

Department of Health, Social Services, and Public Safety

**REVIEW OF CLINICAL PATHOLOGY  
LABORATORY SERVICES**

**PROJECT INITIATION DOCUMENT**

**FINAL DRAFT**

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## INTRODUCTION

### 1.1 Background & Terms of Reference

1.1.1 The Department of Health, Social Services and Public Safety (DHSSPS) has a statutory responsibility to ensure the provision of health and social care for the population of Northern Ireland. Clinical pathology laboratories play an integral part in this.

1.1.2 There are several specialities within pathology and these include:

- Clinical Biochemistry
- Clinical Haematology
- Immunology
- Medical Genetics
- Medical Microbiology
- Anatomical and Cellular Pathology
- Tissue Typing.

1.1.3 The last review of pathology services was undertaken in 1983, and since then the demand for and pattern of service provision has changed considerably. On 10 April 2003, the Chief Medical Officer, Dr Henrietta Campbell announced the Department's intention to undertake a review of clinical pathology laboratory services. She outlined the terms of reference for the review as follows. "This proposed review aims to provide the Department with a strategic plan for strengthening and developing effective, high quality, clinical pathology laboratory services, responsive to the needs of the patients and users. This will take account of the work in progress both locally and nationally, including North/South dimensions, and will address the recommendations of the Public Accounts Committee Report on Laboratory Pathology Services.

1.1.4 The review will also address:-

- The requirements of primary and community care, local hospitals, and acute hospitals in the context of "*Developing Better Services*"
- The need for cost-effective pathology services
- Developments in clinical services and the impact on laboratory pathology services
- New and emerging technologies
- Staffing implications
- Quality issues, including professional qualifications and attaining/retaining accreditation
- The requirements of clinical governance within the HPSS, and
- Capital resource requirements, to include buildings, equipment and IT.
- Teaching and training.
- Research and development
- Management and governance arrangements."

1.1.5 This documents represents the Project Initiation Document, which provides a plan for the project, identifies key stakeholder involvement and clarifies roles and responsibilities.

## **1.2 Project Environment**

1.2.1 Pathology laboratories deliver a complex range of services against a background of significant change within the HPSS and rising levels of user and public expectation. This means that significant demands for high quality services are generated both within the HPSS and by external organisations. In addition, changing employment legislation, CPA accreditation standards, ageing equipment, variations in standards, practices, cost, etc all present challenges for the future.

1.2.2 The current Government is committed to a programme of substantial change and reorganisation in both acute, community, and primary health care services. During recent years a number of strategic initiatives have been launched at both national and regional levels which have a direct bearing on the proposed project:

- **The NHS Plan** - This is a plan for investment in the NHS in England with sustained increases in funding.
- **Modernising NHS pathology** - On 20 June 2002 the Department of Health, London published a consultation paper “ *Pathology – The Essential Service – Draft Guidance on Modernising Pathology Services*”. The paper highlighted pathology’s essential role in delivering effective diagnosis and appropriate care under the success of the NHS Plan. The key change proposed was the introduction of managed pathology networks across NHS Trusts as a model of service delivery as part of the NHS modernisation process and to address the workforce and technology challenges facing NHS pathology services.

Key messages from the consultation process were as follows:

- there is a groundswell of support for change in NHS pathology services
- the focus on delivering high quality, responsive services to clinicians and patients is right
- there is general support in principle – from the Royal College of Pathologists, the Institute of Biomedical Science, the Association of Clinical Biochemists and Amicus, among others - for developing appropriate networks in pathology
- pathology networks can provide a wider strategic vision for pathology services
- an incremental approach to network development is the best way to achieve change without widespread disruption to services
- the need to support and develop staff is vital
- support for change and leadership from professional and other bodies is vital if pathology is to be modernised successfully

- there must be good communication with all those working in laboratories.

It is anticipated that final guidance will be issued during December 2003.

