Monitoring

4.2.1 Progress against QIPP is being managed regionally by the NHS East of England QIPP Steering Committee. The Modernising Pathology project will need to report progress against the project plan to the QIPP Project Management Office as well as the NHS East of England Operations Board, which is attended by Commissioning Chief Executives.

5 Project definition

5.1 Scope

5.1.1 The project is intended to capture actions required against all pathology activity within NHS East of England. It should be noted that some service providers may be linked with organisations outside of the NHS East of England geographical boundaries. In proposing or implementing changes this overlap needs to be taken into account.

5.2 Aims and Objectives

5.2.1 Accountable to the NHS EoE Management Board, the objectives of the Board are to:

- Review commissioning of community pathology services and to produce outline business case(s), specifications, proposals and implement proposals for change
- Review provider networks of pathology services and encourage providers (including networks) produce outline business case(s), specifications, proposals and implement proposals for change

6 Project organisation

6.1 Overview

6.1.1 To take forward the Carter recommendations it is proposed that NHS EoE, Providers and Commissioners should work together to establish a Pathology Transformation Board (draft Terms of Reference attached) to begin work and co-ordinate activity. The Board will be accountable to the EoE Operations Board. The project should be split into five stages:

6.2 Stages

6.2.1 It is proposed that the project is undertaken in five stages

- Stage 1 - Initiation – establishment of Pathology Service Board and plans
- Stage 2 – Benchmarking, base setting and development of SOC(s) – comparison of costs and volumes of activity between Commissioners across

EoE – Development of OBC(s) for one or more community contracts and receive OBC proposals from providers.

- Stage 3a – Development of or more community pathology service contracts including development of model contract documents
- Stage 3b – Support to acute providers to restructure and prepare their businesses for forthcoming change
- Stage 4 - Implement change projects
- Stage 5 – Benefits tracking & review.

6.3 Deliverables and milestones:

6.3.1 The Pathology Transformation Board has approval from the NHS EoE Operations Board to undertake stages one and two over a period of up to nine months, although business cases should be delivered within six months of commencement. Overall project timescales are anticipated to be:

- Form Pathology Service Board and establish terms of reference – April 2010
- The Pathology Service Board should establish Network Structures and agree working relationships – within 3 months of formation, circa June 2010. ?
- Region wide projects should commence from the first meeting of the Pathology Service Board – initial “broad brush” benchmarking exercise to be completed – June 2010
- Develop Commissioning SOC to include estimate of savings achievable and OBC, and agree initial Commissioning projects and specifications - September 2010.
- Solicit and support the development of provider SOC and OBC - September 2010.
- Changes projects/procurement activity should take 6 months from establishment of SOC and Procurement Specifications - From October 2010 to March 2011.
- Service delivery should be 3 to 6 months from completion of change/procurement process, circa July to December 2011 (a total of 18 to 24 months from commencement).

6.3.2 It is acknowledged that the above timetable is provisional and subject to the nature and extent of proposals submitted in strategic and outline business cases. A full project plan is included in Annex D.

6.4 Constraints:

6.4.1 Progress in achieving the goals of this project are inextricably linked to the support and availability of key stakeholders, particularly commissioner and provider leads. It will be necessary for the Pathology Transformation Board to encourage, solicit and endorse involvement of required individuals, teams and organisations in completing tasks and actions required to complete the project.

7 Pathology Transformation Board

7.1 Overview

- 7.1.1 The Pathology Transformation Board (PTB) has been sponsored by the NHS East of England Operations Board. Its remit is as detailed in the Terms of Reference (ToR) (Annex A). The Pathology Transformation Board tasks are:
- Review commissioning of community pathology services and to produce outline business case(s), specifications, proposals and implement proposals for change
 - Review provider networks of pathology services and encourage providers (including networks) produce outline business case(s), specifications, proposals and implement proposals for change.
 - Develop and implement effective communications strategy to involve stakeholders in the process.

7.2 Authority

- 7.2.1 The Pathology Service Board will report and brief the NHS East of England operations board who are ultimately accountable for the pathology programme. To enable the process to be managed swiftly the Operations Board will receive papers on (1) the project initiation, e.g. the process, plan, timeline and governance arrangements (2) any business cases including specifications, assessment and criteria for final decision. This will be formally agreed with the SHA board.
- 7.2.2 The PTB should proceed beyond the end of Phase 2 or December 2010, whichever is sooner, without prior approval of the EoE Operations Board.