- **Clinical Pathology Accreditation** – Within the UK there are two laboratory accreditation bodies, operating in complementary fields, the United Kingdom Accreditation Service (UKAS) and Clinical Pathology Accreditation (UK) Ltd (CPA). Accreditation is the procedure by which formal recognition is given of competence to carry out specific tasks. In July 2003 the DoH has issued a letter which stating that “it will be compulsory for all NHS laboratories in England to enrol with a relevant accreditation scheme.”
- **The Department’s Regional Strategy 2002–2022** – Themes emerging from initial consultation on developing a regional strategy include establishing networks and pathways between professions and services to ensure optimal management of specific conditions. The draft Strategy is now being prepared with a view to issuing for consultation in February 2004.
- **Developing Better Services** – The then Minister, Des Browne, announced his decisions on the proposals in *Developing Better Services* in February 2003. The key decisions set out in his announcement included the replacement of the current configuration of 15 acute hospitals by a network of nine acute hospitals supported by seven local hospitals, with additional local hospitals in other locations, as appropriate.
- **Primary Care Strategy** – One of the corporate objectives of the Department is to ensure the delivery of effective, high quality health and social services. To this end, a key priority is to improve Primary and Community Care services. The Primary Care Directorate of the Department is currently in the process of developing a Primary Care strategy, which will provide the strategic framework for the development of all Primary Care services over the next 20 years. It will also identify key principles and values to underpin the development and delivery of Primary Care services. A primary care strategy framework document will be issued for consultation early in 2004.
- **New Contract for General Practitioners-** It is expected that the new contract for GPs will have implications for the future operation and management of laboratories. For example, objectives in respect of chronic disease management will require extra tests and necessitate electronic transmission of results.
- **Regional Consensus Policy for Point of Care Testing** – With the huge increase in availability of point of care testing at all levels within the HPSS, the Clinical Directors of Laboratory Medicine developed a

consensus policy which has been discussed and agreed in principle by DHSSPS.

- **Legislation** - Recent years have brought about significant changes in legislation affecting employment and professional practice. The legislative agenda continues to develop. In respect of this project, the most relevant pieces of legislation govern areas such as working time, part-time working, equality and professional practise.
- **Quality Framework & Regulation (Best Practice – Best Care)** – In 2001 the DHSSPS published this consultation document outlining a framework for setting standards, delivering services and improving monitoring and regulation in Northern Ireland’s health and personal social services.

The proposals in the document centre on:

- Setting standards - Standards will be improved through the related measures of continuing professional development and strengthened professional regulation from a single body.
- Delivering services - Establishing a statutory duty to quality for Health and Personal Social Services (HPSS) providers.
- Improving monitoring and regulation of services - Extend the range of social care services currently regulated and establish a single regulatory body for care services.
- Ensure equality of provision.
- **The Health & Personal Social Services (Quality, Improvement & Regulations) Order 2003.** The Duty of Quality came into effect in April 2003. It places a statutory duty of quality, to be backed by a system of clinical and social care governance, on the HPSS and creates a new Independent body, the Health and Personal Social Services Regulation and Improvement Authority (HPSSRIA), which will independently inspect and publicly report on the quality of regulated and non-regulated services delivered by both the HPSS and the independent sector.
- **Northern Ireland Audit Office – Review of pathology Services** – during February 2001, the NIAO published the above mentioned review which highlighted a number of key recommendations, including the following:
  - There is a strong case for a greater strategic overview of laboratory service provision by DHSSPS to clarify relationships and agree how the services should be developed alongside clinical services.

- DHSSPS should encourage Trusts to consider the costs and benefits of their present configuration of laboratory services against an off-site service in some locations with on-line access to systems.
- DHSSPS should review its policy on laboratory service provision in the context of the latest strategic thinking about acute hospital services in general.
- One third of all laboratories have not yet obtained full or even partial CPA accreditation. Contracts should only be awarded to accredited laboratories. Corrective action required immediately.
- DHSSPS should assure itself that all action possible is taken to fill vacant consultant posts and to ensure that no laboratory has unconditional accreditation withheld because of lack of cover.
- There is a need for an objective reappraisal of how the technical staff grading and payment system is applied.
- Spending per head of population is 28% more than England. DHSSPS must satisfy itself as to the cause of the variances in costs between hospitals and regions. Comment was also made on the credibility of the pricing process.
- Adoption of common protocols in laboratory testing.
- **Agenda for Change** - this is a national policy document that outlines radical proposals for modernisation of the workforce and payment systems.
- **Information and Communications Technology (ICT) Strategy** - In recognition of the need for strategic investment in ICT, an Information and Communications Technology Strategy has been published. Principles guiding the strategy include supporting and empowering care professionals and support staff in their work; improving the efficiency of current service delivery; facilitating services innovation and development; facilitating cross-sector co-operation and working; supporting the research activities of the HPSS and the wider academic communities; and supporting the development of clinical and social care governance and risk management within the HPSS. New services to be introduced under the Strategy will include electronic transmission of pathology results.
- **Resources** - there are very many competing and increasing demands on the health and personal social services, with limited resources with which to meet those demands. The Health and Personal Social Services cannot meet them all and must be selective as to where it can deliver the greatest benefit to those in greatest need.

### **1.3 Project Rationale/Need for Change**

- 1.3.1 DHSSPS recognise that substantial work needs to be undertaken to provide laboratory services in a way which can fully support the changing business environment being brought about by both internal and external drivers including government policy. The key stakeholders in this project believe that many of the national, regional and local objectives cannot be achieved without changing current working practise and operational systems.
- 1.3.2 Over the last few years it has become apparent that the existing systems currently in use within the laboratories do not adequately address current and future business requirements. The DHSSPS has, therefore, established a collaborative project to review strategic directions for the future provision of clinical pathology laboratory services within Northern Ireland.

### **1.4 Main Project Objective & Timeframe**

- 1.4.1 The main objective of the Review is to provide the Department with a strategic plan for strengthening and developing effective, high quality, Clinical Pathology - Laboratory services, responsive to the needs of patients and users.
- 1.4.2 The project will adopt a partnership approach involving all key stakeholders in the development of a sustainable long-term strategy. This review will take one year to complete. The target date for completion is 30 November 2004. However, consultation will be ongoing throughout the duration of the project and it is anticipated that an Interim Report will be issued in Spring 2004.

## **2 AIM & OBJECTIVES**

### **2.1 Aim**

The overall aim of the review is to provide the Department with a strategic plan for strengthening and developing effective, high quality, Clinical Pathology - Laboratory services, responsive to the needs of patients and users. This will take into account work in progress both locally and nationally including North/South dimensions, and will address the recommendations of the Public Accounts Committee on Laboratory Pathology Services.

### **2.2 Operational Framework**

In order to ensure that the review addresses the terms of reference as presented by the Chief Medical Officer (see 1.1.3 & 1.1.4) the project will be required:

- 2.2.1 To provide an overview of the current arrangements and current problems for clinical pathology - laboratory services in Northern Ireland, in particular:
- the current arrangements for the provision and management of services;
  - the location and user base of current laboratories;
  - staffing arrangements (including training, skill mix, vacancies and Working Time Directive compliance);
  - the arrangements for ensuring quality of service delivery (including CPA, clinical Benchmarking and controls assurance).
- 2.2.2 To document trends and anticipate future demand for clinical pathology - laboratory services in Northern Ireland.
- 2.2.3 To assess the overall provision, effectiveness, efficiency and economy of services, taking account of appropriate benchmarking information and other relevant measures.
- 2.2.4 To identify developments/drivers for change that are likely to impact on pathology services in the future, including technical, clinical and ICT developments and the impact of relevant EU Directives, for example, in-vitro diagnostic devices.
- 2.2.5 To identify human resource issues that will have an impact on services, including changing work patterns, training and career progression, the European Working Time Directive and skill mix issues.
- 2.2.6 To provide a model for the future provision of clinical pathology - laboratory services, taking account of:
- the future configuration of hospitals as outlined in *DBS* and the Ministerial announcement February 2003;
  - the focus on collaborative working arrangements and network development;

- the potential for greater collaboration in the provision of laboratory services within the HPSS;
- the potential involvement of the private sector;
- the development of linkages with the Republic of Ireland;
- the availability of resources; and
- the need to provide timely access to results

2.2.7 To make recommendations to the Departmental Board and the Minister on the future provision of clinical pathology - laboratory services in Northern Ireland, to include resource plans, an assessment of equality implications and a detailed action plan.