7.3 Membership

- 7.3.1 Membership of the Pathology Transformation Board will be proposed by the PTB and subject to approval of the EoE Operations Board as detailed in the ToR (Annex A).

8 Project Team

8.1 Overview and Membership

- 8.1.1 Andrew MacPherson, Director of Strategic Projects, will assemble a core programme team to support the Pathology Service Board. The programme team is expected to be responsible for the day to day progression of the project. Core programme team members mobilise include;
- Ian White, Strategic Projects Manager
 - Pathology Project Manager to be appointed
 - Samantha Sherratt, Communications Manager
 - Laura MacPherson, Project Co-ordinator
 - Martin Peat (Commercial Lead),
 - A Subject Matter Expert to be appointed by the Pathology Service Board,
- 8.1.2 NHS East of England will appoint a lead for Clinical Quality to support this project.

- 8.1.3 The Pathology Service Board and pathology network members will be expected to identify project team members who can help support the process, particularly at network level.

9 Support & Budget

9.1 Budget by Stage

- 9.1.1 NHS EoE Operations Board has approved funds to support the objectives outlined in this paper and the completion of stages 1 and 2. A budget of up to £25,000 per commissioner will be required to complete stages 1 and 2, including liaison with providers on development of proposals but excluding cost of developing these.
- 9.1.2 NHS East of England will provide the Project Director and project planning at its own cost during stage 1 and 2.
- 9.1.3 Costs for other stakeholders will need to rest in the organisation in which there arise. Providers will need to commit to and support the objectives outlined in this paper and the completion of stages 1 and 2 including provision of SOC(s) for reconfiguration options. Commissioners will need to work with providers to support this as required.
- 9.1.4 NHS East of England should provide a core project team to support the project through its 5 stages. It is not possible to be precise as to the costs of support at this stage, as these are dependent on the findings of stage 2 – benchmarking and base setting. Primary care work will support the SOC, OBC, procurements and FBC activities devised by the Pathology Service Board. Acute service support will involve working through four networks, Essex, Beds & Herts, Norfolk & Suffolk and West Anglia to identify opportunities for, and implementing, re-configuration.
- 9.1.5 During later stages costs will be as approved by the Operations Board.

10 Change control

10.1 Overview

- 10.1.1 Effective change control is an essential element of any managed project, without change control there is no management. Following approval of the outline in section 6.2 the project team will develop a detailed project plan for project including a number of sub-stages and associated work packages. Each work package will include specific tolerances. The project plan will include:
- Tolerances for each work package broken down into cost, quality, specification, resources, risk and time.
 - Authority delegated to the Project Director and Team
 - Issues reserved by PTB or EoE Operations Board.
 - Processes for authorising changes both within and outside of any tolerances set.

11 Quality plan

11.1 Overview

11.1.1 Quality assurance and control are key disciplines of successful projects. For Modernising Pathology details of quality assurance control will be included in each group of tasks leading to a completed element of the project or Work Package. Examples of quality assessment include:

- Peer review
- Internal audit assessment
- Board approval, where appropriate.
- DH Gateway Review

11.2 Gateway review

11.2.1 Good Governance of major projects usually includes an independent review of performance at key stages in the progress of the project. This ensures that the project is continuing to plan and is expected to deliver the desired outcomes. It also ensures that each stage has been properly completed before progressing to far with the next stage. It is proposed to use the Office of Government Commerce Gateway Review.

11.3 OGC Gateway Review

11.3.1 The Office of Government Commerce (OGC) has developed an Assessment tool (Gateway Review) that whilst designed for new procurement projects in civil Central Government can equally be used in other like organisations eg the NHS where strategic partnering is central to its objectives.

11.3.2 The Gateway Process examines a project at critical stages in its lifecycle to provide assurance that it can progress successfully to the next stage. It is designed to be applied to projects that procure services, construction/property, IT-enabled business change projects and procurements utilising framework contracts. The process provides project teams with advice and guidance from fellow practitioners.