A priority for the review will be to ensure appropriate involvement of key stakeholders in the development of proposals. This will include at least one workshop, and visits to laboratory facilities.

### **2.3 Scope**

2.3.1 The review will include all hospital laboratories, encompassing routine and specialist laboratories as well as consultant scientific and medical services for the community and primary care sector.

2.3.2 The review will not revisit work already completed or cause the suspension of work on-going but will ensure appropriate partnership working arrangements with completed or ongoing project, for example, the development of a regional ICT system for laboratory medicine, the Regional Workforce Plan, etc.

### **3 PROJECT ORGANISATION**

#### **3.1 Project Organisation**

The project structures have been designed to ensure that key stakeholder representatives are actively involved in all the major decisions. This should help secure ownership and commitment. The structure underlines the need for involvement of professional, user, technical representatives, including representatives from all disciplines.

The structure also provides a focal point for driving the process forward whilst ensuring that all parties are actively contributing to the key decisions and activities that will affect them.

##### ***3.1.1 Project Sponsor***

###### ***DHSSPS***

The Project Sponsor will have the ultimate ownership of and authority over the project process. The Project Sponsor will give direction to and receive recommendations from the Project Board.

##### ***3.1.2 Project Board***

###### **(i) Project Chair**

Dame Ingrid Allen

###### **(ii) Board Members**

The Project Board will consist of senior professionals and representatives of key stakeholders. Members must have the authority to commit appropriate staff and resources throughout the project.

The Project Board will have responsibility for the overall management of the project and will make recommendations to the Project Sponsor and will be involved in the key decision making process.

##### ***3.1.3 Project Manager***

Mrs Louise Skelly

The Project Manager will manage the process and ensure that the products are delivered to the required quality and timescales. She will provide regular updates to the Project Chair and Board highlighting relevant issues and any variances from the project plans. She will also act as the main point of contact for all stakeholders on project related queries.

### **3.1.4 Project Team**

The Project Team will consist of the Project Manager supported by a multidisciplinary team. Project Team members must be able to commit significant time to the project and will have responsibility for producing the required products – for consideration by the Board – to ensure that the Terms of Reference for the Review are discharged in full.

The main activities that the project team will undertake are outlined below:

- produce the Project Initiation Document;
- develop and implement a project communication strategy;
- undertake all project tasks and develop all project documentation including progress reports and exceptional reports.

### **3.1.5 Additional Expertise**

At various stages, throughout the duration of the project the project team will require additional support and expertise from other professionals and expert groups. The project board will approve and commission this support as required.

## **3.2 Project Roles and Responsibilities**

3.2.1 The project will be managed using standard project management methodology amended to suit the specific requirements of the project.

3.2.2 The main activities that each member will be carrying out were highlighted earlier but a more general description of the individual roles and responsibilities required can be found in APPENDIX A - ROLES AND RESPONSIBILITIES.

## **4 PROJECT PLAN**

### **4.1 Introduction**

The project will run from 1<sup>st</sup> December 2003 to 30<sup>th</sup> November 2004 when project closure will occur and has been split into a number of key stages. These stages will be further developed as the project evolves and a more detailed project plan agreed. However the key stages are summarised below,

### **4.2 Project Outline**

**Phase 1 Project Initiation** (November 2003)

**Phase 2 Survey Existing Situation and Identify Issues**  
(Dec 03 – April 04)

- review current supply
- review current and future demands
- identify wider contextual issues
- prepare Interim Report

**Phase 3 Consultation** (May – July 04)

**Phase 4 Preparation of Draft and Final Reports** (August – Nov 04)

## **APPENDIX A - ROLES AND RESPONSIBILITIES**

### **PROJECT SPONSOR**

- DHSSPS

#### **Responsibilities**

The main responsibilities of the Project Sponsor is as follows:

- Ensure the appointment of the Chair of the Project Board;
- Ensure and approve appointments of members of the Project Board;
- Commission the Project Board to draft the Terms of Reference for the project;
- Agree and formally sign off the Terms of Reference;
- Approve the overall cost and timescale for the project; and
- Ensure Project Closure.

## **PROJECT BOARD**

### **Project Chair**

- Dame Ingrid Allen

### **Project Board**

- Dr Derek Allen
- Dr Henrietta Campbell
- Dr Alistair Crockhard
- Dr Nizam Damani
- Dr Dermott Davison
- Dr Colin Hamilton
- Mrs Jackie Jamison
- Mr Stuart McDonnell
- Dr Curly Morris
- Professor Elizabeth Trimble
- Mr Dean Sullivan

The role of the Project Board is to provide overall guidance and direction to the project. Its members must have the ability to either commit or acquire appropriate resources for the project and they must undertake to contribute their own time to the control processes (Project Board Meetings, etc.).

### **Responsibilities**

The main responsibilities of the Project Board are as follows:

- Produce Terms of Reference and agree with Departmental Board;
- Ensure that plans take account of issues or concerns raised by the key stakeholders;
- Present key products and recommendations to the Departmental Board for approval;
- Ensure that individuals allocate sufficient priority to project-related tasks;
- Authorise the initiation of the project;
- Review and approve action based on revised plans as presented by the Project Team;
- Authorise the start of each stage, or recommend termination or suspension of the Project;
- Sign-off acceptance of each completed stage or product; and
- Authorise Project Closure.

## **PROJECT CHAIR**

### **Dame Ingrid Allen**

This is a description of the responsibilities associated with the Chair and should be read in conjunction with the responsibilities of the Project Board as a group.

### **Responsibilities**

The Chair is individually and directly responsible to the Departmental Board for the project. She ensures that the project achieves the expected benefits as measured against its project justification, and that it is completed within the cost and timescales approved by the Project Sponsor.

**Direction To:** The Project Board.

**Direction From:** Project Sponsor.

## **PROJECT MANAGER**

- Mrs Louise Skelly

### **Responsibilities**

The essential elements of this role can be summarised as follows:

- Manage the project to ensure that all the required products are delivered to the desired standard of quality and within the specified constraints of time and cost;
- Organise the project team to meet objectives;
- Anticipate and solve problems, etc;
- Have single-minded energy and determination in driving the project forward; and
- Maintain commitment to the project throughout its lifespan.

The specific tasks are as follows:

### **Project Level:**

- Confirm acceptance of Terms of Reference with the Project Board;
- Plan the project and agree the Plan with the Project Chair and Board;
- Liaise with other projects to ensure work is not overlooked / duplicated;
- Ensure a filing system is set up; and
- Convene and attend Project Initiation, Project Team and Closure Meetings.
- Ensure production of all project documentation;
- Present regular Progress Reports to the Project Chair and Board indicating any deviations from plan and any corrective action taken;
- Monitor the results of all meetings and liaise with the Project Team to assure the overall direction and integrity of the project;
- Attend and chair all Project Team Meetings;
- Manage and provide direction and guidance to Project Team; and
- Ensure the maintenance of the project file.

**Direction To:** Project Team.

**Direction From:** Project Board.

## **PROJECT TEAM**

- Ms Helen Allen
- Mr Peter Auld
- Mr Bertie Kennedy
- Mr Geoff Kennedy
- Mr Brian Magee
- Dr Miriam McCarthy
- Dr Maurice O’Kane

## **Responsibilities**

To produce the required products for the project to the required standard of quality and within specified constraints of time and cost.

The specific tasks are:

- To carry out activities as specified in project plans;
- To consult and liaise with personnel from various specialties /departments as necessary;
- To attend Meetings;
- Complete appropriate project documentation; and
- Liaise with the Project Manager and inform of any deviations from agreed activities.

**Direction From:** Project Manager.