11.3.3 The review is carried out in six phases:

- Gateway Review 0 – Strategic Assessment reviews the Business Strategy and Need
- Review 1 – Business Justification reviews the Business Case its options appraisal and affordability
- Review 2 – Procurement Strategy reviews strategy and requirements and updates Business CASE
- Review 3 – Investment decision – evaluate bids and select Provider
- Review 4 – Readiness for service – award and readiness
- Review5 – Benefits realisation – service delivered benefits received.

11.3.4 Dealing with each in turn, summarising the key activities:

Gateway Review 0 – Strategic Assessment

Gateway Review 0 may be applied at the start up of either a programme or a project. A programme is a portfolio of projects that are selected or commissioned, planned and managed in a co-ordinated way and which together achieve a set of defined business objectives. Gateway 0 is expected at the start-up of a programme and is recommended practice for a major project that is high risk. The programme or project start up process produces a preliminary justification for the programme or project based on a strategic assessment of business needs and an assessment, at a high level at this stage, of the programme or project's likely costs and potential for success. This Gateway Review comes after the business need has been identified and before any further development proposal goes before a project board, executive authority or similar group for authority to proceed.

Gateway 0 focuses on the programme or project business justification. It also provides assurance to the programme or project board that the business requirement has been adequately researched and fits within the department's overall business strategy. Used at programme level, the review will, in addition, examine how the planned portfolio of projects aims to deliver the overall programme objectives, and that the programme management structure, monitoring and resourcing is appropriate.

Review 1 – Business Justification

The project initiation process produces a justification for the project based on business needs and an assessment of the project's likely costs and potential for success. This first Gateway Review comes after a high level business case (the Strategic Outline Case) has been prepared and before any development proposal goes before a project board, executive

authority or similar group for authority to proceed. The review focuses on the project's business justification. It also provides assurance to the

project board that the proposed approach to meeting the business requirement has been adequately researched and can be delivered.

Review 2 – Procurement Strategy

Following Gateway Review 1, when the project board determined that the project was feasible and there was a robust high level business case. This phase defines the procurement strategy, focusing on establishing a clear definition of the project and a plan for its implementation. Any outstanding assumptions from Gateway Review 1 should now be verified.

Gateway Review 2 assesses the project's viability, its potential for success and whether the project is ready to invite proposals or tenders from the market. This review assures the project board that the selected procurement approach is appropriate for the proposed acquisition.

The project team and Gateway review team must be satisfied that due consideration has been given to all the factors, including choices about proposed commercial arrangements with the existing supplier that offer value for money.

Review 3 – Investment Decision

Gateway Review 2 reviewed the procurement strategy before inviting proposals or tenders against the fully developed requirements specification. During this project phase, potential suppliers and partners submitted their proposals or tenders. An

evaluation panel analysed them on a 'like-for-like' basis and recommended the proposal that met all the needs of clients and end-users and which offered the best value for money. This third review should come before placing a work order with a supplier, or at preferred bidder stage and before award of contract.

Review 4 – Readiness for Service

Gateway Review 3 covers the activity up to contract signature. This review focuses on whether the solution is robust before delivery; how ready the organisation is to implement the business changes that occur before and after delivery; and whether there is a basis for evaluating ongoing performance. For property/construction projects, this review takes place after commissioning has been completed. For IS/IT-supported business change, this review takes place after all testing, including business integration and business assurance testing, has been completed and before roll-out or release into production.

Review 5 – Benefits Realisation

This review focuses on ensuring that the project delivers the benefits and value for money identified in the business case and benefits plans. One Gateway 5 review should be enough for projects without a service contract. It should be held 6–12 months after completion of the assets, when evidence of the in-service benefits is available.

The scope of the review will vary depending on whether the project is a long-term service contract or provision of works; the project may start life as a construction project and transfer to a long term service contract. For long term contracts such as strategic partnering arrangements, there should be a Gateway 5 review every three years in accordance with planned project reviews.

A Gateway 5 review is *not* a Post Implementation Review. It takes place after the organisation has carried out a Post Implementation Review or similar major review. It makes use of findings from that internal review, together with an assessment of organisational learning, as evidence of good practice but may or may not include a full review of plans for the future.

11.4 Suitability for Modernising Pathology

- 11.4.1 The Review will measure the project performance at each stage, it will assess the potential for success and the projects risk management. Where individual projects use "central" resources they are assessed to show compliance with the project. Reviewers will assess the Project, its Clients and it's stakeholders in making their assessment.

11.5 Cost

- 11.5.1 DH does not make a direct charge for OGC Gateway reviews, although individual reviewers do sometimes seek to recover expenses, however it should be noted that a dedicated SHA resource will be required at each review point. These costs have been included in phases 1 and 2.

11.6 Benefits measurement

- 11.6.1 The key success criteria is that the recommendations of the carter report are each implemented within East of England to the fullest possible extent. An early requirement of the PTB is to identify and quantify benefits from Carter Report

- 11.6.2 As part of developing strategic outline and, later, full business cases clearly defined and measurable outcomes and benefits should be identified. This will be in a form similar to the template in Annex E.

12 Risks & issues

12.1 Risk Register

- 12.1.1 The purpose of this report is to outline the process for managing risks associated with the Modernising Pathology project including structure for identifying, assessing, categorising and mitigating risks.
- 12.1.2 A risk framework has been established following the Multi Agency Threat and Risk Assessment (MATRA) model. Whilst this model was developed by the Department of Transport to respond to increasing threat to transport services, particularly air travel, the principles and format of the MATRA approach provide a good basis for risk assessment for this project. The needs of this project mirror DOT's requirement for co-ordination across stakeholders and a joined up approach to the consideration and mitigation of risks.
- 12.1.3 Overall the system is similar to that being adopted by NHS organisations seeking to establish robust risk assurance frameworks to minimise the impact of business risks on operational and strategic goals. However, the MATRA model enables the assessment of risks against a predefined template and scoring of impact is assessed in four areas:
- Safety;
 - Operations;
 - Economic, and;
 - Reputation
- 12.1.4 For each area risks identified against two scales, each marked 0 to 4, for likelihood and impact. These are multiplied and provide an overall rating of green (1-2) – the lowest risk rating, amber (3-6) and red (8-16), the highest risk rating.
- 12.1.5 Once identified changes to project activities or further planning processes will be used to seek to mitigate risks, reducing their impact and likelihood where ever possible.

12.2 Integrated Risk Assurance Network

- 12.2.1 To ensure all relevant risks are considered and responded to, not only those directly related to the project it is proposed that the project team establish risk network with other stakeholders. The network, represented by a member of the project team and a lead risk assurance representative from commissioner, provider and service users, will regularly meet either in person or virtually to review the risk log and update it as required.
- 12.2.2 The role of the network will be to:
- Co-ordinate risks identified by any network member organisation impacting on the project directly or indirectly
 - Ensure any risks identified are assessed and recorded on the project risk register and updated accordingly.

- Update the project risk log and any related organisation log as appropriate.
- Ensure risks are escalated to the PTB and/or member organisation senior managers or executive as required.

12.3 Process of Assessment

- 12.3.1 The Strategic Project Team members, advisors and network representatives will meet to review the project plan and used their expertise in areas of services, commercial contracting, pathology services, human resources, IT and other factors to identify and classify risks. These will be collectively reviewed against the matrix to agreed by the network, similar to the example set out in Annex B. Mitigating strategies will be established, and each risk identified and recorded in the risk register. This register will be available for the following PTB meeting for information. Thereafter it reviewed regularly and updated as appropriate.

13 Communications plan

13.1 Overview

- 13.1.1 A marketing, communications and public involvement function will be established within the Strategic Projects Team (SPT) to service, support and facilitate the project through active stakeholder and media engagement, involvement and proactive communications and tactical marketing. To enable this activity a communications plan will be developed for approval by PTB. The plan will include:
- Overview of communications requirements of the project
 - Summary of stakeholders and audiences
 - Details of external stakeholder or influencers for example the National Pathology Forum and representation with such groups.
 - Communications with suppliers of services, equipment and software
 - Media to be utilised for communication
 - Governance, approvals and controls
 - Lines to take and questions and answers
 - Key personnel involved in developing and implementing the plan
- 13.1.2 PTB will receive a report to each Board meeting detailing progress of communications against the plan and any actions required.
- 13.1.3 The completed communications plan will be attached to Annex C

Annex A – Pathology Transformation Board Terms of Reference

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Annex B – Template Risk Register

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Annex C – Communications Plan

To follow

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Annex D – Modernising Pathology Project Plan

To follow

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Annex E – e-Health Modernising Pathology Benefits Template

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